

Informal Consultation on Technical Specifications for a (WHO) International H5N1 Vaccine Stockpile

17-18 October 2007
Centre de Conférences de Varembe (CCV), Salle A
Geneva, Switzerland

Agenda

Wednesday 17 October 2007

09:00-09:15

Opening remarks (*Marie-Paule Kieny*)
Nomination of Chairperson and Rapporteur
Housekeeping announcements

09:15-10:30 **Session 1: Setting the scene**

09:15 Overview of an international H5N1 stockpile (*Peter Carrasco*)
09:35 Summary outcomes of the "Use of H5 vaccines" WHO meeting from
October 1-3, 2007 (*Keiji Fukuda*)
09:55 Lessons learned from other WHO vaccine stockpiles (*Sylvie Briand*)
10:15 Questions for clarification

Desired outcome of session 1: inform audience on what WHO has been requested to do by the World Health Assembly (WHA) resolution 60.28; what the potential policy options to use H5N1 vaccines are; how this meeting's outcomes feed into the decision making process i.e. H5N1 vaccine use and stockpile meetings, the Global Action Plan (GAP) on vaccine supply meeting, Strategic Advisory Group of Experts (SAGE) meeting, Inter-Governmental Meeting (IGM) and WHA 2008.

10:30-11:00 Coffee/tea

11:00-12:30 **Session 2: Quality, safety and efficacy considerations for a WHO international stockpile**

11:00 Current WHO specifications to assure the quality, safety and efficacy of stockpiled H5 vaccines (*Gary Grohmann*)
11:20 Potential target non-clinical and clinical minimum data requirements for regulatory oversight of human H5N1 influenza vaccines in an international stockpile (*Roland Dobbelaer*)
11:40 Strategies to ensure that internationally stockpiled H5N1 vaccines remain safe and effective with special consideration to virus drift variance (*Michael Pfeleiderer*)
12:00 Assuring quality, safety and efficacy of stockpiled H5 influenza vaccines - industrial considerations (*Giuseppe Del Giudice*)
12:20 Discussion

Desired outcome of session 2: identify the minimum non-clinical and clinical pre-licensure considerations for an H5N1 vaccine in a WHO international stockpile. Identify provisions for strains change due to drift variance. Identify provisions to ensure that donations in the stockpile remain adequately potent and acceptable to National Regulatory Authorities (NRAs).

13:00-14:00 Lunch

14:00-15:30 Session 3: Regulatory pathways

- 14:00 Regulatory requirements in a potential recipient country of H5N1 vaccine from an international stockpile (*Lucky Slamet*)
- 14:20 Regulatory oversight of donated H5N1 vaccine by a potential producing country (*Elwyn Griffiths*)
- 14:40 Lot release testing of internationally-stockpiled H5N1 vaccine (*Florence Fuchs*)
- 15:00 Post-use regulatory expectations for an international H5N1 stockpile (*Karen Midthun*)

15:30-16:00 Coffee/tea

- 16:00 Regulatory pathways for stockpiled H5N1 influenza vaccines - industrial viewpoint (*François Verdier*)
- 16:20 WHO prequalification of H5N1 vaccines (*Huib van de Donk*)

Desired outcome of session 3: identify appropriate regulatory strategies for a WHO international H5N1 influenza vaccine stockpile.

16:40-17:30 Session 4: Discussion on regulatory oversight of an international H5N1 stockpile

(Chairperson and Rapporteur)

Desired outcome of session 4: Development of initial conclusions, including potential needs for further studies, on target quality, safety and efficacy considerations, and the regulatory pathway for internationally stockpiled H5N1 vaccines

17:30 Close of day

Thursday 18 October 2007

09:00-10:30 Session 5: Logistics considerations

- 09:00 Experience with practical management of international stockpiles for vaccines: from the factory to the vaccinee (*Ann Ottosen*)
- 09:20 Deployment of H5N1 vaccines (*Ethel Palacios-Zavala*)
- 09:40 Liability issues (*Anne Mazur*)
- 10:10 Operational issues - an industrial perspective (*Norbert Hehme*)

10:30-11:00 Coffee/tea

11:20-12:30 Session 6: Discussion on logistics considerations

Development of initial conclusions, including potential needs for further studies, on target logistics considerations for an international H5N1 vaccine stockpile
(*Chairperson and Rapporteur*)

Desired outcome of sessions 5 and 6: identify the minimum requirements to maintain, distribute, receive and deploy vaccine from a WHO international H5N1 influenza vaccine stockpile.

12:30-14:00 Lunch

14:00-15:30 Session 7: Ethical considerations and the use of a (WHO) international H5N1 stockpile

14:00 Guiding principles (*Paul Gully*)

14:20 Ethical issues (*Andreas Reis*)

14:40 Discussion

Desired outcome of session 7: identify potential governance procedures including acceptance of donations, release of stock and response to requests, and potential cost implications of a WHO international H5N1 influenza vaccine stockpile.

15:30-16:00 Coffee/tea

16:00-17:00 Session 8 (CLOSED SESSION*): Recommendations to WHO

Review of conclusions from all sessions (*Chairperson and Rapporteur*)

Desired outcome of session 8: as clear as possible minimum recommendations for the establishment, operation, and sustainability of an international H5N1 human influenza vaccine stockpile.

* for participants without disclosed conflicts of interest