

Contributing firm
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Selection, clearance and registration

The following trademarks may enjoy protection in Hungary:

- national trademarks filed with the Hungarian Intellectual Property Office (HIPO);
- international trademarks – an international trademark application on the basis of the Madrid Agreement and/or Madrid Protocol shall be filed with HIPO and forwarded to the World Intellectual Property Organisation; and
- Community trademarks (CTM) – the protection of a registered CTM extends to the territory of Hungary as an EU member state. A CTM trademark application is to be filed with the Office for Harmonisation in the Internal Market.

Protectable signs

In accordance with Section 1(1) of the

Trademarks and Geographical Indications Act (11/1997), trademark protection shall be granted to any signs that are capable of being represented graphically, provided that these are capable of distinguishing the goods or services of one undertaking from those of other undertakings.

Signs which may be granted trademark protection include:

- words and combinations of words, including personal names and slogans;
- letters and numerals;
- figures and pictures;
- two or three-dimensional forms, including the shape of goods or of their packaging;
- colours, combination of colours, light signals and holograms;
- sound signals; and
- combinations of the above.

The filing fee for three classes is Ft74,800 (approximately €238); for the fourth and each further class the filing fee is an additional Ft32,000 (approximately €119).

Filing process

The filing date is the date of receipt of the application by HIPO.

If the application meets the requirements for granting a filing date, HIPO will examine the formal requirements.

HIPO carries out a search of earlier rights and sends its report to the applicant.

If a trademark application meets the requirements as to absolute grounds laid down in the Trademarks and Geographical Indications Act, HIPO shall carry out a substantive examination of the trademark application. After sending the search report to the applicant, HIPO shall publish the application in the *Official Gazette* and notify the applicant of this publication.

Within three months of the date of publication of a trademark application, or modification or division thereof, opposition against registration of the trademark may be submitted by holders of earlier rights based on relative grounds for refusal. Third parties may file observations stating that the designation conflicts with absolute grounds for refusal.

If the trademark application meets all requirements, HIPO registers the trademark in the Trademark Register and issues a trademark certificate, together with an extract of the Trademark Register.

Term of protection

Trademark protection lasts for 10 years from the application filing date. Protection can be extended for further periods of 10 years upon the registered owner's request for renewal. The number of renewals is unlimited.

Name of pharmaceutical product

The name of a pharmaceutical product can be an invented name – which cannot be liable to be confused with a common name – or a common or scientific name accompanied by the trademark or the name of the marketing authorisation's holder (Section 1(1)13 of the Act on Medicinal Products for Human Use (95/2005), which complies with Article 1(20) of Directive 2001/83/EC).

The name of the pharmaceutical product cannot be identical or confusingly similar to the name of a proprietary pharmaceutical product for which marketing authorisation has already been granted. Such requirement is not affected if an invented name is registered as a trademark.

The international non-proprietary name of an active ingredient or any confusingly similar designation cannot be registered as a trademark.

Parallel imports and repackaging

Parallel import

Parallel import activities are governed by the Regulation of the Ministry of Health 53/2004 (VI 2) on Wholesale and Parallel Import of Pharmaceutical Products (Parallel Import Regulation).

Parallel importers shall obtain a parallel import licence from the National Institute for Quality and Organisational Development in Healthcare and Medicines (NIP).

Further conditions governing parallel import activities comprise the following:

- The imported pharmaceutical product must originate from a member state of the European Economic Area (EEA);
- The product must have obtained marketing authorisation for the EEA member state from which it originates;
- The product must have obtained marketing authorisation for Hungary; and
- The product must be accompanied by a release document issued by a qualified

person at the manufacturer confirming that the product complies with the product quality requirements stated in the marketing authorisation.

A parallel import licence is valid for five years from its issuance.

Repackaging

'Repackaging' means any action that results in the stripping or relabelling of the original packaging, or the amendment of the patient leaflet therein while keeping the original packaging, in order to comply with the valid marketing authorisation in Hungary.

Pharmaceuticals may be repackaged only in other EEA member states.

Protection of trademarks

The holder of a Hungarian marketing authorisation must be notified 30 days prior to parallel import. The importer is obliged to repackage the product according to the Hungarian marketing authorisation, with minimum possible adverse effects on the trademark. The trademark owner may oppose the repackaging where the repackaging goes beyond the specifications of the Parallel Import Regulation.

With regard to trademark enforcement in connection with parallel imports, the courts' practice is limited to cases where the product has been imported from a non-EEA country – in which case such parallel import qualifies as trademark infringement. When the parallel import originates in the EEA, the trademark owner can file a lawsuit if the above-mentioned rules are breached because any injury to its trademark rights gives cause to terminate the exhaustion exemption. Also, proceedings to cancel the parallel import authorisation of illegally repacked pharmaceutical may form part of any legal defence.

Anti-counterfeiting and enforcement

Closed and controlled distributional chain

The Act on Medicinal Products for Human Use creates a strict, closed and controlled pharmaceutical marketing chain in Hungary, which theoretically excludes any risk of distributing counterfeit products through legally operating dispensaries.

Every member of the distribution chain must hold an administrative authorisation issued by the competent Hungarian pharmaceutical supervisory authority or by the pharmaceutical supervisory authority of an EU member state. In addition, their authorised activity is continuously controlled by the competent authority.

In accordance with Section 12 of the Medicines Act, the supply of medicinal products covers all activities by which pharmaceutical products are made available directly to users, including the manufacture, production, storage and distribution of pharmaceuticals. Unless otherwise provided by law, pharmaceutical products shall be procured and dispensed to patients through pharmacies. Pharmacies may procure pharmaceutical products only from a business entity which is authorised to engage in activities relating to the wholesale distribution of pharmaceutical products.

NIP and the National Public Health and Medical Officer Service play an important role in controlling the pharmaceutical distribution activity: the former controls pharmaceutical products until they reach the pharmacies, while the latter controls retail distribution.

Investigation and identification

Regarding the investigation of counterfeit pharmaceutical products, the competent authorities are the Hungarian Customs and Finance Guard and the police. Modern techniques, chromatographic and spectrographic devices help to analyse the quality of the products.

Prevention

NIP provides information to the public, which recommends purchasing pharmaceutical products from authorised retailers and avoiding unauthorised commercial channels such as street sellers, markets, the Internet and home delivery services.

NIP plays an important role in the international effort to harmonise and enhance the fight against pharmaceutical counterfeiting. NIP is a member of the Heads of Medicines Agencies; it also sends representatives to the agencies' Working Group of Enforcement Officers.

Advertising

The advertisement of pharmaceutical products is strictly regulated in Hungary compared to that of other commercial products.

Regulatory framework

Advertising of prescription pharmaceutical products, over-the-counter products and medical aids is governed by the following regulations:

- the Commercial Advertising Act (48/2008);
- the Act on the General Rules of Safe and Efficient Supply of Medicinal Products (98/2006);

- Regulation of the Minister of Health 3/2007 (II 25) on the Presentation of Medicinal Products for Human Use and Medical Aids;
- Regulation of the Minister of Health 30/2005 (VIII 2) on Labelling and Patient Leaflets of Pharmaceutical Products;
- the Act on Freedom of the Press and on the Basic Rules Relating to Media Content (104/2010); and
- the Code of Ethics of Hungarian Pharmaceutical Manufacturers Association.

The advertisement of unregistered and prescription pharmaceutical products and pharmaceutical products which are reimbursed by the public healthcare system is prohibited in Hungary.

Pharmaceutical products for human use can be advertised to the general public if they can be purchased from a pharmacy without a prescription and are not reimbursed by the public healthcare system. Medical aids can also be advertised when no reimbursement is available. In both cases advertising is allowed only if:

- the product advertised is clearly identified as a pharmaceutical product or a medical aid;
- the advertisement includes the name of the pharmaceutical product, as well as the internationally used common name if the pharmaceutical product contains only one active ingredient, or the name of the medical aid;
- the advertisement contains the information necessary for correct use of the pharmaceutical product or medical aid;
- the advertisement demonstrates the pharmaceutical product and the medical aid based on the summary of the product characteristics or the user's manual;
- the advertisement contains the information leaflet and warning specified in specific other legislation as necessary for the correct use of the pharmaceutical product or medical aid; and
- the advertisement contains an express, legible invitation to read carefully the instructions for the application of the pharmaceutical product or the user's manual of the medical aid.

Generic substitution

Generic substitution is not prohibited in Hungary. NIP publishes the list of those pharmaceutical products that are considered bioequivalent and substitutable

in the same indication. Generic substitution is governed by the Act on General Rules of Safe and Efficient Supply of Medicinal Products (98/2006) and by the Regulation of the Minister of Health and Social Affairs on Prescription and Dispensing of Pharmaceutical Products (44/2004).

Physician's obligations

In the course of prescribing pharmaceutical products and medical aids, the physician shall inform the patient of:

- any alternative to the pharmaceutical product and medical aid prescribed for the treatment; and
- the difference between the estimated costs to be paid by the patient for pharmaceutical products having the same active ingredient and those of the same fixed subsidy group, as well as bioequivalent pharmaceutical products, and medical aids within the same function group.

The physician may exclude substitution with the consent of the patient and state so on the prescription.

The patient is required to verify the receipt of the information by signing the physician's record.

Pharmacist's obligations

In case the physician does not exclude the possibility of generic substitution, the pharmacist shall inform the patient that such substitutes are available at a lower price than the product prescribed.

With the consent of the patient, the pharmacist shall replace the prescribed pharmaceutical product with another, cheaper product.

Probable amendments

An amendment proposed by the government would make it possible in the near future for physicians to prescribe active ingredients only, instead of branded pharmaceuticals. Physicians and pharmacists are discussing the issue.

Issues

Physicians usually exclude the possibility of dispensing a generic substitution when, due to the complexity of the disorder or allergic sensitivity of the patient, the pharmacist may not have appropriate expertise to make the decision. Most physicians oppose the idea that pharmacists may be at liberty to dispense substitutions at all.

In addition, an interesting issue arises with regard to reimbursed pharmaceutical preparations: on the one hand, pharmacists

are legally bound to inform patients about the availability of cheaper products, while on the other hand they are interested in making a higher profit, which – due to their legally fixed margin – is achievable only by selling more expensive preparations. This contradiction is left to the pharmacists to resolve when they have to recommend products to patients, taking all circumstances into account in a given case.

Online issues

E-pharmacies

The operation of e-pharmacies is allowed in Hungary with certain restrictions.

In accordance with Section 21/A(1) of the Regulation of the Minister of Health and Social Affairs on Prescription and Dispensing of Pharmaceutical Products, only those over-the-counter products which are not reimbursed by the public healthcare system may be distributed online. Prescription drugs may not be purchased via the Internet.

The online dispensing and delivery of pharmaceutical products are subject to the general rules of dispensing pharmaceutical products.

According to the Act on Medicinal Products for Human Use – unless otherwise provided by law – pharmaceutical preparations shall be procured and dispensed to the patient by pharmacies.

Thus, e-pharmacies are never literally virtual in Hungary, since only physical, authorised distributors – that is, pharmacists – may operate e-pharmacies and provide a home delivery service.

Pharmacies which provide an online service must report the name of their website to the competent supervisory authority before starting such activity.

Domain names

Use as a domain name of the name of a prescription pharmaceutical product or of a pharmaceutical product which is reimbursed by the public healthcare system may be deemed a commercial advertising activity, which is prohibited for such products under the regulations governing advertising of pharmaceutical products.

The international non-proprietary name of the above-described products may be registered as a domain name only when the pharmaceutical product cannot be identified on the website and neither the name of the manufacturer nor any identifying reference of the pharmaceutical product is displayed. [WTF](#)

**DANUBIA**PATENT & LAW OFFICE LLC
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Professionals in Protecting Intellectual Property

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Georgina Busku is an attorney at law at Sár and Partners Attorneys at Law, which works in close cooperation with Danubia Patent and Law Office LLC. Dr Busku graduated from the Faculty of Law of Eötvös Loránd University in 2006, joining the firm in the same year. Her work focuses on the enforcement of IP law, especially pharmaceutical trademarks. Her practice includes both advisory work and litigation. She is also experienced in general civil law, corporate law and employment law. Her legal experience further covers non-profit organisations, especially foundations, as well as energy law.