The Pharma Code and the Pharma Cooperation Code in 2021: 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 2021 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.

Entry into force of the revised 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. The two pharma codes revised on 14 May 2020 entered into force on 1 January 2021. With regard to the content changes, please refer to the detailed information on the website of scienceindustries[5] and an article in the journal Life Science Law[6]. The implementation of the amendments by the signatory companies did not appear to have led to any significant problems. However, the Code Secretariat answered a number of questions in this regard and also carried out updated training sessions.

Implementation of the Pharma Code

The number of cases dealt with in connection with the PC declined significantly to 72 cases (2020: 118). As the number of complaints filed against competitors declined to the same extent (2021: 19 cases; 2020: 32 cases), the percentage remained more or less the same (2021: 26.4%, 2020: 27.1%). As was the case in 2020, no company submitted a complaint against itself. Following a complaint from a competitor, the Code Secretariat opened a case against a pharmaceutical company that had not signed the PC. Despite several reminders, the company did not react and the case was referred to Swissmedic in accordance with section 75.1 PC, which then opened proceedings. Once again, no case was classified as potentially hazardous to health (2020: 0).

The average duration of proceedings increased (2021: 8.2 days; 2020: 6.8 days). This is due to more discussions with the affected companies, which led to deadlines being extended: doubling of the number of cases with an extension (2021: 20.9%, 2020: 10.2%). This approach has proved its worth in the aforementioned cases and good solutions were found in constructive discussions.

Of the 72 cases opened in 2021, 62 cases (84.7%, 2020 89.0%) were closed after the contested advertising had either been corrected or removed. The Secretariat rejected 11 (15.3%) of the complaints (previous year: 11.0%) because there had been no breach of the Code. Two of these 11 rejected cases were submitted by competitors. In two cases, companies had to be warned because they had not responded in time (previous year: 0). One case was forwarded as mentioned above.

The Code Secretariat conducted one mediation in 2021 (2020: 0) and received notice of eight bilateral negotiations (2020: 4). Two bilateral negotiations were unsuccessful and were submitted to the Secretariat.

Eighty-two pharmaceutical companies (2020: 65) submitted 12,461 specimen copies (2020: 11,036) of their promotional material and information; 88.6% (2020: 84.4%) were sent to the Secretariat electronically.

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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
[6] Jürg Granwehr, Life Science Law, Issue 1/2021; p. 50 et seq.

In 2021, 328 written enquiries (previous year 227) were answered by the Code Secretariat. Of these, 191 enquiries related to the PC and 124 to the PCC (previous year 150 and 111 respectively). An enquiry can concern the PC as well as the PCC. In 2021, the Code Secretariat for the first time successfully conducted two online training courses on professional promotion and five on compliance, each attended by 30 to 40 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.

While the significant decrease in the number of cases opened is remarkable, the percentage of proceedings initiated by competitors remained the same at around a quarter. More specimen copies were submitted as the number of submitting companies had also increased. As already mentioned in the last Annual Report, professional promotion seems to have shifted more to electronic advertising during the pandemic. According to industry experts, the number of advertisements for professional promotion in the relevant Swiss trade media fell by 20% last year. This type of professional promotion tends to be more complex than electronically transmitted advertising measures, as these often focus only on one statement. Printed professional promotion therefore more often involves possible violations of the PC than the more simply structured electronic mailshots. Conversely, these are slightly adjusted repeatedly, with each adaptation resulting in a "new" specimen copy being sent to the Code Secretariat.

Established breaches of the Code

The revision of the codes has led to changes in the section numbers. The sections of the revised PC and those of the old version are therefore listed.

In total, 72 (2020: 118) complaints regarding suspected PC breaches referred to 33 PC requirements (2020: 52). One requirement was mentioned for 59.7% of the cases (2020: 53.4%); two requirements were mentioned for 25.0% (2020: 25.3%) and 3 to 6 requirements were mentioned in 15.3% of the cases (2020: 21.3%; 3 to 8 requirements). The following is a list of the PC requirements that were mentioned often:

- Principle of professional promotion (PC 24.1, old 21): no significant change at 3 breaches (previous year: 3)
- Unproven advertising statements and incorrectly cited references (PC 24.2, old 251, 252): clear decline at 30 breaches (previous year 60: 251: 35 / 252: 25)
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 24.4, 24.5, old 254, 255): clear decline at 13 breaches (previous year: 34)
- Incomplete or impermissible references to literature (PC 25, old 26, 261 to 266): clear decline on the previous year at 21 breaches (previous year: 31)
- Notifications of unqualified superlatives and comparatives (PC 25.8, 25.9, old 267, 268): no significant change at 14 breaches (previous year: 13)
- Obligations of pharmaceutical companies when implementing the PC (PC 6, old 5): significant decrease to 10 breaches compared to 30 in the previous year
- Ban on gifts (PC 15.2, old 142): no punished breaches (previous year: 5)
- Promoting as-yet unauthorised medicinal products or indications (PC 23.1, 23.2, old 231, 232, 24, 241 and 242): clear decline at 4 breaches (previous year: 13)
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 23.3, old 233): at 4 breaches, this figure has doubled at a very low level compared to the previous year (2)
- 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, old 253.2): decline to one breach (previous year: 4)
- Marking mailings as an "important notice" (PC 280, old 28): no breach (previous year: 2)
- Complaints regarding serious breaches of the Code (PC 74, old 641): no breach (previous year 1)
- Referral of a matter to the appropriate State authority (PC 75.1, old 651): one breach (previous year: 0). (In contrast to the previous year, measures had to be taken in this case.)

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

In 2021, 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[7] and e4ethics[8]). It had to intervene in one case (2020: 0). 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 is dependent on questions and complaints received from the companies.

Implementation of Pharma Cooperation Code

Between 20 and 30 June 2021, the companies that signed the PCC for the sixth time disclosed the pecuniary benefits granted in 2020 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 2), 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 2021.

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 84.5% to 87.8% (median: from 91.0% to 93.0%) in 2020. The average consent rate for HCO also increased further from 92.3% to 94.9%. The median here remained at 100%. These rates are good in a European comparison and once again much 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 (2019: 12 companies) and requested to implement measures to increase their consent rate.

The Code Secretariat compiled the figures of the 62 PCC signatory companies (previous period: 58) and by the end of July 2021, was able to put together the following statistics about Switzerland: Transfers of value (ToV) for a total of CHF 182.5 million were disclosed for 2020. As the figure for the previous year was CHF 185.9 million, a decrease of CHF 3.5 million (-1.8%) was achieved. At CHF 6 million, only around half as many payments were made to HCP as in the previous year (CHF 11.5 million or -47.5%). The ToV to HCO also decreased to CHF 93.0 million from CHF 105.3 million in 2019, which equals a decline of 11.6%. In contrast to HCP and HCO, the ToV for R&D services increased from CHF 69.1 million to CHF 83.5 million. This represents an increase of 20.9%. Relatively high payments were still made to HCO in Switzerland compared to other European countries. The significant reduction in ToV for HCP in 2020 is probably largely due to the coronavirus pandemic. ToV to HCO are also likely to have been affected by the corona pandemic, albeit to a smaller degree. This is most likely due to a decline in support for further training. Fewer events could be staged in 2020 or had to be switched to digital channels, which resulted in reduced ToV. The ToV for R&D are subject to strong fluctuations in the individual companies. The increase in 2020 appears to be partly due to increased research activities in the context of coronavirus therapies and the development of vaccines.

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 lobbied for the continuous support of the medical organisations for the transparency initiative. The media showed considerably less interest in this topic in 2021.

Code Secretariat

Dr. med. Daniel Simeon Zurich, February 2022

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