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EMA recommends authorisation of Ibuprofen Kabi (ibuprofen, 400 mg solution for infusion) in the EU

On 23 July 2020, the European Medicines Agency completed a review of Ibuprofen Kabi following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Ibuprofen Kabi outweigh its risks, and the marketing authorisation can be granted in Germany and in other Member States of the EU where the company has applied for a marketing authorisation (Austria, Belgium, Czechia, Hungary, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain) as well as the United Kingdom.

What is Ibuprofen Kabi?

The active substance in Ibuprofen Kabi, ibuprofen, is a non-steroidal anti-inflammatory drug (NSAID) and has been used since the 1960s as a painkiller and anti-inflammatory medicine. It works by blocking an enzyme called cyclo-oxygenase, which produces prostaglandins, substances that are involved in the inflammation process. By reducing the production of prostaglandins, Ibuprofen Kabi is expected to reduce fever and pain linked to inflammation.

Ibuprofen Kabi was developed as a hybrid medicine. This means that it was developed to be similar to a 'reference medicine' containing the same active substance but is given in a different way. While the reference medicine Espidifen 400 mg is available as granules for oral solution, Ibuprofen Kabi is to be given as an intravenous injection (into a vein).

Why was Ibuprofen Kabi reviewed?

Fresenius Kabi Deutschland GmbH submitted Ibuprofen Kabi to the German medicines agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Germany) 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, Czechia, Hungary, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain) as well as the United Kingdom where the company has applied for a marketing authorisation.
However, the Member States were not able to reach an agreement and the Netherlands referred the matter to EMA for arbitration on 16 March 2020.

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The applicant presented results from a comparison of quality aspects of other authorised intravenous ibuprofen solutions, and data from the literature on the pharmacokinetics (how a medicine is absorbed, modified and removed from the body) as well effectiveness and safety of intravenous ibuprofen.

The grounds for the referral were that the company had not provided the required data comparing Ibuprofen Kabi with Espidifen.

What is the outcome of the review?

Based on the evaluation of the available data, the Agency concluded that the data provided are sufficient to support the safety and effectiveness of Ibuprofen Kabi. The Agency therefore concluded that the benefits of Ibuprofen Kabi outweigh its risks and recommended that the marketing authorisation be granted in the concerned Member States.

More about the procedure

The review of Ibuprofen Kabi was initiated on 16 March 2020 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.

A European Commission decision valid throughout the EU was issued on 15 October 2020.