European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency recommends the suspension of the marketing authorisation of Ionsys (fentanyl hydrochloride)

The European Medicines Agency (EMEA) has recommended the suspension of the marketing authorisation of Ionsys (fentanyl hydrochloride), from Janssen-Cilag International NV, because of a defect with the delivery system of the medicine that could lead to patients being overdosed.

Ionsys is a system for the transdermal delivery of fentanyl, an opioid analgesic. It has been authorised in the European Union (EU) since January 2006 and is indicated for the management in hospital of acute moderate to severe post-operative pain. The system is activated on demand by the patient in response to pain.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) was informed by the marketing authorisation holder, Janssen-Cilag International NV, that it had detected corrosion of a component of the system in one batch of Ionsys. This could trigger the self-activation of the system, which could lead to fentanyl overdose. This could subsequently cause respiratory depression, a life-threatening complication.

There have been no reports of serious adverse events associated with the malfunction of the device, in particular no reports related to self-activation of the system, or of overdose as a result. However, the marketing authorisation holder recalled all systems from the EU in September 2008 as a precautionary measure. As a consequence, Ionsys is unavailable and patients have been switched to alternative treatments.

The marketing authorisation holder has started a root-cause analysis of the defect, but has been unable to identify the cause of the defect. The company has also been unable to detect the defect with the quality control systems currently in place in the manufacturing and testing sites. In addition, the company's quality systems have been unable to resolve the problems with Ionsys and to prevent this quality defect occurring.

Because of this and the risks of fentanyl overdose, the CHMP has concluded that the benefits of Ionsys no longer outweigh its risks and has recommended the suspension of the marketing authorisation until the marketing authorisation holder can robustly demonstrate the quality of the product.

The CHMP opinion will now be sent to the European Commission for the adoption of a decision, applicable in all EU Member States.

--ENDS--

NOTES:

1. More information is available in a question-and-answer document.
2. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency
3. Ionsys has been marketed in 12 EU Member States (Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Luxembourg, the Netherlands, Slovenia, Sweden and the United Kingdom).

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4. The review of Ionsys was initiated under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated when there are public health concerns with a centrally authorised medicine.
5. More information on Ionsys is available in the European Public Assessment Report on the Agency's website at: http://www.emea.europa.eu/humandocs/Humans/EPAR/ionsys/ionsys.htm
6. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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