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

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)

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)

Questions

Lunch

5. Commonalities and Particulars & Challenges of Platforms

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)

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)

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)

Discussion

Coffee break

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
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 DANKO AVAREF and Ghana-FDA
Dr. Ajoy CHAKRABARTI, Bill & Melinda Gates Foundation
Dr. Mair Powell, VWP, EMA - TBC
Professor Klaus CICHTUTEK, PEI - TBC
Dr. Jean LANG, EFPIA Infectious Disease SGG & Vaccine Europe R&D Industry Chair

General Discussion

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)

End of meeting