EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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: enzalutamide

Procedure No. EMEA/H/C/PSUSA/00010095/201408

Period covered by the PSUR: 21 December 2013 – 30 August 2014

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Scientific conclusions

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

With regards to “rash”, due to the number of ICSRs detected on the cumulative review provided by the MAH, with a plausible temporal relationship, positive dechallenge and/or rechallenge and the increase of PTs containing “rash” presented in this PSUSA, the MAH is requested to include rash as an adverse reaction in the product information .

In addition, due to plausible temporal relationship between the drug exposure and onset of the events of “tongue oedema”, “lip oedema” and “pharyngeal oedema”, the MAH is requested the three as adverse reactions in the product information.

Due to the cumulative number of ICSRs of “nausea” detected (384) and that in the cumulative search performed by the MAH approximately 25 cases had a plausible temporal association between the event of nausea and enzalutamide, the MAH is requested to include nausea as an adverse reaction in the product information.

And finally, due to the number of cases of “vomiting” with positive dechallenge and rechallenge in some of them and the compatible timelines, the MAH is requested to include vomiting as an adverse reaction in the product information.

Therefore, in view of available data regarding enzalutamide, 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 enzalutamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing enzalutamide is favourable subject to the proposed changes to the product information.

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