16 August 2021
EMA/424585/2021

EMA starts evaluating use of RoActemra in hospitalised adults with severe COVID-19

EMA has started evaluating the anti-inflammatory medicine RoActemra (tocilizumab) to extend its use to include treatment of hospitalised adult patients with severe COVID-19 who are already receiving treatment with corticosteroids and require extra oxygen or mechanical ventilation (breathing assisted by a machine).

RoActemra is considered a potential treatment for COVID-19 because of its ability to block the action of interleukin-6, a substance produced by the body's immune system in response to inflammation, which plays an important role in COVID-19.

EMA's human medicines committee (CHMP) will carry out an accelerated assessment of the data submitted in the application, including results from four large randomised studies in patients hospitalised with severe COVID-19, to decide whether the extension of indication should be authorised. The CHMP's opinion, together with any requirements for further studies and additional safety monitoring, will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

EMA will communicate on the outcome of its evaluation, which is expected by mid-October unless supplementary information is needed.

RoActemra was first authorised in the EU in 2009. More information about the medicine is available on the EMA website.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union