EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Public statement

Docetaxel Mylan

Cessation of validity of the marketing authorisation in the European Union

On 31 January 2015, the marketing authorisation of Docetaxel Mylan (docetaxel) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, MYLAN S.A.S., had not marketed Docetaxel Mylan in the EU since its initial marketing authorisation in January 2012. In accordance with provisions of the sunset clause[1], the marketing authorisation of the medicinal product lapsed as the product had not been marketed in any of the EU Member States within three years of its initial authorisation.

MYLAN S.A.S. confirmed that the product had not been marketed due to commercial reasons.

Docetaxel Mylan was granted marketing authorisation in the EU on 31 January 2012 for treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer.

Docetaxel Mylan is a generic medicine of Taxotere. There are other generic medicinal products of Taxotere authorised and marketed in the EU.

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Report (EPAR) for Docetaxel Mylan will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact