Progress under GAP Pillar 2 "Increase Production Capacity"

Contribution of the WHO Technology Transfer Programme

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Countries with influenza vaccine production capacity in 2006

Countries with first influenza vaccine registered between 2006 and 2012

Countries with planned influenza vaccine production capacity

Countries with planned influenza vaccine fill-finish capacity

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Overall progress 2006-now

Korea, India, Brazil, Thailand, Romania
- pandemic vaccines approved or clinical trials completed
- Current capacity: 320 million doses annually.
- Remaining challenges:
  - Ensure antigen sparing technology optimised
  - Ensure continued NRA approval

Nine others;
- Significant progress: facilities, process, clinical trials
- Need to ensure that momentum is not lost.
- Predicted additional capacity 2013-2016: 300 million
Highlights 2012

- Grants to 14 recipients managed, technical assistance and training provided and progress monitored

- LAIV technology now licensed to 3 manufacturers
  - 1 product prequalified
  - Enhanced generation and supply of LAIV seed strains

- 1 IIV seasonal vaccine approved

- 2 clinical trials supported

- 9 Assessment visits conducted
Progress and status of grantees

- BCHT (China)
  - License to LAIV negotiated
  - Building started

- Biovac
  - Negotiation of bulk supply completed,
  - Filling line ordered;

- Birmex
  - Fill-finish facility nearly completed.
  - Local bulk manufacturer already producing bulk
- **Biofarma (indonesia)**
  - Pilot H5N1 lots produced, adjuvant lots produced.
  - Facility for local antigen production under construction

- **Butantan (Brazil)**
  - Approval of seasonal tIV split vaccine by NRA
    - Capacity: 20 M SH, 10M NH
    - Adjuvant technology: pandemic capacity 120M doses
Cantacuzino (Romania)
- Completion of building, installation of upgraded filling line.
- Adjuvant lots completed

IVAC (Vietnam)
- H1N1 phase 1 trial completed
- H5N1 consistency lots completed.

GPO (Thailand)
- H5N2 LAIV phase 1 trial completed
- H5N2 LAIV phase 2 trial initiated.
- Facility for IIV started.
• **RAZI (Iran)**
  - Review of technologies suitable for local production
  - Negotiation for access to technology initiated

• **RIBSP (Kazakhstan)**
  - National funds secured for building large-scale facility
  - Technologies compared and selected

• **SII (India)**
  - Prequalification of pLAIIV H1N1
  - Efficacy trials of H1N1 vaccine completed
  - Phase III Efficacy trial of seasonal tLAIIV underway in infants
• Torlak (Serbia)
  – Buildings completed and validated
  – Consistency lots (whole inactivated) completed
  – Implementing change to split.

• Vacsera (Egypt)
  – Preclinical lots / immunogenicity
  – Production facility under construction
WHO Technology Transfer Initiative

TTi

- WTPO
- TAG
- GAP
- QSS
- IVR
- HIP
- MoH
- RO, WR
Technology Transfer activities

- Direct assistance
  - Grants, access to technologies
  - Technical advice, TAG, consultants, meetings with MoH,..

- To assist vaccine manufacturer sustainability
  - Technology assessment, IP analysis, investment analysis
  - Facilitate negotiation with technology owners
  - Access to cell lines, strains, SOPs, reagents
    - Influenza and other vaccines

- Other biological technologies: potential to increase sustainability of influenza production
Conclusions

- A lot of progress has been made
  - >300 million pandemic vaccine capacity already.

- A lot still needs to be made 2013-2016
  - Another 300 million to be brought on line.
  - Most infrastructure investments completed.
  - Now need to focus on reaching approval and sustainability

- Challenges
  - Which technology for seasonal and pandemic?
  - Approval pathway for pandemic