GHMC

The Global Guide to **Pharma Marketing Codes**

Vol. 5

This unique guide was produced with the insight and expertise of the world's largest and most robust network of independent healthcare agencies.

LEGAL DISCLAIMER

The Global Guide to Pharma Marketing Codes is designed to provide information on country-specific codes and regulations surrounding the promotion of medicines. Every effort has been made to ensure that the information about relevant codes of practice is accurate and up-to-date and that guidance offered is in line with existing regulations. This document should in no way be seen as a substitute for the relevant regulations or statutes that govern the behavior of those involved in the promotion of medicines. GHMC cannot accept responsibility for any breach of Codes of Practice or statutes that may result from following the advice or guidance in this document.

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PREFACE

Over the past decade, perhaps no industry has evolved as much as the biopharmaceutical industry. The rapid increase in therapeutic advances like anti-obesity drugs, gene therapies, cancer immunotherapies and more, compounded by a once-in-a-lifetime global pandemic, have placed the industry and its innovations under higher scrutiny than ever before.

Along with these industry evolutions there has also been a sea change in the ways we communicate with one another, as new online platforms can rise and fall with astounding speed. Through all of this, there is the challenge of effectively marketing and communicating innovation across diverse markets, where regulatory scrutiny is high and knowing how to adhere to diverse marketing codes market by market is paramount.

With this in mind, we have developed *The Global Guide to Pharma Marketing Codes, Volume 5*, to help pharma marketers keep a finger on the pulse of ever-evolving regulatory frameworks and code updates. This guide provides a comprehensive overview of the essential marketing codes that govern the industry in key countries worldwide. Developed by Global Health Marketing and Communications, it serves as a crucial resource for professionals navigating the complexities of ethical pharmaceutical marketing.

As you explore this guide, you will gain insight into the key principles, channels and guardrails that govern pharmaceutical marketing practices across various regions – topics that our experts handle daily worldwide. Whether you are new in your role, or are a seasoned pro at navigating international waters, this guide will equip you to implement successful, global marketing campaigns that achieve goals, within the regulations applicable in each market. If you need further expertise in global pharmaceutical marketing, please reach out to us at hq@ghmcnetwork.com.

Claire Eldridge
Global Managing Director, GHMC

THE AMERICAS

ARGENTINA

In Argentina, the promotion of medicines is controlled by national legislation and codes of practice. Direct-to-consumer promotion of prescription-only medicine is not permitted, and all information about medicines delivered by pharmaceutical companies must be accurate, verifiable and updated.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
Within the private sector, there is the Ethical Code of Pharmaceutical Marketing Practices from the Argentine Chamber of Medical Specialties. This code applies to the promotion of prescription medicines from pharmaceutical companies and medical professionals within the health sector.

Another private code, the Ethical Code of Good Advertising Practices from the Argentinean Chamber of Non-Prescription Medical Specialties, is based on the statement that every advertisement for over-the-counter products (OTC) must respect the principles of morality and decency and must respect general advertisement laws. Therefore, advertising must be honest, truthful and trustworthy. All member companies of The Argentine Chamber of Over-the-Counter Medicines (CAPEMVel) must adhere to this code.

The Argentinian Medical Association (AMA) has its own Health Team Ethical Code. Section No. 365 states that 'companies related to the provision of medicines and health terms shall strictly respect and adhere to current national legislation on the subject. Any conduct that could lead to mistakes, confusion or concealment of medicinal side effects and secondary effects, or misleading health teams' claims, shall be considered an ethical violation.' For example, the phrase 'cures rheumatic disease' is not true because not all rheumatic disease can be cured.

The law passed by the City of Buenos Aires (Law 5709 of 2016) 'Law for the advertising of benefits or prizes to doctors, states that manufacturers, importers and distributors of medical, biological and pharmaceutical products that grant and/or deliver goods, services, benefits or prizes that may be subject to pecuniary valuation to physicians within the scope of the city of Buenos Aires must inform the local health authority.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
Public relations and advertising are not separately defined and there are no special rules for public relations activities.

Who is responsible for the enforcement of these rules?
The Argentinean Health Authority (ANMAT) and the National Communication Entity (ENACOM), together with the Undersecretary of Consumer Defense, are legally responsible for the enforcement of these rules. Private ethical codes are mandatory for chamber members.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?
According to Camara Argentina de Especialidades Medicinales (CAEMe) Ethical Code 6.1, 'Delivery of promotional items (also called merchandising or gimmicks) for the purpose of serving as product brand and/or company logo reminder,' is allowed, but the promotion items must be related to the area of medicine or pharmacy and/or be beneficial to patients. Promotional items given at events must also be related to the scientific and/or medical activities relevant to the healthcare professional (HCP) they are given to. The Code also states that 'promotional and medical utility items should not be provided on a frequent basis to the same recipient, and they must have a minimal and modest value.' Pharmaceutical companies may hire HCPs for 'the provision of advisory or consulting services such as lecturer or moderator at meetings, training activities, expert meetings, etc., where such participation involves the payment of remuneration and/or expenses related to the provision of the service'.

The following provisions must be followed in order to contract an HCP (individually or as a group):

- Clear identification of a legitimate and genuine need for these services in advance of requesting the services and entering into agreements with prospective consultants.
- Prior to the provision of these services, existence of a written agreement specifying the nature of the services to be provided and the fees to be paid.
- The hiring of healthcare professionals should not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicine.
- The agreement must include a provision pursuant to which the healthcare professional commits to state, in a clear and express manner, that he/she provides services to the company, whenever he/she makes a public statement about an issue that is subject matter of his/her agreement with the company. The Code states that companies should appoint a qualified employee to be in charge of Code compliance.

Who receives concerns and complaints? How does this process operate?
The Supervisory Committee is responsible for investigating any complaints filed regarding promotional activities that do not adhere to the Code. After a complaint is made, the Supervisory Committee performs an investigation. After the investigation, the committee will put forth penalties, which the Board of Directors will ratify or rectify as it sees fit.

Do any promotional or media materials need to be approved by regulatory authorities?
OTC advertising is controlled post publication/broadcast by the Monitoring and Control of Advertising and Promotion of Products Subject to Health Surveillance. In 2005, the 'prior authorization' system was repealed, so pieces are monitored and evaluated once they are issued.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
The most recent development is Resolution No. 627 of 2007, which regulates the promotion of prescription medicines to medical professionals. It discourages and sanctions 'promotional practices' that may motivate medical doctors to prescribe one product in place of another as a result of marketing activities and not based on scientific reasons.

The local regulatory authority (ANMAT) is working on a new guide of recommendations and regulations for the promotion of prescription medicines, including topics like sponsorship, communication in media and websites. The document is in development and is being discussed with the different chambers that regulate pharmaceutical companies in Argentina.

1. (http://www.anmat.gov.ar/boletin_anmat/ BO/Disposicion_9660-2016.pdf)

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
In broadcasting, promotional activity or advertising is defined as 'the transmission of any announcement, made as a result of payment or exchange, to generate consumer interest in the acquisition of the products or services offered.' Annex IX of ANMAT Disposition No.4980 of 2005 defines advertising as 'an organized technique applied through general media to inform or promote features, benefits or qualities of goods or services in order to provoke and obtain its purchase'. Advertising is also classified as the promotion of people, services, goods, activities or organizations in such a way that exhibits a direct or indirect commercial aim (Section 3, Decree 286 of 1981).

Nevertheless, there is no clear line between promotional activities and what is usually presented as 'provision of information' for educational purposes. Promotional activity for medical professionals, according to Resolution No. 627 of 2007, Section 4, should include:

- Essential product information, such as generic and commercial names, composition, pharmaceutical form, indication, contraindication, adverse effects and product dosage information.
- The prescription regime and sales conditions. Per Disposition 6516 of 2015, manufacturers of prescription-only medicines must notify ANMAT of the promotion of products for health professionals and attach the corresponding promotional communicational piece in the format that it will be released (http://www.anmat.gov.ar/boletin_anmat/ BO/Disposicion_6516-2015.pdf). In the past, this Disposition applied also to OTC products, but through Disposition 9660 of 2016 the notification was revoked in that category of products, maintaining the notification in prescription only medicines[1].

How is a "media event" defined?
There are no legal provisions regarding media events for medicines promotion as a distinct entity.

Do the regulations differentiate between consumer and clinical publications?
Resolution No. 627 of 2007 in Section 6 establishes that promotional materials for medical professionals should not be accessible to the general public in any format such as magazines, books or audiovisual media. Sections 9° and 12° state that prescription medicines should only be promoted through media targeted to people who are qualified to prescribe or deliver medications. However, since there is not a 'Press Law' or anything similar in Argentina, there are no regulations aimed directly at the content of publications. This situation is of special relevance because in the case of publications directed

at medical professionals, the editors are the ones who regulate and limit information access to the general public.

Do regulations differentiate between print and broadcast media?
No, they do not.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
Both the CAEMe Ethical Code and Resolution No. 627 of 2007, Section 3, forbid the promotion of a medication that has not been approved by ANMAT for its commercialization.

Nevertheless, there are no objections by law to communicate scientific and technical information about medicines in ongoing clinical trials at professional educational events if they are based on scientific investigations and publications.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
There are no specific regulations governing press releases or media materials, nor media attending clinical events.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
There are no rules about how the press should cover these kinds of congresses and meetings.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
The copy should be independent. Journalists who work for a media outlet are subject to the ethical code or principles established by the employer. In general, reports are owned by the publication itself or occasionally by the journalist. Because of that, the content is not under the control of the sponsor company. The AMA's Ethics Code rules under sections No.383 and No. 384 state that it is a serious breach of professional standards—related to health news dissemination—to make claims or exaggerated results about a therapy that has not been verified through scientific methods. In the same way, it is a serious breach of professional ethics to lead people to self-medicate under the guise of imparting objective information.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No specific mention is made.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Law No. 26032 of 2005 specifies that research, reception and dissemination of information and ideas through the internet is legally considered within the framework of the freedom of the press. Responsibilities are established in the civil and penal code as if it were a print newspaper. However, as is stated in Section 11 of the Ethics Code for the Promotion of Medicines, scientific information should only be accessible by professionals. Although Law No. 16463 of 1964 prohibits any direct promotion of prescription-only medicines to consumers, scientific information online is not restricted only to healthcare professionals. It can also be available to consumers without restriction and without including any kind of advertising claim.

What levels of web security are required?
The promotion of medicine or medical practices through the web is limited under Resolution No. 627 of 2007 of the Department of Health and the Ethics Code, which requires that it must be stated in a very noticeable way that the information is designed for professional use only.

However, non-governmental organizations (NGOs) supported by scientific institutions and professional groups usually have a process of monitoring such websites to evaluate quality and assess if they fulfill the principle of separating professional information from patient information. The use of the mark of approval (WMC) is considered certification of quality.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Websites are expected to comply with what is stated in the Medicines Law. In terms of advertising funding, Article 37 orders the prohibition of any kind of public advertisement of medicine products that have to be sold under written prescription.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
In Argentina, the use of social networks is widespread and constantly growing. As of 2024, approximately 38.9 million people use social networks in the country, which represents about 85.8% of the total population. This high percentage reflects the importance of social media in the daily lives of Argentinians.

The most popular social networks in Argentina are[2]:
- WhatsApp: used by 91.7% of internet users.
- Instagram: with a penetration of 82.6%.
- Facebook: used by 74.6% of users.
- TikTok: with 61.2% of active users.
- X (Twitter): with a penetration of 50.3%.

Argentinians use social media mainly to communicate with friends and family, have fun with multimedia content (videos, memes, etc.), stay informed about news and current events, and follow brands and products. These platforms are not just communication and entertainment tools, but also relevant means for marketing and digital advertising. Companies and brands use them to connect with their audience and promote their products and services effectively.

While there are no rules about social media, the CAEMe Code states that "Whenever a member company finances, ensures, or directly or indirectly organizes the publication of promotional material and/or information in newspapers, magazines, radio, television and any other social communication media, it should be expressly stated that such material and/or information is not presented as an independent editorial topic, and the sponsoring company should be included in a visible place," (5.1).

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
For OTC products, content in forums, including interaction between the company and customers, must respect ANMAT Disposition 4980 of 05. Until 2023, e-commerce was prohibited. With the change of government in December 2023, Health Decree 345, 2024 was issued to regulate Law 27.553 of 2020, which establishes the approval of digital and electronic prescriptions. Section 7 of Decree 345, 2024, modifies certain aspects of the law regarding the professional practice of pharmacists. The new text establishes that "the sale and dispatch must occur at the pharmacy, in the presence of a responsible pharmacist (technical director and/or assistant pharmacist). The sale and delivery to the patient may be agreed on electronic channels determined by the pharmacy, with shipping to the location the patient chooses as convenient. It is the responsibility of the pharmaceutical professional to ensure that the shipping is done safely, in accordance with the applicable requirements and those established by the health authority for such purposes."[3]

For prescription-only medicines, any kind of promotional direct interaction between the company and patient is forbidden, according to Article 19, including Law No. 16463 that states, it is prohibited any public announcement of medicines whose retail sale condition is authorized only by prescription'.

2. Fuente: (https://datareportal.com/reports/digital-2024-argentina)
3. (https://www.boletinoficial.gob.ar/detalleAviso/primera/306098/20240422)

What is mobile adoption like in your region? Are there separate regulations for it?
More than 30 million Argentinians have mobile phones and 84% of those users have smartphones. By 2019, more than 32.9 million will have mobile phones, when the penetration rate will be 73.0%.

We Are Social, a digital media consultancy, conducted a survey in Argentina in 2023. Some key findings include that the country has 1.3 mobile lines per inhabitant, and that the number of social media accounts is equivalent to 80% of the population.[4] The main use of mobile devices is for instant messaging (WhatsApp and Facebook Messenger). TikTok was the most downloaded app in 2023. There are no separate regulations for mobile.

What are the disclosure laws like in your region for non-branded websites?
There is not a specific regulation from ANMAT. Websites developed by pharmaceutical companies with health information or information on specific diseases that do not mention commercial brands or include any symbol that could identify the brand are considered disclosure of scientific or technical information.

What are the requirements for adverse event reporting?
Resolution 706 of 1993 of the Ministry of Health implemented the National Pharmacovigilance System, a formal mechanism that bases its work on spontaneous, voluntary and confidential reporting of adverse reactions by health professionals. The Pharmacovigilance System depends upon the Direction of Evaluation and Registry of Drugs (DERM in Spanish). Its aim is the detection, assessment, understanding and prevention of adverse effects and other problems related to drugs. One of the main regulatory concerns is that pharmaceutical companies quickly report serious or unexpected adverse effects of their drugs and that they regularly report mild to moderate adverse events, mainly for products with less than five years on the market. In regard to working with health professionals, the task is focused on growing the network of peripheral effectors in the link with medical associations, pharmacists and so on. It also works closely with international bodies involved in adverse event reporting, especially with the Collaborating Center of the World Health Organization (WHO), located in Uppsala, Sweden.

The release of information is a key activity for the maintenance of the Pharmacovigilance System. In Argentina, information is released through the ANMAT website (www.anmat.gov.ar) and Newsletter for Professionals, which features letters to professional associations like the Argentinean Pharmaceutical Confederation (COFA) and Argentinean Medical Confederation (COMRA). Specific cases are also published in national and international medical and scientific journals. Reports of adverse events can be done by courier (Av. de Mayo 869, piso 11°, CP AAD1084, Buenos Aires, Argentina), e-mail (snfvg@anmat.gov.ar) or by filling out the form listed on the ANMAT website. ANMAT's Pharmacovigilance Department can receive both internal and external information. There are four possible external suppliers of information:

- Peripheral notifiers: hospitals, universities, etc., that signed an agreement with ANMAT.
- Particular notifiers: healthcare professionals, including physicians, pharmacists, dentists and nurses, from public hospitals, private institutions or private offices, that detect adverse events and directly report to ANMAT.
- Consumers: patients who, either by themselves or through consumers associations, send their reports.
- Pharmaceutical industry: through ANMAT Dispositions No. 3870/99 and 2438/00, the pharmaceutical industry is included in the National Pharmacovigiliance System (SNFVG), and it must report serious or unexpected adverse reactions of its drugs according to terms established in Disposition 5358, 2012. As determined by Disposition 3031, 2024, the pharmaceutical industry has 180 consecutive days to adapt their notification systems to a new reporting system called "eReporting." In 2023, this system underwent a pilot test through a voluntary program involving several companies in the sector. Section 1 of Disposition 3031, 2024 states: "Establish the implementation of the "eReporting Industria" platform as the sole system for companies that are Holders of Registration and Commercialization Authorizations of Medical Specialties to submit notifications to the Department of Pharmacovigilance and Risk Management, the central effector of the National System of Pharmacovigilance, concerning suspected adverse reactions, events supposedly attributable to vaccination and immunization, and other safety issues related to the use of drugs such as medication errors, lack of effectiveness, and exposure during pregnancy."[5]

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Regulations do not refer specifically to advocacy/patient groups, but the fact that the legal framework does not allow direct-to-consumer promotion of prescription medicines needs to be taken into account.

4. (https://observatoriodemedios.uca.edu.ar/we-are-social-2023-los-datos-sobre-la-argentina-en-materia-digital/)
5. (https://www.boletinoficial.gob.ar/detalleAviso/primera/305418/20240405)

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
There are no regulations regarding honoraria for healthcare professionals or advocacy organizations as payment for their collaboration in media activities or events. The AMA Ethics Code accepts that medical doctors sometimes work as employees for pharmaceutical companies and, as such, will participate in promotional activities of the company.

But in that case, the code suggests they should not actively practice medicine at the same time.
Regarding travel outside Argentina, the CAEMe Ethics Code does not allow companies to pay honoraria to professionals for their time nor organize or sponsor an event for health professionals out of the country, with exceptions. International meetings and symposia abroad to be attended by professionals from different countries are permitted to be sponsored, with restrictions.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Resolution 627/2007, Section 16° allows companies to offer funding or scholarships to healthcare professionals in order to participate in congresses, seminars and scientific meetings. Companies must publicly inform, in advance, the conditions of access to those funds or scholarships and the selection process of applicants, with fair and transparent mechanisms for granting. It is expressly forbidden to prescribe certain drugs or products for such purposes. CAEMe specifies that sponsorship is limited to travel expenses, accommodation, meals and fees. Paying for the time dedicated outside of the meeting or encouraging the prescription of particular drugs through payment of expenses is strictly prohibited.

What is possible in terms of media or message training for health professionals or advocacy organizations?
There are no specific rules.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
Section 11° of Resolution No. 627/2007 states that all information about a medicine issued by the producing company must be exact, verifiable and updated.
The pharmaceutical company must allow access to referenced bibliographical material to any professional who may require it.

Although it is not specifically expressed, it is ethical that materials issued from a pharmaceutical company on behalf of third parties should disclose the involvement of the company.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
There are no legal restrictions.

KEY TAKEAWAYS/ SUMMARY

Locally, the major pharmaceutical companies, both in terms of revenues and sales, are Argentinean. In Argentina, the pharmaceutical industry represents an annual market of $5000 million U.S (Dinámica de consumo de medicamentos en el Mercado Farmacéutico Argentino: https://www.iqvia.com/-/media/iqvia/pdfs/argentina/presentation/dinmica-de-consumo-de-medicamentos-en-el-mercado-farmacutico-argentino.pdf), in which the share of that market is 69.5% for national companies and 30.5% foreign. The national companies that lead the local market are from Argentina and were founded more than 70 years ago as family businesses. They also have an established presence in several other countries but are focused mainly on Latin America. Unlike other Latin American countries, the local pharmaceutical industry in Argentina has shown an important growth during the last decades with the

introduction of technology. The industry mainly develops with local technology news and innovative pharmaceutical forms, some of which are also licensed in other countries.

Many top worldwide pharmaceutical companies make important local investments in clinical research. Argentina participates with prestigious centers in several multicentric clinical trials.

Pharmaceutical companies in Argentina have been members of various chambers for several decades:

- Argentine Chamber of Medical Specialties (CAEME): gathers international companies. See http://www.caeme.org.ar.
- Prescription of Medicines by Generic Name, Laboratories (CILFA): includes main national Law No. 25.649, states that every medical prescription pharmaceutical companies. See http://www.cilfa.org.ar/.
- COOPERALA (Business Chamber of Pharmaceutical Laboratories). See https://cooperala.org.ar.
- Argentinean Chamber of Non-prescription medical Specialties (CAPEMVeL): includes both national and international companies with OTC products in their portfolio. See http://www.capemvel.org.ar/.
- CAPGEN (Argentine Quality for People - Accessible Medicines). See https://capgen.com.ar/

Social Security services are represented by Obras Sociales and medicine plans that provide affiliates with a discount on the purchase of medicines, medical attention and diagnostics that by law (Plan Médico Obligatorio, PMO) cannot be less than 40 percent. PAMI, the National Social Security System for retired individuals over 65, is a key player in the local market, often providing extensive coverage for chronic medications, potentially covering up to 100% of the cost.
The Argentinean public health system provides free medical assistance in public hospitals and free distribution of certain medicines for people not affiliated with social security services. The REMEDIAR Program, renamed in 2017 as Universal Coverage of Meds Program (CUS), provides free distribution of outpatient medicines in Prime Care Health Public Centers.
Through Decree 344, 2023 the National Commission for Health Technology Assessment and Clinical Excellence (CONETEC) was created as a decentralized organism under the Secretariat of Access to Health of the Ministry of Health. The goals of the CONETEC are:

1. To conduct the assessment of health technology devices following criteria based on the quality of evidence, clinical benefit, economic impact on equity and public health, among other principles that may be incorporated, and to publish the corresponding reports.
2. To establish technical recommendations for the inclusion, disinvestment, use guidelines, financing and coverage of the health technologies used in the health system considering the ethical, medical, economic and social dimensions, which will serve as the national technical reference. The technical definitions submitted for revision to the National Commission for Health Technology Assessment and Clinical Excellence (CONATEC) shall be binding for the Ministry of Health, its decentralized and deconcentrated organisms.
3. To survey and analyze the scientific information available related to the health technologies.
4. To produce, or request from expert institutions, assessment reports and technical documents about the health technologies based on evidence: clinical practice guidelines, clinical protocols, among others.
5. To analyze and assess the clinical, economic and social health impact, among others, of health technologies at all stages of their life cycle — from the stage before obtaining regulatory authorization for commercialization until the disinvestment.
6. To promote the training and skilling of technical teams to update the methodologies and assessment techniques for health technology.
7. To monitor the clinical and economic results of the health technologies included and used in the set of benefits covered by the health system.
8. To keep all information regarding the methodology used by the organisms to prepare the reports and recommendations updated. The reports shall be public and be available for free to people on various web sites.
9. To ensure the active participation of the relevant stakeholders connected to health technology in all stages of the assessment process.
10. To propose to the decision-makers of the health system the inclusion or exclusion of any health technology in the set of mandatory benefits.
11. To foster the creation of information networks and training in health technology assessment with key stakeholders of the healthcare system.
12. To create simplified versions of the technical documents issued by the National Commission for Health Technology Assessment and Clinical Excellence (CONETEC) using understandable language to facilitate access and usage in health policies, programs, interventions, and actions.

After the Decree, two Resolutions were approved to define how this should work: Resolutions 2092 and 2679, 2023, from the Health Ministry.[6]

Regulatory bodies in Argentina are contemplating patent protection but nothing has been implemented to date. The local environment of the pharmaceutical industry is very competitive. Leading innovation companies face strong competition from generic drug-producing laboratories. These companies invest few resources in research and development and benefit from the production of drugs whose patents have expired or from drugs without patent protection. However, despite not investing in R&D, they do not always offer consumers the lowest prices.

Regarding the prescription of drugs that require simple, double (archived), or special forms, in 2020 Law 27.553 on electronic or digital prescriptions was passed, and in 2024, Decree 345 (which amends Decree 98, 2023) established that prescriptions must be written expressing first the generic name of the drug (a suggested commercial brand may be included), then the pharmaceutical form, then the number of units, and the drug concentration. Pharmacists must inform consumers of the availability of every commercial brand containing the same drug, same amount of units and same concentration, and the different prices of each product. Changing of the drug prescription by the professional is not permitted.

6. (https://www.boletinoficial.gob.ar/detalleAviso/primera/294474/20230920 - https://www.boletinoficial.gob.ar/detalleAviso/primera/295639/20231006#:~:text=RESOL%2D2023%2D2679%2DAPN%2DMS&text=Que%20mediante%20el%20Decreto%20N,y%20se%20establecieron%20sus%20objetivos.)

BRAZIL

The Agência Nacional de Vigilância Sanitária (ANVISA) is an independently managed and financially autonomous governing agency that acts as Brazil's sole regulator of the manufacturing and distribution of prescription medicines. Advertising prescription medicines by any means that promote the medicine's name is strictly prohibited and enforced by ANVISA.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
In Brazil, the regulating body for medicines and food inside the Ministry of Health is ANVISA. Advertising of prescription medicines to the public is prohibited. Advertising campaigns are allowed only for over-the-counter (OTC) medicine that needs no medical prescription. ANVISA also restricts medical congresses, meetings and events, from distributing product samples if it is a prescription or controlled medicine. Promoting a company's or pharmaceutical laboratory's name, however, is allowed.

As medicine advertising becomes extremely controlled, this factor is making the relationship with physicians and health professionals increasingly restricted and difficult.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
In Brazil, public relations and advertising activities are separate. Public relations efforts are the sole communication element with the pharmaceutical market for prescription and controlled medicines. The sector has specific regulations for the relationship with the market, and ANVISA has created rules for it. A communications plan may be interpreted by ANVISA in several ways, therefore, the work of public relations agencies specialized in health is key, because they know the market and its legislation well. Poorly planned communication actions may result in severe fines from the regulating body.

Who is responsible for the enforcement of these rules?
Technical areas, consultants, external advisors and ANVISA experts are responsible.

What are the regulations regarding healthcare professionals (HCP) engagement by pharmaceutical companies? How are these regulations enforced?
Although lay public engagement is strictly regulated by the ANVISA code prohibiting promotion of prescription medicines, there are no prohibitions on materials in professional settings like medical congresses.

Who receives concerns and complaints? How does this process operate?
ANVISA has a call center service for consumers to report any kind of event or complaints about food, pharmaceutical products or health devices. Complaints will be investigated and the agency may apply fines, interrupt operations, shut down establishments, withdraw products from the market and prohibit imports and exports.

What promotional or media materials must be pre-approved by authorities?
It is not mandatory to send public relations materials for previous analysis or approval by ANVISA, but they need to get the agreement from the company's health professionals or responsible areas before being published. It is rare for companies to consult the regulatory agency.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?
In 2000, ANVISA created a resolution/ordinance to regulate publicity/advertising/promotion activities for medicines and rules governing the creation of advertising materials for medicines manufactured and/or marketed in Brazil. Since then, this ordinance has undergone several updates. In a 2011 ordinance, the agency communicated plans to regulate public relations actions, pharma and public relations professionals must comply with all of these rules.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
As advertising for prescription medicines is not allowed, in general, it is very easy to make a distinction between basic information and advertising.

How is a "media event" defined?
Two ways:

1. Awareness situations, and support to medical societies and for the government.
2. Introduction of new products under an ethical positioning, with no promotional actions or actions that state that the product is the best or the most revolutionary in its segment. The focus of the actions is to always emphasise the scientific information.

Do the regulations differentiate between consumer and clinical publications?
Yes, because the materials have different purposes. The promotional material is exclusively for physicians. In this case, ANVISA is even more attentive about these materials. Overall, the content carries information of the label and clinical trials.

Do regulations differentiate between print and broadcast media?
No, the regulation is the same for all media outlets, including newspapers, magazines, radio, television or the internet.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
There are no specific rules in place for these events. public relations agency recommendations can include specific actions with journalists, such as press conferences and workshops in a separate setting from medical events.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media and clinical events treated the same?
While Brazil has restrictive regulations, there are no regulations specific to press releases and media materials. The laboratories' compliance departments and public relations agencies will follow the general rules that govern the issue or production of scientific and information materials that are appropriate for each type of audience and event to be carried out.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
In these cases, when publications receive press releases from the international agencies, they tend to reproduce them, and in some cases they do not follow ANVISA's rules. However, when Brazilian PR agencies receive press releases sent by their clients from abroad, they tend to tailor them to local style.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?
There is no specific regulation, but the rules already determined by ANVISA are followed. Companies can sponsor actions and events, except for the media, and they cannot use the medicine's brand name if it is a prescription or controlled medicine. For OTC medicines, sponsorship activities are allowed if ethical standards are observed.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
There is no difference for employed journalists or freelancers in Brazil. They do not need to submit their report to the regulatory agency or the inviting company. The decision about whether a journalist may or may not accept an invitation from laboratories remains with directors, editors or editors-in-chief, or the journalist if he or she is a freelancer. Accepting an invitation does not obligate the journalist to write a report, either favorable or unfavorable, for the laboratory. The writer is free to decide.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Patients' groups are free to talk to the media on their own, and they can organize such actions independently. Officially, pharmaceutical companies and physicians are not allowed to encourage patients to talk about medicines. If a journalist needs to talk to a source, he or she must find interviewees independently or ask the patients' associations throughout the country.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
An important phenomenon has been found to occur in the healthcare area in Brazil, different from other countries. A recent survey coordinated by Tino Comunicação and conducted by Ibope (a major market research institute in Brazil) has found that Brazilians search for information about prevention, treatment and diseases on the internet, even before seeing a physician. As opposed to other media, there are no clear rules in place for the social networks. However, in general, pharmaceutical companies and public relations agencies will follow the rules already established by ANVISA for other types of media.

What levels of web security are required?
There are no specific regulations regarding web security; however, it is recommended that companies develop PR strategies to respond to potential crises related to their websites and social media channels.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
ANVISA has no specific regulation for the internet yet. As any kind of advertising involving prescription medicines is prohibited, the pharmaceutical companies cannot have portals, websites or blogs that showcase ads with the medicines' brand names. However, on sites, blogs and independent media outlets that have no connections with companies, one can post comments and information, provided that it is done in compliance with the local legislation. The Federal Board of Medicine (CFM) has created specific rules for physicians on the internet. Health professionals are not allowed to promote themselves or medicines, clinics, hospitals or any healthcare-related commerce. If they do, they are subject to the board's sanctions.

What are the most popular social networks in your region?
The top 5 as of 2025 are: WhatsApp, Instagram, Facebook, TikTok and Facebook Messenger. X (Twitter) and LinkedIn are ranked #9 and #10 respectively in Brazil, lower than in some other countries.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Brazil has not yet passed legislation that regulates the use of the internet. This issue is still under discussion. Each new situation is analysed under existing laws or regulations of agencies such as ANVISA.

Are there any self-imposed regulations on social media companies?
Yes, Anvisa regulates the use of social media to promote health products, including medicines, cosmetics and personal hygiene products. This regulation aims to ensure the safety and quality of the products advertised, as well as to prevent misleading advertising practices or those that may harm public health.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Yes, for prescription and controlled medicines. The company cannot have a direct relationship with the consumers to talk about this kind of medicine. However, a direct relationship may be established to talk about the disease and awareness.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2025, Brazil had 263.6 million cell phones in use, with a density of 120.99 devices per 100 inhabitants. The number of people connected to the internet in Brazil in 2025 was 183 million, which represents 86.2% of the population. The cell phone is the main device for accessing the internet in Brazil, with 84.7% of people having a device.

What are the disclosure laws like in your region for "non-branded" websites?
'Non-branded' websites have to show who initiated and supports them.

What is the response level needed for adverse event reporting?
Pharmaceutical companies, hospitals and other organizations have pharmacovigilance services in place that report to ANVISA. The Brazilian agency also carries a direct service for the population and the industry for reporting irregularities and complaints.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
The industry can have relationships with patients, but they must be restricted to informative and scientific initiatives. Sponsorship to non-governmental organizations (NGOs) or patient associations is legitimate provided that they comply with ANVISA's ordinances. Patient associations and NGOs have total freedom, even if sponsored.

Is it possible to pay healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
It is possible to pay health professionals for lectures and as advisory board participants, for example.

The industry can support meetings and patient associations to participate in events, covering tickets, lodging and meal expenses, but they cannot be paid to participate in any action. This is restricted to awareness actions and campaigns, which are meant to be informative, educational or scientific, never mentioning the product's name. Physicians, however, can receive a fee when participating in this kind of action.

What is possible in terms of media or message training for health professionals or advocacy organizations?
Companies are allowed to conduct media training, speaker training, and message training sessions and awareness events and the like, always bearing in mind the educational, informative or scientific objective.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
The rules are the same as for the pharmaceutical industry. Patient associations and NGOs have more freedom to discuss with patients, society and the government about new treatments and the inclusion of medicines than the pharmaceutical companies.

These associations play a key role in access to high cost medicines. It is often through these associations that patients get access to high cost medicines, since the Brazilian Constitution ensures universal right to health.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
ANVISA states that there can be no advertising or action that involves prescriptions or controlled medicines. Pharmaceutical companies, patient associations, NGOs and reputable healthcare services vendors, such as public relations agencies, will already know ANVISA's regulations, and take them into consideration before creating any kind of action.

KEY TAKEAWAYS/ SUMMARY

- The regulatory environment in this market is highly controlled. ANVISA has technicians who constantly watch the market and its movement.
- Media training, speaker training, message training sessions and awareness events are permitted, always bearing in mind the educational, informative or scientific objective.
- The industry is free to develop relationships with patients, but interactions must be restricted to information and scientific initiatives.

CANADA

In Canada the promotion of medicine falls under the jurisdiction of 'The Food and Drugs Act and Regulations' and the 'The Distinction between Advertising and Other Activities' policy. Promotion of drugs prior to approval is prohibited, while the promotion of a prescription drugs to the general public is limited to name, price and quantity. Regulations clearly differ between consumer and clinical publications. There are no formal regulations pertaining to healthcare provider (HCP) engagement by pharmaceutical companies; however, each company has its own internal rules and regulations. Most follow the Innovative Medicines Canada Code of Ethical Practices, which outlines acceptable standards.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

- **The Food and Drugs Act and Regulations:** This Act governs the production, import, export, interprovincial transport, and sale of food, drugs, contraceptive devices, and cosmetics. It ensures products are safe, effective, and appropriately labelled. The Act prohibits advertising of drugs to the general public for diseases listed in Schedule A (e.g., cancer, obesity, anxiety, asthma, depression, and STIs).
- **The Distinction between Advertising and Other Activities:** This Health Canada policy clarifies the line between advertising and non-promotional activities, including education, scientific exchange, investor communications, and labelling. It helps determine when communications about a drug are subject to advertising provisions.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Advertising includes any representation made to promote the sale of a drug. If a message is non-promotional in nature—such as scientific, educational, or shareholder-focused—it is not subject to advertising rules. The context, audience, message content, and delivery method are all evaluated to make this determination.

Key Regulatory Restrictions:

- Pre-approval promotion is prohibited (Section 9(1) of the Act; Section C.08.002 of the Regulations).
- Prescription drug promotion to the public is limited to the drug's name, price, and quantity (Section C.01.044).
- Advertising of treatment for Schedule A diseases to the public is prohibited (Section 3 of the Act).

Health Canada no longer uses Schedule F. Prescription status is now defined by the Prescription Drug List (PDL).

Who is responsible for the enforcement of these rules?

Health Canada is the federal regulator responsible for enforcement. Its Marketed Health Products Directorate (MHPD) investigates complaints and enforces compliance using a risk-based, tiered approach.

What are the regulations regarding HCP engagement by pharma companies? How are these regulations enforced?

Continuing medical education (CME) events and scientific symposia related to drugs are sometimes sponsored by pharmaceutical manufacturers.

Such activities may not be considered advertising when they provide a forum for exchange of information on related clinical and scientific issues. The key factor in determining the status of such an activity is the degree to which the program is independent of the drug manufacturer. The information may be not promotional in the following circumstances:

- Sponsorship by a drug manufacturer is not targeted to specific aspects of the agenda.
- The sponsor's role is adequately disclosed.
- The program is directed to scientists and/or health professionals.
- The program allows for exchange of information/debate.
- The content of the agenda is not influenced by the sponsor.
- The content of an individual presentation is not influenced by the sponsor where it concerns a drug manufactured by that sponsor.
- There is no inducement provided to participants
- There are no ancillary commercial or promotional activities relating to drug products.
- The limitations of the data and of the drug are adequately discussed.

- Discussion of an unauthorized drug or indication for use includes a statement indicating that the drug/indication has not been authorized for marketing in Canada.
- No reference is made to the availability of unauthorized drugs through the Special Access program.

Such activity may be considered advertising when any of the aforementioned conditions are not met or where other factors indicate that the primary purpose of the activity is to promote the sale of a specific drug. Moreover, reports, edited scripts or recorded videos of the proceedings, in whole or in part, that concern a specific drug may be deemed advertising if they are disseminated by the sponsor, or the sponsor's agent, to a wider audience after the meeting.

While there are no formal regulations related to pharmaceutical companies, engagement of HCPs for media purposes, each pharmaceutical company has their own internal rules and regulations that govern these relationships. During the past few years, the industry has come under increasing pressure to voluntarily divulge how much funding they provide to physicians and health organizations annually. So far, 10 Canadian-based pharmaceutical companies have agreed to disclose this information in an effort to make their financial ties more visible – and help neutralise charges of conflict of interest.

Who receives concerns and complaints? How does this process operate?
Health Canada may receive complaints directly or through the Pharmaceutical Advertising Advisory Board (PAAB) or Ad Standards (formerly Advertising Standards Canada). Complaints are assessed based on the potential health risk. Most non-compliant materials are addressed cooperatively via written notice, but Health Canada can escalate to seizures, public advisories, or court action when necessary.

What promotional or media materials must be pre-approved by authorities?
Pre-clearance is not mandatory, but strongly recommended:
- PAAB reviews promotional materials intended for HCPs.
- Ad Standards reviews consumer-directed materials.

Health Canada encourages both processes but does not review or approve advertising directly before dissemination.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?
Yes. In 2017, Ad Standards issued new disclosure requirements for paid influencer endorsements across platforms like X (Twitter), Instagram, Facebook, and YouTube. PAAB also issued updated social media guidance covering sponsor responsibilities, user-generated content, and content moderation.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
The distinction depends on the intent and presentation. If the primary purpose is to promote the sale of a drug, it is considered advertising. Factors that influence this include:
- Who created and paid for the message.
- Where and how it is distributed whether the message focuses on product attributes, efficacy, or comparisons.
- Whether risks and limitations are disclosed.
- Whether repetition or proximity to other promotions exists.

How is a "media event" defined?
An event to generate media attendance and interest in a particular issue and/or product.

Do the regulations differentiate between consumer and clinical publications?
Yes.

Consumer brochures are allowed if they focus on disease education, describe multiple treatment options, and avoid emphasis on one product. If they reference unauthorized drugs or promote specific branded therapies, they may be considered advertising.

Clinical journal supplements are acceptable if they present unbiased symposium content, disclose sponsorship, and maintain editorial separation from promotional messaging.

Do regulations differentiate between print and broadcast media?
No. All forms of media are subject to the same regulatory principles. The key is the message's intent and content, not its format.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
Promoting a drug prior to market authorization is prohibited. However, international conferences may allow limited discussion of unapproved products under strict conditions:
- The material must originate from the global parent company.
- It must be used only within the confines of the event.
- It must clearly state that the product is not authorized in Canada.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

Press Releases/Press Conferences
It is common practice for a pharmaceutical manufacturer to release information on new developments in research and at the time of launch of a new drug or a new indication for use of a previously authorized product.

A press release or information disseminated at a press conference concerning a drug may considered not a promotional activity in the following circumstances:
- The announcement is directed to shareholders or potential shareholders.
- The announcement is limited to the name of the drug and its authorized or proposed therapeutic use.
- No statement is made regarding the degree of safety or efficacy expected.
- No comparison is drawn with other treatments.
- In the case of unauthorized drugs, or unauthorized indications, the message cautions that the safety and efficacy are still under investigation and that market authorization has not yet been obtained.

- There is no attempt to influence the placement or emphasis given in subsequent publication or broadcast, e.g., no payment is made by the manufacturer to influence the visibility (e.g., section) in the press.
- In contrast, a press release or information disseminated at a press conference may be advertising where any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the message is to promote the sale of a drug.
- Undue emphasis is placed on the drug being a 'breakthrough'.
- The press release is subsequently sent or provided to another audience, e.g., mailed to physicians,
- A fee is paid by the sponsor to have the message published or broadcast, or
- In the case of an unauthorized drug, it is indicated that the drug is available through the Special Access program.

Invitations to media events and clinical events are not treated differently. A journalist cannot be paid/ compensated for their attendance, including travel, accommodation, and so on.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
No.

Can pharmaceutical companies pay or sponsor journalists to attend events?
No. Paying a journalist's travel, lodging, or other expenses is considered advertising and may compromise editorial independence. Independent attendance is allowed, but coverage remains outside the sponsor's control.

If a company sponsors a journalist at a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
If a journalist is attending an event independently, their output is considered editorial and does not require review or approval. The rule applies equally to freelancers and staff writers.

Pharmaceutical manufacturers are not allowed to sponsor journalists at scientific meetings. This is considered advertising since the manufacturer is paying the reporter's travel expenses, which could potentially to influence the journalist's story.

Do regulations cover the use of case studies or other third-party advocacy in the media?
There are no specific regulations, but such content could be classified as advertising if it appears promotional or lacks balance.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
No. They are not differentiated.

What are the data security and privacy requirements?
Canada's privacy laws (e.g., PIPEDA) apply to data collection and interactions on digital platforms, but there are no unique pharmaceutical-specific web security requirements beyond those already noted.

Can pharma fund third-party websites?
Yes, but if they do, the site becomes subject to pharmaceutical marketing regulations. Sponsorship must be disclosed, and the content must meet the same standards of balance and non-promotion.

What are the most popular social networks in your region?
As of 2025: Facebook, YouTube, Instagram, LinkedIn, and TikTok dominate. Messaging platforms like WhatsApp and Facebook Messenger are also widely used.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Yes. PAAB's guidance differentiates between:
- Branded drug advertising (must be reviewed).
- Disease and medical information (may be exempt if non-promotional).
- Corporate communication (e.g., press releases, product pipeline).
- Educational programs (must not focus on one therapy).

Are there any self-imposed regulations on social media companies?
No. Platform-specific restrictions are governed by platform terms of service and standard Health Canada rules, not additional laws.

What is the status of mobile usage and does it change anything?
Mobile use accounts for over 55% of social media traffic in Canada. While this increases reach, it does not alter the regulatory framework—rules apply regardless of device.

Are disclosures required on non-branded websites?
Yes. The identity of the sponsor must be disclosed prominently on any website or digital content funded by a pharmaceutical company.

What are the requirements for adverse event reporting?
Manufacturers must report serious or unexpected adverse drug reactions to Health Canada through the Canada Vigilance Program. HCPs and patients can also submit reports voluntarily.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no regulations around this. Each pharmaceutical company has their own policies and procedures which they follow. There are no formal government regulations, but company policies and industry codes (e.g., IMC Code) govern interactions. Travel support to conferences is typically handled through unrestricted educational grants.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events?
Yes, if payments are transparent, reasonable, and consistent with the individual's role and experience. Documentation is typically required, and companies often follow pre-set honoraria rates.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, usually via unrestricted educational grants that do not specify messaging or participation conditions.

Is media training for HCPs or patient advocates allowed?
Yes, as long as it is non-directive and participants are not coached to deliver promotional claims. Training should emphasize transparency and comfort with key messages.

Are there rules for materials written on behalf of third parties?
Such materials must follow the same principles as other educational content:

- Be disease- not product-focused.
- Offer balanced discussion of treatment options.
- Avoid promotional language or emphasis.
- Disclose sponsorship.
- Avoid references to unauthorized drugs unless clearly indicated.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
There are no formal regulations, but interactions are expected to comply with internal compliance policies and applicable industry standards.

KEY TAKEAWAYS/ SUMMARY

- Promotion prior to market authorization is prohibited.
- Prescription drug advertising to the public is limited to name, price, and quantity.
- Materials directed to HCPs and the public should undergo preclearance via PAAB or Ad Standards, though this is not legally required.
- Digital media, social platforms, and influencer campaigns must comply with standard advertising and disclosure rules.
- Journalists may not be paid to attend events.
- Adverse event reporting is mandatory for manufacturers and encouraged for professionals and patients.

CHILE

Promotion and advertising of pharmaceutical products in Chile is ruled and supervised by the national regulations applied by th ISP, an agency under the Secretary of Health. The direct promotion of prescription drugs to consumers is not allowed, except by professionals legally authorized to prescribe such drugs or by pharmacists in charge of delivering the products.

THE BASICS

What laws and codes of practice govern drug promotion?

The advertising of direct sale medicines is regulated by a Supreme Decree (of Health) No. 1876/95, "Regulation of the National System of Control of Pharmaceutical Products, Food for Medical Use and Cosmetics", being the Institute of Public Health (ISP) the Public Service in charge of its application and control.

Law No. 20.724 on Medicines Advertising: enacted in 2014, regulates the advertising and promotion of medicines in Chile. It establishes the requirements and limitations for the promotion of medicines, ensuring that the information provided is accurate, balanced and truthful. The law prohibits misleading or false advertising, as well as the promotion of medicines not authorized by the Institute of Public Health (ISP).

Code of Ethics of the Pharmaceutical Industry in Chile: The pharmaceutical industry in Chile has developed its own codes of ethics that establish guidelines for the ethical promotion of medicines. According to protocols reviewed locally, some multinational companies have adopted their compliance standards and codes of conduct to the current regulations and also according to the trade associations to which they belong such as CIF, Prolmed or Asilfa. The first two have their own annexes to the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) Code of Conduct. In the case of Asilfa, it has its own Ethics and Good Practices Regulation that refers more to the behavior that its members must respect with respect to their peers, suppliers and authorities.

The Institute of Public Health (ISP) of Chile, is the authority in charge of regulating and supervising the promotion of medicines in the country. The ISP grants authorization for the marketing of medicines and supervises advertising and promotion to ensure compliance with applicable laws and regulations.

In addition, the Council of Self-Regulation and Advertising Ethics (CONAR), where TV, radio and agency associations are grouped, has a Code of Ethics with two articles on drug advertising. CONAR is responsible for analyzing and guiding the advertising of direct sale medicines from the perspective of ethics, specifically applying the Chilean Code of Advertising Ethics to the advertising of this type of products, which will be done considering the provisions of the national regulations on the matter.

With respect to marketing, how do regulators define public relations as compared to advertising or other promotional activities?

Advertising involves the direct, paid promotion of a drug, public relations focuses on managing the public image of the company and its products, and other promotional activities can include a variety of initiatives designed to inform and educate about drugs more broadly.

In the code of ethics of the Medical Association of Chile, the physician is explicitly prohibited from any form of advertising, direct or indirect, aimed at obtaining personal advantages or for the healthcare establishments in which he or she carries out his or her activity. As regards the dissemination of scientific work, it states that this must be done in the corresponding scientific publications, and that it is contrary to professional ethics to disseminate it directly and in advance through the non-specialized press, radiotelephony, television, electronic media or any other similar means of information.

According to the document, it is unethical for a physician to appear in the media when it is clear that his or her objective is none other than to attract patients. In this sense, the following conduct is considered reprehensible:

1. The appearance in that kind of media, for advertising purposes, prior request, acceptance or financing of the physician.
2. The appearance of the physician in any media or advertisement of pharmaceutical products, supplies or medical equipment.

3. The appearance in advertisements of health institutions or companies when the professional may be economically benefited thereby.

It is established that scientific societies and specialized organizations will be responsible for the promotion of healthy behaviors that benefit the community. The physician will be able to publish an announcement in the media informing him of the address of a new practice. In any case, this announcement should be made in a sober manner and should never be advertising.

Regarding their relationship with clinical and pharmaceutical product companies, it is indicated that the physician will always maintain a relationship of professional independence with the companies producing or distributing articles for clinical or pharmaceutical use and that decisions affecting their patients must always look after their interests.

Following a 2017 agreement between the Medical Association and the Chamber of Pharmaceutical Innovation, CIF, laboratories and physicians undertook to exclude from their practices personalized invitations to organized national and international congresses, which includes funding for airfares, registration and hotel stays. Likewise, invitations to dinners, lunches, breakfasts, and the delivery of gifts that represent an economic value and can be considered a transfer of value.

While the Drug Law (20.724) states that advertising is only allowed with respect to direct sale drugs, which do not require a prescription, the promotion aimed at doctors and other professionals authorized to issue prescriptions may not be made in the media aimed at the general public.

Incentives to professionals to issue prescriptions by laboratories, importers, distributors or pharmaceutical establishments, such as payments, gifts, services or economic benefits, are prohibited.

Who is responsible for the enforcement of these rules?
The ISP, which reports to the Secretary of Health. ISP's website states that its mission is "to contribute to the improvement of the health of the population, ensuring the quality of goods and services as a National Standardizing and Reference Laboratory, Supervisor and Inspector, in charge of carrying out health surveillance measures."

Private ethical codes are mandatory for chamber members. In the case of the Chamber of Pharmaceutical Innovation, it has conduct agreements with the Medical Association and with patient groups, which are supervised by the signatories themselves.

Who receives the concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
The investigation department of the (ISP) is in charge of verifying the concerns or complaints expressed by any citizen, company or other party. At the same time, it makes periodic visits to all companies under its regulation (including laboratory and pharmacy) to check if they are working within the legal framework.

In its internal regulations, there is a special point about reports: "to investigate complaints about failures in quality, efficacy, safety and advertising of pharmaceutical and cosmetic products, ensuring compliance with current health legislation of establishments that manufacture, import, distribute and/or dispose of these products in order to ensure the health and satisfaction of the population that uses them".

Do any promotional or media materials need to be approved by regulatory authorities?
According to Supreme Decree No. 1 of the Secretary of Health published in 2015, which amends the Regulation of Pharmacies, Drugstores, Pharmaceutical Stores, and Authorized Warehouses, it establishes the obligation to obtain prior authorization from the Public Health Institute (ISP) of any advertising intended for pharmaceutical specialties for which advertising is possible (direct sale), having to "reproduce the exact content, total or partial, of the patient information leaflets and labels, which have been approved in the respective sanitary registration".

Over the past 5 years, what significant regulatory developments have been implemented? Are there any changes to codes of conduct planned in the near future?
In 2015, the processing of the "Drug Law II" began, which amends the Health Code to regulate bioequivalent generic drugs and prevent the vertical integration of laboratories and pharmacies. The bill regulates, among other matters, the prescription and dispensing of medicines, modifying provisions of Article 101 of the Drug Law I. Main issues addressed by the bill refer to price regulation, brand size, patents, essential goods, accessibility and advertising. This legislation is stalled in Congress and no relevant progress is expected in the short or medium term.

On the other hand, the first decree of Law 20,850, known as Ricarte Soto Law, was enacted in 2015 and seeks to ensure the financing of diagnoses and treatments based on drugs, medical devices and food of high cost and proven efficacy, which often have unattainable costs for individuals and their families. Its beneficiaries are all people who have a Social Security System in Chile. This legislation is currently under review, as it requires some adjustments both in the deadlines for defining the admission of new pathologies and in its budget, for which changes are expected in the short to medium term.

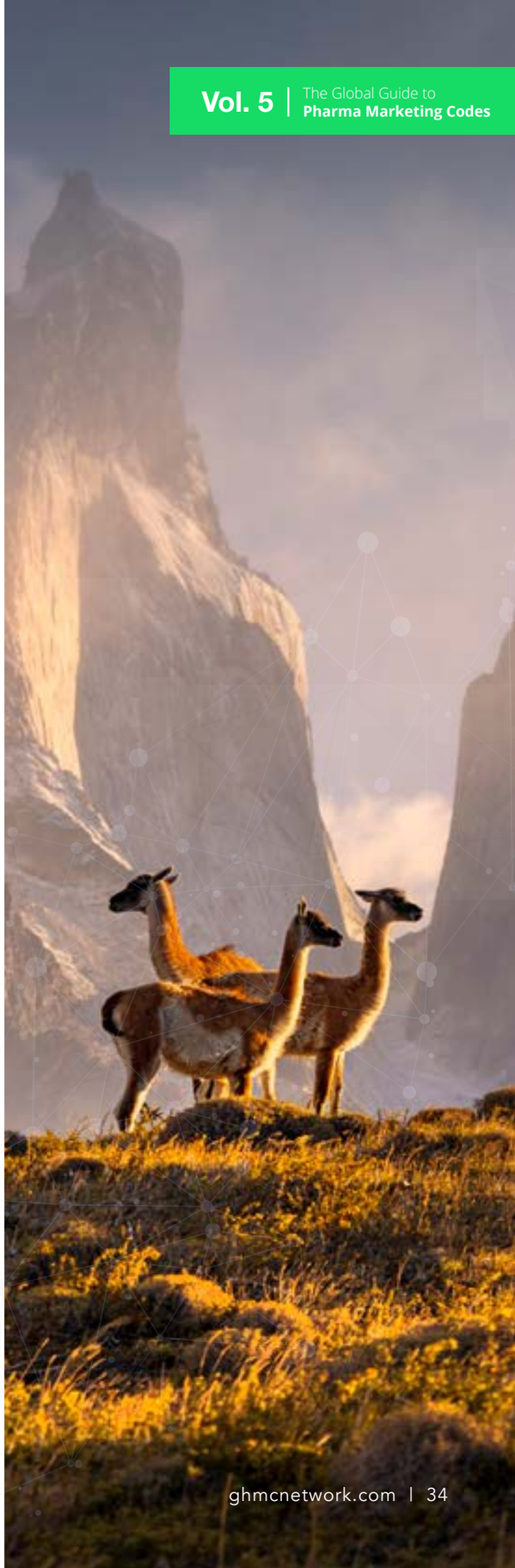
Both laws are shaping a new scenario for the health ecosystem, not only in terms of coverage, but also in the management of its stakeholders and promotion.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
Generally speaking, if brands are named this is considered as promotional material and, therefore, is not considered news by the media and is assigned to the commercial area. The news is published because it is considered to have an informative value that makes it interesting for the public.

In general, "advertisement" and "advertising material" are understood as material broadcast in a television or radio program service that aims to:
1. promote the sale of a product or service or,
2. promote the interests of any organization, commercial enterprise or individual.

This includes messages broadcast by means of words, sound effects (including music), visual presentation, direct advertisements, slogans, descriptions or otherwise, as well as promotional references in a program to any product or service. However, there are no specific definitions to differentiate promotional activities from the provision of information.



How is a media event defined?
Article 1 of Law 19.733, in the media, recognizes the right of people to be informed about facts of general interest.

Does the regulation differentiate between consumer and clinical publications?
Decree No. 1876 distinguishes between products that can be sold directly to the public and those that can only be sold on prescription. The latter can be advertised by physicians or other professionals who can make prescriptions with public advertising when the advertisement refers to the introduction of the drug on the market. Product information must be included.

Article 90 decrees that advertising is not allowed for prescription drugs. The only figures who can promote the products are the professionals who have the legal power to prescribe the drugs and the pharmaceutical chemists in charge of supplying the products. In addition, the patient information leaflet and the professional information leaflet are regulated separately.

A professional information leaflet is "a document containing the pharmaceutical characteristics, including pharmacological, toxicological, clinical and therapeutic properties of a pharmaceutical product or a food for medical or cosmetic use, for the purpose of informing professionals legally empowered to prescribe or dispense pharmaceutical products" (Art. 4 point A1).

A patient information leaflet is "a document intended to inform the patient about a pharmaceutical product, a food for medical or cosmetic use. It contains information to ensure proper use, warnings, contraindications, interactions with other products, precautions and other data determined by the health authority in the registration". The leaflet for direct sale of pharmaceutical products must also note the uses, posology and method of use approved in the registration" (Art. 4 letter B1).

Regarding the media, the Press Law regulates the exercise of the right to express opinion and information but does not differentiate between consumer publications and clinical publications. In media practice, however, a distinction is made between what is news and what is advertising, special edition or "sponsored content."

Does the regulation differentiate between online, print, broadcast and/or streaming media?
Article 2 of Law 19,733 (Press Law) establishes that "for all legal purposes, social communication media are those capable of transmitting, divulging, disseminating or propagating, in a stable and periodic manner, texts, sounds or images destined to the public, whatever the support or instrument used".

The law defines a newspaper as "one that is published at least four days a week and meets the other requirements established by law." This legislation does not establish a distinction for audiovisual media, but it also applies to them because they are media.

As for television, as a means of social communication, it is regulated in Chile by numeral 12 of Article 19 of

the Constitution, which establishes that the National Television Council will be "in charge of overseeing the correct operation of this means of communication". Law No. 18,838ix, which creates the National Television Council (CNTV), defines the correct operation of television.

The existing regulation does not specifically refer to digital media, online or streaming. There are currently two bills in process, which focus on regulating the operation of digital platforms, as well as the dissemination of content, information and services on digital platforms and social networks, both presented in 2021.

What rules specifically regulate press releases and media materials? What are the general principles? Is an invitation to the media or to clinical events treated in the same way?
There is no mention on this point in Decree No. 1876, the code of ethics of the Self-Regulation and Advertising Ethics Council, the code of ethics of the Industrial Association of Pharmaceutical Laboratories, or the code of ethics of the College of Journalists.

These types of methodologies and their regulation depend on the internal protocols of the companies and their compliance rules.

What rules regulate press activity at scientific congresses and meetings, such as holding a press conference or sponsoring media attendance? Do these rules apply equally to licensed and unlicensed products?
There is no mention on this point in Decree No. 1876, the code of ethics of the Council for Self-Regulation and Advertising Ethics, the code of ethics of the Industrial Association of Pharmaceutical Laboratories or the code of ethics of the College of Journalists. Journalists voluntarily choose to participate. In general, the media apply the newsworthiness of an activity to cover or participate in it. While the publication of content, statements or studies must comply with the general rules for those products approved by the ISP.

Does the regulation cover the use of case studies or other third-party outreach materials in the media?
According to the ICF agreement with the Medical Association, companies may produce and distribute scientific dissemination and medical education material related to new therapies and their advantages, aimed at healthcare professionals, either directly or through independent publications (from medical societies, universities, healthcare institutions and professional associations).

In addition, companies must comply with the code that establishes rules that regulate the relationship between patients' associations and pharmaceutical companies associated in the guilds that bring them together. Thus, the coverage of medical cases or studies is circumscribed to the editorial parameters of the media and generally avoiding commercial mentions.

DIGITAL & SOCIAL MEDIA

Are online media different from print and broadcast media and, if so, how are they regulated and supervised?
Currently Chile does not have a law that regulates the rights and duties of digital media, as they are not legally recognized as such. There are currently two bills in the pipeline, which focus on regulating the operation of digital platforms, as well as the dissemination of content, information and services on digital platforms and social networks, both submitted in 2021.

What are the requirements in terms of web security and data privacy?
The Net Neutrality Law, which enshrines the principle of net neutrality for consumers and Internet users, states that distributors and providers must preserve user privacy and protection against viruses and network security.

Also, since 1999, Chile has had a private data protection law 19.628, which safeguards and regulates the use of personal data.

Does the regulation cover the financing or provision of information to websites that are not owned by the company?
The regulation does not specify about financing or providing information to websites that are not owned by the company itself.

However, Article 100 of the Drug Law states that "The promotion of the pharmaceutical product intended for professionals authorized to prescribe it, within the indications of therapeutic usefulness of the respective health registration, may not be carried out through social media directed to the general public. Such promotion may include the delivery of medical samples to these professionals under the terms set forth in the respective registries, to be provided, free of charge, to the persons who use their services".

Likewise, it goes on to state that "the donation of pharmaceutical products made for advertising purposes and economic incentives of any kind, which induce professionals authorized to prescribe and dispense medicines or the employees of the dispensing establishments and any other person involved in the sale or administration of medicines, to favor the use of a certain product, are prohibited".

Article 200 of Decree 3 on the control of pharmaceutical products states that "advertising of pharmaceutical

specialties for direct sale shall only be authorized in advance by the Institute of Public Health. The advertising may only reproduce the exact content, total or partial, of the patient information leaflets and labels that have been approved in the respective sanitary registry".

What are the most popular social networks in your region and what restrictions are there (if any) on the promotion and advertising of biopharmaceuticals through social media/ promoted posts, beyond disease awareness content?
As of January 2024, there were 17.88 million internet users in Chile. Our country's Internet penetration rate stood at 91.0 percent of the total population in early 2024.

According to information from Statista, Chile has the second highest penetration of social networks in Latin America and the Caribbean. Around 84.5 percent of the inhabitants interact on these platforms. According to the most recent data, the most common user profile is women between 25 and 34 years old. As for the most popular social network, Facebook is the one that ranks first, accumulating more than 70% of total monthly visits. In second place is another application belonging to Meta, Instagram, which accounts for around 10%.

By its part, WhatsApp, also owned by Meta, also has an important penetration, being used for more than 80% of mobile phones users.

Despite Facebook's high reach in Chile, the social network that stood out for its expansion in 2022 was LinkedIn, which increased its web traffic by 160%. In terms of number of users, TikTok is the undisputed leader, with a growth of more than 60%. At the opposite pole is Telegram, which experienced the greatest leakage of interested parties. Likewise, Instagram and TikTok have become the most relevant apps for influencer marketing.

The restrictions that exist, regardless of the medium, are those established in the general codes and in the Drug Law on promotion and advertising of products, which were mentioned earlier in this document.

Have local regulators introduced any guidelines on the use of social networks either for disease awareness activities or product promotion?
In 2018, MINSAL presents the Digital Health Strategy or e-Health Plan, whose mission is to contribute to improving the health of the population through the timely, efficient and reliable management of standardized information. The Plan seeks to support and enable the achievement of the sector's health objectives through the intelligent use of information technologies. In other words, its development is a necessary condition for ensuring patient care, disease prevention and efficient resource management in an increasingly complex healthcare environment.

This strategy has its roots in the Health Reform process carried out in Chile in 2004 and 2005, which implied great challenges in terms of installing new models of care and healthcare processes, which in turn required precise management of timely information based on information systems that did not exist at that time. An example of this is the intricate management of the information needed to ensure compliance with the Explicit Guarantees defined in the AUGE Plan.

The only Chilean legal framework governing the marketing industry is Law 19.496, which establishes rules on the protection of consumer rights, and Law 19.628, on the protection of privacy or protection of personal data.

Are there self-imposed rules by social media companies?
The most popular social media companies, Facebook and Instagram, publicly state self-regulation on content and possible content removal and account disabling or termination.

The company reserves the right to remove any content or information shared on the Service if it believes it violates these Terms of Use or our policies (including the Instagram Community Guidelines), or if required by law. The company may stop providing all or part of the Service (including terminating or disabling an account) immediately to protect the community or its services, or if the content poses a risk or legal exposure to the company.

For digital platforms such as forums, does your regulatory body have specific rules for interactions between customers and businesses?
In Chile, the government does not apply any specific rules. The interaction between companies and consumers is governed only by the internal regulations that companies declare on their websites. The authority acts only in cases where government institutions receive a complaint.

How is the adoption of mobile telephony in your region and is there a specific regulation in this regard?
According to the Department of Statistics of the Undersecretary of Telecommunications, as of December 2023 in Chile, there are 26,710,679 cell phone subscribers. This number exceeds the total population (approximately 19 million), which means that many citizens own more than one cell phone. There are no specific regulations in terms of health communication, only telecommunications in general.

What are the disclosure laws like in your region for non-branded websites?
The regulatory information does not specify any special laws or regulations on non-branded websites.

What are the requirements for adverse event reporting?
In Chile there is a National Pharmacovigilance Program, of spontaneous reporting, and it consists of communicating to the ISP, by a health professional, health care center or health registration holders, suspected adverse drug reactions of which it becomes aware, including dependence, abuse, misuse and lack of efficacy.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country to attend a congress or meeting?
In Chile, pharmaceutical legislation does not contemplate special treatment for patient protection groups and advocacy groups. The relationship that develops between these groups and the laboratories is due in most cases to the support or financial support to some campaigns they carry out.

According to documents from the Chilean Secretary of Health, Chilean State considers that these advocacy groups play a key role in three aspects:

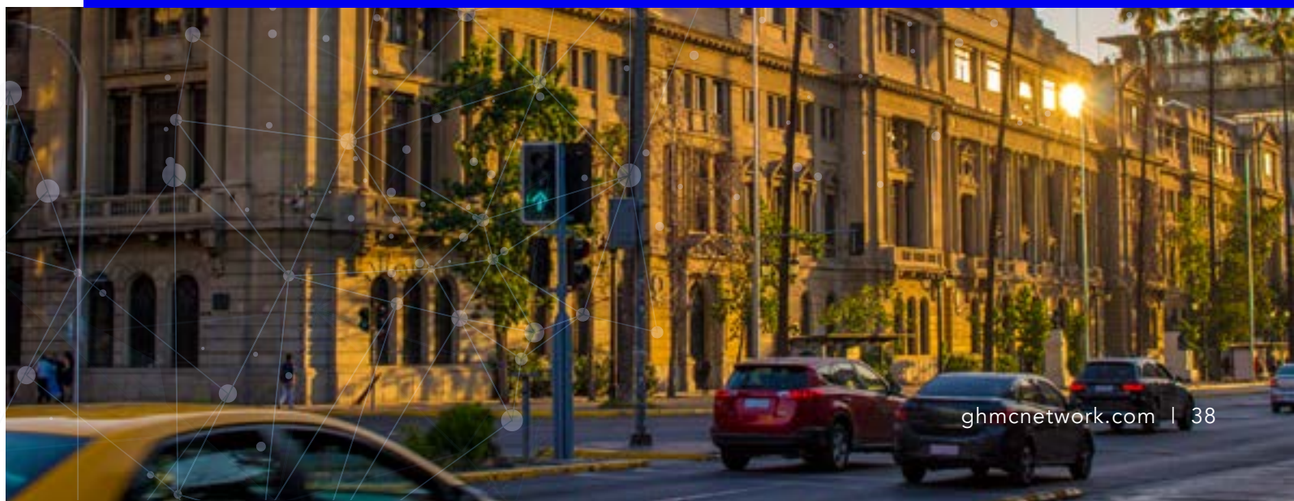
1. Protagonism in raising awareness among the community, authorities, media, etc. about mental illness, its impact on families, the importance for society as a whole and the need to accept diversity.
2. Define and make known their needs and expectations regarding medical and psychosocial treatment of their families, as well as their development and self-help organizations.
3. Defend patients' rights, including those related to their dignity and their right to be treated with respect and without discrimination, access to quality health care and to information and consent to treatment.

On the other hand, companies and laboratories have their codes of compliance and must abide by the Code that sets the rules governing the relationship between Patients' Associations and Pharmaceutical Companies. Some associations have made an agreement of conduct, such as the Chilean Chamber of Pharmaceutical Innovation (CIF), which regulates especially the transfer of value to these stakeholders.

Is it possible to offer fees to health professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay them for travel and other expenses, and is any particular category of travel prohibited?
As for the payment or reward that can be made, although this practice is not regulated in the current legislation, it happens anyway. However, the trend indicates that the associated payment is related to the costs associated with the trip (stay in the country, food, seminar or conference registration).

According to what is indicated in the document "Recommended ethical standards to regulate the relationship between Patients' Associations and the Health Industry" of the ICF, agreed in 2021 and whose standards are of voluntary adherence and are in line with the work done in the "APEC Ethical Consensus Framework" signed by Chile in September 2019, it is indicated that in the relationship and in collaborative activities, it is suggested that there is no payment or consideration (whether this is in goods or services). It is suggested that no retribution from the Patient Groups or Associations (monetary or non-monetary) should be allowed, with the exception of consideration such as training.

The same document states that "it is highly recommended that, if there is funding for actions carried out by third parties (seminars, online conferences, design of campaigns, etc.), mechanisms for knowledge transfer should be generated, so that the receiving organization can replicate similar actions in the future without the need to continuously receive funding".



Likewise, it is recommended that no Health Industry company should financially support a patient's association for more than 3 continuous years on an exclusive basis; nor is it recommended that a single Health Industry company should exclusively support a Patients' Association.

This document does not allude to the payment of travel expenses, but usually the industry itself follows its own internal compliance lines that generally allow the payment of travel and stays for scientific events to non-tourist locations, as well as the defined expenses inherent to the trip, such as meals and transfers.

Is it possible to pay a healthcare professional or an advocacy or patient group to attend a scientific meeting?
As for the payment or reward that can be made, although this practice is not regulated in current legislation and depends on each company, most have transfer scales for the different stakeholders and their performance as spokespersons. Also, the trend indicates that the associated payment is related to travel costs specifically (stay in the country, food, registration at the seminar or conference).

The fees granted to speakers or spokespersons to participate in lectures are defined in a scale managed by the laboratories, where different ranges are contemplated for scientific spokespersons or representatives of patient organizations.

What is possible in terms of media training or messages for professionals or groups of patients?
The relationship with the media and pharmaceutical brands in Chile is not permanent or fluid in all cases.

The independence of the media and the almost null presence of influence peddling for both actors have forced pharmaceutical companies to develop approach plans through the development of workshops and seminars for professionals and the media. Mainly through alliances and as part of their awareness raising plans but through information and education.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
There are no formal rules to govern such an exercise.

What rules govern meetings with advocacy groups or the provision of non-media information to such groups?
Laboratories are governed by their own compliance codes, as well as by the ethics manuals of the pharmaceutical guilds. In addition, the patient groups themselves have rules for working based on the transparency of their leaders.

Generally, these meetings with patient associations should be linked to information or education and should be held with the people in charge of this relationship in the company or the medical area.

KEY TAKEAWAYS/ SUMMARY

Three bullet points summarize the pharmaceutical landscape:

- Chile is a market that imposes many restrictions on the pharmaceutical industry in terms of advertising and promotion. Therefore, companies are under constant supervision by the authorities.
- A public and private health system in permanent regulatory change, both in pathologies and treatments, forces companies to be attentive to the new needs/opportunities that the market requires.
- The growth in the supply of products offered by lower-cost local companies means that the pharmaceutical industry and the subsidiaries of multinationals must change their strategies more frequently than in other markets similar to the Chilean market.

COLOMBIA

Colombia has developed a robust legal framework for regulating the promotion and communication of medicines, ensuring compliance with ethical and professional standards. This framework is guided by various decrees, resolutions, and laws aimed at protecting public health, promoting transparency, and maintaining ethical interactions within the healthcare and pharmaceutical sectors. Key authorities such as INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos), the Ministry of Health, and the Superintendence of Health oversee compliance and enforcement. Recent trends in regulatory updates highlight the evolving focus on digital media, data privacy, and transparency in interactions with healthcare professionals and advocacy groups.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
Colombia has an extensive law development about medicines. The main laws are:

- Decreto 677 – April 26 of 1995.
- Resolucion 9455 – 28 of May of 2004.
- Decreto 2200 – June 28 of 2005.
- Decreto 1011, Resolucion 1043 y 1446 – February 20 of 2006.
- Resolucion 1403 – May 14 of 2007.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
Every advertisement, or promotional activity about medicines, is regulated by the:
Resolucion 1896 – 23 of November 2023.
The responsible is the Grupo de Monitoreo y Publicidad de Medicamentos of the Invima.

Who is responsible for the enforcement of these rules?
The entities responsible for medicines, including complaints, are:

1. INVIMA.
2. SUPERINTENDENCIA DE SALUD.
3. MINISTERIO DE SALUD.

Who receives concerns and complaints? How does this process operate?

1. INVIMA.
2. SUPERINTENDENCIA DE SALUD.
3. MINISTERIO DE SALUD.
4. Every Colombian entity has a COMPLAINT LINK or COMPLAINT E-MAIL ADRESS, known as a PQR. Every Colombian citizen has the right to send a complaint about the health service, and it must respond in no more than 15 working days. If the entity doesn't answer, the citizen is able to begin legal action or a TUTELA, to obtain a response from a judge.

What promotional or media materials must be approved by authorities?
In Colombia every medicine, package, and label, must be approved by the INSTITUTO NACIONAL DE VIGILACIA DE MEDICAMENTOS Y ALIMENTOS – INVIMA.

What are the most recent significant developments in regulations, and are there planned changes to codes of conduct and regulations in the next few years?
The government is working to change the health system, its regulation and laws, however, the Colombian congress has not approved it, but the government is still trying.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
In pharmaceutical communications, promotional activity refers to actions or materials designed to encourage the prescription, purchase, supply, or use of a specific prescription medication (RX) when addressing a group of specialists. This includes activities like advertising, marketing campaigns, or sponsored events focused on influencing healthcare professionals toward a particular product.

In contrast, the provision of information is related to disease awareness campaigns or sharing study data about a specific condition. This type of communication is neutral, evidence-based, and focused on educating healthcare professionals or the public about the disease itself, without directly promoting a specific medication.

How is a media event defined?
A media event is defined as an occurrence or happening that gains significant public attention due to its coverage by media outlets. These events generate widespread interest, engage large audiences, and often become

topics of discussion across various platforms such as television, radio, print media, and social networks.

Do the regulations differentiate between consumer and clinical publications?
In Colombia, regulations in the pharmaceutical and healthcare sector do differentiate between consumer and clinical publications.

Consumer publications are subject to strict guidelines when related to over-the-counter (OTC) medications, ensuring the content is factual, avoids misleading claims, and adheres to advertising regulations established by entities such as INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos). Prescription medications (RX) cannot be advertised directly to the public.

Clinical publications, on the other hand, are targeted toward healthcare professionals and focus on scientific or educational content, such as clinical trial results, treatment guidelines, or disease awareness initiatives. These materials must comply with ethical and regulatory standards and often require internal approval codes from the company to ensure accuracy and compliance.

Do regulations differentiate between print and broadcast media?
The regulation applies equally to both.

What is permitted in relation to off-license or pre- launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
Any material or activity focused on a prescription product that is provided to or viewed by a healthcare professional must have an approval code issued by the company. This code should be accompanied by the month of approval to ensure compliance with regulatory standards.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
There are no specific regulations governing press releases; however, it is important to comply with data protection laws. If a journalist requests to be removed from a database, their information must be promptly deleted.

Regarding media invitations, these need to be relevant and newsworthy to ensure acceptance. Journalists are generally more likely to attend when the topic aligns with significant events, such as World Heart Day, Cholesterol Awareness Day, or World Cancer Day, as well as when new devices, medications, or groundbreaking research are being introduced. Disease awareness campaigns also tend to garner interest. On the other hand, events focused solely on products without a notable innovation or angle are less likely to attract media attention.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Yes, the method of distribution for materials, especially those originating from outside Colombia, is regulated under Decree 677 of 1995. All materials, whether produced domestically or internationally, must comply with Colombian laws when distributed within the country. This includes ensuring that claims are accurate, non-misleading, and aligned with local standards. Materials intended for healthcare professionals, or the public must undergo review to verify compliance with advertising, transparency, and ethical communication requirements.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?
Press activities at congresses and scientific meetings are governed by Resolution 1446 of 2006, which regulates ethical practices in communications within the health sector. Companies can organize press briefings or sponsor media attendance, but these activities must remain educational and not promote specific products, especially non-licensed ones. The regulations apply equally to licensed and non-licensed products, ensuring consistent oversight. Any press activity must prioritize the dissemination of objective, science-based information and avoid commercial or promotional undertones.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
If a company sponsors a journalist to attend a scientific meeting, the resulting content is generally expected to remain independent to uphold journalistic integrity. However, if the content references specific products or claims, it may require review under the company's regulatory procedures to ensure compliance with Colombian advertising and health communication regulations. For freelance journalists, the principles are the same: sponsorship agreements should clearly state editorial independence and ensure no undue influence over the content. Transparency regarding the sponsorship should also be disclosed.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Yes, Colombian regulations cover the use of case studies and third-party advocacy in media communications. Under Decree 677 of 1995, such materials must be accurate, non-promotional, and scientifically supported. The inclusion of patient testimonials, case studies, or advocacy statements must avoid misleading claims or exaggerations. Additionally, transparency about the source of funding or sponsorship for such materials is required to avoid ethical conflicts or misrepresentation.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Yes, online media in Colombia are regulated differently from print and broadcast media, but they share some common guidelines. The Law 527 of 1999 (Electronic Commerce Law) provides the legal framework for online content, ensuring it adheres to transparency, authenticity, and security standards. Additionally, specific regulations like Decree 677 of 1995 and Resolution 1446 of 2006 apply to health-related content, regardless of the platform. The CRC (Comisión de Regulación de Comunicaciones) monitors digital platforms to ensure compliance with advertising standards, data privacy laws (under Law 1581 of 2012), and content accuracy, particularly in sectors like healthcare or pharmaceuticals.

What levels of web security are required?

Web security requirements in Colombia are governed by Law 1581 of 2012 (Personal Data Protection Law) and Decree 1377 of 2013, which establish obligations for the protection of personal data and the use of secure systems. Companies must implement adequate technical and administrative measures to protect sensitive data, including encryption, secure servers, and regular audits. For health-related websites, Resolution 1995 of 1999 emphasizes strict confidentiality and security for medical and personal information. Non-compliance with these requirements can lead to significant penalties under the Superintendence of Industry and Commerce (SIC).

Do the regulations cover funding of, or provision of information to, non-company-owned websites?

Yes, Colombian regulations cover funding and information provision to non-company-owned websites, particularly in regulated industries like healthcare. Any financial support or content contributions must comply with Decree 677 of 1995, ensuring transparency, accuracy, and the absence of promotional bias. Companies must disclose sponsorships and avoid content that could be perceived as covert advertising. Information shared with third-party websites must align with ethical and regulatory standards to prevent conflicts of interest or misinformation.

What are the most popular social networks in your region?

It really depends on the target audience. WhatsApp is the most widely used platform overall. For Gen X and Y, Facebook and Instagram are key, while TikTok is more popular among Gen Z. X (formerly Twitter) is a relevant platform for real-time updates and is also commonly used by Gen X and Y. As for LinkedIn, it is highly active for professional content, but it is not as widely used for messaging as it is in the U.S.

Are there any self-imposed regulations from social media companies?

No.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

Forums are not very common in Colombia. The closest equivalent would be Facebook groups, where we observe that the group administrators play a key role in managing content and interactions.

While there is a Reddit Colombia group, it is also moderated by an administrator and governed by its users, following the platform's community guidelines.

What is mobile adoption like in your region? Are there separate regulations for it?

We do not have exact numbers, but radio is very important and still has a lot of reach, especially in remote areas of Colombia where other media, like TV or mobile technology, might not be as accessible.

What is the response level needed for adverse event reporting?

Adverse effects must be reported within 24 hours of their occurrence or from the moment the individual becomes aware of them. This guideline is based on information provided by companies like Johnson & Johnson and Amgen.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

In Colombia, regulations regarding hospitality to advocacy or patient groups require that it be transparent, reasonable, and aligned with ethical and professional standards. Hospitality must directly relate to educational or professional development objectives, such as attending a congress or meeting, and comply with Decree 677 of 1995 and Resolution 1446 of 2006, which govern ethical practices in the health sector. Extravagant or excessive hospitality is not allowed, and all expenses must be directly tied to the event and properly documented.

When travel to another country is involved, the same principles apply. Sponsorship for travel must be linked to legitimate educational purposes and cannot be perceived as an attempt to influence decisions or advocacy in favor of a particular company or product. Such funding is subject to the Colombian Anti-Corruption Statute (Law 1474 of 2011) and Law 23 of 1981 (Code of Medical Ethics). Additionally, the provided hospitality must comply not only with Colombian regulations but also with the laws and ethical standards of the host country. Full transparency, including documentation of the purpose, funding, and expenses, is required to ensure compliance.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations, or other third parties for their participation in media activities and events?

Yes, it is possible, but it must be done transparently and in compliance with Colombian regulations. Under Law 1474 of 2011 (Anti-Corruption Statute) and the Code of Medical Ethics (Law 23 of 1981), honoraria should be proportional, reasonable, and properly documented to avoid conflicts of interest. These payments must not be tied to promoting specific products or services. Ethical standards outlined by organizations such as ANDI (National Business Association of Colombia) also provide additional guidance.

Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

Yes, travel and other related expenses can be covered, provided they are associated with legitimate activities, such as scientific or educational events. However:

- Expenses must be necessary, reasonable, and proportionate.
- Extravagant travel (e.g., luxury accommodations or unrelated entertainment) is not allowed, as it could violate anti-corruption laws and ethical guidelines.
- Such payments must comply with Colombian anti-bribery regulations and must not be perceived as an attempt to influence medical or commercial decisions.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Yes, health professionals or advocacy groups can be sponsored to attend scientific meetings, but the following conditions must be met:

- Sponsorship should focus on professional development and education, not personal benefit.
- Payments must be transparent, documented, and reported where applicable.
- These activities are regulated under Decree 677 of 1995, which governs ethical practices in health-related marketing and communication.

What is possible in terms of media or message training for health professionals or advocacy organizations?

Media or message training is generally permitted if it is aimed at improving communication skills related to public health or scientific education. However:

- The training content must not be promotional or designed to influence prescribing behavior.
- Payments must be transparent, documented, and reported where applicable.
- Such initiatives must comply with ethical guidelines and the Statutory Health Law (Law 1751 of 2015), which underscores the independence and integrity of healthcare professionals.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

Materials prepared on behalf of third parties must comply with Colombian advertising and transparency standards. Per Decree 677 of 1995, materials should:

- Be accurate and not contain promotional content disguised as educational material.
- Clearly disclose authorship, sponsorship, and any potential conflicts of interest.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Meetings with advocacy groups must adhere to ethical guidelines to ensure there are no conflicts of interest. Information shared must:

- Be factual, transparent, and focused on public health or educational purposes.
- Comply with **Resolution 1446 of 2006**, which regulates health sector marketing practices.
- Prioritize patient welfare and public health over commercial interests.

KEY TAKEAWAYS/ SUMMARY

Regulations Governing the Promotion of Medicines

- The promotion of medicines is regulated by laws such as **Decree 677 of 1995, Resolution 1446 of 2006**, and others. INVIMA oversees the approval of medicines, labels, and promotional materials.
- Promotional activities must differentiate between advertising and providing neutral, educational information, ensuring no direct promotion of prescription medicines to the public.

Digital and Media Regulations

- Online media is regulated under **Law 527 of 1999** and other guidelines, with a focus on transparency, authenticity, and security standards. INVIMA and the CRC monitor compliance.
- Web security for healthcare-related platforms must comply with **Law 1581 of 2012 (Data Protection Law)** and **Decree 1377 of 2013**, emphasizing data confidentiality and technical safeguards.

Hospitality and Sponsorship for Advocacy/Patient Groups

- Hospitality and sponsorship for patient or advocacy groups must be reasonable, transparent, and aligned with educational objectives. Extravagant travel or unrelated entertainment is prohibited under laws like **Law 1474 of 2011 (Anti-Corruption Statute)**.
- Sponsorship for attending international meetings must comply with both Colombian and host-country regulations, ensuring clear documentation and a legitimate educational purpose.

Media Events and Communications

- Press activities at congresses and scientific meetings must prioritize educational content and avoid promotional undertones, as outlined in **Resolution 1446 of 2006**.
- Sponsored journalists, whether freelance or employed, must maintain editorial independence. If content references specific products, it may need regulatory review.

Stakeholder Engagement and Advocacy

- Honoraria for healthcare professionals or advocacy groups is permissible but must comply with ethical and legal standards, focusing on reasonable and proportionate compensation.
- Meetings with advocacy groups should prioritize public health and education, adhering to ethical guidelines and avoiding conflicts of interest.

Use of Case Studies and Third-Party Advocacy

- Case studies and advocacy materials are regulated under **Decree 677 of 1995**, requiring scientific accuracy, transparency about sponsorship, and avoidance of misleading claims.

Adverse Event Reporting

- Adverse events must be reported within 24 hours of awareness, emphasizing swift action to protect patient safety.

MEXICO

Mexico does not have an official regulatory code for public relations in the health sector. Therefore, public relations activities must abide by the regulations that are in place for advertising. In recent years, changes were made to the Regulation of General Health Law in matters of advertising to create tools to avoid and discourage the proliferation of advertisements for the so-called 'miracle products,' which offer fast or definitive cures without any scientific support, and irregular advertising in general. These regulatory changes have contributed to decreasing the excess of publicity for products offering miracle cures with little or no scientific support for diseases with high prevalence rates, such as diabetes, obesity and pain. On the other hand, it also has contributed to regulating digital communication campaigns in the healthcare field, which had no appropriate regulation in the past.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
The promotion of drugs is regulated by the COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), which is part of the Health Ministry. COFEPRIS has specific regulations depending on the audience. There are rules for communications directed towards physicians, and other more strict regulations that address communication with consumers. Unlike countries such as the United States, it is forbidden to mention the brand name of any prescription medication, along with an explanation of what the product is for.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
All communication efforts are integrated under the umbrella of 'advertising' in Mexican law, without specific regulations for other marketing disciplines, such as public relations (PR). Generally speaking, this is what makes the use of PR in the pharmaceutical industry essential. The use of editorial coverage for the communication of messages (when advertising is so harshly restricted) is not against the law and can be undertaken within the advertising rules. In addition to general advertising rules, PR efforts for healthcare have strong ethics codes to which most pharmaceutical companies and PR professionals adhere. These codes dictate that disease awareness campaigns should be based on approved information and scientific data without promoting self-medication or encouraging physician consultation. Codes include the Mexican Association of Pharmaceutical Investigation's (AMIIF) code of intellectual property rights and the Code of the Federación Internacional de la Industria del Medicamento, de Normas de Comercialización de Productos Farmacéuticos (FIIM).

Who is responsible for the enforcement of these rules?
The Health Ministry is responsible—through COFEPRIS for the enforcement of rules.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
The regulations don't come from the government or Health Minister, but from the Ethics and Transparency Council for the Pharmaceutical Industry (CETIFARMA). It is acceptable to pay reasonable fees according to local market indicators for that purpose, the curriculum of the health professional, time invested, reimbursement of travel expenses to moderators and speakers at meetings and congresses, symposia and similar professional or scientific events.

Payments to health professionals for such services shall be based on local market criteria; be commensurate with the time spent, the work performed, and the responsibilities assumed; and shall be adequately documented. The contracting of health professionals will not be used as an incentive to induce, recommend, acquire, supply or manage the products of the contracting company.

Who receives concerns and complaints? How does this process operate?
COFEPRIS is responsible for receiving complaints regarding breaches to the promotional code. Typically, these complaints are submitted to the agency via rival companies, rather than consumers.

Do any promotional or media materials need to be approved by regulatory authorities?
Promotional and PR materials intended for the general public may require prior approval from COFEPRIS, depending on how the product is registered and the nature of the content. In some cases, external approval may not be necessary. Regardless, all materials are typically reviewed and authorized internally by the pharmaceutical or healthcare company's medical, legal, or regulatory affairs departments to ensure compliance with local regulations.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
In February 2005, an important step was taken with the approval of Article 376 of the General Law of Health. Before that, registration of drugs had an undetermined expiration date. With the approval of this reform, laboratories now have to revisit their registries every five years.

Drugs have to comply with bioequivalence and bioavailability tests in order to be placed on the market. In 1997 the application for these tests was approved for generic drugs. Since then, tests are made voluntarily, but they will now become compulsory. From 2010 onwards, only original and generic drugs exist, and similar drugs are disappearing.

An important change was made regarding imports. Pharmaceutical laboratories that sell drugs in Mexico were forced to have a plant locally to be able to import products into the country. This requirement is being abolished. The first group of medications that are free from this requirement are the HIV drugs, which can now be imported from many more countries and companies than before. Others will follow and soon, anyone will be able to import medications. The polemic issue is that the authorities will not easily be able to verify the quality of every company wanting to export to Mexico. There are still many things to be determined around these new import rules. The change was announced by President Felipe Calderón at the VXII International AIDS Conference held in Mexico in August of 2008.

Finally, there is a proposal to ban the distribution of drug samples among physicians to prevent what is known as a grey or black market. This could create important commercial limitations for pharmaceutical companies but is seriously being considered by health authorities.

The latest law update, made in March 2012:

- Media advertisement departments to request the COFEPRIS registration number for the product and also for the campaign—advertisement permission—as part of the advertisement requirement to buy an ad for any health-related product.

The main changes contemplated by the Regulation project 2011–2012 for advertisement include:

a) In general

- The definition of mass media is extended and now includes containers, labels, promotional items and other technological media.
- Limit the claims or recommendations of product use made by public figures and celebrities that have the capacity to influence the health decisions of the population.
- Granting more weight to health messages (messages with greater impact than the health legends established by the Health Law) is proposed.
- Media will be co-responsible for advertising campaigns, requesting the related COFEPRIS advertising permission as well as the product number registration in advance from the advertiser.

b) In health inputs (supplies)

- In order to prevent self-medication promotion, the ability to use indirect advertising of medications that require a medical prescription for their sale is not allowed.
- Use of any type of cartoon is restricted.
- Regarding health services and beauty procedures, more accurate copies are required to avoid deceitful advertising concerning them (liposculpture, mesotherapy, lifting, etc.) when they are advertised as an alternative for obesity control.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
In the pharmaceutical arena, promotional activity is defined as all actions organized or sponsored by a company or by persons under their control, destined to favor the prescription, supply, sale and acquisition of drugs.

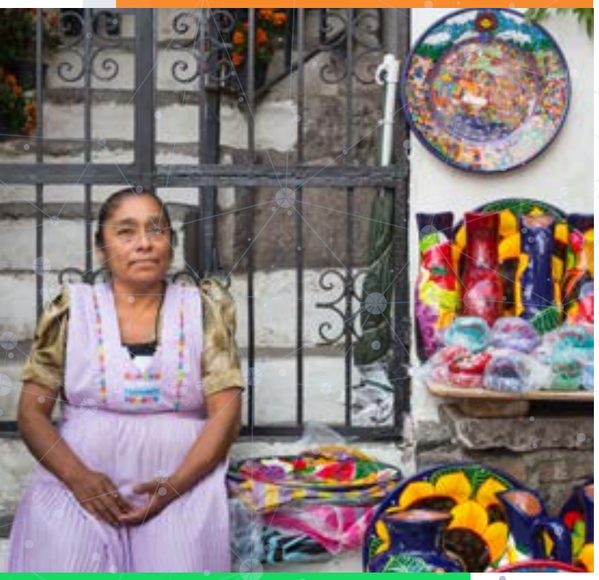
According to the AMIF code of ethics, no promotional activity should hide its objective or nature. Any promotional materials related to drugs and their indications that are sponsored by a pharmaceutical laboratory should clearly identify that a specific company has sponsored them:

- Promotional articles are not subjected to previous authorization when the name, generic denomination or the firm name are included.
- Free samples with the objective of promotion that comply with the requirements of the original products to be sold to the public and that only contain units do not require authorization.
- Samples of drugs that are not over the counter (OTC) cannot be distributed to the general public. These, as well as OTC drugs cannot be provided to minors.

How is a media event defined?
This is not defined in the regulations.

Do the regulations differentiate between consumer and clinical publications?
Advertising for health professionals can only be included in media directed at them, including dictionaries with pharmaceutical specialties and drug guides. Advertisements should be based on a drug's prescribing information. The registration of advertised drugs should always be stated. Information about prescription drugs should only be directed at health professionals and will be authorized at the moment the drug is registered. It should include: the brand name, generic name, formula, uses, therapeutic directions and other information such as warnings, general precautions and/or restrictions during pregnancy. Prescribing information will be authorized when the registration of the drug is approved. Advertising of drugs, including the commercial brand and information regarding the effect of medications, is not allowed in media available for general audiences or consumer media.

Do regulations differentiate between online, print, broadcast and/or streaming media?
In general terms, rules apply for both types of media the same way. However, there are some specifications that have slight differences in each case. For instance, the law points out that media must include the disclaimer, 'Ask your Doctor' and should mention the corresponding precautions the patient must take when the drug represents a danger in the case of a special condition. Printed media must have the text printed, while for radio shows it must be auditory and for TV and cinema visual as well as auditory. In this last case, the written text should last a minimum time equivalent to a fourth of the total duration of the ad. It should be placed horizontally in contrasting colors, in 40 points per letter in proportion to a 40" screen. The auditory legends should be



pronounced at the same rhythm and volume as the ad, clearly and understandably. It is now also mandatory to include both the number of each advertising authorization as well as the number of the product approved by COFEPRIS.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
According to the Good Practices Code of the pharmaceutical industry, the medical information department in each company must assure that the information provided by their professionals must be accurate, balanced, honest, objective and sufficiently complete to allow its addressees to judge for themselves the therapeutic value of the drug. A company should commit itself scientifically and morally to the content of the information it provides. If external service companies participate in the preparation of the information, it is the responsibility of the laboratory to ensure that these companies comply with the Ethics Code. When promoting medical information in consumer media or to general audiences, it has to be undertaken by authorized third parties, such as physicians. There are no restrictions about communicating information from medical seminars or congresses, other than the general rules for drug promotion already discussed. According to the Ethics Code of the AMIIF, the results of a study should be the object of a complete report by the designated coordinator and be transmitted to all investigators as soon as it is available. If the results of the study are published, that is considered appropriate information for researchers. Clinical studies should not be used as disguised promotions.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
There are no restrictions from the Health Ministry for the distribution of press releases. Although no materials of this kind are submitted for authorization, it is common practice to observe the codes of ethics that promote honesty in the information and it is important to have the approval of a physician or a specialist in the matter. As a rule, no information is released to the media without the written approval of the medical department in the pharmaceutical company behind the information. Also, the use of a product's commercial brand name should be avoided. Regarding printed materials for the consumer, the text required by the authorities is usually included. For example, in the promotion of cosmetics-related products it must read: 'Health is Beauty;' for alcoholic beverages: 'Avoid excess'; in the case of medications: 'Ask your Doctor' and for edibles: 'Eat Healthy'.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
No methods of distribution are covered in advance.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
If a company sponsors a journalist to attend a scientific meeting, the copy that results from the journalist's attendance is completely independent of the company and is the property of the organization the journalist represents. In the case of a freelance journalist, he or she is responsible for and owns the material.

Do regulations cover the use of case studies or other third-party advocacy in the media?
There is no regulation in this area.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
In the case of prescription drugs, all online content must be previously approved by COFEPRIS. Online disease information provided by pharmaceutical companies cannot mention commercial names or active ingredients.

What are the web security and data privacy requirements?
In the case of prescription drugs, online information cannot detail illnesses with drug commercial names or active ingredients. All website content additionally must be approved by COFEPRIS.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
External websites are not regulated, but if links take users to a corporate web page it should comply with the rules of all other media.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
According to digital media consumption surveys, at least 85 percent of internet users in Mexico are part of a social network, with Facebook and X (Twitter) being the front-runners. These networks have sophisticated usage regulations and are self-supervised. Some of these regulations involve their participation in advertising activities and bestow the content responsibility to the user, under the terms applied by international regulation and local laws.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
In 2014 COFEPRIS issued Trade No. CAS/1/OR/22/2014, which establishes digital advertising concepts, as well as administrative guidelines for procedures and requirements for the authorization of digital advertising campaigns. These include: the regulation of owned content as well as variable digital content (generated by responses within the conversation). Community manager's responsibilities regarding both owned and organic content include the process required to submit digital campaigns for authorization, as well as the creation of websites, social media profiles and contents, and the way that authorization codes should be displayed in digital ads.

Are there any self-imposed regulations from social media companies?
Facebook is the most popular social media platform in Mexico. To date, they have not provided any specific guidance relating to the marketing and promotion of pharmaceutical products independent of the regulations mandated by COFEPRIS. The same holds true for most other major social media platforms. The burden to ensure content on social media meets regulatory standards falls to the pharmaceutical company, not the social network.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
As with social media platforms, COFEPRIS now regulates consumer interaction on forums under Trade No. CAS/1/OR/22/2014.

What is mobile adoption like in your region? Are there separate regulations for it?
No, there are no separate regulations for mobile applications; the same advertising law applies to mobile devices.

What are the disclosure laws like in your region for non-branded websites?
In the field of health and medications, the same legislation applies, including non-branded websites. All the contents and communication issued by a pharmaceutical corporation must be submitted before and authorized by COFEPRIS. In addition to the official regulations issued by the authorities, the pharmaceutical industry in Mexico—the same as for the rest of the world—has self-regulation mechanisms, based on its own ethics and compliance codes.

What are the requirements for adverse event reporting?
The legislation on pharmaceutical surveillance is extremely severe. The responsibility of companies, as well as everyone who works in them, including business partners, advertising and public relations agencies, must be trained on adverse event reporting, so that they know what to do as soon as one occurs. The companies, physicians, health professionals, and employees that are part of the pharmaceutical industry as well as health affairs (government institutions) are compelled to report to the National Pharmaceutical Surveillance Center (CNV)

any sign of adverse effects in medications, vaccines and medical devices.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

The hospitality at events and meetings should be appropriate, in good taste and secondary to the original purpose. The pharmaceutical code promotes that the purpose of all events or meetings should be scientific or medical education.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

COFEPRIS does not have a specific law to regulate the honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events. These are self-regulated by each pharmaceutical company's compliance codes.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

There is no specific regulation in this matter. By compliance of each company, there are never honoraria to attend these sorts of events. However, given the scientific profile of these meetings it is generally accepted to cover the travel expenses of physicians so they can attend medical events.

What is possible in terms of media or message training for health professionals or advocacy organizations?

With PR campaigns or earned media, health professionals or advocacy organizations are allowed to speak on their own behalf or on behalf of their institution or organization. In this regard, the common practice is to train healthcare professionals on media management and efficient message transmission, but without imposing a particular guideline regarding the content of the information they will provide the media. If they are endorsing a product, campaign, etc., they must believe their messages to maintain ethical behavior. In advertising campaigns, when a physician endorses a campaign in a paid ad (TV or print), COFEPRIS requests by law the insertion of the professional license number of the speaker in order to ensure the credibility of the content.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

The same regulations for advertising govern materials written on behalf of third parties and also the internal compliance codes of each company.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

In order to prevent self-medication promotion, the possibility to make indirect advertising of medications that require a medical prescription for their purchase is not allowed.

KEY TAKEAWAYS/ SUMMARY

- The top authority that regulates the pharmaceutical industry is COFEPRIS.
- The Regulation of the Advertising-Related Health Act applies completely to online and offline communication media.
- In recent years, this law has been applied in an increasingly strict way and pressure has been put on communications related to nutritional supplements and so-called 'miracle products.' One example of this is the latest law update, made in March 2012: media advertisement departments need to request from COFEPRIS, registration numbers of products and also of the campaigns—advertisement permission—as part of the advertisement requirement to buy an ad of any health-related product.

UNITED STATES

As direct-to-consumer promotion of prescription drugs is permitted, the boundaries between promotional activities and the provision of information are much less distinct than in the majority of the world's markets. Promotional activities are carried out under the aegis of providing information necessary for patient care, which empowers them to contribute to and make decisions about their healthcare and medicines. A wide variety of promotional activities are carried out by pharmaceutical manufacturers within published Food and Drug Administration (FDA) guidance. Guidance documents posted on the Office of Prescription Drug Promotion (OPDP) website include DTC Television Advertisements, Responding to Unsolicited Requests for Off-Label Information and Presenting Risk Information in Drug and Device Promotion.

What laws and codes of practice govern the promotion of medicines?

The FDA consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations.

The Center for Drug Evaluation and Research (CDER) is part of the Office of Medical and Tobacco Products, as is the Center for Biological Evaluation and Research which focuses on vaccines and other biologics. Within CDER, the OPDP provides extensive guidance to ensure that all prescription and over the counter (OTC) drug communications in journals, publications, newspapers, broadcast media and even social media comply with approved product labelling. OPDP protects the public through separate groups that focus on prescription and consumer drug promotion.

The Pharmaceutical Research and Manufacturers of America (PhRMA) also provides a Code on Interactions with Healthcare Professionals (HCPs) and has issued Guiding Principles to Direct to Consumer Advertisements about Prescription Medicines. The principles were published in 2002 and last updated in 2021. Both PhRMA guidelines are non-binding and depend on companies to self-regulate.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

The activities traditionally associated with public relations, including media relations, are all categorized as promotional activities. The FDA defines advertising very broadly, including all types of communications activity such as materials printed in journals, stand-alone publications, newspapers and Internet advertising. The FDA does make a distinction between product labelling and drug information as defined by written, printed or graphic elements found on drug wrappers or containers. The United States has some of the most lenient drug-promotion regulations in the world, being one of just a few countries to allow direct-to-consumer branded advertisements and communications in media. Product communications and advertisements, including social media posts, may make statements about a drug's potential benefits, though they must also contain the drug's full important safety information (ISI) description, a principle known as 'fair balance.'

Who is responsible for the enforcement of these rules?

The FDA uses broad discretion in addressing promotional activities that it considers to be in breach of its regulations.

For advertisers who violate the FDA's regulations, including the 'fair balance' rule, the FDA will issue a formal warning letter requesting details on how to remedy the alleged violation, which may be disputed by the manufacturer. If these issues are not adequately addressed, FDA has the authority to initiate judicial proceedings, impose Federal Food Drug and Cosmetic Act (FDCA) violations and relevant penalties. PhRMA and other third-party organizations have no power beyond ethical guidance through codes of conduct and principles for drug promotion.

What are the regulations regarding HCP engagement by pharma companies? How are these regulations enforced?

Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other FDA requirements governing such communications.

In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as

well as members of their staff attending presentations, so long as the presentations provide scientific or educational value. Any such meals offered in connection with informational presentations made by field sales representatives, or their immediate managers, should also be limited to in-office or in-hospital settings. Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate.

Companies should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company.

Financial support from companies for Continuing Medical Education (CME) and for third-party scientific and educational conferences or professional meetings is appropriate. A company should separate its grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a bona fide educational program and that financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending the event, either directly to the individuals participating in the event or indirectly to the event's sponsor. Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the event. Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements. While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution.

Non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials. Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this code.

Companies that choose to use non-patient identified prescriber data to facilitate communication with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.

In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives. Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code that govern the representatives' interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with FDA requirements.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?

Members of the general public can report a problem to the FDA online, via phone, or via mail. When emergencies have occurred, patients or healthcare professionals can report problems to the FDA's emergency line at 1-866-300-4374 or 301-796-8240 24 hours a day. In non-emergencies, the FDA Consumer Complaint Coordinator handles various problems via online forms available on the FDA website.

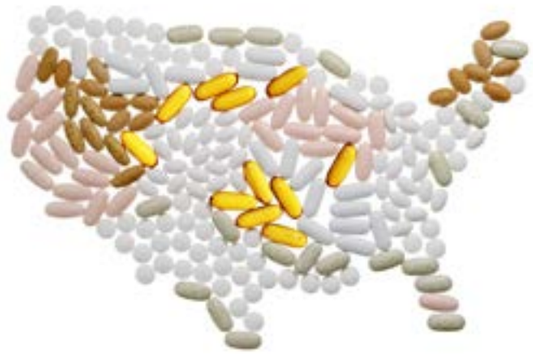
Do any promotional or media materials need to be approved by regulatory authorities?

Pre-approval of promotional materials is not required except in rare instances. For example, FDA may require pre-approval of promotional materials as part of a compliance action. However, OPDP provides opinions on proposed advertisements and labeling pieces before use upon request by an applicant. Note that accelerated approval products are under a "pre submission" requirement. The accelerated approval regulations require that applicants submit to FDA copies of all promotional materials prior to the intended date of dissemination or publication. Preapproval submission may be required of manufacturers with a history of promotional violations. Companies may also voluntarily submit materials for OPDP advice and comment prior to product approval.

All other promotional materials must be submitted to OPDP at the time of initial dissemination. This requirement applies to all companies that market food, drug, device or biologic products in the United States. It is the responsibility of the manufacturer, distributor, packer or any party acting on behalf of the manufacturer to assure that all promotional materials, including advertisements, exhibits, videos, brochures, booklets, mailing pieces, slides and electronically disseminated materials, are submitted.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?

In 2014, following five years of study, the FDA issued its first draft guidance on the use of social media in medical marketing communications. Though as of 2024 this remains in 'draft' form, subsequent, final guidance is hotly anticipated by industry.



The FDA's social media guidance refers to how organizations should present risk and benefit information within character limitations, stating that companies need to adequately represent the risk and benefits within the same communication message.

The draft industry guide for Correcting Independent Third-Party Information about Prescription Drugs and Medical Devices gives advice on appropriate corrective information and appropriate actions to correct misinformation. Additionally, in 2015 the FDA issued its first guidance on medical apps that allow people to monitor and manage medical therapy.

In terms of interactive promotional media, the FDA issued a draft guidance with suggestions for submitting post- marketing materials that appear online. These promotional materials include anything owned or operated by the organization or on its behalf, and promotion materials on third party sites. This also applies to real-time communications. Companies should also submit a monthly list of third party sites (restricted and non-restricted) of which they are active participants.

Further plans for the division include guidance documents on healthcare economic information/formularies, medical practice guidelines, comparative claims, and scientific exchange. Addressing 'off-label' use of prescription drugs, has also been a growing focus of the FDA, along with a trend of prosecuting company executives in the case of egregious violations. In December 2011, the FDA issued draft guidance on Unsolicited Requests for Off- Label Information about Prescription Drugs and Medical Devices. This document provided more detail on how drug and device manufacturers should reply to unsolicited consumer enquiries for off-label usages, through either direct private enquiry or through online or in-person public forums.

The Physician Payment Sunshine Act provision of the Patient Protection and Affordable Health Care Act ('Obamacare') requires pharmaceutical and medical device companies to track any payments or 'transfers of value' to physicians and teaching hospitals as of 2021. The Sunshine Act industry has dramatically changed how the pharmaceutical industry conducts marketing activities. The list of payments covered is extensive and includes fees, gifts, food, beverage, travel/lodging, entertainment, charitable contributions, and royalty or license fees. Companies began submitting the data to the Centers for Medicare and Medicaid Services (CMS) on 31 March 2014. CMS publicly began publicly reporting the data as of 30 September 2014. Even though companies are prohibited from offering any entertainment or gifts that do not advance disease or treatment education under the voluntary PHRMA Code on Interactions with Healthcare Professionals—a practice that is also banned by law in several states—many physicians report still accepting free tickets or gifts.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

As DTC promotion of prescription drugs is permitted, the boundaries between the two are much less distinct than in the majority of the world's markets. Promotional activities are carried out under the provision of necessary information to patients, which empowers them to contribute to decisions about their healthcare and medicines. A wide variety of promotions are carried out by pharmaceutical manufacturers within the guidance of the FDA, largely dependent on public knowledge of a particular disease or condition or how specialized a treatment is.

The FDA requires that all drug advertisements contain information in a Brief Summary, relating to side effects, contraindications and effectiveness. The Brief Summary includes only the risk-related sections of the product's labelling and effectiveness information by giving the product's indication. The current advertising regulations specify that this information disclosure needs to include all the risk information in a product's approval labelling. Advertisements cannot be false, misleading or omit material facts. In the case of DTC advertising versus materials focused on the medical professionals, the FDA encourages companies to use 'consumer-friendly' language to make any contraindications, warnings, and frequently occurring side-effects easier to understand by the general public.

How is a media event defined?

There is no distinction between a media and a public event in the FDA regulations or the PhRMA Code.

Do the regulations differentiate between consumer and clinical publications?

Consumer or clinical/trade publications are categorized as 'reference publications' under the FDCA. A reference publication is defined as a publication that has not been written, edited, excerpted or published specifically for, or at the request of, a manufacturer of a drug or device; has not been edited or significantly influenced by such a manufacturer; is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold; does not focus on any particular drug or device of a manufacturer that disseminates information under Section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and does not present materials that are false or misleading.

In 2014, the FDA released a draft guide for the distribution of scientific and medical publications on unapproved new uses. Manufacturers can distribute this information if it is first published by a third-party organization with a review board and include approved labelling and a comprehensive reference list. This material must be distributed separately from promotional materials.

With regard to the consumer audience, in addition to requiring 'fair balance' of the risks and benefits of a product, the FDA advises that information be written in a way that is simple to understand by the average individual.

Do regulations differentiate between online, print, broadcast and/or streaming media?

Current regulations specify two requirements that all prescription drug broadcast advertisements must meet. Firstly, broadcast advertisements must include the product's most important risk-related information, known as the 'major statement', in the audio or audio and visual parts of the advertisement. Secondly, broadcast advertisements must contain either a brief summary of the advertised product's risk information, or alternatively, make adequate provision for disseminating the product's approval labelling in connection with the ad. Thus, the regulations for broadcast advertisements recognize broadcast's inherent limitations by providing an alternative mechanism for meeting the Act's information disclosure requirement. In 2023, the FDA updated the regulations, mandating that the major statement be neutral, conspicuous and presented in a clear manner.

All broadcast ads are also required to satisfy the 'adequate provision' laid forth in the FDA's 1999 'Guidance for Industry: Consumer-Directed Broadcast Advertisements', which calls for:

- Providing a toll-free phone number for consumers to call to have the approved labelling sent to them;
- Referencing a printed advertisement or brochure that can be accessed with limited technology;
- Providing the address of an Internet website that contains the requisite labelling; and
- Advising consumers to ask doctors or pharmacists for more information.

In 2010, the FDA proposed guidelines that would require manufacturers to present a drug's major side effects and warnings in broadcast advertisements, regardless of how the drug's benefits might be presented.

A March 2012 guidance on the FDA DTC Television Ad Pre-Dissemination Review program states: These categories (products requiring pre-dissemination review) reflect a risk-based approach that will enable the Agency to leverage its limited resources to best protect the public health by ensuring that certain high risk and high impact TV ads accurately and effectively communicate key information about advertised products, including their major risks and indications. Specifically, these categories allow the Agency to review and provide comments on TV ads for prescription drugs with particularly serious risks, and to review and provide comments on TV ads at times when feedback on the risk and indication communication in the ad is particularly critical, including when a product is first advertised on TV and after a product has received a significant safety labeling update or a new or expanded indication.

In the case of print advertisements, the FDA encourages product sponsors to provide consumers with non-promotional, consumer-friendly information consistent with product labelling, along with the information required by the Act and the regulations. Print ads are required to include a Brief Summary which includes all risks listed in its prescribing information.

The advertisement or labelling piece may include the phrase 'FDA approved' if the manufacturer or sponsor has received a letter stating that the product has been approved. The word 'new' may be used in promotional labelling and advertisement for a newly approved product, indication or dosage form for six months from the time a product is initially marketed.

In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labelling. The FDA mandates that DTC advertising direct consumers to report negative side effects to MedWatch, the FDA adverse event reporting program, by incorporating the following language into print ads: 'You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088'.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

Under FDA rules, there is no general restriction on publishing research around pre-licenced uses or discussing it at scientific events. However, manufacturers are prohibited from DTC advertising or promotion of a drug prior to FDA marketing approval. The FDA also forbids any promotion or representation that a drug is safe or effective for use outside of the specific purpose for which it has been approved. This area of 'off-label' marketing has been a focus of the FDA in recent years.

With regard to specific rules around congresses and scientific meetings, each medical society implements a set of policies to be followed by all participants. Most medical societies have regulating committees that are responsible for establishing and enforcing the policies governing all media-related activities. Societies adopt embargo policies for all abstracts presented at their meetings to abide by any agreements made with publishers and to maintain authenticity of study results. Medical meetings take embargoes very seriously, similar to a publication, because if the information is presented in advance for public consumption, it reduces the significance to present to colleagues on-site. Furthermore, advance distribution may unfairly affect stock prices by sharing one company's information prior to competitors. Materials distributed should include a prominent display of the words 'EMBARGOED UNTIL' with the date and time of presentation to avoid any possible negative ramifications.

In December 2011, the FDA issued draft guidance on how industry should respond to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices. The draft guidance clarifies the fact that manufacturers are able to provide information to unsolicited requests on off-label drug or device uses without violating regulations. However, any information provided could potentially be introduced as evidence of a new intended use. Unsolicited requests are defined as both non-public, as in a call, email or direct request via a website from a consumer to the manufacturer, or public request sought in an open forum, either in-person or via an online source, such as message board, website or social media platform. Not covered are solicited requests which are defined in a number of ways, including requests received following company-affiliated presentations, speeches, business reply to solicitation, calls for online videos or other comments, pre-formatted website responses or online and offline distribution of information. Responses to solicited requests for off-label information may be considered evidence of a firm's intent that a drug or device is intended for use other than specifically approved by the FDA. If a firm chooses to respond to an unsolicited request for off-label information, it must do so directly to the individual posing the question— regardless of whether the request is public or non- public—and in a way that is tailored only to the specific question or questions asked, meaning that follow-up may be required to secure additional information on the question asked. Responses should, to the greatest extent possible, be scientific, fair and balanced, published in peer-reviewed articles and should come from the company's scientific or medical personnel, not marketing or sales representatives. Responses must also include approved FDA labelling, a prominent statement indicating that off-label uses are not approved by the FDA, safety warnings and a complete list of scientific references.

The draft guidance specifically recommends against using digital or social media to publicly follow up to unsolicited requests for off-label uses. Specifically, the FDA is concerned that this public discussion may lead to promotion of off-label uses by those not asking the questions, may cause confusion among consumers or medical professionals and may generate future problems, as outdated information can be accessed online for many years.

What regulations specifically cover press releases, media materials and company events? What are the general principles?

FDA restrictions on press releases are informal and developed on a case-by-case basis. To determine whether a release is illegal promotion, the FDA looks at the phrasing of the release, its manner and its scope of distribution. Such materials should be fair, objective and must be directed at an audience whose interest in the content of the materials would be assumed to be reasonable to ensure messages can be understood. The PhRMA Code states that, as a general rule, interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.

According to policies implemented by medical societies, press releases may be issued in the months prior to the meetings to announce that a study will be presented, but the release must not in any way reveal the data or study results. If the study results are reported prior to the embargo date and time, the abstract is subject to removal from the meeting. Most medical societies do not endorse corporate and institutional press materials, and will display such materials strictly as non-affiliated literature.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

The distribution of materials to any media or clinical outlet is reasonable, whereas unsolicited faxing or text messaging to other numbers would not be. No reference is made to the codes of other countries in any of the regulations, although the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) guidance says that promotional material should comply with the regulations in the country of release and distribution, as well as the source. As only the United States and New Zealand permit DTC communication, those sending United States press materials outside the U.S. should take particular care to ensure that their content does not contravene the regulations of the countries where distribution or publication is intended.

In 2025 the FDA announced the availability of a final guidance for industry entitled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/ Cleared Medical Products: Questions and Answers." This guidance describes FDA's enforcement policy regarding certain firm-initiated communications of scientific information on unapproved use(s) of the firm's approved/cleared medical products to health care providers (HCPs) engaged in prescribing or administering medical products to individual patients. This guidance finalizes the revised draft guidance of the same title issued in October 2023. The October 2023 revised draft guidance revised and replaced the draft guidance entitled "Distributing Scientific and Medical Publications on Unapproved New Uses--Recommended Practices," issued in March 2014, which itself revised the final guidance entitled "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," issued in January 2009. This guidance is not for current implementation, pending the Office of Management and Budget's (OMB's) decision on the collection of information.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?

Under FDA rules, there is no general restriction on publishing research around off-label or pre-licenced uses or discussing it at scientific events. However, if the manufacturing company is paying for or dictating the content of any publication, then it violates FDA regulations and may be subject to sanctions.

As communication to lay audiences is permissible under the regulations, no specific rules govern press activity at congresses and scientific meetings. Scientific organizations, such as the American Medical Association (AMA), do have strict guidelines as to events being held at their own major meetings, and the various committees should be consulted in advance of planning.

Press briefings, news conferences, press receptions and other media events—other than those sponsored by the host institution or manufacturer—are not permitted on-site. Organizations planning any off-site media activities,

such as press conferences, satellite media tours and/or social events, are usually required to coordinate with the appropriate communications department. All events are bound by the rules of the meeting and are generally restricted to before or after the hours of the meeting, or at either end of the start or completion of the meeting.

Company events are very common at medical meetings; most events are Continuing Medical Education (CME) and focused on doctors only, and media are not typically invited to attend such events. Other satellite symposia and receptions are open to members of the media. In addition, those holding U.S. events in scientific meetings outside of the United States should take particular care with the content and format of materials and their intended audiences.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
This type of communication and subsequent editorial is permissible under regulations in the United States. However, according to the FDA, if the manufacturing company is paying for or dictating the content of any publication, it falls under FDCA regulations and, with any violations, could potentially result in sanctions.

Journalists are in no way obligated to write and publish content in favor of the sponsoring company. Both sponsored and freelance journalists are free to publish independent reports, and it is unnecessary to go through a company's regulatory procedure for approval on copy.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Regulatory information does not specify the use of case studies or other third-party advocacy in the media.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
An overview of the FDA's guidance around social media promotion and regulation is included above.
In general, advertisements for prescription drugs presented through online venues are regulated under the same FDA regulations as print or broadcast media. Advancements in online advertising options have drawn questions over the scope or feasibility of the FDA to regulate these digital advertisements; however, the FDA remains committed to enforcement of its regulations through online channels.

In the United States, companies are permitted to sell some approved medicines over the internet, leading to a growth in internet pharmacies. These pharmacies are bound by the same regulations as conventional drugstores and the sites are regularly monitored by the Drug Enforcement Agency to ensure compliance. The FDA's Buying Medicines and Medical Products Online Web page and Buying Prescription Medicines Online: A Consumer Safety Guide gives guidance to consumers shopping for healthcare products online.

The use of patient Electronic Health Records (EHR) in clinical trials has also become a hot-button issue. In 2020, the FDA issued draft industry guidance on Use of Electronic Health Record Data in Clinical Investigations.

The guidance covers patient data such as use of medical records, radiology results, immunization history and lab results. The draft guidance sets best practices around EHR interoperability, data quality, certifications, privacy and security.

What are the web security and data privacy requirements?
Patient records are protected through the Health Insurance Portability and Accountability (HIPAA) Act of 1996. Under this law, all websites are required to ensure that input patient medical information is kept confidential through site security.

The Office of the National Coordinator for Health Information Technology, under the Department of Health and Human Services (HHS), oversees privacy and security of online health information. The Coordinator's office in 2015 published a comprehensive guide governing best practices around provider websites in 2015.

Consumer websites, including disease-awareness websites, must comply with all United States Federal Trade Commission regulations and federal laws regarding privacy and security.

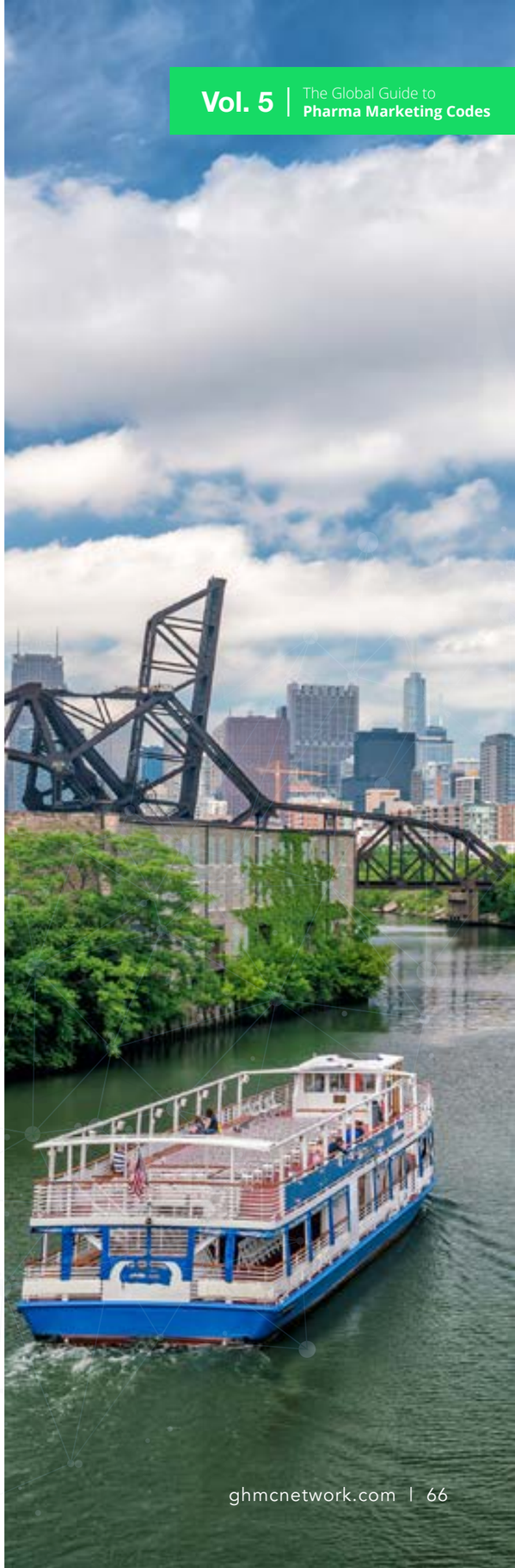
Any website asking users for personal information or using cookies to track metadata should explain exactly what the site will and will not do with the information as part of its Privacy Statement.

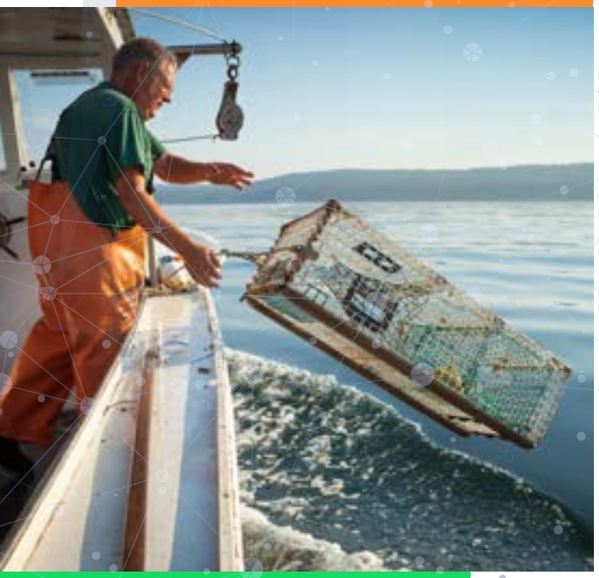
Do the regulations cover funding of, or provision of information to, non-company owned websites?
It is very common in the United States for pharmaceutical manufacturers to engage in legitimate funding of patient groups and other not-for-profit organizations, which may include sponsorship of websites, although, sponsorship should be openly declared. For the provision of information, typical copyright protection and plagiarism laws apply. Information is usually allowed to be reproduced for non-commercial individual reference with all copyright or other proprietary notices retained, and thereafter the contents may not be re-copied, re-produced or otherwise re-distributed.

A draft guidance issued in December 2011, Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices, includes response to unsolicited responses to off-label uses identified through public forums on non-company-owned websites. The FDA advises that companies can respond to these requests, but must do so in line with draft guidance, including direct response to the individual posing the question, specific response only to the questions asked and response from scientific representatives with transparent, fair and balanced information that includes approved labelling and adverse effect information.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
As of 2023, there were more than 246 million social media users in America, which is approximately 72.5 percent of the population.

YouTube, being the most widely used platform, is used by 83% of the U.S. population. Facebook comes in second with 68% of Americans reporting use while 47% say they use





Instagram, 35% use Pinterest, 33% use TikTok and 30% use LinkedIn. Among young adults aged 18-29 who use social media, YouTube and Instagram are the most popular, followed by Facebook, Snapchat and TikTok.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
In 2014-15 proposed two draft guidances for the industry with recommendations to help manufacturers and their representatives accurately communicate online about prescription drugs and medical devices.

The first guidance provides recommendations for the presentation of risk and benefit information for prescription drugs or medical devices using internet/social media sources with character space limitations, such as X (Twitter) and the paid search results links on Google and Yahoo. No matter the internet source used, benefit claims in product promotions should be balanced with risk information. And companies should provide a way for consumers to gain direct access to a more complete discussion of risks associated with their products.

The second guidance provides recommendations to companies that choose to correct third-party information related to their own prescription drugs and medical devices. This draft guidance provides FDA's recommendations on the correction of misinformation from independent third parties on the internet and through social media sites -- any corrections should address all misinformation in a clearly defined portion of a forum on the internet or social media, whether the misinformation is positive or negative.

Are there any self-imposed regulations from social media companies?
In recent years, social media companies have developed extensive guidelines on pharmaceutical-promoted posts; organic content is more of a gray area and may be subject to removal if it is found to be in violation of the platform's overall community guidelines. In addition to complying with each platform's guidelines, FDA rules also apply.

X (previously Twitter):
X provides extensive, country-by-country guidelines as part of its policy on Health and Pharmaceutical Products and Services (https://business.x.com/en/help/ads-policies/ads-content-policies/healthcare.html). This policy applies to X's paid products, which are tweets, trends and accounts.

Meta:
- Facebook:
  - Facebook's advertising policy explicitly prohibits ads that promote prescription drugs and online pharmacies.
  - Facebook also prohibits ads with content that "asserts or implies certain attributes," including medical conditions. Personal health (including before/after photos) is also covered under this policy. Supplement advertisements are permitted if they are targeted to audiences over the age of 18.
- Instagram:
  - A Meta ads account is required to run ads on the platform. Facebook's policies on pharmaceutical advertising content are understood to apply to Instagram, as well.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Forums and blogs fall under FDA's guidance on social media. For forums, the FDCA regulations apply across promotional materials online, including the need to clearly cite warnings and side effects, as well as the necessity to capture and report adverse effects. Any online channels or areas presenting or discussing medical information that are sponsored by the prescription drug manufacturer are currently regulated in the same manner as other promotional materials and are subject to the same conditions and potential penalties for non- compliance.

What is mobile adoption like in your region? Are there separate regulations for it
According to CTIA, The Wireless Association, as of 2022, there were 523 million wireless connections in the United States. About 71% of U.S. households are wireless-only. As of 2016, 85% of American adults have smart phones. The annual wireless revenue incurred was $825 billion in 2022. In February 2015 the FDA issued guidelines regarding mobile medical apps. The FDA has already reviewed and approved apps that support medical professionals, such as a smartphone-based ultrasound and an app that allows doctors to view medical images and X-rays.

What are the disclosure laws like in your region for non-branded websites?
A 2009 study coordinated by Manhattan Research found that 35% of online pharmaceutical consumers use a non-branded website to find information. Experts note that non-branded resources, developed by prescription drug manufacturers, can be very useful in promoting disease awareness, educating diagnosis, introducing rare conditions and navigating compliance issues. There are, however, important compliance steps which are enforced by the FDA. While the FDA has not issued specific guidelines on the regulation of non-branded websites, they are scrutinized by the agency as with any other promotional material paid for by a prescription drug manufacturer. In February 2015, the FDA issued a warning letter to a manufacturer citing claims and presentations in the website about the safety and efficacy of an investigational new drug that was yet to be approved by the FDA under section 502(f)(1) of the FDCA the above drug was considered to be misbranded. The agency has made a clear statement that all websites paid for by prescription drug manufacturers, even if they contain no direct branding or promotional information, will be regulated as with other promotional materials under FDCA. Without providing full disclosure and, whenever relevant information on labelling, warnings and adverse effect reporting, manufacturers may be subject to penalties.

What are the requirements for adverse event reporting?
In December 2016, updates were made to the rules for reporting adverse effects to the FDA for consumers. According to the FDA, product related problems (including adverse events) can be reported online via MedWatch; the FDA Safety Information and Adverse Event Reporting program; The Vaccine Adverse Event Reporting System (VAERS); or the Safety Reporting Portal depending on the product. The document no longer mentions the 15 days time interval between the occurrence of the event and the time of reporting.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no specific regulations covering hospitality to advocacy or patient groups mandated by the FDA or other government agencies. Legitimate funding of varied patient group activities is allowed and common in the United States. However, the PhRMA Code states that it would be ethically fair to restrict funding to modest expenses and travel, and that the meeting should occur in a scientific or academic venue and manner. While adherence to the PhRMA Code is voluntary, some U.S. states do require manufacturers to adhere to the Code while coordinating promotion in their state.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
It is acceptable for those participating in meetings or events, for example as speakers, to receive honoraria. The PhRMA Code states that no recreational or entertainment events may be offered, meals must be judged as 'modest by local standards,' and that meals are provided in a manner conducive to informational communication. Any meals offered in connection with informational presentations should be limited to in-office or in-hospital settings, not as part of an entertainment or recreational event. The inclusion of a healthcare professional's spouse or other guest is inappropriate, as it is offering 'take-out' meals or meals to be eaten without a company representative. The AMA's ethical guidelines state that the teaching faculty and other service providers (i.e., moderators) may be offered reasonable honoraria and reimbursement for travel, lodging

and meal expenses. The amount received must be commensurate with the services they provide. Regarding advocacy groups, there are no legal restrictions on funding specifically relating to the healthcare sector. Pharmaceutical companies routinely provide funding for groups interested in the conditions that their products treat. It should be noted that the Sunshine Act requires all payments to health professionals be reported to the CMS beginning in August 2013. Payments were made public beginning in September 2014. The act requires manufacturers to report payments and transfers of value made to 'Covered Recipients' which refers to U.S. physicians and teaching hospitals but excludes medical residents, nurse practitioners and office staff.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
The PhRMA Code categorically states that financial support should not be offered for the costs of travel, lodging or other personal expenses of any non-faculty healthcare professionals. Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the meeting, including attendees of interactive sessions. Modest, occasional meals are permitted if they are offered in the appropriate circumstances and venues as described in relevant sections of the Code. Implemented in 2013, the Physician Payment Sunshine Act requires all payments to health professionals be reported to the CMS.

What is possible in terms of media or message training for health professionals or advocacy organizations?
Regulators acknowledge that speaker training is an essential activity to enable healthcare professionals to educate and inform their colleagues and peers about benefits, risks and appropriate uses of prescription drugs. The FDA holds companies accountable for the presentations of their speakers, so appropriate training and education is necessary. Section 7 of the PhRMA Code specifically states that 'it is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company-sponsored speaker bureaus to be offered reasonable compensation for their time…and reasonable expenses'. The PhRMA Code additionally recommends that when participants receive extensive training on the company's drug products, they should also receive training on compliance with FDA regulatory requirements for communication about such products.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
Considering all aspects of prescription drug promotion, full and transparent disclosure of sponsorship by a manufacturer as related to any written materials by third parties is required for compliance with FDA and industry regulations.

What regulations cover meetings with, or the provision of, non-media information to advocacy groups?
There are no legal restrictions that cover advocacy groups specifically in the healthcare sector.

KEY TAKEAWAYS/ SUMMARY

- The FDA actively provides guidance and warnings to pharmaceutical companies regarding social media use. Despite this, enforcement has been inconsistent and social media still presents challenges for manufacturers.
- Marketing of 'off-label' uses of prescription medication has been a focus of FDA regulatory scrutiny recently. Strict adherence to the approved uses and dosing is important for manufacturers' marketing programs to avoid penalty. This applies to non-branded materials and websites.
- Full open and transparent presentation of major statements of prescription drug labelling, such as warnings, approved dosing and possible side effects, along with clarification of financial support of physicians and third parties, remains vital in adhering to pharmaceutical marketing regulations in the United States.

GERMANY

In Germany, several constituents make up the overall Freiwillige Selbstkontrolle für die Arzneimittelindustrie (FSA) Code of Conduct, the governing agency responsible for regulating and stipulating the rules for all promotional activities surrounding medicines. Federal guidelines are still undergoing alterations, the most recent of which addresses pharmaceutical companies' ability to objectively promote any type of medicine to the public.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
In Germany, the FSA Code of Conduct (the Code) governs the promotion of medicines. This code was recently amended to take into account the Professional Rules for German Physicians issued by the German Federal Chamber Physicians and the Common Position of the Assessment in Criminal Law of the Co-operation between Industry, Medical Institutions and their Employees, which was published in 2000 by the trade associations and other organizations in the healthcare sector. The content of the Code is also based on the Conduct Recommendations for the Cooperation between the Pharmaceutical Industry and Physicians issued July 2003 by the Verband Forschender Arzneimittelhersteller (VFA), also known as the German Association of Research- based Pharmaceutical Companies, the German Association of Pharmaceutica Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI). Laws include the German Drugs Act (AMG), German Advertising in the Health Care System Act, Law on Advertising in the Field of Healthcare, the German Fair Trade Practices Act (EWG) and the German Penal Code (StGB).

In early June 2016, the anti-corruption law came into force. This new regulation listed 'corruption within the healthcare sector' among the offenses in the criminal code: consequently, doctors found to have corrupt business practices, as well as pharmaceutical and medicine technology companies, can be sentenced to pay fines or go to prison.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
All promotional activities, including public relations and advertising, are defined as the same for the purposes of the Code itself. More specific regulations, as outlined above, govern the rules for advertising. The German Public Relations Association has also developed its own ethical guidelines. In general, advertising and public relations are considered as separate activities.

Who is responsible for the enforcement of these rules?
The conduct requirements of the Code are binding to member companies and monitored and sanctioned by the FSA's arbitrators. They can impose fines of €5,000 to €250,000.

What are the regulations regarding healthcare provider engagement by pharma companies? How are these regulations enforced?
Due to the implementation of the FSA Transparency Code 30 June 2016, all pharmaceutical companies in Germany were required to publish all monetary contributions they have paid to medical institutions, doctors and other partners (e.g., patient initiatives) throughout the previous year.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
Concerns are mainly submitted by competitors who try to stop public relations activities via legal channels.

The German Public Relations Council can also make complaints. Complaints regarding advertisements are more common and are usually a result of direct action through the civil courts using the laws of unfair competition. Furthermore, INTEGRITAS, the association for fair drug advertising, is a self-controlled body of the pharmaceutical industry that executes advertising controls and combats unfair advertising.

Do any promotional or media materials need to be approved by regulatory authorities?
No relevant authorities need to be contacted for pre-approval of promotional or media materials. Companies generally submit materials for internal review by their

legal and medical-scientific departments to make sure that wording or any graphics used are correct.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
In June 2016, the anti-corruption law came into force. This new regulation listed 'corruption within the healthcare sector' among the offenses in the Criminal Code: consequently, corrupt doctors, as well as pharmaceutical and medicine technology companies, can be sentenced to pay fines or go to prison.

The FSA Code of Conduct was revised to reflect the latest requirements issued by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and came into enforcement law in March 2006. On 5 May 2011, the European Court of Justice decided that pharmaceutical companies are allowed to neutrally share the packaging and the unchanged package leaflet on the internet, provided that non-experts have to click actively on the information. The German government is discussing amendments of the health insurance system. However, it is not yet known how this will impact the promotion of medicines.

Furthermore, there were some important changes in the Law on Advertising in the Field of Healthcare (HWG) in 2012. Under specific submissions, it is allowed to communicate scientific outcomes (e.g., studies or expert reports) to the public press. Now, advertisements or public relations can use stories of illness as long as they are not abusive or repulsive or mislead to a wrong self-diagnosis due to an exact description. The same applies for 'before and after' photos. 'Before and after' photos are allowed if they don't show changes from illness or the effect of medicine and are not abusive or misleading. 'Before and after' photos from plastic surgery and in connection with medical devices are not allowed.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
All communication regarding medicines issued by pharmaceutical companies is defined as promotional activity with the following exceptions: labelling of medicines and leaflets; correspondence and documents of a non-promotional nature intended to answer a specific question about a particular medicinal product; factual information, such as announcements relating to labelling changes, adverse warnings, as well as reference material; factual information relating to diseases or human health; and corporate information directed to investors or potential employees.

How is a "media event" defined?
The regulations contain no definitions of a media event, or any meetings with non-medically qualified personnel.

Do the regulations differentiate between consumer and clinical publications?
The German code on promoting medicines does not provide definitions of, or differentiation between, types of media.

Do regulations differentiate between online, print, broadcast and/or streaming media?
The German code on promoting medicines does not provide definitions of, or differentiation between, types of media.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
The provision of medical and scientific information to the media during the development or marketing authorization phases of a product is permitted, provided that this is not part of product-related advertising. This would generally mean that the outcomes of clinical studies or scientific speeches and publications might be made available at scientific meetings or conferences using the generic but not the brand name of the product. Press releases are usually deemed to be unlawful when the anticipated product name is mentioned. In general, it is important to use the generic name and not the brand name prior to product approval. Advertising is prohibited during this stage.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
The German code on promoting medicines does not provide for any specific regulations regarding press relations or other materials. Therefore, they would be subject to the same general principles as all promotional material. Promotion must be based upon sufficient scientific evidence and must be consistent with the information addressed to healthcare professionals. This rule applies in particular to claims referring to specific benefits, qualities or properties of a product or substance.

Promotional materials regarding side effects must also reflect all available findings or be capable of substantiation by clinical experience. They must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. They must also be balanced, fair, objective and based on a current evaluation of all relevant evidence, as well as reflect that evidence clearly. The word 'safe' must not be used without robust evidence, and the word 'new' must not be used to describe any product generally available, or any indication that has been generally promoted, for more than one year.

All materials must contain the following: company name and domicile of manufacturer; name of product; composition of product; therapeutic indication; contraindications; side-effects warnings, if and to the extent required for the labelling of receptacles and outer packages; the indication 'verschreibungspflichtig' (prescription-only); and the date on which the information was generated or last revised.

Section 11 covers clear guidance on the admissibility of references, which must all indicate whether the publication concerns the product in question, its method or treatment as well as the author name, date and source. Materials must also clearly state that they have been sponsored by that company. These regulations are especially important for advertising.

Do regulations cover the use of case studies or other third-party advocacy in the media?
The Code states several times that, where there is a conflict of codes, the stricter code is said to apply, making it important to be acquainted with both the German code on promotional materials (see above) and that of the country of distribution. This is also consistent with the wider international guidelines.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?
For the purposes of the Code, these events would be viewed in the same way as scientific events. It is permissible to organize them at international scientific meetings, such as recognised medical congresses, because the relevant resource or expertise is on-site. For the purpose of hospitality, the media should be treated as doctors, so it is not permissible to pay for their time, but 'reasonable' expenses for travel and accommodation may be covered. Regarding licensing, the same rules apply, so the outcomes of clinical studies or scientific speeches and publications could be made available at scientific meetings or conferences using the generic but not the brand name of the product. Please check the detailed rules before any media event, as the rules are very diverse (www.fs-arzneimittelindustrie.de).

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
If a company has invited the journalist with the express intention of creating and approving publishable copy, then the rules on promotional material will apply. Where a company sponsors the publication of promotional material in journals, it must make sure that such promotional material cannot be confused with independent editorial matter. In the case of any publications made by third parties about medicinal products and their use, which are either wholly or partially sponsored by a company, particular care must be taken to ensure that such publications clearly indicate that the company has sponsored them.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Section 8 of the Code covers transparency and the prohibition of disguised promotion and is quite specific in that any arrangement of publication, whether direct or indirect, that concerns a product or its disease area must be clearly indicated as sponsored. Regarding expert quotations, it is very important that healthcare professionals must not be unfairly influenced and, although it is not specifically addressed, it would seem clear that payment for media work and quotations would not be acceptable.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
There is no specification in the regulations.

What are the web security and data privacy requirements?
There are no specific regulations on the level of security required to restrict healthcare professionals- only websites. However, disclaimer statements are not deemed to be sufficient, and 'safe access systems are recommended, which basically means that websites must be password protected. Websites of pharmaceutical companies should have password-protected areas for healthcare professionals where detailed information about a medication and its indication is published.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Not specifically.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
Facebook is the most popular social network in Germany, followed by Instagram, Pinterest, X (Twitter), YouTube, LinkedIn, reddit, and others.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Regarding social media activities, it is crucial to react promptly, to synchronise the community and process management and undertake a close monitoring process. All social media communication towards patients or the general public must comply with the pharmacovigilance criteria and German law on the advertising of medicinal products.

Are there any self-imposed regulations from social media companies?
Facebook's terms of use within Germany require companies in the pharma industry to permit comments on their pages. Otherwise, general regulations for promotional activities apply.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
In general, there is no requirement to observe or to evaluate online interactions concerning drugs. In individual cases, a product observation exists when there are concrete indications. The admission board prohibits pharmaceutical companies from answering customer questions concerning prescription drugs. A pharmaceutical company can only delete questions from their platform or ask the provider to delete the question.

What is mobile adoption like in your region? Are there separate regulations for it?
More than 80% of the population has a smartphone in Germany, and the percentage is increasing. Nevertheless, the pharmaceutical industry is still reserved when communicating via mobile channels. Also, within mobile adoption, the general rules take effect.

What are the disclosure laws like in your region for 'non-branded' websites?
Non-branded websites have to show who initiated and supported them.

What are the requirements for adverse event reporting?
If a customer/patient posts about adverse reactions to a drug on a pharmaceutical company's forum or on a social media page, the company must pass the information to the authorising authority. This rule is why many pharmaceutical companies do not use the platform for patient feedback.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
The regulations do not specify this information.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
The section of the Code that addresses this is not very specific. It says, 'Physicians or third parties must not be granted payment of any fees for their willingness to meet with or receive information from a pharmaceutical company'.

The legal provisions of the Professional Rules for German Physicians differentiate between 'active' and 'passive' participation in scientific meetings. 'Active' includes giving a presentation, acting as a moderator or rendering another reasonable service. Fees are allowed for this so long as they conform to the guidance outlined above. 'Passive' participants, who are not participating in the activities outlined above, may not be paid. It is acknowledged that a pharmaceutical company may reimburse conference fees as well as reasonable travel and accommodation costs. As with active participants, passive participants need the written approval of their superior or administrator. Accommodation and hospitality must not exceed 'reasonable limits'.

'Reasonable' costs are only permissible if the job-related, scientific nature of the event takes center stage. In 2010, the FSA added the following amendment: 'It is not

allowed to reimburse attendance fees of entertainment programs directly or indirectly to healthcare professionals or other members of the medical body of experts by FSA member companies. It is thus ensured that the financing of entertainment or leisure mes by companies does not take place.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
While there is no specific regulation in this matter, any honoria on travel expenses provided by the pharmaceutical company must be disclosed per the anti-corruption act and fit within the abovementioned regulations.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Member companies may invite healthcare professionals who are particularly concerned with the company's research areas, pharmaceuticals and/or their therapeutic indications to their own job-related training events.

What is possible in terms of media or message training for health professionals or advocacy organizations?
It would seem fair to surmise that, provided the scientific content was robust and deemed as necessary knowledge for the physicians, then 'message' training would be allowed. Media training without scientific content would not be permissible. The rules of moderate hospitality also apply, and the venue must be chosen on the basis of factual criteria, such as geographical location, rather than the leisure facilities offered. In the case of media training, it is important to sustain the expert's independence in front of the media.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
Any materials that have been written or organized by a pharmaceutical company, whether directly or indirectly, are subject to the above-mentioned rules on promotional material, unless they are factual information on diseases. It is clear that the pharmaceutical company must abide by the Code even if it commissions others to design or implement any activities on its behalf.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
As with meetings with healthcare professionals, there must be a reasonable need for the meeting before it can take place. Again, factual information relating to diseases or human health would be nonpromotional and not subject to the Code.

KEY TAKEAWAYS/ SUMMARY

The German code outlines how pharmaceutical companies must act with regard to print and online communication.

- Laws harness the pharmaceutical industry, but not always in ways that benefit the needs of customers or pharmaceutical companies, especially in regard to interactive social media.
- Patients and customers are looking for information and exchange, but the possibilities for pharmaceutical companies to interact are limited.

ITALY

In Italy, pharmaceutical regulation is overseen by the Italian Medicines Agency (AIFA), a division of the Ministry of Health (MoH). Members of the Italian Association of the Pharmaceutical Industries (Farmindustria) follow the Code of Professional Conduct issued by the association, which has recently been updated to align with both European and international standards. In addition to these codes, pharmaceutical marketers must adhere to the provisions of the Institute of Advertising Self-Regulation (IAP). Promotional material, defined as any scientific information provided directly or indirectly by pharmaceutical companies, is subject to regulation. The promotion of prescription-only medicines to the general public remains strictly prohibited.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
The key legal framework remains Title VIII (Articles 113–128) of Legislative Decree No. 219 of 24 April 2006, which implements Directive 2001/83/EC (as amended) and Directive 2003/94/EC into Italian law. These provisions govern advertising of medicinal products to both the public and healthcare professionals. Other relevant legislative instruments include Legislative Decree 229/99 (CME regulations) and Legislative Decree 74/1992, as amended by Decree 67/2000 (concerning misleading advertising, implementing Directive 97/55/EC). Advertising rules also fall under the scope of Legislative Decree 206/2006 (the Consumer Code) and the MoH Guidelines dated 17 February 2010, which govern advertising via the internet, mobile phones (including MMS and SMS), and similar digital media.

The definition of advertising remains broad, encompassing any action intended to promote prescription, sale, or consumption of medicinal products, including the distribution of samples, sponsorships of medical events, and activities by sales representatives. Public relations efforts aimed at informing different target groups are also treated as advertising under this framework. Notably, these rules apply not only to communications with the general public but also to interactions with healthcare professionals and pharmacies.

The legislation does not apply to general health information campaigns that do not reference a specific medicinal product, directly or indirectly. However, the guidelines adopted by the State-Regions Conference on 20 April 2006 and Article 2598 of the Civil Code (addressing unfair competition) also remain relevant, especially concerning scientific information disseminated by sales reps and the prevention of misleading advertising.

The core principles include:
- Medicinal products not authorized under EU law may not be advertised.
- All advertising must align with the approved Summary of Product Characteristics (SmPC).
- Advertisements must be truthful, non-misleading, and promote appropriate product usage.

In the general media, journalistic content remains subject to the ethical rules of the profession.
For example:
- Journalists must not accept compensation that would compromise their independence.
- Articles must clearly distinguish between editorial content and advertising.
- Medicine brand names may not be included in lay press with promotional intent.

Furthermore, Italy's 20 regions retain authority to impose additional requirements for promotional activities directed at healthcare professionals within their jurisdictions.

An additional layer of self-regulation is provided by the Farmindustria Code of Professional Conduct. Most recently updated in November 2023, the Code includes strengthened provisions on scientific exchange, public information dissemination, and educational activities for non-prescribing professionals. The 2023 revision further refines the distinction between promotional and scientific content, introduces clearer guidance on the proper handling of educational materials during scientific events, and reinforces the separation between promotional initiatives and scientific exchange activities. This voluntary Code, which reflects EFPIA and IFPMA standards, is binding for all member companies and increasingly informs the structure of corporate codes of conduct in the pharmaceutical sector.

According to EFPIA's most recent Q&A guidance (updated 2022), social media engagement remains subject to strict content and interaction controls.

Companies must avoid implying product recommendations through disease awareness campaigns, and all content should remain factual, balanced, and non-promotional—even when shared via third-party channels.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
There are no legal distinctions between public relations and advertising under Italian pharmaceutical law or the Farmindustria Code. Public relations, being defined as "informative actions targeted at various audiences," is regarded as a form of advertising and must comply with the same legal provisions as described above.

Who is responsible for the enforcement of these rules?
AIFA serves as the primary regulatory authority, with a broad mandate covering drug research, authorization, distribution control, and communication with healthcare professionals and patients. Promotional materials addressed to healthcare professionals must be submitted to AIFA at least 10 days before dissemination. If AIFA raises no objections during this period, the materials are deemed approved (under the tacit consent procedure). The date of submission must be indicated on all such material.

AIFA may order suspension or cessation of promotional campaigns that fail to comply with regulations. For example, it may halt public awareness campaigns that inappropriately pressure physicians into ordering tests or prescribing medications, or campaigns that exaggerate the benefits of a particular treatment.

What are the regulations regarding healthcare provider engagement by pharma companies? How are these enforced?
Pharmaceutical companies may engage HCPs for services such as consultancy, speaker roles, or participation in advisory boards. The Farmindustria Code requires that such engagements be formalized in a written contract, clearly stating the nature and scope of the work. Contracts must be retained for at least three years. These engagements must be genuine and not serve as disguised promotional incentives. Enforcement is the responsibility of the Supervisory Committee, which monitors compliance among member companies.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
Complaints are investigated by the Supervisory Committee of Farmindustria. Once a violation is suspected or reported, the committee investigates and may recommend sanctions, which are then reviewed by a single-judge tribunal. Companies are notified and granted the opportunity to respond. A decision is issued within 30 days of the hearing. Companies may appeal the decision or comply with the sanctions imposed.

Do any promotional or media materials need to be approved by regulatory authorities?
Yes. The requirement for prior approval depends on the target audience:

- **General public advertising** must be submitted to the MoH at least 45 days in advance. If the MoH does not respond, approval is implied. Authorizations are generally valid for 24 months, unless otherwise stated. Even after tacit approval, the Ministry may revoke authorization if justified.
- **Healthcare professional advertising** must be submitted to AIFA 10 days prior to dissemination, except for the official SmPC, which is exempt from this requirement.

Press releases, while not subject to prior approval, must still comply with the advertising rules under Article 117 of the Decree. Specifically, press content may not:

- Suggest that medical consultation or surgery is unnecessary;
- Imply that a product is without side effects or superior to others;
- Claim that the medicine improves normal health;
- Warn that not taking the medicine may harm health;
- Target children;
- Include celebrity or medical endorsements;
- Compare the medicine to food, cosmetics, or other consumer goods;
- Assert that the medicine is effective because it is "natural";
- Encourage misdiagnosis;
- Reference dramatic or misleading "cures";
- Use disturbing or exaggerated images of the body or disease progression.

It is possible to distribute a press release without prior involvement of AIFA, but the content must follow the same rules for the contents of advertising as defined in Article 117 of the Decree:

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?

- Farmindustria's Code of Conduct was first amended in January 2022 and subsequently revised in November 2023, further clarifying the boundaries between promotional and scientific communication, and introducing enhanced rules on transparency, patient engagement, and event organization.
- AIFA guidelines published in January 2024 introduced structured procedural requirements for national marketing authorization submissions, with detailed timelines and documentation standards.
- The Ministry of Health issued updated guidance in July 2023 on the use of social media and digital platforms for pharmaceutical advertising. The rules restrict promotional activity to static, pre-authorized formats on selected platforms (e.g. Facebook sidebars and YouTube videos without interactivity), while prohibiting the use of Instagram, X (Twitter), and similar channels. These rules also reaffirm that prior authorization is required for any promotional use of the internet.
- The EU Health Technology Assessment Regulation (Regulation 2021/2282) came into effect in January 2025, introducing joint clinical assessments for selected innovative therapies, including oncology and advanced therapy medicinal products (ATMPs).
- Italy's 2025 Budget Law expanded access to the €1.3 billion Innovation Fund, extending eligibility to conditionally innovative medicines and reserve antibiotics in addition to fully innovative treatments.

These developments are reshaping the Italian regulatory landscape, with a strong emphasis on transparency, responsible digital engagement, and the management of early access and innovation pathways.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
Recent 2023 guidelines from the Ministry of Health have strengthened the regulation of OTC and SOP advertising. Any promotional message already approved for one channel (e.g., print) may be extended to another (e.g., web), provided the content is identical and submitted with a formal request. Expiry dates remain linked to the original approval.

Mandatory disclaimers must now accompany advertising based on product type, such as antihistamines ("may cause drowsiness") or NSAIDs ("may cause serious side effects"). SOP adverts must also include clear language about pharmacist dispensing. Display of SOP packages using shelf tags or in-store promotional materials is prohibited.

What is defined as promotional activity as opposed to the provision of information?
Under Italian pharmaceutical law, virtually all materials provided by pharmaceutical companies to healthcare professionals are considered promotional in nature. This includes, for example, visits by medical sales representatives, the dissemination of product literature, and invitations to conferences. Advertising to healthcare professionals is restricted to those licensed to prescribe or dispense medications—typically physicians and pharmacists.

In line with current regulations:

- During promotional visits to physicians, companies must provide the latest authorized SmPC (Summary of Product Characteristics), the classification for supply, and the public price.
- Promotional materials for prescription-only medicines addressed to pharmacists (excluding hospital pharmacists) must be strictly limited to SmPC content. For over-the-counter (OTC) products, broader information may be provided to enable pharmacists to properly advise patients.
- For the general public, advertising is strictly limited to products that do not require diagnosis, prescription, or monitoring by a healthcare professional.

Advertising of prescription-only drugs, narcotic or psychotropic substances, products reimbursed by the National Health Service (even partially), investigational medicines, or any distribution of such products for promotional purposes to the general public remains strictly forbidden.

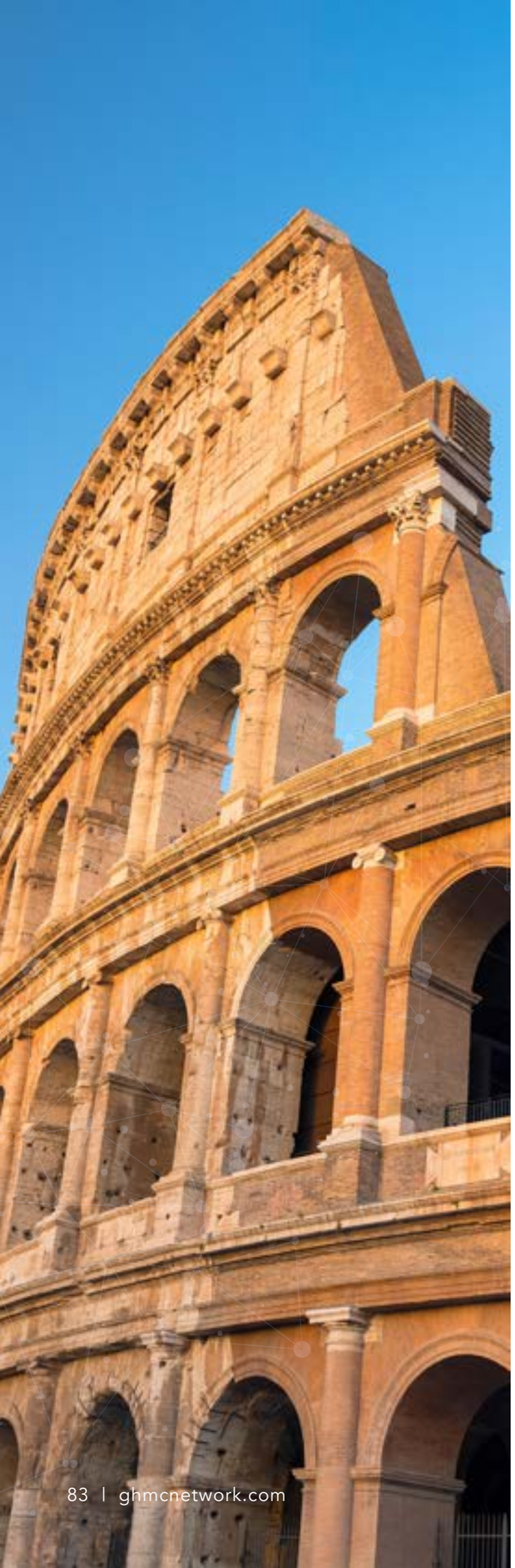
How is a media event defined?
There is no formal definition of a "media event" under the applicable legislation. However, the general principles of advertising and scientific communication continue to apply.

Do the regulations differentiate between consumer and clinical publications?
Yes, there is a clear differentiation. Advertising materials aimed at healthcare professionals (clinical publications) are subject to different content and approval requirements than materials addressed to the general public (consumer publications). For example, clinical publications can include in-depth scientific data, while consumer-directed materials must remain accessible, balanced, and non-promotional.

Do regulations differentiate between online, print, broadcast and/or streaming media?
The regulatory framework applies uniformly across all media platforms. Advertising in print newspapers, for example, may include the authorized product information and illustrations of non-prescription medicines, provided these do not imply promotional claims. Digital, television, and streaming media are subject to the same approval procedures and content limitations. For advertising aimed at the general public, prior authorization by the MoH is mandatory, regardless of the medium used.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
In communications aimed at health professionals (e.g. specialist press), companies may publish details of ongoing or completed clinical trials, even if the product has not yet received marketing authorization. If the information relates to developments in areas of significant public interest (e.g. oncology or rare diseases), it may also be shared with the lay press. However, under no circumstances may the brand name of an unlicensed medicine be used in materials intended for the general public.

Any media content referencing treatments or product launches must be free from financial influence by the pharmaceutical company—meaning no contractual relationship should exist between the company and the journalist or publisher. This aims to preserve journalistic independence and avoid covert advertising. Brand names must not be used in any general or health professional press outlet in a way that might induce product consumption.



What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?

While Legislative Decree 219/2006 does not specifically define rules for press activity at scientific congresses, established practice allows pharmaceutical companies to organize press outreach activities under strict conditions. The content must be factual, scientifically balanced, and must not include any promotional messages or brand names. This applies equally to approved and investigational products.

In accordance with the Italian Constitution and press freedom protections, independent speakers at scientific meetings may present data on off-label uses or investigational compounds. However, the scientific secretariat of the event—not the sponsoring company—is responsible for organizing press briefings. Any such communication must refer to active substances in generic terms, without brand promotion.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

Yes, the regulatory scope covers not only the content but also the origin and method of distribution. When a company based in a European country promotes a product in another EU member state (such as Italy), the rules of both the promoting country and the target country, as well as the EFPIA Code, apply. For non-EU companies marketing in Europe, compliance with both EFPIA and local codes is required. This ensures consistent ethical standards and prevents regulatory arbitrage.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?

The core principle remains unchanged: advertising must always be clearly distinguishable from editorial or educational content. Supplements and editorial materials aimed at the general public are still subject to advertising regulations and may not include brand names or be financed by pharmaceutical companies. However, when signed by a journalist, the responsibility lies with the author and/or publisher. In practice, it remains difficult to classify an article as covert advertising, and freedom of the press may be invoked as a defense.

In the medical press, supplements and advertorials are governed by Article 119 of Legislative Decree 219/2006. Scientific articles published and signed by their authors may be used and redistributed by pharmaceutical companies, with proper permission from the publishing entity. While there are no specific restrictions on using freelance journalists, all content must comply with applicable legislation and is generally subject to prior copy approval.

As of 2025, legislative updates have further tightened the boundaries between communication and promotion. Law No. 103/2023 (amending Law No. 145/2018, Art. 1, paragraph 525) explicitly prohibits emotionally persuasive or suggestive messages in communications directed to the public by private healthcare entities and professionals.

Additionally, the 2023 Ministry of Health guidelines on advertising over-the-counter (OTC) and non-prescription medicines—especially in digital and social media contexts—introduce stricter standards. These emphasize clarity, factual balance, and the exclusion of emotionally charged or misleading messaging. Social media platforms, in particular, are subject to limitations that restrict interactivity and format to ensure compliance with national standards.

No new changes to industry codes of conduct have been announced for 2025; however, the evolving focus on digital transparency and patient-centered communication may lead to future revisions of self-regulatory frameworks such as the Farmindustria Code.

DIGITAL & SOCIAL MEDIA

(The July 2023 MoH guidelines reaffirm that social platforms are subject to strict control. Facebook content is limited to static side-column placements (desktop only); product posts on company pages are not permitted. YouTube videos must have interactivity disabled and be pre-authorized. Instagram, X (Twitter), and similar platforms remain entirely prohibited for promotional use. Additionally, internet materials require their own authorization even if similar content was approved elsewhere. Pop-ups and unsolicited content remain banned.

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

Digital media are subject to the same regulatory principles as traditional formats; however, specific provisions have been introduced to address the unique features of the online environment. According to the Guidelines issued by the Ministry of Health on 17 February 2010, websites disseminating information on medicinal products must limit access to content addressed to healthcare professionals. This access must be restricted through authentication systems, such as encrypted passwords, and registration requiring valid proof of professional qualification.

Although the basic legislative framework mirrors that of other media, the Ministry has emphasized that online content must respect the same requirements on authorization, content neutrality, and non-promotional tone, particularly when directed at the general public.

What are the web security and data privacy requirements?

Although Italy does not yet have a pharmaceutical-specific digital privacy regulation, all online promotional activities must comply with the EU General Data Protection Regulation (GDPR). In addition, companies must adopt appropriate technological measures to ensure that access to promotional information is restricted to authorized users. When collecting personal data for authentication purposes (e.g., during HCP registration for a closed website area), companies must ensure lawful processing and obtain explicit consent, clearly stating the purposes for which the data will be used.

Do the regulations cover funding of, or provision of information to, non-company-owned websites?
Yes. Both the Farmindustria Code and EFPIA Code of Practice provide detailed guidance in this area. Pharmaceutical companies may provide factual, non-promotional product information to third-party websites (e.g., disease awareness platforms or patient association pages), but must ensure full transparency and avoid any suggestion of indirect advertising. If a company financially supports the maintenance or content of such a site, this must be clearly disclosed. The information must also remain compliant with the SmPC and must not promote specific brand names.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
As of the most recent data, Facebook remains the dominant social platform in Italy, followed by Instagram, YouTube, and LinkedIn. However, regulatory restrictions continue to apply to the use of these platforms by pharmaceutical companies.
The Ministry of Health reaffirmed in its 2017 guidance that only static, pre-approved advertising content can be published
on certain social platforms and under tightly controlled conditions:

- **Facebook:** Only banner-style ads (image + caption) may appear in the side column of the user interface and must link externally to a fully compliant, pre-authorized site. Facebook company pages may not feature promotional product posts.
- **YouTube:** Video content is permitted only if it has been pre-authorized by the MoH and all interactive features (comments, likes, shares) are disabled.
- **Other platforms (e.g., X (Twitter), Instagram):** Use for product promotion is prohibited due to the inability to control public interaction with posts.

This framework effectively limits direct promotional use of most mainstream social platforms by pharmaceutical companies in Italy.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Yes. The Ministry of Health has issued clear limitations. Disease awareness campaigns may be run via digital and social platforms provided they do not make direct or indirect reference to medicinal products. These campaigns must focus on education, prevention, and awareness without steering the public toward specific treatments or suggesting that a particular product is available. Moreover, any interactive or user-generated content features must be disabled to preserve the "static" nature of authorized advertising.

Are there any self-imposed regulations from social media companies?
As of now, there are no pharmaceutical-specific advertising codes self-imposed by social media platforms operating in Italy. However, general terms of service—particularly around advertising of regulated products—do apply. Pharmaceutical companies must therefore ensure that both their content and its dissemination method comply not only with Italian law and codes but also with the individual platform's advertising policies.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
No explicit rules exist for forums or interactive platforms. However, the general principles of non-promotion, transparency, and content neutrality still apply. This means pharmaceutical companies must avoid using forums or similar platforms to subtly promote their products. Involvement in discussions must remain strictly informative and scientific, and any support or sponsorship of such forums should be clearly disclosed.

What is mobile adoption like in your region? Are there separate regulations for it?
Mobile phone usage is highly prevalent in Italy, with over 50 million users. While there are no specific laws targeting mobile advertising separately, mobile platforms (e.g., SMS, MMS, and mobile apps) are subject to the same rules as all other digital communications. For example, sending authorized promotional messages via SMS or MMS is permitted, but only with prior consent from the recipient and under strict data protection compliance. The recipient must always be allowed to
opt out.

What are the disclosure laws like in your region for non-branded websites?
'Non-branded websites must clearly disclose their source of funding and content ownership. For example, if a patient organization's website is sponsored by a pharmaceutical company, this must be explicitly mentioned. Moreover, content must remain strictly educational and factual, avoiding any promotional bias. Transparency requirements apply equally whether the website is maintained by the company itself or by third parties acting on its behalf.

What are the requirements for adverse event reporting?
AIFA encourages adverse drug reaction (ADR) reporting from both healthcare professionals and citizens. Reports must be submitted using either the professional or citizen version of the standard ADR reporting form and are entered into the Italian National Pharmacovigilance Network (RNF). Despite the dual reporting system, under-reporting remains a known issue. Companies must ensure that digital platforms—whether owned or third-party—offer clear instructions and contact details for reporting suspected adverse events, in line with pharmacovigilance obligations under EU law.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Italian law does not contain specific legislation governing interactions between pharmaceutical companies and patient advocacy groups. However, relevant principles are outlined in the Farmindustria Code of Professional Conduct. Patient associations play a growing role in Italy's healthcare landscape, partnering with both AIFA and the industry in discussions on clinical trials, early access programs, and public health initiatives.

Article 4.5 of the Farmindustria Code requires that any financial support to patient organizations—whether direct or indirect—must be governed by a prior written agreement specifying the purpose and amount of funding. The following conditions apply:

- The use of the patient organization's logo or branded materials by a pharmaceutical company must be expressly authorized.
- All sponsorship activities must be transparent and devoid of promotional intent.
- Companies are prohibited from positioning themselves as exclusive sponsors of any given patient group.
- Pharmaceutical companies must publicly disclose a list of supported patient organizations on their corporate websites.

While travel sponsorships for patients or their representatives to attend events abroad are not expressly prohibited, such support must remain non-promotional, transparent, and proportionate to the legitimate purpose of the activity.

Are there specific rules for interactions with expert patients, caregivers, or their representatives?
Yes. The 2023 revision of the Farmindustria Code introduced the concept of the "expert patient" and extended transparency requirements to include interactions involving caregivers and patient representatives. Any transfer of value—financial or in-kind—must be properly justified, documented, and clearly disclosed, including the rationale for the selection of recipients. Companies are also expected to ensure fairness and balance in all collaborations with patient organizations, and to publish this information in a transparent manner.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Yes, but strict rules apply. Article 123 of Legislative Decree No. 219/2006 prohibits companies from offering healthcare professionals gifts or benefits unless they are of negligible value (currently understood as less than €20 annually) and relevant to their professional role. Similarly, the State-Regions Guidelines reinforce this restriction, discouraging excessive or unrelated hospitality.

Under Article 4.1 of the Farmindustria Code, engagements such as scientific consultancies, conference speaking engagements, or training activities must be governed by a formal contract. The contract must justify the necessity of the service and define its scope. Moreover, healthcare professionals must disclose the existence of such a relationship when presenting results or participating in public discussions.

Additionally, Article 53 of Legislative Decree No. 165/2001 prohibits civil servants—including NHS-employed healthcare professionals—from engaging in paid activities without prior authorization from their institution. Non-compliance can result in disciplinary or criminal sanctions.

Therefore, while it is permissible to offer honoraria and reimburse travel costs, companies must ensure all such arrangements are:

- Transparent and documented;
- Proportionate and justified;
- In compliance with relevant employment and public sector rules.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Yes, but subject to prior authorization or notification requirements. Companies that are members of Farmindustria must notify AIFA in advance of any scientific meeting, congress, or educational activity they sponsor. The notification should include information on the nature of the event, the participants involved, and the type of support provided

While journalists may be invited and reimbursed for travel and hospitality costs, such support must not compromise editorial independence, nor should the journalist be expected to produce content favourable to the sponsoring company. AIFA's authorization is not required for journalist sponsorships, but transparency and non-promotional conduct remain essential.

What is possible in terms of media or message training for health professionals or advocacy organizations?

There are no specific restrictions prohibiting pharmaceutical companies from offering media or communication training to healthcare professionals or advocacy group members. However, such training must not be promotional in nature, must not encourage the promotion of specific products, and must comply with the general principles of scientific education and professional integrity. Any financial or logistical support for training must be properly disclosed and documented, in line with transparency obligations.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

Any material produced by or on behalf of third-party organizations—such as clinical societies or patient groups—must comply with the same content restrictions that apply to pharmaceutical companies. This means brand names should be avoided, unless
the material is explicitly scientific and directed to healthcare professionals. Materials intended for the general public must remain non-promotional and must clearly disclose the involvement or sponsorship of the pharmaceutical company.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Interactions with patient organizations, even when they do not involve media exposure, are still governed by the principles of transparency, proportionality, and non-promotion. Articles 4.1 and 4.5 of the Farmindustria Code apply to any form of engagement—whether it's the provision of educational materials, involvement in advisory boards, or support for disease awareness campaigns.

Companies must ensure that:

- Any scientific information shared is consistent with the SmPC;
- No promotional messages are conveyed;
- The relationship is disclosed on both corporate and patient organization platforms.

KEY TAKEAWAYS/ SUMMARY

- The 2023 Farmindustria Code expands transparency requirements to include expert patients, caregivers, and their associations, strengthening disclosure obligations.
- Hosting of scientific events must take place in appropriate, professional venues, with clear cost justifications and prior notification to AIFA where required.
- Promotional activities in Italy continue to be tightly regulated under Legislative Decree 219/2006 and the Farmindustria Code, which was last amended in January 2022 to include provisions on scientific exchange and public information.
- Public advertising remains restricted to over-the-counter (OTC) and non-prescription (SOP) medicines, and requires prior authorization by the Ministry of Health, with specific disclaimers based on the product type.
- Advertising content must be extended to other media channels (e.g., from print to digital) only through a formal notification process and without altering the original authorized message.
- Scientific education and information aimed at healthcare professionals is permitted, but must not be promotional in tone or effect, and is subject to clear segregation from public-facing content.

- Social media and digital platforms are subject to strict constraints: Facebook and YouTube may be used only with pre-authorized static content and no interactivity, while Instagram, X (Twitter), and similar platforms remain prohibited for promotional purposes.
- The use of toll-free numbers, point-of-sale displays for SOP products, and unsolicited web content (e.g., pop-ups) is prohibited to prevent indirect advertising.
- Transparency, traceability, and proportionality are essential in interactions with healthcare professionals, patient organizations, and third parties, including clear documentation of sponsorships and service agreements.
- AIFA retains broad authority to suspend or withdraw advertising content that is inconsistent with the authorized SmPC or employs misleading or exaggerated claims.

PORTUGAL

In Portugal, as direct-to-consumer promotion of prescription drugs is not permitted, the boundaries between promotional information as opposed to educational information are more distinct than in other countries, such as the United States.

Promotional activities are conducted by the National Authority of Medicines and Health Products (INFARMED) and the presented information must be scientific, accurate and objective and not misleading.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of medicines in Portugal—both over the counter (OTC) and prescription—is subject to two main standards:

(1) Decree-Law n. º 176/2006 (Aug. 30, 2006) (Code of Medicinal Products), which was amended by Decree-Law n. º 128/2013 (Sept. 5, 2013), which requires additional notification to INFARMED. In 2021, INFARMED approved two new regulations on exceptional use authorizations and on marketing authorizations for medicines without a valid authorization or registration in Portugal, revoking the previous rules and ensuring greater consistency with the rules of the Medicines Act. It has also approved a new Code of Ethics and Conduct with principles and standards to be complied with by INFARMED, which may indirectly impact Pharma and Medtech companies when interacting with the Agency.

(2) APIFARMA's (Portuguese Association of the Pharmaceutical Industry) Ethics Code of Marketing & Pharmaceuticals Practices form, which was revised in November 2022 and entered into force on January 1, 2023. Among other changes, the Code's scope has been extended to include organizations that may not include healthcare professionals, such as scientific societies or universities.

While the Drug Statute regulates the promotion of medicines and conducts censure if not followed, the Ethics Code has disciplinary sanctions attached. It also integrates some of the Drug Statute guidelines from the International Federation of Pharmaceutical Manufacturers and Associations and the European Federation of Pharmaceutical Industries and Associations Ethics Code.

The Code also details the EC Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use. The Advertising Code approved by Decree-Law n. º 330/90 of October 23 states that advertising in general, including all the aspects of the advertising of medicinal products not defined in the Code of Medicinal Products.

Regarding medical devices, Decree-Law n. º 145/2009 of June 17 established the legal framework for advertising. Medical devices are now governed by the Medical Device Regulation (EU) n. º 2017/745 (MDR), which became applicable on 26 May 2021. Its implementation in the internal legal order is ensured by Decree-Law n.º 29/2024 of April 5, which states that the rules laid down in Decree-Law n.º 145/2009 of 17 June, in regards to the advertising of medical devices, remain in force, until the revision and operationalization of the respective regime (EUDAMED).

INFARMED Decree-Law n. º 176/2006 includes articles and chapters such as Section IX, which states: 'It is considered drug advertising for this document, any form of information, canvassing activity or inducement to promote the prescription sale, purchase or consumption of a specific treatment'.

Article n. º 152 says:

1. The advertising of drugs that are not subject to a valid permit or registration for the national market or have been authorized according to Articles 92 and 93 is prohibited.
2. It is prohibited to advertise medicinal products to the general public that:
   - Are subject to prescription;
   - Contain substances defined as psychotropic or narcotic drugs under international conventions that bind the Portuguese State.
   - Are reimbursed by the National Health Service.
3. The information presented in the previous number doesn't preclude:
   - Vaccination campaigns carried out by the industry, if previously approved by INFARMED.
   - Promotion campaigns for generic drugs developed by the industry and approved by INFARMED.
4. The distribution of medicines directly to the public by industry is forbidden.
5. It is forbidden to mention the name of the treatment even if it's related to a sponsorship initiative to the public, unless it has explicit legal approval. Despite this restriction regarding prescription drugs, Article n. º 153 states that non-prescription drugs can be advertised and promoted to the public. The sunshine rules were transposed into Portuguese law through an amendment made in February 2013 to the Portuguese Medicinal Products Act (Decree-Law n. º 176/2006 of Aug. 30).

In 2013, the Code of Medicinal Products had two major changes. In February 2013, it was amended by Decree-Law n. º 20/2013 (Feb. 14, 2013), transposing Directive 2010/84/EU (15 December 2010) and including pharmacovigilance.

Subsequently, the Code was further amended in September 2013 by Decree-Law n.º 128/2013 (5 September 2013), detailing Directive 2009/35/EC (23 April 2009) on the colouring substances that may be added to medicinal products, as well as Directive 2011/62/ EU (June 8, 2011) as regards the prevention of the entry into the legal supply chain of falsified medicinal products and Directive 2012/26/EU (25 October 2012) as regards pharmacovigilance. Other substantial amendments introduced into the Code include those regarding the advertising of medicinal products.

According to the new legal provisions, entities covered by the Code of Medicinal Products must notify INFARMED within 30 days of any offer, sponsorship, grant, or any other amount, good or right assessable in cash terms, granted to any entity (regardless of its form or nature), individual, association, or representative of a certain patient group or medical company, association or corporation that is scientifically oriented or conducting clinical studies.

The Code was further amended on 6 January 2017 by Decree-Law n.º 5/2017, which establishes the advertising principles and a prohibition on NHS hospitals from requesting and receiving benefits from the pharmaceutical industry and other health technology companies, unless INFARMED authorises the receipt of the benefit and it does not harm their impartiality and neutrality.

The other binding document—Ethics Code of Marketing & Pharmaceuticals Practices—presents a more generic approach regarding the promotion of medicines. Article n. º 4 of the Code states: 'Information on the characteristics of the drug should not exceed the limits presented by the available scientific evidence and their preparation must be devoid of any ambiguous data'. Article 9 states: 'The information related to a prescription medicine should only be addressed to the people for whom one can assume, with reasonable accuracy, that they need or have an interest in it'.'

Concerning marketing, how do regulators define public relations compared to advertising or other promotional activities?
Currently, there isn't any form of differentiation. The rules presented for advertising also apply to public relations and media relations. The communications professionals must carefully evaluate the content of the different materials. In these cases, the PR professionals must implement self-regulation with a strict nondisclosure code.

Who is responsible for the enforcement of these rules?
INFARMED and the National Council on Drug Advertising are the main entities that are responsible for enforcing Portuguese law and promotion rules. The Institute controls all drug-related processes from clinical studies, licensing and distribution to all communication activities directed at patients, nurses, pharmacists, and doctors. In the last 10 years, INFARMED has become increasingly aware of media issues, and it now has a specific department that monitors the enforcement of the communication rules.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
In the pharmaceutical sector in Portugal, concerns and complaints regarding marketing or communications content and activities are typically handled by various regulatory bodies and associations. These entities ensure that marketing and communication practices comply with legal and ethical standards. Here is an overview of how this process operates:

1. **INFARMED**

The advertising of medicines is subject to the legal regime laid down in the Medicines Statute, Decree-Law n.º 176/2006, of 30 August, as amended by Decree-Law n.º 128/2013, of 5 September, amended by Law n.º 51/2014, of 25 August and, in the alternative, the provisions of the Advertising Code (Decree-Law n.º 330/90, of 23 October).
Responsibilities:
- Regulation and supervision: INFARMED is the primary authority responsible for regulating and supervising medicines and health products in Portugal.
- Advertising monitoring: INFARMED monitors the advertising and other forms of promotion of medicines to ensure they are accurate, balanced, and not misleading. Marketing Authorization Holders (MAHs) must send advertisements for medicinal products to INFARMED for registration and assessment.

Complaints process:
- Submission of complaints: Anyone can submit complaints regarding the advertising of medicines to INFARMED.

Evaluation and action:
- INFARMED, within the scope of market monitoring and control activities, or through the Medicines Advertising Management System (GPUB), evaluates the complaints received and, if necessary, takes corrective measures which may include sanctions against pharmaceutical companies that violate the rules.

2. **APIFARMA**

The Council of Ethics of APIFARMA receives concerns and complaints. The supervision of the application and compliance with this Code's provisions by member companies is incumbent on the Ethics Committee of APIFARMA, as laid down in its Regulation and the Association's Articles of Association. The applicable sanctions are listed in the APIFARMA Statutes, which include the following from Article 40 of the Statutes. The sanctions applied by the Council of Ethics are:
a. Simple warning.
b. Reprimand.
c. Penalty up to the amount of five years membership fees.

3. **Directorate-General for the Consumer (DGC)**

Responsibilities:
- Consumer protection: The DGC is responsible for protecting consumer rights in general, including those related to misleading or abusive advertising.
- Supervision of commercial practices: This entity supervises commercial practices to ensure they are fair and transparent.

Complaints process:
- Submission of Complaints: Consumers can submit complaints to the DGC via an online portal, by phone, or by mail.
- Investigations and Actions: The DGC investigates complaints and can impose sanctions on companies that violate consumer rights.

Do any promotional or media materials need to be approved by regulatory authorities?
Only the ones considered advertising pieces. INFARMED created the Drug Advertising Management System (GPUB) with Deliberation n. º 044/2008 that monitors, approves, and controls promotional pieces for the pharmaceutical market. Companies must present their materials before starting the marketing process. While the materials will be rejected if they don't comply with the rules, the analysis continues after the launch of the treatment and includes different channels such as television, radio, press and the Internet. Companies must also notify INFARMED in advance of the sponsorship of any congress, symposium, or event of an educational or promotional nature. Complaints from the general population or healthcare stakeholders may also be considered. Before the GPUB submission, the submitted materials must be approved internally by the respective medical departments.

Currently, there is a legislation gap regarding media relations and PR. News isn't considered advertising, but companies (and journalists) can still receive INFARMED letters when a media outlet publishes information regarding a specific prescription treatment using the commercial name.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned soon?
INFARMED is currently evaluating the impact of social media in the process of sharing health information. New guidelines should be available soon.

The Decree-Law n.º 36/2021, of 19 May, approved an important update to the Medicines Act, establishing a clear prohibition of advertising discounts on the price of medicines that cannot be advertised before the general public (i.e., medicines subject to medical prescription, reimbursed medicines and medicines containing controlled substances).

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
This is not defined in Portugal, but National Entities consider the ones exclusively directed to media professionals.

How is a media event defined?
This is not defined in Portugal but National Entities consider the ones exclusively directed to media professionals.

Do the regulations differentiate between consumer and clinical publications?
Yes. In consumer publications, the promotion of prescription drugs is forbidden; specifically, the use of the commercial name for the treatment is not allowed. Any event or promotional action using the product's brand name can't be presented to the general public. Also, journalists of general publications are advised not to assist in particular scientific symposiums sponsored by the pharmaceutical industry. They can, however, interview physicians outside the room. Clinical publications don't have these specific limitations, but any product advertising page must include the drug's leaflet.

Do regulations differentiate between online, print, broadcast, and/or streaming media?
There is no differentiation except for trade media.

What is permitted concerning off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings, and major publications?
A medicine cannot be actively promoted before the marketing authorization allowing its sale or medical supply [the formal authorization is called *Autorização de Introdução no Mercado* (AIM)]. However, publication in clinical newspapers of scientific information before authorization is acceptable if supported by scientific data. Usually that occurs after the presentation of international information from an independent medical source or a press release—medical and general media—about a clinical trial.

In congresses, scientific meetings, and major publications, it is possible to distribute and share scientific information (not for the general media) if there is sufficient scientific data that represents credible information and not promotion.

Pharmaceutical companies can sponsor medical meetings and scientific symposiums before the launch of a product but following Article n. º 159 from INFARMED's Drug Statute:

1. The sponsorship of congresses, symposiums or scientific events directly or indirectly should be documented as well as the promotional materials and the reports published after the completion of those actions and events actions and events.
2. The marketing authorization holder or the company responsible for the information or promotion of the product should keep the data for each of the events or activities sponsored or organized.
3. The documentation referred includes, completely and faithfully, the following:
   - Action and events program.
   - Main entity identification.
   - Copy of the scientific and professional communication.
   - Expense maps, receipts and justification documents.
4. The documentation referred to in the previous paragraphs should be retained for a minimum of five years from the date of the event and made available to entities with supervision powers such as INFARMED.

Furthermore, the recipients of these benefits, which include certain patient groups or medical companies, associations or corporations that are scientifically oriented or conducting clinical studies, but also any entity or individual (specifically healthcare professionals), must notify INFARMED and register such benefits on INFARMED's website. Since 7 October 2014, these rules only apply to transfers of a value exceeding €60 (before 2014, these rules applied to transfers of a value exceeding €25). INFARMED further clarified that any hospital, service, or medical society that organizes a certain congress must be identified as the beneficiary of the event, and not the healthcare professionals. The main rule in this respect is aimed at preventing any type of prescription incentives; therefore, the holders of the marketing authorization or of the registration of medicinal products, as well as companies responsible for the promotion of medicinal products and wholesale distributors, are not allowed to directly or indirectly give or promise to healthcare professionals, or their patients, prizes, offers, bonuses or pecuniary benefits or benefits in kind unless they are insignificant and relevant for medical or pharmaceutical practice.

What regulations specifically cover press releases, media materials and company events? What are the general principles?

The information of the drug characteristics should not exceed the limits backed by the available scientific evidence, and their preparation must be objective.

The information presented in the promotional material or the intended information to promote a drug's good use must:

1. Be based on an updated assessment of all available scientific evidence under the summary of product characteristics.
2. Comply with the marketing authorization.
3. Not lead to incorrect or wrong conclusions.
4. Scientific data that support claims about the product characteristics must be available.
5. Information about side effects should reflect the data available and the clinical experience.
6. Promotion should encourage the rational use of a drug, presenting it objectively and without exaggeration of its properties.
7. All promotional elements, including graphics, illustrations and tables from published studies and integrated promotional material must:
   - Clearly indicate the exact source or sources of the promotional elements;
   - Be faithfully reproduced. In case of need they may be adjusted, mentioning the introduced adjustment.
8. Also, the word "safe" should never be used to qualify a product. Likewise, the word "new" should not be used to describe a product or presentation that has been available for more than a year, or one that has been promoted or launched before. Finally, we write that a drug has no side effects, or risks of toxicity, addiction, or dependence.

It is not forbidden to invite the media to a clinical event, but if INFARMED receives a complaint about an article published in the trade media, they will analyse all the information provided by the responsible pharmaceutical company. This doesn't occur for trade media.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

This issue is not covered, but press materials intended for Portuguese distribution must comply with local regulations.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?

No specific indication is given but press conferences or briefings can be held at congresses and scientific meetings outside the main rooms. Media, general and specialized, can attend. The events should not be dedicated to the presentation of products (except for specialized journalists) since the direct communication of unlicensed products or indications is prohibited. Disease awareness communication is often adopted.

The press conference materials (press releases and media backgrounders) must be approved by the medical department of the hosting organization of the major event and should include a quotation of an important key opinion leader (KOL) (to preserve the reputational focus). This serves both licenced and unlicensed products equally.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?

If the invitation is directed to a journalist from the general media, the resulting copy is independent, but if the communication professional is from a specialized newspaper, then the text goes through the company's regulatory process. Journalists who work in general media (the company that sent the invitation is always referred to at the end) receive a different kind of press kit with more scientific information about the disease and less about the treatment. A freelance journalist is seen in the same way as a specialized one, and the information shared depends on the final goal of that press material. If the information is supposed to impact patients and the general population, then the drug statute must be applied. If it is for internal use or to communicate with physicians, more commercial data can be presented.

Do regulations cover the use of case studies or other third-party advocacy in the media?

There are no specific regulations regarding this issue, but APIFARMA'S Ethics Code of Marketing & Pharmaceuticals Practices states that companies must follow the conduct code when endorsing a partnership with patient associations. These can speak to the media at company press events and, in pressing situations, case histories, but usually the patients talk with the media only during patient association press events.

A common media tactic is to use real-life case studies involving successful treatments shared by patients and physicians. When using a quotation from a key opinion leader (KOL) in a product press release, it is important to know the product and the rationale for the reference.

There isn't any formal guidance, but case studies should not be promotional, and they should not be used to encourage the use of a product.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

Online media are not different from print and broadcast, and the same rules apply; however, a difference is seen in the monitoring process. With the increase in internet access, more and more new media (especially locally) are starting to appear. INFARMED and the National Council on Drug Advertising try to analyse the digital information channels, but most of them are difficult to control daily.

What are the web security and data privacy requirements?

Promotional material about prescription-only medicines can only be placed on a website owned or sponsored by a pharmaceutical company. These must be open only to healthcare professionals and not be directed to the public. Companies can endorse websites that only talk about the disease. Again, INFARMED analyses and approves the information presented.

Do the regulations cover the funding of, or provision of information to, non-company-owned websites?

The Code of Conduct Governing the Relations between the Pharmaceutical Industry and patients' organizations is always present in companies' and institution's relationships.

According to the Code:

Article 6 - Written Agreements

1. All partnerships, services supply and financial support or sponsorships granted by the Companies

to Patients' Associations should be made in writing, through agreements signed by both parties before the beginning of their respective activities, which include the minimum requirements provided for in the Code and the respective contractual models annexed to the Code.

2. Support in kind granted by the Companies to Patients' Associations worth more than € 60.00 should be made in writing, and the respective agreement should include the minimum requirements set out in this Code and in model A annexed to the Code.
3. The services supplied or contracted by the Companies with Patient Advocates, Patient Experts, Patients or Caregivers under the provisions of Articles 9 and 10 are also the subject of written agreements, signed before the start of the provision of services, which must include the minimum requirements set out in models B and C annexed to this Code.
4. Each Company shall set up an internal procedure for the formal approval of the agreements referred to in the previous paragraphs.

Article 7 - Use of logo and materials subject to copyright

1. The use by a Company of a logo, name and/or copyrighted materials belonging to a Patient Association is subject to prior written authorization by the latter.
2. The application for authorization referred to in the preceding paragraph should clearly state the specific purpose and how the logo, name and/or copyrighted materials are used by the Company.

Article 8 - Financing of Patients' Associations

Companies may not ask or require to be the exclusive financing entity of a Patients' Association or of any of its activities or events.

Article 19 - Materials produced by Patients' Associations

1. Companies should not seek to influence the content of the materials produced by the Patients' Associations they sponsor in such a way as to favor their own business interests.
2. The obligation set out in the previous number does not prevent companies from correcting factual and/or scientific inaccuracies in the materials produced.
3. By written request of the Patients' Associations, companies can cooperate in the preparation of scientific or educational texts.

Article 20 - Materials produced by Patients' Associations

1. Member Companies should publicly disclose any benefits in kind or cash which they grant to all entities and natural persons covered by this Code.

According to the above-mentioned new legal provisions, entities covered by the Code of Medicinal Products must notify INFARMED within 30 days of any offer, sponsorship, grant, or any other amount, good or right assessable in cash terms, granted to any entity (regardless of its form or nature), individual, association, or representative of a certain patient group or medical company, association or corporation that is scientifically oriented or conducting clinical studies.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?

Facebook, WhatsApp, and Instagram are the most popular social networks in Portugal. Facebook is the largest social network in Portugal, with 5.9 million users as of 2023.

Created in June 2021, APIFARMA's Guide to the Use of Digital Channels systematises the existing rules of APIFARMA's Code of Ethics, EFPIA's Code of Ethics, IFPMA's Code of Ethics and respective guidelines, and national legislation - Decree-Law n.º 176/2006 of 30 August, in its current wording, applicable to communication carried out through digital channels, without creating any new obligations.

Pharmaceutical companies remain cautious when using social media and have prepared internal guidelines around their usage, as INFARMED has yet to adopt specific regulations for these platforms. However, on March 7, 2024, INFARMED approved a new regulation approving good practices for advertising non-prescription medicines through digital channels.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?

The general rules applicable to advertising medicines in the Medicines Act apply to advertising medicines through the internet and social media. However, while there are no provisions on the use of social media for promotion, the APIFARMA Code of Ethics does guide promotion on the internet or other digital channels in Article 13:

1. Promotion of medicinal products or in vitro diagnostic medical devices on the internet or other digital channels should be based on technical, scientific, and professional principles and in compliance with the national legislation in force and the promotion rules provided for in this Code.
2. Member companies should adopt such measures to guarantee that the promotion on the internet or other digital channels of prescription-only medicinal products or in vitro diagnostic medical devices requiring a healthcare professional's mediation or decision is accessed only by healthcare professionals.

Additionally, INFARMED has issued two Informative Circulars (Informative Circular n.º 229/CD, of 9 November 2011 and Informative Circular n.º 236/CD of 16 November 2011) establishing specific rules on advertising through the internet and other digital channels, stating that pharmaceutical companies can advertise their prescription-only medicines to the general public if the information is exclusively available on pharmaceutical companies' own corporate websites, and not on social networks, or disseminated by any other means.

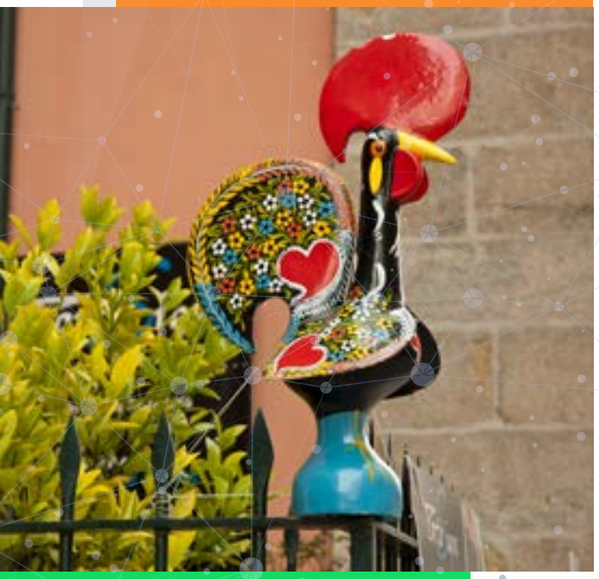
Healthcare professionals' access to advertisements for pharmaceuticals via the internet or social media follows the general rules for advertising to healthcare professionals. The content made available to healthcare professionals through these channels should not be accessible to the general public.

Are there any self-imposed regulations from social media companies?

There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?

Currently, there aren't any rules for digital platform engagement, but the general principles presented in the drug statute should be followed. Pharmaceutical companies



shouldn't express their view about prescription medicines or try to directly engage patients since direct commercial contact is forbidden. A company can start or endorse a forum to discuss a specific disease, but the management of that digital space must be made by an outside entity.

What is mobile adoption like in your region? Are there separate regulations for it?
84.2% of Portugal's population used smartphones as of 2020. Due to the relatively high adoption rate, pharmaceutical companies have begun to invest in apps for consumers and healthcare professionals. However, direct-to-consumer advertising of medical products is still prohibited on mobile devices, so many apps focus on disease awareness and management.

According to APIFARMA's Guide to the Use of Digital Channels, companies that develop applications should follow the same rules defined for websites. The Guide states that companies should ensure that the target audience is well-defined and specified and that if an app targets a specific group, such as healthcare professionals, patients, or carers, it is important that access to the app's content is only made available to this group and under the principles applicable to the media and under the terms of the legislation in force. The promotion of prescription medicine is permitted exclusively to healthcare professionals.

What are the disclosure laws in your region for non-branded websites??
There are no specific laws regarding non-branded websites. As stated in the drug statute, it is not permitted to address the general population with commercial information regarding prescription medicines. The non-branded websites supported by pharmaceutical companies need to respect Article n. º 152 from the Drug Statute.

What are the requirements for adverse event reporting?
Health professionals, inside and outside the National Health System, must inform INFARMED pharmacovigilance as soon as possible about adverse reactions, suspected adverse reactions or serious unexpected situations that occur.

Article n. º 153 from INFARMED's drug statute clearly states that it is forbidden to suggest that the drug effect is guaranteed with no adverse reactions or side effects..

Article n. º 170 from the same document also says that pharmaceutical companies must record and immediately report (through health professionals or other sources) to INFARMED all suspected serious adverse reactions that occur in Portugal.

After that, INFARMED promptly reports the suspected serious adverse reactions to the other European Member States, and to the Agency, within a period not exceeding 15 days after the date of notification.

Amendments to the Medicinal Products Code, established by Decree-Law n. º 20/2013 (Feb. 14, 2013) and Decree-Law n. º 128/2013 (Sept. 5, 2013), concern medicine safety matters. Directive 2010/84 (15 December), which amends Directive 2001/83/EU as regards pharmacovigilance, was transposed into national law in 2013. This reformulated the Portuguese National Pharmacovigilance System and included new requirements to prevent, detect and assess adverse reactions to medicinal products placed on the EU market, as the full safety profile of medicinal products can only be known after they have been placed on the market. Directive 2012/26/EU (Oct. 15, 2012) also amended Directive 2001/83/EU as regards pharmacovigilance and further strengthened the European rules respecting the safety and monitoring of medicinal products and was transposed into national law in 2013.

All developments regarding the safety monitoring and, specifically, the pharmacovigilance of medicinal products that are placed on the Portuguese market, including those that are sent by EMA, are published daily on the INFARMED website.

Also, adverse event reporting must be detailed in press materials for the healthcare media and/or medical material. When a media crisis situation presents itself, the commonly used strategy includes the following hierarchy: communicating with INFARMED—Ministry of Health— Physicians/Nurses/Pharmacists—Patient Associations— Media.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
In Portugal, pharmaceutical companies can provide funding to patient groups for travel and accommodations as long as the hotels are below four stars. This is possible for national and international events, and on more general grants, but according to the Drug Statute, pharmaceutical companies cannot give any commercial information directly to patients or patient groups.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Companies can offer an honorarium to healthcare professionals to participate in meetings, press conferences, medical symposia, or advisory boards, but a contract must be established with the physician with a description of the activity.

According to APIFARMA's Ethics Code of Marketing & Pharmaceuticals Practices, hospitality which includes travel, registration, and subsistence expenses, must not exceed what the recipients would normally be prepared to pay for themselves in the same circumstances. The guests must travel in economy class, stay in four- or three-star hotels, and cannot include family or friends in the global budget.

Also, the funding should not be provided as compensation for time spent in events by health professionals. In the case of international events for which a company sponsors the participation of a health professional, the financing is subject to legal rules from the health professional's country and not the local rules of the international event. Regarding patient group representatives, the honoraria must be given to the respective association.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
No money can be offered to compensate for the time used by healthcare professionals or patient groups to attend the event, and physicians can only be paid when participating.

What is possible in terms of media or message training for health professionals or advocacy organizations?
This is not reported in the Portuguese Drug Statute or the APIFARMA Code. In the last five years, Medical Media Training (MMT) has become quite popular, and we advise using a media training company that specializes in the healthcare area. The first goal of this type of activity is to prepare doctors and patient association representatives for media contacts. When a pharmaceutical company sponsors the media training, they must prepare the information depending on the targets and we must always consider the Portuguese Medicine Law. It is possible to present prescription medicine information for physicians, but not for patient associations. In both cases, all the material must have references regarding the sponsoring company.

If the media training occurs during weekends, the Ethics Code of Marketing & Pharmaceuticals Practices regarding hospitality must be taken into consideration.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
There aren't any specific rules regarding this issue, and third parties are responsible for the content presented. On an internal level, when sponsoring different types of materials, pharmaceutical companies always try to evaluate the information (through the medical department) that must be generic and non-commercial.

Also, quotations from medical or scientific literature inserted in the different materials must be faithfully reproduced and properly referenced.

What regulations cover meetings with, or the provision of, non-media information to advocacy groups?

According to the INFARMED and APIFARMA Statute and Ethics Code, pharmaceutical companies can interact with different patient advocacy groups. However, when working with any patient organization they must present non-promotional information, such as disease

information data without references, direct or indirect, to prescription medicine.

KEY TAKEAWAYS/ SUMMARY

- Portugal has an inflexible Drug Statute Law that prohibits DTC promotion of prescription medicines. The country is aligned with the European Medicines Agency (EMA), and when it comes to new medicine and advertising laws, some influence comes from other European countries.
- Pharmaceutical companies also need to be aware that non-scientific media relations programs can contribute to official requests from the Portuguese Authorities for more information about the degree of influence and participation.
- The Portuguese Pharmaceutical Association Code of Marketing & Pharmaceuticals Practices also positively influences the conduct of the companies on different communication levels.
- Under paragraph 5 of Article 159 of the Medicinal Products Act, legal entities will also be required to declare to the Communications Platform - Transparency and Publicity of INFARMED any kind of sponsorship granted to individuals, including healthcare professionals.
- The upcoming revision of the EU's pharmaceutical legislation reform will influence the national legislation regarding the promotion and advertising of medicines. While the Proposed Directive is expected to maintain the status quo for advertising regulation, it does introduce certain changes, in particular, for comparative advertising.

ROMANIA

Generally, pharmaceutical marketing regulations in Romania are governed by the Ministry of Health through the National Agency for Medicines and Medical Devices (ANMDM), the Romanian Association of International Drug Manufacturers (ARPIM) Code and the Romanian Association for Generic Medicine Producers (APMGR). In addition, the National AudioVisual Council oversees if commercials respect the law.

Romania does not allow pharmaceutical companies to promote prescription medicines to the general public. Companies with a prescription portfolio can only conduct disease-awareness campaigns, in which the only brand reference permitted is to the corporate brand. Over-the-counter drugs can be promoted to end-consumers through an advertising visa only.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
Romanian law no. 95 of 14 April 2006 (republished in the Official Monitor as no. 652 of 28 August 2015) governs the promotion of medicines. The most relevant chapters from this law are Chapter VIII, "Advertising," with Articles 811–814, and Chapter IX, "Informing the public", with Articles 815–826.

According to the law, advertising means: any kind of direct-door information (door-to-door system) as well as any form of promotion intended to stimulate the prescription, distribution, sale or consumption of medicines; advertising for medicines includes in particular:

- Advertising of medicines for the general public.
- Advertising of medicines for persons qualified to prescribe or distribute medicines.
- Visits of medical representatives to persons qualified to prescribe medicines; providing samples; stimulating the prescription or distribution of medicines by offering, promising or granting cash or in kind benefits, unless they have a symbolic value; sponsoring promotional meetings attended by individuals qualified to prescribe or distribute medicines.
- The sponsorship of scientific congresses involving persons qualified to prescribe or distribute medicines and, in particular, the payment of transport and accommodation costs incurred by them.

Another local regulation that governs the promotion of medicine is Order No. 194, issued 23 February 2015 by the Ministry of Health about the norms for evaluating and approving advertising for medicine intended for human use.

Another two codes of practice apply only when their stipulations are more severe than the legislation in force. In such a case, the violation only imposes sanctions on behalf of these respective associations: the ARPIM Code and the APMGR Code.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
There is no differentiation. The rules that local authorities enforce for advertising also apply to public relations and other promotional activities.

Who is responsible for the enforcement of these rules?
Under Romanian law, any activity that seeks to stimulate prescription or consumption, including PR, is regarded as advertising. ANMDM is the main entity responsible for enforcing Romanian law and promotion rules.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?
Pharmaceutical companies are limited in terms of sponsorships for healthcare providers to attend events (for registration fees, travel fees and accommodation costs, etc.). Companies also have a standard fee for booking healthcare providers as speakers that ARPIM and ANMDM regulate. Companies can also hire healthcare providers for scientific consultancy or for clinical studies, for which the fees are greater. Companies must report such hires to the Ministry of Health.

Companies must annually disclose all such sponsorships and hires, with each reporting period covering the previous calendar year in full. For individual disclosures, companies must contact and disclose to ANMDM within three months following the end of the relevant reporting period. And on their own (public) website, they must disclose such sponsorships and hires within six months following the end of the relevant reporting period, in accordance with the provisions of Order No. 194/2015 of the Ministry of Health and the disclosed information must remain in the public domain for a minimum of three years following the disclosure date.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
If a company does not comply with the rules governing advertised medicines, ANMDM will apply sanctions in accordance with existing laws. All pharmaceutical companies that do not comply with these laws and regulations will be published on ANMDM's official website (www.anm.ro). ANMDM inspectors check these companies and their promotional activities to see if they are acting in accordance with Order No. 194 of 23 February 2015, which governs the norms for publicly advertising medicinal products intended for human use.

Do any promotional or media materials need to be approved by regulatory authorities?
All public-facing promotional materials must be pre-approved by ANMDM. Materials for healthcare professionals do not require pre-approval but can be reviewed following complaints or inspections.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
At the time of this guide's publishing, the rules for promoting medicine were last updated in 2015. As a member of the EU, Romania is required to implement all the EU directives that refer to advertising medicine.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
This difference is not defined.

How is a media event defined?
This term is not defined.

Do the regulations differentiate between consumer and clinical publications?
Yes. Companies must first submit all advertising materials that reach consumers to ANMDM and place the materials on the market only after obtaining an advertising visa. ANMDM evaluates advertising materials for healthcare professionals after they're disseminated or as a result of complaints. The materials' design and presentation should be clear and easy to understand. If footnotes are used, they must be legible in size.

Do regulations differentiate between online, print, broadcast and/or streaming media?
No, the regulations for print and broadcast media are the same.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
Pre-launch or off-label promotion is strictly prohibited. No promotion may occur before the product has received marketing authorization.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
Media materials, including press releases, are not allowed to encourage the public to consume or purchase pharmaceutical drugs. Companies are forbidden from promoting prescription medicines to the general public. They may, however, run unbranded educational campaigns under strict conditions.

Clinical events are planned events with a scientific character that are addressed to healthcare professionals and initiated and organized at a local, regional, national or international level (e.g., congresses, symposiums, roundtables, workshops, courses, advisory board meetings, etc.). At such events, companies may offer small gifts or promotional materials to healthcare providers, but ANMDM should have previously approved the items. There are no specific regulations for media events.

Is the method of distribution of such materials covered (with reference to if they are from outside the country where the publication is intended)?
The method of distribution is not regulated.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
The same regulations that apply to all promotional activities apply to congresses and scientific meetings. There are no differences mentioned in Order No. 194 between licensed and non-licensed products.

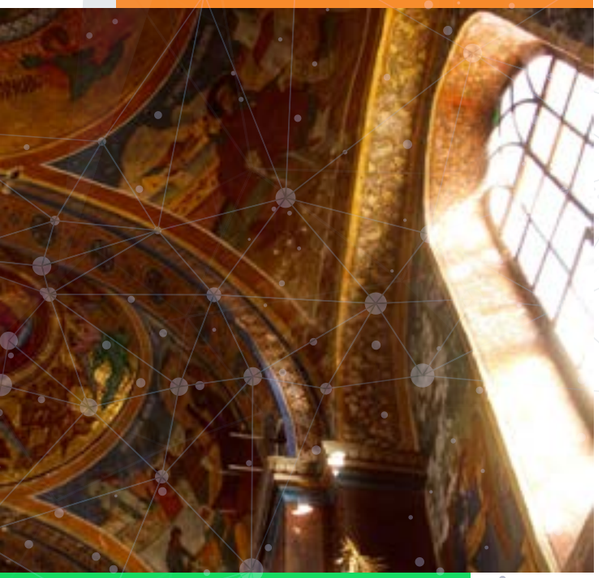
If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
When promotional materials are published in the press following services engaged by a pharmaceutical company, its subsidiary or a related company (i.e., the company's PR agency) should be clearly revealed as the company benefiting from the publication. Such articles must not resemble an independent editorial opinion.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No specific regulations address this issue.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

- For prescription medicines, pharmaceutical companies must provide evidence that they have restricted access to online information from non-healthcare professionals through password protection. Companies must also include the Summary of Product Characteristics with this information.
- All online medical information should be supported by scientific references compatible with the approved Summary of Product Characteristics.
- Romanian users must be informed if certain websites include links that target users from other countries.
- Romanian users must be able to access drug information (the Patient Information Leaflet, or the approved Summary of Product Characteristics) directly from any company's website.
- Websites must specify their target audience.
- Any information from websites that addresses healthcare professionals and is a form of promotion must comply with the regulations governing the content, the advertisement format and how to promote medicine.



What are the web security and data privacy requirements?
Websites must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information. All websites should comply with the EU's General Data Protection Regulation.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
No, the regulations do not cover this area.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
In January 2025, there were **17.8 million internet users** in Romania, representing **94.0% of the total population,** a slight decrease of 99,000 users (–0.6%) compared to the previous year. **There were 13.0 million active social media identities,** equivalent to **68.6% of the total population,** marking a decrease of 300,000 (–2.3%) compared to January 2024.

Social Media Platform Breakdown:

- **Facebook:** 9.90 million users; ad reach equals 52.2% of the total population and 55.6% of the internet population. Gender split: 50.5% women, 49.5% men.
- **YouTube:** 13.0 million users; ad reach equals 68.6% of the total population, or 73% of internet users. Gender split: 50.8% women, 49.2% men.
- **Instagram:** 5.45 million users; ad reach equals 28.7% of the total population, or 30.6% of internet users. Gender split: 53.2% women, 46.8% men.
- **TikTok:** 8.51 million users aged 18+; ad reach equals 55.4% of the adult population and 47.7% of internet users. Gender split: 50.7% women, 49.3% men.
- **LinkedIn:** 4.90 million members; ad reach equals 25.8% of the total population, 31.9% of those aged 18+, and 27.5% of the internet population. Gender split: 52.1% women, 47.9% men.
- **X (formerly Twitter):** 1.63 million users; ad reach equals 8.6% of the total population, 9.9% of those aged 13+, and 10.5% of adults. Gender split: 38.1% women, 61.9% men.
- **Snapchat:** 2.65 million users; ad reach equals 14.0% of the total population, 16.1% of people aged 13+. Gender split: 54.6% women, 44.5% men.
- **Pinterest:** 2.83 million users; ad reach equals 14.9% of the total population, 17.2% of people aged 13+. Gender split: 70.9% women, 23.6% men, 5.4% unknown/unspecified.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Companies are not allowed to promote prescription or over-the-counter medicine on social media. They may, however, run disease-awareness campaigns/education programs on social media with no reference to specific medicine. The only reference allowed is to a medicine's corporate brand.

Are there any self-imposed regulations from social media companies?
Regarding social media, companies should follow the general regulations for promotional activities.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
This particular subject is not addressed.

What is mobile adoption like in your region? Are there separate regulations for it?
In 2024, almost 92% of Romanians have access to the internet, and there are 9 million more active mobile phones than the country's population. Specifically, there are 28 million mobile connections for 19.73 million inhabitants, which is 141.9% of the total population. There are no separate regulations for mobile devices, but because of their high adoption rate, pharmaceutical companies have begun to invest in mobile-friendly websites and apps designed for both consumers and healthcare professionals.

What are the disclosure laws like in your region for non-branded websites?
No specific laws exist addressing non-branded websites. However, each website must clearly identify a) the identity and physical and electronic addresses of the website's sponsor(s)/owner(s); b) full references related to the source(s) of all medical information included on the website; c) the website's target audience (e.g., healthcare professionals, patients and the general public); and d) the website's purpose or objective.

What are the requirements for adverse event reporting?
Companies must report adverse reactions to ANMDM's website via an online form on a dedicated page. These same adverse event reports can be addressed directly to pharmaceutical companies, which should have a green line phone service, which can be dialed free of charge from any home or mobile phone, and a delegated person in charge to take such calls.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Hospitality extended in connection with company-organized events attended by healthcare professionals and with sponsored independent events must be limited to travel, meals, accommodation and genuine registration fees. Airline travel (both domestic and abroad) must be economy

(coach) class; business class or higher is not allowed. In "host countries" where local provisions do not set a limit for meals, the maximum limit is 150 EUR (or the relevant equivalent) per day.

All forms of hospitality offered to healthcare providers must be reasonable in level and strictly limited to an event's duration. Generally, any hospitality must not exceed what healthcare providers would normally pay for themselves.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

Sponsorship, donations and/or grants (monetary, in-kind or otherwise) to public institutions, organizations or associations that are made up of healthcare professionals and/or that provide healthcare or conduct research are only allowed if a) the company's sole purpose is to support healthcare or research; b) the funds are documented and kept on record by the sponsor, donor or grantor; c) the funds do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products; and d) the respective organization did not request or solicit the funds.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Yes, companies may pay healthcare providers (including residents) to attend scientific meetings, but in a limited capacity. Sponsoring independent events and/or healthcare providers to attend such events must not be conditional to any obligation to promote, prescribe, recommend or purchase products.

What is possible in terms of media or message training for health professionals or advocacy organizations?

Pharmaceutical companies may engage healthcare providers for services such as, but not limited to, lectures, consulting and/or advising (e.g., advisory board meetings), involvement in medical/scientific activities and studies, training services (e.g., medical training) and participation in individual or group-based market research. Companies must comply with criteria governing how healthcare providers are selected and sponsored to attend training or events.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

No specific regulations address this issue.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Pharmaceutical companies may sponsor independent events organized by third parties to allow healthcare providers to further their professional development and clinical performance and to improve patient care and patient outcomes.

KEY TAKEAWAYS/ SUMMARY

- Promoting prescription medicine is restrictive in Romania; prescription drugs can be promoted to healthcare professionals only. It is prohibited to leave promotional materials in places accessible to the general public, such as pharmacies, waiting rooms, corridors of hospitals and clinics, etc.
- All advertising materials for the public must be submitted to ANMDM and placed on the market only after obtaining an advertising visa.
- In terms of promotional activities, companies may run disease-awareness campaigns or educational programs for both prescription and over-the-counter medicine. The affiliated corporate brand may be mentioned, but no reference to specific medicinal products, whether direct or indirect, is permitted.
- Companies may sponsor healthcare professionals to attend events, take part in market research, attend lectures, be involved in scientific activities, etc., however, in a limited capacity only.
- Transparent promotion is a key part of Romania's pharmaceutical marketing regulations.
- Prescription Drug Advertising is Prohibited to the Public.
- Only healthcare professionals may be targeted with promotional activities for Rx products. Public campaigns are allowed solely for disease awareness and may only reference the corporate brand—not the product itself.
- Mandatory Pre-Approval for Consumer-Facing Materials.
- Any advertising aimed at the general public (for OTC products) must be submitted to ANMDM and receive an "advertising visa" before dissemination.
- Transparency and Disclosure are Obligatory.
- All sponsorships, consultancy contracts, and engagements with HCPs must be disclosed to the Ministry of Health and published on the company's website within specific timeframes.
- Digital Channels are Regulated Under the Same Principles.
- Online and social media promotion of medicinal products is prohibited. Disease awareness content is permitted if it doesn't reference specific products and clearly defines the intended audience.
- Strict Compliance Applies to Events and Sponsorships.
- Companies may support HCP participation in scientific events, but travel, accommodation, and fees must comply with strict financial limits. Business class travel and excessive hospitality are not allowed.

SPAIN

Any correspondence or material produced by a pharmaceutical company about a medicine or its use is considered promotional, whether or not it makes product-specific claims. All promotional information should be accurate, balanced, fair, objective and sufficiently complete to enable the recipients to form their own opinion about the therapeutic value of the medicine. It must not be misleading and must reflect the most current information.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

There are laws at a National and Autonomous Communities level, but the main code of ethics is issued by the Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria) and the industry's national business association: the Spanish Code of Practice for the Promotion of Medicines and Relations between the Pharmaceutical Industry and the Health Professional (updated in 2023).

Changes in the promotion of pharmaceutical products in Spain has led to a new self-regulation system in the pharmaceutical industry with this new version of the Code of Practice for the Pharmaceutical Industry, ratified by Farmaindustria´s General Assembly in June 2023.

The Code incorporates, among others, the principles of:

- Directive 2001/83/EC of the European Parliament and of the Council, dated 6 November 2001, on the Community code relating to medicinal products for human use.
- Royal Decree 1416/1994 of 25 June 1994 regulating the advertising of medicinal products for human use.
- Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices.
- Law 3/1991, of 10 January, on Unfair Competition.
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes on Interactions with Healthcare Professionals (HCPs), Relationships with Patient Organizations and Disclosure of Transfers of Value.
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices.
- Legal Office Report Number 2016-0172 (REF 143318/2016) dated 22 April 2016 from the Spanish Data Protection Agency (AEPD), reproduced in Annex I of the Code.

The new code essentially addresses three areas:

1. Promotion of Prescription-Only Medicines. Respecting the right of the scientific community to be completely informed about medical and scientific progress, on one hand, and the legitimate interest of companies to inform and promote their products, on the other, this section of the code provides a series of regulations designed to guarantee that the information provided in the context of the promotion of prescription-only medicines is appropriate, honest, precise, objective, complete, accurate and truthful.
2. Relationships with HCPs and Healthcare Organizations. The interactions between healthcare professionals and the pharmaceutical industry have a fundamental influence on patient care and research development; for this reason, it is necessary to establish criteria and guidelines to guarantee that these activities are conducted in a professional and responsible manner.
3. Relationships with Patient Organizations. Patient organizations and the pharmaceutical industry share common interests, such as improving the quality of life of patients and paying attention to their interests. The rules included in this section guarantee that the manner in which companies interact with patients and with the organizations that represent them is appropriate and in compliance with, among others, the principles of independence, mutual respect and transparency. The continuous commitment of pharmaceutical companies to the development, efficacy and rigor of the self-regulation system is the result of the responsible attitude of Farmaindustria members and those companies that have decided to adhere to the Code voluntarily. This commitment is proved by the companies' implementation of robust internal procedures designed to guarantee compliance with the Code, with the aim of ensuring appropriate training of their employees. The transparency of the self-regulating system is offered as an essential tool for promoting

and strengthening confidence in the pharmaceutical industry, facilitating public access to their actions. Proof of this commitment is the publication of the Resolutions of the Jury of the Association for Self-Regulation of Commercial Communications in complaint procedures, information related to clinical trials, collaboration provided to patient organizations and, more recently, the disclosure of transfers of value to healthcare professionals and healthcare organizations. The Code's control functions are carried out by three bodies: the Ethics Oversight Unit, the Ethics Committee and the Self-monitoring Jury. These are responsible for ensuring compliance with the Code, providing advice and guidance to members on its interpretation, mediating in the event of a complaint and settling disputes where conciliation has not been reached.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Public relations is not separately defined. The scope of the Code covers all forms of promotion aimed at health professionals who are qualified to prescribe or dispense medicinal products. It covers all promotional methods, including those traditionally categorized as public relations, such as the sponsorship of scientific congresses and scientific or professional meetings attended by healthcare providers, online communications, the use of audiovisual systems and the provision of gifts and hospitality. It often uses the word advertising interchangeably with the word promotion. Law 1/2015 modifies Article 78 of Law 29/2006, regarding guarantees and the rational use of medicines and health products. This issue is regulated in paragraphs 5, 6 and 7, establishing:

1. That the possibility of direct or indirect advertising aimed at the public is prohibited in the case of a product financed by the National Health System (this prohibition affects manufacturers, distributors and sellers, and all those entities that may come into direct contact with the patient).
2. That the use of incentives, gifts, discounts, prizes, competitions, bonuses or similar methods linked to the promotion or sale to the public of these products is prohibited.
3. That health products intended to be used or applied exclusively by health professionals may not be advertised to the public.
4. That advertising of medical or surgical techniques or procedures linked to the use of specific health products must respect the criteria established for the advertising of health products.

Who is responsible for the enforcement of these rules?

In its major overhaul of procedures in 2002, Farmaindustria started up an Ethics Commission and Code of Practice Surveillance Unit as the body responsible for active monitoring of Code compliance. The aim of the Code is to guarantee that any promotion of medicines for human use is carried out respecting the most stringent ethical principles of professionalism and responsibility. For this purpose, an agreement was signed with the Association for the Self-Regulation of Commercial Communications (Autocontrol) and any cases not solved by conciliation are referred to this organization, which has a reputation for harsh enforcement. The Ministry of Health is responsible for the enforcement of The Law of Guarantees and Rational Use of Medical Products and Medical Devices.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies? How are these regulations enforced?

According to the Code of Ethics issued by Farmaindustria, pharmaceutical companies are not allowed to offer or give healthcare providers any type of gift, incentive or prize. Companies may provide informational or educational materials to doctors as long as the materials are inexpensive (no more than 70€), are relevant to the practice of medicine or pharmacy and directly benefit patient care.

Events that are sponsored or organized by a company must be exclusively science related. Events of recreational nature are prohibited, although welcome cocktails, working luncheons and gala dinners that occur within official programs and meetings are not included. A maximum of 70€ per guest applies to these events.

Hospitality at professional or scientific events must be reasonable and not exceed what healthcare professionals would be willing to pay in the same circumstance. Hospitality includes the costs of travel, registration and accommodation. Payments to rent rooms or attend a meeting/conference are prohibited.

A limited number of free samples may be given to doctors as long as they are authorized to prescribe medicines.

Medical samples must bear the statement 'free medical sample – not for sale.' These regulations are enforced and monitored by the Code of Practice Surveillance and the Code of Practice Committee.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?

Any person or legal entity may submit a legitimate complaint to the Code of Practice Surveillance Unit. The Unit evaluates the complaint and may open an investigation.

The Code of Practice Committee is responsible for mediating between parties involved in a complaint. Both the Surveillance Unit, Practice Committee and the Jury collaborate with 'the aim of promoting effective application of the rules contained in the code, either on its own or at the request of any person with a legitimate interest.' All three bodies are responsible for the complaints process.

'The resolutions of the Jury are reported immediately to the parties for their compliance. Simultaneously, the Jury will communicate these resolutions to the Code of Practice Committee, who will transfer them to the Farmaindustria governing bodies in order to be executed and, where applicable, proceed to collection of pecuniary sanctions imposed by the Jury'.

Do any promotional or media materials need to be approved by regulatory authorities?

Scientific and promotional meetings and events organized or sponsored by pharmaceutical companies must provide previous notification in accordance with the provisions in the Rules of Procedure of the Control Bodies of the Code; failure to do so constitutes an infringement of the Code. This is clarified in the queries that only meetings that meet the following criteria need notification: if they are organized or sponsored (directly or indirectly) by the pharmaceutical company; they include an overnight stay; and they involve the participation of at least 20 healthcare professionals. It is not necessary to notify authorities of congresses organized by a third party (scientific societies, professional organizations, etc.) and sponsored by several pharmaceutical companies, or satellite symposia and other parallel activities, provided that they are listed in the official congress program. In any case, pharmaceutical companies are recommended to voluntarily report any event

organized by third parties in which they plan to participate. Pharmaceutical companies usually submit advertisements to the Ministry of Health, but this is not obligatory. Patient information leaflets have to be reviewed by the Spanish Agency for the Evaluation of Medical Products.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?

FARMAINDUSTRIA adopted the European Code of Practice on the Promotion of Medicines of the European Federation of Pharmaceutical Industries and Associations (EFPIA) as the Spanish Code in 1991. Since this first version, the Code has been revised on a regular basis in order to adapt to and anticipate the new requirements of a constantly evolving society. This process of evolution and continuous improvement is motivated, among other factors, by the obligation to adapt its terms and conditions to regulatory changes and new initiatives on self-regulation, and by the need to provide coverage to all of the activities conducted by pharmaceutical companies with those stakeholders with which they interrelate and interact, as well as the desire to strengthen their compliance and provide the Code with greater credibility and transparency. Our system must guarantee to Healthcare Professionals that the information, medical education and promotion of medicines embody as central elements scientific rigor, transparency and ethics. This has led to this new version of the Code of Practice for the Pharmaceutical Industry, whose latest modification has been ratified by FARMAINDUSTRIA General Assembly in June 2023.

This version includes a new section for the promotion of prescription medicines in the digital environment: promotion of medicines directed to Healthcare Professionals authorized to be recipients of them disseminated through digital channels must be within a context that is technical, scientific or professional. Measures should be taken by companies to ensure that this promotion is only disseminated to these professional groups. There should be a verification system or statement on the Healthcare Professional status of people gaining access or, it should at least include, in a clearly legible, highlighted manner, a warning stating that the information on the web page is intended exclusively for the Healthcare Professional authorized to prescribe or dispense medicines; specialized training is therefore required for the correct interpretation of the information.

In addition, since 2023, Farmaindustria organizes the examination for the Certification of the Code of Good Practice of the Pharmaceutical Industry, a pioneering initiative in Europe, which aims to test the individual knowledge of this Code among professionals who have a relationship with the pharmaceutical industry in our country.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

In general, the Code implies that any correspondence or materials produced by a pharmaceutical company about medicines or their use is promotional, whether or not it makes product specific claims. All promotional information should be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine. It must not be misleading and must reflect the most current information. Gifts, merchandising and meetings for physicians are included in promotional activity.

How is a media event defined?

Regulatory information does not specify a definition for a media event.

Do the regulations differentiate between consumer and clinical publications?

Regulatory information does not specify a differentiation between consumer and clinical publications.

Do regulations differentiate between online, print, broadcast and/or streaming media?

Regulatory information only differentiates between print and broadcast media in regard to the provision of essential information to accompany the materials. All printed material must contain essential information consistent with the data from the summary of product characteristics and prescribing information; different presentations of the product including dosage and form; the selling price and conditions for reimbursement; and, where appropriate, the estimated cost of treatment. For broadcast media, which includes interactive systems, this essential information must be included clearly on the videotape and also be available as a printed document.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

A medicine cannot be promoted prior to the grant of the marketing authorization allowing its sale or supply. This also covers medicines authorized in another country, but that have not obtained authorization in Spain. The publication in scientific media of information prior to authorization would be acceptable if such publication is not deemed to be promotional. Regional guides can be more specific; for example, the Catalonian Guide states that it is possible to engage in the promotion of medicines and indications not authorized in Spain but authorized in the countries represented at the congress. In these cases, the fact that the product is not licensed in Spain must be clearly stated, and all materials drafted in either the language of the country where the medicine is authorized or in English. Pre-launch information usually refers to generic name, not to the brand name.

What regulations specifically cover press releases, media materials and company events? What are the general principles?

All material relating to medicines and their use that is sponsored by a pharmaceutical company must clearly state that it has been sponsored by that company. This also applies to material that in itself is not directly promotional, such as invitations. Exaggerated or all-embracing statements should not be made, nor should there be any unsubstantiated claim that a product has some special merit or property. Statistics, conclusions or any other data from different studies conducted using different methodologies cannot be mixed or compared unless they come from systematic reviews.
The word new cannot be used to describe any medicine that has been generally available or any indication that has been generally promoted for more than two years in Spain. Trademarks or brand names of products from other companies may only be quoted if their ownership is clearly indicated. All information, statements and comparisons must be referenced and well-founded and their foundation made available to physicians on request.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?

The Code covers only the distribution of materials to healthcare professionals, not media. EFPIA regulations give the guidance that the Codes of Conduct of both the country of source and distribution should be followed, with the stricter code prevailing in case of conflict.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?

It is not permitted to sponsor anyone, whether press or a healthcare professional, to attend a meeting. If a journalist is sponsored, then his or her resulting copy becomes subject to the rules of a contractual relationship.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?

Any copy produced by a truly freelance journalist, or one employed to write or broadcast for regular editions or programs as part of his or her professional work in gathering news at congress, is not bound by the Code.

If a company sponsors a journalist to attend, their relationship becomes a contractual relationship and

any resulting copy will be subject to the letter of the Code. The assumption is that the copy should then go through internal regulation in the same way as any other promotional material.

Do regulations cover the use of case studies or other third-party advocacy in the media?
The regulations specifically state that formal authorization for any quotation in any media format is required and that all third-party endorsement must accurately reflect the opinion of the author. Whenever a company finances, ensures or directly or indirectly organizes publication of promotional material in newspapers or magazines, it should be expressly stated that such material is not included as an independent editorial topic and the name of the sponsoring company should be included in a visible place.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Section 8 of the Code is dedicated to promotion via the internet and states that any promotional materials for medicines directed to healthcare professionals via this method of communication must have primarily technical, scientific or professional content. In addition, promotional information must contain a prominent and clearly legible warning indicating that the information contained on the web page is intended only for health professionals qualified to prescribe or dispense medicines and specialized training is therefore required for its adequate interpretation.

What are the web security and data privacy requirements?
The Code specifies that measures must be taken to ensure that this promotion is only accessible to these professional groups. It does not state how this should be carried out, but the implication is that the site should be password-protected.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
The continuous development of the "Information Society" favors the creation of new media, means of delivery and channels of communication that are available to pharmaceutical companies for promotion of their products and interaction with the different stakeholders (Healthcare Professionals, Patient Organizations, the general public, etc.).

The medium, means of delivery or channel of communication used in any case does not exempt pharmaceutical companies from their obligation to comply with the terms and conditions of the Code. In this regard, companies must refrain from using those methods that, due to their nature, characteristics, technical limitations, conditions of use, etc., do not allow for compliance with the requirements and obligations of the Code to be guaranteed for each type of activity.

In all cases, pharmaceutical companies are responsible for the content disclosed through the media, means of delivery or channels of communication that directly or indirectly control or finance exclusively or in the majority. Therefore, usage and style guidelines must be implemented that establish rules of conduct and consequences derived from non-compliance, as well as a procedure for monitoring the content to which they provide access, host, temporarily copy or link. This procedure must address the obligation to correct any irregularity quickly.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
Facebook, Instagram, X (Twitter), TikTok, Telegram and LinkedIn are the most popular social networks in Spain. Previously, Tuenti, a homegrown network, was the most popular social media platform. However, a rapid decline in the number of users led to a closure of the service in 2016.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
According to the Code, companies must 'possess guidelines and rules of conduct for their employees that establish standards for responsible conduct in the digital environment, both for when sharing information about or in the name of the company as well as when using a medium, means of delivery or channel provided by the company'.

Furthermore, any company that is a member of FARMAINDUSTRIA must adhere to the code regardless of medium.

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Each digital platform has its own rules. There are no general laws.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2023, 80,9% percent of Spain's population, over 48 million people, used smartphones. Despite this, there are no specific regulations regarding healthcare apps or other marketing via mobile devices. The general marketing codes still apply.

What are the disclosure laws like in your region for non-branded websites?
Courts make decisions for non-branded websites. Websites about pathologies are only allowed if they do not mention any treatment or product. Either way, any formal complaints would be solved by the courts.

What are the requirements for adverse event reporting?
All adverse event reporting is completed in accordance with official regulations.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Section 17.8 clearly states that any form of hospitality provided by the pharmaceutical industry to Patient Organizations and their members will be reasonable and of a nature that is secondary to the purpose of the meeting, disregarding whether it is organized by the Patient Organization or by the pharmaceutical company. The hospitality provided for meetings will be limited to travel, accommodation and subsistence expenses and registration fees. Companies may only defray or finance these expenses through the Patient Organization and never directly to individual patients. Hospitality will only be extended to attendees. However, for health reasons (for example, disability), they may defray expenses for travel, accommodation, subsistence, and registration of accompanying persons who attend in the role of caregivers.

Hospitality will not include the sponsorship or organization of recreational and/or entertainment activities (cultural, sports, etc.). Organizing or collaborating in meetings that contain elements of entertainment or entertainment activities or are of a recreational nature is prohibited. The welcome cocktail, working luncheons and gala dinners that normally occur within official programs at conferences and meetings are not included in this prohibition provided they are reasonable and moderate and do not include additional elements (cultural, leisure or entertainment, etc.). In all cases, a maximum cost of 70 Euros (including taxes) per guest applies for any form of hospitality associated with meals.

For meetings that take place outside of Spain, the maximum threshold established by the National Association of the country where the meeting occurs will apply. Therefore, for hospitality offered outside of Spain involving meals, the general rule provided for in article 19.4 ("If there is a conflict between rules of the different applicable codes for a given activity, the most strict or restrictive rule will apply") will not be applicable.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Honoraria are possible for healthcare providers only to cover the payment of reasonable fees and reimbursement of out-of-pocket expenses, including travel, for speakers and moderators at meetings, congresses, symposia and similar scientific or professional events. Hospitality, which includes travel, registration and subsistence expenses, must not exceed what the recipients would normally be prepared to pay for themselves in the same circumstances. Hospitality cannot be extended beyond a reasonable period before or after the event. This is clarified in the published queries as being one day before or after the event. In addition, hospitality must always be secondary to the main purpose of the meeting and 'in no case shall social or cultural aspects predominate over scientific issues.'

Answers to the published queries further clarify that 'reasonable' would prohibit anything greater than a four-star hotel.

Regarding disclosure obligation, companies subject to the Code must document and disclose payments and transfers of value that they make, either directly or indirectly, to or for the benefit of the recipients.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
No, money cannot be offered to healthcare professionals to attend events.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
Although this is not specifically addressed, it would seem fair to assume that any materials that are written directly or indirectly by a pharmaceutical company must have sponsorship and involvement clearly indicated and explained.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
This is not covered in the regulations. However, it would be reasonable to assume from EFPIA regulations that matters pertaining to human health and disease without mention of specific products would be permissible, while copy with brand messages would be promotional and need to be clearly marked as promotion.

KEY TAKEAWAYS/ SUMMARY

- The examination for the Certification of the Code of Good Practice of the Pharmaceutical Industry, launched in 2023, is a pioneer initiative in Europe and aims to test individual knowledge of the Code of Good Practice of the Pharmaceutical Industry.
- This code, along with other laws and regulations at a national and regional level, guarantees that the promotion of medicinal products for human use, the interrelation with healthcare professionals and organizations, and the interrelation with patient organizations is carried out in accordance with the strictest ethical principles of professionalism and responsibility.
- This Certification is designed for professionals working in the pharmaceutical industry, but also for those who work in other organizations and who provide their services or have a direct or indirect relationship with pharmaceutical companies subject to Farmaindustria's Self-Regulatory System.
- Farmaindustria's Code of Good Practice is already well established in pharmaceutical companies and valuable publications.

SWITZERLAND

The promotion of medicines in Switzerland is primarily regulated under the Therapeutic Products Act (TPA), with enforcement overseen by Swissmedic, the Swiss Agency for Therapeutic Products. Additional guidance is provided by industry associations such as science industries and Interpharma. Key principles governing pharmaceutical promotion in Switzerland include ensuring that all promotional materials are truthful, scientifically substantiated, not misleading, and presented in a balanced manner, without exploiting fear, exaggeration, or superstition.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of medicines in Switzerland is governed by both legal regulations and self-regulatory industry codes.

Legal and Regulatory Frameworks in Switzerland

Switzerland distinguishes between laws (primary legislation passed by Parliament) and ordinances (secondary legislation issued by the Federal Council to implement those laws). These frameworks include:

i) Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA / HMG). *Type: Federal Law (Primary Legislation).*
- Governs the development, authorization, manufacture, marketing, and advertising of therapeutic products.
- Prohibits misleading, non-objective, or unverifiable promotion.
- Provides the legal basis for implementing ordinances like AWV and OIT.

ii) Ordinance on Advertising of Medicinal Products (AWV). *Type: Ordinance (Secondary Legislation under the TPA)*
- Specifies detailed requirements for promotional content and delivery methods.
- Differentiates rules for healthcare professionals vs. the general public.

iii) Ordinance on Integrity and Transparency in the Therapeutic Products Sector (TPITO). *Type: Ordinance (Secondary Legislation under the TPA)*
- Enforces transparency in financial transfers and services between companies and HCPs/HCOs.
- Prohibits improper advantages and ensures integrity in industry–stakeholder relationships.

iv) Swissmedic Guidelines. *Type: Regulatory Guidance*
- Issued by the national agency Swissmedic.
- Not legally binding, but used to interpret and apply the law consistently.
- Clarifies what is considered acceptable in promotional practices.

v) Federal Act on Unfair Competition (UCA / UWG). *Type: Federal Law (Primary Legislation)*
- Applies across all industries, including pharmaceuticals.
- Prohibits misleading advertising, coercive marketing, and unfair commercial conduct.

Self-Regulatory Frameworks in Switzerland (Codes of Practice)

i) Pharma Code
- Issued by Scienceindustries.
- Regulates promotional activities and interactions with healthcare professionals.
- Applies to all member companies (mostly research-based).

ii) Pharma Cooperation Code (PCC)
- Also issued by Scienceindustries.
- Focuses on the transparency of interactions with HCPs and HCOs.
- Implements the EFPIA Disclosure Code principles.

iii) IFPMA Code of Conduct (2022)
- Global ethical framework for responsible business practices in pharma.
- Emphasizes integrity, transparency, and appropriate HCP/HCO engagements.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

In Switzerland, regulators distinguish clearly between advertising and non-promotional activities, that can include public relations (PR). This differentiation is significant because advertising is subject to specific legal requirements and restrictions under the TPA and its implementing ordinances, particularly the AWV mentioned above.

Advertising
The AWV defines advertising (Article 2(a)) as information, marketing and incentive measures intended to promote the prescription, supply, sale, consumption or use of medicinal products. Key characteristics of advertising include:

- A direct or indirect intent to promote a medicinal product.
- Aimed either at healthcare professionals or the general public.
- Must be objective, verifiable, and not misleading.
- Advertising of prescription-only medicinal products to the general public is prohibited.

Examples of advertising include product brochures, promotional materials, detailing visits, branded social media posts, and product-specific sponsorships.

PR / Non-promotional Communication
While not explicitly defined in the AWV, public relations activities are addressed through Swissmedic guidance and industry self-regulation codes such as the Pharma Code and Pharma PCC mentioned above. In this context, PR refers to communications that are:

- Corporate, scientific, or educational in nature.
- Not intended to promote a specific medicinal product.
- Free from product claims, comparisons, or branding aimed at influencing prescribing or sales.

Examples may include press releases related to corporate activities, publications on research and development, or disease-awareness campaigns that do not reference specific products.

Regulatory Approach
Swissmedic applies a "substance over form" principle. This means that even if a communication is labelled as 'PR', it will be assessed based on its content, context, and likely effect. If it is found to have a promotional intent or impact, it will be classified as advertising and regulated accordingly.

Who is responsible for the enforcement of these rules?

In Switzerland, the enforcement of rules governing the promotion of medicinal products is shared between public authorities and self-regulatory industry bodies. The division of responsibilities depends on whether the rule in question stems from binding legal provisions or from voluntary codes of conduct.

Swissmedic – Swiss Agency for Therapeutic Products
Swissmedic is the national regulatory authority and the principal enforcement body for the legal framework governing therapeutic products, including the TPA and AWV. Swissmedic acts either ex officio or upon complaints, which may come from healthcare professionals, competitors, or the public. They are responsible for:

- Monitoring compliance with advertising and promotional rules.
- Investigating alleged violations (e.g. unlawful promotion, misleading advertising).
- Imposing administrative measures or sanctions, including warnings, fines, or publication bans.
- Assessing whether communications classified as public relations are, in effect, promotional.

Federal Office of Public Health (FOPH)
The FOPH plays a supervisory role, particularly in the context of public health policy and the implementation of transparency and integrity provisions, especially in collaboration with cantonal authorities. It may also participate in overseeing the application of the TPITO.

Cantonal Authorities
Swiss cantons retain subsidiary enforcement powers, especially with respect to on-the-ground inspections, healthcare provider oversight, and monitoring local compliance with therapeutic product laws.

Self-Regulatory Industry Bodies: Pharma Code and PCC enforcement
Enforcement of these voluntary codes of practice, which apply to members of Scienceindustries and Interpharma, is handled by:

- The Code Secretariat (Sekretariat Pharma-Kodex).
- The Code Surveillance Authority (CSA).

Responsibilities include:

- Receiving and investigating complaints.
- Issuing decisions, corrective actions, and (where applicable) publishing violations.
- Promoting consistent interpretation and implementation of the codes.

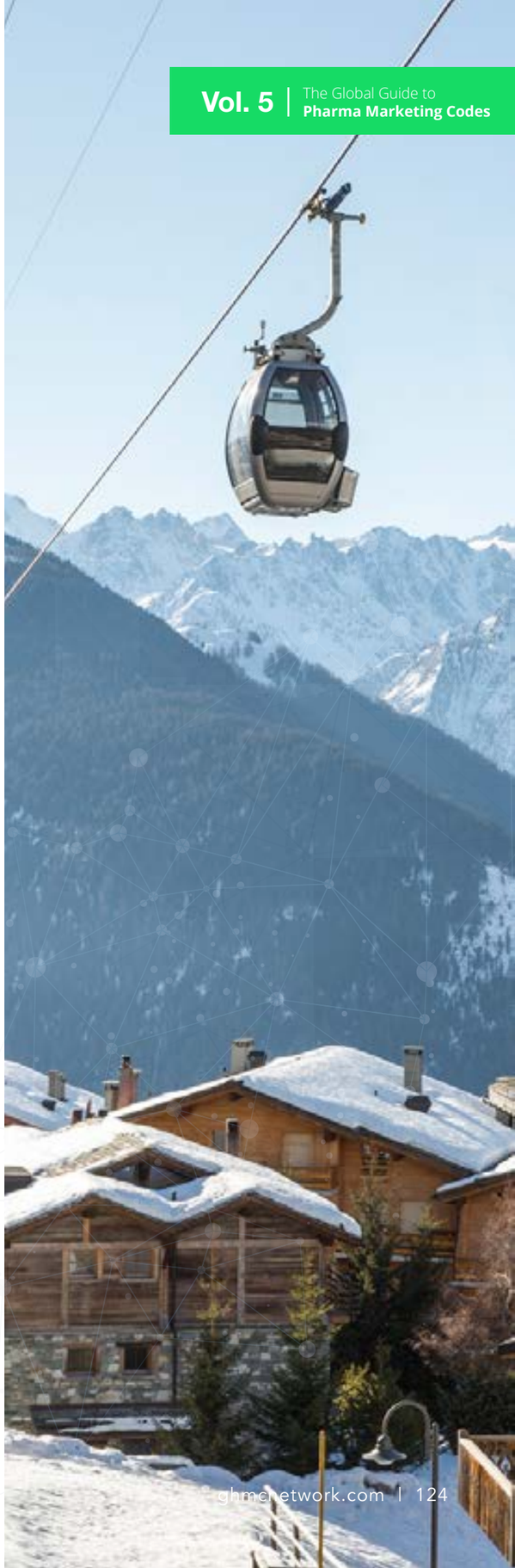
These bodies cannot impose legal penalties, but their findings can carry reputational consequences and result in corrective measures.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?

In Switzerland, concerns or complaints about pharmaceutical marketing and communication activities may be submitted to either regulatory authorities or industry self-regulatory bodies, depending on the nature of the alleged breach. The process and handling of complaints vary according to the recipient and the applicable regulatory framework.

i) **Swissmedic:** The primary authority for overseeing compliance with legally binding rules—such as those set out in the TPA and the Ordinance on AWV. Swissmedic receives complaints from a wide range of sources, including healthcare professionals, patients, competitors, or the general public. Concerns may be submitted in writing via Swissmedic's official website, email, or postal mail. Upon receipt, Swissmedic conducts an internal assessment to determine whether the issue warrants further investigation. If a violation of the legal provisions is established, Swissmedic may take administrative measures such as ordering a cessation of the promotional activity, requiring corrections to advertising material, or imposing sanctions such as fines or public notices. It is important to note that Swissmedic does not act as a mediator in commercial disputes; its role is strictly regulatory and enforcement-focused.

ii) **The Code Secretariat and CSA:** In parallel, companies that are members of Scienceindustries or Interpharma are also subject to self-regulatory oversight through the Pharma Code and the PCC. Complaints concerning breaches of these codes can be submitted to the Code Secretariat, which acts as the first point of contact. The Secretariat reviews the submission for completeness and forwards it to the CSA, the independent body responsible for adjudicating cases. The CSA assesses whether the content or activity in question violates the industry codes, and if so, it may order the company to amend or cease the activity. While the CSA cannot impose fines, its decisions may be published, which can carry significant reputational consequences. Complaints can be submitted by individuals or organizations, and while anonymous complaints are accepted, substantiated submissions with documentation are preferred.



Do any promotional or media materials need to be approved by regulatory authorities?
In Switzerland, promotional and media materials generally do not require pre-approval by regulatory authorities. Companies are, however, fully responsible for ensuring that all materials comply with the TPA, the AWV, and relevant industry codes. Swissmedic does not routinely review promotional content before publication but may do so in specific cases, such as during the marketing authorization process for non-prescription (OTC) medicines, or in the context of inspections or investigations. Materials are, however, subject to post-marketing oversight, and both Swissmedic and the CSA can take action in response to non-compliant advertising. While companies may choose to conduct internal or third-party reviews, this is voluntary and not mandated by regulators.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
Recent Regulatory Developments (2020–2025)
Switzerland distinguishes between laws (primary legislation passed by Parliament) and ordinances (secondary legislation issued by the Federal Council to implement those laws). These frameworks include:

i) Ordinance on Integrity and Transparency in relation to Therapeutic Products (TPITO) – Effective 1 January 2020. This ordinance introduced detailed provisions under Articles 55 and 56 of the TPA, focusing on prohibiting undue advantages and mandating transparency in financial relationships between pharmaceutical companies and healthcare professionals or organizations.
- The FOPH has launched a whistleblowing platform for integrity, transparency and discounts (ITD) of therapeutic products.

ii) Revisions to Human Research Legislation – Effective 1 November 2024.
The Federal Council approved amendments to four ordinances related to the Human Research Act (HRA), including the Clinical Trials Ordinance (ClinO) and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). These changes aim to enhance participant protection and streamline regulatory processes.

iii) Implementation of Transparency Provisions – Effective 1 March 2025. Provisions focusing on transparency in clinical trials and research collaborations were enacted to improve the regulatory framework and align with international standards.

Updates to Industry Codes of Conduct
The PC and PCC have undergone revisions to strengthen ethical standards and transparency.
- **Meal Limits:** The PC now stipulates a maximum value of CHF 100 for meals provided during expert discussions and events.
- **Donations and Grants:** Clarifications were made to ensure that donations and grants are directed to healthcare organizations and patient organizations, not to individual healthcare professionals.
- **Event Sponsorship:** The principle of multi-sponsorship was reinforced to prevent undue influence by a single pharmaceutical company.
- **Advertising Standards:** Enhancements were made to advertising guidelines, including the use of graphics and the term "new," to prevent misleading information.

PCC Transparency Enhancements
The PCC aligned its disclosure requirements with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code, mandating individual-level disclosure of pecuniary benefits to patient organizations, similar to requirements for healthcare professionals and organizations.

THE MEDIA

Pharmaceutical Advertising Laws and Regulations Switzerland 2024-2025
https://iclg.com/practice-areas/pharmaceutical-advertising-laws-and-regulations/switzerland#:~:text=1.2%20How%20is%20%E2%80%9Cadvertising%E2%80%9D%20defined,or%20use%20of%20medicinal%20products.

What is defined as promotional activity as opposed to the provision of information?
In Switzerland, the distinction between promotional activity and the provision of information is primarily governed by the TPA and further detailed in the AWV. Supplementary guidance is provided by Swissmedic and self-regulatory industry codes. This distinction is critical, as promotional activities, especially towards the public - are subject to strict limitations, particularly for prescription-only medicines.

As mentioned earlier, according to Article 2(a) of the AWV, the advertisement of medicinal products is defined as information, marketing and incentive measures intended to promote the prescription, supply, sale, consumption or use of medicinal products. This broad definition includes product brochures, advertisements, and digital campaigns, sponsorships, branded content, and promotional booths. It also includes pharmaceutical sales representative visits and direct communications encouraging prescription or purchase.

Swissmedic and case law apply several key criteria to determine whether a communication qualifies as promotional. These include the presence of a commercial objective, such as influencing prescription, sale, or consumption of a medicinal product (AWV Article 1 para. 1 and Article 2(a), the use of brand names, therapeutic claims, or product comparisons, the employment of persuasive or attention-grabbing design and language, and the targeting of HCPs or the public in a way likely to affect medical decisions. These principles are reinforced by Swissmedic's guidance on advertising, which states that materials are assessed based on content and intent, not their declared purpose: "Advertising is judged by its actual content and its recognizable purpose, regardless of how it is designated."

On the other hand, non-promotional communication refers to factual, objective, and non-commercial content that does not fall within the legal definition of advertising. Examples include packaging material and product information, sales catalogues and price lists (given they do not contain medicinal information about medical products), disease awareness campaigns (provided they do not mention specific products), and public health information issued by or in collaboration with authorities. These types of information are excluded from the scope of the AWV under Article 1, paragraph 2, which clarifies that general information on health or diseases that do not directly or indirectly refer to specific medicinal products is not regarded as advertising. To remain non-promotional, this content must be neutral in tone and free from brand references, avoid implied product claims or marketing messages, and be shared with the primary aim of providing information, instead of persuading.

How is a media event defined?
A media event is a high-visibility occasion attended by journalists in the audience with speakers that may include company representatives, HCPs, patient organization representatives and other key stakeholders. These events may be centered around the introduction of a new drug or medical device to the market, often highlighting the broader context, unmet medical need, regulatory approval, efficacy and safety data, and anticipated benefits for patients. The format of such an event may include a formal presentation where company executives and scientists introduce the product, explain its mechanism of action, outline approved indications, as well as the results of pivotal clinical trials. In addition, subject matter experts such as key opinion leaders (KOLs) may speak to the specific unmet needs the drug/medical device addresses and its expected clinical impact. A patient testimonial may also be featured, offering a glimpse into daily life with the condition and emphasizing the patient's lived experience. The patient should not discuss his/her treatment and/or the outcomes of treatment, nor be present when information about a treatment is being shared.

A dedicated Q&A session typically follows, giving journalists and other attendees the opportunity to ask detailed questions to medical experts and company representatives. Finally, press kits are distributed, providing media with comprehensive materials including press releases, backgrounders, fact sheets, visuals, and access to designated spokespeople.

Do the regulations differentiate between consumer and clinical publications?
Communication with the media around an important milestone such as the publication of a pivotal phase 3 study or the approval of a new treatment is generally accepted as long as it is balanced, factual, accurate, objective, and non-promotional, and the goal is to inform and educate the media (specifically media that are interested in science, pharmaceuticals, health and medicine), and not to encourage them to write about it.

Do regulations differentiate between online, print, broadcast and/or streaming media?
Swiss medicinal product advertising regulations do not explicitly differentiate between media formats such as online, print, broadcast, or streaming. Instead, the AWV and the TPA focus on the content, intent, and target audience of the communication, regardless of the medium used.

However, Swissmedic and the Pharma Code do recognize that digital media can pose specific compliance risks, particularly when prescription-only medicines are inadvertently promoted to the general public. Under Article 5a of the AWV, advertising for prescription-only medicinal products on the internet must be made accessible only to those authorized to prescribe or dispense such products. Companies must therefore take care that online and social media content is properly restricted, such as by using access controls to limit visibility to healthcare professionals where needed. This includes implementing measures such as password protection or verification systems to ensure that only qualified HCPs can access the content. Third-party verification services like DocCheck and swiss-rx-login are commonly used to ensure that only authorized professionals can access this information.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
To ensure legally safe and ethically sound materials and content are aimed at the media (either through a press release or an event), a company should base all its activity on:

- The legal baseline in the AWV and Swissmedic guidance.
- The ethical standards of the Swiss Pharma Code (especially if the company is a member).

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
The same advertising laws that govern all the different types of media, and Swissmedic takes a 'substance over form' approach.

Do regulations cover the use of case studies or other third-party advocacy in the media?
According to AWV Article 22(g), advertisements must not mention or refer to scientific publications, clinical studies, expert opinions, testimonials or recommendations from scientists, HCPs, well-known personalities or medical-pharmaceutical laypeople.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
There are no clear guidelines differentiating online media from print and broadcast as far as we are aware.

What are the web security and data privacy requirements?

https://www.fedlex.admin.ch/eli/cc/2022/491/en

https://www.swissstaffing.ch/docs/en/Legal-Counsel/Factsheets/20230308-merkblatt-datenschutzgesetz-revdsg-en.pdf

https://www.kmu.admin.ch/kmu/en/home/concrete-know-how/sme-management/e-commerce/creating-own-website/business-site-data-protection.html#:~:text=Provide%20a%20data%20protection%20declaration,(consumer%20profile%2C%20advertising).

In Switzerland, the Federal Act on Data Protection (FADP) governs how personal data must be collected, processed and protected. It was fully revised and entered into force on 1 September 2023 (revFADP). In addition to the explicit consent required for the processing of sensitive data, key specifications include:

i) Personal data must only be processed for the purpose originally disclosed to the used (Article 6 revFADP),
ii) Only data that is necessary for the specified purpose may be collected (Article 6 (2) and (4) revFADP).
iii) The user must be informed about the data being collected, its purpose, and the length of time for which it will be stored (Article 19).
iv) Data transfers outside of Switzerland are only permitted if the receiving country ensures an equivalent level of protection or with appropriate safeguards (Article 16-17).
v) Individuals have the right to access, correct, delete or object to the processing of their personal data (Article 25-29).

While the revised FADP does not prescribe specific technical tools, it requires companies to implement appropriate technical and organizational measures to protect personal data from loss, unauthorized access, or misuse (Article 8 and 22 revFADP). Recommended practices, as outlined by the Federal Data Protection and Information Commissioner (FDPIC), include providing a clearly visible privacy policy on the website, and using secure authentication (e.g. SuisseID) and encrypted connections (HTTPS). Where possible, data should be pseudonymized or anonymized, and companies must ensure audit trails and access controls are in place. If a breach poses a high risk to data subjects' rights, it must be reported to the FDPIC without delay (Article 24).

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Yes, in Switzerland, regulations apply even when a pharmaceutical company provides funding or information to a website it does not own. If the company influences the content (such as through sponsorship or supplying medical information), it is responsible for ensuring that the content complies with advertising laws, particularly the ban on promoting prescription medicines to the public. Transparency is essential, and any involvement must be clearly disclosed.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?

https://www.kmu.admin.ch/kmu/en/home/concrete-know-how/sme-management/e-commerce/website-use/online-advertising/social-networks.html

In Switzerland, the most widely used social media platforms include WhatsApp, YouTube, Instagram, Facebook, LinkedIn, TikTok and Pinterest. Among these, Instagram, Facebook, LinkedIn, and increasingly TikTok are commonly used by healthcare companies to reach professionals and the public. However, the use of these platforms for biopharma promotion is tightly regulated.

As mentioned earlier, the promotion of prescription-only medicines is not allowed if it aims to promote a product's use or benefit, even if this is carried out indirectly such as through a sponsored post, patient testimonial or influencer content. Additionally, online advertising to HCPs must be access restricted. However, disease awareness campaigns are permitted although they must remain non-promotional, avoid naming products, and focus strictly on educational content. If a campaign appears to steer patients toward a specific therapy, it risks being classified as unauthorized advertising.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
There is no specific guidance on the use of social media in terms of disease awareness or product promotion activities as far as we are aware. The same medical advertising laws govern all the different types of media.

Are there any self-imposed regulations from social media companies?
The major social media platforms such as Meta (Facebook and Instagram), Google (YouTube), TikTok, and LinkedIn have global advertising policies that also apply to Switzerland. These policies typically restrict or prohibit the promotion of prescription-only medicines, as well as misleading health claims.

Meta: https://transparency.meta.com/policies/ad-standards/content-specific-restrictions/prescription-drugs ; https://transparency.meta.com/policies/ad-standards/restricted-goods-services/drugs-pharmaceuticals

Meta does not allow for the advertisement of prescription drugs in Switzerland.

Google: https://www.advance-metrics.com/en/blog/how-to-use-google-ads-in-healthcare-marketing/

Advertising pharmaceutical products on Google in Switzerland must comply with both Google Ads policies and Swiss law, which can sometimes conflict. Google restricts ads for prescription-only medicines but allows promotion of non-prescription alternatives. It also prohibits the use of many drug names in ad text,

landing pages, or keywords, and forbids misleading claims or unsubstantiated health promises. Additionally, remarketing (retargeting users based on past searches or visits) is banned for all health-related content, including supplements, as Google classifies such data as sensitive personal information.

TikTok: https://ads.tiktok.com/help/article/tiktok-ads-policy-healthcare-pharmaceuticals

TikTok's ad policy prohibits ads for prescription drugs altogether and imposes restrictions on health-related content.

LinkedIn: https://www.linkedin.com/legal/ads-policy?utm_source=chatgpt.com

In Switzerland, LinkedIn prohibits the advertisement of prescription drugs and OTCs.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Switzerland does not have forum-specific legislation, as far as we are aware.

What is mobile adoption like in your region? Are there separate regulations for it?

https://www.swissinfo.ch/eng/society/consumer-trends_smartphones-change-swiss-shopping-habits/44629970#:~:text=More%20and%20more%20people%20in,the%20Swiss%20are%20still%20cautious.&text=The%20Global%20Mobile%20Consumer%20Survey,among%20these%20older%20target%20groups.

https://datareportal.com/reports/digital-2023-switzerland

Mobile adoption in Switzerland is very high. As of 2018, 92% of Swiss adults already owned a smartphone while 5% owned a mobile phone, and as of 2023, 10.6 million cellular mobile connections were active in Switzerland, which equates to 120.9% of the total population.

There are no separate or mobile-specific pharmaceutical advertising regulations in Switzerland, and mobile content is subject to the same rules that apply to all digital communications. Similar to question 2 earlier in this section, the FADP requires transparency, data minimization, and informed consent, obliging app providers to clearly explain how data is collected and used. It also grants users rights over their data and mandates breach reporting.

What are the disclosure laws like in your region for non-branded websites?
In Switzerland, websites must comply with the Federal Data Protection Act (DPA) and the Unfair Competition Act (UCA). The DPA requires explicit user consent for collecting and processing personal data. The UCA mandates clear and accurate disclosure of a website's identity, activities, and products. Non-compliance can lead to financial penalties or criminal prosecution.

What are the requirements for adverse event reporting?
TPA Article 59 (Mandatory notification, notification system and the right to notify): https://www.fedlex.admin.ch/eli/cc/2001/422/en#art_59

Under Article 59 of the TPA, manufacturers and distributors of ready-to-use therapeutic products in Switzerland must have a notification system and report to Swissmedic any adverse events, reactions, or quality defects that may pose a risk to patients, consumers, third parties, or animals. They must also report findings that could affect the product's safety or evaluation, and any suspicion of illegal trade in therapeutic products. Healthcare professionals are required to report serious or previously unknown adverse effects or quality issues relevant to drug safety. Consumers, patients, and third parties may also report adverse events voluntarily. All notifications must follow recognized good vigilance practices, defined by the Federal Council in line with international standards. Employees of relevant organizations are also entitled to report suspected violations of the law.

STAKEHOLDERS/ ADVOCACY GROUPS

https://www.ifpma.org/wp-content/uploads/2022/12/Code-of-Conduct-Pharma-Code.pdf : **part 4**

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
In Switzerland, pharmaceutical companies may provide hospitality to patient organizations, but only under strict conditions outlined in the Pharm Code. Any such hospitality must be modest, appropriate, and directly related to the legitimate purpose of the event. According to Section 46.3, hospitality is limited to travel, meals (including beverages), accommodation, and participation fees. It may only be granted to actual participants, with an exception for a caregiver in cases of justified medical need (e.g. disability) (Section 46.4). Entertainment or leisure activities must not be supported (Section 46.5).

Travel to a congress or meeting in another country is only permitted under specific conditions. As per Section 46.6, an event may be held abroad if either the majority of attendees are from outside Switzerland, making it logistically reasonable to host the event elsewhere, or if the necessary scientific resources or expertise are located in another country. In all cases, the location must be appropriate to the event's purpose and not chosen for its entertainment appeal (Section 46.1–46.2).

Additionally, all support must be agreed in writing, transparently disclosed, and not used to influence or reward the promotion of any prescription-only medicine (Sections 43–45).

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Yes, it is possible to offer honoraria to healthcare professionals and patient/advocacy organizations for participation in media activities and events, provided there is:

- A written contract specifying the nature, purpose, and fair compensation for services (e.g. Sections 44.2.1–44.2.6).
- A justified need for the service, without being an incentive to promote specific products (44.1, 44.2).

Travel and other expenses can also be reimbursed, as long as:

- Venues are appropriate and not extravagant (46.1).
- Hospitality (travel, meals, accommodation, participation fees) is of a modest level and directly linked to the event (46.2–46.3).

- Entertainment or leisure activities are disallowed (46.5).
- Events outside Switzerland are only allowed in justified cases (46.6).

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

https://www.ifpma.org/wp-content/uploads/2022/12/Code-of-Conduct-Pharma-Code.pdf **Section 44-46**

Yes, it is possible, as long as:

- The payment is for legitimate services (e.g. consultancy) and is backed by a written agreement (44.1–44.2).
- Support for attending the meeting (e.g. financial or logistical) is documented in a written agreement and must be transparent and reasonable (45.1–45.2 for patient organizations).

What is possible in terms of media or message training for health professionals or advocacy organizations?

In Switzerland, media training for HCPs or advocacy organizations is possible but must comply with strict ethical and regulatory standards. As per Article 43.1 in the Pharma Code, pharmaceutical companies must safeguard the independence of patient organizations and cannot influence their public messaging. Training may be allowed if it is part of a broader partnership that supports healthcare or research, not product promotion. For example, under Article 45.2.6, non-financial support like training courses can be provided if agreed upon in writing. Furthermore, the purpose must be transparent and justified.

Importantly, such training must also adhere to the general rules and ethical guidelines set forth by Swissmedic and the Pharma Code, and must not, under any circumstance, serve to promote a prescription-only medicine to the public or to patients either directly or indirectly.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

Materials written on behalf of third parties such as clinical institutions or advocacy organizations must comply with strict regulatory and ethical standards in Switzerland. Even when produced under the name of a third party, such content must not be used to indirectly promote prescription-only medicines to the public. The Pharma Code, particularly Article 43.1, emphasizes that pharmaceutical companies must respect the independence of patient organizations and other third parties. While collaboration is permitted, companies cannot influence the content or messaging of the materials, and any involvement must be transparent and clearly disclosed and documented.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Under the AWV, any communication intended to promote prescription-only medicines to the general public is prohibited. Patient advocacy groups, while knowledgeable, are considered part of the general public in this context.

Therefore, any information shared with PAGs must be factual, balanced, and non-promotional. Discussions should focus on disease awareness, treatment landscapes, or regulatory processes without endorsing specific products.

Other guidance issued by the Scienceindustries, the Pharma-Kooperations-Kodex/PCC 2020 includes explicit rules on interactions with patient organizations.

To ensure compliance with Swiss regulations:

- **Maintain Transparency:** Clearly communicate the purpose of interactions, ensuring that PAGs understand the non-promotional nature of the information.
- **Focus on Education:** Provide educational materials about diseases, treatment options, and regulatory processes without promoting specific products.
- **Separate Audiences:** When organizing events, consider holding separate sessions for healthcare professionals and PAGs to tailor content appropriately.
- **Document Interactions:** Keep records of all communications and materials shared with PAGs to demonstrate compliance with regulatory requirements.

KEY TAKEAWAYS/ SUMMARY

Switzerland maintains a stringent regulatory framework for healthcare communications. The Swiss Agency for Therapeutic Products (Swissmedic) and self-regulatory bodies like the PCC enforce rigorous standards to ensure ethical promotion and patient safety. Direct-to-consumer advertising for prescription medicines is strictly forbidden. Promotional activities must not be directed at the general public, with only non-prescription drugs (OTC) being eligible for limited public-facing campaigns under specific conditions. Interactions with patient organizations are permitted but must be non-promotional. Any collaboration must be clearly documented, with public disclosure of sponsorships and respect for the independence of the group. Online content (including social media) must follow the same restrictions as traditional media. Access to promotional content for HCPs must be restricted by professional verification measures.

Acronyms

AWV: Ordinance on Advertising of Medicinal Products
CSA: The Code Surveillance Authority
FADP: Federal Act on Data Protection
FDPIC: Federal Data Protection and Information Commissioner
FOPH: Federal Office of Public Health
HCP: Healthcare professional
ITD: integrity, transparency and discounts

UNITED KINGDOM

In the United Kingdom, the promotion of medicine is controlled by legislation and codes of practice. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry is the code that outlines the guidelines and ensures compliance with legal requirements. It covers the promotion of prescription medicines and is relevant to marketing and public relations activities

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The promotion of medicines is subject to UK law and to self-regulation by the pharmaceutical industry. The main UK legal requirements are consolidated in the Human Medicines Regulations 2012, implemented in July 2012. UK law reflects the requirements of European Directive 2001/83/EC ('on the Community code relating to Medicinal products for human use') and amendments. Additionally, the Windsor Framework, effective from January 2025, brings the licensing of all novel medicines under the jurisdiction of the UK Medicines and Healthcare products Regulatory Agency (MHRA) following Brexit. The MHRA has summarised the legal requirements in The Blue Guide, Advertising and Promotion of Medicines in the UK, the third edition, third revision published in November 2020.

Self-regulation is based on industry codes of practice. For prescription medicines, the ABPI Code of Practice (The Code) applies. The Code is based on UK law and incorporates the principles of the International and European Codes:

- International Federation of Pharmaceutical. Manufacturers Associations (IFPMA) Code of Practice
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals; EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

All members of the ABPI and many non-members have agreed to follow The Code. It is regularly revised, most recently in 2024 (effective from January 2025).
The Proprietary Association of Great Britain (PAGB) is responsible for advertising codes and guidelines for over-the-counter medicines.
The Association of British Healthcare Industries (ABHI) is responsible for the ABHI Code of Business Practice for medical device manufacturers.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

The Code does not specifically define the term public relations, although public relations activities are covered.

Prescription-only medicines must not be advertised to the public. However, non-promotional information about prescription medicines may be provided to the public, 'either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities. etc' (Supplementary Information to Clause 26.2).

Public relations activities are unlikely to be considered promotional if they are restricted to the provision of factual information and are presented in a balanced way. If the purpose is to raise awareness of claims about a product, the activity is likely to be a form of promotion.

Who is responsible for the enforcement of these rules?

The Code is administered and enforced by the Prescription Medicines Code of Practice Authority (PMCPA), which is responsible for the provision of advice, guidance and training on The Code as well as for the complaints procedure. It is also responsible for arranging conciliation between companies when requested to do so and for arranging scrutiny of advertising and meetings.

The PMCPA is not an investigatory body. The complaints procedure is an adversarial process that takes evidence from the complainant and the respondent company into account, although it can seek evidence from third parties where necessary. Sanctions are applied against companies ruled in breach of The Code.

The PMCPA process, including complaints, appeals, rulings and sanctions are set out in the new PMCPA Constitution and Procedure, which came into effect in October 2024.

The MHRA scrutinises journals, magazines and the internet for the promotion of medicines and it vets advertising for new active substances. The MHRA also investigates complaints made to it about advertising. Where necessary, it can take legal enforcement action.

What are the regulations regarding healthcare provider engagement by pharmaceutical companies?

The ABPI Principles of benefiting patients, acting with integrity and in a transparent manner, and treating all stakeholders with respect are key to how the industry operates and to building trust. 'The aim of the Code is to ensure that the promotion of medicines to health professionals and other relevant decision makers is carried out within a robust framework to support high quality patient care.'

The scope of The Code is wide-ranging. 'As well as covering promotional material, it controls samples, meetings, promotional aids, outcome or risk sharing agreements, patient access schemes, collaborative working between the industry and healthcare organisations, including joint working between the pharmaceutical industry and the NHS, the conduct of non-interventional studies, the use of health professionals and other relevant decision makers as consultants and transfers of value to health professionals, other relevant decision makers and healthcare organisations. The Code also sets standards relating to the provision of information to patients and the public as well as relationships with patient organisations.'

With regard to engagement of healthcare providers, The Code specifies, 'No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 10.5 and 19.2' (19.1).

Who receives concerns and complaints? How does this process operate?

The Code is administered by the PMCPA, which is responsible for the provision of advice, guidance and training on The Code as well as for the complaints procedure.

If The Code is breached, complaints are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on completed cases are published by the PMCPA in its Code of Practice Review and on its website. The General Medical Council (GMC), the General Pharmaceutical Council and the Nursing & Midwifery Council are the regulatory bodies for doctors, pharmacists, pharmacy technicians, nurses and midwives. Each organisation sets out standards for ethical and professional conduct in their own Codes of Practice (Supplementary Information to Clause 10.1). If the PMCPA decides that a complaint should be dealt with by one of these organisations, contact details for the correct authority are provided to the complainant. In the event that the complainant is not contactable, the complaint may be forwarded directly to the relevant authority.

Do any promotional or media materials need to be approved by regulatory authorities?

The MHRA vets advertising and promotional materials for new active substances before they can be used. Related non-promotional materials such as press releases, associated media materials and patient support materials are also examined. The MHRA may also pre-vet advertising for other products if, for example, there are safety concerns or if previous advertising has breached regulations. According to MHRA guidelines, the vetting period usually lasts for about two to three months, but it may go on for longer depending on the nature of the promotional materials and any problems found. Companies found in breach of The Code may be required to submit materials to the PMCPA for pre-vetting..

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?

2021 update

The 2021 edition of The Code, which came in to force in July 2021, represented a major update to make The Code easier for companies to use in their day-to-day activities and reflect changes in the operational environment and updates to the European Code.

Content was rearranged into **six themed sections** for ease of use:

- Overarching requirements.
- Promotion to health professionals and other relevant decision makers.
- Interactions with health professionals, other relevant decision makers and healthcare organisations.
- Interactions with health professionals, other relevant decision makers, healthcare organisations, patient organisations and the public including patients and journalists.
- Specific requirements for interactions with the public, including patients and journalists and patient organisations.
- Annual disclosure requirements.

New content was incorporated:

- **Working with the NHS** - introduction of the concept of 'collaborative working' with healthcare organisations. This was intended to reflect the scope of projects on which healthcare organisations and industry could work together for the joint development of patient and/or healthcare centred projects.
- **Contracted services** - A new requirement to disclose payments in aggregate for contracted services paid to members of the public, including patients and journalists from 2022, to be disclosed in 2023 on company websites.
- **Changes to MEGS** - Medical and Educational Goods and Services (MEGS) were replaced and could be provided as either donations or collaborative working.
- **Impact of the pandemic** – The Code recognised that in public health emergencies, temporary supply authorizations for medicines may be given. Various references to temporary supply authorisations included a new clause that a medicine with a temporary supply authorisation must not be promoted unless it is part of a campaign that has been approved by health ministers.

There was also an increased emphasis on the four **ABPI Principles**, which sit alongside the Code:

- **Working with the NHS**
- **Acting with integrity**
- **Promoting transparency**
- **Treating everyone with respect**

As these principles are key to how the industry operates and are essential to build trust, all companies are expected to embed them within their organisations.

2024 update

- Updates to the 2024 edition of The Code include: A new 'high standards' clause for individual (as well as company) responsibility (Clause 5.2). Companies must also have policies in place to clearly communicate corporate standards, expectations and behaviour, and should provide appropriate training (Supplementary Information to Clause 5.1).
- Changes to how prescribing information (Clause 12.1) and adverse event information (Clause 12.6) can be provided, including the use of a prominent QR code in many – but not all – circumstances.
- An updated Constitution and Procedure for the PMCPA to:
  - Further embed the operational independence of the PMCPA, including structural changes to its senior management.
  - Adopt a more proportionate approach to the resolution of simpler and uncontested complaints, including the adoption of an abridged complaints procedure.
  - Make a number of other changes to improve the robustness and efficiency of the complaints procedure.
- Some other elements of The Code have moved from guidance to mandatory requirement, e.g:
  - A written agreement must be in place when companies provide travel support for HCPs to attend an event or meeting. This must be in place before the support is provided and must cover what has been agreed and a breakdown of the costs (Clause 10.4 and its Supplementary Information.
  - ALL materials (previously online materials only) must include a prominent statement on where Prescribing Information can be found, if not immediately apparent.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

The Code defines promotion as, 'any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines (Clause 1.17). A prescription-only medicine must not be promoted prior to its marketing authorisation (Clause 3.1) or promoted to the public (Clauses 3.2 and 26.1).

Provision of certain types of information is not considered promotion. Examples are listed in Clauses 1.17 and 26 of The Code. They include:

- Replies to enquiries from health professionals if the information provided is directly relevant, is accurate, does not mislead and is non-promotional.
- Information on health or diseases, provided it does not refer directly or indirectly to specific medicines.
- Non-promotional information provided to the public about prescription-only medicines, including in response to enquiries from journalists or through public relations activities and the like.
- Information provided about prescription-only medicines must be factual, balanced and must not mislead with respect to their safety. It must not raise unfounded hopes of successful treatment and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine (Clause 26.2).

The Blue Guide advises that, 'particular care should be taken in providing information in response to direct approaches from the media where a company has little or no control over the final production, for example, with television programs, and which could result in the promotion of prescription only medicines to the general public'.

How is a media event defined?

The Code and the regulations do not use the term media event. Pharmaceutical companies or their agents may organise meetings with journalists from the medical or general press, television, radio or other media. Such meetings may take the form of press conferences, face-to-face or virtual briefings or media advisory boards.

Additional guidance on working with the media and journalists is provided by the UK's Healthcare Communications Association (HCA).

Do the regulations differentiate between consumer and clinical publications?

Advertisements for prescription-only medicines may appear in medical journals or other clinical publications intended for health professionals, but not in consumer publications intended for the public. In appropriate circumstances, however, it is permissible to provide factual information about a prescription-only medicine to a journalist working for a consumer publication. Such information must comply with the requirements of The Code.

Material relating to medicines, whether promotional or not, and information about human health or disease which is sponsored by a pharmaceutical company, or where a company has any involvement, must clearly indicate the company's role. This is particularly important when companies are involved in the production of material which is circulated by an otherwise wholly independent party, such as supplements to health professional journals.

The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset (Clause 5.6).

Do regulations differentiate between online, print, broadcast and/or streaming media?

The focus of The Code is on the principles governing promotion to and engagement with different audiences, regardless of the specific channel used.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

A product or indication must not be promoted before the marketing authorisation has been granted. In certain circumstances, however, a pharmaceutical company or its agent may provide non-promotional information relating to an unlicensed product or indication.

It is permissible to issue a news release to the medical or general media about an as-yet unlicensed product or indication if the subject is genuinely newsworthy and appropriate for the intended audience. For example, it may be appropriate to issue a news release to the medical press about the results of a major clinical trial. The information provided must be factual, balanced and non-promotional. The use of brand names should be kept to a minimum. Non-promotional information about products in development may also be made available to shareholders and others with a business interest, including financial media.

With regard to congresses, scientific meetings and major publications, The Code permits, 'the legitimate exchange of medical and scientific information during the development of a medicine…provided that any such information or activity does not constitute promotion' (Supplementary Information to Clause 3.1).

Therefore, pharmaceutical companies may sponsor medical and scientific meetings at which research findings on products or indications in development are presented. The purpose of such meetings must be educational and not promotional. Sponsorship must be disclosed in all materials relating to a meeting. Note that distribution of any company-produced materials from such a meeting, for example proceedings, would be considered as a separate promotional activity.

Companies may sometimes promote products or indications that do not have a UK marketing authorisation at international scientific meetings held in the UK. The Code allows this only if all the following conditions are met (see Supplementary Information to Clause 11.1):

- The event/meeting is truly international, of high scientific standing and with a significant proportion of attendees from countries outside the UK in which the product is licensed.
- The medicine or indication is relevant and proportional to the purpose of the event/meeting.
- Promotional material for a medicine or indication that does not have a UK marketing authorisation is clearly and prominently labelled to that effect.
- In the case of an unlicensed indication, UK approved prescribing information is readily available for a medicine authorised in the UK, even though it will not refer to the unlicensed indication.

- Names of countries in which the medicine or indication is authorised are given. This must include at least one major developed country and it must be stated that registration conditions differ from country to country.
- The material is certified in accordance with Clause 8, except that the signatories need certify only that, in their belief, the material is a fair and truthful presentation of the facts about the medicine.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
The regulations and The Code allow for the provision of non-promotional information about prescription-only medicines to the media through press releases and other media materials. Requirements of The Code (Clauses 10, 24 and 26) include the following::

- Information about a product must be factual, balanced, must not mislead and must be capable of substantiation.
- Information about safety should reflect the evidence and a product must not be described as safe.
- Any mention of competitor products must not be misleading or disparaging.
- Superlatives must not be used to describe a product unless they relate to an indisputable fact.
- A product must not be described as new if it has been available in the UK for more than a year.
- Information must not raise unfounded hopes of successful treatment and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine.

'It is good practice to reference the Summary of Product Characteristics with a press release or press pack relating to a medicine. Companies should also consider including references to other credible sources of information about a condition or a medicine (Supplementary Information to Clause 26.1).

Once a press release is issued, a company should have no control over the placement of any subsequent article. If a company or its agent controls or pays for the placement of an article about a product it will be regarded as an advertisement for the product.

The MHRA considers that press releases should be issued only if their content is genuinely newsworthy. The context in which the medicine will be used and the population for which it has been licensed should also be provided. The content of a press release and the language used should be appropriate for the target readership. The use of brand names should be kept to a minimum.

Pharmaceutical companies are responsible for information issued about their products by third parties such as their public relations agencies (Clause 1.24). In accordance with the supplementary information to Clause 8.3 of The Code, appropriate company staff must examine press releases and media materials to ensure that they do not contravene the requirements of The Code or the regulations.

Invitations to journalists to attend media or clinical events must also comply with The Code, and they must be checked by appropriate company staff before being issued.

If the PMCPA receives a complaint about an article or other report in the media about a medicine, it will judge the case on the information provided by the pharmaceutical company or its agent to the media and not solely on the content of the article itself. All relevant media materials may be reviewed, including press releases, invitations to meetings, etc.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The method of distribution of media materials is not specifically covered in The Code. However, materials intended for the UK must comply with The Code, even if the company responsible is based outside the UK.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
The Code applies to UK press briefings held by or on behalf of pharmaceutical companies and to sponsorship of journalists to attend congresses and scientific meetings. It applies to both licensed and non-licensed products, though information provided about the latter must be considered carefully.

In the case of press briefings and meetings held outside the UK, the local regulations will apply. The requirements of The Code should also be followed if a company invites UK journalists to attend.

If companies sponsor journalists to attend such meetings, the requirements of Clause 10 of The Code on meetings and hospitality should be observed. In particular:

- Any hospitality offered must be limited to reasonable travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting.
- If air travel is involved, only economy class may be offered unless a journalist is providing professional services for the company (e.g., as a speaker).
- Journalists should not be paid simply for their time to attend media events.
- Those participating in media advisory boards or providing professional services for the company may receive appropriate honoraria.

Companies must check any materials that they issue to journalists to ensure that they comply with The Code. It is good practice to include the Summary of Product Characteristics for any medicine discussed.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
Journalists—whether freelance or not—whose travel and accommodation are paid for by a company do not have to submit their copy for approval unless the company pays for what they write or influences its content. If the company provides briefing material, it must review this for compliance with The Code; should there be a complaint under The Code about any resulting article, the case will be judged on the basis of that material.

If a journalist submits copy for an independently written article to a company to review it or to check its accuracy, the company may be regarded as being responsible for the content.

If a company pays a journalist to write an article, it will be held responsible for the content, and it must review it for compliance with The Code. Sponsorship should be declared in the article. However, it is good practice, as advocated by the HCA, not to pay journalists for writing news or feature stories, as they should receive payment for copy from the publications in which their material appears.

Do regulations cover the use of case studies or other third-party advocacy in the media?
It is permissible to use patient case studies, but they should, 'focus on the disease and the impact it has on the patients rather than the specific medicine' (The Blue Guide). They should represent typical, not exceptional, cases.

The use of case studies or third-party advocacy must comply with The Code. In particular, case studies must not be promotional and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine. Companies must review any briefing materials they produce in connection with case studies or third-party advocacy to ensure compliance with The Code.

Companies must not use health professionals, patient organisations or patients themselves as advocates to promote particular products in the media.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
The same rules about compliance apply. The Code applies to information about the availability or use of a prescription medicine in the UK if this information is provided on the internet by, or on behalf of, a UK company, or by an affiliate. This is the case even if the information is put on the internet outside of the UK.

Promotional material about prescription-only medicines may be placed on a website that is owned or sponsored by a pharmaceutical company. Such material must not be directed at the public. A company or company-sponsored website providing information for the public as well as promotion to health professionals must have the sections for each target audience clearly separated and the intended audience identified. This is to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide states that the public should not be encouraged to access material which is not intended for them (Supplementary Information to Clause 26.2).

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Any funding or support given to a non-company owned website must be clearly stated on the website. If a company provides information for such a website, it must ensure that it complies with The Code.
If a company-owned or sponsored website includes links to other websites, it should inform users when they are being directed to a non-company site.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
Social media such as Facebook, X (formerly Twitter) and LinkedIn are widely used in the UK. Each has its own terms and conditions of use and privacy policy. The Code applies to all pharmaceutical company activities in the UK, including social media.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Social media such as Facebook, X (Twitter) and others are widely used in the UK. Each has its own terms and conditions of use and privacy policy, but they do not have self-imposed regulations specifically relevant to the pharmaceutical industry.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
To complement The Code, PMCPA Social Media Guidance 2023 (Updated 2024) has been developed following a multi-stakeholder project which identified the areas where pharmaceutical companies required further guidance. It reflects the relevant UK legal requirements as well as the codes of practice and guidance and advice from the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and the MHRA. It also outlines the PMCPA's views based on available case precedent.

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
The general principles set out in the regulations and The Code apply. Companies can use any method of communication, including social media, provided that relevant requirements of The Code are followed. A company may sponsor a page on a platform that it does not own (e.g., a company Facebook page), but it must make its involvement clear to users.

A company hosting a discussion forum on its website or facilitating a forum on a third-party website is likely to be responsible under The Code for its content. A company that is considering doing this must ensure that it can moderate the site, that the content complies with The Code and that it is appropriate for the intended users, whether they are health professionals or the public.

The requirements of The Code also apply if an employee of a company—or of an agency working for the company— contributes to a non-company discussion forum.

What is mobile adoption like in your region? Are there separate regulations for it?
The use of mobile phones and mobile computing through smart phones, tablets, etc. is widespread in the UK. The general principles set forth in the regulations and The Code apply to communications by or on behalf of pharmaceutical companies, irrespective of the communication medium or the device used to receive the information.

Clause 15.5 of The Code requires that the telephone (including mobile phones), text messages, email, faxes, automated calling systems and other digital communications must not be used for promotional purposes unless the recipient has given prior permission.

What are the disclosure laws like in your region for non-branded websites?
A company can sponsor a non-branded website that provides non-promotional information about health or diseases, but the company's involvement must be clearly declared (Clause 5.6).

'The wording of the declaration of involvement must be unambiguous so that readers are immediately able to understand the extent of the company's involvement and influence... The declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material are aware of it at the outset (Supplementary Information to Clause 5.6).

What are the requirements for adverse event reporting?
Pharmaceutical company policies should ensure they meet their pharmacovigilance responsibilities on digital and social media, including the obligation to record and report any adverse effects that are discussed about their medicines. This should include information about how adverse events can be reported.

'It is recommended that comments underneath advertising/communications and direct messages to company owned or sponsored social media accounts are monitored for pharmacovigilance; alternatively, they can be restricted on certain social media channels (PMCPA Social Media Guidance 2023, updated 2024).

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Companies may provide support to patient organisations to attend meetings and congresses (Clauses 10, 23.2). There must be a detailed written agreement stating the arrangements (Clause 27.2) and companies must publish a list of organisations supported, with information about the support provided (Clause 29).

The requirements of Clause 10 of The Code apply equally to healthcare professionals and other organisations:

- Lavish or deluxe venues, or those renowned for entertainment facilities should not be used.
- Any hospitality offered must be limited to reasonable travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting. However, if a representative of a patient group has a disability, companies may also pay such costs for an accompanying caregiver (Clause 10.1). Otherwise, hospitality must not be offered to accompanying persons unless they are participants in their own right.
- If appropriate, travel to other countries may be paid for, though companies should not organize meetings abroad unless most of the participants are from outside the UK, or expertise or resources relevant to the meeting are located outside the UK.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Companies may pay reasonable costs for participants' travel, accommodation (if needed) and subsistence but should not pay participants simply for their time in attending meetings. Reasonable honoraria may be paid to those providing services—for example, speakers. The Code (Clauses 24.1) states that use of healthcare professionals and representatives of patient organisations as speakers, consultants or advisers must comply with a number of requirements. In particular, there must be a written agreement in place beforehand specifying:

- The services to be provided relevant to meetings and hospitality for patient/ advocacy groups.
- The basis of the remuneration, which should reflect fair market value for the services.
- The obligation of the healthcare professional or patient organisation to declare their relationship with the company whenever writing or speaking in public about a matter covered by the agreement or any other issue relating to the company.

Contracting a healthcare professional or patient organisation to provide services must not be an inducement to prescribe, provide or recommend any medicine. Companies must publish details of payments made for such services each year (Clauses 28 - 31).

Companies sponsoring delegates' air travel to meetings should pay only for economy class, though this restriction does not apply to speakers or those providing other services.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Companies may pay for reasonable travel costs, accommodation, registration fees and subsistence. They may not pay participants for their time in attending meetings, though they may pay honoraria to speakers, advisory board members, etc. Details of such payments should be specified in written contracts or agreements and must be disclosed on an annual basis.

What is possible in terms of media or message training for health professionals or advocacy organisations?

Neither The Code nor The Blue Guide provides specific guidance on media training. If a company works with health professional or advocacy organisations that communicate with the media about a disease or its treatment, it is appropriate to provide them with media training. Anybody who provides information to the media on behalf of a company must be made familiar with the requirements of The Code.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Clause 5.6 of The Code states that material relating to medicines and their uses that is supported by a company must clearly declare the company's sponsorship. This applies to materials written on behalf of patient advocacy organisations or other third parties. Companies must review the information in these materials to ensure that it complies with The Code.

Materials written for patient advocacy organisations must not constitute the advertising of prescription-only medicines to the public. Briefing materials written for third parties that communicate with the media about a company's products must comply with the requirements of The Code. In particular, they must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

When pharmaceutical companies interact with patient organisations or any user organisations such as disability organisations, carer or relative organisations and consumer organisations, companies must (Clause 27.1):

- Respect the independence of the organisations.
- Assure the independence of the organisations, in terms of their political judgement, policies and activities.
- Ensure relationships are based on mutual respect, with the views and decisions of each partner having equal value.
- Not promote or request the promotion of a particular prescription only medicine.
- Ensure the objectives and scope of activities are transparent and support provided by companies must always be clearly acknowledged.

A detailed and certified written agreement (Clause 27.2) must be in place for each for each donation, grant or sponsorship and companies must publish all support provided to patient organisations each year (Clause 29). Details must be provided of financial support and the value of nonfinancial support (Clause 29.2).

Other important considerations in connection with patient advocacy groups are:

- No company may require that it be the sole funder of a patient organisation or any of its programes (Clause 25.1).
- A company must not make public the use of a patient organisation's logo or proprietary material, such as leaflets, without the organisation's written agreement (Clause 25.2).
- A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests, although this does not preclude a company from correcting factual inaccuracies. (Clause 27.4).

KEY TAKEAWAYS/ SUMMARY

- Communications by pharmaceutical companies and their agencies, including media briefings, must comply with the requirements of The Code: information must be accurate, balanced, must not mislead and must not promote prescription-only medicines to the public.
- Relations with patient advocacy groups must be open, with details—including financial arrangements—being made publicly available.
- Companies may sponsor healthcare professionals, journalists and members of patient advocacy groups to attend media events or scientific meetings. Hospitality must be limited to travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting.

ASIA - PACIFIC

AUSTRALIA

The Therapeutic Goods Administration (TGA) is Australia's government authority responsible for evaluating, assessing and monitoring products defined as therapeutic goods. The TGA regulates the supply, manufacturing and advertising of medicines, biologicals (including human cells or tissues), medical devices, other therapeutic goods (e.g. sterilant) and unapproved therapeutic goods.

The promotion of prescription medicines is self-regulated by the Medicines Australia Code of Conduct.

The Australian Register of Therapeutic Goods (ARTG) is the public database of therapeutics goods that can be legally supplied in Australia. This platform can be searched to find details of therapeutics goods approved for supply.

THE BASICS

What laws and codes of practice govern the promotion of medicines?
The Therapeutic Goods Advertising Code (the Code) is the cornerstone of the Therapeutic Goods Advertising regulatory framework. It sets out minimum requirements for advertising therapeutic goods to the public. The Code exists to ensure the advertising of therapeutic goods to the public is conducted in a manner that promotes the safe and effective use of therapeutic goods; is ethical and does not mislead/deceive the consumer; supports informed health care choices, and is not inconsistent with relevant, current public health campaigns.

The promotion of medicines is subject to legislative requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act (TGA), and by self-regulation of the pharmaceutical industry. From July 1, 2022, all advertisers must ensure their advertisements comply with the Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021. This code applies to all elements of advertising (including both therapeutic claims and non-therapeutic claims) and all types of advertising of therapeutic goods to the public.

Self-regulation is based on Medicines Australia's Code of Conduct (the Code), which sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. The Code complements the legislative requirements of the Therapeutic Goods Regulations and the TGA. Code provisions include standards for appropriate advertising, the behavior of medical representatives, and relationships with healthcare professionals.

The Code is recognised by the TGA, the regulator of medicines for marketing and promotion by the prescription medicines industry. The TGA supports the system of self-regulation as being consistent with supporting the Therapeutic Goods Regulations.

Non-prescription medicines, such as over the counter (OTC), pharmacy-only or complementary medicines, are not covered by the Medicines Australia Code of Conduct. While promotional activities and/or advertising to the public for prescription-only and some pharmacist-only medicines is prohibited, direct-to-consumer promotion is allowed for the majority of medicines available for OTC sale.

These non-prescription medicines are regulated by co-regulatory and self-regulatory arrangements operated by the TGA, the Therapeutic Goods Advertising Code Council, the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC).

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
Public relations is not separately defined or differentiated from other promotional activities. According to the Medical Board of Australia, an advertiser is any person or business that advertises a regulated health service. Advertising includes, but is not limited to, all forms of verbal, printed or electronic public communication that promote a health service, in addition to situations in which practitioners make themselves available or provide information for media reports, magazine articles or advertisements.

Information released by a company intends (from the end viewer's point of view) to directly or indirectly promote the use, or supply of a therapeutic good would likely be considered advertising by the TGA, and therefore, must meet legislative requirements as set out in Therapeutic Goods Act and the Therapeutic Goods Advertising Code.

Information that is purely factual and balanced and is disseminated for the appropriate use of the goods, is unlikely to be considered promotional.

Who is responsible for the enforcement of these rules?
The appropriate organization responsible for the enforcement of these regulations depends on the type of product involved. Prescription-only medicines, or interactions by pharmaceutical companies, are governed by the Medicines Australia Code of Conduct. Non-prescription consumer healthcare products are governed by the Consumer Healthcare Products Australia, and medical technology and diagnostics are governed by the Medical Technology Association of Australia.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
Any potential violations/appeals of the Medicines Australia Code of Conduct may be referred to the Code of Conduct and Appeals Committees, following a complaint lodged online. These committees are established by the Code of Conduct.

Before filing a complaint, Medicines Australia encourages the individual/organization to contact the company for a non-industry generated complaint, as a "satisfactory explanation or solution may be immediately available."

Industry-generated complaints should only be filed if, "despite every effort on the part of both the complainant and the subject company, resolution of the matter has not been achievable."

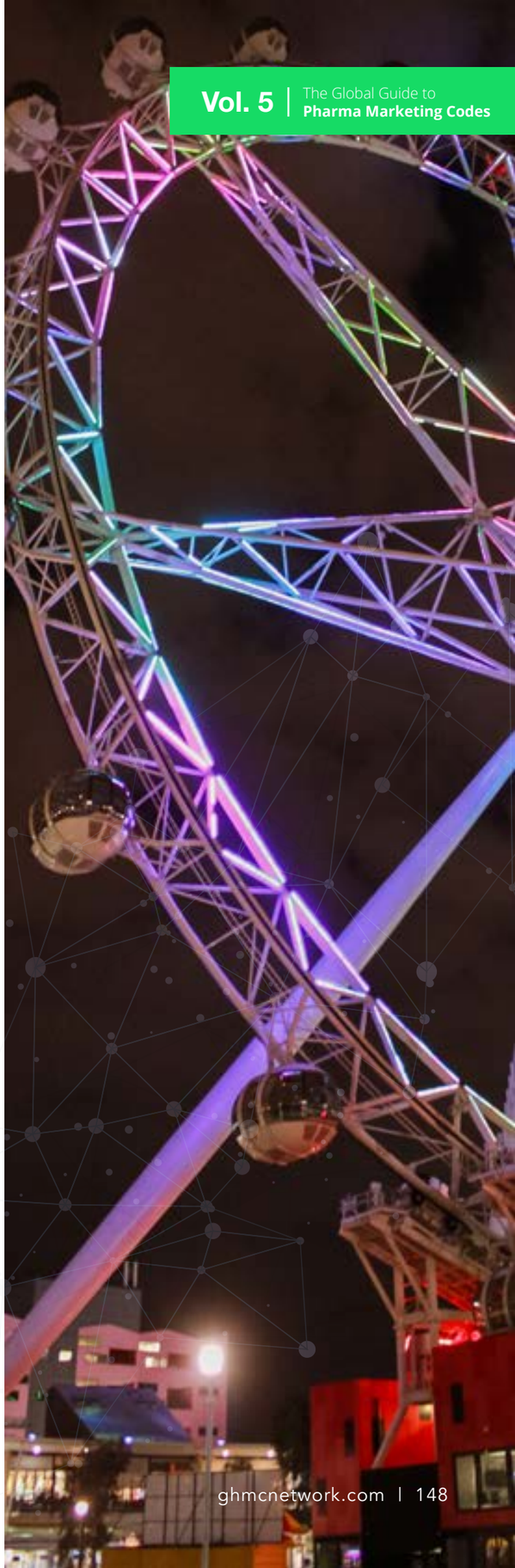
Before a complaint can be sent to Medicines Australia, a meeting between the company and complainants must take place within 10 business days. If this does not occur, a meeting between two senior company executives must occur within two working days. Both parties have five business days to reach a consensus, if not, only then can it be submitted to Medicines Australia for processing. Medicines Australia will not consider complaints submitted before inter-company dialogue has taken place.

Authority to these Committees is delegated under the Constitution of Medicines Australia which stipulates that each member company must conform to, and be bound by, the Code of Conduct, including submitting to the complaints handling process. The complaints handling process they follow reflects the principles of natural justice and procedural fairness.

Adherence to the Code of Conduct is also a requirement for non-member companies as a condition of marketing approval of their prescription medicine products.

Do any promotional or media materials for prescription medicines need to be approved by regulatory authorities?
Any prescription-medicine material intended for healthcare professionals is not subject to pre-approval by the relevant authorities before use. Promotion to the public is not permitted.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
The next revision of the Medicines Australia Code of Conduct has been formally adopted by members and will come into effect on March 30, 2025. The update follows an extensive review with members and the public involving



non-member companies, industry associations, healthcare professionals, the patient community, the TGA and global regulatory bodies.

Key amendments to the code address areas of ambiguity and changing practices in advertising and engagement with healthcare professionals.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
Medicines Australia defines promotional activity and promotional materials as "any representation concerning the attributes of a product conveyed by any means whatsoever for the purpose of encouraging the usage of a product".

- Information is defined as "educational facts regarding the attributes of a product."
- Educational material is defined as "any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims."

Promotional activity for prescription medicines directed at the public would be in breach of the Code. However, educational materials are allowed, for patients to have access to information on medical conditions and treatments which may be prescribed by their doctors.

The content of all promotional and educational materials directed at healthcare professionals must be balanced, accurate and correct. Promotional material must be clearly distinguishable as such, with access to sufficient prescribing information for healthcare professionals to prescribe, Product Information (PI), qualifying statements and references.

How is a media event defined?
The TGA and Medicines Australia do not specifically refer to a media event. However, there are references in the Code of Conduct to communication with healthcare professionals and the general public and their media. This includes the provision of educational or information-based materials or activities (directed at healthcare professionals and the public media) and/or promotional activities (directed at healthcare professionals and their media only).

The purpose of interactions with consumer media must be to 'enhance the quality use of medicines' by providing appropriate, non-promotional information that is relevant to the Australian public.

Although media outlets are not bound by the provisions of the Code, Medicines Australia expects members to work with those who adhere to the principles of the MEAA Journalist Code of Ethics.

Do the regulations differentiate between consumer and clinical publications?
The Code of Conduct differentiates between communication with healthcare professional media and the general public/lay media.

Media releases and all other types of media directed at healthcare professionals, which are promotional in nature, must include:

- Brand name of the product.
- Australian Approved Name(s) of the active ingredient (s) placed adjacent to the most prominent presentation of the brand name.
- Any boxed warnings and/or black triangle statement(s) as required by the TGA.
- A statement directing healthcare professionals to the PI.
- A statement regarding public funding or reimbursement status.
- Name of the supplier and location of registered office.
- Date the material was prepared or last revised.

Media directed to the general public must not be promotional in nature and should be solely informative and educational. Consumer Medicine Information, risk management materials and PI are credible sources that may be made available to the general public.

Product-specific programs, PI and patient aids should only be provided to patients already prescribed the product and not be promotional.

Unregistered therapeutic goods not entered on the Australian Register of Therapeutic Goods (ARTG) may not be advertised in Australia to either consumers or healthcare professionals.

Do regulations differentiate between online, print, broadcast and/or streaming media?
All types of promotional media directed at healthcare professionals have required inclusions, and do not differentiate between online, print, broadcast and/or streaming media.

Media hosted online containing promotional claims should not be made available or accessible to the general public. It is appropriate for companies to make known on their websites that they are bound to the Medicines Australia Code of Conduct and provide a link to the code.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
Press releases are subject to the general regulations of the Medicines Australia Code and the TGA Act. As such, press releases promoting unapproved medicines or indications are prohibited.

Companies may engage with healthcare professional media for promotional purposes, including issuing media releases and developing advertorial content.
Product-specific media statements to consumer media may be issued when the information is relevant to the Australian public. This includes announcements of a new product or indication registration, new public funding such as a PBS listing, or a change to public funding.
In consultation with the TGA, a company may issue a media statement about issues such as product safety, shortages, recalls or withdrawals.

A product-specific media statement announcing a new prescription product or new indication must not be made known to the general public until the product or indication has been registered in Australia and reasonable steps have been taken to inform healthcare professionals of its availability.

Sponsorship of clinical trials or clinical research is not reportable. Medicines Australia will make the completed reports provided by each company publicly available on its website.

A product-specific media statement must contain the following:

- Product brand name.
- Australian Approved Name(s) of the active ingredient (s) placed adjacent to the most prominent presentation of the brand name.
- Approved indications, relevant to the product-specific media statement.
- Therapeutic class.
- Public funding status or restrictions.
- Summary of the side effect profile, precautions, adverse effects, warnings, contraindications and interactions.
- A copy or a link to the product's Consumer Medicine Information (CMI).

It may also include a non-comparative description of the mechanism of action, price and date of product/ indication availability.

Companies listed on the Australian Stock Exchange (ASX) may issue a non-promotional, product-specific media release using the continuous disclosure requirements of the ASX. Such media releases must adhere to the principles of the Code of Best Practice for Reporting by Life Science Companies.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
Any media materials used or intended for Australia must comply with the relevant sections of the Medicines Australia Code of Conduct.

Medicines Australia acknowledges media briefings as a legitimate and useful addition to the distribution of a media release (Code of Conduct Guidelines), provided they are educational with the intention of providing information to healthcare professionals and their media.

The company should not initiate statements or comments regarding products that are not approved for marketing in Australia during press statements or media conferences.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
The sponsorship of a journalist by the company must not be conditional upon any obligation by the journalist to report on a company's product(s).

General media articles concerning specific prescription products must not be initiated by companies. Companies should not seek to encourage the publication of general media articles or its content with the aim of promoting their products, but may, on request, provide educational material or review copy to ensure accuracy.

Do regulations cover the use of case studies or other third-party advocacy in the media?
There are no specific regulations covering the use of case studies.

Medicines Australia recognizes and supports positive and beneficial relationships between industry and patient organizations. Companies may enter relationships with patient organizations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Companies may share information about patient organizations and their representatives. This may include information about prescription medicines if there is a genuine need for the information, the content is relevant to their specific expertise and interest in the therapeutic area and is non-promotional.

DIGITAL & SOCIAL MEDIA

Is online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
The Medicines Australia Code of Conduct does not differentiate between print and broadcast guidelines for promotional and educational content. Any online media activities or materials must be designed to prevent access by members of the public.

What are the web security and data privacy requirements?
Companies must comply with the Australian Privacy legislation regarding the reporting of individual healthcare professional data. Each company must establish a means to ensure maintenance of records which comply with Australian Privacy legislation (Privacy Act 1988).

Any online media materials that are promotional in nature must be designed to only allow access to healthcare professionals. A company-controlled website for healthcare professionals, for instance, should be secured with a password or other login requirement (e.g. provider number). The password should not be easily identifiable, such as the product name.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
It is reasonable for companies to provide financial support and/or significant direct or indirect non-financial support to organizations that work to benefit Australian patients. It is appropriate for these activities to be reported. Funding an educational activity or program can include, but is not limited to, websites.

The Code of Conduct states that when companies make a reference or linkage to non-company-owned website, the following disclaimer must be added:
"The information a reader is about to be referred to may not comply with the Australian regulatory requirements. Further information relevant to the Australian environment is available from the company or via the Product Information."

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
Medicines Australia defines social media as "an umbrella term that incorporates the various online platforms and activities that engage users to participate in, comment on, and create digital content, and to allow them to interact, share information and network with others, including peer-to-peer conversations."

All activities that utilize any social media platform will be considered in the same way as more traditional media activities. Companies are responsible for all content on company-initiated and/or controlled social media sites and activities. Content that does not conform to community standards of ethics and good taste, or which relates to unapproved products or indications, should be promptly removed. Companies should also have policies and procedures which describe the roles and responsibility of its employees and contractors when interacting in the social media space to ensure compliance with the Code of Conduct.

In 2013, the ASMI Social Media Guidelines were created to advise the Australian consumer healthcare market and the heightened importance of ensuring responsible conduct is upheld in the social media era.

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations specifically relevant to the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Medicines Australia does not differentiate digital forums from social media.

What is mobile adoption like in your region? Are there separate regulations for it?
The Medicines Australia Code of Conduct does not provide regulations for mobile phone use. However, promotional material directed at healthcare professionals and educational/informative materials directed at the general public must adhere to the same guidelines for traditional print and broadcast media as specified in the Code. Electronic messaging of promotional materials must comply with the Commonwealth Spam Act 2003 (the Act). Under the Act, no person is permitted to send spam, or unsolicited commercial electronic messages, via email, instant messaging, Short Message Service (SMS) or other phone messaging.

What are the disclosure laws like in your region for non-branded websites?
The Medicines Australia Code of Conduct states all items of an educational nature (e.g. non-branded website), whether intended for the education of healthcare professionals, or to be used by the healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines, and/or assisting a patient in his or her understanding of a condition or disease.

Websites should not focus on the company's product(s). In discussing prescription product options for the disease state, the website may list all the available products, but it must not compare any products.

A company-sponsored disease state website must not have links to websites with information on a company's product(s).

If readers of online material are referred or linked to other reputable information sources that the company has not developed, a statement must be shown before the information is accessed, covering the following information (where relevant):

- The information they are about to be referred to may not comply with the Australian regulatory environment.
- If relevant to the product, readers should refer to the CMI to understand the terms of a product's registration in Australia.
- The intent of providing this further material is informational and not as advice.
- Any information provided by this source should be discussed with their healthcare professional and does not replace their advice.

What are the requirements for adverse event reporting?
The TGA relies on healthcare professionals, the public and industry to identify and respond to safety matters associated with medicines or medical devices in Australia.

Manufacturers and sponsors of medicines and medical devices and their authorized representatives are required to report an adverse event (AE) to the TGA (section 41MP in the Therapeutic Goods Act 1989).

Third parties representing pharmaceutical companies, such as PR agencies, must report an adverse event matter to the pharmaceutical company within 24 hours of the matter being identified. Therefore, third parties must become familiar with the procedure for identifying and tracking adverse event matters when conducting patient-oriented programs on behalf of the organization's clientele.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no specific rules in the Code that set out hospitality for patient advocacy groups.

In August 2012, Medicines Australia established a broad-based transparency working group to draft and develop measures and policies that will improve transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. Informed by the Principles for Transparency, the working group has developed a model which aims to improve transparency about payments and transfers of value between companies and healthcare professionals. The Principles for Transparency dictate the relationship between healthcare professionals and patients should be based on trust and mutual respect. This trust and the quality of the relationship between a healthcare professional and a patient can be threatened when the decision-making by healthcare professionals may be seen to have been compromised by interests other than those of the patient.

All events, initiated or sponsored by companies, must be reasonable and appropriate with respect to hospitality, travel and accommodation, therefore upholding the industry's integrity and reputation.

It is reasonable for the pharmaceutical industry to financially support the education of healthcare professionals through sponsorship of meetings and symposia organized by third parties, and such support is publicly disclosed. Hospitality for educational meetings must comply with the requirements of the Code, with food and beverages secondary to the event and the facility selected for its appropriateness, and not chosen for the purpose of leisure, sporting or recreational activities.

When third-party educational events are independently organized, where the educational content, speaker selection and attendees are made by the third party and not by the company, pharmaceutical companies will still need to complete their own due diligence and research as to whether the venue and hospitality choices being offered as part of the independent event are reasonable and appropriate and uphold their integrity and reputation. It is ultimately the responsibility of pharmaceutical companies to be aware of the activities they sponsor and satisfied they are in line with the Code Principles.

For events overseas, when there is no limit in another country for providing hospitality, the Australian principles should apply.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Companies are responsible for ensuring that all transfers of value are reasonable, appropriate, and balanced when considered in context. All transfers of value should be reported in accordance with the Code. It is reasonable for healthcare professionals to be fairly compensated for legitimate expertise and services provided to the industry, and that such compensation is publicity disclosed to the pharmaceutical industry. Transfers of value to healthcare professionals that must be reported are:

- Fees paid to healthcare professionals in return for speaking at an educational event, consultancy or advisory services.
- Any airfare, accommodation or registration fees directly associated with a meeting, consultancy or advisory service (within or outside Australia).
- Fees paid to healthcare professionals for the purpose of market research only when the identity of the healthcare professional is known to the company.

Travel for healthcare professionals in connection with activities or events is allowed, if it is in direct association with an educational event/to undertake a consulting service. In Australia, companies may sponsor travel for healthcare professionals attending an international educational event in either economy or business class, with domestic air travel and to New Zealand by economy class only. The most direct route should be booked, without the allowance of more time at the destination than is reasonably justified to enable the healthcare professional to effectively participate in the event.

Travel and accommodation for spouses, relatives, guests or companions of healthcare professionals is not allowed.

It is reasonable for the industry to provide a grant or donation to a healthcare organization if it is to implement a quality use of medicine program, for education, training or academic purpose, to improve patient outcomes, or for medical research. It is reasonable for companies to provide financial support to organizations that work with Australian patients, but these activities should be reported.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Sponsorship may be provided to enable a healthcare professional to attend an educational event, provided the meeting is directly related to the healthcare professional's area of expertise, qualifications, experience, and educational needs.

Companies may only sponsor patients and patient organizations to attend third-party scientific and medical conferences if the event is based on a specific therapeutic area of particular interest or relevance to that patient or representative.

What is possible in terms of media or message training for health professionals or advocacy organizations?

There are no specific regulations regarding media or messaging training for healthcare professionals or advocacy organizations.

Where companies undertake sponsorship of a healthcare professional or advocacy organization, the sponsorship must be able to withstand public and professional scrutiny, conform to community standards of ethics and good taste, and/or enhance the quality use of medicines. Companies should also ensure any sponsored experts are fully briefed on the provisions of the Code in the event they may have direct contact with the public or lay media.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

There are no specific rules that govern materials written on behalf of third parties. Guiding principles set out by Medicines Australia state that each party should maintain its independence, disclose relationships, act with integrity, and be clear about the purpose of the collaboration.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no specific regulations regarding meetings with, or provision of, non-media information to advocacy groups.

Medicines Australia recognises and supports positive and beneficial relationships between industry and patient organizations. Companies may enter relationships with patient organizations with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community. Companies and healthcare organizations must remain mindful of the Medicines Australia Guidelines, titled 'Working Together – A Guide to Relationships between Health Consumer Organizations and Pharmaceutical Companies', which involve the following components:

- Respect for independence.
- Achieving and maintaining public trust.
- Fairness.
- Openness and transparency.
- Accountability.

KEY TAKEAWAYS/ SUMMARY

- In Australia, the Therapeutic Goods guidelines and requirements are adopted to ensure high public health standards, the safe use of therapeutic goods, and the honest communication of their benefits, use and effects.
- Direct-to-consumer advertising is allowed for most medicines available for OTC sale, while advertising to the general public of prescription-only and certain pharmacist-only medicines is prohibited. Government-controlled public health campaigns that have been approved by Health Ministers are exempt from this prohibition. The promotion of medicines is self-regulated by the pharmaceutical industry's Medicines Australia Code of Conduct.
- The advertising of therapeutic goods to consumers and health practitioners is controlled by a combination of statutory measures administered by the TGA and self-regulation through the Codes of Practice administered by the relevant therapeutic goods industry associations.

INDIA

The promotion of medicines in India is controlled by the Drugs and Cosmetics Act of 1940 (DCA), The Drugs and Magic Remedies Act and Rules and the newly formed Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024. Direct-to-consumer promotion of prescription-only medicines is not permitted in India. Major emphasis is on responsible behavior, dissemination of credible information and compliance with regulations and codes.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the Drugs and Cosmetics Act of 1940 (DCA) and the Drugs and Cosmetics Rules of 1945 (DCR)1.

Advertising and promotion for a certain category of drugs is controlled by the Drugs and Magic Remedies (Objectionable Advertisements) Act of 1954 and Rules of 1955. These aim to prevent people from medication due to misleading or exaggerated advertisements. There are 54 ailments covered under this action, including fever.

Over-the-counter (OTC) and direct-to-consumer (DTC) have no legal recognition in India. In the absence of any rule, a drug in India is considered OTC unless it is specifically stated as a prescription-only drug. In 2022, the Ministry issued a draft amendment to Schedule K of the Drugs Rules, 1945, however, the country still awaits a robust OTC policy.

Drugs in the system of traditional medicine, such as Ayurveda, Siddha, Unani and Homeopathy, are also controlled by the DCA of 1940 and the DCR.

In March 2024, the Department of Pharmaceuticals (DoP) notified the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024 for the Pharmaceutical and Medical Device Industry, a significant step towards promoting responsible and ethical practices, urging strict adherence. UCPMP 2024 covers crucial areas such as conduct of medical representatives, the provision of brand reminders and free samples, relationships with Healthcare Professionals ('HCPs'), and prohibits conduct of CME, CPD conference, workshops etc. in foreign locations.

The Chief Executive Officers of pharmaceutical and medical device companies bear responsibility for ensuring compliance with the Code and are required to submit a self-declaration in the prescribed format within two months of the end of every financial year, to the Association, for uploading onto their website, or directly onto the UCPMP portal of the DoP.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

'Public relations' is not separately defined, and there are no special rules for public relations activities. Under the Drugs and Magic Remedies Act, advertisement includes any notice, mailing, label, wrapper or other document and any announcement made orally or by any other means.

The UCPMP states that, where a pharmaceutical company pays for or otherwise secures the publication of promotional material in journals, such promotional material must not resemble editorial matters.

Who is responsible for the enforcement of these rules?

The State Food and Drug Administration (FDA) is responsible for enforcing the DCA and the Drugs and Magic Remedies Act.

Once it is established that a breach of the Code has been made by an entity, the Ethics Committee for Pharma Marketing Practices (ECPMP), in each pharmaceutical association can take appropriate action, including suspension or expulsion of the entity from the Association, and other remedial actions. In cases where disciplinary, penal or remedial action falls under the jurisdiction of government agencies, the Committee may forward its recommendations to the relevant authorities through the DoP.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
For activities, as per the UCPMP 2024, all complaints, related to the breach of the Code are required to be addressed to the "Ethics Committee for Pharma Marketing Practices (ECPMP)", "Chief Executive Officer", of any Indian Pharmaceutical Association, who is required to constitute a committee for handling complaints named as "Ethics Committee for Pharma Marketing Practices (ECPMP)". All pharma associations will share on their website the details of complaints received, and the action taken by the ECPMP, and such details should remain uploaded for five years. Such details are also required to be uploaded onto the UCPMP portal of the Department of Pharmaceuticals.

Do any promotional or media materials need to be approved by regulatory authorities?
For advertising health-related products on media directed to consumers, a new directive has come into being. The Honorable Supreme Court has issued a directive in its Order dated 07.05.2024, that all advertisers/ Advertising Agencies must submit a 'Self-Declaration Certificate' before publishing or broadcasting any advertisement. Following this directive, the Ministry of Information and Broadcasting has introduced a new feature on the Broadcast Seva Portal of the Ministry of Information and Broadcasting (MIB) for TV and Radio Advertisements and on Press Council of India's portal for Print and Digital/Internet Advertisements. The certificate, signed by an authorized representative of the advertiser/ advertising agency, needs to be submitted through these portals.

No preapproval is needed, but the material is required to be consistent with the requirements of the Code and laws.

The self-declaration certificate should certify that the advertisement (i) does not contain misleading claims, and (ii) complies with all relevant regulatory guidelines, including those stipulated in Rule 7 of the Cable Television Networks Rules, 1994 and the Norms of Journalistic Conduct of Press Council of India. Advertisers must provide proof of uploading the Self-Declaration Certificate to the relevant broadcaster, printer, publisher, or electronic media platform for their records.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
Very recently, in March 2024, the Department of Pharmaceuticals (DoP) notified the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024 for the Pharmaceutical and Medical Device Industry, a significant step towards promoting responsible and ethical practices, urging strict adherence.

Additionally, the Digital Personal Data Protection Act, 2023 (DPDP) has been introduced that impacts patient privacy.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
Under the Drugs and Magic Remedies Act, an advertisement includes any notice, circular, label or wrapper and any announcement made orally or by any means.

The Code of Marketing Practice cites information about medicinal products that must be:

- Up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.
- Accurate, balanced, fair and objective and must not mislead directly or by implication.
- Be capable of substantiation.

If any educational material to consumers contains company or brand promotion, it should be mentioned as 'Advertisement' in the permissible categories of products to be advertised. All material meant for HCPs should carry a statement 'For the use of the Registered Medical Practitioner only.' The names or photographs of healthcare professionals must not be used in promotional material. The UCPMP 2024 permits brand reminders categorized as: Informational and educational items. The Code permits items such as books, calendars, diaries, journals (including e-journals), dummy device models and clinical treatment guidelines for professional use in healthcare settings, capped at a value of Rs. 1,000 per item. Such items should not have an independent commercial value for HCPs.

How is a media event defined?
Media Event means an event such as a press conference or photo opportunity to which the media is invited. It is a planned activity or occurrence designed to attract media coverage and public attention. Media events include press conferences, product launches, grand openings, promotional events, ceremonies, public announcements, round table meetings of journalists with key opinion leaders or spokespeople of the company, etc.

Do the regulations differentiate between consumer and clinical publications?
Yes, Clinical publications are peer-reviewed by experts in the field, while consumer publications have an Editorial review by staff members.

One cannot advertise any ethical prescription medicines directly to consumers by print, TV or other electronic media, whereas they can be advertisements in medical journals. Any education materials aimed at consumers are to be distributed via a doctor.

Do regulations differentiate between online, print, broadcast and/or streaming media?
Indian regulations distinguish between various forms of media, such as online, print, broadcast, and streaming media. Print media is governed by the Press Council of India, while broadcast media falls under the Cable Television Networks Regulation Act. Online and streaming media are regulated by the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021, which encompass digital news, social media platforms, and OTT services.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
For media materials and company events, it's crucial to adhere to the program Code under the Cable Television Networks Regulation Act, which ensures that ethical standards are maintained. The general principles governing press releases, media materials, and company events also include compliance with the norms set by the Press Council of India. Digital content is subject to the IT Rules 2021, which require publishers to adhere to a code of ethics and establish a grievance redressal mechanism, providing a sense of security and protection to the audience. With digital news media, IT Rules 2021 also applies to social media platforms.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Foreign media content distributed in India must adhere to local compliance requirements, including appointing local officers and having a physical presence. It is subject to the same regulatory oversight as domestic content, ensuring alignment with Indian cultural and legal standards. Content restrictions apply to maintain public order and security.

Distribution methods are regulated, especially for foreign-produced content intended for publication in India. When distributed within the country, foreign publications and digital content must comply with Indian laws. The IT Rules 2021 mandate that digital platforms appoint local grievance officers and comply with Indian jurisdiction. Digital India Act 2023 addresses modern challenges like misinformation and data privacy, emphasizing regulatory scrutiny over digital content, including foreign content. In addition, the Ministry of Information and Broadcasting (MIB) requires prior permission to uplink/downlink satellite channels from outside India.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
Press activities at congresses and scientific meetings, including media outreach and symposiums, are regulated to ensure accurate and ethical reporting. Both approved and unapproved/investigational drugs are subject to strict guidelines to prevent the dissemination of misleading information. Regulations apply equally to all forms of media and include the requirement to disclose conflicts of interest and ensure factual reporting.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Case studies can be given to doctors, not in general media, but not with key opinion leader (KOL) brand endorsements. For example, the name and photograph of a KOL cannot be included. The Medical Council of India (MCI) does not permit doctors or medical organizations to endorse or recommend products to members of the medical community or the lay public. The same applies to third-party advocacy.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
The new draft Bill provides for regulating news and current affairs programs that are broadcast through online papers, news portals, or websites, and carried out as a business, professional, or commercial activity. Newspapers and news agencies are regulated under the Press Council Act, 1978.

The Act establishes the Press Council of India to maintain press freedom and regulate journalistic conduct.

What are the web security and data privacy requirements?
Web security and Data privacy are governed by the Digital Personal Data Protection Act, 2023 (DPDP Act) and Information Technology Act, 2000 (IT Act). The DPDP Act requires data fiduciaries to protect personal data being processed by them or by data processors on their behalf and take reasonable security safeguards to prevent a personal data breach. The Privacy Rules require the information security protocol and policies to be in line with the International Standard IS/ISO/IEC 27001. Accordingly, entities may implement the ISO 27001 standards or other equivalent security standards for protection of data.

From the view of patient testimonials, India recognizes Right to Privacy as a fundamental right. Hence, patient consent & release forms need to be taken care of.

For filming in medical settings, there is no single law in India that governs, so one must comply with the Digital Personal Data Protection Act, 2023 (DPDP), the Clinical Establishments (Registration and Regulation) Act, 2010, and the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
In India, regulations around funding or providing information to non-company-owned websites are guided by various laws and guidelines that ensure transparency, security, and ethical conduct.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
The top social networks in India are Facebook, Whatsapp and Instagram. Standard marketing regulations as applicable for the pharma/biopharma industry promotion and advertising mentioned above apply here too.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Product advertisements are dealt with by ASCI for any false or unsubstantiated claims. In case of use of any influencers, such influencers have to make a disclosure about any monetary or other compensation for the purpose of promotion. This is mandatory.

Are there any self-imposed regulations from social media companies?
Regulations specifically relevant to the pharmaceutical industry include prohibition of targeting specific audiences with diseases.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
The standard global regulations apply here.

What is mobile adoption like in your region? Are there separate regulations for it?
GSMA Intelligence's numbers indicate that mobile connections in India were equivalent to 78.0 percent of the total population in January 2024. The mobile industry is governed by the Telecom Regulatory Authority of India (TRAI).

What are the disclosure laws like in your region for non-branded websites?
Disclosure laws are currently not defined. International guidelines may be applied.

What are the requirements for adverse event reporting?
The Central Drugs Standard Control Organization (CDSCO) and Directorate General of Health Services introduced the Pharmacovigilance Program of India (PvPI) in 2010 to protect the health of patients by ensuring drug safety. The Drugs Controller General of India (DCGI) has called for timely reporting of adverse events related to medical devices and directed all medical device license holders and manufacturers to report any adverse events related to life-saving medical equipment on the government's Materiovigilance program of India (MvPI) platform.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
No regulations exist for advocacy/patient groups or travel.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
As per the UCPMP 2024, pharma and medical device companies can pay honoraria to medical professionals only as speakers in educational events for HCPs. The Indian Medical Council Regulations of 2009 state that a medical practitioner shall not receive any cash

or monetary grants from a pharmaceutical or allied healthcare company for individual purpose.

Medical practitioners may, however, work for pharmaceutical and allied healthcare companies in advisory capacities as consultants, researchers, or treating doctors or in any other professional capacity. In doing so, a medical practitioner shall always ensure that:

- His or her professional integrity and freedom are maintained.
- Patient interests are not compromised in any way.
- Affiliations are within the law.
- All affiliations are fully transparent and disclosed.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

With respect to hospitality, sponsorship and meetings, the Code of Marketing Practice states the following. Companies may provide financial assistance for events that are directly related to continuing education of healthcare professionals. Such support must not attempt to influence healthcare professional judgment. Where appropriate, support to healthcare professionals may cover travel expenses, meals, refreshments, accommodation and registration fees for events organized and held in India only.

Companies must not organize meetings to coincide with sporting, entertainment or other leisure events or activities. Venues that are extravagant or renowned for entertainment or leisure facilities or must not be used.

Any hospitality offered to healthcare professionals must:

- Be reasonable in level
- Be strictly limited to the main purpose of the event at which it is offered.
- Not exceeding the level that recipients would normally be prepared to pay for themselves.
- And must not be extended to spouses or other accompanying persons unless they are healthcare professionals who qualify as participants in their own right.

Funding healthcare professionals to compensate them for the time spent attending the event is not permitted. All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events such as visits to research or manufacturing facilities that are organized or sponsored by or on behalf of a company must be held at an appropriate venue in the country that is conducive to the main purpose of the event.

Companies must maintain a detailed record of expenditures incurred for these events. Moreover, Indian Medical Council Regulations of 2009 state that a medical practitioner shall not accept hospitality like hotel accommodations, for themselves or family members.

What is possible in terms of media or message training for health professionals or advocacy organizations?

There are no rules, but all concerned professionals are expected to comply with the Code of Marketing Practice and the MCI guidelines.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?

Materials written by a third party, such as clinical trial reviews, drug reviews or monographs, should truly reflect the product merits and clearly state the contraindications, precautions, warnings, side effects and so on. They should not overstretch the benefits or conceal any weakness. No KOL endorsements are allowed. Brand names must not be used to refer to products in promotions.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

There are no regulations for advocacy groups, but all concerned professionals are expected to comply with the Code of Marketing Practice and the MCI guidelines.

KEY TAKEAWAYS/ SUMMARY

- The regulatory environment in this emerging market is currently changing. Health is being taken more seriously by the government.
- New codes are now paving the way for marketing practices, both from the ministry for the industry and from the MCI for the doctors.
- The marketing environment for the pharmaceutical industry in India is now moving towards greater regulation.

SINGAPORE

The promotion of medicines in Singapore is regulated primarily under the Medicines Act, and the enforcement of these regulations is governed by the Health Sciences Authority (HSA) and guided by Singapore Association of Pharmaceutical Industries (SAPI). The principles for promoting medicines include ensuring truthfulness, accuracy, substantiation with scientific data, and avoiding the use of fear or superstition. These principles apply universally to all forms of media, whether targeting consumers or clients.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The Singapore Medicines Act, under the purview of the Ministry of Health, was developed in 1975 to provide comprehensive control of all aspects of dealings in medicine and its related products including the manufacturing, import, export, sale, supply, and advertisement of medicinal products in Singapore (applies to Western medicines, Chinese proprietary medicines, cosmetic products, contact lens solutions, etc.).

- In the act, a medicine is described as a "substance used for administration to human beings and animals for the diagnosis, prevention or treatment of ailments including preparations intended for the promotion of health, for anaesthesia or for contraception."
- All medicinal products imported or sold in Singapore require a product license from the HSA. Therefore, a locally registered company that is responsible for the safety, quality and efficacy of the product must obtain a product license from the HSA.
- For the application, Singapore has a New Drug Application (NDA) and a Generic Drug Application (GDA) process. For products already approved by certain regulatory agencies (such as Australia's TGA, the US FDA, etc.), submitting an abridged dossier is possible. Applicants must submit an online application through PRISM (Pharmaceutical Regulatory and Information System) and also submit an accompanying dossier. The accompanying dossier must be in the International Conference on Harmonization (ICH) Common Technical Document (CTD) format.

In line with regulatory systems in many developed countries, all Western medicines are subject to the HSA's post-marketing surveillance program which includes regular compliance checks, product sampling and Adverse Drug Reaction (ADR) monitoring to ensure that they continue to meet the required safety, quality and efficacy standards. Products found not to comply with the HSA's requirements may be suspended from further sales or recalled from the market.

Regulators in Singapore focus on the following aspects to determine whether a promotional activity is or is not in compliance:

- Truthfulness.
- Substantiation.
- Accuracy.
- Comparisons.
- Indiscriminate use.
- Substantiation using scientific data.
- Avoid use of fear and superstition.
- Language.
- Refund.
- Trial use.
- Pregnant or lactating women.
- Endorsements and testimonials from healthcare professionals.
- Endorsements and testimonials from public figures.
- Testimonials by non-professionals.
- Logos, initials and trademarks.
- Normal lifestyle.
- Stress.
- Performance in sports and studies.
- Cure.
- Reference to love and friendship.
- Anti-ageing.
- Reference to sexual function.
- Discourage from medical advice.

Descriptions and explanations of each point can be found on pages 10-13 of the HSA's Regulatory Guidance.

The Singapore Medicines Act has undergone several updates to keep up with evolving healthcare standards and practices. The most recent update to the Medicines Act commenced on November 1, 2022. This update incorporated amendments to enhance regulatory measures and ensure the continued safety, quality, and efficacy of medicinal products in Singapore.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?
All medical advertisements must also comply with the Singapore Code of Advertising Practice (SCAP) drawn up by the Advertising Standards Authority of Singapore, as well as the SAPI Code of Marketing Practice (CMP).

A valid permit from the HSA is required before any public advertisements or sales promotions of medicinal products. The advertisement must not contain unsubstantiated claims, misleading comparisons, or endorsements from healthcare professionals without proper authorization.

The SCAP defines an advertisement as 'any form of commercial communication for any goods or services, regardless of medium used, including advertising claims on packs, labels and point of sale material.' Advertisements include, but are not limited to, the following:

- Advertisements in newspapers (including classified advertisements), magazines, brochures, leaflets, circulars, mailings, posters, plastic cards (including fare cards, cash cards), tickets and other printed publications.
- Advertisements via facsimile transmissions and aerial announcements.
- Advertisements displayed on buildings and vehicles.
- Television, radio, cinema and video commercials.
- Advertisements in information network services, electronic bulletin boards, on-line databases and internet services.
- Advertisements in non-broadcast electronic media such as computer games.
- Mail orders.
- Sales promotions.
- Mailing lists.
- Digital communications in every format, design and context including the world-wide web (Internet) and social media.
- Telephone, etc.

Public relations is an overarching concept for any organized effort to communicate information and to modify attitudes and behavior on behalf of a client or cause. It is usually earned, advertising, which is paid.

Who is responsible for the enforcement of these rules?
For medicine: The HSA and SAPI. For advertising: Advertising Standards Authority of Singapore (ASAS).

With regards to medical advertising, a valid permit from the HSA is required before any public advertisements or sales promotions of medicinal products. The advertisement must not contain unsubstantiated claims, misleading comparisons, or endorsements from healthcare professionals without proper authorization.

What are the regulations regarding the engagement of healthcare providers by pharmaceutical companies? How are these regulations enforced?
The engagement of healthcare providers by pharmaceutical companies must adhere to specific criteria, including having a legitimate need, selecting consultants based on expertise, and ensuring compensation reflects fair market value. This process is monitored and enforced by SAPI. Full criteria include:

- A written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services.
- A legitimate need for the services must be clearly identified and documented in advance.
- The criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service.
- The number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need.
- The hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine.
- The compensation for the services must be reasonable and reflect the fair market value of the services provided.
- Services that can be provided by healthcare professionals include but are not limited to speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration.

Who receives concerns and complaints regarding the use of marketing or communications content and activities? How does this process operate?
Any complaint regarding a potential breach of the Code against a member company must be sent directly to SAPI, i.e. not the Health Sciences Authority or Ministry of Health.

If a complaint against a member company is referred or directed to SAPI by any third party, the complaining member company must pay the applicable processing fee to SAPI to review the complaint.

Complaints to SAPI's Marketing Practices Committee should only be a last-resort action after all reasonable avenues have been exhausted. This includes contacts between the CEOs of both companies, to resolve it amicably.

All complaints of breach of SAPI Marketing Code of Practice must be made in writing and submitted by the CEO of the complainant company (so the CEO of that company is aware that a complaint has been submitted) together with a processing fee of $1,500.00 to SAPI. It will first be validated to ensure that:

- It appears to be a genuine matter, submitted in good faith.
- There is documentation to show that there has been communication between the CEOs of the involved parties, to show that all parties have tried to resolve the issue amicably.
- There is sufficient evidence to enable the complaint to be processed.
- It is not a duplication of any existing case that has already been resolved under the Code.

Do any promotional or media materials need to be approved by regulatory authorities?
For general materials, authorities do not have to approve materials. However, it is imperative to ensure that the content of the materials protects young consumers, does not incite racial/religious feelings, is not in conflict with national interest, and so on.

For promotional materials on medicinal products, an application for an advertisement OR sales promotion permit is needed. The requirements are as follows:

Advertisement

- If an advertisement comes in one copy in more than one language, only one application is required.
- If an advertisement comes in more than one copy, each in a different language, separate applications will be required. As an example, for a leaflet that comes in two copies, one in English and one in Chinese, two applications would need to be made.

Sales Promotion

- Only one application is required for the sales promotion of products in the same range (e.g. different brands of vitamins, up to a maximum of five products) using the same promotional method.
- A copy of the sales promotion mechanics is to be submitted in the application.
- If an advertisement also contains a sales promotion announcement, an application for sales promotion would also be required. The prescribed format is as follows:
  - Name of Product.
  - Promotion Method (e.g. price discount).
  - Press Advertisement, if any (to provide a draft artwork as an attachment).
  - Promotion Materials (e.g. shelf-talker, wobbler), if any (to provide as an attachment).
  - Promotion Venue (e.g. retail pharmacy, shopping malls).

Both the advertisement permit and sales promotion permit numbers have to be legibly printed on the advertisement. Each permit is valid for 1 year from the date of issuance of permit approval.

The processing time for each application is 14 working days, excluding time taken by the applicant to make required changes. Upon successful submission of an application via PRISM, an acknowledgement with an application number will be generated. The application number is not a permit number.

If the application is approved, a permit number will be issued with an endorsed copy of the advertisement or sales promotion.

After the approval of the application AND before the publication of a medical advertisement/a medical sales promotion is conducted, it is mandatory for the company initiating the advertisement and the publisher, media owner or the organiser(s) of the sales promotion to ensure that:

- The advertisement or sales promotion has a valid permit from the HSA.
- The permit number is printed legibly on the advertisement and promotional materials.
- The advertisement has not been amended without prior written permission from the Health Sciences Authority.

A permit is not required for trade, business, or profession.

A permit is not required for the following types of advertisements and sales promotion activities:

- Medical advertisements or sales promotion activities directed exclusively at a person who may lawfully sell or supply any medicinal product in the course of his trade, business or profession (such as healthcare professionals), and not accessible to the general public.
- "Reference advertisement" which contains a brief description of a medicinal product, its use, any contraindications and warnings appearing without charge in a publication which is sent or delivered to practitioners or pharmacists by a person who is not involved in the sale of or dealings in that medicinal product as a manufacturer, supplier, retailer, importer or exporter.
- "Trade advertisement" which is issued in a catalogue, price list or other document for the purpose of supplying the medicinal product by wholesale, but which does not contain any recommendation relating to the use of the product other than as part of the name of the product, or as part of any heading or sub-heading indicating a therapeutic classification.

Medical advertisement sales and promotion guidelines:

The promotional material should not:

- Make any false or misleading claims or representations.
- Make unsubstantiated claims.
- Make comparative claims against another product or brand.
- Use scientific language and data which the public may not understand or be able to verify.
- Use exaggerated terms.
- Contain any language or image that causes fear, alarm, distress to the public of any disease or condition.
- Encourage inappropriate or excessive use.
- Suggest guaranteed results without side effects.
- Encourage incorrect use or self-treatment of serious diseases or discourage from seeking a medical professional's advice.
- Include any endorsement by healthcare professionals or public authority.
- Make use of names, logos and trade service marks of other institutions, companies without their permissions.
- Use the names or logos of HSA and any of our professional groups.
- Offer refunds, in full or partial amounts, to users of the product.

In addition, sales promotion activities directed at the general public should not:

- Offer a medicinal product free of charge with the purchase of a non-medicinal product.
- Offer prizes through lucky draws or contests with the purchase of the medicinal product with terms such as "win a prize" or "get a lucky draw" or equivalent.
- Use terms such as "free", "complimentary", "get a gift" or equivalent.
- Distribute samples of Chinese Proprietary Medicines, Traditional medicines, and Homoeopathic Medicines.

Advertisers may also not claim or indirectly suggest that the product will prevent, alleviate, or cure any of the following diseases and conditions which are specified in the legislation:

- Blindness.
- Cancer.
- Cataract.
- Drug addiction.
- Deafness.
- Diabetes.
- Epilepsy or fits.
- Hypertension.
- Insanity.
- Kidney diseases.
- Leprosy.
- Menstrual disorder.
- Paralysis.
- Tuberculosis.
- Sexual function.
- Infertility.
- Impotency.
- Frigidity.
- Conception and pregnancy.

The above prohibition does not apply to any advertisement or publication which is directed at:

- Practitioners.
- Pharmacists.
- Nurses and midwives.
- Persons undergoing training with a view to becoming practitioners, pharmacists, or nurses and midwives.

Prescription only medicines (POM) and professional-use only MDs (PUO MDs) are not allowed to be advertised to the public.

Cell, tissue, or gene therapy products (CTGTPs) are also not allowed to be advertised to the public.
CTGTPs are health products that contain human cells or tissues, viable animal cells or tissues or recombinant nucleic acids, which are intended for use in humans for a therapeutic, preventive, palliative or diagnostic purpose.

Advertisements of therapy products that are POMs, PUO MDs and CTGTPs by companies that are directed to healthcare professionals should not be made freely accessible to the general public (e.g., published on publicly accessible websites or displayed in publicly accessible areas) to prevent undue patient influence on the preferred use of certain POMs, PUO MDs and CTGTPs.

Providing non-promotional health information to the public:

Publishing factual and educational information on diseases and treatment options is allowed. Providers must ensure the information is accurate, verified, and follows current guidelines.

Educational materials on diseases or medical conditions should be balanced. Health product information must provide an overview of all treatment options and should not promote any specific product or encourage individuals to seek a specific one.

These materials should not include promotional elements such as:

- Mentioning or implying specific brands through visuals or descriptions.
- Highlighting the benefits of specific products.
- Using language that encourages consumer demand, like "get it now," "discounted rate," "fastest," "best," or "safest."

Materials promoting or encouraging the sale of any health product will be considered advertisements and must follow relevant advertisement laws. This includes materials created by both healthcare providers and companies. Both parties are responsible for ensuring compliance with these regulations.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
SAPI reissues its Code of Conduct annually to ensure ethical practices in the marketing and promotion of medicinal products remain up to date – the content of which remains largely unchanged.

With regard to other changes in the near future, only the committee is able to comment on this.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
Promotional activity involves the intention to promote the sale or disposal of a good/service while provision of information is to educate or create awareness.

How is a media event defined?
A media event is staged primarily to attract publicity. The spokesperson of the organization will speak to the invited journalists first. Journalists may pose questions if they wish to.

Do the regulations differentiate between consumer and clinical publications?
The Media Development Authority (MDA) does not differentiate between publications. However, the general principles for promotion of medicinal products must be followed.

Do regulations differentiate between online, print, broadcast, and/or streaming media?
Yes. In the CMP and guidelines by the MDA, print and broadcast are treated differently. Even though they are differentiated, the general principles for promotion of medicinal products still apply.

What is permitted in relation to off-license or pre-launch media activity? Are there specific rules around congresses, scientific meeting, and major publications?
As long as the activities are not illegal, the regulators will not interfere. Communications professionals engaging media shall not use any brand name, unless crucial to the story. The chemical compound of the medicine is usually preferred. This applies to a product launch as well.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
There are no specific regulations that cover press releases and media materials.

The general principles are the same for press releases and media materials. For general materials, companies must ensure that the content of the materials protects the young, does not incite racial/religious feelings, and is not in conflict with national interest. If scientific data are presented, it is best to ensure that all facts are substantiated and have been approved by the HSA.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
Distribution of materials is not regulated, but they should adhere to the general principles noted above.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
There are no known regulations, but all findings should be scientifically sound and substantiated.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?
If it is a journalist from a publication, the written article has to be approved by its editors before publication.

If it is a freelance journalist writing for his/her own personal site, the resulting copy is independent. However, if the article is intended for a certain publication, the editors of that publication will have to vet it first.

Note: No company should provide any form of gift for the journalist in exchange for favorable coverage and/or story angles, as it is against most publications' code of ethics.

Do regulations cover the use of case studies or other third-party advocacy in the media?
No. However, it is highly recommended to use credible or renowned case studies or advocates. Obscure case studies and advocates should be avoided.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Yes. Online media are regulated through the Broadcasting (Class Licence) Notification. They are required to abide by the conditions of the license and to exercise judgment in ensuring that their content complies with the Internet Class License and the Internet Code of Practice.

The Class License scheme operates in a 'catch-all' manner, with internet service providers and internet content providers automatically deemed to be licensed without the need to apply to the MDA for permission to operate a website or publish online. This would include personal homepages, individual 'weblogs' and do-it-yourself online publications.

Such ambiguously crafted rules widen the scope of policy enforcement, giving the authorities discretionary powers to deal with offenders. As a result, self-regulation among Singaporeans is very high.

What are the web security and data privacy requirements?
Web Security:
The Infocomm Development Authority of Singapore states that a website's level of security is dependent on the developer.

However, as a general guideline, if users need to share extensive personal information (e.g. full name, NRIC number, credit card number etc.), the website should be encrypted so as to protect the user entirely.

For materials hosted online that include promotional claims, whether hosted by a Company or a third party, a restrictive mechanism such as password protection for system entry is consistent with ensuring online promotional content is only available to healthcare professionals.

Personal data:
The Personal Data Protection Commission (PDPC) is responsible for administering and enforcing the Personal Data Protection Act (PDPA). Organizations that fail to comply with the PDPA may face financial penalties of up to 10% of their annual turnover in Singapore or SGD 1 million, whichever is higher. The PDPC also issues advisory guidelines to help organizations understand and comply with their obligations under the PDPA.

Under the PDPA, the application of data protection obligations to information published in the media or online is guided by specific principles and exceptions, such as personal data that is publicly available, securing consent for use and meeting protection and accuracy obligations.

The PDPA provides certain exemptions for the collection, use, and disclosure of personal data for journalistic purposes. This aims to balance the need for data protection with the public interest in freedom of the press and information. Journalists and media organizations are often exempt from obtaining consent for data processing (not publishing) related to news reporting and editorial content.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
There are no known regulations, but websites must abide by the conditions of the Class Licence. For sponsors, they have to adhere to legal and accounting standards – e.g. funding should not be obtained illegally.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
Facebook is the top social media network in Singapore with ~80% of the nation's population of 5.6 million people registered on the platform, followed by Instagram ~65% and TikTok ~44%. For mobile messaging apps, WhatsApp is the most popular in Singapore used for both business and personal communications by ~80% of users in Singapore.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
SAPI has issued guidelines to ensure ethical conduct in the marketing and promotion of medicinal products which include specific guidance on the appropriate use of social media for promoting medicinal products, emphasising transparency and accuracy in the information shared.

Companies must comply with the requirements of the Code and not post content which:

- does not conform to community standards of ethics and good taste;
- relates to unregistered products or indications;
- is inappropriate;
- may be considered false or misleading;
- is in breach of any laws or regulations of Singapore; and may represent a patient testimonial or HCP endorsement of a product and that may be viewed or accessed by the general public. User-generated posts on company-owned social media pages that do not comply with the above should be removed as soon as discovered (or at least within one business day) of posting.

Any activity on a social media site by a company employee, or an agent acting on the company's behalf in relation to prescription medicines, must comply with this Code. Company employees or agents who are active on a social media site and who are present on behalf of the company must identify themselves as such.

Personal use of social media by a company employee that potentially identifies them as a company employee (e.g. LinkedIn), or that otherwise references their employer's interests, may be perceived as advertising or promotion of a product. Any social media activity that may be reasonably perceived as such, must be accurate, truthful and comply with this Code. Content must conform to community standards of ethics and good taste. A disclaimer that the views expressed are the company employees own and not those of his or her employer, does not exempt the company employee from this requirement.

Are there any self-imposed regulations from social media companies?
Social media networks have their own policies, which may differ from company to company. For instance, Facebook removes content, disables accounts and works with law enforcement when it believes that there is a genuine risk of physical harm or direct threats to public safety. Facebook may also remove certain kinds of sensitive content or limit the audience that sees it. This is to help balance the needs, safety and interests of a diverse community.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
There are no known rules, but a general guideline is not to tarnish the reputation of your competitor.

What is mobile adoption like in your region? Are there separate regulations for it?
According to the Infocomm Media Development Authority of Singapore's 'Digital Society Report 2023' 97% of residents own smartphones, but the proportion among seniors is lower. Singapore's mobile penetration rate was reported to be 163.8% (according to Statista, based on mobile phone subscriptions), meaning on average Singaporeans have more than one mobile device (e.g. work and personal phones or multiple service providers).

General principles for promotion of medicinal products apply.

What are the disclosure laws like in your region for non-branded websites?
There are no known disclosure laws in Singapore, but SAPI advises that member companies are advised (as part of their internal approval process), whether they have express permission to link to any third-party content.

If the website wants to solicit for donations, it must register itself as a charity with the Registry of Societies.

What are the requirements for adverse event reporting?
The HSA's Adverse Event Reporting program relies upon voluntary reporting of suspected adverse events (AE). The HSA must be notified when one suspects any causal association between the health product taken and the AE experienced by the patient. Reporting an AE does not necessarily mean that there is a definite link between the event and the product.

Reportable AEFI's include:

- Anaphylactoid reaction (acute hypersensitivity reaction).
- Anaphylaxis.
- Persistent (more than three hours) inconsolable screaming.
- Hyptonic-hyporesponsive episode.
- Toxic shock syndrome.
- Severe local reaction.
- Sepsis.
- Injection site abscess (bacterial/sterile).
- Seizures, including febrile seizures.
- Encephalopathy.
- Acute flaccid paralysis.
- Branchial neuritis.
- Intussusception.
- Thrombocytopenia.
- Lymphadenitis.
- Disseminated BCG infection.
- Osteitis/osteomyelitis.
- Death.
- Hospitalisation.
- Disability.
- Any other severe and unusual events suspected to be associated to the vaccine.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
There are no known regulations yet.

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
Healthcare professionals from the civil service are not allowed to accept any payments. For the private sector, it is up to the discretion of the two parties. It is worth noting that some pharmaceutical companies like GSK no longer pay doctors to make presentations on their behalf at medical seminars.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Same as response above.

What is possible in terms of media or message training for health professionals or advocacy organizations?
Regardless of who the spokesperson is, he/she should always be media trained. Media training can be done in-house or outsourced.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
There are no known rules.

What regulations cover meetings with, or provision of non-media information to advocacy groups?
There are no known regulations.

KEY TAKEAWAYS/ SUMMARY

- All medicinal product advertisements must comply with the Singapore Code of Advertising Practice (SCAP) and the SAPI Code of Marketing Practice (CMP). Advertisements must be truthful, accurate, substantiated with scientific data, and avoid using fear or superstition. A valid permit from the HSA is required for public advertisements and sales promotions. Online and social media advertising must comply with the same principles as traditional media.
- Like regulatory systems in many developed countries, all Western medicines are subject to HSA's post-marketing surveillance program, which includes regular compliance checks, product sampling and

Adverse Drug Reaction (ADR) monitoring to ensure that they continue to meet the required safety, quality and efficacy standards.

- If media is engaged, they will not use the brand's name, unless crucial to the story. The chemical compound of the medicine is usually preferred. This applies to the product launch as well.
- The HSA must be notified if one suspects there is a causal association between the health product taken and the AE experienced by the patient. Reporting an AE does not necessarily mean that there is a definite link between the event and the product.
- Healthcare professionals from the civil service are not allowed to accept any payments. For the private sector, it is up to the discretion of the two parties.

Medical devices

Medical devices are classified into four risk classes – class A to D, with class A being the lowest risk class. This classification is based on the intended purpose of the medical device, how it operates, the user, and the type of technology involved.

Medical devices must be registered with HSA to ensure they meet the regulatory requirements before they can be sold, unless they are class A devices which are exempted.

Advertisements of medical devices must comply with the requirements spelled out under the law, including the prohibition of advertisements making reference to a specified list of serious medical conditions such as cancer and diabetes.

What is considered an advertisement?

"Advertisement" refers to the publication, dissemination, or conveyance of any information for the purpose of promotion, and the sale or use of the medical device by any means or in any form, including the following:

- Publication in a newspaper, magazine, journal, or another periodical.
- Display of posters or notices.
- Circulars, brochures, pamphlets, books.
- Letters address to individuals or organizational bodies.
- Photographs or films.
- Sound broadcasting, television, the internet, and other media sources.
- Public demonstration of the use of the health product.
- Offer of trials of the health product to members of the public.
- Door to door sales.
- Exhibitions.
- Competitions.
- Any other activity intended to introduce, publicise, or raise the profile or public awareness or visibility of any medical device for the purpose of promoting the sale or use of it.

Advertisement Prohibitions

Advertisements on registered "professional use only" medical devices are not allowed, unless the advertisement is distributed only to, or contained in, **a publication intended to be circulated to qualified practitioners.**

Advertising to the general public that claim, indicate or suggest that the medical device will prevent, alleviate or cure any of the following diseases or conditions is not allowed:

- Blindness.
- Cancer.
- Cataract.
- Drug addiction.
- Deafness.
- Diabetes.
- Epilepsy or fits.
- Hypertension.
- Insanity.
- Kidney diseases.
- Leprosy.
- Menstrual disorders
- Paralysis.
- Tuberculosis.
- Sexual functions.
- Infertility.
- Impotence.
- Frigidity.
- Conception and pregnancy.

General principles of advertisements

Truthfulness – advertisements should:

- Truthfully state the nature, quality and properties of the medical device.
- Not mislead in any way by ambiguity, exaggeration, omission or otherwise.
- Not include unqualified superlatives.

Substantiation – all claims made in the advertisement must be substantiated with scientific studies.

Accuracy - Recommendations relating to the use of the medical device should be accurately stated in moderate terms and should be relevant to their properties.

Comparisons - Advertisements should not contain comparisons with other products unless scientifically proven. All comparative advertisements should be presented clearly and fairly, without criticising other products.

Indiscriminate use - Advertisements should not directly or indirectly encourage indiscriminate, unnecessary, or excessive use of the medical device.

Use of scientific data - Advertisements should not exploit public ignorance by including unverifiable scientific data. Avoid the misuse of research results and unnecessary quotations from technical and scientific publications.

SOUTH KOREA

The promotion of medicines in South Korea is primarily regulated by the Pharmaceutical Affairs Act (PAA) and the Fair Labelling and Advertising Act (FLAA). Enforcement is overseen by the Ministry of Food and Drug Safety (MFDS), with additional self-regulatory oversight provided by the Korean Research-based Pharmaceutical Industry Association (KRPIA) and the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA). Promotional activities must be truthful, accurate, scientifically substantiated, and must not mislead or exploit consumers.

What laws and codes of practice govern the promotion of medicines?

In South Korea, the promotion of medicinal products is governed by a comprehensive legal and regulatory framework designed to ensure the safety, efficacy, and ethical marketing of pharmaceuticals.

- The Pharmaceutical Affairs Act (PAA) regulates the manufacturing, importation, and sale of drugs and medical devices in South Korea. It outlines the requirements for marketing authorization, labelling, and advertising of medicinal products.
- The Fair Labelling and Advertising Act (FLAA) governs advertising activities in general, ensuring that advertisements are not false or misleading.
- The Ministry of Food and Drug Safety (MFDS) provides guidelines elaborating on advertising standards set out in the PAA, defining 'advertisement of a medicinal product' as any activity publicising the name, manufacturing method, efficacy, or efficiency of a medicinal product using various media to unspecified individuals.
- The Korean Research-based Pharmaceutical Industry Association (KRPIA) has established the Voluntary Code on Labelling and Advertising for Drugs, which applies to member companies' advertising of medicinal products in Korea.
- The Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) has also developed the Fair Competition Code on Transactions of Pharmaceuticals, providing detailed guidelines on ethical business practices.

Marketing Authorization and Product Registration

All medicinal products intended for importation or sale in South Korea must obtain marketing authorization from the MFDS. The application process requires submission of comprehensive data demonstrating the product's quality, safety, and efficacy. The MFDS recognises the International Council for Harmonisation (ICH) Common Technical Document (CTD) format for submissions.

South Korea classifies drugs into categories such as new drugs, generic drugs, and over-the-counter (OTC) drugs, each with specific requirements for approval.

Advertising and Promotion Regulations

The MFDS defines "drug product advertising" as activities by drug manufacturers, marketing approval holders, importers, etc., using various media to publicise the name, manufacturing method, efficacy, or performance of a drug to a large number of unspecified people, including general consumers and medical and pharmaceutical experts.

Key regulations include:

- Prescription Drugs: Direct-to-consumer (DTC) advertising is prohibited, except for certain vaccines.
- OTC Drugs: DTC advertising is permitted but must undergo a preliminary review by the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA).
- Media Channels: Advertising through newspapers, television, radio, internet, and other media is subject to the same standards.
- Online Advertising: Subject to the same regulations as traditional media; no separate rules exist for online platforms.

Compliance and Enforcement

The MFDS and KFTC have the authority to enforce compliance with advertising regulations. They can order the cessation of non-compliant advertisements, mandate corrective statements, and impose penalties, including fines and suspension or cancellation of marketing authorizations. Violations may also lead to criminal penalties, including imprisonment.

Self-Regulation and Ethical Guidelines

The KRPIA's Fair Competition Code and Working Guidelines provide additional guidance for member companies, promoting ethical advertising practices and

ensuring that promotional materials are accurate, balanced, and not misleading. mcprinciples.apec.org

Post-Marketing Surveillance
The MFDS conducts post-marketing surveillance to ensure ongoing compliance with safety, quality, and efficacy standards. This includes regular compliance checks, product sampling, and monitoring of adverse drug reactions (ADRs). Products found not to comply with the MFDS's requirements may be suspended from further sales or recalled from the market.

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

The regulatory framework governing the promotion of medicinal products is primarily established by the Pharmaceutical Affairs Act (PAA) and the Fair Labelling and Advertising Act (FLAA). These laws are enforced by the Ministry of Food and Drug Safety (MFDS) and the Korea Fair Trade Commission (KFTC), respectively.

Advertising: Under the PAA, "drug product advertising" is defined as activities by drug manufacturers, marketing approval holders, importers, etc., using various media to widely publicise the name, manufacturing method, efficacy, or performance of a drug to a large number of unspecified people, including general consumers and medical and pharmaceutical experts. The FLAA further defines "advertising" as the act of broadly informing consumers of a particular business or its products by means of periodicals, newspapers, broadcasting, telecommunications, pamphlets, samples, tickets, the Internet, posters, signs, balloons, videos, records, books, movies, plays, the products of other businesses, and other similar media.

Public Relations (PR): While South Korean regulations do not provide a specific legal definition of "public relations" distinct from "advertising," the distinction is generally understood in practice. Public relations activities involve the dissemination of information and efforts to shape public perception without direct promotion of a specific product. These activities are typically non-commercial and may include press releases, educational materials, and corporate communications aimed at building brand image or informing the public about health-related issues.

Who is responsible for the enforcement of these rules?

The MFDS is the primary enforcement authority for these rules. It conducts inspections, investigates complaints, and issues administrative sanctions such as warnings, suspensions, and has the authority to delist products if any product is found to breach any regulations. The KPBMA and KRPIA support MFDS in the enforcement process via self-regulatory reviews and industry compliance monitoring.

What are the regulations regarding the engagement of healthcare providers by pharmaceutical companies? How are these regulations enforced?

The engagement of healthcare professionals (HCPs) by pharmaceutical companies is governed by a comprehensive framework aimed at ensuring ethical interactions and preventing undue influence on medical practice. The primary regulatory instruments include the Pharmaceutical Affairs Act (PAA) and the Fair Competition Code established by the Korean Research-based Pharmaceutical Industry Association (KRPIA). These regulations are enforced through a combination of self-regulatory mechanisms and oversight by relevant authorities:

Key Criteria for Engaging Healthcare Professionals:

- **Written Agreements:** Prior to the commencement of services, a written contract must be established, clearly outlining the nature of the services to be provided and the basis for remuneration.
- **Legitimate Need:** There must be a clearly identified and documented legitimate need for the services of the HCP, established in advance.
- **Selection Based on Expertise:** HCPs should be selected based on criteria directly related to the identified need, ensuring they possess the necessary expertise to provide the required services.
- **Appropriate Number of Consultants:** The number of HCPs engaged should not exceed what is reasonably necessary to fulfill the identified need.
- **Avoidance of Inducement:** Engagements must not serve as inducements to prescribe, recommend, purchase, supply, or administer any medicinal product.
- **Fair Market Compensation:** Remuneration for services must be reasonable and reflect the fair market value of the services provided. However, the amount shall be determined in accordance with the Act on the Prohibition of Improper Solicitation and Receipt of Money and Valuables, as well as the guidelines of KRPIA or KPBMA.
- **Permissible Services:** Engaged services may include, but are not limited to, speaking at or chairing meetings and events, involvement in medical or scientific studies, clinical trials, training services, participation in advisory board meetings, and participation in market research involving remuneration.

Enforcement Mechanisms:
The KRPIA's Code Deliberation Committee (CDC) is responsible for monitoring compliance with the Fair Competition Code. The CDC has the authority to investigate potential violations, recommend corrective actions, and impose sanctions on member companies that fail to adhere to the established guidelines. Additionally, the Ministry of Food and Drug Safety (MFDS) oversees compliance with the PAA, ensuring that pharmaceutical companies maintain ethical standards in their interactions with HCPs.

Complaint Submission Process:

- **Eligibility:** Complaints can be lodged by member companies of the KRPIA, healthcare professionals, or other stakeholders who identify potential breaches of the Fair Competition Code.
- **Submission Requirements:** Complaints must be submitted in writing and should include:
  - A detailed description of the alleged violation.
  - Supporting evidence or documentation.
  - Information on any prior attempts to resolve the issue amicably between the involved parties.

Investigation and Enforcement:

- **Review by the CDC:** Upon receipt, the CDC evaluates the complaint to determine its validity and whether it warrants a formal investigation.
- **Investigation:** If deemed necessary, the CDC conducts a thorough investigation, which may involve requesting additional information from the parties involved.
- **Deliberation and Decision:** The CDC deliberates on the findings and decides on appropriate corrective actions if a violation is confirmed.
- **Enforcement:** Sanctions for confirmed breaches can include:
  - Recommendations for corrective measures.
  - Public disclosure of the violation.
  - Suspension or expulsion from the KRPIA.

Additional Oversight:
In cases where violations may also contravene national laws, such as the Pharmaceutical Affairs Act or the Fair Labelling and Advertising Act, regulatory bodies like the Ministry of Food and Drug Safety (MFDS) and the Korea Fair Trade Commission (KFTC) may initiate independent investigations and impose legal penalties, including fines or suspension of marketing authorizations.

Pharmaceutical Advertising
The promotion of medicinal products is regulated under the Pharmaceutical Affairs Act (PAA) and the Fair Labelling and Advertising Act (FLAA), enforced by the Ministry of Food and Drug Safety (MFDS) and the Korea Fair Trade Commission (KFTC), respectively.

- **Prescription Drugs:**
  - Direct-to-consumer (DTC) advertising for prescription drugs is generally prohibited, with the exception of vaccines.
- **Over-the-Counter (OTC) Drugs:**
  - DTC advertising is permitted but must undergo a preliminary review by the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA).

Advertising Approval Process:

- Advertisements for OTC drugs must be submitted to the KPBMA for review.
- The review ensures that the advertisement complies with the standards set by the MFDS and does not contain misleading or exaggerated claims.
- Upon approval, the advertisement can be disseminated to the public.

Sales Promotion Activities:

- Sales promotions involving medicinal products must comply with the guidelines set by the MFDS and the KFTC.
- Promotions should not include offers such as free gifts, discounts, or contests that could encourage inappropriate use of medicinal products.
- All promotional materials must be truthful, not misleading, and should not exaggerate the efficacy of the product.

Exemptions from Approval
Certain types of communications are exempt from prior approval requirements:

- **Professional Communications:** Materials directed exclusively at healthcare professionals, such as practitioners, pharmacists, nurses, and midwives, are exempt. These materials are considered educational pieces and not advertisements. This exemption is rooted in the understanding that health care practioners possess the requisite expertise to critically assess medical information, thereby reducing the risk of misleading interpretations.
- **Trade Advertisements:** Catalogues or price lists intended for wholesale supply that do not contain product recommendations are exempt.

Prohibited Content in Advertisements and Promotions
The MFDS prohibits advertisements and promotions that:

- Make false or misleading claims.
- Use unsubstantiated or exaggerated statements.
- Encourage inappropriate or excessive use of medicinal products.
- Suggest guaranteed results without side effects.
- Include endorsements by healthcare professionals or public authorities.
- Use the names or logos of regulatory bodies without permission.
- Offer refunds or suggest that the product can cure serious diseases such as cancer, diabetes, or tuberculosis.

These restrictions aim to ensure that promotional activities do not mislead consumers or encourage misuse of medicinal products.

Educational Materials
Providing non-promotional, factual, and educational information about diseases and treatment options is permitted. Such materials should:

- Be accurate and balanced.
- Not promote specific products.
- Avoid language that encourages consumer demand.

Materials that indirectly promote a product or encourage its sale are considered advertisements and must comply with relevant advertising laws.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
The Korean Research-based Pharmaceutical Industry Association (KRPIA) continues to uphold the Fair Competition Code and Working Guideline, with the most recent comprehensive revision completed in 2017.

While there have been no major overhauls since 2017, KRPIA has issued periodic updates and clarifications to address emerging ethical considerations and to reinforce compliance among its member companies.

With regards to upcoming changes to the codes of conduct, KRPIA has not publicly announced any imminent changes. However, the association remains engaged with global industry trends and continues to monitor developments that may necessitate future revisions.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?
Promotional activity is characterized by the intent to promote the sale or utilization of a medicinal product. Conversely, the provision of information refers to the dissemination of factual, balanced, and non-promotional content intended to educate or raise awareness among healthcare professionals or the public.

How is a media event defined?
Media events, commonly referred to as a press conference, is an orchestrated occasion designed to disseminate information to the media and, by extension, the public. These events are typically convened by corporations, governmental bodies, or public figures to announce significant developments, address pressing issues, or manage public relations. However, in the case of prescription drugs, the target shall be professional journals.

Cultural Considerations:
South Korea's high-context communication culture places significant emphasis on non-verbal cues, hierarchy, and formality. As such, media events are meticulously planned, with attention to protocol, setting, and the hierarchical status of participants. The choice of venue, the order of speakers, and the manner of presentation are all carefully considered to align with cultural expectations and to convey the desired message effectively.

Do the regulations differentiate between consumer and clinical publications?
Yes, the regulations differentiate between print and broadcast media. However, the overarching principles governing the promotion of medicinal products remain consistent across all media types.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
There are no explicit regulations that exclusively govern press releases, media releases and company events. The general materials, companies must ensure that:

- **Accuracy and Truthfulness:** All information disseminated must be accurate, substantiated, and not misleading.
- **Protection of Vulnerable Groups:** Content should be appropriate for all audiences and must not exploit or mislead vulnerable populations, including children.
- **Avoidance of Offensive Content:** Materials must not contain content that could incite racial, religious, or social disharmony.
- **Scientific Substantiation:** Any scientific data presented should be based on credible evidence and, where applicable, approved by the MFDS.
- **Non-Promotional Nature:** For prescription-only medicines, communications should not be promotional in nature when directed to the general public.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
All distribution channels are subjected to the same regulatory standards as seen above.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?

The regulations that govern the press activity are:

- Pharmaceutical Affairs Act (PAA).
- Fair Labelling and Advertising Act (FLAA).
- Voluntary Code on Labelling and Advertising for Drugs.

These regulations collectively ensure that press activities adhere to ethical standards and do not mislead healthcare professionals or the public.

The regulations that govern the press activity for drugs are as follows:

- **Approved Drugs:** Press materials related to approved drugs must be accurate, balanced, and not misleading. They should not exaggerate the benefits or downplay the risks associated with the product.
- **Unapproved/Investigational Drugs:**
  - Information dissemination and promotion is restricted.
  - Any communication should be non-promotional and intended solely for scientific exchange among healthcare professionals.
  - Use of brand names is discouraged; instead, the chemical or generic name should be used.
  - For investigational drugs, information shared during congresses or scientific meetings should be factual, non-promotional, and supported by scientific evidence.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company's regulatory procedure? Is it different for a freelance journalist?

If the journalist is from a publication, any content produced will be governed by the editorial policies and review processes of their respective publications. The sponsoring company does not have the authority to review, edit or approve the content prior to publication.

In the case of a freelance journalist publishing on their platform, the work remains independent. However, if the article is commissioned or submitted to a publication, it will be subjected to that publication' editorial review prior to release.

For ethical considerations, accepting gifts or incentives in exchange for favourable coverage Is considered unethical and is discouraged.

Do regulations cover the use of case studies or other third-party advocacy in the media?

No. However, it is highly recommended to use credible or renowned case studies or advocates. Obscure case studies and advocates should be avoided.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

Yes. While all forms of media in South Korea are subject to overarching legislation such as the 'Broadcasting Act', which ensures content accuracy and serves the public interest, online media are also governed by additional laws tailored specifically to the digital environment.

Chief among these is the 'Network Act', which addresses the unique challenges posed by digital content dissemination. It includes provisions targeting the distribution of illegal material, cyber defamation, and the protection of personal information online.

The Korea Communications Standards Commission (KCSC) is the key regulatory body overseeing content across all media platforms, including the internet. It plays a central role in monitoring and managing online content to prevent the spread of harmful or unlawful information.

These regulatory frameworks aim to strike a balance between safeguarding freedom of expression and protecting users from harmful or illegal content in an increasingly fast-paced and complex digital landscape.

Given the expansive scope of online content, there is an emphasis on self-regulation among online content providers. Major internet service providers and platforms often establish internal guidelines and monitoring systems to ensure compliance with national regulations and to address user concerns proactively.

What are the web security and data privacy requirements?

Web security and data privacy are governed by the Personal Information Protection Act (PIPA) and enforced by the Personal Information Protection Commission (PIPC).

Web Security:
Under PIPA, organizations processing personal data must implement robust technical, administrative, and physical safeguards to prevent unauthorized access, loss, or leakage of personal information. Key requirements include:

- **Encryption:** Personal data must be encrypted during storage and transmission. For instance, passwords should be encrypted using methods like adding a salt value during one-way encryption to defend against attacks.
- **Access Controls:** Implementation of access control systems to prevent unauthorized access to personal data.
- **Audit Logs:** Maintenance of access and operation logs to monitor data handling activities.
- **Malware Protection:** Installation and regular updating of security programs to prevent malware and hacking attacks.
- **Internal Management Plans:** Establishment of internal policies and procedures for the safe handling of personal information.

Personal Data Privacy:
PIPA outlines strict obligations for the collection, use, and disclosure of personal data:

- **Consent**: Organizations must obtain explicit consent from individuals before collecting or processing their personal data.
- **Purpose Limitation:** Personal data should be collected for specific, legitimate purposes and not used beyond those purposes.
- **Data Minimization:** Only the minimum necessary personal data should be collected and retained.
- **Retention and Deletion:** Personal data must be destroyed without delay once the purpose of collection is achieved.
- **Rights of Data Subjects:** Individuals have rights to access, correct, delete, and request the cessation of processing of their personal data.

In the event of a data breach, organisations must:

- **Notify Authorities:** Organizations must report the breach to the PIPC within 72 hours if it affects 1,000 or more individuals, involves sensitive information, or results from illegal external access.
- **Notify Individuals:** Affected individuals must also be informed within 72 hours, regardless of the number of people impacted.

Do the regulations cover funding of, or provision of information to, non-company owned websites?

There are no specific regulations, but all websites must abide by existing laws and guidelines that ensure transparency, legality and ethical standards.

The laws are as follows:

- **Advertising and Sponsorship Transparency**
  The Act on Fair Labeling and Advertising mandates that all advertisements, including those disseminated through third-party platforms, must be truthful and not misleading. This applies to sponsored content on non-company websites, where the sponsoring entity must ensure that the nature of the sponsorship is clearly disclosed to prevent deceptive practices. Failure to do so can result in penalties imposed by the Korea Fair Trade Commission (KFTC).
- **Financial Transactions and Anti-Corruption Measures**
  Financial contributions or sponsorships provided to non-company owned websites must comply with the Act on Prohibition of Improper Solicitation and Graft, which prohibits unlawful solicitation and acceptance of money or valuables in connection with one's duties. Companies must ensure that any funding provided is not construed as an attempt to unduly influence the content or operations of the recipient website.
- **Data Privacy and Protection**
  When providing information to non-company websites, especially if it involves personal data, organizations must adhere to the Personal Information Protection Act (PIPA). This includes obtaining proper consent for data collection and ensuring that data is handled securely and used only for its intended purpose.
- **Self-Regulatory Codes and Industry Guidelines**
  The Korea Communications Commission (KCC) has established self-regulatory codes, such as the Guidelines for Protection of Personal Information in Online Behavioral Advertising, which, while not legally binding, set standards for ethical conduct in online advertising and information dissemination. Companies engaging with non-company websites are encouraged to follow these guidelines to maintain public trust and avoid regulatory scrutiny.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
For mobile messaging apps, KakaoTalk ranks at the top, with 48.34 million monthly active users, equating to 93.4% of the population.

For social media networking apps, YouTube ranks at the top, with 44.3 million users, followed by Instagram with 23.4 million users and lastly X (Twitter) with 10.4 million users in South Korea.

Restrictions on Biopharma Promotion and Advertising via Social Media:
- **Prescription-Only Medicines (POMs):** Advertising of POMs directly to the general public is prohibited. Promotional activities must be directed exclusively towards healthcare professionals.
- **Disease Awareness Campaigns:** While disease awareness campaigns are permitted, they must not reference specific products or suggest that a particular product is the only or best treatment option.
- **Social Media Content:** The Korea Pharmaceutical Manufacturers Association (KPMA) emphasizes that promotional content on social media must be accurate, not misleading, and comply with existing regulations. Companies are responsible for ensuring that content shared on their official social media channels adheres to these standards.
- **Third-Party Endorsements:** Utilizing third-party endorsements or testimonials in social media promotions is subject to strict scrutiny. Such content must not mislead the public regarding the efficacy or safety of a product.

Enforcement and Compliance:
The Ministry of Food and Drug Safety (MFDS) and the Korea Fair Trade Commission (KFTC) are the primary regulatory bodies overseeing pharmaceutical advertising. Non-compliance with advertising regulations can result in penalties, including fines and suspension of product licenses.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
While South Korea does not have any social media specific laws, the existing legal framework applies to digital platforms.

Regulatory Framework:
- **Pharmaceutical Affairs Act (PAA):** The PAA regulates the advertising of medicinal products, prohibiting direct-to-consumer (DTC) advertising of prescription-only medicines (POMs), except for vaccines. This prohibition extends to all media, including social media platforms.
- **Fair Labelling and Advertising Act (FLAA):** The FLAA ensures that all advertisements, regardless of the medium, are not false or misleading. This includes promotional content disseminated via social media.

Self-Regulatory Guidance:
The Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) has established a Code of Practice that, while not legally binding, provides detailed guidance on ethical conduct in the marketing and promotion of medicinal products, including the use of social media.

Key principles from the KPBMA Code include:
- **Transparency and Accuracy:** All information shared on social media must be truthful, not misleading, and comply with applicable laws and regulations.
- **Prohibition of Unregistered Products or Indications:** Content must not relate to unregistered products or indications.

- **Avoidance of Inappropriate Content:** Posts must not contain content that is inappropriate or does not conform to community standards of ethics and good taste.
- **No Patient Testimonials or HCP Endorsements:** Content must not include patient testimonials or healthcare professional endorsements that may be viewed or accessed by the general public.
- **Monitoring User-Generated Content:** User-generated posts on company-owned social media pages that do not comply with the above should be removed promptly upon discovery.
- **Employee Conduct:** Company employees or agents active on social media in relation to prescription medicines must identify themselves as such and ensure their content complies with the Code.
- **Personal Use of Social Media:** Personal social media activity by company employees that references their employer's interests may be perceived as advertising or promotion of a product. Such activity must be accurate, truthful, and comply with the Code, regardless of disclaimers stating that the views expressed are personal.

Are there any self-imposed regulations from social media companies?
Social media platforms each have their own implemented regulation to govern content moderation, user safety and compliance with existing laws. For instance, Facebook prohibits content posing genuine risks to public safety, including threats of physical harm. The platform may remove sensitive content or restrict its audience to balance the needs and safety of its diverse user base. YouTube has guidelines against threats, harassment, and hate speech. Channels repeatedly violating these policies may face demonetization or termination.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Although there are no specific regulations targeting customer and company interactions on digital forums in South Korea, existing laws and encouraged self-regulatory practices provide a framework to ensure these interactions are conducted ethically and fairly.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2024, smartphone penetration in South Korea reached 95.3% across all age groups. Notably, adoption among individuals aged 60 and above surged, with a 12.7 percentage point increase, reaching 60.7% in 2024.

General regulations for promotion of medical products apply.

What are the disclosure laws like in your region for non-branded websites?
There are no specific disclosure laws in South Korea but pharmaceutical companies' websites must adhere to general advertising and pharmaceutical regulations to ensure compliance and ethical standards.

If the website wants to solicit for donations, they must comply with the Act on Collection and Use of Donations. This act requires that entities collecting donations register with the appropriate authorities, such as the Ministry of the Interior and Safety or local governments, depending on the scope of their activities. Failure to register may result in penalties and the prohibition of fundraising activities.

What are the requirements for adverse event reporting?
The Korea Adverse Event Reporting System (KAERS) is a system developed by the Korea Institute of Drug Safety & Risk Management (KIDS) and co-governed by the Ministry of Food and Drug Safety (MFDS) . The regulatory framework mandates both voluntary and compulsory reporting mechanisms, depending on the nature and severity of the adverse event. Reports can be submitted by healthcare professionals, consumers and marketing authorisation holders (MAHs). MAHs are required to report both domestic and international Individual Case Safety Reports (ICSRs) to KAERS.

Reporting guidelines for adverse effects:
- **Reporting Criteria:** Adverse events that are serious, unexpected, or associated with new drugs under re-examination must be reported. Serious adverse events include those resulting in death, life-threatening conditions, hospitalization, disability, or congenital anomalies.
- **Reporting Timelines:** Serious adverse events must be reported within 15 days of awareness. Other AEs should be reported within 30 days.
- **Reporting Format:** Since June 2021, the MFDS mandates the use of the E2B (R3) format for electronic transmission of ICSRs, aligning with international standard.

Reporting guidelines for medical devices:
- **Reporting Obligations:** Manufacturers, importers, and distributors are required to report adverse events associated with medical devices. Events that result in death, serious injury, or require medical intervention must be reported.
- **Reporting Timelines:**
  - **Within 7 days:** If the event leads to death or life-threatening conditions.
  - **Within 15 days:** If the event necessitates hospitalization or prolongs existing hospitalization.
  - **Within 30 days:** For other significant events not covered above.
- **Reporting Process:** Adverse events should be reported to the MFDS through the designated channels. The National Institute of Medical Device Safety Information (NIDS) assists in the collection and analysis of these reports.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?

When sponsoring travel for members of advocacy or patient groups to attend international congresses or meetings, pharmaceutical companies must ensure that:

- The event has a clear scientific or educational purpose.
- The hospitality provided is strictly limited to travel, meals, accommodation, and registration fees.
- The level of hospitality is reasonable and does not exceed what the recipients would normally be prepared to pay for themselves.
- There are no accompanying entertainment or leisure activities that could be perceived as inducements.
- All support is disclosed appropriately, maintaining transparency.

These guidelines are in place to prevent any undue influence on advocacy or patient groups and to maintain the integrity of their contributions to healthcare discussions and policy-making.

Is it possible to offer honoraria for healthcare professionals, advocacy organisations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?

Public Sector Healthcare Professionals

Healthcare professionals (HCPs) employed in the public sector, including those working in government hospitals or institutions, are generally prohibited from accepting honoraria or any form of compensation for participation in media activities or events. This restriction is in place to prevent conflicts of interest and maintain the integrity of public service.

Private Sector Healthcare Professionals

For HCPs operating in the private sector, offering honoraria is permissible under certain conditions. The compensation must be:

- **Reasonable and Proportionate:** The amount should reflect the fair market value of the services provided. However, the amount shall be determined in accordance with the Act on the Prohibition of Improper Solicitation and Receipt of Money and Valuables, as well as the guidelines of KRPIA or KPBMA.
- **Transparent:** All payments should be documented and disclosed in accordance with applicable laws and industry codes.
- **Not Influential:** The honorarium should not serve as an inducement to recommend, prescribe, or promote any medicinal product.

Advocacy Organizations and Other Third Parties

Providing honoraria or covering expenses for advocacy groups or other third parties is allowed, provided that:

- **Purpose:** The support is for legitimate, educational, or scientific purposes.
- **Transparency:** All arrangements are transparent and do not create a perception of undue influence.
- **Compliance:** The support complies with the relevant laws and industry codes.

Travel and Other Expenses

Reimbursement of travel and related expenses is permissible under the following conditions:

- **Direct Relevance:** The expenses are directly related to the event or activity in question.
- **Reasonableness:** Costs are reasonable and not extravagant.
- **Documentation:** All expenses are properly documented and reported.

However, certain categories of travel and expenses are disallowed, including:

- **Leisure Activities:** Expenses related to entertainment or leisure activities not directly associated with the professional event.
- **Accompanying Persons:** Costs for spouses or guests accompanying the HCP or third party, unless they are also participating in the event in a professional capacity.
- **Luxury Accommodations:** Use of luxury accommodations or first-class travel that exceeds what is necessary and reasonable.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

Same as response above.

What is possible in terms of media or message training for health professionals or advocacy organisations?

In South Korea, while there are no specific legal mandates requiring media or message training for healthcare professionals (HCPs) or advocacy organisations, it is considered best practice for health professionals or individuals representing advocacy organisations in public forums to undergo media training.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

There materials produced are subjected to the general legal framework under the Pharmaceutical Affairs Act (PAA) and the Fair Labelling and Advertising Act (FLAA), which is regulated by the Ministry of Food and Drug Safety (MFDS).

The Korean Research-based Pharmaceutical Industry Association (KRPIA) has established a Voluntary Code on Labelling and Advertising for Drugs, which its member companies are expected to follow. This code reinforces the principle that all promotional materials, including those produced by third parties, should be factual, evidence-based, and not misleading.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?

Interactions are subjected to the general legal framework which comprises the Pharmaceutical Affairs Act (PAA) and the Fair Labelling and Advertising Act (FLAA), both enforced by the Ministry of Food and Drug Safety (MFDS).

KEY TAKEAWAYS/ SUMMARY

Medicinal Products

- **Advertising Regulations:** In South Korea, the advertising of medicinal products is governed by the Pharmaceutical Affairs Act (PAA) and the Fair Labelling and Advertising Act (FLAA). All advertisements must be truthful, accurate, and substantiated with scientific data. The use of fear or superstition in advertising is prohibited. Direct-to-consumer (DTC) advertising for prescription drugs is generally prohibited, except for certain vaccines. Online and social media advertising are subject to the same regulations as traditional media.
- **Post-Marketing Surveillance:** The Ministry of Food and Drug Safety (MFDS) conducts post-marketing surveillance, including regular compliance checks, product sampling, and monitoring of adverse drug reactions (ADRs) to ensure ongoing safety, quality, and efficacy of medicinal products.
- **Media Engagement:** When engaging with the media, brand names are typically avoided unless essential to the context. The chemical compound name of the medicine is preferred, including during product launches. However, in the case of professional publications targeting healthcare professionals, brand names may be disclosed.
- **Adverse Event Reporting:** Healthcare professionals and consumers are encouraged to report any suspected adverse events associated with medicinal products to the MFDS. Reporting does not necessarily establish a causal relationship between the product and the event.
- **Honoraria and Payments:** Healthcare professionals employed in the public sector are generally prohibited from accepting honoraria or payments for participation in media activities or events. For private sector professionals, such arrangements are subject to mutual agreement, provided they comply with relevant laws and ethical guidelines.

Medical devices

- **Risk Classification:** Medical devices in South Korea are classified into four risk classes – Class I to Class IV – with Class I representing the lowest risk. This classification is based on factors such as the intended use of the device, its operational mechanisms, the user, and the technology involved.
- **Registration Requirements:** All medical devices must be registered with the MFDS before they can be marketed, except for certain Class I devices, which may be exempted. The registration process ensures that devices meet regulatory standards for safety and efficacy.
- **Advertising Regulations:** Advertisements for medical devices must comply with the Medical Device Act and the FLAA. Advertising that references certain serious medical conditions, such as cancer or diabetes, is prohibited unless the device is intended for use by qualified practitioners and the advertisement is directed exclusively to them.
- **Definition of Advertisement:** An "advertisement" encompasses any activity intended to promote the sale or use of a medical device, including but not limited to publications in newspapers or journals, posters, brochures, letters, photographs, films, broadcasts, internet content, public demonstrations, trials, door-to-door sales, exhibitions, and competitions.
- **Advertising Prohibitions:** Advertising of medical devices intended solely for professional use is restricted to publications or communications directed at qualified practitioners. Public advertisements claiming that a device can prevent, alleviate, or cure specific serious diseases or conditions are prohibited.

Comparative advertisements are allowed only if scientifically proven and should not unfairly criticize other products. Advertisements should not encourage indiscriminate or excessive use and must not exploit public ignorance through unverifiable scientific data or misused research results.

TAIWAN

The promotion of medicines in Taiwan is primarily regulated under the Pharmaceutical Affairs Act, with enforcement carried out by the Taiwan Food and Drug Administration (TFDA) under the Ministry of Health. PreMA has issued its Code of Practice for the Ethical Channel written both in English and Thai to guide all members on how to comply with local regulations.

In addition, the National Drug System Development Committee (NDSDC) of the Ministry of Public Health is responsible for establishing ethical criteria on Thai medicinal drug promotion for all stakeholders. The promotion of prescription drugs must be conducted only to healthcare professionals, as direct promotion to the consumer (DTC) is not allowed.

THE BASICS

What laws and codes of practice govern the promotion of medicines?

The Drug Act of 1967 is still in effect with many revisions. The most relevant part is Chapter XI, Advertisement, which has been amended five times. The definition of an advertisement from The Consumer Protection Act B.E. 2522 (1979) is any act which, by whatever means, causes the statement to be seen or known by ordinary person for trading purposes.' Advertising Media means 'a thing such as newspaper, printed matter, radio, television, post and telegram, telephone or sign board.

Under the Act:

- Pharmaceuticals are substances used for diagnosing, treating, alleviating, or preventing human diseases or influencing body structure and physiological functions.
- Medical devices include instruments and tools intended for diagnosing, treating, alleviating, or preventing human diseases, regulating fertility, or affecting the human body structure or function without pharmacological, immunological, or metabolic means.

Manufacturing or importing drugs requires applying to the Taiwan Food and Drug Administration (TFDA) under the MOHW for product registration. Upon approval, a drug license is issued.

Applications must follow the "Regulations for Registration of Medicinal Products" and adopt the Common Technical Document (CTD) format. Products approved by the U.S. FDA, EU EMA, or Japan MHLW may undergo streamlined reviews with reduced timelines. Priority review and accelerated approval mechanisms are also available.

Additionally, the International Research-Based Pharmaceutical Manufacturers Association (IRPMA), a collaborative group of pharmaceutical companies, has developed marketing standards for its members. These standards are publicly accessible (e.g., IRPMA Code).

With respect to marketing, how do regulators define public relations compared to advertising or other promotional activities?

Regulators in Taiwan generally classify any content involving the following as "advertising":

- Promoting medical efficacy with the intent to attract sales.
- Referencing product names or efficacy to guide consumer purchases.

Activities meeting these criteria are considered "educational promotion" rather than advertising:

- Aimed at health promotion or disease prevention, sharing medical knowledge or research.
- Avoiding specific product names or claims.
- Excluding solicitation for medical services.
- Clearly separating from adjacent advertisements to prevent consumer confusion.

Educational promotions can utilize various channels, including television, print, posters, and online media, provided they adhere to these distinctions.

Who is responsible for the enforcement of these rules?

The public can report issues with healthcare-related advertisements to the MOHW or local health bureaus, providing evidence such as advertising content. Upon investigation and verification, violators may face penalties, escalating fines, or, in severe cases, license revocation for products or medical devices.

Do any promotional or media materials need to be approved by regulatory authorities?
Pharmaceutical advertisements must obtain prior approval from the central or local health authority before publication. Content cannot:

- Misuse another's name for promotion.
- Guarantee efficacy through literature or testimonials.
- Employ interviews or reports for promotional purposes.

Prescription drug advertisements are limited to academic medical journals and are prohibited in public-facing media.

Changes to approved advertising content during the authorized publication period are not permitted. Regulatory authorities may order immediate cessation and require rectification if the content poses risks to public health.

Educational promotions by healthcare institutions or third parties are exempt from these pre-approval requirements but must comply with ethical standards.

Over the past 5 years, what significant developments in regulations have been implemented? Are there any changes to codes of conduct planned in the near future?
Taiwan's "Pharmaceutical Affairs Act" underwent revisions in 2018 and 2019, enhancing drug safety, import/export controls, and new drug regulations to improve traceability. Future updates will align with announcements from regulatory authorities.

THE MEDIA

What is defined as promotional activity as opposed to the provision of information?

- **Promotional activities:** Focus on product/service introductions, purchase channels, and actions (e.g., buying or trial usage).
- **Provision of Information:** Centers on raising awareness and sharing accurate perspectives on a topic. (e.g., disease symptom education).

How is a media event defined?
Media events/activities aim to convey messages to journalists and often include interaction opportunities. Common examples include press conferences, media luncheons, and guided tours.

Do the regulations differentiate between consumer and clinical publications?
The "Pharmaceutical Affairs Act" does not distinctly regulate consumer (e.g., mainstream media) versus clinical publications (e.g., medical journals). Promotional content must adhere to the law, and prescription drug advertisements are restricted to academic publications.

Do regulations differentiate between online, print, broadcast and/or streaming media?
The "Pharmaceutical Affairs Act" recognizes various dissemination channels. Regardless of the medium, drug advertisements require TFDA review and must avoid misleading or exaggerated claims.

What regulations specifically cover press releases, media materials and company events? What are the general principles?
Taiwan has no specific law solely governing press releases or media materials. However, general principles from laws like the "Pharmaceutical Affairs Act" and "Broadcasting and Television Act" apply:

- **Fact-checking:** Ensure accuracy to avoid misinformation.
- **Social responsibility:** Protect public welfare, including minors' well-being, and uphold societal ethics.

What regulations govern press activity at congresses and scientific meetings, such as conducting media outreach, holding a symposium, or sponsoring media to attend? Do the same regulations apply to both approved drugs and unapproved/investigational drugs equally?
No explicit regulations exist for conference-related media activities. However, promotional content for approved or investigational drugs must align with scientific evidence and TFDA guidelines.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Publishing patient or medical information requires written consent under the "Personal Data Protection Act." Drug promotions must maintain accuracy and avoid misleading claims as outlined by the "Pharmaceutical Affairs Act."

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?

- **Broadcast and television:** Governed by the National Communications Commission (NCC), requiring licenses and adherence to fairness and fact-checking standards.
- **Print media:** Overseen by the Ministry of Culture, ensuring compliance with general laws.
- **Online platforms:** Largely self-regulated but subject to general laws, particularly regarding accurate healthcare information.

What are the web security and data privacy requirements?
Data protection adheres to the "Personal Data Protection Act," emphasizing proportionality and transparency in collecting, using, and safeguarding personal information.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
No dedicated regulations apply, but general laws (including account principles) govern:

- Content integrity and copyright adherence.
- Compliance with donation and fundraising rules.

What are the most popular social networks in your region, and what restrictions (if any) are there on biopharma promotion and advertising via social media/promoted posts, beyond disease awareness content?
Widely used platforms include Facebook, YouTube, Instagram, and TikTok, with LINE dominating communication apps at a 90% adoption rate. Forums like Dcard and PTT are also popular.

While no specific laws exist for social media promotions, all public communications must comply with legal standards, ensuring content is truthful and non-misleading. Prescription drugs cannot be promoted publicly unless under educational promotion guidelines.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
There are no specific legal regulations governing pharmaceutical promotion on social media. However, all public pharmaceutical promotions must comply with legal requirements, ensuring that content does not contain exaggerated, false, or misleading information.

Pharmaceutical advertisements must be reviewed and approved by the Ministry of Health and Welfare. Prescription drugs cannot be promoted on public social networks unless they meet the criteria for educational promotion.

Are there any self-imposed regulations from social media companies?
Social media networks establish their own policies, which may vary by company and include public reporting mechanisms. For instance, Facebook has implemented a "Community Standards" policy, which prohibits the posting of content involving violence, crime, adult nudity, or misinformation.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
There are no known specific regulations, but general guidelines advise avoiding harm to others' reputations.

What is mobile adoption like in your region? Are there separate regulations for it?
In Taiwan, 98.4% of individuals aged 16 and older use mobile phones, with 95.8% of these phones having internet access.

There are no specific regulations for pharmaceutical promotion on mobile devices, but all activities must comply with existing legal requirements.

What are the disclosure laws like in your region for non-branded websites?
There are no specific laws, but the following related laws should be noted:

- **Content:** Website operators must ensure content does not infringe others' copyrights. Pharmaceutical promotions must comply with general legal provisions.
- **Sales:** Websites selling pharmaceuticals or medical devices must obtain approval from the Taiwan Food and Drug Administration (TFDA).
- **Fundraising:** Websites must apply for and obtain authorization from the competent authorities before conducting fundraising activities.
- **Data collection:** Websites collecting personal user information (e.g., name, contact details) must obtain user consent and implement appropriate protection measures.

What are the requirements for adverse event reporting?
If adverse reactions occur after using a drug or if defective products are found, users can report them through real-name registration to the original medical institution, the pharmacy where the drug was obtained, or via the internet or telephone to the TFDA's National Adverse Drug Reaction Reporting System.

According to the "Pharmaceutical Affairs Act," severe adverse drug reactions include:

- Death.
- Life-threatening conditions.
- Permanent disability.
- Congenital malformations in fetuses or infants.
- Hospitalization or extended hospital stays.
- Other injuries potentially causing permanent harm that require intervention.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Regulations depend on organizational policies and guidelines, such as those provided by IRPMA, emphasizing transparency and avoiding conflicts of interest. (e.g., IRPMA Code).

Is it possible to offer honoraria for healthcare professionals, advocacy organizations or other third parties for their participation in media activities and events? Is it possible to pay for their travel and other expenses? Is a particular category for travel disallowed?
In Taiwan, many hospitals are public, meaning that doctors in these hospitals have the status of civil servants. Special attention must be given to expense provisions for these doctors:

- **Business travel:** Must comply with the "Guidelines for Domestic Travel Expense Reimbursement" issued by the Directorate-General of Budget, Accounting, and Statistics. Expenses such as transportation and accommodation must be reimbursed based on actual costs incurred. Taxi fares are not reimbursable.
- **Lectures:** Must adhere to the "Civil Servant Integrity and Ethics Guidelines" issued by the Executive Yuan. For participation in private-sector lectures, the hourly remuneration cannot exceed NT$5,000. If the event is organized or invited by parties with a conflict of interest related to the doctor's duties, prior approval from a supervisor is required.

For medical professionals without civil servant status, there are no specific legal regulations. However, the general principles outlined by the "Guidelines of the Taiwan Medical Association" can be referred to. Doctors can accept travel expenses, meal allowances, or lecture fees, but must comply with rules governing the relationship between doctors and pharmaceutical companies, which emphasize transparency, avoiding conflicts of interest, and ensuring clinical decisions are made in the best interests of patients. Additionally, the International Research-Based Pharmaceutical Manufacturers Association (IRPMA) provides relevant guidelines for its member companies. According to the implementation details of its marketing code:

- **Compensation for healthcare professionals:** When inviting healthcare professionals to serve as speakers, moderators, chairs, panelists, or consultants in forums, advisory committees, workshops, seminars, or similar events, remuneration is capped at NT$5,000 per hour (including preparation or discussion time). For periods under 30 minutes, compensation is calculated as half an hour; for periods under 60 minutes, as one hour.
- **Conference moderators/chairs:** Compensation is capped at NT$10,000 per session..
- **Panelists/discussion group members:** Compensation is capped at NT$10,000 per session.
- **When a speaker simultaneously serves as the moderator, chairperson, panelist, or consultant at the same event and venue,** additional remuneration is capped at NT$10,000.
- **The number of moderators/chairs must not exceed the number of speakers.** The ratio of moderators/chairs and speakers to participants must be appropriately balanced. In principle, the number of moderators/chairs should be kept to the minimum required. Moderators/chairs must actively facilitate discussions rather than merely introducing speakers. (International speakers/consultants may be compensated according to international conventions.)

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, as mentioned above.

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for healthcare professionals organized or sponsored by a company should be to provide scientific or educational information and/or to inform healthcare professionals about products.

What is possible in terms of media or message training for health professionals or advocacy organizations?
Media training is commonly arranged by companies or outsourced to agencies. Collaboration with seasoned journalists is also prevalent.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organizations?
No specific regulations exist, but promotional content must adhere to general laws governing advertising.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
No specific regulations apply, though promotional and advertising activities must comply with legal standards.

KEY TAKEAWAYS/ SUMMARY

- Pharmaceutical advertisements and endorsements require MOHW or local health authority approval.
- Educational content must be professional, avoid product names, and prioritize knowledge sharing.
- Transparency and compliance with IRPMA guidelines are critical for ethical practices in marketing and stakeholder engagement.
- Written consent is mandatory for patient testimonials or case studies.

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