GAP and Flu Vaccine Production in Thailand – from Public Health Policy Development to Vaccine Production

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Timeline of Flu Vaccine Development in Thailand

**Demand**
- Seasonal IIV for H. personnel: 0.2 m
- Seasonal IIV for elderly & 7 chronic disease: 2 m.
- Further expansion of seasonal IIV (4+ m.)

**Supply**
- First PPP (05-07)
- Lab scale IIV
- GAP/P1
- Start construction of industrial flu vaccine plant (45 m.$)
- Cabinet approved industrial scale flu vaccine plant

- Second PPP (08-10)
- GAP/P2 R&D H1N1 PLAIV
- Start pilot scale IIV
- Start industrial scale IIV/LAIV (2 m.dose)

- H1N1 PLAIV approved
- Start industrial scale H5N2/LAIV

- H1N1 approved
- Start industrial scale H5N2/LAIV

- Expansion of IIV/LAIV (10 m.dose)
Situation of Flu Vaccine supply

- No domestic production of bulk influenza vaccine
- No experience of egg-based vaccine production before 2007
- Import 2.1 million doses of seasonal influenza vaccine in 2010
  - GPO-MBP supplied approx. 800,000 doses, by formulating and filling imported bulk seasonal influenza vaccine, the remainder 1.3 million doses imported as finished products.
**Progress on domestic flu vaccine production**

- The first Pandemic Preparedness Plan (2005-2007) - support GPO to start R&D for Flu vaccine. The second PPP (08-10) – build and industrial scale Flu vaccine plant
- 2007-2008 – GAP/Phase 1 support GPO on egg-based lab scale IIV (start building egg-based capacity)
- May 2007 – Cabinet approval of $US 45 million for industrial scale IIV plant – construction will finish in mid 2012 aim at industrial
- 2009 – GAP/Phase 2 - H1N1 pandemic turned GPO to start R&D on H1N1 PLAIV in mid July 2009 – TFDA approved July 12th 2011 (2 years after start)
- Technology support from Kaketsuken Japan - start IIV pilot production in 2012 and industrial scale in 2014
- Mid 2011 – start pilot scale H5N2 PLAIV and seasonal LAIV aim at industrial scale production in 2014
The National Pandemic Preparedness Plans

• First (2005-2007)
  “Support research and development of vaccines, antivirals....”

• Second (2008-2010)
  “To set up a local industrial-scale manufacturing plant for pandemic influenza vaccine based on international standard with production of specific pathogen free (SPF) eggs to support the vaccine production processes”
  “To develop staff for industrial-scale vaccine research and development processes”
Situation of Flu vaccine demand

- Before H5N1 outbreak in 2004, no public demand on seasonal flu vaccine
- Mid 2004, first 200,000 doses of seasonal IIV donated by WHO was given to health personnel, to reduce the possibility of re-assortance and for differential diagnosis. It then becomes an annual event.
- Late 2007, the National Health Security Board approved seasonal IIV for elderly with 7 chronic diseases, started in 2008, then gradually expand to cover everyone with 7 chronic diseases and elderly –up to more than 4 million doses required in 2011 – with increasing uptake rate.
- Late 2010, National Vaccine Committee recommended expansion of seasonal IIV to pregnant women, obese with BMI over 35, cerebral palsy, thalassemia or immuno-compromised host, children 6-24 months (financing?)
How to convince for decision on investment

• For investment on industrial scale plant
  “This is for national security. In time of pandemic the global supply will be much lower than the demand, so it is very difficult to get pandemic flu vaccine. It is like investment in fighting aircrafts, tanks and submarine. However, this is investment better as we can supply seasonal vaccine for domestic use as well.

• For increase demand on seasonal flu vaccine
  “The expense of treating these patients is higher than the expense of vaccination (evidence based), so we are actually gain from vaccination”
Long Term Capacity Development Program

“INNE - Individual, Node, Network and Environment”

‘Cabinet approval - December 2010’

1. R&D (GPO, Universities)
2. Production, QC, QA (GPO, Universities)
3. Regulatory (TFDA, DMSc)
4. Surveillance & AEFI (DCD)
The Ultimate Goals

- to eventually build and sustain capacity to manufacture up to 10 million doses of seasonal IIV and 10 million doses of seasonal LAIV per year with WHO pre-qualification

- ability to convert production process to produce the IIV/LAIV, with a production capacity of 60 million doses of pandemic influenza vaccine

- Support Regional Flu Pandemic Preparedness through supply and stockpile and also technology support
Factors contributing to the progresses

- Political leadership/commitments
  - Financial support (US$ 45 million) for industrial Flu Vaccine plant
  - Long-term capacity building plan
  - Increase seasonal vaccine use – sustainability
  - Commitment from international partners – GAP
    - Know-how and technology transfer
    - Support for capacity building – training, visits
    - Workshops for networking, sharing of experiences
    - Great learning days – August 2010, October 2011
      “WHO/GAP, USHHS, NIBSC, IEM, Nobilon, SII, Japan MHLW-Kaketsuken, etc.”
- Collaborative supports from all technical partners
Remaining Challenges:

- Need for guaranteed supply of quality eggs
  - Imported (SPF from Germany, US, Mexico)
  - Domestic supply by DLD, private producers

- Further technical development to solve critical issues – higher yields, stability, anti-serum, sprayers, adjuvants (IIV), non-clinical tests

- Management and R&D capacity development

- Bureaucratic Structure and Systems

- More experience NDRA