EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency updates on pandemic medicines

The European Medicines Agency has reviewed further data on the centrally authorised pandemic medicines, the pandemic influenza vaccines Celvapan, Focetria and Pandemrix, and the antiviral Tamiflu. In the European Union at least 26 million people have been vaccinated so far and worldwide 13 million patients have taken Tamiflu from 1 May 2009 to 31 October 2009. The Agency has reaffirmed their positive balance of benefits and risks in the context of the current H1N1 influenza pandemic.

The immunogenicity data submitted for Focetria and Pandemrix confirm the currently approved dosing schedule, namely that a single dose of these vaccines is able to trigger an immune response that may be sufficient in some age groups to give protection against the H1N1 pandemic influenza.

On 16 December 2009, the Agency published the third in its series of weekly pandemic influenza pharmacovigilance update reports. The benefit/ risk balance of the pandemic vaccines and Tamiflu used for the current H1N1 influenza pandemic continues to be positive. The latest data on the safety of the three pandemic vaccines and Tamiflu show no unexpected serious safety issues. The most frequent adverse reactions that have been reported are non-serious and as expected.

The Agency will continue to closely monitor the vaccines and publish its regular pandemic influenza pharmacovigilance updates (the fourth report will be published on 23 December 2009 and the fifth report on 6 January 2010). The Agency will evaluate all information that becomes available and make further recommendations as necessary.

Notes

1. For more details on the recommended changes, please refer to the updated product information
   for Focetria: http://www.emea.europa.eu/influenza/vaccines/focetria/focetria_pi.html
   for Pandemrix: http://www.emea.europa.eu/influenza/vaccines/pandemrix/pandemrix_pi.html
   and for Celvapan: http://www.emea.europa.eu/influenza/vaccines/celvapan/celvapan_pi.html
2. The latest approved product information for Tamiflu is available here: http://www.emea.europa.eu/humandocs/Humans/EPAR/tamiflu/tamiflu.htm
3. The press release on the risk of fever in young children following vaccination with Pandemrix is available here: http://www.ema.europa.eu/pdfs/general/direct/pr/78440409en.pdf

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

4. The press release on the efficacy and safety of H1N1 pandemic vaccines is available here: http://www.ema.europa.eu/pdfs/human/press/pr/74870709en.pdf
5. The explanatory note on scientific considerations regarding the dosage and co-administration with seasonal vaccines recommendations update for pandemic A(H1N1)v vaccines can be found here: http://www.ema.europa.eu/pdfs/human/pandemicinfluenza/69369909en.pdf
6. More information on adverse reactions reported with centrally authorised pandemic vaccines is provided in the weekly pandemic influenza pharmacovigilance update report: http://www.ema.europa.eu/influenza/updates.html
7. More information on the Agency's activities in relation to the influenza pandemic can be found on the Agency's pandemic influenza website: http://www.ema.europa.eu/influenza/home.htm
8. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

Contact our press officers

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu