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Public statement

Solymbic

Withdrawal of the marketing authorisation in the European Union

On 15 June 2018, the European Commission withdrew the marketing authorisation for Solymbic (adalimumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Amgen Europe B.V., which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Solymbic was granted marketing authorisation in the EU on 22 March 2017 for treatment of rheumatoid arthritis, enthesitis-related arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and non-infectious uveitis.

Solymbic is a biosimilar medicine of Humira. There are other biosimilar medicinal products of Humira authorised and marketed in the EU. Solymbic was a duplicate application to Amgevita, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Amgevita.

The European Public Assessment Report (EPAR) for Solymbic will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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