



Budapest, Hungary,
Wednesday 6 October 2004 from 14:30
to Thursday 7 October 2004, 13:00
at the Hilton Budapest Hotel

SEROLOGICAL POTENCY TESTS FOR DIPHTHERIA AND OTHER VACCINES

PROGRAMME

Working language: English

International Symposium

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

Wednesday 6 October 2004

Opening Session

14:30-14:40 Welcome addresses

- **Dr. A. Artiges**, Director of the EDQM, Council of Europe
- **Dr. R. Dobbelaer**, Chairman of the Biological Standardisation Programme (BSP) Steering Committee and the European Pharmacopoeia Group of Experts 15

General Introduction

Relevance of diphtheria vaccine potency testing by serological models. General overview and experience from the clinics

14:40-15:10 **Dr. C. von Hunolstein**, Istituto Superiore di Sanità, (I)

Session I: Alternative to Challenge Assays in Animals for Vaccines Control

Moderator: **Mr. J-M. Spieser**, EDQM, Council of Europe

Establishment of diphtheria potency assays based on serological methods

. **Development and validation of *in vitro* methods**

15:10-15:30 **Dr. D. Sesardic**, National Institute for Biological Standards and Control, (NIBSC), (UK)

. **Evaluation of serological assays for diphtheria potency testing in combined vaccines: results from collaborative study BSP034**

15:30-15:50 **Dr. R. Winsnes**, Norwegian Medicines Agency (NoMA), (N)

15:50-16:00 Discussion

16:00-16:30 Coffee break

Implementation of tetanus and diphtheria potency assays based on serological methods

. **Introducing serological methods: what is needed for a specific vaccine/combination?**

16:30-16:50 **Dr. R. Winsnes**, NoMA (N)

. **Statistical basis for introduction of one-dilution serological potency assays for combined vaccines**

16:50-17:10 **Mr. A. Daas**, Biostatistician, EDQM, Council of Europe, (F)

17:10-17:20 Discussion

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Session II: Perspectives for combined vaccines control

Moderator: **Dr. R. Winsnes**, NoMA (N)

Implementation of diphtheria and tetanus potency assays by serology on the same animals for routine batch release

. **OMCL's point of view**

8:30-9:00 **Dr. D. Garcia**, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS), (F)

. **Manufacturer's point of view**

9:00-9:20 **Dr F. Brunel**, Aventis-Pasteur (F)

9:20-9:40 **Dr M. Duchêne**, GlaxoSmithKline Biologicals (B)

9:40-10:00 Discussion

Possible extension of serological potency assay to other components of combined vaccines

. **Data from trial phase: BSP034 extension to IPV titration**

10:00-10:20 **Dr. D. Sesardic**, NIBSC (UK)

. **Experience from an OMCL in titration of DT Pertussis vaccine**

10:20-10:40 **Dr. A. Maes**, Institut Supérieur de Santé Publique (ISSP), (B)

10:40-10:50 Discussion

10:50-11:20 Coffee break

Session III: Transposition into regulatory requirements

Moderator: **Mr. P. Castle**, Secretary of the European Pharmacopoeia Commission

Summary of the meeting and definition of action plan

11:20-11:50 **Dr. R. Dobbelaer**, BSP Steering Committee

11:50-13:00 Open discussion with the audience. Participation of World Health Organization (WHO), US Food and Drug Administration – Center for Biologics Evaluation (FDA-CBER), and European Vaccines Manufacturers (EVM) representatives

Scientific Committee: Dr M-E. Behr-Gross, Dr K-H. Buchheit, Mr P. Castle, Dr R. Dobbelaer, Dr D. Sesardic, Mr J.M. Spieser, Dr R. Winsnes

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Registration form and hotel reservation form: available on <<http://www.pheur.org>>