**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
and 1 November 2011**[1]

The Pharma Code (PC) in 2011: 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]).

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]
- *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (EFPIA Patient Organisations Code)*[7]

scienceindustries (Economic Federation of the Chemical, Pharmaceutical and Biotech Industries), supported by the partner associations named in 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 2011

The number of cases dealt with in relation to the Pharma Code fell again in 2011, as had already been the case in previous years, but more markedly (from 127 to 104) than in 2010. This trend must be regarded as positive, but 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 is also no sign that companies have contacted Swissmedic or the courts more than before instead of the Pharma Code Secretariat or that they have refrained from making notifications despite having reason to do so.

In some individual cases, differences have been settled bilaterally, i.e. without involving the Pharma Code Secretariat (3 cases; 2010: 1), in which 6 (2) companies were involved. Companies are encouraged to notify such settlements to the Pharma Code Secretariat for inclusion in the case statistics, but they do not always do so. The question as to whether this is due to negligence or to a limited willingness on the part of individual companies to reach agreement directly with their competitors in order to resolve a specific difference in compliance with the Code must be left open.

The number of manifest breaches fell once again, but the more complex cases did not (breaches which were borderline or only recognized as such on closer examination, as well as ambiguous statements). The trend towards greater compliance continued: this is clearly explained by an improvement of company-internal flows of information for monitoring the sector relevant to the Pharma Code (PC 5[8]) with the help of Standard Operating Procedures (SOP). In this broader context, the Pharma Code Secretariat gives advice to individual companies on fundamental matters in compliance with PC 72 (74 enquiries; previous year: 62).

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[1] German: http://www.sgci.ch/plugin/template/sgci/*/11386
French: http://www.sgci.ch/plugin/template/sgci/*/11387
English: http://www.sgci.ch/plugin/template/sgci/*/11388
[2] List of signatories: http://www.sgci.ch/plugin/template/sgci/*/11489
[3] http://www.ifpma.org/
[4] http://www.efpia.org/Content/Default.asp?
[5] http://www.ifpma.org/ethics/ifpma-code-of-practice/about-ifpma-code-of-practice.html
[6] http://www.efpia.eu/content/default.asp?PageID=559&DocID=11731
[7] http://www.efpia.eu/content/default.asp?PageID=559&DocID=11671
[8] The provisions of the Pharma Code are cited in the Annual Report under 'PC' with the relevant section number.

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 statistics 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 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), fell further (from 15 to 10). The number of cases in which promotions were issued for as yet unauthorized medicinal products or indications (PC 131.1, 131.2 and 133), remained almost unchanged with 21 cases (previous year 22). 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 there were 12 breaches (after an increase to 13 cases in the previous year). The prohibition on veiling or obscuring the intention actually associated with advertising in specialist media (PC 132.2), was not breached (unlike the previous year when 3 cases were recorded).

Complaints about general standards of quality were greatly reduced (64 cases against 84 in 2010). References to literature being incomplete and inadmissible increased once again: 24 cases against 16 in the previous year (PC 143.1, 143.2, 143.3, 143.4, 143.5, 144). There is no identifiable explanation for this substantial increase. In 21 cases (previous year: 28) references were incorrectly cited (PC 141.3). In 10 cases (previous year: 14) the statements used in advertising were not proven (PC 141.2). The expression "safe" was used in 1 case (previous year: 4) without an appropriate qualification (PC 142.1). In 4 cases (previous year: 7) expressions minimizing possible risks were used, for example that the medicinal product concerned did not induce addiction or was harmless (PC 142.2).

With 20 cases (previous year: 38), the number of notifications due to comparisons (unqualified superlatives and comparatives; PC 145) fell again noticeably. This may also be connected with the increase in the use of generics in the case of which no differences are made in promotional material from other preparations containing the same active substance. In 2 cases (previous year: 3), 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: 1), 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 ((previous year: 0 breaches).

No 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: 8) – a pleasing trend. One purported breach of the Pharma Code (PC 2) in connection with an event for physicians was not confirmed as such. Once again, no proceedings were opened in connection 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).

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[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

In 2011 no company (as was already the case in 2010) 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.

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 6 cases (previous year: 5). Unlike the single case reported in the previous year, in 8 cases the change of the person responsible in the company was not notified to the Pharma Code Secretariat as required by PC 524.

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 2011 the average duration of proceedings was 10 working days (2010: average 9.5 working days). The Pharma Code Secretariat informed the company concerned of a notification within the first 3 days (average) of its receipt (previous year: average 2.5 days). As in the past the companies concerned generally responded quickly and constructively in 2011 as they had done in the past. The option to extend the period was used in 7 cases (previous year: 3) or some 7% (2%) of all the cases dealt with. Once again these are gratifying figures. 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 50% (previous year: 101 or 71%) originated from competitors. In 55 cases or 50% (previous year 36 or 25%) the Secretariat raised objections to promotional material (advertisements, mailings etc.) on its own initiative. No notification originated from physicians and other third parties (previous year: 6 cases or 4%). Unlike the situation prevailing in previous years, no notifications were made by more than one company about particular serious breaches. In 2011 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). As in the previous year, the Pharma Code Secretariat conducted one mediation procedure which was successful. To the best of our knowledge, no company had recourse to the courts in 2011 (as had already been the case in the previous year) after completing mediation 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 2011, as in 2010, this was not necessary in any single case. In 2011, 73 procedures were ended (70% of all the cases dealt with against 74 or 58% in the previous year) after the contested advertising was corrected or removed. Because they did not concern a breach of the Pharma Code, the Secretariat rejected 18 (17%) of the complaints received as being unfounded (previous year: 28 or 22%). In 9 cases (9%, in the previous year: 10 or 8%) the concluding letter to the company responsible imposed a condition requiring an amendment to comply with the Code, although (as was also the case in the previous year) in none of the 9 cases was an immediate correction of the advertising stipulated. In one case (previous year: 1) the immediate and complete withdrawal of the disputed advertising was required. All the conditions imposed were accepted by the companies responsible and implemented in a timely manner. In 3 cases (3%; previous year: 12 or 9%), the notifying company requested a reassessment as it did not agree with the conclusion reached by the Secretariat. Unlike the situation in the previous year (2), no case had to be referred to Swissmedic (PC 666).

Communication and practical recommendations[12]

At irregular intervals, the Secretariat reports in abstract form about individual cases which it has assessed pursuant to PC 616[13] to the Pharma Code signatories, with a view to enabling them to learn from the knowledge and experience of other companies. In 2011 other such case reports were published on the scienceindustries Membernet. The series will be continued.

In October 2011 the Pharma Code Secretariat issued its Recommendation No. 6 to the signatories: "Conduct of companies on the occasion of congresses, symposia and similar events which are held under the responsibility of professional organisations for professionals in Switzerland".[14] These recommendations respond to a wish repeatedly expressed by the Pharma Code signatories. They were drawn up in cooperation with the Pharma Code Commission and other professionals drawn from the group of Pharma Code signatories.

[12] http://www.sgci.ch/plugin/template/sgci/*/17383

[13] "It [the Pharma Code Secretariat] shall inform companies periodically about rulings handed down by it (without naming the company or specific medicinal product) as well as about experiences in connection with the practical implementation of the Code that are of general interest.".

[14] http://www.sgci.ch/plugin/template/sgci/*/56727 http://www.sgci.ch/plugin/template/sgci/*/56728

Partial revision of the Pharma Code

A partial revision of the Pharma Code was made on 1 November 2011 (concerning various provisions under PC 4 and PC 925 – 927). In the consultation procedure, the Pharma Code signatories unanimously approved this partial revision. The amendments follow the revision of the EFPIA Patient Organisations Code of June 2011. The corresponding innovations were incorporated into the Pharma Code in a timely manner. One amendment to the EFPIA Healthcare Professionals Code, which provides for a specific limitation of the issue of pharmaceutical samples to professionals was not included in the Pharma Code. For reasons of competition law, scienceindustries refrained from including this requirement in the Pharma Code. A further consideration is that the limitation placed by EFPIA on the issue of free samples of pharmaceuticals corresponds in broad outline to the notification made by Swissmedic in early 2010 ("Samples in advertising to professionals"[15]). For this reason too, no new measures were envisaged within the Pharma Code framework. The measures included in the EFPIA Leadership Statement (see below) concerning medical sales representatives are already largely satisfied by the Swiss pharmaceutical companies through the project for "certified medical sales representatives"[16], implemented by the swiss health quality association (shqa); that is why there is no need to supplement the Pharma Code in this area.

IFPMA Code and EFPIA Codes

In June 2011, the EFPIA revised its two codes referred to in the introduction. It did so following its "Leadership Statement on Ethical Practices: Industry restricts product sampling and sets new standards for sales representatives and congresses"[17] published on 24 June 2010. These changes were implemented in the Pharma Code to the extent necessary and legally acceptable in the partial revision of November 1, 2011 (see above).

In the year under review, the EFPIA also installed an Internet platform open to the public to assess the code compliance of events held for professionals ("e4ethics"[18]). The Pharma Code Secretariat is regularly invited to deliver its opinion on the assessment of congresses in Switzerland. Account will be rendered on this activity area of the Pharma Code Secretariat, which is due to take effect in 2012, starting from the next Pharma Code annual report.

A major revision of the IFPMA Code was made in 2011. It is now called the *IFPMA Code of Practice*[19] and enters into force on 1 September 2012. The corresponding adjustment to the Pharma Code is in preparation; its revised version will enter into force together with the amended IFPMA Code.

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

Zürich, 5 April 2012

[15] http://www.swissmedic.ch/marktueberwachung/00091/00241/01466/index.html?lang=de
[16] http://www.shqa.ch/index.cfm?s=TmpStandard&hmID=11&contentID=30&z=1
[17] http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=9226
[18] http://www.efpia-e4ethics.eu/Farma_EFPIA/FARMA_110085?idDoc=FARMA_110085
[19] http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Code_of_Practice_2012.pdf