European Medicines Agency

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Questions and answers on the referral for Sanohex salbutamol, metered dose aerosol inhaler, 100 µg/dose

The European Medicines Agency (EMEA) has completed a referral procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Sanohex. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Sanohex outweigh its risks, and that the marketing authorisation can be granted in Sweden as well as in the following Member States of the European Union: Austria, Germany, Ireland and Spain.
The review was carried out under an 'Article 29' referral[1].

What is Sanohex?

Sanohex is a medicine in a pressurised inhaler that contains salbutamol as active substance. Salbutamol is a beta2-adrenergic receptor agonist. This means that salbutamol activates the beta2-receptors in the body. When given by inhalation as in Sanohex, salbutamol directly activates the beta2-receptors in the respiratory system. This makes the airways widen, allowing the air to flow more freely.
Sanohex is used to treat the breathing difficulties caused by asthma and chronic obstructive pulmonary disease (COPD). It can also be used to prevent asthma symptoms caused by exercise or other triggering factors, such as house dust, pollen, cats, dogs and cigarette smoke. Sanohex is used to relieve symptoms, and its use should not delay the use of inhaled steroids.
Sanohex is a 'generic medicine'. This means that Sanohex is similar to a 'reference medicine' already authorised in the European Union (EU) called Sultanol inhaler.

Why was Sanohex reviewed?

Hexal AG submitted Sanohex to the Swedish medicines regulatory agency for a decentralised procedure on 5 December 2006. This is a procedure when one Member State (the 'reference Member State', in this instance Sweden) assesses a medicine with a view of 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, Germany, Ireland and Spain). These member states were not able to reach an agreement. On 4 March 2008, the Swedish medicines regulatory agency referred the matter to the CHMP.

The grounds for the referral were concerns regarding that there was not enough data showing that Sanohex is equivalent to the reference medicine. Concerns were also raised regarding how to store the inhaler and the effect of the orientation of the inhaler on the delivery of the medicine.

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Sanohex outweigh its risks, and that therefore the marketing authorisation for Sanohex should be granted in all concerned member states.

The European Commission issued a decision on 12 March 2009.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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