Develop a successful regulatory strategy with expert advice from 8 member state regulators

THE 2ND ANNUAL CONFERENCE ON

CROP PROTECTION: GENERICS, PATENTS AND PARALLEL TRADE

Increasing profitability by uncovering new commercial opportunities and reducing time to market through a better understanding of regulatory systems

6-7 November 2007 | Crowne Plaza City Centre, Amsterdam, The Netherlands

Key Business Insight

Dr Matthew Phillips, Phillips McDougall, UK

Ernst Topitschnig, PINUS TKI d.d., Slovenia

The Most Up-To-Date Regulatory Information

Sylvie Malezieux, Ministry of Agriculture, France

Darren Flynn, PSD, UK

Herman Fontier, Federal Public Service of Public Health, Food Chain Safety and Environment, Belgium

Pavel Minar, State Phytosanitary Administration, Plant Protection Products Division, Czech Republic

Kostas Markakis, Department of Pesticides, Ministry of Agriculture, Greece

A Representative, CTB, The Netherlands

Enn Liive, Estonian Plant Production Inspectorate, Estonia

Mathias Uteb, BVL, Germany

Franka Periă, Pinus TKI d.d., Slovenia

Nicola Mitchell, Life Scientific, Ireland

Terry Tooby, JSC International Ltd, UK

Essential Legal Updates

Noel Akers, N.J.Akers, UK

Claudio Mereu, Mckenna Long & Aldridge, Belgium

New focus for 2007: Enforcing Product Security

Rocky Rowe, European Crop Protection Association, Belgium

Dr Michael J. Carroll, Dow AgroSciences, UK

Debate and Discuss the Most Topical Issues

- ✔ Increase your understanding on the current situation and future prospects for the crop protection industry. Latest market analysis on growth areas and success stories to help you develop winning business strategies
- ✔ Discover how a better understanding of patent law is enabling companies to gain a competitve advantage
- ✔ Be first to hear the latest information on the provisions for generic products under the new regulation. European Parliamentary insight from Hiltrud Breyer, MEP
- ✔ Get to grips with the practicalities of the regulations and re-registration procedures. Up-to-date information and opinions from 6 national regulators: UK, France, The Netherlands, Belgium, Czech Republic, Greece
- ✔ Parallel trade - key information on the provisions that have been drafted by the commision and member states. Feedback from 8 member states, UK, France, Germany, The Netherlands, Greece, Czech Republic, Estonia, Poland
- ✔ Tackling counterfeiting in the agrochemical sector- Strategies and tools for enforcing product security

Updated for 2007 **PRE CONFERENCE WORKSHOP**

Patents as commercial tools in the field of agrochemicals Monday 5 November 2007

An intensive one day course designed to highlight how patents are being used to gain a competitive advantage in the agrochemical sector. Sessions include: The patent specification and its function, patents as a source of information, sources of patent information, patent filing strategies, licensing patent rights and challenging patent validity

Course Leader: **Noel Akers, NJ Akers & Co Ltd**

New for 2007 **POST CONFERENCE WORKSHOP**

Novel and me-too formulations for the generic market Thursday 8 November 2007

An essential one day seminar for all professionals working in the field of novel formulation development and registration. Course highlights include: Choosing the way: novel or me-too formulations, introduction to microencapsulation technology and market growth strategies

Course Leaders: **Microencapsulation AG, Austria**

Supporting Partners: AGROW WORLD CROP PROTECTION NEWS | CROP PROTECTION Monthly

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1. A unique opportunity to gain valuable insight and practical advice from 8 national regulators

PRE CONFERENCE WORKSHOP

Patents As Commercial Tools In The Field Of Agrochemicals

Monday 5 November 2007

09.00 Registration 09.30 Start 16.30 End of Workshop

Session 1: The Patent Specification and its Function
The first session reviews the basic structure of a patent specification, highlighting the legal and practical aspects of each section of the document. In particular, the session will look at the description of a patent specification and the relevant legal requirements, the examples, the claims and abstract. The session will look at examples of patent specifications in the agrochemical sector.

Session 2: Patents as a Source of Information
Patent specifications are published as an inevitable part of the patenting procedure. As a result, the information contained in the specification is available for inspection and review. This session reviews patent specifications in terms of the types of information that may be obtained, including both technical and commercial information relating to the activities of the patent owner or applicant.

Session 3: Sources of Patent Information
Ever increasing amounts of information relating to patents and applications are available to public, in particular through the internet. This session reviews the major sources of information and how they can be used, including legal information that may be obtained relating to patents, applications and their history.

Session 4: Patent Filing Strategies in Detail
To be effective as a commercial asset, a patent portfolio must be assembled according to an appropriate strategy. This session reviews patent filing strategies in detail, including the best use of the various regional and international patent systems to achieve maximum protection for a business.

Session 5: Licensing Patent Rights
Patents are business assets and their commercial exploitation often requires licensing to be undertaken. To realize the full potential of a patent portfolio, an understanding of licensing is essential. This session reviews the licensing of patent rights, the governing laws and regulations, royalty payments and the form of licensing agreements.

Session 6: Challenging Patent Validity
The patents of others can represent major obstacles to your freedom to conduct your business. Accordingly, knowing how to challenge the validity of competitor patents and remove that obstacle is very valuable. Session 7 covers invalidating patents, the grounds for invalidity and the manner in which validity can be challenged. The session also looks at the commercial aspects and strategies for challenging patent validity.

Course Leader : Noël J. Akers

Noël is a Chartered Patent Attorney and European Patent Attorney. He is also a Registered Trade Mark Agent in the UK and admitted to practice before the European Community Trade Mark Office. He graduated from the University of Nottingham with a degree in Chemical Engineering, before qualifying in the patent and trade mark profession. Noël has worked with a number of international corporations and law firms. In particular, he spent a considerable length of time practicing European patent law in the United States, where he was involved in a series of major patent litigation cases with actions in both Europe and the US. As a consequence, Noël developed a specialty in coordinating patent procurement and litigation in cases involving actions in the US and Europe.

Noël has acted as an expert on European patent law and provided expert testimony in a number of US patent litigations, in particular provided evidence on aspects of patentability under European patent law and the law of privilege in the UK.

Immediately prior to establishing N.J. Akers & Co., Noël was a partner with Howrey, a major US law firm, managing the patent department of its London Office.

POST CONFERENCE WORKSHOP

Novel and Me-Too Formulations for the Generic Market

Thursday 8 November 2007

09.00 Registration 09.30 Start 16.30 End of Workshop

Do any of the following statements and questions sound familiar to you and your colleagues?

- I have problems to sell a me-too formulation because of non-chemical identity?
- How can I be certain that I am not infringing a formulation patent?
- How difficult and costly is it going to be to register a new formulation and just how long is it going to take?
- Is my source of active ingredient good enough?
- My product has been subject of an injunction... what should I do next?

If so this workshop is a time efficient way to obtain clear answers and potential solutions to the challenges that professionals working in the area of novel formulation development face on a day-to-day basis. Our expert workshop leaders from the fields of analysis, registration and patent matters, as well as those involved directly with the development of new formulations will be on hand to deliver practical advice to overcome some of your day to day challenges when working with novel and me-too formulations in the generics market. This workshop organized by GAT will help you find new answers to old questions and even to open your mind to feasible and incredible attractive new markets.

Workshop Outline

Session One: Choosing the Way: Novel or Me-Too Formulations ? Advantages and Disadvantages

Me-Too Formulations

- Market situation and extended rumours
- Unravelling ingredients of registered formulations
  - Active Ingredient - Coformulants
- Needs of me-too formulations
  - Active Ingredient(s) (Patent Status, SPC, Combined AIs, Selection of Sources, Purity, Impurities)
  - Coformulants (Patent Status, Sources, Substitutes)
  - Finished product (According 414/91 Annex VI)
- Legal Problems expected
  - Defence against Patent Infringement
  - Defence against "Non-chemical Identity"

New Formulations

- Changing public and Governmental image of "Counterfeit" and "Malignant" generic companies
- Minor and major changes for novel formulations with respect of registered formulations
- Actives prone to be highly benefited of the novel formulations
- Types of formulations with high chances to success in the market
- Registration of new formulations: required studies, field testing, timing

Session Two: Microencapsulation

- Introduction to microencapsulation technology
- Past and new microencapsulation processes and products
- Oil prices rising: use water! Preferred type of formulation in terms of costs and environmental profile
- Registration: make it easier with low toxicological profile of all ingredients
- Needed for combination of actives with stability/incompatibility issues
- Improved performance
- Added value for hi-tech formulations, new markets: WDG/CS CS/SC CS/EW CS/EC

Session Three: Expand your market, protect your market, defend your market

- Patent Problems: how to create them and how to avoid them
- Registration Problems: how to create them and how to avoid them

Course Leaders:

Dr Victor Casaña-Giner, Senior Scientific Manager, **GAT Microencapsulation AG,** Austria
Dr. Victor Casaña Giner is BS&MS in Food Technology, BS&MS in Agricultural Engineering and obtained in Valencia (Spain) his Ph.D in Biotechnology and Agrochemistry. He has an excellent track in research combined with rich experience in patenting and registration matters for the generic industry. He was Federal Employee at the U.S. Department of Agriculture and since its return to Europe he has hold several positions in the field of phytosanitary products, methods and intellectual property consultant.
Dr Miguel Gimeno Dipl. Ing., GAT Microencapsulation AG, Austria
Matthias Reismuller, GAT Microencapsulation AG, Austria

Day One: 6 November 2007

08.15 Registration and Coffee

08.55 Chairman's Introduction

09.00 **Current position and future prospects for the crop protection industry**
- Overview of main markets- make up, performance and growth areas
- Analysis of growing markets

Dr Matthew Phillips, Partner, **Phillips McDougall**, UK

09.30 **Challenges, opportunities, strategies & visions: Are small and mid-sized generics companies at emerging markets outdated/expired models or serious innovators & powerful challengers?**
- Threats and opportunities at emerging markets
- The identification of strengths and weakness of regional players
- Local players' challenges towards markets on customer and competitor side
- Vacuums of visions and potential solutions concepts

Ernst Topitschnig MBA, Ing., Director Business Development Europe, **PINUS TKI d.d.**, and founder, ***tec2trade* GmbH, Technology Transfer & Consulting**, Slovenia

10.00 **Opportunities in the animal health industry**
- Actives used in crop protection and in veterinary medicinal products
- Overview of the registration process for veterinary medicinal products
- Data requirements for each of the registration routes
- How easy is it to register a veterinary medicinal product?

Anne Nallen, **Nallen Regulatory Consulting** (Formerly Head of Regulatory Affairs, *Cross Vetpharm Group*, Ireland)

10.30 Morning Coffee

Practical advice to enable you to get to grips with the existing regulations and prepare to meet the demands of future regulatory requirements

11.00 **Insight from the EU Parliament: Progress and update on provisions for generics under the new regulation**
Hiltrud Breyer, MEP, **The Greens/EFA, European Parliament**

11.00 **Provisions for the registration of off patent products under 91/414**
- Patent products under 91/414
- Regulatory requirements
- Review programme
- Regulatory timetable
- Data protection
- Regulatory strategy

Terry Tooby, Director of Regulatory Affairs, **JSC International Ltd**, UK

11.45 **Member State feedback on registration of generic products**
In this extended session each speaker will present a short overview to outline national opinions and priorities for the registration of off patent products. This will be followed by a Q&A session. Topics for discussion include:
- Current status for the registration of off patent products
- Currently what studies are protected and how can generics companies gain access to this information?
- Feedback on regulation to replace Directive 91/414 including proposals for data protection, sharing and data compensation
- National enforcement of data protection and implementation data compensation- current thinking on how this will this be done, who will judge, what will be the arbitration process
- Forced data sharing for vertebrae studies-how will MS handle this?

Sylvie Malezieux, **Ministry of Agriculture**, France

Darren Flynn, Head of Approval, Secretariat Branch, **Pesticides Safety Directorate**, UK

Herman Fontier, Head of Pesticides, **Federal Public Service of Public Health, Food Chain Safety and Environment**, Belgium

Pavel Minar, **State Phytosanitary Administration, Plant Protection Products Division**, Czech Republic

Kostas Markakis, Pesticides Regulatory Affairs-EU Matters, Department of Pesticides, **Ministry of Agriculture**, Greece

A Representative, **CTB**, The Netherlands

13.15 Lunch

14.30 **Industry experiences of registering off patent products**
- Overview of similarities and differences experienced with national regulators
- Overview of the main challenges for registering off patent products in Europe
- Discussion and feedback on the proposed new provisions
- Experiences in non EU countries (Croatia, Serbia, Bosnia, Macedonia and Ukraine)
- Case studies

Franka Periã, Registration Manager, **Pinus TKI d.d.**, Slovenia

15.00 **A generics perspective: Re-registering products post annex 1**
- Guiding principles and regulatory strategy including choice of reference member state
- Understanding the reference product and data protection
- Data requirements for registration in the Reference Member State and thereafter by the Concerned Member State
- Defining comparability including chemical equivalence and all other areas of the risk assessment with Reference Product and Member State
- Demonstrating comparability to the reference product in order to lever the originator's data package to all possible extent and minimize costs

Nicola Mitchell, Managing Director, **Life Scientific**, Ireland

15.30 **Afternoon Tea and High Speed Networking**
With high speed networking you can make more new business contacts in one session than most people make in 6 months!
- Network with other professionals, one to one, a few minutes at a time
- Leave with a pocket full of business cards and numerous new business connections
- Chances are you'll meet lots of people you wish you had more time with

16.10 **An industry perespective on the new rules for data sharing, protection and compensation**
Speaker to be announced. Please visit www.informa-ls.com/crop

16.40 **Recent litigation in agrochemicals: Lessons learnt and potential impacts**
Claudio Mereu, Managing Partner, **McKenna Long & Aldridge,** Belgium

17.10 End of day Q&A

17.20 End of day one

Evening Symposium

Practical Advice on Submitting Generics Applications in the USA

Registration 18.15 • Start 18.30 • Dinner 20.30

This seminar will cover the processes and procedures for obtaining generic approvals in the USA. The background of the law and practise will be covered in order to provide an understanding of the current procedure.

Outline
- Background of the approval process in the US
- Generic applications: Underlying principles and regulations
- Practical advice for submitting applications in the USA
- Current concerns and future issues
- Opportunities in the US market for off patent agrochemical products

Following the symposium attendees will be able to carry on their discussions sharing and benefiting from the experiences of the course leader and other course attendees over a 3 course dinner.

Fantastic neyworking opportunities - catch up with old colleagues and meet new business contacts from accross the globe (over 85 attendees from 19 countries in 2006)

Day Two: 7 November 2007

08.30 Morning Coffe

08.55 Chairman's Introduction

Discover how a better understanding of patent law is enabling companies to gain a competitive advantage

09.00 **Patents as commercial tools and weapons**

- Patent Specifications as a source of technical and commercial information
  - The structure of a patent specification
  - Technical information
  - Commercial information to be derived
- Major sources of patent information
  - Patent databases
  - Patent Office Registers and legal information
- Patent filing strategies
  - Use of national, regional and international patent systems
  - Timing and costs issues
  - Maximising commercial potential

Noel Akers, Principal and Founder, **N J Akers & Co,** UK

10.00 Morning Coffee

Parallel trade: Provisions and Member State feedback and opinions

10.30 **EU legislation on parallel trade of PPP´s**

- Introduction to the provisions drafted by COM and MS
- Overview of the most discussed issues
- Prospects for the future

Mathias Uteb, Legal Advisor, **BVL**, Germany & Chair, Expert Working Group Parallel Trade

11.00 **Parallel trade- EU and national perspectives**

In this extended session each speaker will present a short overview to outline national opinions and attitudes towards parallel trade. This will be followed by a Q&A session. Topics for discussion include:

- What do national regulations look like at the moment?
- Understanding the mechanics of parallel import- how do different authorities handle this (similarities and differences)
- How are national governments enforcing the regulations?
- When is a product identical according to the law- what criteria do regulators use to judge this?

Sylvie Malezieux, **Ministry of Agriculture**, France

Darren Flynn, Head of Approval, Secretariat Branch, **Pesticides Safety Directorate,** UK

Mathias Uteb, Legal Advisor, **BVL**, Germany

Herman Fontier, Head of Pesticides, **Federal Public Service of Public Health, Food Chain Safety and Environment**, Belgium

Pavel Minar, **State Phytosanitary Administration, Plant Protection Products Division,** Czech Republic

Kostas Markakis, Pesticides Regulatory Affairs-EU Matters, Department of Pesticides, **Ministry of Agriculture**, Greece

Enn Liive, Deputy Director General, **Estonian Plant Production Inspectorate**, Estonia

Ewa Matyjaszczyk, Department of Assessments and Opinions about Plant Protection Products, Poland

12.30 **Parallel trade- overview and update on associated regulations**

- Repackaging Of Parallel Imported Pharmaceuticals – ECJ Judgment Can the recent Boehringer ruling be extended to the agrochemical industry?
- Analysis of the judgement and it's potential implications?
- Why is the principle of trademark exhaustion not applicable to pesticide parallel trade?
- Trademarks –potential applications and implications if extended to the agrochemical industry

Peter Koof, Rechtsanwalt, Germany

13.00 Lunch

14.20 **The concept of product identicality in real life**

- Definition(s) of identicality and sanctioned replacements - major controversy on "Minor Change"
- Products and their registered specifications: Why common origin is no solution to safety issues
- Verification of identicality – suitable (analytical) vs. inappropriate (label only) approaches
- Proof of origin – what a trader might provide and what an authority might demand in the EU
- Homogeneity in an outsourced world – examples of products currently in the market

Jan Schlauer, Vice President, **International Plant Protection Association**

Tackling counterfeiting in the agrochemical sector- Strategies and tools for enforcing product security

14.50 **Counterfeit pesticides: A serious threat to health and the environment**

Industry is experiencing an increase in the growth in the manufacture, distribution and supply of counterfeit and illegal pesticides.

Whether a sophisticated counterfeit of a poor quality fake, the potential for harm to human health or the environment is increased

All illegal pesticides are untested, unregulated and may contain potentially unknown materials, toxic impurities or by-products

The EU has one of the toughest regulatory systems in the world, yet without applying appropriate national control measures, the process is undermined

Industry is currently raising awareness to the problem, and by working with European and national enforcement agencies, policy makers and all stakeholders, especially those in the food chain to combat all types of illegal pesticides, ensuring we maintain the highest levels of human and environmental health and food chain security.

Rocky Rowe, Advisor, Trade Issues, **European Crop Protection Association,** Belgium

15.20 **Spotlight Session- Tools to deliver an anti-counterfeiting strategy**

This session offers technology and product providers an opportunity to provide an interactive and educational tutorial which will address the benefit of their technology or product in the field of product security. If you would like to host this tutorial please contact Martin.Cheung@informa.com

15.20 **Enforcing product security - Agrochemical case study**

- The problem of counterfeit products
- The art of deterrence
- Technical solutions to aid product security - chemical authentication in particular
- Enrolling regulators to enhance timely enforcement
- The future - new technologies will be necessary

Dr Michael J. Carroll, Global Registration Manager, **Dow AgroSciences**, UK

16.20 End of Conference and Afternoon Tea

Feedback for Crop Protection: Generics, Patents and Parallel Trade 2006

"First class conference! I obtained practical and useful information" **Registration Manager, Dow**

"No where else will you find all the people that you want to meet" **Senior Scientific Manager, GAT Microencapsulation**

"We have been waiting for this meeting like this for a long time. Very valid. Excellent networking potential"
Commercial Director, AgriGuard

CROP PROTECTION GENERICS, PATENTS AND PARALLEL TRADE

Informa LifeScience's Crop Protection: Generics, Patents and Parallel Trade Summit is a unique forum designed to bring together all parties involved with the further development and distribution of post patent agrochemical products.
Based on entirely new research the 2007 conference agenda has been designed to ensure that all players in this sector have the key information to fully unlock the potential of post patent products and maximize their revenue generating potential. During the industry research that we conducted the main challenge that was identified in this area was the regulatory burden which is why for this years conference we have brought together 8 member state regulators in order to provide you with sound regulatory advice with which you can confidently go forward and develop your post patent strategies. Uncertainty with parallel trade provisions was also identified as a major concern for your colleagues which is why we will be presenting feedback on the commission and member state discussions for the provision of parallel trade in the proposed new PPP regulation. To clarify any remaining concerns 8 national regulators will be on hand to outline national opinions, procedures and processes for parallel trade. Finally our research has highlighted "product security" as a hot issue for all companies in this sector which is why we have introduced a new session to our agenda this year "Tackling counterfeiting in the agrochemical sector, strategies and tools to enforce security".

5 Key reasons to attend

1 **Access national regulators from 8 Member States:** A rare opportunity to hear first hand information from senior level representatives of: CTB, The Netherlands • Federal Public Service of Public Health, Food Chain Safety and Environment, Belgium • Ministry of Agriculture, Greece • Ministry of Agriculture, France • Pesticides Safety Directorate, UK • BVL, Germany • Estonian Plant Production Inspectorate, Estonia • State Phytosanitary Administration, Plant Protection Products Division, Czech Republic

2 **Hear essential new information and contribute to interactive Q&A sessions:** 20 information packed sessions to provide practical information for delegates to take away and apply whilst dedicated Q&A sessions and informal networking provide a glimpse into the future direction of the regulatory landscape

3 **Debate the most topical issues:** Overview of the current position and future prospects for the crop protection industry , evaluation of the latest situation and future direction for the provisions for generic product registrations under the current and new directive, industry experiences of registering off patent products, re-registering products post annex 1, data sharing, protection and compensation, EU legislation and national opinions on parallel trade of PPP´s and enforcing product security in agrochemicals

4 **Benefit from 3 new conference symposia:**
Patents as a commercial tools in the field of agrochemicals.
Novel and me-too formulations for the generic market
Practical advice on submitting generics applications in the USA

5 **Meet face-to-face with colleagues from across the globe:** Unrivalled networking opportunities, last years launch event attracted over 85 attendees and included European Regulatory Affairs Managers, R&D Managers, Commercial Managers, Registration Managers, Technical Directors, Lawyers and Patent Attorneys from originator and generic agrochemical companies

Can't Attend The Event: Conference Documentation on CD Rom

All attendees will receive a CD Rom, which contains the conference presentations. If you are unable to attend this event and would like to purchase the documentation please contact customer services on Tel: +44(0) 20 7017 7481, Fax: +44(0) 20 7017 7823 or email registrations@informa-ls.com

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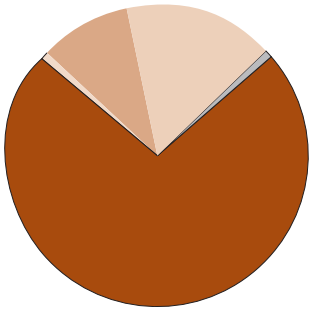
If you provide regulatory services or solutions to the agrochemicals industry the 2nd annual Crop Protection: Generics, Patents and Parallel Trade conference will bring you face-to-face with your target market giving you a unique opportunity to gain exposure for your services, meet potential new business contacts and catch up with existing or previous customers.

Last year's launch event attracted over 85 attendees from 19 countries. Those who attended:
European Regulatory Affairs Managers, R&D Managers, Commercial Managers, Registration Managers, Technical Directors, Lawyers and Patent Attorneys from originator and generic agrochemical companies from across the globe

For more information on how you could benefit from this event and to discuss the full range of lead generating, networking and branding opportunities that exist please contact:

Martin Cheung:
tel: +44(0) 20 7017 4938
email: Martin.Cheung@informa.com



2006 attendee profile by region

- 16%UK
- 71% Europe (Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Portugal, Spain, Sweden, Switzerland, The Netherlands)
- 11% CEE (Poland, Slovenia, Romania)
- 1% Middle East (Israel)
- 1% Asia (Hong Kong)

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*Pre Conference Workshop (5 November 2007)	CQ8028X	£449 + VAT @ 19% = £534.31 ☐	£100	£499 + VAT @ 19% = £593.81 ☐	£50	£549 + VAT @ 19% = £653.31 ☐
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*Evening Symposium (6 November 2007)	CQ8028Z	£300 + VAT @ 19% = £357 ☐	£50	£325 + VAT @ 19% = £386.75 ☐	£25	£350 + VAT @ 19% = £416.50 ☐
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Terms and Conditions

FEE: This includes all technical sessions, lunch and documentation.
CANCELLATIONS: Cancellations received in writing before and on 22 October 2007 will be subject to a service charge of £99. The full conference fees remain payable after 22 October 2007. Substitutions are welcome at any time.
It may be necessary for reasons beyond the control of the organiser to alter the content and timing of the programme or the identity of the speakers. In the unfortunate event that an event is cancelled Informa are not liable for any costs incurred by delegates in connection with their attendance. This contract is subject to English Law.
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