Luxembourg

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Pharmaceutical trademarks are regulated by the general trademark legislation – namely, the 2006 Law Approving the Benelux Convention on Intellectual Property – and by national legislation on medicines and IP rights.

The relevant national legislation includes:

- the Pharmacies Law 1973;
- the Dispensing of Medicines to the Public Law 1975, as amended;
- the Authorisation to Market and Advertise Medicines Law 1983, as amended;
- the 1992 Grand Ducal Regulation on the Authorisation to Market Medicines, as amended;
- the Convention between the *l'Union des Caisses de Maladie* and the Luxembourg Union of Pharmacists 1993;
- the Mass Distribution of Medicines Law 1995, as amended; and
- the IP Law 2009, implementing the EU IP Rights Enforcement Directive (2004/48/EC).

Selection, clearance and registration

Trademark registration

In Luxembourg, pharmaceutical trademarks are registered with the Benelux Trademark Office (BOIP), the trademark office for Belgium, the Netherlands and Luxembourg.

The Benelux Convention on Intellectual Property sets out the requirements for registering a sign as a trademark. Pharmaceutical trademarks must fulfil the same criteria for registration as other trademarks. Specifically, "names, drawings, imprints, stamps, letters, numerals, shapes of goods or packaging and all other signs that can be represented graphically and that serve to distinguish the goods or services of an undertaking shall be considered as being individual trademarks" (Article 2.1(1) of the Benelux Convention).

However, where a sign consists "solely of a shape which results from the nature of the goods, which gives a substantial value to the goods or which is necessary to obtain a technical result", it will not be deemed capable of constituting a trademark (Article 2.1(2) of the convention).

Additionally, the potential trademark must comply with three conditions: legitimacy, availability and distinctiveness.

The potential trademark must be legitimate, meaning that it must not be contrary to morality or to public policy in one of the Benelux countries (Article 2.4(a)). Similarly, it shall not be deceptive as regards the nature, quality or geographical origin of the goods (Article 2.4(b)). Evidently, the trademark must also be available and not subject to prior registration by another party.

The distinctiveness of the sign is essential, as it must be capable of distinguishing the company's products and/or services. If a sign is not sufficiently distinctive to achieve this, it cannot be registered as a trademark. The sign must also be perceived and recognised as a trademark by the public rather than, for

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example, as a simple decorative element.

The BOIP shall refuse to register a trademark on absolute grounds where it:

- is "devoid of any distinctive character";
- "consists exclusively of signs or indications which may serve, in trade, to designate the kind, quality, quantity, intended purpose, value, geographical origin or time of production of the goods or performance of the service, or other characteristics of the goods or services"; or
- "consists exclusively of signs or indications which have become customary in the current language or in the *bona fide* and established practices of the trade" (Article 2.11(1)).

This can be problematic for pharmaceutical trademarks, as frequently these relate to the product's active ingredients or intended use. Additionally, pharmaceutical products often use English language terms, which may or may not be considered as being customary in the language of the average Benelux resident.

For example, in *Cryopharma* (January 26 2010, 2008/AR/2126) the BOIP initially refused to register the mark CRYOPHARMA for Classes 3, 5 (pharmaceutical products), 8 and 10. The BOIP claimed that the prefix 'cryo' and the suffix 'pharma' were common in the medical sector and that they served to designate the kind, quality, quantity or intended purpose of the products. The terms were thus deemed to be descriptive (Article 2.11(1)(c)). The BOIP also considered that the combination of the terms that formed CRYOPHARMA was descriptive. Additionally, it deemed the mark to be devoid of distinctive character (Article 2.11(1)(b)).

Subsequently, the applicant contested the BOIP's refusal before the Brussels Court of Appeal. The court found that the average consumer would most likely understand that 'pharma' related to the word 'pharmacy'. However, it considered that 'cryo' is not used in the current language of the average consumer; consequently, the average consumer would not associate the term 'cryo' as meaning cold. CRYOPHARMA would therefore be viewed by the average consumer as a made-up word, and was thus capable of identifying products and distinguishing them from those of a competitor. The court found against the BOIP, considering that CRYOPHARMA did in fact have a distinctive character.

The court also found that the prefix 'cryo' was not descriptive of the product's uses in the understanding of the general public, and that consequently the trademark CRYOPHARMA, which combined 'cryo' with another word, was not descriptive.

In *Cryopharma* the relevant public was considered to be ordinary consumers and not medical professionals, as the products were not intended exclusively for medical professionals. The court clarified that the 'average consumer' was a consumer who was reasonably well informed and reasonably observant.

Marketing authorisation

In order to distribute medicines in Luxembourg, a marketing authorisation must be obtained from the health minister. The marketing authorisation is valid for five years and then renewable for five-year periods.

If a medicine has been granted a marketing authorisation from another EU member state, the Luxembourg health minister shall grant an authorisation in the form of a recognition of the original authorisation. As such, the Luxembourg marketing authorisation expires when the original marketing authorisation does.

The marketing authorisation specifies whether the medicine is prescription-only or available over the counter.

A marketing authorisation may be refused if the medicine's name is similar to that of another medicine with a different formula which is already on the market, or if the name may lead to errors or to confusion as regards its therapeutic benefits.

Medicines must be labelled and the information leaflet provided in at least one of French, German or Luxembourgish.

Parallel imports and repackaging

The issue of parallel imports is not relevant to the Luxembourg market, as Luxembourg does not produce any medicines and is dependent on medicines imported from abroad.

The import of medicines from the three border countries – France, Germany and Belgium – is facilitated by their proximity and language, as medicines distributed in Luxembourg can be labelled in either French or German.

The main problem in Luxembourg is ensuring that sufficient quantities of medicines are available. As the statistical predictions used by certain laboratories are based on the previous year's consumption, this can cause problems with the allocation of medicines to be distributed. Luxembourg is a small jurisdiction and fluctuations in consumption can result in insufficient supplies for the following year.

The Health Ministry prepared a pre-draft bill dated September 11 2009 on amendments to the Mass Distribution of Medicines Law to remedy this situation by imposing a public service obligation on wholesale medicine distributors to hold sufficient stock to supply Luxembourg's

pharmacies on a daily basis. Wholesalers shall participate in an on-call rota and have measures in place for the urgent delivery of medicines when required.

Anti-counterfeiting and enforcement

The IP Law sets out judicial proceedings for IP rights and states that counterfeiting may be proved by any means. Rights holders can apply to court for an expert to be appointed to prepare a detailed description of the suspected counterfeit goods. This expert may examine any objects, documents or other elements that could establish the alleged counterfeiting. He or she may take photocopies, photographs and video recordings, and take a sample of the suspected goods and the items used to produce or distribute such goods.

The judge can also take a number of interim measures against the alleged counterfeiting party – for example, ordering it to give up the objects or ordering that the objects be moved or modified so as to affect their function. The judge can also order the objects to be placed under seal. Financial earnings which appear to have originated in the suspected counterfeit goods may also be attached.

The rights holder can be required by the judge to pay an amount into court, which may be used in the event that the defendant suffers prejudice and is due damages.

Rights holders can also apply for protective interim measures in order to:

- prevent damages to their IP rights;
- order the cessation of the alleged infringement;
- force the alleged counterfeiting party to deposit money with the court for the potential compensation; and
- seize the suspected counterfeit goods.

Additionally, where the rights holder can demonstrate the existence of circumstances which would compromise the recovery of damages from the alleged counterfeiting party, an attachment order may be granted over the party's moveable and immoveable assets and its bank accounts.

The Criminal Code provides punishments for trademark infringement and counterfeiting. Article 184 of the code provides that persons guilty of trademark infringement may be sentenced to between three months' and three years' imprisonment. Article 191 provides that persons guilty of affixing a false or incorrect manufacturer's name or trade name on goods may be sentenced to between one and six months' imprisonment and/or a fine of up to €5,000.

Advertising

In Luxembourg, the advertising of medicines is regulated by the Authorisation to Market and Advertise Medicines Law and the Grand Ducal Regulation on the Authorisation to Market Medicines.

The advertising of medicines is considered to include all forms of information canvassing or marketing with the objective of promoting the prescription, dispensing, sale or consumption of medicines, including:

- advertising medicines to the public;
- advertising medicines to persons authorised to prescribe or dispense medicines;
- visiting persons authorised to prescribe or dispense medicines;
- providing sample products;
- providing incentives for prescribing or dispensing medicines; and
- sponsoring promotional events or scientific conferences attended by persons authorised to prescribe or dispense medicines.

Advertising must encourage the rational use of the medicine and present it in an objective manner without exaggerating its properties. It must not be misleading.

The advertising of medicines to the public is strictly regulated and is prohibited unless the rights holder has a prior advertising authorisation from the health minister or delegated civil servant. However, general advertising consisting solely of the name and formulation of the product and the name and address of the manufacturer requires no such authorisation (Article 19 of the Authorisation to Market and Advertise Medicines Law).

Additionally, advertising prescription-only medicines, medicines containing psychotropic or narcotic substances and medicines covered by Luxembourg's social security system is prohibited. However, this prohibition does not extend to medicines intended to be used without the intervention of a doctor for the diagnosis, prescription or supervision of treatment.

Advertising directed towards healthcare professionals must include essential information on the product's characteristics, as well as the medicine's dispensing classification.

Advertising medicines in contradiction of the applicable legal provisions may result in a cessation order from the commercial court and may give rise to criminal punishments – namely, a fine of up to €10,000 and/or a prison term of up to six months.

Generic substitution

Generic substitution is permitted in Luxembourg. Due to the low prescription rate of generic medicines compared to other countries, the Luxembourg government has launched information campaigns to raise awareness of generic medicines among the public and medical professions.

Online issues

E-pharmacies

Pharmacies are strictly regulated in Luxembourg and are considered as a public service, organised in the form of concessions. A pharmacy can be established only with a prior government authorisation. There are a set number of pharmacy concessions in the country, which are either private or state pharmacies.

A new pharmacy may be established only if a concession is vacated. In the case of state pharmacies, the details of the vacated pharmacy are published and a new pharmacist is appointed by the state. For private pharmacies, the pharmacist who holds the concession may sell or donate the concession to another pharmacist or transfer the ownership by will or intestacy. The same public service obligations apply to state and private pharmacies. The applicable legislation on pharmacies pre-dates the wide usage of the Internet and thus does not cover the online sale of medicines.

Medicines can be dispensed to the public only from pharmacies or medical dispensaries.

In April 2010 the health minister was quoted in the press on the subject of purchasing medicines online. He highlighted the pitfalls of procuring medicines online and, while acknowledging that purchasing via an online pharmacy is better controlled than purchasing from unknown websites, he did not indicate any intention of the government to discuss the authorisation of e-pharmacies in Luxembourg.

Given the current restrictive regime for pharmacies, it seems unlikely that Luxembourg will legislate on this issue in the near future. WTR

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