

# emea CONFERENCE



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA7/08



## Medicines Legislation

### Aims of the course

This conference follows on from the success of two earlier joint meetings between TOPRA and the EMEA and its aim is to provide a practical insight into the workings of the EMEA. The aim is to bring together regulatory personnel from both the national agencies and industry in order to share regulatory knowledge, specifically when coordinated via the EMEA.

You will hear not only about the existing processes such as the centralized procedure and scientific advice but also how the new paediatric committee has performed over its first year; the impact of the new rules on pharmacovigilance, how the Advanced Therapy committee will be organized and Transparency – how open are we with each other?

The last session of the conference will provide an open forum for discussing emerging topics. An aim of this meeting is also to facilitate networking and there will be ample opportunity to meet many regulatory personnel from agencies and industry and particularly from the EMEA during the refreshment break, lunches and at the evening drinks reception.

### Who should attend

This conference will cover all the major areas of medicines legislation covered by the European Medicines Agency. If you are working at a Europe wide level then this meeting is a must for all levels of regulatory personnel. It will provide you with practical advice on the working of the EMEA within the European regulatory network. As well as speakers from the EMEA there will also be representatives of the national agencies and the European Commission plus Industry representatives to offer their experiences.

### Conference programme includes:

- New Regulatory Legislation
- Scientific Advice
- Paediatrics
- Advanced Therapies
- EMEA processes and procedures
- Pharmacovigilance
- Transparency
- Open Question Session

### Two-day Conference

#### Date:

Tuesday 2nd -  
Wednesday 3rd  
December 2008

#### Venue:

Hilton London Canary  
Wharf Hotel, London  
E14 9SH, UK

#### Timings:

Registration:  
09.00 Tuesday  
2nd December 2008  
Start of Conference:  
09.30 Tuesday  
2nd December 2008  
Close of Conference:  
16.00 Wednesday  
3rd December 2008



#### Lifelong Learning (LLL):

This meeting contributes 12 hours of training to your LLL (sometimes known as Continuing Professional Development) and will enhance your Regulatory Skills relevant in the areas of human and veterinary medicines

For more information or to obtain a booking form, please contact TOPRA via email: [meetings@topra.org](mailto:meetings@topra.org) or tel: +44 (0) 207 538 9502 or go to the website: [www.topra.org](http://www.topra.org)

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## Working party

**Peter Bachmann**

*BfArM, Germany*

**Liz Gifford**

*GlaxoSmithKline, UK*

**Anthony Humphreys**

*EMEA*

**Brenton E James**

*Consultant in Strategic  
Regulatory Affairs in  
Europe, UK*

**Donna Mountfield**

*Chugai Pharma Europe*

**Arielle North**

*EMEA*

**Beatrice Oberlé-Rolle**

*Novartis, Switzerland*

**Giuseppe Pimpinella**

*AIFA, Italy*

**Agnes Saint Raymond**

*EMEA*

**Tomas Salmonson**

*Vice chair CHMP, EMEA  
and MPA, Sweden*

*Supported by TOPRA staff:*

**Christopher Bailey**

*Conference and Training  
Programme Manager*

**Erik Smit**

*Business Development Manager*

# Medicines Legislation

## Speakers include

**Eric Abadie**

*chair CHMP, EMEA and  
Afssaps, France*

**Daniel Brasseur**

*chair of Paediatric Committee  
(PDCO), EMEA*

**Axel Breitstadt**

*MSD (Europe) Inc, Belgium*

**Melanie Carr**

*EMEA*

**Patrick Celis**

*EMEA*

**Ali Harrison**

*AstraZeneca, UK*

**Martin Harvey Alchurch**

*EMEA*

**Ian Hudson**

*MHRA, UK*

**Alan Hunter**

*TOPRA President*

**David Laurie**

*Novartis, Switzerland*

**Patrick LeCourtois**

*EMEA*

**Marisa Papaluca**

*EMEA*

**John Purves**

*EMEA*

**June Raine**

*chair CHMP Pharmacovigilance  
working party and MHRA, UK*

**Irene Sacristan Sanchez**

*Unit F2, European Commission*

**Vincenzo Salvatore**

*EMEA*

**Christian Schneider**

*PEI, Germany*

**Thomas Severin**

*Novartis, Switzerland*

**Lisette Tiddens-Engwirda**

*Vice chair EMEA Management  
Board, Standing Committee of European  
Doctors, Belgium*

**Noel Wathion**

*EMEA*

**Anne Wigmore**

*GlaxoSmithKline, UK*

*Other speakers from National Competent  
Authorities, EMEA, European Commission,  
Industry and other health care related  
bodies have been invited.*



**Book  
Early**  
Places limited



## Conference programme includes:

### 2nd December 2008

#### New Regulatory Legislation

*This session will review the legislation introduced over the past year and that coming up in the near future. The impact upon the EMEA, the European Commission, the EU member states and the committees that they support within the EMEA will be discussed.*

#### Scientific Advice

*New developments in the area of Scientific Advice (SA) and informal briefing meetings: faster/competitive SA process/parallel SA process, SA on conditional approval, new process for Qualification Advice e.g. for biomarkers and experiences with biomarker qualification pilots under the umbrella of Innovation Task Force (ITF) briefing meetings.*

#### Paediatrics

*This session will review the experience of the implementation of the Paediatric Regulations for investigational products (Article 7) and line extensions for patent protected products (Article 8). Experience will focus on applications for Paediatric Investigational Plans, deferrals and waivers from the EMEA and industry perspective. In addition, an update on paediatric activities from the national agencies perspective (Article 45) will be given.*

#### Advanced Therapies

*The Advanced Therapies Regulation (Regulation (EC) No 1394/2007) comes into effect on 30 December 2008 and this session will review the new committee and processes affected by this new regulation*

### 3rd December 2008

#### EMEA processes and procedures

*The scope of the centralised procedure has widened over the years since it was first introduced and now many companies are also choosing it as the procedure of choice for products where the centralised procedure is not obligatory – how has the procedure held up over the last year and what is the future? What should be in the centralised procedure versus the Decentralised procedure?*

#### Pharmacovigilance

*A number of changes in pharmacovigilance reporting have recently been announced and these will be reviewed in this session*

#### Transparency

*Openness is an increasing fact of modern life - what progress has been made and will be made towards increasing transparency?*

#### Open Question Session

*This final session will discuss all the latest emerging topics. Delegates are encouraged to submit their questions before the meeting and also questions will be taken from the floor by the panel of regulatory experts.*

For more information or to obtain a booking form, please contact TOPRA via email: [meetings@topra.org](mailto:meetings@topra.org) or tel: +44 (0) 207 538 9502 or go to the website: [www.topra.org](http://www.topra.org)

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Date: **Tuesday 2nd - Wednesday 3rd, December 2008** Venue: **Hilton London Canary Wharf Hotel** Reference: **CA7/08**

## Two-day conference

### 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 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 7538 9502 or [meetings@topra.org](mailto: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

### Experience in the Subject Area

Negligible  Average  Considerable

#### Your current role

Generics  CRO  European role  Global role  Local affiliate

Other

Experience in Regulatory Affairs Years  Months

Please indicate if in your regulatory experience you have worked in one or more of the following areas:

1) CMC  2) EU clinical trials  3) Variations  4) Medical Technologies

### Discounted fees

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

### Fees and Payment method

**Members**  €1,703.75 = €1,450.00 + €253.75 (17.5% GB VAT)

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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  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).

SIGNATURE	DATE
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  - Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC: LOYDGB21013
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- 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. Unless stated otherwise the official language of all our meetings is English. It may be necessary for reasons beyond the control of the organisers to alter the dates, venue, timing and content of the programme (including speakers) without prior notice; TOPRA regrets that it cannot accept liability for losses incurred by delegates in these circumstances. Meals requiring special preparation (such as Kosher) may incur additional costs.

**Cancellations:** All cancellations must be received in writing 21 calendar days before the start of the course and will be subject to an administration fee of €200. Payment can be in Euro or Sterling. For cancellations after this time, or if the delegate fails to attend the course, no refund of fees will be given. Substitutions may be made at any time. TOPRA reserves the right to cancel the course at any time without liability. In these circumstances, delegates will be offered an alternative date, a credit note or a full refund.

**Additional support:** Please advise TOPRA, at least one month before the meeting, if you have any disability that may require additional support. TOPRA makes no distinction in its admission policy with regards to disability. TOPRA will make every reasonable effort to supply delegates with services that meet their needs.

**Liability:** TOPRA regrets that it cannot accept liability for losses incurred by delegates in the event of postponement or other alterations to the meeting, i.e. timing, venue, etc. Normal TOPRA terms and conditions apply; please contact the TOPRA office for further details.

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