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Press Office

Press release

Sun Pharmaceutical Industries Europe B.V. withdraws its marketing authorisation application for Doxorubicin SUN

(doxorubicin hydrochloride)

The European Medicines Agency has been formally notified by Sun Pharmaceutical Industries Europe B.V. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Doxorubicin SUN (doxorubicin hydrochloride), 2 mg/ml concentrate for solution for infusion.

Doxorubicin SUN was originally intended to be used for treatment of breast cancer, ovarian cancer, progressive myeloma and AIDS-related Kaposi's Sarcoma. The application for Doxorubicin SUN was assessed as a 'hybrid generic' of Caelyx.

The application for the marketing authorisation for Doxorubicin SUN was submitted to the Agency on 5 February 2011. 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 its decision to withdraw the application was based on its inability to address the CHMP's major objections within the available timeframe.

More information about Doxorubicin SUN 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 in the second half of August 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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