Code of conduct of the pharmaceutical industry in Switzerland – Pharma Code

(of 4 December 2003, partial revisions of 1 October 2006, 12 June 2008, 1 September 2010, 1 November 2011, 1 June 2012 and 1 December 2012[1])

The Pharma Code (PC) in 2012: Annual report of the Pharma Code Secretariat

Introduction

The Pharma Code is a behavioural code based on private law whose aim is to encourage ethically correct conduct and avoid unfair competition. 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]. The Pharma Code enacts in Switzerland the stipulations of the higher-ranking codes of the international organisations in the pharmaceutical industry (IFPMA[3], EFPIA[4]).

The foundations of the Pharma Code are:

- *IFPMA Code of Practice (IFPMA Code)*[5]
- *EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals (EFPIA Healthcare Professionals Code)*[6]
- *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (EFPIA Patient Organisations Code)*[7]

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

General matters relating to the practical implementation of the Pharma Code in 2012

The number of cases dealt with in relation to the Pharma Code in 2012 fell again by comparison with 2011 as had already been the case in previous years, but this time only to a slight extent (from 104 to 100). This ongoing trend must be regarded as positive. However, it is not a sign that the companies are making less use of the Pharma Code procedure. As always they are keeping a close watch on their competitors. There was also no sign that companies have contacted Swissmedic or the courts instead of the Pharma Code Secretariat more often than before or refrained from making notifications, despite having reasons to do so.

The request by the Pharma Code Secretariat for pharmaceutical companies to report bilateral agreements reached between them (i.e. without including the Pharma Code Secretariat) on the basis of rules of the Pharma Code proved successful: 9 cases were reported (2011: 3), involving 13 (6) companies. The Pharma Code Secretariat needs information on such agreements to record in its case statistics. However, the Pharma Code Secretariat does not know with any certainty how often this route is in fact chosen. 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.

The Pharma Code Secretariat recognised a further reduction in clearly detectable cases of breaches, but not in the more complex cases (breaches which were borderline or only recognised as such on closer examination, as well as ambiguous statements). This also emerges clearly from the increase in the number of reported breaches of individual points from 153 to 194. There was likewise a noticeable trend towards greater diligence and self-responsibility of the companies concerned (Compliance): the reason for this clearly resides in the improvement of internal corporate pro-

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[1] German: http://www.scienceindustries.ch/engagements/pharmakodex
French: http://www.fr.scienceindustries.ch/engagements/code-pharmaceutique
English: http://www.en.scienceindustries.ch/involvement/pharma-code
[2] List of signatories: http://www.scienceindustries.ch/unterzeichner-des-pharamkodexes
[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://www.efpia.eu/efpia-code-practice-promotion-prescription-only-medicines-and-interactions-healthcare
[7] http://www.efpia.eu/efpia-code-practice-relationships-between-pharmaceutical-industry-and-patient-organisations-amended

cesses within the area of applicability of the Pharma Code (PC 5[8]) using Standard Operating Procedures (SOP). In this broader context, individual companies also consult the Pharma Code Secretariat on fundamental issues in compliance with PC 72 (85 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 Pharma Code Secretariat. It has always been the intention of the Swiss Pharma Code, unlike most similar codes abroad, not to apply sanctions. The role of the Pharma Code Secretariat is primarily to act as an intermediary when dealing with notifications of purported violations of the Pharma Code, a role similar to that of a mediator. Its neutral judgement as to whether a violation of the Pharma Code has or has not occurred in each particular case is virtually always respected by the parties involved. Compared to the implementation of similar foreign codes, the statistics of the Pharma Code always show relatively high 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 rules are consistently remedied within a short space of time and almost always by consensus.

The question of introducing sanctions, particularly fines, arose during the review of the EFPIA Healthcare Professionals Code (see Introduction) in 2006. On that occasion, scienceindustries dispensed with the introduction of sanctions when dealing with code violations, subject to the precedence of national laws and regulations. In the consultation on this issue, 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 reservation mentioned above means that the national law concerning medicinal products also governs advertising for medical products in Switzerland and Swissmedic[9], being the responsible authority, can impose administrative or punitive measures when breaches of the rules occur. In addition, the pharmaceutical companies can bring court actions if they suspect that a breach of the Federal Law on the Prevention of Unfair Competition (UWG)[10] has occurred.

Pharma Code requirements and violations

The number of cases in which promotional statements differed from the drug information for health professionals approved by Swissmedic at the time of marketing authorization (PC 131.3) increased once again (from 10 to 15). The number of cases in which promotions were issued for as yet unauthorized medicinal products or indications (PC 131.1, 131.2 and 133) fell with 15 recorded cases (previous year 21). The same goes for promotional material which did not include all the minimum particulars about the medicinal product required by the PC (PC 131.4, 134 and 135): here the number of breaches remained unchanged at 12. The prohibition on veiling or obscuring the intention actually associated with advertising in specialist media (PC 132.2) was breached in 1 case (previous year: 0) and in 2 cases (previous year: 0) the legibility of the promotional material was insufficient (PC 132.2).

The number of complaints about general standards of quality was much higher (90 cases against 64 in the previous year). References to literature being incomplete and inadmissible fell slightly: 22 cases (24 in the previous year) (PC 143.1, 143.2, 143.3, 143.4, 143.5, 144). In an unchanged number of 21 cases references were incorrectly cited (PC 141.3). In 25 cases (previous year: 10) the statements used in advertising were not proven (PC 141.2). There is no clear explanation for this considerable rise. The expression "safe" was used in 6 cases (previous year: 1) without an appropriate qualification (PC 142.1). In 11 cases (previous year: 4) expressions minimizing possible risks were used, for example that the medicinal product concerned did not induce addiction or was harmless (PC 142.2).

With 29 cases (previous year: 20), the number of notifications due to unqualified superlatives and comparatives (PC 145) rose slightly. In 1 case (previous year: 2), one pharmaceutical was still designated as new more than one year after its marketing authorisation had been issued in Switzerland (PC 146). In 2 cases (previous year: 3), unsolicited free samples were sent (PC 147.2[11]). Identification of a mailing as an “Important notice” (PC 148), which is permitted solely to ensure the safety of medicinal products, was incorrect in 3 cases (unchanged against the previous year).

8 complaints were made about events for the advertisement or provision of information about medicinal products as well as cooperation with organizations of health care professionals (PC 2) (previous year: 0). The increase is probably explained in part by the growing critical attention to this aspect. Once again, no proceedings were opened in connec-

[8] The provisions of the Pharma Code are cited in the annual report under “PC” with the relevant section number.
[9] http://www.swissmedic.ch/index.html?lang=en
[10] http://www.admin.ch/ch/d/sr/c241.html
[11] in conjunction with Art. 10 para. 2, letter a of the Ordinance on the Promotion of Pharmaceuticals, AWV: http://www.admin.ch/ch/d/sr/c812_212_5.html

tion with the sponsorship of clinical trials (PC 3). There were likewise no breaches of the new provisions introduced in 2008 concerning relations between the pharmaceutical industry and patients organisations (PC 4).

In 2011, EFPIA set up an Internet platform open to the public for the Europe-wide assessment of the compliance of congresses and similar events for professionals with the code ("e4ethics"[12]). When assessing international congresses in Switzerland, e4ethics always asks the Pharma Code Secretariat for its opinion. In 2012, it stated a position on 18 such assessment proposals (partly repeated following amendments). In 5 cases, e4ethics amended its assessment in the light of information provided by the Pharma Code Secretariat.

In 2012, no company (as was already the case in 2011) which had signed up to the Pharma Code referred a case directly to the authorities without first making use of the mediation proceedings set out in the Pharma Code, in contravention of the preamble to the Pharma Code.

In 2012, there was one case in which medical sales representatives failed to perform their task in a responsible and ethically correct manner (PC 512). In 4 cases (previous year: 8) a change of the person responsible in the company was not notified to the Pharma Code Secretariat as required by PC 524. The obligation incumbent upon 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 satisfied in 2 cases (previous year: 6).

Statistics

The maximum duration of proceedings stipulated in the Pharma Code (25 working days which may be extended on a single occasion by ten working days in justified cases; PC 661 and 664) proved effective once again. In 2012 as had already been the case in 2011 the average duration of proceedings was 10 working days. The Pharma Code Secretariat informed the company concerned of a notification within the first 2.5 days (average) of its receipt (previous year: average 3 days), accompanied by its own assessment. As in the past, the companies concerned generally responded quickly and constructively in 2012 as they had done in the past. The option to extend the period was used in 3 cases (previous year: 7) or some 3% (7%) of all the cases dealt with. Once again these are gratifying figures overall. They reflect the universal interest in finding an amicable solution to problems of compliance with the Pharma Code as quickly as possible and in the most straightforward and effective manner.

56 notifications or 51% (previous year: 56 or 50%) originated from competitors. In 47 cases or 43% (previous year: 55 or 50%), the Secretariat raised objections to promotional material (advertisements, mailings etc.) on its own initiative. 7 notifications or 6% (previous year: 0) originated from physicians and other third parties. Unlike the situation prevailing in previous years, notifications were made by more than one company about individual, particularly serious breaches. In 2012 there were again no cases which might have resulted in relevant consequences in terms of possible health regulation measures (i.e. cases presenting a direct or indirect risk to patients' health). In 2012, the Pharma Code Secretariat conducted no mediation procedure (1 in 2011). To the best of our knowledge, two companies had recourse to Swissmedic or to the courts in 2012 after completing proceedings under the Pharma Code.

In the event of serious violations, the Pharma Code Secretariat may require the company which is at fault to issue corrective information in a suitable form to the addressees concerned in each instance: in 2012, as in 2011, this was not necessary in any single case. In 2012, 61 procedures were ended (59% of all the cases dealt with against 73 or 70% in the previous year) after the contested advertising was either corrected or removed. Because they did not concern a breach of the Pharma Code, the Secretariat rejected 14 (14%) of the complaints received as being unfounded (previous year: 18 or 17%). In 15 cases (14%, in the previous year: 9 or 9%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code, although, unlike the situation in the previous year, in one of the 15 cases an immediate correction of the advertising was stipulated. In no case (previous year: 1) was the immediate and complete withdrawal of the disputed advertising required. All the conditions imposed were accepted by the companies responsible and implemented in a timely manner. In 11 cases (11%; previous year: 3 or 3%), the notifying company requested a reassessment as it did not agree with the conclusion reached by the Secretariat. As in the previous year, no case had to be referred to Swissmedic (PC 666).

Communication and practical recommendations[13]

At irregular intervals the Secretariat reports in abstract form about individual cases which it has assessed pursuant to PC 616[14] to the Pharma Code signatories with a view to enabling them to learn from the knowledge and experience of

[12] http://www.efpia-e4ethics.eu/Farma_EFPIA/FARMA_110085?idDoc=FARMA_110085
[13] http://www.sgci.ch/plugin/template/sgci/*/17382

other companies. In 2012 further such case reports were published on the scienceindustries membernet. The series will be continued.

Partial revisions of the Pharma Code

The comprehensively revised IFPMA Code of Practice (see below) has been in force since 1 September 2012. The Pharma Code was suitably adapted in that connection. No major changes were required because many of the provisions newly introduced into the IFPMA Code in 2012 had already applied in the Pharma Code. The adjustments of the Pharma Code to the IFPMA Code have likewise applied since 1 September 2012. With the same partial revision of the Pharma Code, the PC Rule on the use of the identifier "Important Notice" (PC 148) was also amended. The new feature is that not only notices relating to pharmaceutical safety must be identified in that way but also all those concerning the withdrawal of a pharmaceutical from the market, restrictions on distribution or application and the cancellation of any such measure.

In the autumn of 2012, Swissmedic indicated that it would be officially publishing the text of all pharmaceutical information (information for professional and patients) on a separate website (swissmedicinfo.ch) beginning in 2013. In the Pharma Code, care therefore had to be taken to ensure that swissmedicinfo.ch is always cited as a source in such cases when professional promotional material refers to the professional information approved by Swissmedic.

IFPMA Code and EFPIA Codes

The IFPMA Code underwent a major revision in 2011. It is now called the IFPMA Code of Practice[15] and entered into force on 1 September 2012. Much of the content was integrated into the worldwide IPFMA Code which was newly inserted in June 2011 into the EFPIA Healthcare Professionals Code and EFPIA Patient Organisations Code applicable in Europe (details on this subject will be found in the Annual Report of the Pharma Code Secretariat for 2011[16]).

In the year under review, EFPIA worked intensively on the creation of a new code making provision for disclosure of payments made by pharmaceutical companies to professionals (especially physicians) and organisations which employ professionals (hospitals, research institutes etc.). This code is to take effect in 2016. The national member associations of EFPIA (scienceindustries for Switzerland) must prepare for national implementation in a corresponding code by the end of 2013.

Appeal

Professional advertising of medicinal products is improved if it undergoes a critical appraisal, especially by the persons to whom it is addressed. All physicians and pharmacists are therefore once again urged to contact the Pharma Code Secretariat if they disapprove of any advertisements, mailings or other professional advertising on ethical or scientific grounds. The same applies to events of advanced and continuing training and to the sponsorship of clinical trials which might be deemed to contravene the Pharma Code.

Secretariat of the Pharma Code

Dr. med. Felix Schwarzenbach

Zurich, 27 March 2012

[14] "It [the Pharma 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."
[15] http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Code_of_Practice_2012.pdf
[16] http://www.en.scienceindustries.ch/involvement/pharma-code/pharma-code-annual-reports