



EVM statement on meeting with the European Medicines Agency to prepare regulatory strategy for approval of vaccines against novel H1N1 strain

On 30 April, the European Vaccine Manufacturers met with the European Medicines Agency (EMA), EU Member States' representatives, the European Commission, the European Centre for Disease Prevention and Control (ECDC), the World Health Organization (WHO) and the European Directorate for the Quality of Medicines and Healthcare (EDQM).

The purpose of the meeting was to discuss the emerging human cases of novel (swine) H1N1 influenza and specifically which regulatory routes manufacturers might use to obtain vaccine authorisation of vaccines against novel H1N1 strain. This was a preparatory meeting to ensure that all parties are ready, if needed. Any decision on a strategy for production of pandemic vaccines will depend on recommendations from the WHO.

The European Vaccine Manufacturers have been preparing for a pandemic scenario for several years, to address the challenges that an outbreak of a potential influenza pandemic would pose to vaccine production, through the development of new technologies, prototype vaccines and production capacity increases.

Industry will continue to work closely with relevant authorities to ensure the most appropriate and efficient response to this potential public health threat.

For more information, please go to:

<http://www.emea.europa.eu/pdfs/human/press/pr/27100009en.pdf>

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

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