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EMA recommends authorisation of Micrazym (porcine pancreas enzymes) in the EU

On 21 March 2024, the European Medicines Agency completed a review of Micrazym following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Micrazym outweigh its risks, and the marketing authorisation should be granted in the Netherlands and in the Member States of the EU where the company has applied for a marketing authorisation: Austria, Belgium, Cyprus, Czechia, Denmark, Finland, Germany, Ireland, Luxembourg, Norway, Slovakia, Spain and Sweden.

What is Micrazym?

Micrazym is a medicine used to treat adults, adolescents and children whose pancreas does not produce enough enzymes (a condition known as pancreatic insufficiency) due to cystic fibrosis or other conditions affecting pancreatic function. Pancreas enzymes are needed to digest fats, carbohydrates and proteins.

The medicine is available in gastro-resistant capsules to be taken by mouth. Gastro-resistant means that the capsule's contents pass through the stomach without being broken down until they reach the intestine. This prevents the active substance from being destroyed by acid in the stomach.

The active substance in Micrazym is a mix of porcine (pig) pancreas enzymes, which is a well-known substance that has been authorised in the treatment of pancreatic insufficiency for more than 10 years.

Why was Micrazym reviewed?

Avva Pharmaceuticals Ltd. submitted a marketing authorisation application for Micrazym 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 (the 'concerned Member States', in this instance Austria, Belgium, Cyprus, Czechia, Denmark, Finland, Germany, Ireland, Luxembourg, Norway, Slovakia, Spain and Sweden), where the company has applied for a marketing authorisation.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

However, the Member States were not able to reach an agreement and the Dutch medicines agency referred the matter to EMA for arbitration on 21 December 2023.

The main grounds for the referral were concerns raised by the Spanish and German medicines agencies regarding the evidence provided by the company to show that the medicine behaves in the same way as an authorised medicine called Creon which also contains porcine pancreas enzymes in gastro-resistant capsules and for which adequate data on safety and efficacy are documented in the literature.

The company provided results from *in vitro* (laboratory) studies to measure how both medicines dissolve (which, among other things, affects how the medicines behave in the body), and compared these results with those for similar authorised medicines. Spain and Germany considered that this approach was not in line with relevant guidelines and that the data presented were not sufficient to demonstrate that Micrazym will behave as expected in the intestine.

What is the outcome of the review?

Based on the evaluation of the currently available data, the Agency considered that there is sufficient evidence to show that the release of Micrazym in the intestines will be comparable to that of Creon.

Although the excipients (ingredients) used in Micrazym to make it gastro-resistant differ in some aspects from those in Creon, they are comparable to those in other similar medicines described in the literature. In addition, the laboratory data show that, as for similar medicines, Micrazym is not broken down at acidity levels usually expected in the stomach and that the medicine is released at the level of acidity usually expected in the intestine.

The Agency therefore concluded that the benefits of Micrazym in the treatment of pancreatic insufficiency outweigh its risks, and the marketing authorisation for Micrazym should be granted in all concerned Member States.

More about the procedure

The review of Micrazym was initiated on 25 January 2024 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 Micrazym on 16 May 2024.