# The Pharma Code (PC[1]) and the Pharma Cooperation Code (PCC[1]) in 2015: Annual Report of the Code Secretariat

## Introduction

The PC and PCC are behavioural codes based on private law. While the PC aims to encourage ethically correct conduct and avoid unfair competition by pharmaceutical companies, the PCC seeks to promote transparency of pecuniary benefits granted under the cooperation between the pharmaceutical companies and stakeholders in the healthcare system. These pharmaceutical codes enact in Switzerland the stipulations of the higher-ranking codes of the international organisations of the pharmaceutical industry (IFPMA[2], EFPIA[3]).

These foundations of the Pharma Codes are:

- *IFPMA Code of Pharmaceutical Marketing Practices (IFPMA Code)*[4]
- *EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals (EFPIA Healthcare Professionals Code)*[5]
- *EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA HCP/HCO Disclosure Code)*[6]
- *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (EFPIA PO Code)* [7]

scienceindustries (Business Association Chemistry Pharma Biotech), supported by the partner associations named in the preamble to each of the codes, is responsible for the Pharma Codes. The revised PC and the PCC entered into force on 1 January 2014.

Pharmaceutical companies operating in Switzerland can voluntarily undertake to comply with the codes; they may do so separately for each of the codes. While a great majority of companies have complied with this invitation in respect of the PC[8], there was also a further year-on-year increase in the number of pharmaceutical companies subscribing to the PCC by the end of 2015[9].

## General matters relating to practical implementation of the Pharma Code in 2015

At 116 compared with 121 in 2014, there was a slight fall in the number of cases dealt with in connection with the PC. There were also 20 cases relating to the PCC (publication of data on patients' organisations) as against only one in the previous year.

The number of reports of bilateral agreements reached between the pharmaceutical companies on the basis of the rules of the PC, but without involving the Code Secretariat, was again small: 8 such cases were reported (2014: 7), involving 13 (2014: 6) companies. The Code Secretariat needs to be aware of such agreements to draw up the most effective case statistics possible. The frequency with which this route is in fact chosen is not known by the Code Secretariat. The question as to whether negligence is the reason for failure to notify must remain open. The extent to which competitors are willing to settle concrete differences bilaterally with reference to the PC is also unclear.

There was once again an overall trend towards a high degree of compliance, i.e. towards improvement of the internal stipulations and processes within companies using standard operating procedures (SOPs) in the area of the application of the PC (PC 5). Although there were relatively few clearly detectable breaches of the Code in 2015, there were once again many complex borderline cases and instances of conduct which can only be shown to be in breach of the Code by a more detailed examination as well as ambiguous statements in professional advertising. There was a substantial increase in the number of enquiries made by individual companies (PC 72, PCC 62) to the Code Secretariat on funda-

[1] The provisions of the two codes are referred to in the Annual Report by "PC" or "PCC" with the relevant section number.
[2] http://www.ifpma.org/
[3] http://www.efpia.eu/
[4] http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html
[5] http://transparency.efpia.eu/the-efpia-code-2
[6] http://transparency.efpia.eu/the-efpia-code-2
[7] http://transparency.efpia.eu/the-efpia-code-2
[8] http://www.en.scienceindustries.ch/involvement/pharma-code/pharma-code-signatories
[9] http://www.en.scienceindustries.ch/involvement/pharma-code/pharma-cooperation-code-signatories

mental issues from 200 to more than 350, with many questions prompted by the first-time publication of information under the PCC and the implementation of data recording and processing at the companies (over 200).

## Established breaches of the Code

This section lists the number of breaches of each requirement of the Pharma Code in 2015, in each case compared to the figures from 2014:

- As in 2014, *no company which had signed up to the PC referred a case directly to the authorities* without first making use of the PC procedure in contravention of the principle set out in PC 15.

- *Promoting as-yet unauthorised pharmaceuticals or indications (PC 231, 232 and 24)*: the number of cases fell slightly (14 cases, previous year: 16).
- *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 marked fall in 2014, the number of cases happily remained stable at 6 (previous year: 5).
- *Promotional materials that did not contain all the minimum information about pharmaceuticals required by the PC (PC 234, 254 and 255)*: the number of cases fell again to 10 (previous year: 13).
- *Prohibition on veiling the intention actually associated with the specialist advertising media (PC 236)*: one breach (previous year: 0).
- *Incomplete or impermissible references to literature (PC 261 to 266)*: there was a pleasing fall in such cases to 14 (previous year: 26).
- *Unproven advertising statements (PC 251)*: at 8 (previous year: 17), the number of these cases fell significantly.
- *Incorrectly cited references (PC 252)*: this issue saw a marked increase from 10 cases in the previous year to 24 in this.
- *Use of the expression "safe" without an appropriate qualification (PC 253.1)*: 5 cases were reported, the same as in the previous year.
- *Use of expressions minimising possible risks, for example claiming that the pharmaceutical concerned did not induce addiction or was harmless (PC 253.2)* there was a fall in such cases to 2 (previous year: 7).
- *Notifications of unqualified superlatives and comparatives (PC 267 to 269)*: the number of cases increased slightly once again to 32 (previous year: 30).
- *Pharmaceutical product still being described as new more than one year after its marketing authorisation had been issued in Switzerland (PC 237)*: only one case (previous year: 4) led to a complaint.
- *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 no cases in this regard either (previous year: 1).

- *Events for the advertising of or provision of information about pharmaceuticals as well as cooperation with organisations of healthcare professionals (PC 3)*: as in the previous year, there were 2 complaints in 2015.

- *Sponsorship of clinical trials (PC 4)*: once again, no proceedings were opened in this regard.

- *Notification of the Code Secretariat in respect of a change of person responsible in the company (PC 524)*: this obligation was neglected in only 4 cases (previous year: 16).
- *The obligation on the part 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)*: this was neglected in 6 cases (previous year: 3).

- *Provisions on relations between the pharmaceutical companies and patients' organisations (PCC 3)*: there were 9 breaches in this regard (previous year: 1). With these provisions having been transferred from the PC valid at that time to the PCC as part of the revision process, however, the requirement to disclose pecuniary benefits, unlike the other disclosures stipulated under the PCC, actually started applying as early as 2015. To raise awareness of the impending requirement to disclose all pecuniary benefits granted to professionals, healthcare organisations and patients' organisations, the Secretariat audited all signatories to the PCC sys-

tematically for the first time, rather than simply carrying out spot checks. This revealed that, in addition to the abovementioned breaches, there were 11 cases of failing to disclose that no patients' organisations were being supported. Although this does not constitute a breach of the PCC, it nevertheless resulted in queries from the Secretariat.

## Statistics

The maximum duration of proceedings stipulated in the PC (in principle within one month with a reasonable extension permitted in justified cases) continues to prove effective. In 2015 the procedures lasted on average for 8 working days representing a satisfactory degree of stability by comparison with 2014 (Ø 8 working days). Within the first 2 days (Ø) after the receipt of a notification (previous year: Ø 2 days) the Code Secretariat passed this on, accompanied by its provisional assessment, to the companies concerned. Another pleasing factor was that the companies concerned as a rule responded quickly and constructively. In no case was an application made for an extension of the time limit as in the previous year.

56 notifications or 47% (previous year: 75 or 59%) originated from competitors. In 61 cases or 52% (previous year: 51 or 40%) the Secretariat raised objections to promotional material (advertisements, mailings etc.) on its own initiative. One notice originated from physicians or other outside persons (1%; previous year: 1 or 1%). In 2015 there was again no case which might have had consequences relevant to health (i.e. cases presenting a direct or indirect risk to the health of patients). In 2015, as had been the case in the previous year, the Code Secretariat conducted no mediation procedure. To the best of our knowledge, as in the previous year no participating company had recourse to a court of law in 2015 after completing proceedings under the PC. Unlike in the previous year, however, 2 cases had to be referred to Swissmedic (PC 651), one by a competitor and one by the Secretariat.

In the event of a serious violation of the Code, the Code Secretariat may require the company which is at fault to send corrective information in a suitable form to the addressees concerned in each instance: in 2015 as in 2014 this was not necessary in any single case. In 2015, 68 proceedings were concluded (59% of all the cases dealt with as against 77 or 64% in the previous year) after the contested advertising had either been corrected or removed. Because there was no breach of the Code, the Secretariat rejected 27 (23%) of the complaints as being unfounded (previous year: 23 or 19%). In 8 cases (7%; previous year: 12 or 10%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code; in 1 of the 8 cases (previous year: 2) an immediate correction of the advertising was required. As in the previous year, the immediate and complete withdrawal of the disputed advertising was not required in any single case. All the conditions imposed were accepted by the responsible companies and implemented in a timely manner. In 10 cases (9%; previous year: 7 or 6%) the notifying company offered new interpretations, necessitating a review by the Secretariat. In 3 cases the new objection was rejected as being unfounded, whilst 4 cases were concluded after the contested advertising was corrected, also taking account of the additional point being criticised. In addition, in 3 cases the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code.

In the 2015 reporting year, all the company websites of the 55 signatories to the PCC were scrutinised in respect of the disclosure of payments to patients' organisations. Payments had not been disclosed in 8 cases (PCC 352). In one case a change of person responsible for the PCC had also not been reported. All the breaches highlighted by the Code Secretariat were rectified by the companies responsible without delay.

Although 11 cases of failure to publish information did not constitute breaches per se as no payments had been made in 2014, no mention of this fact was made on the relevant websites as recommended by the Secretariat in the interests of transparency and to avoid unnecessary queries.

## Ban on gifts now more stringent

On 1 July 2014 the prohibition of gifts entered into force. It is understood as a wide-ranging ban by EFPIA and with few exceptions no more gifts may be given. In the course of 2014, scienceindustries was requested by EFPIA to make the exceptions to the prohibition of gifts stipulated in the PC (PC 143 ff.) more stringent. A transitional period until 1 July 2015 was granted. Since then, only the normal commercial compensation for orders and deliveries of pharmaceuticals and the free distribution of pharmaceutical samples, writing implements and writing blocks without a logo on the occasion of events have been permitted as exceptions from the ban on gifts, together with payment for meals on a modest scale and the provision of information and training materials in compliance with the restrictive principles of EFPIA.

In view of the restrictive attitude of EFPIA the Secretariat adopted a narrow interpretation of the ban and declined to approve a large number of enquiries concerning the further use of various items. The Code Secretariat intervened in

several cases in this regard, cautioning companies or issuing recommendations. In addition, the Code Secretariat declared a campaign by the company Documed to launch a new "Drug Compendium" to be incompatible in its current form with the ban on gifts after consulting the Code Commission. Unlike in the previous year, however, interventions in the run-up to the Christmas season were no longer prominent. A total of 11 breaches (previous year: 7) were recorded (PC 142, 143).

### Proven implementation of the Pharma Codes without penalties

The implementation of the code follows the principle of amicable settlement of conflicts assisted in case of need by mediation by the Code Secretariat. Unlike other foreign codes in the pharmaceutical industry the Swiss Code has deliberately refrained from imposing penalties. In dealing with notifications of conduct in breach of the Code, the Code Secretariat plays an essentially intermediary role similar to that of a Justice of the Peace. Its neutral assessment as to whether a breach of the Code has or has not occurred in a particular case is practically always respected by the parties involved in the case. In comparison with the implementation of similar foreign codes, the statistics concerning the PC always show slightly higher case numbers. However, these are a sign of the universally respected quality of this procedure, i.e. the ease of access and the rapid and transparent decisions taken. As indicated once again in our Annual Report, this always enables conduct in breach of the code to be eliminated rapidly and almost always by joint agreement.

The question of the introduction of penalties and in particular of fines arose in the last revision but one of the EFPIA Healthcare Professionals Code in 2006. At the time, on the basis of the reservation of the priority of national laws and ordinances, scienceindustries waived the application of sanctions for breach of the code when the PC was amended. The question as to the suitable supervisory and implementing model arose again in 2013 when the PC was revised and the PCC created. In the hearing that had taken place beforehand, the companies had spoken out clearly against penalties in the context of both the PC and the PCC, favouring the continuation of the amicable settlement procedure which had proved its worth for many years.

The reservation mentioned here means that Swiss federal law on therapeutic substances likewise regulates professional advertising for pharmaceuticals and that Swissmedic, as the competent authority, can impose administrative or criminal measures in the event of breaches of the rules. Accordingly, there were once again two "further appeals" to Swissmedic in 2015, which actually resulted in more restrictive conditions being imposed in some areas. Moreover the pharmaceutical companies can appeal to the judge if they suspect that there has been a breach of the Federal Act on Unfair Competition (UCA). Overall, the model chosen for Switzerland has proved itself to be successful. As the procedural hurdles are small, instigating proceedings under the Code is a tried-and-tested mechanism for companies as well as for the Secretariat. It is clear once again that the competition is probably by far the most effective watchdog.

### Implementation of the Pharma Cooperation Code

On 24 June 2013, EFPIA[10], the European Federation of the Pharmaceutical Industry, adopted its new *Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (EFPIA HCP/HCO Disclosure Code[11])*. Based on that code, scienceindustries, as the responsible member association of EFPIA in Switzerland, has compiled the PCC which entered into force in January 2014. The partner federations Intergenerika, Interpharma and vips also approved the PCC.

With effect from 2016 the signatory companies will be publishing every year on their public websites details of the pecuniary benefits which they granted in the previous year (for the first time in 2015) to professionals (especially physicians and pharmacists) and to healthcare organisations (especially hospitals and research institutes). The term pecuniary benefits within the meaning of PCC means payments made either directly or indirectly in connection with pharmaceuticals available on prescription in human medicine.

To achieve a high degree of transparency, the disclosure is to be done individually, i.e. naming the recipients personally. This requires the consent of the persons or organisations concerned to disclosure; the cooperation agreements between the companies and these professionals and organisations had to be, or will have to be, supplemented by suitable consent clauses. For that reason scienceindustries has been and still is in close contact with these players, especially the high level national organisations of the medical profession. The FMH[12], the Conference of Cantonal Medical Societies (KKA)[13] and the Swiss Academy of Medical Sciences (SAMW)[14] officially back the transparency initia-

[10] http://www.efpia.eu/
[11] http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code---august-2013-edited-final.pdf
[12] http://www.fmh.ch/
[13] http://www.kka-ccm.ch/index.php?id=9
[14] http://www.samw.ch/en/News/News.html

tive of the pharmaceutical industry and have welcomed the introduction of the PCC. From the very beginning, scienceindustries has kept physicians, pharmacists, hospitals and other healthcare providers up to date on this transparency initiative and is deeply committed to encouraging disclosure in these circles. scienceindustries continued its efforts to raise awareness in 2015 to help promote the widest possible individual disclosure. Although an evaluation of the feedback received from the companies (not substantiated with statistics) continues to paint a promising picture, we cannot afford any let-up in our endeavours to further increase the number of consenting companies and prevent any from withdrawing that consent.

In addition, throughout the 2015 reporting year, the Code Secretariat answered a great many enquiries, some highly detailed, by the signatory companies in connection with the introduction of the PCC at national corporate level. As in the previous year, it organised two workshops for PCC managers in the autumn of 2015 in cooperation with PharmaPraxis and has already planned a follow-up event for the autumn of 2016. Demand for the information flyer produced in the previous year remained high in 2015. In addition, the Q&A document on the PC/PCC was completely revised and significantly expanded in March 2015 and made available to the companies in three languages. This document is in line with EFPIA specifications wherever possible, contains interpretation and practical recommendations for applying the Swiss codes and serves primarily as an implementation aid for signatory companies. The aim is to ensure that the codes are enforced in as uniform a way as possible across all signatory companies. The Code Secretariat explained the transparency initiative and promoted its implementation at further events and platform discussions and in contact with various media representatives.

The Secretariat also addressed matters of communication right from an early stage in the reporting year in view of the first-time publication of information in 2016. In consultation with the Intergenerika, Interpharma and vips federations, the Code Commission made the fundamental decision to communicate actively yet unobtrusively. EFPIA joined scienceindustries in advising signatory companies not to disclose their information before 20 June 2016, i.e. once scienceindustries has announced the transparency initiative and briefly reiterated its content in a press release. scienceindustries also signalled plans for a Q&A document on communications issues, which is set to be made available to companies and healthcare provider organisations in the first quarter of 2016. The document is intended to help signatory companies field any enquiries from the media while also ensuring that recipients are aware of the industry's answers to key questions in this regard. The Code Secretariat will also be providing those responsible for communications on the PCC with additional documents on handling media enquiries on the transparency initiative.

## Communication and practical recommendations

At irregular intervals the Secretariat reports in an abstract form to the Pharma Code signatories on individual cases which it has assessed to enable the signatory companies to learn from the knowledge and experience gained by other companies. Several such case reports appeared on the Membernet in 2015 following a hiatus in 2014. The first ever case study on the PCC was also published. By contrast, the Code Secretariat did not issue any new practical recommendations on the codes in the 2015 reporting year.

## Secretariat of the Codes

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