European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency reaffirms efficacy and safety of H1N1 pandemic vaccines

The European Medicines Agency has reviewed further data on the centrally authorised pandemic vaccines, Celvapan, Focetria and Pandemrix. The Agency has reaffirmed their positive balance of benefits and risks in the context of the current H1N1 influenza pandemic.

The data on Focetria and Pandemrix indicate that a single dose of these vaccines is able to trigger an immune response that may be sufficient to give protection against the H1N1 pandemic influenza in some age groups. For both vaccines, a single dose may be used in adults aged between 18 and 60 years and in children and adolescents (from the age of 9 years for Focetria, and from 10 years for Pandemrix). Pandemrix may also be used as a single dose in the elderly. For certain groups, such as younger children and immunocompromised patients, the recommendation remains that two doses should be given, to ensure that their immune system responds adequately to the vaccination. Further data will become available in the coming months. Data on Celvapan are still being assessed.

The Agency also concluded that Focetria and Pandemrix can be co-administered with non-adjuvanted seasonal flu vaccines.

The Agency, together with the national competent authorities, is continuously monitoring the safety profile of H1N1 pandemic influenza vaccines. With vaccination campaigns ongoing in the European Union, about 5 million people have been vaccinated so far. To date, the side effects reported have mainly been mild symptoms such as fever, nausea, headache, allergic reactions and injection site reactions, confirming the expected safety profile of the three vaccines. A very small number of cases of Guillain-Barré syndrome and foetal death have been reported in patients previously vaccinated with a pandemic vaccine. The Agency is still in the process of gathering all relevant information and evaluating the data. However, on the basis of the available information there is no evidence to link these to the vaccines.

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary.

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NOTES

1. For more details on the changes, please refer to the updated product information for Focetria and Pandemrix in English.
2. The latest approved product information for Celvapan is available.
3. More information on the Agency's activities in relation to the influenza pandemic can be found on the Agency's Pandemic influenza (H1N1) website.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA 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