25 June 2026
EMADOC-1700519818-3264389
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vyndaqel

tafamidis

On 25 June 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Vyndaqel. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted a new pharmaceutical form, 61 mg film-coated tablets, in addition to the already authorised 20 mg and 61 mg soft capsules.

The indication for the new film-coated tablets will be as follows:

> Vyndaqel is indicated for the treatment of wild-type transthyretin amyloidosis in adult patients with cardiomyopathy (ATTRwt-CM).

The indications for Vyndaqel 20 mg and 61mg soft capsules remain unchanged and are described in the Summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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