



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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EMA/CHMP/709919/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Xoterna Breezhaler

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

International non-proprietary name: indacaterol / glycopyrronium bromide

Procedure No. EMEA/H/C/003755/PSUV/0005

Period covered by the PSUR: 19 September 2013 – 19 March 2014



## **Scientific conclusions**

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

The signals of angioedema and hypersensitivity were detected for products containing glycopyrronium and reviewed in a signal procedure. As a result, the PRAC considered that angioedema and hypersensitivity should be included as ADRs in the SmPC of glycopyrronium containing products. As hypersensitivity is already an ADR in the SmPC for indacaterol/glycopyrronium containing products, the PRAC endorsed the MAH's proposal for the inclusion of the ADR angioedema into the SmPC.

Therefore, in view of available data regarding angioedema, 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 Xoterna Breezhaler, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance indacaterol / glycopyrronium bromide is favourable subject to the proposed changes to the product information.

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