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Human Medicines Development and Evaluation

Public statement

Ionsys (fentanyl)

Non-renewal of the marketing authorisation in the European Union

On 24 January 2006 the European Commission granted a marketing authorisation for the whole European Union to Janssen-Cilag International N.V. for Ionsys (fentanyl), a iontophoretic transdermal system to deliver fentanyl transdermally, to be used for the management of acute moderate to severe post-operative pain for use in a hospital setting only.

In January 2009 the European Commission issued a decision for suspension of the marketing authorization of Ionsys for quality related issues. (see http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500014796.pdf)

Ionsys has not been marketed in Europe since October 2008.

The Marketing Authorisation Holder did not apply to renew the marketing authorisation.

Consequently, the five-year marketing authorization for Ionsys expired on 24 January 2011. Pursuant to this decision the European Public Assessment Report for Ionsys will be updated to reflect that the marketing authorisation is no longer valid.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu