World Trademark Review™

Pharmaceutical Trademarks 2017/2018

Serbia

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A Global Guide

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Selection, clearance and registration

Relevant national and international regulatory bodies and requirements

The Intellectual Property Office of the Republic of Serbia is the competent body for the registration of all trademarks in Serbia, including pharmaceutical trademarks.

Trademark registration is governed by the Law on Trademarks (104/2009, as amended).

The Medicines and Medical Devices Agency of Serbia regulates the registration, market approval, commercialisation, packaging, labelling and advertising of medicines. The agency is governed by:

- the Law on Medicines and Medical Devices (30/2010) and its bylaws;
- the Regulation on Advertising Mode for Medicines and Medical Devices (79/2010); and
- the Rulebook on the Contents and Method of Labelling the Outer and Immediate Packaging of a Medicine, Additional Labelling and Contents of the Package Leaflet (41/2011).

Although the Law on Trademarks and the Law on Medicines and Medical Devices do not explicitly refer to each other, they overlap in terms of trade names and registered trademarks for medical products.

Clearance

Serbia has no opposition procedure. Trademarks are fully examined by the Trademark Office *ex officio* on absolute and relative grounds. Once a trademark is registered, it is possible to request only annulment of the mark.

Conducting an official search before filing a pharmaceutical trademark application is recommended in order to prepare for possible similarity objections in the full examination.

It is also possible to conduct an unofficial search through the online register of national trademarks held with the Intellectual Property Office of the Republic of Serbia. International trademarks can be looked up through the World Intellectual Property Organisation's ROMARIN database.

Law on Trademarks and Law on Medicines and Medical Devices

The requirements for registration of pharmaceutical trademarks are the same as

for any trademark: a request for registration in the prescribed form, including a representation of the sign and a list of goods covered, along with the payment of a fee.

Like other trademarks, pharmaceutical trademarks may consist of a combination of words, slogans, letters, numbers, images, drawings, combinations of colours or three-dimensional (3D) shapes, or a combination thereof.

The Law on Trademarks provides no conditions or provisions specifically applicable to pharmaceutical trademarks. Further, the Law on Medicines and Medical Devices provides no obligation for a medicine to have trademark protection in order for it to be placed on the market in Serbia.

However, as companies often wish to obtain trademark protection for the name of the medicine that they intend to launch in Serbia, it is worth knowing that the procedures for obtaining trademark registration and market authorisation have mutual effects.

First, a medicine must have a single name in order to obtain market authorisation. When filing a trademark application for that name, timing is important. The procedure for obtaining trademark protection usually lasts one to two years, with the possibility of delays in case of objections raised in the full examination. It is therefore advisable to file a trademark application in good time before applying for market approval for the corresponding medicine. In practice, if the trademark protection has been sought late, the Law on Trademarks provides for the acceleration of the procedure on a written request.

However, trademark registration should not be obtained too early, since an unused trademark becomes vulnerable for cancellation due to non-use after five years from the date of entry in the trademarks register. In such cases, provided that the procedure for issuance of market authorisation has been commenced, the period of non-use during the wait for market authorisation is exempted under the Law on Trademarks.

Confusion with INNs

According to the Law on Trademarks, generic terms cannot obtain trademark protection. This general prohibition also extends to international non-proprietary names (INNs), being generic terms in the public domain.

The Law on Medicines and Medical Devices does not regulate the names of medicines in detail. It provides generally that the trade name of a medicine should not create confusion with an INN or "generally accepted name".

According to Article 7 of the Regulation on the Content and Labelling of Pharmaceutical Products:

The outer packaging of a medicine shall contain the name of a medicine which may be:

1) The trade name;

2) The [INN] and/or generic name with the trade mark or manufacturer's name, or without them;

3) The chemical name with the trade mark or manufacturer's name, or without them; or

4) The generally known common name or, if there is no generally known common name, the scientific name, with the trademark or manufacturer's name, or without them.

The trade name referred to in paragraph 1, item 1) of the Article should not cause confusion in terms of the name referred to in paragraph 1, items 2) – 4) of the Article.The [INN] shall be the name defined by the World Health Organization.

The Serbian pharmaceutical industry is based on the production of generic medicines. Local manufacturers are often unwilling to make serious investments in trademark protection and generally rely on INNs and variations thereof. This leads to many different manufacturers of the same products, with similar or identical names. This can cause confusion among consumers.

Non-traditional trademarks

In practice, the vast majority of pharmaceutical trademarks are simple word marks consisting of the name of the medicine. On the packaging, they are usually combined with the producer's company logo. In the last decade, trademark owners have started adding other elements to classical word marks – usually a graphic element of some sort.

To date, no pharmaceutical trademarks have been registered as non-traditional trademarks. In a few cases, the packaging is protected as a mark. There have been no cases yet of 3D protection for the shape of a pill.

Parallel imports and repackaging

Key issues

Article 40 of the Law on Trademarks provides for the national exhaustion of trademark rights. This means that the first placement of a trademarked product in Serbia can be executed only by the trademark holder or another party authorised by it.

Article 131 of the Law on Medicines and Medical Devices provides that only the holder of a market authorisation for a pharmaceutical product can import that product. The law provides various other strict rules and controls over the import of pharmaceutical products.

Therefore, parallel imports of medicines do not create major problems in Serbia.

The situation regarding repackaging is similar. The Law on Medicines and Medical Devices provides strict rules for packaging, especially in case of medicines and medical devices that are imported from the European Union and worldwide. The corresponding regulations on labelling and packaging prescribe that all information on the outer and immediate packaging of a medicine must be written in Serbian, in the Cyrillic or Latin alphabet, whereas the INN and generic or chemical name of a medicine must be written only in Latin, in conformity with the usual code of practice.

Enforcement

The Commercial Court in Belgrade is competent to hear trademark infringement cases based on parallel imports, as well as other commercial disputes. The Ministry of Health Department of Inspection deals with violations of rules concerning the packaging of pharmaceutical products. If the violation is deemed to be a commercial offence, the Commercial Court will be competent.

Anti-counterfeiting and enforcement

Counterfeit medicines are not as prevalent in Serbia as elsewhere in the world. According to recent research by the Chamber of Commerce, around 10% of medicines on the Serbian market are counterfeit.

The Law on Medicines and Medical Devices forbids the production and circulation of counterfeit medical products.

Article 2 of the law defines a 'counterfeit' medical product or device as one that is produced or placed on the market with the intention of misleading customers, and that displays false identifying data regarding:

- the manufacturer;
- the place of production;
- the marketing authorisation holder;
- the holder of the register entry kept by the Medicines and Medical Devices Agency;
- the analysis certificate; or
- other data and documentation concerning the product or device.

The article provides that counterfeit medicines may or may not contain the ingredients listed on the declared composition; may contain no active substances, or an insufficient quantity thereof; and may have counterfeit packaging. It further includes in the definition of 'counterfeit' medicines that are considered to be counterfeit by the standards of EU member states and the World Health Organisation.

The production and circulation of counterfeit pharmaceutical products is a commercial offence, for which the Law on Medicines and Medical Devices imposes a fine of RSD1 million to RSD3 million (approximately €8,000 to €25,000) for legal entities. Besides the fine, commercial activities may be forbidden for three to 10 years.

Enforcement

Under the trademark legislation, trademark owners can apply for customs protection to the Customs IP Department of the Ministry of Finance. Infringing goods may be examined and seized.

The Commercial Court is competent to deal with infringement cases that arise from customs supervision, as well as commercial offences.

The Ministry of Health Department of Inspection surveys and enforces the Law on Medicines and Medical Devices and its regulations. The department must permanently remove counterfeit pharmaceutical products from the market. A more detailed procedure regarding counterfeits is provided in the Regulations on the Manner of Quality Control of Medicines and Medicinal Devices (64/2011).

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The government recently announced the planned formation of a coordination body to control the market transit of medicines, including preventing sales of counterfeit medicines and controlling online sales. However, at the time of writing no such body had been formed.

Advertising

Regulatory framework and considerations

Article 3 of the Regulations on Advertising for Medicines and Medical Devices defines 'public advertising' as providing true and scientific information about pharmaceutical products to the general and expert public. It must not mislead the public. Advertising may be done through all media, including:

- the Internet;
- the post;
- visits and promotion to doctors, veterinarians and all types of medical institution;
- direct address to, or sponsorship of, professional and expert assemblies; and
- provision of free samples to pharmaceutical and medical experts.

It is not considered as advertising when a trademark is mentioned only as a reference.

Advertising prescription medicines and medicines funded by public health insurance to the general public is prohibited. As the possibilities of public advertising are limited, pharmaceutical companies have started registering slogans about certain health problems and treatment as trademarks in Classes 41 and 45 (education and information), in order to create wider marketing opportunities.

Generic substitution

Generic substitution is not prohibited as such in Serbia. The Regulation on the Manner of Prescription and Deliverance of Medicines (16/94) provides that pharmacies must issue the medicine prescribed by the doctor. However, if the medicine is unavailable, pharmacies may deliver another product with the same ingredients, with the customer's consent. Doctors are free to choose which medicine they prescribe.

Bearing in mind the economic situation, the most popular medicines in Serbia are generic medicines. This also applies to prescription medicines. Because of the relatively low expenditure on public health insurance, doctors tend to prescribe less expensive medicines.

Key considerations

The key consideration in this area is the possibility of misuse.

Recent years saw a high-profile case in which doctors (mostly heads of clinics), public health institution officials and employees of pharmaceutical companies faced criminal charges for fixing tenders for oncological medicines and exerting influence on certain companies to create higher expenditure on medicines.

There have also been cases in which privately owned pharmacies, acting in concert with a particular wholesaler, promoted a particular pharmaceutical brand that was not always the best choice for consumers.

It is therefore advisable to establish specific guidelines and control in this area, in order to prevent possible misuse and circumvent the vagueness of the laws concerning generic substitution of medicines in retail sales.

Online issues

E-pharmacies

Article 134 of the Law on Medicines and Medical Devices specifically prohibits the sale of medicines and certain types of medical device online, as well as delivery by post. This particularly applies to prescription medicines that can be dispensed only by a licensed pharmacist.

The small number of e-pharmacies that make online sales mostly sell dietary supplements, vitamins, phytomedicines, traditional medicines and medical devices.

The problem of online pharmaceutical sales is not as pervasive in Serbia as in the European Union. Due to the depressed economic situation, consumers tend to procure their medicines through the healthcare system, via a doctor's prescription.

However, a number of private persons offer various pharmaceutical products online. Most of the products are original medicines that were bought in regular pharmacies and are left over from private use. A more important problem in Serbia is the uncontrolled sale of medicines on the black market at significantly lower prices than in pharmacies. In most cases, these medicines have expired and are stored improperly.

The government is focused on warning the public about the possible dangers of consuming black-market medicine. Although the problem with online sales is less prevalent, building awareness in this area might be the key to successful prevention thereof.

Domain names

The domain '.co.rs' is intended for the use of local business entities. In practice, there have been no domain name disputes involving pharmaceutical companies regarding trademarks.

The domain '.rs' can cause problems, as any party – even foreign parties – can register an '.rs' domain on a first come, first served basis. There are no special requirements for '.rs' registration. The domain name is registered immediately after payment is made.

Serbia's official internet domain register includes a number of well-known medicines registered as domain names with the extension '.rs' (eg, 'aspirin.rs' and 'viagra.rs'). However, almost all of them are locked (ie, they are not used, but have most likely been registered in order to prevent others from using them).

Rights holders should register their trademarks as domain names with the extension '.rs' before launching pharmaceutical products on the Serbian market, in order to avoid problems with cybersquatters and unfair competition issues. **WTR**

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