JOINT EMEA/TOPRA **TWO-DAY** MEETING

Medicines Legislation

within the European Regulatory Network

A joint meeting by TOPRA and the European Medicines Agency

A Review of the Medicines Legislation
by the EMEA and National Competent Authorities

The EMEA and TOPRA are organising their second joint meeting on Medicines Legislation. There have been many changes over the last year concerning the planning of medicines development programmes, marketing authorisation approvals and follow-up post approval. This two day meeting will review the operational aspects of regulatory affairs and how you can maximize your effectiveness within the European regulatory network. This is an excellent opportunity to engage in dialogue with EMEA staff working at all levels on practical issues and the programme is designed to facilitate interactive Industry/EMEA discussion sessions.

Representatives from the National Competent Authorities will be present.

Key topics to be discussed in depth include:

3rd December

The fostering of research and innovation:
- One of the key goals of the EMEA Road Map to 2010 was the fostering of research and innovation. This session will discuss how this will be achieved, the activities of the 'Think Tank' and the 'Innovation Task Force'.

Clinical Trials, the way forward:
- The regulation of clinical trials was 'harmonised' by Directive around 3 years ago. This session will explore the way forward for trials across the European Union, the role of the Clinical Trials Facilitation Group (CTFG) and the impact on development programmes post TGN1412 of the new guideline on requirements for First-in-Man Clinical trials.

Better medicines for children - the new Paediatric regulations:
- The new Paediatric Regulation came into effect on 26 January 2007 and will dramatically change the regulatory environment within Europe. There are many new obligations on the health care industry and this session will explore progress to date.

Scientific Advice:
- The interplay of Scientific advice from the EMEA and the National Competent Authorities - who do you consult and why?

4th December

The European Marketing Application Approval procedures:
- This session will guide us through the European Regulatory procedures and discuss the role of the National Competent Authorities.

The review process:
- How can companies improve the outcome of your Marketing Authorisation Application? This session will provide and overview of the review process, the work of Rapporteurs and how to get the best out of the review process.

Enrichment of the Review Process:
- Consistency of assessment and advice across the EU is important - this session will discuss initiatives within the EMEA and across the European Regulatory network to stimulate scientific rigour in the EU.

Risk Management:
- What happens to a medicine when it is released onto the market is now coming under closer scrutiny - this session will review the latest risk management obligations in the EU with examples of recent Risk Management Plans and also what is shared with the USA.

Further speakers
from The EMEA, Industry and National Agencies have been invited.

TOPRA

THE ORGANISATION FOR PROFESSIONALS IN REGULATORY AFFAIRS

Date:

3–4 December 2007

Venue:

Marriott Hotel, Canary Wharf (West India Quay), London.

Speakers:

Marisa Papaluca Amati
Pre-Authorisation Evaluation of Medicines for Human Use, Deputy Head of Sector, Safety and Efficacy of Medicines, EMEA

Peter Bachmann
European and International Affairs, Federal Institute for Drugs and Medical Devices (BfArM) Germany

Stella Blackburn
EMEA

Patrick Le Courtois
Head of Unit, Pre-Authorisation Evaluation of Medicines for Human Use, EMEA

Hans-Georg Eichler
Senior Medical Officer, EMEA

Roz Eijgenhuijsen
Director, Global Regulatory Affairs Ipsen, UK

Bruno Flamion
Chair of the EMEA Scientific Advice Working Party and University of Namur, Belgium

Liz Gifford
Director, MIGU, European and International Regulatory Affairs GlaxoSmithKline, UK

Graham Higson
Vice President, Regulatory Affairs, Astra Zeneca, UK

Anthony Humphreys
Post-Authorisation Evaluation of Medicines for Human Use, Head of Sector, Regulatory affairs and organisational support, EMEA, UK

Carolyn Hynes
Associate Director, Global Regulatory Policy & Intelligence Johnson & Johnson Pharmaceuticals Group, UK

Brenton James
Consultant in Strategic Regulatory Affairs in Europe and TOPRA Board Member, UK

David Laurie
DRA Policy Manager, Novartis Pharma AG, Switzerland

Thomas Lonngren
Executive Director, EMEA

Xavier Luria Oller
Pre-Authorisation Evaluation of Medicines for Human Use, Head of Sector, Safety and Efficacy of Medicines, EMEA

Arielle North
Directorate-Executive Support, EMEA, UK

Beatrice Oberlé-Rolle
Head EU Liaison, Centralised Program Management, Drug Regulatory Affairs Novartis Pharm AG, Switzerland

Agnès Saint Raymond
Pre-Authorisation Evaluation of Medicines for Human Use, Head of Sector Scientific advice and orphan drugs, EMEA, UK

Rui Santos-Ivo
European Commission Enterprise and Industry DG Pharmaceuticals Unit

Fergus Sweeney
EMEA

Noël Wathion
Head of Unit, Post-Authorisation Evaluation of Medicines for Human Use - EMEA

Anne Wigmore
Vice President Anti Viral/Anti Infectives GlaxoSmithKline, UK

For more information or to obtain a booking form please contact TOPRA via:
email: meetings@topra.org tel: +44 (0)20 7538 9502 web: www.topra.org

Medicines Legislation

A joint 2 day meeting by TOPRA and the European Medicines Agency
A Review of the Medicines Legislation
by the EMEA and National Competent Authorities

Ref: CA7/07

Date: 3–4 December 2007 Venue: Marriott Hotel, Canary Wharf (West India Quay), London

Ways to book

Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

Post: TOPRA, 7 Heron Quays, Marsh Wall, London E14 4JB, UK
Fax: +44 (0)20 7515 7836

On receipt of your booking form we will confirm your place in writing and provide directions to the venue. An invoice will be sent separately. To ensure admission, payment must be received prior to the meeting.

If you have any queries, contact us on: **+44 (0)20 7538 9502** or **meetings@topra.org**

Contact details

Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Other

Family name

First name Male ☐ Female ☐

Company name

Job title

Telephone

Fax

E-mail

Work Address

City Postcode

Country

Invoice Address *(If different from above)*

City Postcode

Country

Special dietary requirements

Discounted fees

Personnel in full-time education or work in academia *(full-time)* **may** be entitled to a discount on the above fees. Agency delegates are entitled to a 25% discount. Bulk Bookings may be accepted. In exceptional circumstances special 1- day rates may be applicable – please contact the TOPRA office for details.

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Booking fees

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New Member	☐	€1,551.00 + VAT *(17.5%)* €271.43 = **€1,822.43**
(includes TOPRA Membership Fee for rest of 2007 and 2008)		
Non-Members	☐	€1,716.00 + VAT *(17.5%)* €300.30 = **€2,016.30**

Signature

Date

Terms and conditions

Payment

Payment may be made in sterling or euro equivalent by cheque, credit card or bank transfer.

Cheques: must be made payable to TOPRA and drawn on a UK bank.

Credit card: for payment by credit card please complete the relevant details opposite.

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Cancellations: All cancellations must be received in writing 21 calendar days before the start of the meeting and will be subject to an administration fee of €150 *(or Sterling equivalent)*, payment can be in euros or sterling equivalent. For cancellations after this time, or if the delegate fails to attend the meeting, no refund of fees may be expected. Substitutions may be made at any time. TOPRA reserves the right to cancel a meeting at any time without liability. In these circumstances, delegates will be offered an alternative date, a credit note or a full refund.

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Additional support
Please advise TOPRA, at least one month before the meeting date, if you have any disability that may require additional support.

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