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InFocus

Life sciences & healthcare legal e.bulletin



Taylor Wessing's Life Sciences & Healthcare team celebrate the 20th edition of InFocus

In the last four and a half years since our first issue in April 2004, we have commented on many of the most significant cases, legislative and regulatory changes affecting the life sciences and healthcare sector including the changes to the regulatory framework for medicinal products in Europe to which we dedicated an issue in November 2005; biosimilars; disclosure of origin in patent applications; pharming; medicines for children; the reform of the PPRS; the continuing debate over patents for biological inventions. In this issue we include comment from our guest author Ruprecht Hermans of Brinkhof on the recent reference by the Dutch court to the European Court of Justice on the scope of Article 9 of the Biotechnology Directive. We hope that you continue to find our quarterly updates useful and informative. In future editions this year we will comment on the long awaited EBA decision in WARF on the patentability of human embryonic stem cells. We discussed this case in our February 2007 issue. We are also planning a special issue on the new regulatory regime for advanced therapy products that applies from December this year.

In this issue we also include comment on

- the proposed changes to the regulation of medical devices
- the ABPI Code of Practice - 50 years on and still changing
- new laws on unfair commercial practices and how they will affect companies in the healthcare and life sciences sectors
- the grant of an interim injunction to Eli Lilly in the German Olanzapine patent litigation
- the European Commission's recommendations on private actions for breaches of anti-trust legislation
- how changes to UK tax laws are making it prudent for companies to reconsider their tax bases
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Due to recent changes to the UK tax regime and the uncertainty surrounding the wide ranging proposed changes to the taxation of foreign profits which were set out in a discussion paper published in July 2007, the UK tax regime is increasingly being seen as uncompetitive and overly complex. Many companies, Shire Pharmaceuticals among them, have decided to move their tax base out of the UK

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There will be a new regulatory regime in Europe for advanced therapy products from 30 December 2008. The detailed technical requirements and guidance notes are currently being prepared. The EMEA are seeking input from interested parties

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The Düsseldorf Court of Appeal has recently granted an interim injunction in a patent dispute where the patent in suit had previously been revoked by another German first instance court

[Cybrids and the new HFEA](#) [more](#)

It now looks like the new *Human Fertilisation and Embryology Act* may become law by the end of July. The new law will confirm the legality of research using cybrids and help maintain the UK's lead in this area of research

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Proposed changes to US patent examination practice have been delayed pending an appeal of the recent US court ruling that the new rules were substantive in nature and therefore exceeded the scope of the USPTO's rule making authority under US patent law

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As of July 5, all establishments within which the procurement, testing, distribution, processing and importing/exporting of tissues and cells for human application take place will need to be licensed by the Human Tissue Authority. This is a new requirement. Existing licenses may need to be extended

[Balancing freedom of information against a genuine need for confidentiality](#) [more](#)

The balance that needs to be struck between the public's desire to have free access to information and other parties' rights to keep certain information confidential was brought to our attention again recently, this time in the context of the sometimes emotive subject of animal testing

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A current UK High Court case looks at the use of social networking sites for business contacts and whether (if at all) that information then ceases to be confidential if it is online and shared

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The Commission's initial consultation on a recast of the European medical device directives has closed, but will no doubt be followed by more detailed proposals for reform in due course. However, the MHRA consultation on the implementation into UK law of changes to medical device regulation remains open until 15 August, giving members of the industry a further six weeks to comment on the UK implementation of *EU Directive 2007/47*

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Key features

The revised ABPI Code of Practice – The main changes [Back to contents](#)

The ABPI Code of Practice (the "**Code**") celebrates its 50th anniversary in October this year, having started life as a two page document on 2 October 1958. The event will be marked by "Code Awareness Week", an expanded version of the Code Awareness Day that has been run in the last couple of years. The Code has also been revised in its 50th year, with the new Code taking effect from 1 July 2008, although there is a transition period until 31 October 2008 during which time no promotional material or activity will be regarded as being in breach if it fails to comply solely as a result of new requirements introduced by this latest version of the Code.

Why the changes?

The principal reason for the amendments to the 2006 version of the Code is to ensure compliance with the new EFPIA "Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations" and a revised and updated version of EFPIA's Code on the Promotion of Prescription-Only Medicines. In addition, the amendments are being made to reflect the experience of operating under the 2006 Code and in response to suggestions from the MHRA, ABPI members and patient organisations.

What are the key changes?

The main changes required by the two EFPIA Codes relate to (i) relationships with patient organisations, (ii) relationships with healthcare professionals; and (iii) non-interventional studies.

Other changes provide clarification or reinforcement in a number of areas, such as representative call rates. There are also additions to the Code relating to samples, promotional quizzes and access to information designed for healthcare professionals on the internet.

EFPIA Codes

These provisions of the two EFPIA Codes were discussed in the February 2008 issue of InFocus. In summary:

- **Relationships with patient organisations** – the requirement to have in place a detailed written agreement with a patient organisation has now moved from the Code's supplementary information to become clause 23.3 of the Code. That clause sets out detail of what such agreements must include, such as the type of activity to be carried out by the parties and each of their roles. The Code states that no company may impose a requirement that it be the sole funder of a patient organisation or any of its major programmes, and that a company must not seek to influence the text of patient organisation material in a way that favours the company's own commercial interests, although it may correct factual errors. By no later than 31 March 2009, a company must make publicly available a list of all patient organisations to which it provides financial support or significant indirect or non-financial support. The list must include a short description of the nature of the support. Any sponsorship by the company must be acknowledged from the outset and "*must accurately reflect the nature of the company's involvement*".
- **Relationships with healthcare professionals** – a new clause (20) sets out the points for a company to consider when engaging a healthcare professional, as an advisory board member for example. The Code requires a written agreement to be in place and is aimed at ensuring that any consultancy arrangement is a genuine one.
- **Non-interventional studies** – a new clause (13) includes a definition of a "non-interventional study", which, in general terms, is a prospective study on a marketed medicine used in accordance with its marketing authorisation. The Code "encourages" companies to publish the results of such studies in the same manner as clinical trials.

Other changes

Some of the other material changes to the Code are discussed briefly below.

In relation to the briefing of sales representatives, companies are encouraged to distinguish clearly between "expected call rates" and "expected contact rates". The 2006 version of the Code states that a representative should "not normally" exceed, on average, three calls on a doctor in any year. An addition to the Code clarifies that certain forms of contacts between representatives and doctors will not be regarded as calls, such as contact at group meetings or

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visits in response to specific enquiries. Call rates have been the subject of a considerable number of complaints under the Code in the recent past. The addition of clarificatory wording is no doubt in part intended to address the concerns raised in those cases.

The provisions on the promotion of medicines that are not licensed in the UK at international meetings held in the UK have been made more stringent. The pre-1 July position was that the relevant medicine needed to be authorised in another major industrialised country (EU Member States, EFTA countries, USA, Canada, Australia, New Zealand, Japan, South Africa or Israel) and a significant proportion of the attendees of the meeting needed to be from outside the UK. There is now an additional condition that a significant proportion of the attendees are from countries outside the UK *in which the product is licensed*.

The Code sets out the circumstances in which samples of a medicine can be provided to a healthcare professional. A new provision now states that samples may not be provided of any medicine that has been on the UK market for more than 10 years.

The 2006 version of the Code contained a blanket prohibition on quizzes and competitions as methods of promotion. The new Code now includes a limited exception for the use of quizzes at promotion meetings, where the quiz is used to gauge the attendees' knowledge of the topic at the meeting. No prizes can be offered.

Where information on a company medicine for the general public is provided on a company website that also includes promotional material on the medicines for healthcare professionals, there is no requirement to restrict access to the healthcare professional material, provided that the target audience for each set of information is identified and the intended audience for the information is clear.

An amendment to the Code also clarifies that the provisions on frequency of promotional "mailings" to healthcare professionals (including the cap of eight mailings per year for a particular medicine) does not apply to emails. Promotional emails can only be sent with the prior consent of the recipient.

What should we be doing now?

The transitional period for the introduction of the new Code runs until 31 October 2008. This is not a particularly long time in which to review all promotional materials to ensure they comply with the new Code, and to consider whether arrangements with patient organisations and consultants are properly in place, so companies will need to move quickly to ensure that they are in compliance by the end of October. While many of the changes are clarificatory in nature (or permissive, such as the limited right to use a quiz at a promotional meeting), other changes, including those key ones driven by the EFPIA Codes, may require considerable resource to put in place in time.

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Waiting for justice: Consumer damages actions for breach of the antitrust rules

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Introduction

VLADIMIR: *Well? What do we do?*

ESTRAGON: *Don't let's do anything. It's safer.*

VLADIMIR: *Let's wait and see what he says.*

ESTRAGON: *Who?*

VLADIMIR: *Godot.*

ESTRAGON: *Good idea.*

(Samuel Beckett, Waiting for Godot, Act I)

Like Vladimir and Estragon, competition lawyers had been waiting a long time for the European Commission's views on private damages actions for breaches of competition law. Unlike Godot, however, the Commission's White Paper actually arrived in April this year.

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It has been clear for some time that the nascent private actions regime in competition law needs a clear sense of direction. For many companies under the scrutiny of competition regulators – for example, those involved in the vitamins cartels, the Commission's sector inquiry into the pharmaceuticals sector, or companies presently connected with the Office of Fair Trading's ("OFT") investigations into supermarkets – the problem is more acute, since they could be exposed to consumer damages claims if a regulator finds that an infringement has occurred. But does the future hold large scale consumer class actions in store or merely the general indifference of companies and consumers alike?

In the Commission's view, the White Paper, the latest stage in a process which began in 2003 to address the scarcity of private actions, is a tough but fair package of recommendations designed to ensure that victims of antitrust infringements are fully compensated for their losses, and to avoid the excesses of a US litigation culture. Indeed, in May the Chairman of the OFT appeared to endorse its reforms. However, on closer examination, the ordinary European consumer is likely to find that, where *Waiting For Godot* was famously described as a play in which nothing happens, twice, then the White Paper could be characterised as a series of recommendations where nothing happens, several times over.

The White Paper

For such a short document, the White Paper covers a lot of ground, dealing with: standing; access to evidence; the effect of national competition authority decisions; the fault requirement; damages; the passing on defence; limitation periods; costs; and interaction with leniency programmes. However, for anyone concerned about consumer class actions, it is the recommendations on collective redress, damages, and the passing on defence which are key to the effectiveness of the White Paper. Those recommendations speak directly to any potential claimant's fundamental cost benefit analysis: how much will I get if I win, and will it be worth all the effort?

Collective redress

Individual claims in competition law cases, especially where consumers are involved, can often be diffuse and relatively low value. In deciding whether to bring an action against an infringer, potential claimants have to weigh the considerable costs, delays, and risks involved in bringing a case against a potentially small reward.

One of the White Paper's solutions to the problem is to recommend so-called 'opt in' collective actions, where individuals can *expressly* decide to combine their claims into one action, reducing the cost and time burden on each individual and making the commencement of proceedings more likely. However, a major obstacle to bringing 'opt in' collective actions is that finding like-minded potential claimants and persuading them to contribute to the action can be a time consuming and costly exercise.

'Opt out' collective actions, not recommended by the Commission, remove that practical difficulty almost entirely. Commonly associated with US class actions, the opt out mechanism enables a single person to bring an action on behalf of a *class* of individuals, with those individuals not wishing to participate in the action able to opt out if they wish. The opt out mechanism is, as the Commission itself recognises, undoubtedly a more effective way of ensuring that consumer claims are encouraged. However, the Commission appeared particularly concerned that an opt out mechanism would be perceived as leading to excessive litigation. Why that perception is more important to the Commission than justice for consumers is unclear, but the practical effect of its preferred opt in mechanism is to place a significant obstacle in the path of consumer actions.

Damages

Since any potential claimant will need to devote time and resources to commencing proceedings he has to be reassured that, in the event he wins, it will have been worthwhile in terms of the eventual award. Again, in competition law cases, a particular problem arises because the loss is often highly dispersed and relatively low value.

In this area, the Commission faced two policy choices: to recommend that damages do no more than compensate a victim for his loss; or to introduce a punitive element to damages, to encourage claimants and augment the deterrence effect of a private actions regime. Confronted by the agony of that policy choice, the Commission averted its gaze, neither ruling out the possibility of punitive damages nor recommending them. It accepted that the risk/reward balance in antitrust damages litigation is skewed against bringing actions, and that it is necessary to address this by ensuring that there are sufficient incentives for victims of competition law infringements to bring claims. However, it then went on to avoid recommending punitive damages.

As with collective redress, the rationale was perplexing, but the practical effect of the Commission's recommendation is clear: alongside the 'opt in' mechanism, consumer claimants are being invited to devote their valuable and/or

scarce time to the recovery of often trivial sums in addition to foraging around for like minded individuals who are all interested in doing the same thing.

Passing on

The White Paper also clarified the Commission's position on the so-called 'passing on' defence which permits the infringer, where he is being sued by a 'direct purchaser' (e.g. a distributor rather than a consumer), to argue that any loss suffered by that direct purchaser had been passed on to purchasers further down the chain (e.g. retailers) in the form of higher costs.

The permissibility of the passing on defence had been a matter of some debate, and the Commission came down in its favour. By itself, this is relatively uncontroversial, however, combined with the recommendations on collective redress and damages, the result is that neither consumers nor larger companies are likely to bring claims against infringers. There would be little incentive for consumers, and a powerful deterrent for direct purchasers in the form of the passing on defence.

Conclusion

Clearly, the Commission's aim was to encourage full compensation for victims of antitrust infringements. However, driven by an instinct for paternalism and a distaste for a US culture of consumer empowerment, the recommendations seem likely to fail: they neither provide sufficient incentives to bring a claim, nor do they significantly reduce the burden of such action. Infringing companies may rest a little easier at the thought of consumer class actions. The overall effect of the White Paper is to substitute consumers for competition lawyers in the roles of Vladimir and Estragon: condemned to wait, perhaps endlessly, for the realistic possibility of seeking their own justice against infringers of competition law.

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ECJ to interpret Biotechnology Directive

Monsanto v Cefetra et al. (Court of The Hague 19 March 2008) [Back to contents](#)

In its decision rendered on 19 March 2008 the district court of The Hague (the Netherlands) referred questions to the European Court of Justice on the interpretation of Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ("Biotechnology Directive"). In particular the Dutch court wishes to know whether Article 9 of the Biotechnology Directive should be interpreted as extending the rights conferred by a patent covering a biotechnological invention, or, whether on the contrary it should be interpreted to limit the proprietor's right to prevent the exploitation of material containing the patented product (DNA sequence) on the condition that such product still performs its function.

Monsanto is the proprietor of a European patent in force in the Netherlands covering a DNA molecule comprising DNA encoding a kinetically efficient, glyphosate tolerant EPSP synthase. EPSP synthase is an enzyme found in plants and discovered to be in its natural form the basis for the effectiveness of Monsanto's successful herbicide Round-Up (glyphosate). The invention makes it possible to create transgenic plants containing the patented EPSP synthase. These plants are tolerant to Round-Up.

Monsanto commenced patent infringement proceedings in several European countries against companies importing soy meal from Argentina. The soy meal is produced from transgenic plants according to Monsanto's invention. Monsanto does not own a patent in Argentina. In its decision of 10 October 2007 the UK Patents Court held that Monsanto's patent was not infringed. The reason being that Monsanto in the UK voluntarily limited its patent to cover only "isolated" DNA and the court was of the opinion that therefore their patent did not include the imported soy meal. Although the soy meal still did contain the patented DNA, the DNA was not "separated from other molecular species in the form of a purified DNA fragment" and therefore not "isolated".

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The Dutch court in its decision agrees with the UK court in that it also finds that the DNA found in the soy meal can not be considered "isolated". The Dutch court, like the UK court, also rejected Monsanto's claim that the soy meal should be regarded as a product directly obtained by the process Monsanto had also claimed. The court considered:

"It can be accepted that the soy plant and soy bean have been directly obtained by the method. By means of the previously described crushing process, the beans are then separated, in a number of treatment stages, and worked into different components with a new identity. This process is too drastic to still assume a direct relationship between the method and the soy meal."

The court, on the basis of the reports submitted by the parties, comes to the conclusion that the imported soy meal contains significant portions of the DNA sequence covered by the original claim 6 (which was amended in the UK) of the patent. A "de minimis" defense that was raised was rejected. The court argues:

"In this situation, there is no reason to refuse Monsanto its patent rights, all the more as the DNA is present in the soy meal as a consequence of using the advantages provided by the patent. Possibly it would have to be judged that Monsanto can no longer invoke its patent rights against the trading in soy meal should the DNA present have to be regarded as a coincidental contamination, for example from a previous cargo. That this situation arises here however has not been stated nor has such otherwise been established."

The defendants raised a rather surprising defence. They argued that the scope of protection of the patent at hand is determined exclusively by article 53a of the Dutch Patent Act which implements the Biotechnology Directive in Dutch patent law. According to the defendants, Article 53a limits the scope of protection granted to patents on biological material to material that contains the patented DNA, provided it still performs its function.

Article 53a of the Dutch Patent Act is the implementation in Dutch law of Articles 8 and 9 of the Biotechnology Directive, that provide:

Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.
2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.

According to the decision, the defendants submitted a judgment of the Spanish court, where the court in a similar case had rejected Monsanto's infringement claim because the DNA present in the soy meal does not perform its function. In addition, they relied on an expert opinion arguing the same from Professor Dr. Dres. h.c. Joseph Strauss from the Max Planck Institute in Munich.

Monsanto presented among others the following arguments against the position of the defendants:

- a) Soy meal is not biological material in the sense of the Biotechnology Directive and therefore its implementation is not relevant;
- b) The extent of protection is subject to Article 53.1 of the Dutch Patent Act (comparable to 69.1 European Patent Convention). This article gives absolute protection to the product, in this case to the patented DNA sequence. A limitation of this protection would be contrary to TRIPS.
- c) If Articles 8 and 9 of the Biotechnology Directive are intended to limit the scope of protection, it would be sufficient if the DNA sequence has in the past performed its function.

The Dutch court rejected the first and last argument. It is not relevant whether the alleged infringing material, the soy meal, is biological material, but whether the patent is granted for biological material, which is the case. Moreover, the court did not agree with Monsanto that for the applicability of Article 53a.3 of the Dutch Patent Act (Article 9 of the Biotechnology Directive) it would be sufficient that the DNA present in the soy meal has at any time performed its function. Nonetheless the court decides also on this point to ask the European Court of Justice for its opinion.

As far as the question is concerned whether Article 53a.1, 2 and 3 (8 and 9 of the Biotechnology Directive) indeed limit the scope of protection granted by a patent claiming a DNA sequence, the court is of the opinion that it follows from a systematic application of the law that this is not the case. The article does not specify that it derogates from the general protection provided by Article 53.1 of the Dutch Patent Act.

The court looked at the intention of the Biotechnology Directive. It refers to the preamble subparagraph 8 that states:

"Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;"

The court comes to the conclusion that the Biotechnology Directive does not derogate from the protection granted by Article 53.1 of the Dutch patent Act. On the contrary, it intends to create a minimum protection. This also seems to follow from the wording of articles 8 and 9 of the Biotechnology Directive which use the words "shall extend to" instead of "shall be limited to".

Nonetheless, the Dutch court was of the opinion that the situation is sufficiently unclear to refer questions to the European Court of Justice.

It seems that the Dutch court, however, is correct in its opinion that Articles 8 and 9 cannot be interpreted as limiting the scope of (European) patents. Doing so would boil down to a so-called "a contrario" reasoning, as the Directive does indeed not contain wording that demonstrates that a limitation instead of an extension is intended. What the Directive seems to intend to clarify is that in the event a patented DNA sequence is reproduced in other plants or animals through means of biological reproduction, the patent owner can also prevent the use of these plants and animals, unless this plant or animal does not have the specific characteristics conferred by that sequence.

The European Patent Convention (EPC) also needs to be considered. The extent of protection of a European patent is determined by Article 69.1 of the EPC which should be interpreted the same in all contracting states. However, not all contracting states are subject to the Biotechnology Directive. If it therefore had been the intention of the Directive to limit the extent of protection, implementation of the Directive in the European Patent Convention should have led to a change of, or exception to, Article 69.1 for patents covering biotechnological inventions. However, the changes that were made to the Convention are limited to rules regarding patentability. This seems to demonstrate that the extent of protection has not changed and that, at least in the Dutch Courts, a patent covering a DNA sequence as such can be invoked against the use of any material wherein the DNA sequence is present, in the same manner as this is possible for chemical substances.

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Protecting foreign profits [Back to contents](#)

The announcement by Shire Pharmaceuticals ("Shire") that it will move its tax base from England to Ireland has given rise to a great deal of press coverage as it is the first blue chip company to move purely for tax reasons. United Business Media will also be following Shire in moving to Ireland and many other companies, such as GlaxoSmithKline and WPP have also threatened to move. The move from the UK does not involve any physical movement of Shire's assets from the UK; rather Shire is establishing a new holding company incorporated in Jersey but tax resident in Ireland.

The benefits of this structure are long term benefits which are principally benefits relating to non-UK business generated by these companies. As Shire is an acquisitive group which has significant operations outside the UK, it will benefit over the longer term from foreign profits being outside the UK tax net. Moreover, it relies extensively on intellectual property and generates licence fees and royalties worldwide. Due to recent changes to the tax regime (including those related to capital gains tax and taxation of persons not domiciled in the UK) and the uncertainty surrounding the wide ranging proposed changes to the taxation of foreign profits which were set out in a discussion paper published in July 2007, the UK tax regime is increasingly being seen as uncompetitive and overly complex.

So how did we get here? The past few years have seen offshore tax planning come under increasing scrutiny, both in the UK and internationally. Traditionally, UK companies have used offshore locations to benefit from tax arbitrage and favourable tax treatment on disposal of investments. Offshore companies have often been used to hold interests in foreign companies or assets (including intangibles) or as service providers to group companies. The key requirements for offshore entities is that they do not create incremental tax costs, that they benefit from tax exemption in respect of foreign income and that they also benefit from European Union directives and treaty networks.

European jurisdictions are endeavouring to attract foreign multinationals to set up holding companies in their territories and many now provide exemption from corporate tax on dividends from foreign subsidiaries, which is often accompanied by exemption from capital gains tax on the disposal of such foreign subsidiaries. Some European jurisdictions have even been introducing more beneficial regimes for the taxation of intellectual property.

At the same time, however, tax authorities are increasingly taking a harder line on avoidance and perceived profit shifting to offshore territories. This can be seen in the trend towards increased disclosure requirements for tax planning, international co-operation and the increased scope and application of rules relating to the transfer pricing of transactions between companies within multinational groups. Attention has also turned to holding companies which are used as effective conduits for interest, dividend or royalty income streams in order to minimise or eliminate withholding taxes that would otherwise apply on direct payments to the ultimate recipient of such income streams through the use of appropriate tax treaties (generally referred to as "treaty shopping").

In an attempt, therefore, to improve the UK's competitiveness as a jurisdiction for locating the holding companies of multinational groups and to reduce both the complexity of and the likelihood of challenge (under EU principles) to the existing foreign profits regime, a discussion paper was issued by HM Treasury on 21 June 2007 setting out widesweeping proposals for the reform of foreign profits. There has been a general recognition that the UK rules regarding foreign profits is in desperate need of change.

Under the current regime, UK companies receiving profits made offshore are taxable on those profits, whilst generally receiving a credit for any foreign taxes paid in respect of the profits. The discussion document proposes an exemption for large and medium sized companies from UK tax on dividends derived from foreign companies in which they hold at least a 10% stake. It is universally agreed that this change would be beneficial and would improve the UK's competitiveness as a holding company location.

However, the discussion document also indicates a hardening attitude of the UK Government to the use of offshore financing and to passive or "mobile" income generated offshore. The discussion document indicates that UK companies that borrow money from overseas subsidiaries may no longer obtain full relief for interest paid to those subsidiaries. There are also proposals to extend the operation of anti-avoidance rules regarding financing which could restrict the ability of UK companies to claim deductions for interest expense on financing arrangements.

For the life sciences sector, a major concern relates to the proposed changes to the controlled foreign companies ("CFC") rules. The current CFC rules are designed to prevent tax avoidance or deferral of profits generated in a foreign company controlled by a UK parent by attributing the foreign profits to the UK parent even if such profits have not been brought onshore. Where certain exemptions apply (including where profits are derived from offshore trading

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operations) or generally where tax avoidance has not been the motive for establishing the company offshore, the UK has not applied the CFC rules and has been content to accept deferral of UK tax until the profits are brought onshore as dividends.

The Government is, however, concerned that companies are developing IP in the UK but selling such IP offshore at an early stage such that profits from the exploitation of the IP remain outside the UK tax net until the offshore company distributes any such profits. Accordingly, under the new proposals, a UK tax charge would arise on income of "controlled companies" whether or not the "controlled company" repatriated the income to the UK parent. Rather than considering the offshore company itself, there would be a focus on "good" (trading type income) and "bad" (passive or mobile) income and capital gains, giving rise to a similar approach to the US Sub Part F regime. The reforms would provide a stricter regime in an area where HMRC has seen a significant amount of tax planning. Moreover, the proposals are burdensome from a compliance perspective.

A particular concern under the "controlled company" proposals is the possible apportionment to a UK parent of income arising in a foreign subsidiary from intellectual property held by the subsidiary. The discussion document does not confine the application of the rules to clear tax avoidance where there is a real diversion of profits from the UK. Furthermore, the impact on foreign countries' tax policy is also a real concern if the UK were to try to tax the worldwide intangibles of a UK headquartered group particularly where such intangibles are not closely associated with the UK. This would significantly diminish the UK's competitiveness and could also give rise to EC Treaty concerns. Public statements from the Treasury indicate that they are looking to address concerns relating to the scope of the proposals and have been holding discussions with the business community, but they are not prepared to say, on policy grounds, that any intangibles which have never had any connection with the UK should not be taxable in the UK.

Whilst it is encouraging that consultations on the proposals have been continuing, with proposed legislative changes possibly delayed until 2010, the uncertainty over the proposals is damaging confidence in the UK tax regime. Clearly, UK groups are taking this time to reflect on their existing foreign operations and to assess whether to take steps to effect a move offshore before the implementation of new rules.

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Criminal liability for unfair commercial practices after 26 May 2008 [Back to contents](#)

Consumer Protection from Unfair Trading Regulations 2008

Business Protection from Misleading Marketing Regulations 2008

- Criminal liability for unfair business-to-consumer commercial practices and misleading business-to-business advertising
- Maximum penalty of two years imprisonment and an unlimited fine

After 26 May 2008, traders face criminal sanctions if they engage in unfair commercial practices towards consumers or misleading advertising towards other businesses. The maximum sentence is an unlimited fine and/or up to two years' imprisonment. The directors and others involved can be found guilty. Enforcers also have the power to apply for civil injunctions.

Companies and other traders whose practices are already fair and not misleading, should have little to change. However, fairness in this context is a European concept focused on consumer protection. Given the new criminal sanctions, we recommend that companies and their staff familiarise themselves with the new Regulations.

Why is the new legislation important?

In general, the new law covers all commercial practices in relation to the sale or promotion of goods and services to consumers and all B2B advertising.

InFocus

There are two new laws:

- Consumer Protection from Unfair Trading Regulations 2008 ('CPUT') – these cover all B2C practices (not just advertising), and
- Business Protection from Misleading Marketing Regulations 2008 ('BPMM') – these deal with B2B advertising, including misleading and comparative advertising.

Generally, if a trader's goods or services are ultimately for consumers, the trader will be bound by the CPUT Regulations. The test is whether the trader's act or omission is "directly connected with the promotion, sale or supply of a product to or from consumers". If the trader's goods or services are only supplied on a business to business basis, then the BPMM Regulations apply.

Does this affect companies in the healthcare and life science sectors?

Yes. The new Regulations potentially affect all traders and businesses (including those online). Examples where the CPUT Regulations might apply include:

- The packaging of pharmaceutical products;
- Patient leaflets;
- Advertising, marketing and point of sale materials for consumers;
- After-sales service for consumers of their medical devices.

Examples where the BPMM Regulations might apply include:

- Advertising and marketing materials addressed to doctors, pharmacists and hospitals.

What does the new consumer protection law say?

All unfair commercial B2C practices are prohibited. There are five provisions:

1. **The general prohibition** against practices which contravene the requirements of professional diligence and are likely to distort the economic behaviour of the average consumer
2. **Misleading actions** - an action is misleading if, for example, it contains false information about certain matters, is likely to deceive or creates confusion and it is likely to cause the average consumer to take a transactional decision he would not otherwise have taken. It is interesting to note that this appears to overlap with passing off and yet a misleading action can be a criminal offence whereas passing off is not
3. **Misleading omissions** – this is where, taking account of all the circumstances:
 - (a) a commercial practice omits or hides material information, provides material information in a way which is unclear, unintelligible, ambiguous or untimely or fails to identify its commercial intent; and
 - (b) this causes, or is likely to cause, the average consumer to take a transactional decision he would not have taken otherwise.
4. **Aggressive practices** – this is a commercial practice which:
 - (a) significantly impairs, or is likely to significantly impair, the average consumer's freedom of choice or conduct through the use of harassment, coercion or undue influence; and
 - (b) this causes or is likely to cause the average consumer to take a transactional decision he would not have taken otherwise.
5. **The 31 blacklisted practices** – these are unlawful in all circumstances and include:
 - Displaying a trust mark, quality mark or equivalent without having obtained the necessary authorisation;
 - Claiming that a trader (including his commercial practice) or a product has been approved, endorsed or authorised by a public or private body when the trader, the commercial practices or the product have not, or making such a claim without complying with the terms of the approval, endorsement or authorisation;

InFocus

- Promoting a product similar to a product made by a particular manufacturer in such a way as deliberately to mislead the consumer into believing that the product is made by that same manufacturer when it is not (this could catch look-alike products);
- Falsely claiming that a product is able to cure illness, dysfunction or malformations.
- Describing a product as 'gratis', 'free', 'without charge' or similar if the consumer has to pay anything other than the unavoidable cost of responding to the commercial practice and collecting or paying for delivery of the item;
- Creating the false impression that after-sales service is available in an EEA State other than the one in which the product is sold;

What does the new business protection law say?

Misleading B2B advertising is prohibited. Comparative B2B advertising which does not satisfy certain conditions is also prohibited.

Who is the average consumer?

The CPUT Regulations apply to three types of average consumer:

- (a) one who is reasonably well informed, reasonably observant and circumspect;
- (b) an average member of a particular group to which a consumer practice is directed; and
- (c) an average member of a clearly identifiable group of consumers who are particularly vulnerable because of their mental or physical infirmity, age or credulity.

An example of the third type is blind people. Children could fall into the second and third types.

How to reduce the risk of a breach?

The onerous criminal sanctions for breaching the Regulations mean that traders would be wise to assess their commercial practices as soon as possible. Risks can be minimised if traders have a procedure to ensure that commercial practices are created and reviewed with the Regulations in mind. This may be a two-step process: education and internal checking procedures (if lacking).

Education

The new Regulations may be a catalyst for not only training staff and managers on the new law, but also ensuring that directors are aware of their potential criminal liability. We can present or help you organise appropriate training sessions.

Internal procedures and policies

An effective way to minimise risks is to have in place a formal checking procedure for commercial practices. We can help you establish this (if your company does not already have one). The procedure can include a form or checklist which must be completed by an in-house lawyer or director before any commercial practice is implemented.

Where can I find out more details about the new laws?

For more details click on [this link](#) or visit the Topical Issues section of the Taylor Wessing website and download the 22 May 2008 pdf document entitled "All change please!".

Timothy Pinto
London

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In brief

Advanced therapies – Have your say [Back to contents](#)

The Advanced Therapy Regulation (EU 394/2007) (the Regulation) was adopted on 30 December 2007 and will come into force across the EU on 30 December 2008. It will apply to Advanced Therapy Products¹, as defined in the Regulation after this date. The Regulation lays down provisions applicable to Advanced Therapy Products over and above those that apply pursuant to the current European medicinal regulatory regime² and also any legislation that applies to advanced therapy products which contain human tissue.

The Regulation provides the "bare bones" of the regime to regulate advanced therapy products and the detailed technical requirements are to be set out in guidelines that will be adopted by the European medicines agency (EMA). These guidelines are now being put in place. The first guideline relating to human cell-based products³ was adopted by the EMA 30 May 2008 and will come into force on 1 September 2008. This replaces the Points to Consider on the Manufacture and Quality Control of Human Somatic Cell Therapy Medicinal Products. This guidance note applies to all advanced therapy products that are cell-based except xenogenic cell-based products and provides further detail as regards the EMA's approach to the following areas as they relate to advanced therapy products:

- Risk management (including the factors that should be taken into account to construct specific risk management plans);
- Quality and manufacturing aspects;
- Non-clinical development; and
- Clinical development.

The EMA has also produced a further draft guidance note relating to Safety and Efficacy Follow-up – Risk Management of Advanced Therapy Products⁴. This guidance note is now open for consultation and interested parties should respond and provide their comments by 15 August 2008. Companies interested in commenting can contact [Gareth Morgan](#) of this office to provide assistance if required. This guidance note focuses on the unique issues affecting the pharmacovigilance and follow-up of advanced therapy products. The note will primarily affect two documents that are required to be produced during the approvals process, first the European risk management plan and also the detailed description of the pharmacovigilance system.

Gareth Morgan
London

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1 Gene therapy products, somatic cell therapy products and tissue engineered products

2 Primarily as set out in Directive 2001/83/EC (as amended)

3 EMA/CHMP/410869/2006

4 EMA/149995/2008

Turn in Olanzapine patent litigation: Eli Lilly obtains interim injunction in Germany

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The Düsseldorf Court of Appeal recently issued an interim injunction in favour of English pharmaceutical company Eli Lilly against German generics' manufacturer Stada. This decision has caused uproar in the patent community because the patent in dispute had previously been revoked in first instance proceedings with the Federal Patents Court (*Bundespatentgericht*). The Düsseldorf Court of Appeal's injunction prevents Stada offering for sale and selling drugs containing the agent "Olanzapine", as it is used in Eli Lilly's "Zyprexa", a drug for the treatment of schizophrenia and other dysfunctions of the central nervous system.

The Düsseldorf Court of Appeal in its decision overruled a first instance decision which had dismissed Eli Lilly's request for an interim injunction. The Düsseldorf District Court first refused to grant an interim injunction because Eli Lilly's Olanzapine patent had been revoked by the Federal Patents Court. The Federal Patents Court stated that the subject matter of Eli Lilly's patent was anticipated in a scientific essay; Eli Lilly appealed to the German federal Supreme Court (*Bundesgerichtshof*). According to the bifurcated system in place in Germany, two different and independent courts decide upon infringement and validity of a patent.

The Court of Appeal in granting the injunction regarded the revocation of the patent to be "obviously wrong". Although the judges in Düsseldorf stated explicitly that they respect the bifurcated system and the indicative effect of the Federal Patents Court's decisions on the validity of a patent, they made an exception in this particular case. According to the decision, a patent holder would lose any effective legal protection if a wrong judgement of the Federal Patents Court had to be followed although its flaws can "reliably be identified" by the litigation court which has enough experience to "assess the technical and infringement-related facts". Otherwise, Eli Lilly would face continued infringing activities until the expiry of its patent in September 2011 as a final and binding decision may not be issued in the revocation action before that date.

Dr. Christian Kau
Düsseldorf

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Cybrids and the new HFEA [Back to contents](#)

The new Human Fertilisation and Embryology Act (the Act) has now negotiated the floor of the House of Commons following two days' intensive debate and a free vote on the legislation within the House. The Act has now passed Committee Stage and is awaiting the Committee's report and the Third Reading in the House of Commons. If given royal assent in a speedy fashion, the Act could become law before the end of July.

There were several controversial provisions contained within the Act. The most relevant to life sciences companies was the ability of researchers to increase the availability of human embryonic material by working with cytoplasmic hybrid embryos (also known as "cybrids"). Such hybrid embryos are formed by transferring the nucleus from a human somatic cell into an enucleated animal egg cell. The resulting embryo contains an overwhelming majority of human DNA (the entire complement of the hybrid's nuclear DNA is of human origin) combined with a small minority of animal DNA (the small number of genes contained within the mitochondria of the animal egg cell). This technique would preserve the precious resource of human egg cells only for use *in vitro* fertilisation and experimentation designed to generate potential clinical grade, therapeutic embryonic stem cell lines, rather than in the creation of "research only" embryonic stem cell lines.

The Commons vote came as something of a relief both for the Human Fertilisation and Embryology Authority which has already granted research licences to research groups for projects to derive cytoplasmic hybrid embryos and also to the research groups themselves who have comfort that their work remains within the law in the UK¹.

¹ It should be noted, however, that these decisions of the HFEA to grant such licences has been challenged by judicial review

InFocus

The Prime Minister gave Labour Party MPs a free vote and set out the government's position in a letter delivered prior to the vote. The Prime Minister's position was that he was in favour of approving the Act in the form it was placed before the House of Commons. A key factor in winning the majority of MPs over was the communication of the great potential of this line of research and also that the UK has a lead over most other countries in this research area through creating a permissive, yet tightly regulated environment to encourage this research area whilst seeking to retain public confidence that the work is ethically justifiable. The clearance through the UK Parliament of this piece of legislation adds one further piece to the regulatory jigsaw in this area and gives researchers and companies the freedom to begin to generate the quantities of embryonic material needed to advance this field.

Gareth Morgan
London

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Changes to US patent examination practice [Back to contents](#)

New rules (the "**Rules**") concerning examination practices in the USPTO were due to have come into force at the beginning of November last year. However, the Rules were the subject of a complaint by GlaxoSmithKline against the Director of the USPTO, seeking an injunction against their implementation and a declaration that they were vague and outside the scope of the USPTO's powers.

The US Court has recently given summary judgment in favour of GSK, concluding that the Rules were substantive in nature and therefore exceeded the scope of the USPTO's rulemaking authority under US patent law.

The changes would have limited the number of claims that the USPTO would generally consider in a single application – five independent claims and 25 claims in total (the "**5/25 rule**"). It would be open to applicants to try to circumvent these limits but such measures would involve the expensive preparation of an analysis of the filed claims and the prior art by the applicant (an Examination Support Document, or **ESD**), or would require the filing of divisional applications.

The rule changes would also have required applicants to identify "related" patents and applications to determine the degree of similarity or overlap between them. The 5/25 rule would be applied to related applications as a group, so that applicants might have no choice but to prepare an ESD in order to maintain all the claims.

Finally, it was proposed that there should be a restriction on the number of continuation applications (by which improvements may be added to the claimed invention) that may be filed (the "**2+1 rule**").

The Court found that the 2+1 rule, the 5/25 rule and the ESD requirements constituted a drastic departure from the terms of the Patent Act as they were presently understood. In particular it noted that the Rules might prevent the examination of otherwise meritorious applications. As a result they manifestly changed the existing law and altered applicants' rights. Therefore they were substantive rules.

For patentees, particularly those who tend to file broad applications at an early stage, which are then refined through continuation applications in order better to specify the invention(s) as the development of a commercial product unfolds, the judgment is a welcome one. The USPTO appealed against the decision on 7 May, however, so the final outcome is some way off still.

Edward Vickers
London

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HTA licences now required [Back to contents](#)

As of July 5 this year, the Human Tissue Authority (HTA) requires all establishments within which the procurement, testing, distribution, processing and importing/exporting of tissues and cells for human application take place, to be licensed. This is a new requirement. The relevant legislation came into force in the UK on 5 July 2007 but a 12 month moratorium has been in place since this time while certain clarifications were sought from the Commission by the HTA. Even organisations that are currently licensed by the HTA for activities involving tissue and cells are being encouraged to contact the HTA in order to clarify whether or not their current licence extends to the acts described above.

The legislation that requires these licences to be put into place is the domestic regulations implementing the EU Tissues and Cells Directive. In the UK this is the *Human Tissue (Quality and Safety for Human Application) Regulations 2007* (the Regulations). It is fair to say that the Regulations have caused some confusion because the definition of procurement needed clarification; and the circumstances where establishments can operate under third party licences are also not entirely clear. The HTA wrote to the Chief Executives of all NHS Trusts and maternity units at the end of April setting out the definition of procurement:

"the processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation."

Further, the HTA stated in its April letter that its investigations over the year long moratorium had revealed that maternity units procuring cord blood and also hospital theatres procuring chondrocytes were not acting on behalf of third party licensed establishments and so needed a licence under the Regulations. Any procurement on behalf of third party licensed establishments also needs to conform to standards set out in the HTA's Directions 001/2006 and 002/2007. It should additionally be remembered that, with the exception of procurement and testing of tissue and cells, any of the above activities do not need a licence under the Regulations provided the activity is part of a process regulated by the UK medicines authority, the MHRA.

Given the time it has taken for compliance with this legislation to become mandatory, establishments would do well either to contact [Gareth Morgan](#) in our London office, or to contact the HTA direct if they have any doubts whether what they are undertaking amounts to an activity that requires a licence from the HTA. Following the July deadline, establishments will not be permitted to continue the above activities prior to their licence application being granted and the HTA estimates that a typical turn around time for a licence application under the Regulations is about three months.

Gareth Morgan
London

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Balancing freedom of information against a genuine need for confidentiality

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The recent High Court case *Secretary of State for the Home Office v British Union for the Abolition of Vivisection & Anor [2008] EWHC 892* again highlights the competing interests of those desiring complete openness and accessibility to information and those wishing to protective sensitive information.

This case concerned a request for information about licences granted by the Home Office for animal research.

In 2004 in an attempt to comply with the objectives of the Freedom of Information Act ("FOIA"), the head of the Animal Scientific Procedures Division at the Home Office, Dr. Richmond, implemented a policy whereby applicants for a project licence for animal research could provide an abstract of their licensed work to be displayed on the Home Office website and which could thus be freely accessible to the public. The British Union for the Abolition of Vivisection ("BUAV") then made a request under FOIA for the "actual information" in nine of such licences.

InFocus

Rather than providing redacted documentation, Dr Richmond chose to provide a narrative document containing all information he thought it appropriate to disclose. In doing so, he noted that further information had been provided but was exempt from disclosure by statutory provision.

The provisions in question were s44 FOIA and s24 Animals (Scientific Procedures) Act 1986 ("ASPA").

In the context of animal research, s24 ASPA deems it a criminal offence for any person to disclose information that has been given in confidence. Furthermore, s44 FOIA determines that information is exempt from disclosure if its disclosure is prohibited by any enactment. Dr Richmond interpreted these provisions together, understanding that some information in relation to the licences had been provided in confidence, thus its disclosure was exempted by s44 FOIA.

BUAV sought to challenge this interpretation and appealed to the Information Commissioner who upheld Dr. Richmond's decision. A further appeal was launched to the Information Tribunal who overturned that decision, on the basis that for information to be classed as having been given in confidence, it must be demonstrated that there would be an actionable breach of confidence if it were revealed.

In the High Court Eady J. disagreed with this interpretation, determining instead that in this context information provided in confidence is not limited to commercial secrets but could include a variety of private matters that the applicant legitimately wished to keep confidential. As to the apparent duplication in the legislation¹, Eady J. noted that s24 ASPA had been deliberately retained by the legislature, thus he could assume that there was an intention to provide additional or parallel protection to that provided by FOIA.

Notwithstanding this he noted that the special provisions of s24 ASPA were not in the spirit of the legislature's objective for greater public access to information. Furthermore, the system of publishing abstracts drafted by the applicants themselves would be objectionable to those seeking access to the information.

The Judge had considerable sympathy for BUAV's suggestions regarding the setting of criteria to clearly identify what categories of information a licence applicant could expect to be kept confidential. Although he agreed that such limits should not be defined by the applicants themselves, as in the current system, applicants should have the right for consultation in any process of setting the boundaries.

In conclusion, Eady J. was vocal in his support of an overhaul of the present system and the setting of clear and acceptable criteria for permitting the exclusion from disclosure of information provided in support of any such licence. Although his views alone are unlikely to be the driver of change it seems apparent that if further similar cases arise, the wheels of change will be set in motion and interested parties should be prepared to make their submissions.

For the foreseeable future however s24 ASPA still deems that information 'given in confidence' is not disclosable by the Home Office. If information provided and marked as such is accepted and unchallenged by the Home Office, the applicant has a legitimate interest in expecting that such information is not disclosed to any third party. To this end any information submitted in a licence application that is genuinely confidential should be clearly marked as such.

However, applicants need to be aware of the prospect of change and so watch this space..

Catherine Drew
London

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¹ s41 FOIA exempts from disclosure information the disclosure of which would constitute a breach of confidence.

Ex-employee ordered to disclose his LinkedIn contacts by High Court [Back to contents](#)

It has been recently reported that the High Court has ordered an ex-employee of the recruitment specialists Hays, to hand over business contacts built up on his personal page of the social networking site LinkedIn. The judge also ordered him to disclose all emails sent to, or received by, his LinkedIn account from Hays' computer network, all his documents including emails and invoices that showed any business obtained from the LinkedIn contacts.

Hays has alleged that Mark Ions used the LinkedIn network to approach clients for his own rival agency, set up three weeks before he resigned from his employer. However, Mr Ions argues that Hays encouraged the use of this site for work purposes and that once Hays' contacts accepted his invitation to join his network they were no longer confidential.

The High Court previously considered ownership of contact lists in *PennWell v Publishing (UK) Limited v Isles and others [2007] EWHC 1570 (QB)*, June 2007. Here it held that where a journalist, created and kept his contact list on the employer's computer system, that database or list of information belonged to the employer. This included personal contacts and business contacts which the employee had prior to joining the employer.

The current case is ongoing but highlights the tension between employer and employee over encouraging the use of social networking sites for business contacts and whether (if at all) that information then ceases to be confidential if it is online and shared.

Kathryn Clapp
London

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Regulatory review

Medical devices – All change? [Back to contents](#)

The MHRA, the UK regulatory body for medical devices, is currently consulting on the proposed Medical Devices (Amendment) Regulations 2008, which are designed to implement into UK law Directive 2007/47 (the "**Devices Amendment Directive**"). The Devices Amendment Directive amends the Active Implantable Devices Directive (90/385/EEC) and the Medical Devices Directive (93/43/EEC), but does not change the most recent of the three medical devices directives, the In Vitro Diagnostic Medical Devices Directive (98/79). The Devices Amendment Directive must be implemented into UK law by 21 December 2008, although it is proposed that the amendments will not take effect until 21 March 2010.

The European Commission launched a public consultation on a "recast" of the Medical Devices Directives (being the three original devices directives referred to in the paragraph above). The recast is designed, according to the Commission, to "*improve and strengthen* [the European medical devices framework] *and to meet the growing expectations of European citizens.*" The Commission will use the responses to the consultation to assess (i) the extent to which the three Medical Devices Directives can be improved, and (ii) the socio-economic impact of the changes envisaged. The consultation closed on 2 July 2008.

The MHRA consultation and the Devices Amendment Directive

What changes does the Devices Amendment Directive introduce?

The main changes introduced by the Devices Amendment Directive relate to:

- conformity assessment procedures;
- designation and control of Notified Bodies;
- classification of medical devices; and
- clinical evaluation of medical devices.

Of these, the most significant changes relate to the clinical evaluation of medical devices.

Clinical evaluation of medical devices

The new clinical evaluation regime is intended to address a number of issues with the old regime:

- differences between the Member State competent authorities as to their requirements for, and handling of, clinical evaluations (such as the amount of data required by a particular competent authority);
- differences between competent authorities as to the conclusions reached in relation to a particular device; and
- a lack of post market surveillance responsibilities.

The Devices Amendment Directive introduces a new definition of "clinical data", and all serious adverse events occurring during a clinical investigation will have to be reported to the relevant competent authorities of the Member State in which the clinical investigation is taking place.

Manufacturers of all classes of medical device will be required under the new regime to carry out a clinical evaluation in accordance with Annex X of the Medical Devices Directive, unless they can duly justify why this should not be the case. "Clinical evaluation" does not necessarily include a clinical investigation. There needs to be an *evaluation of clinical data*, which can be in the form of either:

- (a) a critical evaluation of relevant scientific literature relating to the safety, performance, design characteristics and intended purpose of the device, where (i) there is a demonstration of equivalence of the device in question to the device that is the subject of the data and (ii) the data adequately demonstrate compliance with the relevant essential requirements; or

InFocus

(b) a critical evaluation of all clinical investigations made; or

(c) a critical evaluation of combined clinical data from relevant scientific literature and all clinical investigations made.

In relation to Class III medical devices (the highest risk category) and implantable devices, the manufacturer must perform clinical investigations unless it can duly justify reliance on existing clinical data. There is no guidance at this stage as to what a manufacturer would need to do to "duly justify" not carrying out a clinical investigation, although it seems that this standard would be met where a manufacturer is able to provide a suitable critical evaluation to fall within (a) above.

In addition, manufacturers will be required to put in place post market clinical follow-up as part of a post market surveillance plan.

Measures to increase transparency

The Devices Amendment Directive also relaxes the confidentiality regime for medical devices, with the result that the following information will not be treated as confidential:

- information on certificates issued, amended or withdrawn by Notified Bodies;
- information on the registration of persons responsible for placing devices on the market; and
- information sent by manufacturers to users in relation to vigilance procedures.

What input is the MHRA seeking in the consultation?

In general terms, the MHRA has requested the views of manufacturers of medical devices and other interested parties on its proposals for implementation of the Devices Amendment Directive and the effects of implementation.

For example, in relation to the new provisions on clinical data and evaluation, the MHRA is seeking views on the costs and benefits arising from the new requirements.

The closing date for the consultation is 15 August 2008.

The European Commission Consultation

What are the main themes of the consultation?

The Commission consultation has four main themes:

- emerging weaknesses in the legislative framework for the regulation of medical devices;
- the regulation of new and emerging technologies;
- interplay with the global medical devices market; and
- increased simplification and harmonisation of the regime.

Weaknesses in the current framework

The consultation identifies a number of areas in which it suggests that the medical devices regulatory systems could offer better protection, including:

(a) **Notified Bodies** – Individual Member States are responsible for the designation and monitoring of Notified Bodies in their country. With nearly 80 Notified Bodies operating in the EU, the differences in the designation and monitoring regimes in different Member States coupled with a lack of transparency as to the performance of Notified Bodies gives rise, according to the Commission, to concerns that the level of assessment of the safety of medical devices is not consistent throughout the EU. One solution proposed by the Commission is a centralised system of designation and monitoring operated by a new EMEA committee on medical devices.

(b) **Vigilance** – According to the Commission, the EU has a low overall reported rate of medical device adverse events. The consultation document makes a number of proposals to improve the rate of reporting, including imposing a reporting obligation on medical institutions and healthcare professionals, requiring Notified Bodies to review manufacturers' vigilance systems, and making provision for EMEA to co-ordinate vigilance reports.

InFocus

(c) **Transparency** – The Commission suggests that there is a general lack of basic information available on medical devices, such as what medical devices are on the market. In the UK, for example, there is no register of authorised medical devices.

New and emerging technologies

The Commission suggests in the consultation that various new and emerging technologies have challenged the current regulatory framework, exposing gaps in regulation and the scarcity of expertise needed to assess those technologies. The consultation focuses on one technology in particular: devices that consist of, or incorporate, non-viable human cells and tissues. Such devices are not currently regulated at a European level, in contrast to viable human tissues, which are to be regulated under the Advanced Therapies Regulation (1394/2007).

Convergence with the global model

The Commission recognises that the medical devices market is becoming increasingly global, and is therefore seeking opinions as to the extent to which the European medical devices framework should reflect the model of the Global Harmonisation Task Force for Medical Devices (the GHTF, which has as its aim greater uniformity between national medical device regulatory systems).

Simplifying and harmonising the regime

With three principal directives, it is not surprising that the European medical devices regulatory regime has been criticised as fragmented and not user friendly. Adding to this, variations in national implementation, the Commission asks in the consultation whether the regulatory framework should be clarified and restructured as a directly-effective EC Regulation.

The consultation also examines a number of other issues, such as market surveillance and the possible strengthening of the evaluation procedures relating to high risk medical devices such as coronary stents and diagnostics to accompany advanced therapy medicinal products. The Commission is also considering taking steps to reduce counterfeiting of medical devices, by introducing traceability requirements into the essential requirements for devices.

What does this mean for the medical device industry?

The Commission consultation represents the very start of what will probably be a lengthy process of developing and implementing a materially different medical devices regulatory regime from that in place today. Given the likely timescale, the most immediate concern for the devices industry is the amendments introduced by Directive 2007/47. Medical device manufacturers should therefore consider responding to the MHRA consultation, and keep an eye out for the MHRA guidance on the changes that is due to be published at least three months before the new regulations come into force towards the end of 2008. Responses to the MHRA consultation are due by 15 August 2008.

The Commission consultation covers a wide range of issues that will surely be developed further on the basis of consultation responses.

Full details of the MHRA consultation are available at:

<http://www.mhra.gov.uk/Publications/Consultations/Deviceconsultations/CON017800>

A consolidated version of the *Medical Devices Directive (93/43/EEC)* is available at:

http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/cons_vers_93-42-eec.pdf

A consolidated version of the *Active Implantable Medical Devices Directive (90/385/EEC)* is available at:

http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/cons_vers_90-385-eec.pdf

Full details of the Commission consultation are available at:

http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm

Tim Worden
Cambridge

Environmental highlights

REACH Update [Back to contents](#)

The process of **pre-registration** under the EC Regulation for the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemical Substances¹ has now begun for those companies who deal in "phase-in" substances. So what are "phase-in" substances? These are either listed on the EINECS², substances manufactured in the EU or in countries acceding to the EU on 1 January 1995 or 1 May 2004 but not placed on the EU Market or substances called "no longer polymer". Essentially, pre-registration allows for a delay in the requirement to complete full registration. Pre-registration, however, must take place between 1 June and 1 December 2008 for companies to benefit from this staggered approach. A failure to pre-register a phase-in substance with the European Chemicals Agency before the deadline could lead to a manufacturer/importer being banned from trading until a full REACH dossier has been submitted, leading to costs and resource implications. It inevitably follows that failure to pre-register may also have implications for forward sales of "registrable" substances.

At a European level, the EC REACH Fees Regulation, setting out the structure and amounts of the fees and charges which are to be collected by the European Chemicals Agency, the regulatory body overseeing the regime, was published in the Official Journal of the European Communities on 16 April 2008³.

In terms of UK progress, the Government launched a public consultation on draft enforcement regulations on 2 June 2008, which builds upon existing regulatory regimes. UK enforcement provisions must be in place by 1 December 2008 pursuant to Article 126 of the REACH Regulation and it is envisaged that the enforcing authority should be the HSE⁴ in most circumstances, but in addition the Environment Agency, local authorities and the Secretary of State would also have a role to play. Current proposals are that the HSE will be responsible for taking enforcement action for non-compliance in respect of registration and the supply chain, but it will be the Environment Agency, who will enforce environmental breaches of the regime at installations subject to environmental controls. Breaches will be punishable on summary conviction in a Magistrates Court to a fine not exceeding £5,000 and/or three months' imprisonment. On indictment, the penalty will be an unlimited fine and/or two years' imprisonment. Further supplementary offences are also to be created for obstructing enforcing authorities, providing false statements and failing to provide information, which are to be punishable with the same penalties. It is anticipated that new regulations will be laid before Parliament by November 2008 following closure of the consultation on 25 August 2008.

A detailed Taylor Wessing briefing on the implications of the new REACH regime is available on request. Please contact the Environment and Planning Group: s.loken@taylorwessing.com

Waste Electronic and Electrical Equipment ("WEEE")

The WEEE Directive⁵, implemented in the UK by the **Waste Electronic and Electrical Equipment Regulations 2006** (as amended), aims to reduce the amount of WEEE being produced in the EU and its impact on the environment. The regime promotes reuse and recycling by requiring take-back schemes, designated collection facilities and authorising treatment and reprocessing facilities.

At a European level, as part of their general review, the EC are looking at options to amend the Directive by increasing targets for some or all of the ten categories of WEEE collected, reused and recycled, in addition to adding medical devices and extending the scope of the current legislation to cover more, and potentially all, electrical equipment. In addition, it is proposed to include those categories of WEEE that are currently excluded from the scope of the legislation (e.g. military equipment and large stationary industrial tools), to harmonise implementation of the Directive across Member States, expand the definition of "producer" to include distance selling, product labelling requirements and the setting of treatment technology and technique standards.

1 EC Regulation 1907/2006 – In force June 2007

2 European Inventory of Existing Chemicals

3 Commission Regulation 340/2008 on the Fees and Charges Payable to the European Chemicals Agency pursuant to Regulation 1907/2006/EC

4 Health and Safety Executive

5 EU Directives 2002/96/EC and 2003/108/EC

UK Implementation of the Batteries Directive

The Batteries Directive (as amended)⁶, which prohibits certain hazardous substances in batteries, prescribing treatment and recycling requirements for waste batteries came into force on 26 September 2006. The Directive, the aim of which is to reduce the negative impacts of batteries on the environment by prohibiting the marketing of some batteries containing hazardous substances, introduces new measures for the collection and recycling of batteries in line with specified targets, for all batteries, apart from those used in connection with national security.

In view of the fact that the Directive must be given UK effect by 26 September 2008, BERR⁷ recently launched a public consultation on new draft regulations to implement the technical requirements of the Directive. The draft proposals relate to the placing of new batteries and accumulators on the EU market and the design of certain battery powered appliances. The consultation, which follows on from a previous 2007 consultation on the wider aspects of UK implementation, also sets out draft provisions in respect of the composition and labelling of new batteries and accumulators.

Climate Change Bill – Update

The Bill, which contains provisions in order to set legally binding targets for reducing carbon dioxide emissions by 26% by 2020 and 60% by 2050, compared to 1990 levels, is currently making its way through the Parliamentary process.

On the 31 March 2008, the House of Lords proposed a new clause 80 "Guidance on Reporting" which will, if the Bill receives Royal Assent, require companies to report on their greenhouse gas emissions as part of their annual business reviews, thereby imposing a new and onerous obligation on a wide range of companies. At present, section 172 of the Companies Act 2006 prescribes a new duty for companies to promote the success of a company having regard to the environment. In addition, section 417 of the 2006 Act requires companies, apart from small companies, to produce a business review, forming part of the annual directors' report for financial periods and which must include details relating to environmental matters, but only to the extent that it is necessary for an understanding of the company's business.

Climate Change and Carbon Offsetting

The formation of the **International Carbon Reduction and Offset Alliance (ICROA)** was announced on 9 June. This newly established trade association brought together by leading companies in the voluntary carbon offset market (i.e. Carbon Clear, The Carbon Neutral Company, Climate Care etc.) will provide quality assurance and credible carbon management strategies, promoting standards that now exist in the voluntary market. The UK Government has previously announced a framework for a voluntary **Code of Best Practice for Carbon Offsetting**, which was initially to cover Certified Emission Reductions (CERs) compliant with the Kyoto Protocol.

Corporate Manslaughter

The new statutory offence of corporate manslaughter enshrined in the **Corporate Manslaughter and Homicide Act 2007** means that companies and other organisations may face criminal prosecution for manslaughter, thereby reinforcing the need for organisations to take account of health and safety issues. The new offence will apply to corporations, specified public bodies, public police forces and partnerships, trade unions and employers associations from 6 April 2008.

If an offence is committed in respect of the way in which activities are managed or organised, causing a persons death, and/or amounting to a gross breach of relevant duty of care owed to the deceased, the offence will be punishable by way of an unlimited fine in the event of conviction. The court will also have the power to use remedial orders requiring convicted organisations to remedy breaches of duty and publicity orders in order to compel organisations to publicise details of the conviction. Relevant harm must be sustained in the UK or other such specified place (e.g. a British Ship).

Brian Greenwood
*Partner and Head of Taylor Wessing's
Environmental and Planning Group*

Sherryl L'oken
Professional Research Lawyer

If you have any queries on the issues raised in this environmental briefing, or if you would like a fuller explanation of the topics, please contact a member of the Taylor Wessing Environment and Planning Group.

⁶ EU Directive 2006/66/EC on Batteries and Accumulators and waste Batteries and Accumulators
⁷ Department for Business Enterprise and Regulatory Reform

Life science and healthcare news and events

News from the LSH Group [Back to contents](#)

Taylor Wessing scoops TMT team of the year at The Lawyer Awards 2008.

Taylor Wessing won Technology, Media & Telecoms Team of the Year at The Lawyer Awards 2008, held at the Grosvenor House Hotel, London on 25 June.

The Taylor Wessing team won the award for the first GM-crops patent case ever litigated in the UK, after a gruelling three-week trial in the High Court. The firm's defence for Cargill against Monsanto Technology established an important precedent for DNA-based patent claims. The case prompted the first decision in the UK to clarify the scope of protection of claims in biotech patents for the creation of genetically modified organisms. With a number of parallel cases already underway on the patent elsewhere in Europe, the case could have international significance and determine the future of the GM crop industry.

The award comes on the back of a hugely successful and busy year for Taylor Wessing who as we reported in the last issue was also voted **European Life Sciences IP Firm of the Year** at the third annual Managing Intellectual Property Global Awards ceremony at Claridges Hotel, London on 9 April.

Richard Price, a partner in the winning team at Taylor Wessing, comments:

"We are delighted with this award, which recognises the market leading strength and breadth of expertise Taylor Wessing can provide not only with regard to Patents but across the spectrum of the technology, media and telecoms industry."

The Global IP Index

The Global IP Index presents a comprehensive statistical comparison of IP protection and enforcement in 22 of the world's leading economies, rating each jurisdiction for protecting and enforcing patents, trade marks and copyrights.

Based on an innovative analysis of surveys of senior industry figures globally and an array of published empirical data, the index provides a detailed assessment of the relative effectiveness of various jurisdictions for obtaining, exploiting, enforcing and attacking particular types of IP.

The Index has already received a significant amount of press coverage and we hope it goes on to stimulate the IP debate as it is updated to identify changes in people's perceptions and in other measures of competitiveness.

The report can be viewed online at www.taylorwessing.com/ipindex.

We would also like to invite you to participate in the survey, which remains live and can be accessed at www.global-ip-index.com - your views would be greatly appreciated and will feed into the next edition of the IP Index.

If you would like to provide any comments or feedback on any aspect of the Index, we would very much like to hear from you so please don't hesitate to contact us at ipindex@taylorwessing.com.

Implications of the new REACH regime

A detailed Taylor Wessing briefing on the implications of the new REACH regime is available on request. Please contact the Environment and Planning Group: s.loken@taylorwessing.com.

BioPartnering Europe

Members of Taylor Wessing's Life Sciences & Healthcare Group will be chairing a panel discussion session and hosting a workshop at BioPartnering Europe. BioPartnering Europe is being held in London on 12-14 October 2008. Further details are available at <http://www.techvision.com/bpe>.

Mark Your Calendars

Partner Daniel Pavin is speaking at the BIA non executive directors' seminar and dinner event organised by Taylor Wessing in London on 18th September 2008.

Partner Gareth Morgan and Dr Peter Feldschreiber are speaking at the Management Forum Conference [EU Drugs Regulations from Discovery to Marketing and Beyond](#) on 4th September 2008 at the Cavendish Hotel London.

Gareth Morgan is also speaking at the Informa Life sciences Conference [Legal and Regulatory Strategies for Lifecycle Management](#) on 15-16 October 2008 at the Hesperia London Victoria, London.

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Contacts

For further details on any of the topics discussed in this bulletin please contact the editors or your usual contact in the LSH group. If you would like to be taken off the recipient list, or add a colleague's name, please send an email to h.cline@taylorwessing.com. If you are asking to be taken off the recipient list please insert 'Unsubscribe' in the subject line.

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If you would like to receive a copy of our other newsletters please contact us on london@taylorwessing.com

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