18 December 2014
EMA/CHMP/34968/2015
Committee for Medicinal Products for Human Use (CHMP)

Vidaza

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

International non-proprietary name: azacitidine

Procedure No.: EMEA/H/C/000978/PSUV/0029

Period covered by the PSUR: 19 May 2013 – 18 May 2014

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Scientific conclusions

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

Upon request of regulatory authorities, the MAH performed a cumulative safety review of cases of necrotizing fasciitis (NF). The occurrence was 11 NF cases and 2 well documented literature reports, including 6 fatal cases. The data provided was supportive of a causal relation with azacitidine therapy; therefore the risk of necrotizing fasciitis should be included in the product information.

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 Vidaza, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance azacitidine is favourable subject to the proposed changes to the product information.

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