



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2026
EMADOC-1700519818-3343118
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Piqray alpelisib

On 23 July 2026, 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 Piqray. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted an extension to the existing indication as follows:²

Piqray is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with a PIK3CA mutation after disease progression following **an endocrine-based regimen therapy as monotherapy** (see section 5.1 **and for biomarker based patient-selection see section 4.2**).

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, removed text as strikethrough.

