



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 May 2016  
EMA/CHMP/340832/2016  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Kyprolis carfilzomib

On 26 May 2016, 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 Kyprolis. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted an extension to the existing indication as follows<sup>2</sup>:

“Kyprolis in combination with **either** lenalidomide and dexamethasone **or dexamethasone alone** is indicated for the treatment of adult patients with multiple myeloma who have received at least one prior therapy (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 in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> **New text in bold**

