



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2010
EMA/CHMP/793256/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (post authorisation)

Simponi golimumab

On 16 December 2010 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 Simponi. The marketing authorisation holder for this medicinal product is Centocor B.V. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:

Simponi, in combination with methotrexate (MTX), is indicated for:

- the treatment of severe, active and progressive rheumatoid arthritis in adult patients not previously treated with MTX.

Simponi has been shown to reduce the rate of progression of joint damage as measured by X-ray, when given in combination with methotrexate.

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.

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

Simponi, in combination with methotrexate (MTX), is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate.

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.

² The text in bold represents the new or the amended indication.



- **the treatment of severe, active and progressive rheumatoid arthritis in adult patients not previously treated with MTX.**

Simponi has been shown **to reduce the rate of progression of joint damage as measured by X-ray and** to improve physical function, when given in combination with methotrexate.