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Health Service Executive

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MEMO

TO:	Hospital Group CEOs and Clinical Directors
FROM:	Dr Colm Henry, HSE Chief Clinical Officer
CC:	Clinical Directors, Hospital Groups Prof Colm Bergin & Dr Catherine Fleming, Co-Chairs COVID 19 Clinical Advisory Group National Clinical Programme Leads NCAGLS Liam Woods, National Director Acute Operations Helen Byrne, AND, Acute Operations Fionnuala King, Chief Pharmacist Acute Operations
RE:	HSE Interim Advisory Statement on the use of Tocilizumab
DATE:	13th September 2021

Dear Colleagues,

Roche® the manufacturer of tocilizumab (RoActemra®) notified the HSE on the 6th September of a global supply shortage for both the subcutaneous and intravenous preparations due to an increase in the demand in response to the COVID-19 pandemic.

- RoActemra 162 mg solution for subcutaneous injection (pre-filled syringe and prefilled pen) is expected to experience intermittent temporary supply shortage during the month of September 2021.

- RoActemra 20 mg/mL concentrate for solution for infusion (IV) is expected to be temporarily out of stock from September until December 2021.

This is likely to be experienced at patient level within the next couple of weeks. It is important to ensure appropriate steps are taken to minimize the impact to patients. ,. Roche has advised that resumption of supply of the IV product will take upward of 3-4 months.

Further details of the shortage are available at: https://www.hpra.ie/docs/default-source/Shortages-Docs/roactemra-comm-3rd-sep.pdf?sfvrsn=2)

The National Clinical Programme for Rheumatology (NCPR) have worked collaboratively to maintain access of tocilizumab for their patients since the start of the COVID-19 pandemic.

The *HSE Interim Guidance for the Pharmacological Management of Patients Hospitalised with COVID-19* was reviewed and still reflects current evidence. The guidance is available at: https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/hse-interim-guidance-for-the-pharmacological-management-of-patients-hospitalised-with-covid-19.pdf

It would be appreciated if hospitals could ensure that any stock not required to manage patients locally is made available to another hospital within their Hospital Group that is experiencing a stock shortage or outage.

There is continued active engagement with Roche to ensure ongoing prioritization of tocilizumab re-supply to Ireland and active engagement in relation other therapies to determine the evidence for use in COVID-19 and availability of stock.

Clinicians should switch tocilizumab IV patients to alternative therapeutic agents where possible. By taking these measures immediately, it will allow time for alternative strategies to be determined for critical patients.

For patients with inflammatory arthritis on tocilizumab IV, the NCPR recommends considering an immediate switch to a licensed non-anti-IL-6 therapy.

For patients with vasculitis, the NCPR have advised that there is no alternative licensed therapy. The options will be to revert to higher doses of corticosteroids, and should that fail, to consider use of an alternative off-label biologic therapy until anti-IL6 stocks are restored.

The use of SC tocilizumab should be reduced by switching to an alternative therapy where possible.

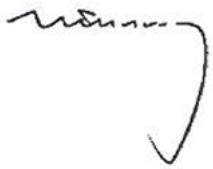
- New tocilizumab SC prescriptions are best avoided for now with all other alternatives considered and they should be under the stewardship of consultants only.

- To manage the national SC stocks, each individual service should look at increasing dose interval in patients who are well controlled. All relevant NCHDs and CNM/ANP staff involved in the care of rheumatology patients should be educated on this issue immediately.

- If a patient is currently sub-optimally controlled on established tocilizumab, alternative therapies should be considered immediately rather than giving it more time to take effect, or adding in a second agent.

It's important that patients who require treatment are protected as much as possible, however as a result of the global shortage there will be limited IV tocilizumab stock available.

Yours sincerely,



Dr Colm Henry
Chief Clinical Officer