



The role of industry in pandemic preparedness

Frequently asked questions

What is the role of industry in pandemic preparedness?

The industry's role is to develop, to produce and to deliver safe and effective vaccines in a timely manner in order to meet public health expectations and to respond to government's requests. This is a critical contribution, because vaccines are complex biological products, requiring specific production processes and long manufacturing lead times.

How have EVM members contributed to pandemic preparedness?

For the first time in history, vaccines were available shortly after the start of a pandemic. Such a rapid response was only made possible thanks to a decade of extensive efforts in research and development, and industrial operations, largely conducted by the research-based pharmaceutical industry, and to a 60-year experience with seasonal flu vaccines. This includes:

- researched and developed prototype vaccines prior to the recent pandemic outbreak;
- conducted clinical trials
- developed new technologies to address the challenges of pandemic influenza
- adapted production facilities
- expanded vaccine production capacity to meet a global demand;

In addition, individual manufacturers:

- are donating 160 million doses of H1N1 vaccines to WHO for use in developing countries;
- are reserving H1N1 vaccine manufacturing capacity for developing country supply;
- are implementing tiered-pricing approaches for vaccine supply to low- and middle-income countries.

(For further information:

http://evm-vaccines.org/pdfs/EVM%20statement_H1N1_contributions_oct2009.pdf)

What assistance did the authorities request from industry to help prepare for a pandemic?

Authorities called on industry to accelerate the research and development of pandemic vaccines and establish the capacity to provide sufficient vaccines for large populations in the shortest possible timeframe. Authorities also required data on the development of these capabilities to ensure the effectiveness of pandemic response plans. To further strengthen their preparations, a

number of governments established vaccine supply agreements with individual manufacturers to avoid the need for complex negotiations following the outbreak of a pandemic. Industry has responded to each of these calls to action.

(For further information:

In June 2006, the European Parliament adopted a resolution on pandemic influenza preparedness calling for increases in vaccine production capacity, and the availability of vaccines for those exposed to a pandemic virus:
<http://www.europarl.europa.eu/sides/getDoc.do?jsessionid=86DD02FE296545D85A0F3ED5F086673F.node2?language=EN&pubRef=-//EP//TEXT+TA+P6-TA-2006-0259+0+DOC+XML+V0//EN.>)

How does industry work with public authorities on preparedness?

EVM members have been highly responsive to calls from the WHO, European Institutions and national governments to put in place robust pandemic preparations, and in recent years global preparedness has reached its highest level ever. As part of industry's response (in addition to the contributions outlined in a previous answer) manufacturers have also provided public health authorities with technical information on vaccine development, production capacity and delivery capabilities to assist their pandemic planning.

(For further information:

In October 2005, a European Parliament resolution on the 'strategy against an influenza pandemic' called for co-operation 'with industry in order to undertake the necessary steps for the production of new vaccines in the shortest possible time': http://www.evm-vaccines.org/pdfs/ep_flupandemic_resolution_Strasbourg_2005-10-26.pdf

In June 2009, EVM members highlighted their role in providing up-to-date information on H1N1 vaccine development and production to health authorities and regulatory agencies around the world: [http://www.evm-vaccines.org/pdfs/EVM%20statement%20on%20H1N1%20QA%20fin.pdf.](http://www.evm-vaccines.org/pdfs/EVM%20statement%20on%20H1N1%20QA%20fin.pdf))

How are pandemic vaccination plans developed?

Public health authorities are responsible for immunisation strategies, including those against pandemic influenza. When developing these plans, authorities consider advice from a range of experts, such as WHO, the European Centre for Disease Prevention and Control (ECDC), the Health Security Committee and local advisory groups. Authorities also require technical information on industrial capabilities to help plan the implementation of local vaccination strategies.

(For further information:

WHO has issued extensive guidance on pandemic preparedness planning: <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>

EU Preparedness plan

http://ec.europa.eu/health/preparedness_response/pandemic_flu_preparedness/index_en.htm

The ECDC has also issued tools to assist pandemic planning:

[http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/pandemic_preparedness.aspx.](http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/pandemic_preparedness.aspx))

What steps did industry and the authorities take to ensure H1N1 vaccines are safe?

H1N1 vaccines are essentially developed, manufactured, controlled, evaluated and licensed using the well-established procedures for seasonal influenza vaccines which have proven to be efficacious and safe in billions of people during the past 60 years. They have also benefited of recent progress in formulations and technologies used in many other vaccines.

H1N1 vaccines have demonstrated their efficacy and safety in specific clinical studies in thousands of subjects in a range of age groups, conducted in respect of strict regulations. These processes are indeed designed and monitored by independent regulatory agencies. The European regulator, the European Medicines Agency – EMA - has established processes to fast-track the appraisal of pandemic vaccines in order to allow their rapid use without compromising safety.

Finally, a comprehensive range of measures is in place to review and monitor the safety of H1N1 vaccines. The latest results from this surveillance have been issued by EMA on January 20. They show that, in the European Economic Area around 34 million people, including at least 258,000 pregnant women, had been vaccinated with one of the three centrally authorised vaccines. The vast majority of reported adverse reactions are non-serious. The EMA considers that the benefit-risk balance continues to be positive.

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(For further information:

WHO has issued a briefing paper outlining the safety of pandemic vaccines:
http://www.who.int/csr/disease/swineflu/notes/h1n1_safety_vaccines_20090805/en/index.html

The EMA issues weekly updates on pandemic safety monitoring:
<http://www.ema.europa.eu/influenza/updates.html>.)

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