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): sevelamer

Procedure No. EMEA/H/C/PSUSA/00002697/201510

Period covered by the PSUR: 31 October 2014 – 30 October 2015

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Scientific conclusions

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

During the reporting period, a total of 8 new cases of serious gastrointestinal disorders associated with the presence of sevelamer crystals were reported. In those cases, sevelamer crystals appeared to have been associated with several non-listed gastrointestinal events such as colitis, ulcer, necrosis and peritonitis. Further evidence is still needed to demonstrate that sevelamer crystals are the causal agent for the gastrointestinal disorders. However, given the seriousness of these events and the number of reported cases, the risk of formation of sevelamer crystals associated with serious gastrointestinal disorders was considered relevance to the prescriber.

Therefore, in view of the data presented in the reviewed PSURs, the PRAC considered that changes to the product information of medicinal products containing sevelamer hydrochloride and carbonate were warranted.

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 sevelamer the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sevelamer 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.