The Pharma Code and the Pharma Cooperation Code in 2020: Annual Report of the Code Secretariat

Introduction

For many years, the Swiss pharmaceutical industry has applied internationally coordinated (see IFPMA[1], EFPIA[2]) self-regulation that goes beyond the law with the Pharma Code (PC[3]) and the Pharma Cooperation Code (PCC[1]). Pharmaceutical companies can voluntarily agree to abide with these codes (see lists of signatories[4]). 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 2020 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 Code.

Revision of the pharma codes

Because of the revision of the Therapeutic Products Act (TPA), the entry into force of the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (VITH) and the code consolidation by the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Swiss pharma codes had to be revised completely. On 14 May 2020, the Board of scienceindustries adopted the two revised pharma codes which entered into force on 1 January 2021.

A number of formal changes were made, such as the addition of several definitions (see section 13 PC and PCC) derived from the EFPIA code consolidation. Except for the disclosure provisions, the PCC's rules of cooperation with healthcare professionals (HCP), healthcare organisations (HCO) and patient organisations (PO) were included in the PC again (see section 4 PC). This closed a gap that resulted from the introduction of the PCC. Although the cooperation provisions were formally restructured, they mostly did not change. Certain material changes were introduced, some of which derive from the TPA revision and the entry into force of the VITH, and some from the new requirements under EFPIA's Code of Practice 2019. For more details, please consult the explanations provided on the website of scienceindustries[5].

Implementation of the Pharma Code

The number of cases dealt with in connection with the PC increased to 118 (2019: 106). As the number of complaints filed against competitors declined from 38 cases in 2019 to 32 cases in 2020, the percentage also dropped (2020: 27.1%, 2019 35.8%). No complaints were submitted by companies against themselves (2019: 2), while one complaint was filed by an HCP (2019: 2). Swissmedic did not transmit any cases (previous year: 1). To the best of the Secretariat's knowledge, no cases were escalated to Swissmedic (2019: 0). No case was classified as potentially hazardous to health (2019: 0).

The average duration of proceedings declined (2020: 6.8 days; 2019: 7.7 days). It can be confirmed that the companies concerned as a rule complied with the process and cooperated quickly and constructively.

In 2020, 105 of the 118 opened cases of a suspected violation of the PC were finalised (89.0%; 2019: 86.8%) after the contested advertising had either been corrected or removed. The Secretariat rejected 13 (11.0%) of the complaints (previous year: 14 cases or 13.2%) because there had been no breach of the Code. Seven of these 13 rejected complaints were submitted by competitors (previous year: 5 by competitors and one by an HCP).

The Code Secretariat did not engage in any mediation in 2020 (2019: 1), but received notice of 4 bilateral negotiations (2019: 6). Another bilateral negotiation was unsuccessful and was finally submitted to the Secretariat.

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[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
[5] Revision 2020 - overview of the changes made

Sixty-five pharmaceutical companies (2019: 65) submitted 11,036 sample copies (2019: 6,008) of their promotional material and information; 84.4% (2019: 88.4%) were sent to the Secretariat electronically. There were several reasons for this sharp increase in the number of sample copies received. Firstly, the Code Secretariat sent reminders to a number of signatory companies who submitted only a few sample copies in previous years, and secondly, the COVID-19 pandemic meant that sales representatives could not visit HCP as often as usual and promotional activities therefore shifted (even more) strongly to mailshots and electronic advertising. The interesting thing is that this hardly affected the number of cases.

In the reporting year, the Code Secretariat for the first time compiled detailed statistics on the enquiries received from member companies in most cases, but also from healthcare companies, congress organisers, law offices and other interested groups. In 2020, 227 written enquiries (previous year around 200) were answered. Of these, 150 enquiries related to the PC and 111 to the PCC. An enquiry can concern the PC as well as the PCC. In its capacity as self-regulatory body for the Swiss pharmaceutical industry, scienceindustries also gave many lectures about various topics and replied to media enquiries.

Established breaches of the Code

Seen overall, the 118 (2019: 106) complaints regarding suspected PC breaches referred to 52 (2019: 41) different PC requirements. One requirement was mentioned for 53.4% of the cases (2019: 55.7%); two requirements were mentioned for 25.3% (2019: 22.6%), and three to eight requirements were mentioned for the remaining quarter (2019: 23.9%; three to seven requirements). The following is a list of the PC requirements that were mentioned often:

- Principle of professional promotions (PC 21): declining at 3 (previous year: 6).
- Unproven advertising statements (PC 251): clearly declining at 26 breaches (previous year: 35)
- Incorrectly cited references (PC 252): no significant change at 25 breaches (previous year: 27)
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 254 and 255): declining at 34 breaches (previous year: 41)
- Incomplete or impermissible references to literature (PC 26, 261 to 266): year-on-year increase to 31 breaches (previous year: 23)
- Notifications of unqualified superlatives and comparatives (PC 267, 268): no significant change at 13 breaches (previous year: 15)
- Obligations of pharmaceutical companies when implementing the PC (PC 5): substantial increase to 30 breaches compared to 10 in the previous year (20 breaches concerned the delivery to the Code Secretariat of sample copies that do not comply with the Code).
- Ban on gifts (PC 142): increase to 5 breaches (previous year: 1)
- Promoting as-yet unauthorised medicinal products or indications (PC 231, 232, 24, 241 and 242): no significant change (13 breaches, previous year: 15)
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 233): on a par with the previous year (3) with 2 breaches
- Use of the expression “safe” without an appropriate qualification (PC 253.1); also on a par with the previous year (1) with 2 breaches
- Use of expressions minimising possible risks (e.g. claiming that the medicinal product concerned does not induce addiction or is harmless - PC 253.2): increase to 4 breaches (previous year: 1)
- Designating mailings as an “important notice” (PC 28, allowed solely to maintain pharmaceutical safety and in the event of interruption or suspension of delivery of a pharmaceutical): increase to 2 breaches (previous year: 0)
- Complaints regarding serious breaches of the Code (PC 641): 1 breach, same as in the previous year
- Referral of a matter to the appropriate State authority (PC 651): no significant change at 3 breaches (previous year: 4). (measures never had to be taken).

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

In 2020, 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 IPCAA[6] and e4ethics[7]). It never had to intervene (2019: 1). With the help of the Code Secretariat, some events were restructured to comply with the codes, which then allowed company support, presumably as a result of the intensified efforts of the Secretariat in the previous years. It has to be noted, however, that it is impossible for the Code Secretariat to have a complete overview of these activities and that it is therefore dependent on questions and complaints received from the companies.

Implementation of Pharma Cooperation Code

Between 20 and 30 June 2020, the companies that signed the PCC for the fifth time disclosed the pecuniary benefits granted in 2019 to HCP (mainly doctors and pharmacists), HCO (mainly hospitals and professional organisations) and PO on their websites. These concerned direct or indirect payments for cooperation relating to prescription-only medicinal products for humans. For two companies (previous year 3), there was a 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 2020.

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 from 82.5% to 84.5% (median of 86.3% to 91%) in 2019. The average consent rate for HCO dropped slightly from 93.4% to 92.3%. The median, however, rose from 98.0% to 100%. These rates are good in a European comparison and once again clearly higher than in other German-speaking countries. In some cases, consent rates have resulted in considerable discrepancies between the individual companies, which are sometimes difficult to understand. Twelve 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 (2018: 18 companies) and requested to implement measures to increase their consent rate.

The Code Secretariat compiled the figures of the 58 PCC signatory companies and by the beginning of August 2020, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 185.9 million were disclosed for 2019. As the figure for the previous year was CHF 181.4 million, this means an increase of CHF 4.5 million (2.5%). For HCP, CHF 11.5 million were disclosed, compared to CHF 12.4 million in 2018 (-0.9%). The ToV disclosed for HCO rose by 8.6% from CHF 96.7 million in 2018 to CHF105.3 million in 2019. ToV of CHF 69.1 million were disclosed for R&D services in 2019, compared to CHF 72.3 million in 2018, which represents a year-on-year change of around -3.2%. Relatively high amounts were thus paid to HCO in Switzerland again compared to the rest of Europe, while the payments to HCP were stable.

scienceindustries remained in close contact with the groups concerned, informed the FMH at its meeting of delegates about the result of the disclosure, and once again campaigned for the continuous support of the medical organisations for the transparency initiative. The media showed considerably less interest in this topic in 2020.

Code Secretariat

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[6] https://www.ipcaa.org/public/ipcaa-healthcare-congress-guidelines
[7] e4ethics