23 June 2022
EMA/711450/2022
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): cefiderocol

Procedure No. EMEA/H/C/PSUSA/00010849/202111

Period covered by the PSUR: 13 November 2020 to 13 November 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on "blood urea increased", "blood creatinine increased" and "neutropenia" from clinical trials and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between cefiderocol and "blood urea increased", "blood creatinine increased" and "neutropenia" is at least a reasonable possibility. The PRAC concluded that the product information of products containing cefiderocol should be amended accordingly.

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