Influenza Global Vaccine Supply

Current status of vaccine production and Pandemic preparedness

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When a pandemic threat appears

Current Situation

- Vaccine manufacturers will not be able to meet the demand
- Non-producing countries will not have vaccine

What can be done?

- Increase uptake of seasonal vaccine to increase production capacity
- With better knowledge of the forecast demand for seasonal vaccine, companies would be in a better position to produce pandemic vaccine

This does not solve the vaccine shortage now
Current vaccine production capacity

- 18 producing countries
- 37 producers
Current vaccine production capacity

- Maximum installed capacity = 420 Md + 30 Md fillers
- Current trivalent vaccine production = 350 Md
  - 300 Md produced for the global market (Europe, North America, Australia)
  - 50 Md for local use (China, Russia, Japan)

Source: GSK website
Pandemic Influenza vaccine

Options for increasing production capacity

1. Smart composition and/or formulation
2. New application forms
3. Increase use of seasonal vaccine in developed and developing countries
4. Continue dialogue with vaccine industry
   - Vaccine production is highly concentrated in Europe and North America
Increasing production capacity

1. Smart composition

- All manufacturers working with reference virus developed by WHO (12 manufacturers from 11 countries)
  - Clinical trials being evaluated (H5N1, H9N2, H2N2, ...)
  - There is a research agenda
  - Regulatory issues being considered

- Results H5 N1: safety and immunogenicity

Preliminary data suggest that H5N1 is safe, well tolerated and immunogenic
Increasing production capacity

1. Smart composition

- Reduce antigen content
  - Sparing: 50% works, but 2 dose schedule (first results Dec 2006)
  - Adjuvant: Alum increases vaccine immunogenicity.

- Regulatory requirements
  - Harmonization between EMEA, FDA and developing countries

WHO meetings in 2006 to facilitate regulatory agreement among developed and developing countries
Increasing production capacity

2. New application forms

- Possible 7.5 µg per dose
  - Intradermal vaccination, need of more clinical data
  - Difficult to implement for mass vaccination campaigns

Considerable level of uncertainty
Increasing production capacity

3. Increase seasonal vaccine coverage in developed countries to 75%

- Age over 50 in
- Those at highest risk
- WHO's target is increase coverage by 60% in 2010

The improved coverage will increase vaccine production by 60%
Increasing production capacity

3. Increase seasonal vaccine coverage in developing countries

- Assist countries on feasibility of local vaccine production (e.g. Thailand)
- Assist countries on regulatory issues, licensing, quality control, standardization (IVB/GIP)
- Assist countries on disease burden studies
- Support to technology transfer
Looking for solutions

4. Continued dialogue with the vaccine industry
   • Second meeting on Influenza vaccines that induce broad spectrum and long lasting immuno-responses, December 2005
   • WHO meeting in January 2006 with the veterinary vaccine manufacturers and regulators
     - Feasibility of using veterinary production facilities for pandemic
     - Regulatory constrains
   • WHO meeting in February 2006 with NRAs, scientific experts and vaccine manufacturers
     - Options to reduce vaccine supply gap in short, medium and long term for seasonal vaccine (cell culture, new facilities)
     - Options for a pandemic vaccine, H5N1, formulations, antigen content, adjuvants
     - Options for increasing vaccine production capacity during pandemic
Influenza pandemic

- Assuming: 900 million doses in 8 months = 3.75 million/day

- Early outbreak detection, diagnosis and notification is essential

The lead time to start production will depend on:

- access to the pandemic virus (7-21 days)
- development of prototype i.e. NIBSC (21-51 days)
- Registration (45-60 days), EMEA = 1 day
Solutions?

- **Short and medium term**
  - R&D for antigen reduction, adjuvants, intradermal use, etc
  - Increase seasonal vaccine use ⇒ manufacturer will be better prepared for production of pandemic vaccines
  - Manufacturers' plans to expand capacity by 2008
  - Early start of vaccine production

- **Long term**
  - New vaccines: cell lines production, new formulations, new strains; cross and long lasting immunogenicity

- **Radical solution required** (seasonal + pandemic vaccines)
Influenza pandemic vaccines

- Goals:
  - In pandemic: equitable and timely supply
  - Inter-pandemic: increase uptake of seasonal vaccine in low and middle income countries

Production
- GMP
- NRAs

Logistic

Campaign

Early begin of production and as much as possible