

The Pharma Code and the Pharma Cooperation Code in 2023: Annual Report of the Code Secretariat

Introduction

For many years, the Swiss pharmaceutical industry has applied internationally coordinated (see IFPMA¹, EFPIA²) self-regulation that goes beyond the law with the Pharma Code (PC³) and the Pharma Cooperation Code (PCC¹). Pharmaceutical companies can voluntarily agree to abide with these codes (see lists of signatories⁴). The support organisation for pharmaceutical self-regulation in Switzerland is scienceindustries, while its Code Secretariat is responsible for the implementation of the codes. When dealing with disputes, the Secretariat primarily acts as an intermediary and applies the principle of the amicable settlement of conflicts. In 2023 too, its neutral assessment was always accepted by the parties involved in the individual disputes and the situation was soon returned to compliance with the codes.

Implementation of the Pharma Code

The number of cases dealt with under the PC fell slightly to 103 from 107 last year. The number of complaints filed against competitors increased significantly (2023: 38.2% / 39 cases; 2022: 13.1% / 14 cases). One company reported itself (2022: 2). Once again, no cases were classified as potentially hazardous to health and therefore serious.

The average duration of proceedings increased to 8.1 days in 2023 (2022: 5.6 days) and thus corresponds again to the duration of proceedings in 2021 (8.2 days).

103 cases were opened in 2023. Of these, 94 cases (91.2%, 2022 83.2%) were closed after the contested advertising had either been corrected or removed. Nine cases (8.8% / 2022: 16.8%) were found not to be in breach of the Code. Two of these 9 cases were initiated by a competitor (2022: 1 of 18). There were delays in two cases due to the complexity of the issues. As in the previous reporting year, no company had to be warned for failing to submit the requested comments on time. In a complaint filed by a competitor, the Code Secretariat was not responsible for assessing the content of advertising to the general public.

The Code Secretariat conducted one mediation in 2023 (2022: 1) and took note of 5 bilateral agreements (2022: 3).

Ninety-one pharmaceutical companies (2022: 90) submitted a total of 12,581 specimen copies (2022: 13,724) of their promotional material and information; 96.9% (2022: 98.3%) were sent to the Secretariat electronically. Only a few specimen copies were sent to the Code Secretariat by post.

The number of cases opened was once again at the average level of recent years, with 72 cases in 2021 appearing to have been an exception. Competitor notifications increased again, as did reports of bilateral negotiations, but here an unknown number of unreported cases must still be expected. The time required for each case increased somewhat, which was due to the complexity of the issues involved.

Established breaches of the Code

A total of 34 (2022: 45) PC requirements were mentioned in the 103 complaints (2022: 107). One requirement only was mentioned for 25.0% of the cases (2022: 33%); two requirements were mentioned for 9.7% (2022: 11.3%) and three to nine requirements were cited in 65.3% of cases (2022: 55.7%; 3 to 8 requirements). The following is a list of the PC requirements that were mentioned often:

- Principle of professional promotion (PC 24.1): further sharp increase to 20 breaches (previous year: 12).
- Unproven advertising statements and incorrectly cited references (PC 24.2): stable at 82 breaches (previous year 82).

¹ IFPMA

² EFPIA

³ The provisions of the two codes are referred to in the Annual Report by "PC" and "PCC" with the relevant section number.

⁴ Signatories of the Pharma Code / Signatories of the Pharma Cooperation Code

- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 24.4, 24.5): slight increase to 23 breaches (previous year: 19).
- Incomplete or impermissible references to literature (PC 25, excluding PC 25.1, 25.4.3, and 25.7): down on the previous year with 15 breaches (previous year: 29).
- Missing indication that references can be requested from healthcare professionals (PC 24.2, 25.1, 25.4.3, and 25.7): strong increase to 49 breaches; these were systematically warned for the first time in 2022 (29 cases in 2022).
- Notifications of unqualified superlatives and comparatives (PC 25.8, 25.9): slight increase to 10 breaches (previous year: 7).
- Obligations of pharmaceutical companies when implementing the PC (PC 6): slight decrease to 11 breaches compared with 14 in the previous year.
- Ban on gifts (PC 15.2): one identified breach (previous year: 1).
- Promotion of as-yet unauthorised medicinal products or indications (PC 23.1, 23.2): up sharply at 13 breaches (previous year: 3).
- Promotional statements differ from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 23.3): 8 breaches compared to 1 in the previous year.
- Use of expressions minimising possible risks (e.g. claiming that the medicinal product concerned does not induce addiction or is harmless (PC 24.3.3): 2 breaches (previous year: 0).

The shift to more disputed requirements per case is due to the fact that a frequent complaint (lack of indication that references can be requested) ultimately resulted in a breach of four different requirements: (PC 24.2, 25.1, 25.4.3, and 25.7). As in previous years, it can also be said for 2023 that the breaches of the PC for which complaints were received could not be qualified as gross breaches. There was no need to threaten to refer a matter to the competent state authority (PC 75.10) in 2023 too.

Support for events promoting postgraduate medical training and continuing medical education (PC 3)

In 2023, the Code Secretariat of its own accord as well as at the request of companies or organisations again reviewed a number of events promoting postgraduate medical training and continuing medical education to check whether they meet the self-regulation requirements. In doing so, the Secretariat applied established international standards (in particular IPCAA⁵ and e4ethics⁶). It had to intervene in two cases (2021: one). With the help of the Code Secretariat, certain events were restructured to comply with the codes, which then allowed company support. It has to be noted that the Code Secretariat on its own cannot obtain a complete overview of these activities. Here too it will continue to be dependent on questions or complaints received from the companies or the organisers themselves.

Implementation of Pharma Cooperation Code

Between 20 and 30 June 2023, the companies that signed the PCC for the eighth time disclosed the pecuniary benefits granted in 2022 to healthcare professionals (HCP – mainly doctors and pharmacists), healthcare organisations (HCO – mainly hospitals and professional organisations) and patient organisations (PO) on their websites. These concerned direct or indirect payments for cooperation relating to prescription-only medicinal products for humans. Six companies (previous year: 8) were slightly behind in the publication of their data; after the Secretariat intervened, complete data sets of good quality could only be published in August 2023, which was very unsatisfactory.

The Code Secretariat compiled the figures of the 66 PCC signatory companies (previous period: 68) and by the end of July 2023, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 217.9 million were disclosed for 2022. In the previous year, the figure was CHF 194.1 million, which corresponds to an increase of CHF 23.8 million. At CHF 7.4 million, slightly more donations were paid to HCP than in the previous year (CHF 6.4 million). ToV to HCO also increased to CHF 121.5 million compared to CHF 106.1 million in 2021. The ToV for R&D services increased slightly from CHF 81.6 million to CHF 88.9 million.

Cooperation payments to HCP was therefore on a par with the previous year in 2022. The effect of the coronavirus pandemic therefore seems to have continued. Once again, a certain shift in direct support

⁵ https://www.ipcaa.org/public/international-healthcare-congress-guidelines/

⁶ https://www.ethicalmedtech.eu/e4ethics/about-e4ethics/

from HCP towards HCO was observed. Cooperation payments to HCO increased by more than CHF 14 million to almost CHF 120 million. Grants for research & development increased slightly again in 2022 after falling slightly in 2021. In this area, it seemed once again that annual contributions from individual companies fluctuate strongly from one year to the other, which can be explained, among other things, by varying levels of activity in the field of clinical research.

To ensure as much transparency as possible, disclosure should be made on an individual basis, i.e. by naming the person who received a benefit, which for reasons of data privacy requires the recipients to agree to the disclosure. Seen overall, the average consent rate for HCP increased once again from 90.4% to 92.4% in 2022. The median rate was as high as 99.7%, which shows that half of the PCC signatory companies had HCP consent rates of 99.7% or higher. The average consent rate for HCO also increased further from 95.8% to 97.2%. The median here remained at 100%. Overall, consent rates continued to develop positively, and only a few companies can still achieve better results. In some cases, consent rates have resulted in considerable discrepancies between the individual companies, which are sometimes difficult to understand. Nine companies who achieved an HCP consent rate of less than 80% in the reporting year were therefore mentioned by name on the website of scienceindustries (2021: 10 companies) and requested to implement measures to increase their consent rate.

With regard to disclosure, scienceindustries was once again in contact with stakeholders and interested media and explained the pharmaceutical industry's transparency initiative.

Pharmaceutical Code enquiries and training

In 2023, the Code Secretariat replied to 242 written or telephone enquiries pursuant to section 8 PC / section 6 PCC (previous year 362). Of these, 162 enquiries related to the PC and 77 to the PCC. The significant decline in enquiries surprises the Code Secretariat insofar as a large amount of consulting work was nevertheless required in 2023. The situation will continue to be monitored. In 2023, the Code Secretariat conducted two online training courses on professional promotion with a total of 79 participants, and two on pharma compliance with a total of 62 participants. In its capacity as self-regulatory body for the Swiss pharmaceutical industry, scienceindustries also gave lectures about various topics and replied to media enquiries.

Code Secretariat

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