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Press Office

Press release

European Medicines Agency updates on pandemic influenza

The Agency's Committee for Medicinal Products for Human Use (CHMP) recommended the granting of a conditional marketing authorisation for a fourth pandemic vaccine, Arepanrix from GlaxoSmithKline Biologicals. This recommendation was made using an emergency procedure which fast-tracks evaluation of new vaccines developed during a pandemic. Information on Arepanrix was evaluated in an accelerated timeframe using a rolling review which started with the submission of the first available data on 17 July 2009. Further clinical studies in children, adolescents and adults are ongoing and results will become available from March 2010 onwards.

The Committee also reviewed further data on the three centrally authorised pandemic influenza vaccines Celvapan, Focetria and Pandemrix and the antiviral Tamiflu.

Immunogenicity results following vaccination with Celvapan as observed in studies in both children and adults were reviewed by the CHMP. The Committee agreed that these results did not support a change from the current two-dose recommendation to a single-dose vaccination schedule. During the review of the new data, the Committee considered the variability seen in serological tests used to measure the patients' immune response after vaccination with Celvapan. The Committee will continue to discuss this issue with vaccination experts and has requested further analyses from the marketing authorisation holder. Once these data are fully analysed the Committee will conclude on this topic.

The Committee recommended updating the product information of Pandemrix to include additional data on the immunogenicity and safety in 3-to-9 year old children after the first half dose of Pandemrix that confirm the expected reactogenicity and immunogenicity profile. No changes are recommended for Focetria as data are still being assessed.

The Committee recommended updating the product information of Tamiflu with safety data in immunocompromised subjects. The Committee also adopted an opinion on compassionate use of an intravenous formulation of Tamiflu to treat critically ill patients having a life-threatening condition due to pandemic or seasonal influenza. This was the first opinion on compassionate use given by the European Medicines Agency.

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

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary. The most recent weekly pandemic influenza pharmacovigilance update report was published on 20 January 2010.

Notes

1. The recommended product information for Arepanrix is available here: http://www.ema.europa.eu/influenza/vaccines/arepanrix/arepanrix_pi.html and the summary of the assessment report is available here http://www.ema.europa.eu/influenza/vaccines/arepanrix/arepanrix.html

2. A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of Arepanrix this relates mainly to studies in children, adolescents and adults. The European Medicines Agency will review new information and update the product information as necessary.

3. For more information on the emergency procedure see here: http://www.ema.europa.eu/influenza/vaccines/authorisation_procedures.htm

4. For more details on the recommended changes for Pandemrix, please refer to the updated product information: http://www.ema.europa.eu/influenza/vaccines/pandemrix/pandemrix_pi.html

5. The latest approved product information for Celvapan is available here: http://www.ema.europa.eu/influenza/vaccines/celvapan/celvapan_pi.html

6. The latest approved product information for Focetria is available here: http://www.ema.europa.eu/influenza/vaccines/focetria/focetria_pi.html

7. For more details on the recommended changes for Tamiflu, please refer to the updated product information http://www.ema.europa.eu/influenza/antivirals/tamiflu/tamiflu_pi.html

8. The press release on the compassionate use of Tamiflu IV is available here http://www.ema.europa.eu/pdfs/human/compassionte_use/4243810en.pdf

9. More information on adverse reactions reported with centrally authorised pandemic medicines is provided in the weekly pandemic influenza pharmacovigilance update report: http://www.ema.europa.eu/influenza/updates.html

10. 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

11. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: http://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