



## **Vaccines to protect against pandemic H1N1 influenza– frequently asked questions**

### **1) What is the vaccine industry doing to help address the H1N1 influenza pandemic?**

EVM members are working hard to complete the preparations needed to manufacture H1N1 vaccines as quickly as possible, to help protect against this new pandemic threat.

- Manufacturers have received the seed viruses required to begin the manufacture of vaccines from the WHO, and have initiated the first steps in the production process. Manufacturers stand ready to move to large-scale production as soon as requested by national authorities and the WHO, and some producers who are not manufacturing seasonal influenza vaccines have initiated full-scale production already.
- EVM members have established regular and ongoing communications with national health authorities and European and international organisations (such as the WHO, European Commission, US Centers for Disease Control and Prevention, European Centre for Disease Prevention and Control, US Federal Drug Administration and European Medicines Agency), to provide up-to-date information on H1N1 influenza vaccine development and production and to help address regulatory issues.

European vaccine manufacturers are better prepared than ever to help address an influenza pandemic. EVM members have been preparing for this scenario for a number of years, developing new technologies and prototype vaccines, and significantly increasing production capacity.

### **2) Have manufacturers developed H1N1 vaccines?**

Manufacturers are undertaking the steps needed for full-scale production of H1N1 vaccines, including the development of the manufacturing strains from the seed viruses provided by the WHO. Several manufacturers have begun production of clinical lots of vaccine to undertake the studies required by EMEA and other global regulatory authorities. Producers stand ready to move to large-scale production as soon as requested by national authorities and the WHO and some manufacturers who are not producing seasonal influenza vaccines have initiated full-scale production already.

### **3) When will H1N1 vaccines become available?**

Vaccine doses should be available for public health authorities in the coming months, if they request the initiation of full-scale production. Some manufacturers who are not producing seasonal influenza vaccines have now begun full-scale production,

and may be able to supply limited amounts of vaccine to health authorities from July if requested.

In contrast to the manufacture of many traditional pharmaceuticals, developing and producing influenza vaccines is a complicated biological process that takes a number of months. The process requires the development of seed strains for manufacture, producing vaccine antigen at large scale, completing vaccine formulation to ensure the correct level of active ingredients and conducting testing and control procedures as required by the regulatory authorities. As part of this process, vaccine manufacturers will require specialised vaccine reagents from the public health authorities, which are expected to be available end July beginning of August.

**4) How safe and effective will the new H1N1 vaccines be?**

Manufacturers are working closely with regulatory authorities to determine the exact testing that will be required before new H1N1 vaccines could be released for wider use, and to establish extensive safety monitoring systems for potential future vaccination programmes. This approach builds on the experience gained with prototype pandemic vaccines, and utilises procedures developed over several years as part of preparations put in place by regulators and manufacturers.

**5) How many doses of H1N1 vaccine can be produced?**

It is not currently possible to give a definitive, industry-wide, production capacity figure, because manufacturers are undertaking the initial stages of production and the precise characteristics of the vaccine strains are not established. In terms of estimated capacity, in May the WHO suggested that up to 4.9 billion doses may be produced within one year assuming a production yield similar to that of seasonal influenza vaccines and dose sparing approaches are utilised.

**6) Have EU countries signed agreements for pandemic vaccines?**

A number of European countries have entered agreements with manufacturers for the supply of vaccines during a pandemic, while several countries have not. No official information has been published regarding the number of countries that have signed contractual agreements with manufacturers.

**7) Will vaccines be provided to countries outside Europe, including developing countries?**

EVM members are global vaccine providers, and many of the influenza vaccines produced in Europe each year are exported. Similarly, H1N1 vaccines would be distributed to health authorities in the EU and around the world. Producers are committed to increasing global access to vaccines, and EVM members support the concept of tiered pricing for the supply of pandemic vaccines to developing countries. In addition, a number of manufacturers have committed to donate large quantities of pandemic vaccines for use by the WHO.

**8) Will manufacturers complete the production of vaccines for the upcoming Northern hemisphere influenza season?**

Seasonal influenza remains a significant threat, causing 3-5 million cases of severe disease and 250,000-500,000 deaths each year, and consequently the ECDC, EU Member States and WHO all recommend vaccination for the elderly and those at risk. Consequently manufacturers are continuing to produce seasonal vaccines, in consultation with the WHO and national health authorities, as protection against annual influenza remains a priority. Manufacture of these vaccines is nearing completion, allowing production to be switched to H1N1 vaccines in the coming weeks if requested by national authorities and the WHO.

**9) What will happen to seasonal influenza vaccine production for the Southern hemisphere?**

Manufacturers continue to supply vaccines for the Southern hemisphere winter influenza season, which is now underway. Producers will retain manufacturing flexibility to answer the call of health authorities for the supply of vaccines in future seasons.

**10) What should be the role of the EU in the fight against the H1N1 pandemic?**

The EU, particularly through its European Centre for Disease Prevention and Control (ECDC), has an important role to play facilitating the sharing of best practise in the implementation of pandemic plans. In addition, the EU through its European Medicines Agency should continue to work with manufacturers to help ensure that vaccines can be made available as quickly as possible, the appropriate safety monitoring mechanisms are in place and outstanding regulatory issues are resolved. As part of these initiatives, regular communications between the Commission and manufacturers are essential to provide strong co-ordination amongst all partners in the fight against pandemic influenza.

**11) Which strain are manufacturers using for H1N1 vaccine production?**

The WHO influenza network makes strains available for manufacture, and national authorities approve which are incorporated in vaccines for local use. H1N1 viruses have been isolated in North America, Europe and Oceania, and WHO recommends that vaccines currently in preparation contain the H1N1 California strain.

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