# The Pharma Code and the Pharma Cooperation Code in 2016: Annual Report of the Code Secretariat

## Introduction

The Pharma Code (PC[1]) and the Pharma Cooperation Code (PCC[1]) are codes of conduct based on private law. Pharmaceutical companies active in Switzerland can voluntarily agree to abide with these codes (see lists of signatories[2]). scienceindustries[3], supported by the partner associations named in the preambles to the codes, is responsible for the Pharma Codes. These pharmaceutical codes enact in Switzerland the stipulations of the higher-ranking codes of the international organisations of the pharmaceutical industry (IFPMA[4], EFPIA[5]). While the PC primarily aims to encourage ethically correct conduct and avoid unfair competition, the PCC mainly seeks to promote transparency of pecuniary benefits granted under the cooperation between the pharmaceutical companies and their partners in the healthcare system.

The Code Secretariat of scienceindustries is responsible for the implementation of the codes. After 16 years, Dr. Felix Schwarzenbach was replaced as the Head of the Secretariat by Dr. Daniel Simeon, who assumed this responsibility on 1 November 2016. When dealing with disputes, the Secretariat primarily acts as an intermediary and applies the principle of the amicable settlement of conflicts. Its neutral assessment is almost always accepted by the parties involved in the individual disputes and the situation is soon returned to compliance to the Code and the law. The impressive number of cases that were dealt with in 2016 confirms the universally respected quality of this procedure, in particular the ease of access and the rapid and transparent decisions taken.

## Statistics regarding implementation of Pharma Code in 2016

At 119 compared to 116 in the previous year, there was a slight increase in the number of cases dealt with in connection with the PC in the reporting year. The number of complaints filed by competitors increased slightly from 54 in the previous year to 56 (47.1% - previous year 46.6%), while the Secretariat raised objections to promotional material on its own initiative in 62 cases compared to 61 cases in the previous year (52.1% - previous year 52%). In 2016, one complaint was filed by a legal representative, while one complaint was filed by a doctor in the previous year. Only one case was classified as potentially hazardous to health (previous year: 2), but three cases were referred to Swissmedic (previous year: 2). At around 300, the number of enquiries addressed to the Code Secretariat in 2016 was on a par with the previous year.

The average duration of proceedings increased slightly from 5.7 days in 2015 to 6.1 days in the reporting year. This was due to the increase in the average time it took the Secretariat to pass on complaints from competitors from 1.5 days to 1.7 days. It was encouraging once again that the companies concerned as a rule complied with the process and responded quickly and constructively.

In 2016, 82 proceedings were concluded (69% of all the cases dealt with as against 68 or 59% in the previous year) after the contested advertising had either been corrected or removed. The Secretariat rejected 20 (17%) of the complaints (previous year: 27 or 23%) because there had been no breach of the Code. In eight cases (7%; same as in the previous year: 8 or 7%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code; in two of the eight cases (previous year: 1) an immediate correction of the advertising was required. In one case (previous year: 0), the immediate and complete withdrawal of the disputed advertising was required. All the conditions imposed were accepted by the responsible companies and implemented in a timely manner. In seven cases (6%; previous year: 10 or 9%) the notifying company offered new interpretations, necessitating a review by the Secretariat. As in the previous year, two cases had to be referred to Swissmedic, and in one case the Code Secretariat carried out a mediation procedure. In 2016, the Code Secretariat was aware of six bilateral negotiations, three of which were unsuccessful. As there is no obligation to inform the Secretariat of these bilateral negotiations, the actual number remains unknown.

[1] The provisions of the two codes are referred to in the Annual Report by "PC" and "PCC" with the relevant section number.
[2] Signatories of the Pharma Code / Signatories of the Pharma Cooperation Code
[3] scienceindustries – Business Association Chemistry Pharma Biotech
[4] IFPMA
[5] EFPIA

## Established breaches of the Code

The total of 119 complaints regarding suspected PC breaches referred to 37 different PC requirements. Arranged in ascending order, this section lists the number of breaches of each requirement of the Pharma Code in 2016, in each case compared to the figures from 2015:

- Ban on gifts (PC 142): one complaint was received (previous year: 11).
- Principle of professional promotions (PC 21): five complaints were received (previous year: 0).
- Promoting as-yet unauthorised medicinal products or indications (PC 231, 232, 241 and 242): the number of cases increased slightly (16 cases, previous year: 14).
- Promotional statements differing from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 233): following a strong decline, the number of cases increased substantially again (17; previous year: 6).
- Prohibition on veiling the intention actually associated with the specialist advertising media (PC 236): one breach (previous year: 1).
- Pharmaceutical product still being described as new more than one year after its marketing authorisation had been issued in Switzerland (PC 237): increased to three cases (previous year: 1).
- Unproven advertising statements (PC 251): at 25 (previous year: 8), the number of these cases increased considerably.
- Incorrectly cited references (PC 252): this issue saw a further increase from 24 cases in the previous year to 28 in 2016.
- Use of the expression “safe” without an appropriate qualification (PC 253.1): only one case was reported (previous year: 5).
- Use of expressions minimising possible risks, for example claiming that the medicinal product concerned did not induce addiction or was harmless (PC 253.2): this increased to 5 cases again (previous year: 2).
- Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 254 and 255): the number of cases increased again to 13 (previous year: 10).
- Incomplete or impermissible references to literature (PC 26, 261 to 266): the number of cases soared to 49 (previous year: 14).
- Notifications of unqualified superlatives and comparatives (PC 267, 268): the number of cases increased slightly once again to 37 (previous year: 32).
- Unsolicited free samples sent (PC 272 in conjunction with Art. 10 para. 2 letter a of the Therapeutic Products Advertising Ordinance, TPAO): unlike in the previous year (2 cases), no cases were reported to the Secretariat.
- 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 one case again (previous year: 0).
- Events for the advertising of or provision of information about medicinal products as well as cooperation with organisations of healthcare professionals (PC 3): there were no complaints (previous year: 2).
- Notification of the Code Secretariat in respect of a change of person responsible in the company (PC 524 and 536): this obligation was neglected in only two cases (previous year: 4).
- Obligation of companies to provide the Code Secretariat with sample copies of their promotional material without the need for a special request to do so (PC 54): as there are indications that some companies do not meet this obligation to the required extent, this matter will be monitored more closely in 2017.
- Complaints regarding serious breaches of the Code (PC 641): one case was recorded (previous year: 0).
- Referral of a matter to the appropriate State authority (PC 651): here too, one case was recorded (previous year: 0).

## Implementation of Pharma Cooperation Code

Between 20 and 30 June 2016, the companies that signed the PCC disclosed the pecuniary benefits granted 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 in connection with 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 requires the recipients to agree to the disclosure. For this reason, scienceindustries was and is in close contact with the groups concerned, in particular the national organisations representing medical professionals, and managed to obtain the approval of the FMH[6], the Conference of Cantonal Medical Societies (KKA)[7], the Association of Swiss Hospitals (H+)[8] and the Swiss Academy of Medical Sciences (SAMW)[9] of the transparency initiative of the pharmaceutical industry. Following a media release published on 16 June 2016 in agreement with these organisations, the companies who signed the PCC finally disclosed their cooperation payments on their websites. As a result, the Code Secretariat received a large number of enquiries from the media regarding the disclosure policy in summer 2016. A total of more than 20 reports were published in various national and regional media. The prevailing tone was cautiously positive, although some criticism was also expressed, in particular about the fact that it is sometimes very difficult to locate the data and the need to improve the degree of individualisation.

The Code Secretariat collated the figures of 58 signatory companies that disclosed their data and prepared the following summary for Switzerland at the beginning of August 2016: of the total amount of CHF 138.6 million in disclosed payments, only around CHF 15.5 million was paid to HCP, which equates to approximately 11%, while the payments of CHF 75.5 million made to HCO account for 55%. Around 34% or CHF 47.5 million was paid to R&D cooperation partners, which is a considerable percentage. According to a survey by EFPIA, relatively high amounts were paid to HCO in Switzerland compared to the rest of Europe, while the payments to HCP were lower than the European average. It can be assumed that a substantial proportion of these HCO payments were made to international professional associations that have offices in Switzerland, which may at least be partially due to the need for these organisations to be located near the World Health Organisation (WHO) headquarters in Geneva.

After the data were published, the Code Secretariat immediately checked whether the data were easy to locate and whether they were complete as required by the PCC and the EFPIA. Warnings had to be issued to nine companies whose data could not be located by a simple internet search. The data provided by another nine companies were not complete, and these companies also had to make corrections regarding the pecuniary benefits paid to PO that have been subject to disclosure for some years. The goal of publishing complete data sets of a good quality could only be reached by August 2016.

The Code Secretariat also systematically checked all reports in order to calculate the rates of consent required by the EFPIA. Eight out of 58 signatory companies achieved complete transparency with regard to their payments to HCP as well as to HCO. Many companies achieved a good rate of consent for their payments to HCO, and 15 companies achieved complete transparency in this regard. However, it seems that, in some cases, consent rates have resulted in considerable discrepancies in the individual companies, which are sometimes difficult to understand. The Code Commission and Code Secretariat therefore encouraged the PCC signatory companies by letter in autumn 2016 to redouble their efforts to implement individual consent or to dramatically improve this area in companies where these rates are low.

**Code Secretariat**

Dr. med. Daniel Simeon Zurich, February 2017

[6] FMH
[7] Conference of Cantonal Medical Societies
[8] Association of Swiss Hospitals
[9] Swiss Academy of Medical Sciences