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Human Medicines Development and Evaluation

Public statement on

Paxene (paclitaxel)

Withdrawal of the marketing authorisation in the European Union

On 19 July 1999 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Paxene, paclitaxel, which had been approved for the treatment of patients with:

- Advanced AIDS-related Kaposi's sarcoma (AIDS-KS) who have failed prior liposomal anthracycline therapy;
- Metastatic carcinoma of the breast (MBC) who have failed, or are not candidates for standard anthracycline containing therapy;
- Advanced carcinoma of the ovary (AOC) or with residual disease (> 1 cm) after initial laparotomy, in combination with cisplatin as first-line treatment;
- Metastatic carcinoma of the ovary (MOC) after failure of platinum containing combination therapy without taxanes as second-line treatment;
- Non-small cell lung carcinoma (NSCLC) who are not candidates for potentially curative surgery and/or radiation therapy, in combination with cisplatin. Limited efficacy data supports this indication.

The marketing authorisation holder (MAH) responsible for Paxene was Norton Healthcare Limited. The European Commission was notified by letter dated 26 October 2009 of the MAH's decision to voluntarily withdraw the marketing authorisation as of 1 March 2010 for Paxene for commercial reasons. Paxene was only marketed in France.

On 26 November 2009 the European Commission issued a decision to withdraw the marketing authorisation for Paxene. Pursuant to this decision the European Public Assessment Report for Paxene will be updated to reflect that the marketing authorisation is no longer valid.

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