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# Update on the new Influenza A (H1N1)

GAVI Board, 3 June 2009

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# Outline

- Epidemiological situation & assessment
- Vaccine related Issues
- Lessons learnt/Major observations
- Action areas



# Epidemiology and disease burden

# Current situation

- As of 2 June 2009
  - 18,965 laboratory confirmed cases reported to WHO (117 deaths)
  - **64 countries** are affected (all WHO regions except AFR region)
- The main affected **age groups** (WER 22 May):
  - Mexico: median age 31 (range 0-75), 75.8% are between the ages of 20-54 years old
  - US: 60% ≤18 yrs old ; Canada: median age 22-24 (range 1-61)
  - UK: 58% 10-29 yrs old; Japan: median age 17 yrs (range 5-44)
- Based on evidence to date, the overall **severity** of this outbreak falls within seasonal flu boundaries



# Epidemiological assessment

- Ongoing spread with 3 distinct situations in countries:
  - Advanced spread in countries of North America and Mexico.
  - Transition in some countries in Europe, Asia, South America and Australia where there are larger number of cases and early spread into the community
  - Limited cases in countries where the cases relate to travelers or communities.
- We remain at **phase 5** but are getting closer to Phase 6 (need to observe substantial proof of sustained community spread in another WHO region besides AMR)



# Key uncertainties\*

- The only thing certain about influenza viruses is that nothing is certain
- Uncertain how fast the new virus will spread throughout the world and whether it will become widely established
- It remains uncertain whether the infectivity and virulence of the new virus will change over time
- Spread of new virus in S/hemisphere could have different and perhaps more severe effects than seen in the N/hemisphere

\*source: report of high level consultation,



# Vaccines related issues

# Novel Influenza A (H1N1) Vaccine Production (1)

- Vaccine is an effective tool to prevent virus spread but also reduce disease severity
- Issues:
  - Sufficient manufacturing capacity should be devoted to seasonal vaccines
  - Global availability at full commercial-scale production ?
- WHO survey of 35 influenza vaccine manufacturers:
  - 21 currently producing seasonal vaccines responded
  - 25 indicated they were envisaging to produce novel vaccine, including 20 of the current producers of seasonal vaccine

# Novel Influenza A (H1N1) Vaccine Production (2)

- Annual capacity of trivalent seasonal vaccine production – 876.4M
- Only 67% (582.5M) of virtual capacity of 876.4 was actually used for 08-09 season
- Production status for bulk for 09-10 season will reach 91% of total planned production by end July 09 (trivalent H1N1, H3N2, B strains) – 75% by end June
- 30 vaccine formulations were reported, including 11 adjuvanted vaccine formulations
- Potential production output assumes that production yield is similar to that usually obtained for seasonal vaccines; the most doses-sparing formulation selected for each manufacturer; production at full capacity
- Best case scenario: ~ 94.5 M doses produced per week (4.9 Bn doses in one year)



# Novel Influenza A (H1N1) Vaccine Production (3)

- Several manufacturers have advanced purchase agreements with countries
- 11/25 manufacturers were willing to reserve 10% of doses for UN procurement (56 M doses)
- 14/25 manufacturers still undecided about procurement to UN (potential additional doses per year= 435.5M)
- 85% of potential production of novel vaccine is concentrated in few large multinationals and large companies and their decisions will have an impact on dose availability for resource-poor countries
- Note: of the 582.5M doses of seasonal vaccines produced for 08-09 season, 470 M were produced for Northern Hemisphere and 112.5 M for -2009- Southern Hemisphere



# WHO/SAGE recommendations on influenza A (H1N1) vaccines

- *14 May: Virtual conference with inputs of >40 stakeholders*
- Manufacturers are urged to develop clinical trial batches and start preparing for a potential future recommendations to move to commercial-scale production
- No interference with present production of N/hemisphere seasonal vaccines
- Number of needed doses of novel vaccine will depend on the spread of the influenza A (H1N1) virus in next few weeks and better definition of groups to be targeted
- Any declaration of phase 6 does not automatically mean that WHO is recommending that manufacturers should switch from seasonal to novel vaccine production
- *Next face to face meeting on 7 July in Geneva*



# Lessons learned & key observations...

- World readiness for a possible emergence of influenza pandemic
  - IHR (WHA 2005) tested in a public health emergency
  - WHO/SAGE recommendations for stockpile and use of H5N1 vaccines just issued
- Science-based approaches remain the bedrock of the response
- Effective communication is paramount
- Efficacious response before and during 1<sup>st</sup> wave of severe pandemic depends on how quick mass vaccination campaign will start and availability of vaccines
- Solidarity and International collaboration are critical components of the response in the first months of a potential several pandemic event
- Success depends on multi-stakeholder approach



# Action areas for a novel influenza A (H1N1) (Potential role for GAVI?)

- Coordinating vaccine production issues
- Harmonizing regulatory pathway
- Policy recommendation for the use of vaccines
- Access to vaccines in developing countries
- Deployment of vaccine within countries
- Post-marketing surveillance



**End**



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