21 January 2014
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Public statement on

Docetaxel Teva Pharma

Cessation of validity of the marketing authorisation in the European Union

On 21 January 2014, the marketing authorisation for Docetaxel Teva Pharma (docetaxel) ceased to be valid in the European Union (EU). Docetaxel Teva Pharma is a generic medicinal product of Taxotere.

Docetaxel Teva Pharma was never marketed in the EU after its initial marketing authorisation in January 2011. In accordance with provisions of the sunset clause[1], the marketing authorisation of a medicinal product lapses if the product is not marketed in any of the EU Member States within three years of its initial authorisation.

There are other generic medicinal products of Taxotere authorised and marketed in the EU.

Docetaxel Teva Pharma was granted marketing authorisation in the EU on 21 January 2011 for the treatment of breast cancer, non-small cell lung cancer, and prostate cancer. The marketing authorisation holder was Teva Pharma B.V.

The European Assessment Report (EPAR) for Docetaxel Teva Pharma will be updated to reflect the fact that the marketing authorisation is no longer valid.

[1] Article 14(4) of Regulation (EC) No 726/2004 ('sunset clause')

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