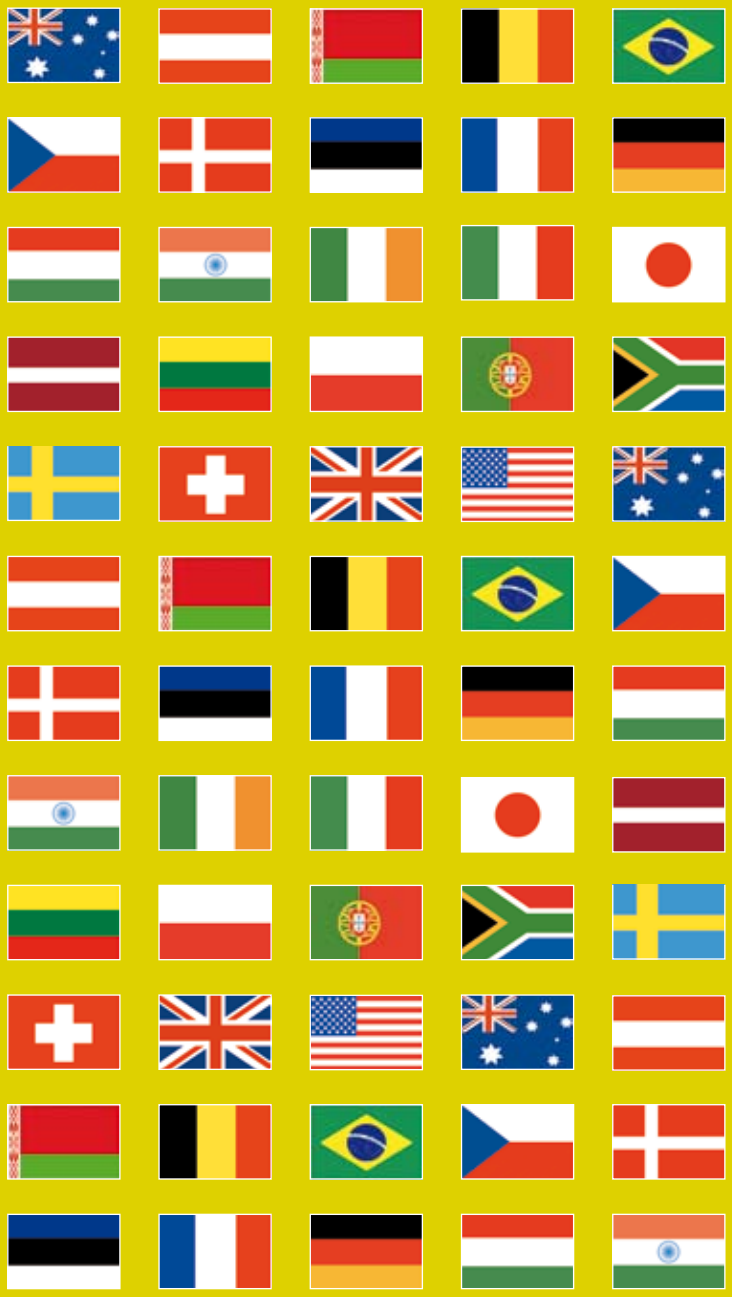
GETTING THE DEAL THROUGH

Life Sciences

in 24 jurisdictions worldwide

Contributing editors: Alexander Ehlers and Cord Willhöft

2010



Published by
GETTING THE DEAL THROUGH
in association with:

Advokaadibüroo bnt Attorneys-at-law
Anderson Mōri & Tomotsune
Arnold & Porter (UK) LLP
Beslay + Le Calvé
Biolato Longo Ridola & Mori
bnt Attorneys APB
bnt Klauberg Krauklis, Attorneys at Law
bnt legal & tax Minsk
Bowman Gilfillan
Brudkowski and Partners
Bruun & Hjejle
Dewallens & partners
DLA Piper LLP
Ehlers, Ehlers & Partner
Griffith Hack Lawyers
Lopes Dias & Associados
Matheson Ormsby Prentice
Mattos Muriel Kestener Advogados
Preslmayr Rechtsanwälte OG
Rajinder Narain & Co
Schönherr
Setterwalls Advokatbyrå AB
Szecskay Attorneys at Law
Wenger & Vieli AG

GETTING THE DEAL THROUGH

Life Sciences 2010

Contributing editors
Alexander Ehlers and Cord Willhöft
Ehlers, Ehlers & Partner

Business development manager
Joseph Samuel

Marketing managers
Alan Lee
Dan Brennan
George Ingledew
Edward Perugia
Robyn Hetherington
Dan White
Tamzin Mahmoud
Ellie Notley

Subscriptions manager
Nadine Radcliffe
Subscriptions@
GettingTheDealThrough.com

Assistant editor
Adam Myers

Editorial assistant
Nick Drummond-Roe

Senior production editor
Jonathan Cowie

Chief subeditor
Jonathan Allen

Production editor
Joanne Morley

Senior subeditor
Kathryn Smuland

Subeditors
Laura Zúñiga
Ariana Frampton
Charlotte Stretch

Editor-in-chief
Callum Campbell

Publisher
Richard Davey

Life Sciences 2010
Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

ISSN 2042-4329

Printed and distributed by
Encompass Print Solutions.
Tel: 0870 897 3239

Law
Business
Research

CONTENTS

United Kingdom

Lincoln Tsang and Jeremy Willcocks

Arnold & Porter (UK) LLP

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The Department of Health is the government department responsible for managing the National Health Service (NHS) in England. There are similar health-care services managed by the devolved governments in Scotland, Wales and Northern Ireland. The Secretary of State for Health is the government minister in charge of the Department of Health. In addition, there are also private health-care providers.

The NHS in England is divided into strategic health authorities (SHA) which are responsible for and manage the health services on behalf of the central government. Each SHA is responsible for the primary care trusts (PCTs) in their area that administer local health-care services.

2 How is the health-care system financed in the outpatient and inpatient sectors?

In England, the NHS, a publicly funded health-care system, provides both primary and secondary care, and is responsible for outpatient and inpatient treatment. Similar services are managed separately by the devolved governments.

The NHS provides free at the point of service treatment to patients, which is ultimately funded through national taxation, although there are some additional charges associated with certain treatments.

Funds provided by the Department of Health to individual PCTs are determined by certain demographic factors. The PCTs then have to allocate their funds to provide the necessary services at a local level, which may involve making contractual arrangements with primary health-care professionals to define the scope of services to be delivered.

Private medical insurance is generally used as an add-on for NHS treatment.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

The advertising of medicinal products in the UK, both to the general public and health-care professionals, is controlled by a combination of legislation and codes of practice.

There are two principal sets of regulations implementing the relevant Community provisions: the Medicines (Advertising) Regulations 1994 (SI 1994/1932) and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933). Further provisions are set out in part VI of the Medicines Act 1968. The Medicines and Healthcare products Regulatory Agency (MHRA) supervises the advertising of medicinal products on behalf of the health ministers or licensing authority. The regulations are supplemented by guidelines published by the MHRA. The latest version is called *The Blue Guide – Advertising and Promotion of Medicines in the UK* and was published in November 2005.

Control by the MHRA is supplemented by industry codes of practice and these codes provide the day-to-day control over the advertising of medicines. The codes have been developed in consultation with the MHRA and are consistent with the legal requirements, while in some cases going beyond them. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice (the Code), administered by the Prescription Medicines Code of Practice Authority (PMCPA), governs the advertising of prescription-only medicines. The latest version of the Code came into operation on 1 July 2008. The Proprietary Association of Great Britain (PAGB) Consumer Code governs the advertising of over-the-counter medicines to the general public and the PAGB Professional Code governs the advertising of over-the-counter medicines to persons qualified to prescribe or supply.

In addition to the controls on medicines, other general legislation is sometimes relevant, such as the Trade Descriptions Act 1968 and the Control of Misleading Advertisements Regulations 1988.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

Regulation 14 of SI 1994/1932 (clause 4 of the ABPI Code) states that, with the exception of audiovisual advertisements and abbreviated advertisements, all advertisements to health professionals must contain essential information compatible with the summary of product characteristics (SmPC). There are special rules to regulate audiovisual advertisements where the essential information must be consistent with the SmPC.

Abbreviated advertisements, which are no larger than 420 cm^2, intended for health-care professionals, may benefit from certain derogations from the main advertising rules, but the essential information must still be consistent with the SmPC.

The basic advertising requirements do not apply to certain promotional aids or items such as pens, notepads and mugs.

5 What are the main rules and principles applying to advertising aimed at the general public?

Non-prescription medicines may be advertised to the general public. The UK domestic law sets out certain conditions which must be complied with. The advertisement must not:

- give the impression that a medical consultation is not necessary;
- suggest that the effects of the medicine are guaranteed, without side effects, or better than or equivalent to another medicine or treatment;
- suggest that taking the medicine will enhance health;
- suggest that health may be adversely affected by not taking the medicine;
- be directed towards children;

- include a recommendation by a health professional or well-known person if this could encourage consumption of the medicine;
- suggest that the product is a food, cosmetic or other consumer product;
- suggest that the safety or efficacy of the product is due to its natural status;
- might, by use of a case history, lead to erroneous self-diagnosis;
- refer, in improper, alarming or misleading terms, to claims of recovery; or
- use improper, alarming or misleading representations of the human body.

6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

The most common infringements relate to advertising materials not presented in a manner consistent with the SmPC or the terms of the authorisation, and the manner in which a medicinal product is promoted to health-care professionals.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

The promotion of a medicinal product must be consistent with the terms of its marketing authorisation and the SmPCs. However, the provision of information regarding off-label use of medicinal products to health-care professionals is permitted in those situations where such provision is a legitimate exchange of scientific information and provided that it does not constitute promotion. Off-label use of a medicinal product is solely at the discretion of health-care professionals according to their clinical judgements in the best interests of the patients under their care.

The question of whether an activity constitutes an acceptable provision of off-label information is closely related to the purpose of the particular activity and whether the overall impression of the activity and the way it is conducted is non-promotional.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

Collaboration between the pharmaceutical industry and health-care professionals is governed by a combinations of laws and codes of practice. In addition to the requirements established in the laws mentioned in question 3 and the ABPI Code, health-care professionals' activities are regulated by a selection of professional codes and guidance. For example, the General Medical Council guidance, the Royal Pharmaceutical Society of Great Britain Code of Ethics for pharmacists and the Nursing and Midwifery Council Code of professional conduct.

Where the collaboration between the pharmaceutical industry and health-care professionals amounts to 'joint working', additional rules apply. Joint working is defined as 'situations where for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery'. The Department of Health has issued the NHS best practice guidance on joint working between the NHS and the pharmaceutical industry and other relevant commercial organisations, together with a toolkit, 'Moving beyond Sponsorship'. The ABPI has also issued guidance notes on joint working taking into consideration the ABPI Code.

Finally, the UK corruption laws, including the Public Bodies Corrupt Practices Act 1889 and the Prevention of Corruption Acts 1906 and 1916 should be considered, particularly if it is likely that an individual health-care professional or NHS employee could benefit personally from any collaboration arrangements.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The underlying principle for the collaboration between the pharmaceutical industry and health-care professionals is that such collaboration must bring benefits to patients. The NHS and the pharmaceutical industry share a common agenda to improve patient outcomes through high-quality and cost-effective treatment and management.

The main rules applying to this collaboration are the commitment by the pharmaceutical industry to promote appropriate use of medicines, promoting health, ensuring high standards and transparency.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

The most common infringements committed by manufacturers with regard to the collaboration with health-care professionals relate to their failure to maintain a clear separation between non-promotional and promotional activities, for example, in the field of the provision of medical and educational goods and services, and donations and grants to health-care professionals.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The 2008 Code introduced provisions that specifically address the interaction between the pharmaceutical industry and patient organisations. Pharmaceutical companies may interact with patient organisations or user organisations to support their work. However, such involvement must be transparent and all arrangements must comply with the Code. The limitations on the hospitality to be provided to health-care professionals are also applicable in the context of hospitality to patient organisations. Sponsorship must be clearly acknowledged and it is a requirement that a list of all patient organisations to which companies provide financial support is publicly available. Companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed in relation to every significant activity or ongoing relationship. The written agreement should set out the activities agreed and the level of funding and refer to the approval process for each party.

There are other codes and guidelines applicable to specific patient groups, such as the Long-Term Medical Conditions Alliance guidelines. In addition, patient organisations themselves are likely to be covered by the rules of the Charity Commission (the regulator and registrar for charities in England and Wales) as well as their own codes.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Anti-competitive conduct under chapter I or II of the 1998 Competition Act is investigated by the Office of Fair Trading (OFT). The OFT will determine whether the conduct infringes the 1998 Act, and can impose substantial fines. Investigations of cartel offences are carried out by or on behalf of the OFT but can only be determined by the criminal courts in the UK.

Anti-competitive conduct that affects trade between EU member states must be assessed under EU law, and may be investigated by the European Commission or the OFT.

13 Is follow-on private antitrust litigation against manufacturers possible?

Private parties may bring actions in civil courts for damages and other civil remedies (such as an injunction) in connection with an alleged infringement of UK or EU competition law. In addition, an action for damages may be brought before the Competition Appeal Tribunal, but only after the OFT or the European Commission has

decided that UK or EU law has been infringed (so-called 'follow-on actions').

The NHS brought civil actions against certain generics manufacturers in an alleged price-fixing cartel; these were settled. In *Devenish Nutrition v Sanofi-Aventis and others* (2007), concerning a follow-on damages action in relation to a vitamins cartel, the High Court decided that only single compensatory damages were available for injury caused by price-fixing cartels. This decision was appealed to the Court of Appeal, where the court confirmed that victims of a cartel are only entitled to be compensated for the actual loss suffered. The Court of Appeal rejected an argument that restitutionary damages should be available purely on the basis that cartelists may make a profit from their breach of competition law. The Court of Appeal explained that it would have to be shown that the case was exceptional and that compensatory damages were not a sufficient remedy to address the wrong that had occurred.

Both the OFT and the European Commission are seeking to encourage the use of private actions in the hope of further deterring anti-competitive conduct.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Unlike medicines, there are no sector-specific statutory provisions governing advertising and promotion of general medical devices, active implantable medical devices or in vitro diagnostic devices. However, the UK Association of British Healthcare Industries (the UK trade association for companies, including medical device manufacturers, involved in the health-care industry) (ABHI) has adopted essentially the same Code of Business Practice developed by the European Trade Association (Eucomed) as the basis for self-regulation by the health-care industry. The Resolution of Complaints procedure itself is similar to the established procedure used by the ABPI. Complaints are dealt with by a Panel comprising health-care professionals, lay persons and the Director-General of ABHI.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The control of medicines in the UK is achieved primarily through the system of licensing and conditional exemptions from licensing laid down in EC legislation and national implementing legislation, the Medicines Act 1968 and relevant subordinate legislation. Many of the provisions of the Medicines Act have now been superseded by regulations implementing EC legislation on medicines.

16 Which authorities may grant marketing authorisation in your jurisdiction?

The MHRA is the competent authority in the UK for the granting of marketing authorisations for medicinal products. The MHRA was set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). The MHRA is the executive agency of the Department of Health that safeguards public health by ensuring that all medicines on the UK market meet appropriate standards of safety, quality and efficacy.

The MHRA is accountable to the relevant health ministers in the UK for the discharge of functions they exercise collectively or singly as the Licensing Authority. The department of health ministers are accountable to parliament on matters concerning human medicines regulation on a UK basis.

The Licensing Authority is advised by the Commission on Human Medicines (CHM), a statutory advisory body, on matters specified in the Medicines Act relating to medicinal products. Another statutory advisory committee established under the Medicines Act is the British Pharmacopoeia Commission that advises on matters relating to the quality and standards of medicines. Expert advisory groups may be established to advise on specialised topics relating to the assessment of safety, quality and efficacy of medicines.

17 What are the relevant procedures?

There are a number of different types of applications and choice of procedures depending on the nature of the active ingredient of the medicinal product. These vary from applications for products containing new active substances, those whose active ingredients have previously been evaluated (known as abridged applications), to biological and biotechnology products.

Applications for products containing new active substances (new chemical entities) can be submitted to the MHRA for a national marketing authorisation or to the EMEA for evaluation under the Centralised procedure. Applicants who have an existing authorisation in another EU member state can apply under the mutual recognition procedure.

Applications for biotechnology products and certain therapeutic products (such as anti-cancer drugs) are required to be submitted through the centralised procedure.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Under Article 24 (4-6) of Directive 2001/83EC, any marketing authorisation which, within three years of being granted, is not followed by the placing on the market of the authorised product will cease to be valid. In respect of generic medicinal products, the three-year period will start on the date of the grant of the authorisation, or at the end of the period of market protection or patent protection of the reference product, whichever is the later date. If a product is placed on the market after authorisation, but subsequently ceases to be placed on the market in the UK for a period of three consecutive years, it will also cease to be valid.

In exceptional circumstances, and on public health grounds, the MHRA may grant an exemption from the invalidation of the marketing authorisation after three years. Whether there are exceptional circumstances and public health grounds for an exemption will be assessed on a case-by-case basis. When assessing such cases, the MHRA will, in particular, consider the implications for patients and public health more generally of a marketing authorisation no longer being valid.

These provisions are implemented in the UK by the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, as amended; in particular, paragraph 6(cc) and 6B of schedule 3 each provide that a breach of the relevant notification obligation by a UK marketing authorisation holder constitutes a criminal offence. Failure to notify a cessation or interruption, or failure to notify within the time limit is, however, not an offence if the marketing authorisation holder took all reasonable precautions and exercised all due diligence to avoid such a failure.

19 Which medicines may be marketed without authorisation?

The Medicines Act contains certain exemptions from licensing and makes provision for further exemptions to be included in statutory orders. Three of the more important exemptions are the manufacture and supply of unlicensed relevant medicinal products for individual patients (commonly known as 'specials'); the importation and supply of unlicensed relevant medicinal products for individual patients; and herbal remedies exemptions.

Medicines legislation, specifically the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, requires that medicinal products are licensed before they are marketed in the UK. However, some patients may have special clinical needs that cannot be met by licensed medicinal products. So that these special needs may be met, the law allows the manufacture and supply of unlicensed medicinal products subject to certain conditions.

The conditions are that there is a bona fide unsolicited order, the product is formulated in accordance with the requirement of a doctor or dentist registered in the UK, and the product is for use by their individual patient on their direct personal responsibility. If a 'special' is manufactured in the UK, the manufacturer must hold a manufacturer's (specials) licence issued by the MHRA. A 'special' may not be advertised.

20 What, according to the legislation and case law, constitute medicinal products?

Medicinal products for human use are defined in Directive 2001/83/EC, and this definition has been adopted by the UK implementing legislation (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994). Medicinal products are defined as:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis.

A product may therefore be considered as a medicinal product due to: its presentation (the 'first limb' of the test) or its function (the 'second limb'). Borderline determination is a matter of national competency. However, there has been a wealth of case law before the European Court of Justice as to the precise meaning of this definition, and the UK courts have tended to follow these findings.

In the UK, classification issues are dealt with by the MHRA, taking account of relevant EC guidance and the MHRA's own guidance. In certain situations, matters may be referred to its advisory committee on borderline products for adjudication.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

The statutory powers covering pharmaceutical pricing are set out in the National Health Service Act 2006 and subordinate legislation. In addition to the statutory scheme, the prices of branded medicines are controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The 2009 PPRS is the latest in a series of voluntary agreements reached between UK governments and the pharmaceutical industry. Both the voluntary 2009 PPRS and the statutory scheme are administered by the Department of Health staff in the Medicines, Pharmacy and Industry Group – Pricing and Supply Branch.

The PPRS does not cover the pricing of new products, and new products can be sold at prices set by the pharmaceutical companies. However, the National Institute of Health and Clinical Excellence (NICE) is an agency that assesses new products, and decides whether they will be able to be received and paid for within the NHS system. This assessment is usually done on the basis of a cost–benefit assessment, whereby NICE assesses whether the product is affordable considering the level of benefit expected from its use.

The 2009 PPRS also includes some flexible pricing schemes, such as value-based pricing, whereby medicines can be priced accordingly to their value at launch, and then the original price may be increased or decreased as the effective value that the medicine offers to NHS patients changes over time. There have recently also been some other incentive initiatives, whereby pharmaceutical companies agree to refund the costs associated with a new product if it is found not to be effective in a particular patient. This increases the exposure of and knowledge about a new product, without the associated risk for a particular PCT of having to pay for an expensive treatment. The PPRS acknowledges that such flexible schemes are beneficial and cost-effective.

22 In which circumstances will the national health insurance system reimburse the cost of medicines?

Inpatient sector

Hospitals are paid based on procedures actually performed. The cost of the procedure is fixed as a national tariff, based on the historical average actual costs associated with the performance of that procedure. Each procedure is assigned a particular health-care resource group (HRG) code, setting out the costs for that procedure. The costs of medicines used in that procedure will be reimbursed as a part of the cost of the procedure as a whole. Payments are received by the PCT based on the number and range of procedures performed in a given period. This is known as 'payment by results'. Medicinal products are not reimbursed individually, and are not named in the relevant HRG code.

However, for certain high-cost products, the HRG code may be adjusted so that the medicinal product is excluded from the HRG system. The costs associated with the use of that product can then be negotiated separately between the relevant hospital and the PCT out of the PCT's funds. Similarly, new drugs may be negotiated separately by the hospital with the PCT.

The provision of off-label or unlicensed products will be a matter for each PCT to consider. A hospital will need to negotiate the reimbursement of such products with the PCT. If a patient has been part of a clinical trial, this may be fairly straightforward. However, the PCT may consider that the price of such unlicensed products is disproportionate and so refuse to reimburse their use.

Outpatient sector

Patients receive prescribed medicinal products from pharmacies in the community. Patients must pay a fixed price for these NHS prescriptions, regardless of the cost of the medicinal product itself.

Pharmacies receive payment for these dispensed products from the Pharmaceutical Price Authority (PPA) based on a national price list, known as the Drug Tariff. However, pharmacies receive stock of products from pharmaceutical companies directly, and can negotiate prices for them. Therefore, if it is able to buy the product at a reduced cost, the pharmacy will effectively make money, as it will receive more for that product than is paid for it.

Medicine quality and access to information

23 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

It is possible to bring private proceedings in relation to counterfeit medicines, in particular in reliance on national trademark rights (under the Trade Mark Act 1994) and national patent rights (under the Patents Act 1997).

To assist in the identification of counterfeit goods and to help stop them being brought into the EU, Regulation (EC) 1383/2003 set up a customs watch notice procedure. The regulation obliges all member states to have a procedure in place whereby applicants can request the national customs authority to take action on discovery of suspected goods. Once customs have detained the goods, the applicant will have the opportunity to inspect or receive samples of them for analysis. Customs may also provide the applicant with information detailing the provenance of the goods. The applicant will

Update and trends

The national implementation of the EU 'Pharmaceutical Package' will have an impact on the current UK legal environment for medicines. However, while two of the proposals in the package – namely, tackling the trade in counterfeit medicines and improving the pharmacovigilance system – are proceeding much as expected, the third proposal, on improving the provision of drug information to patients, is doing less well. The pharmaceutical industry and many members of the European parliament are in favour of this proposal but most of the EU member state governments are not. In any case, the Pharmaceutical Package will not have a real impact on national legislation until 2010 at the earliest.

then have 10 working days in which to initiate proceedings before customs will suspend the detention. All costs relating to the detention and storage of the goods, as well as any liability customs assumed as a result of the action, will be borne by the applicant.

Remedies available for private actions include measures to recall or remove the infringing goods from channels of commerce or their destruction, injunctions against the infringer, and damages.

In addition to enforcement of private rights, legislation exists that enables the UK authorities to take action in relation to counterfeit medicines. In particular, the Medicines Act 1968 sets out numerous offences relating to failure to comply with the legislation. Offences under this Act carry a maximum two-year prison sentence and an unlimited fine. In addition, the Trade Marks Act 1994 (section 92) contains an offence for unauthorised use of a trademark. This carries a possible 10-year prison sentence and fine.

As the regulatory body relating to medicines, the MHRA has an enforcement and intelligence group that plays an active role in identifying and monitoring counterfeit medicines (as well as enforcing many other aspects of UK medicines legislation) and pursing prosecutions under the legislation set out above.

The MHRA also works closely with customs (which is responsible for the identification of counterfeit medicines at the UK border), trading standards (who have centres in each UK local authority and who also deal with health and safety and consumer protection more generally) and, in serious cases, the police and the Serious Organised Crime Agency.

Under the 'Pharmaceutical Package', the European Commission sought to protect the legal supply chain against illicit introduction of counterfeit medicines. The proposal includes certain preventive measures to ascertain identification, authenticity and traceability of medicines. Strengthening the controls of the distribution chain and the manufacturing standards will also help protect the integrity of the legal supply of authentic products. The proposal was made by the Commission in December 2008, and the UK consultation was also issued in December 2008. There was general support for the proposals made by the Commission and the MHRA. The MHRA plans to conduct a further public consultation on their detailed proposals.

24 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

In December 2008, the European Commission published the 'Pharmaceutical Package' which included proposals relating to information to patients. In May 2009, the MHRA held a consultation on these proposals and how they would apply in the UK. The UK responses to this consultation, and the UK government's response, were published in November 2009.

Overall, the majority of respondents agreed with the Commission's proposals and agreed with the UK government's proposals for a self-regulatory approach underpinned by national enforcement provisions. There was no support in the UK for establishing a new European body to approve information prior to dissemination. There was also overwhelming support for maintaining the current ban on direct-to-consumer advertising.

The ABPI Code has some information about providing information to patients. This effectively says that any such information must be clear, accurate and in line with the provisions of the product information. Such information must not be promotional or advertise any particular product.

The MHRA and ABPI have also issued some guidance about disease awareness campaigns, whereby pharmaceutical companies can provide further information for patients. However, such campaigns must again be clear, accurate and in line with the product information, and must not encourage patients to ask their medical professional for any particular product.

There has been some recent guidance aimed at how internet pharmacies supply medicinal products to the public, and what information must be provided about such products. This provides similar guidance as for the pharmaceutical industry.

25 Outline major developments to the regime relating to safety monitoring of medicines.

The European Commission's legislative proposals to strengthen and rationalise the EU systems for maintaining and taking action on any safety issues (known as pharmacovigilance) were published on 10 December 2008.

In summary, the Commission's proposals aim to:

- clarify roles and responsibilities for the parties involved in pharmacovigilance;
- accelerate EU decision-making on drug safety issues;

ARNOLD & PORTER (UK) LLP

Lincoln Tsang **lincoln.tsang@aporter.com**
Jeremy Willcocks **jeremy.willcocks@aporter.com**

Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6100
Fax: +44 20 7786 6299
www.arnoldporter.com

- increase levels of transparency and improving coordination of the communication of safety issues;
- improve oversight of companies' pharmacovigilance systems;
- increase proactive monitoring, including risk management;
- reduce duplicative reporting rules; and
- increase levels of direct patient reporting of adverse drug reactions.

The UK government has confirmed in a consultation document issued by the MHRA, that it broadly welcomes these proposals. The UK government's main policy objective for negotiations regarding this legal initiative is to ensure the UK can continue to provide a high level of public health protection while ensuring that EU pharmacovigilance is rationalised with a view to minimising any duplication of work. Responses and conclusions on this consultation have not yet been published.

GETTING THE DEAL THROUGH®

Annual volumes published on:

Air Transport
Anti-Corruption Regulation
Arbitration
Banking Regulation
Cartel Regulation
Climate Regulation
Construction
Copyright
Corporate Governance
Dispute Resolution
Dominance
e-Commerce
Electricity Regulation
Environment
Franchise
Gas Regulation
Insurance & Reinsurance
Intellectual Property & Antitrust
Labour & Employment
Life Sciences
Merger Control
Mergers & Acquisitions
Mining
Oil Regulation
Patents
Pharmaceutical Antitrust
Private Antitrust Litigation
Private Equity
Product Liability
Product Recall
Project Finance
Public Procurement
Real Estate
Restructuring & Insolvency
Securities Finance
Shipping
Tax on Inbound Investment
Telecoms and Media

For more information or to purchase books, please visit:
www.GettingTheDealThrough.com

ABA Section of International Law
Your Gateway to International Practice

Strategic research partners of the ABA International Section

THE QUEEN'S AWARDS FOR ENTERPRISE 2006

INTERNATIONAL BAR ASSOCIATION

The Official Research Partner of the International Bar Association

LIFE SCIENCES 2010 ISSN 2042-4329