

# Germany

Contributing firm  
**BARDEHLE PAGENBERG**



Author  
**Claus M Eckhardt**

## **Selection, clearance and registration**

On the regulatory side, the Federal Institute for Drugs and Medical Devices is the authority competent to grant a national marketing authorisation for pharmaceuticals marketed in Germany, based on the Medicinal Products Act. Within the framework of the authorisation proceedings, the institute reviews pharmaceutical trademarks in accordance with Article 8 of the act. Typically, pharmaceutical trademarks are either arbitrary, created names or compositions of the company name of the manufacturer and the international non-proprietary name (INN) pertaining to the active ingredients of the pharmaceutical product. In line with the general objective of the Medicinal Products Act to guarantee and ensure quality, efficacy and safety, Article 8 prohibits the use of misleading names which could lead to deception of consumers. The risk of deception is considered to exist, in particular, where the trademark:

- suggests a therapeutic effect of the product which it does not possess;
- creates the impression that the preparation will give certain success or that no harmful effects are to be expected over a prolonged period of use; and/or
- makes a misleading statement concerning the quality of the preparation or its active substance.

As an alternative to a national marketing authorisation, a European marketing authorisation with EU-wide effect may be obtained from the European Medicines Agency (EMA). Both the institute and the EMA undertake review of the proposed trademark for the pharmaceutical on the basis of Article 1(20) of EU Directive 2001/83/EC. This stipulates that the name given to a medicinal product may be either an invented name or a common or scientific name, combined with a trademark or the company name of the manufacturer. The directive defines a 'common name' as the INN recommended by the World Health Organisation or, in the event that no INN exists, the usual common name.

The final hurdle for marketing authorisation is an examination of the chosen trademark as compared to existing pharmaceutical trademarks. To rule out confusion, the proposed trademark must be sufficiently different from these. Therefore, obtaining a registered trademark for a pharmaceutical product is an arduous task, typically requiring more patience than securing trademark protection for product names in other industry areas, since the mark must comply with strict requirements with regard to safety and health hazards.

### **Confusion with INNs**

INNs are excluded from trademark protection as descriptive terms designating the active ingredients and, as such, cannot be monopolised by a single pharmaceutical undertaking. For the purposes of alluding to the active ingredients contained in the product, pharmaceutical trademarks frequently comprise the corresponding INN in combination with either an invented brand name or the company name of the manufacturer. The rationale behind this standard brand strategy is that healthcare professionals (eg, pharmacists and doctors) and end users may identify the active ingredients, while also recognising the brand name in its entirety as an indication of origin. This practice inevitably has the consequence that trademark disputes arise with older registered trademarks that also include the INN. In trademark opposition proceedings the decisive legal issue is invariably whether the conflicting trademarks are confusingly similar due to the inclusion of the INN portion, or whether confusion on behalf of the relevant part of the public is ruled out due to other word elements.

The analysis of whether a certain part of the public is confused as to the origin of the pharmaceutical product may differ depending on their specific knowledge – healthcare professionals such as doctors and pharmacists may not be confused, while the broad public (ie, the end consumer) may be confused. A good example is the Federal Supreme Court's decision in *Maalox v Melox-GRY* (June 1 2011). The Supreme Court confirmed prior decisions of the German Patent and Trademark Office

and the German Federal Patent Court which denied a risk of confusion between the mark MELOX-GRY and the opposition mark MAALOX. In the case at hand, the word portion 'gry' was part of the company name of the applicant, GRY Pharma GmbH. On appeal, the Supreme Court confirmed the Patent Court's view that neither the general public nor specialised healthcare professionals would identify the word element 'gry' as part of the company name. The gist of the decision was that the overall impression of a pharmaceutical trademark may be determined differently depending on the relevant part of the public: to confirm a risk of confusion, it is sufficient that the end consumers may be confused, whereas specialised circles such as doctors and pharmacists may not be, given their knowledge of INNs and company names of pharmaceutical manufacturers.

### **Parallel imports and repackaging**

Parallel imports and repackaging of pharmaceuticals are generally permitted, provided that the importer adheres to legal requirements set up in the established case law of the European Court of Justice (ECJ). The ECJ has consistently ruled that trademark rights are "exhausted" if the rights holder itself puts its products on the market in an EU or EEA member state; such products can be exported to any other EU or EEA state without infringing trademark rights. The rationale behind the principle of exhaustion is the notion that the enforcement of trademark rights to prevent cross-border trade within these territories would constitute an artificial barrier to the free movement of goods which is stipulated under Articles 34 and 35 of the Treaty on the Functioning of the European Union. However, the importer is held to fulfil a number of formal requirements, most notably to give advance notice to the rights holder before importing the goods and to provide it with samples of the imported pharmaceuticals on request. In case of repackaging, relabelling or bundling, the importer must ensure that the pharmaceuticals are in their original condition. Furthermore, consumers must be able clearly to identify the company responsible for the repackaging, relabelling or bundling, as well as the manufacturer of the product.

The German appeal courts and the Supreme Court are constantly refining the legal requirements. In *RENNIE* (February 10 2011) the Supreme Court defined more precisely the circumstances under which repackaging is permitted without infringing the trademark rights of the proprietor. In the case at hand, the defendant imported pharmaceuticals from the Czech Republic, repackaged in packs containing 120 tablets, whereas the original packages contained a maximum of 96 tablets as marketed in the Czech Republic. The rights holder argued that use of a completely new package instead of simply applying new labels to the original pack with new blister packs did not comply with the requirements set out by ECJ case law. The court argued that repackaging in completely new packaging and re-application of the trademark at issue was objectively unnecessary in order to provide the parallel importer with access to the market if the original packages could be used with new labels and by using additional blister packs. The court stated that in such cases, the use of brand-new packaging with a re-application of the trademark, instead of use of the original packaging with labels, served exclusively the interests of the parallel importer in order to increase its commercial success. However, such measures were unwarranted, given the infringement of the rights holder's rights, which can be justified under the principle of exhaustion only in very specific circumstances.

#### **Anti-counterfeiting and enforcement**

EU border seizure regulates the confiscation of pharmaceuticals suspected of infringing trademark rights. Border seizure at European level pertaining to goods imported into the European Union and/or exported from the European Union or goods registered for re-export are subject to the EU Customs Regulation (1383/2003). This regulation, which will be replaced by new EU Regulation 608/2013 from January 1 2014, does not apply to intra-EU trade. However, unauthorised parallel imports may be seized by German customs authorities on the basis of Section 146 of the Trademark Act. For the purposes of covering parallel import situations regarding pharmaceuticals, it is therefore recommended

to have a German national border seizure application in place. The customs authorities carry out only a summary inspection; they do not conduct a detailed, material inspection, but merely a superficial check. If trademark infringement is suspected, the pharmaceuticals are detained and the rights holder is informed of the source of the products and the parties involved in transporting and declaring them at Customs. Inspection of the suspect pharmaceuticals is possible on request. The rights holder has 10 days – extendable for a further 10 days on request – as of notification in which to confirm to Customs whether the goods are genuine. If the declarant has not objected to the destruction, the pharmaceuticals may be destroyed and the importer must bear the costs.

When submitting an application for border seizure, it is advisable to provide as much information as possible on the pharmaceuticals – in particular, how counterfeits or illicit parallel imports can be identified. Also helpful is information on the specific channels of distribution, as well as the place of production and the destinations to which the pharmaceuticals are typically shipped. In addition, information on licence agreements may be helpful in order to assist Customs.

#### **Pharmaceutical advertising**

The advertising of medicinal products is governed by the Law on Advertising in the Field of Healthcare. In addition, the Law against Unfair Competition must be observed. The new provisions of the law, as amended on October 19 2012, made substantial changes relating to further liberalisation.

The law provides no definition of 'advertising'. According to the case law of the German civil courts, the term 'advertising' implies any kind of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of a specific pharmaceutical product. Therefore, almost all information which is published by a pharmaceutical company to the general public or to third parties is likely to be classified as advertising.

However, German law differentiates between 'product advertising' and 'image advertising'. Product advertising is advertising

of a specific product, while image advertising is characterised by advertising using the name of the pharmaceutical company or the entire range of products without reference to a specific product. Image advertising is not subject to advertising law.

Advertising for medicinal products need not be approved, either in general or in specific circumstances. Furthermore, there is no obligation to provide the competent authorities with advertising material.

Advertisements for pharmaceuticals aimed at healthcare professionals must follow the general rules which apply to all advertisements for medicines. They must also abide by specific rules for advertisements targeting professional circles including healthcare professionals and institutions in the healthcare sector.

The general rules prohibit the advertisement of unauthorised medicines. In exceptional circumstances, some factual information can be disseminated before the authorisation for a medicinal product is granted. Price lists can be sent by manufacturers and suppliers of unauthorised medicines to healthcare professionals to whom this information may be relevant, but the price list must contain only factual information regarding the active ingredient, dosage form and strength, and must not contain any product claims.

All advertisements for medicines must also comply with quality standards:

- The advertisement must comply with the particulars listed in the summary of the product characteristics;
- The advertisement must present the product objectively without exaggerating its properties to encourage rational use of the product; and
- The advertisement must not be misleading – advertisements must not state or imply that a product is ‘safe’, as all medicines have the potential for side effects.

Apart from some restrictions, non-prescription medicines may be advertised to the general public. As a general rule, such advertisements relating to non-prescription products must comply with the general provisions for advertising (ie, they must not be misleading).

Furthermore, advertisements for medicinal products – whether for non-prescription or prescription-only products – must provide certain basic information relating to the product. The information must be set apart and clearly distinguished from the other promotional information, and must be clearly legible. An advertisement for medicinal products in the print media or on television must be clearly separated and distinct from the editorial parts of such media. Advertisements that are directed to the general public must provide an invitation to seek the advice of a health professional and to read the packaging leaflet, as follows: “For risks and side effects read the package leaflet or ask your doctor or pharmacist.”

### **Generic substitution**

If the prescribing doctor cites only the active ingredient of the pharmaceutical on the prescription and does not rule out substitution, pharmacists should substitute the original pharmaceutical with a cheaper product. The generic preparation need not have exactly the same size, dosage form and strength, but it must have a marketing authorisation for the same indication. The prescription of generic equivalence is expressly encouraged by the German Federal Health Ministry, given budgetary constraints. In practice, the more well known the pharmaceutical brand, the more likely that doctors will rule out substitution and patients will elect to have the original product prescribed.

### **Online issues**

Mail order pharmacies have been allowed in Germany since January 1 2004. Both over-the-counter and prescription preparations can be purchased by mail order. If foreign pharmacies comply with the standards that apply to German pharmacies, they are allowed to provide mail order services in Germany.

Under German pricing law, prescription and other pharmaceuticals which are paid for by health insurers are subject to fixed prices and may not be sold at lower prices. However, foreign mail order pharmacies have frequently promoted pharmaceuticals by offering bonuses or vouchers.

In proceedings against a mail order

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pharmacy located in the Netherlands, the Supreme Court held that German pricing law also applies to foreign pharmacies. Since the Federal Social Court had decided to the contrary in 2008, the Supreme Court referred the question to the Joint Senate of the Federal Supreme Courts of Justice. In an August 22 2012 decision the Joint Senate confirmed the Supreme Court's view and ruled that German pricing law also applies to foreign pharmacies. However, the Supreme Court held that bonuses or vouchers of €1 for each prescription medicine do not constitute unfair competition. To resolve this contradiction between unfair competition law and pharmaceutical pricing law, the *Bundestag* passed an amendment to the Medicinal Products Act clarifying that cash discounts and non-cash benefits are not allowed in relation to prescription pharmaceuticals.

**BARDEHLE PAGENBERG**

Prinzregentenplatz 7  
81675 Munich, Germany  
**Tel** +49 89 9 28 05 0  
**Fax** +49 89 9 28 05 444  
**Web** [www.bardehle.com](http://www.bardehle.com)



**Claus M Eckhardt**

Partner

[eckhardt@bardehle.de](mailto:eckhardt@bardehle.de)

Claus Eckhardt is a co-managing partner in BARDEHLE PAGENBERG's Munich office and heads the firm's trademark department. His practice focuses on prosecution and enforcement of IP rights in the fields of trademark, design, copyright and unfair competition law. Related advice includes anti-counterfeiting, licensing, merchandising, franchising issues and transactional support.

He is responsible for the management and prosecution of worldwide trademark and design portfolios. His international clients are leaders in their respective industries and come from the pharmaceutical, consumer healthcare, household goods, IT, hotel services, banking and food and beverages sectors.