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Public statement

CYLTEZO

Withdrawal of the marketing authorisation in the European Union

On 15 January 2019, the European Commission withdrew the marketing authorisation for CYLTEZO (adalimumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Boehringer Ingelheim International GmbH, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

CYLTEZO was granted marketing authorisation in the EU on 10 November 2017 for treatment of Rheumatoid arthritis, Juvenile idiopathic arthritis, Axial spondyloarthritis, Psoriatic arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa (HS), Crohn's disease, Paediatric Crohn's disease, Ulcerative colitis, Uveitis, Paediatric Uveitis.

The marketing authorisation was initially valid for a 5-year period. The product had never been marketed in the EU.

CYLTEZO is a biosimilar medicine of HUMIRA. There are other biosimilar medicinal products of HUMIRA authorised and marketed in the EU.

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Report (EPAR) for CYLTEZO will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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