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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/00000274/201805

Period covered by the PSUR: 19 May 2015 to 18 May 2018

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Scientific conclusions

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

Cumulatively, the safety database includes 51 cases with 56 events of pericarditis, myocarditis, and/or endocarditis reported with the use of Vidaza. Pericarditis is the most reported PT (n=35 cases) followed by endocarditis (n=10) and myocarditis (n=9). Although there are some confounding factors, e.g. underlying cancerous conditions of the patients and the presence of other risk factors such as infection and history of cardiac disorders, there are other factors that strengthen this signal, including positive re-challenge, and imbalance in the pooled clinical trials between active and control arms.

Therefore, based on the assessment of all available information for pericarditis, including spontaneous reports identified in the Safety Topic Review, the already listed ADR of pericardial effusion in the Vidaza SmPC and the fact that pericarditis is a listed term for some other products of the same class, the SmPC section 4.8 should be updated by including the term pericarditis under the SOC cardiac disorders with frequency 'uncommon'.

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 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.