WHO proposal for using multi-dose vials of pandemic influenza (H1N1) 2009 vaccines

Background information

WHO has taken the lead in the effort of making pandemic influenza H1N1 vaccines available to countries in the developing world. This effort involves securing large donations of these vaccines. All pandemic influenza H1N1 vaccines to be supplied through WHO require to be prequalified.

On the programmatic side, indications for immunization and using multi-dose vials are included in the manufacturers' packaging inserts, which remain the basis for utilization. However for the purpose of vaccines deployed by WHO, the multi-dose vial policy (MDVP) is proposed, considering the concentration of preservative (thiomersal).

Proposal for usage of multi-dose vials

"Taking into consideration the revised WHO multi-dose vial policy (MDVP)*:

- All WHO prequalified pandemic influenza H1N1 vaccines, except GSK vaccines, from which one or more doses of vaccine have been removed during an immunization session *may be used* in subsequent immunization sessions for up to a maximum of **28 days**, *provided that all stability/sterility conditions are met*.*
- GSK vaccines (Arepanrix and Pandemrix), containing a low concentration of thiomersal, *may be used* in subsequent immunization sessions for up to a maximum of **24 hours**, *provided that all stability/sterility conditions are met*.*"

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* **Extract of the revised WHO multi-dose vial policy (March 2000)**
http://www.who.int/vaccines-documents/DocsPDF99/www9924.pdf
The revised policy applies only to OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines that:

- meet WHO requirements for potency and temperature stability;
- are packaged according to ISO standards; and
- contain an appropriate concentration of preservative, such as thiomersal (injectable vaccines only).

For these vaccines, the revised policy states:
Multi-dose vials of OPV, DTP, TT, DT, hepatitis B, and liquid formulations of Hib vaccines from which one or more doses of vaccine have been removed during an immunization session *may be used* in subsequent immunization sessions for up to a maximum of 4 weeks , *provided that all of the following conditions are met:*

- The expiry date has not passed;
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point.