THE AMERICAS

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The Global Guide to
Pharma Marketing Codes
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This unique guide was produced with the insight and expertise of the largest independent public relations group dedicated exclusively to health and medical communications worldwide.

CONTENTS

AMERICAS

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 behaviour of those involved in the promotion of medicines. GLOBALHealthPR cannot accept responsibility for any breach of Codes of Practice or statutes that may result from following the advice or guidance in this document.

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 teams 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 effect 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.

A recent law passed by the City of Buenos Aires (Law 5709) '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 heathcare 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' (6.8). 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 the 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.

What promotional or media materials must be approved by 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 authorisation' system was repealed, so pieces are monitored and evaluated once they are issued. Also, any communication with medical professionals or pharmacists related to prescription-only medicines to be published in print or broadcast media needs approval from the programme mentioned above.

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 most recent development is Resolution No. 627/2007, 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.

THE MEDIA

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

In broadcasting, promotional activity or advertisement 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.4980/05 defines advertising as 'an organised 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 organisations in such a way that exhibits a direct or indirect commercial aim (Section 3, Decree 286/81). Nevertheless, there is no clear line between promotional activities and what is usually presented as 'provision of information' for educational purposes. Promotional activity to medical professionals, according to Resolution No. 627/2007, 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 Resolution 6516 of 2015, manufacturers of prescription-only medicines must notify ANMAT 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 Resolution applied to OTC products, but Resolution 9660 in 2016 invalidated notification in the products. (http://www.anmat.gov.ar/boletin_anmat/BO/Disposicion_9660-2016.pdf)

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. 627/2007 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 including CDs, DVDs or memory sticks. 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-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
Both the CAEMe Ethical Code and Resolution No. 627/2007, Section 3, forbid the promotion of a medication that has not been approved by ANMAT for its commercialisation.

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 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 or media materials, nor media attending clinical events.

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 reference is made to the distribution of press releases and media materials.

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 licenced and non-licenced products 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 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 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. 627/2007 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 organisations (NGOs) supported by scientific institutions and professional groups usually have a process of monitoring such websites to evaluate quality and assess if they fulfil 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?

Social media has achieved widespread penetration in Argentina: as of 2018 it is estimated that 70% of the population (31 million) are active users who, on average, spend three and a half hours a day on social media sites or apps. YouTube and Facebook are the most popular channels. In Argentina, it is estimated that 68% of active Facebook users connect daily. Regarding the number of followers, Twitter ranks third, slightly above Instagram, which has experienced strong growth in recent years.

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

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 costumers, must respect ANMAT Disposition No. 4980/05. These interactions can never involve the commerce of medicines.

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 authorised only by prescription'.

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%. The main use of mobile is for instant messaging (WhatsApp and Facebook messenger).

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 is the response level needed for adverse event reporting?

Resolution 706/93 of the Ministry of Health implemented the National Pharmaco Surveillance System, a formal mechanism that bases its work on spontaneous, voluntary and confidential reporting of adverse reactions by health professionals. The Pharmaco Surveillance System depends upon the National Direction of Medical Evaluation (DEM). 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

regards 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 Organisation (WHO), located in Uppsala, Sweden.
The release of information is a key activity for the maintenance of the Pharmaco Surveillance 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 Pharmaco Surveillance 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 stablished in Disposition 5358/12. Those reactions that are not classified as serious or unexpected must be periodically communicated, always indicating that events are reported in Argentina.

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.

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?

There are no regulations regarding honoraria for healthcare professionals or advocacy organisations 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 organise 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 organisations?

There are no specific rules.

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

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 $500 million U.S., in which the share of that market is 69.5% for national companies and 30.5% foreign. The two companies that lead the local market are from Argentina and were founded more than 70 years ago as family businesses (Laboratorio Roemmers and Laboratorios Bagó). They also have an established presence in several other countries but are focused mainly in Latin America. Unlike other Latin American countries, the local pharmaceutical industry in Argentina has shown an important growth during the last 10 years with the introduction of technology. The industry mainly develops with local technology news and innovative pharmaceutical forms, some of which are also licenced 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 are gathered in Argentina are members of several chambers:

- Argentine Chamber of Medical Specialties (CAEME): gathers international companies. See http://www.caeme.org.ar.
- Industrial Chamber of Argentinean Pharmaceutical Laboratories (CILFA): includes main national pharmaceutical companies. See http://www.cilfa.org.ar/.
- Business Chamber of Pharmaceutical Laboratories (COOPERALA): includes national pharmaceutical companies. See http://www.cooperala.com.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: Argentinean Chamber of Generic Drugs and Hospital Drug use manufacturers. See: http://www.capgen.org.ar/

Social Security services are represented by Obras Sociales and medicine plans that provide affiliates with a discount in the purchase of medicines, medical attention and diagnostics that by law (Plan Médico Obligatorio, PMO) cannot be less than 40 percent. PAMI is the National Social Security System for retired people who are older than 65 years and plays a key role in the local market. The Argentinean public health system provides free medical assistance in public hospitals and free distribution of certain medicines for people not affiliated to social security services. The Programme REMEDIAR freely distributes ambulatory medicines in Prime Care Health Public Centers.

Different actors are now discussing the need of having a medical technology assessment agency. The project is already being discussed in Parliament and the new agency is expected to be functioning in Argentina in the next two years.

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 a 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. In general, their prices are lower as they do not have to deal with the cost of large structures.

Since 2002, Prescription of Medicines by Generic Name, Law No. 25.649, states that every medical prescription must be written expressing first the generic name of the drug, 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.

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 specialised 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 engagement by pharmaceutical companies? How are these regulations enforced?

Engagement with HCPs is strictly regulated by the ANVISA code prohibiting promotion of prescription medicines. As mentioned, HCPs cannot be provided with any branded materials, even while at medical conferences. As such, it is very difficult to establish effective partnerships with the HCP community.

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. Denouncements 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 exclusive 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-licence 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 or 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 the 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 licenced and non-licenced 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. Neither must they submit their reports either to the regulating agency or to 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 favourable or unfavourable, 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?
In Brazil the most popular networks are Facebook, Twitter and LinkedIn. There are many bloggers in beauty, cosmetics and healthcare and quality of life that comment on these subjects openly.

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 from social media companies?
There are no specific self-regulations from social media companies related to healthcare beyond their general terms of service.

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 2017, there were 242 million mobile phones in Brazil. However, there are not specific regulations for mobile devices.

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 organisations 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 denouncements.

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 organisations (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 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?

In Brazil, it is not common and not advisable to offer fees for physicians and patients to meet with the press. It is allowed, though, to pay a fee for physicians if they participate in media trainings for journalists or lectures, workshops and courses for other healthcare professionals.

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

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 organisations?

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 organisations?

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.

THE BASICS

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

- **The Food and Drugs Act and Regulations:** An act of the Parliament of Canada regarding the production, import, export, transport across provinces, and sale of food, drugs, contraceptive devices and cosmetics (including personal cleaning products such as soap and toothpaste). First passed in 1920 and most recently revised in 1985., the Act attempts to ensure that these products are safe, that their ingredients are disclosed and that drugs are effective and are not sold as food or cosmetics. It also states that cures for diseases listed in Schedule A (including cancer, obesity, anxiety, asthma, depression, appendicitis, and sexually transmitted diseases), cannot be advertised to the general public.
- **The Distinction between Advertising and Other Activities:** This policy was created by Health Canada to clarify the distinction between advertising to promote the sale of a drug and activities that are not primarily intended to promote the sale of a drug (e.g., education, scientific exchange, labelling, shareholder's report, etc.). This policy is NOT intended for use in determining whether or not the drug advertising provisions of the Food and Drugs Act and Regulations are observed.

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

There are numerous provisions within the Food and Drugs Act and Regulations that apply to drug advertising. In order to determine the applicability of those provisions it is first necessary to determine whether or not a particular message can be considered to be advertising. For the purposes of the Act, advertising is defined as including 'any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device'. If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the Food and Drugs Act and Regulations.

There is a particular need to distinguish between advertising and non-promotional information in the following situations:

Prior to market authorisation:

- Promotion of a drug prior to market authorization is not permitted (Section 9(1) of the Act, Section C.08 002 of the Regulations) because the terms of such authorization have not been established and the proposed indication(s) for use have not been verified.

After market authorisation when information on a drug is disseminated to the general public:

- Promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Regulations).
- A drug (prescription or nonprescription) may not be advertised to the general public for the treatment, prevention or cure for any Schedule A disease (Section 3 of the Act).

Who is responsible for the enforcement of these rules?

Health Canada is the federal department of the Government of Canada that is responsible for national public health. Health Canada is the national regulatory authority for health product advertisements.

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 programme 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 programme is directed to scientists and/or health professionals
- The programme 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, and
- No reference is made to the availability of unauthorized drugs through the Special Access Programme.

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 organisations 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?

Heath Canada receives concerns and complaints. When addressing advertising complaints, Health Canada's first priority is protecting the health and safety of Canadians. Health Canada's approach to addressing and resolving complaints uses the most appropriate level of intervention proportional to the health risk.

All complaints are treated with the same vigilance, whether Health Canada identifies a potential advertising issue itself, receives a complaint directly or is referred a complaint from an Advertising Preclearance Agency (APA). Each complaint is asked to confirm whether the advertisement complies with legislative and regulatory requirements and to determine the potential health risk posed. Health Canada prioritises and takes action to address complaints based on whether they pose a potential health risk and the degree of that risk.

Health Canada takes a staggered approach and will escalate measures if and as needed. In most cases, compliance is successfully achieved using a cooperative approach. This involves Health Canada informing the party of their non-compliance, usually through a compliance letter. The letter may request corrective action or discontinuation of the advertisement.

In general, for advertising activities considered to pose a low health risk to Canadians, the company is informed

of the non-compliance and asked to take the appropriate corrective measures. In cases where the health risk is higher, Health Canada follows up as needed to verify that the requested action has been completed to Health Canada's satisfaction.

Health Canada may consider stronger action for advertising activities determined to pose a high health risk. These actions could include seizing the non-compliant advertising materials, site visits, issuing a public communication, or initiating enforcement proceedings (e.g., seeking an injunction or fines where a court order has been breached), to minimize the potential health risk to Canadians. For complaints that involve the advertising of an unauthorised health product, Health Canada takes action to confirm that the company stops both the advertising and sale of the non-compliant health product in Canada, as the sale of unauthorised health products is not permitted.

What promotional or media materials must be pre-approved by authorities?

Materials developed by pharmaceutical manufacturers directed at Canadian healthcare professionals for the purpose of advertising or promoting a product to increase their awareness of that brand should be reviewed by the Pharmaceutical Advertising Advisory Board (PAAB).

Materials directed at consumers should be reviewed by Advertising Standards Canada (ASC), a national not-for-profit advertising self-regulatory body. Note: both PAAB and ASC approvals are voluntary. However, Health Canada strongly recommends that industry have their health product advertising material reviewed 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?

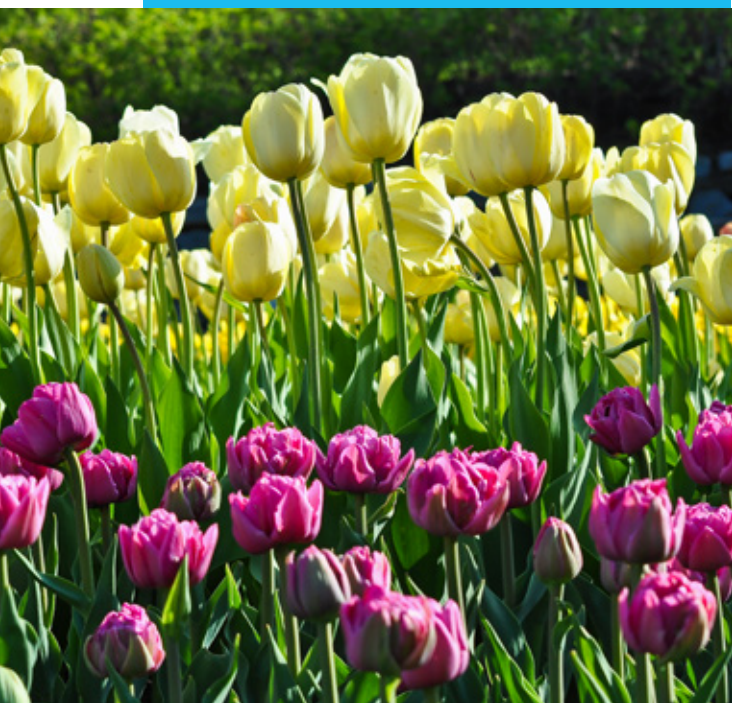
In early 2017, ASC issued new rules that will require full disclosure by sponsored bloggers and influencers of any paid endorsements or mentions of products and services. These new rules apply to bloggers and individuals who use social media--including Twitter, Instagram, Facebook and Snapchat.

THE MEDIA

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

To determine if a message is advertising, the purpose of the message is very significant. It must be determined whether the primary purpose of the message is to promote the sale of a drug or to provide information. When the primary purpose is not clear, the following factors should be considered in determining whether the message is primarily intended to promote the sale of a drug:

- What is the context in which the message is disseminated? For example, when and how is the message delivered? What is the milieu or medium of dissemination? Is it a science-based message delivered to scientists/healthcare professionals by an expert, e.g., researcher at a conference with a varied agenda, or is it a product-related message delivered to a



group of practicing physicians by the pharmaceutical manufacturers sales representative at a meeting with a limited agenda?

- Who are the primary and secondary audiences?
- For example, are the target audiences limited or unlimited in scope? Are the primary and the secondary audiences the same? Where they are different, the message to the secondary audience is more likely to be advertising.
- Who delivers the message (the provider)? e.g., the drug manufacturer/its agent or an independent third party (e.g., patient support group)? Where delivered by an independent party, the message is less likely to be considered as advertising.
- Who sponsors the message and how? Is it the drug manufacturer/its agent or an independent third party? is the sponsorship funding targeted to a specific message, or is it added to the general operating budget for an organisation, conference etc.? If the message is sponsored by an independent third party and the funding is added to the general operating budget, the message is less likely to be advertising. Where any fee is paid by the manufacturer to have the message disseminated, it is more likely to be advertising.
- What influence does a drug manufacturer have on the message content i,e, what are the linkages between the information, the provider and the manufacturer, the provider and the writer, etc.? Where the drug manufacturer exerts influence (e.g., preparing, editing) on the message content, it is more likely to be advertising.
- What is the content of the message? Are the facts described objectively in a balanced manner, or is emphasis placed n a particular drug or its merits? Is the message balanced with respect to description of risks as well as benefits of a treatment option? Can the message withstand a test for scientific rigour? Is the information set in an appropriate context, e.g., a discussion of disease management, scientific research?
- With what frequency is the message delivered? For example, is it delivered once or repeatedly? Where the same message is delivered repeatedly, the message is more likely to be considered as advertising.

No one factor in itself will determine whether or not a particular message is advertising. Each message must be evaluated on its own merit and other factors may apply. This clarification should assist in distinguishing between advertising and non-promotional information. It is only after having determined that the primary purpose of a message is advertising that an assessment can be made regarding compliance with the regulations pertaining to drug advertising.

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 Publications

Consumer brochures include leaflets/brochures that may make reference to, but do not accompany, a drug product,

and are made available directly or indirectly to the consumer by a drug manufacturer, or other organisation, by various means, e.g., by mail, in retail outlets, in health professionals waiting rooms, and so on.
Declaration of sponsorship of such a brochure by a drug manufacturer does not in itself render the information promotional. Consumer brochures may be considered non-promotional information in the following circumstances:

1. The content is disease related rather than product related
2. The various treatment options (drug and non-drug) and their respective
3. No emphasis is placed on one drug product, e.g., excessive use of a brand name or description of a product as a "breakthrough", and no emphasis is accorded to the merits of one drug product
4. No reference is made to an unauthorised drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained),
5. No reference is made to the availability of unauthorised drugs through the Special Access Programme.

Consumer brochures may be advertising when any of the aforementioned conditions are not met, or where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

- Consumer brochures also include leaflets/brochures that are not product-specific but expound on the pharmacological properties/actions of an ingredient, e.g., herb, vitamin, mineral, etc., and are made available in retail outlets selling products containing the same ingredients.

Such information packages may be considered to be advertising for a drug product when displayed in close proximity to or distributed with products containing the same ingredient, in the same retail outlet.

Clinical Publications
Journal supplements are usually comprised of a collection of articles that deal with related issues or topics, are published as a separate issue of the journal, or as a second part of a regular issue, and are funded by sources other than the journal publisher, e.g., by the pharmaceutical manufacturer
Where publication is sponsored, in whole or in part, by a drug manufacturer, it may be considered not a promotional activity in the following circumstances

- The content of the insert comprises unedited symposium proceedings that address a variety of issues relating to different disease entities or drug treatments
- The content of the insert reports on a variety of treatment approaches for the same medical condition, the publication is targeted to its customary readership
- No link is established between conventional advertising and the articles, e.g., by proximity, sponsorship by the pharmaceutical manufacturer is declared in such a way that there is no obvious link to a drug discussed
- The supplement is identified in such a way that it is distinct from the regular journal edition

In contrast, a journal supplement may be advertising where the aforementioned conditions are not met and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug, for example:

- the supplement, in whole or part, is disseminated by the sponsor rather than by the publisher of the journal itself, the publication or an article contained in it is edited by the sponsor, or
- a conventional advertisement is placed in close proximity to an article discussing an unauthorized use for the same chemical entity/drug product.

Do regulations differentiate between print and broadcast media?

No.

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

According to the Distinction Between Advertising and Other Activities, promotion of a drug prior to market authorisation is not permitted (Section 9(1) of the Food and Drugs Act, Section C.08 002 of the Regulations) because the terms of such authorisation have not been established and the proposed indication(s) for use have not been verified.

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 unauthorised drug, it is indicated that the drug is available through the Special Access Programme.

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.

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 licenced and non-licenced products equally?
In Canada, the regulations forbid sponsoring media to attend congresses and scientific meetings.
In the context of an international conference, display of a drug product prior to market authorisation in Canada, or a product that is labelled for a use that has not been authorised in Canada, may be considered not a promotional activity in the following circumstances:

- the conference must clearly be an international event, e.g., a significant proportion of the conference delegates are from other jurisdictions,
- the material must emanate from the parent company of the manufacturer,
- the material must only be for use within the confines of the conference, and
- the material is prominently identified as not being authorised for sale in Canada

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?
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?
No.

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 levels of web security are required?
N/A

Do the regulations cover funding of, or provision of information to, non-company owned websites?
If funding for a website is provided by a pharmaceutical company, the website is subject to the regulations that govern pharmaceutical marketing. The Food and Drugs Act, The Distinction Between Advertising and Other Activities, and so on.

What are the most popular social networks in your region?
Facebook, YouTube, Twitter, Facebook Messenger and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
In January 2013, the PAAB introduced a 'Guidance document for online activities.' There are four types of messages that may be posted (1.1):

1. Drug advertising
   - Must adhere to the same requirements as traditional drug advertisements.
2. Medical and disease information
3. Corporate information and promotion
   - Materials such as press releases, price lists and development pipeline information are not considered promotional. When a drug is mentioned, sponsors must 'align their discussions to the limits of drug advertising,' (1c).
4. Education and learning programmes
   - These are events or materials whose primary purpose is to better healthcare to Canadian patients (1d).

Are there any self-imposed regulations form social media companies?
No. The only social media regulations are the PAAB's.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
According to the PAAB's 'Guidance document for online activities':

- Terms and Conditions: The sponsor should provide in a clear and accessible manner the terms and conditions for users to engage in user generated content (UGC) on a sponsored site with clear

statements about what types of comments will be removed or modified. For example, a site may forbid any discussion of drug therapy and will remove any posts that include them.

- Monitoring the Conversations: Sponsors must monitor the UGC to ensure that compliance is maintained. An effective monitoring strategy can also assist in managing the risk to the sponsor that is inherent when the content is opened to users. To improve the effectiveness of the monitoring it is recommended that sponsors use a semantic, automatic filtering mechanism (e.g. brand key words, side effects) if the social technology supports it. Specifically, monitoring, and correction on the same site, is recommended for the following:
  1. Correcting misinformation: Users might post inaccurate information about a disease state or its treatment, the sponsor should monitor the UGC to correct any misinformation. Given the need for such corrections to occur in a timely manner, they may be made without PAAB pre-clearance provided content is limited to that which is required to address the misinformation. Caution should be exercised when correcting such misinformation as to ensure compliance with the regulations.
  2. Adverse event monitoring: As a complement to providing a statement referring reporters to the pharmacovigilance / medical department of the sponsor, it is recommended to include a reference for the reporting of adverse events directly to Health Canada and provide the relevant Health Canada web-site address and toll-free number.
  3. Off-label discussions: Discussions of a treatment that fall outside of the terms of marketing authorisation (TMA) can occur in UGC. As the sponsor is fully responsible for the content of the site (including the content created by the community) failure to address off-label discussions will render the site non-compliant. Off-label discussions must be removed outright.
- Ongoing Management of Interactive Content: All postings by users must be monitored as per the directives set out in corporate policies to that effect. Postings on company sites should be promptly triaged in accordance with the applicable corporate policy for determination of an appropriate response. Additionally, it is recommended that those individuals responding on behalf of the company receive specific training in the areas of adverse event monitoring and drug advertising.

As part of monitoring, online discussions postings that contain potential adverse event reports will need to be addressed according to established corporate policies and procedures for handling and reporting spontaneous adverse event reports. The Health Canada requirements, including follow up to obtain the necessary elements needed to report an adverse event, will need to be addressed when appropriate.

- Removal and Correction of Misinformation (including off-label discussions) When visitors post comments that are in direct violation with the site's Terms of Use (such as posts mentioning specific products) it is recommended that the sponsor develop a process for removing these posts should these contravene the rules for drug advertising. It is recommended that sponsors develop standard responses for when a post needs to be removed.
- Responding to Requests from Individual Users: Any product-related question from a user on a site not intended for product discussion must be responded to in a manner that is visible to the requestor only. In other words, the reply should not be made public. One-on-one correspondence is exempt from the rules of advertising. If a sponsor elects to respond to an individual user in a public forum such that all users can view the response, the drug advertising rules may be triggered.

Moreover, any request for information from a user for an unapproved product or for a use of a marketed product that is inconsistent with the TMA should be handled by the sponsor's medical information department.

What is mobile adoption like in your region? Are there separate regulations for it?
There are more than 20 million social media users that access social media via their mobile device. This makes up 55% of Canada's population. In total, more than 30 million Canadians have a cell phone. However, there are not distinct regulations for mobile phones and social media.

What are the disclosure laws like in your region for non-branded websites?
The websites sponsor is required to be disclosed on the site.

What is the response level needed for adverse event reporting?
According to CWTA, social media use is 23 million, with 63% active users, and 20 million social users accessing data through mobile application. More than 55% of the total population uses social media.

Manufacturers, healthcare professionals, and consumers can report adverse reactions to Health Canada and its partners. Depending on the product, reporting is either voluntary or mandatory.

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.

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?
Yes, it is possible to provide HCPs with honoraria to compensate them for their expertise and time away from their office. Many Canadian pharmaceutical companies have rules and have established monetary rates around how much HCPs can be compensated based on their specialty and level of experience. They can also be compensated for their travel and other expenses, however, companies also have individual rules around this as well.

For advocacy organisations, companies normally provide a grant. Yes, they can cover travel.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, through an unrestricted grant.

What is possible in terms of media or message training for health professionals or advocacy organisations?
Media / message training is allowed for HCPs and advocacy organisations. However, it must be made clear that the messages/training are simply a guide, and they are not expected to say or do anything that makes them uncomfortable, or that would put them in a compromising situation.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisation?
According to The Distinction Between Advertising and Other Activities, patient support groups often publish information in the form of brochures/leaflets that are intended to promote a better understanding of a disease

and its treatment among members and potential members. It can be difficult to distinguish between advertising and educational information in this context.
Declaration of sponsorship of the brochure by a drug manufacturer does not in itself render the brochure promotional. Patient support group publications that include information on drugs may be an educational activity in the following circumstances:

- the content is disease related rather than product related, and the various treatment options (drug and nondrug) and their respective risks and benefits are discussed in an objective manner,
- no emphasis is placed on one drug product, e.g., excessive use of a brand name or description as a 'breakthrough', and no emphasis is accorded to the merits of one drug product,
- no reference is made to an unauthorised drug beyond the mention that research is underway in a particular area, in which case, the regulatory status should be indicated (i.e., market authorization not yet obtained), and
- no reference is made to the availability of unauthorised drugs through the Special Access Programme.

Patient support group publications may be advertising where any of the aforementioned conditions are not met, and where other factors indicate that the primary purpose of the publication is to promote the sale of a drug.

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

KEY TAKEAWAYS/ SUMMARY

- If a message regarding a drug is not considered to promote sale or disposal, it is not subject to the advertising provisions of the Food and Drugs Act and Regulations.
- Promotion of a drug prior to market authorisation is not permitted. The promotion of a prescription drug (Schedule F) to the general public is limited to name, price and quantity (Section C.01.044 of the Regulations).
- Pharmaceutical manufacturers are not allowed to sponsor journalists to attend scientific meetings. This is considered advertising since the manufacturer is paying the reporter's travel expenses therefore, this could potentially to influence the journalist's story.
- If a website is funded by a pharmaceutical company it is subjected to the rules and regulations of The Food and Drugs Act /The Distinction between Advertising and Other Activities.
- Adverse Drug reporting is to be submitted to Health Canada and its partners. Depending on the product, this may be considered mandatory or voluntary.

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, there were 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 of 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 of products offering miracle cures with little or no scientific support for diseases with high prevalence rates in the country 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 the COFEPRIS for the enforcement of rules.

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

The regulations doesn't come from 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 in the promotional code. Typically, these complaints are submitted to the agency via rival companies, rather than consumers.

What promotional or media materials must be pre-approved by authorities?

Advertising and promotional materials are always submitted to the relevant authorities. In the case of press releases and other PR communication tools, authorisation and approval usually come from the pharmaceutical company's medical department, which is responsible for content. There's no need to submit information that will appear in editorial media sections for approval.

What are the most recent significant developments and are there planned changes to codes of conduct and regulations in the next few years?

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 a registration number for the product and also for the campaign—advertisement permission—as part of the advertisement requirement to buy an ad of 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 the advertising campaigns, requesting previously from the advertiser the related COFEPRIS advertising permission as well as the product number registration.

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 organised 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 code of ethics of the AMIIF, 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 authorisation 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 authorisation.
- 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 registry of advertised drugs should always be stated.

Information about prescription drugs should only be directed at health professionals and will be authorised 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 authorised when the registry 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 print and broadcast 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 is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?

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 assure 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 authorised 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 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 restrictions from the Health Ministry for the distribution of press releases. Although no materials of this kind are submitted for authorisation, 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.

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 licenced and non-licenced products equally?
No regulation on this matter exists.

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 organisation 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 levels of web security are required?
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 takes 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?
According to digital media consumption surveys, at least 85 percent of internet users in Mexico are part of a social network, with Facebook and 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 authorisation 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 authorisation, as well as the creation of websites, social media profiles and contents, and the way that authorisation 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 authorised 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 is the response level needed for adverse event reporting?

The legislation on pharmaceutical surveillance is extremely severe. The responsibility of the companies, as well as everyone who work 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 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?

COFEPRIS does not have a specific law to regulate the honoraria for healthcare professionals, advocacy organisations 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 sort 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 organisations?

With PR campaigns or earned media, health professionals or advocacy organisations are allowed to speak on their own behalf or on behalf of their institution or organisation. 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 an 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 licence 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 s?

The same regulations for advertisement 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 the 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 the 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 is 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.

THE BASICS

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' Association (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 March 2009. 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 categorised 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 organisations have no power over and above ethical guidance.

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 programme funded by the company is a bona fide educational programme and that the 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 (except as set out in Section 9 below). 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 programmes offer important educational opportunities to healthcare professionals, they are distinct from CME programmes, 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? 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.

What promotional or media materials must be approved by authorities?

Pre-approval of all promotional materials is required by the FDA for products being considered for accelerated approval and those where patient safety issues exist. 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.

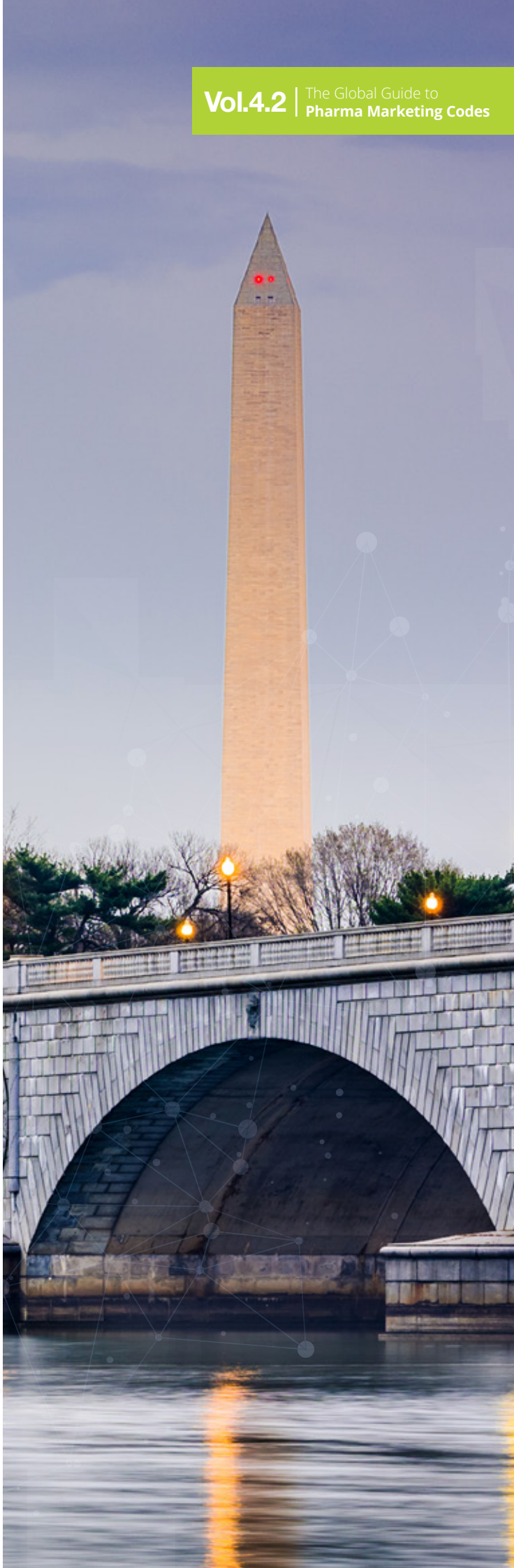
All other promotional materials must be submitted to OPDP at the time of initial dissemination. This requirement applies to all companies that market food, drug, device or biologic products in the United States. It is the responsibility of the manufacturer, distributor, packer or any party acting on 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.

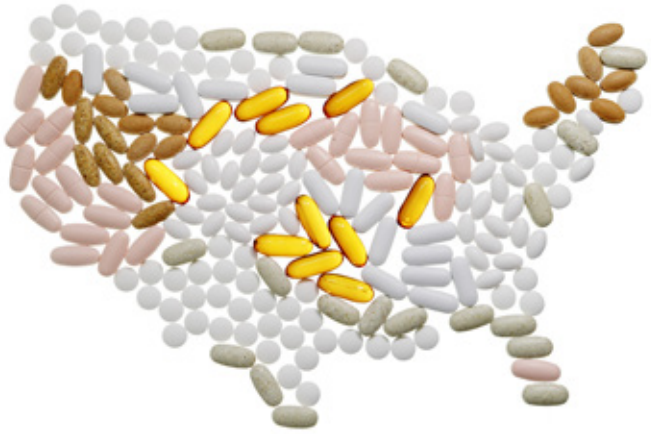
What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?

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 2017 this remains in 'draft' form, subsequent, final guidance is hotly anticipated by industry.

The FDA's social media guidance refers to how organisations 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 organisation 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 sited (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 1 August 2013. 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 licence 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 promotion is carried out by

pharmaceutical manufacturers within the guidance of the FDA, largely dependent on public knowledge of a particular disease or condition, or how specialised a treatment.

The FDCA 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 contradictions, 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 categorised 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 organisation 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 print and broadcast 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 recognise broadcast's inherent limitations by providing an alternative mechanism for meeting the Act's information disclosure requirement. In 2007, 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 call 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. (Please note, these guidelines were not in effect at the time this document went to print).

A March 2012 guidance on the FDA DTC Television Ad Pre-Dissemination Review Programme 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 inclue 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 programme, 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-licence 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 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 publically 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 and media materials? What are the general principles? Are invitations to media or clinical events treated the same?

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 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.

A manufacturer may disseminate information, under Section 551 of the FDCA, on a new use only if the manufacturer prepares and submits a list of materials for distribution to the Secretary of Health and Human Services. A list containing the titles of the articles and reference publications relating to the new use of drugs or devices by the manufacturer, along with a list of any clinical trial information used to promote the drug or medical device, must be provided to the Secretary sixty days prior to dissemination.

Companies exhibiting at medical meetings are encouraged to distribute meeting-relevant press releases and backgrounders on-site at the meeting; while there are exceptions, most meetings will allow some space for exhibitor news, given that the documents are approved in advance by the communications staff. Approved materials should have appropriate embargo information, time and date of the presentation, as well as a reference to the meeting presentation. Materials to be distributed must relate to data being presented at the meeting; other background and general company information will not be accepted. In some cases, material may be distributed, but only if it is unbranded (product and company) and aids understanding of the release information.

According to the draft guidance document, as of July 2014, the FDA has issued some regulations in terms of presenting risk/benefit information as well as other product information on internet/social media platforms with character space limitations. In doing so it seems that the FDA has differentiated to some extent between online, print and broadcast media - the FDA considers Interactive promotional media (which it clearly states includes- microblogs like Twitter and social networking sites like Facebook) as a separate entity. However as of now, these are only draft 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 licenced and non-licenced products 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 organisations, 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 reception and other media events—other than those sponsored by the host institution or manufacturer—are not permitted on-site. Organisations 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 on 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 ha 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 favour 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 question 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 2016, 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 levels of web security are required?

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 inputted 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.

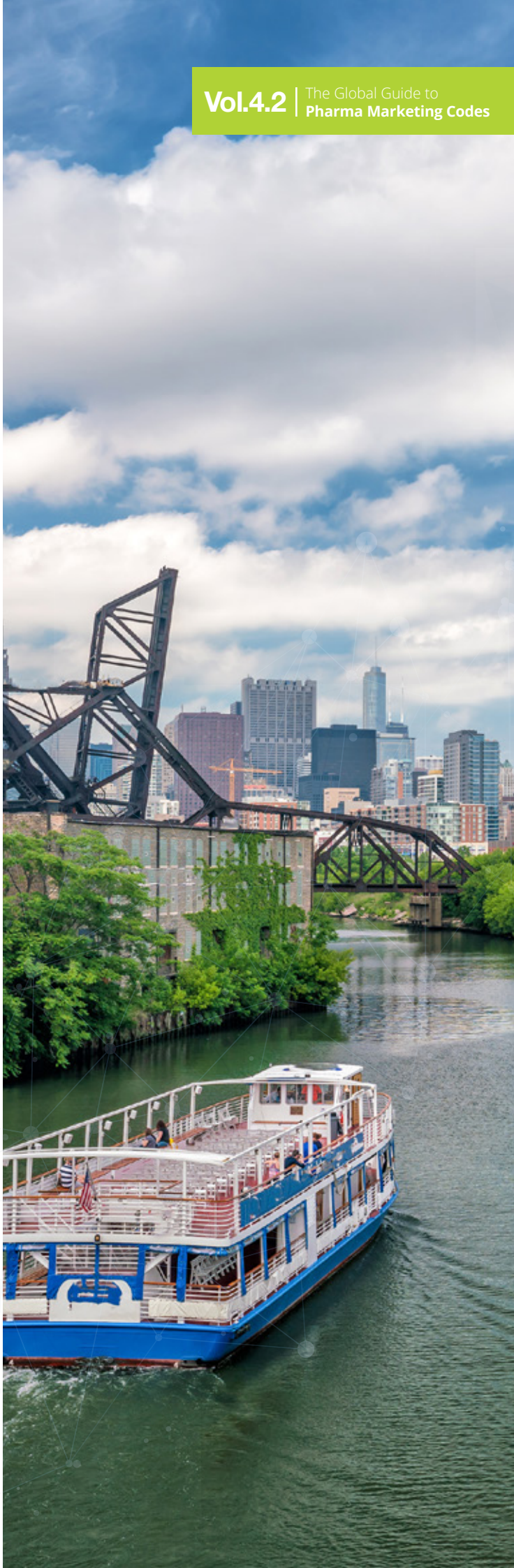
Do the regulations cover funding of, or provision of information to, non-company owned websites?

It is very common in the United States for pharmaceutical manufacturers to engage in legitimate funding of patient groups and other not-for-profit organisations, 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?

As of 2017, more than seven in ten Americans use social media platforms regularly.



Around 68% of all U.S. adults are Facebook users, while 28% use Instagram, 26% use Pinterest, 25% use LinkedIn and 21% use Twitter. Youtube is also a top social media site.

Among teens and young adults who use social media, Snapchat is the most popular platform (7% of users), followed by Facebook (7%), Instagram (73%) and Twitter (4%).

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 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 pertaining to 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.

Twitter:
Twitter provides extensive, country-by-country guidelines as part of its policy on Health and Pharmaceutical Products and Services (https://support.twitter.com/articles/20170441). This policy applies to Twitter's paid products, which are tweets, trends and accounts.

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) are also

covered under this policy. Supplement advertisements are permitted as long as they are targeted to audiences over the age of 18.

Instagram:
Because Facebook owns Instagram and a Facebook 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 discussion 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 December 2015 there were 377.9 million wireless subscriber connections in the United States. About 49% of U.S. households are wireless-only. As of 2016, 78% of American adults have smart phones. The annual wireless revenue incurred was $191.9 billion as of December 2015.

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 manufacturer citing claims and presentations in the website about the safety and efficacy of an investigational new drug that is 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 is the response level needed 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 Programme; 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 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 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?
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. Inclusion of a healthcare professional's spouse or other guest is inappropriate, as 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 as long as 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 organisations?

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 programmes 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. Payments for participation in media training must be reported to the CMS beginning in August 2013. Payments will be made public beginning in September 2014.

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

As consistent with 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 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 has only recently begun to actively provide 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 programmes 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.

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