EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2013
EMA/CHMP/720313/2013
Committee for Medicinal Products for Human Use (CHMP)

Eklira Genuair

International non-proprietary name: aclidinium bromide

Procedure No. EMEA/H/C/002211/PSUV/0007

Period covered by the PSUR: 20 July 2012 to 20 January 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for Bretaris Genuair and Eklira Genuair, the scientific conclusions of PRAC are as follows:

There are no new data on efficacy and no new major safety concerns have been identified during the period of review.

There were a number of cases (8) reported where patients did not use the Genuair device correctly and where doses were missed as a result. Extensive instructions on correct use of the device are already included in the Patient Information Leaflet and SmPC. However, in contrast to the majority of inhaled COPD medications, the SmPC does not advise prescribers that patients should be instructed on the correct use of the device. Therefore, in view of the data regarding reports of patients not using the Genuair device correctly, 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(s)

On the basis of the scientific conclusions for Bretaris Genuair and Eklira Genuair the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing the active substance aclidinium bromide is favourable subject to the proposed changes to the product information.

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