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Public statement

Temybric Ellipta (fluticasone furoate / umeclidinium / vilanterol)

Cessation of validity of the marketing authorisation in the European Union

On 14 June 2022, the marketing authorisation of Temybric Ellipta (fluticasone furoate / umeclidinium / vilanterol) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, GlaxoSmithKline Trading Services Limited, had not marketed Temybric Ellipta in the EU since its initial marketing authorisation. In accordance with provisions of the sunset clause[1], the marketing authorisation of the medicinal product lapsed as the product had not been marketed in any of the EU Member States within three years of its initial authorisation.

GlaxoSmithKline Trading Services Limited confirmed that the product had not been marketed due to commercial reasons.

Temybric Ellipta was granted marketing authorisation in the EU on 12 June 2019 for treatment of adult patients with chronic obstructive pulmonary disease (COPD). The marketing authorisation was initially valid for a 5-year period.

Temybric Ellipta was a duplicate application to Trelegy Ellipta, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Trelegy Ellipta and its other duplicate Elebrato Ellipta.

The European Public Assessment Report (EPAR) for Temybric Ellipta will be updated to indicate that the marketing authorisation is no longer valid.

[1] Article 14(4) of Regulation (EC) No 726/2004 ("sunset clause")

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