PC and PCC practice*



Guidelines no. 6 to the Pharma Code¹

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.

Guidelines

Section 142 Pharma Code (PC²) applies 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 143 PC:

- 1. The customary remuneration for healthcare professionals in connection with orders and deliveries of medicinal products;
- 2. Deliveries free of charge of medicinal product samples to healthcare professionals (within the framework of the Swissmedic guidelines);
- Items, information and training materials of modest value which are intended exclusively for healthcare professionals and for medical or pharmaceutical further and advanced training and which, in both cases, are also of benefit for patients (this category of exemption is examined in detail below);
- 4. Writing implements or folders of modest value provided by pharmaceutical companies to participants at events; these writing implements and folders may not bear the name of the pharmaceutical company or any specific medicinal products.
- 5. Finally, pharmaceutical companies can pay for meals (including beverages) of an appropriately modest value for healthcare professionals. The figure of CHF 150 per healthcare professional per meal applies as the maximum. Since all rules on exemptions relating to the principles of integrity state the modest value as a guideline, spending on meals should also remain below the aforementioned maximum limit.

The laws and regulations applicable in this context as well as their enforcement by the authorities are reserved. Special mention should also be made here of the following Swissmedic communication dated 15/01/2006: "With reference to the ban on the promise and acceptance of pecuniary benefits in accordance with Article 33 of the Therapeutic Products Act in particular in connection with support for further and advanced training for medical persons from the pharmaceutical industry"³. According to this communication (cf. Section IV.3.2.a and c), a maximum of CHF 300 per enterprise, healthcare professional and year applies analogously to the ban on gifts in the context of Section 143.3 PC.

¹ https://en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code

² These guidelines also apply to the implementation of Section 142 et seq. of the Pharma Cooperation Code (PCC)

³ https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/advertising-of-medicinal-products/promises-and-acceptance-of-material-benefits.html

^{*} PC: Pharma Code; PCC: Pharma Cooperation Code

Concerning Section 143.3 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:

Section 143.3 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 relevant provisions of the EFPIA Code. 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 still be issued:**

- 1. Medical textbooks;
- 2. Anatomical models;
- 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 143.3 PC must be subject to strict interpretation and consequently these only cover relatively few items, information and training materials.

Since its introduction, the international pharmaceutical associations as well as the Code Commission intended to achieve a comprehensive application of the ban on gifts. To ensure that this ban cannot be easily evaded, the **scope of personal application is comprehensive**. Thus 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 auxiliary and support personnel**, regardless whether they qualify as healthcare professionals in a strict legal sense.

PC Sections that have to be observed in this context

14 Integrity principles

- 141 Where pharmaceutical companies cooperate with healthcare professionals or healthcare organisations, such cooperation and the pecuniary benefits granted in return must not constitute an inducement to recommend, prescribe, acquire, supply, sell or administer specific medicinal products for humans.
- Pharmaceutical companies may not accord any undue benefits to healthcare professionals or healthcare organisations; in particular, they may not offer, promise or grant any gifts (either in cash or non-cash considerations).
- 143 The following are reserved:

144

- 143.1 Usual remuneration for healthcare professionals in connection with orders and deliveries of medicinal products;
- 143.2 Delivery of free of charge samples of medicinal products to healthcare professionals;
- 143.3 Objects, information and training materials of moderate value provided for healthcare professionals which are intended solely for the 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 shall not be product branded,
- 143.4 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;
- 143.5 Payment for meals (including beverages) on a reasonable and modest scale, subject to a maximum amount of CHF 150 per healthcare professional per meal. This amount applies only to events which are held in Switzerland. For events which are held abroad, the limits set out in the code which claims territorial validity for the host country, apply to all the participants regardless of where they have their primary practice or definitive business address or their registered business headquarters

The laws and ordinances applicable in this connection are reserved as is their enforcement by the State authorities.

April 2019 Code Secretariat