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Public statement

Kromeya

Withdrawal of the marketing authorisation in the European Union

On 17 December 2019, the European Commission withdrew the marketing authorisation for Kromeya (adalimumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Fresenius Kabi Deutschland GmbH, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Kromeya was granted marketing authorisation in the EU on 2 April 2019 for the treatment of plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, axial spondyloarthritis, juvenile idiopathic arthritis, Crohn's disease, ulcerative colitis and non-infectious uveitis. The marketing authorisation was initially valid for a 5-year period. The product had never been marketed in the EU.

Kromeya is a biosimilar of Humira. There are other biosimilar medicinal products of Humira authorised and marketed in the EU.

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European Public Assessment Report (EPAR) for Kromeya will be updated to indicate that the marketing authorisation is no longer valid.

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