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InFocus

Life sciences & healthcare legal e.bulletin



Introduction

This is the 19th issue of InFocus, Taylor Wessing's life sciences and healthcare e.bulletin.

Key issues discussed include:

- EU proposals to harmonise laws on provision of Information to patients
- A recent case which considers if "goods in transit" can infringe trade marks
- Reporting adverse events in clinical trials - MHRA recommends change in the law
- New laws on execution of documents
- User testing of PILs
- Standard clinical trials agreements in the UK, France and Germany
- The Patent Prosecution Highway initiative

In addition, the recent decisions of the District Court of The Hague in the cases of Ratiopharm/ Merck & Co, Inc. and MSD Manufacturing/ Ratiopharm et al are discussed by our guest authors Richard Ebbink and Mark van Gardingen of Brinkhof, Amsterdam who represented Ratiopharm, Sandoz, Centrafarm, and Apothecon in this case.

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Key features

Regulation of the supply of information on medicinal products to patients in Europe – harmonisation in 2008 [Back to contents](#)

The European Commission is carrying out a public consultation on its legal proposal relating to the provision of information on medicinal products to patients (the "Commission Consultation"). The key objectives of the proposed legislative changes are:

- to establish a framework for the provision of good-quality, objective, reliable and non-promotional information on prescription-only medicines to members of the public;
- to maintain the prohibition on the advertising of prescription-only medicines to consumers; and
- to avoid unnecessary bureaucracy in implementing the new framework.

The consultation closed on 7 April 2008. Contributions are expected to be made publicly available on the "Pharmaceuticals" website of the Directorate General Enterprise and Industry (http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm).

Why is the Commission proposing these changes?

Article 88a of Directive 2001/83/EC, which was introduced by Directive 2004/27/EC, required the Commission to report to the European Parliament and the Council during 2007 on the current practice on the provision of information to patients and its risks and benefits to patients. The report was required to look in particular at the use of the internet for the provision of such information. In addition to reporting, the Commission was required, if appropriate, to put forward an information strategy: "*to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability.*" (Article 88a, Directive 2001/83/EC).

The Commission's "Report on the Current Practice with regard to Provision of Information to Patients on Medicinal Products" was published on 20 December 2007, and concluded that, in summary:

- There is a lack of harmonisation among Member States as to the type of information on medicinal products available over the internet.
- Not only is there unequal access to information for patients and consumers in different Member States, but there are no EU quality standards for the information which is provided to patients and consumers.
- Some Member States disseminate information to patients through public bodies (such as the relevant regulatory authorities) and others do so through public private partnerships (often including a pharmaceutical company as part of the partnership).
- A lack of information to patients may lead to uninformed choices by those patients.
- An increase in quality and appropriateness of information available to patients "*would be expected to contribute to achieve better health conditions and also to contribute to a more efficient use of resources*".

A copy of the Commission's report is available at: http://ec.europa.eu/enterprise/pharmaceuticals.index_en.htm.

Key concepts of the proposed legislative changes

The Commission Consultation states that the fundamental objective of the legal proposal – which the Commission intends to propose to the European Parliament and Council by the end of 2008 – is to provide rules to harmonise the provision of medicinal product information to patients across Member States.

No change to the ban of advertising of prescription only medicines

Directive 2001/83 (as amended) provides a detailed, non-exhaustive definition of "advertising of medicinal products" and prohibits the advertising of prescription-only medicines to the public. The legal proposal will not, according to the Commission Consultation, amend the prohibition on advertising of prescription-only medicines to the public, but

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it will set out clear criteria for distinguishing between "advertising" and "information" relating to a product which is regarded as non-promotional and which can be provided to the public.

Information which can be provided to the public should be "compatible" with a product's Summary of Product Characteristics (SmPC) and Patient information Leaflet (PIL), and "*should not go beyond the key elements specified in them*".

The Commission Consultation also suggests that "*other limited medicine-relating information*" could be given, such as information about scientific studies.

Monitoring of the provision of information to the public

The Commission Consultation proposes that the approach to the monitoring of the provision of information to the public should depend on whether the relevant patient or consumer is passively receiving the information (a "push" by the information provider) or actively seeking the information (a "pull" by the patient):

- "Push" – information providers are to inform the relevant body (see below) about their activities before action is taken.
- "Soft pull" – where a patient has searched for information on a product and locates information provided by the relevant information provider, the provision of such information by the information provider (whether onto a website or verbally to a third party who then records that information and makes it available) should be notified to the relevant body, who will then monitor the information.
- "Pull" – where a patient or consumer asks a pharmaceutical company a question on a specific product, the relevant body should monitor compliance by following up any complaints it receives on the pharmaceutical company's response.

Quality of the information provided

Any information provided should be "*objective and unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information*". In particular, the Commission Consultation recommends that comparisons between medicinal products should not be permitted.

Monitoring body

The Commission Consultation proposes that each Member State sets up a "national co-regulatory body" which should adopt a code of conduct on the provision of information to patients, and monitor and follow up on relevant industry activities.

The national co-regulatory body should consist of public authorities and a mix of healthcare professionals, patient organisations and the pharmaceutical industry. The body's activities would be overseen by the relevant Member State's national competent authority, and an EU Advisory Committee would be available to give opinions on national codes of conduct and to settle any disputes between national co-regulatory bodies.

The Commission Consultation refers to two alternative options for monitoring: one where regulation is carried out directly by national medicines regulatory authorities, while the other has a self-regulatory basis.

Commentary

The Commission clearly recognises the increasing power of the internet as a tool for patients to inform themselves about their conditions and the range of treatments available to them. With this background, it seems prudent to introduce formal regulation of the provision of information on medicinal products to the public, so as to ensure that the public have access to consistent, reliable and relevant information throughout the EU.

However, there are a number of areas where the scope of the Commission legal proposal is as yet unclear:

- In relation to the "push" of information to patients, how much information will the information provider need to supply in advance to the relevant national body? Is it sufficient to notify the fact, and general terms, of the "push", or is the Commission in effect proposing a pre-vetting system whereby the exact material is reviewed and pre-approved by the relevant body? If it is the latter, this may represent a considerable delay for the information provider, and a significant administrative burden for the relevant body.

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- What level of guidance will the Commission provide on the distinction between "advertising" and the provision of non-promotional "information"? The Commission Consultation states that "*clear criteria should distinguish the information that is allowed from the information that is not allowed*".
- Will the Commission expressly permit the "push" of information through television and radio? These possibilities are referred to in the Commission Consultation, and can be expected to provoke strong views in the consultation process.

And what position will the UK Government take? While it will no doubt agree that it is good to try to ensure that the information available to patients is balanced, up-to-date and accurate so that the "informed patient" is a correctly informed patient, a better informed patient is more likely to have a view as to which branded prescription-only medicine they would like their doctor to prescribe, with obvious cost implications for the NHS.

Pharmaceutical companies should consider the published responses to the Commission Consultation and ensure that they track the Commission's legal proposal later this year. Although the implementation of the legislative changes is at least a couple of years off, the changes are likely to represent an opportunity for the industry, although both the scope of that opportunity, and the administrative burden attached to it, are not yet clear.

Tim Worden

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Carry On Freighting – *Eli Lilly v 8PM Chemist* [Back to contents](#)

With the growth of online pharmacies, it is increasingly possible for consumers in some countries to buy genuine but cheaper pharmaceutical goods from overseas suppliers. In a recent case, *Eli Lilly v 8PM Chemist*, the Court of Appeal considered whether a trade mark owner could stop such goods in transit through the UK on the basis of trade mark infringement. The Court decided that they could not, unless the goods had been put into free circulation in the UK.

Facts

The case concerned genuine Eli Lilly branded prescription drugs in respect of which Lilly owned UK and Community trade marks.

The Lilly drugs were ordered by US customers through a Canadian website, which placed the order with a Turkish supplier. The Turkish supplier packaged the genuine Lilly drugs, which bore Lilly's trade marks, in brown boxes and air freighted them to 8PM in the UK. 8PM posted the brown boxes in the UK to customers in the US without opening them. The Lilly trade marks were therefore never visible in the UK.

8PM carried out their activities in the UK under a Customs procedure called "Inward Processing Relief Suspension". This enables the processing of products in the UK without VAT or duty.

The judge had granted Lilly an interim injunction and 8PM appealed. The Court of Appeal was asked to consider whether 8PM's activities could amount to trade mark infringement.

The decision

The Court decided that the essential function of Lilly's trade marks (namely, to guarantee the identity of origin of the marked goods) was not jeopardised, as the marks were not visible in the Community.

The Court considered whether 8PM had imported and/or exported goods bearing its trade marks (under s.10(4)(c) Trade Marks Act 1994). In order to have infringed, 8PM must have been using Lilly's marks "in the course of trade".

Following the ECJ's decision in *Class International v Colgate Palmolive* (C-405/03 [2005] ECR I-8735), the Court held that 8PM had not infringed. Even though the goods were physically present in the Community, they were not released into free circulation and so had not become Community goods. Lilly's right of first marketing in the Community was therefore not affected. The goods were not being used "in the course of trade" and so were not imported or

exported for the purposes of European trade mark law. The injunction against 8PM was discharged.

What effect does this case have on goods in transit?

This case makes it clear that goods in transit bearing UK or Community trade marks, which are brought into the UK from outside the Community, will not infringe those trade marks unless the goods are subsequently put onto the market in the UK.

While this may seem unfair from the trade mark owner's point of view, the decision appears to be a sound application of *Class International*. The goods in transit were not put on the market and did not limit the trade mark owner's right of first marketing in the Community, and consequently there was no infringement in the UK.

Mark Dennis

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The Patent Prosecution Highway - streamlining patent prosecution and reducing costs [Back to contents](#)

In the global economy many companies and some individual applicants have an increased need to acquire patent protection for the same invention in a variety of different countries. This often requires separate patent applications to many different national intellectual property offices, each considering the patent application independently of the others.

The Patent Prosecution Highway (PPH) is a set of initiatives for providing accelerated patent prosecution procedures by sharing information between participating patent offices. Participating patent offices benefit from and exploit relevant work previously done by another participating patent office with the goal of reducing examination workload, avoiding duplication of effort, improving patent quality and speeding up the patent prosecution process. Details of the existing and proposed PPH projects can be found in Table 1.

The Patent Prosecution Highway allows patent applicants who have received an examination report from one of the participating national intellectual property offices, which finds that at least one claim in the application is patentable, to request accelerated examination of a corresponding patent application filed in another participating country. Patent applicants are required to submit search and examination reports prepared by the other patent office in order to qualify for accelerated treatment.

In the UK the development of work sharing arrangements between the UK Intellectual Property Office (UK-IPO) and other national patent offices is a key recommendation of the Gowers Review of Intellectual Property. This led to PPH pilot agreements being signed with the Japanese Patent Office (JPO) in July 2007 and the US Patent and Trade Mark Office (USPTO) in September 2007. The pilot agreements were initially signed for one year and it was anticipated that they would build upon the initial success of the PPH piloted by the USPTO and the JPO. In March this year the UKIPO announced that the initial PPH project has been a success and that the scope of the PPH pilot agreements with the USPTO and the JPO is to be extended.

To date, the PPH pilot at the UK-IPO has only considered requests for accelerated examination relating to applications that were initially filed and examined at either the JPO or the USPTO. The UKIPO in its announcement in March has said that the pilot scheme is now being extended to cover examination reports issued by the JPO and USPTO that arise from an international application.

Under the new extended procedure, once the international application has been examined at either the JPO or the USPTO the applicant will be able to request accelerated examination at the UK-IPO. The agreement also allows accelerated examination at the JPO and the USPTO when the UK-IPO conducts an examination of an international application before it is examined at the JPO or USPTO.

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The European Patent Office (EPO) has also recently announced that, as part of its existing (since 1983) trilateral cooperation arrangement with the USPTO and the JPO, it will participate in a pilot PPH scheme with the USPTO. This follows the announcement in January 2008 of the permanent implementation of the PPH between the JPO and the USPTO. The USPTO and JPO PPH had been piloted since July 2006. Up to now the EPO has resisted participating in the PPH project on account of concerns that its reputation for patent quality might be compromised.

The EPO and the USPTO have agreed to conduct a bilateral, PPH comparable pilot program, in which European applicants can participate on the basis of an EPO Extended European Search report. The pilot scheme is scheduled to start in September 2008. The details of the scheme have yet to be announced. The JPO is also considering participating in a scheme with the EPO.

Table 1: PPH Projects (March 2008)

Participating Patent Offices	Status of Project
CIPO - USPTO	This pilot program commenced on January 28, 2008, for a period of one year ending on January 28, 2009
JPO - USPTO	The pilot program started in July 2006. The trial period was originally scheduled to last for one year, until July 3, 2007, but was extended until January 3, 2008. The program has been implemented on a full-time basis since January 4, 2008
JPO - KIPO	The pilot program started in April 2007
JPO - UK-IPO	The pilot program started on July 1, 2007 and is scheduled to last one year. Its scope was extended to cover international applications in March 2008
JPO - GPTO	A pilot program will be implemented in March 2008
KIPO - USPTO	The pilot program began on January 28, 2008, for a period of one year ending on January 28, 2009
UK-IPO - USPTO	The pilot program started on 4 September 2007, and is scheduled to last one year. Its scope was extended to cover international applications in March 2008
EPO -USPTO	The pilot program is scheduled for implementation in September 2008

Helen Cline

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In brief

Gillette "squeeze" used by Dutch courts to clear the way for Ratiopharm [Back to contents](#)

Decisions of the District Court of The Hague of 13 February 2008 in the cases of: *Ratiopharm / Merck & Co, Inc.* (docket number 2007/1682) and *MSD Manufacturing / Ratiopharm et al.* (docket number 2007/1689)

On February 13, 2008, the District Court of The Hague nullified the Dutch part of a European patent held by Merck & Co, Inc for alendronate used in the treatment of osteoporosis (divisional patent EP 1 175 904 for a 70 mg once weekly dosage regime).

The Dutch court also, for the first time in Europe, we believe, granted a declaratory judgment that tablets containing 70 mg of *generic* alendronate, intended for use once weekly to treat osteoporosis, were obvious to the skilled man on the priority date of the 904 patent, thereby in effect granting a (what the court qualified as a "Gillette like") declaration of non-infringement under any other pending or future divisional patents based on the same priority filing.

The Dutch court referred to the decision of Mr Justice Kitchin on 31 July 2007 in a parallel case in the High Court of England and Wales. This decision accepted the same reasoning but, because of a settlement for the UK, did not have to go into the merits.

Richard Ebbink and Mark van Gardingen Brinkhof, Amsterdam

Our guest authors, Richard Ebbink (richard.ebbink@brinkhof.com) and Mark van Gardingen (mark.vangardingen@brinkhof.com) of Brinkhof, Amsterdam (www.brinkhof.com) represented Ratiopharm, Sandoz, Centrafarm, and Apothecon in this case. The authors have available a more detailed summary of the case. Please email them if you would like a copy.

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India considers whether to grant a compulsory licence for export under TRIPs [Back to contents](#)

Natco, a small Indian drug manufacturer, has applied for a compulsory licence to supply two anti-cancer drugs to Nepal under section 92A of the Indian Patents Act 2005. This section implements the proposed article 31bis of the Trade-related aspects of Intellectual Property rights (TRIPS) Agreement allowing compulsory licences to be granted for export. Natco's application follows Apotex's successful application for an export licence in Canada to supply HIV/AIDS therapies to Rwanda in September 2007.

Natco made its application for compulsory licences to export erlotinib (Roche) and sunitinib (Pfizer) in September 2007 but despite this has not been awarded a compulsory licence yet. One of the main sticking points is whether the patentee has a right to be heard in the application. Natco argues that under section 92A there is no right for the patentee to be heard although reports suggest that the Patent Office is likely to allow the patentees to be heard under the principles of natural justice. The parties made oral submissions on 19 March 2008, which were to be followed by written submissions seven days later. There is no decision as yet.

Once this preliminary issue has been resolved, the case will be decided on its merits. Section 92A requires only that the application is in order and that an order has been received from a foreign government with a need for the drug and a lack of manufacturing capability. There is a suggestion that the letter from the Nepalese government does not make any explicit reference to a national emergency or a lack of manufacturing capability and that this might be a problem with Natco's application. Nepal is on the UN's list of Least Developed Countries so the latter is unlikely to be a problem. The Patent Office's decision will clarify whether the letter is sufficient for the purposes of section 92A.

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It is interesting that some of the requirements of Article 31bis do not appear to be included expressly in section 92A, such as the need for Nepal to notify the WTO (which Nepal does not appear to have done) and the need to negotiate with the patentee prior to applying for the licence. It is, of course, possible that the section will be interpreted in line with Article 31bis to include these requirements and, if it is, Natco's application seems certain to fail.

In any event, it will be significant whether the Indian Patent Office grants a licence to Natco to supply Nepal's needs or not. It is also interesting that these provisions have been used again so soon after the first licence was granted to Apotex in Canada.

Matthew Royle

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MHRA investigation into GSK's reporting of adverse events in Seroxat paediatric clinical trials

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On 6 March, the MHRA published its report into GSK's alleged failure to report in a timely manner to the MHRA certain adverse event data from clinical trials in children of its anti-depressant, Seroxat (paroxetine). Certain data from those trials, a pooled analysis from all paediatric trials of Seroxat, suggested a causal association between the anti-depressant and an increased risk of suicidal behaviour. The MHRA's report concluded that there was insufficient evidence to provide a realistic prospect of a criminal conviction for the alleged breach of pharmacovigilance legislation by GSK, and that there was, at the time of the alleged offences, a "significant gap in the law governing drug safety".

Between April 1994 and January 2002, GSK carried out a number of clinical trials on the use of Seroxat in children and adolescents, a patient population for which the medicine was not approved. Of those trials, only one was conducted (in part only) in the UK. During that time, EU legislation only required the reporting of adverse reactions to a medicine under "normal conditions of use" (i.e. within the medicine's approved indication(s)). Relevant UK legislation at the time, the Medicines Act 1968, did require the reporting of adverse events during clinical trials, but a failure to do so was not a criminal offence. The reporting obligation applied only to trials carried out wholly or partly in the UK. According to the MHRA report, the pooled analysis was only submitted by GSK to the MHRA in May 2003 in connection with GSK's proposed application for the authorisation of Seroxat for use in children.

Although current EU legislation provides that it is a criminal offence to fail to report adverse events in all clinical trials, it does not apply to clinical trials outside the EU. The legislation clarifies that there is an obligation to report relevant safety information arising from clinical trials outside normal conditions of use. However, the MHRA report concludes that the legislation should be clarified further to ensure that there is an obligation to report regardless of the source of the clinical trial, and that the timescale for reporting is clear. Although the EU is currently consulting on a strengthening of drug safety monitoring, the MHRA recommends that UK legislation should be amended in the interim.

A copy of the MHRA report can be found at:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON014153>

Tim Worden

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Patient Information Leaflets and user testing Legislation [Back to contents](#)

All medicines are required by European and UK Law to be accompanied by a Patient Information Leaflet (PIL). European Law dictates the content of PILs and the Member State regulatory Agencies enforce this. By 1 July 2008, to improve quality, the PILs of all medicines marketed in the European Union must have been tested on potential patients.

User testing

To comply with requirements set out in European Law PILs for all medicinal products granted a marketing authorisation (MA) after 30 October 2005 have had to “reflect the results of consultations with patient groups to ensure that [the leaflet] is legible, clear and easy to use”. The results of these assessments are provided to the competent authority, in the UK the MHRA.

A transitional period was given until 1 July 2008 for existing MA holders to review and/or revise their PILs and carry out user testing on sample patient groups. By 1 July 2008 it is a legal requirement that all medicines on the market in European Union must have PILs that have been user tested.

The reason for user testing is to help produce a PIL that most users of a medicine can use to take safe and accurate decisions about their medicine.

In its guidance on the user testing of PILs, the Medicines, Health and Regulatory Authority (MHRA) in the UK have said that they will not require that any particular method of testing is used. The MHRA has said it will look for evidence that those likely to rely on the PIL can find and appropriately use the information.

Non-marketed products

There is no requirement to user test the PIL of products that will not be marketed on 1 July 2008. However, if marketing is recommenced, then the MA of these products will need to be updated.

Bridging to nationally authorised leaflets tested in different Member State

It is possible where a MA holder has identical products licensed in another Member State and the PIL has been the subject of user testing in the language of that Member State to use the user testing data for the UK PIL. The user testing data will of course have to be translated into English.

What happens if MAs do not comply on 1 July

In the UK the MHRA recommended that all existing MA holders submit their new PIL and user testing data by 31 December to ensure they meet the deadline. If you missed this deadline the MHRA is recommending that you notify the Patient Information Quality Unit (PIQ) of the MAs affected.

The MHRA guidance on user testing is available at [link](#)

To share best practice the MHRA have on their website a selection of [“user tested” PILs](#)

Helen Cline

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Company execution clauses - 6 April 2008 changes [Back to contents](#)

The Companies Act 2006 (section 44) introduces an additional, simpler method for companies to execute deeds.

As previously allowed for, a deed will still be validly executed by using the company's common seal or, if it is signed on behalf of the company, by either two directors, or one director and a secretary (or joint-secretary). However, from 6 April 2008, a deed will be validly executed if it is signed by a single director in the presence of a witness (who attests the signature). It is understood that the provisions relating to foreign companies will not change.

This will give companies increased flexibility when deeds are to be signed, and could be very useful in situations where there are time demands and there is only one director immediately available to sign.

When is a deed required?

A deed is required for any transaction where there is no consideration given by the party receiving the benefit and is also a statutory requirement for certain documents. Some common examples of deeds include:

- The grant of a power of attorney
- The release or discharge of a debt
- The conveyance of land or transfer or creation of any interest in land (including a mortgage or charge)
- Any mortgage or charge if it is to confer the statutory powers of sale, insurance and appointment of a receiver
- The sale by a mortgagee or chargee under the statutory power of sale if the sale is to overreach subsequent mortgages and charges

What you should do next?

We suggest that companies review any internal procedures regarding signing authorities, to take into account the new arrangement whereby a deed will be able to be signed by only one director. We also suggest that companies check that their articles of association do not prevent deeds being executed in this way and do not provide any restrictions.

William Stuart-Lee

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Regulatory review

"Standard" Clinical Trials Agreements – a summary comparison of the positions in the UK, France and Germany [Back to contents](#)

Putting in place a watertight contract is an essential part of any clinical trial set up for sponsors, trials sites and clinical research organisations alike. The negotiation of such agreements can take some time, causing a delay in starting the trial and, ultimately, in getting a new medicine to the market. "Standard form" agreements should mean that the process is streamlined, and that less time is lost in negotiating the contract.

The table below gives an overview of the standard form arrangements in place in each of the UK, France and Germany, and also outlines the most common areas of negotiation for clinical trials agreements. A full-length article on this will appear in the next edition of InFocus.

	UK	France	Germany
Are there any "standard form" clinical trials agreements?	<p>Yes, there are two.</p> <p>The first is an agreement between the sponsor of the trial and the NHS Trust at which the trial is to take place. This "model Clinical Trial Agreement", or "mCTA", is published by the ABPI, BIA and Department of Health. It was first released in 2003, and was updated and revised in 2006.</p> <p>The second is an agreement between the sponsor of the trial, the NHS Trust at which the trial is to take place, and the contract research organisation engaged by the sponsor. Known as the "CRO mCTA", it was first published in 2007 by the ABPI, BIA and Department of Health.</p>	<p>Yes, public hospitals use a standard form clinical trial agreement when acting as a trial site.</p>	<p>No, there are no widely accepted "standard form" clinical trials agreements in Germany. Most sponsors have their own standard agreements which they negotiate with each trial site.</p>
Is their use compulsory?	<p>No, although their use in unamended form is strongly endorsed by the NHS, the UK Government and industry.</p>	<p>No. Although public hospitals commonly use a standard form agreement, such agreements are not endorsed by the government or industry, and their use is not mandatory.</p>	<p>As noted above, there are no standard form agreements.</p>

	UK	France	Germany
If used, are the terms of such agreements open to negotiation?	Yes, although as noted above, their use in unamended form is strongly encouraged in order to help realise one of the key aims of the standard agreements: to reduce the time taken to set up trial sites and thereby increase the competitiveness of the UK as a venue for clinical trials.	Yes, the terms are open to negotiation. Sponsors generally regard the standard clinical trial agreements used by public hospitals as inadequate. As a result, such agreements are systematically renegotiated.	Sponsors will negotiate the terms of their own standard agreements with each clinical trial site.
What are the most commonly negotiated areas in clinical trial agreements?	The points of negotiation vary according to a range of factors, such as the precise nature of the trial and the sponsor's internal governance rules and SOPs. However, in general terms, the most commonly negotiated areas appear to be the provisions relating to intellectual property arising from the trial, and caps on the NHS Trust's liability.	Provisions relating to the ownership of intellectual property rights in the trial results, and the publication of those results, are the most commonly negotiated points.	The most common area for negotiation in any clinical trials agreement is intellectual property. Recent changes to the law on employee inventions mean that the intellectual property provisions of clinical trials agreement require particular attention when dealing with university hospitals. Other clauses which are commonly negotiated include those relating to liability for adequacy of data and to remuneration where possible conflicts with statutory provisions against anti-corruption have to be kept in mind.

Tim Worden, Benjamin Grzimek and Valerie Budd

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Environmental highlights

EC REACH Workshop

The EC REACH Regulation for the Registration, Evaluation, Authorisation and restriction of Chemical Substances¹ entered into legislative force on 1 June 2007 throughout Member States. Under the regime which regulates the registration and safe use of chemicals, companies who deal in quantities of chemicals greater than one tonne per year must pre-register their chemicals between 1 June and 1 December 2008 in order to benefit from staggered registration deadlines. A **failure to pre-register by 1 December 2008** could, ultimately, lead to a manufacturer or importer being banned from trading until a full REACH dossier has been submitted.

As part of a joint working initiative, the EC and the European Chemicals Agency hosted a workshop on the new regime in Brussels on 14 April 2008. Its aim was to alert companies to the requirements of EC Regulation in order that they do not miss the pre-registration window, focusing on the key elements of regulation and practical aspects of registration. In addition, up to date guidance papers and advice on compliance should be made available to companies as part of a practical implementation package.

In the UK, "**REACH Ready**", a subsidiary of the Chemical Industry Association in the UK, intends to hold a **pre-registration workshop in May** of this year in Manchester.

Biofuels Review

In response to growing concern and debate over potential negative environmental and economic impacts of biofuel production, such as loss of food crops, displacement and deforestation, the Department for Transport (DFT) announced, on 21 February, a UK review of the indirect impacts of biofuel production. The Review is to be led by the newly created Renewable Fuels Agency (a non-departmental public body), focusing in particular on the wider environmental and economic impacts of biofuel production in order to inform both UK and EU policy beyond 2010 targets, investigating indirect land use change and potential risks to food prices. The Renewable Transport Fuel Obligation (RTFO) is still set to be introduced in April 2008 placing an obligation on fuel suppliers to ensure that a certain percentage of sales are made up from renewable transport fuel, including biofuels by 2010. No moratorium on production was announced.

COMAH (Control of Major Accident Hazards) Regime – Update

The Control of Major Accident Hazards Regulations (as amended) implement the Seveso II Directive² on major hazards in the UK, the main aim of which is the prevention and mitigation of the effects of major accidents involving dangerous substances. The COMAH regime applies largely to the chemicals industry, however, it can impact on some storage activities, explosives and nuclear sites. Following a 2007 consultation exercise, the Environment Agency, the HSE (Health and Safety Executive) and SEPA (Scottish Environmental Protection Agency) in February published a revised containment policy, "Containment of Bulk Hazard Liquids at COMAH Establishments" for those installations that fall within the COMAH umbrella, together with a report on significant improvements made at 50 identified COMAH sites following on from the Buncefield oil depot incident in 2005.

The revised policy establishes a framework for all COMAH regulators such as the HSE and the Environment Agency to drive forward improvements in the storage of dangerous bulk liquids, with a requirement for particular standards to be met by COMAH sites handling petrol, products and other fuels. Primary containment measures for the hazardous liquid, using tanks, pipe works, valves and controls apply. In addition, there are various other requirements which relate to containing or mitigating the effect of a hazardous liquid once it has been released by the use of bunds, underground tanks, pipe works, and fire controls. Operators must assess, minimise and monitor risks, ensuring that regular inspections take place at sites.

¹ EC Regulation 1907/2006

² EC Directive 96/82/EC

InFocus

At a European level, the EC is reviewing the implementation of the Seveso II Directive, as part of its plans to revise and update European legislation. The focus of the Review is whether the requirements of the Directive on operators of bulk hazardous liquid storage sites are sufficient to prevent and mitigate accidents, at the same time investigating the differences in implementation and compliance between Member States and possible market distortion. Views are being sought by way of an online questionnaire.

Implementation of the Environmental Liability Directive ("ELD")

The Department for the Environment, Food and Rural Affairs (DEFRA) have indicated that the ELD, which came into force on 30 April 2004, should be transposed into UK domestic laws by December 2008. In view of this, the Government is currently consulting on draft implementing regulations and guidance. Responses should be made by 27 May 2008.

The ELD imposes a liability regime for those who have caused damage to biodiversity, water or land, which may lead to significant risk of harm to human health. A precautionary approach is advocated, together with the employment of preventative measures in order to avoid damage, with remedies to rectify damage that does occur.

Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2008 (RoHS)

The new 2008 Regulations came into force on 1 February 2008, revoking and incorporating provisions of the 2006 Regulations with two key changes relating to exemptions set out in the Annex to the Directive and in respect of enforcement in the UK. By accommodating future changes and exemptions, the new Regulations will not need to be revised. Furthermore, the new Regulations strengthen the powers of the National Weights and Measures Laboratory, enabling enforcement officers to require a person to provide it with information that could help establish if producer obligations have been met or not.

Guidance issued by the Department for Business Enterprise and Regulatory Reform has also recently been updated. The EC are also consulting on a further list of hazardous substances as candidates for inclusion in the RoHS Directive.

Emissions Update

As part of a wider package of proposals, on 23 January, the EC published proposals for a new directive to amend the current EU ETS³. If implemented, the new Directive would introduce a single EU wide emissions cap, with the EC being responsible for setting the total number of Co₂ allowances available rather than individual Member States, thereby avoiding problems of over allocation threatening the "cap and trade" market. In addition, the proposals are to expand the scheme to cover new sectors from 2013 and to provide increased auctioning and longer phases, the scheme's third phase to last eight years. The EU is committed to reducing its overall emissions by at least 20% below 1990 levels by 2020 and "20 20 by 2020: Europe's Climate Change Opportunity" sets out the EC's aims and objectives in this regard.

Carbon Reduction Commitment

A mandatory emissions trading scheme to apply to a wide range of large non-energy intensive businesses and the public sector (e.g. large offices and banks, large retailers, supermarkets and hotels, rail operators, hospital and universities, central government departments and local authorities). The UK Government published its response to a 2007 Consultation on options for implementation on 13 March. The Government anticipate that the CRC will commence in 2010, with further consultations taking place in Summer 2008 prior to implementation. It is likely that the CRC will impose additional burdens and costs on both private and public sectors.

It will take into account the mandatory targets set out in the Climate Change Bill, which is to cut UK emissions by at least 26% against 1990 levels by 2020.

Brian Greenwood - Partner and Head of Taylor Wessing's Environmental and Planning Group.
Sherrill 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.

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Life science and healthcare news and events

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

European Life Sciences IP Firm of the Year and Member of PLC's Life Sciences Industry Super League

Taylor Wessing was voted **European Life Sciences IP Firm of the Year** at the third annual Managing Intellectual Property Global Awards 2008 ceremony at Claridges Hotel, London on 9 April. The Global Awards are awarded to single firms, corporations and individuals excelling across the board for their IP expertise, and mark the culmination of a five month-long World IP Survey research undertaken by MIP.

Taylor Wessing has also been selected as a member of PLC's recently published 2008 **Life Sciences Industry Super League**. The Industry Super League identifies the leading firms globally for life sciences advice and recognises those law firms that have most successfully developed their practices in line with needs of clients in the last 12 months.

The MIP award and Taylor Wessing's inclusion in PLC's Life Sciences Industry Super League come on the back of a hugely successful year for Taylor Wessing's Life Sciences and Healthcare Group, during which it advised on many high-profile cases and transactions. Among them was advising Oxford BioMedica on its exclusive worldwide licence to Sanofi-Aventis of the cancer vaccine Trovax. This deal was duly recognised by being awarded SCRIP's "Licensing Deal of the Year Award" and the "techMARK 2007 Achievement of the Year Award" in the techMARK Awards organised by the London Stock Exchange.

On the patent litigation side, Taylor Wessing acted for Cargill in the first genetically modified crops trial in the UK. It successfully defended an action brought on three patents by Monsanto for importation from Argentina of allegedly infringing soya meal into the UK derived from glyphosate-resistant soya bean plants.

Global Intellectual Property Index

In May 2008, Taylor Wessing, in partnership with Managing Intellectual Property Magazine, is launching the Global Intellectual Property Index. This important piece of research will identify the best and worst jurisdictions to obtain, exploit, enforce and attack particular types of intellectual property. It will be compiled using the responses from a questionnaire, together with a number of independent factors.

For further details of the Global Intellectual Property Index and the methodology used to create it, please visit [Taylor Wessing Global Intellectual Property Index](#).

If you have a questions about the survey please contact [Sharon Philbey](#).

Partner Simon Cohen and associates Gareth Morgan and Matthew Royle have published an article "Litigating biotech patents in Europe" in the IAM publication [IP in the life sciences industries 2008](#).

Mark Your Calendars [Back to contents](#)

Dr Gareth Morgan is speaking on how current legislative proposals will affect advanced therapies at C5's Seminar [EU Pharma Law & Regulation](#) at the Crowne Plaza, St James, London on 28 and 29 April 2008

Associate Tim Worden is speaking on "Intellectual property terms in collaboration and licence agreements" at a Falconbury's conference ["Negotiating, Drafting and Understanding Commercial Contracts for the Pharmaceutical Industry"](#) on 4 June 2008 at the Grange Fitzrovia Hotel in 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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