19 June 2025
EMA/CHMP/141494/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Nubeqa

darolutamide

On 19 June 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 Nubeqa. The marketing authorisation holder for this medicinal product is Bayer AG.

The CHMP adopted a new indication to include treatment of adult men with hormone-sensitive metastatic prostate cancer, in combination with androgen deprivation therapy. The full indications for Nubeqa will therefore be as follows:[2]

> 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 androgen deprivation therapy (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 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] New text in bold

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