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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): docetaxel

Procedure No. EMEA/H/C/PSUSA/00001152/201611

Period covered by the PSUR: 01 December 2013 to 30 November 2016

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Scientific conclusions

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

Injection site recall reaction (recurrence of skin reaction at a site of previous extravasation following administration of docetaxel at a different site) has been observed at the site of previous extravasation. Based on the data reviewed in this PSUR, the PRAC considers that a causal relationship between the injection site recall reaction and docetaxel is supported. Therefore, the PRAC concluded that the product information should be updated to include the adverse reaction “Injection site recall reaction” with a frequency unknown.

Hypersensitivity reactions have been reported with docetaxel in patients who previously experienced hypersensitivity reactions to paclitaxel. Patients who have previously experienced a hypersensitivity reaction to paclitaxel may be at risk to develop hypersensitivity reaction to docetaxel, including more severe hypersensitivity reaction. Based on the data reviewed in this PSUR, supported by the literature review, the PRAC considers that the product information should be updated in order to inform health care professional that these patients should be closely monitored during docetaxel therapy initiation and to include the adverse reaction hypersensitivity reaction with a frequency unknown.

Differences in the information related to the risk of potential effects of alcohol and interactions with other medicinal products have been observed in the docetaxel products information. The PRAC considers that the product information should be updated in order to reflect a common wording on this risk based on the latest QRD template, excipients guideline and information review during this PSUR.

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 docetaxel the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing docetaxel 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.