

**Recommendations No. 2 to the Pharma Code<sup>1</sup>****Professional promotion for pharmaceuticals: procedure to be followed in the event of suspected conduct in breach of the code by competitors****Initial situation**

Swissmedic repeatedly reports notifications by pharmaceutical companies claiming that a competitor is infringing certain provisions on professional promotion for pharmaceuticals. In such cases Swissmedic is automatically required to open proceedings. However, the breaches to which the complaint refers *seldom prove relevant to health policing*.

As a rule these are conflicts under the *law of unfair competition* between competitors. If the pharmaceutical companies place this burden upon Swissmedic, resources are tied up whose use for health policing tasks takes priority in the public interest and certainly also in that of the pharmaceutical industry itself!

**o The purposes of the Pharma Code and those of State Law are different**

In Art. 118<sup>2</sup>, the Swiss Federal Constitution requires the Federation, within the framework of its competences, to take action to protect health (known as *health policing measures*). This includes e.g. the adoption of regulations on the use of therapeutic substances. The Federal Authorities have set out these measures in the Therapeutic Products Act (TPA)<sup>3</sup> with the accompanying ordinances.

As an *official agency of the Confederation*, Swissmedic is entitled and required to take health policing measures relating to professional promotion for pharmaceuticals. These measures are based on the Pharmaceuticals Publicity Ordinance (AWV)<sup>4</sup>, Art. 3<sup>5</sup> ff.

Various provisions of the AWV on professional advertising are similar to the rules on professional promotion set out in the *Pharma Code (PC)*. However, the latter are more detailed. While the AWV authorises Swissmedic to take action to protect human health against breaches of the law and ordinances through health policing measures, the *purpose* of the rules on professional promotion contained in the PC is founded on the law on unfair competition. The requirement of integrity is one of the *fundamental rules of fair competition*. On that basis the PC stipulates that pharmaceutical companies must *not mislead* readers of a professional medium through the information and advertising provided by them. On this subject the PC lays down the following principle for *professional promotion* in its Section 21:

**21 Principle**

In the professional promotion of medicinal products and information about such products, ethics, accuracy, topicality, balance, fairness and the absence of misleading information are to be regarded as generally valid principles. The material used for professional promotion and information must facilitate the correct assessment of the benefits and risks of a medicinal product and its correct application.

Sections 251 – 253 confirm this principle under the heading “Requirements concerning the content of professional promotion”:

251 The statements made in professional promotion must be proven.

252 They must not be misleading through distortion, inappropriate emphasis, omission or in any other way.

253 The following in particular are prohibited because they are misleading:

<sup>1</sup> <http://www.scienceindustries.ch/engagements/pharmakodex-und-pharma-kooperations-kodex>

<sup>2</sup> <http://www.admin.ch/opc/de/classified-compilation/19995395/index.html#a118>

<sup>3</sup> <http://www.admin.ch/opc/de/classified-compilation/20002716/index.html>

<sup>4</sup> <http://www.admin.ch/opc/de/classified-compilation/20011778/index.html>

<sup>5</sup> <http://www.admin.ch/opc/de/classified-compilation/20011778/index.html#a3>

\* PC: Pharma Code; PCC: Pharma Cooperation Code

253.1 Use of the word "safe" except in conjunction with an appropriate objective qualification;

253.2 Information to the effect that a medicinal product has no undesirable effects, does not cause habituation, is risk-free or harmless or other expressions which suggest that a substance is harmless.

The obligation of integrity *prohibits* the signatories of the PC from *denigrating* either directly or indirectly their competitors or their products in professional pharmaceutical promotion (indirect denigration means presenting their own product as being comparatively more advantageous than is in fact the case). The Federal Law on the Prevention of Unfair Competition (UWG)<sup>6</sup> is based on the same principle. Its Chapter 1 (Title "Purpose") 1<sup>st</sup> Section (Title: "Unlawful nature of unfair competition") makes the following stipulation:

**Art. 2 Principle<sup>7</sup>**

*Every misleading conduct or business behaviour which is in breach of the principle of loyalty and good faith and which influences the relationship between competitors or between suppliers and customers is unfair and unlawful.*

o **Preference for the Pharma Code procedure over the Swissmedic or court procedure**

Pharmaceutical companies which have made a commitment to respect the PC may ask for the non-contentious conflict resolution procedure to be adopted. There are three main reasons for choosing this procedure instead of reporting a competitor to Swissmedic or opening court proceedings on the grounds of breach of the UWG law on unfair competition:

- **The Pharma Code procedure is both fast and straightforward:** In principle within one month which can be suitably extended in justified cases a professionally qualified decision will be taken by the experienced code secretariat which is not dependent upon any private interests. The exchange of correspondence is standardised and transparent to the parties involved in the procedure. If this is necessary for conflict resolution purposes, the Code secretariat holds a mediation discussion with the parties directly concerned.
- **The Pharma Code procedure relieves Swissmedic of the burden of dealing with the procedures which present no health policing problems:** breaches of the rules of the PC are hardly ever likely to put the health of the public at risk. Professional promotion is intended solely for professionals; in addition, by reason of their training and experience professionals are in principle able to correctly understand and judge the content of professional promotion. Depending on the severity of a breach and its potential implications for health policing the time limit within which the pharmaceutical company must desist from its conduct in breach of the Code and confirm that it has done so to the Code secretariat will be determined. In this way the purpose of the TPA will be efficiently attained.
- **The Pharma Code procedure is preferable to court proceedings under the UWG:** For the signatories, the Pharma Code procedure assures conflict resolution more quickly and at significantly lower cost than taking the matter to court. Experience shows that court proceedings on conflicts concerning professional promotion involve heavy expenditure because as a rule the courts are not particularly familiar with the subject matter and first have to obtain the necessary professional expertise before a correct and fair decision can be taken. A timely judgement is therefore also seldom handed down: once it has been adopted the interest in the matter at dispute has generally ceased to exist.
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## Recommendations

- ⇒ As a matter of principle, the pharmaceutical companies are **recommended to submit all suspected breaches of the rules of professional promotion by competitors to the Code secretariat**: here they can expect a fair procedure, expertly conducted and brought to a rapid conclusion. This procedure

<sup>6</sup> <http://www.admin.ch/opc/de/classified-compilation/19860391/index.html>

<sup>7</sup> <http://www.admin.ch/opc/de/classified-compilation/19860391/index.html#a2>

does not exclude *subsequent* proceedings with Swissmedic or the courts, in particular if the Pharma Code procedure does not lead to the cessation of the breach.

- ⇒ The presumed breaches of the rules on professional promotion are **very seldom relevant for health policing purposes**. Placing the burden of dealing with them upon Swissmedic is therefore as a rule not the best way of arriving at a rapid resolution of a conflict between competitors.
- ⇒ In the same spirit it is **not advisable** to take **court proceedings** in the area of professional promotion for pharmaceuticals on grounds of a presumed breach of the UWG law. All too often the **ratio between the cost involved** (court and other costs, length of the proceedings) **and the desired benefit is unfavourable**.
- ⇒ The possibility of arriving at a **bilateral solution** to a conflict between competitors in the area of professional promotion for pharmaceuticals through direct contact is always open. If this approach does not lead to the desired aim the Code secretariat can always be approached for a non-contentious conflict resolution, if necessary with mediation.
- ⇒ Finally the **Code secretariat is available for consultations** to prevent potential breaches of the PC and conflicts with competitors. In this connection reference should be made to Sec. 7 of the PC:
  - **7 Consultative activity of the Code Secretariat**
    - 71 To safeguard its independence in the assessment of notifications of suspected breach of the Code, the Code Secretariat shall not assess any forms of conduct, documents or publications governed by this Code before they have been implemented or circulated by the pharmaceutical companies.
    - 72 On request, it shall provide information about the interpretation of provisions of this Code, without determining the accuracy of certain statements made in the documents or publications of a pharmaceutical company.

## Extracts from the Pharma Code rules that are relevant in this context

*The following rules apply to the notification of suspected conduct in breach of the code:*

### 15 Principles of conduct

- 151 Pharmaceutical companies which undertake to comply with this Code acknowledge the rules of enforcement of this Code if proceedings are taken for breach of the Code.
- 152 As long as relevant proceedings are pending, they will in principle not refer the matter at the same time to a State authority or to a court on grounds of breach of the Swiss legal order.
- 153 The safeguarding of rights which may be endangered or defeated by compliance with these principles of conduct is reserved.

### 62 Notifications

- 621 The Code Secretariat investigates, either on its own initiative or upon receiving notification, alleged breaches of the Code.
- 622 Anyone may notify the Code Secretariat of circumstances which are suspected to be in breach of the Code.
- 623 The Code Secretariat acts upon notifications if they are made in writing and the charge is founded. If necessary, it may ask the notifying person to supplement or document his substantiation and set an appropriate deadline for doing so.
- 624 The Code Secretariat will not respond to anonymous or manifestly unfounded notifications.
- 625 To clarify notifications, the Code Secretariat may request documents from the relevant pharmaceutical companies and set an appropriate deadline for them to comply; it may also put questions to their staff or appointed agents.

*If a breach of the Code is proven and the company concerned does not desist, the following provisions apply to further action:*

### 65 Procedure for unresolved cases

- 651 Should the pharmaceutical company concerned fail to comply within the set period with the ruling of the Code Secretariat, or should it decline to do so or fail to comply with its confirmation pursuant to Section 636 or 641, the

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- Code Secretariat may refer the matter to the appropriate State authority for a judgment after a warning to comply has not been respected.
- 652 At the same time, the Code Secretariat shall inform in writing the pharmaceutical company or the person who reported the breach of the Code to the Code Secretariat.
- 66 Duration of the proceedings**
- 661 The proceedings according to this Code shall be completed within the shortest possible deadline. They shall not last for more than one month.
- 662 In justified cases, the Code Secretariat may extend the duration of the proceedings by a reasonable length of time.
- 663 The proceedings commence on the date when the Code Secretariat receives notification of a charge, or on the date when a case is opened by the Code Secretariat.
- 664 The duration of the procedure ends upon the date of receipt of timely confirmation by the pharmaceutical company concerned that it will comply with the request of the Code Secretariat or the outcome of the consensus settlement to the proceedings recorded by the Code Secretariat and will cease in a timely manner its conduct in breach of the Code and guarantee that it will desist from such conduct in future.
- 665 If cessation of the breach of the Code is not possible in the light of the concrete circumstances, the pharmaceutical company shall guarantee in writing to the Code Secretariat that it will desist from such conduct in future.
- 666 The Code Secretariat and the parties to the proceedings shall use their best endeavours to ensure that the proceedings can be brought to a speedy conclusion.
- 667 If the proceedings cannot be concluded by the specified time limit, the case shall be deemed to be unresolved (Section 65).Assessment