

Garrigues

# Portugal

**Pharmaceutical trademarks in Portugal must meet both the requirements for registration as a trademark and those for eligibility as a medicine name, which are much stricter**

The protection and enforcement of pharmaceutical trademarks raise numerous IP issues – mainly because such marks are associated with healthcare, which is recognized as a fundamental constitutional right, either from a private point of view or from a public health perspective. Consequently, trademarks for pharmaceutical products and medicines present certain characteristics due to the nature of the products. However, these characteristics do not result from specific trademark law provisions, but from limitations derived from other regulations.

With regard to medicines, Portugal has followed the European and international evolution in the field of industrial property law. Trademarks for pharmaceutical products and medicines, regardless of whether they are protected by a national, international or Community trademark registration, must meet the legal requirements applying to medicines, as well as the rules of the official Portuguese body regulating the pharmaceutical sector – INFARMED. INFARMED grants marketing authorizations and approves medicine names.

## **Protection of pharmaceutical trademarks and medicine names**

The Industrial Property Code contains no specific provisions on pharmaceutical trademarks and does not expressly state that the registration of an international non-proprietary name (INN) as a trademark is prohibited. However, INNs do not meet the absolute requirements for registration – namely, that a trademark must have distinctive character.

INFARMED and the Portuguese Industrial Property Office (IPO) are not required to cooperate in the registration of pharmaceutical trademarks.

## **Pharmaceutical trademarks**

The code provides that a trademark may consist of a sign or group of signs which are

capable of being represented graphically – namely, words (including personal names), designs, letters, numbers, sounds or the shape of the product or its packaging – provided that they are capable of distinguishing the products and/or services of one company from those of another. A trademark may also consist of an advertising slogan for the goods and/or services at issue.

Trademark law does not differentiate between pharmaceutical trademarks and marks for other types of products: if the requirements for registration are met and no specific exclusion applies, registration will be granted. The requirements for the registration of trademarks are less strict than those applying to medicine names under the Medicines Statute (Decree Law 176/2006 of August 30 2006) and under regulations set forth by INFARMED.

There is no explicit prohibition against the registration of a pharmaceutical trademark consisting of a three-dimensional shape, sound or combination of colours. The IPO's practice is generally restrictive with regard to the registration of sound marks and holograms, partly due to the difficulty in representing such marks graphically. Olfactory or single-colour marks may not be registered. However, the registration of a non-traditional trademark for pharmaceutical products is *de facto* ineffective since a medicine name must be legible and pronounceable. This requirement implies that a pharmaceutical trademark must be a verbal sign.

An INN will be considered to lack distinctive character. Moreover, an INN, as a generic word, falls within the scope of Article 223 of the code, which provides that a trademark consisting exclusively of indications that may serve in trade to designate the nature of the goods do not have distinctive character. The IPO's Guidelines for the Examination of Commercial Distinctive Signs state that the examiner should check the databases of INFARMED and the World Health Organization with a view to ascertaining whether the sign applied for corresponds to an active ingredient, generic name or pharmaceutical substance. If so, registration will be refused.

## **Medicine names**

The fundamental criterion for eligibility as a medicine name is the protection of public health – namely, whether the prescription, sale and use of the medicine is safe.

The Medicines Statute provides that a medicine name may consist of:

- a trademark that is unlikely to be confused with the non-proprietary name of the product;
- a non-proprietary name accompanied by a trademark; or
- a non-proprietary name accompanied by the name of the applicant or of the holder of the marketing authorization.

In addition to the statute, the regulations of INFARMED also apply. In April 2009, within the context of a simplification and transparency initiative, the practice developed by INFARMED led to the publication of the Guidelines for the Acceptance of Medicine Names. The guidelines bring together a set of criteria and principles which must be met in choosing the name of a medicine. As a general rule, a medicine name will be accepted where no risk to public health has been identified.

According to the guidelines, the name of a medicine must be unequivocal, legible and pronounceable, and cannot convey a message likely to be related to the use of the medicine or constitute a promotional feature. The guidelines apply to all medicine names regardless of the type of marketing authorization procedure used – namely, national, mutual recognition or decentralized. The centralized procedure constitutes an exception, since it follows its own specific guidelines.

In summary, the legislation governing medicine names provides as follows:

- A medicine name cannot be confusingly similar, from a visual and phonetic point of view, to the name of another medicine which is already in use in the market. The degree of similarity allowed takes into account:
  - the therapeutic indications;
  - the target population;
  - the pharmaceutical form;
  - the administration route;

- the classification for sale purposes; and
  - the potential risk of confusion.
- There must be no likelihood of confusion between the medicine name and the INN of any of the active ingredients of the product.
  - A medicine name cannot contain part of the INN or the stem of the INN of a group of active ingredients.
  - A medicine name cannot contain the name – or an abbreviation or part thereof – of the applicant or holder of the marketing authorization or of another company, except where the name of the medicine consists of a non-proprietary name followed by the name of the applicant or holder of the authorization. Likewise, the medicine name must not contain the pharmaceutical form – or an abbreviation or part thereof – of the medicine.

#### Trademark selection

The fact that the IPO has registered a sign as a trademark does not mean that it will be automatically eligible as a medicine name. The sign must be assessed by INFARMED, which applies criteria based on the defence of public health, rather than principles of trademark law.

Therefore, pharmaceutical companies are advised, when choosing the name of a medicine, to ensure that the latter is eligible as a medicine name before applying for registration as a trademark with the IPO. Applicants should also conduct searches in the INFARMED databases. It is also advisable to determine whether identical or similar marks are registered in Portugal and other countries of the European Union for identical or similar goods, since trademark owners may oppose the use of both identical and confusingly similar trademarks.

Applicants for the registration of a pharmaceutical trademark must thus take into account the requirements set forth by the Medicines Statute and the practice of INFARMED, since these are more restrictive than the provisions of the Industrial Property Code. Applicants should bear in mind that although a sign that consists of part of an INN or stem may be registered as a trademark, it is not registrable under INFARMED's rules.

#### Likelihood of error or confusion

The likelihood of error or confusion arising from the registration and use of a trademark is assessed by reference to the average consumer. The guidelines of the IPO provide that with regard to prescription-



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only medicines, the relevant consumer consists of pharmacists and doctors. The latter are highly specialized experts who are able to notice slight differences between trademarks. However, with regard to over-the-counter medicines, the guidelines set out that this rule is not valid. This is supported by the decision of the Portuguese Supreme Court of Justice of January 30 1985. Nevertheless, it is difficult to see how this rule can be applied by the examiners in practice, since trademark applications contain no indications concerning the prescription and sale of the products covered by the trademark.

INFARMED follows a different approach: even in the case of prescription-only medicines, it considers that the relevant consumer consists of end consumers – that is, the patients. Although the jurisprudence reveals that there is still uncertainty surrounding the concept of 'consumers' for the purpose of assessing the risk of error or confusion, the general tendency seems to be that the relevant consumers are the patients, rather than professionals or specialists (see, eg, the decision of Supreme Court of Justice of May 15 2001). However, the courts have stated that even though error or confusion on the part of end consumers is more dangerous in terms of public health, even health professionals, despite their qualifications and high level of attention, may be misled or confused.

#### Conclusion

In summary, pharmaceutical companies are advised to choose their trademarks based on both the requirements for registration of a sign as a trademark and those for the approval of a medicine name. [WTR](#)