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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

Active substance: decitabine

Procedure No. EMEA/H/C/PSUSA/00009118/201605

Period covered by the PSUR: 2 May 2015 to 1 May 2016

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Scientific conclusions

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

The cumulative review on interstitial lung disease retrieved 3 cases of organising pneumonitis where a causal relationship with decitabine could not be excluded considering a compatible chronology of event onset, absence of alternative origin identified, and diagnosis confirmed by biopsy. In addition, the cumulative review identified 6 cases of interstitial lung disease (ILD) (broad term) of concerns. Based on this review and considering the events seriousness, the PRAC considered that the product information should be updated to add a warning on interstitial lung disease (including pulmonary infiltrates, organising pneumonia and pulmonary fibrosis). Careful assessment of patients with an acute onset or unexplained worsening of pulmonary symptoms should be performed to exclude ILD. If ILD is confirmed, appropriate treatment should be initiated. In addition, ILD (including pulmonary infiltrates, organising pneumonia and pulmonary fibrosis) should also be added in the description of selected adverse reactions of the summary of product characteristics and ILD should be added as an adverse reaction with a frequency not known.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing decitabine were warranted.

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