Overview of Global and Regional Influenza Vaccine Production Capacity

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World Health Organization
## Seasonal trivalent vaccine production capacity (2009 survey)

<table>
<thead>
<tr>
<th>Manufacturers</th>
<th>Total annual capacity (10^6 doses)</th>
<th>2008 Northern hemisphere production (10^6 doses)</th>
<th>2009 Southern hemisphere production (10^6 doses)</th>
<th>2009 planned Northern hemisphere production (10^6 doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Companies A</td>
<td>656.7</td>
<td>368.6</td>
<td>107.5</td>
<td>387.7</td>
</tr>
<tr>
<td>Companies B</td>
<td>195.3</td>
<td>92.5</td>
<td>5.0</td>
<td>96.0</td>
</tr>
<tr>
<td>All</td>
<td>852.0*</td>
<td>461.1</td>
<td>112.5</td>
<td>483.7</td>
</tr>
</tbody>
</table>

*Not including LAIV (MedImmune)

**Companies A**: capacity to produce at least 2.10^6 doses of novel H1N1 vaccine per week

**Companies B**: capacity to produce less than 2.10^6 doses of novel H1N1 vaccine per week
### 2009/10 Seasonal Trivalent Influenza Vaccine Production by WHO Region

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Number of manufacturers</th>
<th>NH</th>
<th>SH</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>AMR</td>
<td>5</td>
<td>134.1</td>
<td>17</td>
<td>151.1</td>
</tr>
<tr>
<td>EMR</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>EUR</td>
<td>10</td>
<td>253.1</td>
<td>29.5</td>
<td>282.6</td>
</tr>
<tr>
<td>SEAR</td>
<td>6</td>
<td>0.2</td>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>WPR</td>
<td>14</td>
<td>106.6</td>
<td>5.5</td>
<td>112.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>37</strong></td>
<td><strong>494</strong></td>
<td><strong>54</strong></td>
<td><strong>548</strong></td>
</tr>
</tbody>
</table>

NH = Northern Hemisphere; SH = Southern Hemisphere;
AFRO = WHO Regional Office for Africa; AMR = WHO Region of the Americas; EMR = WHO Eastern Mediterranean Region; EUR = WHO European Region; SEAR = WHO South East Asia Region; WPR = WHO Western Pacific Region
Future production capacity (2008 – 2016)
Seasonal doses per year, assuming 10 months of operation

Source: Expert interviews; company statements; news articles; UBS Report: “Flu Vaccine Capacity Outstripping Demand” – Nov. 2006; Oliver Wyman analysis.
Influenza Vaccine Production Capacity by Manufacturer in Developing Countries

Doses in million

->50
110

- Doses seasonal flu vaccine required annually
- Current max production capacity
- Doses of pandemic H1N1 vaccine produced
- Planned Capacity by 2015
Influenza Vaccine Manufacturers (June 2011; Actual and Potential)

- Australia: CSL
- USA: Medimmune/Sanofi-Pasteur
- Canada: GSK
- Mexico: Birmex
- Brazil: Instituto Butantan
- China: CNGB/Hualan/Neptunus/GSK/Sinopharm/Sinovac/Tianyuan
- Japan: Biken/CSTRI/Denka Seiken/Kitasato
- Romania: Cantacuzino
- Russian Federation: Microgen
- Czech Republic: Baxter
- Germany: GSK/Novartis
- France: Sanofi Pasteur
- Switzerland: Berna-Crucell
- Austria: Baxter
- Italy: Novartis
- Serbia: Torlak
- Egypt: Vacsera
- India: Panacea Biotec/SII
- Thailand: GPO
- Viet Nam: IVAC/Vabiotech
- Indonesia: BioFarma
- The Netherlands: Solvay
- Hungary: Omnivest
- Australia: CSL
- Canada: GSK
- USA: MedImmune Sanofi-Pasteur
- Mexico: Birmex
- Brazil: Instituto Butantan
- China: CNGB Hualan Neptunus/GSK Sinopharm Sinovac Tianyuan
- Japan: Biken CSTRI Denka Seiken Kitasato
- Romania: Cantacuzino
- Russian Federation: Microgen
- Czech Republic: Baxter
- Germany: GSK Novartis
- France: Sanofi Pasteur
- Switzerland: GSK Novartis
- Austria: Baxter
- Italy: Novartis
- Serbia: Torlak
- Egypt: Vacsera
- India: Panacea Biotec SII
- Thailand: GPO
- Viet Nam: IVAC/Vabiotech
- Indonesia: BioFarma
- One producer (AdImmune) in Chinese Taipei
Estimated pandemic vaccine production capacity, 2015 based on a best case scenario of seasonal capacity

2015 pandemic capacity
Million doses; cumulative

6 months
(14-week production)

12 months
(40-week production)

Available vaccine supply
% of world population

42.4%
121.0%

12.6%
35.9%

6.3%
18.0%

Weeks from candidate vaccine virus release

Low case
Base case
High case

1 Percentage of the population that could be vaccinated with two doses of vaccine, as per the target of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply, given the estimated vaccine supply. World population in 2015, 7.3 billion.

WHO 10.44
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
## Surge potential using existing approved technologies

<table>
<thead>
<tr>
<th>Seasonal technology</th>
<th>Pandemic vaccine technology</th>
<th>Capacity enhancement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inactivated split or subunit</td>
<td>Inactivated whole cell</td>
<td>~ 3 fold</td>
</tr>
<tr>
<td>Inactivated split or subunit</td>
<td>Inactivated split or subunit plus oil-in-water adjuvant</td>
<td>6-12X</td>
</tr>
<tr>
<td>Inactivated split or subunit</td>
<td>LAIV</td>
<td>Up to 50X</td>
</tr>
<tr>
<td>LAIV</td>
<td>LAIV</td>
<td>-</td>
</tr>
</tbody>
</table>
Conclusions

- Global influenza vaccine production capacity has increased sharply to over 800 million doses trivalent seasonal vaccine from 350 million in 2006;

- New manufacturers have been established in developing countries, which brings hopes to more adequate production capacity and equitable access in case of a future pandemic;

- Adequate production capacity is still lacking in some regions of the world, in particular in sub-Saharan Africa and Central Asia.

- Surge capacity for pandemic vaccine should be optimized