14 September 2017
EMA/818971/2017
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): carfilzomib

Procedure No. EMEA/H/C/PSUSA/00010448/201707

Period covered by the PSUR: 20 July 2016 - 19 January 2017

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Scientific conclusions

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

Following a request from the PRAC, the MAH provided a full assessment of all reported cases using the 'Hearing impairment' Standardized MedDRA Query (narrow). Review of the MAH's clinical trials and safety database retrieved a high number of cases of tinnitus. Considering the imbalance observed in completed randomized controlled trials, short last dose latency, plausible mechanism of action (accumulation of un-degraded, potentially sensorineural and ototoxic proteins) and a potential class effect with tinnitus listed as adverse drug reaction for bortezomib, the PRAC concluded that tinnitus should be added as a new adverse drug reaction with a frequency 'common' in section 4.8 of the SmPC and section 4 of Package Leaflet.

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