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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: enfuvirtide

Procedure No. EMEA/H/C/PSUSA/00001217/201503

Period covered by the PSUR: 13 March 2014 – 12 March 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for enfuvirtide, the scientific conclusions of CHMP are as follows:

During routine signal detection activities, a review of five case reports of high level term amyloidosis cases related to enfuvirtide was extracted from Eudravigilance. The signal was considered potentially serious and the marketing authorisation holder performed a cumulative review of high level term amyloidosis. The information provided regarding the signal of local amyloidosis gives evidence based on two well documented cases that enfuvirtide as a peptide can cause cutaneous amyloidosis at the injection site. In view of the above, it is considered that cutaneous amyloidosis at the injection site should be reflected as an adverse reaction in the product information of Fuzeon.

Therefore, in view of available data regarding Fuzeon, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for enfuvirtide the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing enfuvirtide is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation should be varied.