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EMA recommends authorisation of Gelisia (timolol, eye gel) in the EU

On 15 December 2022, the European Medicines Agency completed a review of Gelisia following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Gelisia outweigh its risks, and the marketing authorisation should be granted in the Netherlands and in the following Member States of the EU: France, Germany, Italy, Romania and Spain.

What is Gelisia?

Gelisia is an eye gel that is used to reduce pressure inside the eye in adults who have ocular hypertension (when the pressure in the eye is higher than normal) or open-angle glaucoma (a disease where the pressure in the eye rises because fluid cannot drain out of the eye).

The marketing authorisation application for Gelisia is a hybrid application. 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 substance in a gel formulation. The reference medicine for Gelisia is Geltim.

Gelisia contains the active substance timolol maleate.

Why was Gelisia reviewed?

The applicant for Gelisia, SIFI S.p.A., submitted an application 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 France, Germany, Italy, Romania and Spain) where the company has applied for a marketing authorisation.

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

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

The grounds for the referral were concerns raised by Spain. The Spanish medicines regulatory agency considered that additional testing and further statistical analyses of the results should have been carried out by the company to demonstrate that Gelisia and the reference medicine have similar viscosity (consistency of the gel) and equivalent therapeutic effects.

What is the outcome of the review?

The European Medicines Agency reviewed the totality of the data provided by the company, including additional statistical analyses that confirmed that the medicines have similar viscosity. The Agency considered that the data provided were sufficient to demonstrate that Gelisia and the reference medicine have equivalent therapeutic effects.

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

More about the procedure

The review of Gelisia was initiated on 10 November 2022 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 Gelisia on 27 February 2023.