Snapshot of Current Influenza Vaccine Manufacturing Capacity Worldwide and Summary of WHO-HHS Activities to Promote Technology Transfer

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Expanding Global Vaccine Production Capacity

- **Goal** - Ensure global capacity to produce pandemic influenza vaccine meets global needs during a pandemic

- **Need** – 70% of world population with two doses of vaccine within 6 months (10 billion doses)

- **Seasonal Capacity**
  - 876 million doses annually
  - Estimated to grow to 1,7654 billion in 2015
  - **But…seasonal Demand…**
    - 400 million doses

- **Pandemic Capacity: currently function of seasonal capacity**
  - Yield, monovalent, dose sparing with adjuvant,
Global pandemic (H1N1) 2009 vaccine: Planned vs actual production*

June 2009 survey assumed
- 1:1 H1N1 to seasonal yields
- Most dose sparing formulation for each manufacturer
- Use of full production capacity

In reality
- 1:3 H1N1 to seasonal yields
- Not all manufacturers could use their most dose sparing formulation
- Production capacity was used for seasonal vaccine
- Demand collapsed in 2010

*As of 10 January 2010
Strategies to increase production capacity include:

- Increasing the uptake of seasonal vaccine
- Shifting to higher yielding technologies including live attenuated vaccine and use of adjuvants
- Maintaining and/or building new capacity
- WHO – HHS
  - Help developing countries to develop influenza vaccine manufacturing capabilities and capacity for sustainable pandemic readiness
## Three rounds of project initiation since 2007

### 2007
- Bio Farma, Indonesia
- Birmex, Mexico
- Instituto Butantan, Brazil
- IVAC, Viet Nam
- Governmental Pharmaceutical Organization (GPO), Thailand
- Serum Institute of India (SII), India

### 2009
- Cantacuzino Institute, Romania
- Green Cross Corporation, Korea
- Razi Institute, Iran
- Torlak, Serbia
- Vacsera, Egypt

### 2011
- Biovac, South Africa
- RIBSP, Kazakhstan
Major Accomplishments

- 7 of the 11 have produced clinical lots of pandemic vaccine
- 4 have completed pandemic vaccine clinical trials
- 4 have licensed pandemic vaccine for human use
- Estimated capacity: 200 million doses by 2015
Lessons Learned

● Manufacturing capacity building cannot happen in a vacuum
  – Regulatory, Clinical, Policy
  – Strong, local government support is needed throughout

● Sustainability of pandemic influenza production capacity is dependent on:
  – Ability to produce a pandemic influenza vaccine
  – Producing something in that facility that keeps facility running

● Training staff on influenza vaccine production is not sufficient – know how and expertise on alternative marketable products essential