Cross learning experience human and animal vaccine licensure based on technology platforms

A Joint CEPI/IABS/ZAPI Workshop

June 29-30, 2020

Palais de l'Académie Royale des Sciences
Brussels, Belgium

AGENDA

Scientific Committee

Daniel BRASSEUR, co-Chair Scientific Committee
former CHMP-PDCO-VWP chair at the EMA; CEPI consultant
Murray LUMPKIN, co-Chair Scientific Committee
former Deputy Director, FDA; Bill & Melinda Gates Foundation

Dr. Barney GRAHAM	**NIH, Deputy Director and Chief, Viral Pathogenesis Laboratory**
Dr. Mélanie SAVILLE	**Director, Vaccine Development, CEPI**
Prof. Dr. Johan NEYTS	**Rega Institute Louvain, Belgium, specialist of DNA vaccine PLLAV**
Dr. Marion GRUBER	**FDA, Director, Office of Vaccine Research and Review – CBER**
Dr. Ivo CLAASSEN	**EMA, Head of Veterinary Medicines Division**
Dr. Marco CAVALERI	**EMA, Head of Anti-infectives and Vaccines**
Prof Dr. Jeffery ALMOND	**Oxford University; Chairman of the Board, Osivax**
Dr. Jean-Christophe AUDONNET	**Senior Director, Vaccines R&D; ZAPI Project Coordinator; Boehringer Ingelheim Animal Health**
Dr. Emmanuel HANON	**Senior Vice President, Head of R&D, GSK Vaccines**
Dr Ajoy CHAKRABARTI	**Bill & Melinda Gates Foundation Vaccine Development**
Dr Steve BLACK	**The Brighton Collaboration, Task Force for Global Health**

MONDAY June 29th

08:00 **Welcome**
9:00 **Opening**

9:00 **1. Welcome and Introduction - CEPI & IABS**
Dr. Joris VANDEPUTTE, International Alliance for Biological Standardization (IABS)
Dr. Richard HATCHETT, Coalition for Epidemics Preparedness Innovation (CEPI)

Chairpersons:
Dr. Dean SMITH, Health Canada
Dr. Daniel BRASSEUR, co-Chair Scientific Committee; former CHMP-PDCO-VWP chair at the EMA; CEPI consultant

2. Focus/Objective

9:15 Vaccine Technology Platforms: What are we talking about?
Dr. David VAUGHN
Senior Program Officer, Integrated Clinical Vaccine Development
Bill & Melinda Gates Foundation (Seattle, Washington - USA)

3. Scene setting
Experience with emergency situations: success & failures

9:30 Animal : state of the current licensing situation: regulatory requirements in force and currently licensed vaccines
Ivo CLAASSEN
Head of Veterinary Medicines Division
European Medicines Agency, EMA (Amsterdam, The Netherlands)

9:45 Human: influenza past experience success & failure
Dr. Ralf WAGNER
Senior Scientific Officer for Viral Regulation and Research
Federal Institute for Vaccines and Biomedicines, PEI (Langen, Germany)

10:00 Emergency preparedness: Lessons learned in the development of an Ebola vaccine
Dr. Jayanthi WOLF
Executive Director, Global Regulatory Affairs
MSD (North Wales, Pennsylvania - USA)

10:15 **Discussion**

10:30 **Coffee break**

Chairpersons:
Dr. Ralf WAGNER, Paul-Ehrlich-Institut, PEI (Langen, Germany)

4. New Technologies

Animal vaccines: ZAPI project
11:00 **Dr. Jean-Christophe AUDONNET**
Senior Director, Vaccines R&D; Coordinator ZAPI IMI Project
Boehringer Ingelheim Animal Health France (Lyon, France)

11:15 Experience with technology platforms in animal vaccines - US regulatory approach
Dr. Carol GIBBS
Senior Staff Microbiologist
U.S. Department of Agriculture, USDA Center for Veterinary Biologics - Policy, Evaluation & Licensing (Ames, Iowa - USA)

11:30 Advanced human vaccines in the pipe-line (Viral vectors, VSV-Measles-ChAd…) and RNA, DNA technologies
Dr. Mark VAN OOIJ
Scientific Director
Janssen Vaccines (Leiden, The Netherlands)

11:45 The CEPI portfolio : Examples of vaccine candidates based on platforms
Dr. Nicholas JACKSON
Head of Programs & Technology
Coalition for Epidemics Preparedness Innovation, CEPI (London, United Kingdom)

12:00 **Questions**

12:30 **Lunch**

Chairpersons:
Dr. Carol GIBBS, U.S. Department of Agriculture, USDA Center for Veterinary Biologics - Policy, Evaluation & Licensing (Ames, Iowa - USA))
Dr. Svein Rune ANDERSEN, Coalition for Epidemics Preparedness Innovation, CEPI

5. Commonalities and Particulars & Challenges of Platforms

13:30 Manufacturing & quality control – what is platform generic, what is vaccine specific?
Dr. Dean SMITH - TBC
Head and Senior Scientific Evaluator of Vaccines
Health Canada (Ontario, Canada)

13:45 Vaccine platforms : pre-clinical package, how far can we go?
Dr. Kaat SMITS
Nonclinical Assessor
Federal Agency for Medicines and Health Products, FAMH (Brussels, Belgium)

14:00 To what extent can clinical trials be pre-arranged?
Professor Stephen LUBY
Professor of Medicines (Infectious Diseases and Geographic Medicine)
Director of Research, Center of Innovation for Global Health
Stanford University (Stanford, California - USA)

14:15 **Discussion**

14:45 **Coffee break**

Chairpersons:
Dr. Nicholas JACKSON, CEPI
Professor Pieter NEELS, IABS

15:15 How can use of platform technologies influence the size of the safety database needed to support product safety? Can the risks of the antigen and the platform be dissociated?
Professor Steve BLACK
Emeritus Professor of Pediatrics, Cincinnati Children's Hospital
SPEAC Workpackage lead, The Brighton Collaboration (Berkeley, California)

15:30 What kind of risk taking in emergency situation?
Professor Jean-Michel DOGNE
Member of the Pharmacovigilance Risk Assessment Committee PRAC
European Medicines Agency, EMA (Amsterdam, The Netherlands)

15:45 Challenges to proof vaccine efficacy for outbreak vaccines
Dr. Jakob CRAMER
Head of Clinical Development
Coalition for Epidemics Preparedness Innovation, CEPI (London, UK)

16:00 **General Discussion**

17:00 **Short conclusion & End Day 1**

TUESDAY, MARCH 17th

08:00 **Welcome**
8:30 **Start**

Chairpersons:
Dr. Mimi DARKO, Ghana-FDA
Dr. Debra Yeskey, Coalition for Epidemics Preparedness Innovation (CEPI)

6. Regulatory issues
Facilitating vaccine development through the use of platform technology

8:30 EU approach
Dr. Marco CAVALERI
Head of Anti-infectives and Vaccines
European Medicines Agency, EMA (Amsterdam, The Netherlands)

8:50 Facilitating vaccine development through the use of platform technologies: US FDA perspective
Dr. Marion GRUBER
Director, Office of Vaccine Research and Review - CBER
Food Drug Administration, FDA (Silver Spring, Maryland - USA)

9:10 AVAREF, Asian regulators
Dr. Mimi DARKO
Chief Executive Officer at Food Drug Administration (Accra, Ghana)
African Vaccine Regulatory Forum-AVAREF (WHO office Brazzaville, Congo)

9:30 WHO Regulatory preparedness activities to facilitate access of emergency vaccines
Dr. Carmen RODRIGUEZ HERNANDEZ - TBC
Group Lead Vaccine assessment
World Health Organisation, WHO (Geneva, Switzerland)

9:50 **Coffee break**

10:15 **Panel Discussion**

How can « tried and true » vaccine platform streamline vaccine development and gain regulatory acceptance ?

Dr. Marion GRUBER, FDA
Dr. Marco CAVALERI, EMA
Dr. Carmen RODRIGUEZ-HERNANDEZ, WHO – TBC
Dr. Emer Cooke, WHO - TBC
Dr. Mimi DARKO AVAREF and Ghana-FDA
Dr. Ajoy CHAKRABARTI, Bill & Melinda Gates Foundation
Dr. Mair Powell, VWP, EMA - TBC
Professor Klaus CICHUTEK, PEI - TBC
Dr. Jean LANG, EFPIA Infectious Disease SGG & Vaccine Europe R&D Industry Chair

11:00 **General Discussion**

11:45 Conclusions & Recommendations
The Way Forward….

Dr Murray LUMPKIN
Deputy Director Integrated Development
Lead for Global Regulatory Systems Initiatives
Bill & Melinda Gates Foundation (Seattle, Washington - USA)

12:00 **End of meeting**