



International
Federation of
Pharmaceutical
Manufacturers &
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Issue Brief

Ensuring Ethical Promotion of Pharmaceutical Products: The IFPMA Code

Overview

Promotion of medicines, vaccines and biotech products is essential. It informs healthcare professionals about new treatment options, helping them to provide the most appropriate solutions for each of their patients. Secondly, it helps companies to obtain an adequate return on their sizeable R&D investment – during the limited period of market exclusivity granted by intellectual property rights – so that they can continue to invent new treatments.

The pharmaceutical industry has a moral obligation - above and beyond any legal requirements - to communicate health information with integrity, accuracy, clarity and completeness. Upholding these principles in communications with all stakeholders is vital. How the pharmaceutical industry regulates its communication and interaction with the healthcare professionals is perhaps the most critical application of this responsibility.

Establishing Self-Regulation with the IFPMA Code

Conceived in 1981, the IFPMA Code of Pharmaceutical Marketing Practices was the first international self-regulation mechanism in the pharmaceutical industry, preceding even the World Health Organization's (WHO) Ethical Criteria on Medicinal Drug Promotion, issued in 1988. The IFPMA Code has evolved into a self-regulatory instrument to govern the promotion of pharmaceutical products to healthcare professionals - including doctors, pharmacists and nurses. The IFPMA Code was born out of pharmaceutical companies' mindfulness that healthcare professionals' responsibility to their patients must be considered when promoting medicinal products.

The IFPMA Code is based on several core principles:

- *Basis of Interaction:* Relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine; interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.
- *Independence of Healthcare Professionals:* Healthcare professionals should not be influenced to prescribe, recommend, purchase, supply or administer a product because of any benefits offered (financial or otherwise).
- *Appropriate Use:* Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggeration.
- *Local regulations:* All relevant laws, local regulations and industry codes must be observed.
- *Transparency of Promotion:* All company-sponsored material relating to pharmaceutical products and their uses should clearly indicate by whom it has been sponsored; clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must be conducted with a primarily scientific or educational purpose.

The IFPMA Code serves as the basis of a flexible, self-regulatory structure. It allows for more detailed national codes that can impose additional requirements to address specific local concerns. This approach offers significant advantages. It ensures that all abiding companies are operating on a "level playing field," because there are often wide differences between countries' regulatory and legal systems governing pharmaceuticals. It can provide more complete and detailed guidance than might be offered by case law or regulatory requirements. It can be updated quickly to adapt to

new technology or the emergence of new areas of concern. Finally, it is more efficient and cost-effective than other alternatives.

Ensuring the Code Stays Relevant and Accessible

The IFPMA Code is a living document. It continues to be revised to coincide with evolving views on interactions between companies, health professionals and technology developments. Periodic revision helps to ensure that pharmaceutical marketing practices are seen to be ruled by the highest ethical standards. For instance, the Code was expanded in 2000 to address concerns about the increasing use of the Internet and the issues raised by this powerful new communications channel.

In that same spirit of timely adaptation and improvement, the latest version of the IFPMA Code was launched on 1st January 2007. It goes beyond previous versions of the Code, to place tighter restrictions on hospitality and gifts to healthcare professionals, including a ban on cash gifts, as well as setting limits on company sponsorship of international scientific events.

Great strides have been made to ensure that the Code is easily accessible and understandable to IFPMA members and stakeholders. The Code's language has been amended for greater clarity, including the addition of a Q&A that explains its principles and provisions. The complete Code document, an interactive training module and information on how to lodge a complaint when a breach of the Code is suspected are all available online at www.ifpma.org/ethicalpromotion. Additionally, anyone can report a potential breach of the Code directly to the IFPMA Secretariat by e-mail, via marketingcode@ifpma.org.

Applying and Enforcing the Code

The IFPMA Code applies to all pharmaceutical products, including prescription, generic and over-the-counter (OTC) medicines, that are promoted to healthcare professionals by member companies worldwide. Adherence to and compliance with the Code is a condition of IFPMA membership.

In the event of a conflict between the IFPMA Code and local laws or regulations, member associations must adopt codes that meet local requirements but are consistent with – and at least as comprehensive as – the IFPMA Code. For countries where there is no national code, the IFPMA Code supplies one.

Compliance is monitored and promoted by a Code Compliance Network (CCN), which gathers worldwide experts to discuss the latest developments and issues in the field of ethical promotion of medicines. The network's membership includes national industry association representatives and international compliance professionals working for member companies. By serving as a global forum for international experts and practitioners, the CCN facilitates the exchange of best practices and national experiences. More than 100 members of the network meet regularly to discuss latest developments and issues in the field of ethical promotion of medicines. Furthermore, the IFPMA has provided assistance to its members worldwide by organizing Code roll-out meetings and training sessions in all regions.

Alleged breaches of the IFPMA Code are investigated using a series of steps to ensure that a case is processed and resolved properly. Most cases fall under national codes, many of which require more than the IFPMA Code. In such cases, the relevant IFPMA member association will process and report on the case.

In some countries, local legal or regulatory processes come into effect. In circumstances where a national code body cannot adjudicate - for example, an alleged infraction in a developing country with no local IFPMA affiliated association - the IFPMA complaint procedure can be used by any party, including healthcare professionals and members of the public. The IFPMA complaint procedure provides adjudication and appeals.

In the event of any confirmed breach of Code, the IFPMA implements what is possibly the most effective sanction of all: making a public report on the IFPMA website, which will call into question the reputation of the company concerned.

Conclusion: Successes and the Way Forward

Some recent studies indicate the increasingly positive impact of the IFPMA Code. Familiarity and understanding of the Code has increased substantially, as Code training sessions have doubled

and the number of trainees more than tripled over a four-year period. There have also been notable decreases in breaches of Code-related conduct, regarding information accuracy, printed promotional materials, and industry-sponsored events.

But still more can be done to increase the impact of the Code and to promote a genuine level playing field in the marketing arena. For example, the generic pharmaceutical industry has no code regulating the promotion of its products. Dialog between a wide range of external parties – the general public, governments of developing and developed nations, healthcare professionals, and patient-focused non-profit groups – can help to build trust between the industry and stakeholders. Ongoing dialog will also help to guide the IFPMA in future revisions of its Code. This ensures that it remains relevant and effective in an evolving legal, regulatory and technological environment, and in the light of changing public expectations. In addition, engaging more closely with healthcare professionals and governments will encourage better scrutiny of the behavior of all players, including generic and national R&D pharmaceutical companies not currently governed by the Code.

All of this should help to build more trust and understanding amongst stakeholders. The IFPMA Code's most basic tenet is protecting the best interests of the patient – thereby making a strong industry contribution to a widely shared public goal.

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About the IFPMA:

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 26 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal (www.ifpma.org/ClinicalTrials), the IFPMA's Ethical Promotion online resource (www.ifpma.org/EthicalPromotion/) and its Health Partnerships information (www.ifpma.org/HealthPartnerships/) – Developing World) help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

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