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Chemie
Pharma
Schweiz

Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code) of 4th December 2003[1]

The Pharma Code (PC) in 2007: Annual Report of the Pharma Code Secretariat

General matters relating to the practical implementation of the Pharma Code

Concerning Pharma Code *proceedings*: 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) has proved an effective measure. On average, proceedings were completed within 11 working days (cf. 12 in 2006). Once again, in all cases the Pharma Code Secretariat informed the company concerned of a notification within the first 4 days of its receipt, together with the Secretariat's assessment. It is gratifying to report that the companies concerned generally responded quickly and constructively. The option of extending the period needed was required in only 3 cases (cf. 5 in 2006) out of a total of 166 cases (cf. 193 in 2006), or approximately 2% (cf. 3% in 2006). In comparison with last year, the total number of cases dealt with in connection with the Pharma Code in 2007 fell by 16% (166 cf. 193). 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 observe 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 from making notification in spite of having reason to do so.

Notably, an encouraging trend has become apparent namely: obvious violations have become less common. On the other hand, there was still a large number of quite complex cases in which the violation could be considered borderline, for example when a statement was open to several interpretations or the violation was recognisable as such only on closer examination. For the Secretary of the Pharma Code this trend admittedly required more work, however, this makes the job more demanding and more interesting, as cases of this sort often require in-depth investigation 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 quite a lot of large and small companies have improved their in-house procedures. Generally speaking, greater weight is being 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 on 61 occasions (cf. 58 in 2006).

122 notifications, or 68% (cf. 139 or 68.5% in 2006), originated from *competitors*. In 52 cases, or 29% (cf. 61 or 30% in 2006), the Secretariat raised objections to promotional material (advertisements, mailings, etc.) *on its own initiative*. 5 notifications (3%; cf. 3 or 1.5% in 2006), originated from *physicians* and other third parties, with certain more serious violations often giving rise to several notifications. As in the preceding year, only one case occurred which was not only of concern because of unfair competition but could also have had significant consequences in terms of health policy (i.e. directly or indirectly jeopardising the health of patients). As it was not possible in this case to reach a definitive agreement, the Pharma Code Secretariat referred it to Swissmedic for judgement in accordance with PC 45. The company concerned withdrew the objectionable promotional material shortly thereafter.

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 authorisation (PC 131.3) increased slightly (from 17 to 23). In contrast, it is gratifying to note that the number of cases for which promotions (PC 131.1, 131.2 and 133) of as yet unauthorized medicinal products or indications decreased to 23 (cf. 40 in 2006). There were only 16 cases this year (cf. 21 in 2006) of promotional material not including all the minimum particulars about the medicinal product (PC 131.4, 134 and 135). Complaints about general standards of

[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

quality remained stable at a high level of 127 cases (cf. 133 in 2006). In 36 cases (cf. 40 in 2006) the references to the literature were incomplete or inadmissible (Pharma Code 143.1, 143.2, 143.3, 143.4, 143.5, 144). As in the preceding year, *references were incorrectly cited* (PC 141.3) in 26 cases, however, there were only 26 cases this year (cf. 34 in 2006) in which *promotional statements were unsubstantiated* (PC 141.2). The expression "safe" was used without appropriate qualification in 4 cases (cf. 5 in 2006) (PC 142.1). In 3 cases (cf. 5 in 2006) expressions minimising possible risks were used, for example that the medicinal product concerned induces no addiction or is harmless (PC 142.2).

After a constant increase over several years, notifications due to *unqualified superlatives and comparisons* (PC 145) decreased with 50 cases (cf. 55 in 2006). There was no case this year (cf. 1 in 2006) in which unsolicited *samples* were sent or in which medicinal products were 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[2]). Identifying a mailing as an "*Important notice*" (PC 148), which is admissible only to ensure the safety of medicinal products, was incorrectly used in 4 cases (cf. 1 in 2006). In 9 cases the obligation on companies to *make available* to the Pharma Code Secretariat *sample copies of their promotional material without being requested to do so* (PC 441) was not fulfilled, remaining unchanged versus 2006. In connection with *events and support given to postgraduate training and continuing medical education of health-care professionals* (PC 2), most companies have amended their in-house guidelines to conform to the Pharma Code, and thus there were only isolated complaints this year, as in the preceding year (1 violation; cf. 4 in 2006). It is a pleasure to report that in this respect too, further measures were taken on the part of physicians to avoid conflicts of interest. In connection with the sponsoring *of clinical trials* (PC 3) there were also no proceedings in the year under review. In 3 cases (cf. 2 in 2006) companies which had signed up to the Pharma Code contacted the authorities directly, in contravention of the Preamble to the Pharma Code. In 3 cases (cf. none in 2006) companies omitted to report a change of responsible person to the Secretariat in accordance with PC 422.

Pharma Code, EFPIA Code and IFPMA Code

At the beginning of 2006 the new "EFPIA Code of Practice for the Promotion of Medicines", 2004 Edition (EFPIA Code) came into force, published by the European Federation of Pharmaceutical Industries and Associations (EFPIA). The EFPIA Code, to which the Pharma Code refers in the Preamble, is not applicable per se in the individual countries of the national member associations but is implemented in the Codes of the national EFPIA member associations. The Swiss Pharma Code required no amendment as a consequence of the EFPIA Code, 2004 Edition. However, the Pharma Code Committee has recommended the following measures and a report can be made here of their implementation:

1. *The provision of more information to pharmaceutical companies about rulings under the terms of PC 433.5[3], so that all signatories can learn from the mistakes of individual companies:* in the year under review, 3 cases were reported (cf. 4 in 2006) via the SGCI Membernet in a neutral format, which were received with great interest. This practice will be continued.
2. *In the event of serious violations, the Pharma Code Secretariat can require the company at fault to issue corrective information in a suitable form to the addressees concerned:* this was not necessary in a single case in 2007.
3. *Differentiated compilation of case statistics, particularly according to degree of severity, including with regard to the annual report on the implementation of the Pharma Code to the EFPIA Secretariat:* in 2007, 101 proceedings (61% of all cases dealt with; cf. 118 or 61% in 2006) were concluded once the objectionable promotion had been corrected or withdrawn. The Secretary rejected 39 of the complaints received (23%; cf. 40 or 21% in 2006) as invalid because they did not involve an infringement of the Code. In 11 cases (7%; cf. 15 or 8% in 2006) the concluding letter to the company responsible included a condition requiring an amendment to conform with the Code. In 3 of the 11 cases (2%; cf. 2 or 1% in 2006) an immediate correction of the promotion was requested. In 4 cases (2%; cf. 6 or 3% in 2006) the immediate and complete retraction of the objectionable promotion was requested. All the conditions imposed were accepted by the companies responsible and implemented promptly. In 8 cases (5%; cf. 12 or 6% in 2006) the notifying company requested a re-assessment as it was not in agreement with the conclusion reached by the Secretariat. Three

[2] http://www.admin.ch/ch/d/sr/812_212_5/a10.html

[3] "In particular, 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."

cases (cf. 1 in 2006) were referred to either Swissmedic (1 by a company and 1 by the secretariat) or to a court (1 by a company).

On 1st January 2007 the IFPMA Code of Pharmaceutical Marketing Practices (IFPMA Code)[4], amended in certain details, came into force. The Pharma Code also refers to the IFPMA Code in its Preamble. SGCI Chemie Pharma Schweiz amended certain details in the Pharma Code (particularly in Part 2) to bring it into line with the amended IFPMA Code, for implementation on the same date.

In 2007 the EFPIA Code was again partially revised; its new title is now: "EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals"[5]. In parallel, the EFPIA approved a new "EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations"[6]. Both EFPIA Codes come into force on 1st July 2008 and have to be implemented at national level by then by the EFPIA member associations. SGCI Chemie Pharma Schweiz will amend the Pharma Code correspondingly for implementation at the same time.

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 again 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 training 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

Zürich, March 2008

[4] http://www.ifpma.org/EthicalPromotion/index.aspx?3_html
[5] http://www.efpia.org/content/default.asp?PageID=150
[6] http://www.efpia.org/content/Default.asp?PageID=151