16 October 2025
EMADOC-1700519818-2475296
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Scemblix

asciminib

On 16 October 2025 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 Scemblix. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted a change to the existing indication as follows:[2]

> Scemblix is indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase (Ph+ CML-CP) ~~previously treated with two or more tyrosine kinase inhibitors~~ (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (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] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Removed text as strikethrough

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