



## **EDQM – ECVAM Meeting**

### **Alternatives to whole cell pertussis vaccine potency assay**

**16 March 2005**

**Ramada Park Hotel, Geneva (Zurich Room)**

### **Final Programme**

**(1.) Introduction to purpose of the meeting** (J-M Spieser, EDQM, Council of Europe)

**(2.) General Introduction**

Whole cell pertussis vaccine quality control (E. Griffiths, Health Canada)

**(3.) Alternatives** (*Chair: C. Hendriksen*)

*Introductory talk:* Humane and Science-based improvements of Whole Cell Pertussis Vaccine Quality Control: An Overview (C. Hendriksen, Utrecht University)

*Scientific presentations of data obtained with the Kendrick test and with alternatives, including humane end-point alternatives:*

- Ethical Approach for Testing the Potency of Pertussis Vaccine (S. Jadhav, Developing Country Vaccine Manufacturers' Network)
- OMCL Experience with OCABR of Whole Cell Pertussis Vaccines and potential of alternatives for the current routine control tests (R. Dobbelaer, SIPH, Belgium)
- Retrospective analysis of Kendrick data. Whole Cell pertussis vaccine elimination of nasaly infected mice with B. Pertussis (A. Gzyl, National Institute of Hygiene, Poland)
- Kendrick Test: the AFSSAPS experience (P. Chagnaud, AFSSAPS, France)
- Whole Cell Pertussis potency assay: GSK experience (Frédéric Mortiaux, GSK)
- Whole Cell Pertussis potency assay: Sanofi Pasteur experience (Alain Sabouraud, Sanofi Pasteur, France)
- Experiences at NVI with whole cell pertussis vaccine: serological potency testing in mice and guinea pig and combination with toxicity (Johan van der Gun, NVI, Netherlands)

**(4.) Round Table Discussion (Chair: R. Dobbelaer)**

*Introductory talks*

- Policy of the Ph. Eur. for lot release assay of combined vaccines for human use. Approach to and review of progress towards simplified lot release assay (M-E. Behr-Gross, EDQM)
- Potency testing of whole cell pertussis vaccine(s): WHO perspective (I. Knezevic, WHO)

**EDQM**

Mr. J-M. Spieser  
Dr. M-E. Behr-Gross  
Mrs. C. Chamberlin

**WHO**

Dr. I. Knezevic  
Dr. D. Wood

**UNICEF**

Ms. E. Molari

**PAHO**

Dr. M. Angeles Cortes

**ECVAM**

Dr. M. Halder

**Health Canada**

Dr. E. Griffiths

**FDA**

Dr. B. Meade  
Dr. J. Arciniega

**OMCLs**

*Belgium* – Dr. R. Dobbelaer (*SIPH*)  
*France* – Dr. P. Chagnaud (*AFSSAPS*)  
*Hungary* – Dr. I. Karaes (*Johan Bela National Center for Epidemiology*)  
*Italy* – Dr. C. Von Hunolstein (*ISS*)  
*Poland* – Dr. A. Gzyl (*National Institute of Hygiene*)  
*Romania* – Mrs. V. Iancu (*National Medicines Agency*)  
*U.K.* - Dr. M. Corbel, Dr. D. Xing (*NIBSC*)  
*Germany* – Dr. U. Roskopf (*PEI*)

**Manufacturers**

*IFPMA – EVM* – Dr. M. Duchêne, Mr. F. Mortiaux, Mr. D. Lambrigts (*GSK*),  
Dr. A. Sabouraud (*SanofiPasteur*)

*Brazil* - Dr. W. Quintillo (*Instituto Butantan*)  
*Croatia* – Dr. T. Sindik Milosevic (*Institute of Immunology*)  
*Germany* - Dr. L. Hoffmann (*Chiron Vaccines*)

*India* - Dr. L. R. Sood (*Biological E. Ltd*)  
*Netherlands* – Dr. J. van der Gun (*NVI*)  
*Poland* – Dr. M. Cwiernia (*BIOMED SA*)  
*Romania* – Dr. M. Mazilu (*The Cantacuzino Institute*)  
*Serbia* – Dr. P. Beljanski, Dr. V. Kovacevic (*Institute of Immunology and Virology Torlak*)

*Developing Country Vaccine Manufacturers' Network* - Dr. S. Jadhav

**Representatives from other countries or organizations**

*Brazil* – Dr. A. Alves de Souza de Oliveira Dias (*Instituto Nacional de Controle de Qualidade Saude*)  
*Japan* – Dr. Y. Horiuchi (*National Institute of Infectious Diseases*)  
*Mexico* – Dr. G. Gallegos Flores (*Laboratorio Nacional de Salud Publica*)  
*Netherlands* – Dr. C. Hendriksen (*Utrecht University*)  
*Russian Federation* – Dr. T. Bektimirov (*Tarasevic State Institute for the Standardization and Control of Medical Biological Preparations*)

(5.) **CONCLUSIONS: Possibilities for implementation of internationally harmonised alternatives to current test - Action plan for replacement of the Kendrick test** (*Chairs: R. Dobbelaer, I. Knezevic, J-M. Spieser*)

*Regulators:* Prerequisites to move from Kendrick Test to alternative(s) in the Ph. Eur. monographs and in the WHO guidelines

*Licensing authorities:* Expectations for validation data on alternative(s) to the Kendrick Test

**SCIENTIFIC COMMITTEE**

Dr. M-E. Behr-Gross, Dr. K-H. Buchheit, Mr. P. Castle, Dr. R. Dobbelaer,  
Dr. F. Fuchs, Dr. M. Halder, Dr. C. Hendriksen, Dr. I. Knezevic, Mr. J-M. Spieser



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