Istanbul, Turkey,

27-28 October 2005

at the Hilton Istanbul Hotel

Certification of Suitability of Monographs of the European Pharmacopoeia

Implementation of the 5th Edition
New procedures for revision and renewal of certificates

Programme

Working language: English

International Conference

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

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Thursday, 27 October 2005, *9:00 - 12:00*

Opening Session

• Welcoming addresses

9:00 Official representative of the Turkish authorities and **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

Plenary Session

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

• Opening Remarks and Introduction: The Evolution of the 5th Edition of the European Pharmacopoeia and its impact on the Certification procedure. Control of Impurities: What has changed and general requirements

9:30 **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

• Overview of the Certification procedure, its objectives and its place within the European regulatory framework, and an update on the EU Review

9:50 **Dr J. L. Robert**, Chair QWP (EMEA) and Chair of the Steering Committee of the Certification Procedure (EDQM, Council of Europe)

10:10 Discussion

10:20 Coffee Break

• New developments in Certification: Implementation of the 5th Edition of the European Pharmacopoeia. Revision of the Notes for Guidance on TSE products. The new procedures for revision and renewal of certificates. Technical Advice: How to obtain advice and the benefits of exchanging information. Programme of Inspections: Why it was established, who is involved, and how it works

10:50 **Ms C. Pouget**, Head of the Certification Unit (EDQM, Council of Europe)

11:20 Discussion

• How to use Certificates of Suitability in MA Applications - Suggestions & perspectives: Viewpoint of a regulator

11:30 **Mrs E. De Rooij Lamme**, RIVM (NL), Chemical Assessor for the Certification Procedure

11:50 Discussion

12:00 Lunch break

Workshops and One-to-One Sessions

In the afternoon, there will be a series of parallel workshops (13:30-15:00 and 15:30-17:00) covering topics such as:

- **Workshop 1**: *New procedures for the revision and renewal of certificates*
With the participation of: Dr P. Platzer, Bundesministerium für Artzneimittel (A); Dr C. Nopitsch Mai, BfArM (D); Mrs H. Bruguera, Certification Unit, EDQM, Council of Europe and Mrs C. Hurlé, Certification Unit, EDQM, Council of Europe

- **Workshop 2**: *An outline of the main deficiencies in dossiers and how to avoid them*
With the participation of: Dr S. Jones, Medicines and Healthcare products Regulatory Agency (UK) and a second Chemical Assessor for the Certification Procedure ; Dr P. Poukens Renwart, Certification Unit, EDQM, Council of Europe and Mr D. Byrne, Certification Unit, EDQM, Council of Europe

- **Workshop 3**: *Focus on sterile products: How to prepare a dossier and prepare for inspections*
With the participation of: Dr M. Dash, Medicines and Healthcare products Regulatory Agency (UK) and a second Chemical Assessor for the Certification Procedure ; Dr A. McMath, Certification Unit, EDQM, Council of Europe and Ms F. McLeod, Certification Unit, EDQM, Council of Europe

- **Workshop 4**: *Inspection of manufacturing sites: Chemical products*
With the participation of: Dr O. Gross, WHO (CH) and a second Chemical Assessor for the Certification Procedure ; Ms C. Pouget, EDQM, Council of Europe and Ms A. Gazal, Certification Unit, EDQM, Council of Europe

Thursday 27 October 2005 afternoon (13:30 - 17:00)				
	Workshop 1 Revision & renewals procedures	Workshop2 Deficiences in dossier	Workshop 3 Sterile products	Workshop 4 Inspections
13:30 15:00	Session 1 75 participants	Session 1 50 participants	Session 1 25 participants	Session 1 50 participants
15:00 - 15:30	Coffee break			
15:30 17:00	Session 2 75 participants	Session 2 50 participants	Session 2 25 participants	Session 2 50 participants
Friday 28 October 2005 morning (9:00 - 12:30)				
9:00 10:30	Session 3 50 participants	Session 3 75 participants	Session 3 25 participants	Session 3 50 participants
10:30 - 11:00	Coffee break			
11:00 12:30	6 One-to-One Sessions 9 participants/session			

More information concerning the speakers and consultants in the workshops and one-to-one sessions is available on our website http://www.pheur.org.

Friday, 28 October 2005 *9:00 - 16:00*

Workshops and One-to-One Sessions

• Final session of each of the workshops
9:00

10:30 Coffee Break

• One-to-One personal appointments
11:00
Members of the EDQM scientific team and assessors will be available to discuss specific issues and to provide advice. The One-to-One sessions will be for 15 minutes per person and will be organised under several topics (such as renewals, variations, etc.). Prior appointment is necessary.

12:30 Lunch

Plenary session

• The Uses, Interests and Limits of Certificates: Viewpoints from the industry associations and regulatory authorities
14:00 Invited speakers: representatives from EFPIA, CEFIC-APIC, EGA and regulatory authorities

• Open Discussion & Debate: Views and questions from participants
15:00

• Final Conclusions. The benefits and cross-functional links between the Certification procedure, the European Pharmacopoeia, the EMEA, and National Authorities
15:30 **Dr J. L. Robert**, Chair QWP (EMEA) and Chair of the Steering Committee of the Certification Procedure (EDQM, Council of Europe)

• Feedback from the workshops and the conference
15:45 **Dr M. Morris**, Chair of the European Pharmacopoeia Commission

Close of meeting

16:00 Coffee break

Organisation

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