**Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code)
of 4 December 2003, partial revisions of 1 October 2006, 12 June 2008 and 1 September 2010**[1]

The Pharma Code (PC) in 2010: 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 behaviour and avoid unfair competition. Pharmaceutical companies operating in Switzerland may offer a voluntary undertaking to sign up to this code. The vast majority of companies have signed up to date[2]. The Pharma Code enacts in Switzerland the conditions prescribed by the higher-ranking codes of international organisations in the pharmaceutical industry (IFPMA[3], EFPIA[4]). These principals of the Pharma Code are:

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

SGCI Chemie Pharma Schweiz[8] is responsible for the Pharma Code, supported by its partner associations named in the preamble of the Code.

General matters relating to the practical implementation of the Pharma Code in 2010

Once again the number of all cases heard in 2010 in connection with the Pharma Code fell again compared to the previous years, but more markedly (from 136 to 127) than in 2009. This decrease is essentially a positive development and does not indicate that companies have become more restrained with regard to the Pharma Code process. As always, companies are observing their competitors very closely. There is also no sign that companies have contacted Swissmedic or the courts more than before instead of the Pharma Code Secretariat or indeed that they have refrained completely from making notifications despite having reason to do so. In exceptional instances, differences have been settled bilaterally i.e. without involving the Pharma Code Secretariat (1 case, which involved 2 companies (2009: 7 cases, involving 9 companies). Companies are encouraged to notify such occurrences to the Pharma Code Secretariat so that they may be recorded in case statistics, but this is not always complied with. It remains an open question as to whether this happens through negligence, or whether it is connected to the relatively low level of willingness on the part of individual companies to reach agreement directly with their competitors to resolve a practical difference in accordance with the Code.

Obviously recognisable violations have diminished again, but not the more complex cases (violations which were borderline or only recognised as such on closer examination, as well as ambiguous statements). There was still evidence of the trend towards greater compliance i.e. to an improvement of company-internal flows of information for monitoring the sector relevant to the Pharma Code with the help of standard operating procedures (SOPs). In this context the Pharma Code Secretariat gave advice to individual companies on fundamental matters in accordance with PC 72[9] on 62 occasions (previous year: 63).

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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] 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/EthicalPromotion/index.aspx
[6] http://www.efpia.eu/content/default.asp?PageID=559&DocID=3483
[7] http://www.efpia.eu/content/default.asp?PageID=559&DocID=3484
[8] http://www.sgci.ch/plugin/template/sgci/1/*?selected_language=en
[9] The requirements (articles) of the Pharma Code are cited in the Annual Report using “PC” and the relevant marginal figures.

Proven implementation of the Pharma Code without sanctions

The Pharma Code is enforced according to the amicable resolution of conflict, 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 intermediary when dealing with notifications concerning 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 exists or not in each particular case is virtually always respected by the parties involved. When compared to the implementation of similar foreign codes the statistics of the Pharma Code show relatively high case numbers. These are a sign of the high quality of the procedure in the opinion of all parties i.e. the low access threshold and quick and transparent decisions. This annual report shows once more that it is successful in removing violations of rules within a short time and almost always by consensus.

The question of introducing sanctions, particularly fines, arose in 2006 during the last review of the EFPIA Promotion Code (see introduction). At that time SGCI Chemie Pharma Schweiz dispensed with the introduction of sanctions in dealing with code violations, subject to the precedence of national laws and ordinances. In the consultation on this question the companies spoke out clearly against sanctions i.e. they were in favour of retaining the non-adversarial mediation proceedings which had proven itself in practice over many years. The reservation mentioned means that the national law concerning medicinal products also governs advertising for medical products and Swissmedic, being the competent authority, can initiate administrative or punitive measures. Pharmaceutical companies can bring court actions if they suspect a violation of the Federal Law against Unfair Competition (UWG).

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) again decreased slightly (from 18 to 15). The number of cases for which *promotions were issued for as yet unauthorized medicinal products or indications* (PC 131.1, 131.2 and 133) remained almost the same, with 22 cases (previous year: 21). After a clear drop in 2009, there was an increase from 7 to 13 cases of *promotional material which did not include all the minimum particulars about the medicinal product* (PC 131.4, 134 and 135). In 3 cases (previous year: 0) there was a breach of the prohibition on *veiling or obscuring the intention actually associated with advertising in specialist media* (PC 132.2).

Complaints about general standards of quality remained stable at 84 (previous year: 83). References to *literature being incomplete and inadmissible* fell from 22 cases in the previous year to 16 (PC 143.1, 143.2, 143.3, 143.4, 143.5, 144). In 28 cases (previous year: 19) *references were incorrectly cited* (PC 141.3) – a marked increase for which there is no identifiable explanation. In 14 cases (previous year: 22) the *statements used in advertising were not proven* (PK 141.2). The expression “safe” was used in 4 cases (previous year: 0) without appropriate qualification (PC 142.1). In 7 cases, (previous year: 3), *expressions minimising possible risks* were used, for example that the medicinal product concerned did not induce addiction or was harmless (PC 142.2).

At 38 cases (previous year: 47), the number of notifications due to *comparisons (unqualified superlatives and comparatives,* PC 145) fell further; the figure is, however, still too high. In 3 cases (previous year: 1) a medicinal product was still described as *new* (PC 146) more than one year after its marketing authorisation in Switzerland. Only once (previous year: 1) were *unsolicited samples sent or medicinal products supplied as such but were not identified as “free samples” (*PC 147.2 in conjunction with Art. 10 Para. 2 Letter a of the Ordinance on Advertising of Medicinal Products[10]). Identifying a mailing as an “*important notice”* (PC 148 – which is permitted solely to ensure the safety of medicinal products), was correct in all cases (cf. 5 violations in the previous year).

Events for the advertisement or provision of information about medicinal products as well as cooperation with organizations of health care professionals (PC 2) gave rise to 8 complaints (previous year: 3). No breach of any specific rule in the Pharma Code was identified in connection with one particular event for medics. However, the conduct of the company concerned in respect of one speaker was not compatible with the spirit and intent of the Pharma Code.

There were again no proceedings in the year under review in connection with the sponsoring of *clinical trials* (PC 3). Similarly there were no violations in connection with the new conditions on *relationships between the pharmaceutical industry and patient organizations* (PC 4) introduced in 2008.

[10] http://www.admin.ch/ch/sr/812 212 5/a10.html; English translation

In 2010 no company (previous year: 1) which has signed up to the Pharma Code contacted the authorities directly without first making use of the mediation proceedings set out in the Pharma Code, in contravention of the Preamble to the Pharma Code.

There were 5 cases (previous year: 3) where the obligation incumbent upon companies to provide the Pharma Code Secretariat with *sample copies of their promotional material without being requested to do so* (PC 54) was not fulfilled. As in the previous year, in only one case did a company omit to report a change of responsible person to the Secretariat in accordance with PC 524.

Statistics

The *maximum duration of proceedings* introduced by the Pharma Code (25 working days, extendable on a single occasion by 10 working days in justified cases: PC 661 and 664) proved effective again. In 2010 the duration of proceedings was 9.5 working days on average, a pleasing reduction compared to 2009 (average 10.5 working days). The Pharma Code Secretariat informed the company concerned of a notification within the first 2.5 days of its receipt (previous year: 3 days), together with the Secretariat's assessment. It is also gratifying to report that the companies concerned generally responded quickly and constructively. The option to extend the period was only needed in 3 cases, or about 2% of all cases heard (unchanged from the previous year).

101 notifications or 71% (previous year: 98 notifications or 67%) originated from *competitors*. In 36 cases or 25% (previous year: 44 cases or 30%) the Secretariat raised objections to promotional material (advertisements, mailings etc) *on its own initiative*. 6 notifications originated from *physicians* and other third parties (4%: 4 or 3% in the previous year), with certain more serious violations often giving rise to several notifications. There were again no cases in 2010 which might have resulted in relevant consequences in terms of possible health regulation measures (i.e. cases directly or indirectly jeopardising the health of patients). As in the previous year, the Pharma Code Secretariat conducted one mediation procedure, which was successful, unlike the mediation procedure in 2009. A further mediation procedure was sought by one side and offered by the Pharma Code Secretariat, but ultimately refused by the other side for understandable reasons. So far as is known, in 2010 no company had recourse to the courts after having been involved in mediation proceedings under the Pharma Code (previous year: 1).

In the event of serious violations the Pharma Code Secretariat may require the company at fault to issue *corrective information* in a suitable form to the addressees concerned. In 2010, as in 2009, this was not necessary. In 2010 74 proceedings (58% of all cases dealt with; previous year 72, or 53%) were ended after the advertising complained about was corrected or removed. The Secretariat rejected 28 (22%) of the complaints received as invalid (previous year: 34 or 25%) because they were not violations of the Pharma Code. In 10 cases (8%; in the previous year: 16 or 12%) the concluding letter to the company responsible imposed a condition requiring an amendment to conform with the Code, although (as was also the case in the previous year) in none of the 10 cases was an immediate correction of the advertising required. In one case (previous year: 1) the immediate and complete withdrawal of the advertising subject to complaint was requested. All conditions imposed were accepted by the companies responsible and implemented in a timely manner. In 12 cases (9%; in previous year 13 or 10%) the notifying company requested a re-assessment, as it was not in agreement with the conclusion reached by the Secretariat. Unlike in the previous year (0 cases), two cases needed to be referred to Swissmedic (PC 666).

Communication

At irregular intervals the Secretariat reports in abstract form about individual cases it has assessed in accordance with PC 616[11], with the intention of allowing all signatories to learn from the appropriate knowledge and experience of other companies. In 2010 three other such case reports were brought to the attention of the companies in the SGCI Membernet. The process is being continued.

Formal partial revision of the Pharma Code

In the reporting year the Pharma Code underwent formal revision. In the consultation, the signatories to the Pharma Code unanimously approved this part revision, having already supported the advisory Pharma Code Committee (PC 8). Particularly affected by this revision were the provisions of the Pharma Code in relation to duties on companies and supervision of observance (PC 5 and 6), which were arranged more

[11] "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"

comprehensibly and in part subject to a simplification of processes. No changes in the content of the Pharma Code were involved.

Pharma Code, IFPMA Code and EFPIA Code

On 24 June 2010 the EFPIA published its *"Leadership Statement on Ethical Practices: Industry restricts product sampling and sets new standards for sales representatives and congresses"*[12]. The EFPIA is looking to use this to assist in leveraging some of the key areas in its two Codes (cf. Introduction) to wider adoption. SGCI Chemie Pharma Schweiz is progressively seeking to take account of this declaration of intent under the Pharma Code and in the Swiss legal order.

The restriction on the issuing of free samples of medicinal products planned by the EFPIA corresponds in basic outline to the communication from Swissmedic from early 2010 ("Musterpackungen in der Fachwerbung" – on sample packs in advertising to professionals)[13], which is why no new measures are envisaged under the Pharma Code framework. The measures envisaged in the "Leadership Statement" in relation to medical sales representatives are already largely satisfied by Swiss pharmaceutical companies via the project for certification of medical sales representatives implemented by the *swiss health quality association (shqa),* "zertifizierte(r) Pharmaberater"[14]. In the reporting year, the EFPIA therefore commenced preparations for an internet toolkit to pre-assess the compliance of events as medical congresses with the Pharma Code and the EFPIA Healthcare Professionals Code. It also introduced a partial revision of the EFPIA Patient Organisations Code.

There was no change to the IFPMA Code in 2010.

Appeal

Professional advertising of medicinal products is improved if it is critically appraised, especially by those to whom it is addressed. Thus it is once against stressed to all physicians and pharmacists 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 relating to postgraduate and continuing medical education and to the sponsoring of clinical trials which are deemed to contravene the Pharma Code.

Secretariat of the Pharma Code

Dr. med. Felix Schwarzenbach

Zurich, 31 March 2010

[12] EFPIA Leadership Statement: http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=9226;
EFPIA Press release: http://www.efpia.eu/content/default.asp?PageID=559&DocID=9227
[13] http://www.swissmedic.ch/marktueberwachung/00091/00241/01466/index.html?lang=de
[14] http://www.shqa.ch/index.cfm?hmID=11&action=hm11&contentID=30&s=TmpStandard&z=1