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EMA recommends authorisation of Rambis (ramipril / bisoprolol) in the EU

On 15 December 2022, the European Medicines Agency completed a review of Rambis following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Rambis outweigh its risks, and marketing authorisation should be granted in Poland and in the other Member States of the EU where the company has applied for a marketing authorisation (Czechia and Slovakia).

What is Rambis?

Rambis is a medicine for patients with certain long-term heart conditions and high blood pressure in whom these conditions are well controlled by a combination of two medicines called ramipril and bisoprolol.

Rambis contains both ramipril and bisoprolol and is intended as a replacement for patients taking these medicines separately. Patients taking Rambis will have ramipril and bisoprolol at the same dose and schedule as before.

Why was Rambis reviewed?

Adamed Pharma S.A. submitted a marketing authorisation application for Rambis to the Polish medicines regulatory agency for evaluation under a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Poland) 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 Czechia and Slovakia) where the company has applied for a marketing authorisation.

However, the Member States were not able to reach an agreement and the Polish medicines regulatory agency referred the matter to EMA for arbitration on 22 June 2022.

The grounds for the referral were concerns from the medicines agency in Czechia that the company had not complied with the relevant guideline for combination medicines. The parts of the guideline at issue were those requiring the company to show how each of the active substances contributes to the

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medicine's overall effects and to show that the benefits of the combination outweigh the risks for all strengths and uses.

What is the outcome of the review?

Based on the evaluation of all the available data, the Agency concluded that there is sufficient evidence to support the use of the ramipril and bisoprolol combination. Furthermore, having both substances in the same medicine will benefit patients who need them.

The Agency therefore concluded that the benefits of Rambis outweigh its risk and recommended that marketing authorisation be granted in all concerned Member States.

More about the procedure

The review of Rambis was initiated on 22 June 2022 at the request of Poland 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 Rambis on 15 February 2023.