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Chemie
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Schweiz

Code of Conduct of the Swiss Pharmaceutical Industry
(Pharma Code) of 4 December 2003

The Pharma Code (PC) in 2005: Annual Report of the Pharma Code Secretariat

This is the second annual report on the practical implementation of the Code of Conduct of the Swiss Pharmaceutical Industry of 4 December 2003 (Pharma Code, PC) in force since 2004[1].

General Remarks on Practical Implementation

The maximum duration of a proceeding of the Secretariat introduced with the Pharma Code (25 working days, one extension of 10 working days possible in justified, well-founded cases) has proven effective: During 2005, proceedings were successfully settled in an average of 14 working days (as compared to 13 in 2004). Upon a company being reported, the Pharma Code Secretariat forwarded the notice filed along with the Secretariat's assessment to the respective company within 3 (4) days. The extension option had to be exercised in only in 5 (2004: 8) or approximately 3% (2004: 4%) of the total 182 (2004: 213) cases dealt with by the Secretariat in 2005.

In 2005 there was fortunately a drop from 213 to 182 in the total number of cases dealt with in connection with the Pharma Code. However, the cases exhibited a tendency towards increased complexity, the result being that there was no drop in the Secretariat's overall workload. In addition, the Pharma Code Secretariat provided advice to 64 (2004: 61) different companies in issues related to section 6 of the Pharma Code. 137 notices or 75% (2004: 174 or 73%) were filed by *competitors;* in 47 cases, or 26% (2004: 54 or 23%), the *Secretariat* itself initiated a proceeding when objecting to promotional material (advertisements, mailings, etc.). 5 notices (3%, 2004: 12 or 5%) were filed by *physicians* and others, with several notices frequently being filed for the same violation (this also explains why the total slightly exceeds 100%).

As in the previous year, there were no cases in 2005 which were questionable from the point of view of unfair competition and public health aspects. What is relevant from the point of view of public health extends to matters which may jeopardize the health of patients, whether directly or indirectly, or can mislead or deceive them. In this context, Swissmedic – the Swiss Agency for Therapeutic Products – is the competent authority for policing public health matters.

Requirements of the Pharma Code and Violations Thereof

- After a drop in 2004 from 30 to 17 differences in promotional messages as compared to the *information for health care professionals* approved by Swissmedic in its authorization (PC 131.3), there was a spike again to 27.
- At 32 (2004: 31), the number of cases involving advertising for *non-approved* medicinal products and indications (PC 131.1, 131.2 and 133) remained at a relatively high level.
- Fortunately, there were only 9 cases (2004: 24) of promotional materials not listing all of the *minimum details* pertaining to the medicinal product as prescribed by the Pharma Code (PC 131.4 and 134).
- Complaints concerning *general qualitative requirements* dropped from their substantial level in the years preceding (from 125 to 107).
- There were 25 (2004: 31) cases in which the *bibliographic references* were incomplete or impermissible. Only 25 (2004: 43) cases involved references not being correctly cited (PC 143.3), meaning that the special attentiveness of the Secretariat in these matters proved somewhat successful.
- Cases in which the promotional message was *not substantiated (*PC 141.2): 17 (unchanged).

[1] German: http://www.sgci.ch/plugin/template/sgci/*/11386; http://www.sgci.ch/plugin/template/sgci/*/11723
French: http://www.sgci.ch/plugin/template/sgci/*/11387; http://www.sgci.ch/plugin/template/sgci/*/11724;
English: http://www.sgci.ch/plugin/template/sgci/*/11388; http://www.sgci.ch/plugin/template/sgci/*/11927

- The expression *"safe"* was used in 7 (2004: 0) cases *without an appropriate qualification* (PC 142.1).
- In 6 cases (2004: 4), *expressions were used which downplayed possible risks*, e.g. the medication was said not to cause addiction or was purportedly risk-free or harmless (PC 142.2).
- After the continuous increase during the past couple of years, the notices filed on account of *unqualified superlatives and comparisons* (PC 145) remained virtually unchanged at 63 cases (2004: 58).
- 3 cases (2004: 2) involved the unsolicited mailing of *samples of medicinal products* or dispensing of items which were not properly labeled as "free sample" (PC 147.2 in association with article 10, paragraph 2, letter a of the Ordinance on Advertising of Medicinal Products[2]).
- The labeling of a broadcast as *"Important Notice"* (PC 148) — a designation which may only be used for ensuring medicinal product safety — was improperly used in 2 cases (2004: 1).
- During the year under review, companies exhibited improved compliance with their obligation of sending the Pharma Code Secretariat a *sample copy of their promotional material without having to be specifically requested* (PC 441) after having been sent a number of reminders (3 violations as compared with 7 violations in 2004).
- The *organization and support of postgraduate training and continuing education of health care professionals* (PC 2) was frequently the topic of advice sought from the Secretariat during the year under review. Only 2 (2004: 3) violations were reported in this connection.
- There were no proceedings initiated during the year under review with regard to the *sponsoring of clinical trials* (PC 3).

Pharma Code and EFPIA Code

The new EFPIA Code (EFPIA Code of Practice on the Promotion of Medicines, 2004 edition[3]) entered into force at the beginning of 2006. It is not directly applicable in the individual countries of the national member associations of EFPIA, the European Federation of Pharmaceutical Industries and Associations. However, in their individual codes, the national member associations have to ensure that they achieve the EFPIA Code's objectives (rules of conduct and implementation thereof).

In its capacity as national member association, SGCI Chemie Pharma Schweiz, after consulting with the Pharma Code Committee, established that the Pharma Code complies with the EFPIA Code and thus requires no adaptation. In particular, SGCI Chemie Pharma Schweiz dispensed with the introduction of sanctions in dealing with violations of the Pharma Code (although recommended by the EFPIA Code, subject to the precedence of national laws and ordinances) as companies unequivocally had, when drafting the Pharma Code, decided against sanctions and opted instead for non-adversarial mediation proceedings in dealing with controversies concerning violations of the Pharma Code, a method which has proven itself in practice over many years.

One decisive factor in this connection in Switzerland is that national law concerning medicinal products also governs advertising for medicinal products and that Swissmedic can initiate administrative or punitive measures in the event of violations of the law. In addition, pharmaceutical companies can also bring court action concerning advertising for medicinal products in cases involving violations of Unfair Competition Act. Consequently, the Pharma Code will be continued without any modifications with regard to its code of conduct or practical implementation. SGCI Chemie Pharma Schweiz informed EFPIA to this effect in a timely, well-founded manner.

In order to take due account of the objectives pursued with the EFPIA Code — particularly concerning discipline associated with compliance with the EFPIA Code — the Pharma Code Committee recommended that information and communication pertaining to the rules embodied in the Pharma Code including consistent adherence thereto be intensified. This extends in particular to periodically informing the signatories of the Pharma Code in a practical manner with the objective of preventing violations by fostering a good knowledge of the Code and heightening the awareness of pharmaceutical companies in reporting suspected improper conduct of competitors to the Pharma Code Committee. Reporting to Swissmedic or court action should not be considered unless the Pharma Code proceeding has not resulted in an amicable elimination of a violation (cf. also the last section of the Preamble of the Pharma Code).

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[2] http://www.admin.ch/ch/d/sr/812_212_5/a10.html
[3] www.efpia.org/6_publ/codecon/Promomedicines2004.pdf

The Pharma Code Committee recommended the following measures in particular:

1. Providing more information to pharmaceutical companies concerning case decisions pursuant to PC 433.5[4] so that all signatories can learn from the mistakes of individual companies. During the year under review, there were seven cases reported in the SGCI Membernet which met with considerable interest. This practice will be continued.
2. In dealing with serious violations, the Pharma Codex Secretariat can have the offending company issue a corrected notification in suitable form to those concerned. This was not required in any case in 2005.
3. Differentiated collection of case statistics, most particularly according to severity, among other things in view of the annual reporting to the EFPIA secretariat concerning the implementation of the Pharma Code.

The following should be noted concerning 3. above:

- In 2005, 101 proceedings (56% all of cases dealt with) were closed after the offending advertising was *corrected or discontinued*.
- The Secretariat rejected 39 (21%; 2004: 42 or 20%) of the complaints received as *unfounded* as they didn't involve any violation of the Pharma Code.
- In 24 cases (13%) a *condition* was imposed on the offending company in a concluding letter requiring it to adapt its conduct so as to comply with the Pharma Code, with immediate correction of advertising being demanded in 11 of the 24 cases (6%).
- In 7 cases (4%) the companies were called upon to immediately *withdraw* the advertising entirely.
- *All conditions were accepted* by the offending companies and *implemented in a timely manner*.
- In 11 cases (6%) the reporting company requested a *reassessment* after not being satisfied with the way the Secretariat handled the matter.
- 2 cases *were referred* to Swissmedic or a court by the reporting company.
- The Pharma Code Secretariat referred *one case to Swissmedic for its assessment* pursuant to section 45 of the Pharma Code after no conclusive agreement could be reached by way of correspondence or mediation.

Appeal

Advertising for medicinal products can be improved when it is subjected to critical scrutiny, particularly by those to whom it is directed. Consequently, all physicians and pharmacists are once again called upon to contact the Pharma Code Committee if they find fault with an advertisement, commercial, broadcast or other promotional measure for ethical or scientific reasons. According to the new Pharma Code, this also applies to postgraduate training and continuing education events as well as to the sponsoring of clinical trials that are suspected of being in violation of the rules of the new code.

Pharma Code Secretariat

Dr. med. Felix Schwarzenbach Zurich, February 2006

[4] "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."