EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/562220/2016
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): eribulin

Procedure No. EMEA/H/C/PSUSA/00001254/201511

Period covered by the PSUR: 15 November 2014 – 14 November 2015

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Scientific conclusions

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

During a cumulative review of severe skin reaction events, three cases of Stevens-Johnson syndrome (SJS) were identified where a causal association is assessed as at least possible including two reports with reasonable time to onset and biopsy confirmed. All three cases included concomitant medications which list SJS and toxic epidermal necrolysis (TEN) as adverse events in the SmPC. However, considering the circumstances these drugs were considered less likely to have caused the events. Based on the three cases of SJS and the potentially life-threatening and severe consequences of the event SJS/TEN an update of section 4.8 of the SmPC is recommended.

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

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for eribulin the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing eribulin is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.