EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): ceftaroline fosamil

Procedure No. EMEA/H/C/PSUSA/00010013/201504

Period covered by the PSUR: 29 October 2014 – 28 April 2015

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Scientific conclusions

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

Temporal relationships with ceftaroline are noted in the majority of the 17 reported cases of eosinophilia, together with positive dechallenge specifically after ceftaroline withdrawal in 3 cases. Eosinophilia is a listed event for other cephalosporin antibacterials and the EU SmPC for ceftaroline already lists several blood dyscrasias including leucopenia, neutropenia and anaemia.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information 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 ceftaroline fosamil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ceftaroline fosamil is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.