COVID-19: Guidance on clinical trials for institutions, HRECs, researchers, and sponsors

Supplementary advice: tocilizumab shortages

Due to serious global shortages of intravenous tocilizumab (Actemra), the Therapeutic Goods Administration (TGA) are recommending urgent conservation of stock.

The following supplementary advice is provided to support the guidance issued by all state and territory Departments of Health, the TGA, National Health and Medical Research Council (NHMRC) and the Clinical Trials Project Reference Group (CTPRG) with respect to the conduct and management of clinical trials during the COVID-19 pandemic.

This advice provides general information to institutions conducting or overseeing research, Human Research Ethics Committees (HRECs), researchers and sponsors in the context of medicines shortages during the COVID-19 pandemic. It is directed towards those involved in clinical trial research and other relevant clinical research, but also may be of use to institutions, HRECs and researchers in other fields.

Tocilizumab (Actemra) is used to treat rheumatoid arthritis (RA), systemic juvenile idiopathic arthritis (sJIA), polyarticular juvenile idiopathic arthritis (sJIA) and giant cell arteritis (GCA) and cytokine release syndrome (CRS). It is also used off-label to treat critically ill COVID-19 patients. Recently, the World Health Organisation (WHO) recommended the use of Actemra for the treatment of COVID-19.

Roche is currently experiencing shortages of multiple presentations of Actemra in Australia. This is due to significant increases in global demand for Actemra in response to the COVID-19 pandemic.

This is an evolving issue worldwide. The TGA has been working with Roche, wholesalers, health professionals, states and territories and Medicines Australia to manage the shortage in Australia. The shortage is expected to affect supplies at a patient level for some clinical settings until at least January 2022. The TGA provides update advice on this developing situation on their website (https://www.tga.gov.au/alert/shortages-tocilizumab-actemra-medicines).

Sponsors of clinical trials using commercial stock of Actemra IV in the protocol are requested to:

- **Delay and/or pause recruitment of new patients into existing clinical trials between now and January 2022**
- **Delay commencement of new clinical trials where any stock of Actemra IV is required as a rescue or comparator medication**
- **Advise TGA and Roche if any stock of Actemra IV supplies will be required between September 2021 to January 2022 for ongoing trials**
- **Advise TGA and Roche if delayed clinical trials activity frees up existing stock, or if you are aware of any unused Actemra stock that may not be needed between now and January 2022 that could be redirected, even if short-dated or recently expired.**

TGA contact: medicine.shortages@health.gov.au

Medicines Australia contact: Vincent Tran (vincent.tran@medicinesaustralia.com.au)

Authored by:

All State and Territory Departments of Health through the Clinical Trials Project Reference Group
https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials

The National Health and Medical Research Council
https://www.nhmrc.gov.au/research-policy/COVID-19-impacts

The Therapeutic Goods Administration
https://www.tga.gov.au/