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Questions and answers on Kantos Master and associated names (beclomethasone dipropionate / formoterol fumarate, inhaler)

Outcome of a procedure under Article 13 of Regulation (EC) 1234/2008

On 17 January 2013, the European Medicines Agency completed an arbitration procedure for Kantos Master and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) had been asked to arbitrate on a requested change to the marketing authorisation for these medicines to include a new use as rescue therapy for acute relief of asthma symptoms. The Committee concluded that the benefits of Kantos Master outweigh its risks in the new use and the change to the marketing authorisation can be granted in Germany and the following Member States: Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Romania, Slovenia, Spain, Sweden and the United Kingdom.

What is Kantos Master?

Kantos Master is a medicine that contains two active substances: beclomethasone dipropionate, a corticosteroid (a medicine that reduces inflammation), and formoterol fumarate, a bronchodilator (a medicine that opens the airways, allowing easier breathing) with a long duration of action.

Kantos Master is used as maintenance therapy in patients who have asthma. It is inhaled once or twice a day, in order to keep asthma under control and reduce symptoms. If patients develop symptoms of asthma (wheezing and difficulty breathing) inhalation of a separate bronchodilator medicine with a rapid onset and short duration of action is advised for relief (rescue therapy).

Kantos Master is marketed in all EU Member States except Czech Republic, Ireland, Malta Portugal and Slovakia under the names Kantos, Formodual, Foster, Inuxair, Innovair and associated names. The company that makes the medicine is Chiesi.

Why was Kantos Master reviewed?

Kantos Master is authorised under a mutual recognition procedure based on an initial authorisation granted by Germany. In December 2011, the company applied for an additional use in Germany. The company wanted the authorisation to be recognised in the following Member States: Austria, Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Lithuania,

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Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom (the 'concerned Member States'). The application was for the use of Kantos Master for both maintenance therapy of asthma and for relief of symptoms when they arise instead of the use of a separate short-acting bronchodilator (maintenance and reliever therapy, or MART).

However, the Member States were unable to reach agreement on whether to accept this indication for Kantos Master. On 13 December 2012, Germany referred the matter to the CHMP for arbitration.

The grounds for the referral were the concerns of Sweden that the data on Kantos Master submitted in the application were not sufficient to demonstrate its effectiveness for MART. In particular, in the main study comparing the use of Kantos Master for MART versus maintenance treatment with Kantos Master plus a short-acting bronchodilator given for relief, there were concerns that the comparison group might not have been receiving adequate maintenance treatment, which could have made the results in the MART group look better than they really were.

What are the conclusions of the CHMP?

The Committee looked at the study presented by the company to support its application.

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP agreed that Kantos Master has been shown to reduce the risk of severe exacerbation of asthma and prolong the time between exacerbations when part of the dose is given on an as-needed basis as MART. The CHMP noted that MART was not compared with the standard of care according to current guidelines, but agreed that there was no evidence that patients in the comparison group had been undertreated, as patients in both groups had shown clinical benefit from their maintenance treatment. It also took note of relevant literature supporting the principle of using such a combination of corticosteroid and long-acting bronchodilator (beclometasone and formoterol) for MART.

The CHMP therefore concluded that the benefits of Kantos Master for MART outweigh its risks and recommended that the marketing authorisation be granted in Germany and the concerned Member States.

The European Commission issued a decision on 10 April 2013.