18 December 2020
EMA/687749/2020
EMEA/H/C/004866

Public statement

Halimatoz

Withdrawal of the marketing authorisation in the European Union

On 18 December 2020, the European Commission withdrew the marketing authorisation for Halimatoz (adalimumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Sandoz GmbH, which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Halimatoz was granted marketing authorisation in the EU on 26 July 2018 for treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis.

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

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European Public Assessment Report (EPAR) for Halimatoz will be updated to indicate that the marketing authorisation is no longer valid.

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