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

The Pharma Code (PC) in 2006: Annual Report of the Pharma Code Secretariat

General matters relating to the practical implementation of the Pharma Code

The maximum duration of proceedings of the Secretariat (25 working days, extendable on a single occasion by 10 working days when justified due to well-founded reasons), introduced by the Pharma Code (PC) in 2004, has proved an effective measure: on average, the proceedings were completed within 12 (2005: 14) working days. In all cases, the Pharma Code Secretariat informed the company concerned of the notification together with its assessment within the first 4 (3) days of receipt of a notification. The option of extending the period was made use of in 5, or approximately 3%, of the total of 193 cases dealt with.

The total number of cases dealt with by the Pharma Code Secretariat rose slightly in 2006, following a decrease in the preceding year (+6% to 193 cases, 2005: 182). In addition, the Pharma Code Secretariat advised individual companies on 58 occasions (2005: 64 occasions) in accordance with PC 6 in cases of principle. 139 notifications, or 68.5% (2005: 137, or 75%), originated from *competitors.* In 61 cases, or 30% (47, or 26%), the *Secretariat* raised objections to promotional material (advertisements, mailings etc.) on its own initiative. 3 notifications (1.5%; 2005: 5, or 3%) originated from *physicians* and other parties, and often several notifications were received relating to serious violations. Unlike the preceding year, one case occurred in 2006 which was serious both in respect of ethical advertising under the law and from the health policy aspect: this promotion could have resulted in inappropriate actions on the part of trusting health care professionals, with the possible consequence of jeopardy to patients' health. The Pharma Code Secretariat cautioned the company straight away and the company concerned withdrew the promotion immediately. In this way, potential risks could be avoided promptly.

PC requirements and violations

In the year under review, 17 promotional statements did not concur with the *professional information* which had been approved by Swissmedic at the time of the marketing authorisation (PC 131.3). The number of violations of this sort decreased again (following an increase in 2005 from 17 to 27). With 40 cases, however, (2005: 32), the prohibited *promotion of medicinal products or indications not yet granted marketing authorisation* increased (PC 131.1, 131.2 and 133) – possibly a consequence of the fact that the Secretariat was paying greater attention to the observance of this rule. In 21 cases (2005: 22), promotional materials did not contain all the *minimum particulars about the medicinal product* stipulated in PC 131.4, 134 and 135. Complaints about the *general qualitative requirements* increased again (from 107 to 133), following a decrease in the preceding year. In 40 (37) cases the *references to the literature were incomplete or inadmissible*. References were cited incorrectly in 26 (25) cases (PC 141.3). The number of cases of *unsubstantiated promotional statements* (PC 141.2) doubled from 17 to 34, apparently due in particular to the majority resulting from reciprocal monitoring by competitors (30 out of 34 cases). In 5 (7) cases, the *expression "safe"* was used *without appropriate qualification* (PC 142.1) and in 5 (6) cases use was made of *expressions minimising possible risks* (PC 142.2), for example, that the medicinal product in question induces no habituation or is harmless.

Whereas notifications had always risen in the past due to *unqualified superlatives and comparisons* (PC 145), they fell by 13% in the year under review to 55 cases (2005: 63). There was only one case this year (3) of health care professionals being sent unsolicited *samples* or medicinal products provided as such but not identified as "free samples" (PC 147.2, also: 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 done in one case (2005: 2).

The obligation of companies who have signed the Pharma Code *to make available* to the Pharma Code Secretariat *sample copies of their promotional material without being requested to do so* (PC 441), was fulfilled less punctiliously in the year under review (9 violations, compared with 3 in the preceding year). In connection with *events and support given to the postgraduate training and continuing medical education* 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
[2] German: http://www.admin.ch/ch/d/sr/812_212_5/a10.html French: http://www.admin.ch/ch/f/rs/812_212_5/a10.html

health care professionals (PC 2), most companies have brought their in-house guidelines into accord. Unlike the preceding year, this gave rise to hardly any advisory activity; similarly, there were only 4 (2005: 2) violations. In connection with the *sponsoring of clinical trials* (PC 3) there were also no proceedings in the year under review. In 2 cases (2005: 0) signatories to the Code contacted the authorities direct (i.e. they did not contact the Pharma Code Secretariat first), in contravention of the well-founded principle laid down in the Preamble to the Pharma Code.

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)[3] 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 new EFPIA Code. 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 the pharmaceutical companies about rulings as referred to in PC 433.5, so that all signatories can learn from the mistakes of individual companies:* in 2006 the Secretariat sent reports to the signatories on 4 (2005: 7) cases, 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 2006.
3. *Categorised recording 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 2006, 118 proceedings (61% of all cases dealt with; 2005: 101 cases, or 56%) were concluded once the promotion complained about had been corrected or discontinued. The Secretary rejected 40 (21%; 2005: 39, or 21%) of notifications received as invalid because they did not involve an infringement of the Code. In 15 cases (8%; 2005: 24 cases, or 13%), the Secretary imposed a condition in the concluding letter to the company responsible requiring amendment to conform with the Code, and demanded an *immediate correction* of the promotion in 2 of the 15 cases (1%; 2005: 11 cases, or 6%). In 6 cases (3%; 2005: 7 cases, or 4%) he demanded the *immediate, complete retraction* of the promotion complained of. All the conditions imposed were accepted by these companies and implemented promptly. In 12 cases (6%; 2005: 11 cases, or 6%) the notifying company demanded a re-assessment as it was not in agreement with the conclusion reached by the Secretariat. One case (2005: 2) was passed on to Swissmedic or to a court by the notifying company. In 2006 the Secretariat had no need to refer any case to Swissmedic for assessment in accordance with PC 45 due to lack of agreement (2005: 1 case).

In 2006 certain provisions of the Pharma Code were amended or added to following consultation with the signatories[4]. The amendments were necessitated by the completely revised "*IFPMA Code of Pharmaceutical Marketing Practices*", published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)[5]. The new IFPMA Code came into force on 1st January 2007, as did the correspondingly amended Pharma Code, which refers to the IFPMA Code in its Preamble.

Appeal

Professional advertising of medicinal products gets better if it is appraised critically, especially by those to whom it is addressed. Thus we appeal 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, End of March 2007

[3] http://www.efpia.org/Objects/2/Files/Promomedicines2004.pdf
[4] See references to the amended provisions of the Pharma Code in Footnote 1 on the title page of the Pharma Code.
[5] http://www.ifpma.org/pdf/IFPMA-TheCode-FinalVersion-30May2006-EN.pdf