

EDQM SYMPOSIUM

Standardisation & Control of Allergen Preparations - Establishment of Reference Preparations and ELISAs for the Major Allergens

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24 November 2011, Strasbourg, France

Duration: 1 day; Working language: English

Supported by the PEI Paul-Ehrlich-Institut, Langen, Germany

PROGRAMME

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: Dr Karl-Heinz Buchheit, Deputy Head of the Biological Standardisation Programme,
Network of OMCL and HealthCare Dept, 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*

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

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

17:10 Close of the meeting

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