

HERBAL DRUGS & HERBAL DRUG PREPARATIONS

25 September 2009

Duration: 1 day, Location: University of Vienna, Pharma Centre, Althanstrasse 14, Vienna, Austria

Working language: English

In cooperation with the Society for Medicinal Plant and Natural Product Research (GA)

PROGRAMME

8:30-9:00 Registration on site

9:00-9:15 Opening remarks

Dr Susanne Keitel, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

Prof. Dr Brigitte Kopp, the Society for Medicinal Plant and Natural Product Research (GA)

FIRST SESSION

Progress in analytical techniques applied to quality control of herbal drugs or herbal drug preparations: concrete case examples

9:15-9:35 Progress in analytical techniques applied to quality control of herbal drugs or herbal preparations: concrete case examples

Prof. Dr Markus Veit, International Drug Regulatory Affairs Services (D)

9:35-9:55 Quality control of herbal drugs - emerging methods and approaches

Prof. Matthias Hamburger, Institut für Pharmazeutische Biologie, University of Basel (CH)

9:55-10:15 Discussion with the audience

10:15-10:45 Coffee break

SECOND SESSION

Introduction of new assay methods in the European Pharmacopoeia and regulatory implications

10:45-11:05 Update from EDQM

Dr Michael Wierer, European Pharmacopoeia Department, EDQM, Council of Europe

11:05-11:25 Introduction of new assay methods in the European Pharmacopoeia and regulatory implications - Industry Viewpoint

Dr Barbara Steinhoff, Association of the European Self-Medication Industry (AESGP)

11:25-11:45 New practical experience with instrumental methods recently introduced into the European Pharmacopoeia

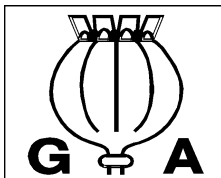
Dr Bernhard Klier, PhytoLab GmbH Co KG (D)

11:45-12:05 Regulatory implications of the introduction of new assay methods in the European Pharmacopoeia

Dr Burt Kroes, Medicines Evaluation Board (NL) & Chairman of the European Medicines Agency (EMA) Committee on Herbal Medicinal Products (HMPC) Quality Drafting Group

12:05-12:35 Discussion with the audience

12:35-14:00 Lunch break



THIRD SESSION

Update on recent discussions and developments

14:00-14:20 Reference Standards for Herbal Drugs and Herbal Drug Preparations

Dr Ulrich Rose, Laboratory Department, EDQM, Council of Europe

14:20-14:40 Characterisation of constituents by group determinations – a pragmatic approach for Herbal Drugs and Herbal Drug Preparations

Dr Anton Biber, Deutsche Homöopathie-Union GmbH & Co. (D)

14:40-15:00 Update on methods and limits for the microbiological quality of herbal medicinal products

Dr Keith Helliwell, William Ransom and Son plc (UK)

15:00-15:10 Discussion with the audience

15:10-15:40 Coffee break

15:40-16:00 Development of the HMPC's work programme

Dr Burt Kroes, Medicines Evaluation Board (NL) & Chairman of the European Medicines Agency (EMA) Committee on Herbal Medicinal Products (HMPC) Quality Drafting Group

16:00-16:20 Update on EDQM's work programme including a progress report on Traditional Chinese Medicines (TCM)

Ms Melanie Bald, European Pharmacopoeia Department, EDQM, Council of Europe

16:20-16:30 Discussion with the audience

FOURTH SESSION

Round-Table Discussion

16:30-17:15 Round-table discussion with the participation of representatives from the regulatory authorities, associations and industry

- Dr Linda Anderson, Medicines and Healthcare Products Regulatory Agency (MHRA)
- Prof. Matthias Hamburger, Institut für Pharmazeutische Biologie, University of Basel
- Dr Susanne Keitel, Director, EDQM, Council of Europe
- Dr Burt Kroes, Medicines Evaluation Board & Chairman of the EMA's HMPC Quality Drafting Group
- Prof. Dr Fritz Kemper, Chairman, European Scientific Cooperative on Phytotherapy (ESCoP)
- Prof. Dr Brigitte Kopp, representative from the Society for Medicinal Plant and Natural Product Research (GA)
- Dr Frank Waimer, Dr. Willmar Schwabe GmbH Co. KG (D)

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