European Medicines Agency

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Public statement on the recommendation to lift the suspension of the marketing authorisation for Optison (perflutren)

On 18 May 1998, the European Commission granted a marketing authorisation (MA) valid throughout the European Union (EU) for the medicinal product Optison (perflutren). Optison is a diagnostic agent for the enhancement of contrast effect in echocardiography investigations. The manufacturing authorisation holder (MAH) is GE Healthcare AS.

The product is manufactured at Mallinckrodt Inc in the United States of America (USA). In November 2005, serious findings during an inspection of the manufacturing facility by the Food and Drug administration (FDA) led to the closure of the facility pending restoration of compliance with good manufacturing practice (GMP) at the site.

The Norwegian Medicines Agency, the competent authority supervising the import of Optison into the EU and European Economic Area, suspended parts of the manufacturing licence of the importer prohibiting further import.

In the context of the second renewal of the MA, the Committee for Medicinal Products for Human Use (CHMP) therefore recommended that the marketing authorisation for Optison be suspended until this situation was remedied. On 12 June 2008, the European Commission issued a Decision to suspend the marketing authorisation for Optison.

On 30 April 2008, the MAH informed the EMEA that the programme of improvement actions to the manufacturing process had been successfully completed. A positive re-inspection of the manufacturing site was carried out by the Norwegian Medicines Agency on 13 June 2008.

On 25 June 2009, following a request from the MAH, the CHMP recommended the lifting of the suspension of the marketing authorisation of Optison.

This recommendation was forwarded to the European Commission for the adoption of a decision.

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