

Pandemic Influenza vaccines: current status (24/9/2552)

Pandemic (H1N1) 2009 briefing note 11

24 SEPTEMBER 2009 | GENEVA -- **Regulatory authorities have licensed pandemic vaccines in Australia, China and the United States of America, soon to be followed by Japan and several countries in Europe. The length of the approval process depends on factors such as each country's regulatory pathway, the type of vaccine being licensed, and the stage of manufacturers' readiness to submit appropriate information to regulatory authorities.**

Production capacity

In May 2009, WHO estimated that, in a best case scenario, worldwide production capacity for pandemic vaccines would be approximately 5 billion doses per year. Since then, better information on production yield and appropriate vaccine formulation has become available.

WHO currently estimates worldwide production capacity for pandemic vaccines at approximately 3 billion doses per year. While this figure is lower than previously projected, early data from clinical trials suggest that a single dose of vaccine will be sufficient to confer protective immunity in healthy adults and older children, effectively doubling the number of people who can be protected with current supplies.

These supplies will still be inadequate to cover a world population of 6.8 billion people in which virtually everyone is susceptible to infection by a new and readily contagious virus. Global manufacturing capacity for influenza vaccines is limited, inadequate and not readily augmented.

Pandemic vaccines have their greatest impact as a preventive strategy when administered before or near the peak incidence of cases in an outbreak. Both regulatory authorities and vaccine manufacturers have made extraordinary efforts to expedite the availability of vaccines.

Many affluent countries have previously contracted with manufacturers to obtain sufficient vaccine supplies to cover their entire populations. However, most low- and middle-income countries lack the financial resources to compete for an early share of limited supplies. Vaccine supplies in these countries will largely depend on donations from manufacturers and other countries.

Availability in developing countries

Last week, donations of pandemic vaccines for use in developing countries were announced by the United States of America, in concert with Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland and the United Kingdom. Similar support from additional countries is anticipated and warmly welcomed.

WHO will be coordinating the distribution of these donated vaccines. Earlier this year, WHO conducted surveys with its regional and country offices to identify countries that will not have pandemic vaccines unless supplies are donated.

Teams with expertise in field operations, vaccines, and the logistics of their distribution are now working in the JW Lee Centre for Strategic Health Operations (the SHOC room). Initially, they will be distributing an estimated 300 million doses of vaccine to more than 90 countries.

Distribution of the first batches of donated vaccines is expected to begin in November. WHO continues to recommend that health workers be given high priority for early vaccination.

Vaccine safety

National regulatory authorities for medicines carefully examine the known and suspected risks and benefits of any vaccine prior to its licensing. Because the pandemic virus is new, both non-clinical and clinical trials are being conducted to gain essential information on immune response and safety. Outcomes of trials completed to date suggest that pandemic vaccines are as safe as seasonal influenza vaccines.

Side effects are expected to be similar to those observed with seasonal influenza vaccines. Common side effects include local reactions at the injection site (soreness, swelling, redness) and possibly some systemic reactions (fever, headache, muscle or joint aches). In almost all vaccine recipients, these symptoms are mild, self-limited and last 1-2 days.

However, even very large clinical trials will not be able to identify possible rare events that can occur when pandemic vaccines are administered to many millions of people.

WHO advises all countries administering pandemic vaccines to conduct intensive monitoring for safety and to report adverse events. Many countries already have systems for monitoring vaccine safety in place.

International sharing of data from such post-marketing surveillance will be vital in guiding risk-benefit assessments and determining whether changes in vaccination policies are needed. WHO has developed standardized protocols for data collection and reporting in real-time, and will communicate findings to the international community via its web site.

Source:

http://www.who.int/csr/disease/swineflu/notes/pandemic_influenza_vaccines_20090924/en/index.html