European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends authorisation of additional vaccine for influenza pandemic (H1N1) 2009

The European Medicines Agency has recommended to the European Commission that an additional vaccine against influenza A(H1N1) ('swine flu'), Celvapan from Baxter, be granted a marketing authorisation. Adoption of an authorisation decision by the European Commission is expected shortly.

This recommendation follows the authorisation of Focetria, from Novartis, and Pandemrix, from GlaxoSmithKline, by the European Commission on 29 September 2009.

As for Focetria and Pandemrix, this recommendation will allow the manufacturer to replace the flu virus strain in the current 'mock-up' vaccine with the A(H1N1)v strain causing the current pandemic.

Celvapan is a non-adjuvanted vaccine. This means that it does not contain 'adjuvants' to enhance the immune response. The Committee for Medicinal Products for Human Use (CHMP) is currently recommending a two-dose vaccination schedule, at an interval of three weeks, for adults, including pregnant women, and for children from six months of age. Clinical trials in adults and in children are ongoing, and more results will become available from mid-October 2009 onwards.

Vaccination strategies are decided by the government in each European Union (EU) Member State, taking the information provided by the Agency for each pandemic vaccine into account.

As with all medicines, rare adverse reactions may only be detected once the vaccine is being used in large numbers of people. The Agency has requested that Baxter implement the same plans as for the other pandemic vaccines, to actively investigate and monitor the safety of Celvapan as soon as it is being used across the EU, so that action can be taken as early as possible if a safety issue emerges. As part of this, the manufacturer has committed to carry out post-authorisation safety studies in about 9,000 subjects.

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

Other applications for marketing authorisations for pandemic vaccines are still under review.

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NOTES

1. 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.
2. The product information for Celvapan in English is available here.
3. A summary of the assessment report in English is available here.
4. More information on the recommendation for the authorisation of Focetria and Pandemrix is available in a press release and a question-and-answer document.
5. Information from the European Commission on the authorisation of Focetria and Pandemrix is available in a press release.
6. Further information on Focetria and Pandemrix is available in the European Public Assessment Reports (EPARs).

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 27 Fax (44-20) 74 18 84 09
E-mail: press@emea.europa.eu http://www.emea.europa.eu

7. Further information on the scientific considerations regarding the licensing of pandemic A(H1N1)v vaccines is available in an Explanatory Note.
8. Information from the World Health Organization (WHO) on A/H1N1 influenza can be found here.
9. Information about the European Centre for Disease Prevention and Control (ECDC) can be found here.
10. Information on the European Commission's influenza activities can be found here.
11. A link to EU Member States' national pandemic plans can be found here.
12. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu