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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): cabazitaxel

Procedure No. EMEA/H/C/PSUSA/00000476/201506

Period covered by the PSUR: 18 June 2014 – 17 June 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for cabazitaxel, the scientific conclusions of CHMP are as follows:

A cumulative query in Eudravigilance database had retrieved several serious cases of interstitial lung disease (16 cases) and pneumonitis (8 cases). A fatal outcome was reported in 6 cases out of the 16 interstitial lung disease cases. In some patients who developed an interstitial lung disease /pneumonitis following a previous docetaxel treatment, an aggravation or a recurrence of the interstitial lung disease /pneumonitis was observed after cabazitaxel introduction (4 out of 16 interstitial lung disease cases). Among these 4 cases, 3 had a fatal outcome. Therefore, the PRAC considered that the sections 4.4 and 4.8 of the SmPC should be updated to include interstitial pneumonia/pneumonitis and interstitial lung disease. The package leaflet should be updated accordingly.

During the reporting period, a new signal “Pancytopenia/Bone marrow suppression” was detected following a request during the review of the additional precaution on anemia. According to cumulative tabulations, 7 serious bone marrow failure adverse drug reactions were reported during the reporting period, and 24 serious cases in total from post marketing sources. In addition, 3 cases of bone marrow failure or aplasia had a fatal outcome during the reporting period. All were unsolicited cases for which the marketing authorisation holder causality was “possible” for cabazitaxel. The PRAC therefore considered that the section 4.4 of the SmPC should be updated to add a warning on bone marrow suppression.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing cabazitaxel were warranted.

Based on the renewal procedure which was completed in November 2015 and after review of data on safety and efficacy, the PRAC considered that cabazitaxel should be removed from the list of products requiring additional monitoring.

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