22 October 2015
EMA/CHMP/670627/2015
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Cosentyx

secukinumab

On 22 October the Committee for Medicinal Products for Human Use (CHMP) adopted two positive opinions recommending changes to the terms of the marketing authorisation for the medicinal product Cosentyx. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted two new indications as follows:

> Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate.
>
> Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

For information, the full indications for Cosentyx will be as follows[2]:

> "Plaque psoriasis
>
> Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
>
> **Psoriatic arthritis**
>
> **Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate (see section 5.1).**
>
> **Ankylosing spondylitis**
>
> **Cosentyx is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.**"

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
**Send a question via our website** www.ema.europa.eu/contact

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.