

## **Ethics and compliance in global pharmaceutical industry marketing and promotion: The role of the IFPMA and self-regulation**

Brendan Shaw\* and Paige Whitney  
*IFPMA, Geneva, Switzerland*

Companies in many industries are engaging in a changing business environment where the community is expecting greater transparency and ethical standards than in the past. This has been for a variety of reasons associated with globalization, technological and social changes. The pharmaceutical industry is one industry where such issues are regularly under the spotlight. In this context the IFPMA works with its member companies and national associations to enhance the agenda of self-regulation and ethical behavior. The global IFPMA Code of Practice, and the many national industry association codes that implement it, have evolved over time to help the industry take the lead in driving greater ethical standards and transparency. This article will review the current international business literature on ethics generally, review the functions and evolution of the IFPMA Code of Practice and examine some of the more recent evidence and analysis of the role of pharmaceutical industry codes, ethics and reputation in the pharmaceutical industry.

Keywords: Ethics, compliance, pharmaceutical, codes, transparency

### **1. Introduction**

In response to a changing business environment, the pharmaceutical industry has made significant efforts toward ensuring compliant and ethical business practices in its marketing and promotion. These efforts have been directed at both to the industry's own operations and its interactions with other stakeholders in the health system, such as healthcare professionals, patients and patient organizations. Changing industry dynamics, new models of business, shifting regulation and legislation, and changing community expectations are all driving significant evolution in the self-regulation model of compliance and ethics of the pharmaceutical industry. This article examines the evolving landscape of industry self-regulation of marketing and promotion through different institutions and organizations, particularly focusing on the role of the International Federation of Pharmaceutical Manufacturers and Association's (IFPMA) in this evolution. The various pharmaceutical industry associations and companies that are members of IFPMA have also contributed to this evolutionary industry self-regulatory model. The efforts of the pharmaceutical industry over the

---

\*Corresponding author: Brendan Shaw, IFPMA, Geneva, Switzerland. E-mail: b.shaw@ifpma.org.

last few decades demonstrate the growing importance of self-regulation in marketing and promotion and the industry's emphasis on compliance resulting in sustained relations within the healthcare system. It is an example of industry self-regulation at work.

## **2. Current pressures for change in business ethics**

The pharmaceutical industry is not unique in facing an evolving ethical and regulatory environment. Many industries are facing increased calls for observance to greater ethical standards and be seen to be operating by those standards [1,2]. Businesses are facing greater scrutiny of their operations and business models are changing as community expectations are changing and because of globalization [3,4]. Factors influencing this growing push for a new ethical basis for business include globalization, greater community awareness of the impacts of business on social and environmental issues, the development of international agreements and organizational guidelines on ethics and rights, economic crises, and the growth of transparency generally with developments in technologies such as the internet and social media [5]. As the world is coming together, businesses are under more scrutiny now than ever. Moreover, there is a discussion in the international business literature whether the adoption of new ethical standards and engagement in corporate social responsibility is part of an emerging new view of global governance [6].

In response to these pressures, there have been a variety of international and national initiatives by business, governments and international organizations to develop principles, codes, frameworks, regulations and legislation to establish global ethical standards for business. For example, at the national level countries such as the United States and the United Kingdom have introduced recent legislation to address bribery and corruption that has jurisdiction over companies operating in other countries. At the international level, organizations such as the OECD and the United Nations have undertaken a range of initiatives to introduce global ethical business standards [7]. The OECD's instruments to enhance business ethics and the UN activities for business ethics improvement have both acknowledged current global trends in the pharmaceutical industry, indicating that there can be alignment between the interests of society and those of investors [8]. However, the aforementioned pressures and improvements suggest that regulatory environments and competition within the industry reinforce the importance of strong ethical governance [2].

## **3. Evolution of pharmaceutical industry codes and IFPMA's role**

In the pharmaceutical industry, trust and ethics are particularly important. As a key part of healthcare system, the ethical basis on which the companies in the industry interact with each part of the healthcare system takes on a special level of importance.

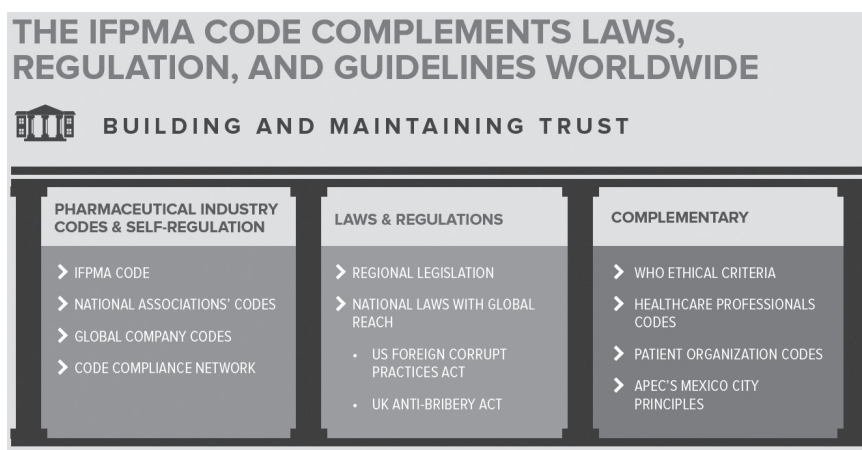


Fig. 1. Interaction between pharmaceutical industry codes and other regulations and guidelines [17].

Of particular importance is the relationship between companies and healthcare professionals and patients, and the way that the industry promotes and communicates to these stakeholders. As consumers become more enlightened and empowered to learn about the industry, many companies have developed their strategies to ensure a transparent relationship between industry and consumer. This has been part of a global effort on the part of the pharmaceutical industry, implemented at the company, national and international level.

The pharmaceutical industry has taken a range of efforts over the years to ensure ethical communication and interaction between healthcare professionals and patients [9]. These efforts have been designed to ensure that the information, where permitted, is balanced, accurate and centered on what is best for the patient. "In these interactions, it is essential that governments, the healthcare community and patients are confident that pharmaceutical companies, wherever they operate in the world, act in an ethical and professional manner [10]."

Since 1981 when it was first introduced, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)'s Code of Practice has served as a basis for the creation of national codes of conduct for pharmaceutical industries all over the world. Through this Code, together with the various national industry association codes around the world that implement it, the pharmaceutical industry has adopted a self-regulatory model of ethical compliance.

The IFPMA Code of Practice, together with national industry association codes, complements other regulations, laws and guidelines that together regulate the ethical compliance of the pharmaceutical industry. As can be seen in Fig. 1 industry codes of practice coincide with government legislation and regulation, such as the United States' Foreign Corrupt Practices Act and the United Kingdom's Bribery Act, as well as codes of practice for healthcare professionals, patients, and guidelines issued by organizations such as the World Health Organization (Fig. 1).

The IFPMA's Code of Practice is a model of self-regulation for pharmaceutical industry's activities in medicines promotion, communication and interaction with key stakeholders such as healthcare professionals, medical institutions and patient organizations. Although self-regulatory, the IFPMA Code is not voluntary. The Code is a condition of membership to the IFPMA for both member companies and national associations. By virtue of membership, all 30 pharmaceutical companies and 48 national associations of IFPMA are required to observe and implement the IFPMA Code. Often the national association codes contain more detail about what is required at the national level and are responsible for implementation of the more detailed code in their own country. Codes generally have compliance and enforcement mechanisms built into them as part of the system of ethical compliance. In many cases, companies' own compliance provisions go beyond the requirements of the IFPMA and national codes [9].

The most recent edition of the IFPMA Code of Practice covers the following areas of ethical interaction [10]:

- Basis of Interactions
- Pre-Approval Communications and Off-Label Use
- Standards of Promotional Information
- Printed Promotional Material
- Electronic Materials, including audiovisuals
- Interactions with Healthcare Professionals
- Samples
- Clinical Research and Transparency
- Support for Continuing Medical Education
- Interactions with Patient Organizations
- Company Procedures and Responsibilities
- Infringement, Complaints, and Enforcement

The IFPMA Code has been revised and updated on any number of occasions since its inception in 1981, as have the national industry association codes. For example, the 2012 revision of the IFPMA Code of Practice inserted new principles into the Code alongside the provisions in recognition of the fact that one code cannot anticipate all potential issues in all countries. The principles attempt to establish minimum standards for all codes and pharmaceutical industry ethical interaction around the world. The eight principles are:

1. The health-care and well-being of patients are the first priority for pharmaceutical companies
2. Pharmaceutical companies will conform to high standards of quality, safety, and efficacy as determined by regulatory authorities
3. Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate, and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence

4. Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products
5. Promotion must be ethical, accurate, balanced, and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use
6. Pharmaceutical companies will respect the privacy and personal information of patients
7. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry-sponsored clinical trials in patients, and
8. Pharmaceutical companies should adhere to applicable industry codes in both the spirit and the letter. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Similarly, revisions to the IFPMA Code of Practice over the last 10 years have led to new developments such as new restrictions on gifts and hospitality, updates to code complaint procedures, transparency, interactions with patient organizations, new provisions on continuing medical education and advisory boards, and requirements for company staff to be trained on code and compliance matters [10].

The current pressures on the pharmaceutical industry to improve ethics have enabled the industry codes to be more representative of sound business practices than laws or regulations. Industry codes can be proactively modified to reflect current needs and trends, and can directly address the criticisms or gaps in practices in a timely and efficient manner, arguably in a more timely and effective manner than other international regulatory efforts could achieve.

In addition to ongoing evolution of the IFPMA Code of Practice, other initiatives at the international level have helped bolster the global pharmaceutical industry's ethical framework. IFPMA has released reports for guidance to companies and national associations on topics such as sponsorship of meetings and events [11], and working with other global healthcare associations to release a Consensus Framework on Ethical Collaboration between Patient Organizations, Healthcare Professionals and the Pharmaceutical Industry [12]. This latter initiative is helping to encourage dialogue at the national level on ethics between various stakeholders groups in a number of countries. IFPMA also conducts capacity building activities in member countries and regions with industry staff and external stakeholders to build local knowledge and awareness of ethical standards, the IFPMA Code of Practice, and the importance of maintaining an ethical framework of business interaction more generally.

This capacity building work has included engagement with regional organizations, particularly the Asia-Pacific Economic Cooperation (APEC) forum. IFPMA has contributed to the establishment of The Mexico City Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector [12] which were agreed by APEC countries in 2011 and based on the IFPMA Code of Practice [13]. The agreement

and subsequent supporting work is designed to establish ethical business practices and codes of practice in pharmaceutical industries in APEC countries.

Of course, pharmaceutical companies themselves are developing more comprehensive internal ethics and compliance structures. The growth in internal compliance processes and teams within companies is another reflection of the growth in industry self-regulation [9,13].

#### **4. Impact**

The efforts by the global industry to develop and evolve its self-regulatory model of compliance are having an impact. The result of international collaboration on ethics and compliance initiatives has led to an international framework of self-regulation for the global pharmaceutical industry's marketing and promotion activities.

For example, many national codes have been updated and expanded over the last 10 to 20 years, both in developed and emerging markets. Code revisions at the national level occur periodically in various countries. One IFPMA survey found that most industry associations had completed a revision of their national code within the last few years of the survey [14]. Each of these expansions has aimed at building the industry's reputation and ensuring that industry codes are relevant to the evolving nature of health systems and community expectations. Whilst necessarily often going into more detail at the national level than the global code, the IFPMA Code of Practice provides a benchmark for these national codes. National associations have introduced variations in things such as reporting systems, pre-approval activities and complaint handling procedures [14].

There is also some evidence that industry self-regulatory activity is leading to improved ethical behavior. Data from a study of UK and Sweden self-regulation conducted from 2004–2012 reported that the number of complaints and cases ruled in breach of the code on a yearly basis decreased by an average of 5 cases per year for both countries [15]. Similar trends have been reported in Australia, where the number of annual code complaints has fallen significantly since the mid-2000s [16]. Whether these trends are primarily due to national codes per se, or a combination of codes together with national and international regulation is difficult to determine from the data. However, clearly the number of cases in this sample of countries has been falling, a reflection perhaps of the improving ethical behavior of the pharmaceutical industry.

Another example of the global industry impact can be seen through the results of the APEC-business ethics program. Since 2011, the Business Ethics for APEC SMEs Initiative enabled more than 1,000 individuals from approximately 650 organizations in the 21 APEC countries to participate in 13 initiative programs [18], establishing it as one of the largest ethics mentor networks in the Asia-Pacific region [19]. In 2015, APEC recorded that 60 biopharmaceutical associations had established new pharmaceutical codes of ethics, representing 14,000 companies in the region.

## 5. Conclusion

Trust and ethics are key to the pharmaceutical industry and the broader healthcare sector. Having comprehensive code compliance and business ethics frameworks for marketing and promotion, and being able to demonstrate these, are important to the pharmaceutical industry's reputation and its ability to provide patients with the care they need. With this in mind national and international institutions will continue to update their codes and expand their reach to the global audience.

The evolving ethical and compliance standards operating at the national and international level in the pharmaceutical industry are an example of the global evolution of international business ethics seen across many industries. The industry has adopted a self-regulatory model that has complemented and supported other initiatives in the regulatory or legislative space, as well as individual pharmaceutical company ethical programs.

The industry's efforts to upgrade and develop its ethical and compliance framework, such as the activities of the IFPMA and its member associations and companies, are an example of the broader trend towards greater business ethical frameworks across all business sectors.

## References

- [1] International Business Ethics Institute, *Codes of Ethics*, 2016. <http://business-ethics.org/>.
- [2] G. Dubcova, *Actual Trends in Theory and in Practice of the International Business Ethics*, Research project for Grant Agency in the Slovak Republic, pp. 1–12.
- [3] M. Kaptein, "The battle for business ethics: A struggle theory," *Journal of Business Ethics*, 2015, 3.
- [4] A. Crane and D. Matten, Managing Corporate Citizenship and Sustainability in the Age of Globalization, *Business Ethics*, Oxford University Press, 3<sup>rd</sup> ed., 2010, pp. 20–24.
- [5] W. Cragg, Ethics, globalization and the phenomenon of self-regulation: an introduction, *Ethics codes, corporations and the challenge of globalization*, 2005, pp. 1–19.
- [6] A. Scherer, G. Palazzo and H. Trittin, The Changing Role of Business in Global Society: Implications for Governance, Democracy, and the Theory of the Firm, *Transnational Corporations and Transnational Governance*, 2015, pp. 355–387.
- [7] OECD, *Key Activities*, in Secretary-General's Report to Ministers, 2015, pp. 50–61.
- [8] A. Smith-Meyer, Business Compliance: Governance-Compliance-Ethics, *OECD*, 2015, pp. 3–20.
- [9] J. Francer et al., Ethical pharmaceutical promotion and communications worldwide: codes and regulations, *Philosophy, Ethics, and Humanities in Medicine*, 9: 7, BioMed Central Ltd. 2014, pp. 1–17.
- [10] IFPMA, *IFPMA Code of Practice*, 2012, pp. 1–24.
- [11] IFPMA, *Note for Guidance on Sponsorship of Events and Meetings*, 2014, pp. 1–3.
- [12] IFPMA, Consensus Framework for Ethical Collaboration between Patients' Organizations, Healthcare Professionals and the Pharmaceutical Industry, *International Alliance of Patient Organizations, International Council of Nurses, International Federation of Pharmaceutical Manufacturers and Associations, International Pharmaceutical Federation, World Medical Association. 2014. Consensus Framework on Ethical Collaboration between Patient Organizations, Healthcare Professionals and the Pharmaceutical Industry*, 2014, pp. 1–4.
- [13] J.M. Logsdon and D. Wood, Global Business Citizenship and Voluntary Codes of Ethical Conduct, *Journal of Business Ethics*, 2005, p. 55.

- [14] IFPMA, *Code Compliance Network (CCN) Global Code Comparison*, 2012, pp. 4–11.
- [15] A.V. Yetterqvist, J. Merlo and S. Mulinari, Complaints, Complainants, and Rulings Drug Promotion in the United Kingdom and Sweden 2004–2012: A Quantitative and Qualitative Study of Pharmaceutical Industry Self-Regulation, *PLOS Medicine*, 2015, p. 3.
- [16] Medicines Australia, Code of Conduct Annual Reports, various years, *Medicines Australia*, <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/annual-reports/>.
- [17] IFPMA, Health and trust in the innovative pharmaceutical industry, *IFPMA Infographic*, 2014.
- [18] APEC, Business Ethics for APEC SMEs Initiative: Overview, June 2016, pp. 1–2. <http://mcprinciples.apec.org/CMFiles/Resources%202015/GeneralOverview.pdf>.
- [19] APEC, Enhancing SME Business Ethics in the Healthcare Industry, 26 June 2014, [http://www.apec.org/Press/Features/2014/0626\\_ethics.aspx](http://www.apec.org/Press/Features/2014/0626_ethics.aspx).