20 November 2014
EMA/CHMP/717569/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

ellaOne

ulipristal acetate

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product ellaOne. The variation concerns a change in the classification for supply of ellaOne from "medicinal product subject to medical prescription" to "medicinal product not subject to medical prescription". The marketing authorisation holder for this medicinal product is Laboratoire HRA Pharma, SA.

This change in the classification for supply of ellaOne is based on the fact that the CHMP agreed that the criteria for classifying a medicine as subject to medical prescription as laid down in the European Commission Guideline do not apply to ellaOne. Therefore the Committee recommended that the change in the supply classification is approvable.

The currently approved indication for ellaOne is:

“Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.”

Detailed conditions 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 the variation 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 within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

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