



15 September 2016
EMA/CHMP/582037/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Stelara ustekinumab

On 15 September 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Stelara. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.

The CHMP adopted a new indication as follows:

“Crohn’s Disease

Stelara 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 TNF α antagonist or have medical contraindications to such therapies.”

For information, the full indications for Stelara will be as follows²:

“Plaque psoriasis

Stelara is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A) (see section 5.1).

Paediatric plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adolescent patients from the age of 12 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see section 5.1).

Psoriatic arthritis (PsA)

Stelara, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease modifying anti rheumatic drug (DMARD) therapy has been inadequate (see section 5.1).

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**



Crohn's Disease

Stelara 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 TNF α antagonist or have medical contraindications to such therapies."

In addition, the CHMP recommended the approval of a new intravenous formulation which is to be used in the Crohn's disease indication only.

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.