



H1N1 pandemic influenza vaccines: clinical testing, regulatory review and ongoing surveillance

As the world's leading influenza vaccine manufacturers, EVM members are committed to the rapid and safe supply of vaccines to protect populations against H1N1 pandemic influenza. EVM members work with regulators and health authorities across Europe to ensure these vaccines meet rigorous safety and efficacy standards.

Rapid and safe vaccine supply

Pandemic influenza presents significant public health challenges. Large populations require vaccines targeting the newly emerged virus strain in as short a period as possible. Consequently, regulatory authorities have developed processes to fast-track the appraisal of pandemic vaccines, to allow their rapid use without compromising safety. These procedures build on the extensive experience gained with seasonal influenza vaccines over the last 60 years, and the results of clinical trials conducted on a range of prototype pandemic vaccines and new H1N1 vaccines. As a result, a comprehensive range of measures is in place to review and monitor the safety of pandemic vaccines. These include regulatory assessment, ongoing clinical testing and wide-scale surveillance as part of broader vaccine use.

Regulatory review, testing and monitoring

Each year, manufacturers update the composition of seasonal influenza vaccines so they contain the most important circulating strains. Tens of years of experience with this process shows that changing the viral strains in vaccines produced using the same manufacturing, control and quality processes does not affect the safety or protection offered. Authorities have built on this knowledge to develop fast-track regulatory procedures for pandemic vaccines.

In Europe, a number of H1N1 vaccines are currently in production based on previously approved prototypes or 'mock-ups'. These were developed prior to the pandemic using other potential pandemic strains such as H5N1 viruses, and they completed clinical safety and immunogenicity testing in thousands of subjects. These vaccines are now being updated with the H1N1 strain. Following the European 'mock-up' approach, regulators review the strain change data for these H1N1 vaccines as they become available. This rolling review accelerates the regulatory process. Clinical testing is ongoing with H1N1 vaccines in a range of age groups, with further studies planned. These safety and immunogenicity trials will involve thousands of subjects, and the results will also be reviewed by the regulatory authorities as they become available. When the regulators have approved the vaccines - a number of H1N1 vaccines have already received marketing authorizations - and they are used more broadly in the general population, they will undergo extensive monitoring with analysis and closer tracking in specialized groups who are vaccinated, such as pregnant women. This is designed to quickly detect any potential issues that may emerge with wider use. Importantly, this approach has the potential to rapidly generate significant information about the vaccines' use in a way that even very large clinical trials could not.

EVM member companies are major suppliers of vaccines worldwide, producing the majority of vaccine doses in Europe. EVM members are: Baxter, Crucell, GlaxoSmithKline Biologicals, MedImmune, Novartis Vaccines, sanofi pasteur, sanofi pasteur MSD, Solvay Biologicals, and Wyeth Vaccines

A number of other new pandemic vaccines without previous prototype approvals are also in development in Europe. When clinical studies are completed with these vaccines, they will undergo fast-track regulatory review to accelerate their availability. Once approved for wide-scale use they will also undergo extensive surveillance.

Regulatory authorities in a number of countries have adopted a process similar to the European model. Others, notably the USA, directly utilize experience with seasonal vaccines to regulate H1N1 vaccines. In this approach, established regulatory procedures for strain changes can apply to H1N1 vaccines whose production, quality and control processes remain the same as those for currently approved seasonal influenza vaccines. This expedites the review process while leveraging the extensive database built up previously with the administration of millions of doses of seasonal vaccines. To complement this data, clinical trials of H1N1 vaccines are underway in the USA with further studies planned. These will include thousands of subjects, including children and other special populations. In addition, the US Centers for Disease Control and Prevention is developing an extensive monitoring program designed to rapidly detect any issues that may emerge with wider vaccine use.

Regulators, health authorities and manufacturers have worked hard over many years to optimize pandemic vaccine manufacturing, testing and monitoring processes. The procedures now in place ensure these vaccines can be provided as quickly as possible without compromising safety, so that their benefits far outweigh potential risks.

Further information

- WHO paper on the safety of pandemic influenza vaccines:
http://www.who.int/csr/disease/swineflu/notes/h1n1_safety_vaccines_20090805/en/index.html
- European regulatory review for pandemic influenza vaccines:
<http://www.emea.europa.eu/pdfs/human/press/pr/46856809en.pdf>

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