



27 February 2020
EMA/85157/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Entyvio vedolizumab

On 27 February 2020, 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 Entyvio. The marketing authorisation holder for this medicinal product is Takeda Pharma A/S.

The CHMP recommended the addition of a new pharmaceutical form: a 108mg solution for injection to be given subcutaneously. The new formulation is to be used as maintenance treatment for all the authorised indications of Entyvio:

“Ulcerative colitis

Entyvio is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF α) antagonist.

Crohn’s disease

Entyvio is indicated for the treatment of adult patients with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF α) antagonist.”

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

