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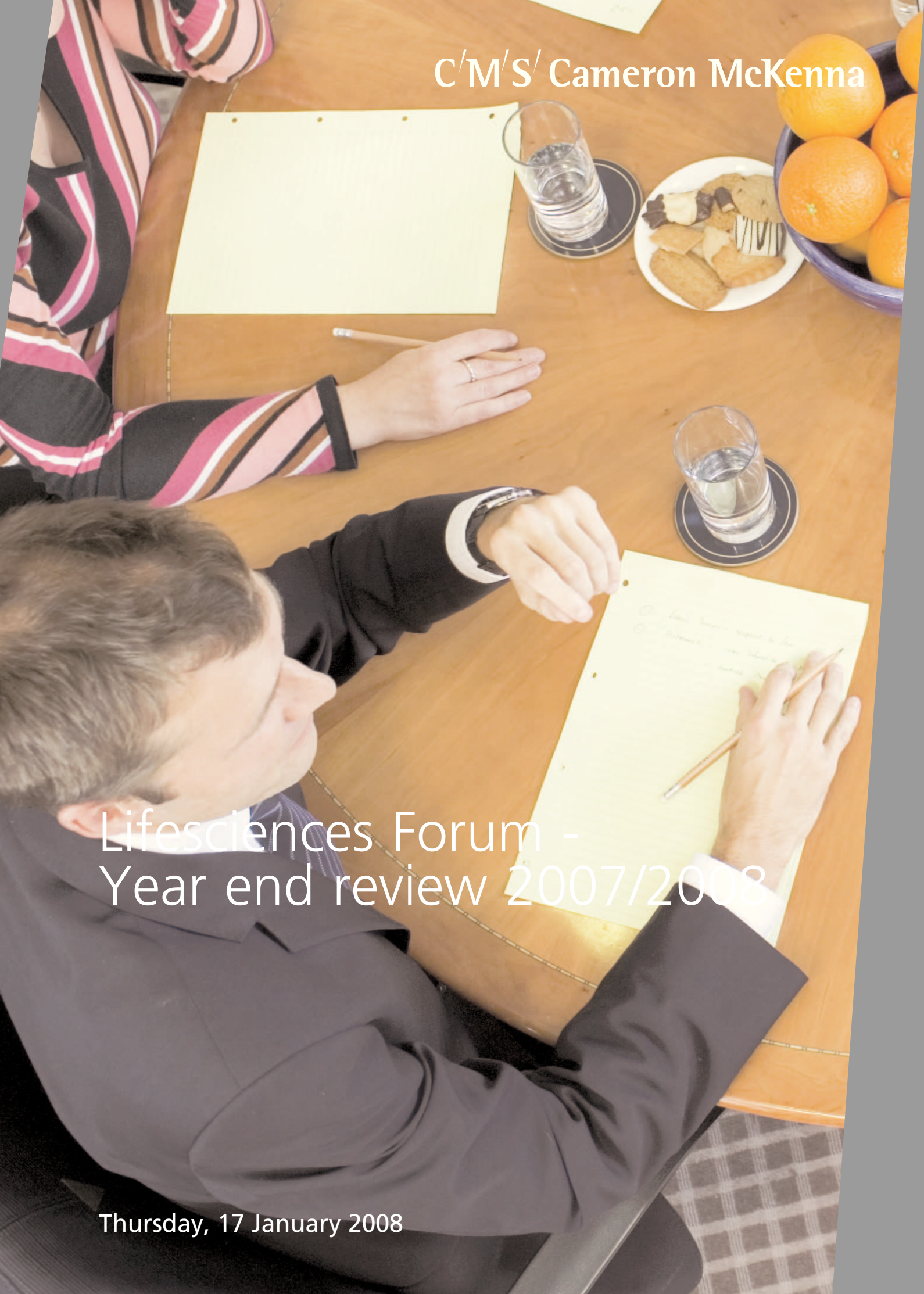

Lifesciences Forum - Year end review 2007/2008

Thursday, 17 January 2008

Agenda

Welcome to today's seminar, **Lifesciences Forum - Year-end review 2007/2008.** Issues we will cover today include:

9.00	Registration with tea and coffee	Lobby
9.30	Introduction	Nick Beckett

9.35	Competition
	• OFT market studies
	  • PPRS
	  • Distribution of medicines
	• PPRS and branded generics
		David Marks

10.00	Commercial Update • Freedom of Information Act • Unfair Commercial Practices Directive	Sarah Hanson
10.20	Intellectual Property Update • Boehringer ECJ Parallel Trade Decision • EMEA Guidance on Single Trade Mark Requirement • Trade Mark Relative Grounds • Patent Entitlement	Nick Beckett
10.50	Coffee	Lobby
11.10	Regulatory Update • Paediatric Use Regulation • Judicial Review of NICE • Revised medical devices directive • Regulation on advanced therapy	Shuna Mason

11.35	Review of the year's Corporate deals	Michael Draper
12.00	China – Lifesciences industry	Jonathan Selvadoray
12.10	Questions	All
12.15	Close with lunch	Lobby

We should be delighted to discuss any of today's topics or related issues in further detail with you. The "Speakers" section includes the relevant contact information.

We hope that you find this briefing informative and practical, and we look forward to welcoming you to future briefings and seminars.

Speakers

Nick Beckett

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Nick's practice covers all areas of intellectual property (contentious and non-contentious), with particular expertise in patent litigation, patent counselling and parallel trade matters in the pharmaceutical, biotechnology, medical device and agrochemical sectors.

Nick has for many years advised numerous life-sciences clients on a variety of intellectual property issues relating to pharmaceutical products including fluoroquinolone antibiotics, non-sedating antihistamines, antidepressants, acellular pertussis vaccines, high affinity monoclonal antibodies, enzyme replacement therapy and photodynamic therapy. Nick has also advised in relation to needleless injection devices, blood transfusion leucodepletion devices, argon plasma coagulation probes, neuromuscular blocking monitor devices, prosthetics and contact lenses.

David Marks

Partner, Competition and EU
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David has specialised for over 20 years in EU and competition law, David advises on a broad range of areas from mergers and compliance issues to state aid and procurement. His work spans a cross section of industry sectors particularly in relation to lifesciences, as well as telecoms and infrastructure projects. David has practised in Brussels, as well as in London, and is a member of the legal committee of the Association of British Pharmaceutical Industries.

Sarah Hanson

Partner, Commercial
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Sarah has over 10 years' experience of providing lifescience companies with corporate and commercial advice. She specialises in negotiating and drafting commercial agreements for biotech, pharmaceutical and medical device clients, including agreements relating to in and out licensing, sales and distributor arrangements, research and development, manufacturing and supply, strategic alliances and co-promotion and co-marketing arrangements. During her time with the firm she has been on secondment with Warner Lambert (now part of Pfizer).

Shuna Mason

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Shuna specialises in providing regulatory and product safety legal advice and representation to companies across the lifesciences sector (covering pharmaceuticals, medical devices, human tissue, diagnostics and crop protection). As well as advising R&D companies upon general regulatory issues affecting product development, marketing and promotion of lifesciences products, she has also represented companies in judicial review proceedings of regulatory authorities in connection with regulatory decisions concerning data exclusivity and the institution of enforcement action. She has also advised upon and managed regulatory challenge issues across a variety of jurisdictions on behalf of clients as well as advising and representing them in connection with regulatory enforcement activity and product liability claims.

Michael Draper

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Michael specialises in lifesciences-related transactions, including the financing of companies at all stages of their development, biopharma IPOs on major stock exchanges and secondary offerings. Michael also has extensive M&A experience in the sector and recently acted for Pfizer on its $16.6 bn disposal of Pfizer Consumer Healthcare to Johnson & Johnson.

Jonathan Selvadoray

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Jonathan is the Chief Representative of CMS Bureau Francis Lefebvre Shanghai office. He advises on a wide range of corporate matters, with a particular focus on M&A and lifesciences related issues such as product liability. He specialises in drafting and advising on intellectual property licence agreements, collaboration arrangements (including research and development agreements, joint ventures, and partnerships), sales and distributor arrangements, research and development, manufacturing and supply. Jonathan also has experience advising in relation to patent, design, copyright, trademark, and confidential information issues.

Before moving to China in 2002, he acted for more than two years as legal adviser at the Swiss Institute of Intellectual Property (department international trade relations) and member of the Swiss delegation to the WTO and was part of the negotiation team on the accession procedure of China. He has closely cooperated during that time with the Association of pharmaceutical research firms in Switzerland. Jonathan speaks English, French, German, Spanish and Chinese (Mandarin).

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Lifesciences Forum – Year end review 2007/2008

Thursday, 17th January 2008

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The PPRS and Pricing

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Early renegotiation of the PPRS

- OFT market studies into
  - PPRS
  - distribution of medicines
- GSK v DoH interpretation of 1999 PPRS

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2007

- Feb OFT market study report on PPRS
- March Injunction against Pfizer's DTP scheme rejected
- April OFT launches market study on distribution of medicines
- June High Court rules on GSK v DoH 1999 PPRS dispute
- August DoH announces intention to reopen 2005 PPRS
- Dec OFT market study report on distribution of medicines

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GSK v DoH

- Interpretation of 1999 PPRS
- 4.5% price reduction
- Branded drugs dispensed against generic prescriptions
- If part of price reduction, no £28m overpayment by GSK
- Court found for GSK
  - PPRS was a binding contract not a loose understanding
  - counted as part of price reduction
  - noted that price reduction by company did not always mean cost saving for NHS

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PPRS – OFT Market Study

- Launched in Sept 2005 - did the PPRS do what it said on the tin?
- Reported Feb 2007
- Recommended
  - value-based pricing
  - pre-launch assessment
  - HTA/NICE involvement
- Recognised UK international influence
- Concerns from industry
  - unrealistic approach
  - deters innovation
  - slows launch process

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Distribution of Medicines – OFT Market Study

- Prelude - Pfizer's launch of DTP
  - sells direct to pharmacies
  - appointment of sole logistics provider (Unichem)
- Wholesalers
  - complained to OFT
  - applied for injunction
- OFT would not grant interim measures against Pfizer
- Court refused injunction
- Pfizer DTP launched March 2007

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- OFT launches market study into distribution of medicines
- not just about DTP - also use of fewer wholesalers by other pharma cos
- OFT report
  - no action against Pfizer/DTP
  - DoH to consider service levels
  - changes should not cost DoH more
  - distribution chain discounts to be factored into PPRS discussions already underway

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2008

- DoH aiming to complete PPRS price renegotiation by mid 2008
- DoH to consider service level issues
- OFT monitoring developments in the pharma supply chain

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The PPRS and Pricing

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Freedom of Information Act 2000

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Freedom of Information Act 2000

- Applies to public authorities:
  - listed in Schedule 1;
  - designated by the Secretary of State; and
  - companies that are publicly owned.
- Act is regulated by the Information Commissioner.
- Publication scheme.

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Freedom of Information Act 2000 & the MHRA

MHRA

- Publication scheme
- Classes include:
  - organisational structures;
  - corporate publications;
  - guidance notes and application forms;
  - vigilance schemes;
  - RAMA database.

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MHRA Guidance

- Common understanding of what will be disclosed, withheld, or disclosed only after consultation with third parties:
  - replaces the 2004 Memorandum of Understanding;
  - not legally binding;
  - application of public interest test may result in different outcome to those set out in the Guidance.
- Signatories:
  - MHRA (medicines division)
  - Veterinary Medicines Directorate
  - Association of British Pharmaceutical Industry
  - National Office of Animal Health (NOAH)
  - Food Ethics Council (FEC)

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2004 Traffic Light Document (old law)

Part 2 of the Memorandum of Understanding sets out likely disclosure responses using a 'traffic light' system:

G* = already published routinely

G = disclosure on demand without consultation

A = disclosure on demand after consultation with relevant third party (subject to editing out of commercial confidential information)

R = anticipated that disclosure will not take place as information will be confidential, commercially sensitive or information which would otherwise be exempt from disclosure.

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2007 MHRA Guidance (new law)

The new guidance provides a tabulated form of the main types of information held by the regulatory bodies:

- Table 1: Documents that are routinely published.
- Table 2: Information that the MHRA will disclose on request (and may in some cases inform interested third parties as they do so).
- Table 3: Information that the regulatory bodies may be able to disclose after checking whether disclosure is in the public interest.

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Impact of 2007 MHRA Guidance

- In practice, the 2007 MHRA Guidance is unlikely to make any significant difference.
- The information listed in tables 1 and 2 is essentially the same as that which was denoted Green or Green * in the 2004 MOU.
- Table 3 provides examples of information within the listed documents where the public interest needs to be checked before disclosure as well as information that the authorities anticipate they will be able to disclose.
- The change is the reflection of the greater commitment to disclosure by the MHRA.

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What should you be doing?

- Educate staff
- Mark submissions 'Private & Confidential'
- Submit documents in two versions where possible
- Written acknowledgement from MHRA
- Do not ignore a notification from the MHRA

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Unfair Commercial Practices Directive

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Background

- No general law against unfair trading in the UK.
- "The UCP Directive seeks to stamp out unfair selling and create marketing methods in a simpler and more effective way than the current sector specific laws… It will put in place a comprehensive framework for dealing with sharp practices and rogue traders who deliberately set out to exploit the loopholes in existing legislation."
  - DTI consultation document.
- April 2008: implementing regulations for the Unfair Commercial Practices Directive are due to come in to force.
- Applies only to business-to-consumer transactions.

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Scope

- "The Directive shall apply to unfair business to consumer **commercial practices**… before, during and after a commercial transaction in relation to a product."
  - UCP Directive, Article 3(1)
- "…any act, omission, course of conduct or representation, commercial communication including advertising and marketing, by a **trader**, directly connected with the promotion, sale or supply of a product to a **consumer**."
- Focus is on the protection of the economic interests of the consumer.

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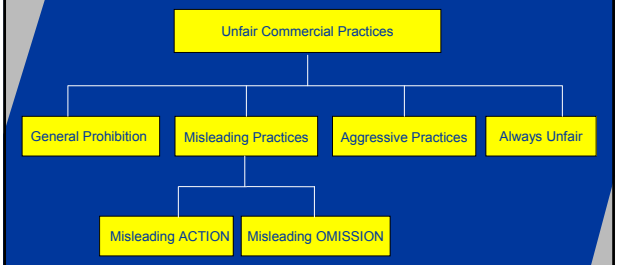
Categories of Unfair Practices



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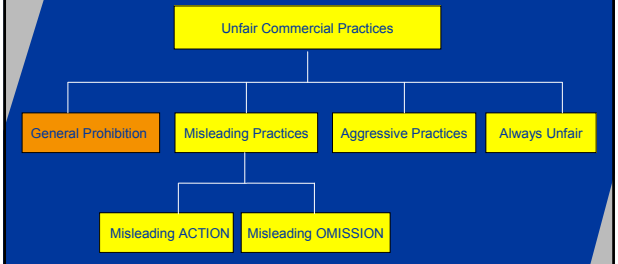
General Prohibition



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General Rule

- Unfair commercial practices are prohibited – these are:
  - practices that run contrary to the requirements of professional diligence; and
  - which materially distort a consumer's economic behaviour, or is likely to do so.
- Catch all provision where action does not fit into a more precise category.
- Benchmark will be judged by the standards of "the typical consumer."

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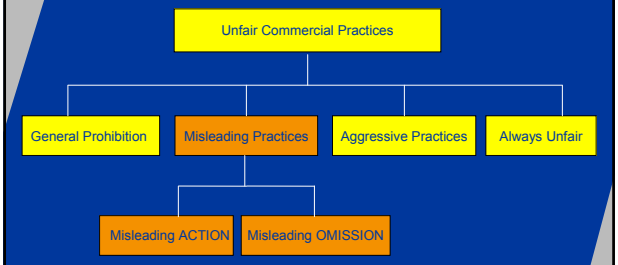
Misleading Practices



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Misleading Actions – General Rule

- Contains false information

OR

- **deceives,** or is likely to deceive the consumer

AND

- causes, or is likely to cause, typical consumer to enter into a transaction he would not otherwise have made.

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Elements of deception

- Existence/nature of product;
- Main characteristics of product;
- Extent of trader's commitments;
- Price or the manner in which it is calculated;
- Need for a service, part, replacement or repair;
- The nature, attributes and rights of the trader or his agent;
- The consumer's rights.

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Misleading Omissions – General Rule

- A commercial practice is misleading if:
  - it omits material information needed to take an informed decision; or
  - material information is hidden or provided in an unclear, unintelligible, ambiguous or untimely manner; or
  - fails to identify the commercial intent of the practice; AND
  - this causes/is likely to cause the average consumer to take a transactional decision he would not otherwise have taken.
- Material information includes a number of the same elements of deception required for a Misleading Action.

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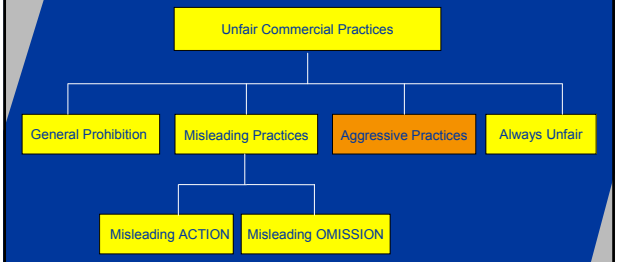
Aggressive Practices



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General Rule

- A commercial practice which:
  - by means of harassment, coercion, use of physical force or undue influence;
  - significantly impairs/is likely to impair freedom of choice or conduct; and
  - causes/is likely to cause the average consumer to take a transactional decision that he would not otherwise have made.

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Aggressive – factors to consider

- Non-exhaustive list depending on the factual content.
- Factors include:
  - timing, location, nature or persistence;
  - use of threatening or abusive language or behaviour;
  - exploitation by the trader of any specific misfortune or circumstance which impairs the consumer's judgment;
  - threats to take action that cannot legally be taken.

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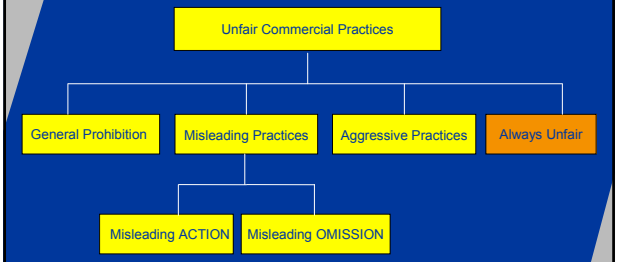
Always Unfair



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General Rule

- Annex 1 of the Directive lists 31 practices that will always be considered unfair.
- No need to consider the effect on the consumer.
- Practices include:
  - falsely claiming to be a signatory to a code of conduct;
  - "Bait and Switch" practices;
  - falsely stating that a product will be available for a very limited time;
  - falsely claiming that a product is able to cure illness, dysfunction or malformations;
  - presenting rights given to consumers in law as a distinctive feature of the trader's offer.

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Summary

- Commercial practice can still be unfair within the general prohibition even if neither:
  - 'misleading' or 'aggressive'; nor
  - falls within specific practices in Annex 1.
- General prohibition:
  - must alter consumer's decision; and
  - trader must knowingly or recklessly have breached professional diligence.
- Misleading and Aggressive practices:
  - must alter consumer's decision; and
  - strict liability offence.
- Unfair practices in Annex 1:
  - no need consider effect on consumer; and
  - strict liability offence.

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What should you be doing?

- Businesses should:
  - review existing business practices to analyse their fairness and ensure none fall within the 31 practices banned in all circumstances; and
  - analyse if anything you are failing to do amounts to a misleading omission.
- New regulations for B2B eg: the Business Protection from Misleading Marketing Regulations.

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Intellectual Property - Overview

- European Pharmaceutical Parallel Trade
- EMEA Single Trade Mark Requirement
- Trade Marks - Relative Grounds Assessment
- Patent Entitlement

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European Pharmaceutical Parallel Trade

Parallel Trade

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- Parallel trade
  - Concerns products put on the market in one country by the IP rights owner or with its consent which are then imported into another country
- "Exhaustion of rights"
  - "Intellectual property rights in one territory not enforceable against goods put on the market in another territory by him or with his consent"
  - No international exhaustion in EEA (*Silhouette* (trade marks)*; Laserdisken* (copyright))
- Repackaging
  - To what extent is repackaging of pharmaceuticals allowed? *Boehringer Ingelheim & Others -v- Swingward*

Over-labelling

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De-branding

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Co-branding

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Repackaging – Established Principles

Roche (1978) / BMS (1996) cases

- "Necessary" repackaging permissible
- Condition of product must be unaffected
- Must state name of manufacturer and repackager
- Repackaging must not damage trade mark
- Importer must notice to trade mark owner

Boehringer/Lilly/GSK (2000-)

- Second Reference to ECJ – AG Opinion: 6 April 2006 – ECJ Decision delivered 26 April 2007 – Court of Appeal Hearing from **29 January 2008**

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Boehringer Ingelheim & Others -v- Swingward

- Advocate General's Opinion -
  "Article 7(2) therefore clearly is an exception to the basic principle of the free movement of goods. Accordingly, it should not be generously construed"

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Boehringer – Issues on Referral to ECJ

- Over-labelling – Do same principles apply for over-labelling as re-boxing? ⇨ AG Opinion: B*MS* principles do not apply
- Reboxing - Does necessity test also apply to the manner of reboxing? ⇨ AG Opinion: Necessity test only applies to right to rebox not manner of reboxing
- Damage to Reputation – more than just defective, poor quality, untidy boxes? ⇨ AG Opinion: Yes
- Debranding/Co-branding ⇨ AG Opinion: Not permitted if serious risk of harm to trade mark
- Burden of Proof ⇨ AG Opinion: Shared bewteen parties
- Notice – what if not given? ⇨AG Opinion: Separate, "effective and dissuasive" sanction required

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Boehringer – ECJ Decision

- Over-labelling – Do same principles apply for over-labelling as re-boxing? ⇨ ECJ: *BMS* principles do apply
- Reboxing - Does necessity test also apply to the manner of reboxing? ⇨ ECJ: Necessity test only applies to right to rebox not manner of reboxing
- Damage to Reputation – more than just defective, poor quality, untidy boxes? ⇨ ECJ: Yes
- Debranding/Co-branding ⇨ ECJ: In principle liable to damage reputation – but question of fact for national court
- Burden of Proof ⇨ ECJ: Lies with importer
- Notice – what if not given? ⇨AG Opinion: Trade mark infringement – same remedy not disproportionate

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Boehringer - Implications

- Positive for Brand owners
  - Any form of repackaging creates very real risks to guarantee of origin
  - Act of repackaging prejudicial to specific subject matter – no need to assess actual effects
  - Any repackaging may be prohibited UNLESS
    a) Necessary
    b) Legitimate interests of trade mark protected
  - All *BMS* criteria equally important
  - Burden of proof on importer

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Boehringer – Implications

- Significant in practice
  - More vigilance by trade mark owners
  - Necessary at all?
  - Over-stickering
  - Notice
  - Co-branding/De-branding

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Single Trade Mark Requirement

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Single Trade Mark Requirement

An application for a marketing authorisation under the centralised procedure must:

"*…take account of the unique, Community nature of the authorisation requested and, **otherwise than in exceptional cases** relating to the application of the law on trade marks, shall include the use of a **single name** for the medicinal product*"

(Art.6(1) Regulation (EC) No 726/2004)

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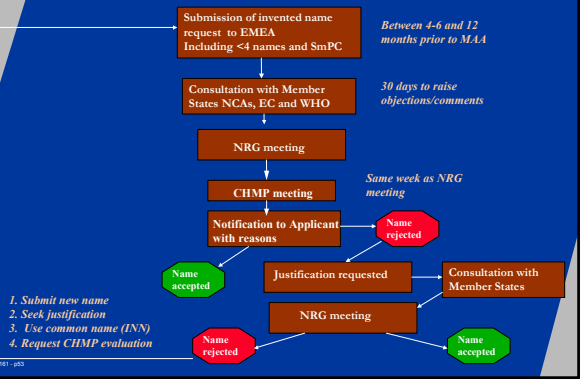
Name Review Process



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General Criteria

- Single trade mark (Art.6(1) Regulation (EC) No 726/2004)
- No confusion with common name Art.1(20) Directive 2001/83/EC
- No inclusion of INN stem (WHA46.19)
- No confusion to existing medicinal product (Para 2.1.1 Guideline)
- No misleading therapeutic and/or pharmaceutical connotations (Para 2.1.1 Guideline)
- Not misleading regarding composition (Para 2.1.3 Guideline)
- No promotional message (Para 2.3.2 Guideline)
- Not offensive (Para 2.3.3 Guideline)
- Use capital letters to reflect trade mark registrations (Para 2.3.4 Guideline)
- Comply with product specific guidance: vaccines, biologicals, orphan medicinal products, OTCs, generics, hybrids, biosimilars, fixed combinations, prodrugs (Paras 2.3.5-2.4.7 Guideline)
- Qualifiers/Abbreviations now acceptable (Para 2.3.1 Guideline)

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Revised Guidance Note – Revision 5

- Revision 5:
  - Issued: February 2007
  - Deadline for comments: April 2007
  - Adoption by CHMP: July 2007
- Key Changes:
  - Derogation: “enough evidence of its failed efforts”
  - Qualifiers/abbreviations acceptable
  - “Different” not “completely new” name for new indications with stand-alone MA
  - Guidance may not apply for non-prescription products
  - Product specific guidance e.g. vaccines, biologicals
  - 4 names per application (rather than 3)
  - Final appeal to CHMP (exceptionally)

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Trade Marks - Relative Grounds Assessment

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Trade Marks - Relative Grounds Assessment

- As from 1 October 2007, UKIPO will not examine a trade mark on relative grounds
- New procedure:
  - Registrar will still conduct search
  - Applicant notified – in examination report - 2 month period to withdraw or amend
  - Owners of conflicting marks notified – on publication – 3 months to oppose
- ‘Opt in’ procedure for CTMs
- Greater onus on brand owners

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Patent Entitlement

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Patent Entitlement

Yeda v Rhone-Poulenc Rorer, House of Lords, 24 October 2007

- Section 7 Patents Act 1977: "patent for an invention may be granted primarily to the inventor or joint inventor ..and to no other person"
- Section 37 Patents Act 1977: procedure to challenge entitlement
- Markem v Zipher: claim to patent entitlement must be based on breach by patentee of claimant's rights e.g. breach of confidence or contract
- House of Lords allowed appeal – section 7 required Court only to decide who was the "inventor" (actual deviser of the invention)
- In practice, evidence required on 2 issues: what is the invention? Who is the inventor?

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Overview

- EC Regulation on paediatric use medicines
- 1st judicial review of NICE
- Review of the medical devices directive
- EC Regulation on advanced therapies
- Trends?

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Regulation (EC) 1901/2006 on medicinal products for paediatric use

- Aims to facilitate development and accessibility of paediatric drugs and improve the information available
- New obligations for innovator MA holders and applicants to generate, collect and file paediatric data
- Incentives and rewards available
- Introduced NEW **Paediatric Use Marketing Authorisation** (PUMA) for off-patent drugs

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Reg (EC) 1901/2006: New filing obligations

MAH/MAA must file:

- Paediatric study results as per PIP (compliance report); OR
- proof of waiver / deferral

From:

- 26 July 2008: new drug applications
- 26 January 2009: on-patent/SPC (or SPC-qualifying)

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Reg (EC) 1901/2006: Waivers

- EMEA decision on class waiver (17 adult only conditions): 3 December 2007
  - http://www.emea.europa.eu/pdfs/human/paediatrics/55189407en.pdf
- 3 EMEA product-specific waiver decisions

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Reg (EC) 1901/2006, Arts.45&46: Submission of paediatric studies

- By 28 January 2008 MAHs of authorised products must submit to CAs studies and/or line listing for any paediatric studies completed by 27 January 2007
  - http://www.hma.eu/uploads/media/PaedReg_Guidance_Submission_information.pdf
  - http://www.hma.eu/uploads/media/QA_Paed_Regulation_Art_45_46.pdf
- Submission of other MAH-sponsored paediatric studies to CAs within 6 months of completion

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1st judicial review of NICE

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Eisai's judicial review of NICE

- NICE Guidance restricted use of Aricept to moderate Alzheimer's patients, excluding mild sufferers
- Eisai's judicial review = 1st challenge to NICE before the courts
- Alzheimer's Society and Shire were co-litigants
- 5 out of 6 arguments failed at 1st instance
- Appeals listed to start 14-15 April 2008

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The Model / procedural fairness

- HTA a consultation process
  - not a judicial / quasi judicial process
- No right for Eisai to "quality-assure" the Model
- Eisai was not denied access to significant information or the opportunity to make an "intelligent response"

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Unlawful Discriminatory Impact

- NICE's failure to address the question of whether the use of MMSE test was discriminatory against atypical groups made its Guidance unlawful
- Article 8 ECHR did not take the disability and race issues further
- NICE's Guidelines did not save the Guidance from being discriminatory

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Irrationality

- Appeal Panel / Court's function is not to decide which expert is to be preferred
- Court rejected all four grounds on which irrationality claim was based

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Implications for industry

- Court approval of NICE's procedures and disclosure practices
  - Better prospects where technology offers a cure or availability is a 'life and death decision'?
- Only very restricted scope to re-open expert debate
  - very high threshold for 'irrationality'
  - NICE free to judge weight if approach rational
  - NICE hierarchy of evidence supported
- Need for careful scrutiny of Guidance for lack of clarity with potential impact upon atypical patient sub-groups

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Implications for industry

- Similarities between NICE appeal and judicial review: confines substantive challenges within HTA process
- Court reluctance to interfere with decisions to allocate finite resources
- Court approval of current NICE methods and approach may adversely affect challenges to future decisions re
  - Pre-launch appraisals
  - Price negotiations
- Court approval of NICE model for HTA may encourage still more markets to adopt NICE-type HTAs or cross-refer to NICE Guidance

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Revision of the European Medical Devices Directives

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Implementation of revisions

- 2007/47/EC amending directive changes:
  - MDD (93/42/EEC)
  - AIMD (90/385/EEC)
  - Biocides directive (98/8/EC)
- Publication of national implementing laws by 21 December 2008 (+ disclosure to COM)
- Application of national implementing laws from 21 March 2010

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Major changes: Definitions

- MD definition revised re software:
  - Standalone software is a MD
  - "normal" software is not
- New definitions:
  - "clinical data"
  - "single use device"
- Demarcation borderline with medicines must take particular account of the principal mode of action
- Non-viable human tissue-engineered products with device action still outside scope

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Clinical evaluation

- Necessary for every device but there are options :
  - literature route (equivalence + adequacy)
  - clinical investigation route (always for Class III / implantables unless due justification not to)
  - or a combination of above
- Documentation of clinical evaluation required for Technical File + continuous updating requirement with PMS data
- Notified Body assessment (if applicable)
- Notification by manufacturers of the (early) end of a clinical investigation
- Immediate reporting of all serious adverse events

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Other changes:

- New Essential Requirements (Annex I):
  - design for patient safety
  - design for lay, professional, disabled or other users
  - labelling known risks for re-use of SUDs
  - Machinery Directive ERs apply if more specific (Art.3)
- Some reclassifications
- PMS and Vigilance: obligations for custom made manufacturers (Annex VIII) and non-confidentiality of field safety notices (also new Vigilance MEDDEV since 1.1.08)
- E-labelling in future, but only following a legal implementation procedure (Art.11(14))
- Manufacturer's QMS must include OEM-compliance monitoring measures (Annex II)

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Regulation (EC) 1394/2007 on advanced therapy medicinal products

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Scope

- Gene therapy MPs and Somatic cell therapy MPs – as per directive 2001/83/EC, Annex I definitions
- Tissue Engineered Products:
  - Contains / consists of engineered cells or tissues (animal or human); AND
  - Presented OR used with a view to regenerating, repairing or replacing a human tissue
- ONLY exclusively non-viable tissue products with no medicinal action are excluded from scope
- Still no EU regulation of non-viable human tissue "device" products – only national laws apply
- EMEA to publish scientific recommendations on borderline classification
- Custom-made ATMPs excluded from MA requirement (Art.28 amending Art.3, Directive 2001/83/EC)

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EU ATMP Regulation: implementation

- Application to:
  - all new ATMPs from 30.12.2008
  - Gene therapy MPs and Somatic cell therapy MPs on the market at 30.12.2008 from 30.12.20011
  - Tissue Engineered Products on the market at 30.12.2008 from 30.12.2012

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Main provisions

- Mandatory centralised procedure for authorisation leading to Community MA (Committee for Advanced Therapies (CAT) at EMEA)
- Same regulatory principles as for biotech but new filing rules re type and amount of quality, preclinical and clinical data
- Donation, procurement, testing as per directive 2004/23/EC on human T&Cs
- Risk Management Systems for PMS (and Risk Management Plans, if particular cause for concern)
- Traceability obligations for both MAH and HCP-users
  - minimum 30 year retention requirement for MAH
  - EMEA is default data holder (liquidation of MAH)
  - retention requirements survive revocation, suspension, withdrawal of MA

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Specific rules to follow:

- New filing requirements re quality, preclinical and clinical data (R(13))
- COM Guideline adapting GCP & GMP directives (Arts.4&5)
- Specific rules for SmPC, labelling and packaging adapting directive 2001/83/EC
- EMEA guidelines (Art.14) for:
  - Post-market follow-up
  - Efficacy
  - Risk management
  - Adverse reactions
- COM Guideline for traceability

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Trends?

- More clinical data
- Closer review of / access to clinical data by CAs / NBs
- Increasing emphasis on PMS / vigilance

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Regulatory Update

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Corporate Deals of 2007

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Overview

- Mainly M&A/licensing
- IPO's/secondary issues
- Early stage/private fundraisings
- Trends
- Predictions

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M&A

Acquirer	Target	Value
AstraZeneca	MedImmune	$15.2 billion
Schering-Plough	Organon Biosciences	$14.4 billion
Celgene	Pharmion	$2.9 billion
Shire	New River Pharmaceuticals	$2.65 billion
GSK	Reliant	$1.65 billion
Merck	Sirna Therapeutics	£1.1 billion
Vectura	Innovata	£270 million
Lilly	Hypnion	$315 million
Pfizer	Coley Pharmaceuticals	$164 million

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Licensing

Licensor	Licensee	Value
OncoMed	GSK	$1.4 billion
Antisoma	Novartis	$890 million
Renovo	Shire	£825 million
Oxford Biomedica	Sanofi-Aventis	€547 million
Idera	Merck	$421 million
Silence Therapeutics	AstraZeneca	$400 million

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IPOs/Secondary Issues

- Official List
- AIM
- NASDAQ
- Swiss

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Early Stage/Private Funding

- Exits
- UK activity?
- USA/Europe?

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Trends (in M&A) (1)

- Patent cliff looms closer
- Antibodies
- Vaccines
- RNAi

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Trends (in M&A) (2)

- OTC/Consumer Health
- Generics
- Facilities disposals
- Outsourcing

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Predictions

- More (competitive) M&A
- Rapid DD
- Earn-outs?
- Biotech/biotech?
- Big Pharma/big pharma?
- More co-development?
- The credit crunch?

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Major changes occurred in 2007

- More rigorous inspection measures following SFDA's scandals
- Revised drug registration regulation
- Amendment to the labelling regulations
- Regulation on drug recall

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Major changes expected for 2008

- Improved drug reimbursement policy
- Consolidation in the pharma industry
- Environmental protection standards for pharma companies
- Drastic changes in the distribution system: level playing field
- Possible integration of SFDA into Ministry of Health (MoH)
- Increase in the number of foreign R&D Centers

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Why establishing an R&D Center in China?

- Human resources (capacities and lower cost)
- Clinical trials (cost, patient pool, litigation)
- Tax privileges (income tax, deductibility of technology development expenses, import duty and VAT)

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What are the conditions of establishment of an R&D Center?

- Fixed business premises and equipment
- Minimum registered capital of USD 2 million
- Ratio between technical personnel and overall staff (80% in Shanghai)

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Lifesciences Forum – Year end review 2007/2008

Thursday, 17th January 2008

Seminar attendance record

Law Society CPD hours

Details for this seminar are as follows:

Seminar title:	Lifesciences Forum - Year end review 2007/2008
Date of seminar:	Thursday, 17 January 2008
Number of CPD hours:	2.5 hours

How to claim Law Society CPD hours

Delegates must sign the form at the registration desk. All solicitors keep a note of their own CPD hours. They need to make a note of the seminar title, date, number of CPD hours and the CMS Cameron McKenna reference number, which is 073/CMCK.

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A Year in Pharmaceuticals

January 2008

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A round-up of ten topical issues that faced the pharmaceutical industry in 2007 and what they could mean for 2008...

A Year in Pharmaceuticals

EU Regulation of medicinal products for paediatric use

On 26 January 2007, the EU Regulation on medicinal products for paediatric use (Regulation (EC) 1901/2006, as amended by (EC) 1902/2006) came directly into force across the EU (although the application of the main provisions is staggered until approximately mid-2009). The Regulation aims to facilitate the development and accessibility of medicinal products for use in children; to ensure children's medicinal products are subject to high quality ethical research and to improve the information available on the use of medicinal products in different paediatric populations.

The Regulation provides that in future, subject to waiver or deferral, companies must submit paediatric data (in the form of results and studies that comply with an agreed paediatric investigation plan), whenever they apply for a marketing authorisation for a new product not previously authorised in the Community (from 26 July 2008), or for a variation or extension of an existing marketing authorisation concerning a new indication, pharmaceutical form or route of administration (from 26 January 2009).

The Regulation provides rewards and incentives to encourage the completion of paediatric studies within an agreed timeframe. Incentives include a six-month extension of the supplementary protection certificate ("SPC") for products protected by SPC or patent, or full data exclusivity (under the 8+2+1 rules) for products not covered by IP rights and where a new indication is developed exclusively for use in the paediatric population.

The new obligations to generate and collect paediatric data will inevitably increase the cost of bringing new products to market. Companies may wish to re-assess their product development and marketing portfolios and arrangements in light of the new opportunities and obligations.

OFT's PPRS Study

In February 2007, the OFT published its market study on the operation of the Pharmaceutical Price Regulation Scheme ("PPRS"). The study recommended retaining the PPRS structure of a pact between industry and government, but removing the current profit cap on an individual company's drug portfolio and replacing it with an up front, per drug, value-based price approval.

Value-based assessments may be difficult to conduct, as they would be based on a broad 'equivalence' between products. Therapeutic comparisons have already proved problematic in the introduction of limited reimbursement lists, in establishing data exclusivity, in identifying relevant product markets for competition law purposes and in creating specifications for therapeutic tendering. There are also concerns that value-based assessments will delay drug launch, eating into a drug's effective patent life.

A renegotiation of the PPRS scheme between industry and the Department of Health is currently underway.

Direct to pharmacy distribution model and OFT's study on distribution of medicines

In March 2007, Pfizer implemented a new "Direct to Pharmacy" model for distribution of its pharmaceutical products, following the High Court's rejection of an application by wholesalers for an interim injunction to stop it. Under the new system, pharmacies and dispensing doctors are buying Pfizer prescription medicines directly from Pfizer and not through third party wholesalers. Pfizer arranges delivery of products through a single logistic service provider (LSP), Unichem.

The wholesalers that applied for the interim injunction against Pfizer argued that the scheme and the exclusive appointment of Unichem were anti-competitive, but the Court rejected the application for reasons of delay and on the merits. The wholesalers had also complained to the OFT, which in April 2007 launched a market study into UK medicines distribution.

Following completion of its market study, the OFT published its recommendations to the Government in December 2007. The OFT did not object to direct to pharmacy schemes, recognising that they had advantages as well as some potential drawbacks when compared with the traditional wholesale model. The OFT recommended that:

- the Department of Health made further changes to the Pharmaceutical Price Regulation Scheme (PPRS) to ensure that NHS medicine costs do not increase as a result of changes in distribution
- if the Government is concerned about reductions in service standards to pharmacies, it should seek agreement of manufacturers to adopt minimum service standards; Government should also pay less if service standards are reduced.

The Government has 90 days in which to respond to the OFT's recommendations. This ties in with the current renegotiation of the PPRS which the Department of Health aims to conclude by mid-2008.

Boehringer -v- Swingward ECJ Parallel Trade Decision

In April 2007, the European Court of Justice gave judgment for the second time in the long-running *Boehringer v Swingward* parallel trade case. The Court gave judgment on a number of matters:

- Overstickered packs. The Court confirmed that previous case law determining the protocol that parallel traders should comply with to avoid trade mark infringement, applies to over-stickered parallel traded products as well as reboxed products
- Necessity test. The Court confirmed that a parallel trader must show that the action of repackaging was necessary to parallel trade a product, but it need not show that the extent of repackaging (i.e. the manner and style of repackaging) was necessary
- Co-branding, de-branding and over- stickering. The Court noted that aspects of repackaging such as co-branding (where the parallel importer's trade mark is placed alongside the proprietor's trade mark), de-branding (where the proprietor's trade mark is removed) and over-stickering may damage a proprietor's trade mark and so provide legitimate reasons for that proprietor to object to the parallel trade. However, the ECJ said that it was a matter of fact for the national court to decide in each case as to whether a particular case of co-branding, de-branding or over-stickering damaged the trade mark
- Burden of proof. It is for the importer to prove that it has complied with any conditions set down in case law as necessary for a parallel trader to avoid infringing a proprietor's trade mark
- Notice. The ECJ confirmed that, where a parallel trader fails to provide notice to the trade mark proprietor that it intends to parallel import the proprietor's products, this lack of notice constitutes trade mark infringement. The sanction for such infringement must be proportionate, effective and a sufficient deterrent.

Branded generics included in PPRS pricing

The High Court has considered the status of PPRS in a dispute relating to the 1999-2004 PPRS.

The PPRS is an agreement between the Department of Health and the pharmaceutical industry that restricts the maximum profits that can be made from the sales to the NHS of medicines covered by the scheme. The price regulation provisions allow members of the scheme to determine the prices of their individual products at launch and also control subsequent price increases. In the 1999-2004 scheme participants were also required to reduce their overall prices by at least 4.5% in comparison to list prices.

The products covered by the PPRS are "all branded, licensed NHS medicines". Generics (unbranded copies of out-of-patent products) as well as branded medicines sold over the counter and those products supplied predominately under private prescriptions are not covered under the PPRS. However, "branded generics" (copies of patent-expired products that bear a brand name) along with branded products supplied through tendering processes or local/central contracts are included.

A dispute over the application of the PPRS arose between GSK and the Department of Health, which was referred to a panel appointed under the scheme. The question was whether branded medicines, reimbursed as generics, should be included when calculating the overall price reductions given by a particular pharmaceutical company. The panel found in favour of the Department of Health and decided that these medicines should not be included.

GSK appealed the decision of the panel to the High Court. The Court first found that it had jurisdiction to hear the case, on the basis that the PPRS does constitute a binding contract between the Department of Health and the pharmaceutical companies participating in the scheme. The Court went on to find that GSK was not prohibited from including sales of branded products sold to fulfil generic prescriptions in any calculation of list price reductions. The Court also noted that due to supply chain issues beyond companies' control, reductions by companies in pricing levels did not always translate into equivalent cost savings for the Department of Health.

This decision, along with the OFT market studies on the operation of the PPRS and on the distribution of medicines, is an important part of the backdrop to the current PPRS renegotiation.

First judicial review of a decision of NICE

In the first ever judicial review of *NICE Eisai Ltd v National Institute for Health and Clinical Excellence*, Eisai Limited challenged the decision of the NICE Appeal Panel and the consequent guidance issued by NICE in relation to a particular class of Alzheimer's medicines, which the guidance stated should not be made available to mild Alzheimer's sufferers. The High Court decided that the consultation procedure employed by NICE (including the disclosure of only a "read only" version of the economic model used by NICE) did not deny Eisai access to significant information or the opportunity to make an intelligent response. The court decided that NICE were under no obligation to allow consultees to quality assure the model and that there was no substantive legal right for consultees to see every document.

The Court rejected all four grounds on which Eisai claimed there had been errors of reasoning which robbed both the guidance and the decision of the NICE Appeal Panel of logic. The Court declined to open up the underlying experts' debate about the clinical and cost-effectiveness of this class of Alzheimer's disease medicines by deciding which experts were to be preferred. However, the Court did decide that the NICE guidance was unlawful in its treatment of certain non-typical patient groups and discriminated against them in breach of anti-discrimination legislation. In consequence, NICE has had to revise its guidance to ensure that this no longer discriminates against those non-typical groups of patients.

Eisai has applied to the Court of Appeal for permission to appeal the High Court decision on the point of NICE's refusal to disclose a fully executable version of the economic model.

Lifesciences aspects of the Companies Act 2006

The main company law development in 2007 (which affect lifesciences companies in common with companies operating in all other sectors) was the increasing impact of the Companies Act 2006. This is a mammoth piece of legislation (comprising exactly 1,300 sections) that recasts all legislation relating to the establishment and operation of companies in the United Kingdom. The process of bringing the Act into force began in 2007 and will continue through to October 2009.

Most of the Act's changes are relatively slight and represent incremental improvements in administration and good practice. Sometimes the changes are more radical. At the risk of gross over-simplification, the principal areas of change made by the Act relate to: the codification of directors' core duties and rules on derivative actions (see below); modernisation of company administration (for example relating to the passing of shareholder resolutions and communications with shareholders generally); expanded reporting obligations to a company's shareholders; and simplification of the law relating to financial assistance (given in connection with the acquisition of a company's shares) and relating to reductions of a company's share capital, at least in relation to private companies.

Amongst the myriad detailed changes made by the new legislation, we would pick out three areas worthy of mention in the context of lifesciences companies:

- The new law on directors' duties and their enforcement. The directors of companies in all sectors need to inform themselves about this. The previous common law relating to directors' duties has now been codified and reduced to seven core duties. These cover a clarification of the objective of a company's management (i.e. to promote the success of the company for the benefit of all its members); the clarification of the standard of competence to be expected from directors (to exercise reasonable care, skill and due diligence in a formulation which combines both subjective and objective elements); and strict but workable provisions relating to the avoidance and management of conflicts of interest. In carrying out their duty to promote the success of the company, directors must also have regard to a number of specific "corporate social responsibility" factors (including the impact of their decisions on suppliers, customers, employees, the community and the environment)
- In parallel with this codification, the Act introduces a new means of enforcing, on behalf of the company, the duties owed by directors to the company. This "derivative action" can be brought by any shareholder in the company. There has been much concern that this procedure would allow activist shareholders or pressure groups (e.g. animal rights activists) to bring actions based on, for example, the directors of a lifesciences company failing to take into account the impact of its activities on the environment (i.e. animals involved in pre-clinical testing). There are, however, a number of hurdles which need to be overcome before such a derivative action can be brought, let alone succeed. It should also be remembered that a successful action can only be based on a breach of duty by a director to the company which results in a loss to the company (not to any individual shareholders)
- New law on availability of residential addresses. We are not there yet, but by October 2009 significant improvements should have been made in keeping confidential the residential addresses of both directors and shareholders. By then, the only significant risk of directors' residential addresses being easily accessed by third parties (including pressure groups) will be in relation to information filed before 1 January 2003 (such older information having been recorded on microfiche at Companies House and, therefore, difficult to expunge)
- For those setting up new lifesciences companies, the balance of convenience and advantage between incorporating as a public company or a private company will have shifted further in favour of private companies.

New Guidance on how MHRA and VMD will deal with requests for information under FOIA

In November 2007 the Medicines and Healthcare products Regulatory Agency (MHRA) and other parties published guidance on how they will deal with requests for information under the Freedom of Information Act 2000 (FOIA).

This guidance replaced a memorandum of understanding (MOU) that had been in place since late 2004, which used a 'traffic light' system to differentiate between types of information. In the 2004 MOU each information type was coded green, amber or red in accordance with the ease of their disclosure. A good number of the amber

classifications left considerable room for disagreement, particularly over the amount of sensitive material to be redacted before disclosure.

The new guidance, like the MOU, categorises information into three tables according to when it may be published:

- documents that public bodies will routinely publish online/in print
- documents/information that public bodies will disclose on request
- documents/information that public bodies may be able to disclose on request if disclosure is in the public interest.

It is intended to be helpful for regulators, information requestors and industry. Whilst it does not intend to be a legally binding document, it provides guidance and a statement of good practice for the MHRA when dealing with an individual request under the FOIA.

The new guidance is intended to reflect the greater spirit of openness and commitment to disclosure that the Access to Information legislation was designed to foster in public bodies but in practice it has not affected what the regulatory bodies disclose as they treat each request on its own merits in accordance with the legislation and accompanying legislative guidance.

House of Lords clarifies rules of law and procedure in patent entitlement disputes

In the decision of *Yeda Research and Development Co Ltd v Rhone-Poulenc Rorer International Holdings Inc and Another*, in 2007 the House of Lords overturned the broad principle established in *Markem Corporation v Zipher Ltd (2005)* that any claim of entitlement to a patent (including by someone claiming to be the true inventor) must be based upon 'some other rule of law', for instance, breach of contract or confidentiality. The only determination for the Court to make is to decide who was the inventor of the claimed invention. The decision also clarified the procedure relating to amending an entitlement claim, specifically how the limitation period applies to an application for amendment.

UK IPO will no longer examine trade mark applications on relative grounds

From 1 October 2007, the UK Intellectual Property Office (UKIPO) stopped examining trade mark applications on relative grounds and the onus is now on proprietors of potentially conflicting marks to object to the mark. Owners of CTMs and certain Madrid Protocol registrations may 'opt in' to the notification system of the UKIPO to receive details of applications for potentially conflicting marks automatically.

Previously, the UKIPO considered applications on both absolute and relative grounds, so an application would not be registered if it was identical with or confusingly similar to an earlier mark. Under the new system implemented from 1 October 2007, the Registrar will continue to undertake searches of the registers as part of the examination process for each new application, but merely inform the applicant of the search results and any potentially conflicting earlier trade marks. It is then the applicant's choice whether to withdraw the application or proceed despite the risk of conflict. However, an application will automatically proceed to publication unless withdrawn by the applicant.

Provided there are no other objections to registration, there is a two month period between issuing the examination report and accepting the application and arranging for its publication, during which it can be amended or withdrawn. If and when the application proceeds to publication in the Official Trade Marks Journal, the owners of any relevant conflicting marks will be notified (provided they are entitled to automatic notification or have opted in). A three month window in which proprietors of an earlier mark may oppose conflicting applications will begin on the date of publication.

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