



FINAL PROGRAMME
QUALITY ON THE MOVE:
DYNAMICS OF THE EUROPEAN PHARMACOPOEIA

International Conference organised by the
European Directorate for the Quality of Medicines (EDQM), Council of Europe
4-6 October 2004, Budapest Hungary

From 9:00 Registration

Monday 4 October 2004

13:45-18:30

OPENING SESSION

13:45 Welcome addresses:

Dr M. Morris, Chair of the European Pharmacopoeia Commission

Prof. T. Paál, President Director General, National Institute of Pharmacy, Hungary

PLENARY SESSION

Moderator: **Prof. Dr H. G. Kristensen**,
Former Chair of the European Pharmacopoeia Commission

Roles of the European Authorities: Areas of Activity and Synergy

14:00 Commission of the European Communities (EC): **Mr P. Brunet**, DG Enterprise (EC)

14:20 European Agency for Medicines (EMA): **Dr T. Lönngren**, EMA

14:40 European Directorate for the Quality of Medicines (EDQM): **Dr A. Artiges**, EDQM

15:00 The European Pharmacopoeia Dynamics: the 5th Edition - New concepts:

Dr M. Morris, Chair of the European Pharmacopoeia Commission

New Approaches and Prospects for Development in the Field of the Quality of Medicines in Europe

- **Viewpoint of the Regulatory Authorities: EMA working parties**

15:20 Quality Working Party (QWP): **Dr J. L. Robert**, QWP, EMA

15:35 Biotech Working Party (BWP): **Prof. J. H. Trouvin**, BWP, EMA

15:50 Coffee break

16:20 Herbal Medicinal Products Working Party (HWP): **Dr K. Keller**, HWP, EMA

16:35 Immunologicals Working Party (IWP): **Prof. O. Papadopoulos**, IWP, CVMP, EMA

16:50 Inspectorate Working Party: **Mrs E. Cooke**, Inspection Unit, EMA

- **Viewpoint of the European Pharmacopoeia and its partners**

17:05 European OMCLs Network: **Dr P. Jongen**, Advisory Working Group of General OMCL Network

17:20 Procedure for Certification of suitability: **Prof. D. Calam**, Certification Steering Committee of the EDQM

17:35 Biological Standardisation Programme: **Dr R. Dobbelaer**, Biological Standardisation Steering Committee

- **Viewpoint of the Industry**

17:50 European Federation of Pharmaceutical Industries and Associations (EFPIA)

Dr J. Berridge, Quality Working Group, EFPIA

18:05 Discussion

18:20 Closure

19:45 Conference dinner

Tuesday 5 October 2004

8:30-12:30 BALLROOM A

Impurities: Revision of the Ph. Eur. policy: Why? How?

Moderators: **Prof. J. M. Midgley** and **Mr J. Van Rompay**

Chairs of Groups of Experts Chemistry-Synthetic Products (10A) and (10B)

Impurities Control in European Pharmacopoeia Monographs: Current Policy

8:30-8:50 **Mr P. Castle**, Secretary to the European Pharmacopoeia Commission

8:50-9:00 Discussion

The pharmaceutical industry viewpoint: Strategy to set up specifications during the development of drugs

9:00-9:20 **Dr A. Rotar**, KRKA (SL)

9:20-9:30 Discussion

OMCLs view of the European Pharmacopoeia Policy

9:30-9:50 **Dr A. Mayrhofer**, Bundesinstitut für Arzneimittel (BfA) (A)

9:50-10:00 Discussion

10:00-10:30 *Coffee Break*

Residual metal catalysts and alkylating agents: a toxicological perspective

10:30-10:50 **Dr Snodin**, Parexel (UK)

10:50-11:00 Discussion

Liquid chromatography (LC): Qualification of columns

11:00-11:20 **Prof. Dr J. Hoogmartens**, Katholieke Universiteit Leuven (B)

11:20-11:30 Discussion

New technologies: Validation/ Development in analytical technology

Hyphenated techniques: LC-MS, MS-MS, LC-NMR: their role in impurities control

11:30-11:50 **Dr W. Luijten**, Technologie Servier (F)

11:50-12:00 Discussion

Impurities in critical drugs

12:00-12:20 **Prof. Dr U. Holzgrabe**, Institut für Pharmazie und Lebensmittelchemie Am Hubland (G)

12:20-12:30 Discussion

8:30-12:00 BALLROOM C

Herbals: new specific and general monographs

Moderators: **Prof. Dr G. Franz** and **Prof. Dr A. J. Vlietinck**

Chairs of Groups of Experts on Phytochemistry (13A) and (13B)

Options and limitations for the phyto-equivalence

8:30-8:50 **Dr M. Veit**, LAT GmbH (G)

8:50-9:00 Discussion

Improvement of analytical techniques in monographs for the identification and quantification of natural compounds

9:00-9:20 **Prof. M. Hamburger**, University of Jena, Institute of Pharmacy (G)

9:20-9:30 Discussion

Special aspects of active or inactive markers in herbal products: Analytical techniques and reference standards

9:30-9:50 **Dr B. Klier**, PhytoLab GmbH & Co (D)

9:50-10:00 Discussion

10:00-10:30 *Coffee Break*

Analytical techniques: selection of marker compounds, use of expensive markers, use of working standard extracts and use of batch specific extracts for the analysis of herbal medicinal products

10:30-10:50 **Dr F. Soldati**, Pharmaton SA (CH)

10:50-11:00 Discussion

The regulators viewpoint

- The European level

11:00-11:20 **Dr K. Keller**, BfArM (G)

11:20-11:30 Discussion

- The national level

11:30-11:50 **Dr P. Claeson**, Medical Products Agency (S)

11:50-12:00 Discussion

8:30 – 10:00 BALLROOM B

European Biological Standardisation Programme (BSP)

Moderators: **Dr R. Dobbelaer** Chair of Group of Experts on Sera and Vaccines (15)
and **Mr J. M. Spieser**, Biological Standardisation Division, EDQM

Biological Standardisation: what for and for whom?

8:30-8:50 **Mrs A. M. Georges**, EVM/GlaxoSmithKline (B)

8:50-9:00 Discussion

Challenges for vaccines of the future: Standardisation of new testing

9:00-9:20 **Mr A. Sabouraud**, Aventis-Pasteur (F)

9:20-9:30 Discussion

New perspectives/impact from new technologies and developments in licensing and surveillance for biological standardisation

9:30-9:50 **Prof. J. H. Trouvin**, AFSSAPS (F)

9:50-10:00 Discussion

8:30-10:00 ENDRE ROOM

CLINIC 1: Dosage forms and general monographs

One to one consultations with: **Prof. C. Graffner**, Chair of Group of Experts on Dosage Forms and Standard Terms (12) and **Mrs I. Mercier**, EDQM

10:00-10:30 *Coffee break*

10:30-12:00 BALLROOM B

Blood/ Plasma products

Moderators: **Prof. Dr R. Seitz**, Chair of Group of Experts Human Blood & Blood Products (6B)
and **Mr P. Castle**, European Pharmacopoeia Commission, EDQM

The development of blood product monographs: from pasteurisation to NAT testing

10:30-10:50 **Mrs E. Sandberg**, Danish Medicines Agency (DK)

10:50-11:00 Discussion

Current state of blood product safety

11:00-11:20 **Prof. Dr R. Seitz**, Paul-Ehrlich Institut (D)

11:20-11:30 Discussion

International collaboration in developing standard preparations

11:30-11:50 **Dr T. Barrowcliffe**, National Institut for Biological Standards & Control (UK)

11:50-12:00 Discussion

10:30-12:00 ANJOU ROOM

Certification: New developments of the procedure and how to better prepare your dossiers

Moderators: **Prof. D. Calam**, Certification Steering Committee of the EDQM
and **Ms C. Pouget**, EDQM

Review of the programme of inspections of manufacturing sites

10:30-10:45 **Ms C. Pouget**, EDQM

10:45-10:55 Discussion

The main deficiencies found in dossiers

10:55-11:15 Mrs H. Bruguera, EDQM

11:15-11:20 Discussion

When alternative methods are used to replace those described in the Ph.Eur. monographs

11:25-11:40 Ms A. M. Ambrose, National Medicines Agency (UK)

11:40-11:50 Discussion

New procedures for revision/renewal of certificates

11:50-12:00 Mrs H. Bruguera, EDQM

12:00-12:10 Discussion

10:30-12:00: ENDRE ROOM

CLINIC 3: Pharmaceutical Ref. Substances & Preparations

One to one consultations with: Dr A. Lodi, Dr V. Egloff and Dr U. Rose, EDQM

12:00-14:00 Lunch Break

13:30-14:00: ENDRE ROOM

CLINIC 2: Biologicals and Biotechnology products

One to one consultations with Dr J. W. Dorpema, Chair Group of Experts Biological Substances Ph. Eur. Commission and Mr P. Castle, European Pharmacopoeia Commission, EDQM

14:00-15:30 BALLROOM A

International Harmonisation

Moderators: Dr M. Morris, Chair of the European Pharmacopoeia Commission and Mr P. Castle, European Pharmacopoeia Commission, EDQM

The harmonisation process in Europe

14:00-14:20 Mr P. Castle, European Pharmacopoeia Commission

14:20-14:30 Discussion

The harmonisation process in Japan

14:30-14:50 Dr S. Tsuda, Office of Compliance and Standards, PMDA (J)

14:50-15:00 Discussion

The harmonisation process in the United States of America

15:00-15:20 Dr R. Williams, United States Pharmacopoeia (USA)

15:20-15:30 Discussion

14:00-15:30 BALLROOM B

Pharmaceutical dosage forms, standard terms

Moderators: Prof. C. Graffner Chair of Group of Experts on Galenical products (12) and Prof. Dr H. G. Kristensen, Chair of Group of Experts on Microbiology (1)

Dosage form monographs and standard terms. How the system is constructed and works, and future developments

14:00-14:20 Prof. C. Graffner, Medical Product Agency (S)

14:20-14:30 Discussion

International harmonisation of Q6A items (dissolution, disintegration, dose uniformity).

What are the implications?

14:30-14:50 Dr C. Vermaat, N.V. Organon (NL)

14:50-15:00 Discussion

Physical quality of solids and powder characterization techniques

15:00-15:20 Dr M. Veillard, Aventis (F)

15:20-15:30 Discussion

14:00-15:30 BALLROOM C

Excipients

Moderators: **Prof. H. De Jong**, Chair of Group of Experts on Organic Chemistry-Synthetic Products (10C) and **Dr P. H. Vree**, Health Care Inspectorate (NL);

Near infrared for characterisation of cellulotics

14:00-14:20 **Dr M. Josefson**, Astra-Zeneca (S)

14:20-14:30 Discussion

Calorimetric methods to characterise solid-state materials

14:30-14:50 **Prof. G. Buckton**, London University (UK)

14:50-15:00 Discussion

Viewpoint of IPEC on impurities in excipients

15:00-15:20 **Dr C. Moreton**, Idenix (USA) and representative of IPEC Americas

15:20-15:30 Discussion

14:00-15:30 ANJOU ROOM

Pharmaceutical waters

Moderators: **Dr J. L. Robert**, Quality Working Party, EMEA and
Dr A. Bevilacqua, Mettler-Toledo Thornton (USA)

Note for guidance

14:00-14:20 **Dr J. L. Robert**, Quality Working Party, EMEA

14:20-14:30 Discussion

International harmonisation of pharmacopoeia monographs for water

14:30-15:10 **Dr A. Bevilacqua**, Mettler-Toledo Thornton (USA)

15:10-15:30 Discussion

14:00-15:30 ENDRE ROOM

CLINIC 4: Herbals

One to one consultations with **Prof. Dr A. J. Vlietinck**, Chair Group of Experts of Ph.Eur. Commission on Phytochemistry and **Dr E. Pel**, EDQM (team 1);

Prof. Dr G. Franz, Chair Group of Experts of Ph. Eur. Commission on Phytochemistry and
Dr P. Poukens Renwart, EDQM (team 2)

14:00-15:30 BELA ROOM

CLINIC 5: Certification

One to one consultations with:

Mrs A. M. Ambrose, National Medicines Agency (UK) and **Ms C. Pouget**, EDQM (team 1);
Dr D. De Kaste and **Dr A. McMath/Mrs H. Bruguera**, EDQM (team 2)

15:30-16:00 *Coffee Break*

16:00-17:30: BALLROOM A

Microbiological techniques

Moderators: **Prof. Dr H. G. Kristensen**, Chair of Group of Experts on Microbiology (1) and
Dr S. Guyomard, Aventis Pharma (F)

International harmonisation: Microbiological examination and quality of non-sterile products

16:00-16:20 **Dr S. Guyomard**, Aventis Pharma (F)

16:20-16:30 Discussion

Innovative microbiological methods

- Update on European Pharmacopoeia activities

16:30-16:50 **Prof. S. Denyer**, Welsh School of Pharmacy (UK)

16:50-17:00 Discussion

- Application of rapid detection methods to pharmaceutical water

17:00-17:20 **Prof. M. Nasu**, Graduate School of Pharmaceutical Sciences (J)

17:20-17:30 Discussion

16:00-17:30: BALLROOM B

Certification: New developments of the procedure and how to better prepare your dossiers

(same programme as in morning session)

16:00-18:00: BALLROOM C

Pharmaceutical reference substances

Moderators: **Prof. H. De Jong**, Chair of Group of Experts
on Organic Chemistry-Synthetic Products (10C) and **Prof. J. Miller**, EDQM

Assay CRSs: establishment strategy and how to be used

16:00-16:20 **Dr U. Rose**, Scientific Officer, EDQM, Council of Europe

16:20-16:30 Discussion

Impurities and system suitability mixtures as reference substances, needs, constraints and the reality

16:30-16:50 **Dr A. Lodi**, Deputy Head of Laboratory Division, EDQM, Council of Europe

16:50-17:00 Discussion

Industry viewpoint

17:00-17:20 **Mr T. Bourquin**, Sanofi-Synthelabo (F)

17:20-18:00 **Panel discussion and conclusions**

16:00-17:30: ANJOU ROOM

Cell and gene therapy products

Moderators: **Dr X. Chenivresse**, AFSSAPS (F) and **Prof. K. Cichutek**, PEI (G)

A control scheme for viral vectors in gene therapy products

16:00-16:20 **Dr D. Malarme**, Transgène (F)

16:20-16:30 Discussion

Guidelines for production and control of cell and gene therapy products: experience in the USA

16:30-16:50 **Dr G. Murano**, Genentech (USA)

16:50-17:00 Discussion

Special control methods for cell therapy products

17:00-17:20 **Dr B. Panterne**, AFSSAPS – DLC (F)

17:20-17:30 Discussion

16:00-17:30: ENDRE ROOM

CLINIC 6: Chemical Impurities

One to one consultation with: **Mr J. Van Rompay**, Chair of Group of Experts Chemistry-Synthetic
Products (10B) and **Mrs B. Jacquet**, EDQM (team 1);

Prof. J. M. Midgley, Chair of Group of Experts Chemistry-Synthetic products (10A) and
Dr A. S. Bouin, EDQM (team 2)

17:30 Closure, Free evening

Wednesday 6 October 2004
8:30-13:00 BALLROOM ABC

Moderator: **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

8:30 Workshops conclusions and General Discussion

- **Dr M. Morris**, Chair of the European Pharmacopoeia Commission, (Pharmaceutical dosage forms, International Harmonisation)
- **Prof. H. J. De Jong**, First Vice-Chair of the European Pharmacopoeia, (Excipients, Pharmaceutical reference substances, Pharmaceutical waters)
- **Dr H. Koszegi-Szalai**, Second Vice-Chair of the European Pharmacopoeia Commission (Certification, Herbals, Impurities)
- **Mr P. Castle**, Secretary to the European Pharmacopoeia Commission (Blood/plasma products, Biological Standardisation Programme, Microbiological techniques, Cell and Gene therapy products)

Action Plan for the Future: Recommendations from the Industry:

9:30 European Federation of Pharmaceutical Industries and Associations (EFPIA):

Dr J. Berridge

9:45 European Generic Medicines Association (EGA): **Mrs S. Kox**

10:00 Association Européenne des Spécialités Grand Public (AESGP): **Dr H. Cranz**

10:15 European Chemical Industry Council, Active Pharmaceutical Ingredients Committee (APIC/CEFIC): **Dr H. Leblanc**

10:30 International Pharmaceutical Excipients Council (IPEC-Europe): **Dr U. Kettenring**

10:45 Coffee Break

11:15 Herbal industry: **Dr H. Cranz**

11:30 International Federation for Animal Health (IFAH): **Dr S. Zänker**

Perspectives for the World Health Organisation

11:45 **Dr S. Kopp**, WHO

Perspectives for International harmonisation

12:00 The Society of Japanese Pharmacopoeia (JP): **Dr Y. Takeda**

12:15 The United States Pharmacopoeia (USP): **Dr. Eric Sheinin**

Perspectives for the 6th Edition of the European Pharmacopoeia and Final Conclusions

12:30 **Dr M. Morris**, European Pharmacopoeia Commission

12:45 Lunch