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Questions and answers on Alcover granules (sodium oxybate 750, 1250 and 1750 mg)

Outcome of re-examination of procedure under Article 29(4) of Directive 2001/83/EC

On 22 June 2017, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of Alcover granules. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Alcover granules did not outweigh their risks, and the marketing authorisation could not be granted in Austria or in the following Member States of the EU: Denmark, Finland, France, Ireland, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom.

The company requested a re-examination of the initial opinion. After reviewing the grounds for this request, the CHMP re-examined the opinion and confirmed on 12 October 2017 that the marketing authorisation could not be granted.

What are Alcover granules?

Alcover granules are a medicine that was expected to be used to treat acute alcohol withdrawal syndrome and to support medium to long-term abstinence in alcohol-dependent adults with a very high level of alcohol consumption. The active substance in Alcover granules, sodium oxybate, attaches to receptors (targets) on nerve cells of the brain and spinal cord for a substance called gamma-aminobutyric acid (GABA), leading to a calming of the activity of these cells. Since it targets these receptors in the same way as alcohol, Alcover granules were to be used to treat the effects of stopping alcohol use in alcohol-dependent patients, including agitation, tremor (shaking) and problems sleeping, and to support continued abstinence.

Alcover syrup is available in Austria and Italy.

Why were Alcover granules reviewed?

Debrégeas & Associés Pharma submitted a marketing authorisation application for Alcover granules to the Austrian medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Austria) assesses a medicine with a view to granting a marketing authorisation that will be valid nationally as well as in other Member States

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(the ‘concerned Member States’, in this instance Denmark, Finland, France, Ireland, the Netherlands, Poland, Portugal, Spain, Sweden and the United Kingdom).

However, the Member States were not able to reach an agreement and the Austrian medicines regulatory agency referred the matter to the CHMP for arbitration on 22 December 2016.

The grounds for the referral were concerns raised by several Member States that the benefits of Alcover granules were not clearly demonstrated and there were various risks including the risk of dependence, misuse and side effects.

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 data submitted in support of the marketing authorisation application for Alcover granules were insufficient and of inadequate quality to demonstrate that the medicine would be effective in the proposed uses. Risk minimisation measures were proposed for the known risks. However, the CHMP concluded that, since the benefits of Alcover granules were not clearly demonstrated, the marketing authorisation could not be granted in the reference and concerned Member States.

After re-examination, the CHMP confirmed its initial opinion that the marketing authorisation could not be granted. The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 18/12/2017.

This decision only concerns the marketing authorisation application for Alcover granules and does not affect Alcover syrup.