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: aliskiren, aliskiren/amlodipine, aliskiren/hydrochlorothiazide

Procedure No. EMEA/H/C/PSUSA/00000089/201409

Period covered by the PSUR: 1 October 2013 – 30 September 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for aliskiren / aliskiren, amlodipine / aliskiren, hydrochlorothiazide, the scientific conclusions of CHMP are as follows:

During the reporting a number of serious and non-serious adverse drug reactions (ADRs) from post-marketing data sources regarding “hyponatraemia” raised a concern that leading to the submission of a cumulative review from the Marketing Authorisation Holder (MAH). The cumulative review retrieved 187 cases out of which 57 were sufficiently documented, in 8 of these cases a causal relationship could not be ruled out. In 3 additional cases where severe hyponatremia was associated with neurological symptoms such as brain oedema or major confusion and cerebral oedema, causality could also not be excluded.

The MAH submitted an analysis with 1407 cases of “dyspnoea”, in 13 of them there was positive dechallenge and three cases with positive rechallenge. The PRAC considered the cases of dechallenge and rechallenge to be important causal relationship information that contributes to confirm the safety signal.

Therefore, in view of available data regarding aliskiren, aliskiren/amlodipine and aliskiren/ hydrochlorothiazide, 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 aliskiren / aliskiren, amlodipine / aliskiren, hydrochlorothiazide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing aliskiren / aliskiren, amlodipine / aliskiren, hydrochlorothiazide is favourable subject to the proposed changes to the product information

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