United Kingdom

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Selection, clearance and registration
Trademarks in the United Kingdom are governed by the Trademarks Act 1994. Regulation and enforcement of the rules governing the pharmaceutical industry are carried out by the Medicines and Healthcare Products Regulatory Agency (MHRA). Where EU-wide approval is required, the relevant regulatory authority is the European Medicines Agency (EMA).

Registration
Section 1 of the Trademarks Act establishes the main function of a trademark: a mark that can be represented graphically and capable of distinguishing the goods or services of one undertaking from those of another. A trademark must fulfil this function to be registered. An application can be rejected under absolute grounds or on opposition by a third party.

Absolute grounds for refusal under Section 3 focus on distinctiveness. The UK IP Office will refuse an application for a mark that it considers to be devoid of distinctive character or to have become customary or generic. Applications that are descriptive of the kind, quality, quantity, intended purpose, value, geographical origin or time of production of the goods or services will also be rejected.

Relative grounds for refusal under Section 5 arise where an existing registered or prior pending third-party trademark conflicts with the mark applied for. *Alcon Inc v OHIM* (Case C-412/05) examined the likelihood of confusion in the context of pharmaceuticals. It concluded that the relevant consumer for pharmaceutical products is the health professional and the end consumer. *Aventis Pharma SA v OHIM* (Case T-95/07) established that the end consumer will exercise an "above average" level of attention to pharmaceutical products, given the potential medical implications if products are confused.

A trademark search on a specialist pharmaceutical database should be carried out to minimise the risk of third-party oppositions on relative grounds.

Non-traditional trademarks
The definition of a 'trademark' extends to

shapes, motions, colours, tastes and sounds. The UK IP Office examines applications taking into account the requirements set out by the European Court of Justice (ECJ) in *Libertel* (Case C-104/01), *Sieckman* (Case C-273/00) and *Shield Mark* (Case C-283/01). It has proved difficult to show trade origin in a colour or shape, resulting in many applications, such as a tablet shape, being refused. An application to register a strawberry taste for pharmaceutical products was refused in *Eli Lilly and Co's Application* ((R120-2001/2) [2004] ETMR 4).

The English High Court has ruled that a colour is capable of being registered. This is not true for all colours, however, as despite the issue coming back before the ECJ on a number of occasions, the court has resolutely refused to impose a rule against the registration of colours (*London Societe des Produits Nestle SA v Cadbury UK Limited* [2012] EWHC 2637).

Marketing approval

Applications for pharmaceutical trademarks must satisfy the requirements of the MHRA and marketing authorisation obtained for every product. Centralised European marketing authorisation, effective in the United Kingdom, can also be granted.

International non-proprietary names

An international non-proprietary name (INN) is a unique name that is globally recognised for a particular pharmaceutical product and cannot be registered as a trademark.

The MHRA has issued guidance for proposed product names, which covers the construction of pharmaceutical trademarks and the similarity of invented names to existing INNs.

The EMA assesses proposed names through the Name Review Group and by reference to the Guidelines on the Acceptability of Names for Human Medicinal Products Processed Through the Centralised Procedure. The guidelines address whether the proposed name could cause confusion with another product, convey misleading pharmaceutical connotations or be misleading with respect to the composition of the product. Further, an invented name should not be derived from its own INN.

Parallel imports and repackaging

The rules regarding parallel trading reflect those of the European Union. Regulated by the MHRA, the UK Parallel Import Licensing Scheme enables a parallel import licence to be obtained, allowing medicinal products authorised in other member states to be marketed in the United Kingdom subject to various requirements. Requirements depend on the nature of the parallel licence obtained (simple, standard or complex).

Pharmaceutical repackaging

Parallel importers of pharmaceutical products into the United Kingdom that are already on the market in other parts of the European Economic Area rely on Article 7(1) of the EU First Trademarks Directive (2008/95/EC), which provides for the exhaustion of the rights conferred by a trademark. A rights holder cannot use its rights to prevent resale of its branded goods within the European Union when these goods were first put on the market in the European Union by the rights holder or with its consent. To meet local requirements for marketing authorisation, importers are required to repackage products before they are imported. Product manufacturers and rights holders rely on Article 7(2) of the directive, which states that Article 7(1) will not apply where there is a legitimate reason for the rights holder to oppose the further commercialisation of the goods, especially where the condition of the goods has been altered or impaired. It is now established that where repackaging is deemed necessary by the importing member state, the repackaging should be assessed in terms of whether it damages the reputation of the trademark.

Implied consent

Exhaustion of rights applies when the goods were first placed on the market by the rights holder or with its consent (which can be implied). In *Zino Davidoff SA* (Case C-414/99) the importance of a rights holder's ability to control the initial marketing of goods in the European Economic Area was emphasised; subsequent UK case law makes it difficult for an importer to establish implied consent (see *Roche Products v Kent Pharmaceuticals Limited* [2006] EWCA Civ 1775). In *Mastercigars Direct v Hunters & Frankau* ([2007] ECWA Civ 196) and *Honda Motor Co Ltd v Neesam* ([2008] EWHC

338 (Ch)), implied consent by the rights holder was found. The facts of the cases, including the behaviour of the rights holder in *Mastercigars* and previous dealings between the parties in *Honda*, were consistent with implied consent to the import.

Goods in transit

Potentially infringing goods in transit in the United Kingdom give rise to infringement only if the goods are used in the United Kingdom in the course of trade. *Eli Lilly and Co v 8PM Chemists Ltd* ([2008] FSR 12) concerned the import of pharmaceutical products from Turkey into the United Kingdom in sealed boxes which were then sent on to the United States. Pharmaceutical companies including AstraZeneca, Eli Lilly and Pfizer unsuccessfully claimed trademark infringement. The court was not persuaded by the risk that consumers in the United States might incorrectly view the origin of the goods as the United Kingdom.

Goods in transit do not fall under the definition of a 'counterfeit product'. This was illustrated in *Nokia Corporation v HMRC* ([2009] EWHC 1903 (Ch)), where counterfeit telephones passed through the United Kingdom during transportation from Hong Kong to Colombia. The telephones were not deemed counterfeit because they had not been placed on the UK market. The ECJ also held in *Koninklijke Philips Electronics NV v Lucheng Meijing Industrial Company Ltd* and *Nokia Corporation v HMRC* (C-446/09 and C-495/09) that goods in transit did not come under the responsibility of customs authorities in the European Union.

Anti-counterfeiting and enforcement

The United Kingdom is a transit point and end-user market. It is seldom used as a base for the manufacture of counterfeit medicine and marketing authorisation must be obtained for every pharmaceutical product. Due to clear evidence that the UK pharmaceutical market is attractive to counterfeiters, the MHRA introduced a new falsified medical products strategy in 2012.

Prevention

Pharmaceutical manufacturers employ various measures to prevent copying, such as a complex shape and/or markings that are difficult to reproduce. Manufacturers work closely with UK Customs through customs monitoring and the use of covert markings to enable identification of counterfeits. The MHRA also conducts public campaigns highlighting the risks of obtaining medical products from unregulated websites and issues guidance to pharmacists jointly with the General Pharmaceutical Council. To minimise the risk of counterfeit medicines reaching consumers, the MHRA licenses all steps of the medicine distribution system, including manufacture, distribution and storage, and monitors the supply and manufacture of medical devices.

Since 2006 the MHRA has convened a bi-annual meeting of the Anti-counterfeit Stakeholders Group, whose membership includes trade associations for manufacturers, wholesalers, parallel traders, generics manufacturers, Her Majesty's Revenue and Customs and the police. The objective of this forum is to share information and intelligence concerning the seizure of falsified medical products, reports of falsified medical products, unusual or suspicious market activity and information from industry concerning demand, as well as to update a watchlist of the medical products determined to be most susceptible to counterfeiting activity. The watchlist is then circulated to law enforcement agencies, ports, postal hubs, regulators and the pinch points within the supply chain.

The MHRA has actively engaged with a number of other member states regarding delivery of training to over 150 police, customs and regulatory officials throughout Europe involved in the investigation of cases concerning falsified and illegal medicinal products.

Criminal enforcement

Criminal enforcement is the principal method of preventing the distribution of counterfeit pharmaceutical products in the United Kingdom.

The MHRA has a well-developed enforcement group comprising a case referral centre, an intelligence unit, operations teams and a prosecution unit. Appropriate legal powers, including entry to premises, inspection and seizure, are afforded to appropriately trained and authorised staff. The MHRA can prosecute.

The primary legislation relied on comprises:

- the Medicines Act 1968 (maximum of two

years' imprisonment and an unlimited fine);
- the Trademarks Act (maximum of 10 years' imprisonment and an unlimited fine); and
- the Proceeds of Crime Act 2002 (maximum of 14 years' imprisonment and an unlimited fine).

Further criminal penalties are available under the EU Customs Regulations (1383/2003) and the Medical Devices Regulations.

Civil enforcement

Civil enforcement is rarely pursued, due to disproportionate cost, and is likely to be economically viable only where collective action is taken by several brand owners. A successful civil action can result in a search order without notice to the defendant, a freezing injunction or an interim injunction. However, a defendant can be entitled to compensation if an order is incorrectly granted.

Advertising

Since August 2012 the relevant UK legislation is Part 14 of the Human Medicines Regulations 2012. This codifies and replaces the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994. Part 14 implements Title VIII of the directive (as amended).

Chapter 1 of Part 14 sets out general definitions relevant to advertising. These supplement the general definitions in Part 1 of the regulations. Chapter 2 of Part 14 contains rules on the contents of advertisements and promotions. Chapter 3 contains provisions for enforcing the requirements in Chapter 2, including the making of complaints about advertisements, applications to court by health ministers and the making of determinations by health ministers as to whether the regulations have been breached.

The advertisement of pharmaceutical products is also governed by two trade associations, each with its own code of practice. The Association of the British Pharmaceutical Industry Code of Practice for the Pharmaceutical Industry, administered by the Prescription Medicines Code of Practice Authority, is the self-regulatory system covering prescription medicines. Advertisement of over-the-counter medicines to the general public is regulated by the Proprietary Association of Great Britain. The codes of practice exist to supplement, and in some instances surpass, the regulations. Self-regulation is the principal method of dealing with complaints.

The regulations prohibit certain advertisements, including advertisement of prescription-only medicines to the public and advertisements directed (exclusively or principally) at children. The regulations also require that advertisements:
- state that the advertised product is a medicine;
- state the name of the medicine, including the common name if there is only one active ingredient; and
- include instructions for use of the product and adequately direct consumers to the instructions.

The MHRA is responsible for enforcing the regulations and deals with complaints. It publishes the outcome of investigations, as well as the *Blue Guide* on the advertisement and promotion of medicines in the United Kingdom. The most common method of enforcement is via vetting of advertisements before publication. The agency is also involved in monitoring published material, handling complaints and enforcing penalties for advertisements that fail to comply. Breach of the regulations is a criminal offence resulting in a fine and/or up to two years' imprisonment.

Generic substitution

The Medicines Act 1968 does not permit automatic generic substitution, except in emergencies or under strict hospital control.

On October 25 2011 the MHRA issued a consultation document on the need to consolidate the UK medicines legislation, with the aim of rationalising and simplifying existing fragmented medicines legislation The MHRA identified a number of concerns regarding generic substitution, including that:
- patients could be confused by a change in the appearance of their medication;
- practitioner workload would increase in counselling and reassuring patients regarding changes in medication appearance; and

- the use of similar packaging, size, shape and colour to the original by generic substitution could result in the original product not being sold.

Due to these and others concerns, it was confirmed that automatic generic substitution would not proceed. Pharmacists can dispense generic medicine if a generic prescription is received, but specific branded product must be dispensed for branded prescriptions.

Online issues

E-pharmacies

The rapid growth of the Internet and e-pharmacies poses many dangers, including an increase in the purchase of incorrect or fake medicine, and the illegal sale of prescription-only medicines. In September 2010 the Royal Pharmaceutical Society of Great Britain was split into:

- the General Pharmaceutical Council, the independent regulator; and
- the Royal Pharmaceutical Society, the representative body for pharmacists and pharmacies.

The council introduced a logo to be displayed on legitimate online pharmacy sites to provide a way for consumers to identify registered online pharmacies. The logo includes a direct link to the council's website, enabling consumers to verify the registration details of the pharmacy and the pharmacist(s) behind the e-pharmacy's website.

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into effect on April 1 2013, replacing the 2012 regulations and reflecting new National Health Service (NHS) architecture, in which the NHS Commissioning Board is responsible for maintaining pharmaceutical lists, and the Health and Wellbeing Boards are responsible for developing and publishing pharmaceutical needs assessments.

Domain names

Domain names in the United Kingdom are allocated by Nominet on a first come, first served basis. Nominet provides a dispute resolution service that is broadly similar to the Uniform Domain Name Dispute Resolution Policy, but generally faster, cheaper and more streamlined. The use of the name of another business as a domain name may constitute passing off.

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Gemma Boore is a trainee in the London office of Edwards Wildman Palmer LLP. She has spent the first year of her training contract working in litigation – first in the insurance and reinsurance department, and then in commercial litigation. She then spent six months doing business law and is now working in the IP department. Her recent experience includes drafting shareholder and investment agreements, conducting research into the regulation of remote gaming, and preparing submissions in trademark opposition proceedings.