The Global Guide to Pharma Marketing Codes

This truly unique guide was produced with the insight and expertise of the largest independent public relations group dedicated exclusively to health and medical communications worldwide.

Vol. 3
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.

INFORMATION CONTAINED WITHIN THIS DOCUMENT DOES NOT CONSTITUTE LEGAL ADVICE.
Table Of Contents

- Preface ....................................................................................................................................5
- Foreword ................................................................................................................................6
- Introduction ..............................................................................................................................8
- Argentina ................................................................................................................................12
- Australia ................................................................................................................................21
- Brazil .....................................................................................................................................32
- Chile .....................................................................................................................................38
- France ....................................................................................................................................45
- Germany ................................................................................................................................53
- India .......................................................................................................................................60
- Italy .........................................................................................................................................67
- Japan .....................................................................................................................................77
- Mexico ....................................................................................................................................85
- Poland .....................................................................................................................................93
- Portugal ...................................................................................................................................99
- Spain ......................................................................................................................................109
- Turkey ...................................................................................................................................117
- United Kingdom .....................................................................................................................122
- United States of America ........................................................................................................134
- About GLOBALHealthPR Partners ........................................................................................149
Preface

We live in an age of incredible scrutiny, especially when it comes to healthcare. As the global financial crisis maintains its grip on wallets and bank accounts, every penny must be closely watched. Increasingly savvy and connected consumers have access to greater amounts of information about the products and services that they need for their families. Experiencing both budgetary constraints and the watchful eyes of their constituents, governments around the globe have increased their oversight and regulation of the health industry, particularly when it comes to pharmaceutical marketing.

Long an area of active engagement, governments are expanding their vigilance in pharmaceutical marketing. Greater consumer touch points, such as advances in online communication and social media, have added complexities to the regulatory roles of agencies around the globe. Keeping up-to-date on the diverse regulatory landscape is of critical importance for pharmaceutical manufacturers to avoid potentially costly government penalties.

To help navigate health communications regulations, the GLOBALHealthPR partners are privileged to offer you what we believe is a truly unique compendium: the third edition of The Global Guide to Pharma Marketing Codes. If your job requires you to understand and succeed in the marketing of pharmaceutical products on a regional or international basis, then you’ll find this publication indispensable.

Thank you for your interest—I’d be happy to hear your feedback.

John J. Seng
Chair, GLOBALHealthPR
Founder and President, Spectrum
Foreword

The relationship between pharmaceutical marketers and regulatory agencies reflects upon a nation’s health policy. In one respect, pharmaceutical marketing professionals, in any country, must be well-educated about, and adhere to, the laws governing medical promotion. To support that education, and adherence, regulatory agencies are obliged to constantly provide information and guidance to these professionals, who are responsible for sharing important medical information with the public.

While these partnerships are dictated by each nation’s governing bodies and can vary greatly between countries, medical advancements cross national borders link us together in a global mission. Every day, the pharmaceutical industry expands globally, and every medication prescriber, purchaser, dispenser and user is affected by this international dynamic.

The Food and Drug Law Institute (FDLI) shares in the responsibility to educate communication professionals and is proud to support GLOBALHealthPR in the international publication of its third edition of the *The Global Guide to Pharma Marketing Codes*. This overview of basic healthcare promotional regulations provides a helpful baseline of information. The Food and Drug Law Institute, founded in 1949, is a non-profit organisation that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction. Because one major cornerstone of our mission is to ensure an open, balanced marketplace of ideas to inform innovative public policy, law and regulation, we see a growing need to regularly connect with communications professionals. The *Global Guide* serves as a vehicle to bridge the educational gap on this component of food and drug law.
FDLI is pleased to support this publication, one of the most comprehensive global compilations of pharmaceutical marketing codes. We are proud to facilitate relationships between pharmaceutical marketers and law professionals, as communication is essential to advancing health and facilitating understanding of, and compliance with, legal and regulatory requirements. As laws and medicines progress, society progresses as well. By maintaining this network of relationships, we can ensure an open, honest dialogue across all involved parties, thereby contributing to successful outcomes for our organizations and the public at large.

Susan C. Winckler, RPh, Esq,
President & CEO
Food and Drug Law Institute
Introduction

The Global Guide to Pharma Marketing Codes will help marketers maximise public relations opportunities around the world. This publication provides an overview of basic healthcare promotional regulations and answers the most frequently asked questions about what is and isn’t permitted with respect to the media and third-party involvement. This truly unique guide was produced with the insight and expertise of the largest independent public relations group dedicated exclusively to health and medical communications worldwide. GLOBALHealthPR is an international partnership uniting some of the world’s most successful independent, entrepreneurial, owner-managed healthcare public relations firms and their affiliates from major markets in Europe, the Americas and Asia.
Individuals are empowered to access information and question the actions of others in a way never before imagined. In recent years, this e-connectivity has allowed for everything from greater democratic expression, leading to the toppling of totalitarian dictatorships, to new ways to express creativity and interact with friends, family, colleagues and partners.

Governments and regulators are well aware of this shift and understand that they will be held accountable for sound leadership and protection of their people. Nowhere is this realisation more prevalent than in the healthcare arena. Across the globe, government regulators are stepping up their oversight and enforcement of safe, sound and effective health solutions to protect their citizens. As a result, the pharmaceutical industry must maintain its commitment to addressing regulations on how it promotes and markets drugs to avoid regulatory infringement, or even worse, an active and vocal opposition from target consumers.

Added to the complexity and pitfalls for pharmaceutical marketers are evolving communications platforms. Social media, interactive websites, mobile apps and other technologies provide marketers with new ways to connect with consumers and medical professionals to promote products, educate communities and position their brand or breakthrough drugs. At the same time, regulators are strained to play catch-up and provide clear and effective rules for these new communications platforms.

In this environment, it is important for pharmaceutical marketers to be fully aware of the promotional codes for pharmaceutical products enacted around the globe. The areas of the codes that relate to public relations activities are often the most ambiguous and open to interpretation. It can be difficult for marketers to stay abreast of changes, which poses huge challenges for multi-national pharmaceutical companies responsible for ensuring full compliance with multiple regulatory bodies. These challenges are increased when events and communication efforts take place in countries other than the point of research or information is issued to the media. Company headquarters will have internal compliance procedures, but these are not foolproof, and nothing can replace local market knowledge, particularly in the current climate.

New communications platforms, such as social and digital media, provide fantastic opportunities for marketers to connect with consumers on a global scale. New and sometimes ambiguous regulations, however, cause many marketers to be more cautious than ever with their brand plans. With a clear and thorough understanding of the global pharmaceutical promotional regulations, marketers can be more confident in developing programs that inspire, educate and positively impact patients, while avoiding sanctions from governments or complaints from consumer watchdogs.

This guide is designed to help busy marketers get the most out of public relations opportunities around the world. It provides an overview of basic healthcare promotional regulations and answers the most frequently asked questions about what is and isn’t possible with respect to paid and earned media and third-party involvement.

GLOBALHealthPR was launched in 2001 to meet the needs of pharmaceutical clients interested in genuine global representation—people on the ground who deliver objective-led campaigns with individual market sensitivities in mind. The need for healthcare communications expertise on a global level has never been more acute. As our international community becomes more closely connected, the need for accurate, targeted and successful communications on a local level becomes imperative.

Many of the world’s top pharmaceutical companies and advocacy groups rely on GLOBALHealthPR partners to reach their customers, and the group has been responsible for groundbreaking global and local communications for leading brands, organisations and conferences.
Individual country and regional government regulatory agencies have long provided oversight of approval and access to pharmaceuticals, helping to support the health and safety of their people. In the last few decades, led by the increased awareness of medicines and the rise of the multi-billion dollar pharmaceutical industry, health organisations and the pharmaceutical industry have collaborated to establish checks and balances related to the promotion and marketing of pharmaceutical products. The launch of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Pharmaceutical Marketing Code in 1981 and the World Health Organization (WHO) Ethical Standards Relating to Drug Promotion in 1983 reflect this conscious move by the pharmaceutical industry to adhere to high standards and practices.

Gradually, individual countries instituted their own codes, but the pharmaceutical marketing landscape is constantly changing, and national and international codes are continually being revised. While the industry’s leaders in North America and Western Europe pushed the early charge for regulations, in recent years the growth of developing nations across Asia and South America has shifted the balance to a truly global scale. With production and, increasingly, innovation and new drug discoveries coming from the East, particularly India and China, new regulatory groups are influencing those of the West and oftentimes establishing stricter guidance and measures.

The IFPMA Code, which was revised on 1, January 2007, is the least specific of the various codes. It is intended to define universally applicable baseline standards of marketing practice and is based on the WHO definition of ethical criteria for drug promotion. The code bows to the fact that a substantial proportion of its 51 member associations have their own country codes of practice; individual companies are also actively encouraged to formulate their own codes with even more specific requirements and additional rules. The IFPMA Code establishes basic ethical ground rules, stating that all communications should be fair, accurate, balanced and not misleading, and that promotion should never be disguised. Sponsorship of events, materials or articles should be clearly marked, and the code discourages inappropriate hospitality and off-label or non-licensed promotion. To accompany the launch of the latest revision, the IFPMA added an ethical promotion section to its website, which will publish details of cases ensuing from any complaints upheld, including the name of the company in breach (www.ifpma.org).

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative body of the industry in Europe, comprising 2,200 companies directly and indirectly in 31 European countries. Its stated purpose is to ensure that promotion of medicines is truthful and ethical, and its stated aim is to foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients. The EFPIA Code sets out the minimum standards with which members must comply and clearly indicates that the more stringent regulations of individual country codes should be followed over and above where applicable.

The code echoes the basic tenets of fairness, accuracy and balance in healthcare communications laid down in the IFPMA Code. Its latest revision, adopted 1 January 2012, is very specific regarding the transparent and ethical relationships between the pharmaceutical industry and patient organisations. This is the first time that the pharmaceutical industry members of EFPIA have committed to following similar ethical rules in working with patient organisations and it has prompted a revision of several individual country codes to bring them in line with its requirements. EFPIA also has a separate Q&A document that clarifies sections of the code and offers guidance on events, hospitality, gifts and inducements.
following the raising of questions over articles 9 and 10 of its Code. It is worth reviewing this document before holding an event or inviting attendees to a meeting in any of the 31 EFPIA member states.

With their unmatched reach and influence, digital promotional platforms are a central part of today’s world. The regulation and oversight of these areas, however, has been surprisingly slow to take hold. In its 2007 update, the EFPIA Code did include an appendix covering Guidelines for Internet Websites Available to Healthcare Professionals, Patients and the Public in the EU. While this section demarcates the regulations for transparency – as well as content and specific regulations for e-mail enquiries, links from other websites, scientific review and privacy – the guidelines have yet to be updated to address social media, such as Facebook and Twitter, which play an important role in communication today.

The rapid rise in online promotional opportunities has caught many regulators off guard. In the United States, the Food and Drug Administration (FDA) has yet to issue full guidelines on digital and social media promotional vehicles, yet has in recent years sanctioned drug manufactures for violations with promotional websites. The closest that US regulators have come is draft guidelines issued in December 2011 on responses to unsolicited questions of off-label uses of drugs and medical devices, allowing for direct and private response to questions received via public online channels.

The various voluntary country codes often go far beyond the level of detail in the wider regulations, although in some cases they provide less guidance. When working across countries, in the event of a conflict of national codes it is stipulated but also good practice to apply the more restrictive code. In all cases it should be noted when using translations that the original language versions of the documents prevail, so it may be worth getting a particularly ambiguous point verified by a native language speaker before proceeding.

The delivery of healthcare communications across countries should be viewed as an exciting challenge to meet rather than a series of barriers to overcome. Communication in our ever elusive world, when undertaken optimally and in line with regulations, can be beneficial and rewarding.
Argentina

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

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

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

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

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

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

The ANMAT and the Federal Authority of Audiovisual Communication Services (AFSCA), together with the Undersecretary of Consumer Defense, is legally responsible for the enforcement of these rules. Private ethical codes are mandatory for chamber members.

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Complaints to ANMAT usually come from industry competitors and consumers. Complaints presented to AFSCA usually are ‘ex officio’, but they may also come from consumers. The Direction of Fair Trading that depends on the Undersecretary of Consumer Defense also receives complaints and/or consultation both from companies and consumers.

In terms of advertising, breaches are sanctioned according to Laws No. 16.463 and No. 18.284 and Decree No. 341/92.

5. Are any materials subject to pre-approval by the relevant authorities before they are used?

OTC advertising is controlled post publication/broadcast by the Monitoring and Control of Advertising and Promotion of Products Subject to Health Surveillance. In 2005, the “prior authorisation” system was repealed, so pieces are monitored and evaluated once they are issued.

Also, any communication with medical professionals or pharmacists in relation to prescription-only medicines to be published in mass media, print or broadcast media needs approval from the programme mentioned above.
What are the most recent significant developments, and are there any planned changes in the next few years?

The most recent development is Resolution No. 627/2007, which regulates the promotion of prescription medicines to medical professionals. It discourages and sanctions ‘promotional practices’ that may motivate medical doctors to prescribe one product in place of another as a result of marketing activities and not based on scientific reasons.

The Media

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

In broadcasting, promotional activity or advertisement is defined as ‘the transmission of any announcement, made as a result of payment or exchange, to generate consumer interest in the acquisition of the products or services offered’. Annex IX of ANMAT Disposition No. 4980/05 defines advertising as ‘an organised technique applied through general media to inform or promote features, benefits or qualities of goods or services in order to provoke and obtain its purchase’. Advertising is also classified as the promotion of people, services, goods, activities or organisations in such a way that exhibits a direct or indirect commercial aim (Section 3, Decree 286/81). Nevertheless, there is no clear line between promotional activities and what is usually presented as ‘provision of information’ under the banner of educational activities.

Promotional activity to medical professionals, according to Resolution No. 627/2007, Section 4°, should include:

- Essential product information, such as generic and commercial names, composition, pharmaceutical form, indication, contraindication, adverse effects and product dosage information;
- The prescription regime and sales conditions.

How is a ‘media event’ defined?

There are no legal provisions regarding media events for medicines promotion.

Do the regulations differentiate between consumer and clinical publications?

Resolution No. 627/2007 in Section 6° establishes that promotional materials for medical professionals should not be accessible to the general public in any format such as magazines, books or audiovisual media including CDs, DVDs or memory sticks. Sections 9° and 12° determine that prescription medicines should only be promoted through media (any format) directed only at persons qualified to prescribe or deliver medications.

However, since there is not a ‘Press Law’ or anything similar in Argentina, there are no regulations aimed directly at the content of publications. This situation is of special relevance because in the case of publications directed
at medical professionals, the editors are the ones who regulate and limit information access to the general public.

10 Do the regulations differentiate between print and broadcast media?

No, they do not.

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

Both the CAEMe Ethical Code and Resolution No. 627/2007, Section 3°, forbid the promotion of a medication that has not been approved by ANMAT for its commercialisation.

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

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

There are no specific regulations governing press releases or media materials, nor media attending clinical events.

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

No reference is made to the distribution of press releases and media materials.

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

There are no rules about how the press should cover these kinds of congresses and meetings.

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

The relating copy is supposed to be independent. Journalists who work for a media outlet are subject to the ethical code or principles established by the employer. Most of them rule that reports are owned by the publication itself or occasionally by the journalist. Because of that, the content is not under the control of the sponsor company. AMA’s Ethics Code rules under sections No. 383 and No. 384 that it is a serious breach of professional standards—related to health news dissemination—to make claims or exaggerated results about a therapy that has not been verified through scientific methods.

In the same way, it is a serious breach of professional ethics to lead people to self-medicate under the guise of imparting objective information.

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

No specific mention is made.
Internet & Digital Media

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

Law No. 26032 specifies that research, reception and dissemination of information and ideas through the Internet are legally considered within the framework of the freedom of the press. Responsibilities are established in the civil and penal code as if it were a print newspaper. However, as is stated in Section 11 of the Ethics Code for the Promotion of Medicines, scientific information should only be accessible by professionals.

Although Law No. 16463 prohibits any direct promotion of prescription-only medicines to consumers, scientific information online is not restricted only to healthcare professionals. It can also be available to consumers without restriction and without including any kind of advertising claim.

17. What levels of Web security are required?

The promotion of medicine or medical practices through the Web is limited under Resolution No. 627/2007 of the Department of Health and the Ethics Code, which regulates that it must be stated in a very noticeable way that the information is designed for professional use only.

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

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

Websites are expected to comply with what is stated in the Medicines Law. In terms of advertising funding, Article 37 of Medicines Law orders the prohibition of any kind of public advertisement of medicine products that have to be sold under written prescription.

19. What are the most popular social networks in your region? Do they have self-imposed regulations?

Facebook is clearly the leading social network in Argentina in terms of both reach and users. Twitter’s reach increased significantly within the country during the last year, and the prevalent use for this network is immediate information (through journalists’ and media’s tweets), and also to post banal/trivial contents. Photo sharing sites, like Flickr and Instagram, are also very popular. In Argentina, instant messengers have lost users’ attention, and Facebook chat has become more popular instead. For video calls, Skype is the most recurrent site. On the other hand, YouTube and Vimeo are the main sites for posting and sharing videos. The use of MySpace, Bandcamp and SoundCloud for listening to and sharing music has increased. Use of the professional network LinkedIn showed an increase during the last year, but it is still not yet widely used.

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

For OTC products, content in forums, including interaction between the company and costumers, must respect ANMAT Disposition No. 4980/05. These interactions can never involve the commerce of medicines.
For prescription-only medicines, any kind of promotional direct interaction between the company and patient is forbidden, according to Article 19, including Law No. 16463 that states, ‘it is prohibited any public announcement of medicines whose retail sale condition is authorised only by prescription’.

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

According to the latest reports, smartphone sales in Argentina have increased 217% in one year. This type of mobile monopolizes 40% of all mobile phones in Argentina. Android is the most-used device platform in the country.

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

There is not a specific regulation stated from ANMAT, the national regulatory authority. Websites developed by pharmaceutical companies with health information or information of specific diseases that do not mention commercial brands or include any symbol that could identify the brand are considered disclosure of scientific or technical information.

What is the response level needed for adverse event reporting?

Resolution 706/93 of the Ministry of Health implemented the National Pharmaco Surveillance System, a formal mechanism that bases its work on spontaneous, voluntary and confidential reporting of adverse reactions by health professionals. The Pharmaco Surveillance System depends upon the National Direction of Medical Evaluation (DEM). Its aim is the detection, assessment, understanding and prevention of adverse effects and other problems related to drugs (UMC–WHO, 2000).

One of the main regulatory concerns is that pharmaceutical companies quickly report serious or unexpected adverse effects of their drugs and that they regularly report mild to moderate adverse events, mainly for products with less than five years on the market. In regards to working with health professionals, the task is focused on growing the network of peripheral effectors in the link with medical associations, pharmacists and so on. It also works closely with international bodies involved in adverse event reporting, especially with the Collaborating Center of the World Health Organisation (WHO), located in Uppsala, Sweden.

The release of information is a key activity for the maintenance of the Pharmaco Surveillance System. In Argentina, information is released through the ANMAT website (www.anmat.gov.ar) and Newsletter for Professionals, which features letters to professional associations like the Argentinean Pharmaceutical Confederation (COFA) and Argentinean Medical Confederation (COMRA). Specific cases are also published in national and international medical and scientific journals.

Reports of adverse events can be done by courier (Av. de Mayo 869, piso 11º, CP AAD1084, Buenos Aires, Argentina), e-mail (snfv@anmat.gov.ar) or by filling out the form listed on the ANMAT website.

ANMAT’s Pharmaco Surveillance Department can receive both internal and external information. There are four possible external suppliers of information:
- Peripheral notifiers: hospitals, universities, etc., that signed an agreement with ANMAT. There are currently 66 peripheral notifiers in the country.
- Particular notifiers: healthcare professionals, including physicians, pharmacists, dentists and nurses, from public
hospitals, private institutions or private offices, that detect adverse events and directly report to ANMAT.

- Consumers: patients who, either by themselves or through consumers associations, send their reports.
- Pharmaceutical industry: through ANMAT Dispositions No. 3870/99 and 2438/00, the pharmaceutical industry is included in the SNFVG, and it must report serious or unexpected adverse reactions of its drugs within a period of 10 days. Those reactions that are not classified as serious or unexpected must be periodically communicated, always indicating that events are reported in Argentina.

Stakeholders/Advocacy Groups

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

Regulations do not refer specifically to advocacy/patient groups, but the fact that the legal framework does not allow direct-to-consumer promotion of prescription medicines needs to be taken into account.

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

There are no regulations regarding honoraria for healthcare professionals or advocacy organisations as payment for their collaboration in media activities or events. The Argentinian Medical Association Ethics Code accepts that medical doctors sometimes work as employees for pharmaceutical companies and, as such, will participate in promotional activities of the company. But in that case, the code suggests they should not actively practice at the same time.

Regarding travel outside Argentina, the CAEMe Ethics Code does not allow companies to pay honoraria to professionals for their time nor organise or sponsor an event for health professionals out of the country, with exceptions. International meetings and symposia abroad to be attended by professionals from different countries are permitted to be sponsored, with restrictions.

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

Resolution 627/2007, Section 16° allows companies to offer funding or scholarships to healthcare professionals in order to participate in congresses, seminars and scientific meetings. Companies must publicly inform, in advance, the conditions of access to those funds or scholarships and the selection process of applicants, with fair and transparent mechanisms for granting. It is expressly forbidden to prescribe certain drugs or products for such purposes.

CAEMe specifies that sponsorship is limited to travel expenses, accommodation, meals and fees. Paying for the time dedicated outside of the meeting or encouraging the prescription of particular drugs through payment of expenses is strictly prohibited.

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

There are no specific rules.
What rules govern materials written on behalf of third parties, such as clinical or advocacy organisations?

Section 11° of Resolution No. 627/2007 states that all information about a medicine issued by the producing company must be exact, verifiable and updated. The pharmaceutical company must allow access to referenced bibliographical material to any professional who may require it.

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

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

There are no legal restrictions.

Key Takeaways/Summary

Locally, the most important pharmaceutical companies, both in terms of revenues and sales, are Argentinean. In Argentina, the pharmaceutical industry represents an annual market of $5 million U.S., in which the share of that market is 69.5 percent for national companies and 30.5 percent for foreign ones. The two companies that lead the local market are from Argentina and were founded more than 70 years ago as family businesses (Laboratorio Roemmers and Laboratorios Bagó), and they are now present in several other countries and focused mainly in Latin America. Unlike other Latin American countries, the local pharmaceutical industry in Argentina has shown an important growth during the last 10 years with the introduction of important technology. The industry mainly develops with local technology news and innovative pharmaceutical forms, some of which are also licensed in other countries.

In Argentina, medicine prices are controlled by the Trade Secretary. This means companies cannot raise the price of their products without previous permission. The Trade Secretary gives pharmaceutical companies the possibility of a raise in their products’ prices every three months, with a maximum increase that varies from 12 to 16 percent for the whole year.

Many top worldwide pharmaceutical companies make important local investments in clinical research. Argentina participates with prestigious centers in several multicentric clinical trials. During 2011 the government interfered with imported medicines. Foreign pharmaceutical companies are asked to present a commercial balance for exported/imported products. Due to this decision, CAEME, the chamber that gathers international pharmaceutical companies, committed $600 million investment for local clinical research.

Pharmaceutical companies are gathered in Argentina in four chambers:

• Argentine Chamber of Medical Specialties (CAEME): gathers international companies. See http://www.caeme.org.ar/.
• Industrial Chamber of Argentinean Pharmaceutical Laboratories (CILFA): includes main national pharmaceutical companies. See http://www.cilfa.org.ar/.
• Argentinean Chamber of Non-prescription medical Specialties (CAPEMVeL): includes both national and international companies with OTC products in their portfolio. See http://www.capemvel.org.ar/.

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

Law in Argentina contemplates patent protection but is not yet in full force. The local environment of the pharmaceutical industry is very competitive. Leading innovative companies face a strong competition from generic drug-producing laboratories. These companies invest few resources in research and development and benefit from the production of drugs whose patents have expired or from drugs without patent protection. In general, their prices are lower as they do not have to deal with the cost of large structures.

Since 2002, Prescription of Medicines by Generic Name, Law No. 25,649, states that every medical prescription must be written expressing first the generic name of the drug, then the pharmaceutical form, then the number of units and the drug concentration. Pharmacists must then inform consumers of the availability of every commercial brand containing the same drug, same amount of units and same concentration, and the different prices of each product. Changing of the drug prescription by the professional is not permitted.
Australia

The Therapeutic Goods Administration (TGA) is Australia’s regulatory authority for therapeutic goods, and the promotion of medicines is self-regulated by the pharmaceutical industry’s Medicines Australia Code of Conduct. Direct-to-consumer promotion is allowed for the majority of medicines available for over-the-counter (OTC) sale, while promotional activities and/or advertising to the general public for prescription-only and certain pharmacist-only medicines is prohibited.
The Global Guide to Pharma Marketing Codes

The Basics

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

The promotion of medicines is subject to legislation requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act (TGA) and by self-regulation of the pharmaceutical industry.

Self-regulation is based on Medicines Australia’s Code of Conduct (the Code), which sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. The Code complements the legislation requirements of the Therapeutic Goods Regulations and the TGA.

Code provisions include standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals. Medicines Australia’s Code of Conduct, which was established in 1960, is revised on a regular basis to reflect the current community and professional standards and current government legislation. The latest Code of Conduct edition is available at www.medicinesaustralia.com.au.

The Code is recognised by the TGA, the regulator of medicines for marketing and promotion by the prescription medicines industry. The TGA supports the long-established system of self-regulation as being consistent with supporting the Therapeutic Goods Regulations.

TGA is Australia’s regulatory authority for therapeutic goods. It performs a range of assessment and monitoring activities to ensure that the therapeutic goods available in Australia are of an acceptable standard, with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

Non-prescription medicines, such as over-the-counter (OTC), pharmacy-only or complementary medicines are not covered by the Medicines Australia Code of Conduct. These medicines are regulated by co-regulatory and self-regulatory arrangements operated by the TGA, the Therapeutic Goods Advertising Code Council, the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC).

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

Public relations activities are subject to the communication and promotion provisions of the Medicines Australia Code of Conduct and are not separately defined or differentiated from other promotional activities. Media releases must be educational and not include promotional statements or claims, or comparisons with other products.

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

Medicines Australia is responsible for administering and enforcing the Code of Conduct, which sets standards for the ethical marketing and promotion of prescription medicines. Any potential violation of the Code may be referred to the Medicines Australia Code of Conduct Committee. The matter is handled mainly through the Medicines Australia Complaints Handling Process. The Code of Conduct Committee is responsible for imposing sanctions on companies found to be in breach of the Code. Expert advice may be sought externally by the Code and Appeals Committees in determining whether or not a breach has occurred.
The Code of Conduct Committee comprises an independent lawyer, representatives from the Australian Medical Association (AMA), the Royal Australian College of General Practitioners (RACGP), Australian Divisions of General Practice (ADGP), the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT), the Therapeutic Goods Administration (TGA), Consumer Health Forum of Australia (CHF), Patient Support Group, Medicines Australia and medical representatives from a company with no product in the complaint class.

Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Anybody can submit a concern or complaint to Medicines Australia, although most complaints about promotional activity in 2009 and 2010 were made by rival pharmaceutical companies or the Medicines Australia Monitoring Committee.

The complaints and appeals procedures vary between industry and non-industry complainants.

A non-industry complainant is a member of the general public, healthcare professional, academic or a member of the TGA. Non-industry complainants may lodge a complaint free of charge in relation to the activities of, or materials developed by, the Australian manufacturer/sponsor of a prescription medicine. The appeals process for non-industry complainants is also free of charge. Anonymous complaints will not be accepted. However, upon request by the complainant, the Code Secretariat will withhold the plaintiff’s name from the company against which he or she has lodged a complaint.

An industry plaintiff (i.e. pharmaceutical company) may lodge a complaint free of charge. However, an industry complainant must post a bond of $20,000 AUS when lodging an appeal. Before lodging a concern or complaint, an industry complainant must first demonstrate that the company has engaged in inter-company dialogue and that the complainant and the subject company have made every effort to resolve the matter before it is referred to Medicines Australia.

The Medicines Australia Code of Conduct Committee has the power to direct withdrawal of advertising, require corrective letters or advertisements and impose company fines for breaches of the Code.

For breaches of the Code, the subject company is required to withdraw any promotional activity immediately and to notify Medicines Australia of the withdrawal within five working days of the receipt of the decision(s). Failure to comply with this requirement may result in the matter being publicised and forwarded to the TGA or the Australian Competition and Consumer Commission (ACCC).
Corrective action must be completed within 30 calendar days of the receipt of the decision(s), and failure to comply with this action results in the Code Committee imposing a fine of up to $50,000 AUS and forwarding the matter to the TGA or the ACCC.

Monetary fines are categorised by the level of breach (i.e., minor, moderate, repeat of previous breach, etc) up to a maximum of $250,000 AUS. An extra $50,000 AUS can be charged for failing to pay the fine within 30 calendar days from receipt of the decision(s).

Are any materials subject to pre-approval by the relevant authorities before they are used?

Any prescription medicine materials intended for healthcare professionals and their media are not subject to pre-approval by the relevant authorities before they are used. However, advertisements for non-prescription medicines appearing on television or radio or in newspapers, consumer magazines, billboards or cinema films require approval before publication.

If a company is found to be in breach of the Medicines Australia Code of Conduct for any materials once they are used, the Code Committee may issue corrective action to the company, including revised content and a letter to specifically correct the statement found in breach of the Code. This corrective letter must be provided to the Code Committee for pre-approval prior to publication.

What are the most recent significant developments, and are there any planned changes in the next few years?

Medicines Australia reviews the Code of Conduct every three years after seeking input from interested parties. The latest edition (Edition 16) was authorised by the ACCC on 3 December 2009 and came into effect on 1 January 2010. The most significant developments during the last review include:

- Companies can now interact with healthcare media as they would healthcare professionals.
- Companies must now disclose on their websites the list of Health Consumer Organisations to which they provide direct or indirect financial support.
- Qualifying statements on promotional items must appear directly below or adjacent to the relevant claim to encourage company transparency.

The Media

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

Medicines Australia defines promotional activity and promotional materials as ‘any representation concerning the attributes of a product conveyed by any means whatsoever for the purpose of encouraging the usage of a product’.

Information is defined as ‘educational facts regarding the attributes of a product’, where an educational material is defined as ‘any representation or literature which is intended to provide information about a medical condition or therapy which does not contain specific promotional claims’.

Promotional activity for prescription medicines directed at the general public would be in breach of the Code. However, educational materials are allowed. The content of all promotional and educational materials directed at healthcare professionals must be balanced, accurate, correct and fully supported by the product information (PI), literature data on file and appropriate industry source.
How is a ‘media event’ defined?

The TGA and Medicines Australia do not specifically refer to a ‘media event’. However, there are references in the Code of Conduct to communication with healthcare professionals and the general public and their media. This includes the provision of educational or information-based materials or activities (directed at healthcare professionals and the general public media) and/or promotional activities (directed at healthcare professionals and their media only).

Companies are encouraged to seek the advice of the Medicines Australia Chief Executive or delegate prior to arranging press statements or media conferences directed at the general public (Section 12.4 of the Code).

Do the regulations differentiate between consumer and clinical publications?

The Code of Conduct differentiates between communication with healthcare professional media and the general public/lay media.

Media releases directed at healthcare professional media must include product precaution information, adverse reactions, warnings, contraindications and interactions. Media articles directed at the general public must not refer to specific prescription products and should be solely informative and educational.

Do the regulations differentiate between print and broadcast media?

The Code of Conduct refers to strict requirements regarding the various types of promotional materials directed at healthcare professionals and their media, including print media and audiovisual media materials. However, the regulations 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?

Promotional activities are not permitted for products or indications yet to be approved for registration in Australia by the TGA. A company must formally receive TGA approval for the product or indication and its PI before proceeding with any promotional activities.

Product-specific media releases (educational, not promotional) should not be directed at the general public and its media until the product has been registered in Australia and reasonable steps have been taken to inform the medical and pharmacy professions of its availability.

For international congresses or meetings held in Australia, starter packs of products (approved overseas but not in Australia) may be displayed but not distributed, and educational and promotional materials may be made available only if the majority of attendees originate from the country in which the product has been approved.

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 Medicines Australia Code of Conduct specifically covers media releases intended for healthcare professionals and their media. The general principles include:

- The purpose of the media release is to provide current, accurate and balanced information about products available in Australia.
- A media release may be issued to announce a new product, indication, dosing or formulation, to announce a new Pharmaceutical Benefits Scheme (PBS) listing.
(government subsidy programme) in response to a change to the safety profile of a product or to alert healthcare professionals to the results of significant new research (provided such research is consistent with the PI).

- The media release must include product precautions, adverse reactions, warnings, contraindications and interactions.

Media materials such as media releases intended for the general public must not promote a product, but rather provide current, accurate and balanced information about products available in Australia. Media releases intended for the general public media must include product precaution information, adverse reactions, warnings, contraindications and interactions.

Companies listed on the Australian Stock Exchange (ASX) may issue a non-promotional, product-specific media release in line with the continuous disclosure requirements of the ASX. Such media releases must adhere to the principles in the Code of Best Practice for Reporting by Life Science Companies.

Companies may sponsor journalists to attend medical conferences, provided they are only writing for healthcare professionals (e.g., GP or pharmacy trade media). The sponsorship should not be conditional upon any obligation by the journalist to report on a company’s product(s).

Any media materials used or intended for Australia must comply with the relevant sections of the Medicines Australia Code of Conduct, regardless of the media materials’ country of origin.

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

Companies or third parties may arrange press statements or media conferences, but they are encouraged to first seek advice from a Medicines Australia delegate (ideally, the chief executive).

Medicines Australia acknowledges media briefings as a legitimate and useful addition to the distribution of a media release (Code of Conduct Guidelines), provided they are educational with the intention of providing information to healthcare professionals and their media.

The company should not initiate statements or comments regarding products that are not approved for marketing in Australia during press statements or media conferences.

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

The sponsorship of a journalist by the company must not be conditional upon any obligation by the journalist to report on a company’s product(s).

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

All media materials intended for healthcare professionals and their media should not be readily accessible to the general public, including print, broadcast and Internet-based media materials.
Do regulations cover the use of case studies or other third-party advocacy in the media?

There are no specific regulations covering the use of case studies. Third-party advocacy groups, such as health consumer organisations (HCOs), may receive an unrestricted grant for educational purposes from a pharmaceutical company provided the company does not seek to influence the text/content of HCO material in a manner favourable to its own commercial interests.

- Disease education activities in the media are permitted solely to provide information, promote awareness and educate the public about health, disease and their management. The following conditions apply to disease education activities in any media (Section 12.7 of the Code):
  - References to a specific prescription product must not be made. References to the availability of different treatment options are allowed, but they should not be used to encourage the general public to seek a prescription for a prescription-only product.
  - The emphasis of the activity should be on the condition and its recognition and should cover the key characteristics of the disease.
  - If discussed, management options should be presented in a comprehensive, balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment.

Internet & Digital Media

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

Medicines Australia’s Code of Conduct refers to online media under the umbrella term ‘Internet’, which includes websites, podcasts, e-newsletters and social media activities and materials. The rules governing online media promotion and education are consistent with the print and broadcast guidelines in the Code of Conduct, and are regulated and monitored in the same way.

In relation to the use of the Internet or online media, Medicines Australia supports a company’s right to provide accurate and scientifically reliable information on a product, intended for the healthcare professional only. Promotional online media activities or materials must be designed to prevent access by members of the general public.

What levels of Web security are required?

Any online media materials that are promotional in nature must be designed to only allow access to healthcare professionals. A company-controlled website for healthcare professionals, for instance, should be secured with a password or other login requirement (e.g., provider number). The password should not be easily identifiable, such as the product name.

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

Companies may sponsor health consumer organisations via an unrestricted educational grant. The grant may be used to fund an educational activity or programme, including but not limited to, a non-company-owned website. The company must not direct or influence the health consumer organisation, unless the company is seeking to correct any factual inaccuracies on the non-company-owned website or document.

The Code of Conduct states that when companies make a reference or linkage to non-company-owned website:
smartphones and other tablets. Promotional material must not be accessible to the general public, and all material must comply with the standards of advertising and promotion to healthcare professionals according to Sections 1 and 2 of the Code.

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

In Australia, there are more than 1.16 mobile phones for every person. Promotional material directed at healthcare professionals and educational/informative materials directed at the general public by mobile phones must adhere to the same guidelines for traditional print and broadcast media as specified in the Medicines Australia Code of Conduct. In addition, electronic messaging of promotional material directed at healthcare professionals (including mobile media platforms like iPhone and iPad applications) must comply with Sections 1 and 2 of the Code, and also comply with the Commonwealth Spam Act 2003 (the Act). Under the Act, no person is permitted to send ‘spam’, or unsolicited commercial electronic messages, via email, instant messaging, SMS or other phone messaging.
What are the disclosure laws like in your region for ‘non-branded’ websites?

The Medicines Australia Code of Conduct states that all items of an educational nature (e.g., non-branded website), whether intended for the education of healthcare professionals or to be used by the healthcare professional in consultation with a patient, must be dedicated to improving the quality use of medicines and/or assisting a patient in his or her understanding of a condition or disease.

Company disease state websites should not focus on the company’s product(s). In discussing prescription product options for the disease state, a company may list all the available products, but it must not compare any products. A company-sponsored disease state website must not have links to websites with information on a company’s product(s). The website should always contain a statement to the effect: ‘For further information, talk to your doctor’.

What is the response level needed for adverse event reporting?

The TGA relies on healthcare professionals, the public and industry to identify and respond to safety matters associated with medicines or medical devices in Australia.

Manufacturers and sponsors of medicines and medical devices and their authorised representatives are required to report an adverse event (AE) to the TGA (section 41MP in the Therapeutic Goods Act 1989).

Third parties representing pharmaceutical companies, such as PR agencies, must report an adverse event matter to the pharmaceutical company within 24 hours of the matter being identified. Therefore, third parties must become familiar with the procedure for identifying and tracking adverse event matters when conducting patient-oriented programmes on behalf of the organisation’s clientele.

Stakeholders/Advocacy Groups

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

While there is no specific regulation for hospitality to advocacy/patient groups, there are some guidelines for sponsorship of individual patients and HCO representatives. Companies may only sponsor patients and HCO representatives to attend third-party scientific and medical conferences if the event is based on a specific therapeutic area of particular interest or relevant to that patient or HCO representative. This type of sponsorship must be publicly disclosed by the pharmaceutical company.

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 of travel disallowed?

Honoraria for healthcare professionals, an advocacy organisation or other third parties for participation in media activities is not specifically covered in the Medicines Australia Code or the Therapeutic Goods Regulations.

Under the Medicines Australia Code of Conduct, hospitality may not be provided for healthcare professionals, advocacy organisations or other third parties without education. Hospitality must always be secondary to education and must not be extravagant.
The Global Guide to Pharma Marketing Codes

The company must provide and internally review objective evidence of the educational value of the event that clearly describes the educational purpose of the event.

For more information, see next question and answer.

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

Healthcare professionals or advocacy/patient groups are prohibited from being paid by the pharmaceutical company for their attendance at an Australian or international educational event. However, the Medicines Australia Code of Conduct states:

‘Sponsorship may be provided to a healthcare professional to attend an educational event provided the meeting is directly related to the healthcare professional’s area of expertise’ (Section 9.7.1 of the Code).

Sponsorship must be formally documented and may include flights within Australia (economy class only), flights outside of Australia (economy or business class only), a reasonable level of accommodation and any meals and beverages secondary to the educational content. A company may not sponsor entertainment nor the travel costs and expenses for family or travelling companions. Financial or material benefits should not be conditional upon any obligation by the healthcare professionals to recommend, prescribe, dispense or administer a company’s prescription product(s).

Companies may only sponsor patients and HCO representatives to attend third-party scientific and medical conferences if the event is based on a specific therapeutic area of particular interest or relevance to that patient or HCO representative (see Question 25 for more information).

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

Where companies undertake sponsorship of a healthcare professional or advocacy organisation, the sponsorship must be able to successfully withstand public and professional scrutiny, conform to community standards of ethics and good taste, and/or enhance the quality use of medicines.

Companies should also ensure that any sponsored experts are fully briefed on the provisions of the Code in the event they may have direct contact with the general public or lay media.

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

Sections 13.2 and 13.3 of the Code state that a company must not seek to influence materials written on behalf of or by HCO in a manner favourable to the company’s commercial interests. Company use of a HCO logo or proprietary material must have formal consent of the HCO.

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

Advocacy groups are covered under the Relationship with Health Consumer Organisations (HCOs) section of the Code (Section 13), whereby companies may enter into relationships with HCOs with the objective of enhancing the quality use of medicines and supporting better health outcomes for the Australian community.

Companies and HCOs must remain mindful of the Medicines Australia guidelines, ‘Working Together—A Guide to Relationships between Health Consumer...’
Organisations and Pharmaceutical Companies’, which involve the following components:

- Respect for independence;
- Achieving and maintaining public trust;
- Fairness;
- Openness and transparency; and
- Accountability.

In addition, no company may request to be the sole funder of an HCO or any of its major programmes, make public use of an HCO logo or proprietary material without prior consent, or seek to influence HCO written materials to serve its own commercial interests. The company must provide a list on its website of HCOs to which it provides financial support and/or significant direct/indirect non-financial support.

**Key Takeaways/Summary**

In Australia, therapeutic goods guidelines and requirements are adopted to ensure high public health standards, the safe use of therapeutic goods and the honest communication of the benefits, uses and effects of therapeutic goods.

Direct-to-consumer advertising is allowed for the majority of medicines available for OTC sale, while advertising to the general public of prescription-only and certain pharmacist-only medicines is prohibited. Government-controlled public health campaigns that have been approved by health ministers are exempt from this prohibition.

The advertising of therapeutic goods to consumers and health practitioners is controlled by a combination of statutory measures administered by the TGA and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations.
Brazil

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

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

In Brazil, the regulating body for medicines and food, inside the Ministry of Health, is ANVISA (National Agency for Sanitary Surveillance). Advertising of prescription medicines for the lay public is prohibited. Advertising campaigns are allowed only for OTCs, medicines that need no medical prescription.

ANVISA’s action is also restrictive in medical congresses, meetings and events, where the distribution of medicine samples or any other kind of material holding the medicine’s name is prohibited, if it is a prescription or controlled medicine. Promoting the company’s or pharmaceutical laboratory’s name, though, is allowed.

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

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

In Brazil, public relations and advertising activities are entirely distinguished. Today PR actions are the sole communication element with the pharmaceutical market for prescription and controlled medicines. The sector has specific regulations for the relationship with the market, and ANVISA has created rules for it. A communications plan may be interpreted by ANVISA in several ways, therefore, the work of PR agencies specialised in health is key, because they know the market and its legislation well. Poorly planned communication actions may result in severe fines from the regulating body.

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

Technical areas, consultants, external advisors and ANVISA’s (National Agency of Sanitary Surveillance) experts are responsible.

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

ANVISA has a call center service for consumers to report any kind of event or complaints about food, pharmaceutical products or health devices. Denouncements will be investigated and the agency may apply fines, interrupt operations, shut down establishments, withdraw products from the market and prohibit importations and exportations.

5. Are any materials subject to pre-approval by the relevant authorities before they are used?

It is not mandatory to send PR materials for previous analysis or approval by ANVISA, but they need to get the agreement from the company’s health professionals or responsible areas before being published. Very seldom do companies consult the regulatory agency in such cases.

6. What are the most recent significant developments, and are there any planned changes in the next few years?

In 2000, ANVISA created a resolution/ordinance to regulate publicity/advertising/promotion activities for medicines and rules to be followed to create advertising materials for medicines manufactured and/or marketed in Brazil. Since then, this ordinance has undergone several updates. In a 2011 ordinance, the agency communicated plans to regulate PR actions, and we need to pay attention to all these rules.
The Media

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

As advertising for prescription medicines is not allowed, this issue is pretty clear and we observe the predominance of awareness actions.

How is a ‘media event’ defined?

We define media events in two distinct moments:
- Awareness situations, and support to medical societies and for the government.
- Introduction of new products under an ethical positioning, with no promotional actions or actions that state that the product is the best or the most revolutionary in its segment. The focus of the actions is to always emphasise the scientific information.

Do the regulations differentiate between consumer and clinical publications?

Yes, because the materials have different approaches. The promotional material is exclusive for physicians. In this case, ANVISA is even more attentive about these materials. Overall, the content carries information of the label and clinical trials.

Do the regulations differentiate between print and broadcast media?

No, the regulation is the same for all media outlets, including newspapers, magazines, radio, television or the Internet.

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

There are no specific rules in place for these events. PR agency recommendations can include specific actions with journalists, such as press conferences and workshops in a distinct setting from medical events.

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

Because Brazil has restrictive regulations, the laboratories’ compliance departments and PR agencies already follow the rules that govern the issue or producing of scientific and information materials that are appropriate for each type of audience and event to be carried out.

Do the regulations differentiate between print and broadcast media?

No, the regulation is the same for all media outlets, including newspapers, magazines, radio, television or the Internet.

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

In these cases, when publications receive press releases from the international agencies, they tend to reproduce them, and in some cases they do not follow ANVISA’s rules. However, when the Brazilian PR agencies receive press releases sent by their clients from abroad, they tend to adapt them to the local reality with a text format that is appropriate in the country.

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

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

There is no difference for employed journalists or freelancers in Brazil, and they do not need to submit their reports either to the regulating agency or to the inviting company. The decision about whether a journalist may or may not accept an invitation from laboratories remains with directors, editors or editors-in-chief or the journalist if he or she is a freelancer. Accepting an invitation does not obligate the journalist to write a report, either favourable or unfavourable, for the laboratory. The writer is free to decide.

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

Patients’ groups are free to talk to the media on their own, and they can organize such actions. Officially, laboratories and physicians are not allowed to encourage patients to talk about medicines. If a journalist needs to talk to a source, he or she must find interviewees independently or ask the patients’ associations throughout the country.

Internet & Digital Media

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

A very important phenomenon has been found to occur in the healthcare area in Brazil, different from other countries. A recent survey coordinated by Tino Comunicação and conducted by Ibope (a major market research institute in Brazil) has found that Brazilians search for information about prevention, treatment and diseases on the Internet, even before seeing a physician. As opposed to other media, there are no clear rules in place for the social networks. The product and pharmaceutical laboratories’ websites, however, as well as the social networks’ sites, follow the rules already established by ANVISA.

What levels of Web security are required?

It is very important to have a PR strategy for the social networks. They are important for crisis management situations and to increase the awareness about a number of health issues.

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

ANVISA has no specific regulation for the Internet yet. As any kind of advertising involving prescription medicines is prohibited, the pharmaceutical companies cannot have portals, websites or blogs that showcase ads with the medicines’ brand names. However, on sites, blogs and independent media outlets that have no connections with companies, one can post comments and information, provided that it is done in compliance with the local legislation. The CFM (Federal Board of Medicine) has created specific rules for physicians on the Internet. They are not allowed to promote themselves or medicines, clinics, hospitals or any healthcare-related commerce. If they do, they are subject to the board’s sanctions.
What are the most popular social networks in your region? Do they have self-imposed regulations?

Both in Brazil and in other countries, the most popular networks are Facebook, Twitter and LinkedIn. There are many bloggers in beauty, cosmetics and healthcare and quality of life that comment on these subjects openly. Brazil has not yet passed legislation that regulates the use of the Internet. This issue is still under discussion. Each new situation is analysed under existing laws or regulations of agencies such as ANVISA.

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

Yes, in regard to prescription and controlled medicines. The company cannot have a direct relationship with the consumers to talk about this kind of medicine. However, a direct relationship may be established to talk about the disease and awareness.

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

No, there are not. It is worth mentioning, though, that the applications (apps) for mobiles are mostly focused on classes A and B, and they do not reach the vast majority of the population, mainly in regard to healthcare.

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

Brazil has no specific legislation for the Internet. Pharmaceutical companies cannot create sites for their prescription medicines. No advertising action is allowed whatsoever in any kind of media. ANVISA has a group of technicians who constantly survey the web to identify possible irregularities, and severe punishments may apply. This agency is highly respected by the healthcare sector, and many materials are submitted to the regulatory departments of the pharmaceutical companies for a thorough assessment before publishing any content.

What is the response level needed for adverse event reporting?

Laboratories, hospitals and the like have pharmaco vigilance services in place that report to ANVISA. The Brazilian agency also carries a direct service for the population and the industry for reporting irregularities, denouncements and the like.

Stakeholders/Advocacy Groups

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

The industry is free to keep relationships with patients, but the actions with them must be merely restricted to informative and scientific initiatives.

Sponsorship to NGOs or patients’ associations is legitimate provided that they comply with ANVISA’s ordinances. Patients’ associations and NGOs have total freedom, even if sponsored or receiving any kind of support. They cannot be induced to any kind of action.

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 of travel disallowed?

In Brazil, it is not common and not advisable to offer fees for physicians and patients to meet with the press. It is allowed, though, to pay a fee for physicians if they participate in media trainings for journalists or lectures, workshops and courses for other healthcare professionals.
Is it possible to pay a health professional or advocacy/patient group to attend a scientific meeting?

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

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

Companies are allowed to conduct media training, speaker training, and message training sessions and awareness events and the like, always bearing in mind the educational, informative or scientific objective.

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

The rules are the same as for the pharmaceutical industry. Patients’ associations and NGOs have more freedom to discuss with patients, society and the government about new treatments and the inclusion of medicines than the pharmaceutical companies.

These associations play a key role in the access to high-cost medicines, mainly when in addition to the high cost there is also medium and high complexity. It is often through these associations that patients get access to high-cost medicines, since the Brazilian Constitution ensures universal right to health.

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

Once again, this is a matter of ANVISA’s action reach. Provided that there is no advertising or action that involves prescriptions or controlled medicines, there should be no problem.

Pharmaceutical companies, patients’ associations, NGOs and healthcare services vendors, such as PR agencies, already know ANVISA’s regulations, and they take them into consideration before creating any kind of action, with any kind of media and audience involved.

Key Takeaways/Summary

The regulatory environment in this market is very severe. ANVISA has technicians who constantly watch the market and its movement.

Media training, speaker training, message training sessions and awareness events are permitted, always bearing in mind the educational, informative or scientific objective.

The industry is free to develop relationships with patients, but interactions must be restricted to information and scientific initiatives.
Chile

The promotion and advertising of pharmaceutical products in Chile is governed by national regulations enforced by the Institute of Public Health, a dependent organisation of the Ministry of Health. Direct-to-consumer promotion of prescription-only medicines is not permitted except by professionals with the legal power to prescribe those medicines or pharmacists in charge of delivering the products.
The Basics

1. **What laws and codes of practice govern the promotion of medicines?**

In Chile, the promotion and advertising of pharmaceutical products is governed by the Regulation of the National System of Control of Pharmaceutical products, Food with Medical Uses and Cosmetics, Decree No. 1876.

Also, the Council of Self-regulation and Ethics in Advertising, where the associations of TV, radio and agencies are grouped, has an Ethical Codex with two articles about the advertising of medicines. The Ethical Codex of the Industrial Association of Pharmaceutical Laboratories says that the association will accept that code while advertising.

2. **Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?**

No, it is not defined. The codes and decree deal mainly with advertising and promotion.

3. **Who is responsible for the enforcement of these rules, and how strictly are they implemented?**

The Institute of Public Health is responsible, and that institute depends on the Ministry of Health. The website of the Institute for Public Health says that its mission ‘contributes to improving the health of the population, ensuring the quality of goods and services as a National Laboratory and Reference Normalize, Supervisor and Inspector, responsible for making health surveillance measures’.

Private ethical codes are mandatory for chamber members.

4. **Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?**

The Institute of Public Health’s investigation department is in charge of verifying the concerns or reports expressed by any citizen, company or other party. At the same time, it makes regular visits to all the businesses under its regulation (including the laboratory and pharmacy) to check if they are working inside the legal frame.

In their internal rules, there is a special point about the reports: ‘investigate complaints of failure of quality, effectiveness, safety and advertising of pharmaceutical products and cosmetics, ensuring compliance with existing health legislation of the establishments that manufacture, import, distribute and/or who have these products in order to ensure health and the satisfaction of the population that uses them’.

Any import or national product must have a sanitary registry given by the Institute of National Health. This can be cancelled if the Institute detects significant changes in the therapeutic indication, composition, dosage forms, application and conditions announced in the labelling or advertising or promotion by professionals who are not approved at the register. Violations of the provisions relating to advertising and promotion compromise public health.

5. **Are any materials subject to pre-approval by the relevant authorities before they are used?**

Article 88° of Decree No. 1876 says that the advertising of food for medical use and similar pharmaceutical products and special cosmetics will not require the prior approval of the Institute.
The same regulation said that the Ministry of Health can, in certain cases, suspend the publicity that was previously authorised.

What are the most recent significant developments, and are there any planned changes in the next few years?

Regulatory information does not specify recent significant developments.

The Media

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

Regulatory information does not specify promotional activity.

Advertising is defined as a ‘set of procedures used to raise awareness, highlight, or distinguish the public directly or indirectly, through any means or process of diffusion, the characteristics, delivery, sale and use of the products covered by this regulations and in accordance with the provisions contained on the matter’ (Art. 4 letter Y).

Promotion to the professional is defined as ‘a set of communication procedures, aimed at professionals legally authorised to prescribe or dispense pharmaceuticals, as the case, in order to publicize and report on the products covered by this regulation’ (Art. 4 letter Z).

How is a ‘media event’ defined?

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

Do the regulations differentiate between consumer and clinical publications?

Decree No.1876 differentiates between the products that can be sold directly to the public and the ones than can only be sold with a doctor’s prescription. These can be advertised by doctors or other professionals that can make prescriptions with public advertising when the ad is about the medicine’s introduction into the market. The information of the product should be included.

Article 90 decrees that advertising is not allowed for medicines that require a prescription.

The only figures able to promote the products are the professionals who have the legal faculty to prescribe the medicines and the pharmaceutical chemists in charge of delivering the products.

Also, the patient information brochure and professional information brochure are regulated separately.

A professional information brochure is ‘a document that contains the pharmaceutical characteristics, including pharmacological, toxicological, clinical and therapeutic properties of a pharmaceutical product or food for medical or cosmetic use, in order to inform practitioners legally qualified to prescribe or dispense pharmaceuticals products’ (Art. 4 point A1).
A patient information brochure is ‘a document designed to inform the patient of a pharmaceutical, food, medical or cosmetic use. It contains information to ensure proper usage, warnings, contraindications, interactions with other products, precautions and other information to determine the health authority in the registry. The booklet of pharmaceutical direct sales must also note uses, dosage and method of use approved in the registry’ (Art. 4 letter B1).

Do the regulations differentiate between print and broadcast media?

The second article of Law 19733 (Media Law) establishes that those suitable for transmission, disclosure, dissemination or propagation, both stably and regular, text, sounds or images intended for public, whatever the medium or instrument used.

The law defines a newspaper as ‘one which is published at least four days each week and meets other requirements of the law’.

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

Regulation of the Institute does not provide information about these points, but there is relevant information in the Ethic Code of the Medical College, which is the association of the doctors. In Title V, Articles 54 and 55, it is determined that the doctor must have an independent relationship with the pharmaceutical companies, among other companies related to health. It says the doctor can accept low minimal compensation or invitations to reunions or congresses only if this action doesn’t restrict his or her independence. It is not ethical to accept travel or similar offers of concern from pharmaceutical companies.

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 is no mention about this point in Decree No.1876; the ethics code of the Council of Self-regulation and Ethics in Advertising, the ethics code of the Industrial Association of Pharmaceutical Laboratories, or the ethics code of Journalist College.

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

Regulatory information does not specify material distribution.

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

There is no mention about this point in Decree No.1876; the ethics code of the Council of Self-regulation and Ethics in Advertising, the ethics code of the Industrial Association of Pharmaceutical Laboratories, or the ethics code of Journalist College. Journalists voluntarily choose to take part.

However, the ethics code of Journalist College mentions in Chapter I, Article 10, that ‘the journalist can not publish, in advance, any informative material that was given with a certain date and hour of publication’.

Also, there are internal ethics codes in the mass media that the employees must follow, but they are not publically published.
If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company’s regulatory procedure? Is it different for a freelance journalist?

There is no mention of this in Decree No. 1876, the ethics code of the Council of Self-regulation and Ethics in Advertising, the ethics code of the Industrial Association of Pharmaceutical Laboratories, or the ethics code of Journalist College.

Regardless, this point is part of the negotiation between the company and the journalist. In general, the company that invites the professional does not control the material for publication. It is not forbidden to ask to see the piece before publication, but the journalist can refuse to share it.

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

The regulations do not specify this information.

### Internet & Digital Media

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

Law No. 20453, Neutrality in the Net, establishes that ‘nobody can arbitrarily block, interfere, discriminate or restrict the right of any Internet user to use, send, receive or offer any content, application or legal service through the Internet, and/or any other activity or legal use done through the net’.

What levels of Web security are required?

The law of Neutrality in the Net says the dealers and suppliers must preserve user privacy and protection against viruses and network security.

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

The regulations do not specify the funding or provision of information to non-company-owned websites.

What are the most popular social networks in your region? Do they have self-imposed regulations?

The most popular social networks in Chile are Facebook and Twitter, and both cases have internal regulation at the international level. Official government statistics show that Internet penetration is 36.58 percent. The most prevalent social network in Latin America is Facebook with 8 million users in Chile and a penetration rate of 45 percent. Furthermore, Chile is in tenth place for Twitter penetration at an international level, with a rate of 13.2 percent.

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

In Chile, the government does not apply any specific rules. The interaction between companies and consumers is ruled only by the internal regulation that companies declare on their websites. The authority acts only in cases where government institutions have an interest in blogs and forums on the Internet.
What is mobile adoption like in your region? Are there separate regulations for it?

According to official data, there are 22 million lines recorded in Chile, equivalent to 133 percent penetration of mobile phones for this year. The authorities project a growth rate close to 10 percent by the end of 2012.

On the current regulations, this year a law passed allowing mobile phone users to change their company without losing their phone number. Thus, more than 500,000 people have changed operators during the first half of this year.

Chilean regulations for this activity have tightened the requirements to companies operating, and at the same time they have given greater freedom to consumers.

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

Regulatory information does not specify any special laws or regulations about non-branded websites.

What is the response level needed for adverse event reporting?

Regulatory information does not specify.

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 Chile, the pharmaceutical legislation does not provide special treatment for protection groups for patients and advocacy groups. The relationship that develops between these groups and laboratories is due in most cases to support or financial support for some campaigns that they make, although it remains a practice advocacy groups increasingly reject.

The State of Chile considers that these advocacy groups play a key role in three aspects:

- Leading role in sensitizing the community, the authorities, media, etc. about mental illness, its impact on families, the importance for society as a whole, and the need to accept diversity.
- Defining and publicising their needs and expectations with respect to medical and psychosocial treatment of their families as well as their development and self-help organisations.
- Defending the rights of patients, including those related to their dignity and their right to be treated with respect and without discrimination ever, access to quality health care and information and treatment consent.

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 of travel disallowed?

A significant number of advocacy organisations in Chile, many of which are integrated into the action plan of the Ministry of Health, are also part of a national programme.

One can find the following groups, for example:

- National Association of Relatives and Friends of Mentally Handicapped (ANAFADIS)
- Beneficiaries of the program Corporation PRAIS Region Metropolitana
• Alzheimer Corporation
• Chilean Association of Parents and Friends of Autistic (ASPAUT)
• Parents and Friends of Autistic (PANAUT)
• Association of Parents of Children with Epilepsy (APADENE)

On the economic and financial support to these groups, most experience shows that brands can approach them through monetary cooperation to operations, but in general economic contributions must be made indirectly, as support groups also have the support the government gives itself in some cases.

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

With regard to the payment or reward that can be made, although this practice is not regulated under current legislation, it happens anyway. However, the trend indicates that the associated payment is related to costs associated with travel (staying in the country, food, registration for the seminar or lecture).

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

The relationship with the media and pharmaceutical brands in Chile is not permanent or fluid in all cases.

The independence of the media and almost no presence of influence peddling for both actors have forced pharmaceuticals to develop to develop plans of approach through the development of educational workshops and seminars for professionals and the media.

Thus, during a calendar year there are instances where the media can participate together with medical professionals and pharmaceutical companies.

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

In Chile, since it is forbidden to advertise in mass prescription drugs, the pharmaceutical industry directs its marketing to the doctor, who ultimately will be decided by the patient.

Against this backdrop, the Chilean Academy of Medicine postulates that it is the responsibility of the physician to determine if a gift is acceptable. There are modest gifts such as a pencil or a notebook that are not reprehensible to accept. However, there are other gifts or services that are clearly unethical because they may unethically influence a doctor.

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

Regulatory information does not specify.

Key Takeaways/Summary

Three bulleted points summarize the pharma landscape:

• Chile is a market that puts many restrictions on the pharmaceutical industry in the areas of advertising and promotion. Therefore, companies are under constant supervision from the authority.
• A public health system and private permanent regulatory change, both in pathologies such as treatments, forces companies to be alert to new needs/opportunities that the market requires.
• The growth in the supply of products at lower-cost, local businesses shows that the pharmaceutical industry and the subsidiaries of multinationals must change their strategies more frequently than in other markets similar to Chile.
In France, the promotion and advertising of pharmaceutical products is largely governed by the French Public Health Code and the French Pharmaceutical Industry Association’s guidelines of good practice. Guidelines issued by the French Drug Agency (ASNM), though not legally binding, must also be taken into account. Direct-to-consumer advertising is permissible for non-prescription medicines provided no presentation of the medicine is reimbursable by French social security and mandatory mentions are respected. Any promotional material intended for viewing by the general public or directed to healthcare professionals is subject to pre-approval by the ANSM.
The Basics

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

Promotion of medicines in France is mainly governed by the French Public Health Code:
- Articles L 5122-1 to L5122-17 give a general definition of publicity and draw the legal frame—what can be done, what role for the commission of publicity control and what sanctions;
- Articles R-5122-1 to 5122-47 specify the rules, given the class of the medicine;
- Articles L4113-5, L4113-6, L4113-8 underline the independence of all medicines prescribers (physicians or pharmacists) and define the special situations in which a company can offer a subvention to a physician;
- Articles L-4163-1 to 4163-4 refer to the sanction if the articles above are not abided by.

Some of the Public Health Code articles have been recently amended following the vote of the new law on medicines.

Next to the French Public Health Code, the guidelines issued by the French Drug Agency (the reputation of the former agency AFSSAPS Agence Francaise de Sécurité Sanitaire des Produits de Santé, being stained by recent scandals, among them the Mediator affair) are now replaced by the National Agency for Medicines and Health products Security (ANSM) must be known. Although they are not legally binding, French courts assert that they must be taken into account by pharmaceutical companies. The ANSM receives the mandatory application forms before product publicity, and a commission checks prior to every published advertisement or ‘propaganda’ material released.

Lastly, the code of practice issued by Les Enterprises du Medicament (LEEM), the French Pharmaceutical Industry Association, proposes guidelines of good practice: Charte de la Visité Medicale and the Référentiel des Bonnes Pratiques de la Visite Médicale des Entreprises du Médicament. The Charte pour la communication sur Internet des entreprises pharmaceutiques was also signed by the LEEM and the French Drug Agency in 2006. These materials may be amended in the following month, regarding the changes in the law. No official translations of the documentation exist, and any dispute will refer to original French material.

To sum up the French context: the recent scandals (MEDIATOR – PIP) have created a climate of suspicion. The law has been amended. Moreover, the law interpretation may be impacted by the scandals. In this context, agencies like the Haute Autorité de Santé (High Authority for Health) are very reluctant to use experts who have disclosed conflicts of interest.

Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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, and how strictly are they implemented?

The ANSM (former AFSSAPS) gives approval of all publicity material. The French drug agency is helped
by the Commission de contrôle de la publicité et de la diffusion de recommandations sur le bon usage du médicament: the commission publishes recommendations about how publicity campaigns should be held, how media can be used in a promotional context and the good use of medicines. The ANSM can withdraw a commercial which doesn’t conform with the 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), ANSM’s inspectors, as well as agents from the DGCCRF (The French Ministry of Finance Direction against Fraud) or tax agents. A pharmacist, a physician or a dentist getting profit from illegal promotional activity can get a €75,000 fine, a two-year prison punishment and can be deprived of his or her professional duties for 10 years.

Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Concerns are brought to the ANSM by competitors, who may even 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 up to 10 percent of the turnover made by a company from that medicine. Further criminal sanctions may also be applicable.

See also the answer to Question 3.

Are any materials subject to pre-approval by the relevant authorities before they are used?

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 on these products intended for viewing by 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 any planned changes in the next few years?

The former agency AFSSAPS Agence Francaise de Sécurité Sanitaire des Produits de Santé, stained by recent scandals, has become the new ANSM.

The control over conflicts of interest is tightened: agencies will seek experts with no conflicts of interest. Publicity directed to health professionals is subject to the ANSM approval (it used to be controlled a posterior, it’s now controlled a priori).
A collective ‘door-to-door selling’ is experienced within the hospitals.

The Media

proximity to the provision of information?

The French Public Health Code categorises anything that is 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 usually deem something issued by a pharmaceutical company as promotional, whatever the context. It is useful to note that when audio, video or interactive media are given to a physician, it is mandatory that they be accompanied by a document (10.3 of LEEM Code).

How is a ‘media event’ defined?

There are no legal provisions regarding media events for medicines promotion.

Do the regulations differentiate between consumer and clinical publications?

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

• Medical products do not have to be prescribed by a physician and are not reimbursed by French Social security schemes/or belong to a promotional campaign in favour of vaccination;
• The advertisement includes all mandatory mentions (as defined in Public Health Code article L5122-6).

• Publications aiming at professional audience can insert commercials for medical products provided:
• The advertisement includes all mandatory mentions (as defined in Public Health Code article R5122-8).
• Both types of commercials need a visa from the ANSM before the publication.

Do the regulations differentiate between print and broadcast media?

No differentiation is made.

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

Direct promotion of products without marketing authorisation is not permitted.

Unlicensed products may be discussed at scientific meetings, provided the manufacturing company has not organised or directly or indirectly sponsored the meeting. Providing the information or data during a congress organised by a professional clinical 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?

As a general principle, all promotional material must be objective and consistent with the ‘bon usage’ (appropriate use) of the product. The Public Health Code further details that the following information must appear on a medicines advertisement: the price of the product (if determined by
the French authorities); the daily cost of the treatment; and its reimbursement by French social security schemes.

The former AFSSAPS advised that all press materials should mention the sources of scientific references. The promotion must 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 medicinal product concerned. It should be based on an up-to-date-evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis and omission, or in any other way.

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

An invitation to a congress issued by a pharmaceutical company or one of its agencies is possible, on condition discussions and presentations deal with clinical studies in a scientific perspective. The journalists’ articles would make no mention of a medicine name.

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

This is not covered. Under EFPIA regulations, the materials must conform to both the codes of practice of the issuing and receiving country. In cases of 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 licensed and non-licensed products equally?

See answer to Question 12.

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

This is not covered by the French regulations, as expenses and travel for third parties are allowed under EFPIA regulations, provided the journalist’s time had not been paid for or the nature of his or her outputs dictated then material 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, such promotional 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, which 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, as this is not covered, the wider regulations apply. The EFPIA Code states that quotations must be faithfully reproduced (4.01), and that where a company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter (7.03).
Internet & Digital Media

Is on-line media differentiated from print and broadcast and, if so, how is it regulated and monitored?

In 2006, the Leem together with the AFSSAPS signed the Charte pour la communication sur Internet des entreprises pharmaceutiques, presenting guidelines for Web communication. The French document is available at the following url: http://afssaps.sante.fr/pdf/5/charte_com_internet.pdf.

Among the guidelines:

- The corporate part of the website must be clearly separated from the commercial part: the promotion for products must be clearly distinguished from the general information on the company.
- Advertising must conform with the French Public Health Code restrictions regarding the audience. Banners aiming at healthcare professionals must not be accessible to consumers; they have to be available on pages that will only be accessible to registered healthcare professionals; mentions that ought to be included in the 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 has to be registered by the ANSM as well as the commercial itself).
- A printed copy of the promotional materials used for e-mailing campaigns has to be registered by the ANSM, and the French drug agency must get a copy of the e-mail at the following address: celluleinternet@ansm.sante.fr.

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 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 these will be interpreted remains to be seen.

What are the most popular social networks in your region? Do they have self-imposed regulations?

Facebook and Twitter are the most popular social networks in France.

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

There are no specific rules.

No publicity for health professionals can be published. The French Agency for the Web Normalization (AFNOR) is working on an authenticity norm that would help fight against fake testimonies about products or services. It’s not specific to health and healthcare communication. It should be implemented at the end of 2012.
What is mobile adoption like in your region? Are there separate regulations for it?

Eighty-five percent of French people over 12 have a mobile phone.
• Smartphone usage continues to increase especially among people with higher income:
  • 22 percent of French people between 12 and 17 have a smartphone.
  • 35 percent between 18 and 24
  • 30 percent between 25 and 39
  • 13 percent between 40 and 59
  • 5 percent between 60 and 69%
There is no specific regulation.

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 as information: experts don’t have to disclose their conflicts of interest or information of specific diseases that do not mention commercial brands or include any symbol that could identify the brand, are considered disclosure of scientific or technical information.

What is the response level needed for adverse event reporting?

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 that pharmaceutical companies can provide various funding to patient groups, which may include reimbursement of expenses.

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 of travel disallowed?

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

On this matter the Public Health Code (Public Health code L4113-5 and L 4113-6) details that specific requests from physicians 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, and to the Conseil Départemental de l’Ordre des Médecins (regional medical board) for congresses at the regional level. A request for an opinion file (together with a letter of request written by the clinician, congress programme, 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 (Public Health Code L4113-6) incurred must not exceed what the participants would have paid for themselves’. They must not include family members’ or friends’ accommodations (see also answer to Question 3 above).

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

See answer to Question 21 above. In addition, 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).
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, which is sponsored by a company must clearly indicate that it has been sponsored by that company (Leem Guidelines 7.04). 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, such promotional 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 would 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

Due to major health crises, the French regulation is moving: all the actors (agencies, industry, physicians) are very cautious not to reproduce the old schemes that led to the crises.

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

1. **What laws and codes of practice govern the promotion of medicines?**

In Germany, the Code of Conduct of the Members of the Association Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V (FSA), also known as the FSA Code of Conduct (the Code), governs the promotion of medicines. This code was recently amended and takes into account the Professional Rules for German Physicians issued by the German Federal Chamber Physicians and the Common Position (also known as 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 FSA Code of Conduct is also based on the Conduct Recommendations for the Cooperation between the Pharmaceutical Industry and Physicians issued by the Verband Forschender Arzneimittelhersteller e.V. (VFA), also known as the German Association of Research-based Pharmaceutical Companies, the German Association of Pharmaceutical Manufacturers (BAH) and the German Association of the Pharmaceutical Industry (BPI) in July 2003 (vfa.de/en). Laws include the German Drugs Act (AMG), German Advertising in the Health Care System Act (HWG), the German Fair Trade Practices Act (EWG) and the German Penal Code (StGB).

2. **Who is responsible for the enforcement of these rules, and how strictly are they implemented?**

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.

3. **Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?**

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, which executes advertising post-controls and combats unfair advertising.

4. **Are any materials subject to pre-approval by the relevant authorities before they are used?**

There are no relevant authorities that have to be contacted for pre-approval. 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 any planned changes in the next few years?

The FSA Code of Conduct was recently revised to reflect the latest requirements issued by EFPIA. The revised version 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 further amendments of the health insurance system. However, it is not yet known how this will impact the promotion of medicines.

Furthermore, there have been some important changes in the 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 PR 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, repulsive or misleading. Before-and-after photos from plastic surgery and in connection with medical devices are not allowed.

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 the 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 meetings and major publications?

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

What regulations 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 regulation regarding press releases, etc., and they would therefore 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.

Promotion about side effects must also reflect all available findings or be capable of substantiation by clinical experience (8.4). It must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. It must also be balanced, fair, objective and based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly (5.2). The word ‘safe’ must not be described 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 very clear guidance on the admissibility of references, which must all indicate whether the publication concerns the product in question, its method or treatment; the author name; date; and source. Materials must also clearly state that they have been sponsored by that company (8.3). 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 publication is intended)?

The Code states several times that where there is a conflict of codes then the stricter code is said to apply, so it would be important to be acquainted with both the German Code on promotional materials (see above) and that of the country of distribution. This is also consistent with the wider international guidelines.
What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?

For the purposes of the Code, these events would be viewed in the same way as scientific events. It is permissible to organise them at international scientific meetings, such as recognised medical congresses, because the relevant resource or expertise is on-site (20.8). 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 a 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 pays for, or arranges the publication of promotional material in journals, it must make sure that such promotional material cannot be confused with independent editorial matter (8.2). 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 (8.3).

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 (see also answer to Question 14). Regarding expert quotes etc., it is very important that healthcare professionals must not be unfairly influenced (see Section 6 on collaboration and also the Code of Conduct for Physicians), and although it is not specifically addressed, it would seem clear that payment for media work and quotes would not be acceptable.

Internet & Digital 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 health 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? Do they have self-imposed regulations?

Facebook is the biggest and most popular social network in Germany, followed by Xing, StudiVZ and MeinVZ. Since 15 August 2011, Facebook’s terms of use require companies within the pharmaceutical industry to permit the comment function on their Facebook pages. Twitter usage has also increased in the last two years.

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 31 percent 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 of 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’ (18.5).
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 in Question 22 above. ‘Passive’ participants, who are not making any presentations etc., 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’ (19.3).

‘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 programmes by companies take place.

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 said companies’ research areas, pharmaceuticals and their therapeutic indications to their own job-related training events (20.1). 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 (3.3). 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 letter of the Code even if it commissions others to design or implement any activities on its behalf (3).

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 (1.3) would be nonpromotional and not subject to the letter of 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 pharmaceutical industries’ possibility to interact is limited.
India

The promotion of medicines in India is controlled by the Drugs and Cosmetics Act, The Drugs and Magic Remedies Act and Rules and the newly formed Code of Marketing Practice. Direct-to-consumer promotion of prescription-only medicines is not permitted. Major emphasis is on conducting oneself responsibly, keeping the regulation and code in perspective.
The Basics

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

In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the Drugs and Cosmetics Act of 1940 (DCA) and the Drugs and Cosmetics Rules of 1945 (DCR)1. Advertising and promotion for a certain category of drugs is controlled by The Drugs and Magic Remedies (Objectionable Advertisements) Act of 1954 and Rules of 1955. These aim to prevent people from self-medication under the influence of misleading and exaggerated advertisements. There are 54 ailments covered under this action, including fever.

OTC and DTC have no legal recognition in India, hence regulations apply to all those drugs that are not included in the list of ‘prescription-only drugs’.

Drugs falling in the system of traditional medicine, such as Ayurveda, Siddha, Unani and Homeopathy, are also controlled by the Drugs and Cosmetics Act of 1940 (DCA) and the Drugs and Cosmetics Rules of 1945 (DCR)1. Very recently, the Department of Pharmaceuticals has formulated a voluntary Code of Marketing Practice for the Indian Pharmaceutical Industry. Per this code, all promotional material issued by a product authorisation holder or with his authority must be consistent with the requirements of this Code.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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

Under the Drugs and Magic Remedies Act, advertisement includes any notice, mailing, label, wrapper or other document and any announcement made orally or by any other means.

The recent Code of Marketing Practice states that ‘where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter’.

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

The State FDA is responsible for enforcing the Drugs and Cosmetics Act and the Drugs and Magic Remedies Act. If a complaint is received, the rules are strictly implemented. The Code of Marketing Practice was recently released, so it remains to be seen how strictly it will be implemented.

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Per the Code of Marketing Practice, any individual or company can make a complaint in the prescribed format. Besides letters to the editor, when media reports indicate that a company may have breached the Code, the matter will be treated as a complaint. The author of the article, or the editor where no author is named, will be treated as the litigant. Any complaint received by the Department of Pharmaceuticals will also be forwarded to the Committee for Pharma Marketing Practices, the complaint-handling committee, within the concerned association.

Once it is established that a breach of the code has been made by a company, the committee can take one of the following decisions:
• Suspend or expel the company from the Association;
• Reprimand the company and publish details of that reprimand;
• Or require the company to issue a corrective statement. The proposed content, mode and timing of dissemination must be provided to the committee for approval and to be put on the association website.

Whoever violates the provisions of the Drugs & Magic Remedies Act shall, on conviction, be punishable with imprisonment, which may extend to six months, with or without fine. In the case of subsequent convictions, the imprisonment can be extended to one year. The document, article or thing which contains the offending advertisement can be seized and confiscated.

If a company contravenes any of the provisions of the Act, every person who was in charge of the business of the company at the time of the offence shall be held accountable. An officer authorised by the State Government can search for and seize any advertisement which he has reason to believe contravenes provisions of this Act. He must then inform the magistrate. The provisions of the Code of Criminal Procedure of 1898 (5 of 1898) shall, so far as may be, apply to any search or seizure under this Act as they apply to any search or seizure made under the authority of a warrant issued under section 98 of the said Code.

Are any materials subject to pre-approval by the relevant authorities before they are used?

No preapproval is needed, but the material is expected to be consistent with the requirements of the Code and laws.

What are the most recent significant developments, and are there any planned changes in the next few years?

The most significant development is the introduction of the voluntary Code of Marketing Practices for Indian Pharmaceutical Industry in June 2011. After its six-month review, if it is found that the Code has not been implemented effectively by the pharmaceutical associations/companies, the government will consider making it a statutory code. As per this code, the promotion of prescription medicines to medical professionals must be consistent with the requirements of the Code.

The Media

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

While there is no clear-cut differentiation, under the Drugs and Magic Remedies Act, advertisement includes any notice, circular, label, wrapper or other document and any announcement made orally or by any other means.

As per the recent Code of Marketing Practice, information about medicinal products must be:
• Up-to-date, verifiable and accurately reflect current knowledge or responsible opinion;
• Accurate, balanced, fair and objective and must not mislead directly or by implication;
• And capable of substantiation.

Also, promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a pharmaceutical company pays for, secures or arranges the publication of promotional material in journals, the promotional material must not resemble editorial matter. Promotional materials in journals
that refer by brand name to a product of the sponsoring pharmaceutical company must comply with Clause 3.3 of this Code as appropriate, irrespective of the editorial control of the material published.

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

Prelaunch media advertisements in lay press or media conferences involving consumers are not allowed as a means of promotion. CME programmes may be held for doctors in India, but not at exotic locations that facilitate entertainment versus scientific proceedings. The record of expenses incurred in this regard must be maintained by the company. However, results of clinical trials can be published in medical or professional journals and company websites that are viewed only by medical professionals.

12. 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, and all such material is expected to meet requirements of the Code.

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

No reference is made to the distribution of press releases and media materials.

With respect to technical and other informative material within promotional material, the date of printing or the last review must be stated. Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising or unsuitable for public view.
What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?

There are no rules about how the press should cover congresses and these kinds of meetings.

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

Journalists are never sponsored by the company, and the copy written by the journalist is independent. The company has control only over the press release, which will go through the company’s regulatory procedure.

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

Yes. Case studies can be given to doctors, but not with Key Opinion Leader (KOL) brand endorsements. For example, the name and photograph of a key opinion leader cannot be included. The Medical Council of India (MCI) does not permit doctors or medical organisations to endorse or recommend products to members of the medical community or the lay public. The same applies to third-party advocacy.

Internet & Digital Media

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

No, online media are currently not differentiated. Hence, as a rule of thumb, regulations that are applicable to print and broadcast are applied to online media.

What levels of Web security are required?

Levels of Web security are not defined.

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

Information on websites must comply with legislation.

What are the most popular social networks in your region? Do they have self-imposed regulations?

The most popular social networks in India are Facebook, Twitter, Orkut and LinkedIn. Standard global regulations apply to these networks.

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

The standard global regulations apply here.

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

Mobile adoption is huge in India. There are around 800 million users and the number is still growing, which qualifies India as one of the largest mobile adoption countries. Again, there are no separate regulations for it.

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

Disclosure laws are currently not defined.
What is the response level needed for adverse event reporting?

This is not defined. The Central Drugs Standard Control Organisation (CDSCO) and Directorate General of Health Services introduced in 2010 the Pharmacovigilance Programme of India (PvPI) to protect the health of the patients by ensuring drug safety.

Stakeholders/Advocacy Groups

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

No regulations exist for advocacy/patient groups.

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 of travel disallowed?

There are no regulations regarding honoraria as payment for healthcare professional or advocacy organisation collaboration in media activities or events. However, the Indian Medical Council Regulations of 2009 state that a medical practitioner shall not receive any cash or monetary grants from a pharmaceutical or allied healthcare company for individual purpose.

Medical practitioners may, however, work for pharmaceutical and allied healthcare companies in advisory capacities as consultants, researchers, or treating doctors or in any other professional capacity. In doing so, a medical practitioner shall always ensure that:

• his or her professional integrity and freedom are maintained;
• patient interests are not compromised in any way;
• affiliations are within the law;
• and affiliations are fully transparent and disclosed.

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

With respect to hospitality, sponsorship and meetings, the Code of Marketing Practice states the following. Companies may provide financial assistance for events that are directly related to continuing education of healthcare professionals. Such support must not attempt to influence a healthcare professional judgment. Where appropriate, support to healthcare professionals may cover travel expenses, meals, refreshments, accommodation and registration fees for events organised and held in India only.

Companies must not organise meetings to coincide with sporting, entertainment or other leisure events or activities. Venues that are extravagant or renowned for entertainment or leisure facilities or must not be used.

Any hospitality offered to healthcare professionals must:

• be reasonable in level;
• be strictly limited to the main purpose of the event at which it is offered;
• not exceed the level that recipients would normally be prepared to pay for themselves;
• and must not be extended to spouses or other accompanying persons unless they are healthcare professionals who qualify as participants in their own right.

Funding of healthcare professionals to compensate them for the time spent in attending the event is not permitted.

All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events such as visits to research or manufacturing facilities that are organised or sponsored by or on behalf
of a company must be held at an appropriate venue in the country that is conducive to the main purpose of the event.

Companies must maintain a detailed record of expenditures incurred for these events. Moreover, Indian Medical Council Regulations of 2009 state that a medical practitioner shall not accept hospitality like hotel accommodations for self or family members.

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

There are no rules, but all concerned professionals are expected to comply with the Code of Marketing Practice and the MCI guidelines.

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

Materials written by a third party, such as clinical trial reviews, drug reviews or monographs, should truly reflect the product merits and clearly state the contraindications, precautions, warnings, side effects and so on. They should not overstretch the benefits or conceal any weakness. No KOL endorsements are allowed. Brand names must not be used to refer to products in promotions.

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

There are no regulations, but all concerned professionals are expected to comply with the Code of Marketing Practice and the MCI guidelines.

Key Takeaways/Summary

- The regulatory environment in this emerging market is currently changing. Health is being taken more seriously by the government.
- New codes are now paving the way for marketing practices, both from the ministry for the industry and from the Medical Council of India for the doctors.
- Compared to a strictly controlled manufacturing environment, the marketing environment for the pharmaceutical industry in India is less regulated but will move towards greater regulation in times to come.
Italy

In Italy, pharmaceutical regulation is governed by The Italian Medicines Agency (AIFA), a division of the Ministry of Health. 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, and 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. This Decree implements under Italian legislation Directive 2001/83/EC (and subsequent modifications) on the Community Code on medicinal products for human use and Directive 2003/94/EC. Other relevant provisions on advertising of medicinal 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. As well as in relation to advertisements to the general public are: the Legislative Decree No. 205 of 6 September 2006, (the Consumer Code); the Guidelines of the Ministry of Health of 17 February 2010 concerning advertising, of medicinal products via the Internet, telephone (including MMS and SMS) (the Ministry of Health Guidelines); and the code issued by the Institute of Advertising Self-Regulation (IAP).

Title VIII Sections 113–128 of the Decree concerns the Advertising of Medical Products, defined 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 subject to this legislation. The Decree regulates advertising to the general public, advertising to health operators (MDs 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 on scientific information provided by medical sales representatives of 20 April 2006 (the State-Regions Conference Guidelines) and Article 2598 of the Civil Code regarding misleading advertisement contrary to fair business practices are also relevant.

The main principles concerning the advertising of medicinal products are the following:

- Advertising of medical products that have not been authorised by 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 interests and confusion about 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 in order to increase its consumption.
Specific for Italy, the 20 regional Governments in Italy can also regulate promotional activities to doctors and pharmacists in 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.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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 also answer to Question 1.

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

AIFA (Italian Medicines Agency) is the division of the Italian Ministry of Health dealing with all drug-related issues ranging from research support, licensing, control of distribution, to 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 shall be submitted to AIFA at least 10 days prior to its dissemination.

In 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.

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

If AIFA suspects that media materials are breaking rules regarding advertising of pharmaceutical products, it can order the publication of a rectification message. The right to appeal against the order of the AIFA may vary from a simple recourse to AIFA itself or be a jurisdictional recourse to the Administrative Court (or TAR).

Sometimes consumer advocacy groups may wish to point out that the messages relating to public relations activities of pharmaceutical companies are misleading or incomplete. But most complaints likely come from competitors, who may take action both by informing the AIFA and/or the Industry association Farmindustria (when its members are involved).

For violations of the Farmindustria Code of Ethics,
sanctions vary from written reprimand to temporary suspension or to expulsion of the responsible company from the association. The same applies, more or less, for breaches of the Journalists’ Charter cited above; see answer to Question 1.

Are any materials subject to pre-approval by the relevant authorities before they are used?

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 Ministry of Health (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; it needs, however, to justify its reasons.

Advertising to health professionals (MDs and hospital pharmacists):
• Must be submitted to the Italian Drug Agency (AIFA) and approved.
• With the sole exception of authorised SmPC, promotional material disseminated to healthcare professionals shall be submitted to AIFA at least 10 days prior to its dissemination. See also answers in Questions 3 and 4.

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. Publicity content that is not permitted
Advertising to the public of a medicine cannot contain any element that:
a. Makes a medical consultation or surgical intervention appear unnecessary, in particular by offering a diagnosis or proposing a corresponding therapy;
b. induces to believe that a medicine is free of undesirable side effect or superior or equal to another treatment or another medicine;
c. induces to believe that the medicine can improve the normal state of good health of the subject;
d. induces to believe that the non-use of the medicine can have a prejudicial effect on the normal state of good health of the subject;
e. is directed exclusively or generally towards children;
f. includes a recommendation of scientists, medical operators or persons well known to the public;
g. compares the medicine to a food product, a cosmetic product or another consumer product;
h. induces to believe that the safety or effectiveness of the medicine is owing to the fact that it is a ‘natural’ extract;
i. can lead to a wrong self-diagnosis;
j. refers in an inappropriate, impressive or false manner to evidence of cure;
k. utilises in an inappropriate, impressive or misleading way visual representations of changes to the body caused by illness of lesions, or of the action of a medicine on the human body or any its parts.
What are the most recent significant developments, and are there any planned changes in the next few years?

In 2012, Farmindustria (the Italian Association of the Pharmaceutical Industries), 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 health-care 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.

As to advertising to pharmacists (with the exception of those working in hospitals):
• The legislation provides that 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 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. See also answer to Question 1.

How is a ‘media event’ defined?

This is not specifically defined.

Do the regulations differentiate between consumer and clinical publications?

See answers to Questions 1, 5 and Question 7.
10. Do the 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 reproduction of the product, or of pictures, 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 Ministry of Health. See answers in Questions 1, 5 and 7.

11. 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 unlicensed drug. When the scientific studies contain significant development in a disease of general interest, it is possible to also publish information in the lay press or on radio/TV and 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 (lay/health professional), 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. See also answers in Questions 1, 5 and 7.

12. 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 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. See answers in Questions 1, 5 and 11.

13. 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.

For more information concerning the Internet see answer to Question 17.
What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-unlicensed 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 unlicensed 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 a company’s regulatory procedure? Is it different for a freelance journalist?

The general principle is that advertising should always be easily distinguished from 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?

See answers to Questions 14 and 15.

Internet & Digital Media

Is on-line media differentiated from print and broadcast and, if so, how is it regulated and monitored?

Websites must comply with the legislative basis and the self-regulation Codes. However, the Guidelines of the Ministry of Health of 17 February 2010 concerning advertising, and of medicinal products via the Internet, 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 Question 17 regarding encryption.

Also, on 22 December 2010, the Italian Communications Authority (AGCOM) published a draft regulation, which relates to AGCOM’s powers in respect of 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.

19 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. See also answer to Question 17 and need to follow general regulations as outlined in answer in Question 1.

20 What are the most popular social networks in your region? Do they have self-imposed regulations?

The great majority of Italian Internet users use instant messaging services. More and more social websites and specialised websites are coming up, also in the healthcare sector. They are overall governed by their own code of conducts and the general Italian regulations; see also answer to Question 17.

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

No specific rules exists. The general rules and guidelines apply; see answers Questions 1, 5, 17 and 20.

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

See answers to Questions 17 and 20.

23 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. See answers to Questions 14, 15 and 25. General regulations as outlined in the answer to Question 1 will apply.

24 What is the response level needed for adverse event reporting?

The Italian Medicines Agency (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 spontaneous reporting procedure exists, surveys show that certainly 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 Farmindustria Code of Professional Conduct, 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; and
- pharmaceutical companies must include on their own Internet sites the list of the patients’ associations that they support.

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 of travel disallowed?

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 provides 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 specifies 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 of Professional Conduct, provides that collaboration with healthcare professionals (e.g., scientific consultancies, speeches at conferences, studies, scholarships) need to be in the form of a written contract, clarifying the need for the service, 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. See also the answer in Question 1.
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. Regarding journalists’ hospitality, fees and expenses, including travel expenses, may be paid directly by pharmaceutical companies and no AIFA permission is needed. See answers in Questions 1, 25 and 26.

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. See answers to Questions 5, 14 and 15.

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

See answers to Questions 25 and 26.

Key Takeaways/Summary

- The retail market for pharmaceuticals in Italy has been hard hit 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.
Japan

Promotional materials are defined as ‘brochures, advertisements in medical journals, Internet webpages for the medical profession and audiovisual materials’. The Code of Practice in Japan denotes necessary information for communication to the healthcare professionals by the industry as ‘all requisite information on quality, efficacy, safety relating to the use of its drugs’.
The Basics

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

It is an obligation of the pharmaceutical industry to strictly comply with the Pharmaceutical Affairs Law, the Anti-Monopoly Act and all other relevant laws and regulations, as well as the industry’s self-regulations.

The Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry enacted the Fair Competition Code in 1984 and is enhancing fair and transparent dealings for member companies.

Aiming at the thoroughness of an ethics code and compliance of member companies, the Japan Pharmaceutical Manufacturers Association (JPMA) enacted the JPMA Promotion Code for Prescription Drugs (JPMA Promotion Code) in 1993, the Charter of Corporate Behavior in 1997 and the Compliance Programme Guideline in 2001.

JPMA revises its Promotion Code following the amendment of IFPMA, Pharmaceutical Affairs Law, Personal Information Protection Law and so on.

Having the IFPMA’s issue of a Code of Practice, the JPMA revised accordingly the JPMA Promotion Code in September 2012 in the form of the JPMA Code of Practice and enacted it in April 2013.

The JPMA Code of Practice is an comprehensive, self-imposed regulation relating to interactions with the health care community, in which the JPMA Promotion Code is provided. There was no significant amendment of the code itself.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

Public relations and advertising are both equally categorised as ‘promotion’ (see also answer to Question 7).

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

The Promotion Code Committee, composed of members of the JPMA and opinion leaders selected from the outside, is charged with administering the code, including measures relating to code infractions. (Regarding the strictness, see answer to Question 4).

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Any and all violations of, or deviations from the respective laws and regulations and the industry’s self-regulations in promotional activities of drugs, shall be treated as breaches of the JPMA Promotion Code, even if such violations or deviations are not specifically mentioned in the JPMA Promotion Code.

When situations that contravene the spirit of the JPMA Promotion Code arise, the Promotion Code Committee will take actions in light of another, separately established procedure of penalties for failure to comply with the code.

Top management of the member companies is responsible for informing the related persons of the facts, establishing in-house systems, solving problems and clarifying the causes in order to prevent recurrences.
JPMA believes that this is the only means by which society’s trust in the pharmaceutical industry may be preserved.

Are any materials subject to pre-approval by the relevant authorities before they are used?

No materials are subject to pre-approval as standard.

What are the most recent significant developments, and are there any planned changes in the next few years?

The latest version is dated September 2012. There was no significant amendment of the code itself.

The Media

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

Promotional materials are defined in the JPMA Promotion Code as ‘brochures, advertisements in medical journals, Internet webpages for the medical profession, audiovisual materials such as slides and VTR and other materials’.

Member companies of JPMA shall produce and use those materials in compliance with the Pharmaceutical Affairs Law and relevant self-regulations.

The statements contained therein shall be correct, fair and objective based on scientific data.

1. Statements regarding indications, dosage and administration, and any other statements, shall not deviate from the approved items. When scientific data are presented at international scientific meetings, such statements can also refer to unapproved drugs (except for drugs not approved in any country) when based on the attached guidelines.

2. No false, exaggerated or misleading expression shall be used regarding efficacy and safety. Advantageous claims relating to safety such as ‘there are few adverse reactions’ shall not be cited without qualification and must be supplemented with a summary of data on which such claims are based.

3. Fair statements shall be made by presenting both efficacy data and safety data, including adverse reactions.

4. Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using their generic names.

5. Competitors or competitors’ drugs shall not be slandered or defamed.

6. Extraordinary data shall not be presented by using an expression that may give an impression that the data represents a universal fact.

7. Misleading or indecent photos, illustrations and the like that are not suitable to the socially respected role of drugs shall not be used.
8. When an advertisement is aimed mainly to promote only the name of a drug, the statements in such advertisements shall include the name (brand name), therapeutic category (product abbreviation), regulatory classification, generic name status of NHI drug price listing and the contact and address for more detailed information.

9. Member companies shall appoint a Management Representative for promotional materials, advertising and the like and establish an in-house auditing system so that only audited promotional materials and advertisements are used.

How is a ‘media event’ defined?

There is no specific definition of a media event in regulations.

Do the regulations differentiate between consumer and clinical publications?

The MHLW (Ministry of Health, Labour and Welfare, Japanese Government) prohibits companies from advertising and promoting prescription drugs directly to consumers. Anything bearing the product’s brand name should not be seen by the general public.

However, disease awareness ads are exempt from regulations by the current administrative guidance in Japan. The purpose of a disease awareness ad, a type of DTC advertising, is to inform consumers about a disease, make them aware of disease symptoms and encourage them to consult a doctor. Companies, although not allowed to show their brand names, are able to expand their market by disease awareness ads.

Meanwhile, when producing promotional and advertising materials on clinical publications, the correctness, fairness and objectivity based on a scientific basis should be considered. Information should be provided about not only the effects, but also drug safety.

Do the regulations differentiate between print and broadcast media?

No differentiation is made.

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

When scientific data are presented at international scientific meetings, information about off-licensed or pre-launched drugs is permitted to be offered under certain conditions based on the guidance in the JPMA promotion code. Permission will not be given for drugs not approved in any country.

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 communications are classified in the same way (see answer to Question 7).

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

The JPMA promotion code stipulates as below:

- Dissemination of information on drugs overseas:
  Member Companies shall provide, either directly or indirectly through local agents, information on drugs that is globally consistent and in accordance with relevant
pharmaceutical affairs laws, regulations and promotion codes to the overseas healthcare professionals.

- **Subsidiary companies overseas**
  When an overseas subsidiary company of a Member Company (a company in which the Member Company holds over 50 percent of the equity or shares) conducts promotional activities, the Member Company shall ensure that the subsidiary will adhere to the promotion code established by the national organisation of pharmaceutical companies of the country or, if no such local code exists, to The International Federation of Pharmaceutical Manufacturers & Associations Code.

- **Overseas licensees and agents**
  Member Companies entering into licensing and agency agreements shall require their licensees and agents to respect the promotion code established by the seven national organisations of pharmaceutical companies of the country or the IFPMA Code.

- **Activities overseas for the Japanese healthcare professionals**
  Member Companies shall comply with the JPMA Promotion Code when they undertake activities aimed at the Japanese healthcare professionals overseas by holding seminars, study meetings or scientific meetings.

- **Activities in Japan for healthcare professionals from overseas**
  When Member Companies invite healthcare professionals from overseas to seminars or study meetings in Japan, they shall comply with the promotion code established by the national organisation of pharmaceutical companies of the country or, if no such local code exists, to the IFPMA Code.

- **What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?**
  No specific indication about press activity is given.

- **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?**
  No direct guidance is given about journalists and editorials. Editorial coverage is determined by journalists who are expected to report facts in the most objective and unbiased way.

- **Do regulations cover the use of case studies or other third-party advocacy in the media?**
  Guidance is noted in the JPMA Promotion Code as below:

  1. Comparisons with other drugs shall be based on scientific data and, in principle, shall be made using their generic names.

  When making a comparison with another drug, the drug that it is being compared against shall, in principle, be referred to using its generic name.

  However, when making a comparison with one's own product or when agreement has been obtained from the company supplying the comparison drug, the proprietary name may be used.

  Further, when the data of a competitor is used in literature, the agreement of the company concerned must be obtained.
In using the results of clinical trials performed for comparison with drugs supplied by a competitor, careful attention must be paid to the contractual conditions between the companies, as noted in the JPMA’s ‘discussions regarding the supply and acceptance of drugs for comparison’.

2. Competitors or competitors’ drugs shall not be slandered or defamed.

According to the Guideline for Specifying Product Information Summaries for Prescription Drugs, Member Companies must take great care in preparing the Product Information Summaries so that they are not perceived as slander or defamation. In these summaries and other promotional printed matter, it is not permissible to include everything just because it is a fact.

Including comparative data that emphasise the advantages of one’s own product is biased against a competitor’s product and is deemed to be slander or defamation.

There is a possibility that the supply of improper information, including the falsified price-related information or misleading price comparison in promotional materials or promotional activities, may be deemed as slander or defamation.

Careful attention is being paid to the introduction of clinical results and non-clinical results, such as animal studies. But areas in which attention tends to be insufficient include ‘background of development’ and ‘analysis of interactions’.

In ‘background of development’, the purpose of development may in some cases be stated as developing a drug that represents an improvement over an existing drug. In such a case, excessive emphasis on the disadvantages of the existing drug could be taken as slander or defamation, and the inclusion must be carefully crafted.

When introducing data on using a combination of drugs, reference the curve (AUC) for blood concentration versus time documentation requirements to avoid slander or defamation.

### Internet & Digital Media

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

There are basically no different regulations among print, broadcast and Internet/digital media, but some guidance for Internet media is noted in the JPMA Code as below:

The Internet is a means by which anyone can freely access all information, but when a pharmaceutical manufacturer uses its website to provide healthcare professionals with product-related information, the Code of Fair Practice in the Advertising of Drug and Related Products requires it to restrict access to persons who are not healthcare professionals.

So long as it does not infringe the laws of Japan (it does not appeal to patients or the general public), the website is recognized as appropriate provision of information when it fulfills the conditions set forth below.

- The name of the pharmaceutical company is provided, information is targeting healthcare professionals and access is allowed only if the website user confirms that the information is targeting healthcare professionals.
- The information is appropriate for healthcare professionals.
• The content and the website are appropriate for healthcare professionals and the owner (author) of any linked external website is recognised.

What levels of Web security are required?

Regarding the level of Web security, see answer to Question 17.

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

Yes, the information on non-company-owned websites must abide by the related regulations that the company’s websites must follow.

What are the most popular social networks in your region? Do they have self-imposed regulations?

In Japan, Mixi and GREE are the most popular social networks. These social networks allow people to create communities with other people who have the same hobbies or interests, while Facebook and Twitter are gaining popularity.

If business activities come under the Law Concerning the Protection of Personal Information, privacy policies and statements have to be noted on social network sites.

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

There are no specific rules, but the Law Concerning the Protection of Personal Information, the Pharmaceutical Affairs Law, the Anti-Monopoly Act, the PPMA Promotion Code and related regulations are applied to digital platforms.

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

According to the data in 2010 announced by the Ministry of Internal Affairs and Communications, the mobile adoption rate in Japan is 87.5 percent.

There are no specific regulations for mobile, but the Law Concerning the Protection of Personal Information, the Pharmaceutical Affairs Law, the Anti-Monopoly Act, the PPMA Promotion Code and related regulations are applied to mobile.

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

Regulations do not specify this information.

What is the response level needed for adverse event reporting?

Regulations do not specify this information.

Stakeholders/Advocacy Groups

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

No specific mention is made of patient groups. However, the commentary that accompanies Section 7 (seminars and study meetings) states that social gatherings and other events held in conjunction with seminars or study meetings must be on a modest scale, so that they do not obscure the original objective of the seminar or study meeting, or appear to a third party as unusual.
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 of travel disallowed?

See answer to Question 20 above. The section also goes on to say that using an opportunity set up for the provision of information as an excuse to offer entertainment ‘fundamentally undermines the status of the pharmaceutical enterprise’. It defers to the IFPMA Code on the specifics, which states that payments of reasonable honoraria and reimbursement of expenses for speakers are customary and proper.

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

It is possible to pay doctors for their time if such payment is kept to a modest level. In the case of health professionals who work for a public hospital, such as a national hospital organisation, such payment could be subject to a charge of bribery under both the Criminal Code and the National Public Official Moral Code.

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

No specific guidance is given.

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

No specific mention is made. IFPMA regulations on transparency are clear that if materials are sponsored by a company, either directly or indirectly, then that fact should be clearly stated.

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

Meetings are permissible provided that the nature of the meeting is reasonable and modest (see also answer to Question 20 above). Provision of any material should not include brand names of drugs and must comply with the guidance on promotion to the lay audience.

Key Takeaways/Summary

- The Japanese domestic prescription drugs’ market in 2012 was more than 9 trillion yen. In spite of the reduction of prescription drugs’ standard prices and the spread of generic drugs, the figure surpassed the existing record.
- The generics market share in Japan in 2012 was around 25 percent, which was less than the target figure by Ministry of Health, Labour and Welfare, 30 percent. MHLW will promote and accelerate Generic drugs furthermore to curtail medical expenses. With this MHLW’s strong policy and the decline of innovative drug development capacity, name-brand drug makers have been strengthening generic drugs.
- The discovery by Shinya Yamanaka, Nobel Prize winner, has been influencing in the understanding of the mechanisms that cause disease, furthering the potential for new drugs and realizing regenerative medicine.
Mexico does not have an official regulatory code for public relations in the health sector. Therefore, it has to abide by the regulations that are in place for advertising. In recent years, there were changes made to the Regulation of General Health Law in Matters of Advertising with the objective of garnering more and better tools to avoid and discourage the proliferation of advertisements of the so-called ‘miracle products’, which offer fast or definitive cures without any scientific support—and irregular advertising in general.

These changes reflect the Mexican reality. On one hand, there is an excess of publicity and a lack of regulation of products with little or no scientific support offering miracle cures for diseases with high prevalence rates in the country such as diabetes, obesity and pain. On the other, there are very strict controls and regulations for pharmaceutical products that comply with all health regulations and have scientific support but they are given little flexibility by the authorities to perform advertising and communication awareness campaigns.
What laws and codes of practice govern the promotion of medicines?

The promotion of drugs is regulated by the COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios), which is part of the Health Ministry (Secretaría de Salud). They have specific regulations depending on the audience. There are rules for communication directed at physicians, and other more strict regulations that address communication with consumers. Unlike countries like the United States, it is forbidden to mention the brand name of any prescription medication, along with an explanation of what the product is for.

Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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

Who is responsible for the enforcement of these rules, and how strictly are they implemented?

The Health Ministry is responsible—through the COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios)—for the enforcement of rules.

Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Rival companies submit most complaints. We find that it is very seldom when a consumer complains.

The advertising for drugs and other health-related products envisaged in the General Law for Health and its policies on the subject is classified into two sections, according to Article 310: I) Directed at health professionals and II) Directed at the consumer. It explicitly mentions that: ‘advertising directed at the general public can only include over-the-counter medicines and herbal remedies’.

No direct-to-consumer advertising is allowed for drugs that require a prescription. Advertising for the professional health sector can only be undertaken in media addressed to that specific sector without reaching the final consumer or patient. In the case of a breach, sanctions range from a fine of 4,000 times the minimum wage to the suspension from the sanitary registry.
Are any materials subject to pre-approval by the relevant authorities before they are used?

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

What are the most recent significant developments, and are there any planned changes in the next few years?

In February 2005, an important step was taken with the approval of Article 376 of the General Law of Health. Before that, registration of drugs had an undetermined expiration date. With the approval of this reform, laboratories have to re-visit their registries every five years.

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

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

Finally, there is a proposal to ban the distribution of drug samples among physicians to prevent what is known as a grey or black market. This could create important commercial limitations for pharmaceutical companies, but is seriously being considered by health authorities. The latest law update, made in March 2012:
- Media advertisement departments need to request the Commission for the Protection against Health Risks (COFEPRIS) for a registration number of the product and also of the campaign—advertisement permission—as part of the advertisement requirement to buy an ad of any health related product.

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

A) In general
- The definition of mass media is extended and now includes containers, labels, promotional items and other technological media.
The Media

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

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

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

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

How is a ‘media event’ defined?

This is not defined in the regulations.

Do the regulations differentiate between consumer and clinical publications?

Advertising for health professionals can only be included in media directed at them, including dictionaries with pharmaceutical specialties and drug guides. Advertisements should be based on a drug's prescribing information. The registry of advertised drugs should always be stated.

Information about prescription drugs should only be directed at health professionals and will be authorised at the moment the drug is registered. It should include: the brand name, generic name, formula, uses, therapeutic directions and other information such as warnings, general precautions and/or restrictions during pregnancy. Prescribing information will be authorised when the registry of the drug is approved. Advertising of drugs, including the commercial brand and information regarding the effect of medications, is not allowed in media available for general audiences or consumer media.

Do the regulations differentiate between print and broadcast media?

In general terms, rules apply for both types of media the same way. However, there are some specifications that have slight differences in each case. For instance, the law points out that media must include the disclaimer: “Ask your Doctor’ and should mention the corresponding precautions the patient must take when the drug represents a danger in the case of a special condition.

Printed media should have the text printed, for radio shows it must be auditory and for TV and cinema visual as well as auditory. In this last case, the written text should last a minimum time equivalent to a fourth of the total duration of the ad. It should be placed horizontally in contrasting colors, in 40 points per letter in proportion to a 40” screen. The auditory legends should be pronounced at the same rhythm and volume as the ad, clearly and understandably.
What is permitted in relation to off-licence or pre-launch media activity? Are there specific rules around congresses, scientific meetings and major publications?

According to the Good Practices Code of the pharmaceutical industry, the medical information department in each company must assure that the information provided by their professionals must be accurate, balanced, honest, objective and sufficiently complete to allow its addressees to judge for themselves the therapeutic value of the drug. A company should commit itself scientifically and morally to the content of the information it provides.

If external service companies participate in the preparation of the information, it is the responsibility of the laboratory to assure that these companies comply with the Ethics Code.

When promoting medical information in consumer media or to general audiences, it has to be undertaken by authorised third parties, such as physicians. There are no restrictions about communicating information from medical seminars or congresses, other than the general rules for drug promotion already discussed. According to the Ethics Code of the AMIIF, the results of a study should be the object of a complete report by the designated coordinator and be transmitted to all investigators as soon as it is available. If the results of the study are published, that is considered appropriate information for researchers. Clinical studies should not be used as a disguised promotions.

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

There are no restrictions from the Health Ministry for the distribution of press releases. Although no materials of this kind are submitted for authorisation, it is common practice to observe the codes of ethics that promote honesty in the information and it is important to have the approval of a physician or a specialist in the matter. As a rule, no information is released to the media without the written approval of the medical department in the pharmaceutical company behind the information. Also, the use of a product’s commercial brand name should be avoided. Regarding printed materials for the consumer, the text required by the authorities is usually included. For example, in the promotion of cosmetics-related products it must read: ‘Health is Beauty’; for alcoholic beverages: ‘Avoid excess’; in the case of medications: ‘Ask your Doctor’ and speaking of edibles: ‘Eat Healthy’.

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

No methods of distribution are covered in advance.

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

No regulation on this matter exists.
If a company sponsors a journalist to attend a scientific meeting, is the resulting copy independent or does it need to go through a company’s regulatory procedure? Is it different for a freelance journalist?

If a company sponsors a journalist to attend a scientific meeting, the copy that results from the journalist’s attendance is completely independent of the company and is the property of the organisation the journalist represents. In the case of a freelance journalist, he or she is responsible for and owns the material.

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

There is no regulation in this area.

Internet & Digital 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?

In the case of prescription drugs, online information cannot detail illnesses with drug commercial names or active ingredients.

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

Websites are not regulated, but if the link takes a user to a corporate web page it should comply with the rules of all other media.

What are the most popular social networks in your region? Do they have self-imposed regulations?

According to digital media consumption surveys, at least 85 percent of Internet users in Mexico are part of a social network, with Facebook and Twitter being the front-runners.

These networks have sophisticated usage regulations and are self-supervised. Some of these regulations involve their participation in advertising activities and bestow the content responsibility to the user, under the terms applied by international regulation and local laws.

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

There is no specific regulation in Mexico to control the advertising or communication activities of companies on the Internet. The actual advertising laws, such as the Regulation of the Advertising-Related Health Law and the Copyright Law are applied to govern the activity of companies in digital media, which is now considered on the new extensive definition of media.

Changes were made recently to the Regulation of the Advertising-Related Health Act aimed at having more and better tools to avoid and discourage the proliferation of advertising that promotes miraculous products and irregular advertising in general. These changes foresee the application of the same advertising legislation for other technological media (that is, applications on the Internet and social networks).

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

No, there are no separate regulations for mobile applications; the same advertising law applies to mobile devices.
What are the disclosure laws like in your region for ‘non-branded’ websites?

In the field of health and medications, the same legislation applies, including ‘non-branded’ websites. All the contents and communication issued by a pharmaceutical corporation must be submitted before and authorised by COFEPRIS.

In addition to the official regulations issued by the authorities, the pharmaceutical industry in Mexico—the same as for the rest of the world—has self-regulation mechanisms, based on its own ethics and compliance codes.

What is the response level needed for adverse event reporting?

The legislation on pharmaceutical surveillance is extremely severe. The responsibility of the companies, as well as everyone who work in them, including business partners, advertising and public relations agencies, must be trained on adverse event reporting, so that they know what to do as soon as one occurs. The companies, physicians, health professionals, and employees that are part of the pharmaceutical industry as well as health affairs (government institutions) are compelled to report to the National Pharmaceutical Surveillance Center (CNV, Centro Nacional de Farmacovigilancia) any sign of adverse effects in medications, vaccines and medical devices.

Stakeholders/Advocacy Groups

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

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

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

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

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

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

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

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

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

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

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

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

Key Takeways/Summary

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

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

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

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

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

The relevant government regulation that has been in force in Poland since September 2001 is the Pharmaceutical Law Act (Dz.U. 2001 nr 126 poz. 1381), and its amendment, implemented on 1 December 2008, concerning the advertising of prescription medicines (Dz.U. 2008 nr 210 poz. 1327).

In addition, self-regulation of the pharmaceutical industry is administered through INFARMA, the Polish pharmaceutical industry association, under The Pharmaceutical Industry Code of Good Marketing Practices, Interactions with Healthcare Professionals and Patient Organisations.

This Code sets forth norms 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 of the pharmaceutical industry with healthcare professionals and patient organisations and is binding for all of the INFARMA member companies and associations that do business in the European Union, which Poland joined in 2004.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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

However, the section of the Pharmaceutical Law Act that is dedicated to the advertising of medical products defines advertising broadly, and it 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 (see Question 11).

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

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).

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Concerns and complaints are submitted to the Main Pharmaceutical Inspector. Technical claims of efficacy, safety and cost-effectiveness are referred to the Polish Agency for Health Technology Assessment (Agencja Oceny Technologii Medycznych, or AOTM) for evaluation. The manufacturer bears all legal responsibility for producing, selling and distributing its product in a lawful way. Wholesalers, distributors and dispensing pharmacists are not liable in such cases.

5. Are any materials subject to pre-approval by the relevant authorities before they are used?

No, there is no pre-approval process in place.
What are the most recent significant developments, and are there any planned changes in the next few years?

Polish Law is very strict in terms of pharmaceutical regulations. The government is the sole purchaser of pharmaceutical products (reimbursement is through the State Health Foundation or Narodowy Fundusz Zdrowia, NFZ), and relations between the government and the pharmaceutical industry are generally quite adversarial.

However, in May 2011 the Court of Justice of the European Union released two important opinions whose effect is to liberalise the approach towards advertising of pharmaceutical products. These changes may influence Polish restrictive policies and open a new path towards less harsh policies.

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 under 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 in 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, as such. 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 the 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 meetings and major publications?

According to the Pharmaceutical Law Act, among 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; and,

• 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 and 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.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where 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 cross-country differences 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 licensed and non-licensed products equally?

There is no clear statement about the sponsoring of media attendance to congress 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.

Internet & Digital 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.

What are the most popular social networks in your region? Do they have self-imposed regulations?

The most popular social networks in Poland are social networking and blog websites, such as:
- http://nk.pl/
- http://twitter.com
- http://pl-pl.facebook.com/
- http://grono.net/
- http://www.mojageneracja.pl/
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: licensed nurses and midwives.

## 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 not 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 of 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 also 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 are extremely popular. The Polish patient advocacy and support community are growing in size and sophistication.
Portugal

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

Promotional activities are carried out under the strong supervision of INFARMED and the presented information must be scientific, accurate and objective in order to be comprehended and not be misleading.
The Basics

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

The promotion of medicines in Portugal—both OTC and prescription—is subject to two main documents: (1) The Drug Statute—Decree-Law No. 176/2006 from INFARMED (the Portuguese Drug Agency institute connected with the Health Ministry) and (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 implies judicial consequences if not respected, the Ethics Code has disciplinary sanctions attached, and 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 IFARMED Decree-Law No. 176/2006 includes some insightful 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 participated by the National Health Service;

3. The information presented in the previous number doesn’t preclude:
   • Vaccination campaigns carried out by the industry, if previously approved by INFARMED;
   • Promotion campaigns for generic drugs developed by the industry and approved by INFARMED.

4. The distribution of medicines directly to the public by industry is forbidden.

5. It is forbidden to mention the name of the treatment even if it’s related with a sponsorship initiative to the public, unless the expression is approved accordingly with this law.

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

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 informs that: "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".

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

No. Currently there isn’t any form of differentiation described, and PR is part of the bigger promotion puzzle. 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 some self-regulation with a strict non-disclosure code.

3 Who is responsible for the enforcement of these rules, and how strictly are they implemented?

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 excesses, and it now has a specific department that monitors the enforcement of the communication rules.

Concerns and complaints can be presented by anyone from the general population to physicians, but they usually come from competitors that present the respective complaints to INFARMED and APIFARMA. According to Article No. 348 of the Penal Code, the publication or distribution of prohibited advertising represents a crime of disobedience, with application of penalties and administrative measures, such as paying a fine or even losing the respective reimbursement.

Are any materials subject to pre-approval by the relevant authorities before they are used?

Yes, but 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 material 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. There is cross-information analysis, and complaints from the general population or healthcare stakeholders are considered. Before the GPUB submission, the submitted materials must be approved internally by the respective medical departments.

Currently there’s a legislation hole regarding media relations & PR results. News isn’t considered an advertising piece 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 any planned changes 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.
The Portuguese Ministry of Health is also evaluating new methods to increase the generic medicines quota—in 2011, 21.01 percent of the market (421 million Euros)—and implemented in August 2011, the Electronic Prescription Act. This act was created to control the proliferation of false medical recipes. The Portuguese Physicians (about 50,000) give prescriptions through the computerised IMED programme that is connected to the Central Administration of the Health System (ACSS).

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 medicine’s advertising page must include the drug’s leaflet.

Do the regulations differentiate between print and broadcast media?

No differentiation is presented except if they are specialised or 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 grant of 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 unequivocal 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 sponsoring 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 justify documents.

4. The documentation referred in the previous paragraphs should be retained for a minimum period of five years from the date of the event and made available to entities with supervision powers such as INFARMED.

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.

6. All promotional elements, including graphics, illustrations and tables from published studies and integrated promotional material must:
   - Clearly indicate the exact source or sources of the promotional elements;
   - Be faithfully reproduced. In case of need they may be adjusted, mentioning the introduced adjustment.

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. That doesn’t occur for the specialised 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?

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

2. The information presented in the promotional material or the intended information to promote a drug’s good use must:
   - Be based on an updated assessment of all available scientific evidence in accordance with the summary of product characteristics;
   - Comply with the marketing authorisation;
   - Not lead to incorrect or wrong conclusions.

3. Scientific data that support claims about the product characteristics must be available.

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where 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 licensed and non-licensed 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 specialised journalists) since the direct communication of unlicensed products or indications is prohibited. A disease awareness communication is often adopted.

The press conference material (press release 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 KOL (to preserve the reputational focus). This serves for both licensed and unlicensed products equally.

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

If the invitation is directed to a journalist from the general media, the resulting copy is independent, but if the communication professional is from a specialised 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 KOL in a product press release, it is important for one to know the product and the respective theme.

There isn’t any formal guidance but case studies should not be promotional, and they should not be used to encourage an increase in prescription.

Internet & Digital 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 exponential 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, and it 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’ Organizations is always present during companies’ and institutions relationship. According to the Code:

Article 3
Agreement
1. Companies which want to provide direct or indirect financial support and significant non-financial support to Patients’ Organizations 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 non-financial 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’ Organization is subject to a written authorisation 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
Materials produced by Patients’ Organisations
1. Companies should not try to influence the contents of materials produced by Patients’ Organisations they sponsor, so as to favour their commercial interests.
2. This information should be disclosed for the first time by company members of EFPIA until the end of the first quarter of 2009 (including the activities which started or were in progress on 1 January 2008).
3. The obligation provided for in the previous number does not prevent companies to correct evidence-based and/or scientific inaccuracies existing in produced materials.

Article 6
Transparency
1. The list of Patients’ 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 Patients’ Organisations is disclosed in a clear and transparent manner.

Article 7
Financing
1. No company can impose itself as to being the exclusive sponsor of a Patients’ Organisation or of its main programs.

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.
What are the most popular social networks in your region? Do they have self-imposed regulations?

Facebook, with 4.2 million Portuguese users, and Twitter, with about 150,000, are currently the most popular social networks. Twitter is a curious case because most of the influential journalists, including healthcare ones, can be followed and engaged in this micro blogging space. Some pharmaceutical companies have already started to prepare specific internal guidelines for social network engagement, but most of them still don’t have any documents prepared and adopt a cautious engagement. On a governmental level, INFARMED is still waiting for international guidelines from FDA and EMA before presenting a local regulation.

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?

With the boom of WiFi Internet and the growth of smartphones and tablet computers, pharmaceutical companies started, especially in 2011, to adopt and create different mobile applications. The applications are divided into two main groups. For medical targets, we have iPad literatures, new aggregate scientific news smartphone apps or even social networks.

For the general population, the creation of mobile apps must be informative and related to a specific disease or tips for prevention. There isn’t a separate regulation for mobile, but the drug statute legislation must be fulfilled. Since DTC campaigns are not allowed in any way or form, the mobile communication for patients and the general population must be created with that in mind.

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 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 source) 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.

Also, the adverse event reporting must always be enumerated 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.

Companies can offer an honorarium to healthcare professionals to participate in meetings, press conference, medical symposium or advisory board, 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 honorarium must be given to the respective association.

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 of travel disallowed?

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 honorarium must be given to the respective association.

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

As stated previously, no money can be offered to compensate the time used by healthcare professionals or patient groups to just 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, we 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 a very inflexible Drug Statute Law that prohibits DTC promotion of prescription medicine. The county is aligned with 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.
Spain

Any correspondence or materials produced by a pharmaceutical company about medicines or their 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 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

1. 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 is the Spanish Code of Practice for the Promotion of Medicines and Relations between the Pharmaceutical Industry and the Health Professional (July, 2008).

This Code echoes the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code in spirit, language and format. The National Association of OTCs (ANFEP) also has a Code of Ethics that covers any direct-to-consumer promotion. Regarding legal issues, The Law of Guarantees and Rational Use of Medicinal Products and Medical Devices was published in 2007 and replaces the 1990 Medicines Law. Reference should also be made to the Royal Decree 1416/1994, which ostensibly covers the advertising of medicines for human use, although it covers some aspects that overlap with public relations practice, such as congress sponsorship, hospitality and honoraria. Health matters are often devolved to the 17 Autonomous Communities into which the country is divided. Catalonia (2003) and Madrid (2002) have detailed sets of rules, which should be checked before the decision to hold a promotional event in either region is taken.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

‘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 professionals, 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’. General criteria in The Law of Guarantees and Rational Use of Medical Products and Medical Devices are: only non-prescription drugs can be advertised; the advertising has to make clear that it is a drug and add certain advice; the Ministry of Health may limit or forbid advertising because of public health or safety; and bonuses, gifts and prizes are forbidden the same as advertising of health products that aren’t financed by government.

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

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.
Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Although concerns and complaints stem from other pharmaceutical companies, the Spanish Agency for the Evaluation of Medical Products (Agencia Española del Medicamento) also makes submissions. Both the complainant and the respondent companies agree to preserve confidentiality in the processing of the complaint and its resolution until the decision has been published (if applicable). The Farmaindustria Code sets out breaches or infringements, which are classified as minor, serious and very serious; the latter with particular reference to repeated offences. Punishments range from a warning or admonition, to fines of €6,000 to €36,000, or even expulsion from the organisation. The Jury of Autocontrol also has recourse to financial penalties.

In general, these are the most important examples of actions taken against pharmaceutical companies. It is also worth noting that any violation of the Royal Decree is subject to fines that may reach €1,000,000. In addition, a precedent for criminal liability was set in 2001 when the Spanish Supreme Court convicted a doctor and laboratory staff. The amounts collected from monetary sanctions are used to set up a special fund at Farmaindustria for promotion of the rational use of medicines.

Are any materials subject to pre-approval by the relevant authorities before they are used?

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 professionals. 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, and 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 any planned changes in the next few years?

The last five 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 10 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 some more of the 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 up-to-date evidence (3.1). Gifts, merchandising and meetings for physicians are included in ‘promotional activity’.

How is a ‘media event’ defined?

Regulatory information does not specify a definition of 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 the 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 is to include interactive systems, this essential information must be included clearly on the videotape and also be available as a printed document (2.2).

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 which 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 promotion. 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 or indication is not licensed 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 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 (4.4). This also applies to material that in itself is not directly promotional (5.3), such as invitations. Exaggerated or all-embracing statements should not be made; neither should there be any unsubstantiated claim that a product has some special merit or property (3.5). Statistics, conclusions or any other data from different studies conducted using different methodologies cannot be mixed or compared unless they come from systematic reviews (3.4). 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 (3.6). Trademarks or brand names of products from other companies may only be quoted if their ownership is clearly indicated (3.7). All information, statements and comparisons must be referenced and well-founded and their foundation made available to physicians on request (3.9). (See Question 7).

Is the method of distribution of such materials covered (with particular reference to if they are from outside the country where 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 licensed and non-licensed 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' (see Question 15; see Question 11).

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?

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 (6.2) and that all third-party endorsement must accurately reflect the opinion of the author (6.1). 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 (5.2).

Internet & Digital 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 (8.1). 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 (8.3).

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 (8.2.) 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? Do they have self-imposed regulations?

Facebook, Twitter, LinkedIn and Tuenti, which is a Spanish social network for people between 14 and 25 years old, are the most popular.

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?

There are no specific regulations. In Spain, mobile applications are used quite frequently.
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 of travel disallowed?

Honoraria are possible for healthcare professionals only and 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 (11.6). 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, and 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’ (11.2). Answers to the published queries further clarify that ‘reasonable’ would prohibit anything over a four-star hotel.

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

In no case can money be offered to merely compensate the time used by healthcare professionals to attend the event (11.12).

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 fair 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 fair to assume from EFPIA regulations that matters pertaining to human health and disease without mention of specific products would be permissible, whereas copy with brand messages would be promotional and need to be clearly marked as such.

Key Takeaways/Summary

Pharma marketing continues to develop in Spain due to:
- Strict ethical codes
- Global rules for pharmacies
- New stakeholders (autonomous regions, patients associations, scientific societies)
- Increased control by the government
Turkey

In Turkey, any information that is relayed regarding medicine must be objective, accurate, easily intelligible and in compliance with laws and regulations set forth by the Pharmaceutical Manufacturers Association of Turkey (IEIS) and the Ministry of Health. Public relations activities are the only means of providing information as DTC promotion is prohibited.
The Global Guide to Pharma Marketing Codes

The Basics

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

Promotion of medicine must be in compliance with high ethical standards, and the information that is provided to healthcare professionals must be devised so as to assist them in serving their patients better. This information must be objective, accurate, easily intelligible and in compliance with all laws and regulations in effect. Opinions put forth with respect to treatment indications and conditions must take into consideration current scientific findings and must provide sufficient detail regarding side effects, contra-indications and necessary precautions that must be taken.

Based on this fundamental principle, in addition to the regulation issued by the Ministry of Health on promotion and related matters, the Pharmaceutical Manufacturers Association of Turkey (IEIS), in order to fulfil its obligations more effectively, has drafted and put into effect the IEIS Code for Promotion of Medicinal Products in 1990.

This code, which contains provisions parallel to those specified in the Promotion Regulation of the Ministry of Health, functions as a self-auditory mechanism among IEIS members. The functionality of this mechanism is insured by the IEIS Supervisory Committee, which has the power to impose legal sanctions.

The IEIS Code for Promotion of Medicinal Products, with which all IEIS member companies are obliged to comply, shall provide the necessary assistance to our industry in protecting ethical standards in the promotion of pharmaceuticals.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

The Ministry of Health is responsible for the enforcement of these rules, and it is strictly implemented by the Ministry of Health and IEIS.

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Complaints to The Ministry of Health or Radio & Television Supreme Council usually come from competitors and consumers. The authorities have the jurisdiction to punish those who do not comply by issuing warnings or fines.

5. Are any materials subject to pre-approval by the relevant authorities before they are used?

All communication material is subject to approval of the municipality health office, but it is not frequently applied. Companies usually rely on guidance from their law departments or communication agencies.

6. What are the most recent significant developments, and are there any planned changes in the next few years?

There are no changes on the horizon.
The Media

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

Direct-to-consumer promotion of prescription-only medicines is not permitted, so public relations activities are the only means of providing information. Vitamins and supplements promotion is allowed.

It is very important that information shared is up-to-date, verifiable and accurately reflects current knowledge or responsible opinion. The information should also be accurate, balanced, fair, objective and must not mislead either directly or by implication.

How is a ‘media event’ defined?

Regulatory information does not specify a definition of media events.

Do the regulations differentiate between consumer and clinical publications?

One cannot advertise any prescription medicines directly to the consumers by print, TV or other electronic media. Any education materials aimed at consumers have to be given to the consumer via a physician. Vitamins and supplements may be advertised.

Do the regulations differentiate between print and broadcast media?

Regulatory information does not specify a differentiation 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 meetings and major publications?

Regulatory information does not specify off-license or pre-launch media activity rules.

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

Regulatory information does not specify press releases or media materials.

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

Regulatory information does not specify material distribution.
What regulations govern press activity at congresses and scientific meetings, such as holding a press briefing or sponsoring media to attend? Do these regulations apply to both licensed and non-licensed products equally?

Regulatory information does not specify how the press should cover medical congresses and meetings.

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

Journalists shall not be sponsored by the company directly, and the copy written by the journalist is independent. The company has control only over the press release that will be distributed through the company’s regulatory procedure.

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

Regulations do not specify the use of case studies or other third-party advocacy in the media.

Internet & Digital Media

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

Online media is currently not differentiated.

What levels of Web security are required?

Regulatory information does not specify levels of Web security.

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

Information on websites must comply with the legislation.

What are the most popular social networks in your region? Do they have self-imposed regulations?

The most popular social networks in our region are Facebook (Turkey has one of the largest populations on Facebook), Twitter and LinkedIn. The standard regulations globally apply to these networks.

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

Regulatory information does not specify rules for customer/company interactions on digital platforms. The standard regulations globally apply here.

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

Regulatory information does not specify mobile adoption.

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

Regulatory information does not specify disclosure laws for non-branded websites.

What is the response level needed for adverse event reporting?

Regulatory information does not specify a response level needed for adverse event reporting.
Stakeholders/Advocacy Groups

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

Regulatory information does not specify hospitality to advocacy/patient groups.

2. 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 of travel disallowed?

There are no regulations regarding honoraria for healthcare professionals or advocacy organisations as payment for their collaboration in media activities or events. The payment of travel and other expenses by companies may be criticized by media, so companies are careful about this.

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

Any support to be provided with regard to the participation of healthcare service personnel to these meetings shall never be bound to a prerequisite (i.e., specific prescription of a product by a physician).

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

Regulatory information does not specify the possibilities of media or message training for health professionals or advocacy organisations.

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

Materials written by the third party (e.g., clinical trial review or drug review, monograph, etc.) should truly reflect the product merits, not conceal any weakness, clearly state the contraindications, precautions, warnings, side effects, etc. and not overstretch the benefits.

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

Regulatory information does not specify meetings or non-media information sharing to advocacy groups.

Key Takeaways/Summary

- The promotion of medicines in Turkey is controlled by the Ministry of Health.
- DTC promotion of prescription-only medicines is not permitted, so public relations is very important.
- A major emphasis is placed on conducting oneself responsibly, keeping the regulation and code in perspective.
United Kingdom

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

1. 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, www.mhra.gov.uk) has summarised the legal requirements in The Blue Guide, Advertising and Promotion of Medicines in the UK, the third edition published in July 2012.

Self-regulation is based on industry codes of practice. For prescription medicines the ABPI Code of Practice (The Code) applies. This was established by the Association of the British Pharmaceutical Industry (ABPI, www.abpi.org.uk). It 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 2012.

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

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


Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

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 22.2).

Public relations activities are unlikely to be considered promotional if they are restricted to the provision of factual information (see Question 7). 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, and how strictly are they implemented?

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 (see Question 4). 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 (see Question 5). The MHRA also investigates complaints made to it about advertising. Where necessary, it can take legal enforcement action.

Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Anybody can submit complaints to the PMCPA about materials or activities that they believe infringe The Code. The Director of the PMCPA also takes up certain issues as complaints, for example media criticism of a company’s activities.

When the PMCPA contacts a company about a complaint, that company has 10 working days to respond. The matter is then referred to the Code of Practice Panel to determine whether there has been a breach of The Code. If the complainant or the respondent company disagrees with the Panel’s ruling, it may appeal to the Appeal Board. At the conclusion of the case, a report is published on the PMCPA website and elsewhere.

Companies found to have breached The Code must pay an administrative charge, the amount depending on the number of matters ruled in breach. They must also provide a written undertaking that the promotional activity or use of the material in question will cease forthwith and that all steps will be taken to avoid a similar breach. Depending on the seriousness of the matter, further sanctions may include:

- A public reprimand.
- A PMCPA audit of the company’s procedures in relation to The Code.
- Promotional material to be submitted to the PMCPA for pre-vetting before use.
- A requirement that the company should issue a corrective statement.
- A requirement that the company should recover items ruled in breach.
- Suspension or expulsion of the company from the ABPI.
- Alternatively, complaints may be made to the MHRA. If it identifies potential breaches of the regulations it may ask the company to:
  - Amend or withdraw the advertisement;
  - Issue a corrective statement; or
  - Submit future advertising for review before it is used.

The MHRA may also take statutory action to prohibit the use of advertising that it deems to be in breach of the regulations.
Are any materials subject to pre-approval by the relevant authorities before they are used?

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, for example if 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 (see Question 4).

What are the most recent significant developments, and are there any planned changes in the next few years?

A new edition of The Code was published in January 2012, with changes in two areas:

- **Clause 17**
  Samples may now be provided for new medicines only. The number of samples of a particular medicine is limited to no more than four per health professional per year for no more than two years.

- **Clause 17 Starter Packs**
  The provision of starter packs is not permitted. Starter packs are small packs designed to provide sufficient medicine for a primary care prescriber to initiate treatment in such circumstances as a call out in the night.

- **Clause 23**
  If a patient organisation provides services to a company, such as participating in advisory boards or speaking at meetings, there must be a written contract or agreement. This must specify the nature of the services and the basis for payment. The company must publish—at least once a year—a list of patient organisations that provide services to it and the amount paid to each.

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, purchase, recommendation, sale, supply or use of its medicines’ (Clause 1.2). Prescription-only medicines must not be promoted to the public (Clause 22.1).

Provision of certain types of information is not considered promotion. Examples are listed in Clauses 1.2 and 22 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 22.2).

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, www.hca-uk.org).

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 (see Question 7).

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, The Code)

Do the 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 unlicensed product or indication.

It is permissible to issue a news release to the medical or general media about an as-yet unlicensed product or indication if the subject is genuinely newsworthy and appropriate for the intended audience. For example, it may be appropriate to issue a news release to the medical press about the results of a major clinical trial. The information provided must be factual, balanced and non-promotional. The use of brand names should be kept to a minimum. Non-promotional information about products in development may also be made available to shareholders and others with a business interest.

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 19.3).

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 licensed;
- 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 must be given of countries where the medicine or indication is authorised, including at least one major developed country; and
- 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 22) 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; and
- 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 22.2).

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 licensed should also be provided. The content of a press release and the language used should be appropriate for the target readership. The use of brand names should be kept to a minimum.
Information about the launch of a new product or indication must not be released to the general media until steps have been taken to inform health professionals.

Pharmaceutical companies are responsible for information issued about their products by their public relations agencies (Clause 22.5, The Code). 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.

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

The Code applies to UK press briefings held by or on behalf of pharmaceutical companies, and to sponsorship of journalists to attend congresses and scientific meetings. It applies to both licensed and non-licensed products (information provided about the latter must be considered carefully—see Question 11).

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 19 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; and
- 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.

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

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 Healthcare Communications Association (www.hca-uk.org), not to pay journalists for writing news or feature stories—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?

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.

Internet & Digital Media

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

The same rules about compliance with The Code apply irrespective of the media used.

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 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 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 (The Code, Clause 24.1,
Supplementary Information). The Blue Guide states that the public should not be encouraged to access material not intended for them.

13. 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.

14. What are the most popular social networks in your region? Do they have self-imposed regulations?

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.

15. 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 has issued informal guidance on digital communications (http://www.pmcpa.org.uk/?q=node/920). This notes that companies can use any method of communicating, 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.

16. 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.

17. 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 23, The Code). There must be a detailed written agreement stating the arrangements (Supplementary Information to Clause 23.3) and companies must publish a list of organisations supported, with information about the support provided (Clause 23.7).

The requirements of Clause 19 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 carer (Supplementary Information to Clause 23.2). 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 of 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 20.1 and 23.8) 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 20.2 and 23.8).

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 (see Question 26).

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 healthcare professionals 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 (see Question 12). 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 23) and that their involvement is made known from the outset. They must have a detailed written agreement (Clause 23.3) describing the arrangements. Companies must publish a list of all patient organisations to which they provide financial or significant non-financial support. 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 23.7).

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 23.4);
- A company must not make public use of a patient organisation’s logo or proprietary material, such as leaflets, without the organisation’s written agreement (Clause 23.5); and
- A company must not seek to influence the text of patient organisation material in a manner favourable to its own commercial interests (Clause 23.6).

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.
United States

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

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

The FDA consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations. The Center for Drug Evaluation and Research (CDER) is part of the Office of Medical and Tobacco Products, as is the Center for Biological Evaluation and Research which focuses on vaccines and other biologics. Within CDER, the Office of Prescription Drug Promotion (OPDP)—Part of the Office of Medical Policy—provides an extensive handbook to ensure that all prescription and over-the-counter (OTC) drug communications in journals, publications, newspapers, broadcast media and even telephone communications meet the requirement of complying with approved product labelling. OPDP protects the public through separate groups that focus on prescription and consumer drug promotion.

2. Is ‘public relations’ separately defined? What are the criteria, and how is public relations differentiated from other promotional activities, such as advertising?

The activities traditionally associated with public relations, including media relations, are all categorised as promotional activities. FDA defines advertising very broadly, including every type of communications activity including materials printed in journals, stand-alone publications, newspapers and Internet advertising under this rubric. FDA does make a distinction between product labelling and drug information as defined by written, printed or graphic elements found on drug wrappers or containers. This difference between advertising and labelling is not clearly defined, however, and has generated questions and uncertainty in specific situations.

3. Who is responsible for the enforcement of these rules, and how strictly are they implemented?

The FDA has wide powers, which it frequently uses, to address promotional activities that it considers to be in breach of its regulations. In certain cases, violations are addressed prior to dissemination of the advertisement in the pre-approval phase (see Question 5). If an advertisement airs and is found to be in violation, the FDA will issue a formal warning letter requesting details on how to remedy the alleged violation, which may be disputed by the manufacturer. The letter is initiated by OPDP but officially originates from the FDA center which regulates the product in question. If these issues are not adequately addressed, FDA has the authority to initiate judicial proceedings, impose FDCA violations and relevant penalties. PHRMA and other third-party organisations have no power over and above ethical guidance.

4. Who submits concerns or complaints, and what powers do the authorities have to punish those found in breach?

Complaints may be submitted by anyone, although they most frequently come from industry competitors. FDA stringently monitors the promotional environment for potential regulatory violations. All product promotional materials must be submitted to OPDP upon initial dissemination to allow for compliance assessment. FDA has police powers and can issue warning letters, available for public viewing on the FDA website, in order to publish corrective statements and/or fines. In serious cases, the FDA may seize products, require limited or extended product recalls or seek initiate criminal proceedings.
OPDP reviewers are responsible for reviewing complaints about alleged promotional violations, initiating enforcement actions on promotional materials that are deemed false and misleading, comparing product labelling and promotional materials of closely related products to ensure that regulatory requirements are consistently applied, and acting as a liaison between it and other FDA divisions on promotional issues.

Are any materials subject to pre-approval by the relevant authorities before they are used?

Pre-approval of all promotional materials is required by the FDA for products being considered for accelerated approval and those where patient safety issues exist. Pre-approval submission may be required of manufacturers with a history of promotional violations. Companies may also voluntarily submit materials for OPDP advice and comment prior to product approval.

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

What are the most recent significant developments, and are there any planned changes in the next few years?

As reviewed in more detail later in this guide, online channels are playing an increasingly important role in medical marketing communications. Clear and consistent regulatory guidelines on how to appropriately engage in these platforms are hotly anticipated by industry. FDA has alluded to the fact that it will issue guidance on social and digital media engagement, but it has not as yet and is observing the evolving market. FDA regulators are committed to communicating with health professionals and regulated industries on the evolving nature of social communications, but firm guidance is still lacking. Additionally, FDA regulates the growing field of medical apps that allow people to monitor and manage medical therapy and some body functions, although a specific guidance has not yet been issued.

Future plans for the division include guidance documents on health care economic information/formularies, medical practice guidelines, comparative claims, and scientific exchange. As noted, FDA is still working on Internet/social media promotion guidelines.

There has also been a growing focus by the FDA to address ‘off-label’ use of prescription drugs, along with a trend of prosecuting company executives in the case of egregious violations. In December 2011, the FDA issued draft guidance on Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices. This document provided more detail on how
drug and device manufacturers should reply to unsolicited consumer enquiries for off-label usages, through either direct private enquiry or through online or in-person public forums.

The PhRMA Code was first enacted on 1 July 2002. Revisions were made in January 2004, and included further answers to some Frequently Asked Questions, which mostly concern the permissible nature of hospitality and gifts to physicians, with an updated version enacted in January 2009. The PhRMA Guiding Principles to Direct to Consumer Advertisements about Prescription Medicines has been revised, and the updated principles took effect in March 2009.

The Physician Payment Sunshine Act provision of the Patient Protection and Affordable Health Care Act (‘Obamacare’) requires pharmaceutical and medical device companies to track any payments or “transfers of value” to physicians and teaching hospitals as of 1 August 2013. The list of payments covered is extensive and includes fees, gifts, food, beverage, travel/lodging, entertainment, charitable contributions, and royalty or license fees. Companies will submit the data to the Centers for Medicare and Medicaid Services (CMS) on 31 March 2014. CMS will begin publicly reporting the data as of 30 September 2014. Even though companies are prohibited from offering any entertainment or gifts that do not advance disease or treatment education under the voluntary PhRMA Code on Interactions with Healthcare Professionals—a practice that is also banned by law in several states—many physicians report still accepting free tickets or gifts.

The Media

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

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

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

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

Do the regulations differentiate between consumer and clinical publications?

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

In January of 2009, the FDA updated guidelines on good reprint practices for the distribution of medical journal articles containing information on off-label use of drugs or medical devices. New rules allow for the distribution of such materials as long as they are in a peer-reviewed publication that is edited by experts on the subject with no affiliation to the manufacturer. The article should be distributed in its entirety with proper references and should be separate from promotional information.

The FDA mandates that advertisements focused on consumer versus clinical publications or other media channels must both feature the brief summary of complications, warnings and side effects, as well as being truthful and ‘fair balanced’. With regards to the consumer audience, the FDA does advise that information be written in a way that is simple to understand by the average individual, versus the scientific information that may be presented to medical professionals.

Do the regulations differentiate between print and broadcast media?

Current regulations specify two requirements that all prescription drug broadcast advertisements must meet. Firstly, broadcast advertisements must include the product’s most important risk-related information, known as the ‘major statement’ in the audio or audio and visual parts of the advertisement. Secondly, broadcast advertisements must contain either a brief summary of the advertised product’s risk information, or alternatively, make adequate provision for disseminating the product’s approval labelling in connection with the ad. Thus, the regulations for broadcast advertisements recognise broadcast’s inherent limitations by providing an alternative mechanism for meeting the Act’s information disclosure requirement. In 2007, the FDA updated the regulations, mandating that the major statement be neutral, conspicuous and presented in a clear manner.

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

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

In 2010, the FDA proposed guidelines that would require manufacturers to present a drug’s major side effects and warnings in broadcast advertisements, regardless of how the drug’s benefits might be presented. (Please note, these guidelines were not in effect at the time this document went to print).

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

In the case of print advertisements, the FDA encourages product sponsors to provide consumers with nonpromotional, consumer-friendly information consistent with product labelling, along with the information required by the act and the regulations.

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

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

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

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

In regards to specific rules around congresses and scientific meetings, each medical society implements a set of policies to be followed by all participants. Most medical societies have regulating committees that are responsible for establishing and enforcing the policies governing all media-related activities. Societies adopt embargo policies for all abstracts presented at globalhealthpr.com
their meetings to abide by any agreements made with publishers and to maintain authenticity of study results.

Medical meetings take embargoes very seriously, similar to a publication, because if the information is presented in advance for public consumption, it reduces the significance to present to colleagues on-site. Furthermore, advance distribution may unfairly affect stock prices by sharing one company’s information prior to competitors. Materials distributed should include a prominent display of the words “EMBARGOED UNTIL” with the date and time of presentation to avoid any possible negative ramifications.

In December 2011, the FDA issued draft guidance on how industry should respond to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices. The draft guidance clarifies the fact that manufacturers are able to provide information to unsolicited requests on off-label drug or device uses without violating regulations. However, any information provided could potentially be introduced as evidence of a new intended use.

Unsolicited requests are defined as both non-public, as in a call, email or direct request via a website from a consumer to the manufacturer, or public request sought in an open forum, either in-person or via an online source, such as message board, website or social media platform. Not covered are solicited requests which are defined in a number of ways, including requests received following company-affiliated presentations, speeches, business reply solicitation, calls for online videos or other comments, pre-formatted website responses or on- and off-line distribution of information. Responses to solicited requests for off-label information may be considered evidence of a firm’s intent that a drug or devices is intended for use other than specifically approved by the FDA.

If a firm chooses to respond to an unsolicited request for off-label information, it must do so directly to the individual posing the question—regardless of whether the request is public or non-public—and in a way that is tailored only to the specific question or questions asked, meaning that follow-up may be required to secure additional information on the question asked. Responses should, to the greatest extent possible, be scientific, fair and balanced, published in peer-reviewed articles and should come from the company’s scientific or medical personnel, not marketing or sales representatives. Responses must also include approved FDA labelling, a prominent statement indicating that off-label uses are not approved by the FDA, safety warnings and a complete list of scientific references.

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

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

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

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

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

The distribution of materials to any media or clinical outlet is reasonable, whereas unsolicited faxing or text-messaging to other numbers would not be (see Question 12). No reference is made to the codes of other countries in any of the regulations, although International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) guidance says that promotional material should comply with the regulations in the country of release and distribution, as well as the source. As only the United States and New Zealand permit DTC communication, those sending United States press materials outside the U.S. should take particular care to ensure that their content does not contravene the regulations of the countries where distribution or publication is intended.

A manufacturer may disseminate information, under Section 551 of the Federal Food, Drug and Cosmetic Act, on a new use only if the manufacturer prepares and submits a list of materials for distribution to the Secretary of Health and Human Services. A list containing the titles of the articles and reference publications relating to the new use of drugs or devices by the manufacturer, along with a list of any clinical trial information used to promote the drug or medical device, must be provided to the Secretary 60 days prior to dissemination.

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

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

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

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

Press briefings, news conferences, press reception and other media events—other than those sponsored by the host institution or manufacturer—are not permitted on-site. Organisations planning any off-site media activities, such as press conferences, satellite media tours and/or social events, are usually required to coordinate with the appropriate communications department. All events are bound by the rules of the meeting and are generally restricted to before or after the hours of the meeting, or on either end of the start or completion of the meeting.

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

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

This type of communication and subsequent editorial is permissible under regulations in the United States. However, according to the FDA, if the manufacturing company is paying for or dictating the content of any publication, it falls under FDCA regulations and, with any violations, could potentially result in sanctions.

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

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

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

Internet & Digital Media

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

Advertisements for prescription drugs presented through the Internet or other online venues are regulated under the same FDCA regulations as print or broadcast media. Advancements in online advertising options have drawn question over the scope or feasibility of the FDA to regulate these digital advertisements; however the FDA remains committed to enforcement of its regulations through online channels. The FDA has noted that it plans to issue guidelines on a variety of issues associated with online advertising and communications. However, at time of printing, they were not available.

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

In March 2010, PhRMA issued a statement to the FDA encouraging more thorough review of its regulation and enforcement of online dissemination, particularly through social media, blogs and online forums. PhRMA notes that without clear guidelines, manufacturers are at a disadvantage to communicate health information to consumers. While the FDA has yet to clarify its position on online and social media promotion, manufacturers continue to make use of the platforms for promotion, spending, an average of $750,000 in online marketing in 2011, according to a study by Cutting Edge Information. As of early 2013, Internet presence continues to grow, evidenced by hundreds of Facebook pages, Twitter feeds and YouTube channels despite the fact that individual adverse events discovered through social media have long been feared by the legal and regulatory departments of drug manufacturers in the United States. The question remains: Are companies required to follow up on those reports as they would on reports coming from other sources?

Draft guidance issued December 2011, Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices, does reference requests received through online resources. Citing websites, forums, emails and social media platforms, the draft guidance is the closest yet presented to online guidance. Focusing more on the response to off-label questions, the draft guidance advises against public posting in response to unsolicited questions, received through either public or non-public forums, but rather responding directly to the individual posing the question.

What levels of Web security are required?

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

Websites routinely track the paths visitors take through their sites to determine what pages are being used.

However, many health-related websites ask the visitor to ‘subscribe’ or ‘become a member’. In some cases, this may be done so they can collect a fee or obtain relevant information for the visitor. In all cases, the subscription or membership will allow the website owners to collect personal information about their visitors.

Many commercial sites sell ‘aggregate’ data about their visitors to other companies—what percentage are women with breast cancer, for example. In some cases, they may collect and re-use information that is personally identifiable, such as a visitor’s ZIP code, gender and birth date.

Any website asking users for personal information should explain exactly what the site will and will not do with the information. The FDA website, for example, spells this out in its Privacy Statement.

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

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

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

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What are the most popular social networks in your region? Do they have self-imposed regulations?

Social media play an increasingly important role in the United States. Leading social media platforms, notably Facebook and Twitter, have become ubiquitous tools in the day-to-day lives of millions of Americans. Once a place to connect with friends and family, social media channels have evolved to become, for many, the primary source of news and information, including health-related questions.

As noted in Question 17, the FDA has yet to issue clear guidelines as regards prescription drug promotion online, including social media channels. The agency maintains the FDCA regulations across promotional materials online, including the need to clearly cite warnings and side effects, as well as the necessity to capture and report adverse effects.

The interactive and engaging nature of social media, particularly the scope with which consumers can highlight adverse effects, whether true or not, has caused questions and concerns regarding manufacturer’s engagement in social media efforts. In a March 2010 statement, PhRMA encouraged FDA to push clear guidelines on appropriate social media interactions by manufacturers. The Association of the British Pharmaceutical Industry (ABPI) has issued a white paper and guidance on the subject. Regulations are still forthcoming.

While the FDA has previously indicated that it will issue guidelines for digital and social media, analysts are divided as to their expectations on this. Given the fact that social media platforms are constantly evolving, with new elements, updates and even new endeavors appearing each day, the FDA may be strained to maintain their guidance of these different platforms. One keen example of these changes came in August 2011 when Facebook—the largest social media network in the world, with more than 800 million active users worldwide—changed its rules to prevent pharmaceutical manufactures from having closed profiles. This meant that consumers were free to voice opinions and, potentially adverse effects, on the public Facebook pages of manufacturers. This change caused many manufacturers to shut down their Facebook presence amid fears of an increased monitoring and reporting burden and potential action by regulators.

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

As noted in Question 17, the FDA has yet to issue clear guidelines as regards prescription drug promotion online, including online forums. The agency maintains the FDCA regulations across promotional materials online, including
the need to clearly cite warnings and side effects, as well as the necessity to capture and report adverse effects. Any online channels or areas presenting or discussion medical information that are sponsored by the prescription drug manufacturer are currently regulated in the same manner as other promotional materials and are subject to the same conditions and potential penalties for non-compliance.

The closest that the FDA has come to regulation of customer/company interactions on digital platforms is with draft guidance on Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices, issued in December 2011. This document allows for response to unsolicited questions on off-label use, received through social media, email or company-owned websites. Companies choosing to respond to these requests, but must do so in line with draft guidance; including direct response to the individual posing the question, specific response only to the questions asked and response from scientific representatives with transparent, fair and balanced information that includes approved labelling and adverse effect information.

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

According to CTIA, The Wireless Association, as of June 2012 there were 321.7 wireless connections in the United States, or 102 percent of the U.S. population of 313.4 million. Forty-two percent of those are smart phones that enable users to employ health, entertainment, travel and other apps. Almost 36 percent of households are wireless only, and the mobile industry is worth $178.4 billion.

In July 2011, the FDA proposed guidelines on smartphone/tablet applications (apps) that address health issues. FDA has already reviewed and approved apps that support medical professionals, such as a smartphone-based ultrasound and an app that allows doctors to view medical images and X-rays. Proposed guidelines would extend this oversight to cover apps that are used as an accessory to a regulated medical device, such as viewing medical images, and apps that transform a smartphone or similar device into a regulated medical device, such as an electrocardiograph device to detect abnormal heart rhythms.

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

A 2009 study coordinated by Manhattan Research found that 35 percent of online pharmaceutical consumers use a ‘non-branded’ website to find information. Experts note that ‘non-branded’ resources, developed by prescription drug manufacturers, can be very useful in promoting disease awareness, educating diagnosis, introducing rare conditions and navigating compliance issues. There are, however, important compliance steps which are enforced by the FDA.

While the FDA has not issued specific guidelines on the regulation of ‘non-branded’ websites, they are scrutinized by the agency as with any other promotional material paid for by a prescription drug manufacturer. In May 2010, the FDA issued warning letters to one manufacturer citing several violations associated with two ‘non-branded’ sites, including promotion of off-label uses of drugs, failure to disclose associated risks and unsubstantiated dosing claims.

The agency has made a clear statement that all websites paid for by prescription drug manufacturers, even if they contain no direct branding or promotional information, will be regulated as with other promotional materials under FDCA. Without providing full disclosure and,
wherever relevant, information on labelling, warnings and adverse effect reporting, manufacturers may be subject to penalties.

24 What is the response level needed for adverse event reporting?

The FDA requires that all manufacturers report adverse events through the MedWatch programme within 15 days of receiving such information, regardless of how it is received. Regulations mandate that print and broadcast promotional materials direct consumers to report adverse effects through the MedWatch toll-free number or website. With the advance of social media, and the open lines of dialogue that consumers have with manufacturers, the scope for adverse event reporting is much greater.

Despite the ease for consumers to note adverse events related to prescription drugs, medical devices and other medical products, researchers, including BuzzMetrics, have found that increased online conversation does not directly correlate to increased adverse event reporting. Regardless, the greater burden of listening and reporting required by manufacturers engaged in social media can strain resources and many choose not to engage. Without clear guidance by the FDA on the scope and frequency of monitoring required by manufacturers, and the nature to which it is regulated—as noted in Question 17—has created a grey area with regards to adverse event reporting in the digital space.

Stakeholders/Advocacy Groups

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

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

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

It is acceptable for those participating in meetings or events, for example as speakers, to receive honoraria. The PhRMA Code states that no recreational or entertainment events may be offered, meals must be judged as ‘modest by local standards’, and that meals are provided in a manner conducive to informational communication. Any meals offered in connection with informational presentations should be limited to in-office or in-hospital settings, not as part of an entertainment or recreational event. Inclusion of a healthcare professional’s spouse or other guest is inappropriate, as is offering “take-out” meals or meals to be eaten without a company representative.

The AMA’s ethical guidelines state that the teaching faculty and other service providers (i.e., moderators)
may be offered reasonable honoraria and reimbursement for travel, lodging and meal expenses. The amount received must be commensurate with the services they provide. Regarding advocacy groups, there are no legal restrictions on funding specifically relating to the healthcare sector. Pharmaceutical companies routinely provide funding for groups interested in the conditions that their products treat.

It should be noted that The Physician Payment Sunshine Act requires all payments to health professionals be reported to the Center for Medicare and Medicaid Services (CMS) beginning in August 2013. Payments will be made public beginning in September 2014.

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

The PhRMA Code categorically states that financial support should not be offered for the costs of travel, lodging or other personal expenses of any non-faculty healthcare professionals. Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the meeting, including attendees of interactive sessions.

Such payment is possible under federal law; however, is considered ethically suspect by the AMA, as well as PhRMA. The AMA’s ethical guidelines provide that industry subsidies should not be accepted to pay for the cost of travel, lodging or other personal expenses of physicians merely attending conferences or meetings, or to compensate the physician’s time.

The Physician Payment Sunshine Act requires all payments to health professionals be reported to the Center for Medicare and Medicaid Services (CMS) beginning in August 2013. Payments will be made public beginning in September 2014.

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

Regulators acknowledge that speaker training is an essential activity to enable healthcare professionals to educate and inform their colleagues and peers about benefits, risks and appropriate uses of prescription drugs. The FDA holds companies accountable for the presentations of their speakers, so appropriate training and education is necessary. Section 7 of the PhRMA Code specifically states that ‘it is appropriate for healthcare professionals who participate in programmes intended to recruit and train speakers for company-sponsored speaker bureaus to be offered reasonable compensation for their time…and reasonable expenses’. The PhRMA Code additionally recommends that when participants receive extensive training on the company’s drug products, they should also receive training on compliance with FDA regulatory requirements for communication about such products. Payments for participation in media training must be reported to the Center for Medicare and Medicaid Services (CMS) beginning in August 2013. Payments will be made public beginning in September 2014.

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

As consistent with all aspects of prescription drug promotion, full and transparent disclosure of sponsorship by a manufacturer as related to any written materials by third parties is required for compliance with FDA and industry regulations.

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

There are no legal restrictions that cover advocacy groups specifically in the healthcare sector.
Key Takeaways/Summary

- Online marketing channels, including social media, are playing an increasingly important role. While currently regulated by the FDA in a similar manner to traditional media platforms, this has been inconsistent and presented challenges for manufacturers. Specific online and social media guidelines are anticipated by the FDA in the near future to clarify key elements, such as monitoring and reporting of adverse events.

- Marketing of 'off-label' uses of prescription medication has been a focus of FDA regulatory scrutiny recently. Strict adherence to the approved uses and dosing is important for manufactures’ marketing programmes to avoid penalty. This applies to ‘non-branded’ materials and websites.

- Full open and transparent presentation of major statements of prescription drug labelling, such as warnings, approved dosing and possible side effects, along with clarification of financial support of physicians and third parties, remains vital in adhering to regulation in the United States.
About GLOBALHealthPR Partners

GLOBALHealthPR is an international partnership uniting some of the world’s most successful independent healthcare public relations firms and their affiliates.

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Argentina

GLOBALHealthPR is represented in Argentina by Paradigma-PEL Comunicación, a Buenos Aires-based agency specialising in healthcare communications with vast experience in the pharmaceutical market.

Among Paradigma’s main services are the coordination of press and public relations campaigns, media training, medical writing and media management. The agency has developed campaigns for global pharmaceutical companies like Novartis, Merck Sharp & Dohme, Roche, Bayer, Merck Serono, Galderma, Bausch + Lomb and Allergan as well as national pharmaceutical companies like Bagó, Sinergium Biotech and Elea.

Co-founders Patricia Blanco, María Eugenia De la Fuente and Laura Torres Cárdenas created Paradigma-PEL Comunicación in 2002.

Before founding Paradigma-PEL Comunicación, Patricia began her healthcare communications career in 1997 in El Cronista Comercial newspaper’s health section. Over the next several years, she worked in the communication research department at CEIL, one of the CONICET (National Council of Scientific and Technical Research) research centers. Patricia also served as an account director for a public relations agency specialising in healthcare communication, managing campaigns for top pharmaceutical companies.

Eugenia began her career in healthcare communication in 1994 at the Argentinean Food and Drug Administration press department. She then managed several communication campaigns for top pharmaceutical companies as the healthcare editor for a print and digital publication. Eugenia has served as both producer and presenter for various health radio and TV programmes throughout Buenos Aires.

Laura began her healthcare marketing career in 1999 when she produced health radio programmes and began managing campaigns for several pharmaceutical companies in 2000. She also spent several years managing clients at the press department of advertising agency Euro RSCG.
GLOBALHealthPR is represented in Australia by VIVA! Communications—a dynamic, strategic and independent health and wellness communications agency based in Sydney.

Established in 2002, VIVA! Communications specialises in delivering award-winning counsel to the local and international medical, pharmaceutical (medicines and devices), biotech and community health and wellness sectors.

The Australian company has earned an enviable reputation for delivering proactive, innovative, versatile and outcomes-driven work of the highest quality. VIVA! Communications strategists combine extensive PR, journalism, science and marketing expertise to influence and stand out from the crowd—to be seen and heard. Their unsurpassed passion for health and wellness communication campaigns tailored to the unique goals and objectives of their clientele, compiled with a voracious desire to exceed client expectations, is what sets them apart.

From ventricles and vessels to viruses and vaccines, VIVA! Communications, in partnership with GLOBALHealthPR, covers the full spectrum of health and wellness communications.

Kirsten Bruce, the Principal of VIVA! Communications, launched the Sydney-based health and wellness communications agency in July 2002. Kirsten has specialised in health and wellness communications for more than 17 years. During this period, she has held many senior roles in international and local public relations agencies, as well as in-house communication positions.

Throughout her communications career, Kirsten has consistently developed and delivered award-winning strategic communications campaigns for clients spanning the medical, pharmaceutical (medicines and devices), biotech and community health and wellness sectors. She has also worked for not-for-profit health professional and patient organisations. Kirsten has won many PR accolades throughout her career. Most recently, she was awarded the highly prestigious Public Relations Institute of Australia (PRIA) National Golden Target Award and NSW State Award for Excellence (PRIA) for various health, product and device-related programmes that she coordinated during 2008, 2009, 2010 and 2011, respectively.

Kirsten has a BA degree majoring in Communications (PR and journalism) and an MA degree in International Relations and Japanese. She is a member of the Public Relations Institute of Australia (PRIA) and a committee member of the Registered Consultancies Group (RCG), Sydney.
Brazil

GHPR is represented in Brazil by Tino Comunicação. Created in 2006, Tino Comunicação was the first communication agency in the Brazilian market to focus exclusively on developing solutions for companies and brands intended to convey messages that combine health- and quality of life-related issues to the Brazilian consumer. We use our expertise in PR, digital media and advertising to encourage our clients to use communication in an integral fashion. We develop communication projects that are not only the press services usually used in the communication of brands and products.

Our work is supported by a sound tripod, formed by the expertise inherited from the agencies that originated Tino: public relations, digital intelligence and social media.

Tino Comunicação was founded by Regiane Monteiro, journalist and former editor of the Journal of Health Diário de São Paulo. In addition to collaborating with the O Globo newspaper, magazine Health! It’s Vital, Editora Abril and other publications, she worked for 12 years in the coverage of the pharmaceutical industry. She won the Editora Abril’s Award in Health Journalism in 2002, and won the Brazilian stage of the Novo Nordisk’s World Award Diabetes, in 2005.

Her partner, Cristiano Calamonaci, holds graduate degrees in business administration and an MBA in Marketing, and has worked in the digital market since 2000. Backed by America On Line, Cristiano founded the portal Cielo, the first e-commerce community for micro- and small enterprises in Latin America. He is a former member of the Full Jazz agency that received the Bull Market seal, given only to the 400 leading companies in the world able to make corporations and products become relevant through communication strategies. He is also founder and vice president of APADI, the São Paulo Association of Digital Agencies.
GLOBALHealthPR is represented in Chile by Alkance Comunicaciones, a Santiago-based agency dedicated to healthcare communications and journalism at the local, regional and global levels.

With 16 years of experience in health communications and journalism, Alkance’s multidisciplinary team of experts brings the best results to its clients each day. Alkance works in the field of strategic communications, media relations, media training, public affairs, sustainability, crisis communications, corporate social responsibility, social media communication, internal communication and congresses and events. The agency has done work with Merck Sharp & Dohme (MSD); Kimberly-Clark; Philips Corporate & Health Care Division; Vida Cel, the first bank of mother cells in Chile; Las Condes Clinic; fertility programs; and Fundación Gantz, as a leading nonprofit institution in the treatment of fissures labiopalatinas. Alkance is a member of Pinnacle’s Health Care Committee.

Patricia Habit, Executive Director and Partner of Alkance, has worked in the communication world for over 20 years and previously worked for 11 years in the press media. More than 15 years ago she created her first PR agency, PMC Communications. She has directed and designed successful PR strategies for organisations, corporations and companies of different industries. She is an expert in public matters and strategic alliances. A market strategy and new ideas led her to create a second agency: Alkance Communications. This company provides support that allows long-term relationships with clients and innovates strongly with the new world trends.

Andrés Tolosa, Manager Director and Partner of Alkance, has 12 years of experience in the areas of marketing and communications. He has served as a Director at Universidad Andrés Bello of the Economist Post Graduate Degrees and is tied to the managerial world as Director of Companies related to the Technologies of Information and Marketing Communication. He is also a commercial engineer with a master’s degree in International Business from Europe.
GLOBALHealthPR is represented in France by MHC Communication. In addition to its core strengths of public relations and media relations, the agency offers strategic counselling, brand management, issues management and international coordination. MHC Communication has a broad capacity to develop and implement strategic communication programmes. Its key focus is on successful client service and strong results based on proximity and flexibility, partnership, personal commitment and enthusiasm and creativity.

Marie-Hélène Coste, Director, is a healthcare communication specialist with more than 20 years’ experience in marketing and issues management for pharmaceutical, medical devices and healthcare providers, including learning societies. She gained invaluable experience at large international agencies Fleishman-Hillard and Burson-Marsteller before creating MHC Communication, and has a wide network of allies among medical opinion leaders, authorities and journalists.

Véronique Simon, Senior Executive, has more than 10 years’ experience as a speaker and media trainer. She also worked as a freelance journalist covering public health and medical issues. Experienced in editorial management and international coordination of business process, Véronique now specialises in Internet-based marketing and communication.

Dominique Robelet, broadcast expert and consultant, has more than 20 years’ experience working in audio-visual communication. A very experienced script writer, producer of television documentaries and health programmes, she also created the first European TV channel ‘Canal santé’.
Germany

In Germany, GLOBALHealthPR is represented by fischerAppelt, founded in 1986 in Hamburg. Excellent integrated communication requires two major skills: specialised expertise combined with a comprehensive insight and the ability to think in various channels and disciplines. This is the reason fischerAppelt launched the Federation of Ideas. It is a union of independent and specialised agencies from all communication disciplines: public relations, design, advertising, TV/moving images and digital communication. Each agency has excellent expertise in its specific area of operation. All together, they form a well-adjusted team that develops and implements integrated ideas. In 2011, for the fourth time, German business journalists voted fischerAppelt the agency with the most professional press work. In 2011, fischerAppelt was awarded agency of the year in Germany by the Holmes Report.

fischerAppelt knows that convincing corporate and product communication designed to build trust is the deciding factor in today’s healthcare markets. Clear and concise communication for both physicians and patients is the core of a ‘healthy’ campaign. fischerAppelt’s health campaigning translates medical facts, trends, moods and political parameters into dynamic conceptual topics and emotional messages. It successfully represents pharmaceutical market leaders such as GSK, Roche and Novartis in the field of OTC, as well as prescription products and corporate issues.

Sabine Seifert, Managing Director and Head of the Healthcare and Brand Communication Units, has eleven years of experience in public relations and media management with a strong focus on healthcare consulting. She has significant knowledge in the field of launch and re-launch strategies, as well as corporate communications. Sabine has been responsible for the implementation, management and controlling of public relations and integrated communication campaigns involving a diverse range of pharmaceutical companies and professional institutions. Thanks to the enormous growth of the Healthcare Unit in the last years, fischerAppelt now has three branch offices in Germany: Hamburg, Frankfurt and Munich.
India

GLOBALHealthPR is represented in India by MediaMedic Communications Pvt.Ltd., an Mumbai-based agency specialising in building health brands.

Founded in 2005 in Mumbai, MediaMedic Communications offers its services for:

- Pharmaceuticals
- Nutraceuticals
- Healthcare

MediaMedic Communications believes that a company or brand needs an integrated communications approach that has the strategic vision at its core. Thus, in communication, MediaMedic gives utmost importance to strategy and objective achievement.

All personnel of MediaMedic are professionals that understand health regulations as well as the consumer; hence, is uniquely positioned in this space. With a rich experience in all aspects of pharmaceutical- and health-related communications, MediaMedic has taken strides in using new technology and media for this fast-growing sector in India.

The client list of MediaMedic includes large and small pharmaceutical, nutraceutical and FMCG companies in India including Piramal Healthcare, SunPharma, Glenmark, Pfizer, Bisleri, Marico and many others.

MediaMedic Communications is co-founded by Priti Mohile and Dinesh Chindarkar in 2005. Priti earlier headed the marketing division of a large Indian pharma company and created a blockbuster brand for them. Dinesh has extensive brand management experience in the healthcare space and is equipped with communication skills across multimedia.
GLOBALHealthPR is represented in Japan by LBS Co., Ltd., a Tokyo-based agency. LBS, spinning off from IBM Japan, was established in 1993 with its corporate slogan ‘To Bring The World To Japan, Japan To The World’.

Japan has been perceived as a relatively difficult market to explore, and the healthcare business is not exceptional. A complicated healthcare system, a slow and cumbersome process caused by the strict regulations, high costs of conducting business, and complex Japanese business customs often perplex non-Japanese.

However, considering Japan’s rapidly aging society and the fact that the Japanese drug market is the second largest in the world followed by the United States, Japan is an attractive market.

LBS staff members with bilingual capabilities of Japanese and English and professional expertise provide integrated communications services from making strategic communications plans to their concrete implementations, including media relations, PR events, publications, risk management and so on.

Especially, LBS possesses unique influencers human network with government, leading media, opinion leaders and competent partners, whose advices are essential to make the best judgment and effectively promote the PR activities.

LBS stands for our three defining characters as follows:
L = Love, for the job and the people we serve
B = Beauty, in the quality of our work
S = Smile, in our hearts.

With these qualities as the cornerstone of our activities, all of us at LBS are fully dedicated to satisfying the needs of clients.
Mexico

GHPR is represented in Mexico by PR Partners (PRP), a creative and innovative communication agency that develops PR strategies with a high level of segmentation, strategic basis and a focus on results.

In its clients’ words, the PRP team is committed, strategic, professional, punctual, visionary, ethical and proactive.

PRP was founded in 2000 and it is comprised by a multidisciplinary group of 40 professionals. It is divided into four business units: Pharma (prescription products), Healthcare (health and beauty products, as well as OTC and other health related clients), Corporate and Consumer. The business units are supported by a media department that provides media intelligence, updated data bases and quality information regarding journalists, which allows for high efficiency in message segmentation and results.

PRP’s client portfolio is comprised mainly of multinational companies with great challenges in communication and a high demand for quality service by its providers. The average permanence in the management of our accounts is four years, due to the quality service with added value, which differentiates PRP from many companies in its field.

The healthcare clients include Mayo Clinic, Pfizer, Merck, Sanofi, Janssen and Nycomed a Takeda Company, among others. On other sectors, clients include companies such as Walmart, American Express, DHL, Melia Hotels International, Daimler and Nestlé.
Poland

GLOBALHealthPR is represented in Poland by Alfa, a Warsaw-based PR company. Alfa specialises in building communication strategies for companies and institutions in Poland as well as in effective external, internal and crisis communications. Our team has gained its experience working in large corporations and international PR agencies, and as reporters and editors who have published articles in over a dozen top Polish and international periodicals. In recent years, we’ve worked for such companies and associations as Novartis, MSD-Merck, Gilead Sciences, Glaxo Smith Kline, Sanofi Aventis and PhRMA.

Alfa co-founders and Managing Directors, Andrzej Kropiwnicki and Przemyslaw Barowicz have worked in PR and media since the early 1990s. Each has extensive communications experience having worked at and run a number of high-profile PR network agencies.

Andrzej has 15 years of media and PR counseling experience. He has led PR activities for such customers as inter alia, MSD, Novartis, PhRMA, Carolina Medical Center, GSK, Sanofi Aventis, Coca Cola, Goodyear, Deutsche Boerse and BlackRock. He is a skilled media crisis manager, spokesperson trainer and lecturer. As a journalist, he has published or edited articles for numerous periodicals, including the International Herald Tribune, Haaretz, Rzeczpospolita, Wprost, Playboy and Focus. He is a trained simultaneous interpreter of English and Russian. He is also the co-author of a series of books on the cultural heritage and background of a number of European and world countries.

Przemek has worked in public relations since 1997. Formerly the Managing Director of Alert Media Communications, he has prior agency and business communications experience at Burson-Marsteller, BCA/Edeleman PR Worldwide and Bank Pekao SA. He specialises in corporate and product communications strategy, crisis management and internal communications. His previous assignments included development of communication strategies and implementation of projects for Coca-Cola, Citibank, Deutsche Boerse, Goodyear, Kraft Foods, Pilkington, Polish Telecom and Unilever. He is a graduate of the Faculty of Journalism and Political Sciences at Warsaw University as well as of the MBA Program of the International School of Management.

Legal Disclaimer: All materials were prepared for the Global Guide by Dr. Ken Rabin prior to his being appointed senior consultant to Alfa Communications.
GLOBALHealthPR is represented in Portugal by Guess What PR, an innovative and global agency with extensive healthcare communications experience.

Always looking to provide the best PR services, Guess What PR mixes intelligence, imagination, creativity and innovation to execute campaigns for the pharmaceutical industry, advocacy groups and patient associations. Guess What PR’s strong and senior teams, composed of specialists and strategists with vast industry experience, share with enthusiasm the philosophy of ‘Guess What, how can we go further down the road?’ In order to present brilliant ideas and exceed client expectations, this Lisbon-based agency believes in innovation and downright hard work. In the evolving world of communications, it is more difficult to convince stakeholders to purchase a specific product or service. Guess What PR understands the basic characteristic for the pursuit of an efficient partnership relies on a continuous search for new tendencies and communication possibilities.

Guess What PR co-founders and Managing Partners, Jorge Azevedo and Renato Póvoas, launched their consultancy in 2008. Both obtained valuable communication experience at a number of high-profile PR network agencies in the healthcare arena. They met in 2003 at Weber Shandwick Portugal, and in 2004 they launched the first Portuguese PR company specialising in healthcare communications, MediaHealth® Portugal. ‘Guess what?’ one asked the other in 2008. ‘Let’s create an integrated company and go beyond what we have achieved’. And guess what? They are still doing it.

Before Guess What PR, Jorge founded and was the Executive Manager of MediaHealth® Portugal, the first Portuguese communications agency dedicated to the healthcare area. Previously, he had the opportunity to work as Account Manager of the Healthcare Department at Weber Shandwick and serve as a member of the Board of International HealthCare Group between 1999 and 2004. During this period, he worked on multiple projects for Pfizer, Lilly, Roche, Boheringer Inghelheim, Novartis and Schering Plough. He launched his healthcare communications career at Hill and Knowlton as a Senior Account. With a Post-Graduation in Companies Management, ISCTE–Lisbon, Jorge also teaches Media Relations at ETIC Communication School in Lisbon.

Prior to Guess What PR, Renato had a major role in the success of the country’s first healthcare-focused PR and communication agency, MediaHealth® Portugal. Renato successful implemented campaigns for clients such as Sanofi Pasteur, Abbott and Roche. He started his PR and communication career at the Portuguese communication INFORFI Consultores and then became Senior Account at Weber Shandwick. He has a Post-Graduation in Marketing Management from ISCTE–Lisbon.
Spain

GLOBALHealthPR is represented in Spain by Berbés, a health-only communications firm.

Berbés prides itself on providing accurate and reliable health information, enabling the public to make informed decisions while simultaneously ensuring that its innovative and successful client strategies will also provide benefits to the public’s health. Berbés’ commitment to excellence is its defining character and the reason why its clients value the agency so highly. In 2006, Berbés was awarded the I Prize PR Noticias for its performance as the best public relations agency in the healthcare sector. The prize, organised by Spain’s leading public relations e-magazine, is especially valuable to Berbés as it was awarded by the magazine’s readers.

Mary Sol Berbés Gutiérrez, Managing Director and Founder of Berbés, is a fully qualified health journalist with a wealth of communications and lobbying experience, including heading up a specialist health division of IBC (International Business Consultants) and running public relations for IAMER (International Mental Deficiency Research and Advice Institute). She is a founding partner of ANIS (National Health Informers Association) and a member of the Management Committee for Communications of various different pharmaceutical companies.

Juan Luis Recio Díaz, Executive Director, has been with Berbés since its inception. He has a wide-range of policy experience including several years as Head of Protocol of the Presidency of the Xunta of Galicia. He also has a varied journalistic and writing background, encompassing roles as author, editor and publisher, and he has published several of his own works. He is a keen supporter of new technology and runs his own blog about lifestyles and gastronomy at www.periodistadigital.com.
GLOBALHealthPR is represented in Turkey by OptimumBrand, a leading Istanbul-based agency with a special unit (OptimumHealth) dedicated to healthcare communications.

Founded 1996 in Istanbul, OptimumBrand shapes its services around three disciplines:
- Strategy
- Communication
- Interaction

OptimumBrand believes in the necessity of market research and the importance of intensive planning for enabling the right strategy and the right communication and interaction activities in order not to waste the precious resources of the company.

To identify itself with its clients’ brands OptimumBrand cares about understanding the general business strategies of its clients, digesting them and creating communication strategies in harmony. While communicating tactical decisions that are formed around these strategies, OptimumBrand puts special emphasis on interaction to increase the effectiveness of communications.

OptimumBrand has a ‘Client comes first’ principle with the following values:
- It considers its clients as ‘partners’, and their brands as one of its own;
- It appreciates that the brand is the most important ‘asset’ of the company;
- It offers a complete service, focusing on the picture in a holistic manner; and
- It gives as much importance to results by taking the responsibility to follow up.

Since it started, it has developed campaigns for different pharmaceutical companies like Merck Serono, New York Presbyterian Hospital, Houston Methodist Medical Center, Motus Wellness Center and Cellasene.

OptimumBrand was founded by Seyhan Ayel Girit. During her career, Seyhan has held management positions with reputable public relations firms within Turkey. She and her team assisted in leading foreign and local clients with strategic planning and marketing research and has dealt with all public relations and communication aspects, along with organisations. Besides her agency experience, she established and managed the Marketing Department of Emirates Airlines in Turkey before founding in 1996 OptimumBrand with her partners. She has been the General Manager of the company ever since. Seyhan is a member of IPRA (International Public Relations Associations) and HDD.
GLOBALHealthPR is represented in the United Kingdom by Aurora, a London-based healthcare and marketing communications agency.

Aurora is a multi-award winning agency made up of smart-thinking and motivated marketing communications experts. This team loves talking healthcare. Aurora delights in having happy clients and knows that great work is achieved in an environment of mutual respect: It’s more productive when it’s enjoyable.

Aurora cares about clients and the work it does for them. It has a team of experts specialising in media, digital, market access, medical education and branding.

Aurora co-founders and Managing Directors, Claire Eldridge and Neil Crump launched the consultancy in 2005. Each has extensive communications experience, having worked at and run a number of high-profile PR network agencies.

Seven years on, Aurora continues to go from strength to strength, delivering innovative campaigns for its clients. In 2012, Aurora was crowned Independent Consultancy of the Year at the prestigious Communiqué awards. The company also won the Excellence in UK Media Relations award on behalf of its client Novartis Pharmaceuticals. This was swiftly followed by success at the PM Digital awards when Aurora won the Gamification Award for its App, Sorted: the Daily Organiser, on behalf of Janssen.

To cap a glorious year, Neil and Claire have also been named Agency Heads of the Year at the celebrated Public Relations Consultants Association awards.
GLOBALHealthPR is chaired as well as represented in the United States by Spectrum, a health-only, science-based communications firm. Today, it takes more than innovation and discovery to bring medical care to people, and Spectrum is there for all stages of a product’s life cycle—from clinical trial recruitment to market preparation and launch. Spectrum’s public affairs experts help clients achieve change in overly restrictive public policies and broaden awareness of new access programmes to life-saving medicines on the state and federal levels. When it comes to helping organisations who advocate for improved understanding and awareness of disease, Spectrum understands the need to deliver.

Based in Washington, D.C., Spectrum ranks among the top health-only independent public relations firms in the United States. John Seng, Founder and President of Spectrum and Chair of GLOBALHealthPR, leads Spectrum’s staff of approximately 30 professionals who work on as many as 150 programmes for more than 30 national and international clients. Before Spectrum, John supervised marketing, corporate communications, media relations and product promotion activities for healthcare clients of major public relations agencies. He also managed national consumer media programmes and developed direct-to-consumer public relations programmes while at Pfizer Inc. in New York. John serves on the board of directors of the Progeria Research Foundation, the Council of Public Relations Firms and the Society for Women’s Health Research.
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Statista 2013

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United States of America

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