



22 June 2017  
EMA/CHMP/398319/2017  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Faslodex fulvestrant

On 22 June 2017, 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 Faslodex. The marketing authorisation holder for this medicinal product is AstraZeneca UK Ltd.

The CHMP adopted a new indication as follows<sup>2</sup>:

“Faslodex is indicated for the treatment of ~~postmenopausal women with~~ estrogen receptor positive, locally advanced or metastatic breast cancer **in postmenopausal women:**

- **not previously treated with endocrine therapy, or**
- **for with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on ~~therapy with an~~ antiestrogen therapy.**”

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, removed text as strikethrough**

