



European Medicines Agency
Press Office

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Press release
European Medicines Agency receives first pandemic influenza vaccine application

The European Medicines Agency has received the first application for a pandemic influenza vaccine, submitted by GlaxoSmithKline Biologicals.

The application uses 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 fee waivers for the evaluation of core dossiers and for scientific advice. The Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP), has also made a commitment to accelerate the scientific evaluation of applications for scientific advice and marketing authorisations for pandemic influenza vaccines 'core dossiers'.

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. 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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