

EUROPEAN COOPERATION AND SYNERGY IN QUALITY STANDARDS BEYOND THE EUROPEAN PHARMACOPOEIA

Symposium organised by the
European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
15 - 16 June 2007, Strasbourg, France
Duration: 1 day, Working language: English

PROGRAMME

Registration: 13h00 onwards

Friday 15th June 2007
13h45-18h00

Moderator: **Dr Michael Morris**, Irish Medicines Board and Former Chair of the European Pharmacopoeia Commission

General introduction

How to handle the quality of extemporaneous and small-scale preparations at a European level? Problems and issues for hospitals and community pharmacies to consider

14h00-14h20 Mr Vlain Fenton May, SMPU (UK)

SESSION 1

Quality standards for extemporaneous preparations

14h20-14h35 Dr Pieter H. Vree (NL)

GMP for preparation of medicines in small quantities and the annexe for cytotoxics in the Swiss Pharmacopoeia

14h35-14h50 Prof. Dr Stefan Mühlebach, Swissmedic (CH)

The view of hospital pharmacists

Quality standards for the preparation of medicinal products

- *Dutch hospital pharmacies*

14h50-15h05 Dr Paul P. H. Le Brun, Apotheek Haagse Ziekenhuizen (NL)

The need for new standards

- *Danish hospital pharmacies*

15h05-15h20 Dr Van N. Handlos, Rijshospitalet (DK)

- *View of French hospital pharmacies*

15h20-15h35 Dr Patrick Rambourg, CHU Montpellier Pharmacie St Eloi (F)

Discussion with the panel of speakers

15h35-15h50

15h50-16h20 Coffee break

SESSION 2

The German system of standard licenses and standard registrations (Standardzulassung)
16h20-16h40 **Dr Thomas Zapf**, Federal Institute for Drugs and Medical Devices (D)

Standard licences and Formulae magistralis - The European perspective
16h40-17h05 **Prof. Dr Dietrich Schnädelbach**, BfArM (D)

Licensing of German standard preparations
17h05-17h20 **Dr Susanne Keitel**, BfArM (D)

Viewpoint from an inspector
17h20-17h35 **Ms Gudrun Eichler**, Staatl. Gewerbeaufsichtsamt Hannover (D)

Discussion with the panel of speakers
17h35-18h00

Saturday 16th June 2007

8h30-13h00

Moderator: Prof. Dr Stefan Mühlebach, Swissmedic

SESSION 3

National Experiences of Formularies

The British experience
8h30-8h45 **Dr Gerard Lee**, MHRA (UK)

The Italian experience
8h45-9h00 **Prof. Maurizio Cignitti**, ISS (I)

The French experience
9h00-9h15 **Prof. Jean-Claude Chaumeil**, University of Paris V (F)

The Belgium experience in relation with the Therapeutic Magisterial Formulary
9h15-9h30 **Mrs Paule Jacqmain**, Agence Fédérale des Médicaments et des Produits de Santé
(B)

Discussion with the panel of speakers
9h30-10h00

10h00-10h30 *Coffee break*

SESSION 4

The specific case of radiopharmaceuticals manufactured extemporaneously in hospital radiopharmacies

General introduction

10h30-10h40 **Prof. Alfons Verbruggen**, Laboratory for Radiopharmacy, Universitair Ziekenhuis Gasthuisberg Radiofarmacie (B)

Current practices for preparation of radiopharmaceuticals in hospitals and PET centres: experience and considerations from the field

10h40-10h55 **Radiopharmacy practice in the UK**

Prof. Stephen Mather, Imperial Cancer Research Fund Department Nuclear Medicine, St Bartholomew's Hospital, London (UK)

10h55-11h10 **Dr Ivan Penuelas**, Unidad de Radiofarmacia, Clinica Universitaria de Navarra, Pamplona (E)

Guidelines for Good Radiopharmaceutical Practice (from the Radiopharmacy Committee, European Association of Nuclear Medicine)

11h10-11h20 **Dr Clemens Decristofo**, University Klinik für Nuklearmedizin (A)

EU Guidelines to Good Manufacturing Practice

Annex 3: Manufacture of Radiopharmaceuticals

11h20-11h35 **Dr Elisabeth Norbygaard**, Danish Medicines Agency (DK)

Discussion with the panel of speakers

11h35-12h00

CLOSING SESSION

Final round table Discussion: Is there a need for a European approach and a harmonisation of standards and formularies?

12h00-13h00 With the participation of: **Mr Vlain Fenton May**, SMPU (UK), **Dr Gerard Lee**, MHRA (UK), **Dr Michael Morris**, European Pharmacopoeia Commission, **Prof. Dr Stefan Mühlebach**, Swissmedic (CH), **Prof. Dr Dietrich Schnädelbach**, BfArM (D), **Prof. Alfons Verbruggen**, Universitair Ziekenhuis Gasthuisberg Radiofarmacie (B), **Dr Pieter H. Vree** (NL), **Dr Agnès Artiges**, EDQM/Council of Europe and **Dr Van N. Handlos**, Representative of the European Association of Hospital Pharmacists.

13h00 Closure of the symposium