Prague, Czech Republic
14-15 October 2010

Quality of medicines in a globalised world: dreams and reality

Programme

International Conference

Organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

Working language: English
Duration: 2 days

edqm
European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Thursday, 14th October 2010 *8:30 - 18:00*

Programme

A Posters Session is open to all participants for the entire duration of the Conference

8:00 **Registration**

Opening Session

8:30-8:45 Opening remarks
Dr Susanne Keitel, Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
Welcome address
H.E. Mr Leoš Heger, Minister of Health of the Czech Republic

Plenary Session

Current and new issues concerning global markets and the quality of medicines: how to face the challenges and opportunities of globalisation

Moderator: **Prof. H. J. de Jong**, Former Chair of the European Pharmacopoeia Commission

- **European perspectives**

8:45-9:00 Pharmaceuticals Unit, Directorate General Health and Consumers, European Commission (EU)
Dr Patrick Deboyser, Advisor to DG Sanco
9:00-9:15 Heads of Medicines Agencies (HMA)
Dr Kristin Raudsepp, Member of the HMA
9:15-9:30 European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
Dr Susanne Keitel, Director

- **International perspectives - Regulatory Authorities**

9:30-9:45 US Food and Drug Administration (FDA)
QbD and analytical considerations – Opportunities and challenges
Dr Moheb M. Nasr, Director of the Office of New Drug Quality Assessment
9:45-10:00 Japan - National Institute of Health Sciences (NIHS)
International harmonisation and scientific development of quality practices
Dr Yukio Hiyama, Chief, Division of Drugs

10:00-10:30 *Coffee break*

- **International perspectives - Pharmacopoeias**

10:30-10:45 United States Pharmacopeia
Dr Roger L. Williams, Chief Executive Officer
10:45-11:00 Japanese Pharmacopoeia
Dr Toru Kawanishi, Director, Division of Drugs, National Institute of Health Science, MHLW
11:00-11:15 Chinese Pharmacopoeia
Dr Huiyi Li, Director of Chemical Drugs Department
11:15-11:30 Indian Pharmacopoeia
Dr G. N. Singh, Secretary-cum-scientific Director
11:30-11:45 Brazilian Pharmacopoeia
Building the Mercosul Regional Pharmacopoeia
Dr Gerson Pianetti, Chair of the Brazilian Pharmacopoeia

Thursday, 14th October 2010 *8:30 - 18:00*

- **Industry**

11:45-11:55 European Federation of Pharmaceutical Industries and Associations (EFPIA)
Dr Georges France, EFPIA Technical Development and Operations Committee

11:55-12:05 European Generic Medicines Association (EGA)
Ms Suzette Kox, Director for Scientific Affairs

12:05-12:15 Association of the European Self-Medication Industry (AESGP)
Dr Barbara Steinhoff, AESGP

12:15-12:25 International Association for Animal Health (IFAH)
Dr Jochen Wieda, Chairman IFAH-Europe

12:25-12:35 European Chemical Industry Council, Active Pharmaceutical Ingredients Committee (CEFIC/APIC)
Dr Matthew Moran, Vice-President APIC

12:35-12:45 International Pharmaceutical Excipients Council (IPEC-Europe)
Current and new issues concerning global markets and the quality of medicines: How to face the challenges and opportunities of globalisation – Europe
Mrs Beam Suffolk, Chair of IPEC-Europe

12:45-12:55 Plasma Protein Therapeutics Association (PPTA-Europe)
EDQM and Plasma Protein Therapies: A story of success
Dr Ilka Von Hoegen, PPTA-Europe

13:00-14:30 *Lunch*

14:30-18:00 **Workshop sessions**

Friday, 15th October 2010 *8:30 - 17:00*

8:30-12:00 **Workshop sessions**

12:00-13:30 *Lunch*

Plenary Session

Moderator: **Dr Susanne Keitel**, Director, EDQM, Council of Europe

13:30-15:00 **Reports from the workshop sessions**

Needs and recommendations

15:00-15:20 National Competent Authority (NCA)
Dr Jiri Deml, Deputy Director, State Institute for Drug Control, Czech Republic

15:20-15:40 European Medicines Agency (EMA)
Prof. Hans-Georg Eichler, Senior Medical Officer

15:40-16:00 World Health Organization (WHO)
Dr Sabine Kopp, QA and Safety Medicines

16:00-16:30 *Discussion*

16:30-16:45 Final conclusions
Dr Marianne Ek, Chair of the European Pharmacopoeia Commission

16:45-17:00 Closing remarks
Dr Susanne Keitel, Director, EDQM, Council of Europe

17:00 *Reception*

Workshop Sessions

Five parallel workshops; all workshops are repeated twice with the same presentations; the first Session on Thursday afternoon and the second repeat Session on Friday morning.

	Workshop 1 Characterisation of biological molecules **Room** Aquarius + Taurus	**Workshop 2** New technologies and their impact on the Pharmacopoeia **Room** Zenit	**Workshop 3** Control of impurities - A Challenge for all stakeholders **Room** Nadir	**Workshop 4** Application of 3R principles in a globalised world: Dream or reality **Room** Leo + Virgo	**Workshop 5** The European Pharmacopoeia - Is it prepared for the future? **Room** Tycho
	Thursday 14 October 2010 afternoon (14:30-18:00)				
14:30-18:00	**Session 1**	**Session 1**	**Session 1**	**Session 1**	**Session 1**
	Friday 15 October 2010 morning (8:30-12:00)				
8:30-12:00	**Session 2**	**Session 2**	**Session 2**	**Session 2**	**Session 2**

Workshop 1 - Room Aquarius+Taurus: Characterisation of biological molecules

Moderator: **Dr Maria Sol Ruiz**, Vice-Chair of the Biotechnology Working Party (BWP, EMA)

Points of view of regulators:

- European aspects
  Dr Alan Fauconnier, Federal Agency for Medicines and Health Products (B)
- World Health Organization (WHO)
  Dr Hye Na Kang, Scientist

- *Coffee break*

Points of view of industries:

- An Innovator's Perspective on the Characterization of Biosimilars
  Dr Anthony Mire-Sluis, Executive Director, Global Product Quality and Quality Sciences Amgen Inc. (USA)
- Target directed development of biosimilar products
  Dr Martin Schiestl, Sandoz GmbH (A)

Panel Discussion

Workshop 2 - Room Zenit: New technologies and their impact on the Pharmacopoeia

Moderator: **Ms Lina Ertle**, Agence française de sécurité sanitaire des produits de santé - Afssaps (F)

PAT, RTR, QbD, Design Space, Design of Experiments - what is behind them?
Prof. Gert Ragnarsson, Medical Products Agency - MPA (S)

The application of RTR in the pharmaceutical industry - dream or reality?
Mr Marc Goeller, Novartis Pharmaceuticals Corp. (USA)

- *Coffee break*

PAT and RTR for Biologicals - Is there a need for special requirements?
Dr Kowid Ho, Afssaps (F)

RTRT and consequences for the Pharmacopoeia - a European regulatory perspective
Dr Keith Pugh, Medicines and Healthcare products Regulatory Agency - MHRA (UK)

Panel Discussion

Workshop 3 - Room Nadir: Control of Impurities - A challenge for all stakeholders

Moderators: **Dr Andrea Lodi**, Laboratory Department, EDQM, Council of Europe
Dr Michael Wierer, European Pharmacopoeia Department, EDQM, Council of Europe

Advances in LC/MS and other hyphenated techniques
Dr Bastiaan Venhuis, National Institute for Public Health and the Environment - RIVM (NL)

The use of fast LC for analysis of pharmaceutical substances
Prof. Jos Hoogmartens, Katholieke Universiteit Leuven (B)

• *Coffee break*

Control of purity and impurities - other technologies (e.g. NMR, capillary electrophoresis, etc)
Dr Ian McEwen, Medical Products Agency - MPA (S)

Analytical technologies and strategies for combating illegal medicines
Dr Andreas Mayrhofer, Austrian Agency for Health and Food Safety - AGES PharmMed (A)

Panel Discussion

Workshop 4 - Room Leo+Virgo: Application of 3R principles in a globalised world: dream or reality?

Moderator: **Dr David Wood**, WHO

Challenges for the application of the 3R principles globally
Prof. David Morton, University of Birmingham (UK)

European Pharmacopoeia Achievements and Perspectives
Dr Lukas Brückner, Chair of Ph. Eur. Group of Experts on Veterinary sera and vaccines (15V)

Food and Drug Administration (FDA) Perspective
Dr Konstantin Chumakov, Center for Biologics Evaluation and Research - FDA (USA)

• *Coffee break*

Achieving the 3Rs in a globalised world: Feedback from VICH
Dr Kornelia Grein, European Medicines Agency (EMA)

Association of SouthEast Asian Nations (ASEAN) Perspective
Dr Jeewon Joung, Korean Food and Drug Administration - KFDA, Center for Official Lot Release (KR)

European Vaccine Manufacturers' Perspectives
Dr Cécile Ponsar, GlaxoSmithKline Biologicals (B)

Round-table Discussion: how can the dream become reality?

Workshop 5 - Room Tycho: The European Pharmacopoeia – Is it prepared for the future?

Moderator: **Dr Hilda Köszegi Szalai**, National Institute of Pharmacy (H)

Statement by:
European Union Regulatory Authorities
Dr Jean-Louis Robert, Laboratoire National de Santé (L)

Pharmaceutical Industry
Mr Mark Wiggins, Merck Co Inc. (USA)
Dr Bernhard Wolf, Ratiopharm (D)

Official Medicines Control Laboratory - OMCL
Dr Philippe Girard, Swissmedic (CH)

Scientific Programme Committee

Dr L. Brückner, Chair of Ph. Eur. Group of Experts on Veterinary sera and vaccines (15V);
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Dr M. Morris, Chair of Ph. Eur. Group of Experts on Dosage forms and methods (12);
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Dr M. Wierer, Deputy Head of the European Pharmacopoeia Department, European Directorate for the Quality of Medicines & HealthCare (EDQM)/Council of Europe.

Organisation Committee

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