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Refusal of marketing authorisation for Budesonide Sun (budesonide, nebuliser suspension)

On 25 June 2020, after re-examining its initial opinion, the European Medicines Agency confirmed its recommendation that the marketing authorisation of Budesonide Sun and associated names cannot be granted in the Netherlands or in other Member States of the EU where the company has applied for a marketing authorisation (Germany, Italy, Poland, Spain and Sweden), or the United Kingdom.

The Agency had issued its initial opinion on 27 March 2020. The company that applied for marketing authorisation of Budesonide Sun was Sun Pharmaceutical Industries Europe B.V.

What is Budesonide Sun?

Budesonide Sun is a medicine that was to be used to treat asthma in adults and children in whom a hand-held inhaler did not adequately control their asthma, suspected asthma in children aged 6 months to 4 years, and serious croup (a viral infection of the upper airways in children) that requires a stay in hospital.

Budesonide Sun contains the active substance budesonide, which belongs to a group of anti-inflammatory medicines known as corticosteroids. It was to be available as a suspension (250, 500 or 1,000 micrograms / 2 ml) given by inhalation through a nebuliser device.

Budesonide Sun was developed as a generic medicine. This means that Budesonide Sun was developed to contain the same active substance and work in the same way as a 'reference medicine' already authorised in some EU countries called Pulmicort Respules. For more information on generic medicines, see the question-and-answer document here.

Why was Budesonide Sun reviewed?

Sun Pharmaceutical Industries Europe B.V. submitted Budesonide Sun to the Netherlands for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the Netherlands) 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 where the company has applied for a marketing authorisation (the 'concerned Member States', in this instance Germany, Italy, Poland, Spain and Sweden), as well as the United Kingdom.

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However, the Member States were not able to reach an agreement and the Dutch medicines regulatory agency referred the matter to EMA for arbitration on 27 September 2019.

The grounds for the referral were concerns raised by the United Kingdom and Italy that the laboratory data submitted to support the application were not sufficient to show that Budesonide Sun is equivalent to Pulmicort Respules. In particular, the company did not demonstrate that the amount of active substance delivered by nebulisation with Budesonide Sun is equivalent to that of the reference medicine, and therefore that the medicine would have the same therapeutic effect.

What is the outcome of the review?

Based on the evaluation of the currently available data, the Agency concluded that equivalence to the reference medicinal product has not been shown. The Agency therefore concluded that the benefits of Budesonide Sun do not outweigh its risks and recommended that the marketing authorisation should not be granted in the concerned Member States. The initial refusal was confirmed after re-examination.

More about the procedure

The review of Budesonide Sun was initiated on 27 September 2019 at the request of the Netherlands, under Article 29(4) of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision on the marketing authorisation of Budesonide SUN on 19 August 2020.