EUROPE & AFRICA

GLOBAL HEALTHPR®
WE WORK. TOGETHER.

The Global Guide to **Pharma Marketing Codes**

Vol.4.2 | Book 2

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

EUROPE & AFRICA

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.

DENMARK

Promotion of medicines are governed by the Danish Medicines Act (DMA), the Executive Order No. 1154 of 22 October 2014 and the Advertising Order Etc. of Medicinal Products (the Advertising Order). The Danish Health and Medicines Authority (DHMA) has issued guidance note No. 10356 of 29 December 2014 on the advertising of pharmaceuticals (the DHMA Guide). Additionally, members of the Danish Association of the Pharmaceutical Industry (Lif) shall, in accordance with the Articles of Association, comply with decisions made by the Ethical Committee for the Pharmaceutical Industry (ENLI), which includes an ethical code regarding promotion of medical products and an ethical code regarding collaboration with health professionals. Although not legally binding, these ethical codes from ENLI are widely recognised by the pharmaceutical industry. The Danish national regulatory framework for promotion of medicinal products is largely based on European Union (EU) legislation. Similar to EU legislation it is prohibited to aim advertisement of medical products at children. Furthermore, the Danish legislation on advertisement on prescription medicinal products, and the rules on design and content of advertisements in general, is similar to EU legislation.

THE BASICS

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

Information distribution on pharmaceuticals is governed by the DMA, the Executive Order No. 1154 of 22 October 2014, the Advertising Order, the Marketing Act, DHMA guidelines and ethical codes from Lif and the ENLI.

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

Advertisements or promotional activities of medicines is defined as any form of informational activity or influencing customers with the purpose of enhancing sales and increasing the demand for a product. However, information and communication on general disease and health are allowed. For example: disease awareness public relations (PR) campaigns are legal. Exceptions that are subject to the rules of the Advertising Order include informative material on health and disease, provided that no direct or indirect reference is made to specific products. Patient information folders distributed by either a prescriber when prescribing a medicinal product or a pharmacy when dispensing a product are allowed, provided that the folder contains only factual information of significance. Press releases that give factual and concise details about a medicinal product, are newsworthy, have the press as the target audience and are distributed to a range of reporters or media to obtain journalistic review and comment prior to publication are also allowed.

Who is responsible for the enforcement of these rules?

The Medicines Act, the Orders, the DHMA Guide and the Marketing Act are enforced by the DHMA and the Consumer Ombudsman. Pursuant to the Advertising Order, §68 (2 and 4) the marketing authorisation holder must keep a copy of, or other documentation on, the advertisement for two years and on request be available to the DHMA, who subsequently controls whether the procedures have been done according to the rules.

Furthermore, if a company violates the rules of the DMA, they can be reported to the DHMA, who will decide if a violation has taken place.

All members of the LiF shall, in accordance with the Articles of Association, comply with decisions made by the ENLI, which includes an ethical code regarding promotion of product and an ethical code regarding collaboration with healthcare providers (HCPs). Although not legally binding, these ethical codes from ENLI are widely recognised by the pharmaceutical industry. There are no specific standard operating procedures (SOPs) for the government of promotional activities; however, according to ENLI's Codes on Advertisement, Article 20(2), every member company is obliged to select at least one person in charge to ensure that the company along with its subsidiaries comply with rules and regulations. The person shall approve all material before distribution. If a company violates the ethical codes, ENLI can sanction the company with a fine. At the beginning of each month the rulings are published by ENLI on their website.

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

The obligation to report association between pharmaceutical companies and HCPs who prescribe medicine follows from the Danish Health Act, Part 61a, and the DMA, sections 18(1) and 43 b-c, and is further described in the Executive Order No. 1154 of 22 October 2014 and the DHMA's guidelines. All engagement between pharma and HCPs who prescribe medicine, financial or non-financial, must be reported to the DHMA. According to the Executive Order No. 1154 of 22 October 2014, Article 7, a HCP is not allowed to be affiliated with pharmaceutical companies, medical device manufacturers or special stores for medical equipment unless the HCP has reported this to the DHMA or after the application has been approved by the DHMA.

Furthermore, ENLI provides ethical codes on pharmaceutical companies' collaboration with patient associations and the Danish hospital service, with the objective of securing high ethical standards for pharmaceutical companies' collaboration with HCPs.

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

The supervisory activities on advertising are made by the DMA supplemented by trade specific self-regulatory bodies that monitor the legitimacy of advertising activities in parallel and collaboration with the DMA. There are five self-regulating bodies: the ENLI, the Marketing Board of the Danish Association of the Veterinary Pharmaceutical Industry, the Danish Pharmacy Committee, the DMA Ethical Council, and the Ethical Board of the Danish Association of Suppliers to the Health Industry. Even though a complaint about an advertisement falls under the activities of one of the self-regulatory bodies, a complainant can also complain directly to the DHMA. If a company violates the rules of the DMA, they can be reported specifically to the DHMA, who decides whether a violation has taken place. The report is made by means of an e-form available on DHMA's website. When the authority reviews a complaint, it may obtain an opinion from the relevant self-regulatory body. According to section 68(1) and (2) of the DMA, the holder of a marketing authorisation for a medicinal product must keep a copy of or other documentation of any form of advertising for a medicinal product for at least two years. In this period, the marketing authorisation holder must keep a copy of all advertising material regardless of form. The material must be made available to the DHMA on request.

What promotional or media materials must be approved by authorities?

A new medicinal product cannot be marketed until it has been approved by means of a marketing authorisation. An application must be submitted to DHMA, who assess the application and conclude the assessment by either an approval or a denial to get the marketing authorisation. As stated earlier, the holder of the marketing authorisation must keep a copy of or other documentation of any form of advertising for a medical product for at least two years. The material must be made available to the DHMA on request. According to section 17(2) of the Advertising Order, the advertising material must be stored in print or similar form, or electronically in a generally available format. In addition to the advertisement itself, the person advertising the medicinal product must keep information about how the advertisement was used in practice, cf. section 17(3) of the Advertising Order: 1) The advertisement's target audience, i.e. the group that the advertisement is targeted to 2) Distribution method 3) A list of media in which the advertisement was placed 4) The period when the advertisement was running.

With regards to HCPs association with pharmaceutical companies, in the event of a promotional activity, with or without payment, the HCP must notify the DHMA first. Notification must be submitted electronically using a form on the DHMA's website.

Member companies of LiF are obliged to inform ENLI about events where HCPs attend. The member companies are also obliged to inform ENLI about all printed advertisements and electronic texts targeted to HCPs. The member companies must send in the report online at www.enli.dk. It is possible for the company to apply for a pre-approval on ENLI's aforementioned website. In such cases ENLI will charge an extra fee for the service. ENLI states in section 21(1) and (5) of the Promotion Code that pharmaceutical companies are obliged to report activities to ENLI 1) which are organised or co-organised by a pharmaceutical company, and the event is fully or partially directed towards Danish HCPs, 2) where a pharmaceutical company, without organising or co-organising the event, provides financial (sponsor) support to a so-called third party event, fully or partially directed towards Danish HCPs, 3) where a pharmaceutical company buys an exhibition stand at a congress in Denmark. The report concerning those

activities must be filed within 10 working days prior to the opening day of the event. Reports concerning sponsorships must be filed no later than 10 working days after a binding promise to provide financial support has been made or, in case of exhibition, at least 10 working days prior to the opening day of the event. Reports on promotion material must be filed at least on the same day as the printed promotion material is distributed.

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

The most recent development has been the legislation concerning HCPs and patient organisations association with pharmaceutical companies that was written into Danish law in October 2014. The rules can be found in the DMA § 202(a-c) and in the Advertising Order §24-28.

THE MEDIA

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

The term advertising in the context of the pharmaceutical legislation is defined in section 1(1) of the Advertising Order: Advertising of medicinal products means any form of door-to-door information or canvassing activity designed to promote the prescription, supply, sale or consumption of medicinal products.

Necessary and specific information or documentation, which serves safety purposes and not promotional purposes, e.g. information about changes to the packaging, or new adverse reactions or manufacturing defects is not considered as promotional activity.

All promotion targeted to a public audience must clearly state that it is an advertisement about a pharmaceutical product so that it is easily recognised as such by the audience. Furthermore, the information must meet the criteria for minimum information listed in the Advertising Order §5-§9.

How is a media event defined?

This is not specifically defined. However, the Advertising Order §6-9 clarifies the rules on advertising in movies, the radio, television and on the internet, respectively. Media relations, i.e. a media event, should comply with the rules in the Advertising Order on press releases: they must give factual and concise details about a medicinal product, be generally newsworthy, have the press as the target audience and be distributed to a range of reporters or media to obtain journalistic review and comment prior to publication.

Do the regulations differentiate between consumer and clinical publications?

It is possible to advertise in clinical publications for prescription medicines. In public media it is only possible to advertise for over-the-counter (OTC) medicine.

Do regulations differentiate between print and broadcast media?
The regulations on print and broadcast media is defined in the Advertising Order §5-§9. There is some variation in regards to the criteria for information, however, they are mostly very similar to each other whether it is in print or broadcasting. There is no difference in PR media relations.

What is permitted in relation off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?
The rules do not specifically address this in regards to media. The company must have a marketing authorisation and pre-launch activities and commercials on off-label use are prohibited. Press releases are an exception and can be issued and journalists can be invited in i.e. medical conferences where phase 3 data are published. This, however, does not apply to off-licence.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
According to the Advertising Order §2, the rules on medicine advertising do not apply to press releases that give factual and concise details about a medicinal product, are generally newsworthy, have the press as the target audience and are distributed or made available to a range of reporters or media.

However, a press release which appears as an advertisement because of subjective content, misleading information or exaggeration will not be considered a press release. It will be considered an advertisement for a medicinal product. If a press release is paid for and placed in a media channel, it will also be considered advertising. A pharmaceutical company can make a press release available to the press in a press area on its website for three weeks. After that, it will no longer be generally newsworthy and could be considered advertising. This will be based on an individual assessment.

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)?
Method of distribution is not regulated. Material from other countries also needs to comply with Danish rules and regulations.

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?
All media contact has to comply with the criteria for press releases, cf. §2(7) of the Advertising Order. Journalists can be invited in i.e. medical conferences where phase 3 data are published. This does not apply to off-licence.

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?
There are no general rules on this. Each pharmaceutical company has its own rules that may require that the copy go through regulatory procedures. Therefore, it depends on the case and company. However, it is not advisable to make the copy go through the company's regulatory, as it can be regarded as advertising

Do regulations cover the use of case studies or other third-party advocacy in the media?
Third parties, such as HCP and patient testimonials, can be used in the media if the association has been reported to and accepted by the DHMA. This is only allowed for OTC medicine and not prescription medicine. Patient testimonials must not mention prescription medicines, as it will be regarded as advertisement. According to the Advertising Order, §10(7) it is prohibited to make public advertisements, which contain any recommendation from a HCP or a third-party that because of its standing is in the position to encourage the use of medical products.

DIGITAL & SOCIAL MEDIA

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

What levels of web security are required?
Log-ins are required for websites with information on prescription medicine. Patient information on specific prescription medicine must only be available for the patient via a password provided by the doctor. The regulation distinguishes between advertising aimed at the public and HCPs. Regarding advertising on the internet, article 9(2-3) of the Advertising Order states that advertising on the internet is generally considered as public advertising. However, if access to the online information is limited to HCPs, for instance by the use of personal login with password, this will be treated as advertisement targeting HCPs.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Regulation only applies to company owned and/or hosted websites. However, the company is held responsible if the company-owned website links to other pages with prescription medicine.

What are the most popular social networks in your region?
Facebook, Twitter, Youtube, LinkedIn, Snapchat and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Yes, the Nordic Consumer Ombudsmen has published a position on social media marketing on 3 May 2012 stating that traders who use social media marketing must comply with the general rules applicable to internet marketing. Furthermore, ENLI has a guide to pharmaceutical companies use of social media for advertising.

Are there any self-imposed regulations from social media companies?
Social media platforms have their own codes of conduct. Facebook's Advertising Policies provide guidelines about which ads are acceptable and unacceptable on the site. The Facebook guidelines prohibit the promotion or sale of prescription pharmaceuticals. The guidelines can be found here: https://en-gb.facebook.com/business/help/223106797811279

Limitations to what may be published in these channels regarding pharmaceuticals are also governed by local laws and ethical guidelines for the pharmaceutical industry. Since the regulations distinguish between advertising to the public and to HCPs, advertising to HCPs on social media must be separated from the public. In such case, the party responsible for the advertisement on Facebook can create a page that is closed to the public and give health professionals access on an individual basis.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Yes, this is described in ENLI's guide to the use of social media for advertising.

What is mobile adoption like in your region? Are there separate regulations for it?
Access to social media through mobile devices is widespread in Denmark. In May 2015, 81% of internet users in Denmark owned a smartphone. Smartphone usage is predicted to continue to grow in the short term. There is no regulation addressing mobile devices separately.

What are the disclosure laws like in your region for non-branded websites?
The host of the website should not be more than one click away. On non-branded websites the owner or host of the site must be clearly stated. Pursuant to the Advertising Order Article 2(2), informative material on health and disease are not covered by the regulation, provided that no reference, direct nor indirect, is made to specific medical products. This could be anything from conventional leaflets to comprehensive internet websites. On the contrary, if the medical product is mentioned on a website accessible to the public, it is regarded as advertisement to the public and thus must

comply with the requirements for advertising to the public, cf. Article 9 of the Advertising Order.

What is the response level needed for adverse event reporting?

In pursuant to the DMA Part 5, Article 53, the holder of the marketing authorisation for a medicinal product must operate a pharmacovigilance system to monitor the safety of the medicinal products, assess the possibilities for risk minimisation and, if necessary, take appropriate measures. The company is obliged to keep records of suspected adverse reactions and make such records available to the Danish Medicines Agency. Furthermore, the company holding the marketing authorisation must report information on suspected adverse reactions to the Danish Medicines Agency or the European Medicines Agency. Doctors, dentists and veterinarians must report all serious adverse drug reactions to the Danish Medicines Agency no later than 15 days after they have come to their attention.

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?

Patient organisations do not fall under the Advertising Order's provisions on hospitality and congresses or meetings abroad, since they are aimed at HCPs only. However, ENLI's Ethical Rules for Collaboration between Patient Organisations and the pharmaceutical Industry state that support, in principle, may be granted for all activities, projects and purposes within the sphere of the organisation's work. Professional activities should always be the main intention of the collaboration and services must be proportionate to the compensatory measures. Events organised or sponsored by or on behalf of pharmaceutical companies must be held at a suitable location that contribute to the main purpose of event and which is not too extravagant or renowned for their entertainment facilities.

For congresses or meetings held abroad, the general ENLI rule is that a company must not organise or sponsor an event abroad, except when the majority of attendees are from abroad or when the location of the relevant resources or expertise involved in the event means that holding it in another country makes better logistical sense. Patient organisations can be invited or sponsored to attend congresses or meetings abroad, however it requires a report of association to the DHMA

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 not allowed to offer honoraria for HCPs and advocacy organisations for their participation in media activities. According to section 22(1) of the Advertising Order, economic advantages must not be offered or given to HCPs for advertising purposes or otherwise to promote the sale of a medicinal product. This does not extend to the remuneration of the services of HCPs or pharmacies when such remuneration is proportionate to the service offered. Both the giver and recipient of remuneration must, on request, present the basis for determining the size of remuneration to the DHMA, cf. section 24(1). Consequently, a HCP may receive payment for a service offered to a pharmaceutical company if the service is a natural element in an ordinary, mutually-binding agreement between the HCP and the company and if the service offered and consideration received in return are proportionate. Section 26(1) of the Advertising Order gives HCPs the opportunity of sponsorship of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medicinal products. This also applies to hospitality in connection with participation in courses and other professional activities involving pharmaceuticals and pharmacy matters. Furthermore, it gives HCPs the opportunity of sponsorship of direct expenses for courses and other professional activities, e.g. fees paid to external speakers, course fee expenses, or expenses to buy course material.

According to the Advertising Order, section 21(1), a patient organisation must publish on its website any economic advantages, including financial sponsorships (moneys) and payments in kind that the organisation has received from pharmaceutical companies. The information must be published on the website in such a way that the value of economic advantages is specified for each pharmaceutical company, cf. section 21(2) of the Advertising Order.

According to ENLI, all forms of hospitality offered to healthcare professionals must be kept at a reasonable level and be strictly limited to the main purpose of the promotional or professional event. As a general rule, the hospitality provided must not exceed the amount that recipients employed in the health sector would normally be prepared to pay for themselves. Companies must not provide or offer meals (food and beverages) to HCPs, except in those cases where the value of such meal does not exceed one of the following monetary thresholds: Danish Krone (DKK) 400 for lunch, DKK 700 for dinner or DKK 1,200 covering all meals at all-day meetings/ conferences, etc. The monetary thresholds apply to meals in Denmark. When providing meals in other European countries, the monetary thresholds laid down by the pharmaceutical industry associations in these countries must be complied with.

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

No. it is not allowed to pay a HCP or patient organisation to attend a scientific meeting and funding must not be offered to compensate the time spent by healthcare professionals in attending the events.
According to the Advertising Order, Article 26, pharmaceutical companies can give or offer a HCP training and professional information in the form of payment of direct expenses in connection with professional relevant courses, conferences, training, etc., in which the HCP participates or arranges. The provision in section 26(1) gives health professionals the opportunity of sponsorship of direct expenses for meals, travel, accommodation, etc. in connection with advertising of or professional information about medicinal products. This also applies to hospitality in connection with participation in courses and other professional activities involving pharmaceuticals and pharmacy matters. The provision in section 26(2) gives the opportunity of sponsorship of direct expenses for courses and other professional activities, e.g. fees paid to external speakers, course fee expenses or expenses to buy course material. These services must be reasonable in level and must be strictly limited to the main purpose of the promotional or professional activity, cf. section 26(2) of the Advertising Order.

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

Pharmaceutical companies are not allowed to give media or message training for HCPs. According to the Pharmaceutical Industry's Code of Practice on Promotion, Etc., of Medicinal Products aimed at Healthcare Professionals, the transmission of informational or educational materials to HCPs is permitted, provided it is inexpensive and directly relevant to the practice of medicine or pharmacy business and directly beneficial to the care of patients. Message alignment with HCPs and advocacy organisations are used.

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

ENLI rules also apply to third parties operating on behalf of these companies, such as consultancies, including for example advertising agencies, communication agencies, etc.

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

It is regulated by the Danish law on HCPs association with the pharmaceutical industry. Meetings and relations between pharmaceutical companies and patient organisations and other organisations are regulated by Article 2 in ENLI's Ethical Rules for Collaboration between Patient Organisations, Etc., and the Pharmaceutical Industry. Patient organisations are advised to write their own material.

KEY TAKEAWAYS/ SUMMARY

- Regardless of being a member of the trade association for the research-based pharmaceutical industry in Denmark's LiF or not, the best way to avoid any breach of law or regulations is to ensure that your company adhere to their ethical guidelines.
- The Danish market is highly regulated, but PR, public affairs and communication activities on disease awareness are still possible when correctly performed.
- It is important to remain in compliance with all updates to regulation and ethical standards.
- There is a high need for transparency.

FRANCE

In France, the health regulations are changing to avoid repeating major health crises. The National Agency for the Safety of Medicines and Health Products (ANSM) took over the French Agency for the Health Security of Medicines and Health Products (AFSSAPS) and implemented new responsibilities and missions to strengthen the safety of medicines and health products throughout the country. The ANSM has also created stricter legal constraints regarding publicity within the healthcare industry.

THE BASICS

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

The French Public Health Code mainly governs the promotion of medicines, and it defines health products in Part 5. Articles L 511-1 to L511-4 define medication. To address dietary products that contain chemical or biological substances not classified as food, Article L 511-4 was created by the LAW n ° 2016-41 of 26 January 2016, Article 151, which redefines:

- drugs or classes of drugs for areas of major therapeutic interest;
- classes of drugs for which a break in treatment is likely to involve the vital prognosis of patients in the short or medium term; and
- drugs that represent a significant reduction in disease severity for patients.

The following details various parts of the code:

- Articles R-5122-1 to 5122-47 specify the rules for different classes of medicine.
- Articles L 5122-1 to L5122-17 define 'publicity' and explain the legal aspects—what's permitted, how publicity is controlled and what sanctions may be imposed.
- Articles L.5122-6 to L.5122-8-1 and Articles R.5122-3 to R.5122-7 –list the rules for advertising to the general public.
- Articles L.5122-9 and L.5122-12 and Articles R.5122-8 to R.5122-17 cover advertising for health professionals.
- Articles L4113-5, L4113-6, L4113-8 explain the independence of all physicians or pharmacists prescribing medicine and define the special situations in which a company can offer a subvention to a healthcare professional.
- Articles L-4163-1 to 4163-4 refer to the sanction that may be imposed if the rules are not abided by.

The rules for advertising drugs are strict. Such advertising is subject to control by the National Agency for the Safety of Medicines and Health Products (ANSM).

The term 'advertising' covers advertisements in the press or on television, brochures, scientific or medical publications, mailings and posters. This advertising is subject to an a priori control for advertising intended for the general public and for advertising intended for healthcare professionals.

Additionally, the French Drug Agency (formerly called AFSSAPS/Agence Francaise de Sécurité Sanitaire des Produits de Santé) issued guidelines that have been replaced since May 2012 by the ANSM's guidelines. Although they are not legally binding, French courts assert that pharmaceutical companies must take the guidelines into account. The ASNM receives mandatory application forms that it reviews before a product may be advertised to the public, and a commission checks all material prior to every advertisement or 'propaganda' piece's release. If the ANSM approves an application, it issues a visa (GP or PM.

Last, the code of practice issued by Les Entreprises du Médicament (LEEM), the French Pharmaceutical Industry Association, proposes guidelines of good practice in its Charte de la Visite Medicale and Référentiel des Bonnes Pratiques de la Visite Médicale des Entreprises du Médicament.

LEEM and The Comité Economique des Produits de Santé (CEPS) also signed the charter for communication of pharmaceutical companies in 2004, and it was updated in 2014 and renamed a 'promotional information charter' (concerning the certification of promotional information activity). The Haute Autorité de Santé (HAS) proposed a new procedure (using a repository) in two stages:

1. A first section published in 2016 dedicated to pharmaceutical companies
2. A second component in 2017 for subcontractors (with part 1 being taken over)

This repository makes it possible to audit the quality management system of companies in the following areas: policy for promotional information, training and evaluation of people responsible for promotional information activity through canvassing or prospecting and rules of professional conduct applicable to these people and their careers.

These materials may be amended shortly after this guide's publication. No official translations of the documentation currently exist, and any dispute must adhere to the original French material.

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

There is little differentiation. The Public Health Code defines promotion of pharmaceutical products as 'any form of information, including the door-to-door selling, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

Who is responsible for the enforcement of these rules?

The ANSM approves all publicity material. The French Drug Agency is helped by the Commission de Contrôle de la Publicité et de la Diffusion de Recommendations sur le Bon Usage du Dédicament. The commission publishes recommendations about how publicity campaigns should be held, how media can be used in a promotional context and how to properly use medicines. The ANSM can withdraw a commercial that doesn't conform with French law.

The pharmacists and physicians' independence (as defined in the French Public Health Code, L-4163-1 to 4163-4) is controlled by public health inspectors (from the French Ministry of Health), the ANSM's inspectors, agents from the French Ministry of Finance Direction against Fraud or tax agents. A pharmacist, a physician or a dentist who makes a profit from illegal promotional activity may receive a €75,000 fine, be subject to a two-year prison punishment and be deprived of his or her professional duties for 10 years.

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

Publicity directed to healthcare professionals is subject to the ANSM's approval (it used to be controlled *a posterior*, it's now controlled *a priori*).

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

Concerns are brought to the ANSM by competitors, who may take direct legal action on the grounds of unfair competition if they are able to prove that they have suffered as a result. The penalties are among the toughest in Europe. The most serious punishment would result in a product being taken off the list of reimbursed medicines or a fine that could be anything from up to 10% of the turnover a company made from the medicine. Further criminal sanctions may also be applicable.

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

Direct-to-consumer advertising is permissible for medicines that are not reimbursed by French social security schemes, on condition:

- No presentation of the medicine is reimbursable.
- Mandatory mentions are respected.

Any promotional material of these products intended for the general public or directed to healthcare professionals is subject to pre-approval by the ANSM (via the Commission de Contrôle de la Publicité).

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

Since 2012, the former agency AFSSAPS has been the new ANSM.

The control over conflicts of interest is tightened – agencies seek experts with no conflicts of interest. Publicity directed to healthcare professionals is subject to the ANSM's approval (it used to be controlled a posterior, it's now controlled a priori).

The device 'Transparency of the links of interests' introduced by the drug security law (Law n ° 2011–2012 of 29 December 2011) was widened by the health law (Law of modernization of our health system n ° 2016-41 of 26 January 2016). Drug companies are required to publish on the public database (www.transparence.gouv.fr) financial information on the remuneration paid to the various players, with the intent to further strengthen the transparency of the links.

The publication of information relating to each link of interest (convention, remuneration and benefits) is done twice a year and remains online for five years.

The HAS has extended the Drug Promotion Charter to all the people and situations potentially concerned by promotional activity. The regulation must thus apply 'whatever its form (by telephone or email[,] for example, and no longer only face to face), or the place (wherever an exchange can be made and not only on the place of practice of the professional)'.

To hold a promotional activity, manufacturers must respect the HAS charter and its reference system (updated in 2016 and March 2017). The new standard reinforces the quality of information communicated to healthcare professionals; communications about drug safety data must be systematically offered to them, and at least one approved communication by the ANSM must be submitted. Scientific and medical information must not be promotional.

The new reference framework also strengthens the conditions for organizing promotional visits to healthcare institutions. Visits must now be organized formally and tracked, and contacts with professionals in training (interns, students, etc.) are subject to prior agreement or support by experienced professionals.

In parallel, the HAS recalls that it provides independent and reference information for health products, in particular via the public drug database, the opinions and summaries of opinions of its evaluation committees and fact sheets. good use of the drug published on its website.

Other news encompassed in this charter includes the LEEM and CEPS deciding to create the National Observatory of Promotional Information to measure the quality of promotional practices based on objective, verifiable and transparent criteria.

The agency is able to trace the practices of companies and report to the LEEM and CEPS, via a trusted third party, the noticeable discrepancies. On this basis, the CEPS can

sanction companies whose practices do not comply with the charter's principles.

This new reporting process will not replace the control and audit certification already exercised by the High Health Authority, which will still be completed.

THE MEDIA

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

The French Public Health Code categorises anything designed with the 'intention of promoting the sale or prescription of a medicinal product' as promotional. This is sometimes difficult to assess, as in the case of scientific data. However, as a general rule, the authorities will deem material issued by a pharmaceutical company promotional, whatever the context. The regulation is applicable regardless of the context, form (phone, email, etc.) and place (wherever an exchange may be done and not only at the professional's place of practice).

When a healthcare professional receives audio, video or interactive media, it must be accompanied by documents, as defined in the LEEM code, including but not limited to a summary of the product characteristics mentioned, the maximum price for its sale to the public and the situation of the product with regard to reimbursement by health insurance organisations or public authorities.

How is a media event defined?

There are no legal provisions defining media events for medicinal promotion, but a priori, it depends by default on advertising rules and constraints for the general public.

Do the regulations differentiate between consumer and clinical publications?

Yes, relating to the audience. Publications targeting consumers can insert commercials for medical products, provided:

- the medical products do not have to be prescribed by a physician and are not reimbursed by French social security schemes or do not belong to a promotional campaign in favour of vaccination;
- the advertisement includes all mandatory mentions (as defined in Public Health Code Article L5122-6); and
- publications targeting a professional audience can insert commercials for medical products if –
  - » the advertisement includes all mandatory mentions (as defined in Public Health Code Article R5122-8) and
  - » the commercials have a visa from the ANSM.

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 meeting and major publications?

Direct promotion of products without marketing authorisation is not permitted. Unlicenced products may

be discussed at scientific meetings if the manufacturing company has not organised or directly or indirectly sponsored the meeting. Providing promotional information or data during a congress organised by a healthcare professional or advocacy body is fine.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
Generally, promotional material must be objective and consistent with a product's 'bon usage' (appropriate use). The Public Health Code further details that the following information must appear on a medicine's advertisement: its price (if determined by the French authorities), the daily cost of the treatment and its reimbursement by French social security schemes. The ANSM has advised that all press materials should mention the sources of scientific references. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion about the therapeutic value of a medicinal product. The product's claims should be based on an up-to-date-evaluation of all relevant evidence and reflect that evidence clearly. Claims must not mislead by distortion, exaggeration or undue emphasis and omission, or in any other way.

As a general rule, information must promote the rational use of medicines with objective presentation.

A pharmaceutical company or one of its agencies may invite a journalist to a congress if the discussions and presentations will deal with clinical studies in a scientific perspective. Journalists' articles may not mention a medicine by its commercial name, but may include the chemical name.

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. Under the European Federation of Pharmaceutical Industries and Associations (EFPIA) regulations, the materials must conform to both the issuing and receiving country's codes of practice. When the codes conflict, the stricter code prevails.

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?
See answer to the following question.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
The French regulations do not cover this consideration, because expenses and travel costs for third parties are permitted under EFPIA regulations if the journalist's time wasn't paid for or the nature of his or her outputs would not be deemed as promotional. However, under the regulations on transparency, EFPIA states that, where a company pays for or otherwise secures or arranges the publication of promotional material in journals, the material must not resemble independent editorial matter (LEEM guidelines 7.03). Under EFPIA regulations, material relating to medicines and their uses, whether promotional in nature or not, that is sponsored by a company must also clearly indicate that it has been sponsored by that company (LEEM guidelines 7.04).

Do regulations cover the use of case studies or other third-party advocacy in the media?
Again, because this is not covered, the wider regulations apply. The EFPIA Code states that quotations must be faithfully reproduced (4.01) and that when a company pays for or otherwise secures or arranges for promotional material to be published in journals, the material must not resemble independent editorial matter (7.03).

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
In 2006, the LEEM and AFSSAPS signed the Charte pour la Communication sur Internet des Entreprises Pharmaceutiques, which presents guidelines for web communication.

Among the guidelines:

- A website must present the information required by Article 6 of Law No. 2004-575 of 21 June 2004 on confidence in the digital economy and must identify the operator and recipients targeted and the type of information disseminated.
- Advertising must be clearly identified, which can be done by any means clearly perceptible to make unequivocal to the public a message's advertising nature.
- The corporate part of a company's website must be clearly separated from the commercial part; product promotion must be clearly distinguished from the general information about the company.
- Advertising must conform with the French Public Health Code restrictions regarding audience. Banners targeting healthcare professionals must not be accessible to consumers but available on pages accessible to registered healthcare professionals only; mentions that ought to be included in an advertisement (according to Public Health Code Articles R 5122-3 and R5122-8) have to be accessible via a link to a special page (which must be registered by the ANSM as well as the commercial itself).

- Depending on the type of product presented, the promotional pages could be subject to a request for prior authorization to the ANSM (drugs and DM/DMDIV, according to the lists fixed by orders) before allowed online, or they could be the subject of a posteriori control without deposit (DM/DMDIV outside the aforementioned lists).

- A printed copy of the promotional materials used for email campaigns has to be registered by the ANSM, and the French Drug Agency must receive a copy at celluleinternet@ansm.sante.fr.

What levels of web security are required?

An advertisement must be adapted to its recipients. Advertisements intended for healthcare professionals must appear on pages reserved for them only. In addition, the the CHMP or the Centre Spécialités Pharmaceutiques (CSP) imposes restrictions on how certain advertisements are distributed and prohibits including any public advertising for class IIb and III refundable DMs, DMIAs and breast implants and for medicines subject to compulsory medical prescription, refundable or under advertising restrictions to the general public mentioned in the AMM.

Other media, like internet headers or pop-ups, may have lighter requirements only if all the mandatory information that the CSP provided appears clearly in the hyperlinked pages. At a minimum, these supports must show the name of the health product; its destination or indication; its status (medical device or medication); and, where appropriate, an age limit.

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

Guidelines for websites under the new EFPIA Code, which supplements the French regulations, describe to what extent non-promotional product information may be published on websites that patients and the general public access. Although the information must be factual, balanced and consistent with the summary of product characteristics, the guidelines seem to expand the scope for the kind of information that companies are allowed to make available to the general public, which meets an industry need. How these will be interpreted remains to be seen.

What are the most popular social networks in your region?

Facebook remains the most popular, with 61% of French internet users active on it and 44% active on Facebook Messenger, but France is experiencing growth with other platforms, like YouTube (31%), WhatsApp (24%) and Instagram (20%).

YouTube channels are increasingly used as 'video directories' that then relay to other sites, such as LinkedIn or Twitter.

The number of followers for pharma companies on Twitter is increasing more slowly – by 15%, to 2 million internet users.

Communities following the pharmaceutical industry on YouTube and Instagram are smaller, with respectively 106,000 and 77,000 subscriber accounts at one of the 20 largest laboratories, but both platforms recorded strong increases in 2017 (+50% for YouTube and +67% for Instagram).

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

Yes, the ASNM Charter for communicating about and promoting health products (medicines and medical devices) on the internet and in electronic media. The functionalities inherent to open social networks (like Facebook, Twitter, YouTube, etc.) lead to linking to pages with comments and messages whose content is free and uncontrollable (through sharing functions, in particular). In addition, the '[x] people like' feature displays the number of people who liked a page, and can be interpreted, if it is devoted to a health product, as a certificate of cure by the public or a surety if a healthcare professional likes it, and this is, therefore, contrary to the public health code. Consequently, promoting health products to the general public in the form of a page like this is not permitted, except if these engagement functions can be disabled by the page's owner. Likewise, sharing a website's promotional page to an open social network is not allowed.

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

No.

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

No.

No publicity for healthcare professionals can be published. The French Agency for the Web Normalization is currently working on an authenticity norm that would fight against fake testimonies about products or services. It's not specific to health and healthcare communications.

An operator setting up this type of service must achieve a real moderation of discussions held in order not to jeopardize the proper use of health products that would be mentioned. A posteriori moderation must at least be carried out under the operator's responsibility, who must put in place sufficient means to ensure that remarks that do not respect the regulations in force cannot last more than 24 working hours. Setting up a charter or leaving users to report an abuse is not acceptable because it risks allowing comments that do not respect the current regulations.

Regarding discussion forums and personal contribution spaces hosted on a third-party site, the operator can occasionally intervene in a discussion about one of his or her products to rectify erroneous information, in particular by providing links to the summary of product characteristics (RCP) or the notice. However, the answer should not promote the drug or medical device concerned.

What is mobile adoption like in your region? Are there separate regulations for it?
Of the French population, 77% of which owned a smartphone as of 2017, smartphone usage continues to increase, especially among people with higher incomes:

- 83% of French people between 12 and 17 years old have a smartphone.
- 98% between 18 and 24 years old have a smartphone.
- 92% between 25 and 39 years old have a smartphone.
- 81% between 40 and 59 years old have a smartphone.
- 55% between 60 and 69 years old have a smartphone.
- 35% 70 years old and older have a smartphone.

There are no separate regulations for mobile adoption.

What are the disclosure laws like in your region for non-branded websites?
For health information, there are no disclosure laws. Experts' interviews are considered reliable information. Experts don't have to disclose their conflicts of interest or information about specific diseases that do not mention commercial brands or include any symbol that could identify the brand, because this is considered disclosure of scientific or technical information.

What is the response level needed for adverse event reporting?
Adverse events have to be reported to the ANSM.

STAKEHOLDERS/ ADVOCACY GROUPS

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

The regulations allow pharmaceutical companies to provide various funding to patient groups, such as reimbursement for expenses. The reasonableness of the hospitality is assessed according to the main purpose of the event, which must remain exclusively professional and cannot be quantified, with its appreciation being multifactorial. Thus the following is taken into account: the medical interest of the event, qualification of invited health professionals, type and level of benefits provided and partially or totally paid for (transport, hotels, restaurants, etc.), the timetable provided by the program during the event, the topics covered and the medical content and participating scientist(s).

The duration of the hospitality is strictly limited to that of the scientific event. The reimbursements for these events are limited to all or part of the expenses relating to transportation, meals, accommodations and registration fees. Care can only be offered to healthcare professionals who are qualified to be full participants. The level of care offered to healthcare professionals must be 'reasonable' and strictly related to the main purpose of the event. It should not exceed what healthcare professionals would normally pay for themselves if they had borne the cost. Meals, including drinks, offered in this context cannot exceed €60, including tax.

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 pay a healthcare professional reasonable compensation for professional services rendered (such as giving a presentation), but not simply for attending such an event. It is also possible to pay or reimburse reasonable expenses incurred by attendees.

On this matter, the Public Health Code (L4113-5 and L 4113-6) details that specific requests from healthcare

professionals to have all or part of their travel and accommodation expenses paid for must be submitted to the Conseil National de l'Ordre des Médecins (national medical board) for a national/international congress or to the Conseil Départemental de l'Ordre des Médecins (regional medical board) for congresses at the regional level. A request for an opinion file (paired with a letter of request written by the healthcare professional, congress programme and total expenses to be covered) must be submitted to the board authorities within a reasonable timeframe before the event takes place (clause 11 of the LEEM guidelines suggests one month). The levels of travel and accommodation must be 'reasonable and suited to the occasion and the expenses incurred must not exceed what the participants would have paid for themselves' (Public Health Code L4113-6). Expenses must not include family members' or friends' accommodations.

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

See the answer to the previous question. Additionally, the EFPIA Code specifically states that 'funding must not be offered to compensate merely for the time spent by healthcare professionals in attending events' (LEEM guidelines 11.01).

Legal and regulatory framework was strengthened by the health law of 26 January 2016. Companies are obligated to declare the amount of remuneration they paid to stakeholders on the transparency site hosted by the Ministry of Social Affairs and Health.

All of the following are considered health actors working with companies:

- healthcare professionals and their associations;
- students aiming for health professions and their associations;
- the associations of users of the health system (including patient associations);
- health establishments;
- academies, foundations, learned societies and consulting companies or organisations involved in the health products or services sector;
- legal entities publishing press, radio or television services and online public communication services;
- software publishers that help with prescriptions and dispensing; and
- legal entities providing initial or ongoing training for healthcare professionals or participating in this training.

The French Anti-kickback Law has been the subject of several amendments, the last of which is the health law of 26 January 2016.

The text first clarifies the nature of prohibited transactions; authorized transactions are not considered benefits (such as the employment contracts of healthcare professionals employed in companies) and transactions that may be subject to derogations (service contracts, grants or subsidies that encourage research or associations, hospitality or funding training). The law also sets up a new control regime – from now on, all transactions that exceed the financial thresholds (set by decree) must be authorized

by the professional orders or by an administrative authority (which remains to be designated).

Below the thresholds, transactions must be reported to the professional orders or the administrative authority. An order was issued on 19 January 2017 to clarify the framework for this reform. It was scheduled to take effect no later than 1 July 2018, but implementation has been delayed and a new date has not been set.

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?

Under EFPIA regulations, material relating to medicines and their uses, whether promotional in nature or not, that a company sponsors must clearly indicate that it has been sponsored by that company (LEEM guidelines 7.04). Under the regulations on transparency, EFPIA states that when a company pays for or otherwise secures or arranges promotional material to be published in journals, the material must not resemble independent editorial matter (LEEM guidelines 7.03).

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

The regulations allow the provision of non-promotional information, including factual information relating to human health or diseases, provided that there is no reference, even indirect, to specific, branded medicinal products.

KEY TAKEAWAYS/ SUMMARY

Because of major health crises, French regulation is changing; all the actors, such as agencies, industry and healthcare professionals, are cautious not to reproduce the old schemes that led to the crises. Key takeaways include the following:

- There is a new agency for the medicines and health product security (ANSM).
- The publicity legal constraints are stricter
- The fight against conflicts of interests has been tightened.

GERMANY

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

THE BASICS

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

In Germany, the FSA Code of Conduct (the Code) governs the promotion of medicines. This code was recently amended to take into account the Professional Rules for German Physicians issued by the German Federal Chamber Physicians and the Common Position of the Assessment in Criminal Law of the Co-operation between Industry, Medical Institutions and their Employees, which was published in 2000 by the trade associations and other organisations in the healthcare sector.

The content of the Code is also based on the Conduct Recommendations for the Cooperation between the Pharmaceutical Industry and Physicians issued July 2003 by the Verband Forschender Arzneimittelhersteller (VFA), also known as the German Association of Research-based Pharmaceutical Companies, the German Association of Pharmaceutica Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI). Laws include the German Drugs Act (AMG), German Advertising in the Health Care System Act, Law on Advertising in the Field of Healthcare, the German Fair Trade Practices Act (EWG) and the German Penal Code (StGB).

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

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

All promotional activities, including public relations and advertising, are defined as the same for the purposes of the Code itself. More specific regulations, as outlined above, govern the rules for advertising. The German Public Relations Association has also developed its own ethical guidelines. In general, advertising and public relations are considered as separate activities.

Who is responsible for the enforcement of these rules?

The conduct requirements of the Code are binding to member companies and monitored and sanctioned by the FSA's arbitrators. They can impose fines of €5,000 to €250,000.

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

Due to the implementation of the FSA Transparency Code 30 June 2016, all pharmaceutical companies in Germany were required to publish all monetary contributions they have paid to medical institutions, doctors and other partners throughout the previous year.

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

Concerns are mainly submitted by competitors who try to stop public relations activities via legal channels.

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

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

No relevant authorities need to be contacted for pre-approval of promotional or media materials. Companies generally submit materials for internal review by their legal and medical-scientific departments to make sure that wording or any graphics used are correct.

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

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

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

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

THE MEDIA

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

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

How is a media event defined?

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

Do the regulations differentiate between consumer and clinical publications?

The German code on promoting medicines does not provide definitions of, or differentiation between, types of media.

Do regulations differentiate between print and broadcast media?

The German code on promoting medicines does not provide definitions of, or differentiation between, types of media.

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

The provision of medical and scientific information to the media during the development or marketing authorisation phases of a product is permitted, provided that this is not part of product-related advertising. This would generally mean that the outcomes of clinical

studies or scientific speeches and publications might be made available at scientific meetings or conferences using the generic but not the brand name of the product. Press releases are usually deemed to be unlawful when the anticipated product name is mentioned. In general, it is important to use the generic name and not the brand name prior to product approval. Advertising is prohibited during this stage.

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

The German code on promoting medicines does not provide for any specific regulations regarding press relations or other materials. Therefore, they would be subject to the same general principles as all promotional material. Promotion must be based upon sufficient scientific evidence and must be consistent with the information addressed to healthcare professionals. This rule applies in particular to claims referring to specific benefits, qualities or properties of a product or substance.

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

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

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

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

The Code states several times that, where there is a conflict of codes, the stricter code is said to apply, making it important to be acquainted with both the german code on promotional materials (see above) and that of the country of distribution. This is also consistent with the wider international guidelines.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

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

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

If a company has invited the journalist with the express intention of creating and approving publishable copy, then the rules on promotional material will apply. Where a company sponsors the publication of promotional material in journals, it must make sure that such promotional material cannot be confused with independent editorial matter. In the case of any publications made by third parties about medicinal products and their use, which are either wholly or partially sponsored by a company, particular care must be taken to ensure that such publications clearly indicate that the company has sponsored them.

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

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

DIGITAL & SOCIAL MEDIA

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

There is no specification in the regulations.

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

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

What are the most popular social networks in your region?
Facebook is the most popular social network in Germany, followed by Instagram, LinkedIn, Pinterest, Xing and Snapchat. Twitter use has also increased recently.

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

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

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

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

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

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

STAKEHOLDERS/ ADVOCACY GROUPS

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

Is it possible to offer honoraria for healthcare professionals, advocacy 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?
The section of the Code that addresses this is not very specific. It says, 'Physicians or third parties must not be granted payment of any fees for their willingness to meet with or receive information from a pharmaceutical company'.

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

'Reasonable' costs are only permissible if the job-related, scientific nature of the event takes center stage. In 2010, the FSA added the following amendment: 'It is not allowed to reimburse attendance fees of entertainment programmes directly or indirectly to healthcare professionals or other members of medical body of experts by FSA member companies'. It is thus ensured that the financing of entertainment or leisure mes by companies does not take place.

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

While there is no specific regulation in this matter, any honoria on travel expenses provided by the pharmaceutical company must be disclosed per the anti-corruption act and fit within the abovementioned regulations.

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

Member companies may invite healthcare professionals who are particularly concerned with the companies research areas, pharmaceuticals and/or their therapeutic indications to their own job-related training events. It would seem fair to surmise that, provided the scientific content was robust and deemed as necessary knowledge for the physicians, then 'message' training would be allowed. Media training without scientific content would not be permissible. The rules of moderate hospitality also apply and the venue must be chosen on the basis of factual criteria, such as geographical location, rather than the leisure facilities offered. In the case of media training, it is important to sustain the expert's independence in front of the media.

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

Any materials that have been written or organised by a pharmaceutical company, whether directly or indirectly, are subject to the above-mentioned rules on promotional material, unless they are factual information on diseases. It is clear that the pharmaceutical company must abide by the Code even if it commissions others to design or implement any activities on its behalf.

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

As with meetings with healthcare professionals, there must be a reasonable need for the meeting before it can take place. Again, factual information relating to diseases or human health would be nonpromotional and not subject to the Code.

KEY TAKEAWAYS/ SUMMARY

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

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

ITALY

In Italy, pharmaceutical regulation is governed by The Italian Medicines Agency (AIFA), a division of the Ministry of Health (MoH). Members of the Italian Association of the Pharmaceutical Industries abide by the Code of Professional Conduct of Farmindustria. In addition to the decrees set forth by these organisations, pharmaceutical marketers must adhere to the code issued by the Institute of Advertising Self-Regulation (IAP). Promotional material includes any scientific information provided by pharmaceutical companies direct-to-consumer. promotion of prescription-only medicines is not permitted.

THE BASICS

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

In Italy, Title VIII (Articles 113-128) of Legislative Decree No. 219 of 24 April 2006 (the Decree) is the most relevant for the regulation of the advertisement of medicinal products to the general public and healthcare professionals. The Decree implements under Italian legislation Directive 2001/83/EC (and subsequent modifications) on the community code on medical products for human use and Directive 2003/94/EC. Other relevant provisions on advertising of medical products and the activities of pharmaceutical companies are set out in Legislative Decree 229/99 regarding CME principles and in Legislative Decree 74/1992, as amended by Legislative Decree 67/2000 on unfair advertising, implementing Directive 97/55/EC. Additional regulations regarding advertisements to the general public include: the Legislative Decree No. 205 of 6 September 2006, (the Consumer Code); the Guidelines of the MoH of 17 February 2010 concerning advertising, of medicinal products via the internet and telephone, including MMS and SMS (the MoH Guidelines); and the code issued by the IAP

The Decree defines the advertising of medical products, as 'every informative action, search for clients or exhortation aimed to promote prescription, sales or consumption of medical products'. Any scientific information provided directly or indirectly by pharmaceutical companies (supply of samples, sponsorship of meetings and events, activities of sales representatives) is considered as advertising (to health professionals or to the general public) and should be carried out in accordance with the provisions set forth in the Decree. Public relations activities include 'informative actions to different targets', and are also subject to this legislation. The Decree regulates advertising to the general public, advertising to health operators (physicians and hospital pharmacists) and advertising to chemists/ drugstores. The Decree does not regulate general information about public health when it does not mention (either directly or indirectly) a particular drug (e.g., health campaigns or disease information).

Regarding advertising to healthcare professionals, the regional Guidelines of the State-Regions Conference of 20 April 2006 (the State-Regions Conference Guidelines) and Article 2598 of the Civil Code are also relevant. The State-Regions Conference Guidelines concern scientific information provided by medical sales representatives, while the latter regards misleading advertisement contrary to fair business practice.

The main principles concerning the advertising of medicinal products are:

- Advertising of medical products that have not been authorised by European Union (EU) law is prohibited;
- Advertising of medicinal products must always comply with all the requirements listed in the relevant authorised summary of product characteristics (SmPC)
- Advertisements must not be misleading and must promote correct use of the products being advertised.

General press articles are the responsibility of the journalists, authors of the articles and of the publisher/ owner of the journal/media, as regulated by the codes of journalism, e.g., the Charter on Information and Publicity and the Charter on the Duties of Journalists. In general:

- A journalist is not allowed to accept any payment causing a conflict of interest to his/ her professional role
- Articles should be written in a way that enables the reader to easily distinguish between information and advertising
- The brand name of a medicine should not be mentioned in the lay press with the intent of increasing its use

Specific to Italy, the 20 regional governments in Italy

can also regulate promotional activities to doctors and pharmacists within their own territory.

Another important code is the Code of Professional Conduct of Farmindustria, the Italian Association of the Pharmaceutical Industries, as amended 23 October 2012. This is a voluntary agreement entered into by the pharmaceutical companies belonging to Farmindustria. The Code sets out to regulate relations not only between companies but also their relations with the scientific and health sectors. All member companies of Farmindustria must accept and comply with its provisions. Recently, most of the pharmaceutical companies have adopted their own Corporate Code of Conduct, which is a compendium of the Government Decree and the Farmindustria Code.

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

As far as the different decrees and the Farmindustria Code are concerned, no special rules apply to public relations activities as distinct from advertising. Because public relations activities include 'informative actions to different targets', they are subject to the same legislation. For more details, see the answer to the first question.

Who is responsible for the enforcement of these rules?

The Italian Medicines Agency (AIFA) is the division of the MoH which deals with all drug-related issues , including research support, licensing, control of distribution and all communication activities directed at patients and doctors. AIFA has the authority to regulate information and activities about drugs and diagnostics. With the sole exception of authorised SmPC, promotional material disseminated to healthcare professionals must be submitted to AIFA at least 10 days prior to its dissemination.

In the case of no reply from AIFA, dissemination of promotional material shall be considered authorised (the 10-day tacit consent procedure). Reference to the date of submission to AIFA shall be placed on the authorised promotional material. In case of failure to comply with its guidelines, AIFA can order termination or suspension of the advertising and can issue a corrective statement to be published. For example, AIFA has powers to stop a screening campaign that might encourage the general public to ask their health professionals to prescribe specific tests that would increase Ministry costs. Or, it may stop an advertising campaign which overemphasises the effects of a particular drug.

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

According to Farmindustria's Code, pharma companies may hire healthcare providers (HCPs) for scientific consultancy. Pharma companies must create a contract that specifically stipulates the nature of the service and the HCP's relationship with the company. The pharma company must keep the contract for at least three years.

These regulations are enforced by The Supervisory Committee.

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

The Supervisory Committee receives complaints. The committee carries out investigations into complaints, and upon an investigation's conclusion, proposes a specific sanction and notifies the company. This sanction is then sent to the single-judge tribunal.

The single-judge tribunal then notifies the company that official proceedings have begun, during which the company may file a defense brief. The company's legal representative then participates in discussions before the judge. Thirty days after the discussions, the judge will submit a ruling. The company may submit an appeal, or comply with the recommended sanctions.

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

The difference between advertising and public relations activities is that for public relations activities there is no prior control, whereas both advertising messages to the general public and information provided to health professionals are subject to the prior approval of the Italian regulatory authority.

Advertising to the general public:

- Must be submitted to and authorised by the MoH 45 days before publication. No answer from the MoH within 45 days means implicit approval
- The authorisation is valid for 24 months, unless a shorter period is indicated in the authorisation
- In the case of implicit approval, the authorities can nevertheless order any time the suspension of the advertising; however the authorities need to justify its reasons

Advertising to health professionals (MDs and hospital pharmacists):

- Must be submitted to the AIFA and approved
- With the sole exception of an authorised SmPC, promotional material disseminated to healthcare professionals shall be submitted to AIFA at least 10 days prior to its dissemination.

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

Art. 117 states tha publicity content to the public regarding a medicine that is not permitted advertising cannot contain any element that:

1. Makes a medical consultation or surgical intervention appear unnecessary, specifically by offering a diagnosis or proposing a corresponding therapy;
2. Leads a member of the public to believe that a medicine is free of undesirable side effect or superior or equal to another treatment or another medicine;
3. Leads a member of the public to believe that the medicine can improve the normal state of good health of the subject;
4. Leads a member of the public to believe that the non-use of the medicine can have a prejudicial effect on the normal state of good health of the subject;
5. Is directed exclusively or generally towards children;

6. Includes a recommendation of scientists, medical operators or persons well known to the public;
7. Compares the medicine to a food product, a cosmetic product or another consumer product;
8. Induces to believe that the safety or effectiveness of the medicine is owing to the fact that it is a 'natural' extract;
9. Can lead to a wrong self-diagnosis;
10. Refers in an inappropriate, impressive or false manner to evidence of cure;
11. Utilises in an inappropriate, impressive or misleading way visual representations of changes to the body caused by illness or lesions, or of the action of a medicine

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

Farmindustria to comply with legal provisions of statute law and the Codes of Conduct of European and international federations of the pharmaceutical industry (EFPIA and IFPMA), amended its Code of Professional Conduct on 23 October 2012. No legal change is expected in the near future, although it is likely that the increase in availability of generic drugs will lead to tighter controls on promotional materials.

THE MEDIA

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

All the material that the pharmaceutical industry provides to doctors is considered as promotional (advertising). Further limitations are set according to different categories of providers.

Advertising to healthcare professionals:

- Limited to those healthcare professionals who may prescribe or sell medicinal products, typically medical doctors and pharmacists
- Advertising to healthcare professionals during visits of sales representatives shall, in principle, always include presentation of the most recently authorised SmPC, supply classification and public price
- Advertising to medical doctors also includes visits to laboratories and centers of research aimed at improving scientific knowledge

Advertising to pharmacists (excluding those working in hospitals):

- Advertising of prescription medicinal products shall be limited to the sole information contained in the SmPC.
- Advertising of non-prescription medicinal products may include all information that may be relevant to the pharmacist for advising patients on their adequate use.

Advertising aimed at the general public:

- Limited to medicinal products that do not require the help of a medical doctor for diagnosis, prescription and monitoring of their use.

Advertising of medicinal products that are available on medical prescription only; that contain substances defined as psychotropic or narcotic, that are reimbursed, even in part, by the National Health Services (NHS) or that are intended for research and development trials, as well as distribution of medicinal products to the public by the industry for promotional purposes, is forbidden.

How is a media event defined?

This is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?

Yes, regulators have separate requirements for advertisments targeted at HCPs and consumers. See the previous question for additional information.

Do regulations differentiate between print and broadcast media?

The same conditions apply. Advertising in newspapers with only the reproduction of the authorised medicinal product information and a picture or graphic of the product, or pictures, and graphic reproductions of a medicinal product that is available without prescription placed on price labels is acceptable.
Advertising of medicinal products aimed at the general public is subject to the prior authorisation of the competent committee of the MoH

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

In the specialist press for health professionals, it is possible to publish information regarding clinical trials of an unlicenced drug. When the scientific studies contain significant developments in a disease of general interest, it is possible to also publish information in the lay press or on radio/TV and the internet. The information is generally provided by print, radio and television journalists as part of their professional services. References to any treatment, research or launching of a product can be made provided that there is no contractual relationship between the pharmaceutical company and the publisher or the journalists. In any kind of press, either general or health professional and in TV and radio broadcasting, it is forbidden to use the brand name. Dissemination to the public in written publications, radio or television images or with a reference to the name of a medicinal product in a way that may cause its consumption is also forbidden.

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

The Decree does not specifically mention press releases. It is common practice, however, to consider press releases permitted when they relate to a potential improvements in public health and do not contain the brand name of the product. It is important that the

message provides scientific information and that the information is factual, balanced and non-promotional.

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)?
Clinical studies are also published on the internet and can be consulted by relevant journalists. In general, if a medical company is promoting in its own country, then its local country code is applied to the conduct of the promotional activities, plus the EFPIA code.

- For a non-European company promoting in a European country, the EFPIA code applies, along with the local code in the country in which the promotional activities are taking place.
- If a European company based in one country is promoting in a second European country, then the national codes of both countries and the EFPIA code apply.

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?
The Decree provides that advertising and promotion of medical products may relate only to products for which marketing authorisation has been issued. However, based on the Italian Constitution and the liberty of the press, it is possible in scientific meetings for independent scientific speakers to provide information regarding new active agents or new off-label indications and to discuss recent developments of clinical trials regarding unlicenced products or indications. The scientific secretary of the meeting may organise a press conference or distribute press releases. It is forbidden to use the brand name of the product. Scientists and journalists can only use a generic name.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
The general principle is that advertising should always be easily distinguished from educational information. Supplements and editorials to the general public are subject to the same regulations as advertising (i.e., the brand name of products cannot be mentioned) and cannot be paid for by the drug producer. However, if signed by a journalist, the liability is on the writer and/or the publisher. In practice, it is quite difficult to demonstrate that an article is a form of concealed advertising and the author/journalist/publisher can always appeal to the principle of the freedom of the press. For supplements and advertorials in the medical press, the same rules of Decree 219/2006 (Article 119) apply. Original scientific papers published in scientific journals and signed by their authors can be used and distributed by pharmaceutical industries or others with the permission of the publishing company. There are no specific limitations on the use of freelance journalists. Rules about content apply as stated above and are relevant to prior copy clearance.

Do regulations cover the use of case studies or other third-party advocacy in the media?
Per questions 15 and 16, as long as the product name is used, general health information provided by a third party group can be included in the media. The burden to meet legal standards falls on the journalist writing the article, not on the original provider of information.

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
Websites must comply with the legislative basis and the self-regulation codes. However, the Guidelines of the MoH of 17 February 2010 concerning advertising, and of medicinal products via the internet and telephone (including MMS and SMS) state that information directed to healthcare professionals and regulated by the Ministry must be accessible exclusively to these professionals, even when broadcasted via the internet. Therefore, companies should provide access only with an encrypted password given out to doctors, pharmacists and other health professionals after they are duly registered following the submission of their identification materials.

What levels of web security are required?
This is not yet fully specified; however, see answer to previous question.

Also, on 22 December 2010 the Italian Communications Authority (AGCOM) published a draft regulation, relating to AGCOM's powers in respect to the protection of copyright on electronic communications networks. In the first instance, AGCOM said it is competent to protect copyright on 'electronic communications networks', a term which includes television and telecommunications networks and the internet. This draft regulation provides an indication of a possible future regulating authority.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Guidelines for websites under the new EFPIA Code, which supplements the Italian regulations, describe to what extent non-promotional product information may be published on websites accessible by patients and the general public. Although the information must be factual, balanced and consistent with the SmPC, the guidelines seem to expand the scope for the kind of information that companies will be allowed to make available to the general public, which meets an industry need. How this will be interpreted remains unclear. The general rules and guidelines apply in this case as well.

What are the most popular social networks in your region?

More than half of the Italian population used social media regularly as of 2017. Facebook dominates the social landscape in Italy, with an 87% market share, while Twitter is a distant second, with a 4% share. YouTube and Google+ were also popular, as was Instagram.

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

In March 2017 the MoH updated the guidelines regarding internet Advertising on over-the-counter products. The advertising message, authorised by the Ministry on the basis of the MOH' committee for advertising, has to be static and not editable by the promoter of the ADV or other subjects.

The use of the social network -- which in general allows the users to manifest their own opinions -- compromises this static requirement guaranteed by law. Therefore, the use of social networks is not allowed except for the following cases:

Facebook:
It is possible to use Facebook for advertising messages (image, script, video, audio) only on the right column of the "Social Wall/Timeline". This type of insertion allows attaching images and a short texts. Clicking on the insertion/banner you will be directed to an external site. Facebook business pages (e.g., pharma company pages on Facebook) cannot show posts of products. Advertising on other social networks (e.g., Twitter, Instagram, etc.) is not allowed.

Youtube:
It is allowed to use Youtube for advertising messages (image, script, video, audio) - that have obtained authorisation by the MoH - with full interactivity functions disabled (like, share, comments).

Mail, SMS and MMS Messages:
It is possible to distribute authorised advertising messages via mail, SMS or MMS on condition that the company declares that the messages will be disseminated exclusively with the consent of the person who will be free to revoke constent at any time the consent.

Links:
Links from sites, banners, and other promotional material authorised by the Ministry and addressed to the general public are allowed under the condition that the company warn the user with the following statement: 'You are abandoning the Company's XXXXXX site ... with content authorised by the current legislation on health advertising'. This statement is not required in case the link refers to the SPC or SmPC) or to an image/packaging of the product.

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?

No specific rules exist. The general rules and guidelines apply.

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

In 2017 there were an estimated 50 million mobile phone users in Italy, or 80% of the population. Regulations for mobile advertising and marketing follow the general social and digitla media guidelines.

What are the disclosure laws like in your region for non-branded websites?

Non-branded websites have to show who initiated and supports them. For example, it must be clear if the website of a patient organisation is funded by pharmaceutical companies. General regulations will apply as well.

What is the response level needed for adverse event reporting?

The AIFA states that reports of adverse reactions (ADRs) are an important source of information since they allow detecting of potential safety issues associated with the use of the medicines available on the national territory. The reporting form for healthcare professionals is a simple form to be filled in to report adverse events relating to any drug. Reports are entered into the RNF, allowing the instant monitoring of adverse reactions. However, pharmacovigilance according to AIFA involves the whole community and the report on the occurred ADRs can be provided not only by the healthcare professionals, but also by citizens through the completion of the proper citizen's reporting form. Although this dual reporting procedure exists, surveys show that not all incidents get reported.

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?

Patient associations are becoming increasingly important in Italy and form partnerships with both AIFA and the pharmaceutical industry to discuss research plans, compassionate use programmes, new drugs and improvements to existing products. Patient associations have an important role in public relations and lobbying activities and are often financially supported by the pharmaceutical industry to help distribute information on diseases and treatments. Constraints on payments to these groups are not detailed in existing regulations. Collaboration of the pharmaceutical industry with patient organisations is not expressly regulated by the law in Italy. There are a number of provisions, however, which are relevant, including Article 4.5 of the Farmindustria Code, which provides that:

- All forms of economic support, whether direct or indirect, by the pharmaceutical company towards a patients' association must be based on a specific and preliminary agreement aimed at regulating the amount of financing and the reasons for its disbursement, and need to be entered into in accordance with specific internal procedures
- Public use by a pharmaceutical company of the logo or material owned by a patients' association must be authorised in advance by the association
- Any form of sponsorship by the pharmaceutical companies regarding patients' associations must be transparent and without promotional objectives
- No company can request to be the sole financier of a patients' association
- Pharmaceutical companies must include a list of the patients' associations they support on their websites.

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 not allowed?

The main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare professionals include the following:

- Article 123 of Legislative Decree No. 219 states that when giving out scientific information before healthcare professionals, the granting, offer or promise of gifts, pecuniary advantages or benefits in kind is forbidden unless they are inexpensive and relevant to the practice of medicine or pharmacy; a similar provision is also contained in the State-

Regions Conference Guidelines, which specify that inexpensive gifts or gadgets shall be understood as goods having an economic value of no more than €20 per year
- Article 4.1 of Farmindustria Code, provides that collaboration with healthcare professionals (e.g., scientific consultancies, speeches at conferences, studies, scholarships) must be in the form of a written contract, clarifying the need for the service and specifying its nature; the consultant also needs to disclose the relationship with the pharmaceutical company whenever there is a public presentation about the results of this collaboration
- Finally, according to Article 53 of Legislative Decree No. 165 of 30 March 2001, civil servants (including healthcare professionals working for the NHS) may not perform any paid activities unless a prior authorisation has been obtained

Failure to comply with the rules above may cause criminal liability, for example for criminal corruption. Sanctions range from imprisonment to fines.

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

Italian law allows under certain conditions pharmaceutical companies to sponsor scientific meetings, congresses, courses, prizes and grants.

Sponsorship activities require prior authorisation or communication to health authorities. Farmindustria members are required to give prior notice to AIFA of any meeting and event that they sponsor. Journalists' hospitality, fees and expenses, including travel expenses, may be paid directly by pharmaceutical companies and no AIFA permission is needed.

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

There are no limitations regarding participation in media training programmes.

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

In general, it is not permitted to use a pharmaceutical product's brand name in media materials (only a generic reference can be mentioned) unless the name of the product is central to the news.

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

Article 4.1 and 4.1 of the Farmaindustria Code apply to the provision of information to patient groups and healthcare professionals.

Any form of sponsorship and provision of information must be transparent and without promotional objectives.

KEY TAKEAWAYS/ SUMMARY

- The retail market for pharmaceuticals in Italy has been significantly affected by the overall economic climate, and no new legal regulations have been adopted in recent years.
- Any scientific information provided directly or indirectly by pharmaceutical companies (supply of samples, sponsorship of meetings and events, activities of sales representatives) is considered promotional (to health professionals or to the general public) and should be carried out in accordance with the Italian legislation.
- Advertising aimed at the general public shall be limited to medicinal products that do not require the help of a medical doctor for diagnosis, prescription and monitoring of their use.

NORWAY

Promotion of medicines in Norway is governed by the Pharmaceutical Laws, the regulations on Pharmaceuticals, Norway's Association of the Pharmaceutical Industry's (LMI) Guidelines and Rules for Cooperation and Advocacy Groups/Healthcare Providers (HCPs). Although not legally binding, LMI's guidelines are widely recognised by the pharmaceutical industry as an expression of fair and ethical marketing. The national regulatory framework for promotion of medicinal products specifically states that its legislated regulations do not stop the industry from having their own structure and process for marketing pharmaceuticals. The national regulatory framework for promotion of medicinal products is largely based on EU legislation. It is, for instance, prohibited to advertise medicinal products that are not authorised to sell in Norway or to aim advertisements of medicinal products at children. In addition, advertisements on prescription medicinal products may not be aimed at the general public, with the exception of vaccination campaigns against infectious diseases.

THE BASICS

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

Information distribution on pharmaceuticals is governed by the pharmaceutical laws, the regulations on pharmaceuticals, LMI's Rules for Pharmaceutical Marketing and the agreement between LMI and the Norwegian Doctors' Association (Dnlf) regarding guidelines and rules for cooperation between the pharmaceutical industry and patient advocacy groups.

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

Information designed to enhance sales and increase the demand for a product, which mainly focus on the benefits rather than the potential risks associated with the pharmaceutical product, might be considered advertising or promotional activity. Public relations is not defined separately.

Who is responsible for the enforcement of these rules?

The Council for Pharmaceutical Information, established by LMI and the Norwegian Medical Association (NMA), is responsible for controlling the adherence to the Rules for Pharmaceutical Marketing Every employee of a pharmaceutical company involved in production or approval of information directed towards HCPs must be fully familiar with the regulations in the Rules for Pharmaceutical Marketing. Every firm must have a scientific department handling all information. They must appoint a compliance officer who is responsible for approving all informative material for distribution. This person may be a doctor, pharmacist or a person of sufficient educational competence to assess the material.

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

According to pharmaceutical laws, doctors, dentists, veterinarians, pharmacists or fish health biologists may not participate in marketing with recommendations and thereby encourage the use of pharmaceuticals. According to the Rules For Pharmaceutical Marketing, HCPs are allowed to be used as consultants by the industry given that there is a written contract, the actual need is clearly defined and that the compensation is reasonable in comparison to the service provided by the HCP.

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

According to the Pharmaceutical Law, § 13-10, the Norwegian Medicines Agency (SLV) is responsible for compliance of pharmaceutical marketing. Any company violating marketing regulations may be forced to stop that specific marketing activity and corrective actions may be administered. With repeated violations, all marketing measures for a medicine may be stopped for an unspecified amount of time, or permanently. Aside from these agency regulations, the industry may have their own control measures.

The industry's pharmaceutical information is subject to ongoing audit by the Council for Pharmaceutical Information, run by the LMI and NMA. All members of LMI are obliged to submit all information and marketing material to the Secretary of the Council.

Complaints regarding members of LMI or NMA may be submitted. The council's verdict on all matters is final and binding.

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

SLV may pre-approve specific promotional material targeting users of a prescription drug, e.g. regarding advanced forms of administration, or other important user information.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?
The Rules for Pharmaceutical Marketing were last updated 14 November 2014.

1 January 2016, television commercials for over-the-counter (OTC) pharmaceuticals were legalised in Norway.

THE MEDIA

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

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

Do the regulations differentiate between consumer and clinical publications?
No, the regulations are the same.

Do regulations differentiate between print and broadcast media?
No, the regulations are the same.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meeting and major publications?
The rules do not specifically address this issue.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
In accordance with business practice, press releases are not considered marketing, even if this contradicts the view of the SLV. LMI disagrees with the authorities and urges their members to continue to issue relevant press releases that are balanced, leaving the decision to publish in the hands of media editors.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The method of distribution is not regulated. Material from outside of the country also needs to fulfill Norwegian rules and regulations.

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?
Journalists may receive congress reports containing news on research, ongoing studies and preliminary research findings, given that the information is relevant and balanced.

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

Do regulations cover the use of case studies or other third-party advocacy in the media?
Third-party advocacy of medicinal products in media by HCPs or patients on behalf of pharmaceutical companies or their PR agencies is not allowed. However, an article regarding a patient, written by a journalist, is protected by the freedom of speech. Pharmaceutical companies are still not allowed to use these statements, or refer to them.

DIGITAL & SOCIAL MEDIA

Are online media channels treated differently from print and broadcast and, if so, how are they regulated and monitored?
There is no difference in the regulations between online media and print media.

What levels of web security are required?
This issue is not specified.

Do the regulations cover funding of, or provision of information to, non-company owned websites?
Cooperation with third parties, e.g. patient advocacy groups, is allowed but must be transparent. All pharmaceutical companies must publish an annual list of which patient advocacy groups to which they contribute economic or significant non-economic support to.

What are the most popular social networks in your region?
Facebook, Twitter, Youtube, LinkedIn, Snapchat, Google+, Pinterest and Instagram.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
No.

Are there any self-imposed regulations from social media companies?
Social media platforms have their own codes of conduct. Limitations to what may be published in these channels regarding pharmaceuticals are not governed by such codes of conduct, but by local laws and ethical guidelines for the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Any adverse events, including such reported through social media, shall be reported to the authorities within 24 hours by the pharmaceutical company.

What is mobile adoption like in your region? Are there separate regulations for it?
There are no separate regulations for mobile devices. Use of social media through mobile devices is widespread.

What are the disclosure laws like in your region for non-branded websites?
Information regarding the pharmaceutical company behind the information must be included. This information must include the name of the company or their Norwegian agent and contact information.

Pharmaceutical information on websites must clearly include information regarding target audience. This includes links to websites containing pharmaceutical information, e.g. from non-branded websites, where the information by the

link needs to clarify the target group for the information at the link. If the link leads to a page with HCP information, a disclaimer should be used that asks the visitor to confirm his or her category before accessing the information.

What is the response level needed for adverse event reporting?

According to the Regulation on Pharmaceuticals, § 10-5, pharmaceutical companies are obliged to report all severe adverse events within 15 days to EudraVigilance. Other suspected adverse events shall be reported within 90 days.

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?

According to the rules for cooperation between the pharmaceutical industry and patient advocacy groups, congresses or meetings arranged by a pharmaceutical company shall address their area of expertise and the major part of the programme must be scientific or profession-related. A company is not allowed to sponsor ordinary or internal activities of an advocacy/patient group. The meeting should be held in Norway, if possible. Destinations associated with leisure or entertainment are to be avoided. All forms of representation shall be at a reasonable level and shall be subordinate to the scientific purpose of the activity. Costs that may be covered by a pharmaceutical company are limited to travel, meals, accommodation and registry fees for participants as well as, in special cases, also for their personal assistant. It is allowed to travel to another country if a majority of the participants are from another country than Norway or due to certain experts being from that country.

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 possible to offer honoraria if a HCP or advocacy/patient organisation representative is participating in a media activity targeting journalists. Honoraria is to be reasonable in regards to the time required to perform the activity. All cooperation shall be preceded by a written contract specifying the project, its purpose and the budget.

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

According to the agreement between LMI and Dnlf

regarding guidelines for cooperation, Chapter 2, section 2.2, it is allowed to sponsor a HCP to attend a scientific meeting within the pharmaceutical company's own area of expertise. They may cover travel, meals and accommodation within reasonable limits.

According to the rules for cooperation between the pharmaceutical industry and patient advocacy groups, pharmaceutical companies may sponsor an advocacy/ patient group's participation at a conference, including travel, meals and accommodation expenses, within reasonable limits.

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

There are no limitations in regards to message training.

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

If pharmaceutical companies, or PR agencies operating on their behalf, produce written material on behalf of third parties, their support shall be announced for transparency. In accordance with the Rules for Cooperation Between the Pharmaceutical Industry and Patient Advocacy Groups, a company may not affect the text in a material from the patient advocacy group in such a way that it favors their own interests.

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

Pharmaceutical companies' relations and meetings with advocacy groups are regulated by the Rules for Cooperation Between the Pharmaceutical Industry and Patient Advocacy Groups.

KEY TAKEAWAYS/ SUMMARY

- The distinction between PR and advertising in cases of promotion of medicinal products has become less relevant from a regulatory point of view. Promotion of prescription medicinal products may not be aimed directly at the general public, with the exception of vaccines.
- Even though it is not officially allowed to send press releases to media regarding pharmaceuticals, companies continue to do so in accordance with business practices. It is important, however, that the press releases are relevant and balanced.
- Regardless of being a member of LMI or not, the best way to avoid any breach of law or regulations is to ensure that your company adheres to its ethical guidelines.

POLAND

Any correspondence or materials produced by a pharmaceutical company about medicines or their use is promotional, whether or not it makes product-specific claims. All promotional information should be accurate, balanced, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine. It must not be misleading and must reflect the most up-to-date evidence.

THE BASICS

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

The relevant government regulation that has been enforced in Poland since September 2001 is the Pharmaceutical Law Act and its amendment, implemented in December 2008, concerning the advertising of prescription medicines.

In addition, self-regulation of the pharmaceutical industry is administered through the Employers' Association of Innovative Pharmaceutical Companies (INFARMA) under the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations (the Code).

the Code sets forth standards for promotional activities and refers to all forms and methods of medicinal product advertising, particularly advertising materials, press advertisements and the activity of medical representatives. The Code also regulates issues of interactions between the pharmaceutical industry, healthcare professionals and patient organisations and is binding for all of the INFARMA member companies and associations that do business in the European Union.

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

There is no official definition of public relations (PR) in Poland, so there are no laws that specifically regulate the PR practice. The only national PR code is the Kodeks Dobrych Praktyk of the Polish Public Relations Consultancies Association (ZFPR).

However, the section of the Pharmaceutical Law Act that is dedicated to the advertising of medical products defines advertising broadly and is interpreted to cover all promotional activities and direct marketing. The law also differentiates what is not considered as advertising, and specifically describes those advertising practices that may be considered legal.

Who is responsible for the enforcement of these rules?

The ultimate power establishing and implementing pharmaceutical laws and regulations resides in the Polish Parliament (Sejm), acting through the Polish Ministry of Health (Ministerstwo Zdrowia or MZ). The agency within MZ that administers pharmaceutical law in Poland is the Main Pharmaceutical Directorate (Głowny Inspektorat Farmaceutyczny) and the officer who oversees advertising is the Main Pharmaceutical Inspector (Głowny Inspektora Farmaceutyczny).

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

The basis of HCP engagement by companies is outlined in the Pharmaceutical Law and specified in the Regulation of the Minister of Health of 21 November 2008 in the advertising of medicinal products. The bill specifies what is considered an advertisement, i.e. visiting doctors, sponsoring doctor's participation in a conference, distributing samples, and details processes and procedures for advertisements.

The representatives should be prepared to receive reports on adverse effects. It is enforced by the Chief Pharmaceutical Inspector, who can order illegal advertisments be stopped.

The Code also details standards for gifts, donations to healthcare organisations, sponsorship of healthcare professionals and services rendered by healthcare organisations to the signatories of the Code and employing consultants. Those activities should be carried out in accordance with the Code and documented.

Another regulation is the Disclosure Code, which states 'a self-regulation of the innovative pharmaceutical companies associated' in INFARMA. It defines the rules for providing information on cooperation between signatory companies and medical profession

representatives and healthcare organisations. The Disclosure Code is part of the European project which aims to increase transparency of innovative pharmaceutical companies' cooperation with the medical community. It was prepared by the European Federation of Pharmaceutical Industries and Associations (EFPIA), which is represented in Poland by INFARMA. The provisions of the Disclosure Code are implemented simultaneously by 33 affiliated associations and EFPIA member companies.

According to the Disclosure Code, all cooperation agreements of the signatory companies with the medical profession representatives and healthcare organisations, effective from 1 January 2015, shall include an additional consent form to share personal data. In June 2016, signatory companies published disclosure reports on their websites.

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

If the actions of one INFARMA Code signatory disrupts the interests of another signatory, they can lodge a complaint with the Disciplinary Court. Others can also complain if the company's actions are not in sync with the Code. The Court does not replace the enforcement and courts of general law, but rather looks into code infringement to the benefit of the whole pharmaceutical industry. The general law infringements are handled by general law courts.
Sanctions are specified in Article 57 1.

If any breach of the Code provisions is found, the Court may, considering the type and degree of harmfulness of the breach as well as the benefits gained by the defaulting party and whether or not the Court has declared a breach of the provisions of the Code by the same entity over the previous 12 months, rule as follows

1. A prohibition on the continuation of the challenged actions, in particular, the immediate withdrawal of the advertising materials breaching the provisions of the Code from all mass media
2. A reprimand or rebuke
3. An order to submit a single or repeated statement of particular wording to specified mass media or to specified addressees
4. A notice to the Main Pharmaceutical Inspector regarding the decision
5. A notice to The European Federation of Pharmaceutical Industries and the Associations for the International Federation of Pharmaceutical Manufacturers and Associations) regarding the decision that was issued;
6. a notice regarding the decision to affiliated entities of the party breaching the Code; the obligation to publish the decision or its parts in specified mass media once or multiple times; the suspension or expulsion from INFARMA in the case of gross breaches of the Code.

The sanctions may be imposed cumulatively. The Code is available in English on INFARMA website. Potentially, a complaint may also be sent to Chief Pharmaceutical Inspector, who can order arrest of advertisements activities

What promotional or media materials must be approved by authorities?

No, there is no approval process in place.

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

The only significant change would be if the State Health Fund (Narodowy Fundusz Zdrowia or NFZ) is dismantled. If this happens, the reimbursement process will change. However, while there is discussion of the fund changing, this is only speculation.

THE MEDIA

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

In the original Pharmaceutical Law Act, enforced in 2001, there is a distinction between advertising and information dissemination (see Question 11). Promotional activity is covered in the broad definition of advertising.

How is a media event defined?

There is no one, clear definition of a media event available. There are no legal provisions regarding media events for medicine promotions, as such. However, the role of companies in supporting media events and the contents of the materials that are disseminated in conjunction with such events are regulated within the context of advertising.

Do the regulations differentiate between consumer and clinical publications?

The regulations (especially amendment: Dz.U. 2008 nr 210 poz. 1327) do not differentiate between consumer and clinical publications. However, as in all European countries, product brand identification is not acceptable in consumer communications but is allowed in the advertising and promotion of pharmaceutical products to medical practitioners authorised to issue prescriptions or to those involved in the distribution (such as wholesalers or distributors) or dispensing (pharmacists) of pharmaceutical products.

Do regulations differentiate between print and broadcast media?

No, the regulations do not differentiate between print and broadcast media.

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 Pharmaceutical Law Act, the permitted promotional activities are:

- Correspondence, including attached informational, non-promotional materials, sent by manufacturers in response to doctors' questions about the product (including its characteristics)
- Informational notices about changes in packaging, side effect warnings, prices
- Information about health or illnesses of people and animals, provided they do not mention, even indirectly, the medicinal product

The Pharmaceutical Law Act does not provide any specific information about congresses, scientific meetings or major publications and media relations.

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 in the Pharmaceutical Law Act regarding these issues.

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)?
Polish regulations do not extend beyond Poland. However, the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations states that any information delivered to professionals outside the country (such as at international congresses) should mention essential differences bewtween countries in the registration and indications for the medicine.

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 clear statement about the sponsoring of media attendance to congresses and scientific meetings. The Pharmaceutical Law Act does, however, state that it is illegal to offer such sponsorship to pharmacists and individuals authorised to issue prescriptions when the organisers' 'acts of generosity' go beyond the merits or purposes of the meeting or conference.

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 are no legal constraints controlling journalists' coverage of an organised congress or meeting, or their use of informational materials distributed at such events.

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

DIGITAL & SOCIAL MEDIA

Are online media differentiated from print and broadcast and, if so, how are they regulated and monitored?
There is no regulation of this area.

What levels of web security are required?
There is no regulation of this area.

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

What are the most popular social networks in your region?
Facebook is the most popular social network in Poland and Instagram is gaining increasing traction in the market. Twitter and YouTube are also among the top social media platforms.

NK, a native Polish social network established in 2006, has experienced a rapid decline in its user base and influence in recent years, replaced by the global networks.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
According to the Polish law, pharmaceutical companies must not share information on RX medicines with the general public -- only with the doctors.

This also means social media, which is why pharmaceutical companies who sell prescription medicines seldom run their own social media profiles on disease awareness. Most commonly patient organisations do this. Patients can talk about their prescription with other patients. Websites which can be fully controlled by the owner exist and are used to build awareness.

Are there any self-imposed regulations from social media companies?
There are no self-imposed regulations from social media companies.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
It depends on a particular site.

Each forum has its own policies. Most of them don't accept spam, and any information that looks like spam will be removed by the site administrator. If a company wants to communicate with users via forums, it has to first contact the site administrator, and ask for conditions. For instance, forums of goldenline.pl do not allow users to use brand or product names. Such comments are considered advertising and treated as spam. The only possible way to inform the customer is to talk about the problem or social issue addressed by the product.

What is mobile adoption like in your region? Are there separate regulations for it?
In Poland, there is minimal access to mobile applications that would provide medical information to physicians, medical students or interns, so there is little regulation surrounding mobile adoption in the health sector.

What are the disclosure laws like in your region for non-branded websites?
There are no official laws concerning non-branded websites. However, there is a section in the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations devoted to websites. The Code states that the site should include information about the sponsor of the website, contact details, the aim, and the addressees of the site.

What is the response level needed for adverse event reporting?
The amendment to the Pharmaceutical Law assumes that each person eligible to prescribe, dispense or administer a medicinal product should immediately report any suspected adverse event directly to the producer or to the Office for Registration of Medicinal Products, Medical Devices and Biological Products. Initially, this obligation concerned only doctors and pharmaceutical companies. A more recent amendment added two new professions: licenced nurses and midwifes.

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 clear distinctions in the Pharmaceutical Law Act. The Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations, however, states that the criteria used by the company to choose the advocacy/patient groups invited to an event should be objective and based on merit. The place chosen for such a meeting should not be extravagant in terms of entertainment offered. Acts of hospitality of the sponsors should not exceed the main aim of the meeting. The sponsor should cover the expense of no more than: the trip, accommodation, congress registration fee., and catering. These sponsorships should not cover any expenses of any accompanying persons (i.e., family, friends).

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?
Generally speaking, it is possible under certain conditions to offer honoraria to healthcare professionals and/or advocacy/patient group leaders (see Question 25). There are no special comments excluding any particular category of travel.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
According to the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations, it is prohibited to pay a health professional or advocacy/patient group

compensations for time spent going to a meeting/ congress, but it is acceptable to pay them for the costs of their presence at the specific event (see Question 25).

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

There are no regulations on this subject.

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

According to The Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations, the sponsor should always respect the independence of the third party and cannot expect an exclusive partnership.

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

The only operative regulations can be found in the Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations.

KEY TAKEAWAYS/ SUMMARY

- It must be kept in mind that Poland spends less money per capita on healthcare and medicines than almost every other country in Europe. The cost of medicines is controlled tightly and is generally quite low, although patients are subject to co-pays that are proportionately quite high relative to other European countries. One way that Poland controls the amount of money it spends on prescription medicines is to carefully ration the use of the newest products and often to delay their broad availability until an array of generic versions (branded or otherwise) can be added to the reimbursement list.
- If a company is suspected of abusing advertising and promotion, the MZ will not hesitate to use the mass media (which is generally negative towards the industry) to 'name and shame' that company. One notable instance was the publication of a photo of numerous women doctors enjoying a luxurious day spa during a company-sponsored medical education meeting.
- Polish professionals and lay audiences alike are avid consumers of health and medical information. The best medical writers, both for the trade and general media, are very good and very willing to let third-party medical information sources review their quotes and facts for accuracy. Social media is extremely popular. The Polish patient advocacy and support community are growing in size and sophistication.

PORTUGAL

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

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

THE BASICS

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

The promotion of medicines in Portugal—both over-the-counter (OTC) and prescription—is subject to two main standards: (1) Decree-Law n.º 176/2006 (Aug. 30 2006) (Code of Medicinal Products), which was amended by Decree-Law n.º 128/2013 (Sept. 5 2013), which require additional notification to INFARMED. (2) APIFARMA's (Portuguese Association of the Pharmaceutical Industry) Ethics Code of Marketing & Pharmaceuticals Practices form.

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

The Code also details the EC Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use. The Advertising Code approved by Decree-Law n.º 330/90 of October 23 states that advertising in general, including all the aspects of the advertising of medicinal products not defined in the Code of Medicinal Products. Regarding medical devices, Decree-Law n.º 145/2009 of June 17 should be noted, as it establishes legal framework for advertising.

Gral - INFARMED Decree-Law No. 176/2006 includes articles and chapters such as Section IX, which states: 'It is considered drug advertising for the purposes of this document, any form of information, canvassing activity or inducement in order to promote the prescription sale, purchase or consumption of a specific treatment'.

Article No. 152 says:
1. The advertising of drugs that are not subject to a valid permit or registration for the national market or have been authorised according to Articles 92 and 93 is prohibited;
2. It is prohibited to advertise medicinal products to the general public that:

- Are subject to prescription;
- Contain substances defined as psychotropic or narcotic drugs under international conventions that bind the Portuguese State;
- Are distributed by (?) National Health Service;

3. The information presented in the previous number doesn't preclude:

- Vaccination campaigns carried out by the industry, if previously approved by INFARMED;
- Promotion campaigns for generic drugs developed by the industry and approved by INFARMED.

4. The distribution of medicines directly to the public by industry is forbidden.
5. It is forbidden to mention the name of the treatment even if it's related with a sponsorship initiative to the public, unless it has explicit legal approval.

In spite of this restriction regarding prescription drugs, Article No. 153 states that non-prescription drugs can be advertised and promoted to the public.

The sunshine rules were transposed into Portuguese law by means of an amendment made in February 2013 to the Portuguese Medicinal Products Act (Decree-Law 176/2006 of Aug. 30).
In 2013, the Code of Medicinal Products had two major changes. In February 2013, it was amended by Decree-Law n.º 20/2013 (Feb. 14, 2013), transposing Directive 2010/84/EU (15 December 2010) and including pharmacovigilance.

Subsequently, the Code was further amended in September 2013 by Decree-Law n.º 128/2013 (5 September 2013), detailing Directive 2009/35/EC (23 April 2009) on the colouring substances that may be

added to medicinal products, as well as Directive 2011/62/EU (June 8, 2011) as regards the prevention of the entry into the legal supply chain of falsified medicinal products and Directive 2012/26/EU (25 October 2012) as regards pharmacovigilance. Other substantial amendments introduced into the Code include those regarding the advertising of medicinal products.

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

The other binding document—Ethics Code of Marketing & Pharmaceuticals Practices—presents a more generic approach regarding the promotion of medicines. Article No. 4 of the Code states: 'Information on the characteristics of the drug should not exceed the limits presented by the available scientific evidence and their preparation must be devoid of any ambiguous data'.

Article 9 states: 'The information related to a prescription medicine should only be addressed to the people for whom one can assume, with reasonable accuracy, that they need or have an interest in it'.

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

Currently there isn't any form of differentiation. The rules presented for advertising also apply to public relations and media relations. The communications professionals must carefully evaluate the content of the different materials. In these cases, the PR professionals have to implement self-regulation with a strict nondisclosure code.

Who is responsible for the enforcement of these rules?

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

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

Article 20 of the APIFARMA Code states that:

a. Pharmaceutical Industry companies may provide support to institutions, organisations or associations of Health Professionals providing healthcare or are engaged in research if:

i. They are made with the purpose to support healthcare provision or research;

ii. They are preceded by a written request of the beneficiary entity, dated, signed and addressed to the donor;
iii. They are documented and recorded by the donor;
iv. They are not an incentive nor the contribution to the recommendation, prescription, purchase, supply, sale or administration of certain medicinal products, nor the use, prescription, dispensing, selling, purchase or the consumption of in vitro diagnosis medical devices.

b. The supports mentioned in the previous number may be financial or non-financial contributions.
c. When the support is benefits in kind they should not bear the name or the logo of a medicinal product.
d. No support should be granted to HCPs individually.

Pharmaceutical companies are also allowed to provide HCPs with informational/education materials as long as the materials are of low cash value and relevant to the health practice (Article 21). Pharmaceutical companies are also allowed to hire HCP consultants 'to participate, among others, in lectures, meetings, take part in medical/scientific studies, clinical trials, training programmes, follow up of counselling and market research committees,' as long as they are (Article 22). Specific limitations of this practice are also listed under Article 22 and include the following:

- The number of selected healthcare professionals should not exceed the reasonable number of professionals required to achieve the identified purpose
- The contracting company should keep all records related to the services provided by the healthcare professionals
- The obligation of the healthcare professional to identify himself/herself as a consultant of the company, whenever he/she writes or lectures in public on subjects which are the object of the contract or agreement
- Limited market studies, such as phone interviews or questionnaires sent by mail/email/internet, are excluded from the scope of this article if the healthcare professional is not consulted in a recurrent manner and the payment for the service is suitable and not excessive

The Council of Ethics of APIFARMA oversees the enforcement of these regulations.

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

The Council of Ethics of APIFARMA receives concerns and complaints. In the case of a violation, the 'Association should ask the offender to immediately put an end to the irregular activity and to undertake, in writing, the obligation to not relapse in that practice,' (Article 30). The applicable sanctions are listed in the APIFARMA Statutes, which include the following from Article 29 of the Statutes:

- Simple warning;
- Reprimand;
- Penalty up to the amount of five years membership fees;
- Suspension up to one year;
- Banishment

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

Only the ones considered advertising pieces. INFARMED created the Drug Advertising Management System (GPUB)

with the Deliberation No.044/2008 that monitors, approves and controls the promotional pieces for the pharmaceutical market. Companies must present their materials before starting the marketing process. While the materials will be rejected if they don't comply with the rules, the analysis continues after the launch of the treatment and includes different channels such as television, radio, press and Internet. Complaints from the general population or healthcare stakeholders may also be considered. Before the GPUB submission, the submitted materials must be approved internally by the respective medical departments.

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

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

INFARMED is currently evaluating the impact of social media in the process of sharing health information. New guidelines should be available soon.

Between 2011 and 2014, Portugal has been under an EU/IMF Financial Assistance Programme (FAP) which involved a set of initiatives including structural legal measures relating to public finances, financial stability and competitiveness. In relation to the health sector the FAP, which has not been used since 2014, involved:
Reorganisation and rationalisation of the public hospital network through specialisation, concentration and downsizing of hospital services, joint management and joint operation of hospitals;
Legal and administrative measures to control and decrease the price of medicines subject to medical prescription and of reimbursed medicines;
Reduction of debt due to suppliers of the NHS, including pharmaceutical companies (Sustainability of NHS Memorandum of Understanding);
Improvements in the billing and collection of revenues from NHS moderating fees (taxas moderadoras), insurance companies and fees for the treatment of cross-border/foreign patients;
Improvement of the monitoring and assessment system of doctors' prescription process regarding medicines and diagnostic in terms of volume and value and as against prescription guidelines and peers;

- Additional centralised public tenders for active substances and medical devices, and establishment of an observatory for prices and acquisitions.
- In 2016, the Ministerial Order, a Working Group for the Prevention of and the Fight against Fraud in the National Health Service;
- Rules for prescription, dispensing and accountability of medicines;
- Compulsory e-prescription and international non-proprietary name (INN) prescribing: mandatory INN prescribing for all active substances (06/2012);
- Stimulus to improve efficiency resulting from the use of generic medicines and biosimilar - access to truly innovative medicines;
- Changes in pharmacies' margins in the international reference price system and in the pricing of generics;

Despite the end of the FAP, part of the referred measures will continue to be adjusted and monitored during 2016 by national public authorities.

THE MEDIA

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

All the material that the pharmaceutical industry provides to doctors such as brochures, newsletters, advertorials in medical journals and internet web pages for the medical profession are considered promotional.

How is a media event defined?

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

Do the regulations differentiate between consumer and clinical publications?

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

Do regulations differentiate between print and broadcast media?

There is no differentiation except for trade media.

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

A medicine cannot be actively promoted prior to the marketing authorisation allowing its sale or medical supply (the formal authorisation is called Autorização de Introdução no Mercado (AIM). However, publication in clinical newspapers of scientific information prior to authorisation is acceptable if supported by scientific data. Usually that occurs after the presentation of international information from an independent medical source or from a press release—medical and general media—about a clinical trial.

In congresses, scientific meetings, and major publications, it is possible to distribute and share scientific information (not for the general media) as

long as there are sufficient scientific data that represent credible information and not promotion.

Pharmaceutical companies can sponsor medical meetings and scientific symposiums prior to the launch of a product but in accordance with Article No. 159 from INAFRMED's Drug Statute:

1. The sponsorship of congresses, symposiums or scientific events directly or indirectly should be documented as well as the promotional materials and the reports published after the completion of those actions and events
2. The marketing authorisation holder or the company responsible for the information or promotion of the product should keep the data for each of the events or activities sponsored or organised
3. The documentation referred includes, in a complete and faithful way, the following
   - Action and events programme
   - Main entity identification
   - Copy of the scientific and professional communication;
   - Expense maps, receipts and justification documents.
4. The documentation referred in the previous paragraphs should be retained for a minimum of five years from the date of the event and made available to entities with supervision powers such as INFARMED. Furthermore, the recipients of these benefits, which include certain patient groups or medical companies, associations or corporations that is scientifically oriented or conducting clinical studies, but also any entity or individual (specifically healthcare professionals), must notify INFARMED and register such benefit on INFARMED's website. Since 7 October 2014 these rules only apply to transfers of a value exceeding €60 (prior to 2014, these rules applied to transfers of a value exceeding €25). INFARMED further clarified that any hospital, service or medical society that organises a certain congress must be identified as the beneficiary of the event, and not the healthcare professionals

The main rule in this respect is aimed at preventing any type of prescription incentives; therefore, the holders of the marketing authorisation or of the registration of medicinal products, as well as companies responsible for the promotion of medicinal products and wholesale distributors, are not allowed to directly or indirectly give or promise to healthcare professionals or their patients prizes, offers, bonuses or precuniary benefits or benefits in kind unless they are insignificant and relevant for medical or pharmaceutical practice.

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

The information of the drug characteristics should not exceed the limits backed by the available scientific evidence, and their preparation must be objective. The information presented in the promotional material or the intended information to promote a drug's good use must:

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

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

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

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

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 specific indication is given, but press conferences or briefings can be held at congresses and scientific meetings outside the main rooms. Media, general and specialised, can attend. The events should not be dedicated to the presentation of products (except for specialized journalists) since the direct communication of unlicenced products or indications is prohibited. A disease awareness communication is often adopted.

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

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

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

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

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

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

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

DIGITAL & SOCIAL MEDIA

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

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

What levels of web security are required?

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

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

The Code of Conduct Governing the Relations between Pharmaceutical Industry and patients' organisations is always present during companies' and institutions relationship. According to the Code:

Article 3

Agreement

1. Companies that want to provide direct or indirect financial support and significant non-financial support to Patients' Organisations should put it in writing, by means

of an agreement signed by both parties, according to the form included in Appendix of this Code.
2. The agreement mentioned in the previous number should mention the express amount of the financing, as well as its purpose or a description of the significant nonfinancial support as the case may be.
3. Each company should establish internal proceedings of formal approval of the agreements mentioned in the previous numbers.

Article 4

Use of logo and materials subject to copyright

1. The public use by a Company, in the scope of the agreements mentioned in the previous article, of a logo and/or materials subject to copyright belonging to a Patients' Organisation is subject to a written authorization given by the latter.
2. The authorisation request mentioned in the previous number should clearly indicate the specific objective and the way the logo and/or materials subject to copyright are to be used by the company.

Article 5

1. Companies should not try to influence the contents of materials produced by patient organisations they sponsor.
2. Companies may correct evidence-based and/or scientific inaccuracies existing in produced materials.
3. Companies may contribute to the preparation of texts of scientific nature, if requested by patient organisations.

Article 6

Transparency

1. The list of patient organisations sponsored by each company in the scope of the agreements mentioned in article 3 should be disclosed, each year, with a short description of the nature of the provided support.
2. Companies should make sure that the information on the sponsorship of patient organisations is disclosed in a clear and transparent manner on request of any stakeholder or through the institutional website of the Company, until May 31 of each year.

Article 7

Financing

1. No company can impose itself as to being the exclusive sponsor of a patient organisation or of its main programmes.

INFARMED regulations aren't clear about the pyramid of influence, but it is important that companies comply with the general principles presented in the drug statute.

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

What are the most popular social networks in your region?

Facebook is the largest social network in Portugal, with 5.9 million users as of 2017. Pharmaceutical companies remain cautious when using social media and have prepared internal guidelines around their usage, as INFARMED has yet to adopt specific regulations for these platforms.

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

While there are no provisions on the use of social media for promotion, the APIFARMA Code of Ethics does provide guidance for promotion on the Internet in Article 11:

1. Internet promotion of medicinal products or in vitro medical devices should be based on technical, scientific and professional principles, and in compliance with the national legislation of force.
2. Companies should adopt such measures so as to guarantee that the promotion of prescription only medicinal products or in vitro medical devices requiring a healthcare professional's mediation or decision is accessed only by healthcare professionals.

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

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

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

Currently, there aren't any rules for digital platform engagement, but the general principles presented in the drug statute should be followed. Pharmaceutical companies shouldn't express their view about prescription medicines or try to directly engage patients since direct commercial contact is forbidden.

A company can start or endorse a forum to discuss a specific disease, but the management of that digital space must be made by an outside entity.

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

65% of Portugal's population used smartphones as of 2017. Due to the relatively high adoption rate, pharmaceutical companies have begun to invest in apps for consumers and healthcare professionals. However, direct-to-consumer advertising of medical products is still prohibited on mobile devices, so many apps focus on disease awareness and management.

What are the disclosure laws like in your region for non-branded websites?

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

What is the response level needed for adverse event reporting?

Health professionals, inside and outside the National Health System, must inform the INFARMED pharmacovigilance as soon as possible about adverse reactions, suspected adverse reactions or serious unexpected situations that occur.

Article No.153 from the INFARMED's drug statute clearly states that it is forbidden to suggest that the drug effect is guaranteed with no adverse reactions or side effects. Article No.170 from the same document also says that the pharmaceutical companies must record and immediately report (through health professionals or other sources) to INFARMED all suspected serious adverse reactions that occur in Portugal.

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

Recent amendments to the Medicinal Products Code, established by Decree-Law n.º 20/2013 (Feb. 14, 2013) and Decree-Law n.º 128/2013 (Sept. 5, 2013), concern medicine safety matters. Directive 2010/84 (15 December),

which amends Directive 2001/83/EU as regards pharmacovigilance, was transposed into national law in 2013. This reformulated the Portuguese National Pharmacovigilance System, and included new requirements to prevent, detect and assess adverse reactions to medicinal products placed on the EU market, as the full safety profile of medicinal products can only be known after they have been placed on the market. Directive 2012/26/EU (Oct. 15, 2012) also amended Directive 2001/83/EU as regards pharmacovigilance, and further strengthens the European rules respecting the safety and monitoring of medicinal products, and was transposed into national law in 2013.

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

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

STAKEHOLDERS/ ADVOCACY GROUPS

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

In Portugal, pharmaceutical companies can provide funding to patient groups for travel and accommodations as long as the hotels are below four stars. This is possible for national and international events, and on more general grants, but according to the Drug Statute, pharmaceutical companies cannot give any commercial information directly to patients or patient groups.

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

Companies can offer an honorarium to healthcare professionals to participate in meetings, press conferences, medical symposia or advisory boards, but a contract must be established with the physician with a description of the activity.

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

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

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

No money can be offered to compensate the time used by healthcare professionals or patient groups to attend the event, and physicians can only be paid when participating.

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

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

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

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

There aren't any specific rules regarding this issue, and third parties are responsible for the content presented. On an internal level, when sponsoring different types of materials, pharmaceutical companies always try to evaluate the information (through the medical department) that must be generic and non-commercial. Also, quotations from medical or scientific literature inserted in the different materials must be faithfully reproduced and properly referenced.

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

According to the INFARMED and APIFARMA Statute and Ethic Code, pharmaceutical companies can interact with different patient advocacy groups. However, when working with any patient organisation they must present non-promotional information, such as disease information data without references, direct or indirect, to prescription medicine.

KEY TAKEAWAYS/ SUMMARY

- Portugal has an inflexible Drug Statute Law that prohibits DTC promotion of prescription medicines. The county is aligned with the European Medicines Agency (EMA), and when it comes to new medicine and advertising laws, some influence comes from other European countries.
- Pharmaceutical companies also need to be aware that non-scientific media relations programmes can contribute to official requests from the Portuguese Authorities for more information about the degree of influence and participation.
- The Portuguese Pharmaceutical Association Code of Marketing & Pharmaceuticals Practices also positively influences the conduct of the companies on different communication levels.
- Pursuant to paragraph 5 of Article 159 of the Medicinal Products Act, legal entities will also be required to declare to the Communications Platform - Transparency and Publicity of INFARMED any kind of sponsorship granted to individuals, including healthcare professionals.

ROMANIA

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

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

THE BASICS

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

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

According to the law, advertising means:

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

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

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

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

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

There is no differentiation. The rules that local authorities enforce for advertising also apply to public relations and other promotional activities.

Who is responsible for the enforcement of these rules?

ANMDM is the main entity responsible for enforcing Romanian law and promotion rules.

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

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

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

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

What promotional or media materials must be pre-approved by authorities?
All promotional or media materials not intended for a company's internal use must be pre-approved by authorities.

What are the most recent significant developments, and are there planned changes to codes of conduct and regulations in the next few years?
At the time of this guide's publishing, the rules for promoting medicine were last updated in 2015. As a member of the EU, Romania is required to implement all the EU directives that refer to advertising medicine.

THE MEDIA

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

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

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

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

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
The rules do not specifically address this issue.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
Media materials, including press releases, are not allowed to encourage the public to consume or purchase pharmaceutical drugs. Companies are also forbidden from promoting or communicating about medicine to the general public.

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

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

The method of distribution is not regulated.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

The same regulations that apply to all promotional activities apply to congresses and scientific meetings. There are no differences mentioned in Order No. 194 between licenced and non-licenced products.

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

When promotional materials are published in the press following services engaged by a pharmaceutical company, its subsidiary or a related company (i.e., the company's PR agency) should be clearly revealed as the company benefitting from the publication. Such articles must not resemble an independent editorial opinion.

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

No specific regulations address this issue.

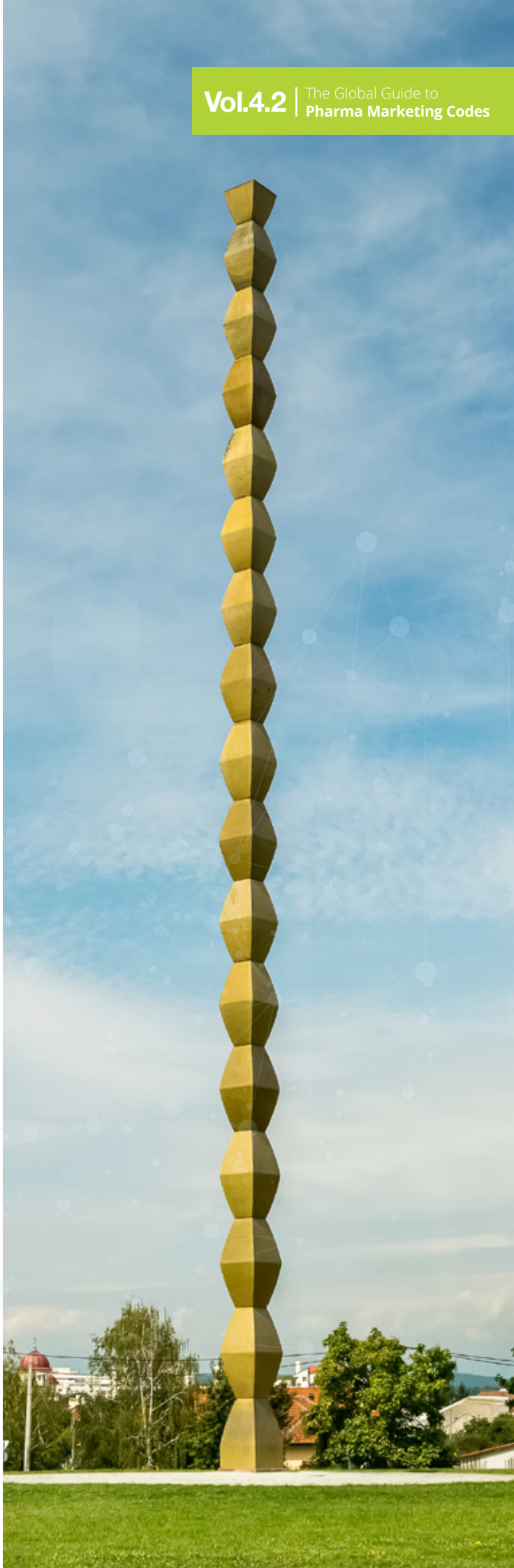
DIGITAL & SOCIAL MEDIA

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

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

What levels of web security are required?

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



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

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

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

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

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

What is mobile adoption like in your region? Are there separate regulations for it?
More than 50% of Romanians used a smartphone at the end of 2016, and the percentage is growing quickly. There are no separate regulations for mobile devices, but because of their high adoption rate, pharmaceutical companies have begun to invest in mobile-friendly websites and apps designed for both consumers and healthcare professionals.

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

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

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Hospitality extended in connection with company-organized events attended by healthcare professionals and with sponsored independent events must be limited to travel, meals, accommodation and genuine registration fees. Airline travel (both domestic and abroad) has to be economy (coach) class; business class or higher is not allowed. In "host countries" where local provisions do not set a limit for meals, the maximum limit is 150 EUR (or the relevant equivalent) per day.

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

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

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes, companies may pay healthcare providers (including residents) to attend scientific meetings, but in a limited capacity. Sponsoring independent events and/or healthcare providers to attend such events must not be conditional to any obligation to promote, prescribe, recommend or purchase products.

What is possible in terms of media or message training for health professionals or advocacy organisations?
Pharmaceutical companies may engage healthcare providers for services such as, but not limited to, lectures, consulting and/or advising (e.g., advisory board meetings), involvement in medical/scientific activities and studies, training services (e.g., medical training) and participation in individual or group-based market research.

Companies must comply with criteria governing how healthcare providers are selected and sponsored to attend training or events.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
No specific regulations address this issue.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
Pharmaceutical companies may sponsor independent events organized by third parties to allow healthcare providers to further their professional development and clinical performance and to improve patient care and patient outcomes.

KEY TAKEAWAYS/ SUMMARY

- Promoting prescription medicine is restrictive in Romania; prescription drugs can be promoted to healthcare professionals only. It is prohibited to leave promotional materials in places accessible to the general public, such as pharmacies, waiting rooms, corridors of hospitals and clinics, etc.
- All advertising materials for the general public must be submitted to ANMDM and placed on the market only after obtaining an advertising visa.
- In terms of promotional activities, companies may run disease-awareness campaigns or educational programs for both prescription and over-the-counter medicine. The affiliated corporate brand may be mentioned, but no reference to specific medicinal products, whether direct or indirect, is permitted.
- Companies may sponsor healthcare professionals to attend events, take part in market research, attend lectures, be involved in scientific activities, etc., however, in a limited capacity only.
- Transparent promotion is a key part of Romania's pharmaceutical marketing regulations.

SOUTH AFRICA

The promotion and advertising of pharmaceutical products in South Africa is governed by legislation enforced by several organisations. Companies may not promote direct-to-consumer Schedule 2 and higher medicines. Medicines that fall under this scheduling status include all prescription drugs, as well as certain over-the-counter products sold in pharmacies. Healthcare professionals are the only ones authorised to advise, inform consumers about and prescribe those medicines.

THE BASICS

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

The Medicines and Related Substances Act 101 of 1965 (Medicines Act), amended most recently in 2002, is the primary legislation under the Ministry of Health. Relevant provisions are located in Sections 18, 20 and 35(1)(x). These sections must be read with Regulation 42 of the General Regulations published under the Medicines Act (GN 859/25 August 2017). The act relates to health products' marketing, including Western medicines and homeopathic and alternative medicines.

The South African Code of Marketing Practice under the Marketing Code Authority (MCA), together with the associated guidelines to the MCA Code (MCA Guidelines, from February 2015), guide the marketing and promotion of all products, including medicines. The MCA Code and MCA Guidelines apply to industry associations, pharmaceutical manufacturers, distributors and wholesalers but are only binding to the members of the MCA Code, either directly or through industry associations.

The Health Professions Act 56 of 1974, published under the Health Professions Council of South Africa's (HPCSA's) Ethical Rules, along with the HPCSA Guidelines on Over-Servicing, Perverse Incentives and Related Matters (HPCSA Guidelines), are binding for all healthcare professionals. The Health Professions Act sets out the ethical rules for registered practitioners' conduct related to promoting, selling and prescribing medicines under Rule 23 of the HPCSA Ethical Rules and Rule 3.3 of the HPCSA Guidelines.

The Advertising Standards Authority's Code of Advertising Practice (ASA Code) is not a national law but a self-regulated code of conduct for telecommunications companies, marketers and advertisers that are ASA members.

The Consumer Protection Act 68 of 2008 is enforced by the National Consumer Commission (NCC) and also applies to the promotion of medicines in South Africa.

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

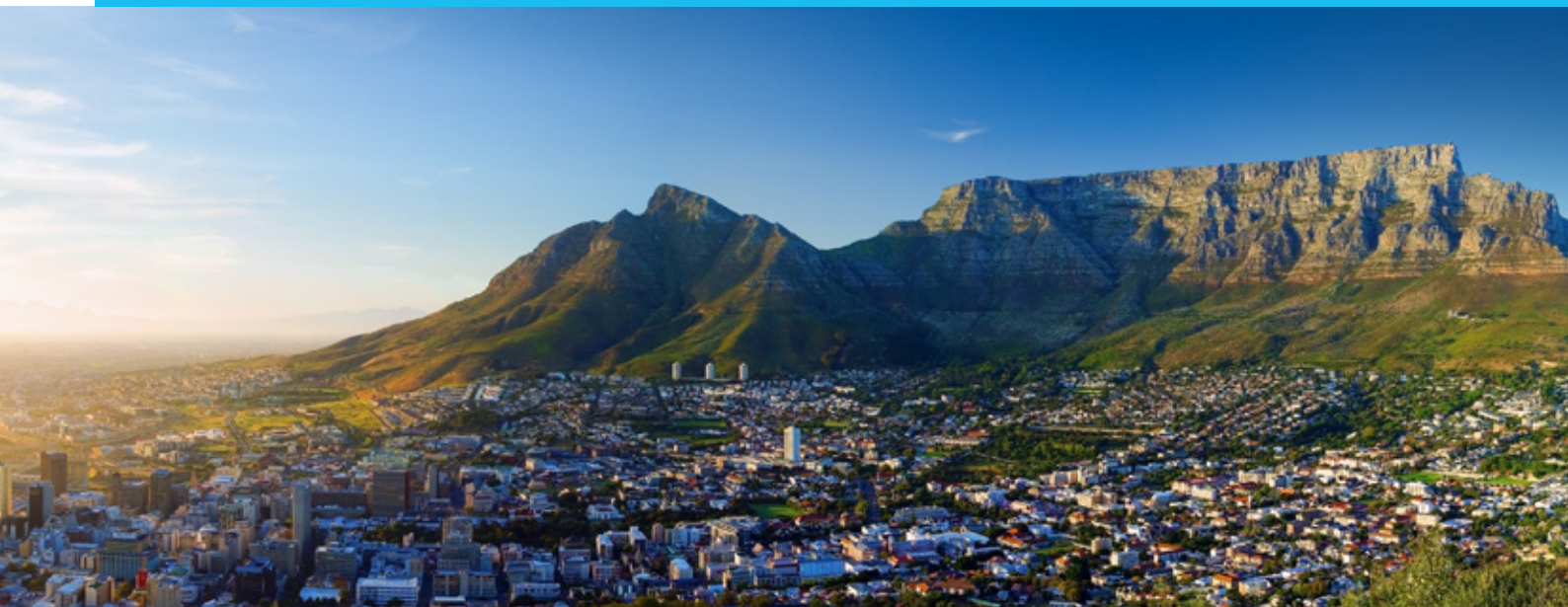
Public relations and advertising are not defined separately, and there are no special rules for public relations activities.

Who is responsible for the enforcement of these rules?

The Medicines Act, which forms the main legislation controlling medicine regulation, is enforced by the South African Health Products Regulatory Authority (SAHPRA). The NCC enforces the Consumer Protection Act, while the South African Code of Marketing Practice, the associated guideline to the MCA Code and the ASA Code are self-regulated by members and member organisations.

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

The Medicines Act prohibits any person from supplying free medicines outside a clinical trial setting. No gift, benefit in kind, rebate, discount, kickback or other pecuniary advantage may be offered or given to healthcare professionals as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any health product. Healthcare professionals may receive occasional gifts and promotional items, provided that they are inexpensive and of minimal intrinsic value, are not for personal use, are of educational and/or scientific value, benefit the patient and/or are relevant to the practice. Inexpensive gifts not related to a professional's practice may be given only once per year in recognition of significant national, cultural or religious occasions.



Companies are permitted to organise or sponsor meetings and events, including Continued Professional Development (CPD, also known as Continuing Medical Education or CME), which are subject to some restrictions:

- The payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, are permitted if it is in terms of a written contract.
- No product promotion is allowed in a CPD meeting room.
- Payment for registration fees, travel and accommodations must be made to the professional associations/organisers.
- No standalone entertainment or other leisure, social or sporting activities may be planned or arranged.
- Healthcare professionals may not receive direct payment for any other services, apart from speaker engagements.

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

Complaints can be filed directly with the appropriate regulatory authority. Contravening the Medicines Act or the General Regulations constitutes an offence. If a complaint is brought to the South African Police Service (SAPS), SAHPRA enforces the offence with the office of the National Prosecuting Authority (NPA). Competitors may lodge a complaint with the ASA, MCA, SAHPRA, NCC or SAPS.

In the event that a company contravenes the ASA Code, the ASA has the power to order its members to withdraw the contravening advertisement. The ASA can indirectly enforce its code against non-members by requiring ASA members to refuse to publish or broadcast a contravening advertisement.

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

In general, no laws or codes require advertising to be approved before use. However, the regulations state that no advertisement for a medicine may contain a statement that conflicts with or goes beyond the evidence submitted to and accepted by the Medicines Control Council in the process of that medicine's registration. Additionally, a decree of prior approval must be inserted into a medicine's approved package.

The ASA may direct an advertiser that has breached the ASA Code to submit a proposed amendment to the advertisement for pre-publication advice. Also, the ASA may require an advertiser that has been the subject of more than one adverse ruling within 12 months to submit all future advertising to the ASA prior to publication for the next six months.

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

The most recent development is Regulation 42 of the General Regulations published under the Medicines Act (GN 859/25 August 2017). The MCA Code and its associated guidelines are updated annually.

THE MEDIA

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

Per the MCA Code, promotional activity is defined as 'any activity associated with Health Product promotion'. As such, the provision of information involving a branded pharmaceutical product could be considered promotional activity. Promotional events are defined as events organised in association with a health product's promotion. CPD or CME events that comply with the MCA Code's requirements are not considered promotional events.

Companies may provide training and education to the

general public and may also sponsor training that other organisations provide. Educational materials should offer accurate, balanced information on a subject area and include a clear indication of which company has produced or sponsored the material. However, under the Medicines Act and the General Regulations, advertising a Schedule 2, 3, 4, 5 or 6 medicine to the general public is a criminal offence.

How is a media event defined?

No explicit legal provisions define media events for medicinal promotion as a distinct entity.

Do the regulations differentiate between consumer and clinical publications?

Advertising a Schedule 2, 3, 4, 5 or 6 medicine to the general public is a criminal offence. Schedule 2 and above medicines may only be advertised to pharmacists, medical practitioners, dentists, veterinarians and other authorised prescribers, or in a publication which is only accessible to such persons, as there is a legal separation between publications directed to consumers and those directed to healthcare professionals.

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?

No person may 'sell' any medicine prior to it being registered. Section 14(1) of the Medicines Act does not distinguish between healthcare professionals and the general public in its application. The term 'sell', in turn, is defined to include 'advertise'. The provision of a pharmaceutical product's off-label information prior to its registration is considered promotional and the prohibition applies irrespective of whether or not the product has been registered with a medicines regulatory authority in another jurisdiction outside South Africa.

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

No explicit regulations govern press releases, media materials or 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 references are made about 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?

No rules govern how the press should cover congresses and scientific meetings.

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

Journalistic output from scientific meetings is not covered in any acts, codes or guidelines. However, the resulting work should be independent and balanced. A company that sponsors a journalist must not place conditions on the journalist's reporting on the company's product.

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

Regulatory information does not specify how case studies or third-party advocacy should be handled.

DIGITAL & SOCIAL MEDIA

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

The regulations don't differentiate between online, print and broadcast media. However, the requirements for all also apply to promotional material on the internet and other forms of advertising.

What levels of web security are required?

Applying a password-protection scheme to promotional material is prudent in relation to prescription-only medicines. This also applies to promotional material that is placed on the internet outside of South Africa by or with a South African company's authority or its affiliate's authority and that makes specific reference to a medicine's availability or use in South Africa. Companies must also clarify any time a user leaves any of their websites and is directed to a site not belonging to them and, therefore, is not necessarily covered by the MCA Code.

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

Per the MCA Code, internet users must be clearly informed when they leave any of a company's sites, or sites sponsored by a company, or they are directed to a site not belonging to the company. Any references or links to other reputable information sources must be to those that provide valuable educational material that would enhance the quality of products' use. When a company makes such a reference or link, it must clearly display the following statement before the user accesses the reference material:

> *The information a reader is about to be referred to may not comply with the South Africa regulatory requirements. Information relevant to the South Africa environment is available from the company or via the Package Insert.*
> (Guideline to Clause 22.2 of the MCA Code in the MCA Guidelines)

Companies should also be cautious when including references or links to other informational sites. References or links to any non-compliant sites may put companies at risk of breaching the MCA Code and should be removed without delay.

What are the most popular social networks in your region?

As of 2018, the most popular social networks in South Africa were:

1. Published advertisements appear in print, in Facebook (16 million users)
2. Twitter (8 million users)
3. LinkedIn (6.1 million users)
4. Instagram (3.8 million users)

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

Per the MCA Guidelines, companies that engage in social media activities that include discussion boards and sharing of audio/visual content should consider several factors involving community management, including, but not limited to:

- How to join and the purpose of the forum
- Guidelines for inclusion/exclusion of sensitive or offensive subject matter
- A notice that conversations may be monitored
- The responsibilities for monitoring and reporting adverse events posted via the platform

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

Not specifically in regard to South Africa; see the United States chapter for further information on this question.

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

Other than the rules stated in the previous question about the use of social media for disease awareness or product promotion activities, no.

In addition, companies may not include lists of healthcare professionals or their hospitals or clinics on company-developed websites. However, it is possible to include a link to healthcare

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

As of mid-2018, more than half of South Africa's 56.7 million citizens used a smartphone. Specific rules apply to companies that wish to make promotional and educational materials available to healthcare professionals via various media's mobile platforms or applications (Note 12 to Clause 5 of the MCA Code, as contained in the MCA Guidelines).

What are the disclosure laws like in your region for non-branded websites?

Companies must make clear to internet users when they leave any of a company's sites, or sites sponsored by the company, or they are directed to a site not belonging to the company (Clause 22.5 of the MCA Code). All references or links to other reputable information sources must provide valuable educational material that would enhance the quality of products' use. When a company makes such a reference or link, it must clearly display the following statement before the user accesses the reference material:

> *The information a reader is about to be referred to may not comply with the South Africa regulatory requirements. Information relevant to the South Africa environment is available from the company or via the Package Insert.* (Guideline to clause 22.2 of the MCA Code in the MCA Guideline)

What is the response level needed for adverse event reporting?

The MCA Code states that, 'Healthcare Sales Representatives/consumer promoters must notify their company regarding any information received in relation to the use of health products which they promote, particularly any information relating to adverse event 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?

The MCA Code allows companies to extend hospitality to patient groups. Per the guidelines, 'It is permitted to use [healthcare professionals] and/or patient organisations as consultants and advisers, whether in groups or individually, for services such as speaking at and chairing of meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research, where such participation involves a FFS/Honorarium and/or reimbursement of travel expenses and/or the provision of hospitality.'

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?

The MCA Code allows honoraria for healthcare professionals, advocacy groups or third parties in prescribed events—with conditions, as described in answer to the previous question.

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?
Yes. The same provisions from the previous question apply.

What is possible in terms of media or message training for health professionals or advocacy organisations?
No specific rules govern media or message training. However, the MCA Code does state that, 'Companies may provide training and education to Consumers and may also sponsor training provided by other organisations. The relevant training material shall be accurate, contain balanced information on the subject, and include a clear indication of which Company has produced the sponsored material.'

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
No specific regulations govern materials written on behalf of third parties, as opposed to manufacturers. All materials must comply with the MCA Code.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
See answer to previous question.

KEY TAKEAWAYS/ SUMMARY

- Pharmaceutical marketing codes in South Africa are defined by several governmental entities, however, the industry is largely self-regulated. Disputes may be handled in or out of court and can be initiated by the public, competitors or governmental agencies.
- Pharmaceutical marketing codes and guidelines have been universally adopted by the industry to promote high professional and ethical healthcare standards; the safe use of therapeutic goods; and the honest communication of medicines' benefits, uses and effects.
- Direct-to-public marketing of Schedule 2 and higher drugs is not permitted, and the advertising of therapeutic goods to health practitioners is controlled by legislation outlined by the Medicines Act and Consumer Protection Act, which SAHPRA administers. The MCA and ASA are the organisations responsible for interpreting the legislation and defining marketing codes and guidelines.

SPAIN

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

THE BASICS

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

The main code of ethics is issued by the Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria) and the industry's national business association: the Spanish Code of Practice for the Promotion of Medicines and Relations between the Pharmaceutical Industry and the Health Professional (June, 2014).

Changes in the promotion of pharmaceutical products in Spain has led to a new self-regulation system in the pharmaceutical industry with this new version of the Code of Practice for the Pharmaceutical Industry, approved by the governing bodies of Farmaindustria in December 2013 and ratified by Farmaindustria General Assembly in June 2014.

The Code incorporates, among others, the principles of:

- Directive 2001/83/EC of the European Parliament and of the Council, dated 6 November 2001, on the Community code relating to medicinal products for human use. Farmaindustria CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY 2014 5. These texts are the non-official translation of the Spanish version of the texts approved by Farmaindustria General Assembly. The Spanish versions shall always prevail.
- Law 29/2006, of 26 July, on Guarantees and Rational Use of Medicinal Products and Medical Devices.
- European Federation of Pharmaceutical Industries and Associations (EFPIA) Codes on Interactions with Healthcare Professionals (HCPs), Relationships with Patient Organisations and Disclosure of Transfers of Value.
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practices.

The new code essentially addresses three areas:

1. Promotion of Prescription-Only Medicines. Respecting the right of the scientific community to be completely informed about medical and scientific progress, on one hand, and the legitimate interest of companies to inform and promote their products, on the other hand, this section of the code provides for a series of regulations designed to guarantee that the information provided in the context of the promotion of prescription only medicines is appropriate, honest, precise, objective, complete, accurate and truthful.
2. Relationships with HCPs and Healthcare Organisations. The interactions between healthcare professionals and the pharmaceutical industry have a fundamental influence on patient care and research development; for this reason, it is necessary to establish criteria and guidelines to guarantee that these activities are conducted in a professional and responsible manner.
3. Relationships with Patient Organisations. patient organisations and the pharmaceutical industry share common interests, such as improving the quality of life of patients and attention to their interests. The rules included in this section guarantee that the manner in which companies interact with patients and with the organisations that represent them is appropriate and in compliance with, among others, the principles of independence, mutual respect and transparency.

The continuous commitment of pharmaceutical companies to the development, efficacy and rigor of the self-regulation system is the result of the responsible attitude of Farmaindustria members and those companies that have decided to adhere to the Code voluntarily. This commitment is proved by the companies' implementation of robust internal procedures designed to guarantee compliance with the Code, with the aim of ensuring appropriate training of their employees. The transparency of the self-regulating system is offered as an essential tool for promoting and strengthening confidence in the pharmaceutical industry, facilitating public access to their actions. Proof of this commitment is the publication of the Resolutions of the

Jury of the Association for Self-Regulation of Commercial Communications in complaint procedures, information related to clinical trials, collaboration provided to patient organisations and, more recently, the disclosure of transfers of value to healthcare professionals and healthcare organisations.

Apart from that, the government has published the Royal Legislative Decree 1/2015, which does not introduce any changes referred to promotion of pharmaceutical products.

With respect to healthcare technologies and products, Fenin, the Spanish multi-sector federation that groups manufacturing, import and distribution companies and associations of healthcare technologies and products, has not published updates in the last four years.

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

Public relations is not separately defined. The scope of the Code covers all forms of promotion aimed at health professionals who are qualified to prescribe or dispense medicinal products. It covers all promotional methods, including those traditionally categorised as public relations, such as the sponsorship of scientific congresses and scientific or professional meetings attended by healthcare providers, online communications, the use of audiovisual systems and the provision of gifts and hospitality. It often uses the word advertising interchangeably with the word promotion'

Law 10/2013 modifies Article 78 of Law 29/2006, regarding guarantees and the rational use of medicines and health products. This issue is regulated in paragraphs 5, 6 and 7, establishing:

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

Who is responsible for the enforcement of these rules?

In its major overhaul of procedures in 2002, Farmaindustria started up an Ethics Commission and Code of Practice Surveillance Unit as the body responsible for active monitoring of Code compliance. The aim of the Code is to guarantee that any promotion of medicines for human use is carried out respecting the most stringent ethical principles of professionalism and responsibility. For this purpose, an agreement was signed with the Association

for the Self-Regulation of Commercial Communications (Autocontrol) and any cases not solved by conciliation are referred to this organisation, which has a reputation for harsh enforcement. The Ministry of Health is responsible for the enforcement of The Law of Guarantees and Rational Use of Medical Products and Medical Devices.

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

According to the Code of Ethics issued by the Farmaindustria, pharmaceutical companies are not allowed to offer or give healthcare providers any type of gift, incentive or prize. Companies may provide informational or education materials to doctors as long as the materials are inexpensive (no more than $67 USD), are relevant to the practice of medicine or pharmacy and directly benefit patient care.

Events that are sponsored or organised by a company must be exclusively science related. Events of recreational nature are prohibited, although welcome cocktails, working luncheons and gala dinners that occur within official programmes and meetings are not included. A maximum of $67 USD per guest applies to these events.

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

A limited number of free samples may be given to doctors as long as they are authorised to prescribe medicine. Medical samples must bear the statement 'free medical sample – not for sale'.

These regulations are enforced and monitored by the Code of Practice Surveillance and the Code of Practice Committee.

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

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

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

'The resolutions of the Jury are reported immediately to the parties for their compliance. Simultaneously, the Jury will communicate these resolutions to the Code of Practice Committee, who will transfer them to the Farmaindustria governing bodies in order to be executed and, where applicable, proceed to collection of pecuniary sanctions imposed by the Jury', (30).

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

Scientific and promotional meetings and events organised or sponsored by pharmaceutical companies must provide previous notification in accordance with the provisions in the Rules of Procedure of the Control Bodies of the Code (11.8); failure to do so constitutes an infringement of the Code (11.9). This is clarified in the queries that only meetings that meet the following criteria need notification: they are organised or sponsored (directly or indirectly) by the pharmaceutical company; they include an overnight stay; and they involve the participation of at least 20 healthcare professoinals. It is not necessary to notify authorities of congresses organised by a third party (scientific societies, professional organisations, etc.) and sponsored by several pharmaceutical companies, or satellite symposia and other parallel activities, provided that they are listed in the official congress programme. In any case, pharmaceutical companies are recommended to voluntarily report any event organised by third parties in which they plan to participate. Pharmaceutical companies usually submit advertisements to the Ministry of Health, but this is not obligatory. Patient information leaflets have to be reviewed by the Spanish Agency for the Evaluation of Medical Products.

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

The last fifteen years have seen a great deal of change in the marketplace. In early 2002, the Farmaindustria General Assembly approved a much more stringent guide than that which previously existed, which was a version of the old EFPIA Code and had been in existence for almost 15 years. This latest version was enhanced by the addition of implementation guides, the formation of the above-mentioned body to enforce compliance and the establishment of a query system. Queries are henceforth addressed to and answered by the Code of Practice Surveillance Unit, are resolved by the Code of Practice Committee and are binding. Despite these far-reaching changes, approval of the new EFPIA Code late in 2004 required the Farmaindustria Code to incorporate additional European elements to bring its Code in line with the European regulations. These were finally approved and issued in June 2005. There are no further planned changes in the next few years. The new Law of Guarantees and Rational Use of Drugs and Health Products was also approved recently and put in place a new price reference system and promotion of generics and drug prescription by active ingredient. The previous Drug Law was put into effect in 1990, under a socialist government. These kinds of laws generally change to reflect the perspectives of the political group in power.

THE MEDIA

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

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

How is a media event defined?

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

Do the regulations differentiate between consumer and clinical publications?

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

Do regulations differentiate between print and broadcast media?

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

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

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

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

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

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The Code covers only the distribution of materials to healthcare professionals, not media (Section 7). EFPIA regulations would give the guidance that the Codes of Conduct of both the country of source and distribution should be followed, with the stricter code prevailing in case of conflict.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?
It is not permitted to sponsor anyone, whether press or a healthcare professional, to attend a meeting. If a journalist is sponsored, then his or her resulting copy becomes subject to the rules of a contractual relationship.

If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through the company's regulatory procedure? Is it different for a freelance journalist?
Any copy produced by a truly freelance journalist, or one employed to write or broadcast for regular editions or programmes as part of his or her professional work in gathering news at congress, is not bound by the Code.

If a company sponsors a journalist to attend, their relationship becomes a contractual relationship' and any resulting copy will be subject to the letter of the Code. The assumption is that the copy should then go through internal regulation in the same way as any other promotional material.

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

DIGITAL & SOCIAL MEDIA

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

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

Do the regulations cover funding of, or provision of information to non-company owned websites?
This is not specifically covered with relation to the internet, although the general principles of provision of information to the media would apply

What are the most popular social networks in your region?
Facebook, Instagram, Twitter and LinkedIn are the most popular social networks in Spain. Previously, Tuneti, a homegrown network, was the most popular social media platform. However, a rapid decline in the number of users led to a closure of the service in 2016.

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
According to the Code, companies must 'possess guidelines and rules of conduct for their employees that establish standards for responsible conduct in the digital environment, both for when sharing information about or in the name of the company as well as when using a medium, means of delivery or channel provided by the company', (8).

Furthermore, any company that is a member of FARMAINDUSTRIA must adhere to the code regardless of medium (8).

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

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Each digital platform has its own rules. There are no general laws.

What is mobile adoption like in your region? Are there separate regulations for it?
As of 2017, 67% percent of Spain's population, over 46 million people, used smartphones. Despite this, there are no specific regulations regarding healthcare apps or other marketing via mobile devices. The general marketing codes still apply.

What are the disclosure laws like in your region for non-branded websites?
Courts make decisions for non-branded websites. Websites about pathologies are only allowed if they do not mention any treatment or product. Either way, any formal complaints might be solved by the court.

What is the response level needed for adverse event reporting?
All adverse event reporting is completed in accordance with official regulations.

STAKEHOLDERS/ ADVOCACY GROUPS

What do the regulations say about hospitality to advocacy/patient groups? How does this affect travel to another country for a congress or meeting?
Section 11.3 clearly states that hospitality, including travel and attendance at professional and scientific events, should not be extended to anyone other than healthcare professionals, although, advocacy/ patient groups are usually invited by the industry. Pharmaceutical companies cannot give any information directly to patients or patient groups.

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?
Honoraria are possible for healthcare providers only to cover the payment of reasonable fees and reimbursement of out-of-pocket expenses, including travel, for speakers and moderators at meetings, congresses, symposia and similar scientific or professional events. Hospitality, which includes travel, registration and subsistence expenses, must not exceed what the recipients would normally be prepared to pay for themselves in the same circumstances. Hospitality cannot be extended beyond a reasonable period before or after the event. This is clarified in the published queries as being one day before or after the event. In addition, hospitality must always be secondary to the main purpose of the meeting and 'in no case shall social or cultural aspects predominate over scientific issues'. Answers to the published queries further clarify that reasonable would prohibit anything greater than a four-star hotel.

Regarding disclosure obligation, companies subject to the Code as established in articles 19.1 and 19.3 must document and disclose payments and transfers of value that they make, either directly or indirectly, to or for the benefit of the recipients.

Payments or transfers of value associated with activities not detailed in Appendix 1 of the Code include the provision of materials regulated in Article 10, Guarantees of Independence, samples regulated in Article 13, hospitality associated with dinners or luncheons regulated in Article 11 Scientific and Professional Meetings

Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting? No, money cannot be offered to healthcare professionals to attend events.

What is possible in terms of media or message training for health professionals or advocacy organisations?
This is not specifically outlined, although Clause 5.2 states that 'promotional material and activities should not be designed to disguise their actual purpose or nature'. Given the spirit of the entire Code, it would be reasonable to assume that all briefing materials relating to such an activity must be clearly referenced, substantiated and marked as having been sponsored by a pharmaceutical company.

What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?
Although this is not specifically addressed, it would seem fair to assume that any materials that are written directly or indirectly by a pharmaceutical company must have sponsorship and involvement clearly indicated and explained.

What regulations cover meetings with, or provision of, non-media information to advocacy groups?
This is not covered in the regulations. However, it would be reasonable to assume from EFPIA regulations that matters pertaining to human health and disease without mention of specific products would be permissible, while copy with brand messages would be promotional and need to be clearly marked as promotion.

KEY TAKEAWAYS/ SUMMARY

Pharmaceutical marketing continues to develop in Spain due to:

- Strict ethical codes
- Global rules for pharmacies
- New stakeholders (autonomous regions, patient associations and scientific societies)
- Increased control by the government

SWEDEN

In Sweden, the promotion of medicine is governed by the Pharmaceutical Law, by the Medical Products Agency's regulations for marketing pharmaceuticals and by Läkemedelsindustriföreningen's (LIF's, the trade association for the research-based pharmaceutical industry in Sweden) Ethical Guidelines (LER). Although not legally binding, the LER rules are widely recognised by the pharmaceutical industry and applied by courts as an expression of fair and ethical marketing. The national regulatory framework for promoting medicinal products is largely based on EU legislation. For example, it's prohibited to advertise medicinal products that are not authorised for sale in Sweden or to target children when advertising medicinal products. Advertising prescription medicinal products to the general public is also prohibited, with the exception of vaccination campaigns against human infectious diseases.

THE BASICS

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

Information distribution on pharmaceuticals is governed by the Pharmaceutical Law, by the Medical Products Agency's regulations for marketing pharmaceuticals and by LIF's LER.

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

Information that is clearly intended to enhance sales and increase the demand for a product and that mainly focuses on the benefits and not the potential risks of a product might be considered an advertising or promotional activity.

Who is responsible for the enforcement of these rules?

The pharmaceutical companies themselves are responsible for following LER rules and regulations. Companies are not subject to legal requirements for having specific standard operating procedures (SOPs) governing promotional activities, however, according to LER, Article 129, every member company must have at least one individual responsible for ensuring that its communication complies with rules and regulations. This person approves all material before it is distributed. If a company appears to be violating the rules, it can be reported to the Information Audit Board (IGN).

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

According to the provisions and guidelines issued by LIF, Läkemedelsverkets föreskrifter (LVFS) 2009:6 §7, companies may not have healthcare providers, scientists or any individual who could use his or her position to promote pharmaceuticals participate in marketing pharmaceuticals to the general public.

And according to LER, Chapter 2, Article 2a, all cooperation between pharmaceutical companies and healthcare providers must follow the principles of usefulness, transparency, proportionality, moderation and documentation. Article 4b further states that, if there is a legitimate need, healthcare providers may participate in research, education, conferences, product development and advisory boards as part of their normal duties. Such participation must be outlined in writing between the healthcare provider, his or her employer and the pharmaceutical company. All remuneration must be reasonable and paid to the employer. The healthcare provider is also required to disclose the cooperation when making public statements on a subject that is part of the engagement.

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

IGN functions under LIF with one chairman and two board members. Member companies send to IGN copies of all their marketing materials that target the public and healthcare professionals. IGN will then audit the companies' pharmaceutical information on an ongoing basis and, by its own initiative or after external reports, rule on whether marketing measures and market activities regarding pharmaceuticals are compliant with good business practices. If they are not, IGN may issue a fine of up to 500,000 Swedish Krona (SEK) to be paid to LIF. IGN's rulings may be appealed to the Committee for Assessment of Pharmaceutical Information (NBL). The committee may issue a nonbinding statement if it deems such action appropriate. If a governmental body is the party filing the concern or complaint, NBL issues the final ruling.

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

Pharmaceutical companies that are members of LIF can apply for pre-approval of a website or vaccination campaign. Websites must provide pharmaceutical treatment information to patients who are actively searching for it. Thus, a company cannot actively promote a website. Additionally, the company providing

the information must clearly identify itself and include its mailing address and e-mail address. A medically responsible person at the company must approve all information on a website and the information needs to be covered in the Summary of Product Characteristics or at www.fass.se. Every web page or relevant section of a page should include the date of its latest update. Information on prescription drugs may only be published after IGN has reviewed and approved it. A prescription drug's product name is permitted to be visible in a domain name and also permitted to be mentioned (but not occupy an essential amount of space) on a website.

Promoting a prescription treatment to the public is allowed in the case of vaccination campaigns only, which IGN needs to review and approve. These campaigns aim to inform the public about necessary protection against infectious diseases. A product name, product logotype, generic name or such may not be promoted.

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

LER is updated, on average, once or twice a year. The latest version is available on its website. When the European Federation of Pharmaceutical Industries and Associations and the International Federation of Pharmaceutical Manufacturers and Associations update their codes of conduct and regulations, LER is also updated.

At the time of this guide's publication, the most recent update from August 2016 is valid beginning 15 June 2016, when the 'pharmacy agreement' was replaced with new ethical rules for associations with pharmacy staff (LER, Chapter 2, Section 2).

On 1 January 2017, the Information Audit Function (IGM) was replaced with IGN. IGM had been divided into two sections: IGM Public and IGM Professional. IGN is a board that covers both areas.

THE MEDIA

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

Provision of information regarding pharmaceuticals is characterised by being meaningful and balanced. It is not scant, incomplete or easily misunderstood. Further, pharmaceutical information needs to be simply recognised as such. The sender of the information shall be easily recognisable, and the information needs to meet the criteria for 'minimum information'.

Promotional activity is characterised by methods that attempt to sell a product.

How is a media event defined?

This term is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?
No, the regulations are the same.

Do regulations differentiate between print and broadcast media?
No, the regulations are the same.

What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?
The rules do not specifically address this in regards to media.

What regulations specifically cover press releases and media materials? What are the general principles? Are invitations to media or clinical events treated the same?
After a verdict by the Medical Products Agency in 2011, journalists are considered part of the public and do not have a special status. Hence, pharmaceutical companies should not provide them with press releases about prescription pharmaceuticals, because this would be considered marketing to the public. However, LIF continues to advise its members to proceed in accordance with current business practices, saying that press releases are allowed, given that they are directed towards journalists and contain news of public interest. Press releases, however, must be medically correct, relevant, balanced and not have any marketing character. Certain information might vary in relevancy between medical journalists and regular media. Accordingly, two different press releases with different depth of information are often issued for these two target groups. If a company is reported to IGN for issuing an imbalanced press release, IGN would have to adhere to the rule that journalists are part of the public. For this reason, pharmaceutical companies are now more careful when presenting information in press releases.

Invitations to clinical events (for healthcare providers) must state the purpose and content of the event, the expected time frames, the time and place, which costs are covered by the pharmaceutical company and any side arrangements. If specific pharmaceutical information is going to be part of the event, it must be clearly stated in the invitation.

For media events, if there is a risk that journalists will ask questions about prescription drugs during the presentation, LIF would consider the event marketing towards the public, because the company should be able to anticipate such questions when planning the event. Hence, LIF advises companies not to host educational media events for journalists about disease.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where the publication is intended)?
The method of distribution is not regulated. Materials from outside Sweden also must fulfil Swedish rules and regulations.

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?
Journalists are allowed to receive congress reports containing news on research, ongoing studies and preliminary research findings, if the information is relevant and balanced. Even if journalists, according to the Pradaxa verdict of 2011, are considered part of the public without special status, they are still considered able to make independent decisions about how to handle the information they receive.

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

Do regulations cover the use of case studies or other third-party advocacy in the media?
Third-party advocacy, by healthcare providers or patients on behalf of pharmaceutical companies or their PR agencies, of medicinal products in media is not allowed. However a journalist may write an article on his or her own initiative about a patient, because this is protected by the freedom of speech. Pharmaceutical companies are still not allowed to use such articles, or refer to them, because this would breach LER, Article 8 and Article 108.

DIGITAL & SOCIAL MEDIA

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

What levels of web security are required?
This is not specified.

Do the regulations cover funding of, or provision of information to non-company owned websites?
Cooperation with third parties (e.g., patient advocacy groups) is allowed but must be transparent. Their regular activities may not be funded, and any project that is subject to cooperation must be defined in writing and may not be so extensive that the third-party organisation cannot survive without the company's support.

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

Have local regulators introduced any guidance on the use of social media for either disease awareness or product promotion activities?
Yes, LIF has a document regarding their regulations and its adaption to social media.

Are there any self-imposed regulations from social media companies?
No. While social media companies have their own codes of conduct, limitations to what pharmaceutical companies may publish on social media are not governed by such codes of conduct, but by local laws and ethical guidelines for the pharmaceutical industry.

For digital platforms like forums, does your regulatory body have specific rules for customer/company interactions?
Yes, LIF has a document regarding their regulations and its adaption to digital platforms.

What is mobile adoption like in your region? Are there separate regulations for it?
Mobile devices have no separate regulations. Use of social media through such devices is widespread.

What are the disclosure laws like in your region for non-branded websites?
The pharmaceutical company behind a non-branded website must always disclose the name of the company or its Swedish agent and its contact information.

Pharmaceutical information on websites must also clearly include information about the intended target group. This also applies to links to other websites containing pharmaceutical information (e.g., from non-branded websites); the information near the link needs to clarify the target group for that website. If the link leads to a page with healthcare provider information, it is wise to have a disclaimer through which the visitor confirms his or her category before accessing the information.

What is the response level needed for adverse event reporting?
Pharmaceutical companies must report all adverse events to the Medical Products Agency without further notice.

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?
Congresses or meetings arranged by a pharmaceutical company must address its area of expertise, and the majority of the program must be scientific or profession-related. A company is allowed to sponsor members from an advocacy or patient group's participation in congresses in another country, but only to an extent of 50% of the total cost. A company is not allowed to sponsor an advocacy or patient group's ordinary or internal activities. While meetings should be held in Sweden, if possible, travel to another country is permitted if necessary for holding the conference. Cities holding major concurrent international events must be avoided and companies should not financially sponsor meetings that take place during such events. Whether a city is acceptable or not is decided by the LIF compliance officer, whose decision cannot be appealed.

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, a company may offer honoraria if a healthcare provider or advocacy/patient organisation representative is participating in a media activity targeting journalists. Honoraria must be reasonable regarding the time required to perform the activity and must be paid to the healthcare provider's employer. Expenses for travel, meals and accommodations, within reasonable limits, may be covered.

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

No, a company may not pay a healthcare professional to attend a scientific meeting.

Pharmaceutical companies may, however, sponsor an advocacy/patient group's participation at a conference, including the expenses for travel, meals and accommodations within Sweden. For international conferences, companies may only sponsor up to 50% of the total expenses. Companies are not allowed to contribute more to an activity than the actual cost of the activity, which is specified in a written agreement.

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

There are no limitations for message training.

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

If pharmaceutical companies, or PR agencies operating on companies' behalf, produce written material on behalf of third parties, the companies' support must be announced for transparency.

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

Pharmaceutical companies' relations and meetings with advocacy groups and other organisations are regulated by LER, Chapter 3, Section 1: 'Ethical rules for cooperation between pharmaceutical companies and organisations/advocacy groups'.

KEY TAKEAWAYS/ SUMMARY

- The distinction between PR and advertising in cases of promotion of medicinal products has become less relevant from a regulatory point of view. Promoting prescription medicinal products may not be aimed at the general public, with the exception of vaccines.
- Regardless of being a member of LIF or not, the best way to avoid any breach of law or regulations is to ensure that your company adheres to its ethical guidelines.
- Even though journalists are considered part of the public, according to the law, who may not receive information on prescription drugs, LIF advises its members to continue issuing balanced and relevant information to journalists on prescription drugs and to make their own decisions on publishing. However, LIF advises against pharmaceutical companies hosting media education events, which opens them up for questions from journalists on prescription drugs and creates the obvious risk of marketing.

UNITED KINGDOM

In the United Kingdom, the promotion of medicine is controlled by legislation and codes of practice. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry is the code that outlines the guidelines and ensures compliance with legal requirements. It covers the promotion of prescription medicines and is relevant to public relations activities.

THE BASICS

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

The promotion of medicines is subject to UK and European Law and to self-regulation by the pharmaceutical industry. The main UK legal requirements have been consolidated in the Human Medicines Regulations 2012, implemented in July 2012. UK law reflects the requirements of European Directive 2001/83/EC ('on the Community code relating to Medicinal products for human use') and amendments. The Medicines and Healthcare products Regulatory Agency (MHRA) has summarised the legal requirements in The Blue Guide, Advertising and Promotion of Medicines in the UK, the third edition, first revision published in September 2014.

Self-regulation is based on industry codes of practice. For prescription medicines, the ABPI Code of Practice (The Code) applies. The Code is based on UK law and incorporates the principles of the International and European Codes. All members of the ABPI and many non-members have agreed to follow The Code. It is regularly revised, most recently in 2019.

The Proprietary Association of Great Britain (PAGB) is responsible for advertising codes and guidelines for over-the-counter medicines.

The Association of British Healthcare Industries (ABHI) is responsible for the ABHI Code of Business Practice for medical device manufacturers.

- IFPMA Code of Practice (International Federation of Pharmaceutical Manufacturers Associations)
- EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals; EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (European Federation of Pharmaceutical Industries and Associations)

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

The Code does not specifically define the term public relations, although public relations activities are covered. Prescription-only medicines must not be advertised to the public. However, non-promotional information about prescription medicines may be provided to the public, 'either in response to a direct enquiry from an individual, including enquiries from journalists, or by dissemination of such information via press conferences, press announcements, television and radio reports, public relations activities and the like' (Supplementary Information to Clause 26.2).

Public relations activities are unlikely to be considered promotional if they are restricted to the provision of factual information. If the purpose is to raise awareness of claims about a product, the activity is likely to be a form of promotion.

Who is responsible for the enforcement of these rules?

The Prescription Medicines Code of Practice Authority (PMCPA) is responsible for administering The Code and the complaints procedure. It also provides advice, guidance and training. Although established by the ABPI, it operates independently of the Association.

Enforcement of The Code is carried out mainly through the complaints procedure. In addition, the PMCPA arranges for the scrutiny of samples of advertisements, other promotional items and meetings in relation to the requirements of the Code. Sanctions are applied against companies ruled in breach of the Code.

The MHRA scrutinises journals, magazines and the internet for the promotion of medicines and it vets advertising for new active substances. The MHRA also investigates complaints made to it about advertising. Where necessary, it can take legal enforcement action

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

Clause 17 of the Code discusses how pharmaceutical companies may only send samples of a product to a qualified healthcare professional (17.1), no more than four samples may be provided to the same doctor during the course of one year (17.2), samples may only be supplied after a written request has been signed and dated (17.3) and the sample must be labeled 'free medical sample – not for resale' (17.5, 17.9).

According to the Code, 'No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3' (18.1).

Healthcare providers attending a company organised scientific meeting or conference may not use materials (pens, notebooks, pencils) that bear the names of donor companies, the name of any medicine or any information about medicines.

If the Code is breached, complaints are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports on completed cases are published by the PMCPA in its Code of Practice Review and on its website.

The Code is administered by the PMCPA, which is responsible for the provision of advice, guidance and training on the Code as well as for the complaints procedure.'

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

Clause 18.1 (Supplementary Information) states that, 'The General Medical Council (GMC) is the regulatory body for doctors and is responsible for giving guidance on standards of professional conduct and on medical ethics'. According to the GMC, during an investigation evidence is collected and reviewed. After the investigation, the GMC may, 'issue advice or a warning to the doctor' or agree with the doctor that he or she will 'restrict their practice, retrain or work under supervision'.

The Medical Practitioners' Tribunal Service (MPTS) may also be called upon for a hearing.

'When action is needed to protect the public or to maintain public confidence in doctors, an MPTS tribunal can suspend a doctor's right to work, or restrict their practice – for example by requiring them to work under supervision, or undergo further training. If necessary, a tribunal can also suspend or restrict a doctor's right to work while the investigation is conducted.'

In serious cases, the GMC can remove a doctor from the medical register, which means that they are no longer able to work as a doctor in the UK. After this decision has been made, the GMC must inform other regulators around the world.

The General Pharmaceutical Council (GPC) is the regulatory body for pharmacists and pharmacy technicians. The GPC operates in a similar manner to the GMC. After a concern is brought to attention, an investigation is opened about potential misconduct.

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

The MHRA vets advertising and promotional materials, before they may be used for new active substances. Related non-promotional materials such as press releases, associated media materials and patient support materials are also examined. It may also pre-vet advertising for other products if, for example, there are safety concerns or if previous advertising has breached the regulations. According to MHRA guidelines, the vetting period usually lasts for about two to three

months, but it may go on for longer depending on the nature of the promotional materials and any problems found.

Companies found in breach of the Code may be required to submit materials to the PMCPA for pre-vetting.

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

A new edition of the Code was published in January 2019, with changes in a number of areas:

- An updated definition of promotion and additional clarification concerning risk minimisation plans (Clause 1.2)
- Additional information about Conditional Marketing Authorizations, the Early Access to Medicines Scheme and Compassionate Use; clarification on advance notification of new products/product changes (Clause 3)
- Changes to reflect updated requirements by the General Pharmaceutical Council and the Code of the Nursing and Midwifery Council on the provision of gifts and hospitality (Clauses 18.1 and 22.1)
- Updated information on:
  - Requirements for legibility of Prescribing Information (Clause 4.1)
  - Prescribing Information for digital and audio-visual materials (Clauses 4.4, 4.5 and 5.2)
  - Required text for adverse event reporting (Clause 4.9)
  - Journal advertising and the the provision of journal reprints (Clauses 6.1, 6.2, 6.3 and 10.1)
  - Certification requirements (Clauses 14, 14.1, 14.2, 14.4)
  - Provision of genetic, biomarker or other specific testing (Clause 18.1)
  - Value of patient support items (Clause 18.2)
  - Transfers of value (Clause 24.1)
  - Reporting of financial information (Clause 26.2)
  - Disclosure of support to patient organisations (Clause 27.7)

These changes are reflected where appropriate in the revised ABPI Code of practice and do not impact on the wording of the text under review.

THE MEDIA

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

The Code defines promotion as, 'any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines' (Clause 1.2). Prescription-only medicines must not be promoted to the public (Clause 26.1).

Provision of certain types of information is not considered promotion. Examples are listed in Clauses 1.2 and 26 of the Code. They include:

- Replies to enquiries from health professionals if the information provided is directly relevant, is accurate, does not mislead and is non-promotional.

- Information on health or diseases, provided it does not refer directly or indirectly to specific medicines.
- Non-promotional information provided to the public about prescription-only medicines, including in response to enquiries from journalists or through public relations activities and the like.
- Information provided about prescription-only medicines must be factual, balanced and must not mislead with respect to their safety. It must not raise unfounded hopes of successful treatment and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine (Clause 26.2).

The Blue Guide advises that, 'particular care should be taken in providing information in response to direct approaches from the media where a company has little or no control over the final production, for example, with television programmes, and which could result in the promotion of prescription only medicines to the general public'.

How is a media event defined?

The Code and the regulations do not use the term media event. Pharmaceutical companies or their agents may organise meetings with journalists from the medical or general press, television, radio or other media. Such meetings may take the form of press conferences, face- to-face or virtual briefings or media advisory boards.

Additional guidance on working with the media and journalists is provided by the UK's Healthcare Communications Association (HCA).

Do the regulations differentiate between consumer and clinical publications?

Yes. Advertisements for prescription-only medicines may appear in medical journals or other clinical publications intended for health professionals, but not in consumer publications intended for the public. In appropriate circumstances, however, it is permissible to provide factual information about a prescription-only medicine to a journalist working for a consumer publication. Such information must comply with the requirements of the Code.

A publication that has been sponsored by a pharmaceutical company must clearly indicate this sponsorship so that readers immediately understand the company's involvement (Clause 9.10).

Do regulations differentiate between print and broadcast media?

The regulations and the Code apply equally to print and broadcast media.

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

A product or indication must not be promoted before the marketing authorisation has been granted. In certain circumstances, however, a pharmaceutical company or its agent may provide non-promotional information relating to an unlicenced product or indication.

It is permissible to issue a news release to the medical or general media about an as-yet unlicenced product or indication if the subject is genuinely newsworthy and appropriate for the intended audience. For example, it may be appropriate to issue a news release to the medical press about the results of a major clinical trial. The information provided must be factual, balanced and non- promotional. The use of brand names should be kept to a minimum. Non-promotional information about products in development may also be made available to shareholders and others with a business interest.

With regard to congresses, scientific meetings and major publications, The Code permits, 'the legitimate exchange of medical and scientific information during the development of a medicine...provided that any such information or activity does not constitute promotion' (Supplementary Information to Clause 3).

Therefore, pharmaceutical companies may sponsor medical and scientific meetings at which research findings on products or indications in development are presented. The purpose of such meetings must be educational and not promotional. Sponsorship must be disclosed in all the papers relating to a meeting and in any published proceedings (Clause 22.4).

Companies may sometimes promote products or indications that do not have a UK marketing authorisation at international scientific meetings held in the UK. The Code allows this only if all the following conditions are met (see Supplementary Information to Clause 3):
The meeting has a high scientific standing, with a significant proportion of attendees from countries in which the product is licenced.

- The medicine or indication is relevant to the purpose of the meeting.
- Promotional materials must clearly state that the product/indication does not have a UK marketing authorisation.
- The names of countries where the mdicine or indication is authorised must be given, including at least one major developed country.
- It must be stated that registration conditions differ from country to country.

In addition, if the product is authorised in the UK but the indication is not, the UK prescribing information must be available.

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

The regulations and the Code allow for the provision of non-promotional information about prescription-only medicines to the media through press releases and other media materials. Requirements of the Code (Clauses 7, 8 and 26) include the following:

- Information about a product must be factual, balanced, must not mislead and must be capable of substantiation.
- Information about safety should reflect the evidence and a product must not be described as safe.
- Any mention of competitor products must not be misleading or disparaging.
- Superlatives must not be used to describe a product unless they relate to an indisputable fact.
- A product must not be described as new if it has been available in the UK for more than a year.
- Information must not raise unfounded hopes of successful treatment and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine.

'It is good practice to include the summary of product characteristics with a press release or press pack relating to a medicine' (Supplementary Information to Clause 26.2).

Once a press release is issued, a company should have no control over the placement of any subsequent article. If a company or its agent controls or pays for the placement of an article about a product it will be regarded as an advertisement for the product.

The MHRA considers that press releases should be issued only if their content is genuinely newsworthy. The context in which the medicine will be used and the population for which it has been licenced should also be provided. The content of a press release and the language used should be appropriate for the target readership. The use of brand names should be kept to a minimum.

Pharmaceutical companies are responsible for information issued about their products by their public relations agencies (Clause 26.5). In accordance with the supplementary information to Clause 14.3 of the Code, appropriate company staff must examine press releases and media materials to ensure that they do not contravene the requirements of the Code or the regulations.

Invitations to journalists to attend media or clinical events must also comply with the Code and they must be checked by appropriate company staff before being issued.

If the PMCPA receives a complaint about an article or other report in the media about a medicine, it will judge the case on the information provided by the pharmaceutical company or its agent to the media and not solely on the content of the article itself. All relevant media materials may be reviewed, including press releases, invitations to meetings, etc.

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

The method of distribution of media materials is not specifically covered in the Code. However, materials intended for the UK must comply with the Code, even if the company responsible is based outside the UK.

What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licenced and non-licenced products equally?

The Code applies to UK press briefings held by or on behalf of pharmaceutical companies and to sponsorship of journalists to attend congresses and scientific meetings. It applies to both licenced and non-licenced products, though information provided about the latter must be considered carefully.

In the case of press briefings and meetings held outside the UK, the local regulations will apply. The requirements of the Code should be followed if a company invites UK journalists to attend.

If companies sponsor journalists to attend such meetings, the requirements of Clause 22 of the Code on meetings and hospitality should be observed. In particular:
Any hospitality offered must be limited to reasonable travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting.

- If air travel is involved, only economy class may be offered unless a journalist is providing professional services for the company (e.g., as a speaker).
- Journalists should not be paid simply for their time to attend media events.
- Those participating in media advisory boards or providing professional services for the company may receive appropriate honoraria.

Companies must check any materials that they issue to journalists to ensure that they comply with the Code. It is good practice to include the Summary of Product Characteristics for any medicine discussed.

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

Journalists—whether freelance or not—whose travel and accommodation are paid for by a company do not have to submit their copy for approval unless the company pays for what they write or influences its content. If the company provides briefing material, it must review this for compliance with the Code; should there be a complaint under the Code about any resulting article, the case will be judged on the basis of that material.

If a journalist submits copy for an independently written article to a company to review it or to check its accuracy, the company may be regarded as being responsible for the content.

If a company pays a journalist to write an article, it will be held responsible for the content and it must review it for compliance with the Code. Sponsorship should be declared in the article. However, it is good practice, as advocated by the HCA, not to pay journalists for writing news or feature stories, as they should receive payment for copy from the publications in which their material appears.

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

It is permissible to use patients' case studies, but they should, 'focus on the disease and the impact it has on the patients rather than the specific medicine' (The Blue Guide). They should represent typical, not exceptional, cases. The use of case studies or third-party advocacy must comply with the Code. In particular, case studies must not be promotional and must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine. Companies must review any briefing materials they produce in connection with case studies or third- party advocacy to ensure compliance with the Code.

Companies must not use health professionals, patient organisations or patients themselves as advocates to promote particular products in the media.

DIGITAL & SOCIAL MEDIA

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

The same rules about compliance apply. The Code applies to information about the availability or use of a prescription medicine in the UK if this information is provided on the internet by, or on behalf of, a UK company, or by an affiliate. This is the case even if the information is put on the internet outside of the UK. Companies should review such information to ensure compliance. If there is a complaint under the Code, the PMCPA will require full details about the information provided.

What levels of web security are required?

Promotional material about prescription-only medicines may be placed on a website that is owned or sponsored by a pharmaceutical company. Such material must not be directed at the public. If the website is publicly accessible, it should have separate areas for consumers and healthcare professionals (Supplementary Information). The Blue Guide states that the public should not be encouraged to access material not intended for them.

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

Any funding or support given to a non-company owned website must be clearly stated on the website. If a company provides information for such a website, it must ensure that it complies with the Code.

If a company-owned or sponsored website includes links to other websites, it should inform users when they are being directed to a non-company site.

What are the most popular social networks in your region?

Social media such as Facebook, Twitter and others are widely used in the UK. Each has its own terms and conditions of use and privacy policy, but they do not have self-imposed regulations specifically relevant to the pharmaceutical industry.

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

The promotion and advertising of medicinal products in the UK is governed by general laws on advertising. This self-regulatory practice is founded on the Codes of Practice, the ABPI's Code of Practice for the Promotion of Prescription-Only Medicines (the ABPI Code) and the PAGB's Medicines Advertising Codes that relate to over-the-counter medicines.

The main challenge for companies at this point is to combine the existing regulatory framework with additional specific guidance provided by the above mentioned codes and then apply that to social media.

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

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

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

The general principles set forth in the regulations and the Code apply. The PMCPA issued informal guidance on digital communications in March 2016. This notes that companies can use any method of communication, including social media, provided that relevant requirements of the Code are followed. A company may sponsor a page on a platform that it does not own (e.g., a company Facebook page), but it must make its involvement clear to users.

A company hosting a discussion forum on its website or facilitating a forum on a third-party website is likely to be responsible under The Code for its content. A company that is considering doing this must ensure that it can moderate the site, that the content complies with The Code and that it is appropriate for the intended users, whether they are health professionals or the public.

The requirements of The Code also apply if an employee of a company—or of an agency working for the company—contributes to a non-company discussion forum.

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

The use of mobile phones and mobile computing through smart phones, tablets, etc. is widespread in the UK. The general principles set forth in the regulations and The Code apply to communications by or on behalf of pharmaceutical companies, irrespective of the communication medium or the device used to receive the information. Clause 9.9 of The Code requires that the telephone (including mobile phones), text messages, email and other electronic communications must not be used for promotional purposes unless the recipient has given prior permission.

What are the disclosure laws like in your region for non-branded websites?

A company can sponsor a non-branded website that provides non-promotional information about health or diseases, but the company's involvement must be clearly declared (Clause 9.10, The Code).

What is the response level needed for adverse event reporting?

The ABPI Pharmacovigilance Expert Network (PEN) has issued guidance on the management of adverse events from social media and company-sponsored websites (http://www.abpi.org.uk/our-work/library/guidelines/). This notes that companies should regularly screen websites for which they are responsible and collect any reports of adverse events with their products. It is advisable on any company-sponsored site to provide a

mechanism for the user to report adverse events to the company—for example by providing online reporting forms or company contact details.

Companies are not expected to screen external websites but if they become aware of adverse events reported on non-company websites they should review the details and determine whether they should be reported.
A company may 'listen in' to a social media site or actively communicate with users on the site. If it does so, the ABPI PEN recommends that it has a project plan specifying the objectives and responsibilities, including the management of any adverse events reported. It also recommends that monitoring for adverse events should be carried out only for the period of the project specified in the project plan. The company should, where feasible, declare its presence by registering on the site using the company name.

STAKEHOLDERS/ ADVOCACY GROUPS

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

Companies may provide support to patient organisations (Clause 27, The Code). There must be a detailed written agreement stating the arrangements (Supplementary Information to Clause 27.3) and companies must publish a list of organisations supported, with information about the support provided (Clause 27.7).

The requirements of Clause 22 of The Code are relevant to meetings and hospitality for patient/ advocacy groups. Meetings must be held in appropriate venues—lavish or deluxe venues or those renowned for entertainment facilities should not be used. Any hospitality offered must be limited to reasonable travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting. Exceptionally, if a representative of a patient group has a disability, companies may also pay such costs for an accompanying caregiver (Supplementary Information, Clause 27.2). Otherwise, hospitality must not be offered to accompanying persons unless they are participants in their own right. If appropriate, travel to other countries may be paid for, though companies should not organise meetings abroad unless most of the participants are from outside the UK, or expertise or resources relevant to the meeting are located outside the UK.

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

Companies may pay reasonable costs for participants' travel, accommodation (if needed) and subsistence but should not pay participants simply for their time in attending meetings.

Reasonable honoraria may be paid to those providing services—for example, speakers.

The Code (Clauses 23.1 and 27.8) states that use of healthcare professionals and representatives of patient organisations as speakers, consultants or advisors must comply with a number of requirements. In particular, there must be a written agreement in place beforehand specifying:

- The services to be provided;
- The basis of the remuneration, which should reflect the fair market value of the services; and
- The obligation of the healthcare professional or

patient organisation to declare their relationship with the company whenever writing or speaking in public about a matter covered by the agreement or any other issue relating to the company.

Contracting a healthcare professional or patient organisation to provide services must not be an inducement to prescribe, provide or recommend any medicine.
Companies must publish details of payments made for such services each year (Clauses 23.2 and 27.8).
Companies sponsoring delegates' air travel to meetings should pay only for economy class, though this restriction does not apply to speakers or those providing other services.

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

Companies may pay for reasonable travel costs, accommodation, registration fees and subsistence. They may not pay participants for their time in attending meetings, though they may pay honoraria to speakers, advisory board members, etc. Details of such payments should be specified in written contracts or agreements and must be disclosed on an annual basis.

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

Neither the Code nor The Blue Guide provides specific guidance on media training. If a company works with health professional or advocacy organisations that communicate with the media about a disease or its treatment, it is appropriate to provide them with media training. Anybody who provides information to the media on behalf of a company must be made familiar with the requirements of the Code.

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

Clause 9.10 of the Code states that material relating to medicines and their uses that is supported by a company must clearly declare the company's sponsorship. This applies to materials written on behalf of patient advocacy organisations or other third parties. Companies must review the information in these materials to ensure that it complies with the Code. Materials written for patient advocacy organisations must not constitute the advertising of prescription-only medicines to the public. Briefing materials written for third parties that communicate with the media about a company's products must comply with the requirements of the Code. In particular, they must not be intended to encourage patients to ask prescribers for a specific prescription-only medicine.

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

When working with any patient organisation companies must ensure that the arrangements comply with the Code (Clause 27) and that their involvement is made known from the outset. They must have a detailed written agreement (Clause 27.3) describing the arrangements. Companies must publish a list of all patient organisations to which they provide financial or significant non-financial support each year. They must also report on the support provided to each organisation in sufficient detail to enable readers to understand the significance of the support. Details must be provided of financial support and the value of non-financial support (Clause 27.7).

Any information that a company provides to a patient organisation must not constitute advertising of prescription-only medicines to the public. Information relating to the company's products must comply with the Code. It must be factual, balanced and must not be provided with the aim of encouraging the public to ask prescribers for a specific prescription-only medicine.
Other important considerations in connection with patient advocacy groups are:

- No company may require that it be the sole funder of a patient organisation or any of its programmes (Clause 27.4);
- A company must not make public the use of a patient organisation's logo or proprietary material, such as leaflets, without the organisation's written agreement (Clause 27.5); and
- A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests (Clause 27.6).

KEY TAKEAWAYS/ SUMMARY

- Communications by pharmaceutical companies or agencies, including media briefings, must comply with the requirements of The Code: information must be accurate, balanced, must not mislead and must not promote prescription-only medicines to the public.
- Relations with patient advocacy groups must be open, with details—including financial arrangements—being made publicly available.
- Companies may sponsor healthcare professionals, journalists and members of patient advocacy groups to attend media events or scientific meetings; hospitality must be limited to travel costs, accommodation, registration fees and subsistence and must be secondary to the purpose of the meeting.

REFERENCES

EUROPE & AFRICA

DENMARK

- Bekendtgørelse om sundhedspersoners tilknytning til lægemiddel- og medicovirksomheder og specialforretninger med medicinsk udstyr. (n.d.). Retrieved from https://www.retsinformation.dk/Forms/R0710.aspx?id=165316
- Mobile Phones in Denmark. (n.d.). Retrieved from http://www.euromonitor.com/mobile-phones-in-denmark/report
- ENLI. (2017). Lægemiddelindustriens kodeks vedrørende reklame mv. for lægemidler rettet mod sundhedspersoner.
- ENLI. (2017). GUIDE vedr. brug af digitale medier i reklameaktiviteter.
- ENLI. (2016). GUIDE vedr. økonomisk sponsorstøtte og udstillingsstande.

FRANCE

- https://solidarites-sante.gouv.fr/ministere/acteurs/instances-rattachees/article/charte-de-la-visite-medicale
- http://www.dm-experts.fr//wp-content/uploads/2014/04/Charte-Internet-2014.pdf
- https://www.ticpharma.com/story.php?story=545
- https://fr.statista.com/statistiques/505110/taux-de-penetration-du-smartphone-par-age-france/
- https://www.blogdumoderateur.com/etude-deloitte-francais-smartphone

GERMANY

- Code of Conduct of the Members of the Association 'Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V' (FSA Code of Conduct)
- Germany, Bundestag. (2017). Law on the marketing of medicines.
- Germany, Bundestag. (2016). Gesetz gegen den unlauteren Wettbewerb (UWG).
- Germany, Bundestag. (2013). GERMAN CRIMINAL CODE.
- Smartphone users in Germany 2015-2022 | Statistic. Retrieved from https://www.statista.com/statistics/467170/forecast-of-smartphone-users-in-germany/
- A guide to social media platforms in Germany. Retrieved from http://www.wordbank.com/blog/social-media/essential-german-social-media-guide/

ITALY

- CODE OF CONDUCT FARMINDUSTRIA(Rep.). (2016). Farmindustria.
- Top five social media and messaging apps Italy 2017 | Survey. Retrieved from https://www.statista.com/statistics/730082/top-five-social-media-and-messaging-apps-in-italy/
- Facts&figures of pharmaceutical industry in Italy(Rep.). (2017). Farmindustria.
- Italy, Parliament of the Republic. (2006). Legislative Decree No. 219 of April 24, 2006 on the Implementation of Directive 2001/83/EC (& Subsequent Amending Directives) on the Community Code on Medicinal Products for Human Use, and the Directive 2003/94/EC.
- Post-Marketing Surveillance. (n.d.). Retrieved from http://www.aifa.gov.it/en/content/post-marketing-surveillance

NORWAY

- Norway, Storting. (2017). Forskrift om legemidler - Advertising for medicines.
- LEGEMIDDELINDUSTRIENS. (2018). Retrieved May 9, 2018, from http://reklameregler.lmi.no/wp-content/uploads/2018/04/LMI-Bransjeregler-2018.pdf
- Norway, Storting. (2018). Retrieved May 9, 2018, from https://lovdata.no/dokument/SF/forskrift/2009-12-18-1839
- Snapchat Second-Most Popular Social Site in Norway. (2015, October 30). Retrieved from https://www.emarketer.com/Article/Snapchat-Second-Most-Popular-Social-Site-Norway/1013173
- Smartphone users in Norway 2014-2021 | Statistic. Retrieved from https://www.statista.com/statistics/494647/smartphone-users-in-norway/

POLAND

- Poland: Social network penetration 2017 | Statistic. Retrieved from https://www.statista.com/statistics/284441/poland-social-network-penetration/
- The Employers' Union of Innovative Pharmaceutical Companies. (2015). Infarma Disclosure Code.
- The Employers' Union of Innovative Pharmaceutical Companies. (2008). Infarma Code of Good Practices.
- Poland, Parliament of Poland. (2001). Pharmaceutical Law of the Republic of Poland.

PORTUGAL

- Portugal, Assembly of the Republic, District Attorney's Office of Lisbon. (2013). DL n.º 128/2013, de 05 de Setembro - Code of Medical Products.
- Practical Law, Menéres, A. (n.d.). The sunshine rules in Portugal. Retrieved from https://content.next.westlaw.com/0-586-7345?transitionType=Default&contextData=(sc.Default)&__lrTS=20180509173945146&firstPage=true

REFERENCES CONTINUED

- Top Countries by Smartphone Penetration & Users. (n.d.). Retrieved from https://newzoo.com/insights/rankings/top-50-countries-by-smartphone-penetration-and-users/
- APIFARMA. (2018). Código Deontológico.
- APIFARMA. (2003). Código de Boas Práticas de Comunicação.

ROMANIA

- "ARPIM CODE On the promotion of prescription-only medicines to, and interactions with, Healthcare Professionals". Available at: http://arpim.ro/wp-content/uploads/2018/04/ARPIM-Ethics-Code_2018_ENG.pdf
- "Romanian Generic Medicines Manufacturers Association – APMGR. Ethical Code of Conduct Concerning the Promotion of Prescription – Only Medicines. Available at: http://www.apmgr.org/cod.pdf
- "The Government Order No. 194 of February 23, 2015, on the approval of the Norms for the evaluation and approval of publicity at medicines for human use", available at: https://www.anm.ro/_/ORDINE/OMS_194_2015.pdf
- "National Audio-Visual Code", available at: http://arhiva.cna.ro/reglementari/decizii/d18706.html?fbclid=IwAR0-x_bCxZ4fVIq2Bw05JKdZ3wC54CaUrGdoJBpcWGXu_m7cgqSb9qjENew

SOUTH AFRICA

- Global Legal Group (2006). The International Comparative Legal Guide to: Pharmaceutical Advertising. Chapter 37, South Africa.
- International Comparative Legal Guides (2018). Pharmaceutical Advertising 2018. Retrieved from https://iclg.com/practice-areas/pharmaceutical-advertising-laws-and-regulations/south-africa
- Marketing Code Authority (2014). SA Code of Marketing Practice. Retrieved from https://www.marketingcode.co.za/images/sacodemarketingpractice.pdf
- BusinessTech (2018). More than half of South Africans now own a smartphone: study. Retrieved from https://businesstech.co.za/news/internet/255995/more-than-half-of-south-africans-now-own-a-smartphone-study/

SPAIN

- Top Countries by Smartphone Penetration & Users. (n.d.). Retrieved from https://newzoo.com/insights/rankings/top-50-countries-by-smartphone-penetration-and-users/
- Farmaindustria. (2016). Código De Buenas Prácticas 2016. Retrieved from http://www.codigofarmaindustria.org/servlet/sarfi/codigo/codigo.html

SWEDEN

- Etiska regelverket (2018). Retrieved from https://www.lif.se/etik/etiska-regelverket/.
- Läkemedelsverkets författningssamling (2009). Retrieved from https://lakemedelsverket.se/upload/lvfs/LVFS_2009-6.pdf.

UNITED KINGDOM

- Healthcare Communications Association Code of conduct. (n.d.). Retrieved from https://www.hca-uk.org/About-the-HCA/Code-of-conduct
- United Kingdom, Medicine and Healthcare Products Regulatory Agency. (2014). The Blue Guide: Advertising and Promotion of Medicines in the UK.
- United Kingdom, Parliament. (1994). The Medicines (Advertising) Regulations.
- Ethics | ABPI. (n.d.). Retrieved May 9, 2018 from http://www.abpi.org.uk/ethics/
- Prescription Medicines Code of Practice Authority. (2019). Code of Practice.
- PAGB Consumer Code Archives. (n.d.). Retrieved May 9, 2018, from https://www.pagb.co.uk/codes-guidance/consumer-code/
- PAGB Professional Code Archives. (n.d.). Retrieved May 9, 2018, from https://www.pagb.co.uk/codes-guidance/professional-code/

- List of Popular Social Networks | Social Media Ltd. (n.d.). Retrieved from https://social-media.co.uk/list-popular-social-networking-websites
- UK smartphone penetration continues to rise to 85% of adult population. (n.d.). Retrieved from https://www.consultancy.uk/news/14113/uk-smartphone-penetration-continues-to-rise-to-85-of-adult-population

GLOBALHealthPR Headquarters

250 Vesey Street, Suite 2630
New York, NY 10281, USA

+1.212.468.5370

www.globalhealthpr.com