European Medicines Agency

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Questions and answers on the referral for Budesonide Sandoz nasal suspension with 32 or 64 microgram per spray

The European Medicines Agency (EMEA) has completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Budesonide Sandoz. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Budesonide Sandoz outweigh its risks, and the marketing authorisation can be granted in Germany and in the following Member States of the European Union, the Czech Republic, Denmark, France, the Netherlands, Norway, Sweden and the United Kingdom. The review was carried out under an 'Article 29' referral[1].

What is Budesonide Sandoz?
Budesonide Sandoz is an anti-inflammatory medicine. It is used to treat and prevent the symptoms of seasonal allergic rhinitis (allergy to pollen, also known as hayfever) and perennial allergic rhinitis (when the allergy is due to other triggers, such as house dust or animals). It can also be used to treat nasal polyps (growths in the lining of the nose).

The active substance, budesonide, is a corticosteroid, which is a type of substance that helps to reduce inflammation.

Budesonide Sandoz is almost identical to another medicine authorised in the European Union, Rhinocort. The only difference is that it contains very small amounts of ascorbic acid (an anti-oxidant).

Why was Budesonide Sandoz reviewed?
Sandoz Pharmaceuticals GmbH submitted Budesonide Sandoz to the German medicines regulatory agency for a decentralised procedure. This is a procedure when one Member State (the 'reference Member State', in this instance Germany) 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 the Czech Republic, Denmark, France, the Netherlands, Norway, Sweden and the United Kingdom). However, the Member States were not able to reach an agreement and the German medicines regulatory agency referred the matter to the CHMP for arbitration on 4 August 2008.

The grounds for the referral were a disagreement among Member States on the use of the medicine in adolescents and children (over 6 years of age). The German authorities recommended that the medicine should not be authorised for use in children, as no studies had been carried out in this age group. However, another Member State, the Netherlands, recommended that the medicine should also be authorised for use in children, as the medicine on which it is based, Rhinocort, can be used in this population.

[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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What are the conclusions of the CHMP?
Based on evaluation of the currently available data, including the studies carried out to compare the way Budesonide Sandoz is handled by the body to that of Rhinocort, and the scientific discussion within the Committee, the CHMP concluded that the benefits of Budesonide Sandoz outweigh its risks, and that therefore the marketing authorisation for Budesonide Sandoz should be granted in all concerned Member States for patients aged from 6 years. The CHMP also recommended that the product information for the medicine in Germany be amended. The amended information to healthcare professionals and patients is available here.

The European Commission issued a decision on 7 May 2009.

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