



European Medicines Agency
Press Office

London, 24 February 2006
Doc. Ref. EMEA/35322/2006

Press release
European Medicines Agency receives second application for human pandemic influenza vaccine

The European Medicines Agency has received an application for a pandemic influenza vaccine, submitted by Chiron.

This is the second application to use the 'core dossier' approach, a novel European approach that allows the evaluation and approval of an application based on a 'mock-up vaccine' before the outbreak of a pandemic. Once the actual virus strain has been identified at the time of the outbreak of the influenza pandemic, a variation to the core dossier is submitted to incorporate that strain.

The EMEA introduced, in 2005, a number of incentives to encourage companies to use the core dossier approach. These include a commitment of the Agency's Committee for Medicinal Products for Human Use (CHMP) to accelerate the scientific evaluation of applications for scientific advice and marketing authorisations for pandemic influenza vaccines 'core dossiers', as well as fee waivers for scientific advice.

Work on pandemic influenza preparedness began in 2003 and the EMEA issued its draft pandemic influenza crisis management plan in 2005 for public consultation. The plan aims to establish efficient procedures for the assessment and authorisation of pandemic influenza vaccines via the centralised procedure and for surveillance of vaccines and antiviral medicines used in a potential pandemic.

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NOTES

1. The pandemic influenza crisis management plan is currently out for consultation and can be found at: <http://www.emea.eu.int/pdfs/human/vwp/39740305en.pdf>
2. Guidelines on the core dossier can be found here: <http://www.emea.eu.int/pdfs/human/vwp/471703en.pdf> and <http://www.emea.eu.int/pdfs/human/vwp/498603en.pdf>
3. A core summary of product characteristics for pandemic influenza vaccines was adopted in 2005 and can be found here: <http://www.emea.eu.int/pdfs/human/vwp/19303104en.pdf>
4. The EMEA review on influenza antiviral medicinal products for use in pandemics can be found here: <http://www.emea.eu.int/pdfs/human/pandemicinfluenza/33997205.pdf>
5. The EMEA received a pandemic influenza vaccine application previously. A press release can be found at: <http://www.emea.eu.int/pdfs/general/direct/pr/42591605en.pdf>.
6. In addition to preparations for pandemic influenza in humans, the Agency's Committee for Medicinal Products for Veterinary Use has recently published a reflection paper on avian influenza vaccine for emergency use in birds. The paper can be found here: <http://www.emea.eu.int/pdfs/vet/iwp/4685306en.pdf>
7. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.eu.int>

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