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Human Medicines Development and Evaluation

Public statement on

Teslascan (mangafodipir)

Withdrawal of the marketing authorisation in the European Union

On 22 May 1997 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Teslascan (mangafodipir) for diagnostic use only. Contrast medium for diagnostic Magnetic Resonance Imaging (MRI) for the detection of lesions of the liver suspected to be due to metastatic disease or hepatocellular carcinomas. As an adjunct to MRI to aid in the investigation of focal pancreatic lesions.

The marketing authorisation holder (MAH) responsible for Teslascan was GE Healthcare AS. The European Commission was notified by a letter dated 4 May 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Teslascan for commercial reasons.

On 21 June 2012 the European Commission issued a decision to withdraw the marketing authorisation for Teslascan.

Pursuant to this decision the European Public Assessment Report for Teslascan will be updated to reflect that the marketing authorisation is no longer valid.

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