EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: cabazitaxel

Procedure No. EMEA/H/C/002018/PSUV/0023

Period covered by the PSUR: 17 June 2013 to 17 December 2013

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Annex IV

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Scientific conclusions

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

The MAH performed a safety review of anemia as requested by the PRAC following the assessment of the last PSUR (PSUR 6). Of the 254 cases with associated anemia events, 130 cases recovered from 181 events; 24 cases were recovering from 31 events; 13 cases recovered from 19 events with sequelae; 1 case stabilized with 1 event of anemia; 31 cases did not recover from 39 events. 38 cases had an unknown outcome with 69 events. There were 18 cases with a fatal outcome and associated with 23 anemia pertaining events.

From this review, it appears that the occurrence of anemia is not confounded by concomitant treatments which could cause this adverse event. Therefore cabazitaxel appears to be causing those anemia events.

As a consequence the MAH has proposed with this PSUR to update section 4.4 of the SmPC to amend the current warning on the risk of anemia in patients treated with cabazitaxel in order to include that haemoglobin and haematocrit should be checked before treatment and in case of anemia symptoms or blood loss. This update to the cabazitaxel product information was supported by the PRAC.

Therefore, in view of available data regarding anaemia, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Jevtana, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance cabazitxel is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.