

Switzerland

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Selection, clearance and registration

In Switzerland, in order to be eligible as a pharmaceutical trademark, a name must meet the requirements defined by Swiss legislation concerning pharmaceutical products, as well as those generally applicable to trademarks.

Pharmaceutical law

Pharmaceutical products are regulated by the Federal Act on Pharmaceuticals and Medical Devices and a number of implementing ordinances enacted by the Swiss government or the regulator, the Swiss Agency for Therapeutic Products ('Swissmedic').

In contrast to the EU approach (see Article 1(20) of EU Directive 2001/83/EC), neither the Act on Pharmaceuticals and Medical Devices nor the implementing ordinances define the kinds of names that are eligible for pharmaceuticals. However, the name of a pharmaceutical must be submitted to Swissmedic when applying for a marketing

authorisation and, according to Article 7(3) of the Ordinance on Pharmaceuticals, Swissmedic may reject the application if the chosen name is contrary to public order or morality, is misleading or may cause confusion. The right to reject misleading names stems from a key objective of the Act on Pharmaceuticals and Medical Devices: the protection of consumers from deception (Article 1(2)(a)). For example, a risk of deception is assumed to exist if the name of a pharmaceutical is confusingly similar to another name used for a pharmaceutical based on a different active ingredient. Further, if a likelihood of confusion is identified between the names or trade dresses of two different pharmaceuticals that could have severe consequences, Swissmedic may order appropriate measures to eliminate the risk (eg, a change in name or typeface of trade dresses – Article 12a of the Ordinance on the Authorisation of Medicines). Otherwise, Swissmedic does not examine whether a name chosen for a pharmaceutical infringes a trademark or other IP right of a third party. Finally, Swissmedic will reject a name for a pharmaceutical if it consists of a World

Health Organisation-approved international non-proprietary name (INN) or a sign that is confusingly similar to an INN. It will also reject a name if an INN or an INN stem is applied in the wrong context.

Trademark law

The Trademark Act does not specifically deal with trademarks for pharmaceuticals. Names of pharmaceuticals are eligible for trademark protection under the same conditions as any other mark. Thus, the name of a pharmaceutical may be protected as a trademark if it:

- is distinct and does not otherwise belong to the public domain; and
- is not misleading or contrary to public order, morality or applicable law (Article 2 of the Trademark Act).

Further, the name must not be confusingly similar to a prior trademark claimed for pharmaceuticals or similar products (Article 3 of the Trademark Act). However, this is examined by the Swiss Federal Institute of Intellectual Property (IGE) or a court only if the holder of the prior trademark raises an opposition or files an infringement action.

With respect to the application of such rules to pharmaceutical trademarks, the following can be noted:

- According to the IGE's registration guidelines, INNs are considered to be part of the public domain if claimed for pharmaceuticals. Thus, INNs or signs that are confusingly similar to INNs are not eligible to be trademarks for pharmaceuticals or similar products. However, names of pharmaceuticals that are based on INNs may be registered if the INN has been modified to an extent that the name of the pharmaceutical has achieved distinctiveness. Whether this is the case must be determined from the perspective of the relevant public (see below regarding the determination of the relevant public). The mere fact that the relevant public recognises that the name of a pharmaceutical is based on or alludes to an INN does not exclude its eligibility as a trademark. For example, SIMVASTAT (Trademark CH 510 477) was held to be a sufficient modification of the INN 'Simvastatin' (see Section 4.4.2.6 of the

IGE Trademark Guidelines).

- Names which relate to the mode of action or functioning of a pharmaceutical are – due to their descriptive character – ineligible for trademark protection. Therefore, terms such as '*rapide*', '*retard*' or '*dolo*' are excluded (see Section 4.4.2.2.4 of the IGE Trademark Guidelines).
- For over-the-counter products, the question of whether a trademark has a distinctive character or is confusingly similar to a prior right must be assessed from the perspective of the consumer (ie, patients). With respect to prescription drugs, the Swiss Federal Administrative Court has held that physicians and pharmacists are part of the relevant public (Decision B-6097/2010, *Belladerm*). Since physicians and pharmacists recognise any specific meaning behind the name of a pharmaceutical, based on their specialised knowledge, the risk that a name (including terms referring to the mode of action, indications or other characteristics of a pharmaceutical) is ineligible for trademark protection is higher for prescription drugs compared to over-the-counter products.

As in most other jurisdictions, trademarks must genuinely be used in Switzerland in order to remain valid and enforceable. However, the owner of a trademark is exempt from the obligation to use the trademark if valid reasons for non-use exist (Article 12(1) of the Trademark Act). In respect of trademarks for pharmaceuticals, such a valid reason is generally assumed to exist if the trademark cannot be genuinely used due to pending marketing authorisation proceedings (provided that the trademark owner itself has not caused a significant delay in proceedings).

It is possible to protect the shapes of pharmaceuticals as three-dimensional trademarks. However, the IGE is reluctant to recognise the distinctive character of a shape. This forces the applicant to prove, by means of opinion surveys, that the specific shape has achieved secondary meaning due to its longstanding use on the market. Therefore, only a few shapes of pharmaceuticals have been granted trademark protection in Switzerland (eg, the shape of Viagra pills – although only

in combination with the colour blue – and Rennie tablets (Trademarks 547 204 and P-476 710, respectively)). The protection of a taste as a trademark is not possible in Switzerland. Although theoretically a colour could be registered as a trademark, the IGE's high demands regarding proof of the distinctive character of a colour exclude this possibility.

Parallel imports and repackaging

Swiss IP legislation creates significant barriers to parallel imports of pharmaceuticals. While it is recognised that the principle of international exhaustion applies to trademark rights, patent rights are considered to be exhausted only if the product concerned is put on the market with the rights holder's consent within the European Economic Area (EEA) (Article 9(1) of the Patent Act). Moreover, according to Article 9(5) of the Patent Act, the patent owner's consent is always required if the price of the product concerned is determined by public authorities. As a result, parallel imports of any patent-protected pharmaceuticals that are reimbursed by public health insurance are excluded. Therefore, parallel imports are possible only in respect of over-the-counter products (but if such products are still patent protected, only if they are imported from EEA member states) and pharmaceuticals that are no longer patent protected.

Pharmaceuticals that may be parallel imported can benefit from simplified admission proceedings, provided that the pharmaceuticals have already been admitted in Switzerland and were imported from a country with an admission system regarded as equivalent to the Swiss system (at present, EEA member states, Australia, Japan, Canada and the United States). To benefit from the simplified proceedings, the parallel importer must demonstrate that the parallel-imported pharmaceuticals satisfy the same requirements as those already admitted (in particular, with regard to labelling and medical information), and that it can ensure that all products fulfil the same safety and quality requirements as those of the first applicant (Article 14(2) of the Act on Pharmaceuticals and Medical Devices, and Articles 28 and following of the Ordinance on the Simplified Admission of Pharmaceuticals and the Admission of Pharmaceuticals by

Notification Proceedings). When admitting parallel-imported pharmaceuticals, Swiss medic does not examine whether the product concerned is still patent protected. Thus, it is up to the patent owner to assert and enforce its patent rights against a parallel importer in civil court proceedings.

Neither the Trademark Act nor Swiss case law explicitly addresses the issue of repackaging. However, legal doctrine tends to apply the principles on repackaging developed by European Court of Justice case law (in particular, C-348/04, *Boehringer Ingelheim*, April 6 2007). Accordingly, in order to safeguard the rights holder's legitimate interests, a parallel importer must inform the rights holder of its intention to repackage its goods. Furthermore, the repackaging must not affect the condition of the contents, and the new package must contain information about the identity of the parallel importer and the original manufacturer. Finally, the rights holder's reputation may not be injured as a consequence of the repackaging. From a regulatory perspective, the parallel importer must demonstrate within the framework of the simplified admission proceedings that the repackaging complies with the principles of good manufacturing practice.

Anti-counterfeiting and enforcement

Switzerland signed the Council of Europe's Medicrime Convention in 2011. The convention aims to protect public health and safety. Swiss law already provided a good legal basis for preventing the import of falsified pharmaceuticals and widely met the requirements set out in the convention. Nonetheless, some amendments to the Act on Pharmaceuticals and Medical Devices and other Swiss statutes are still required in order to achieve full compliance. Some of the required amendments have already been fed into the legislative process (including those aimed at improving criminal penalties). Others are expected to be submitted to interested parties for consultation in the second and third quarters of 2013.

Swiss IP rights provide for both civil and criminal penalties. While actions based on trademarks must be filed with the competent cantonal courts, civil actions based on

patents fall under the exclusive jurisdiction of the Swiss Federal Patent Court, which was established in 2012.

An effective means of proceeding against the import of counterfeited pharmaceuticals is to use customs measures. Based on related applications by trademark and patent owners (which are valid for a two-year period), the Swiss customs authorities temporarily seize suspicious deliveries from abroad and notify the rights holders. The rights holder then has the possibility to examine the goods and, if they are infringing, to file a court action requesting the permanent seizure and destruction of the goods (Articles 70 and following of the Trademark Act).

Advertising

The marketing of pharmaceuticals in Switzerland is primarily regulated at a federal level, in particular in Articles 31 and following of the Act on Pharmaceuticals and Medical Devices and – in more detail – the Ordinance on Advertising Pharmaceuticals. In addition, industry codes of conduct (eg, the Code of Conduct of the Pharmaceutical Industry) play an important role in Switzerland.

The advertising of prescription pharmaceuticals or pharmaceuticals that are reimbursed by public health insurance is restricted to advertisements directed at healthcare professionals – that is, persons who prescribe or dispense pharmaceuticals. Public advertising is admissible only for non-reimbursable over-the-counter products (Articles 31(1) and 32(2)(a) of the Act on Pharmaceuticals and Medical Devices, and Articles 65(2) and 68(1)(d) of the Ordinance on Advertising Pharmaceuticals).

Factual information on human health and diseases that is not linked (directly or indirectly) to a specific pharmaceutical is not considered as advertising (Article 1(2)(c) of the Ordinance on Advertising Pharmaceuticals). As public advertising is prohibited for prescription drugs, the delineation of such information from advertising is of particular relevance in connection with this category of pharmaceutical. Swissmedic and the courts tend to take a strict approach in this respect. Information published by or on behalf of a pharmaceutical company that highlights –

without naming particular products – certain categories of pharmaceutical (ie, by referring to advance product information) may already qualify as prohibited advertising if consumers can link such statement to a product of the company (eg, through an internet search).

As a consequence, pharmaceutical trademarks may be used only in public advertisements for non-reimbursable over-the-counter products. No such restrictions exist for the use of a trademark in advertisements directed at healthcare professionals.

Advertisements, with or without reference to trademarks, must comply with the general requirements applicable to advertising as set out in the Act on Pharmaceuticals and Medical Devices and the Ordinance on Advertising Pharmaceuticals. They may refer only to indications and uses which have been approved. Advertisements which are misleading or contrary to public policy and morality, or which incite excessive, abusive or inappropriate use of pharmaceuticals, are prohibited (Article 32(1) of the Act on Pharmaceuticals and Medical Devices, and Article 5(1) of the Ordinance on Advertising Pharmaceuticals). The advertising of pharmaceuticals that are not admitted for marketing in Switzerland is illegal (Article 32(1) (c) of the Act on Pharmaceuticals and Medical Devices). Comparative advertising is admissible if directed at healthcare professionals, provided that it is accurate, objective and not misleading, and that the statements made can be proved by published clinical studies conducted in accordance with good clinical practice (Article 14(1) in connection with Article 5(5) of the Ordinance on Advertising Pharmaceuticals). In any event, advertisements must be recognisable as such (Articles 5(4) and 16(3) of the Ordinance on Advertising Pharmaceuticals). Advertisements on radio and in television or cinemas, which are admissible only for non-reimbursable over-the-counter products, must include specific warnings and are subject to an advance authorisation procedure (Articles 17 and 23 of the Ordinance on Advertising Pharmaceuticals).

Generic substitution

According to Article 52a of the Federal Act on Health Insurance, pharmacists are entitled to substitute an original pharmaceutical with

any cheaper reimbursable generic, unless the prescribing physician has expressly requested that the original be dispensed. In case of a substitution, the pharmacist must inform the prescribing physician. As a means of controlling increasing public healthcare costs, the replacement of the right to substitute with an obligation to substitute has even been considered.

Online issues

Pharmaceutical trademarks may be registered and used on websites which provide information concerning the relevant pharmaceutical. However, due to the prohibition on advertising prescription drugs, the use of a prescription drug trademark is admissible only if the website contains advertisements or information only for healthcare professionals. The website operator must ensure that the general public cannot access such website by appropriate means (eg, passwords). No restrictions exist in respect of the use of trademarks of over-the-counter products as domain names.

In Switzerland, the distance sale of drugs – in particular, through online pharmacies – is permissible without restriction for pharmaceuticals that may be dispensed without the advice of a healthcare professional (Article 27 of the Ordinance on Pharmaceuticals). However, for all other categories of pharmaceutical, specific authorisation is required. Such authorisation is issued at the cantonal level if the following requirements are met (Article 27 of the Act on Pharmaceuticals and Medical Devices):

- The pharmaceuticals concerned have been prescribed by a physician;
- No conflicting safety requirements exist;
- Appropriate counsel by a physician is guaranteed; and
- Adequate medical supervision of the effect of the pharmaceutical is guaranteed.

In addition, such authorisation is subject to a cantonal retail trade licence for the operation of a pharmacy and the implementation of a quality assurance system (Article 29(1)/(2) of the Ordinance on Pharmaceuticals).

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