



## **H1N1 pandemic influenza vaccines: the role of adjuvants**

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. Several manufacturers have developed pandemic vaccines containing adjuvants, which have the potential to broaden the immune system's response while simultaneously stretching vaccine supplies.

### **Adjuvants' role and clinical profile**

Adjuvants are used to enhance the immune response to a number of vaccines. This response may be earlier, more potent, broader or longer lasting than that produced by an unadjuvanted split or sub-unit vaccine. While most seasonal influenza vaccines have not traditionally contained adjuvants, an adjuvanted influenza vaccine has been available for many years in Europe. This vaccine has been administered to over 40 million people, providing a significant database of clinical experience.

In recent years, clinical studies with pre-pandemic and prototype pandemic influenza vaccines have shown that adjuvants have the potential to generate broad immune responses that may protect against different, related viral strains, even with reduced doses of vaccine. Following clinical studies in thousands of subjects, European regulators previously approved several prototype or 'mock-up' pandemic vaccines containing these adjuvants. The adjuvants have now undergone clinical testing in tens of thousands of subjects. The experience gained with vaccines containing these adjuvants, both in clinical studies and wider influenza immunization campaigns in Europe, shows that while local reactions at the injection site and mild systemic reactions may be increased, their overall safety profile is similar to non-adjuvanted vaccines.

### **Use of adjuvants in H1N1 pandemic vaccines**

Building on this experience, a number of manufacturers are now producing adjuvant-containing H1N1 pandemic vaccines. Clinical studies are also underway to further evaluate these H1N1 vaccines, with additional trials planned. These studies include thousands of subjects in a range of age groups, including children.

Before any vaccines can be used more widely they must receive approval from regulatory authorities. Two adjuvanted H1N1 vaccines were recently licensed by the EMEA. Following approval, wider-scale use of pandemic vaccines will be complemented by extensive monitoring programs designed to rapidly detect any potential issues that may emerge.

### **Supply of adjuvant-containing H1N1 pandemic vaccines**

The WHO Strategic Advisory Group of Experts on Immunization recognizes the importance of the production and use of adjuvants in H1N1 vaccines, in light of their potential to increase vaccine supplies and the potential need to help protect against different, related viral strains.

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*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*

Many governments in Europe and around the world are sourcing adjuvant-containing pandemic influenza vaccines. In the US, adjuvanted influenza vaccines have not been introduced previously, and the American authorities do not currently plan to incorporate adjuvants in H1N1 pandemic vaccines. Rather, they are considering using vaccines based on the non-adjuvanted seasonal influenza vaccines utilized each year. However, to allow a flexible response to the pandemic, the US has committed significant funds to purchase adjuvants for the national pandemic stockpile, for use if required.

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 SAGE recommendations on H1N1 vaccines: <http://www.who.int/wer/2009/wer8430.pdf>
- European regulatory review for pandemic influenza vaccines: <http://www.emea.europa.eu/pdfs/human/press/pr/46856809en.pdf>
- US purchase of adjuvants: <http://www.hhs.gov/news/press/2009pres/07/20090713b.html>

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