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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): lutetium (177Lu) oxodotreotide

Procedure No. EMEA/H/C/PSUSA/00010643/202112

Period covered by the PSUR: 20 December 2020 – 19 December 2021

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for lutetium (177Lu) oxodotreotide, the scientific conclusions of CHMP are as follows:

In view of the available data on hypersensitivity reactions from a cumulative review of hypersensitivity and anaphylactic reactions from post-marketing sources, the PRAC concluded that the product information of products containing lutetium (177Lu) oxodotreotide should be amended accordingly.

In view of the available data on angioedema from one case with positive rechallenge, the PRAC concluded that the product information of products containing lutetium (177Lu) oxodotreotide 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 lutetium (177Lu) oxodotreotide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lutetium (177Lu) oxodotreotide 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.