



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommends authorisation of two vaccines for influenza pandemic (H1N1) 2009

The European Medicines Agency has recommended to the European Commission that two vaccines against influenza A(H1N1) ('swine flu') be granted a marketing authorisation. Vaccines are one of the most important tools in the management of an influenza pandemic, helping to reduce illness and deaths by building up immune protection against the pandemic flu virus. To ensure that authorised vaccines are available before the start of the flu season in the coming autumn and winter months, the Agency's Committee for Medicinal Products for Human Use (CHMP) expedited its assessment.

The vaccines concerned are Focetria (Novartis) and Pandemrix (GlaxoSmithKline). Decisions on the granting of European Union-wide marketing authorisations for the vaccines by the European Commission are expected shortly. Vaccination strategies are decided by the government in each EU Member State, taking into account the information provided by the Agency for each vaccine.

The Committee is currently recommending a two-dose vaccination schedule, at an interval of three weeks, for adults, including pregnant women, and children from six months of age. The Committee acknowledged that there are preliminary data suggesting that one dose may be sufficient in adults. The Agency is expecting further data from ongoing clinical studies over the coming months and these recommendations may be updated.

Focetria and Pandemrix were authorised using the so-called 'mock-up' approach. This approach allowed development and authorisation of these vaccines in advance of the pandemic, based on information generated with a different virus strain that could have caused a pandemic (an H5N1 influenza virus strain). Once the A(H1N1)v virus strain causing the pandemic was identified by the World Health Organization, the manufacturers were able to include it in the mock-up vaccines to prepare final pandemic vaccines.

Decades of experience with seasonal influenza vaccines indicate that insertion of a new strain in a vaccine should not substantially affect the safety or level of protection offered. The Committee's recommendation to authorise these two vaccines is based on the information on the quality, safety and immunogenicity, including information on clinical trials in more than 6,000 subjects, generated at the time of the authorisation of the mock-up vaccines, as well as on information relating to the change in strain from H5N1 to H1N1.

Further clinical trials in adults and in children are ongoing and more results will become available from October/November 2009 onwards.

The vaccines recommended for authorisation, Focetria and Pandemrix, contain 'adjuvants' (substances that enhance the immune response so that less viral material can be used in each dose of vaccine). They are widely used in vaccine manufacture and have a good safety record. The adjuvant in Focetria has been used in another flu vaccine since 1997 in more than 45 million doses. The adjuvant in Pandemrix has been tested in clinical trials involving several thousand subjects.

As with all medicines, rare adverse reactions may only be detected once the vaccines are used in large numbers of people. The Agency has requested that vaccine manufacturers implement plans to actively investigate and monitor the safety of vaccines as soon as they are used across the EU, so that action

can be taken as early as possible if a safety issue emerges. As part of this, the manufacturers have committed to carry out post-authorisation safety studies in about 9,000 subjects for each vaccine.

The Committee will continue to evaluate all information that becomes available and make further recommendations if necessary, to ensure that the benefits of these vaccines outweigh their risks, taking into account spread and severity of the pandemic.

Other applications are still under review, including one additional mock-up vaccine.

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NOTES

1. More information is available in a [question-and-answer document](#).
2. More information on the Agency's activities in relation to the influenza pandemic can be found on the Agency's new [Pandemic influenza \(H1N1\) website](#).
3. More information about mock-up vaccines is available [here](#).
4. The product information in English is available: for [Focetria](#); for [Pandemrix](#).
5. A summary of the assessment report is available: for [Focetria](#); for [Pandemrix](#).
6. WHO information on A/H1N1 influenza can be found [here](#).
7. Information about the European Centre for Disease Prevention and Control (ECDC) can be found [here](#).
8. Information on the European Commission's influenza activities can be found [here](#).
9. A link to EU Member States' national pandemic plans can be found [here](#).
10. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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