Recommendations No. 2 to the Pharma Code

Professional promotion for medicinal products: 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 medicinal products. In such cases Swissmedic is automatically required to open proceedings. However, the breaches to which the complaint refers *seldom prove relevant to health policing*.

Often 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!

Assessment

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

In Art. 118, 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) 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 medicinal products. These measures are based on the Pharmaceuticals Publicity Ordinance (AWV), Art. 3 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. In Sections 24.1 to 24.3, the PC sets out the following content requirements for professional promotion:

24.1 Professional promotion must be exact, balanced, fair, objective and sufficiently complete to allow healthcare professionals to form their own opinion about the therapeutic value of the medicinal product in question. It must be based on and clearly present a current assessment of all relevant evidence.

24.2 The statements made in professional promotion must be supported by evidence, which must be provided to healthcare professionals on request. They must not be misleading through distortion, inappropriate emphasis, omission or in any other way. Promotional statements about adverse reactions of medicinal products must in particular reflect the current state of knowledge or be evidenced by clinical experiences.

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

24.3.1 Use of the word “safe”, except in conjunction with an appropriate objective qualification;

24.3.2 The use of the word “new”, unless the following conditions are met: Medicinal products, indications, possible applications, dosages, pharmaceutical forms and packaging may only be described as new for the first 12 months after they have become available or have been advertised in Switzerland. As such, they may only be called “new” for 18 months after they were first authorised in Switzerland. The information must make clear on

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

what this attribute is based.

24.3.3 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) is based on the same principle. Its Chapter 1 (Title "Purpose") 1st Section (Title: "Unlawful nature of unfair competition") that makes the following stipulation:

Art. 2 Principle

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.

Advantage 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 generally the courts are not particular 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.

Recommendations

By signing the PC, pharmaceutical companies recognise the enforcement rules for proceedings for conduct in breach of the Code (Section 14.1 PC). Therefore, in the event of disagreements about conduct that they believe falls within the scope of this Code or constitutes a violation of state law in this context, these pharmaceutical companies undertake to always first initiate arbitration proceedings with the Code Secretariat (see section 71 ff.) (section 14.2 PC). Here they can expect

a fair procedure, expertly conducted and brought to a rapid conclusion. This procedure 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 (Section 14.2 and 14.3 PC).

A pharmaceutical company can submit a report of a suspected PC violation to the Code Secretariat at any time (Section 72.2 PC). This notification must be submitted in writing, ideally electronically, and must be accompanied by a statement of reasons (Section 72.3 PC). After a formal pre-control of the report (Section 72.4 PC), the Code Secretariat checks the content of all the advertising complained about. This content check can lead to three results:

a) There is no violation; in this case, the Code Secretariat informs the notifying party of this decision; the potentially defendant party is not informed.

b) There is a possible violation of the PC; the Code Secretariat assesses it in the same way as the notifying party.

c) There is a possible violation of the PC; but the Code Secretariat does not judge it in the same way as the reporting party.

In the case of outcome (b) and (c), the Code Secretariat prepares an assessment for the defendant, listing all possible violations of the PC. It should be noted that the Code Secretariat may have found other possible violations of the PC. This assessment will be sent to the defendant party for comments. For the sake of transparency, the substantiated complaint is enclosed with the notifying party. The defendant party should only comment on the assessment of the Code Secretariat. All correspondence should always be copied to all parties involved.

There is also always the possibility of bilaterally resolving a conflict between competitors in the field of advertising for medicinal products in direct contact. The results of these bilateral discussions should be reported to the Code Secretariat immediately after conclusion, stating the parties involved, the advertising concerned and the outcome of the bilateral discussion. The Code Secretariat will examine whether this bilateral agreement is in conformity with the Code and, if so, will record this in writing for the attention of the parties concerned. If this bilateral approach does not lead to the desired result, notification can still be made to the Code Secretariat.

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 Section 8 of the PC.

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