# EVOLUTION TO THE NEXT STEP - THE NEEDS OF THE FUTURE?

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

TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA4/09

## *The European Medicines Agency - what will the future bring us and what do we need to know today?*

The 4th annual EMEA round-up of the year and look towards the next year - a firm favorite with many European regulatory affairs personnel as the key year end event to reflect on the year gone by and to plan for the upcoming year.

### 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.

### Conference programme includes

- European Union future regulatory activity – The Pharmaceutical Package, European Commission update; EMEA Road map 2015; HMA Strategy paper
- Pharmacovigilance and Risk Management
- Working internationally
- Reacting and planning for change - EMEA restructuring
- Paediatrics - clinical studies
- Clinical Trials
- Variations
- CHMP

### Conference working party

- **Anthony Humphreys,** Head of Sector, Regulatory Affairs and Organisational Support, Post-Authorisation Evaluation of Medicines for Human Use, EMEA
- **Arielle North,** Scientific Administrator, EMEA
- **Agnès Saint Raymond,** Head of Orphan Drugs, Scientific Advice and Paediatric Medicines, EMEA
- **Tomas Salmonson,** Vice Chair CHMP, Medical Products Agency (MPA), Sweden
- **Peter Bachmann,** European and International Affairs, BfArM, Germany
- **Beatrice Oberlé-Rolle,** Drug Regulatory Affairs, Nobel Biocare, Switzerland
- **Brenton E James,** Consultant in Strategic Regulatory Affairs in Europe, UK
- **Liz Gifford,** Director, Global Regulatory Affairs, GlaxoSmithKline, UK
- **Donna Mountfield,** Associate Director of Regulatory Affairs, Chugai Pharma Europe, UK

*Supported by TOPRA staff*

***Please note:*** *there will be a drinks reception on the evening of the 1st December to facilitate networking*

For more information or a booking form, please visit **www.topra.org/emea2009**

## Two-day Conference

**Date:**
Tuesday 1st to Wednesday 2nd December 2009

**Venue:**
East Wintergarden, Canary Wharf, London

**Timings:**
8.00 Registration for 9.00 Start on 1st December

17.30 Close on 2nd December

TOPRA/ EMEA 12hrs*

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# TUESDAY 1ST DECEMBER 2009

09.00 Welcome and Introduction from Paolo Biffignandi, TOPRA President, VI.REL Pharma S.a.s., Italy and Thomas Lönngren, Executive Director, European Medicines Agency

## SESSION 1

### European Union: The latest information on future regulatory activity for pharmaceuticals

In the near future significant developments proposed by the European Commission, the European Medicines Agency and the Heads of Human Medicines Agencies will be released and have a very important impact on all stakeholders involved in Medicinal Products. This session includes an update on the Pharmaceutical Package, the EMEA Road Map to 2015 and the Heads of Medicines Agencies Strategy Paper.

**Chaired by**

***Irene Sacristan-Sanchez,*** *Deputy Head DG Enterprise and Industry, Pharmaceuticals Unit, European Commission*

***Brenton James,*** *Consultant in European Regulatory Affairs in Europe, UK*

09.20 Introduction to this session - Brenton James, Consultant in European Regulatory Affairs in Europe, UK

09.25 The Pharmaceutical Package - Irene Sacristan-Sanchez, Deputy Head DG Enterprise and Industry, Pharmaceuticals Unit, European Commission

09.45 The EMEA Road Map to 2015 - Noel Wathion, Head of unit Patient Health Protection, EMEA

10.05 Heads of Medicines Agencies Strategy Paper - Marcus Müllner, Division Manager, AGES PharmMed/Austrian Medicines and Medical Devices Agency, Austria

10.25 Speaker Panel with this sessions' speakers and invited panellist: Judith Creba, Head of EU Liaison and Policy, Novartis, Switzerland will comment upon the presentations and all attendees are invited to ask questions of the speakers.

11.00 Coffee break

## SESSION 2

### Pharmacovigilance and Risk Management

This session will cover new regulatory developments within the area of Pharmacovigilance. Topics to be covered in this session include updates on topics such as ICH and CIOMS, the implementation of the ICH E2F DSUR guideline in Europe and Risk Management Plans.

**Chaired by**

***Peter Arlett,*** *Head of Sector Pharmacovigilance and Risk Management, EMEA*

***Donna Mountfield,*** *Associate Director of Regulatory Affairs, Chugai Pharma Europe, UK*

11.30 Introduction - Peter Arlett, Head of Sector Pharmacovigilance and Risk Management, EMEA

11.40 Hot Topics - Peter Arlett, Head of Sector Pharmacovigilance and Risk Management, EMEA

12.00 Implementation of Development Safety Update Reports (DSURs) in Europe - Barry Arnold, EU Qualified Person for Pharmacovigilance, AstraZeneca R & D, UK

12.20 EU Risk Management Plans (RMP) - Stella Blackburn, Risk Management Coordinator, EMEA

12.40 Speaker Panel with this sessions' speakers

13.00 Lunch

## SESSION 3

### Working internationally

This session will explore working internationally with recent initiatives in the areas of transatlantic cooperation, Bilateral agreements (Japan, US, Canada etc), Clusters and with specific examples such as GMP and GCP.

**Chaired by**

***Emer Cooke,*** *International Liaison Officer, EMEA*

***Tomas Salmonson,*** *Vice Chair CHMP, Medical Products Agency (MPA), Sweden*

14.00 Bilateral agreements and clusters - Emer Cooke, International Liaison Officer, EMEA

14.20 Inspections, GCP and clinical trials

14.40 GMP - Oliver Gross, Scientific Administrator, EMEA

15.00 Speaker Panel with this sessions' speakers

15.30 Tea and Coffee

## SESSION 4

### Reacting and planning for change – EMEA restructuring

This session will review the recent reorganisation of the EMEA, the reasons for this and the impact on stakeholders such as Heads of Medicines Agencies (HMA) and the impact on resources and training.

**Chaired by**

***Arielle North,*** *Scientific Administrator, EMEA*

***Pat O'Mahony,*** *Chair of EMEA Management Board, Chief Executive Officer of IMB, Ireland*

16.00 EMEA Reorganisation - Patrick Le Courtois, Head of Unit, Human Medicines Development and Evaluation, EMEA

16.30 HMA resource planning and Training - Gro Ramsten Wesenberg, Director General Statens Legemiddelverk, Norwegian Medicines Agency, Norway and Martina Cvelbar, Head of Agency, Javna Agencija Republike Slovenije za Zdravila in Medicinske Pripomočke, Slovenia

17.00 Open Session: Questions from the floor followed by drinks reception

# WEDNESDAY 2ND DECEMBER 2009

08.30 Opening Remarks

## SESSION 5

### Paediatrics – clinical studies

This session will review the type of clinical trials that are usually included in Paediatric Investigations Plans, discuss aspects related to study feasibility from the view of sponsors and agencies and give advice on the set-up and conduct of long-term safety monitoring in children.

**Chaired by**

***Agnès Saint Raymond,*** *Head of Orphan Drugs, Scientific Advice and Paediatric Medicines, EMEA*

***Angelika Joos,*** *Director Regulatory Policy Europe, Merck Sharp & Dohme (Europe) Inc, Belgium*

08.40 Overview of clinical studies in Paediatric Investigation Plans (PIPs)

09.00 Are Paediatric trials feasible?

09.20 How to establish long-term safety in children?

09.40 Speaker Panel with this sessions' speakers

10.15 Tea and Coffee

## SESSION 6

### Clinical Trials

This session will review the state and recent developments in relation to the conduct of clinical trials across the EU. The achievements within the voluntary harmonisation procedure will be reviewed as well as general observations in relation to safety reporting and issue assessment.

**Chaired by**

***Beatrice Oberlé-Rolle,*** *Drug Regulatory Affairs, Nobel Biocare, Switzerland*

10.15 Introduction

10.55 Clinical Trial Harmonisation - Hartmut Krafft, Head of sector, clinical trials, Paul-Ehrlich-Institut (PEI), Germany

11.15 CTFG activities - Chantal Bélorgey, Head of Division on Evaluation of Special Status Medicinal Products and Clinical trials, Afssaps, France

11.35 Industry observations

11.45 Tranparency of Clinical Trials

12.15 Lunch

## SESSION 7

### Variations

The new Variation Regulation EC (No) 1234/2008 will apply from 1 January 2010 to products authorised via MRP, DCP and CP procedures. New key provisions concern the possibility for MAHs to group the submission of variations in one application, or to present the same variation(s) affecting more than one MA for a 'worksharing' procedure. In addition, any variation which is not classified in the Regulation's Annex or its implementing guideline, will be considered as a Type IB variation by default.

**Chaired by**

***Peter Bachmann,*** *European and International Affairs, BfArM, Germany*

***Hilde Boone,*** *Scientific Administrator, EMEA*

13.15 Introduction: Background and future work sharing - Peter Bachmann and Hilde Boone

14.05 Industry viewpoint on work sharing - Fiona Reekie, Director, Johnson & Johnson Pharmaceuticals, UK

14.15 Speaker Panel with this sessions' speakers

14.45 Tea and Coffee

## SESSION 8

### Committee for Medicinal Products for Human Use (CHMP) – achievements and challenges

This session will review the operation of the CHMP within the European regulatory network. Subjects to be covered by key speakers from Regulatory Agencies (including the CHMP Chair) include the CHMP's current activities and workload, it's achievements and successes and the way it interacts with other key committees and stakeholders (e.g. CAT, PDCO, SAGs). The session will include discussion on some of the hot topics associated with the Centralised Procedure (e.g. Rapporteur selection, the contribution of peer review and SAGs, transparency) and will discuss some of the challenges that face the CHMP in the future with the Centralised Procedure. An example of a successful Centralised Procedure will be presented by an industry speaker.

**Chaired by**

***Eric Abadie,*** *Chair of CHMP, Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps), France*

***Liz Gifford,*** *Director, Global Regulatory Affairs GlaxoSmithKline, UK*

15.15 Introduction by the Chair of CHMP - Eric Abadie, Chair of CHMP, Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps), France

15.30 CHMP Work Load – Anthony Humphreys, Head of Sector, Regulatory Affairs and Organisational Support, Post-Authorisation Evaluation of Medicines for Human Use, EMEA

15.50 Committees and Working Parties - Xavier Luria Oller, Head of Sector, Safety and Efficacy of Medicines, EMEA

16.10 Special Projects - Eric Abadie, Chair of CHMP, Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps), France

16.30 Case study - Alan Morrison, Head of Global Regulatory Affairs, Amgen, UK

16.45 Speaker Panel with this sessions' speakers

17.15 Summary of the last two days

17.30 Close of Meeting

*Other speakers from EMEA, European agencies, European Commission and Industry have been invited. Programme might be subject to change.*

**BOOKING FORM 2009**

emea

TOPRA

Date: 1st – 2nd December 2009 Venue: East Wintergarden, Canary Wharf, London, UK Reference: CA4/09

# Evolution to the next step – the needs of the future?

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

**Discounted fees:**
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