



26 January 2023  
EMA/33048/2023  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Nubeqa darolutamide

On 26 January 2023, 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 Nubeqa. The marketing authorisation holder for this medicinal product is Bayer AG.

The CHMP adopted a new indication to include treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC).

For information, the full indications for Nubeqa will be as follows:<sup>2</sup>

NUBEQA is indicated for the treatment of adult men with

- non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease (see section 5.1).
- **metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel and androgen deprivation 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**

