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# InFocus

Life sciences & healthcare legal e.bulletin



## Introduction

This is the 18th issue of InFocus, Taylor Wessing's life sciences and healthcare e.bulletin.

Key issues discussed include:

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- Appealing non-binding patent opinions of the UK IPO
- The new CRO mCTA introduced by the DOH in October 2007
- The HFEA's recent approval of research creating hybrid chimeras
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# Key features

## New EFPIA Codes of Practice – What you need to know [Back to contents](#)

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative body of the pharmaceutical industry in Europe. It is made up of national industry association bodies from European countries, as well as a number of pharmaceutical companies. On 5 October 2007, EFPIA adopted a new “Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations” (the “Patient Organisation Code”) and a revised and updated version of their Code on the Promotion of Prescription-Only Medicines (the “Code”).<sup>1</sup> Both Codes will be effective throughout Europe from 1 July 2008, and set down a minimum standard which national member associations must adopt in their own codes of practice.

### What changes have been made to the Code?

The Code has been expanded considerably and now includes sections dealing with the use of consultants by pharmaceutical companies, non-interventional studies of marketed medicines, and grants to support healthcare or research. Changes have also been made to the Code in relation to hospitality, sponsorship of healthcare professionals and the provision of samples.

#### Relationships with healthcare professionals

The main driver behind the changes appears to be to increase transparency in the relationship of the pharmaceutical industry with healthcare professionals and patients. For example, the Code includes detailed provisions on how the relationship between a pharmaceutical company and a healthcare professional acting as a consultant to that company should be documented. Such an arrangement must be a “genuine consultancy”, based on a written agreement between the parties specifying the nature of the services to be provided and the basis of payment for the services. The Code also sets out a number of other criteria which all need to be fulfilled: for example, the number of healthcare professionals retained should not be greater than the number reasonably required for the identified need, and the level of compensation payable should be reasonable and should reflect fair market value.

It is important to note that, where a pharmaceutical company sponsors a healthcare professional to attend a particular international event, the funding will be subject to the rules of the country in which the healthcare professional carries out his or her profession, and not the country in which the event takes place.

#### Non-interventional studies

A non-interventional study is defined in the Code as a study where the medicine in question is prescribed in the usual manner in accordance with its marketing authorisation. Again, the Code sets out a number of criteria which must all be fulfilled where a company carries out a non-interventional study. The list of criteria is long, but includes a requirement that sales representatives may only be involved in such studies in an administrative capacity, and must not be linked to the promotion of any medicinal product. Although the Code only obliges companies to comply with the provisions on non-interventional studies that are completed after 1 July 2008, it does strongly encourage companies to be compliant in relation to studies completing before that date.

#### No inducements to prescribe

The Code emphasises that consultancy arrangements, the giving of samples of medicines, educational grants and the like should not be provided as an inducement to prescribe specific medicines.

### What do I need to know about the Patient Organisation Code?

The new Patient Organisation Code is designed to “ensure that relationships between the pharmaceutical industry and patient organisations take place in an ethical and transparent manner”. As with the Code, there is an emphasis on transparency.

<sup>1</sup> Both Codes are available through the EFPIA website, <http://www.efpia.org>

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The Patient Organisation Code defines a “patient organisation” as a non-for-profit organisation, mainly composed of patients and carers, which represents and supports the needs of patients and/or carers.

### The principles of the Patient Organisation Code

The principles underlying the Patient Organisation Code are:

- The independence of patient organisations shall be assured.
- Partnerships between patient organisations and pharmaceutical companies shall be founded on mutual respect.
- The pharmaceutical industry shall not request, and patient organisations shall not undertake, promotion of a particular prescription-only medicine.
- The objectives and scope of any partnership shall be transparent.
- Funding of patient organisations from a broad range of sources is to be welcomed.

### Applicable codes

The Patient Organisation Code requires a pharmaceutical company and patient organisation in a partnership to have in place a written agreement in certain circumstances (see below). Such a written agreement must include details of which codes apply to the relationship.

The applicable codes for a particular partnership are determined as follows:

- Where the pharmaceutical company is located in Europe, the national code of the country where the company is located applies. Otherwise the Patient Organisation Code applies.
- In the case of a partnership and activities taking place in a particular European country, the code of that country will apply for the relevant activity.
- For cross-border partnerships and activities, the code of the European country in which the patient organisation has its main European base will apply.

It will not always be clear from the outset which countries will be involved in a partnership’s proposed activities, which suggests that the pharmaceutical company and patient organisation will need to keep their written agreement under review to ensure that it correctly documents the applicable codes.

### Key provisions of the Patient Organisation Code

**Written agreements** - where the partnership involves the provision of financial support and/or significant non-financial support by the pharmaceutical company to the patient organisation, a written agreement must be in place. Annex I to the Patient Organisation Code is a template for such written agreements.

**Use of logos** – pharmaceutical companies must obtain written permission from a patient organisation to use the organisation’s logo (and any other proprietary material). The purpose of using the logo must be made clear.

**Editorial control** – pharmaceutical companies must not seek to influence the content of patient organisation material they sponsor in a way which favours their own commercial interests.

**Transparency** – pharmaceutical companies must make available a list of patient organisations to which they provide financial support and/or significant non-financial support. The list must be made available for the first time by no later than the end of March 2009, and thereafter must be updated at least yearly.

### What do I need to do now?

Although the new Codes are not effective until 1 July 2008, pharmaceutical companies should consider them in detail now when planning marketing campaigns and proposed activities with patient organisations. Pharmaceutical companies should also monitor changes to national codes in European countries, which will be amended prior to July 2008 to take into account the new Codes.

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However, it is important to note that some national codes already go some of the way towards addressing the new provisions in the Codes. For example, the UK national trade association, the Association of the British Pharmaceutical Industry (ABPI), has provisions in its 2006 Code of Practice (the “ABPI Code”) dealing with the relationships of pharmaceutical companies and patient organisations. The ABPI Code currently requires member pharmaceutical companies working with patient organisations to put in place written agreements and to publish a list of patient organisations to which they provide financial support (although there is no apparent need where the support is non financial).

However, changes will still be required to the ABPI Code, and the ABPI has announced that it will be revising the ABPI Code to take account of the new Codes. InFocus will monitor and report on those changes.

*Tim Worden*

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## The new contract research organisation model clinical trial agreement [Back to contents](#)

On 27 October 2007, the Department of Health introduced a new contract research organisation model clinical trial agreement (the "CRO mCTA"). The CRO mCTA was developed by a working group made up of representatives from the Department of Health, the NHS, the ABPI, ABPI member companies and CROs. It is intended to be a model agreement for use in relation to commercial, industry-sponsored Phase II to IV trials of investigational medicinal products undertaken in NHS hospitals and managed by CROs.

The roll-out of the CRO mCTA follows on from the launch in October 2006 of a revised version of the 2-way (sponsor/NHS Trust) model Clinical Trial Agreement ("mCTA"). As with the mCTA, the CRO mCTA is intended to help ensure clinical trial sites are up and running as soon as possible, thereby decreasing the time to market for new medicinal products and making the UK a more competitive location for clinical research. There are no previous versions of the CRO mCTA - the 2007 version is the first.

### Is the CRO mCTA any different from the 2006 mCTA?

The CRO mCTA is based very closely on the mCTA, so the original guidance on the mCTA remains relevant.

The main differences between the CRO mCTA and the mCTA:

- relate to the extent to which the sponsor has delegated to the CRO – in other words the division between the sponsor and the CRO of the sponsor's rights and obligations in relation to the trial – and how this is reflected in the operative terms of the agreement;
- require the sponsor and the CRO to set out in an appendix (Appendix 5) a summary of which of the sponsor's trial related duties and functions under ICH GCP have been delegated to the CRO; and
- provide the NHS Trust with the right to require the sponsor to take over the CRO's responsibilities under the agreement where the CRO materially breaches the agreement or undergoes an insolvency event.

In some instances, the CRO mCTA provides for both the CRO and sponsor to have certain rights or obligations under the agreement. For example, the CRO mCTA includes the right for either the sponsor or the CRO to terminate the agreement where the clinical investigator leaves and a replacement acceptable to all three parties cannot be found. While it is clearly desirable for a CRO to have the right to terminate the agreement - presumably on the instructions of the sponsor - this right is potentially problematic when coupled with the right of the CRO to object to a replacement investigator. Although this is unlikely to be an issue where the commercial relationship between sponsor and CRO is good, this does effectively give the CRO a unilateral termination right where an investigator leaves. It is hard to see why the right to object to a new investigator should extend beyond the NHS Trust and the Sponsor to include the CRO.

Appendix 5 of the CRO mCTA is blank, leaving the parties to decide how much detail of the CRO's duties and functions should be included in the agreement. The Department of Health guidance notes on the CRO mCTA state that Appendix 5 is not intended to reproduce ICH GCP, but that it will "summarise for the benefit of staff and all parties administering the trial site, issues over which the NHS body will liaise with the CRO."

### Do we have to use the CRO mCTA?

As for the mCTA, use of the CRO mCTA is not mandatory for NHS Trusts or ABPI or BIA member companies. However, the routine use of the agreement without amendment is "strongly commended" by the Department of Health, the ABPI and the BIA.

The Department of Health guidance notes acknowledge that the use of the CRO mCTA may not be appropriate where a CRO undertakes only a very limited range of services for the sponsor, such as drafting the Ethics Committee submission. In such cases, the notes state that the mCTA between the sponsor and the NHS Trust could be used instead. This highlights a potential issue with the "one size fits all" approach to a three way NHS/sponsor/CRO agreement: the degree to which the sponsor wishes the CRO to have rights or functions in relation to a particular trial site will vary considerably, suggesting that amendments to the CRO mCTA will be inevitable.

### Sponsor/CRO contractual arrangements

One of the key points to consider before signing up to the CRO mCTA is its relationship with the contract between the sponsor and the CRO.

The Department of Health guidance notes acknowledge that the use of the CRO mCTA may not be appropriate where a CRO undertakes only a very limited range of services for the sponsor, such as drafting the Ethics Committee submission. In such cases, the notes state that the mCTA between the sponsor and the NHS Trust could be used instead. This highlights a potential issue with the “one size fits all” approach to a three way NHS/sponsor/CRO agreement: the degree to which the sponsor wishes the CRO to have rights or functions in relation to a particular trial site will vary considerably, suggesting that amendments to the CRO mCTA will be inevitable.

The sponsor/CRO contract should be reviewed carefully to check that it does not conflict with the provisions of the CRO mCTA. Sponsors and CROs should also give careful consideration to which agreement should take precedence in the event of a conflict between the two.

### Conclusion

Like the mCTA, the CRO mCTA is to be welcomed. However, the involvement of a third party and, in most cases, the existence of an on-going contractual arrangement between the sponsor and CRO is bound to increase the chances of the need for amendments to the precedent agreement. Such amendments will take time and ultimately detract from one of the stated aims of the CRO mCTA: to make the UK a more competitive arena for clinical research.

Sponsors and CROs should review the CRO mCTA in detail, as well as their current contractual arrangements with each other. Such a review should allow the early identification of potential conflicts between agreements, and enable sponsors and CROs to analyse whether they can realistically use the CRO mCTA without amendment.

*Tim Worden*

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See also:

[Model Clinical Trial Agreement](#)

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## UK IPO opinions can be appealed to the High Court [Back to contents](#)

In *DLP Ltd v Scrabo Bathing Care* [2007] EWHC 2669 (PAT) a decision of the English High Court delivered in November, Kitchin J ruled that non-binding opinions on patents given by the UK Intellectual Property Office (“UKIPO”) could be appealed from the first appeal stage heard by a Hearing Officer, to a High Court judge. InFocus readers will recall that we reviewed the first tranche of opinions provided by the UKIPO in the May 2006 InFocus (which is available on the [Newsletters](#) page of our website). The new opinions regime was introduced by the Patents Act 2004 and was brought into effect by the Patents (Amendments) Rules 2005 which introduced new Sections 74A and 74B of the Patents Act 1977 (The Act).

The procedure set out in Sections 74A and 74B of the Patents Act 1977 provides for an appeal to, or a review by, a hearing officer (and then the High Court) in certain specified circumstances

The 2006 article noted that one key to widespread acceptance of the opinion system would be the swift development of a body of practice and procedure that would, not inevitably, lead to appeals from the UKIPO to the High Court. It was suggested that such appeals would defeat the object of the opinions system.

In the DLP case Kitchin J sets out the aims of the opinions system<sup>2</sup>:

“Importantly, the opinion is not binding for all purposes (section 74(A)(4)). The aim of the scheme was explained in a consultation paper issued by the Patent Office (as it then was) before the rules were finalised. In short, it is intended to provide a low cost service which helps to resolve patent disputes, and so encourages innovation, by providing a quick, balanced and affordable way for parties to get an impartial assessment of key infringement and validity issues... However, it was hoped that an opinion might assist the parties to focus their minds on the key issues, test and understand the strength of their cases and so better enable them to negotiate a settlement rather than engaging in litigation.”

In the DLP case the opinion concluded that Scabo’s shower tray did not infringe DLP’s patent. The hearing officer agreed and DLP appealed to the High Court

Kitchin J (referring to an earlier hearing before Pumfrey J) considered that the questions to be asked were:

1. Does the legislation give a patentee a right to appeal to the Court in such circumstances; and
2. Even in the event that it does, should the Court entertain such an appeal in any event (given the stated purpose was to put in place a speedy, cost effective system)?

Kitchin J agreed with both counsel that there had been a decision against which there was a prima facie right to appeal – this was the decision of the Hearing Officer at the UKIPO to affirm certain aspects of the initial opinion, in particular the overall conclusion. No statutory exclusion against this type of appeal existed. Kitchin J also decided that the fact that the UKIPO procedure only resulted in non-binding opinions or decisions did not preclude the High Court hearing the appeal either.

However, it was made clear that any appeal from a decision of the Hearing Officer in this procedure is likely only to involve a review of the decision of the Hearing Officer, not a rehearing. This review should be restricted to a review of whether the Hearing Officer’s review of the initial opinion was wrong. Kitchin J went to lengths to explain that the UKIPO opinions service was necessarily hamstrung by the procedure within which it worked. In particular, the opinion could only be as complete and accurate as the starting point (The UKIPO works with the prior art and evidence provided by the parties) which is likely to be incomplete. Further Kitchin J stressed that the procedure results in an opinion. He thought that it was likely that two reasonable people approaching the same set of facts could in theory arrive at different opinions neither of which could be characterised as wrong, merely being the opinions of different people looking at the same set of facts. Therefore, upon review by a Hearing Officer, an opinion should only be set aside if it can be shown that the examiner made an error in principle or reached a conclusion on the available evidence that was clearly wrong. It follows then that the High Court can only set aside a decision of a Hearing Officer if he had failed to recognise any such error of the Examiner.

<sup>2</sup> See paragraph 9 of the judgment

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Kitchin J then reviewed the arguments that were put forward by the patentee, namely that considering the language of claim 1, it was clear that the products in question infringed the patent. Kitchin J's review was summarised in the final paragraph that reads:

*"Both the examiner and the Hearing Officer considered the skilled person would understand the words of claim 1 to mean the shower tray must itself include a trough. They directed themselves correctly in law and considered the claim in the light of the specification and through the eyes of the skilled person. It was not an opinion which was clearly wrong. Indeed, I think it was a reasonable view for them to take. This appeal must be dismissed."*

One of the key points to consider before signing up to the CRO mCTA is its relationship with the contract between the sponsor and the CRO.

However, this case has clarified that the High Court will hear these appeals despite them defeating some of the aims of the opinions process, in providing a cheap, speedy service to obtain non-binding opinions.

***Dr Gareth Morgan***

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## The HFEA approves two projects involving cytoplasmic hybrid embryo production

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When the original proposed new Human Fertilisation and Embryology Bill was found to include a provision banning the creation of cytoplasmic hybrid embryos there was an outcry. What was once a relatively unknown area of embryonic cell research was thrust into the spotlight. The creation of such hybrid embryos had been ongoing for over a century in academic research. The proposed ban was based on the results of a public consultation carried out by the government. The proposed Bill has delayed licence grants for projects where cytoplasmic hybrid embryos are to be created and triggered a year of intense activity by scientific and pro-life organisations to lobby for their desired legislative positions to become law.

In September 2007 the HFEA announced it was prepared to now grant licences for research involving the creation of cytoplasmic hybrid embryos and in January 2008 the HFEA granted two such licences one from King's, London and other from the Institute of Human Genetics in Newcastle University<sup>3</sup>. These licences provide permission for researchers to produce cytoplasmic hybrid embryos in projects involving (i) the creation of disease models better to enable the study of numerous specific diseases and (ii) to study the reprogramming of the nucleus during embryonic development.

These project approvals followed close on the heels of the report of the public consultation from the HFEA last October.

In its report, the HFEA concluded, that despite significant public misgivings about this type of research, it would approve projects working with embryonic tissue where the project involved the creation of cytoplasmic animal-human hybrids. However, the HFEA considered that such projects should only be approved where the applicant demonstrated that the creation of such hybrids was "necessary and desirable" and where the planned research also met the overall standards required for any embryo research. This decision paved the way for the HFEA licence committee (Licence Committee) to consider two applications for approval of work involving the creation of cytoplasmic hybrid embryos that had stalled since the initial furore surrounding the proposed above described new Bill.

The HFEA also considered that further efforts should be made to enhance the public understanding of this area of science in order that it may better comprehend the scientific basis for the research. In general, the HFEA found that the more informed the public were, the more likely they were to be in favour of this field of research.

### The future

It is stated within the minutes of the meetings in which the Licence Committee approved the projects that the approval is based on the law as it currently stands. Hence, to the extent that the new Human Fertilisation and Embryology Bill currently passing through the House of Lords renders this work illegal, the applicant was advised to monitor the legal situation during the time it conducts the work under the current licence.

A number of high profile reports<sup>4</sup> have urged the legislators not to diminish the scope of research that is currently possible in this area in the UK. The HFEA is now approving research projects that involve the creation of cytoplasmic hybrid embryos after subjecting the applications to peer review and rigorously querying the necessity of the use of cytoplasmic hybrids within the research. Whilst we have in this article focused on the possibility of a ban on the creation of hybrid embryos the proposed Bill has now reached a stage where this is increasingly unlikely. However, two further provisions were hotly debated at the proposed Bill's second reading in the House of Lords. The first relates to the limitation of cloning work to source tissue for which express informed consent for use in cloning experiments has been obtained. This would create significant problems for researchers as the vast majority of tissue held within UK tissue banks will not comply with this provision, having been obtained under much more "general" consents for any use in medical research. This raises a significant issue as where should the requirement for such express informed consent stop? It seems that because hybrid embryo production has been thrust into the spotlight, more by accident

<sup>3</sup> Both projects received approval in the meeting of the HFEA Licence Committee, 9 January 2008

<sup>4</sup> HFEA report, October 2007; also the joint report of the MRC, Academy of Medical Sciences, Royal Society and the Wellcome Trust submitted to the House of Lords July 2007.

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The second limitation is that no tissue obtained from children should be used in cloning experiments, no matter whether express informed consent is obtained from the parents. This has been criticised as preventing the creation of model cell lines to study childhood diseases or to test treatments for such diseases.

Scientific organisations have argued that the above provisions, even if enacted, should not be applied retrospectively, as this would seriously devalue the current tissue collections held in the UK and increase costs by forcing such stocks to be duplicated for embryo research.

Therefore, the proposed new Bill could make the above work illegal in one fell swoop, by removing the right to use to source tissue from which the human nuclei are obtained. Given the high feelings generated by this subject, the final passage of the proposed new Bill will be followed with a mixture of hope and trepidation by both the scientific and pro-life campaigners.

If readers are interested in the details of the proceedings of the Licence Committee meeting or would like further information on the passage of the proposed Bill through the UK legislature, they should contact either [Dr Gareth Morgan](#) or [Helen Cline](#) for further information.

*Dr Gareth Morgan*

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### European Commission's pharmaceutical sector investigation [Back to contents](#)

The European Commission's decision to launch a sector wide investigation into the pharmaceutical industry backed up with dawn raids demonstrates the Commission's concern over the bringing of generics to market.

The primary focus of the investigation is on intimidatory patent litigation, reverse payments to generic companies and why there is a much smaller reduction in price in Europe of branded products following generic entry than in the USA. By initiating a sector investigation the Commission will be able to cast its net much wider, including during the dawn raids, than if it had initiated an investigation into specific abusive behaviour under Article 82.

The present investigation is not directed at specific companies. Its purpose is to enable the Commission to gather information and draw conclusions about the sector. If it discovers issues that need attention, it can be expected to launch proceedings against individual companies probably under Article 82. At the very least the investigation will enable the Commission to be informed of the workings of the industry.

The Commission is due to publish an interim report in the autumn with a final report in spring 2009. This appears an ambitious timetable.

*Martin Baker*

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### New UK immigration laws – Scoring points? [Back to contents](#)

From next year, immigration law in the UK is facing a major shake-up in what the Home Secretary is calling, “the most significant change in managed migration in the last 40 years”. Essentially, a “point-based system”, similar to that currently adopted in Australia will be introduced and will replace the majority of existing immigration laws, including all work permit and HSMP schemes. With the aim of consolidating more than 80 existing work and study application routes into only five tiers, it is clear that the Home Office are determined to make a real and visible difference to how migrants are permitted entry into the UK

While it remains to be seen whether these changes will be beneficial for employers, it will not change the extent to which employees are ‘tied’ to the employer. There is no doubt, however, that employers will have more responsibility towards work permit holders they employ.

#### Why the change?

Between 2001 and 2005, migrants contributed 15% to 20% of the growth in the UK and contributed to approximately £6 billion to output growth in 2006. The Government is keen to continue encouraging migrants to come to the UK for this reason.

However, the current system is viewed by many as being cumbersome and offering little certainty to employers and to individuals wishing to come to the UK. Of course, it would also be naïve to fail to recognise the increase political spotlight that immigration has found itself under in recent years, and this has undoubtedly motivated a number of the proposals currently being discussed.

The aim of “PBS” is to be firmer, faster and fairer. By making the application system simpler and more transparent, it is hoped that only those migrants that the UK actually needs will be allowed to come to work or study in the UK. The current HSMP is a hybrid of PBS and its success has helped to prompt the Government into introducing an across the board points-style system.

Additionally, the introduction of the ‘sponsor’ requirement for all but one of the tiers is a wholesale change in the way immigration is viewed, and places additional responsibilities on the employer.

Only the statement of intent for the first of the five tiers has been issued, and many of the proposals are still being finalised. However, the basic principles are unlikely to vary too much from their current form and I set these out below.

#### What are the new tiers?

There are currently over 80 different application routes to work or study in the UK. It is hoped that the majority of these will be encapsulated into one of the following five tiers:

##### Tier 1 – Highly Skilled Individuals to contribute to growth and productivity

The tier is aimed at attracting the most highly skilled workers and will replace the current HSMP scheme and points will be awarded on a similar basis to the current scheme. This tier will also include post-study work applications (replacing the current IGS), entrepreneurs and investors.

Highly skilled migrants will be free to seek employment anywhere in the UK and these applicants will not be required to have a sponsor, making it easier for employers to take on such migrants. These migrants will be required to have English skills at Council of Europe level ‘C1’.

##### Tier 2 – Skilled workers with a job offer to fill gaps in the UK labour force

This tier will replace the current work permit schemes and will be available to migrants who are filling a particular job within the EEA, which no suitable worker from the EEA could fill. The applicants must pass the “Resident Labour Market Test” or RMLT, meaning that the jobs must be advertised for at least two weeks. This is similar to the current system and is a tool used to protect the domestic labour force.

These migrants will be required to have English skills at level ‘B2’ (approximately ‘C’ grade at GCSE).

### **Tier 3 – Low Skilled Workers to fill specific temporary labour shortages (The implementation and design of this tier has been frozen)**

When this tier is developed, it is likely that it will be quota-based and permission to work will be strictly time limited.

### **Tier 4 – Students**

These applications are available for those students who want to come to the UK to study for 6 months or more – the educational institution will be the sponsor. The leave will be tied to the institution but not the course of study.

### **Tier 5 – Youth Mobility and Temporary Workers**

This tier will replace the current working holidaymaker scheme. It will cover, for example, creative workers and sportsmen and women.

## **What is sponsorship?**

It is believed that those who benefit from migration should help in maintaining the integrity of control, and therefore the leave of migrants will now be tied to a sponsor (sponsors are not required for Tier 1 applicants). A certificate of sponsorship will be issued by the sponsor asserting that the applicant is suitable.

Sponsors will be required to be on a list of licensed sponsors and will be required to show the following:

- it is a bona fide establishment;
- it is registered with HMRC and have audited accounts; and
- it is registered with the appropriate authorities.

Sponsors will be under a duty to report to the authorities if the migrant fails to show up to work and provide details to the Border & Immigration Agency of request.

All sponsors will be graded, either 'A' or 'B'. The 'B' rating is transitional and gives sponsors who have not complied with the regulations a chance to get their 'house in order'. If a sponsor does not improve, it is likely that their licence would be withdrawn. A licence will also be withdrawn if a key person in an organisation is convicted of a serious immigration offence.

Licences will be required to be renewed every four years.

## **Time frames**

Everything in this article is subject to change, but the general principles of the five tiers and the introduction of sponsors is unlikely to change. It is envisaged that Tier 1 will be launched in the first quarter of 2008, with Tiers 2 and 5 in the third quarter of 2008 and Tier 4 in the first quarter of 2009.

## **UK visa decision making process**

The issuing of visas to migrants is also changing. UKVisas are moving away from intention bases decision and most decisions will now be taken on paper alone. The rationale behind this is that PBS should make everything more predictable and transparent and therefore decisions regarding visa applications should not be as subjective as they were previously.

Biometric information will need to be provided by all migrants by the end of 2008.

More controversially, full appeal rights are being replaced by an internal administrative review – therefore decisions will only be overturned if there has been an error of fact.

**Mark McCanney**

## Capital gains tax reforms [Back to contents](#)

Alistair Darling, the Chancellor of the Exchequer, announced the proposed changes to capital gains tax (CGT) in the Pre-Budget Report (PBR) on 9 October 2007. Under the proposed changes, disposals made on or after 6 April 2008 by individuals and trustees will be subject to a single rate of CGT of 18%. Taper relief and the indexation allowance will also be abolished for disposals on or after this date.

In a further announcement on 24 January, in response to significant corporate lobbying against these changes, the Chancellor announced a concession for entrepreneurs selling business assets, which significantly reduces the CGT rate on certain capital gains up to a maximum level of gains. This relief will take effect from 6 April 2008, as part of the wider CGT reform.

The abolition of the taper relief rules is generally seen as the Government's response to recent criticism that the private equity sector has been paying too little tax on excessive profits. The proposed changes, however, are considerably more far reaching and give rise to many 'winners and losers', including individuals, employees with company share plans and other smaller businesses.

### Current regime

Currently, the effective rate of CGT for individuals and trustees is predominantly determined by the taper relief rules. Under the taper relief rules the effective rate of tax differs according to whether the asset disposed of is classified as a business asset or a non-business asset and the period of ownership of the asset. At present, the rate of tax on disposals of business assets falls to an effective rate of 10% after only two years of ownership, whereas for non-business assets the rate falls to 24% only after 10 years of ownership.

### Proposed changes to the CGT regime

The key proposals affecting the CGT regime for individuals and trusts (not companies) from 6 April 2008 are the abolition of the taper relief regime and the introduction of a flat CGT rate of 18%, irrespective of the period of ownership of the asset disposed of. The Chancellor has subsequently introduced the entrepreneurs' relief, which is targeted at small business owners and 'business angels'. The new relief reduces the CGT rate from 18% to 10% for the first £1 million of lifetime capital gains realised by an individual on disposals of qualifying assets. Any gains in excess of the lifetime limit will be taxed at the standard 18% rate (as will any other capital gains from the disposals of non-qualifying assets).

Qualifying assets include the whole or part of any trading business and shares and securities in a trading company or the holding company of a trading group (but only where the individual in question is both an employee, director or other office holder and holds 5% or more of the ordinary shares of the company and 5% or more of the voting power).

Other changes applying to disposals of capital assets on or after 6 April 2008 include the abolition of the indexation allowance (which eliminates increases in value attributable to inflation from the charge to capital gains tax) and simplification of the share identification rules which operate to match shares disposed of with shares acquired for capital gains tax purposes.

Most other CGT reliefs will continue to apply including private residence relief, business asset roll-over relief and hold-over relief on gifts of business assets. The annual exemption for individuals and trustees will also remain, along with the ability to offset capital losses brought forward against chargeable gains.

### Impact of the changes

The proposed changes are problematic for taxpayers who would benefit from the 10% rate on business assets under the current regime. This is likely to lead to the sale of such business assets (e.g. shareholdings in private limited companies carrying on a trade) prior to 6 April 2008 as people try to beat the deadline and 'lock in' the taper relief on business assets available under the current regime. For example, employees holding shares in their employer may have to pay CGT at the 18% rate on the disposal of those shares on or after 6 April 2008, compared with the current effective rate of 10% (after a period of ownership of just two years) if the disposal is made before that date.

## InFocus

Taxpayers who had anticipated deferring their gain until, on or after 6 April 2008 in order to receive the maximum amount of taper relief (for example, through a rollover of the gain into loan notes issued in consideration of a disposal of shares in a target company to a purchaser) are also likely to be worse off as a result of the proposed changes.

The introduction of the entrepreneurs' relief offers some relief from the additional tax burden, however the £1 million threshold for capital gains qualifying for the relief, assessed on a lifetime basis, will mean that many business owners will still face considerably higher tax liabilities overall.

In addition, the relief only applies to capital gains arising on disposals of assets held for the purposes of a trade or shares and securities in trading companies where the taxpayer is both an employee or office holder and holds 5% or more of the voting power and ordinary share capital of the company. This means, for example, that former owners of companies who now hold loan notes and/or earn out rights, will not qualify for the relief and will face an immediate increase in their CGT liability on any redemption or disposal of their loan notes after 5 April 2008.

There is however, a silver lining for taxpayers holding non-business assets, including second homes and most shareholdings in listed companies or investment companies, along with taxpayers who dispose of their business assets where full business taper relief would not be available (i.e. where the period of ownership is less than two years).

## What next?

The delay on the part of the Government has put taxpayers in a position of considerable uncertainty and instability and means that taxpayers affected by the changes have only weeks to implement any necessary planning. We would advise all taxpayers potentially impacted by the above changes to consider undertaking the appropriate tax planning prior to the introduction of the new rules on 6 April 2008.

*Rochelle Whaanga*

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## EU ratifies amendment to TRIPS on compulsory licences [Back to contents](#)

On 19 November 2007, the EU formally ratified the addition of article 31bis to the TRIPS Agreement ([see instrument](#)). This followed the earlier decision of the EU parliament on 24 October 2007 ([see decision](#)) which had been concerned about whether this amendment would be widely used and improve access to medicines to developing countries as the WTO had intended.

The amendment was proposed by the decision of the WTO council of 9 December 2005 and is based on the decision of the WTO council of 20 August 2003 which had already been implemented by EU Regulation 816/2006. Two thirds of WTO members (101 out of 151) must ratify the amendment for it to become part of the TRIPS Agreement. Currently only 14 members have ratified the amendment although it is interesting from a constitutional point of view what the effect of the EU's ratification of the amendment will have on the members of the EU.

Article 31bis allows a country to grant compulsory licences to companies to manufacture a patented drug only for export to countries that do not themselves have manufacturing capabilities. The licences are limited to products used for treatment of HIV/AIDS, tuberculosis, malaria and other epidemics. Only one compulsory licence has so far been granted under these provisions and this was in Canada to allow Apotex to supply HIV/AIDS drugs to Rwanda (See October 2007 InFocus on the [Newsletters](#) page of our website).

*Dr Matthew Royle*

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# Regulatory review

## The borderline between medicinal products and medical devices and the Advanced Therapy Regulation [Back to contents](#)

### Introduction

This article describes the regulation of healthcare products which combine pharmacologically or biologically active ingredients with medical devices such as delivery systems. This area of product development is fraught with difficulty and the aim of this article is to clarify the regulatory legislation so that clear and focused advice and decisions can be made in order to avoid costly mistakes in product development strategies and subsequent regulatory submissions.

The development, manufacture and distribution of medicinal products in the UK is governed by the implementation of Directive 2001/83/EC into the Medicines Act 1968 together with the various regulations and orders made under the Act, supplemented by an extensive range of 'soft law' such as the Rules Governing Medicinal Products in the European Union.

The regulation of medical devices and active implantable devices is governed by Directives 93/42/EEC and Directive 90/385/EEC.

As the development of 'advanced medical therapies' (gene therapy, somatic stem cell derived products and tissue engineering) progresses, the problems of identifying the scientific issues and the data required for regulatory purposes are mounting. In particular the question of borderlines with other types of products that have biological mechanisms such as cosmetics and/or medical devices are becoming increasingly difficult to resolve.

This article attempts to give a bird's eye view of the current regulatory legislation and the interplay between the regimes for medicinal products and medical devices from the perspective of the development and regulation of advanced medical therapies later this year.

Medicinal products are defined in Article 1(2) of Directive 2001/83/EC as: 'any substance or combination of substances presented as having properties for the prevention or treating disease in human beings; or ...any substance or combination of substances which may be used or administered to human beings either with a view to restoring, correcting or modifying physiological function by exerting a pharmacological, immunological or metabolic action, or to making a diagnosis'. Thus the first paragraph defines a medicinal product by virtue of its presentation while the second paragraph is concerned with the product's function.

The amending Directive 2004/27/EC inserts a new Article 2(2) into Directive 2001/83/EC: 'In cases of doubt where taking into account all its characteristics, a product may fall within the definition of a medicinal product and within the definition of a product covered by other community legislation, the provisions of this Directive (i.e. Directive 2001/83/EC) shall apply.' This effectively codifies the supremacy of the definition of medicinal product over other community definitions.

The European Court of Justice has consistently held that classification of a medicinal product under this second paragraph must be carried out on a case by case basis (Case C-369/88 Delattre). This was a referral from the Judge d'Instruction at the Tribunal de Grand Instance, Nice to the ECJ for a preliminary ruling under Article 177 of the EEC Treaty on several questions on the concept of illness or disease and medicinal products and their definition in Community law on the compatibility with EEC law of the monopoly granted to Pharmacists for the distribution of medicinal products. Mr. Delattre was a Pharmacist who was prosecuted for marketing a number of products ranging from medicines to food stuffs and cosmetics that advertised medicinal claims and health benefits without having been granted marketing authorization. Some eleven products were involved including slimming products, products for facilitating digestion, blood circulation, 'herbal treatment' for the legs and antismoking pills, among others. The Court held that the pharmacological effects of a product are the primary consideration under the second paragraph. The effect(s) must be more than minimal and should be sufficient to confer the function of treating or preventing disease. There appears to be no substantive guidance as to the degree of efficacy but the MHRA regards 'significant clinical effect' as the yardstick.

As regards the borderline between medicinal products and medical devices, unlike other regulatory regimes, the Community legislation contains a set of specific rules for determining the demarcation between them. Medical devices are mostly non-pharmaceutical products defined in Article 1(2) of Council Directive 93/42/EEC:

*'..medical device, measuring instrument, apparatus...or other article, whether used alone or in combination including the soft ware necessary for its proper application intended by the manufacturer to be used in human beings for the purpose of: diagnosis, monitoring, treatment, alleviation or a compensation for an injury, a handicap, investigation, replacement or modification of the anatomy or of a physiological process, such as control of contraception and which does not achieve its principle or intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.'*

Article 1(5) provides that the Directive does not apply to medicinal products covered by Directive 2001/83/EC. However, Articles 1(3) and 1(5) specify detailed rules for products that combine a device and medicinal product. In particular, if a device incorporates as an integral part a substance which would in isolation be a medicinal product, but which acts upon the human body with an action ancillary to that of the device then the product is covered by Directive 93/42/EEC. If the action is more than ancillary the product is to be treated as a medicinal product under Directive 2001/83/EC (e.g. a pre-filled insulin syringe).

Article 2(2) of Directive 2001/83/EC refers to 'taking account of all its characteristics'. This enables the competent regulatory authority (the MHRA in the UK) to determine whether the product meets the definition of medicinal product or device. In the UK the Court of Appeal has confirmed that the MHRA has the responsibility for determining the classification of a product as a medicine or medical device (*R v Medicines Control Agency ex parte Pharma Nord UK Ltd 1998*, EWCA Civ 81, 44 BMLR 411).

The classification procedure is set out in Regulation 3A of the Medicines for Human Use (Marketing Authorizations etc.) Regulations 1994 and the MHRA Guidance Note No 8; 'A Guide to what is a Medicinal Product, June 2007. The procedure involves the issue of a provisional determination by the Licensing Authority, giving the applicant the right of appeal to an independent review panel. Following the advice from the review panel, the MHRA issues a final determination. Such a final decision may be subject to judicial review and could be overturned if the MHRA is found to have applied Community law incorrectly, the decision is 'Wednesbury' unreasonable or if there has been some procedural failing. The Court will not substitute its own decision on the merits.

If a prosecution is commenced against a person marketing a medicinal product without marketing authorization (schedule 3 Medicines for Human Use (Marketing Authorizations etc., Regulation 1994), the burden of proof is on the prosecution to demonstrate beyond reasonable doubt that the product is in fact a medicinal product. Although the Regulation and MHRA Guidance provides for a formal determination by the Regulatory Authority, a person may commit an offence even if such determination has been issued.

### Advanced therapy medical products

The problem of demarcation is further compounded with the advent of 'advanced therapy medical products'. This is a new category of products based on gene therapy, somatic cell therapy and tissue engineering. These developments have been fuelled by rapid advances in biology, biotechnology and medicine. A number of gene therapy and stem cell therapy derived products are already undergoing clinical trials for some inherited diseases, diabetes, Parkinson's disease and other neurodegenerative disorders.

Also tissue engineering is being applied to product development for regenerating repairing and/or replacing human tissue. This nascent field of regenerative medicine already has produced treatments for diseases of skin, cartilage and bone.

These therapies share several regulatory, scientific and economic features and form a coherent category of products for the purpose of regulation. However, current regulatory policy and legislation is unable to cover this category comprehensively and with certainty. This category of products largely consists of combinations of medicinally active ingredients with innovative delivery systems and it exemplifies the difficulties in demarcating the borderline between medicinal products and medical devices.

In response to this problem the European Commission has now published Regulation (EC) No 1394/2007 for the regulation of such advanced therapies. The Regulation was formally adopted on 30 October 2007. The Regulation on advanced therapy medicinal products was published in the Official Journal on 10 December 2007. It will apply from 30 December 2008. The Regulation will amend Directive 2001/83/EC together with amendments to Regulation (EC) No 726/2004 on the harmonization of applications for marketing authorization via the centralized submission route.

## InFocus

The new legislation recognizes the need to bridge this regulatory lacuna by integrating all advanced therapy medical products under a single framework of regulatory legislation.

The Regulation builds on the experience gained with the existing medicines regulatory regime in Europe and only creates additional regulatory requirements when necessary to achieve harmonization in areas where application of current Community legislation has proven insufficient.

In particular the Regulation recognizes that advanced therapy products are neither devices nor conventional medicines. The technical requirements for demonstrating safety and efficacy, for example the type of pre-clinical and clinical data required, will be highly specific and will depend on the level of risk inherent in the product. The high level requirements are already described in Annex 1 to Directive 2001/83/EC.

The Regulation will establish detailed guidelines for tissue engineered products. Thus the current requirements for gene therapy and stem cell therapy products will not be affected by the new regulation. The main change to these products will be establishment of a new central scientific committee – the Committee for Advanced Therapies.

In summary advanced medical therapies will be defined as:

Gene therapy products are as defined in Annex 1 to Directive 2001/83/EC.

Somatic cell therapy products will be defined in the Regulation as:

*'... a tissue engineered product contains or consists of engineered cells or tissues and is presented as being for use in or being administering to human beings with a view to regenerating, repairing or replacing a human tissue. A tissue engineered product may contain cells or tissues of human or animal origin. The cells or tissues may be viable or non-viable and may also contain additional substances such as cellular products, biomolecules, biomaterials, chemical substances, scaffolds or matrices'.*

Importantly, as regards regulation of borderline products, it defines combined advanced therapy medicinal products as: 'medicinal product where it fulfills the following condition: it must incorporate as an integral part of the product, one or more medical devices within the meaning of Article 1(2) (a) of Directive 90/385/EEC and the cellular or tissue part must be liable to act on the human body with action that cannot be considered as ancillary to that of the devices referred to.'

A product which may fall both within the definition of a tissue engineered product and within the definition of a somatic cell therapy medicinal product shall be considered as a tissue engineered product.

A key change is the establishment of the new scientific Committee on Advanced Therapies (CAT). This Committee will be responsible for classifying the regulatory status of these products. Up to now this has been the responsibility of the EMEA secretariat.

The device component of the products will still have to be CE marked and the legislation states that the CAT should recognize the decision of the notified body as regards the CE mark. The Committee will have members with expertise in medical devices and will have the discretion to assess this as they wish.

The CAT will re-evaluate all current cellular medicines; there will be no grandfather clause. One interesting facet of the legislation is the 'hospital exemption' for unlicensed products: Recital 6 of the Regulation specifies that the scope of the legislation is to regulate products intended to be placed on the market in Member States and either prepared industrially. Advanced therapy products prepared on a non-routine basis according to specific quality standards (such as GMP) in a hospital under the exclusive professional responsibility of a medical practitioner, should be excluded from the scope of the regulation provided that the rules related to quality and safety are not undermined.

The new legislation thus presents a comprehensive scheme of the scientific and legal principles underlying the analysis of regulatory requirements for the marketing authorization of this group of these major innovative treatments.

**Dr Peter Feldschreiber**

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# Environmental highlights

## 2007/2008 Public Bills

A number of Public Bills on the environment are currently making their way through the Parliamentary process. The Bills follow on from the 2007 Queen's Speech and prescriptive White papers published on planning, climate change energy matters setting out the Government's agenda for new legislative frameworks:

### Planning Bill

The Right Honourable Hazel Blears MP, Secretary of State for Communities and Local Government, presented the Planning Bill to Parliament on 27 November 2007. The Bill, as it currently stands, sets out a package of wide ranging reforms to the Town and Country Planning System for England and Wales, which is based to a large extent on the proposed reforms comprised in the recent Planning White Paper, "Planning for a Sustainable Future" (May 2007). The Bill and its predecessor, the White Paper, have met with much opposition and controversy, not least over the Government's plans for major infrastructure projects. In view of this, the Bill is likely to change during its course through Parliament, being subject to scrutiny by both houses, combined with ongoing political debate.

In summary, the Bill aims to establish a new Infrastructure Planning Commission, which will oversee a new single consents regime for Major Infrastructure Projects to be underpinned by new National Policy Statements. A planning charge will be introduced and will be known as the "Community Infrastructure Levy", ensuring that the costs of providing new infrastructure for development are met. Finally, changes are to be made to the current planning system, the aim of which is to speed up the process, in particular, for small scale residential developments and renewable energy projects. A duty is to be placed on all planning authorities to include policies in their Development Plan Documents on mitigating and adapting to climate change.

### Climate Change Bill

The Bill was presented to Parliament on 14 November 2007. Its primary objective, to place a legal obligation on Government to reduce carbon dioxide emissions in the UK by 26-32% by 2020 and by 60% by 2050. A series of five yearly carbon budgets are proposed by Government, the first budget period being anticipated to run from 2008 to 2012, coinciding with the second phase of the EU ETS (EU Emissions Trading Scheme). The Bill follows on from the draft Climate Change Bill, launched by the Prime Minister on the 30 March 2007, its key objectives, to make voluntary national targets for the reduction of CO<sub>2</sub> emissions legally binding, providing a long-term framework for climate change policy in the UK, and to enable the UK to lead by example and drive international negotiations on a post Kyoto Protocol Agreement. In addition to legally binding targets and carbon budgets, the Bill also requires the Government to make an annual statement to Parliament, stating the levels of, and the changes in, greenhouse gases, as defined in the Bill. A new "Committee on Climate Change", an independent body, is to be established to advise Government on how best to achieve its targets and how to set carbon budgets. The Committee would also be required to deliver an annual progress report to Parliament, reporting every five years at the end of each "carbon budget period" on current and predicted impacts of climate change and its proposals for adaptation. Finally, the Bill enables the Government to introduce new national emissions trading schemes to help meet its emissions reductions targets.

## EU Emissions Trading Scheme ("EU ETS") Update

### Second phase of EU ETS

- The first phase of the "cap and trade" emissions trading scheme ended on 31 December 2007. Prior to this, the EC completed their allocation of national allowances to all Member States pursuant to the Scheme on the 26 October 2007, setting the scene for phase 2, Member States in turn prescribing their own allocations for participating industries in National Allocation Plans. Phase 2 of the EU ETS began on 1 January 2008 and will run until 31 December 2012.

### EU ETS to cover aviation emissions by 2012

- On 20 December 2007, and after the UNFCCC (United Nations Framework Convention on Climate Change) conference in Bali on the future of the Kyoto Protocol (i.e. Protocol to the Convention to reduce greenhouse gasses), EU Environment Ministers reached a political agreement on draft EU legislation to include aviation within the scope of the EU ETS. The UK Government has welcomed the development, which will, if implemented, cover all flights entering and leaving the EU, not just internal European flights, from January 2012, end of the second phase of the EU ETS. New EU legislation would see aviation emissions being capped at 2004-2006 levels, with further growth in emissions being cancelled out by emission reductions in other sectors covered by the Scheme. Airlines would be regulated by the EU country in which they run the majority of their flights, with breaches of regulation leading to legal action. Consistent enforcement throughout the EU will be paramount, with operators being banned from operating in the EU as a last resort.

In terms of implementation, it is anticipated that the draft European Directive will go before the EU Parliament, with a final decision being made in the spring of 2008.

### UK companies fined under the EU ETS

- The Environment Agency has fined four companies for failing to surrender sufficient allowances required by the Scheme by the relevant due date (30 April 2006) to cover emissions for the first year of trading under the EU ETS (2005/2007):
  - Alpha Steel (steel recycling company) fined approximately £565,000/€839,000
  - David Platt (ceramic tile company) fined approximately £122,000/€181,000
  - Mars (UK) (Foods Stuffs Company) fined approximately £53,000/€78,000
  - Scandstick (adhesive products company) fined approximately £20,000/€29,000

Penalties for failure to submit the required allowances are set to rise by €40 per tonne of CO<sub>2</sub> in 2008 to €100 for phase two of the EU ETS.

### Implementation of emissions trading auctions

- A new consultation investigating the practicalities of delivering auctions in the UK, which are due to take place during the second phase of the EU ETS (2008-2012) was published by Defra on 21 December 2007. In accordance with the UK's National Allocation Plan, which sets out Member States' final allocations of CO<sub>2</sub> allowances for participating sectors covered by the Scheme, the UK Government is committed to auctioning 7% of CO<sub>2</sub> allowances during phase 2 (i.e. 85 million allowances over a five year period). The UK will also auction or sell any surplus allowances set aside for new entrants and from closures of installations under the scheme. A cap of 10% will persist on auctioning of allowances in phase 2.

### Standard environmental permits

The Environment Agency is at present consulting on draft standard rules and guidance prior to the implementation of the Environmental Permitting Programme ("EPP"), the aim of which is to streamline the permitting process, merging the Pollution Prevention and Control and Waste Management Regimes into a single system. The EPP, a joint Government initiative is due to come into force in April 2008 under new "environmental permitting regulations", after which, standard permits for low to medium risk operations will be available from the Environment Agency that do not require a site specific assessment of risk. The new standard permit will comprise one condition that refers to a set of standard rules, which define activities that an operator may carry out, in addition to specifying certain restrictions on those activities. There will be no right of appeal against the conditions imposed in standard permits and they cannot be varied.

### Restriction on the use of certain hazardous substances in electrical and electronic equipment (ROHS) Regulations 2006 – Proposed changes

A new Business, Enterprise and Regulatory Reform (BERR) consultation was published in October 2007, setting out proposed changes to the ROHS 2006 Regulations (i.e. Regulations prohibiting the marketing of new electrical and electronic equipment that contains more than the prescribed levels of hazardous substances). The proposals are not to change the substance of the key obligations in the 2006 Regulations, nor the range of persons on whom the regulations are imposed. The changes are instead limited to specific areas of exemption applications of hazardous substances, in addition to the investigation and enforcement of compliance with producers' obligations:

## InFocus

- The list of exempt applications of hazardous substances listed in Schedule 2 to the 2006 Regulations is to be amended following three EC Decisions, which amend the list of exempt applications in the ROHS Directive. BERR propose removing the current list, referring to the exempt applications of restricted substances in the Directive's Annex, in the alternative, as amended from time to time.
- BERR propose to amend and clarify the enforcement provisions in order to make the regime clearer and more effective. It is intended that there should be a new power to require the production of documents and information in order to assist the National Weights Measures Laboratory (NWML) in establishing identity of producers for any given item of electrical and electronic equipment ("EEE"). This would enable the enforcing authority by written notice to require persons (i.e. producers) to provide it with relevant information in order to establish whether or not there has been an infringement of the producers' obligations or a failure to comply with a compliance notice. Finally, the Government intend to introduce for new procedural offences of obstruction and supplying false information.

BERR anticipates that new regulations will be made by the beginning of 2008.

### **ROHS: Enforcement action**

- The first enforcement action in the UK was recently confirmed by the NWML and concerned the sale of electrical equipment containing too much lead. This is the first instance of enforcement action taking place in the UK since the introduction of the Regulations in July 2006.

### **EC consultation on changes to ROHS Directive**

- The consultation, published in December 2007, sets out broad proposals for change, including the addition of further product groups and hazardous substances to the scope of the Directive. Proposed legislation is anticipated in 2008 and the consultation closes on the 13 February 2008.

### **WEEE (Waste Electrical and Electronic Equipment): Update**

BERR has recently admitted that it is struggling with the concept of "individual producer responsibility", a core feature of the European Directive on WEEE. Practical difficulties in implementing such a concept have been emerging. In order for individual producer responsibility to work, a producer must know how many of its products enter the waste stream each year and the end of life costs. In theory, an incentive to producers to design for recycling. Under the UK regime, however, producers pay costs based on tonnage of EEE that they place on the market, which is split across ten categories of EEE dealt with under the Regulations. In reality, those producers who invest in making products easier to recycle are left subsidising producers who make no such effort. Concerns about individual producer responsibility, therefore, appear to be the reason for the Government's lack of action. Indeed, the Government have recently admitted to the House of Lords Science and Technology Committee that to introduce a new system would be expensive, stating that there is nothing to stop manufacturers or producers now putting in place an individual producer responsibility system, as it is now precluded by the Regulations. Producers, however, disagree with the Government and say that the current regulations prevent them from acting, making producers jointly responsible for the recycling of products, thereby ensuring that it is impossible to implement individual producer responsibility. Under the UK Regulations, compliance schemes had until 31 December 2007 to submit to the Environment Agency ideas regarding how individual producer responsibility could be addressed in the UK.

### **REACH – New guidance on data sharing**

The EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, came into force on 1 June 2007 and is being phased in gradually. The regime requires the registration and authorisation of most dangerous chemicals, with responsibility for testing being placed on the industry. The European Chemicals Bureau has already published guidance notes on the new regime and recently had issued new guidance on data sharing between manufacturers and importers which includes:

- Calculation and sharing of costs of data collection.
- EU competition or issues arising from sharing business information.
- The sensitive issue of confidential business information on chemical formulas and testing.
- Technical guidance on the process of data sharing.
- Working procedures for the mandatory data showing process known as "Substance Information Exchange Forums".

## InFocus

*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](#)

**[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.

We are delighted to invite you to contribute your views. We would be extremely grateful if you could take the time to respond to this questionnaire, which should take no more than five minutes to complete. In return for your help, we will send you a copy of our findings.

The survey is aimed at those who deal with intellectual property issues on an international basis and if you have colleagues who specialise in intellectual property, please pass details of the survey on to them.

To participate in the questionnaire, please [click here](#).

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

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

Partner [Daniel Pavin](#) spoke at the Pharmaceutical Licensing Group Workshop on 24th January on "Effective Strategies for resolving licensing and collaboration agreement disputes".

[Dr Gareth Morgan](#) spoke on "Legal and regulatory challenges in the revised Directive 2001/83" at the 7th EGA Regulatory & Scientific Affairs Conference at the Radisson Hotel, Brussels on 31 January 2008.

## Mark Your Calendars [Back to contents](#)

[Tim Worden](#) is speaking on "Resolving disputes in R&D agreements" at the Hawksmere Conference "Drafting and enforcing R&D contracts" on 7 February at the Rubens Hotel in London.

Partner [Malcolm Bates](#) is participating in the Panel discussion, "Putting Your Contract Under The Microscope - Dissecting The Key Clauses Which Will Affect Your Partnership" led by James Singleton, Associate General Council, Merck Serono at Biobusiness 2008 on 26-28th February 2008 at the Intercontinental Geneva.

Taylor Wessing is hosting its 4th Annual Brands Forum on 11 March 2008 in London. Ruth Annand will chair the Forum and David Keeling Second Board of Appeal OHIM, will speak on protecting trade marks with a reputation. For the full programme please [click here](#). If you would like to attend please contact [Elizabeth Richards](#).

[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.

# 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](mailto: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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