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EMA recommends refusal of authorisation for Lidocain/Prilocain Idetec and associated names (lidocaine/prilocaine cream)

On 14 October 2021, the European Medicines Agency completed a review of Lidocain/Prilocain Idetec and associated names following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Lidocain/Prilocain Idetec could not be shown to outweigh its risks, and the marketing authorisation could not be granted in Denmark or in the other Member State of the EU where the company has applied for a marketing authorisation (in this case, the Netherlands).

In November 2021 EMA started a re-examination of its opinion at the request of the company; however, the re-examination procedure was stopped as the applicant decided to withdraw its application for marketing authorisation.

What is Lidocain/Prilocain Idetec?

Lidocain/Prilocain Idetec is a cream to be applied to the skin and genital area to prevent pain during minor surgical or medical procedures, and for the treatment of leg ulcers. It contains the active substances lidocaine and prilocaine, which are local anaesthetics that are absorbed through skin or the membranes of the genitals to numb the nerves in the area and prevent pain.

The marketing authorisation application for Lidocain/Prilocain Idetec was a hybrid application.[2] This means that the developer asked for it to be authorised on the basis that it was equivalent to a 'reference medicine' containing the same active substances in a complex cream formulation. The reference medicine for Lidocaine/Prilocain Idetec is EMLA 5% cream.

Why was Lidocain/Prilocain Idetec reviewed?

International Drug Development submitted Lidocain/Prilocain Idetec to the Danish Medicines Agency (Lægemiddelstyrelsen) for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Denmark) 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

[1] This Q&A document was updated on 28 January 2022 to mention the applicant's decision to withdraw their marketing authorisation application
[2] Article 10(3) of Directive 2001/83/EC

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'concerned Member States', in this instance the Netherlands) where the company has applied for a marketing authorisation.

However, the Member States were not able to reach an agreement and Denmark referred the matter to EMA for arbitration on 5 March 2021.

The grounds for the referral were the concerns of the Netherlands that equivalence between the therapeutic effect of Lidocain/Prilocain Idetec and that of its reference product, EMLA cream, had not been established based on the studies and references to the scientific literature that had been provided.

What is the outcome of the review?

Lidocain/Prilocain Idetec is a cream with a local action on the areas to which it is applied. In a hybrid application evidence has to be provided to show that the medicine is equivalent to the reference product, and so will have the same effects. Although the company provided data from a study under laboratory conditions and a clinical study in children, as well as information from scientific literature, EMA's human medicines committee (CHMP) considered that the data provided were not sufficient to allow it to conclude on equivalence of effect.

Based on evaluation of the currently available data, the Agency therefore concluded that the benefits of Lidocain/Prilocain Idetec and associated names do not outweigh its risks, and that the marketing authorisation should not be granted in Denmark or the Netherlands.

More about the procedure

The review of Lidocain/Prilocain Idetec and associated names was initiated on 25 March 2021 at the request of Denmark, 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 CHMP opinion was forwarded to the European Commission, which issued a final decision valid throughout the EU on 28 March 2022.