The Pharma Code and the Pharma Cooperation Code in 2019: 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[3]). 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 2019 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 and the law. The consistently high number of cases confirms the unabated and universal respect for this procedure, in particular the ease of access and the rapid and transparent decisions taken.

Implementation of the Pharma Code

At 106 (2018: 129), the number of cases dealt with in connection with the PC declined. As the number of complaints filed against competitors declined to the same extent (2019: 38 cases; 2018: 42 cases), the percentage was much the same (2019: 35.8%, 2018 32.6%). In two cases, the complaint was submitted by the company itself (2018: 3). Two complaints were received from HCP (2018: 1), while one case concerning a breach of fairness in advertising was transmitted by Swissmedic. It could be finalised within three days. To the best of the Secretariat's knowledge, no cases were escalated to Swissmedic (2018: 0). No cases were classified as potentially hazardous to health (2018: 0). Sixty-five pharmaceutical companies (2018: 64) submitted 6,008 sample copies (2018: 6,001) of their promotional material and information; 5,314 sample copies (88.4%; 2018: 84.0%) were sent to the Secretariat electronically.

The average duration of proceedings was more or less the same (2019: 7.7 days; 2018: 7.6 days). It can be confirmed that the companies concerned as a rule continued to comply with the process and cooperated quickly and constructively.

In 2019, 92 of the 106 opened cases of a suspected violation of the PC were finalised (86.8%; 2018: 87.6%) after the contested advertising had either been corrected or removed. The Secretariat rejected 14 (13.2%) of the complaints (previous year: 11 cases or 8.5%) because there had been no breach of the Code. Five of the 14 rejected cases were submitted by competitors and one by an HCP.

The Code Secretariat did not do any mediation in 2019 (2018: 1), but received notice of 6 bilateral negotiations (2018: 1).

As in the previous year, the Code Secretariat again answered more than 200 enquiries in the reporting year, mostly from member companies, but a considerable number were also from professional associations, congress organisers, law offices and other interested groups, including media representatives. More than half of the enquiries concerned the PC, while the PCC and the introduction of the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (VITH) also gave rise to many enquiries. In its capacity as self-regulatory body for the Swiss pharmaceutical industry, scienceindustries also gave many lectures about the VITH and organised a cross-stakeholder event on this topic together with the Swiss Health Quality Academy (shqa).

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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

Established breaches of the Code

The total of 106 (2018: 129) complaints regarding suspected PC breaches referred to 41 (2018: 43) different PC requirements. One requirement was mentioned in 55.7% of the cases (2018: 41.9%); two requirements were mentioned for 22.6% (2018: 24.0%), and three to seven requirements were mentioned for the remaining quarter (2018: 33.1%). The following is a list of the PC requirements that were relevant or mentioned very often:

- Principle of professional promotions (PC 21): at 6 (previous year: 13), the number of cases declined.
- Unproven advertising statements (PC 251): at 35 (previous year: 38), the number of cases was stable.
- Incorrectly cited references (PC 252): at 27 (previous year: 39), the number of cases declined.
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 254 and 255): the number of cases dropped substantially at a high level to 41 (previous year: 81).
- Incomplete or impermissible references to literature (PC 26, 261 to 266): the number of cases declined further to 23 (previous year: 43).
- Notifications of unqualified superlatives and comparatives (PC 267, 268): the number of cases declined sharply to 15 (previous year: 21).
- Obligations of pharmaceutical companies when implementing the PC (PC 5): the number of cases fell to 10 from 17 in the previous year.
- Ban on gifts (PC 142): one complaint was received (previous year: 0).
- Promoting as-yet unauthorised medicinal products or indications (PC 231, 232, 241 and 242): the number of cases increased noticeably again (15 cases, previous year: 6).
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 233): the number of cases (3) declined noticeably from the previous year (12).
- Use of the expression “safe” without an appropriate qualification (PC 253.1): one case was reported, the same as in the previous year.
- Use of expressions minimising possible risks, for example claiming that the medicinal product concerned did not induce addiction or was harmless (PC 253.2): one case was reported, the same as in the previous year.
- 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): the Secretariat once again recorded no cases (previous year: 0).
- Inducement to attend a specialist conference (PC 313): one case compared to two in the previous year.
- Complaints regarding serious breaches of the Code (PC 641): one case was recorded (previous year: 3).
- Referral of a matter to the appropriate State authority (PC 651): four cases were recorded (previous year: 0). No cases had to be forwarded, however.

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

In 2019, 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[5] and e4ethics[6]). It had to intervene in one case (2018: 2; 2017: 18), presumably as a result of the intensified efforts of the Secretariat in 2018 and 2017. 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 2019, the companies that signed the PCC for the fourth time disclosed the pecuniary benefits granted in 2018 to healthcare professionals (HCP, mainly doctors and pharmacists), healthcare organisations (HCO, mainly hospitals and professional organisations) and patient organisations (PO) on their websites.

[5] https://www.ipcaa.org/public/ipcaa-healthcare-congress-guidelines
[6] https://www.ethicalmedtech.eu/e4ethics/about-e4ethics

Pecuniary benefits as defined by the PCC are benefits granted either directly or indirectly for cooperation with the above-mentioned groups in connection with prescription medicinal products for human use and the related research and development (R&D).

The Code Secretariat immediately checked the data upon publication to ensure that they were complete and published on time in accordance with the requirements of the PCC. For three companies, 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 2019.

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 77.1% to 82.5% (median of 86.3%). The average consent rate for HCO improved once again to 93.4% (impressive median of 98.0%). These rates are considerably higher than in the other German-speaking countries, which deserves recognition. However, it seems that, in some cases, consent rates have resulted in considerable discrepancies in the individual companies, which are sometimes difficult to understand. According to the decision taken by the Code Commission, 18 companies who achieved an HCP consent rate of less than 80% in 2018 were listed by name on the website of scienceindustries. All 18 companies were contacted and requested to formulate measures with which they will increase the consent rates. Based on these discussions, the Code Secretariat expects a further improvement in the consent rate for 2019.

The Code Secretariat has compiled the figures of the 60 PCC signatory companies (57 data sets) and by the beginning of August 2019, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 181.4 million were disclosed for 2018. As the figure for the previous year was CHF 162.3 million, an increase of CHF 19.1 million (11.8%) was achieved. For HCP, CHF 12.4 million were disclosed, compared to CHF 12.5 million in 2018 (-0.8%). At a total of CHF 96.7 million, the ToV disclosed for HCO increased by 6.4% in 2018 to CHF 96.7 million from CHF 90.8 million in 2017. ToV of CHF 72.3 million were disclosed for R&D services in 2018, compared to CHF 59.0 million in 2017, which represents a year-on-year change of around 22.6%. Relatively high amounts were thus paid to HCO in Switzerland again compared to the rest of Europe, while the payments to HCP were stable. The renewed increase of CHF 13.3 million for R&D services is worth mentioning.

scienceindustries remained in close contact with the groups concerned, informed the FMH at its meeting of delegates about the result of the disclosure, and lobbied for the continuous support of the medical organisations for the transparency initiative. Media interest in this topic was greater again in 2019 than in the previous year, which can be attributed to a media campaign by the Axel Springer Ringier association. In spite of transparent communication by scienceindustries and the signatory companies, media reporting about the topic was questionable, which necessitated scienceindustries to publish a counter-statement. In September 2019 scienceindustries also organised a media event to discuss the topic where the transparency initiative was explained again and the consolidated data were presented to interested media representatives. Representatives of the FMH, the Swiss Group for Clinical Cancer Research (SAKK) and company representatives of the Code Commission presented examples to explain the importance of cooperation between specialists such as professional organisations and the pharmaceutical industry. The media representatives criticised the fact that there is no standard disclosure platform, but this is not the objective of the transparency initiative. The companies want to create individual transparency about their cooperation programmes rather than set up a comparative platform allowing a search for individual service providers. For the industry, this is not its primary task.

Code Secretariat

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