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Questions and answers on Flutiform and Iffeza (fluticasone propionate/formoterol fumarate, 50/5, 125/5 and 250/10 micrograms, pressurised inhalation, suspension)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

On 19 April 2012, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicines Flutiform and Iffeza and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Flutiform and Iffeza outweigh the risks, and that the marketing authorisation can be granted in the United Kingdom and in the following Member States of the EU: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia and Sweden.

What are Flutiform and Iffeza?

Flutiform and Iffeza are asthma medicines containing two active substances, fluticasone propionate and formoterol fumarate. They are to be used for the treatment of asthma in situations where the combination of an inhaled corticosteroid (such as fluticasone propionate) and a long-acting beta 2 agonist (such as formoterol fumarate) is appropriate.

Fluticasone propionate is an inhaled corticosteroid with high local anti-inflammatory activity and has been shown to reduce symptoms of asthma and reduce exacerbations of asthma.

The selective long-acting beta 2 agonist formoterol fumarate exerts an effect on beta 2 receptors on the smooth muscle in the lung to produce relaxation of the airways and bronchodilatation. When inhaled, formoterol fumarate helps to keep the airways open allowing the patient to breathe more easily.

Flutiform will also be marketed as Flofera and Flutiformo.

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Why were Flutiform and Iffeza reviewed?

Napp Pharmaceuticals Ltd submitted marketing authorisation applications for Flutiform and Iffeza and associated names to the UK medicines regulatory agency under the decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the UK) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia and Sweden).

However, the Member States were not able to reach an agreement and the UK referred the matter to the CHMP for arbitration on 22 December 2011.

The grounds for the referral were concerns raised by The Netherlands over data showing that the levels of fluticasone propionate in the blood following dosing with Flutiform and Iffeza are lower than when fluticasone propionate is given alone, which may indicate a lower amount of fluticasone propionate being deposited in the lungs. In the light of this The Netherlands questioned the long-term efficacy of this product in respect of asthma control.

What are the conclusions of the CHMP?

The CHMP looked at all the available evidence on the benefits and risks of the medicine in the treatment of asthma and concluded that the questions raised over its long-term effectiveness had been adequately addressed. Therefore, the Committee concluded that the benefits of Flutiform and Iffeza outweigh the risks and that marketing authorisation should be granted in all concerned Member States.

The European Commission issued a decision on 28 June 2012.