

# Additional Questions to IFPMA Code of Practice 2019 / **Practical examples**

## Preamble

The purpose of this document is to provide additional interpretation and further guidance towards the relevant provisions of the Code of Practice. This document is not binding by itself. It holds practical examples and guidance that must be read with the spirit of our Ethos and the Code in mind. IFPMA member companies and member associations are encouraged to take into account the considerations given in this document when implementing the IFPMA Code of Practice in their daily practice and use it as internal tool.

### **1. Does the IFPMA Code apply to the promotion and marketing of over-the-counter (OTC) products that may also be prescribed by healthcare professionals (HCPs)?**

Yes, the IFPMA Code applies to the promotion of over-the-counter (OTC) products directed towards healthcare professionals. However, OTC products when promoted to the general public fall outside the scope of this Code.

There are three groups of products:

- Prescription-only products: in scope
- OTC products that are promoted towards HCPs: in scope
- OTC products that are not promoted towards HCPs: out of scope

*Please check Q&A 2.2 and Q&A 4.2 of IFPMA Code.*

### **2. Do non-medicines such as dietary supplements/nutritional products and cosmetics fall under the scope of the IFPMA Code?**

No. The IFPMA Code applies to pharmaceutical products. (Art. 1.2). Only OTC that are promoted towards HCPs are covered.

*Please check Q&A 2.2 and Q&A 4.1 of IFPMA Code.*

### **3. Why did IFPMA decide to include a global ban on gifts and promotional aids related to prescription-only medicines?**

A survey amongst IFPMA member companies showed that this change is wanted by the R&D pharmaceutical industry and it is its aligned way of thinking and doing business. The provisions on Gifts and Other Items were outdated and did not reflect the current values of the industry. In particular, the language on Promotional Aids (Article 7.5.2) was out of step with society's expectations of the pharmaceutical industry, and members strongly supported the prohibition to be able to meet these ethical expectations about the appropriate behavior of our companies.

PhRMA and EFPIA had already banned promotional aids in their code revisions, in 2009 and 2013 respectively. Their rationale was that these items do not advance disease or treatment education — even if they are practice-related items of minimal value (such as post-its, mouse pads, calendars, plasters, bags or binders and similar “reminder” items with company or product logo).

The industry places great reliance on its professional relationships with HCPs leading to society's confidence that optimal patient care is ensured. Promotional aids send the wrong message, as they trivialize the important, professional relationship that must exist between medical representatives and healthcare professionals. This relationship is based on a mutual exchange where both sides win by

sharing expertise and scientific knowledge, enabling the development and effective use of new medicines and vaccines.

- 4. If a company has an educational tool for patients (whether given directly to patients or through HCP), can they put their company or product name on such material?**

There is a specific section in the Code on informational or educational items (Art. 7.5.3). These educational tools can only be branded with the company name (not product name), unless the product's name is essential for the correct use of the item by the patient.

- 5. According to the new IFPMA Code (Q&A14) a company is allowed to provide pens and notepads at company organized events. If there is a document to be distributed, can the company provide plastic folders with company name or product name on the plastic folder for the purpose of holding the document? Will this folder be considered a promotional aid?**

There are no other exceptions related to promotional aids, apart from pens and notepads in order to take notes during the meeting. IFPMA does not allow company or product branded bags, binders or plastic folders to carry documents at a congress, as these clearly qualify as promotional aids. If there is a need for a "technical solution" to distribute a bunch of documents, it is up to each company to take the right decision depending on the number of documents: using binding rings, a paper clip or a USB key loaded with the documents.

*Please check Art. 7.5 and Q&A 14 of IFPMA Code.*

- 6. At company organized events, can industry provide branded paper or plastic bags to HCPs to not drop the promotional brochures on the way home?**

As in question 5 such item would be considered as a non-permitted promotional aid.

*Please check Art. 7.5 and Q&A 14 of IFPMA Code.*

- 7. In the cases where company branding is allowed, could it include a reference to the therapeutic area, for example "COMPANY NAME – Oncology"?**

According to the IFPMA Code this would be acceptable as the therapeutic area is not a product name. However, there may be national laws and regulations that define this differently and consider that there is a connection with the product.

- 8. There are regions where HCPs and HCOs should have certain items for their daily practice, but they don't due to lack of resources. Would it be possible to give this type of basic medical utility items considering the low level of healthcare infrastructure, e.g. stethoscopes only to HCPs working in underserved areas?**

No, these items should be provided by their employers. The only way would be to provide such items in form of a donation to the HCO and not to the individual HCP. The aim of the prohibition is to avoid personal use of the item by the HCP or potential undue influence.

**9. Is it acceptable to provide at company organized events beverages (coffee or water) and snacks (cookie or candy) to participating HCPs?**

The Code regulates this topic in its article 7.1.5 which establishes the limits of hospitality at events, indicating that refreshments or meals should be provided exclusively to participants of the event, and should be moderate and reasonable as judged by local standards. So, in this case it is the local association who should establish if a cookie or candy is moderate and reasonable.

**10. During a 3rd party congress, would paper coffee mugs, napkins, sugar sachets at the company booth be considered a gift? Could those be company branded?**

Depending on local regulation, single-use, disposable tableware can be company branded for use at a 3rd party event company booth. Product branding is not allowed. Please make sure to follow the guidelines of the national association as to which refreshments may be served in them.

**11. Is the restriction of providing promotional items to HCPs applicable to medical devices?**

No, it only applies to prescription-only medicines or in the context of an activity, congress or meeting related with prescription-only medicines.

**12. Can pens and notepads still be provided to HCPs to take notes during interactions that take place outside the context of events?**

No, it is not allowed to offer or provide pens and notepads outside the context of a company organized event, except when solely related to the promotion of OTC products.

*Please check section 7.5.1.2 and Q&A 14 of IFPMA Code.*

**13. There could be situations where the same HCP will be called on by an OTC sales representative and a prescription-only medicines sales representative. In one case, the HCP might be given a promotional aid, in the other case not. How can companies avoid confusion at HCP level?**

If the sales representatives are two different employees, the OTC sales representative can provide promotional aids to the HCP whilst the prescription-only medicines sales representative cannot. If – as a general rule and to avoid confusion in the market place – it is one and the same employee visiting the HCP, he/she cannot provide any promotional aids as he/she also represents the prescription-based products. However, there might be situations (e.g. smaller countries or lacking company staff resources in a given market) where there is only one sales representative who has to deal with both OTC and prescription-only medicines for a specific region. Here, the local IFPMA member association may issue further guidelines following the spirit of the recent changes to the IFPMA Code. At least, there should be an appropriate separation between OTC and prescription-only medicines, e.g. by promoting the products during two different visits.

**14. Can a memory stick preloaded with educational data be of a fancy design that resembles the product, i.e. inhaler/bottle?**

No, a fancy designed memory stick with a resemblance to the product would qualify as a gift.

15. In instances where value guidance is not provided by the local industry association(s), where the local industry association is not an IFPMA member, or where there is no local industry association, should companies determine their own values (for 'minimal', 'modest' and 'reasonable')?

Yes, a company should use its good ethical judgment and in such cases benchmark against neighboring countries with a similar cost of life where the local industry association has set a value guidance.

16. Do the principles related to items of medical utility apply to clinical trials as well?

For clinical trials this is in general not the case, since the purpose is different. The items might be in most cases an essential part of the trial, provided it is carried out in the prescribed manner. The items covered in Q&A 15 are items of medical utility used in the normal business practice of HCPs. Therefore, they should be considered as expenses to the practice and supplied by HCPs or their employers. Not covered are more specialized items provided in the context of clinical trials (e.g. a special diagnostic testing equipment). These items are not considered as routine business expenses and as such could still be supplied by pharma companies to the institution (hospital, clinic etc.) if needed in the clinical trial with the understanding that it is a legitimate payment for the clinical trial set out in the agreement and appropriately accounted for in the financial arrangement.

17. Is IFPMA expecting its members to adopt the Ethos in their codes "verbatim"?

The Ethos is intended to illustrate the spirit of the Code and to give members context in situations where no specific provisions of the Code apply. It underpins the provisions and provides overarching principles to consider for situations not addressed in the Code. We want to create a common language on values and principles that is shared by all members and therefore we do expect a public embracement of the Ethos (e.g. statement/link on the website).