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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): edotreotide

Procedure No. EMEA/H/C/PSUSA/00010552/202112

Period covered by the PSUR: 8 December 2020 – 7 December 2021

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Scientific conclusions

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

Considering the available data from the literature on misinterpretation of PET imaging due to uptake of 68-Gallium edotreotide by splenosis and accessory intrapancreatic spleen, the PRAC considers a causal relationship with edotreotide is at least a reasonable possibility, in view of a plausible mechanism of action. The PRAC concluded that the product information of products containing edotreotide should be amended accordingly.

In view of available data from the literature on the potential for misinterpretation of PET imaging due to uptake of 68-Gallium labelled somatostatin analogues by reactive lymph nodes following vaccination including cases with a close temporal relationship to receipt of COVID-19 vaccination, the PRAC concluded that the product information of products containing edotreotide 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 edotreotide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing edotreotide 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.