26 March 2020
EMA/318994/2020
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): panobinostat

Procedure No. EMEA/H/C/PSUSA/00010409/201908

Period covered by the PSUR: 23 August 2018 – 22 August 2019

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Scientific conclusions

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

In view of available data from the literature regarding DNA damage in an *in vivo* dose-dependent molecular mechanisms study in murine bone marrow cells, the PRAC concluded that the existing wording in section 5.3 of the Summary of Product Characteristics of products containing panobinostat should be amended to include this information.

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