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

The Pharma Code (PC) in 2009: 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]
- *EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals*[6]
- *EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations*[7]

SGCI Chemie Pharma Schweiz[8] has pledged observance of the code, supported by its partner associations named in the preamble of the Pharma Code.

General matters relating to the practical implementation of the Pharma Code in 2009

Once again the number of all cases heard in 2009 in connection with the Pharma Code fell compared to the previous years, but somewhat less steeply (from 138 to 136). 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. Increasingly, differences have been settled bilaterally i.e. without involving the Pharma Code Secretariat (7 cases, which involved 9 companies.) Companies are encouraged to notify such occurrences to the Pharma Code Secretariat so that they may be recorded in case statistics.

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 inter-company 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 6[9] on 63 occasions (as in previous year).

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 num-

[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=559XDocID=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 of the Pharma Code are cited in the Annual Report using “PC” and the relevant marginal figures.

bers. 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).

PC 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 slightly (from 14 to 18). In contrast, the number of cases for which *promotions were issued for as yet unauthorized medicinal products or indications* (PC 131.1, 131.2 and 133), fell remarkably to 21 (cf. 28 in the previous year). There were only 7 cases (cf. 25 in the previous year) of *promotional material which did not include all the minimum particulars about the medicinal product* (PC 131.4, 134 and 135). Complaints about general standards of quality remained stable at 83 (cf. 82 in the previous year). Following a clear reduction in the previous year (from 36 to 13) references to *literature being incomplete and inadmissible (PC 143.1, 143.2, 143.3, 143.4, 143.5, 144)* increased again to 22 cases. In 22 cases (cf. 19 in the previous year) *references were incorrectly cited* (PC 141.2). The expression "safe" was used in 0 cases (cf. 7 in previous year) without appropriate qualification (PC 142.1). In 4 cases, (cf. 3 in the previous year), *expressions minimising possible risks* were used, for example that the medicinal product concerned did not induce addiction or was harmless *(PC 142.2).*

With 47 cases (cf. 45 in the previous year) notifications due to *unqualified superlatives and comparisons* (PC 145) remained stable at a high level, after a fall sustained over several years. In one case (0 in the previous year) a medicinal product was described as *new* (PC 146) more than one year after its marketing authorisation in Switzerland. Only once (0 in the previous year) 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 admissible only to ensure the safety of medicinal products, was incorrect in 5 cases (cf. 6 in the previous year).

In connection with *events for the advertisement or provision of information about medicinal products as well as cooperation with organizations of health care professionals* (PC 2) there were 3 complaints (cf. 5 in the previous year). 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 industry and patient organisation* (PC 4) introduced in 2008. Also in the process of development, the publication of such support measures by companies requested by the Recommendation No. 4[11] in the series "Pharma Code Practice[12].

There were 3 cases (cf. 4 in previous year) 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 541) was not fulfilled. One company (cf. 1 in the previous year) which had signed up to the Pharma Code contacted the authorities directly, in contravention of the Preamble to the Pharma Code. In one case (cf. 1 in the previous year) companies omitted to report a change of responsible person to the Secretariat in accordance with PC 522.

Statistics

The maximum duration of proceedings introduced by the Pharma Code in 2003 (25 working days, extendable on a single occasion by 10.5 working days in justified cases) proved effective again, although the duration of proceedings was 12.5 working days on average, a clear reduction compared to 2008 (after an

[10] http://www.admin.ch/ch/sr/812 212 5/a10.html
[11] http:/www.sgci.ch/plugin/template/sgci/*/38207
[12] http://www.sgci/ch/plugin/template/sgci/*/17382

increase from 11 working days to 12.5 in the previous year). The Pharma Code Secretariat informed the company concerned of a notification within the first 3 days of its receipt (cf. 5 in the previous year), together with the Secretariat's assessment. It is gratifying to report that the companies concerned generally responded quickly and constructively. An extension of the period was only needed in 3 cases (cf. 6 in the previous year) or about 2% of all cases heard (4.5% in the previous year).

98 notifications or 67% (86 or 61% in the previous year) originated from *competitors*; in 44 cases or 30% (51 or 36% in the previous year) the Secretariat raised objections to promotional material (advertisements, mailings etc) *on its own initiative*. 4 notifications originated from *physicians* and other third parties (3%: 4 or 3% in the previous year) with certain more serious violations often giving rise to several notifications. There were no cases in 2009 (1 in the previous year) which might have resulted in significant consequences in terms of possible health risks (i.e. directly or indirectly jeopardising the health of patients). However one company involved brought a case to court after mediation through the Pharma Code Secretariat failed *(*cf. 0 in the previous year*).*

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 2009 as in 2008 this was not necessary. In 2009 72 proceedings (53% of all cases dealt with; in the previous year 94 or 68%) were ended after the promotion complained of was corrected or removed. Because these were not violations of the Pharma Code the Secretariat rejected 34 (25%) of the complaints received as not conclusive (in previous year 20 or 14%). In 16 cases (12%; in the previous year: 14 or 10%) the concluding letter to the company responsible imposed a condition requiring an amendment to conform with the Code and in none of the 16 cases (as in the previous year) was an immediate correction of the promotion required. In one case (cf. 0 in the previous year) the immediate and complete restriction of the objectionable promotion was requested. All conditions imposed were accepted by the companies responsibly and implemented in a timely manner. In 13 cases (10%; in previous year 10 or 7%) the notifying company requested a re-assessment, as it was not in agreement with the conclusion reached by the Secretariat. No case was referred to Swissmedic as in the previous year.

Communication

At irregular intervals the Secretariat reports in abstract form about individual cases it has assessed In accordance with PC 533.5[13], with the intention of allowing all signatories to learn from the appropriate knowledge and experience of other companies. In 2009 four other such case reports were brought to the attention of the companies in the SGCI Membernet. The process is being continued. In the report year the Pharma Code Secretariat made one further recommendation (No. 5) in the series "Pharma Code Practice". It is entitled "Cost sharing by those attending events which are held or supported by pharmaceutical companies."[14] The recommendation is based with regard to content on a survey implemented previously among pharmaceutical companies.

Pharma Code, EFPIA Code and IFPMA Code

In the year of report the international codes of higher ranking to the Pharma Code (see introduction) did not change which is why the Pharma Code did not itself require any amendments.

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

[13] The Pharma Code Secretariat ensures [...] „that companies are periodically informed 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.cg/plugin/template/sgci/*/43912 (German) http://www.sgci.cg/plugin/template/sgci/*/43913 (French)