



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 August 2024  
EMA/518554/2023  
EMA/H/C/004650

## Public statement

---

# Tremelimumab AstraZeneca (tremelimumab)

## Withdrawal of the marketing authorisation in the European Union

On 6 November 2023, the European Commission withdrew the marketing authorisation for Tremelimumab AstraZeneca (tremelimumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, AstraZeneca AB, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Tremelimumab AstraZeneca was granted marketing authorisation in the EU on 20 February 2023 for the treatment of metastatic non-small cell lung cancer (NSCLC). The marketing authorisation was initially valid for a 5-year period.

Tremelimumab AstraZeneca contains the same active substance as Imjudo, which is authorised in the EU to treat metastatic NSCLC and advanced or unresectable hepatocellular carcinoma. The marketing authorisation holder will maintain the marketing authorisation for Imjudo.

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Assessment Report (EPAR) for Tremelimumab AstraZeneca will be updated to indicate that the marketing authorisation is no longer valid.

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union

