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Technology & Life Sciences Group: Life Sciences Bulletin

BioBrief

In this the first edition of BioBrief, an Arthur Cox Technology & Life Sciences Group Bulletin, we look at a range of issues affecting the Life Sciences sector and some recent developments in relevant law.

The "InBrief" and "About Us" sections provide some information on who we are and what we have been up to recently. As ever, any feedback you may have on these bulletins is welcome.

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We hope you find BioBrief of interest. However, if you would prefer not to receive it in the future, please reply to our e-mail with "Unsubscribe" in the Subject box.

Clinical Trials: The Regulatory Challenges

In the wake of the recent publication of the report of the Innovation Taskforce, and at a time in Ireland when the emphasis is increasingly on the need to become a global innovation hub, it is appropriate to consider whether the current regulatory framework for clinical research is fit for purpose. Many in the research sector believe that the clinical trials regulatory framework in Ireland, and in the wider European Union remains as challenging as ever. Criticism of the framework often focuses on the existence of two separate overseeing bodies: the competent authority of the Member State (in this case the Irish Medicines Board); and an ethics committee constituted in accordance with law, and the requirement to seek the prior approval of both entities before commencing a clinical trial. The counter argument to that of course is that the potential risks to human health involved in clinical research justify the weight of regulation. The other common complaint derives from the absence of complete harmonisation across member states of the European Union, an increasingly prevalent issue as declining levels of participation in clinical trials mean that clinical researchers are forced to spread their research across numerous trial sites in many member states.

The recent conclusion of a public consultation on the operations of the Clinical Trial Directive 2001/20/EC could mark the beginning of reform of regulations in this area at European level with an ultimate effect on Irish law, but in the interim, it is important to be familiar with the current Irish regulatory framework.

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The Regulations

Clinical trials in Ireland conducted in human subjects and involving investigational medicinal products, are regulated by the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 and 2006 which implement certain provisions of the Clinical Trials Directive 2001/20/EC and the Good Clinical Practice Directive 2005/28/EC.

The Ethics Committee Approval

Ethics Committees are provided for in Regulations 6 and 7 of the Clinical Trials on Medicinal Products for Human Use Regulations, 2004. Ethics Committees consist of up to 21 members, of which a minimum of one third must be lay members and at least half of those lay members must be persons who are not and never have been health care professionals, and must be approved by the Minister for Health and Children. Each Ethics Committee sets out its own procedures but a clinical trial cannot be approved unless at least the chairperson and six other members are present when the proposal is considered.

The Clinical Trial Authorisation

Following Ethics Committee Approval, a clinical trial authorisation ("CTA") must be obtained by a sponsor or a person authorised to act on his behalf who is established in the Community from the Irish Medicines Board ("IMB"). Prior to issuing a CTA, the IMB will require that the sponsor or the person authorised to act on his behalf in relation to the trial, is established in the Community, a favourable Ethics Committee opinion has been obtained in relation to the protocol, and insurance and indemnity cover for the conduct of the trial are in place. The sponsor must also have registered with Eudravigilance the adverse event monitoring body of the EMEA. If a CTA application involves a trial site in a third country, the IMB may require an undertaking from the sponsor or the owner of such premises, to permit the premises in that country to be inspected by or on behalf of the IMB for the purposes of ensuring GCP is adhered to.

Once an application for a CTA is submitted to the IMB, the IMB has thirty days in which to give written notice to the sponsor setting out either the grounds for refusing the CTA, granting the CTA or granting the CTA subject to conditions. If no written notice is given by the IMB, a clinical trial may be treated as if it had been authorised. If the IMB refuses a CTA or grants it subject to conditions, the sponsor may make an amended request to the IMB within fourteen days, and the IMB must respond to such amended request within sixty days, again setting out the grounds for refusing the amended application for a CTA, granting the CTA or granting the CTA subject to conditions. Different timescales apply to CTA applications in respect of clinical trials involving medicinal products for gene therapy and somatic cell therapy including xenogenic cell therapy, or containing genetically modified organisms. The IMB cannot authorise a clinical trial involving gene therapy if the use of those products would result in modifications to any subject's germ line genetic identity.

Safety and Integrity of Trial Subjects

Maintaining the safety and preserving the integrity of trial participants is the central motivation of the regulatory framework. The sponsor must obtain each trial subject's informed consent to their participation in the trial, and inform them of the trial's procedure and right to withdraw at any time. The consent should also include appropriate consents to data processing. The trial must be conducted in accordance with good clinical practice ("GCP"), and comply with the ICH Guidelines on GCP, European Commission Guideline ENTR/CT3 2006, the Declaration of Helsinki and all relevant guidelines. The sponsor must notify the IMB within seven days of any breach of GCP. The sponsor must also ensure that all correct safety reporting is conducted and that urgent safety measures are taken when there is an immediate hazard to health or safety. Medicines and devices must be provided free of charge, except in circumstances where the trial is a non-commercial clinical trial concluded by an investigator-sponsor without the participation of the pharmaceutical industry in circumstances where the investigator-sponsor has no commercial or financial interest in the outcome of the trial insofar as the products have not been obtained free of charge by the investigator-sponsor. The sponsor must maintain a trial master file and retain all essential documents relating to the clinical trial for at least five years after its completion.

A sponsor may amend the protocol at any time, however if the amendment is a substantial amendment, a notice must be sent to the IMB, and in certain circumstances, the Ethics Committee. The IMB and Ethics Committee will accept or reject the proposed amendment within 35 days. The sponsor must notify the IMB and the Ethics Committee of the completion or early termination of the trial, within 15 days. The IMB may suspend a CTA at any time, and a sponsor may appeal a suspension within 28 days.

Commentary

Practical difficulties are confronted by researchers on a daily basis due to the absence of complete harmonisation of the regulatory regimes in across European member states and the red-tape and delays associated with the required dual approval procedure. In response to these criticisms as well as other difficulties with the practical application of the Clinical Trial Directive 2001/20/EC, the European Commission launched a public consultation on the "Functioning of the Clinical Trials Directive" on 9 October 2009 which closed on 8 January 2010. It remains to be seen the extent to which the concerns of the research community will be taken on board in the reform of the regulatory framework, and the manner in which the revised legislative instrument will obtain a balance between creating a framework which is conducive to research, while at all time placing the health and safety of clinical trial participants at the forefront.

Case Note: Hygeia Chemicals Limited v Irish Medicines Board

On 27 January 2010 the Supreme Court ruled in favour of Hygeia Chemicals Limited in an appeal against the decision of the Irish Medicines Board to revoke authorisations in respect of two veterinary medicinal products for the treatment of worm infestations found in sheep. Although the facts of this case concerned veterinary medicinal products, and the decision was made against the backdrop of the veterinary medicine regulatory framework, the decision is an interesting one for all those involved in the life sciences industry in Ireland, given that it contains a rare analysis and discussion of the administrative and decision-making procedures of the Irish Medicines Board, which is the statutory body with responsibility for the regulation of human medicines, veterinary medicines, medical devices and blood and tissue establishments in Ireland. The judgment also includes an interesting discussion of the use of the "precautionary principle" in assessing the risk-benefit balance of medicinal products placed on the market.

Background

The dispute had its origins in a review of products containing organo phosphate ("OP") conducted by the Advisory Committee for Veterinary Medicines of the Irish Medicines Board (the "ACVM") in 2000. During the relevant period Hygeia's products contained 10% diazinon, an OP and were sold in plastic containers.

At the time of the review by the ACVM there was no recognised standard for the appropriate "delivery system" (container) for such products. Nevertheless, the ACVM decided that from 31 October 2002 new closed delivery systems or similar would be required. Such systems were already in use by two of Hygeia's competitors. This deviated from the IMB's own standards published in 2000, and it was unclear as to what basis the ACVM has made their decision to require a "closed-system" over an "open-system". Of further doubtfulness was the testing employed by the ACVM. This included what was loosely termed a "toilet test" (used to check for spillage occurring when decanting the product from the container), and did not appear to involve any rigorous testing methodology.

Hygeia disputed the ACVM's decision, and provided its own risk-analysis data to support its existing systems. Nevertheless as of 31 October 2002, the IMB revoked Hygeia's manufacturing authorisation. Hygeia appealed the decision. The appeal was heard by the same committee that had conducted the original review, with no set standards or formalities. The IMB argued that the "precautionary principle" permitted them to revoke the authorisation even in the absence of concrete scientific evidence on the basis that they had a legitimate public health concern. Hygeia sought judicial review of the IMB decision, but Finnegan P, sitting in the High Court, agreed with the decision of the IMB.

Hygeia then appealed the High Court decision to the Supreme Court, listing 21 separate grounds for appeal, which can be distilled to three primary headings. Firstly Hygeia alleged that the procedures of the ACVM were contrary to the principles of natural and constitutional justice. Secondly Hygeia claimed that there was bias in both the initial hearing and appeal heard by the IMB. Thirdly Hygeia claimed that the High Court judge had erred in law in applying the "precautionary principle" test to the facts.

Supreme Court Findings

The Supreme Court upheld Hygeia's appeal on the first and third grounds, but not on the basis of the second ground, alleged bias.

The Supreme Court noted the potential seriousness and economic cost of the revocation of an authorisation. This, the court said, is a "very clear restraint on property rights" and any procedure which purported to restrain such rights would have to do so under "established principles of law" to "ensure the appropriate respect for Constitutional rights". The court found an absence of respect for Hygeia's rights in the nature of the review and appeals process, the lack of any clear published procedures, and the failure of the ACVM to demonstrate that there was any coherent and "appropriate" national or international standard in relation to the types of permissible container.

The Supreme Court recognised that the "precautionary principle" has become a well acknowledged general principle of EU Law, confirmed by two leading judgments of the Court of First Instance, *Artegodan GMBH & Others v Commission of the European Communities* and *Pfizer Animal Health v Council of the European Union*. The "precautionary principle" requires competent authorities to take all appropriate measures to prevent specific potential risks to public health, safety and the environment by giving precedence to the requirements related to the protection of those interests and without having to await definitive evidence of the risk involved. The Supreme Court noted that there are four dimensions to application of the "precautionary principle", summarised as follows:

(a) Where a product has been licensed, there is a presumption that it is safe to use as of the time of its authorisation;

(b) Where there is a proposed revocation of/refusal to renew an authorisation, it is up to the competent licensing/authorising body to demonstrate that the product is no longer safe, even where the precautionary principle applies;

(c) Where the "precautionary principle" is applied in light of an absence of authoritative scientific evidence, the withdrawal must be based on the most up to date,

comprehensive scientific or technical information and such information is to be gathered from scientific opinion based on the principles of excellence, transparency and independence; and

(d) Any risk assessment carried out in light of the scientific opinion must be done as thoroughly as possible.

The Supreme Court held that the High Court had erred in failing to take full consideration of the technicalities of the application of the "precautionary principle". The court found that the withdrawal of Hygeia's authorisation by the ACVM did not comply with the "precautionary principle", and that the taking of preventive measures on the basis of a purely hypothetical risk is inappropriate.

Conclusion

The judgment is a welcome clarification on the applicability of the "precautionary principle" under Irish law. It also serves as a reminder to any competent regulatory body of the potential seriousness and economic cost of the revocation of an authorisation, and the very serious responsibility that they face in balancing this interest against any potential risks to public health, and the importance of ensuring that any review or suspension of such an authorisation is undertaken in accordance with procedures that are fair, objective, clearly identified and published.

Life Science Companies on the Move: Corporate Migration to Ireland

Multinational groups continually review their position in terms of optimal location for operational and fiscal purposes. Current holding structures may appear under threat by recent announcements against perceived offshore tax havens. The possibility of the taxation of foreign profits or the imposition of withholding tax on payments has come to the fore and many corporate groups with a parent company incorporated in countries like Bermuda or the Cayman Islands have migrated to other jurisdictions to locate their top holding company in a jurisdiction that has a good network of tax treaties and trade agreements. A migration may also be efficient for groups located in jurisdictions with overly complex tax systems, including strict controlled foreign company (CFC), transfer pricing, thin capitalisation and other rules that add to compliance costs. Recent examples of companies in the life sciences sector who have made the move to Ireland include Warner Chilcott, Covidien and Shire.

How to Migrate

The tax residence of an existing holding company can sometimes be changed by moving its place of effective management and control outside of its existing jurisdiction for tax purposes. However, since this can trigger a tax charge on exit in some jurisdictions (e.g. the UK), it is often more effective to incorporate a new parent company in the new jurisdiction and interpose the new parent company between the existing parent company and the public shareholders. For public companies incorporated in a common law jurisdiction, this can often be done by way of a cancellation scheme of arrangement approved by the court or share-for-share exchange. In effect, the public shareholders agree to the cancellation or swap of their shares in the existing parent company in return for shares of an equivalent amount in the new parent company. For public companies incorporated in the EU, this can also be achieved by re-registering the existing parent company as a "Societas Europaea" or "SE" (the new form of European public company) and then moving its registration to Ireland. EU parent companies can also migrate to Ireland by merging with an Irish public company under the Cross-Border Merger regulations.

Establishing a new parent company as a resident outside the jurisdiction of the existing parent is often only part of the migration process as it is often beneficial to transfer the foreign operations of the group from the original parent company to the new parent company and restructure the group to derive maximum benefit from the migration.

A decision to migrate cannot be taken lightly. It is likely to have substantive consequences for the governance and operations of the group and it is important therefore to select a jurisdiction that requires the minimum of changes while at the same time offering the maximum flexibility.

Why Ireland

The reasons for selecting Ireland include the following:

- Ireland's low corporation tax rate (corporation tax on trading profits is 12.5%) and the ability to repatriate profits to Ireland without tax costs.
- Ireland has a signed comprehensive double tax treaties with 55 countries, including the U.S. and all EU member states; of which 46 are in effect with the remainder to come into force shortly, including many with the Middle Eastern states.
- Ireland is a member of the OECD and the EU and is the only English-speaking jurisdiction in the euro-zone.
- Like the UK and the U.S., Ireland is a common law jurisdiction and its legal concepts will be recognised by most investors; in addition, the laws relating to personal property and the transfer of assets and the concepts of legal and equitable title are similar to those in the UK and the U.S.
- A new parent company can be incorporated speedily in Ireland as either a public limited company or as a "Societas Europaea" ("SE").
- Irish public companies must prepare their accounts in accordance with IFRS and must prepare consolidated group accounts where they have subsidiaries (but transitional relief is now available to enable modified US GAAP to be used in certain circumstances for a four year period).

- The Irish Stock Exchange (ISE) currently has responsibility for the approval of any public offer prospectus required to be issued by an Irish company. The ISE provides an efficient and comparatively speedy approval procedure for prospectuses.
- Takeover bids for public companies incorporated in Ireland are regulated by the Irish Takeover Panel whose rules are based on the Takeover Code of the UK Takeover Panel as well as incorporating the EU Takeover Directive 2004/25/EC.
- Ireland has an experienced and efficient Commercial Court which can resolve disputes speedily in a cost effective manner.
- Dublin is an established international financial centre.
- Ireland has a skilled and well-educated labour force.

Taxation

Key reasons for Ireland's popularity as a destination for corporate migrations are its favourable tax regime, the fact that it is an "onshore" EU jurisdiction and the professional and administration services that are available locally. In addition, as the tax laws in Ireland are objectively ascertainable, tax rulings prior to a transaction proceeding are rarely required but may be available if desired. The following tax points are of particular relevance:

- 12.5% rate of corporation tax applies to trading profits and trading dividends. A rate of 25% applies to passive income.
- The rate of capital gains tax is 25% however the sale of shares by a non-Irish resident is usually exempt from capital gains tax. An exemption also exists for disposals of 5%+ corporate shareholdings held for at least 12 months in trading companies/groups that are EU/tax treaty resident.
- Shares in Irish incorporated companies can be transferred through the CREST System. They can also be deposited with a depository bank so that they can then be traded as ADRs or under an arrangement that is equivalent to an ADR structure. The transfer of ADRs (or shares held under an arrangement that is equivalent to an ADR structure) which are issued in respect of Irish companies and traded on a stock exchange in the U.S. or Canada are not subject to stamp duty. Shares in Irish incorporated companies which are transferred through the CREST System are subject to stamp duty at the rate of 1%.
- No dividend withholding tax applies to dividends paid to persons resident in an EU or an Irish tax treaty country or on U.S./Canadian listed shares held through ADRs (subject to collection of relevant forms). It is also possible to implement structures using income access shares where it is necessary to allow shareholders to continue to receive non-Irish dividends.
- Dividends received by an Irish incorporated company are taxed at 12.5% or 25% but a flexible credit system usually eliminates any tax liability on receipt; also other tax free cash repatriation techniques are available.
- No interest withholding tax applies to interest paid (i) to persons resident in an EU or an Irish tax treaty country or (ii) on listed bonds or commercial paper.
- A specific tax credit is available in Ireland for research and development activity.
- Ireland operates a favourable and flexible securitisation and finance company regime.
- Ireland does not have any thin capitalization rules.
- Ireland does not have any controlled foreign company/ Subpart F rules.
- Ireland currently has a comprehensive framework of double taxation agreements. The agreements generally cover income tax, corporation tax and capital gains tax (direct taxes).

Obtaining and maintaining tax residence in Ireland for the new parent company is not simply a matter of ensuring that it is incorporated in Ireland. It is also generally necessary for the central management and control of the company to be located in Ireland and not elsewhere. The central management and control of a company is located in the jurisdiction in which the significant decisions relating to the strategic direction of the company are taken. In a case where those decisions are taken by the directors of the company at board meetings, this will generally be the jurisdiction in which those board meetings are held. However, the location of board meetings is not determinative where the powers of the board have been delegated or where the board simply "rubber-stamps" decisions taken outside the board meeting. These rules mean that a multinational group moving to Ireland must ensure that all the significant strategic decisions relating to the group are taken at board meetings held in Ireland, in which the directors actively address the issues being put to them and reach a considered decision.

Competition Law Enforcement: Spotlight on Pharmaceutical Industry

Recent years have seen an increase in competition law enforcement by the European Commission ("Commission") and other competition authorities in the pharmaceutical industry. This period of increased scrutiny began in January 2008 when the Commission launched a sectoral enquiry into the industry by undertaking a series of unannounced inspections ("dawn raids") at the premises of some innovative and generic pharmaceutical companies. The

purpose of the enquiry was to establish whether agreements between pharmaceutical companies or the misuse of patent rights could have infringed the competition rules contained in Articles 101 and 102 of TFEU (formerly Articles 81 and 82 of the EC Treaty). When the Commission's report was published in July 2009, it indicated that it would step up its scrutiny of certain business practices, such as patenting strategies designed to exclude competitors rather than pursue innovation, and settlement agreements that limit generic entry, and to assess whether, in the legal and economic circumstances, they would be compatible with competition law.

Since the publication of the report, there has been further enforcement activity in the sector as evidenced by the dawn raids that the Commission undertook in the sector towards the end of 2009.

Competition law enforcement is not only restricted to action by the Commission. There has been increasing interest in the distribution of pharmaceutical products in Ireland. In 2009 the Irish Competition Authority published a notice providing guidance on the application of competition law to collective negotiations by pharmacy contractors in the community pharmacy sector as a result of concerns that collective action was being used to defeat price reductions sought by the Irish State. In previous years, the Competition Authority had also investigated the role of the HSE and whether its actions fell within the scope of the Irish competition rules.

The Irish Competition Authority also maintains close contacts with the other EU competition authorities and the OECD and in 2009 made a submission to the OECD on generic pharmaceuticals.

In the light of these developments, it is likely that the competition law enforcement spotlight will remain on the pharmaceutical sector for some time to come. This, coupled with the more general objective to eliminate cartel activity in all sectors of the economy, means that competition law compliance should be high on the agenda for all companies and individuals operating in the pharmaceutical industry.

In Brief

In this section, we let you in on what we have been up to in the past few months. If you would like further information about any of the items below, please contact any member of the Technology & Life Sciences Group.

Commercialising Knowledge Seminar 2009: Arthur Cox hosted a seminar on issues for the third and fourth level education sector in respect of the commercialisation of knowledge on 20 November 2009. The conference provided an interesting overview of some of the key legal issues faced by those operating in the technology transfer sector. Topics covered ranged from clinical trials (with particular focus on regulatory challenges) and the implications of the recent Charities Acts to a consideration of recent developments in the law of copyright and guidance on the conclusion and enforceability of contracts. This was the second of our third and fourth level seminars and we plan to hold a similar event later in 2010. We would welcome your thoughts on this, and in particular any topics which you feel would be of interest to you.

Freedom of Information and Data Protection: **Colin Rooney** contributed an article to December's Privacy and Data Protection journal entitled "The interaction of data protection and freedom of information law in Ireland".

PLC Cross-Border Handbook on Life Sciences: Arthur Cox have contributed a chapter to the Practical Law Company Cross-Border Handbook on Life Sciences for 2010, setting out a summary of Irish legal provisions in relation to pharmaceutical regulation, intellectual property and product liability. A copy of the chapter is available on our website at: http://www.arthurcox.com/publications/plc_life_sciences_handbook_2009_2010.html.

New Addition: On 1 March, the Technology & Life Sciences practice group was delighted to welcome **Iseult Ní Ghallchóir** to the team. Iseult joins us from an in-house role in the headquarters of a global pharmaceutical company.

BioConnect: On 15 March, **Lisa Kinsella** attended the BioConnect Ireland event where the topic under discussion was "Connected Health".

Sourcing: **Pearse Ryan** discusses the Irish experience of sourcing in troubled times in an article entitled "Sourcing in Troubled Times" which was published by the Society for Computers and Law and which is available to SCL members on the SCL website: www.scl.org, and otherwise available on request from Pearse, at: pearse.ryan@arthurcox.com.

EU Pharmaceutical Forum: **Declan Hayes**, **Colin Kavanagh** and **Lisa Kinsella** will be attending the 19th Annual EU Pharmeceutical Law Forum in Brussels on 6 May.

About Us

Featured Contributors

Ailish Finnerty Partner
Ailish Finnerty is a Partner in our Tax Group, which has represented most of the companies that have migrated their tax residency to and/or established their corporate headquarters in Ireland in recent times. If you have any questions or wish to discuss any issues raised in this article, please feel free to contact Ailish.
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Fiona McKeever is a Partner in our EU & Competition Group. Fiona regularly advises clients on EC and Irish merger control and those under investigation by competition authorities. She has also designed and implemented competition law compliance programmes for a number of companies, including those operating in the pharma sector. If you would like further information on any of these developments or on competition law in general, please do not hesitate to contact Fiona.
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Pearse specialises in outsourcing, sourcing and technology transactions, including business process, information technology and facilitates management outsourcing, system and software procurement. Pearse also practices in related areas, involving e-commerce, computer fraud/security, IT-related disputes and advising on re-orientation of ongoing problem projects. Pearse acts for a broad range of life science companies, principally advising on sourcing matters.
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Bob specialises in intellectual property law. He has published the definitive intellectual property law texts: *Irish Copyright and Design Law*, *Intellectual Property Law in Ireland*, and the most up to date contract law text: *Contract Law in Ireland (6th edition) 2008*. He has recently been appointed to Chair the Sales Law Review Group, a body that will report to the Government on necessary changes to Irish Sales law in 2010.
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