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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): tedizolid phosphate

Procedure No. EMEA/H/C/PSUSA/00010369/202006

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ANNEX IV

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE VARIATION TO THE TERMS OF THE MARKETING AUTHORISATION(S)

Scientific conclusions

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

In view of available data on thrombocytopenia from the literature and spontaneous reports, including 10 cases medically confirmed with a close temporal relationship and three possible positive de-challenges, the PRAC considered a causal relationship between tedizolid phosphate and thrombocytopenia is at least a reasonable possibility. Additionally, in 9 out of the 10 cases the event occurred with therapies longer than those recommended in the SmPC (6 days) and in 5 cases renal impairment was present (4 chronic of which 2 were in dialysis, and 1 acute renal impairment). The PRAC concluded that the product information of products containing tedizolid phosphate should be amended as follows:

Update section 4.4 of the SmPC to include that patients with renal impairment and those who receive treatment for longer than recommended are at higher risk to develop the event of thrombocytopenia and add a recommendation to minimise the risk.

Update of section 4.8 of the SmPC to add the adverse reaction thrombocytopenia under the frequency "unknown".

The Package leaflet is updated 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 tedizolid phosphate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tedizolid phosphate 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.