20 February 2014
EMA/CHMP/68182/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Incruse

umeclidinium bromide

On 20 February 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Incruse, 55 µg, inhalation powder, pre-dispensed intended for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

The applicant for this medicinal product is Glaxo Group Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Incruse is umeclidinium bromide, a Drug for obstructive airway diseases (R03). The ATC code is not yet assigned. Umeclidinium bromide is a novel long acting muscarinic antagonist (LAMA) that exerts bronchodilatory activity by competitively inhibiting the binding of acetylcholine with muscarinic cholinergic receptors on airway smooth muscle.

The benefits with Incruse are its ability to improve the trough FEV1 (lung function endpoint) and to improve COPD symptoms as measured by TDI SGRQ score responders.

The most common side effects are nasopharyngitis and upper respiratory tract infection. An increased incidence of cardiovascular and cerebrovascular events that may occur with Incruse is a potential safety concern. Therefore cardiovascular and cerebrovascular events have been included as an important potential risk in the Risk Management plan and the applicant will conduct a post-authorisation safety study to further investigate this risk.

A pharmacovigilance plan for Incruse will be implemented as part of the marketing authorisation.

The approved indication is: "maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)." It is proposed that Incruse be prescribed by physicians.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Incruse and therefore recommends the granting of the marketing authorisation.