12 October 2017
EMA/675100/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Faslodex

fulvestrant

On 12 October 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 an extension to the existing new indication as follows:[2]

"Faslodex is indicated:

- **as monotherapy** for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:
  - not previously treated with endocrine therapy, or
  - with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy.
- **in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy (see section 5.1).**

In pre- or perimenopausal women, the combination treatment with palbociclib should be combined with a luteinizing hormone releasing hormone (LHRH) agonist."

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.

[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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