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Committee for Medicinal Products for Human Use (CHMP)

Zaltrap

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

International non-proprietary name: aflibercept

Procedure No. EMEA/H/C/002532/PSUV/0009

Period covered by the PSUR: 4 August 2013 – 3 February 2014

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Scientific conclusions

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

Six out of 10 cases of medication errors concerned the omission of a micro-filter, the use of a micro-filter with a pore size other than 0.2 micron or use of a filter made of a material other than indicated in the SmPC. The number of cases reporting a medication error relating to filter use is relatively low. Information regarding the use of a filter, including its pore size and material, is currently included in section 4.2 of the SmPC. However, in order to target those involved in the reconstitution/preparation of the product for administration, this information is recommended to be moved from section 4.2 to section 6.6 of the SmPC and to include instead a cross reference to section 6.6 in section 4.2 of the SmPC.

Therefore, in view of available data regarding aflibercept regarding medication errors related to the filter use, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Zaltrap, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance aflibercept is favourable subject to the proposed changes to the product information.

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