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/00010391/201806

Period covered by the PSUR: 20 December 2017 – 19 June 2018

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Scientific conclusions

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

A number of haematological malignancies, most notably myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) have been reported in clinical studies and in the literature with the use of Lutetium 177. Although patients had received prior chemotherapy in some studies and the clinical studies were mostly uncontrolled, there was no previous chemotherapy in other studies and the reporting frequency is generally consistent. The PRAC also notes that for other Lu-177 containing products, MDS and AML are considered adverse reactions with a frequency of common and uncommon, respectively. In conclusion, the PRAC considers that it would be important for HCPs and for patients to be appropriately informed as to the frequency of these tumours, as it may be a factor in a patient's decision whether or not to receive treatment. An update to the product information to appropriately reflect the frequency of these tumours is therefore recommended.

Two well documented cases of Lutetium 177 extravasation were reported in the literature during the reporting period. The SmPC for other Lutetium-containing products advises that in case of extravasation, the infusion should be immediately ceased. Overall, the PRAC considers that it would be important for HCPs to be reminded of the potential for extravasation and the need to immediately cease the infusion and to promptly implement measures to reduce the potential for harm. As a result, section 4.4 of the SmPC should be updated with the inclusion of a new warning on extravasation.

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) chloride the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lutetium (177Lu) 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.