

## *Guidelines no. 5 to the Pharma Code<sup>1</sup>*

### Practice regarding the ban on gifts

#### Background

In 2014 already, the pharmaceutical industry agreed to implement a comprehensive ban on gifts, which was tightened further in 2015. This ban on gifts makes provision for very few exceptions only. The following guidelines are based on the practice that has developed over the past few years.

#### Recommendations

Sections 15.1 and 15.2 Pharma Code (PC) apply a strict ban on gifts which covers tangible as well as intangible benefits. Consequently, the ban on gifts covers all kinds of benefits and items, unless they are explicitly exempt from this ban. The following are exempt pursuant to Section 15.3 PC:

1. Objects, information and training materials of modest value as defined by section 13.8 of this Code (maximum CHF 300 per healthcare professional and year) provided for healthcare professionals that are intended solely for a medical or pharmaceutical activity or are used for post-graduate or continuing education in medicine or pharmacy and which, in both cases, are also beneficial to patients; these items can include the company name, but may not be product branded;
2. Writing implements and pads of modest value, made available to participants at events by pharmaceutical companies; these writing implements, and pads may not bear any references to the pharmaceutical company or to particular medicinal products;
3. Financial contributions to support research, postgraduate medical training and continuing medical education, provided that the criteria set out in this Code are fulfilled;
4. Appropriate compensation for contributions of equal value, in particular price discounts or rebates on orders, deliveries and purchases of medicinal products, provided that they have no influence on the choice of treatment;
5. Delivery of free of charge samples of medicinal products to healthcare professionals.

The laws and regulations applicable in this context as well as their enforcement by the authorities are reserved. Art. 55 of the Therapeutic Products Act (TPA) in particular as well as the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (VITH) and further information of the Federal Office of Public Health (FOPH) on the latter, such as the explanatory report, should be mentioned in particular<sup>2</sup>. In accordance with Art. 3 VITH, **a maximum of CHF 300 per enterprise, healthcare professional and year applies. This upper limit has now been explicitly adopted in the most recent revision of the Code, after this limit had previously "only" applied via the practice recommendation.**

Concerning Section 15.3.1 PC, the following practice has been established as regards the items, information and training materials of modest value that may still be issued while respecting the ban on gifts:

<sup>1</sup> This recommendation also applies to Sections 15.1 to 15.3 PCC

<sup>2</sup> <https://www.bag.admin.ch/bag/de/home/gesetze-und-bewilligungen/gesuche-bewilligungen/itw-geldwerte-anreize/faq-itw.html>

\* PC: Pharma Code; PCC: Pharma Cooperation Code

Section 15.3.1 PC excludes specific items, information and training materials of modest value from the ban on gifts if they are **exclusively intended for medical or pharmaceutical activity** or serve to promote medical or pharmaceutical further and advanced training and, in both cases, are **of benefit for patients**. In the interpretation of this Section, general reference must be made to the **comprehensive understanding of the ban on gifts** pursuant to the IFPMA Code of Practice 2019 as well as the EFPIA Code of Practice. In addition, the term "exclusively" used in the PC means that items of all kinds that can also be used for purposes other than the stated medical or pharmaceutical purposes are also covered by the ban on gifts. Therefore, only those items and resources which are typical and standard for use in medical practice are permitted. **By contrast, any items which are not intended and suitable "exclusively for medical or pharmaceutical activity" are not permitted.** These items must also always be of benefit for patients.

With a view to all these guidelines, the **following items, information and training materials can be issued:**

1. Medical textbooks;
2. Anatomical models;
3. Explanations in animated form (e.g. of an effect mechanism or the application of a medicinal product which the doctor can use in patient consultations) contained on a storage medium such as a USB memory stick; in this context, the scope of the presentation should be no greater than necessary;
4. Consumables for dispensing to patients such as individually packed pre-injection swabs;
5. Materials that promote patient compliance, such as pill boxes and dispensers, reminder aids (including in electronic form);
6. Brochures or other information material about a disease, its effects and treatment, which are issued to patients via the doctor;
7. Training materials for self-injections or inhalations, without any active substances.

**Non-permitted items which are clearly covered by the ban on gifts are:**

1. Consumables which the doctor has to purchase in any event, such as stethoscopes, injection material, gloves, etc.
2. Office material of any kind, such as diaries, calendars, post-it notes, desk pads, etc.;
3. Electronic devices and accessories such as notebooks, tablets, smartphones, printer cartridges, etc.

**IN CONCLUSION:** The exemptions under Section 15.3.1 PC must be subject to strict interpretation and consequently these only cover relatively few items, information and training materials. This also applies regardless of any more generous practice of the FOPH with regard to Art. 3 VITH.

Since the introduction of the ban on gifts, it is an explicit request of the international pharmaceutical associations and the Code Commission to achieve a comprehensive application of this ban. To ensure that this ban cannot be easily evaded, the **scope of personal application is comprehensive**. The ban on gifts applies to **all healthcare professionals** (such as doctors, chemists, druggists, etc.) as well as **all representatives of healthcare and patient organisations** and **all support personnel**, regardless whether they qualify as healthcare professionals in a legal sense or not.

In this context, it is also worth mentioning that allowances for meals are only permissible within the framework of expert discussions and thus as a substitute fee for the provision of a service in return (cf. Art. 7 VITH). However, these may not be given as a gift, i.e. they may not be paid separately from any consideration. In order to clarify this in the PC, the guidelines for meals were no longer regulated as an exception to the ban on gifts, but as an independent integrity regulation.

At the same time, the maximum limit was reduced to CHF 100 (cf. Section 15.4 PC), making self-regulation stricter than the law. The latter also allows this amount to be exceeded, but then requires a written agreement. In addition, self-regulation stipulates that this maximum rate must also be applied to catering during events, a requirement that is not provided for in the law.

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