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): lutetium (177Lu) chloride

Procedure No. EMEA/H/C/PSUSA/00010391/201912

Period covered by the PSUR: 19 December 2018 to 19 December 2019

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Scientific conclusions

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

In view of available data on extravasation from the literature and the existing warning on extravasation in the summary of product characteristics, and furthermore , considering the risk of radiation nephropathy and appropriate methods to detect renal disease from the literature and spontaneous reports, the PRAC concluded that the product information of products containing lutetium (^{177}Lu) chloride should be amended accordingly.
Furthermore, in view of available data on pancytopenia and neutropenia from the literature, studies and from spontaneous reports including in some cases a close temporal relationship and a plausible mechanism of action, and on xerostomia from studies and a plausible mechanism of action, the PRAC considers a causal relationship with lutetium (^{177}Lu) chloride is established and concluded that the product information of products containing lutetium (^{177}Lu) chloride 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 (^{177}Lu) chloride the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lutetium (^{177}Lu) chloride 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.