EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/CHMP/420471/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

RoActemra

tocilizumab

On 23 June 2013, 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 RoActemra. The marketing authorisation holder for this medicinal product is Roche Registration Limited.

RoActemra is available in two different pharmaceutical forms, a concentrate for solution for infusion and a solution for subcutaneous injection. The CHMP adopted an extension to the existing indication for the solution for subcutaneous injection as follows:

RoActemra, in combination with methotrexate (MTX), is indicated for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.

For information, the full indications for RoActemra solution for subcutaneous injection will be as follows[2]:

"RoActemra, in combination with methotrexate (MTX), is indicated for

- **the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.**
- the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

RoActemra 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."

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
[2] New text in bold

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