EDQM SYMPOSIUM
Standardisation & Control of Allergen Preparations - Establishment of Reference Preparations and ELISAs for the Major Allergens
Bet v 1 and Phl p 5 a
24 November 2011, Strasbourg, France
Duration: 1 day; Working language: English
Supported by the PEI Paul-Ehrlich-Institut, Langen, Germany

DRAFT PROGRAMME

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OPENING SESSION

8:15-8:45 Registration

8:45-9:00 Welcome Address and General Introduction
Dr Susanne Keitel, Director, European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe

SESSION 1: SETTING THE SCENE
Moderator: EDQM, Council of Europe

9:00-9:20 Use of allergens and their standardisation
Dr Lars Jacobsen, European Allergen Manufacturers Group (EAMG)

9:20-9:40 Current control of allergens
Dr Jacqueline Dayan Kenigsberg, Afssaps (FR)

9:40-10:00 Discussion

10:00-10:30 Coffee break

SESSION 2: THE BSP090 PROJECT
Moderator: Dr Carlo Pini, Chair of the Working Group on Allergens, Istituto Superiore di Sanità (ISS) (IT)

10:30-10:50 The European Union CREATE* Project
Dr Ronald van Ree, Academic Medical Centre, University of Amsterdam (NL)

10:50-11:10 BSP090: Physico-chemical characterisation of candidate reference preparations
Dr Martin Himly, University of Salzburg (A)

11:10-11:30 BSP090: Results from Phases 1-2
Dr Susanne Kaul, PEI Paul-Ehrlich-Institut (DE)

11:30-11:50 BSP090: Results from Phase 3
Dr Oliver Dehus, PEI Paul-Ehrlich-Institut (DE)

11:50-12:10 Impact of the new BRPs/ELISA on the control of allergen preparations
Dr Joerg Kleine-Tebbe, Allergie-und Asthma Zentrum Westend (DE)

12:10-12:40 Discussion

12:40-14:15 Lunch break

*Development of Certified Reference Materials for Allergenic Products and Validation of Methods for their Quantification
SESSION 3: THE EUROPEAN PHARMACOPOEIA & REGULATORY ENVIRONMENT

Moderator: Dr Karl-Heinz Buchheit, Deputy Head of the Biological Standardisation Programme, Network of OMCL and HealthCare Dept, EDQM, Council of Europe

14:15-14:35  Presentation of the revised general monograph and future plans
              Dr Carlo Pini, Istituto Superiore di Sanità (ISS) (IT)

14:35-14:55  The CHMP’s Note for Guidance on Allergen Products
              Prof Stefan Vieths, PEI Paul-Ehrlich-Institut (DE)

14:55-15:30  Discussion

15:30-16:00  Coffee break

SESSION 4: GENERAL DISCUSSION

Moderator: Prof Stefan Vieths, PEI Paul-Ehrlich-Institut (DE)

16:00-17:00  General Discussion

- New candidate references and ELISAs
- Possibilities to speed up the process for establishment of methods and standards
- Alternative approaches to ELISA (MS)
- Need for methods for absorbed / modified preparations?
- Future of allergen control in Europe

17:00-17:10  Closing Remarks
              Dr Susanne Keitel, Director, EDQM, Council of Europe

17:10 Close of the meeting

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For further information, please contact
the EDQM Public Relations Division & Documentation:
Ms Clare Williams Stoeckel, Tel.: +33 (0)3 90 21 42 89**, Fax: +33 (0)3 88 41 27 71**
E-mail: clare.williams@edqm.eu
Postal address: EDQM, 7 allée Kastner, CS 30026, F-67081 Strasbourg, France

** Leave out 0 if calling from outside France