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

The Pharma Code (PC) in 2008: 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]). SGCI Chemie Pharma Schweiz[5] has pledged observance of the code, supported by its partner associations named in the Foreword of the Pharma Code. The Pharma Code is enforced according to the principle of amicable resolution of conflict, if necessary supported by mediation through the Pharma Code Secretariat.

General matters relating to the practical implementation of the Pharma Code in 2008

Once again the number of all cases heard in 2008 in connection with the Pharma Code fell compared to the previous year (from 166 to 138). 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. Essentially we should welcome this; companies are requested to notify such occurrences to the Pharma Code Secretariat so that they may be recorded in case statistics.

Notably an encouraging trend has become more established. Obviously recognisable violations have become less common. On the other hand there were still a large number of more complex cases where the violations could be considered borderline, for example when a statement was open to several interpretations or the violation was only recognised as such on closer examination. This trend admittedly required more work for the Pharma Code Secretariat. It made the job more demanding and more interesting as cases of this sort often required in-depth investigations and discussion. It is noted with pleasure that the effort to achieve better professional advertising is clearly bearing fruit. It has also become evident from our personal contacts that a number of large and smaller-sized companies have once more improved their in-house procedures (Standard Operating Procedures, SOP). Generally speaking, greater weight is placed on compliance today. In addition to dealing with notifications, the Pharma Code Secretariat gave advice to individual companies on fundamental matters in accordance with PC 6[6] on 63 occasions (cf. 61 in previous year).

PC requirements and violations

Encouragingly 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 again (from 23 to 14). 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), increased slightly again to 28 (cf. 23 in previous year). There were 25 cases this year (cf. 16 in 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 fell to 82 (cf. 127 in previous year). On the other hand, something of a curiosity, one complaint was about a promotion where the writing was barely legible (PC 132.1). The particular ob-

[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.sgci.ch/plugin/template/sgci/1/*?selected_language=en
[6] The requirements of the Pharma Code are cited in the Annual Report using “PC” and the relevant marginal figures.

servation made in the previous year of references to the *literature being incomplete and inadmissible (PC 143.1, 143.2, 143.3, 143.4, 143.5, 144) had obviously borne fruit in the review year*: *such violations only occurred in 13 cases* (cf. 36 in the previous year). In 21 cases (cf. 26 in previous year) *references were incorrectly cited* (PC 141.3 and 143.3). The expression "safe" was used in 7 cases (cf. 4 in previous year) without appropriate qualification (PC 142.1). In 3 cases, similar to 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).*

Notifications due to *unqualified superlatives and comparisons* (PC 145) fell once again (to 45 cases cf. 50 in the previous year). Once again there were no cases in which unsolicited *samples* were sent or in which medicinal products were supplied as such but were not identified as "free samples" (PC 147 in conjunction with Art. 10 Para. 2 Letter a of the Ordinance on Advertising of Medicinal Products[7)] – after rising steadily for many years. Identifying a mailing as an "important notice" (PC 148), which is admissible only to ensure the safety of medicinal products, was incorrect in 6 cases (cf. 4 in previous year).

In connection with *events and support given to postgraduate training and continuing medical education of health-care professionals* (PC 2) there were more complaints once more (5; 1 in the previous year). Encouragingly, further measures were taken on the part of physicians to avoid conflicts of interest (SAMS guidelines[8]). There were similarly no proceedings in the year under review in connection with the sponsoring of *clinical trials* (PC 3).

In only 4 cases (cf. 9 in previous year) 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. Happily no companies (cf. 3 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. 3 in the previous year) companies omitted to report a change of responsible person to the Secretariat in accordance with PC 522.

Statistics and communication

The maximum duration of proceedings introduced by the Pharma Code in 2003 (25 working days extendable on a single occasion by 10 working days in justified cases) proved effective again, although the duration of proceedings rose to 12.5 working days on average after a reduction from 12 to 11 working days on average in the previous year. The Pharma Code Secretariat informed the company concerned of a notification within the first 5 days of its receipt (cf. 4 in 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 6 (4%) of all cases heard (3 or 2% in the previous year).

86 notifications or 61% (122 or 68% in the previous year) originated from *competitors*; in 51 cases or 36% (52 or 29% 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%: 5 or 3% in the previous year) with certain more serious violations often giving rise to several notifications. In the review year there was 1 case (1 in previous year) which might have resulted in significant consequences in terms of health policy (i.e. directly or indirectly jeopardising the health of patients). After the intervention of the Pharma Code Secretariat the company concerned immediately withdrew the objectionable promotion.

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 2008 this was not necessary, as in 2007.

Reporting on the practice of the Pharma Code Secretariat with regard to case decisions in the sense of PC 533.5[9]. At irregular intervals the Secretariat reports in abstract form about individual cases it has assessed with the intention of allowing all signatories to learn from the appropriate knowledge and experience of other companies. In 2008 3 additional case reports of this kind were brought to the knowledge of companies in the SGCI membernet. The process is being continued.

Differentiated compilation of case statistics, particularly according to degree of severity, including with regard to the annual report to the EFPIA Secretariat on the implementation of the Pharma Code: in 2008 94 proceedings 68% of all cases heard (previous year 101 or 61%) were concluded once the objectionable promotion had been corrected or withdrawn. The Secretary rejected 20 (14%; previous year 39 or 23%) of

[7] http://www.admin.ch/ch/sr/812 212 5/a10.html
[8] Cooperation between physicians and industry, implementation of guidelines; http://www.samw.ch/content/d Ethik Richtlinien.php
[9] "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."

the complaints received as invalid because they did not involve a violation of the Code. In 14 cases (10%; previous year 11 or 7%) the concluding letter to the company responsible included a condition requiring an amendment to conform with the Code and in none of the 14 cases (0%; previous year 3 or 2%) was an immediate correction of the promotion required.

There were no cases where the immediate and complete restriction of the objectionable promotion was requested (0%; previous year 4 or 2%). All the conditions imposed were accepted by the companies responsibly and implemented promptly. In 10 cases (7%; 8 or 5% previous year) the notifying company requested a re-assessment as it was not in agreement with the conclusion reached by the Secretariat. No case (cf. 1 in previous year) was referred to Swissmedic (PC 555.6).

Pharma Code, EFPIA Code and IFPMA Code

On 1 July 2008 the revised *"EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals"*[10] and the new *"EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations"*[11] came into force. At the same time SGCI Chemie Pharma Schweiz undertook a partial review of the Pharma Code as the international codes of EFPIA and IFPMA are to be implemented and applied within the relevant national codes.

The regulation of advertising about medicinal products (PC 1) did not undergo any material changes based on the EFPIA Codes. It did, however, bring clarification (PC 121.1 and 555.6) that the sometimes similarly sounding promotional regulations in the Pharma Code and in the government Medicaments Act are different with regard to their *motivation*. The *Pharma Code* is based on *honesty and ethics*, the government law on prescriptions to *protect from health risks (protection against the endangering of life and deception)*. The following sections of the Pharma Code are new because of the EFPIA Codes mentioned:

- Involvement of consultants by pharmaceutical companies (PC 15)
- Supplements regarding events (PC 212, 213, 223, 24, 27)
- Contracts for services (PC 29)
- Non-interventional studies using authorized medicinal products (PC 37)
- Relationships of the pharmaceutical industry with patient organizations (PC 4)
- In-house monitoring of pharmaceutical companies (PC 613, 62).

The amended Pharma Code includes a general transitional arrangement valid until the end of 2008 (Final Provisions PC 104). The Pharma Code Secretariat has granted signatories an extended transitional period to the end of March 2009 to implement PC 4 (new) in conjunction with an appropriate recommendation (No. 4)[12] in the Series of Pharma Code Practice[13]. In the review year, therefore, the new conditions of the Pharma Code coming in to force on 1 July 2008 had not yet been the subject of proceedings by the Pharma Code Secretariat.

The *IFPMA Code of Pharmaceutical Marketing Practices* (IFPMA Code)[14] was not amended in 2008.

Appeal

Professional advertising of medicinal products is improved if it is critically appraised, especially by those to home 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.

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Secretariat of the Pharma Code

Dr. med. Felix Schwarzenbach

[10] http://www.efpia.eu/content/default.asp?Page1D=559&DocID=3483
[11] http://www.efpia.eu/content/default.asp?PageID=559&DocID=3484
[12] http://www.sgci.ch/plugin/template/sgci/*/38207; http://www.sgci.ch/plugin/template/sgci/*/38252 (not available in English)
[13] http://www.sgci.ch/plugin/template/sgci/*/17382; http://www.sgci.ch/plugin/template/sgci/*/17384 (not available in English)
[14] http://www.ifpma.org/EthicalPromotion/index.aspx