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Committee for Medicinal Products for Human Use (CHMP)

Dacogen

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

International non-proprietary name: DECITABINE

Procedure No. EMEA/H/C/002221/PSUV/0011

Period covered by the PSUR: 02 May 2013 to 01 November 2013

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Scientific conclusions

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

The MAH provided a cumulative review of the reports of caecitis, typhilitis and neutropaenic colitis events reported with Dacogen. 7 cases were discussed by the MAH in detail.

The PRAC acknowledged the confounding factors in some cases reported and known background occurrence of neutropenic enterocolitis in individuals with hematologic malignancies who are neutropenic and have a breakdown of gut mucosal integrity. Nevertheless, taking into account the possible causal association between decitabine administration and the development of caecitis / neutropenic colitis and due to the seriousness of the event (fatal issue reported for 5 out of the 7 cases), the PRAC considers that that changes to the product information are warranted to reflect the risk of enterocolitis, including neutropaenic colitis and caecitis in section 4.8 of decitabine EU SmPC and relevant section of the PL. 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 Dacogen, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance DECITABINE is favourable subject to the proposed changes to the product information.

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