



European Medicines Agency
Press office

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PRESS RELEASE

EMA recommends authorisation of first pre-pandemic influenza vaccine

The European Medicines Agency today recommended the authorisation of the first 'pre-pandemic vaccine' for humans against influenza caused by the H5N1 virus. This is an avian influenza ('bird flu') virus strain that has the potential to evolve into a pandemic influenza virus affecting humans.

Prepandrix, from GlaxoSmithKline Biologicals, is a pre-pandemic vaccine that is intended to trigger an immune response against the H5N1 strain of the influenza virus before or during an officially declared influenza pandemic, in accordance with official guidance.

An influenza pandemic is a global outbreak of influenza that leads to serious illness in large numbers of people. It is caused by an influenza virus strain against which most or all humans have no natural protection, and which has mutated into a form that spreads easily from person to person. Health authorities are concerned that the next pandemic could occur at some point within the next few years and could be caused by the H5N1 strain.

The EMA recommendation has been sent to the European Commission for the adoption of a marketing authorisation decision.

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Notes:

1. A summary of opinion for Prepandrix is available [here](#)
2. Pre-pandemic vaccines are part of the commitment intended to help Member States prepare for pandemic influenza. Other approaches include the authorisation of mock-up vaccines, two of which (Daronrix and Focetria) are authorised at the level of the European Union. A third mock-up vaccine (Pandemrix) was recommended for marketing authorisation during the February 2008 meeting of the Committee for Medicinal Products for Human Use (CHMP).
3. A question-and-answer document explaining mock-up pandemic flu vaccines is available [here](#)
4. A summary of opinion for Pandemrix is available [here](#)
5. More information about authorised mock-up pandemic influenza vaccines is available:
For Daronrix click [here](#)
For Focetria click [here](#)
6. The EMA pandemic influenza crisis management plan can be found [here](#).
7. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.emea.europa.eu

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