

# PUBLIC ICH MEETING

14 November 2008

Brussels, Belgium

*Radisson SAS Hotel*

Rue Fossé-aux-Loups - 47  
1000 Brussels



European Federation of Pharmaceutical  
Industries and Associations



International Conference on harmonisation of technical requirements for registration of pharmaceuticals for human use

## Objectives of the Meeting

In May 2007 the ICH Steering Committee agreed to the organisation of focused **Public ICH Regional Meetings**.

The first such European regional public ICH meeting will take place at the **Radisson SAS Hotel in Brussels on 14 November 2008**.

This **Public ICH Meeting** will provide an opportunity to be informed on the recent developments at ICH in the context of **globalisation** and **increasing international inter-agency cooperation**. It will also provide an opportunity to receive the latest news on «hot topics», to make comments to the ICH experts and rapporteurs and to raise questions on **quality topics, safety topics, standards development topics** and **efficacy topics**.

This event will also give participants the opportunity to meet with regulators and industry experts from both ICH and non ICH regions.

# Agenda

- 9.00 Welcoming address  
**Christine-Lise Julou - EFPIA - Steering Committee Member for ICH**
- 9.10 Overview of recent developments in ICH  
*(including the role and continuing value of ICH in the context of globalisation and increasing inter-Agency cooperation)*  
**Thomas Lönngren - Executive Director EMEA**
- 9.40 Enhanced cooperation on harmonisation priorities  
**Session Chair: Peter Arlett - Co-Chair GCG**
  - Evolution and achievements of GCG  
**Kohei Wada - Co-Chair GCG**
  - The new ICH Regulators Forum - **Peter Arlett - EU**
  - Perspective from a Regional Harmonisation Initiative RHIs  
**Saleh Abdullah Bawazir - SFDA & GCC**
- 10.00 Questions & Answers concerning the first session  
*Panel including all speakers for first session and Mike Ward (Health Canada)*
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|--------------|---------------------|
| <b>10.15</b> | <b>Coffee Break</b> |
|--------------|---------------------|
- 10.30 Safety Topics  
*Outcome of preceding meetings of the Safety Experts Working Groups*  
**Session chair: Beatriz Silva Lima - Chair CHMP- Safety Working Party**
  - Brief presentation of the guidelines on the agenda of the Brussels meeting and hot news coming out of the meeting
    - Revision of Guidance on Genotoxicity Testing & Data Interpretation for Pharmaceuticals intended for human use (ICH S2(R1): **Peter Kasper - BfArM and S2(R1) EWP**)
    - Revision of Non-Clinical Safety Studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals ICH M3(R2): **David Jones - MHRA & M3(R2)EWP**
    - Revision of Guideline Preclinical Safety Evaluation of Biotechnology-derived pharmaceuticals - **Jennifer Sims Rapporteur S6(R1)**
    - Guideline Oncology Therapeutics ICH S9 - **Klaus Olejniczak BfArM & S9EWP**
  - Questions & Answers

11.30 Standard Topics

*Standards development for the electronic exchange of information*

**Session chair: Andrew Marr - Rapporteur ICH M2**

- High level objectives of M2 and Involvement of SDOs (why has a link been established with SDOs) - **Andrew Marr**
- Applications (ICSRs & IDMP): latest news coming out of the meeting of 11-13 November
  - Individual Case Safety Reports (ICSR)  
**Ayumi Endo - MHLW - Rapporteur E2B(R3) TBC**
  - Identification of medicinal products (IDMP)  
**Sabine Brosch - EMEA - Rapporteur ICH M5**
- Update on eCTD - **Joe Cipollina - Pfizer/PhRMA & ICH M2 IWG**
- MedDRA: development and use of standards for the exchange of information - **Patricia Mozzicato - MSSO**
- Questions & Answers - **Chairman and Speakers for the session**

**12.40 Lunch Break**

13.40 Efficacy Topics

*Update on the development of new guidelines using state of the art tools and systems to strengthen the clinical assessment of new medicines*

**Session chair: Solange Rohou - Chair EFPIA Efficacy ad hoc Group**

- Biomarkers and E16 - **Lois Hinman - Rapporteur ICH E16**
- Overview of other ongoing ICH efficacy topics:
  - Update on E2F: development Safety Update Reports  
**Spiros Vamvakas - EMEA Technical Coordinator for ICH**
  - E14: Question and Answer document: what's next?  
**Solange Rohou - AstraZeneca/EFPIA & E14 IWG**
  - E7: Update and next steps  
**Solange Rohou - AstraZeneca/EFPIA & E7 IWG**
- Questions & Answers

14.15 Quality Topics

*Modernisation of technical requirements for the manufacturing of high quality medicines and encouraging their continual improvement throughout their entire lifecycle*

**Session chair: Jean-Louis Robert - Chair CHMP-Quality Working Party and Rapporteur ICH Quality Implementation Working Group**

This session will provide:

- Hot news on the outcome of the discussion on ICH Quality Topics during the week

- Quality Development in the ICH process

**Jean-Louis Robert - EU**

- Annex to Q8 Pharmaceutical Development

**Robert Baum - Pfizer/PhRMA & Q8(R1) EWG**

- Q11 Development and Manufacture of the drug substances

**Brian Withers - Rapporteur ICH Q11**

- Implementation of Q8, Q9 and Q10

**George France - Wyeth/EFPIA & Quality IWG**

- Harmonisation of Pharmacopoeias

**Michael Wierer - EDQM & Pharmacopoeial Discussion Group**

- A platform for interaction between a panel of members of ICH Quality Working Groups and the audience

16.15 Conclusion of meeting

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**Christine-Lise Julou - EFPIA**

# Registration Information

Participants are invited to use the attached registration form.

## **FEES FOR INDUSTRY PARTICIPANTS**

**EURO 300,- (VAT inclusive) per person (all bank charges to be paid by the forwarder). This fee covers participation in the Public ICH Meeting, refreshments and cold buffet lunch.**

## **PAYMENT AND CANCELLATION**

An invoice will be mailed **upon receipt of your payment**. (a proforma invoice could be however sent upon request only). We recommend to register for **6 November 2008** at the latest.

**No reimbursement will be made in the event of cancellation after 6 November 2008.**

Payment must be **received prior to the meeting** (and at least 3 days before the event) to allow participation in the meeting.

## **ACCOMMODATION**

Participants are invited to make their own arrangements. **EFPIA will not arrange any hotel booking**. Room reservations can be made via internet (Radisson SAS Hotel Brussels site link: <http://www.royal.brussels.radissonsas.com>)

# Registration Form

**PUBLIC ICH MEETING - 14 November 2008**

First name: .....

Family name: .....

Company or association: .....

Company Address: .....

Invoicing Address (Please indicate the invoicing address only):

.....

V.A.T. number (IMPORTANT!!!! The VAT will be indicated on the invoice):

.....

Telephone: ..... Fax: .....

E-mail: .....

Will attend the ICH Public Meeting. Will transfer the sum of EURO 300,- to the EFPIA account No. 210 0613223 41 (IBAN BE88 210.061.32.23.41, BIC GEBABEBB), Fortis, Agence Bascule, Avenue Molière 516, B-1050 Brussels).

Date: ..... Signature: .....

**Please note that the invoicing address and VAT number will be mentioned on the invoice.**

To be returned to Anita Colin ([anitacoln@efpia.org](mailto:anitacoln@efpia.org))  
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