29 May 2019
EMA/299749/2019
EMEA/H/A-29(4)/1472

EMA recommends authorisation of Syner-Kinase (urokinase) in the EU

EMA completes review following disagreement among EU Member States

On 28 February 2019, the European Medicines Agency completed a review of Syner-Kinase and associated names following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Syner-Kinase outweigh its risks, and the marketing authorisation granted in the United Kingdom can be recognised in other Member States of the EU where the company has applied for a marketing authorisation.

What is Syner-Kinase?

Syner-Kinase is a medicine used to dissolve blood clots in the lungs, in deep veins, in arteries in the arms, hands, legs and feet, or in catheters or cannulae (surgical tubes) placed in a vein. Syner-Kinase contains the active substance urokinase, a natural enzyme that helps to dissolve blood clots in the body.

Why was Syner-Kinase reviewed?

The marketing authorisation holder, Syner-Medica Ltd, requested that the marketing authorisation for Syner-Kinase granted in the UK on 29 September 2006 be recognised in France, Germany, the Netherlands and Spain (the 'concerned Member States'). However, the Member States were not able to reach an agreement and the UK medicines agency referred the matter to EMA for arbitration on 5 July 2018.

The grounds for the referral were concerns that the data provided by the company, which included published data on other urokinase-containing medicines, were not sufficient to demonstrate that the benefits of Syner-Kinase outweigh its risks. Concerns were also raised regarding the manufacturing and purification processes for the active substance urokinase, which is extracted from human urine.

What is the outcome of the review?

Having reviewed the available data, EMA considered that Syner-Kinase is comparable to the urokinase products mentioned in the published literature, and that the data are adequate to support its proposed use. The Agency also considered that the data provided by the company show that the purification process is suitable for the removal of possible viral and prion impurities. Finally, the company

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

demonstrated that the production of the semi-purified urokinase (an intermediate step in the production of the active substance) is adequately controlled, and that this intermediate is manufactured at a site that complies with the principles and guidelines of Good Manufacturing Practice (GMP).

Therefore, based on the evaluation of the available data, the Agency concluded that the benefits of Syner-Kinase outweigh its risks, and that the marketing authorisation for Syner-Kinase should be granted in all concerned Member States.

More about the procedure

The review of Syner-Kinase was initiated on 26 July 2018 at the request of the United Kingdom, 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.

A European Commission decision valid throughout the EU was issued on 16/05/2019.