Poland

Contributing firm
Patpol

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Selection, clearance and registration

Applicable laws
The following laws cover pharmaceutical trademarks in Poland:

- the Law on Industrial Property of June 30 2000 (*Journal of Laws* 2001, No 49, item 508, uniform text of June 13 2003; *Journal of Laws* No 119, item 1117, with later amendments); and
- the Pharmaceutical Law of September 6 2001 (*Journal of Laws* 2004, No 53, item 533 with later amendments) and related regulations.

The Pharmaceutical Law is almost entirely based on the principles of EU law. All Community regulations and judgments of the Court of Justice of the European Union (ECJ) relating to pharmaceutical issues – including trademarks, repackaging and parallel imports – are directly applicable in Poland.

National bodies and procedures
The Patent Office is the main national body responsible for granting trademarks.

The Ministry of Health is the main body responsible for issuing decisions on the registration and approval of medicinal products. The registration procedure for trademarks intended to designate medicinal products is governed by the procedure and requirements set out by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. This is a government agency responsible for evaluating the quality, efficacy and safety of medicinal products, medical devices and biocidal products.

The Main Pharmaceutical Inspectorate is a central organ of the Polish administration with the authority to supervise whether the regulations of the Pharmaceutical Law have been met in the field of advertising. Appeals against its decisions are filed with the Warsaw District Administrative Court. A defeated party may bring a cassation complaint before the Supreme Administrative Court.

A business entity intending to produce or import medicinal products must file an application for approval with the Main Pharmaceutical Inspectorate. This must specify the official name of the medicinal product and its name as used in ordinary trade.

Medicinal product names and trademarks
Pursuant to Polish law, only a sign that has been registered as a trademark with the Patent Office grants the holder the exclusive right to use the mark in commerce throughout Poland. A trademark or service mark may be any sign that is capable of being represented graphically and that distinguishes the goods of one undertaking from those of others. The following may all be considered as trademarks: words, designs, ornaments, combinations of colours, three-dimensional shapes of goods or of their packaging, and melodies or other acoustic signals. Rights of protection will not be granted for signs:

- whose use infringes third parties' personal or economic rights;

- that are contrary to law, public order or morality; or
- that, by their nature, may mislead the public, in particular as to the goods' properties or geographic origin.

A right of protection shall not be granted for a sign if it:

- constitutes a form or another feature of the goods or their packaging;
- is dictated exclusively by the nature of the goods or their packaging;
- is necessary to achieve a technical result; or
- gives substantial value to the goods.

Trademark examination/registration proceedings before the Patent Office are independent of proceedings before the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. However, earlier findings of one institution cannot be disregarded by another official body.

Pharmaceutical trademarks must not only comply with the Law on Industrial Property, but also meet the requirements for pharmaceutical product names set out in other regulations. The name of a pharmaceutical product can be:

- an invented name not liable to be confused with a common name;
- a common or scientific name accompanied by a trademark; or
- the name of the marketing authorisation holder.

Common names should be international non-proprietary names (INNs) recommended by the World Health Organisation. Optionally, if such name has not been attributed to a given product, an ordinary chemical name should be used.

According to established case law, obtaining an authorisation to release a medicinal product under a given name is not exempt from liability in cases where the name violates third parties' trademark rights. The applicant must therefore pay attention to the Industrial Property Law and the Law on Combating Unfair Competition.

Rights holders should comply with the announcement of the president of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products issued on March 12 2008. The announcement concerns the process of naming medicinal products and substituting names that are similar or identical to those already registered. Accordingly, new names of medical products should:

- differ from earlier registered products' names by at least three letters and not include a sequence of more than two of the same letters – the applicant must issue a justified written statement if seeking a waiver from this rule;
- avoid any likelihood of confusion (eg, in print, spelling and pronunciation) with regard to earlier registered names;
- not carry any promotional or advertising information related to the application process or use of the product;
- not comprise symbols such as ® or TM; and
- not contain the following:
  - personal names or surnames (including the name of the product's inventor);
  - names of abstract persons, which are used together with scientific titles, aliases or pseudonyms;
  - expressions with a religious, geographical or historical association; or
  - obscene words or words suggesting obscene content.

Apart from these specified exceptions, there is a wide choice of names that can be used for medicinal products. In the event of decentralised procedures or mutual recognition, it is recommended that the name of the product be the same in each EU member state. INNs must be used within the EU territory. A medicinal product for which authorisation is sought at EU level must have the same name across the European Union.

The name of a medicinal product shall also be written on the packaging in Braille.

Parallel imports and repackaging

Regulations on the parallel import of pharmaceutical products were introduced into Polish law through amendments to the Pharmaceutical Law. The relevant amendments became effective on May 1 2004 – the date of Poland's accession to the European Union.

According to the above regulations, 'parallel imports' include any activity based on importing a pharmaceutical product from an EU member state or member state of the European Free Trade Association that meets the following criteria:

- The imported medicinal product has the same active substance, the same indications up to the third level of anatomical therapeutic chemical classification, the same strength, the same administration route and the same form as a pharmaceutical product authorised for marketing in Poland, or a similar form with no therapeutic differences.
- The imported medicinal product and the product authorised for marketing in Poland are simultaneously reference medicinal products or generic medicinal products both in the country of import and in Poland.

Parallel imports are possible upon obtaining a parallel import licence from the Health Ministry. Such licences are issued based on the assessment report prepared by the chairman of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The application for a parallel import licence must include a sample of the packaging and information leaflets to accompany the product. The parallel importer can place the pharmaceutical product on the market under:

- the name used in Poland;
- the name used in the EU member state from which the product is imported; or
- a common name or scientific name together with the trademark or name of the parallel importer.

The parallel importer must inform the marketing authorisation holder in Poland of the date it expects to place the product on the market in Poland at least 30 days in advance. Parallel import licences last for five years.

In order to place a product on the market, the parallel importer must ensure that the packaging meets local standards. The Polish authorities insist that medicinal products be repackaged into new boxes and that the original packaging then be bundled together with information leaflets in Polish. Therefore, a product shall be repackaged into packaging which has been approved in the parallel import licence. Also, the information leaflet attached to the product shall be consistent with the parallel import licence. However, the process of repackaging frequently results in conflicts between the parallel importer's rights and the exclusive rights of industrial property rights holders, including trademark rights. There is no case law in Poland in this respect; therefore, ECJ case law is crucial to the resolution of disputes in this area.

Poland's accession to the European Union created the possibility of importing cheaper medicinal products from other EU countries to Poland, while limiting the export of medicinal products from Poland to other EU countries. Based on the

Accession Treaty, the so-called 'special mechanism' provides for an exception from the principle of the Euro-exhaustion of rights to a patent and supplementary protection certificate in relation to all medicinal products that enjoyed patent protection in EU member states in the period during which such protection was not possible in Poland (medicinal products have been patentable in Poland since January 15 1993).

Anti-counterfeiting and enforcement

Counterfeit medicines in Poland are tackled within the existing official system and under the existing criminal prosecution bodies. The detection and suspension of imported counterfeit medicines are most frequently conducted by border guards or the police.

Advertising

The requirements regarding the advertising of pharmaceutical products in Poland are specified under the Pharmaceutical Law of September 6 2001 (uniform text, *Journal of Laws* 2008, No 45, item 271, with later amendments) and the Regulation of the Minister of Health on the Advertising of Medicinal Products of November 21 2008 (*Journal of Laws* No 210, item 1327).

Pharmaceutical products may be advertised exclusively by the parties responsible for those products or with their consent.

An advertisement for a pharmaceutical product cannot be misleading. It should present the product objectively and inform about its rational use. The advertisement cannot offer or promise any advantages, directly or indirectly, in return for purchasing the product or providing evidence of having purchased the product. Advertisements cannot be addressed to children or contain any element that might be addressed to children.

It is forbidden to advertise pharmaceutical products that have not been admitted to trade in Poland or for advertisements to contain information that is inconsistent with the officially approved product description. Special restrictions are also imposed upon advertising directed to specialists and the public.

The advertisement of a medicinal product targeted to the public must contain the following essential information:

- the medicinal product's name;
- the INN of the active substance or the 'complex product' in the case of medicinal products containing more than three active substances;
- the dose of the active substance or active substance concentrations, with the exception of a complex product;
- the product's pharmaceutical form;
- indications for therapeutic use;
- contraindications; and
- identification of the responsible entity.

Any advertising of a medicinal product targeted to the public that is made in an audiovisual form or in a static visual form shall contain a warning, defined by the law.

The Supreme Administrative Court has held that publishing the names of contraceptives on a website that is designed to inform about the various methods of family planning cannot be treated as encouragement of their use and therefore cannot be deemed to be a public advertisement of medicinal products. The Main Pharmaceutical Inspectorate recently held that publishing information in the form of a television spot that relates to the product rather than the manufacturer is beyond the scope of sponsorship and ordered the cessation of such actions.

Generic substitution

Generic substitution is allowed under Polish law. Generic drugs must be traded under the name of the company producing them, together with the INN or invented name.

Online issues

E-pharmacies

The sale of medicinal products takes place only under the terms and conditions set out in the Pharmaceutical Law. The sale of medicines is reserved for 'public pharmacies'. In addition, the right to the retail resale of certain drugs without a prescription and some prescription drugs is granted to 'pharmacy points of sale'. The sale of selected drugs without a prescription can also be conducted by so-called 'out-pharmacy market points'. These include herbal-medical shops, specialised medical supply stores, pet shops, herbal/chemist shops/drugstores and public shops – provided that the staff have appropriate qualifications. The law precisely regulates all features with which a public pharmacy and a pharmacy point of sale must comply. It already implies the existence of physical premises that are open to the public and intended to offer the sale of drugs. According to the law, public pharmacies and pharmacy points are authorised to conduct mail-order sales addressed to the public only for medicines purchased without a prescription. Additionally, the term 'pharmacy' is a reserved name that is legally protected under the Pharmaceutical Law and criminal law, as well as under unfair competition regulations. Any entity wishing to use the term 'pharmacy' must meet strict regulatory requirements. Online operators that do not meet the conditions set out in the regulations can neither use the term 'pharmacy' nor trade in pharmaceutical products.

Domain names

Domain names involving pharmaceutical trademarks can be obtained from cybersquatters through:

- mediation;
- alternative dispute resolution proceedings; or
- civil court proceedings.

However, a recent judgment of the Polish Competition and Consumer Protection Court suggests that alternative dispute resolution is unlikely to succeed if the disputed domain name is registered in the name of a natural person. WTR

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