Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code)
of 4 December 2003, revised on 6 September 2013[1]

The Pharma Code (PC) in 2013: Annual report of the Code Secretariat

Introduction

The Pharma Code is a code of practice based on private law, the aim of which is to encourage an ethically correct conduct and avoid unfair competition by pharmaceutical companies. Pharmaceutical companies operating in Switzerland may give a voluntary undertaking to comply with this code. To date, the vast majority of companies have signed up[2]. In Switzerland the Pharma Code enacts the stipulated requirements of the higher ranking codes of the international organisations of the pharmaceutical industry (IFPMA[3], EFPIA[4]).

These foundations of the Pharma Code are:

- *IFPMA Code of Pharmaceutical Marketing Practices (IFPMA Code)*[5]
- *EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals (EFPIA Healthcare Professionals Code)*[6]

scienceindustries (Business Association Chemistry Pharma Biotech), supported by its partner associations named in the preamble to the Pharma Code, is responsible for this code.

In the year under review, scienceindustries revised the Pharma Code, as usual in agreement with the partner associations named in the preamble and following consultation with the Pharma Code signatories. scienceindustries, supported by the partner associations named in the preamble, also published the new Pharma Cooperation Code in the year under review.

By the end of 2013, the Pharma Code also implemented in Switzerland the *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (EFPIA Patient Organisations Code)*[7]. As part of this revision of the Pharma Code, the rules on cooperation between the pharmaceutical companies and patient organisations were embodied in the newly created Pharma Cooperation Code.

Because the Pharma Code Secretariat will be responsible for supervision of the Pharma Code and of the Pharma Cooperation Code with effect from 2014, it will be known in future as the *Code Secretariat*. The revised Pharma Code and the Pharma Cooperation Code came into force on 1 January 2014. For further details, see the relevant section below in this annual report.

General matters relating to practical implementation of the Pharma Code in 2013

In 2013, unlike in previous years, the number of cases dealt with in relation to the Pharma Code rose significantly compared with 2012 (from 100 to 120). One possible reason for this trend reversal was the intensive discussion surrounding the revision of the Pharma Code and the creation of the new Pharma Cooperation Code. Both these developments directed increasing attention once again to the Pharma Code. Similarly, a number of signatories failed to report changes in the named persons responsible for the Pharma Code (PC[8] 536[9]/*536*[10]). In view of these circumstances, the increase in the number of cases handled by the Code Secretariat must be seen in an altogether positive light.

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[1] German: http://www.scienceindustries.ch/engagements/pharma-kodex-und-pharma-kooperations-kodex
French: http://www.fr.scienceindustries.ch/engagements/code-pharmaceutique-et-code-de-cooperation-pharmaceutique
English: http://www.en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code
[2] List of signatories: http://www.en.scienceindustries.ch/involvement/pharma-code/pharma-cooperation-code-signatories
[3] http://www.ifpma.org/
[4] http://www.efpia.eu/
[5] http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html
[6] http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code---2013-consolidated-final-2.pdf
[7] http://transparency.efpia.eu/uploads/Modules/Documents/code_po2011.pdf
[8] The provisions of the Pharma Code are cited in the annual report as "PC" with the corresponding section number.
[9] PC numbers in normal script refer to the rules set out in the version of the Pharma Code which was valid until the end of 2013.
[10] PC numbers in *italics* refer to the analogous rules in the Pharma Code which were revised on 6 September 2013 and have been in force since 1 January 2014.

The number of reports of bilateral agreements reached between pharmaceutical companies on the basis of the rules of the Pharma Code, but without involving the Code Secretariat, was again small: 6 such cases were reported (2012: 9), involving 8 companies (2012:13). The Code Secretariat needs to be aware of such agreements for drawing up case statistics which are as meaningful as possible. It is currently unaware of how often this route is actually chosen. The question as to whether negligence is the reason for failure to notify still remains unanswered. The extent to which competitors are willing to settle concrete differences bilaterally with reference to the Pharma Code is also unclear.

In 2013, there were further clearly detectable cases of breach of the code of practice, including more complex cases (breaches which were borderline or only recognized as such on closer examination, as well as ambiguous statements in professional advertising). We saw a continuation of this trend towards greater compliance, i.e. towards improvement of the internal stipulated requirements and processes within companies using standard operating procedures (SOP) in the area of application of the Pharma Code (PC 5/*5*). In this broader context, individual companies also consult the Code Secretariat on fundamental issues in compliance with PC 72 / *72* (62 enquiries; previous year 74).

Proven implementation of the Pharma Code without sanctions

The Pharma Code is enforced according to the principle of amicable conflict resolution, if necessary supported by mediation through the Code Secretariat. Unlike most similar codes abroad, the intention of the Swiss Pharma Code has always been to avoid sanctions. The Code Secretariat acts primarily as an intermediary when dealing with notifications of conduct in breach of the Pharma Code; its role in this respect is similar to that of a mediator. Its neutral assessment as to whether conduct in breach of the Code has or has not occurred in each particular case is almost always respected by the parties involved. Compared to the implementation of similar foreign codes, the statistics for the Pharma Code always show slightly higher case numbers. These are a sign of the high quality of the procedure in the opinion of all the parties concerned, i.e. a low access threshold and quick and transparent decisions. This annual report shows once again that breaches of the Code are consistently remedied within a short space of time and almost always by consensus.

The question of introducing sanctions, particularly fines, arose during the last review of the EFPIA Healthcare Professionals Code in 2006. At that time, scienceindustries dispensed with the introduction of sanctions when dealing with Code violations, acting on the proviso that national laws and regulations take precedence. In the consultation on this matter, the companies spoke out clearly against sanctions, i.e. they were in favour of retaining the non-adversarial mediation procedure which had proved its merit in practice over many years. The above-mentioned proviso means that the national law concerning medicinal products in Switzerland also governs advertising for medical products and Swissmedic[11], being the responsible authority, can impose administrative measures or sanctions when breaches of the rules occur. In addition, the pharmaceutical companies can bring court actions if they suspect that there has been a breach of the Swiss federal law on the prevention of unfair competition (UWG)[12].

Incidentally, the issue of the suitable supervisory and implementing model arose once again in 2013 during the revision of the Pharma Code and the creation of the Pharma Cooperation Code. In the consultation process, clear preference was given to the proposal of maintaining the Swiss supervisory model which had proved successful over many years for both Codes; it was felt that this model should also be adopted for the Pharma Cooperation Code. This model has proved successful, primarily because competition must surely be far the most effective watchdog.

Pharma Code requirements and established breaches of the code

There was a further increase (from 15 to 20) in the number of cases in which promotional statements differed from the information on medicinal products for health professionals approved by Swissmedic when the marketing authorisation was approved (PC 131.3/*233*). By contrast, there was a slight decrease in the number of cases in which advertising was carried out for as yet unauthorised medicinal products or indications (PC 131.1/*231*, 131.2/*232* and 133/*24*) (13 cases, previous year: 15). The number of cases in which promotional material did not include all the minimum information about pharmaceuticals as required by the PC, reduced to 8 (previous year 12) (PC 131.4/*234*, 134/*254* and 135/*255*). Unlike in the previous year (previous year: 1), there were no further breaches of the ban on concealing the actual intention associated with specialist advertising media (PC 132.2/*236*).

Following a substantial increase in the previous year, there was an equally significant reduction in the number of complaints about the general standards of quality: from 90 to 66. With 18 cases (previous year: 22) there was only a small reduction in incomplete or impermissible references to literature (PC 143.1/*261*, 143.2/*262*, 143.3/*263*, 143.4/*264*,

[11] https://www.swissmedic.ch/index.html?lang=de / https://www.swissmedic.ch/index.html?lang=fr
[12] http://www.admin.ch/opc/de/classified-compilation/19860391/index.html
http://www.admin.ch/opc/fr/classified-compilation/19860391/index.html

143.5/*265*, 144/*266*). References were not correctly cited (PC 141.3/*252*) in 17 cases (previous year 21). In 16 cases (previous year: 25) the advertising statements were not proven (PC 141.2/*251*). The expression "safe" was used without appropriate qualification in 5 cases (previous year: 6) (PC 142.1/*253.1*). Expressions minimising possible risks, e.g. claiming that the medicinal product concerned did not induce addiction or was harmless (PC 142.2/*253.2*), were used in 5 cases (previous year: 11).

The number of notifications of unqualified superlatives and comparatives (PC 145/*267-269*) rose again to 36 cases (previous year: 29). The number of cases in which a pharmaceutical product continued to be designated as new more than one year after its marketing authorisation had been issued in Switzerland (PC 146/*237*) was 2 (previous year: 1). No unsolicited free samples were sent (previous year: 2), (PC 147.2/*272*, in conjunction with Art. 10 para. 2 a of the Pharmaceuticals Advertising Ordinance, AWV[13]). The designation of mailings as an "important notice" (PC 148/*28* – allowed exclusively safeguarding pharmaceutical safety and in the event of interruption to or halt in the supply of a medicinal product) was incorrect in 5 cases (previous year: 3 cases).

2 complaints (previous year: 8) were made in 2013 about events for the specialist advertising of or provision of information about medicinal products, as well as on the cooperation with organisations of healthcare professionals (PC 2/*3*). On the other hand, once again there were no proceedings opened in connection with the sponsorship of clinical trials (PC 3/*4*). There were 2 new breaches (previous year: 0)in connection with the provisions on relations between the pharmaceutical companies and patient organisations (governed by PC 4 until the end of 2013[14]).

Unlike in 2012 (no cases), 2 companies which had signed up to the Pharma Code referred a case directly to the authorities without first making use of the Pharma Code procedure, in contravention of the principle set out in the preamble to the Pharma Code up to the end of 2013 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/*54*), was not respected in 5 cases (previous year: 26). In 10 cases (previous year: 4) the change of person responsible in the company was not notified to the Code Secretariat as required by PC 524/*524*. This is also related to the signing of the new Pharma Cooperation Code in which the Code Secretariat has systematically compared the names of the new persons responsible with the existing data from the Pharma Code.

Statistics

The maximum duration of proceedings stipulated in the Pharma Code (25 working days until the end of 2013 which may be extended on a single occasion by 10 working days in justified cases; PC 661/*661* and 664/*664* – now: in principle within one month with the possibility of an appropriate extension in justified cases) proved effective once again. In 2013, the proceedings lasted on average for 8 working days representing a satisfactory trend by comparison with 2012 (average 10 working days). Within the first 2 days (Ø) after the receipt of a notification (previous year: Ø 2.5 days) this was forwarded by the Code Secretariat, accompanied by its assessment, to the companies concerned. Another pleasing factor was that the companies concerned as a rule responded quickly and constructively. In no case was there any need for a time limit to be extended (previous year: 3 cases; around 3% of all the cases dealt with).

66 notifications or 55% (previous year: 56 or 54%) originated from competitors. In 53 cases or 44% (previous year: 47 or 46%) the Secretariat raised objections to promotional material (advertisements, mailings etc.) on its own initiative. 2 notices originated from physicians and other third parties (2%; previous year: 7 or 7%). In 2013 there was again no case which might have had consequences relevant to health regulation measures (i.e. cases presenting a direct or indirect risk to patient health). In 2013, as in the previous year, the Code Secretariat did not conduct any mediation proceedings. 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 breaches of the Code, the Code Secretariat may require the offending company to send corrective information in a suitable form to the addressees concerned in each instance: in 2013 as in 2012 this was not necessary in any single case. In 2013, 73 proceedings were concluded (58% of all the cases dealt with compared with 61 or 59% 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 25 (20%) of the complaints received as being unfounded (previous year: 14 or 14%). In 15 cases (12%; in the previous year: 15 or 14%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code; in one of the 15 cases (0 in the previous year)

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

[14] Since 1 January 2014, cooperation between pharmaceutical companies and patient organizations is no longer covered by the Pharma Code, but by the new Pharma Cooperation Code (in its Sec. 3: http://www.en.scienceindustries.ch/_file/12952/pharma-kooperations-kodex-2013-e.pdf)

an immediate correction of the advertising was required. In no case (previous year: 0) was the immediate and complete withdrawal of the disputed advertising stipulated. All the conditions imposed were accepted and implemented in a timely manner. by the companies responsible In 13 cases (10%; previous year 11 or 11%) the notifying company asked for a review because it was not in agreement 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 666/*651*).

Communication and practical recommendations

At irregular intervals the Secretariat reports in an abstract form to the Pharma Code signatories pursuant to PC 616/*616*[15] about individual cases which it has assessed, with a view to enabling other companies to learn from the knowledge and experience gained. In 2013, further such neutral case reports were published on the scienceindustries Membernet. The series is being continued. In the year under review, the Code Secretariat issued no practical recommendations[16] but did adapt the existing recommendations in early 2014 to the revised Pharma Code and the new Pharma Cooperation Code.

Partial revision of the Pharma Code and creation of the new Pharma Cooperation Code

On 24 June 2013 EFPIA[17], 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[18])*. That Code requires the pharmaceutical companies to disclose all their payments ("transfers of value"), in particular to physicians and hospitals. This obligation of disclosure applies with effect from 2016 and will for the first time cover the payments made to professionals or healthcare organisations in 2015, e.g. for consultancy and services or for research work . At the same time, EFPIA decided to amend its *Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (EFPIA HCP Code[19])*. Under this Code, a general ban has been imposed on gifts by pharmaceutical companies to professionals (in particular physicians) (with a transitional period in Switzerland expiring at the end of June 2014). In future only certain items, information and training materials of modest value which are intended solely for the medical or pharmaceutical activity or used for further or advanced medical or pharmaceutical training and are also of benefit to patients in both cases, will be permitted. The EFPIA HCP/HCO Disclosure Code and the amended EFPIA HCP Code have to be implemented as usual by the National Member Federations of EFPIA: they were required to draw up appropriate codes by the end of 2013. For the implementation of the EFPIA HCP/HCO Disclosure Code, scienceindustries adopted the new Pharma Cooperation Code and revised the existing Pharma Code to implement the amended EFPIA HCP Code[20].

Appeal

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

Secretariat of the Pharma Code

Dr med. Felix Schwarzenbach

Zürich, mid-March 2014

[15] "It [the Code Secretariat] informs the companies regularly of enforcement decisions (without naming companies or particular pharmaceuticals) and of practical experience of enforcement which is in the general interest)".
[16] http://www.en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code/pharma-code-and-pharma-cooperation-code-practice
[17] http://www.efpia.eu/
[18] http://transparency.efpia.eu/uploads/Modules/Documents/efpia-disclosure-code---august-2013-edited-final.pdf
[19] http://transparency.efpia.eu/uploads/Modules/Documents/efpia-hcp-code---2013-consolidated-final-2.pdf
[20] http://www.en.scienceindustries.ch/involvement/pharma-code-and-pharma-cooperation-code