**Code of Conduct of the Pharmaceutical Industry in Switzerland**

# The Pharma Code (PC[1]) and the Pharma Cooperation Code (PCC[1]) in 2014: 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 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]

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 Code. The revised PC and the PCC entered into force on 1 January 2014. As the Pharma Code Secretariat has been responsible for supervising both codes since 2014 it has been known as the *Code Secretariat* since that date.

Pharmaceutical companies operating in Switzerland can voluntarily undertake to comply with the codes; they may do so separately for each of the codes. Up to now a great majority of companies have complied with this invitation in respect of the PC [7] and by the end of 2014 a substantial number of pharmaceutical companies had also subscribed to the PCC [8].

## General matters relating to practical implementation of the Pharma Code in 2014

After a substantial increase to 120 cases in 2013, the number of cases dealt with in connection with the Pharma Code in 2014 remained stable at 121. The Code Commission sent out for the first time a concise fact sheet about the Pharma Code to the persons responsible for that code. It then became clear that some signatories had failed to notify changes in the persons responsible for the Pharma Code in their respective companies (PK 536).

The number of reports of bilateral agreements reached between the pharmaceutical companies on the basis of the rules of the Pharma Code, but without involving the Code Secretariat, was again small: 7 such cases were reported (2013: 6) involving 6 (2013: 8) companies. The Code Secretariat needs to be aware of such agreements to draw up the most effective possible case statistics. 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 Pharma Code is also unclear.

In 2014 there were few clearly detectable breaches of the Code of Conduct but many complex cases once again (borderline cases or 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). Once again a trend towards greater compliance was observed, i.e. towards improvement of the internal stipulations and processes within companies using standard operating pro-

[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/uploads/Modules/Documents/efpia-hcp-code---2013-consolidated-final-2.pdf
[6] http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code-2014.pdf
[7] http://www.scienceindustries.ch/engagements/pharma-kodex-und-pharma-kooperations-kodex/unterzeichner-des-pharmakodexes
[8] http://www.scienceindustries.ch/engagements/pharmakodex/unterzeichner-des-pharma-kooperations-kodexes

cedures (SOP) in the area of the application of the Pharma Code (PC 5). There was a substantial increase in the number of enquiries made by individual companies to the Code Secretariat on fundamental issues from 62 to more than 200, especially in connection with the Pharma Cooperation Code (more than 100) and the newly introduced prohibition of gifts (PC 72, PCC 62).

## Pharma Code requirements and established breaches of the Code

The number of cases in which promotional statements differed from the drug information for health professionals approved by Swissmedic at the time when marketing authorisation was given (PC 233) fell again significantly (from 20 to 5). The number of cases in which promotions were issued for as yet unauthorised medicinal products or indications (PC 231, 232 and 24) on the other hand rose slightly (16 cases, previous year: 13). At 13 (previous year: 8) the number of cases in which promotional materials did not contain all the minimum information about pharmaceuticals required by the PC (PC 234, 254 and 255) increased again. The prohibition on veiling the intention actually associated with the specialist advertising media (PC 236) was not breached; that had already been the case in the previous year.

The number of complaints about general standards of quality remained stable with 64 cases after a steep reduction in the previous year to 66 cases. With 26 cases (previous year: 18) there was an increase in incomplete or impermissible references to literature (PC 261, 262, 263, 264, 265, 266). In just 10 cases compared to 17 in the previous year references were not correctly cited (PC 252). In 17 cases (previous year: 16) the advertising statements were not proven (PC 251). The expression “safe” was used in 5 (previous year: 5) cases without an appropriate qualification (PC 253.1). In 7 cases (previous year: 5) expressions minimizing possible risks were used, for example claiming that the medicinal product concerned did not induce addiction or was harmless (PC 253.2).

With 30 cases (previous year: 36) the number of notifications of unqualified superlatives and comparatives (PC 267-269) fell slightly once again. In 4 cases (previous year: 2) a pharmaceutical product was still being described as new more than one year after its marketing authorisation had been issued in Switzerland (PC 237). In 2 cases (previous year: 0) unsolicited free samples were sent (PC 272 in conjunction with Art. 10, para. 2 letter a of the Pharmaceutical Advertising Ordinance, AWV[9]). The designation of 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) was incorrectly used in one case (previous year: 5 cases).

As in the previous year, there were 2 complaints in 2014 about events for the advertising of, or provision of information about, medicinal products as well as cooperation with organisations of healthcare professionals (PC 3). Once again no proceedings were opened in connection with the sponsorship of clinical trials (PC 4). There was one breach (previous year: 2) in connection with the provisions on relations between the pharmaceutical companies and patients’ organisations (PCC 3).

Unlike the situation in 2013 (2 cases) no company which had signed up to the Pharmaceutical Code referred a case directly to the authorities without first making use of the Pharma Code procedure in contravention of the principle set out until the end of 2013 in the preamble to the Pharma Code and since 2014 in PC 15.

The obligation on the part of companies to provide the Pharma Code Secretariat with sample copies of their promotional material without the need for a special request to do so (PC 54) was not respected in 3 cases (previous year: 5). In 16 cases (previous year: 10) the change of person responsible in the company was not notified to the Code Secretariat as required by PC 524. This increase is also connected to the first mailing to all the responsible persons referred to previously.

## Newly introduced prohibition of gifts

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. From then on only the normal commercial compensation for orders and deliveries of pharmaceuticals, the distribution free of charge of pharmaceutical samples, writing implements and writing blocks without a logo will be permitted as exceptions from the ban on gifts on the occasion of events, 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.

[9] http://www.admin.ch/opc/de/classified-compilation/20011778/index.html

The Code Secretariat has been approached by a number of companies about the implementation of the ban on gifts. In view of the restrictive attitude of EFPIA the Secretariat adopted a narrow interpretation of the prohibition and declined to approve some enquiries concerning the further use of various items (including diaries). In the run-up to the Christmas season the Code Secretariat had to intervene in a few cases and required signatory companies to respect the ban on gifts and cease making Christmas presents. A total of 7 breaches occurred (PC 142, 143).

## Statistics

The maximum duration of proceedings stipulated in the Pharma Code (until the end of 2013, 25 working days which can be extended once by 10 working days in justified cases; PC 661 and 664 – new: in principle within one month with a reasonable extension permitted in justified cases) proved effective once again. In 2014 the procedures lasted on average for 8 working days representing a satisfactory degree of stability by comparison with 2013 (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.

75 notifications or 59% (previous year: 66 or 55%) originated from competitors. In 51 cases or 40% (previous year: 53 or 44%) 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: 2 or 2%). In 2014 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 2014, 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 after completing the Pharma Code proceedings.

In the event of 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 addresses concerned in each instance: in 2014 as in 2013 this was not necessary in any single case. In 2014, 77 proceedings were concluded (64% of all the cases dealt with against 73 or 58% 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 23 (19%) of the complaints as being unfounded (previous year: 25 or 20%). In 12 cases (10%; in the previous year: 15 or 12%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the code; in 2 of the 15 cases (1 in the previous year) 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 7 cases (6%; previously 13 or 10%) the notifying company asked for a review because it did not agree with the way in which the case had been settled by the Secretariat. As in the previous year no case had to be referred to Swissmedic (PC 651).

## Proven implementation of the Pharma Code without penalties

The implementation of the code follows the principle of amicable settlement of conflicts assisted in case of need by mediation by Code Secretariat. Unlike most similar 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 the 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. By comparison with the implementation of similar foreign codes the statistics concerning the Pharma Code 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 Pharma Code was amended. In the hearing on this matter the companies had spoken out clearly against penalties, i.e. in favour of the continuation of the non-contentious amicable settlement procedure which had proven its worth for many years. The reservation mentioned here means that in Switzerland the State Law on Therapeutic Substances likewise regulates professional advertising for pharmaceuticals and Swissmedic[10] as the competent authority can impose administrative or criminal measures in the event of breaches of the rules. Moreover the pharmaceutical companies can appeal to the

[10] https://www.swissmedic.ch/index.html?lang=de

judge if they suspect that there has been a breach of the Federal Act on the Prevention of Unfair Competition (UWG)[11].

It is also worth noting that the question as to the suitable supervisory and implementing model arose again in 2013 on the occasion of the PC revision and the creation of the PCC. At the hearing, the proposal to retain the Swiss supervisory model, which had proven its worth for many years, for both these codes was clearly advocated, i.e. this model was likewise adopted for the PCC. This model has proved successful primarily because competition is by far the most effective watchdog.

### 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. In 2014 no such case reports appeared on the Membernet; the series is to be continued again in 2015. However, in the year under review the Code Secretariat issued new practical recommendations about the recently introduced PCC[12] and began to translate the recommendations into English; that process will be continued.

### Implementation of the Pharma Cooperation Code

On 24 June 2013, EFPIA[13], 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[14])*. 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, completed 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[15], the Conference of Cantonal Medical Societies (KKA)[16] and the Swiss Academy of Medical Sciences (SAMW)[17] are now officially favouring the transparency initiative of the pharmaceutical industry and welcome the introduction of the PCC. scienceindustries plans to continue the information and promotion of awareness among physicians and pharmacists in 2015, so making a contribution to the widest possible individual disclosure.

In addition, throughout the reporting year, the Code Secretariat answered numerous detailed enquiries by the signatory companies in connection with the introduction of the PCC at national corporate level. In the autumn of 2014 in cooperation with PharmaPraxis it organised two well-attended workshops for PCC managers and has already planned follow-up events for the autumn of 2015. Besides, the Secretariat has provided information flyers for the companies, which were ordered in large quantities. On the occasion of further events and platform discussions and in contact with various media the Code Secretariat presented the transparency initiative and promoted its implementation. At the end of December 2014 the FAQ were received from EFPIA and the Code Secretariat will go on to effect a comprehensive revision of the Q&A concerning the PC and PCC in 2015.

[11] http://www.admin.ch/opc/de/classified-compilation/19860391/index.html
[12] http://www.scienceindustries.ch/pharmakodex-praxis
[13] http://www.efpia.eu/
[14] http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code---august-2013-edited-final.pdf
[15] http://www.fmh.ch/
[16] http://www.kka-ccm.ch/index.php?id=9
[17] http://www.samw.ch/de/Aktuell/News.html

## Appeal

Professional advertising of medicinal products and cooperation between the pharmaceutical companies and professionals will be improved if they undergo a critical appraisal, especially by professional circles. All physicians and pharmacists are therefore urged once again to contact the Code Secretariat if they disapprove, on ethical or scientific grounds, of any professional advertising or other conduct of a pharmaceutical company which falls within the scope of application of the PC or PCC.

## Secretariat of the Pharma Code

Dr med. Felix Schwarzenbach Zurich, February 2015