Poland

Contributing firm
Patpol

Author
Maria Jurek

Selection, clearance and registration

Legal framework

The legal framework governing trademarks and pharmaceuticals in Poland consists of:

- the Industrial Property Law of June 30 2000; and
- the Pharmaceutical Law of September 6 2001 and related regulations.

The Pharmaceutical Law is almost entirely compliant with EU directives. All Community regulations and judgments of the European Court of Justice (ECJ) relating to pharmaceutical issues – including trademarks, repackaging and parallel imports – are directly applicable in Poland. Similarly, products that were granted a marketing authorisation by the European Commission in the course of a centralised authorisation procedure may be marketed in Poland.

National bodies and procedures

The Polish Patent Office is the main national body responsible for granting trademarks.

A marketing authorisation for a medicinal product is required in order to commercialise that product legally. Such authorisation is issued by the president of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products; it can be granted in the course of a national, mutual recognition or decentralised procedure, or a centralised procedure.

The president of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is a governmental administrative authority supervised by the minister of health and entitled to issue marketing authorisation decisions and maintain a national register of authorised products. The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products acts as the administrative and scientific agency responsible for assuring the appropriate quality, safety and efficacy of pharmaceuticals, medical devices and biocidal products. The office collaborates closely with the European Medicines Agency.

The main pharmaceutical inspector, also supervised by the minister of health, is the main governmental administration executing tasks for the Pharmaceutical Inspection – that is, supervising the conditions of production, importation, distribution and advertising of medicinal products.

Medicinal product names and trademarks

Pharmaceutical trademarks must not only comply with the Industrial Property Law, but also meet the requirements set out for product names in the Pharmaceutical Law. Under that statute, 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
- a common or scientific name accompanied by the name of the marketing authorisation holder.

Common names should be international

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

Rights holders are advised to comply with the guidelines of the president of the Office for Registration of Medicinal Products dated March 12 2008. The guidelines provide practical hints for naming conventions – for example:

- new names 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;
- 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 include symbols such as ® or TM; and
- not contain personal names and surnames, names of abstract persons and expressions with a religious, geographical or historical association.

According to the Industrial Property Law, 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 trademarks: words, designs, ornaments, combinations of colours, three-dimensional shapes of goods or of their packaging, and melodies or other acoustic signals.

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 from one institution cannot be disregarded by another official body.

Parallel imports and repackaging

Parallel imports have been allowed in Poland since May 1 2004 – the date of Poland's accession to the European Union.

According to the principle of Community exhaustion of rights, the owner of IP rights loses its rights after the introduction of a medicinal product on the market of any country in the European Union or Economic Area. The product can be then traded freely by authorised pharmaceutical wholesalers in these countries.

Under the Pharmaceutical Law, parallel imports include any activity based on importing a pharmaceutical product from an EU member state or a 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; and
- 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 import is possible upon obtaining a parallel import authorisation from the president of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. An authorisation is valid for five years.

The parallel importer must inform the marketing authorisation holder in Poland, the main pharmaceutical inspector and the president of the Office for Registration of Medicinal Products, at least 30 days in advance of the date on which it expects to place the product on the market in Poland.

In order to place a product on the market, the parallel importer must ensure that the packaging meets local standards. Parallel-imported products are repackaged into packages that are labelled in Polish and that include a leaflet in Polish. Parallel-imported products may be marketed under the name:

- used on the Polish territory;
- used in the state from which the medicinal product is imported; or
- that is common or scientific for that product, accompanied by the trademark or the name of the parallel importer.

The process of repackaging frequently results in conflicts between the parallel importer's rights and the exclusive holder of industrial property rights, including trademark rights. The parallel importer must meet the following requirements:

- The repackaging must not adversely affect the original condition of the product;
- The new packaging must contain information about the company manufacturing and repackaging the product;
- The presentation of the repackaged product must not harm the reputation of the trademark or its owner; and
- The rights holder must have been previously notified of the intention of the parallel importer to introduce the repackaged product onto the market.

In case of violation of these rules, the owner of the IP rights can object to the parallel importation of its product.

There is no case law in Poland in this respect; therefore, ECJ case law is crucial to the resolution of disputes in this area.

Anti-counterfeiting and enforcement

The Pharmaceutical Law contains no *expressis verbis* legal definition of 'falsified medicinal products'.

According to the statistics provided by the WHO, more and more counterfeit medicines are available worldwide. The occurrence of falsified medicines (the term 'falsified' is distinct from 'counterfeit', which applies to the infringement of IP rights) increases every year in the European Union, including Poland.

In most cases, falsified medicinal products are imported into Poland via postal delivery. These products are sold online by illegal pharmacies, auction sites, sex shops and markets/bazaars, as well as through discussion forums and listings.

With respect to falsified medicinal products, legal protection can be obtained on the basis of relevant provisions of the Pharmaceutical Law, the Code of Criminal Law and the Act on Combating Unfair Competition.

In 2007 a special Falsified Medicinal Products Team was founded by the Ministry of Health (the team was further expanded in 2010). The team is composed of, among others, the main pharmaceutical inspector, the president of the Office for Registration of Medicinal Products, the national public prosecutor, the chief commander of the National Police and the chief of the Customs Service. In addition to the prosecution of individuals violating the law, the team conducts public awareness campaigns about falsified medicines.

In June 2011 the European Parliament adopted Directive 2011/62/EU on falsified medicines. The new legislation will be applicable from January 2 2013. It introduces tougher rules, including security measures with regard to packages of medicinal products, improved border control and strengthened record-keeping requirements for wholesale distributors.

Only cooperation with the customs authorities (eg, by submitting request for Customs protection) and law enforcement agencies, as well as the monitoring of websites, may lead to an effective fight against this dangerous phenomenon.

Advertising

The requirements regarding the advertising of

pharmaceutical products in Poland are specified in:

- the Pharmaceutical Law and the Regulation of the Minister of Health on the Advertising of Medicinal Products of November 21 2008; and
- EU law, including judgments of the ECJ.

'Advertisement of a medicinal product' is defined as any activity consisting of informing and encouraging the use of the product by increased prescription, delivery, sale and consumption.

Regulations differentiate between advertisement to the public and to specialists.

An advertisement for a pharmaceutical product:

- may not be misleading;
- should present the product objectively and inform about its rational use;
- may not offer or promise any advantages, directly or indirectly, in return for purchasing the product or providing evidence of purchase; and
- may not 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 authorised for use in Poland or to present advertisements containing information that is inconsistent with the officially approved product information.

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;
- contra-indications; and
- identification of the responsible entity.

Such advertisement must not, among other things:

- include a presentation of the advertised product by persons known to the public, scientists, people with medical or pharmaceutical education or suggesting possession of such education, or refer to the recommendation to such persons;
- suggest that it is possible to avoid medical assistance or surgery; and
- suggest that taking the product could improve the condition of a healthy person.

Any advertising of a medicinal product targeted to the public that is made in an audiovisual form or in a static visual form must contain a warning that a patient should read the package leaflet before using the product.

Prescription-only medicinal products may be advertised only to persons entitled to prescribe (medical doctors) and distribute (pharmacists) these products.

Polish law permits comparative advertising. In the case of an ad for medicinal products containing different compositions of active substances, their simultaneous presentation is acceptable if the presentation of each of the medicinal products meets the conditions of relevant law. The issue of comparative advertisement is also broadly presented in the Act on Combating Unfair Competition.

Generic substitution

Generic substitution is allowed under Polish law. Generic drugs should be named in accordance with naming conventions and are usually marketed under the INN accompanied by the name of the company that produces or invented them.

Generic substitution appears to be encouraged by the Polish health authorities for financial reasons. Pharmacists are obliged to inform patients of available generic substitutes. With new regulations on reimbursement, generic pressure is expected to increase.

Online issues

E-pharmacies

Under the Pharmaceutical Law, mail-order retail sale of over-the-counter medicines (medicines sold without prescription) by pharmacies and pharmacy points is allowed.

According to the statistics provided by the WHO, over 50 % of falsified medicines are offered via the Internet. That is why Directive 2011/62/EU makes it easier to distinguish between legal and illegal online pharmacies throughout the European Union by creating an EU-wide logo to identify legal online pharmacies.

Domain names

In order to secure its rights, the owner of a pharmaceutical trademark should register domain names corresponding to its trademarks and company name. In case of registration by a third party of a domain containing a designation that is identical or similar to a registered trademark, the owner of the trademark may demand the transfer of that domain name in certain circumstances.

According to the Industrial Property Law, infringement of a trademark consists of unlawful use in the course of trade of a trademark that is identical or similar to a trademark registered in respect of identical or similar goods or services if a likelihood of misleading the public – including, in particular, a risk of associating the trademark with a registered trademark – exists.

In cases concerning domain names, relevant provisions of the Act on Combating Unfair Competition may apply. According to a general clause, an act of unfair competition shall be considered to be an activity that is contrary to the law or good practices which threatens or infringes the interest of another entrepreneur or customer. The Act may apply even if the infringer (the registrant of the disputed domain name) is not formally registered as an entrepreneur, but is a physical person who even casually (not officially) conducts business. A physical person may be regarded as an entrepreneur if the use of the disputed domain name does not appear as use in the private sphere of the defendant's life or is aimed at generating profits.

Domain names cases concerning no content on the website are not obvious examples of infringement from the legal point of view. For some time, many arbitrators of the Arbitration Court (which has been handling such cases since 2003) considered the registration of a domain featuring the trademark of a third party as 'use in the course of trade'. However, this approach changed recently. It is connected to the harmonisation of Polish law with EU law. In the large majority of cases, the arbitrators now carefully analyse the use of the trademark; the mere fact of registering a domain name that is identical to a trademark is no longer treated as an act of infringement of a trademark owner's rights.

If the registrant of a domain name is a resident in Poland, one of the following courts can examine the case under proceedings similar to those of the Uniform Domain Name Dispute Resolution Policy:

- the Arbitration Court at the Polish Chamber of Information Technology and Telecommunication;
- the Arbitration Court at the the Polish Chamber of Commerce;
- a common court; or
- the Court for Community Trademarks and Designs in Warsaw, if the trademark owner holds a Community trademark registration. WTR

Biographies
Patpol

Patpol
162J Nowoursynowska Street,
02-776 Warsaw, Poland
Tel +48 22 644 9657
Fax +48 22 644 9600
Web www.patpol.com.pl

Maria Jurek
Lawyer
maria.jurek@patpol.com.pl

Maria Jurek has been with Patpol since 2007 as a lawyer in the legal department. She graduated from Warsaw University, Faculty of Law and Administration. She is currently a PhD student at Warsaw University; her doctoral dissertation concerns industrial property law and includes issues relating to pharmaceutical law. Her main areas of practice are trademark infringement and unfair competition matters (focusing on both prosecution and litigation), domain name disputes and cases relating to customs seizures of counterfeit goods.