The Pharma Code and the Pharma Cooperation Code in 2018: 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 2018 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 universal respect for this procedure, in particular the ease of access and the rapid and transparent decisions taken.

Statistics regarding implementation of Pharma Code in 2018

At 129 (33%; 2017: 121, 32%), the number of cases dealt with in connection with the PC rose slightly. The number of complaints filed against competitors was more or less stable at 42 cases (2017: 39). One complaint was filed by an HCP (2017: 0). No cases were classified as potentially hazardous to health (2017: 0), and to the best of the Secretariat's knowledge, no cases were escalated to Swissmedic (2017: 0). Sixty-four pharma companies (2017: also 64) submitted 6,001 sample copies (2017: 4,657) of their promotional material and information; 5,040 sample copies (84.0%; 2017: 77.8%) were sent to the Secretariat electronically. This increase is explained by the fact that the Code Secretariat regularly reminds companies to submit sample copies electronically whenever possible and in a timely manner.

The average duration of proceedings decreased from 8.7 days in 2017 to 7.6 days in the reporting year. It can be confirmed that the companies concerned as a rule continued to comply with the process and cooperated quickly and constructively.

In 2018, 113 proceedings were concluded (88% of all the cases dealt with as against 74% in the previous year) after the contested advertising had either been corrected or removed. The Secretariat rejected 11 (9%) of the complaints (previous year: 7%) because there had been no breach of the Code. In three cases, the complaint was submitted by the company itself (2017: 0). In one case (2017: 1), the Code Secretariat carried out a mediation procedure. Except for one case, all the conditions imposed were accepted by the responsible companies and implemented in a timely manner. As the exception concerned a once-off advertising measure, all the parties involved agreed not to escalate the matter further. In 2018, the Code Secretariat was aware of one bilateral negotiation (2017: 6). As there is no obligation to notify bilateral negotiations, the actual number remains unknown.

As in the previous year, the Code Secretariat answered some 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.

Established breaches of the Code

The total of 129 complaints (2017: 121) regarding suspected PC breaches referred to 43 (2017: 38) different PC requirements. One requirement was mentioned in 42% of the cases; two requirements were mentioned for around one-quarter of the cases, and three to seven requirements were mentioned for the remaining third. The following is a list of the PC requirements that were relevant or mentioned very often:

[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

- Principle of professional promotions (PC 21): at 13 (previous year: 12), the number of cases was stable.
- Unproven advertising statements (PC 251): at 38 (previous year: 24), the number of cases increased further at a high level.
- Incorrectly cited references (PC 252): at 39 (previous year: 30), the number of cases increased further at a high level.
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 254 and 255): the number of cases once again rose substantially to 81 (previous year: 37).
- Incomplete or impermissible references to literature (PC 26, 261 to 266): the number of cases declined noticeably to 43 (previous year: 60).
- Notifications of unqualified superlatives and comparatives (PC 267, 268): the number of cases rose sharply to 21 (previous year: 10).
- Obligations of pharmaceutical companies when implementing the PC (PC 5): the number of cases increased to 17 compared to 6 in the previous year.
- Ban on gifts (PC 142): no complaints were received (previous year: 2).
- Promoting as-yet unauthorised medicinal products or indications (PC 231, 232, 241 and 242): the number of cases increased noticeably (6 cases, previous year: 1).
- 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 (12) increased year-on-year (7).
- Use of the expression “safe” without an appropriate qualification (PC 253.1): one case was reported (previous year: 3).
- Use of expressions minimising possible risks, for example claiming that the medicinal product concerned did not induce addiction or was harmless (PC 253.2): declined to one case (previous year: 3).
- 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 recorded no cases (previous year: 2).
- Inducement to attend a specialist conference (PC 313): 2 cases compared to 18 in the previous year.
- Complaints regarding serious breaches of the Code (PC 641): three cases were recorded (previous year: 0).
- Referral of a matter to the appropriate State authority (PC 651): this year again, no cases were recorded (previous year: 0).

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

In 2018, 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 two cases (2017: 18), which is down considerably on the previous year, presumably as a result of the intensified efforts of the Secretariat in 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 2018, the companies that signed the PCC for the third time disclosed the pecuniary benefits granted in 2017 to healthcare professionals (HCP, mainly doctors and pharmacists), healthcare organisations (HCO, mainly hospitals and professional organisations) and patient organisations (PO) on their websites. 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).

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 in 2017 remained at 73%, although the median could be increased to some 83%. The average consent rate for HCO improved to around 90%, with the median rate as high as 97%. 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

[5] Guidelines of the International Pharmaceutical Congress Advisory Association – IPCAA
[6] https://www.ethicalmedtech.eu/e4ethics/about-e4ethics

between the individual companies, which are sometimes difficult to understand. The Code Commission therefore decided that scienceindustries will publish the names of PCC signatory companies who achieved an HCP consent rate of less than 80% in 2018 on its website in 2019. This was communicated to the signatory companies with a request to uphold and intensify their efforts in this regard. scienceindustries remained in close contact with the groups concerned, informed the FMH[7] 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.

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 a few companies, there was a short 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 2018.

The Code Secretariat has compiled the figures of the 59 companies that published data and by mid-July 2018, was able to put together the following statistics about Switzerland: At CHF 162.5 million, disclosures of transfers of value (ToV) increased by CHF 9.2 million from CHF 153.3 million in 2017, which is an increase of almost 6% on the previous year. CHF 12.5 million was disclosed for HCP compared to CHF 14 million in 2017, which represents a decline of - 11% year-on-year. At a total of CHF 91 million, the amount disclosed for HCO was stable compared to CHF 90 million in 2017. ToV of CHF 59 million were disclosed for R&D services, compared to CHF 49 million in 2017, which represents a year-on-year change of around 21%. Relatively high amounts were thus paid to HCO in Switzerland again compared to the rest of Europe, while the share of payments to HCP declined further. The changes in absolute figures in these two categories, however, are small, while the CHF 10 million increase for R&D services is quite substantial.

Public interest in this topic was considerably more muted in 2018 than in previous years and focused on a few interested media. Criticism was once again levied at the lack of a simple overview and the insufficient degree of individualisation for the disclosure. While the second point of criticism was answered by the aforementioned decision, the industry took a further step towards improved transparency by the publication of an overview of the 2017 disclosure figures on the website of scienceindustries.

Code Secretariat

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[7] FMH