21 May 2026
EMADOC-1700519818-3169949
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Keytruda

pembrolizumab

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Keytruda. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted a new indication as follows:

> KEYTRUDA, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment, is indicated for the treatment of adults with resectable muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.

The full indications for Keytruda are available in the summary of product characteristics (SmPC) on EMA website.

For information, on 21 May 2026 the CHMP also adopted extensions to three indications for Keytruda solution for injection as monotherapy for the treatment of adolescents 12 years and older with:

- advanced (unresectable or metastatic) melanoma;
- Stage IIB, IIC or III melanoma as adjuvant treatment after complete resection;
- relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or after at least two prior therapies when ASCT is not a treatment option.

Further information is available in a dedicated summary of opinion on the EMA website.

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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