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New International Pharmaceutical Practice Code Tightens Restrictions on Gifts

Introduction

On January 1, 2019, the revised [Code of Practice](#) issued by the International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)) went into effect. Among the most consequential revisions to the Code, which is binding on all member companies and associations wherever they operate, is a blanket prohibition on gifts provided to health care professionals (HCPs). Cultural courtesy gifts (such as mooncakes or condolence payments), as well as non-monetary promotional aids and reminder items for prescription-based medicines (branded Post-its, mouse pads, etc.), where previously permitted, are now banned. This brings the global IFPMA Code in line with similar prohibitions already in effect in Europe and the United States.

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In the medical device industry, [AdvaMed](#), a global trade organization for medical technology companies, recently announced changes to their own Code of Ethics on Interactions with U.S. Health Care Professionals, which will go into effect in 2020.¹ Among other revisions, these changes revise the Code's gift policy to clarify that member companies are not permitted to provide gifts to HCPs even in recognition of life events, including funerals. While the AdvaMed Code currently only applies to interactions with U.S. HCPs, if past changes are any indicator, these changes will likely be rolled out to other geographies in the coming years. A recent example of this phenomenon can be seen in the global phase-out of direct sponsorship of HCPs for their attendance at conferences and events. In the United States, this practice was first [banned](#) by AdvaMed and PhRMA (AdvaMed's counterpart in the pharmaceutical industry) in 2009, beginning years of discussion in other jurisdictions. Finally, prohibitions on direct sponsorship were rolled out in early 2018 by medical technology trade associations across the world, acting in coordination with and following the lead of the United States. Direct sponsorship has now been [phased out](#) in the AdvaMed China Code, the MedTech Europe Code, the Mecomed Code (regulating the Middle East and North Africa), and the APACMed Code (regulating the Asia-Pacific region).

These changes are all part of a larger trend towards hostility to any type of gifts to HCPs within the life sciences industry more broadly. Indeed, there have been recent media reports of major pharmaceutical companies updating their global gifts policies to ban all gifts to HCPs. This article will provide an overview of these changes. We also discuss various compliance risks associated with the changes, in light of both the IFPMA and AdvaMed Codes and within the broader regulatory environment. Lastly, we will review recent cases brought under the United States Foreign Corrupt Practices Act (FCPA) against life sciences companies in connection with gifts given to HCPs to further illustrate the compliance challenges facing the industry.

The 2019 IFPMA Code Changes and Global Effects

Background of IFPMA

The pharmaceutical industry is highly regulated, and the regulatory regimes are often complex and overlapping. Companies are generally subject to both the public laws and regulations of the states in which they operate, and self-regulation through trade associations such as IFPMA. One of IFPMA's objectives is to provide integration and

¹ Ropes & Gray has prepared an [in-depth review](#) of the new AdvaMed Code.



leadership to the many national and regional pharmaceutical industry trade associations, each of which typically has its own local code of conduct and mechanisms for administering complaints and violations. At least 50 national and regional associations are members of IFPMA, including EFPIA (Europe), PhRMA (United States), RDPAC (China), and AMIIF (Mexico). The 2019 revisions to IFPMA’s code of conduct are binding on all of these member associations, and their own local codes of conduct must meet IFPMA’s global minimum requirements.

Overview of Changes to New 2019 IFPMA Code of Practice

The previous version of the IFPMA Code, which was issued in 2012, prohibited gifts for the personal benefit of HCPs, but explicitly allowed promotional aids and stated in its Q&A section that social courtesy gifts such as those for significant “national, cultural or religious events” could be acceptable. With the explicit ban on social courtesy gifts and the removal of the provision for promotional aids when they are in connection with prescription drugs, the IFPMA brings its global 2019 Code more in line with the stricter guidelines already imposed by some of its member organizations on a regional or national level. IFPMA specifically cites the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) codes as early leaders in the increased regulation of gifts to HCPs.

The first key update to the gift-giving provisions in the 2019 Code is the addition of “social courtesy gifts” to the list of items considered improper gifts for the personal benefit of HCPs. In a supplemental Q&A provided by IFPMA to accompany the new Code, it [states](#) “[N]ow IFPMA members are banning any exceptions like customary gifts for significant national, cultural or religious events (for example mooncakes or condolence payments).”

The second new gift-giving [provision](#) is a broad prohibition on giving HCPs promotional aids (a non-monetary item given for a promotional purpose) related to prescription-only medicines. This includes Post-its, calendars, diaries, and any similar “reminder” items with company or product logos. This breaks from the previous 2012 Code, which permitted promotional aids for prescription-only medicines as long as they were relevant to the HCP’s practice. The only narrow exception to this ban in the 2019 Code is for pens and notepads provided at company-organized events, solely for note-taking purposes. Even these materials, however, must be of the minimum value and quantity for their note-taking purpose.

The new promotional aid restrictions are intended to avoid any perception of undue influence from the pharmaceutical industry on HCP prescribing decisions, and the IFPMA states that these changes are necessary to keep pace with society’s evolving and increasingly high expectations regarding the industry’s interactions with HCPs. Because of the emphasis on HCP prescribing decisions, the 2019 Code continues to allow providing promotional aids of minimal value and quantity to HCPs when the aids relate to over-the-counter medicines, provided that they are relevant to the HCP’s practice.

The 2019 IFPMA Code also includes a new “Ethos,” which replaces the “Guiding Principles” of the previous Code. The [stated goal](#) of the new Ethos is to “shift from a rules-based approach to a Code based on values and above all, patients’ trust.” Rather than a list of numbered principles, the new Ethos is represented graphically in a chart, with “Trust” at the center supported by IFPMA’s other fundamental values, including honesty, care, fairness, and respect. The IFPMA [intends](#) this emphasis on patient trust to result in better business behaviors between its members and HCPs.

Case Study: Chinese RDPAC Changes in Relation to IFPMA Code

As many national trade associations have done, China’s R&D-based Pharmaceutical Association Committee (“RDPAC”) has consistently changed its code over the years to follow the IFPMA Code. A review of changes over

recent years serves to illustrate how the IFPMA Code guides the creation of national codes, while national codes may sometimes impose stricter requirements than the IFPMA Code itself.

- In 2012, IFPMA issued the previous version of its Code, which remained current until the present version in 2019. RDPAC amended its own code in 2012 as well, substantially adopting the new IFPMA requirements.
- RDPAC then revised its own code again in 2015, although no new IFPMA code had been issued. These changes included a [prohibition](#) on the giving of cultural gifts (“风俗礼品”; which is the same Chinese word later used to translate “social courtesy gifts” in the 2019 IFPMA Code) to HCPs. This change was above and beyond what IFPMA required at the time.
- In 2017, RDPAC again revised its code without changes to the gift-giving provisions.
- In late 2018, RDPAC [announced](#) that it had again issued a new Code, incorporating the changes to the 2019 IFPMA Code. The 2019 RDPAC Code is not yet available online at this time, but will presumably include updates reflecting the new IFPMA Code’s prohibition on prescription drug promotional aids and maintain its cultural gift ban.

Compliance Risks Associated With New IFPMA Code

The impact these changes to the IFPMA Code will have from a compliance perspective merits careful consideration. As a trade association, IFPMA’s Code is self-regulatory “soft law” rather than state-enacted law, which would have corresponding investigative and enforcement bodies. While IFPMA does provide a [limited process](#) for hearing complaints, adjudicating disputes, and publishing opinions concerning its Code, its enforcement capability is limited. National IFPMA member organizations, for their part, often have their own [complaint and enforcement processes](#). The practical result of this is that, while all IFPMA members and their affiliates are now subject to the cultural courtesy gift and prescription medication promotional aid bans, the full range of self-regulatory requirements and enforcement mechanisms will continue to differ country to country.

Additionally, it is not always clear how much bite the new Code and the updated national codes have in practice. For instance, as discussed above, China’s IFPMA-affiliated industry group RDPAC [implemented a ban](#) on cultural gifts (“风俗礼品”) as early as 2015. However, the practice of giving gifts to doctors, including mooncakes, appears to have continued largely unchanged. For instance, it was reported in Chinese media that in September 2018, one Guangdong doctor received gifts valued at RMB 100,000 (\$14,700 USD) in observance of the 2018 Mid-Autumn Festival, when mooncakes are traditionally given ([link in Chinese](#)). The degree to which compliance in China may change, in light of the new 2019 RDPAC code and Chinese press attention surrounding IFPMA’s new focus on cultural courtesy gifts, remains to be seen. The recent changes to the IFPMA Code have received coverage in Chinese press, in part because the IFPMA Code explicitly highlights the giving of mooncakes as being inconsistent with its new rules ([link in Chinese](#)).

But while non-compliance with the IFPMA Code may not necessarily lead to sanctions from IFPMA or national member associations, as suggested by China’s example above, some conduct prohibited by the Code is also prohibited by a wide variety of local and international laws and regulations, depending on where the companies operate. Some of these laws are vigorously enforced by government regulators. For instance, interactions between pharmaceutical R&D companies and HCPs may be subject to more generalized national bribery and corruption

legislation, including the U.S. Foreign Corrupt Practices Act (FCPA) and the U.K. Bribery Act, as well as local laws such as South Korea's Kim Young-ran Act or Brazil's Clean Companies Act.

Specifically, anti-bribery legislation has potential application to the giving of gifts to HCPs; these acts criminalize (among other behavior) the giving of cash or gifts to foreign government officials intended to influence them or improperly secure business. In countries with state-run health systems, including China and various countries throughout Europe and South America, HCPs often qualify as foreign government officials. This has led to criminal enforcement and millions of dollars in penalties for numerous pay-to-prescribe schemes in the recent past, discussed below. Understanding the differences and overlap between the cultural courtesy gift ban under the IFPMA Code and anti-bribery legislation is an important part of managing risk for pharmaceutical companies. Key distinctions to highlight are whether the HCPs can be classified as foreign officials, and whether the gifts in question were made with the intent of influencing prescribing decisions or securing future business. While neither of these determinations matter under the IFPMA Code, which prohibits any gift by a pharmaceutical company to any HCP, regardless of intent and regardless of the nature of the countries' health care system, these distinctions remain hugely important for anti-corruption enforcement. Member companies should consult with their legal counsel, including competent local counsel, to address individual compliance and enforcement risk at this level.

Beyond direct enforcement risk, failing to comply with the new changes can lead to other types of risk. IFPMA is a leader in the pharmaceutical field, and part of its function is to set norms and expectations within the industry; failing to meet these norms creates reputational risks, and invites scrutiny from other actors, including the media and government regulatory bodies.

Case Studies and Compliance Challenges

By prohibiting "cultural courtesy gifts," IFPMA is specifically targeting customs that are common business practices in certain parts of the world, but that may create the appearance of a bribe, conflict of interest, or improper influence when viewed outside of their cultural context (regardless of the intent behind the gift). This is in line with the IFPMA Ethos, also new to the [2019 Code](#), which "aims to shift from a rules-based to a values-based code." It will also be challenging to implement for companies operating in regions where the giving of mooncakes and condolence payments remains a common practice. Even before these more stringent changes to the IFPMA Code were put into effect, many major pharmaceutical companies failed to prevent payments and gifts that amounted to bribes under the FCPA and other anti-corruption statutes, and faced enforcement actions and large penalties as a result.

As recently as September 2018, Charles Cain—FCPA Unit Chief of the SEC Enforcement Division—remarked on the prevalence of pay-to-prescribe bribery in the pharmaceutical industry, and [indicated](#) that scrutiny and enforcement would continue: "While bribery risk can impact any industry...more work needs to be done to address the particular risks posed in the pharmaceutical industry."

A sample of recent FCPA cases demonstrates that bribes given to HCPs remain a huge compliance risk for life sciences companies throughout the world, especially in China: [Orthofix](#) (2017, Brazil); [AstraZeneca](#) (2016, China and Russia); [Novartis](#) (2016, China); [Bristol Myers Squibb](#) (2015, China). IFPMA and AdvaMed member corporations clearly face significant risk in this area; each of the companies listed above is a member of its respective trade association. These and similar FCPA cases have resulted in hundred of millions of dollars in penalties. Scrutiny is only expected to increase in light of IFPMA's new Code.

Companies that are members of any IFPMA-affiliated trade group are well advised to carefully scrutinize their own gift policies and internal controls, and consider how they will comply with these new, stricter rules. Those companies

doing business in regions where cultural courtesy gifts are commonplace, including China, South Korea, Vietnam, Japan, and many other parts of Asia, should do so with particular care.