



Where are we in our understanding of the association between narcolepsy and 2009 adjuvanted influenza A (H1N1) vaccines?

**October 23, 2015
Warwick Hotel
Geneva, Switzerland**

In collaboration with the World Health Organization

This meeting will be held under Chatham House Rule

The overall objective of this meeting is to exchange the latest information on research into development of narcolepsy following vaccination with 2009 adjuvanted influenza A (H1N1) vaccines.

The specific meeting objectives are:

- To discuss new data on narcolepsy and adjuvanted 2009 influenza A (H1N1) vaccines – epidemiology; pathophysiology of narcolepsy; and hypotheses on potential biological mechanism of actions;
- To discuss possible implications for seasonal and pandemic influenza vaccines as we move forward;
- To discuss options for collaboratively addressing vaccine rare event safety signals given availability of newer biomarkers, epidemiology, molecular biology and immunology tools and knowledge.

The expected outcomes are:

- A mutual understanding of a possible relationship between narcolepsy and adjuvanted 2009 influenza A (H1N1) pandemic vaccines
- A mutual understanding for the implications of this finding for seasonal and pandemic influenza vaccines
- A delineation of future research steps to be taken to expand knowledge and understanding of narcolepsy, narcolepsy and biomarkers, and inciting factors for narcolepsy
- A delineation of future research steps to be taken to expand knowledge and understanding of the current hypotheses between narcolepsy and vaccination with 2009 adjuvanted influenza A (H1N1) vaccines
- A common understanding of which stakeholders are needed to develop an effective strategy and framework for addressing vaccine rare event safety signals given availability of newer biomarkers, epidemiology, molecular biology and immunology tools and knowledge

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Scientific Committee

Daniel Brasseur, CHMP, FAMHP, Brussels

Kari Johansen, European Centre for Disease Prevention and Control (ECDC)

Noni MacDonald, Dalhousie University, Canada

Pieter Neels, IABS-EU, Lyon, France

Hanna Nohynek, National Institute for Health and Welfare, Finland

Joris Vandeputte, IABS, Geneva Switzerland / IABS-EU, Lyon, France

David Wood, World Health Organization (WHO), Geneva, Switzerland

AGENDA Friday, October 23, 2015

- 09:00: Welcome and Introduction
Joris Vandeputte, Executive Director, IABS; Chair, IABS-EU
- 09:05 Objectives for the meeting
Chairs : **Daniel Brasseur**, CHMP, FAMHP, Brussels
Noni MacDonald, Dalhousie University, Canada
- 09:10 Clinical picture of childhood narcolepsy following the 2009 H1N1 pandemic vaccination campaign in Finland
Markku Partinen, Helsinki Sleep Clinic, Vitalmed Research Center, Finland
- 09:30 Narcolepsy after vaccination with pandemic vaccines
Liz Miller, Public Health England, United Kingdom
- 10:15 Risks of neurological and immune-related diseases, including narcolepsy, after vaccination with Pandemrix:
Ingemar Persson, Medical Products Agency, Uppsala, Sweden
- 10:35 Coffee Break
- 11:00 Results from Germany
Doris Oberle, Paul-Ehrlich-Institut, Langen, Germany
- 11:20 Results from a GSK study in Canada
Philippe De Wals, Quebec Heart and Lung Institute, Laval University, Quebec, Canada
- 11:40 Viewpoint US / Influenza program
Frank Destefano, CDC, Atlanta, Georgia, USA



- 12:00 Global view
Thomas Verstraeten; Kaatje Bollaerts , P95, Belgium
- 12:30 Lunch
- 13:30 Introduction on potential pathophysiology plus genetics
Tomas Olsson, Karolinska Institutet, Stockholm, Sweden
- 13:55 Antigenic differences between AS03 adjuvanted influenza A (H1N1) pandemic vaccines: implications for pandemrix-associated narcolepsy risk
Outi Vaarala, AstraZeneca Translational Science, Sweden
- 14:15 An hypothesis on a potential biological mechanism for development of narcolepsy following H1N1pdm09 infections and H1N1pdm09 containing vaccines
Sohail Ahmed, Novartis Vaccines & Diagnostics s.r.l. - a GSK company, Siena, Italy; **Lawrence Steinman**, Stanford University, Stanford, California, USA
- 15:00 Alternative hypotheses
Robbert van der Most, GlaxoSmithKline Biologicals, Wavre, Belgium
- 15:20 Roundtable Discussion
Chair: Prof. Hans-Georg Eichler, European Medicines Agency (EMA), London, United Kingdom
- Panel:
Claire-Anne Siegrist, University of Geneva, Switzerland
Steven Anderson, CBER / FDA, USA
Daniel Brasseur, CHMP, FAMHP, Brussels
Jean-Michel Dogné, PRAC, FAMHP, Brussels
Martin Friede, World Health Organization (WHO)
Paul-Henri Lambert, University of Geneva, Switzerland
Tomas Olsson, Karolinska Institute, Stockholm, Sweden
Pasi Penttinen, ECDC, Sweden
Jens-Ulrich Stegmann, GlaxoSmithKline, Wavre, Belgium
- 16:20 Wrap up
Norman Baylor, Biologics Consulting Group, Virginia, USA
- 16:25 Conclusions and next steps
David Wood, World Health Organization (WHO)
- 16:30 End

