Emergencies preparedness, response

Safety of pandemic vaccines

Pandemic (H1N1) 2009 briefing note 6

6 AUGUST 2009 | GENEVA - WHO is aware of some media reports that have expressed concern about the safety of vaccines for pandemic influenza. The public needs to be reassured that regulatory procedures in place for the licensing of pandemic vaccines, including procedures for expediting regulatory approval, are rigorous and do not compromise safety or quality controls.

Vaccines are among the most important medical interventions for reducing illness and deaths during a pandemic. However, to have the greatest impact, pandemic vaccines need to be available quickly and in large quantities.

During the 1957 and 1968 pandemics, vaccines arrived too late to be used as an effective mitigation tool during the more severe phases of the pandemics. Influenza vaccines had not yet been developed when the 1918 pandemic swept around the world, eventually killing an estimated 50 million people.

In 2007, as part of preparedness for an influenza pandemic, WHO worked together with health officials, regulatory authorities, and vaccine manufacturers to explore a broad range of issues surrounding the regulatory approval of pandemic vaccines. [1]

Ways were sought to shorten the time between the emergence of a pandemic virus and the availability of safe and effective vaccines. Different regulatory pathways were assessed, and precautions needed to ensure quality, safety, and effectiveness were set out in detail.

Fast-track procedures for approval

Regulatory authorities have shown great flexibility in developing procedures for fast-tracking the approval and licensing of pandemic vaccines.

In some cases, pandemic vaccines are not regarded by regulatory authorities as entirely “new” vaccines, as they build on the technology used to produce vaccines for seasonal influenza, established procedures for testing and regulatory control, and an extensive body of safety data.

In such cases, approval procedures are similar to those applied to “strain changes” made each year when seasonal vaccines are modified to match circulating viruses in the Northern and Southern Hemispheres.

Specific regulatory procedures have been devised to expedite the