European Union

Contributing firm
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Selection, clearance and registration

Regulatory bodies

The European Medicines Agency (EMA) is responsible for the scientific evaluation of applications for European marketing authorisations for human and veterinary medicines.

Under the centralised procedure set out in Article 3(1) of EU Regulation 726/2004, pharmaceutical companies submit a single marketing authorisation application to the EMA. Once granted, the authorisation is valid in all EU member states, as well as the member states of the European Economic Area (EEA) (ie, Iceland, Liechtenstein and Norway).

The centralised procedure is compulsory for certain pharmaceutical products, including:

- human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- certain veterinary medicines;
- medicines derived from biotechnology processes;
- advanced therapy medicines, such as gene therapy; and
- officially designated 'orphan medicines' for rare human diseases.

For medicines that fall outside these categories, companies can submit an application for a centralised marketing authorisation to the EMA if the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorisation would be in the interest of public or animal health (Article 3(2) of Regulation 726/2004). In all other cases, marketing authorisation is granted by the designated agencies of the member states.

Naming requirements

According to Article 6(1) of Regulation 726/2004, applications for medicinal products submitted via the centralised procedure must include a single name for the product in the Community, except in exceptional cases relating to the application of the trademark law – for example, where the proposed trademark

has been cancelled, opposed or objected to under a member state's trademark law (EMA Guidelines on the Acceptability of Names for Human Medicinal Products, CPMP/328/98).

Article 1(20) of the EU Human Medicines Directive (2001/83/EU) states that the name of a pharmaceutical product may be either:

- an invented name not liable to be confused with the common name;
- a common or scientific name accompanied by either a trademark or the name of the marketing authorisation holder.

The directive defines a 'common name' as the international non-proprietary name (INN) recommended by the World Health Organisation or, if no INN exists, the usual common name.

When evaluating an application, the EMA will consider whether the (invented) name proposed for a medicinal product could create public health concerns or potential safety risks, and in particular whether the name:

- could be liable to cause confusion in print, handwriting or speech with the name of an existing medicinal product;
- could convey misleading therapeutic or pharmaceutical connotations; and
- could be misleading with respect to the composition of the product.

Confusion with INNs

Article 1(20) of the directive states that the name of a pharmaceutical product must not be liable to be confused with the common name. The guidelines contain detailed rules in this respect, for both invented names that are similar to INNs and names that contain an existing INN stem.

The question of whether a likelihood of confusion exists between two trademarks derived from the same INN has been discussed in various Office for Harmonisation in the Internal Market opposition proceedings. In a July 17 2009 decision (R 584/2008-1) the First Board of Appeal had to decide on an opposition against a Community trademark application for LIPOTAXEL, based on the earlier Community trademark RIBOTAXEL, both for goods in Class 5, among others. The board noted that the suffix 'taxel', which appeared identically in both trademarks, was an INN identifying a particular pharmaceutical substance. Therefore, the suffix was held to be descriptive for the products in question and to have only a low degree of distinctiveness. As a consequence, and due to the differences in the initial elements of the trademarks, the board held that no likelihood existed with respect to Class 5 goods.

Non-traditional trademarks

Generally, a Community trademark may consist of any sign that is capable of being represented graphically and distinguishing the goods or services of one undertaking from those of other undertakings. The shape of goods and their packaging is explicitly listed as a possible trademark form in Article 4 of the EU Community Trademark Regulation. Colour and sound marks are also accepted, while olfactory and taste marks have been declined protection (for olfactory marks, see the European Court of Justice (ECJ) judgment in *Siekmann* (C-273/00, December 12 2002).

According to changes proposed to the Community Trademark Regulation (published by the European Commission on March 27 2013), Article 4 is to be amended in order to include colours and sounds explicitly as possible trademark forms. Further, the requirement that the mark be "capable of being represented graphically" is to be changed so that it is sufficient that the mark is capable of being represented "in a manner which enables the competent authorities and the public to determine the precise subject of the protection afforded to its proprietor". It remains to be seen whether these changes, if implemented, will lead to an increased significance of non-traditional trademark forms.

Parallel imports and repackaging

General principles

Trademark rights are exhausted across the EEA if the mark owner puts a pharmaceutical on the market in an EEA member state. Thus, parallel imports of pharmaceuticals from one member state to another are permissible and do not infringe the owner's trademark rights. In case of repackaging and/or relabelling, parallel imports are permissible under the following conditions set out by the ECJ in, among others, *Paranova* (C-276-05, December 22 2008):

- The reliance on trademark rights by the

owner contributes to the artificial partitioning of the markets between member states.
- The repackaging does not affect the original condition of the product inside the packaging.
- The new packaging clearly states who repackaged the product and the name of the manufacturer.
- The presentation of the repackaged product is not liable to damage the reputation of the trademark or its owner.
- The importer gives notice to the trademark owner before the repackaged product is put on sale and, on demand, supplies it with a specimen.

Enforcement

To enforce trademark rights against parallel imports, the trademark owner must bring claims for trademark infringement in the national courts. The defendant can raise the plea of exhaustion of trademark rights and must then demonstrate that the criteria set down by the ECJ are complied with.

Individual import of pharmaceuticals without marketing authorisation

In a recent decision (C-185/10, March 29 2012) the ECJ had to rule on a provision of the Polish Law on Medicinal Products that dispensed with the requirement for a marketing authorisation for medicinal products from outside Poland which had the same active substances, dosage and form as those having obtained a marketing authorisation in Poland, on condition that, among other things, the price of those imported products was "competitive". The court declared the provision to be incompatible with Article 6 of the Human Medicines Directive, as it did not comply with Article 5, according to which a member state may, in order to fulfil a special need, exclude from the scope of the directive a medicinal product supplied in response to a good-faith unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient.

The court held that where medicinal products with the same active substances, dosage and form are already authorised and available on the national market, there is no question of a special need. The court emphasised that financial considerations cannot in themselves lead to the existence of a special need, in particular since member states remain competent to set the price of medicinal products and the level of reimbursement by national health insurance schemes.

Anti-counterfeiting and enforcement

Counterfeit and falsified medicines are a major problem in the European Union. According to the recent Report on EU Customs Enforcement of IP Rights, almost 115 million products with a domestic retail value of approximately €1.27 billion were detained at EU borders in 2011. Of the articles detained, medicines accounted for 24% of the overall amount; they were also the top category with respect to the number of articles detained in postal traffic (36%).

The EU Falsified Medicines for Human Use Directive (2011/62/EC) aims to prevent falsified medicines from entering the legal supply chain and reaching patients. The directive had to be transposed into national law by January 2 2013.

According to the directive, a distinction must be made between counterfeit medicines and falsified medicines.

Counterfeit medicines

'Counterfeit medicines' are medicines that do not comply with IP rights or that infringe trademark law. The legal framework for anti-counterfeiting measures such as cross-border seizures is laid down in the EU Customs Regulation (1383/2003) and the respective national customs laws.

Falsified medicines

'Falsified medicines' are defined in the directive as medicinal products bearing false representations of:
- their identity, including their packaging, labelling, name or composition;
- their source, including their manufacturer, the country of manufacture or origin or the marketing authorisation holder; or
- their history, including records and documents relating to distribution channels.

The new measures introduced by the directive to harmonise safety and strengthen control measures across the European Union include:
- an obligatory authenticity feature on the outer packaging;

- a common EU-wide logo to identify legal online pharmacies and to make it easier to distinguish them from illegal online pharmacies;
- tougher rules on the controls and inspections carried out on producers of active pharmaceutical ingredients; and
- increased record-keeping requirements for wholesale distributors.

Import of active substances from third countries

The Falsified Medicines Directive also contains rules concerning the import of active substances into the European Union. From July 2 2013 such substances may be imported only if they are accompanied by written confirmation from the competent authority of the exporting third country that:

- the standards of good manufacturing practice applicable to the manufacturing plant concerned are at least equivalent to those in the European Union;
- the manufacturing plant concerned is subject to regular, strict and transparent controls; and
- in the event of findings relating to non-compliance, information on such findings is supplied to the European Union without delay.

The written confirmation requirement is dispensed with if the exporting country is included in a list of countries whose regulatory framework ensures a general level of protection equivalent to that of the European Union, taking into account:

- the country's rules for good manufacturing practice;
- the regularity of inspections to verify compliance with such practice;
- the effectiveness of enforcement of good manufacturing practice; and
- the regularity and rapidity of information provided by the third country relating to non-compliant producers of active substances.

Advertising

The advertising of medicinal products is governed by the respective national laws. These have been partly harmonised by Titles VIII and VIIIa of the Human Medicines Directive.

General principles

The term 'advertising' is defined broadly to include any form of information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products to the general public, as well as to persons qualified to prescribe or supply them.

Any advertising of a medicinal product in respect of which a marketing authorisation has not been granted is prohibited, and all parts of an ad must comply with the particulars listed in the summary of product characteristics. In addition, the ad must present the product objectively and without exaggerating its properties, and must not be misleading.

Additional rules apply in respect of advertising medicinal products to the general public. If the medicinal product is available on prescription only, advertising to the general public is prohibited. Over-the-counter medicines can be advertised to the general public, provided that such advertising contains no material which:

- gives the impression that a medical consultation or surgical operation is unnecessary;
- suggests that the effects of taking the medicine are guaranteed, unaccompanied by adverse reactions or better than, or equivalent to, those of another treatment or medicinal product;
- suggests that the health of the subject could be enhanced by taking the medicine or affected by not taking the medicine;
- is directed exclusively or principally at children;
- refers to a recommendation by scientists, health professionals or celebrities;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- could, through a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers in improper, alarming or misleading terms to claims of recovery; or
- uses in improper, alarming or misleading terms pictorial representations of changes

in the human body caused by disease or injury, or of the action of a medicinal product on the human body.

Advertising of medicines on the Internet

In May 5 2011 judgment (C-316/09, *MSD Sharpe & Dohme v Merckle*), the ECJ had to rule on the interpretation of the Human Medicines Directive with respect to restrictions on advertising on the Internet. The ECJ held that the dissemination on a website of information relating to medicinal products available only on prescription is not prohibited if the information is accessible on the website only to someone who seeks to obtain it and consists solely in the faithful reproduction of the packaging of the medicinal product and the literal and complete reproduction of the package leaflet or the summary of the product's characteristics. However, if the information relating to the medicinal product is selected or rewritten by the manufacturer, dissemination is prohibited, since such manipulation of information can be explained only by advertising purposes.

Generic substitution

Prescriptions, the price of pharmaceuticals and the level of reimbursement fall within the exclusive competence of the member states. There are no rules at EU level regarding generic substitution.

Online issues

The ECJ ruled on the legality of e-pharmacies in, *DocMorris* (C-322/01, December 11 2003). It held that a national prohibition on the mail order sale of medicinal products whose sale is restricted to pharmacies in the member state concerned was a measure with an effect equivalent to a quantitative restriction for the purposes of Article 34 of the Treaty on the Functioning of the European Union, but that Article 36 of the treaty could be relied on to justify such a prohibition insofar as the prohibition covers only medicinal products subject to prescription. However, an absolute prohibition on the sale by mail order of medicinal products, including products not subject to prescription in the member state concerned, could not be justified.

The ECJ also ruled that Article 88(1) of the Human Medicines Directive precludes a national prohibition on advertising the sale by mail order of medicinal products which may be supplied only in pharmacies in the member state concerned if the prohibition also covers medicinal products which are not subject to prescription.

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