Industry Perspective: Strategies and costs associated with increasing seasonal influenza vaccine use from high to low income countries since 2006

Dr. Michael Watson, sanofi-pasteur
on behalf of IFPMA IVS

WHO GAP II Meeting, 12-14 July 2011, Geneva
Agenda

- Introduction
- Drivers of Influenza vaccination
- Vaccine production capacity and usage
- Industry activities and contribution
- Flu Summit Proposal
- Pandemic Preparedness
- Conclusions
Why do WHO and national health authorities recommend annual vaccination?

Annual Global Seasonal Flu disease burden estimates:
- 3-5 million cases of severe illness
- **250,000 to 500,000 deaths** (WHO Fact Sheet, 2009)

Annual US influenza data:
- >200,000 hospitalizations
- approx. 36,000 deaths
- Influenza/pneumonia 8th leading cause of death in the US in 2009

Influenza vaccine available since 1950s!!

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1SR Mostow Am Rev Respir Dis 1986;134:1
2(National Vitals Statistics Reports, Vol. 59, No. 4)
2007/2008 EU Flu vaccination coverage far below WHO target

WHO 2010 target = 75%

Professor THOMAS SZUCS, Institute of Social- and Preventive Medicine, University of Zurich
http://www.evm-vaccines.org/pdfs/annex5.pdf
Introduction

Drivers of Influenza vaccination

Vaccine production capacity and usage

Industry activities and contribution

Flu Summit Proposal

Pandemic Preparedness

Conclusions
Getting from vaccine to vaccination

- Increasing vaccination requires:
  - Capacity and capability to generate Local/regional burden of disease studies and cost-effectiveness estimates/studies
  - Clear vaccination policy
  - Local advocates at all levels
  - Tailored communication/engagement programs
  - Enough vaccine and clear demand forecasts
  - Ability to finance vaccine and vaccination campaign
  - Capability and capacity to implement – Health systems
  - Good vaccino-vigilance program
  - Vaccine compensation fund e.g. GBS

- **Disease burden**
  - At least 924,478 outpatient visits from influenza
  - Between 12,575 and 75,801 hospitalizations

- **Cost of disease**

<table>
<thead>
<tr>
<th>Outpatient:</th>
<th>US$</th>
<th>19.0 – 32.8 million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumonia:</td>
<td>US$</td>
<td>4.4 – 30.1 million</td>
</tr>
</tbody>
</table>

Simmerman et al. Vaccine 2004, 2006
The weight of some drivers in EU

1. Pro-active HCW
2. Education on the vaccine and disease
3. Adequate funding of vaccination
4. Lifestyle factors

Communication

- If my doctor (nurse) recommended it: <65 yrs at risk (2440), 65 yrs+ (3906)
- More information on vaccine efficacy: <65 yrs at risk (2440), 65 yrs+ (3906)
- More information on the disease: <65 yrs at risk (2440), 65 yrs+ (3906)
- More information on vaccine tolerance: <65 yrs at risk (2440), 65 yrs+ (3906)
- If it were cheaper or reimbursed: <65 yrs at risk (2440), 65 yrs+ (3906)
- Travel to high risk influenza regions: <65 yrs at risk (2440), 65 yrs+ (3906)
- Vaccination at work: <65 yrs at risk (2440), 65 yrs+ (3906)

Education

- <65 yrs at risk (2440)
- 65 yrs+ (3906)

Financing

- Travel to high risk influenza regions
- Vaccination at work

Facilitation

- Communication
- Education
- Financing
- Facilitation

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Vaccination of Healthcare workers – We’ll never reach our destination if the driver doesn’t want to go there!

WHO 2010 elderly target = 75%

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Industry produces according to expected market “demand”:
- Production overcapacity is economically unsustainable
### Projections for demand and supply seasonal influenza vaccines

**2009**

<table>
<thead>
<tr>
<th>Demand:</th>
<th>449 million*</th>
</tr>
</thead>
<tbody>
<tr>
<td>(theoretical) Global production capacity:</td>
<td>876 million **</td>
</tr>
</tbody>
</table>

**2015**

<table>
<thead>
<tr>
<th>Demand:</th>
<th>Depends on national policies and their implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(theoretical) Global production capacity:</td>
<td>1.764 billion **</td>
</tr>
</tbody>
</table>


**Technical studies under resolution WHA63.1 Dec 2010**
Need to bridge the gap to ensure sustainability

Current situation:
Pandemic = Demand / Vaccine uptake
Production capacity
Need to bridge the gap to ensure sustainability

Current situation:
Seasonal =

Demand / Vaccine Uptake

Production capacity
Demand / Vaccine Uptake = Production capacity

Ideal situation:
Seasonal & Pandemic =

Need to bridge the gap to ensure sustainability
IFPMA survey on seasonal dose distribution and vaccine uptake: influenza vaccine provision in 157 countries (2004-2009)
Steady increase in production capacity and dose distribution.....but uptake remains low......
Provision of seasonal influenza vaccines in 157 countries (2009)

TOP 10
- Luxembourg
- Netherlands
- Malta
- Qatar
- USA
- France
- Japan
- Spain
- Canada
- Italy
Who plays what role in bridging the gap between demand and production capacity?
Seasonal and Pandemic Influenza Control: Collaboration of Stakeholders is Essential

**Drivers**

- Surveillance, strain selection, warnings
- Local/regional burden of disease & C/E data
- Policy, demand, funding, delivery, Safety surveillance
- Delivery, Communication, system adaptation
- Supply, GISRS funding, Tech. transfer & R&D.

**Primary responsibility**

- WHO GISRS
- ?
- Public Health Authorities
- Health Care Workers
- Industry
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## Financial contributions to GISN made by IFPMA IVS members

<table>
<thead>
<tr>
<th>Recipient</th>
<th>Purpose</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York Medical College</td>
<td>Development of high growth reassortants</td>
<td>For 2011: 1,893,934 Swiss Francs (estimated US$ 2.05 million)</td>
</tr>
<tr>
<td>WHO Essential Regulatory Lab - NIBSC</td>
<td>Isolation of seasonal influenza viruses in eggs</td>
<td></td>
</tr>
<tr>
<td>WHO Influenza CC - Australia</td>
<td></td>
<td></td>
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<tr>
<td>WHO Influenza CC – CDC Atlanta</td>
<td></td>
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<tr>
<td>WHO Influenza CC – NIMR London</td>
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</tbody>
</table>
### Future Financial contributions to GISRS by global pharmaceutical manufacturers under the PIP Framework

<table>
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<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>GISRS</td>
<td>Annual partnership contribution to WHO for Improving global pandemic influenza preparedness &amp; response*</td>
<td>Global industry committed to 50% running costs ~USD 28 million (2010)</td>
</tr>
</tbody>
</table>

* WHO PIP Framework (2011)
Seasonal flu vaccine production increased 3-fold

**Assumptions**

- Base (most likely) case assumes that when the US sponsored cell facilities come on-line, the same amount of egg-based capacity will be rationalized.
- The best case assumes that there will be no rationalization of capacity when the US cell facilities come on-line.

(from Oliver Wyman study, 24 February 2009)
# Technology Transfer & Local Production is Ongoing for Influenza Vaccines

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>PRODUCTION INITIATIVE</th>
<th>COMPANY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil - Butantan</td>
<td>Production and supply pandemic influenza H1N1 vaccines to Brazilian government.</td>
<td>sanofi pasteur</td>
</tr>
<tr>
<td>(Sept 2009)</td>
<td>Vaccine formulation, filling and packing in Brazil</td>
<td></td>
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<tr>
<td>Brazil (1999)</td>
<td>Agreement with Butantan to build a facility to manufacture seasonal influenza vaccines</td>
<td>sanofi pasteur</td>
</tr>
<tr>
<td>WHO / Thailand</td>
<td>License granted to WHO for egg-based seasonal and pandemic live-attenuated influenza</td>
<td>Merck &amp; Co. (Nobilon)</td>
</tr>
<tr>
<td>(Feb 2009)</td>
<td>vaccine technology; WHO to sub-license to developing country public sector vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>manufacturers; Thailand is the 1st country to request sub-license</td>
<td></td>
</tr>
<tr>
<td>China, Hong Kong &amp; Macau</td>
<td>Joint venture agreement with Shenzhen Neptunus Interlong Bio-Technique Co Ltd to</td>
<td>GSKBio</td>
</tr>
<tr>
<td>(Nov 2008 / June 09)</td>
<td>develop &amp; manufacture seasonal influenza vaccines and pre-pandemic / pandemic influenza</td>
<td></td>
</tr>
<tr>
<td>China (Nov 2007)</td>
<td>Agreement with the Chinese authorities to build a facility to manufacture seasonal and</td>
<td>sanofi pasteur</td>
</tr>
<tr>
<td></td>
<td>pandemic influenza vaccines</td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td>Agreement with Bio Farma to build a facility to manufacture seasonal influenza vaccines</td>
<td>Biken</td>
</tr>
<tr>
<td>Mexico - Birmex</td>
<td>Build a facility to manufacture seasonal and pandemic influenza vaccines.</td>
<td>sanofi pasteur</td>
</tr>
<tr>
<td>(Mar 2009)</td>
<td></td>
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</tbody>
</table>
• Financial contribution to developing **candidate pandemic vaccine viruses**

• Investment in **clinical development** of vaccines

• Innovative technologies to **shorten timeframe** between development and delivery of vaccines

• Investment in **novel approaches**:  
  – Recombinant technologies  
  – Cell base vaccine production  
  – Improved immune response  
  – Quadrivalent vaccines  
  – “Universal vaccine”  
  – User-friendly administration (i.e. needle free such as patches)
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## Industry actions to improve global pandemic preparedness

| Extension and/or Increase in Production Capacity | • Investment in extension of vaccine capacity for local production  
• Continual increase in vaccine production capacity and antiviral capacity |
| Contributions | • 166 million vaccine doses pledged to WHO for the H1N1 vaccines during the 2009 pandemic  
• At least 120 million vaccine doses pledged to WHO for the H5N1 stockpile and the next pandemic  
• Tiered pricing for vaccines and antivirals in developing countries  
• Supply to the WHO Rapid Response stockpile  
• Continuous collaboration with the WHO and other stakeholders for the implementation of the PIP Framework |
| Technology Transfer and Technical Assistance | • Enhancement of technology transfer projects in developing countries  
• Continued support and technical assistance for ongoing technology transfer projects in countries such as Brazil, China, Indonesia, Mexico, and Thailand |
Other drivers of sustainable pandemic vaccine accessibility

- Better disease surveillance in lower and middle income countries;
- Improved health systems for deployment of vaccines;
- Establish Seasonal influenza vaccine recommendations to:
  - Reduce disease
  - Establish and maintain health systems
  - Generate seasonal vaccine demand and therefore pandemic capacity
- Technological innovation to increase:
  - Speed of production
  - Surge production capacity
  - Vaccines per unit of antigen
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Rationale:
Successful vaccination is about successful partnership between all stakeholders. This is currently missing for Global Influenza Vaccination

Objective:
- Provide a multi-stakeholder platform to ensure co-coordinated activity to improve public health protection against influenza

Stakeholders:
- All relevant stakeholders in influenza vaccination. Including healthcare professionals, public health officials, organizations of at-risk patients and senior citizens, and other public and private organizations.

Goals (to be refined, but including):
- Share best practice
- Improve awareness and promote implementation of recommendations
- Improve the supply and timely distribution of flu vaccines
- Prepare for pandemic flu

Call to action:
- Identify appropriate countries and local organizations (i.e. scientific, regulatory body, WHO regional office, etc.) to lead this initiative
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Conclusion: All Stakeholders

- Successful vaccination is based on successful partnership:
  - Must work together to be successful e.g. Flu Summit

- Key areas for improvement:
  - Burden of disease and cost-effectiveness data from Lower and middle income countries:
    - Need to agree clear roles and responsibilities and funding
  - Clear Policies supported by:
    - Funding
    - Clear demand forecasts
    - Support at all levels
    - Excellent communication and engagement at all levels – not just education
    - Patient friendly delivery/access
    - Good vaccino-vigilance and compensation systems
  - Commitment from producers:
    - Meet projected vaccine demand:
      - Investment
      - Technology transfer
      - Innovation to:
        » Increase speed, doses per unit of antigen and surge capacity
    - Set aside a proportion of production capacity for tiered pricing and donations for influenza pandemics.
Thank you