EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): paclitaxel

Procedure No. EMEA/H/C/PSUSA/00002264/201812

Period covered by the PSUR: 27/12/2015 To: 27/12/2018

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Taking into account the PRAC Assessment Report on the PSUR(s) for paclitaxel, the scientific conclusions of CHMP are as follows:

Neuropathy is a known ADR with the use of paclitaxel. Review of the post-marketing data revealed that neuropathy can persist after discontinuation of paclitaxel treatment. Data from published literature and administrative claims databases confirmed the persistence of neuropathy with paclitaxel exposure beyond 12 months. Based on the data provided, it is recommended to update the current information on neuropathy in the SmPC, by adding information concerning persistent neuropathy after paclitaxel discontinuation.
Based on a cumulative review of data from all the MAHs, the causal role of paclitaxel for palmar-plantar erythrodysesthesia syndrome is at least a reasonable possibility. From the cases of palmar-plantar erythrodysesthesia syndrome and symptoms received by the MAHs, there were several cases with a positive dechallenge and with a positive rechallenge. In addition, palmar-plantar erythrodysesthesia syndrome associated with paclitaxel treatment has been reported in clinical trials and in the published literature. Therefore, the SmPC of paclitaxel should be updated with the inclusion of palmar-plantar erythrodysesthesia syndrome as an ADR in section 4.8 under SOC Skin and subcutaneous tissue disorders. A frequency of 'not known (cannot be estimated from available data)' is considered appropriate. The PL should be updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for paclitaxel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing paclitaxel is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.