27 January 2022
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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): azacitidine

Procedure No. EMEA/H/C/PSUSA/00000274/202105

Period covered by the PSUR: 18 May 2018 To: 18 May 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

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

In view of available data on risk(s) from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between azacitidine and differentiation syndrome is at least reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing azacitidine should be amended accordingly.

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