Legal and regulatory update

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This section is intended to be a synopsis of recent legal developments and is not intended to be exhaustive. If any issue referred to in this section is to be relied upon, specific advice should be sought. Please contact:

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Legal and regulatory update

Regulatory

Consolidation and review of the regulatory framework for medicinal products

The Commission has presented an amended proposal for a European Parliament and Council Directive on the Community code relating to medicinal products for human use (COM (2000) 830 final, of 15th December, 2000). This replaces the proposal it presented on 28th June, 1999, codifying Council Directives 65/65/EEC, 75/318/EEC, 75/319/EEC, 89/342/EEC, 89/343/EEC, 89/381/EEC, 92/25/EEC, 92/26/EEC, 92/27/EEC, 92/28/EEC and 92/73/EEC. The new version is intended to effect pure codification without modifying the substance of the Directives being codified, and also to take account of further Commission Directives which have come into force in the mean time. The proposal would leave Regulation (EC) No 2309/93, under which the European Medicines Evaluation Agency (EMEA) and centralised procedure were established, unaffected.

The Commission also, on 22nd January, 2001, issued the final version of its discussion document on the review of Community pharmaceutical legislation. This short paper sets out the options for possible modifications both to the centralised and to the mutual recognition procedures. As to the former, the options are for various different ways of extending the scope of a procedure which is generally felt to have worked very well. As to the latter, the paper discusses various options for overcoming the criticisms levelled at this procedure, notwithstanding the improvements in it since 1998. The paper also discusses the approval of generic medicinal products and proposes that in future generic versions of products be authorised either centrally (where at present no generics can been authorised until 2005), or under the decentralised procedure, at the option of the applicant, whereas at present generics must be authorised under the same procedure and by the same authority that authorised the reference product. Another topic specifically addressed is veterinary medicinal products, as to which the need to encourage applications for authorisation to place products on the market for 'minor' species and/or indications is recognised, as well as the problems that arise from the need, in relation to such products for food-producing animals, to establish maximum residue limits for the active pharmaceutical substances concerned.

Meanwhile the 'Rules governing medicinal products in the European Community', which set out the 'fine detail' of medicinal products regulation, continue to undergo revision. Thus, following the revision to Volumes 2A (Procedures for Marketing Authorisation) issued on 25th October, 2000, concerning the mutual recognition procedure, a further revision to Volume 2A, and also one to Volume 2B (Presentation and Content of the Dossier), both of which form part of Volume 2 (Notice to Applicants) were issued on 17th January, 2001, and 9th January, 2001, respectively. The most recent revisions concern respectively the centralised procedure and the administrative data to be provided in the summary of the dossier.

Orphan medicinal products

The Committee for Orphan Medicinal Products has adopted and has published on 15th January, 2001, a revision to its internal rules of procedure as well as a paper setting out the general principles of the procedure for Orphan Medicinal Product Designation. By 18th January, 2001, the Committee had delivered 29 positive opinions, as a result of which 14 designations had been granted by then by the Commission, and one negative opinion.

The Pharmaceutical Industry Competitiveness Task Force – Final Report

The Pharmaceutical Industry Competitiveness Task Force, a joint initiative of the pharmaceutical industry in the UK and the UK Government, has published its Final Report dated March 2001. In addition to recommendations as to intellectual property protection (two aspects of which are discussed further below) it discusses developments in the UK market, and includes sections on the regulation of medicines licensing, clinical research, the science base and biopharmaceuticals, the wider economic environment, competitiveness and performance indicators, and sets out an agreed action plan.

Biocidal products

Regulations were laid before the UK Parliament on 16th March, 2001, on the placing on the market of biocidal products (such as disinfectants, preservatives, pest control and antifouling products, but not plant protection products). The Biocidal Products Regulations 2001 came into force on 6th April, 2001, and introduced a new regulatory scheme that will ultimately require all biocidal products to be authorised before they can be placed on the market. The new Regulations implement the Biocidal Products Directive (98/8/EC) which aims to harmonise the European market for biocidal products and their active substances. Biocidal products containing an active substance new to the European market after 14th May, 2000, must be authorised under the new Regulations before they can be placed on the market. Biocidal products containing an active substance which was marketed prior to this date may continue to be produced and sold subject to current national controls, until the active substance has been reviewed. The new Regulations will eventually replace the current controls in the UK on non-agricultural pesticides under the Control of Pesticides Regulations 1986. The evaluation of active substances will be carried out by individual Community member states, and it will be for industry to supply the data required. The final decision, as to whether an active substance can be used in biocidal products, will be made by the European Commission acting on the advice of a committee of representatives of all member states.

Product liability

On 26th March, 2001, the High Court in London gave judgment in *A & others -v- National Blood Authority & others* holding that the claimants, recipients of blood infected with the Hepatitis C virus, were entitled to expect that the blood and blood products transfused to them would be free from infection. Blood and blood products contaminated with the virus were accordingly defective within the meaning of Article 6 of the Product Liability Directive 1985 (implemented in the UK as section 3 Consumer Protection Act 1987). Under such a 'strict liability' regime there was no need to prove negligence. Here it was held that the defendants should have taken steps to reduce the risk of transmitting the virus in blood once the risk was appreciated and certainly earlier than they did, which was more than 18 months after the USA, Japan and several other European countries had introduced routine screening for the virus in all blood transfusions. Accordingly the defendants, as producers of a defective product, were liable to the claimants in damages. In the six test cases heard, damages were set at between £10,000 and £210,000, but over 100 other claimants will also be entitled to damages as a result of the decision. Moreover, the decision leaves the door open for further compensation to such claimants if their condition gets worse.

Competition law

The national UK competition authority, the Office of Fair Trading (OFT), has according to its press release issued on 30th March levied a fine of £3.2m on Napp

Pharmaceuticals, accusing it of charging excessive prices for sustained release morphine tablets to patients in the Community, while supplying hospitals at discount levels that blocked competitors. This is the first financial penalty to be set by the OFT under its powers under Chapter II of the Competition Act 1998, which came into force on 1st March, 2000, and parallels within the UK the European Community competition law regime established under the EC Treaty. The Chapter II prohibition in UK law is equivalent to that under Article 82 (formerly 86) of the EC Treaty, concerned with abuse of a dominant position. No further details other than those in the press release are available from the OFT at the time of writing, but the OFT states in this that it proposes to make a direction requiring the company to bring the infringements to an end, in particular by immediately reducing the price of the tablets to the community, and limiting the degree to which community prices can exceed hospital prices. The company is reported to be contesting the decision and the financial penalty through appeal proceedings.

Intellectual property

Parallel imports

The Pharmaceutical Industry Competitiveness Task Force (see above) has agreed in its Final Report that pharmaceuticals should not be included in any European Community moves to international exhaustion of trade marks and that there should be no moves to extend international exhaustion to patents.

The UK association of parallel importers, the British Association of European Pharmaceutical Distributors, has failed in its challenge to the modulation provisions of the revised Pharmaceutical Price Regulation Scheme (PPRS), in effect from 1st October, 1999. The PPRS is a voluntary, non-statutory scheme which indirectly controls the prices of branded prescription medicines to the NHS in the UK by regulating the profits that companies can make on these sales. The modulation provisions gave companies flexibility as to how they applied price cuts across their product range to achieve the negotiated one-off across-the-board price reduction of 4.5 per cent. In a judgment given on 14th March, 2001, in *R v Secretary of State for Health, ex parte (1) British Association of European Pharmaceutical Distributors (2) Dowelhurst Ltd & Association of the British Pharmaceutical Industry (Affected Party)* the Divisional Court held that such provisions were not contrary to Articles 28 or 81 of the EC Treaty by reason of their effect on parallel imports, which the applicants had alleged allowed discriminatory targeting against parallel importers. The applicants are expected to appeal the decision.

At the European Court of Justice, yet further cases concerning parallel imports, in addition to those discussed in the last issue (namely Case C-172/00 *Ferring v Eurim-Pharm*, Case C-443/99 *Merck, Sharpe & Dohme v Paranova* and Case C-143/00 *Glaxo & ors v Dowelhurst & anr*) continue to pile up. The new references are Case C-433/00 *Aventis Pharma Deutschland GmbH v Kohlpharma GmbH & MTK Pharma Vertriebs GmbH*, from Germany, concerning the opposition by a trade mark proprietor to the import of medicinal products after repackaging and reaffixing of the trade mark, and Case C-15/01 *Paranova Lakemedel & ors v Medical Products Agency*, from Sweden, and which raises similar issues as to the impact of regulatory constraints on parallel imports to those addressed in Case C-94/98 *R v MCA ex parte Rhone-Poulenc Rorer* in which the ECJ gave judgment on 16th December, 1999, and Case C-172/00 *Ferring v Eurim-Pharm*.

Supplementary protection certificates

A further reference has been made to the ECJ in the area of supplementary protection certificates (SPCs) in addition to those discussed in the last issue – Case C-258/99 *BASF* and Case C-127/00 *AB Hassle v Ratiopharm*. The new reference – Case 454/00 – *VIS Farmaceutici v Duphar International Research BV*, questions whether an SPC can

be used to prevent the manufacture of the active from which the medicinal product (the subject of the SPC) is formulated. The effect of this, if answered in the affirmative, would be that an SPC would be effective even where the active was to be exported and not formulated into the medicinal product the subject of the SPC for marketing in the country in which the SPC applied.

Regulatory data protection

The Pharmaceutical Industry Competitiveness Task Force (see above) has recommended in its Final Report that:

- a 10 year period of exclusivity harmonised across the European Community is appropriate for data supporting first applications to market new medicines in the Community;
- Community law should be clear so that a further period of exclusivity is available for data supporting changes to licences to include new indications for existing medicines;
- other data on safety and efficacy supporting amendments to licences should be given additional periods of exclusivity as for data justifying new indications;
- the concept of 'essential similarity' as defined in Council Directive 65/65 as amended needs clarification to ensure that it continues to assess risk to patient safety appropriately. Products where there is a significant change to the delivery mechanism or that utilise different salts, esters or other derivatives of an active substance should not be considered to be essentially similar;
- within the context of the same Directive the term 'is marketed' needs to be interpreted (if necessary, as a result of change in European law) to mean 'has been authorised' of abridged licences to copy products.

Of all the recommendations made in the section of the Report dealing with intellectual property these are the most specific.

Company/commercial law

Budget

7th March, 2001, Budget – Tax Alterations Enterprise Management Incentive (EMI) Scheme

The rules governing the EMI scheme will be amended to make it easier for companies to operate the EMI scheme. The amendments that will be made are as follows:

- the limit that options may only be granted to 15 key employees of the company will be removed (although the £100,000 limit per employee remains);
- options may be granted over a maximum of £3m worth of shares (rather than the effective limit of £1,500,000 under the previous rules);
- the time limit to notify the Inland Revenue of the grant of EMI options will be extended from 30 days to 92 days.

These changes will have effect from the date the Bill introducing the amendments receives Royal Assent (probably around June/July 2001).

Increasing innovation

In the Pre-Budget report the Chancellor stated that the Government would be looking at measures to boost investment in R&D. Last year the Government introduced new R&D tax measures aimed at small to medium enterprises, which provide such companies with an additional deduction for qualifying R&D expenditure.

The Government is now seeking views on a new tax incentive aimed at encouraging innovation by larger companies. A consultation paper has been issued alongside the Budget called 'Increasing Innovation' which outlines the issues that need to be considered in the design of an incremental R&D tax incentive. The paper sets out the Government's preference for an incremental R&D incentive, so that relief is focused on those companies that increase their R&D expenditure beyond current levels. The consultation paper may be

found at the Inland Revenue website[1] (views on issues raised are sought by 7th June, 2001).

The Government is also launching an independent study into the supply of highly skilled scientists and engineers in the UK to ensure that the mechanisms linking business and higher education work as effectively as possible. The study should be completed by February 2002.

Vaccines for killer diseases

The Chancellor has announced that there will be consultation with interested parties on the development of a new vaccines tax credit to stimulate research into the development of vaccines and drugs to combat malaria, TB and AIDS/HIV to be introduced in the Finance Bill 2002. The proposed relief will provide companies undertaking research into specified diseases with an extra 50 per cent relief on qualifying expenditure on top of existing relief for R&D expenditure.

Legislation

Consultation Paper (Department of Trade and Industry (DTI) – Steering Group) Modern Company Law for a Competitive Economy, Trading Disclosures – January 2001 (comments to be received by 12th April, 2001)

Background

The Company Law Review Steering Group has published a consultation paper dealing with the disclosure of a company's identity.

The Companies Act 1985 and the Business Names Act 1985 (BNA) contain a number of provisions dealing with company identification.

Summary

The Steering Group has invited views on a number of issues:

- Should companies be required to display their names at any premises other than their registered office and any service address?
- Should the requirement under the BNA that the company's name be in a prominent position (so that it may easily be read by any member of public) be adopted as the rule?
- Should a company that is trading under a name that is not its corporate name be required to display its service address alongside its corporate name? If so, at which premises and in which documents?
- Should the list of documents upon which a company's name must be included be updated? The Steering Group recommends that it should and considers that the requirements should apply regardless of the method of delivery so that, for example, electronic communications such as e-mails and website publications would be included.
- What should the fuller particulars that are currently required on business letters and order forms consist of and on which documents should they be required?
- Should there be a civil sanction under which legal proceedings brought by a company (to enforce a contract in relation to which the company is in breach of the trading disclosure requirements) may be dismissed by the court?
- Should the requirement for the company to disclose its name apply to any advertisement that is a direct attempt to persuade someone to enter into a contract?

Comment This consultation paper could potentially lead to an increased administrative cost to companies in order to ensure their compliance with any new corporate identity regulations that may come into force. In addition, the consultation paper appears to be aimed at providing more information to the public to allow them to identify the corporate identity behind any actions carried out by the company.

Financial Law Panel paper 'E-Commerce – Review of Legal Implications: Jurisdiction', January 2000

Background

The Financial Law Panel has published a paper assessing the impact of developments in e-commerce on private international law.

Summary

The paper recognises that traditional underlying assumptions of the existence of territorial boundaries may not be appropriate for regulation in respect of e-commerce because it is essentially borderless. It deals with Jurisdictional issues in relation to e-commerce disputes and the position under the 1968 Brussels Convention and 1980 Rome Convention, the need to amend existing rules relating to tort actions, particularly defamation, and infringement of intellectual property rights, the relevance of alternative dispute resolution schemes and trust marks in this area, regulation of the Internet, cybercrime, Internet banking, financial promotion and the Financial Services and Markets Act 2000.

The Companies Act 1985 (Electronic Communications) Order 2000

Background

After a period of consultation undertaken by the DTI, this Order was made pursuant to sections 8 and 9 of the Electronic Communications Act 2000 and came into force on 22nd December, 2000.

Summary

The Order modifies various provisions of the Companies Act 1985 (1985 Act) and related legislation such as the model articles of association in Table A. It enables companies to be incorporated by electronic means (subject to the publication of directions by the Registrar). It also enables companies and members to use electronic communications in place of existing provisions that require written documents. Companies may take advantage of the electronic communications regime regardless of any restrictions in their articles of association.

The Order covers the following matters:

- Incorporation. It will be possible to incorporate a company electronically following the establishment of necessary systems at companies house and the issue of directions by the Registrar.
- General meetings. The Order permits a shareholder or auditor to exercise his right to require that accounts and reports be laid before the company in general meeting (under section 253 of the 1985 Act) by means of electronic communication.
- Elective resolution. The Order permits a member of a private company which has elected by elective resolution under section 366A of the 1985 Act to dispense with the holding of annual general meetings (AGMs) to require by electronic means the holding of an AGM.
- Notices of meetings. The Order provides that notices of meetings (containing certain required details) may be sent to a member electronically to an address notified by the member. The amendments to Table A provide that proof that a notice contained in an electronic communication was sent in accordance with guidance issued by the Institute of Chartered Secretaries and Administrators' (ICSA) is conclusive evidence that the notice was given.
- Proxies. The Order provides that members may lodge an appointment of a proxy electronically where the company agrees and has provided an address. If the company's articles do not contain provisions relevant to the use of electronic proxies, the newly amended Table A provisions may be used.
- Statements. The Order provides for statutory declarations currently required by various provisions of the 1985 Act to be made by way of electronic statement instead, if desired.
- Accounts and annual reports. The Order amends sections 238 and 251 of the 1985 Act, allowing companies to send copies of

their annual accounts, directors' report, auditor's report and summary financial statements to members by electronic means rather than by post.
- Charges. The Order amends section 403 (entries of satisfaction and release) and section 419 (entries of satisfaction and relief) of the 1985 Act to allow statements relating to charges to be given by electronic communication instead of statutory declaration.
- Delivery to the Registrar. The Order adds a new section 707B to the 1985 Act which provides for the use of electronic communications for the delivery of documents to the Registrar.

ICSA best practice guide

The Institute of Chartered Secretaries and Administrators (ICSA) has published a guide supporting the Order. It gives companies and those who administer shareholder communications guidance on offering the facility to shareholders and maintaining an appropriate register, establishing records necessary for proof of sending, security, identification of audited materials on a website, electronic delivery of proxy forms, a specimen invitation to use electronic communications and recommended best practice covering many aspects of communications between a company and its shareholders.

Comment The Order together with the ICSA guide offer an opportunity for companies to revolutionise the way in which they communicate with their members, increasing the speed and efficiency of such communications. Before companies can take advantage of the new regime, they will need to put in place relevant computer and record-keeping systems.

Reference

1. URL: http://www.inlandrevenue.gov.uk/budget2001