

Vaccines for protection against
Pandemic (H1N1) Influenza in India:
procurement, production

Presentation at National Media
Communication Workshop on
Pandemic Influenza

23 July 2009



Initiatives for Vaccines for H1N1

Meeting with Vaccine Manufacturers

- Presently seasonal flu vaccine is not manufactured in India and is imported for domestic use
- WHO has released four seed strains for preparation of H1N1 vaccine after influenza pandemic declared by WHO
- Four foreign vaccine manufacturers have shown interest for selling imported vaccine
 - Sanofi Pasteur
 - Novartis
 - GSK
 - Baxter
- Technical merits of individual vaccines being assessed before considering placing import orders



Initiatives for Vaccines for H1N1

Meeting with Vaccine Manufacturers

- GOI accorded high priority for indigenous vaccine production
- Three vaccine manufacturers in India have shown interest for producing vaccine
 - Serum Institute of India Ltd, Pune
 - Panacea Biotec Ltd, Baddi
 - Bharat Biotech, Hyderabad
- Have given a short, intermediate and long term developmental plan indicating
 - assistance needed from the Government
 - possible deliverables at each stage



Egg-based vs. Cell based

- Amongst the various approaches available for production of flu vaccine, the egg-based technology is most feasible for large scale production
 - Cost effective, high yields; long time of production, dependence on eggs
 - Rapidly expanded and scaled up in times of emergency
- Serum Institute of India has acquired adequate infrastructure and skills to produce egg based influenza vaccine, and shown interest in cell based vaccine also
- Two Indian manufacturers (Panacea and Bharat Biotech) willing to invest in cell-based technology
- DCGI has put in place procedure(s) to import foreign made vaccines in case of exigencies subject to WHO guidelines about safety, immunogenicity etc, (expected by end of July 2009) and regulatory approvals from the country of origin accordingly



License to import by DCGI

- DCGI issued licenses to import WHO released seed strains to start preliminary work towards development of indigenously produced vaccine
- SIIL and PBL have received imported WHO recommended seed strain and started R&D work (inactivated)
- Bharat Biotech : In process of getting the seed strain



Live Attenuated Influenza Vaccine (LAIV)

- Advantages of LAIV
 - Speed, scale and cost of production
 - Given by nasal route, cutting down need for needle and syringe
 - Manufacturing less complex
- LAIV for seasonal flu vaccine licensed by US FDA in 2003
- Has been evaluated in approx 49 000 individuals in 48 completed studies, found to be safe; in use in Russia for seasonal influenza since 1954
- No report of reversion to wild type virus, chances remote
- SIIIL expected to receive LAIV strain by end of this month
- WHO has negotiated an agreement between SIIIL and a Russian firm (Nobilon) to transfer technology to produce live attenuated cold adapted egg based influenza vaccine for H1N1
- SIIIL is expected to receive LAIV strain by end of this week



Volumes of Vaccine Requirements

● Requirements

● Priority according to the guidelines given in Ministry of Health's Preparedness Plan

- Health care providers
- Persons at extremes of age
- Persons with co-morbidities
- Essential services providers
- Law enforcement agencies, police, armed forces etc

● To be revisited as the events evolve



Summary

- Procedures being put in place by DCGI to import subject to finalization of WHO guidelines
- Technical merits (safety, immunogenicity, adjuvants etc) of vaccines being assessed
- Seed strains received by Indian manufacturers
- Both types (inactivated and live attenuated) may be permitted for manufacture so as to have cafeteria choice in case there is a problem
- Experiments in ferrets (to be imported) important before conducting minimum testing in humans (as may be decided keeping in mind new WHO guidelines): GoI to expedite as facilitator
- Commercial aspects to be negotiated: Department of Health with expertise may handle this
- LAIV for human clinical trials/ application by 4-5m
- Inactivated vaccine for human trials/ application by 6m

