# The Annual European Medicines Agency Review of the Year and Outlook for 2011 and beyond

***A joint meeting between TOPRA and the European Medicines Agency***

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

TOPRA

TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA5/10

## What does the Future for European Regulatory Affairs hold?

### Programme includes

**EU: The Latest Information on Future Regulatory Activity for Pharmaceuticals**

The European Commission's Pharmaceutical Package, the European Medicines Agency 2015 Road Map and the Heads of Human Medicines Agencies Strategy paper II - how will these key documents impact on all stakeholders involved in Medicinal Products.

**Scientific Advice**

This session focuses on capturing how the situation for gaining EU scientific advice is advancing by hearing from the EMA Scientific Advice committees and a representative from a national Health Technology assessment body.

**The EMA and its New Working Party Structure**

CHMP agreed at its May meeting that there will be 3 permanent WPs and a number of temporary WPs and also drafting groups. These WPs will be supervised by a co-ordination group which will be lead by the chair of the CHMP and supported by a consistency group.

**What will be the Future Role of the Regulatory Agencies?**

In this open forum, senior figures from National Competent Authorities, pharmaceutical industry, patients groups and Health Technology bodies will explore possible future development of regulatory agencies. Themes to be discussed will include:

- Benefit - Risk Assessment
- Relationship between Agencies and HTAs
- How to achieve access to the European Market

**The Triangle of CHMP, PDCO and SAWP**

This session will involve representatives from CHMP, SAWP and/or PDCO and will discuss how these 3 groups operate and how they work with each other.

**Clinical Trials**

Clinical Trials - Problems and Solutions. Is the EU open for clinical trials or is bureaucracy making companies and individuals go elsewhere? The Clinical Trials Directive (CTD) was meant to streamline the clinical trial process across Europe but has it really done so? This session will look at problems, suggest solutions for discussion and review recent developments in the conduct of clinical trials in the EU.

**Transparency**

This session will look at how transparency works in practice from an EMA viewpoint. It will outline the recent developments at the European level and how some principles could be implemented into the European regulatory context. Today, the web enables instant access to any new information from a global community. It is important in this respect to outline some initiatives which are taking place in other regions, specifically the FDA Transparency Initiative launched in 2009. Reactions from patients as well as the research community will be sought.

**The Centralised Approval Process – Knowing the Rules to Navigate Successfully**

This session will review from a strategic point of view the procedural operation linked to the filing of a marketing authorisation application (MAA) especially addressing how to interact optimally during the MAA review process and how to interpret the feedback.

### Working Party

**Peter Bachmann,** European and International Affairs, BfArM, Germany and CMD(h) Member
**Liz Gifford,** Director, Global Regulatory Affairs, GlaxoSmithKline, UK
**Frieda Houghton,** Senior Director, Worldwide Regulatory Strategy, Pfizer, UK
**Ian Hudson,** Director of Licensing, MHRA, UK and Member of CHMP
**Anthony Humphreys,** Head of Regulatory, Procedural and Committee Support, EMA
**Brenton E James,** Consultant in Strategic Regulatory Affairs in the European Union (Working Party Chair), UK
**Angelika Joos,** Head Regulatory Policy EU and Most of World, Merck Sharp & Dohme (Europe) Inc, Belgium
**Angela Miller,** Director, Global Regulatory Affairs, Oncology, Eisai Ltd, UK
**Arielle North,** Scientific Administrator, EMA
**Marie-Helene Pinheiro,** Regulatory Affairs Advisor, EMA
**Agnès Saint Raymond,** Head of Human Medicines Special Areas, Human Medicines Development and Evaluation, EMA
**Fiona Reekie,** Director, Global Regulatory Policy & Intelligence, Janssen Pharmaceutical Companies of Johnson & Johnson, UK
**Gonzalo Calvo Rojas,** Co-ordinator of Clinical Evaluation, AEMPS, Spain and Member of CHMP
**Beatrice Oberle Rolle,** Head of Regulatory Affairs, Nobel Biocare, Switzerland
**Tomas Salmonson,** Medical Products Agency (MPA), Sweden and Vice Chair CHMP
**Elmar Schmitt,** Senior Manager Global Regulatory Oncology, Merck KGaA, Germany

For more information – and to book your place – visit **www.topra.org/ema2010**

## Two-day Conference

**Date:**
6–7 December 2010

**Venue:**
The Marriott Hotel, Grosvenor Square, London

LIFELONG LEARNING TOPRA/ EMA 12hrs*

**Lifelong learning**

* For more information please visit www.topra.org/lifelonglearning

email: meetings@topra.org tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: www.topra.org

# BOOKING FORM 2010

## The Annual European Medicines Agency Review of the Year and Outlook for 2011 and beyond

***A joint meeting between TOPRA and the European Medicines Agency***

**Date:** 6–7 December 2010 **Venue:** London, UK **Reference:** CA5/10

## 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, Bellerive House, 3 Muirfield Crescent, London E14 9SZ

**Fax:** +44 (0) 20 7537 2003

**Email:** meetings@topra.org

On receipt of your booking form we will confirm your provisional 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 7510 2560** or **meetings@topra.org**

Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Other

Family name

First name Male ☐ Female ☐

Company name

VAT reg. no.

Job title

Telephone

Fax

E-mail

**Work Address**

City Postcode

Country

**Invoice Address** *(If different from above address)*

City Postcode

Country

**Special dietary requirements**

## Fees and Payment method

| | | |
|---|---|---|
| **Members** | ☐ | **€1,756.63** = €1,495.00 + €261.63 (17.5% GB VAT) |
| **Non-Members** | ☐ | **€2,226.63** = €1,895.00 + €331.63 (17.5% GB VAT) |

*The VAT rate charged will be the prevailing rate at the time of invoicing.*

Cheque enclosed ☐ Cheque No

Bank transfer ☐ Date of transfer ☐☐ / ☐☐ / ☐☐

Please charge my debit/credit card ☐ Purchase Order No.

## Debit/Credit card details

*(For cards accepted, see payment section below)*

Debit Card (preferred) ☐ Visa ☐ MasterCard ☐ American Express ☐

Card No

Expiry date ☐☐ / ☐☐

Security code ☐☐☐ *Visa, MasterCard, Debit cards: the last 3 digits AFTER the card number in the signature area of the card.*

**Card holder name** *(as given on card)*

**Billing address for card** *(must be provided if different from the Work Address)*

City Postcode

Country

*TOPRA will seek authorisation from the card-issuing company before confirming any reservation. (VAT Registration No.: GB 342 7398 40).*

By signing below, I confirm that I agree with TOPRA's Terms & Conditions of Booking. These are available from the office or on the TOPRA website at: **www.topra.org/bookingTandC**

SIGNATURE DATE

## Terms and conditions *(**Please note:** TOPRA's full standard Terms & Conditions are available on the website at **www.topra.org/bookingTandC**).*

**Payment:**

- **Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Euro or Sterling.
- **Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. All cards will be charged in Sterling.
- **Bank Transfers:** may be made to Lloyds TSB Bank PLC. Please quote the delegate's name and the course reference in the transmission details. The delegate must pay all bank charges.
- **Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC LOYDGB21013
- **Euro Transfers:** Account No: 86330987, Sort Code: 30-00-09, IBAN: GB19 LOYD 3000 0986 3309 87, BIC LOYDGB21013
- Your place is secured only upon receipt of full payment.

**Please note:**
Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks, buffet lunches and drinks reception.

**Discounted fees:**
Personnel in full-time education, working in academia (full-time) or working for a statutory regulatory body may be entitled to a discount on the above fees. Please contact the TOPRA office for details.

**Cancellations:**
All cancellations must be received in writing 28 calendar days before the start of the course and will be subject to an administration fee of €150 + GB VAT. Payment can be in Euro or Sterling.

**Data Protection:**

☐ *We may occasionally send you promotional or other information about TOPRA's products and services. If you do not wish to receive this information, you can opt out of future communications by ticking this box*

☐ *We may occasionally send you promotional or product information from organisations and companies other than TOPRA. If you do not wish to receive this information, you can opt out of future communications by ticking this box*