

# Medicinal products in Switzerland: Where does information stop and advertising begin?

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The advertising of medicinal products is highly regularized. Advertising must be in line with the product information accepted by the Swiss Agency for Therapeutic Products, Swissmedic, and reflect the state of the art. Moreover, advertising for medicinal products subject to prescription may not be directed at the general public. Where the provisions of the Federal Law on Therapeutic Products (LTP) and the Ordinance on Advertising for Medicinal Products leave scope for interpretation, Swissmedic and the courts take a tough stance to protect public health, prevent the addressees from being misled and prohibit incentives for an excessive or inappropriate use of medicinal products.

The legal definition of advertising is broad. It includes any kind of information and/or marketing activity which aims at increasing the sale and/or use of medicinal products. However, the legal provisions on advertising do not apply to general information on health or diseases, which neither directly nor indirectly refers to specific medicinal products. But where is the demarcation line between information and advertising? The following recent court cases and examples illustrate the important practical impact of the answer to this question:

Pfizer owns a marketing authorization for Relpax containing the agent triptain and being sold on prescription. Several other competitive migraine medicines containing triptain are sold.

Pfizer sent a brochure to 939,000 women. Besides general information about migraine, it was stated that the agent triptain was best suited to combat medium and strong migraine. Neither possible side effects nor alternative medicine containing different agents were mentioned. However, women suffering from migraine were advised to visit their physician. Trademark Relpax was not mentioned. The Supreme Federal Court held Pfizer liable for prohibited and misleading advertising to the general public and obliged it to send a costly rectification to all the former addressees. Brochures about an illness may be qualified as advertising if they refer to one type of medicine/active agent only and leave alternative medicine/agents unmentioned and/or if the information is unbalanced.

In another decision it was held that a report about a disease which only mentions the indication of a medicinal product but not its trademark may qualify as advertising if the disease and the medicinal product are so closely connected that the indication is directly associated with the specific medicinal product (e.g. Viagra).

Supported by such strict decisions, Swissmedic issued interpretative guidelines. In its guideline about internet marketing Swissmedic



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requires that access to advertising for prescription-only products must be limited to health care professionals by means of password protection. Although the public may consult medicinal magazines and may find plenty of medicinal information on the Internet (e.g. on US websites), a click through solution where site visitors must confirm that they are healthcare professionals was held to be insufficient.

Not only does the pharmaceutical industry expose itself to administrative and penal proceedings if its information about prescription-only products is qualified as advertising to the general public, but it also risks the medicinal product not being registered on or being removed from the list of reimbursable products.

Two other examples show a strict interpretation of the law by the courts and Swissmedic:

Although it goes without saying that the physician's therapeutic decision should not be based on advertising but on the product information, scholarly literature and specific needs of the patient, the Supreme Federal Court confirmed that scientific findings resulting from clinical studies and published in peer-reviewed medical journals may not be advertised as long as the product information has not been updated. Neither the fact that it takes Swissmedic several months to approve updates nor that the law requests advertising to reflect the state of the art has been addressed.

Moreover, Swissmedic takes the view that sending

copies of study reports which have been published in peer-reviewed journals to professionals qualifies as advertising, if done by pharmaceutical companies.

This practice in my view is patronizing towards both the public and the healthcare professionals. It is argued that professionals should not be exposed to patients who hold an 'informed' opinion on which product they would like to be prescribed. However, nowadays patients can and do inform themselves about different medicinal products and therapies and may wish to discuss what they have learned with their physician. This does not necessarily influence the physician's independent therapeutic decision, and is why indirect reference to a specific prescription-only medicinal product should be confirmed in exceptional circumstances only. Professionals have critical minds and are interested in new scientific findings. As long as such new findings, which have not yet found their way into the product information, are presented in a sober, neutral and objective manner, they should be qualified as information and not as advertising.

Only a differentiated practice allows a well-balanced decision between economic freedom on one side and the protection of the public health on the other. ■

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