Recommendation for conservation of tocilizumab (Actemra) during shortage when using for COVID-19 treatment

In response to the global shortages of tocilizumab products, the Medicine Availability Working Group (MAWG) of state and territory health department representatives has been working with the TGA to assess stock levels and availability of tocilizumab and baricitinib for COVID-19 patients.

Multiple presentations of tocilizumab (Actemra) products are in critical shortage due to global demand in response to the COVID-19 pandemic. The MAWG therefore recommends the urgent conservation of intravenous tocilizumab to enable treatment of as many patients as possible who require this treatment.

Conservation and patient management advice for the registered indications of tocilizumab has been published in a <u>joint statement</u> from the Australian Rheumatology Association, Arthritis Australia and TGA. Consideration should be given to whether patients have treatment alternatives when determining how to allocate supply.

MAWG recommends the urgent conservation of intravenous tocilizumab with the following criteria for treatment of hospitalised COVID-19 patients:

- Baricitinib (Olumiant) should be used instead of tocilizumab when considered for patients who are receiving supplemental oxygen but are not mechanically ventilated.
- Intravenous tocilizumab should be reserved for patients with COVID-19 when baricitinib is not clinically appropriate.
- When used for COVID-19 patients only one dose of intravenous tocilizumab should be administered.

The MAWG conservation recommendations are based on consideration of updated guidelines from the <u>National COVID-19 Clinical Evidence Taskforce</u> in light of the critical shortage of tocilizumab.

While treatment of COVID-19 is not a registered indication for tocilizumab or baricitinib in Australia these products have been conditionally recommended for use in certain hospitalised patients with COVID-19 by the National COVID-19 Clinical Evidence Taskforce.

The MAWG includes representatives of state and territory health departments and provides advice to the Department of Health on management of supply of medicines used for COVID-19 patients in Australian hospitals.

Current forecasts and the uncertainty of global supply indicate the need to urgently conserve tocilizumab to support ongoing access for people hospitalised with COVID-19 for whom baricitinib is not suitable, including:

- Special patient groups (pregnant women, adolescents, children)
- Patients who cannot be administered medications via the oral/nasogastric route
- Patients who are mechanically ventilated.

Health professionals should refer to the updated guidelines from the <u>National COVID-19</u> <u>Clinical Evidence Taskforce</u> for information on appropriate use of these unapproved treatments and any local requirements for off-label prescribing.

The TGA continues to work very closely with Roche Products Pty Limited, the sponsor of tocilizumab, to manage the shortage. Further information about actions taken to address the shortage is available on the TGA website.

The advice in this document on the recommendation for conservation will be reviewed as availability of tocilizumab changes.