

The Pharma Code and the Pharma Cooperation Code in 2022: 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 (PCC³). 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 2022 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 increased to 107 from 72 cases last year. The number of complaints from competitors declined significantly in percentage terms (2022: 13.1% / 14 cases; 2021: 26.4% / 19 cases). Two companies reported themselves (2021: 0). Once again, no case was classified as potentially hazardous to health (2021: 0).

The average duration of proceedings fell sharply in 2022 to 5.6 days (2021: 8.2 days). In contrast to the previous year, only around 11% of cases required discussions with the affected companies; these had led to various extensions of deadlines in the previous year (2021: 20.9%).

107 cases were opened in 2022. Of these, 89 cases (83.2%, 2021 84.7%) were closed after the contested advertising had either been corrected or removed. In 18 cases (16.8%/2021: 15.3%) it was ultimately found that there had been no breach of the Code. One of these 18 cases was initiated by a competitor (2021: 2 of 11). There were delays in two cases due to the complexity of the case (2021: 0). In none of the cases did a company have to be warned for failing to submit the requested comments on time (2021: 2). In the case of one complaint from a competitor, the Code Secretariat did not consider itself responsible.

The Code Secretariat conducted one mediation in 2022 (2021: 1) and received notice of three bilateral negotiations (2021: 8).

90 pharmaceutical companies (2021: 82) submitted a total of 13,724 specimen copies (2021: 12,461) of their promotional material and information; 98.3% (2021: 88.6%) were sent to the Secretariat electronically. Only a few specimen copies were sent to the Code Secretariat by post. Both the number of submitting pharmaceutical companies and the number of submitted specimen copies increased further.

The number of cases opened was once again in line with the average for recent years; the 72 cases in 2021 seem to have been an exception. Competitor notifications continued to decline, as did reports of bilateral negotiations, but here an unknown number of unreported cases has to be expected. The time required for each procedure decreased as the questions tended to be more concise and therefore fewer clarifying discussions with the companies were required.

Established breaches of the Code

A total of 45 (2021: 33) PC requirements were mentioned in the 107 complaints (2021: 72). One requirement only was mentioned for 33.0% of the cases (2021: 59.7%); two requirements were mentioned for 11.3% (2021: 25.0%), and in 55.7% of cases, three to as many as eight requirements were mentioned (2021: 15.3%; 3 to 6 requirements). The following is a list of the PC requirements that were mentioned often:

- Principle of professional promotion (PC 24.1): sharp increase to 12 breaches (previous year: 3).

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](#)

- Unproven advertising statements and incorrectly cited references (PC 24.2): sharp increase to 82 breaches (previous year 30), even considering that 29 cases were sanctioned in combination with three further PC requirements (see below).
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 24.4, 24.5): slight increase to 19 breaches (previous year: 13).
- Incomplete or impermissible references to literature (PC 25, excluding PC 25.1, 25.4.3, and 25.7): slightly up on the previous year with 29 breaches (previous year: 21).
- Missing indication that references can be requested from healthcare professionals (PC 24.2, 25.1, 25.4.3, and 25.7): 29 breaches; these were systematically sanctioned for the first time in 2022.
- Notifications of unqualified superlatives and comparatives (PC 25.8, 25.9): clear decline to 7 breaches (previous year: 14).
- Obligations of pharmaceutical companies when implementing the PC (PC 6): the number of breaches increased to 14 compared to 10 in the previous year.
- Ban on gifts (PC 15.2): one punished breach (previous year: 0).
- Promoting as yet unauthorised medicinal products or indications (PC 23.1, 23.2): unchanged at 3 breaches (previous year: 4).
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 23.3): one breach compared to 4 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): no breach (previous year: 1).
- Marking mailings as “important notice” (PC 210): no breach (previous year: 0).
- Complaints regarding serious breaches of the Code (PC 74): no breach (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 2022 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 appropriate State authority (PC 75.10) in 2022 (2021: 1).

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

In 2022, 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 2022, the companies that signed the PCC for the seventh time disclosed the pecuniary benefits granted in 2021 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. For eight companies (previous year two), there was a slight delay in the publication of their data; after the Secretariat intervened, complete data sets of good quality could be published just a few days after 1 July 2022.

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

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

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 87.8% to 90.4% in 2021. The median rate was as high as 97.3%, which shows that half of the PCC signatory companies had HCP consent rates of 97.3% or higher. The average consent rate for HCO also increased further from 94.9% to 95.8%. The median here remained at 100%. These rates are good in a European comparison and once again clearly higher than in other German-speaking countries. There are sometimes considerable discrepancies between the individual companies in terms of consent rates, which do not always appear to be comprehensible. Ten 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 (2020: 11 companies) and requested to implement measures to increase their consent rate.

The Code Secretariat compiled the figures of the 68 PCC signatory companies (previous period: 62) and by the end of July 2022, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 194.1 million were disclosed for 2021. In the previous year, the figure was CHF 182.5 million, which corresponds to an increase of CHF 11.6 million (+6.3%). At CHF 6.4 million, slightly more payments were made to HCP than in the previous year (CHF 6.0 million or +5.4%). The ToV to HCO also increased to CHF 106.1 million from CHF 93.0 million in 2020, which equals an increase of 14.1%. The ToV for R&D services decreased slightly from CHF 83.5 million to CHF 81.6 million (-2.2% compared to 2021).

Cooperation payments to healthcare professionals were therefore on a par with the previous year in 2021. The effect of the coronavirus pandemic seems to have continued in 2021. Once again, a certain shift in direct support from HCP towards HCO was observed. Cooperation payments to HCO increased by more than CHF 10 million to almost CHF 106 million. Grants for research and development decreased 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.

With regard to disclosure, scienceindustries was once again in contact with the stakeholders to explain the pharmaceutical industry's transparency initiative. Media interest in the topic was relatively low in 2022.

Pharmaceutical Code enquiries and training

In 2022, the Code Secretariat replied to 362 written or telephone enquiries pursuant to section 8 PC/section 6 PCC (previous year 328). Of these, 223 enquiries related to the PC and 87 to the PCC (previous year 191 and 124 respectively). An enquiry can concern the PC as well as the PCC. In 2022, the Code Secretariat conducted three online training courses on professional promotion (previous year 2) with a total of 123 participants, and two on pharma compliance (previous year 5) with a total of 67 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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Zurich, February 2023