15 March 2010
EMA/164498/2010
Press Office

Press release

Mylan S.A.S. withdraws its marketing authorisation application for Docetaxel Mylan (docetaxel)

The European Medicines Agency has been formally notified by Mylan S.A.S. of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product Docetaxel Mylan (docetaxel), 10mg/ml powder and solvent for solution for infusion.

The medicine was developed as a generic medicine to be used for breast cancer, non small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer. The reference medicinal product for Docetaxel Mylan is Taxotere, which has been authorised in the European Union since 1995.

The application for the marketing authorisation for Docetaxel Mylan was submitted to the Agency on 30 June 2009. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the application was withdrawn because the Committee considers that the data provided do not allow it to conclude on a positive benefit-risk balance.

More information about Docetaxel Mylan and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 15-18 March 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. A generic medicine is a medicine which is similar to a medicine that has already been authorised (the 'reference medicine'). Generic and reference medicines are used at the same dose to treat the same disease, and they are equally safe and effective.
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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