European Medicines Agency

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PUBLIC STATEMENT ON

INFERGEN
(Interferon alfacon-1)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 1 February 1999 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Infergen, solution for injection, intended for the treatment of patients of 18 years and older with chronic hepatitis C virus and serum markers for hepatitis C virus (HCV) infection.

Infergen is currently marketed in Czech Republic, France, Germany and Italy. The Marketing Authorisation Holder responsible for this medicinal product is Astellas Pharma Europe B.V.

On 6 April 2006, the European Commission was notified by Astellas Pharma Europe B.V. of its decision to voluntarily withdraw the marketing authorisation for Infergen for commercial reasons. Therapeutic alternatives are available throughout the European Union, including alpha interferons, pegylated alpha interferons and ribavirin for use with (pegylated) alpha interferons in combination therapy.

On 5 May 2006 the European Commission issued, a decision to withdraw the marketing authorisation for Infergen. Pursuant to this decision the European Public Assessment Report for INFERGEN has been removed from the EMEA website.

The Marketing Authorisation Holder for Infergen will continue to be responsible for any remaining product on the market until the expiry date (November 2007) of the latest released batch in the European Union.

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