01 August 2024
EMA/323458/2024
EMEA/H/C/005542

Public statement

Tizveni (tislelizumab)

Withdrawal of the marketing authorisation in the European Union

On 5 July 2024, the European Commission withdrew the marketing authorisation for Tizveni (tislelizumab) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Beigene Ireland Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Tizveni was granted marketing authorisation in the EU on 19 April 2024 for the treatment of locally advanced or metastatic non-small cell lung cancer in adults. The marketing authorisation was initially valid for a 5-year period.

Tizveni is an identical product to Tevimbra, which is authorised in the EU to treat locally advanced or metastatic non-small cell lung cancer and unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma in adults.

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European Public Assessment Report (EPAR) for Tizveni will be updated to indicate that the marketing authorisation is no longer valid.

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