Public statement

Lifmior 
Cessation of validity of the marketing authorisation in the European Union

On 16 February 2020, the marketing authorisation of Lifmior (etanercept) ceased to be valid in the European Union (EU).

The cessation of validity is due to the fact that the marketing authorisation holder, Pfizer Europe MA EEIG, had not marketed Lifmior 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.

Pfizer Europe MA EEIG confirmed that the product had not been marketed for commercial reasons.

Lifmior was granted marketing authorisation in the EU on 13 February 2017 for treatment of rheumatoid arthritis in adults, certain forms of juvenile idiopathic arthritis, plaque psoriasis in adults and children, psoriatic arthritis in adults, ankylosing spondylitis in adults and axial spondyloarthritis in adults.

The marketing authorisation was initially valid for a 5-year period.

Lifmior is an identical product to Enbrel, the reference medicinal product. There are biosimilar medicinal products of Enbrel authorised and marketed in the EU.

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European Public Assessment Report (EPAR) for Lifmior will be updated to indicate that the marketing authorisation is no longer valid.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