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EMA/CHMP/709901/2014
Committee for Medicinal Products for Human Use (CHMP)

Ultibro 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/002679/PSUV/0003

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Ultibro 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 Ultibro 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 should be varied.