

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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| 10.15 | Coffee Break |
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- 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

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):

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

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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)
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