



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# Medicine Shortage Management: Working Together for Effective Management

Lessons Learnt from the Actemra (tocilizumab) shortage

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2022 ARCS Annual Conference

May 2022

**TGA** Health Safety  
Regulation

# Overview

- TGA role in medicine shortages
- About the Actemra shortage
- Working together: key focus areas
- Summary of learnings

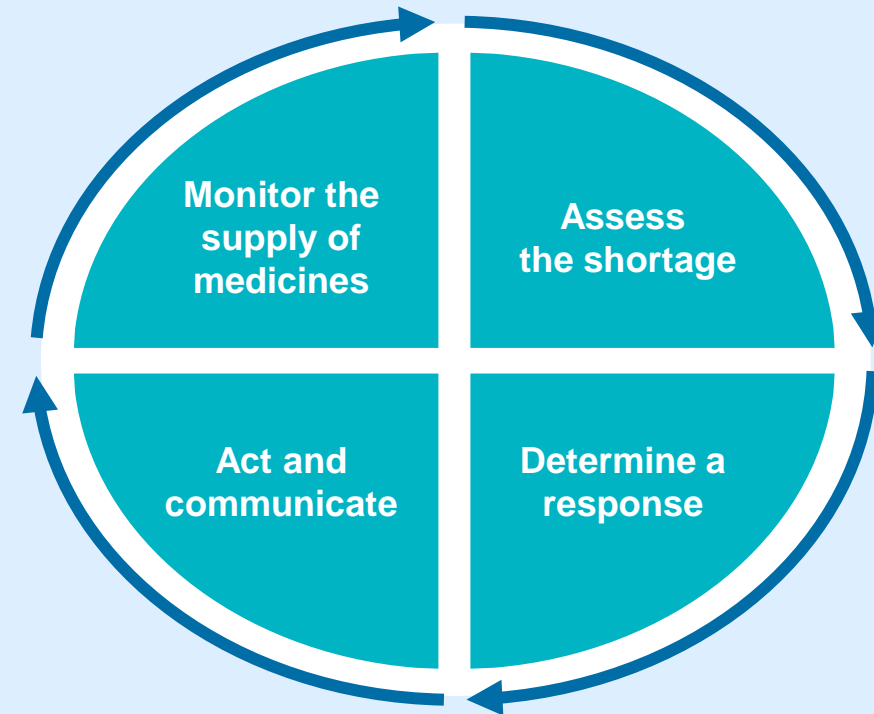
# The role of the TGA in Medicine Shortages



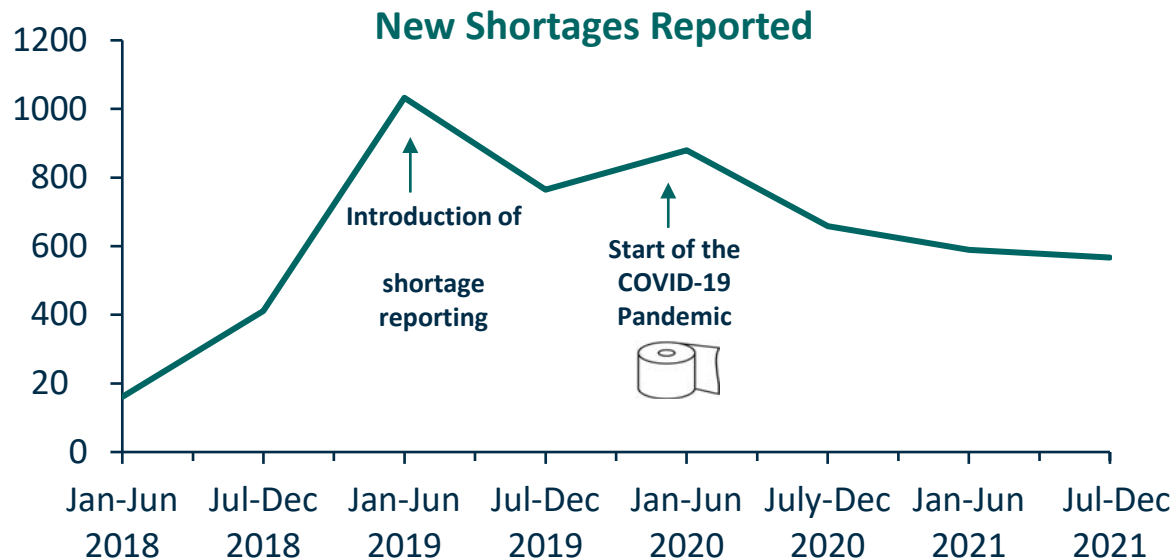
## Our Goal

To reduce the impact of medicine shortages for Australian consumers and health professionals.

To facilitate continual access of medicines, where possible.



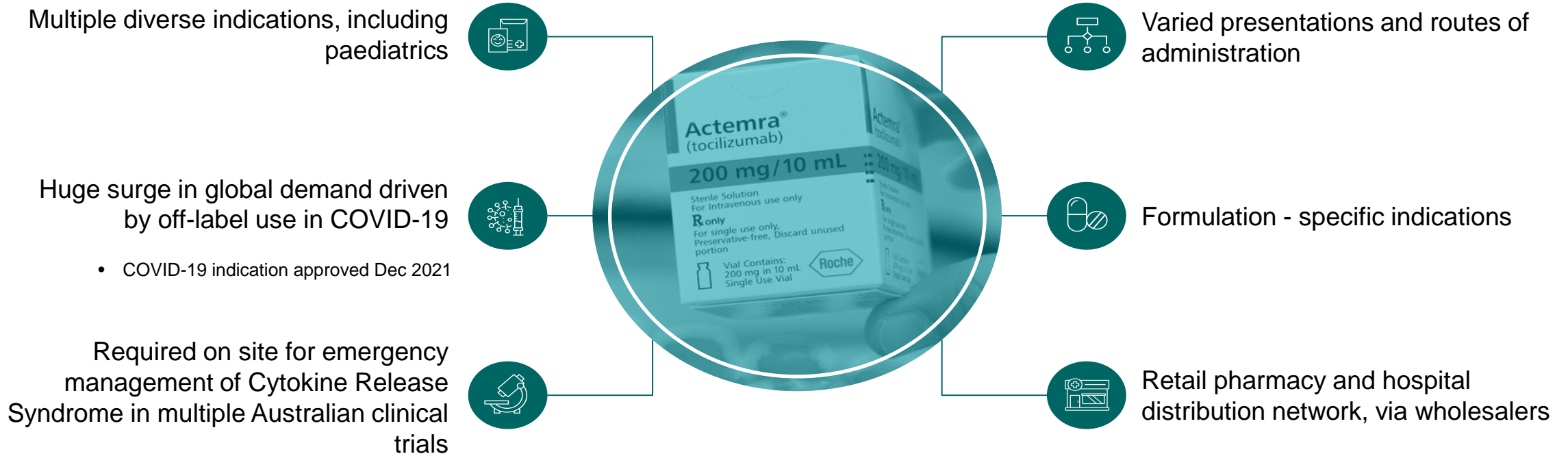
## Impact of COVID-19 on medicine shortages



**The COVID-19 pandemic has been a catalyst for change in the way signals are received and shortages are managed**

- **No increase** in the number of new shortages reported
- **Increased** supply monitoring
- **Increased** engagement
- **Increased** methods used in managing shortages

# Actemra (tocilizumab) shortage – the perfect storm:



**Current Status: SC shortage resolved, IV supply improving**

# Delta Strain Incidence Increases in Australia Coinciding with Shortage

## Australia Situation

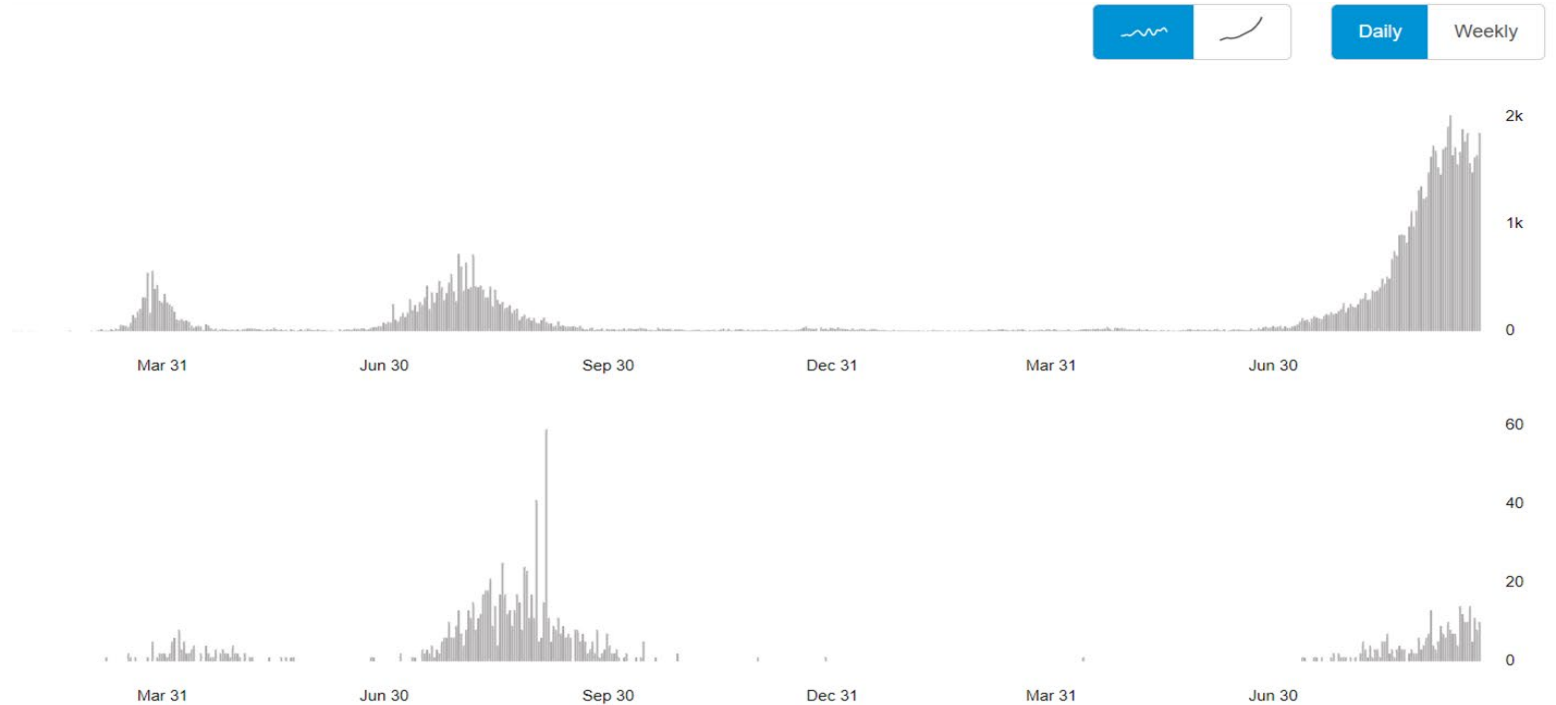
**92,179**  
Confirmed cases



**1,196**  
deaths




Source: World Health Organization



## Working towards a common goal – reducing patient impact




# Key to Shortage Management:



01

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**Early Intervention**



02

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**Collaboration**



03

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**Patient-centred approach**





# Early Intervention

# Early intervention

## Managing stock inventory

Constrain supply – PBS wholesalers

Expedition of regulatory approvals

Potential substitutes

Assessment of medicine availability

## Analysing patient impact

Diversity of clinical use

Population groups

Prescribing behaviour

Hospital vs Community Pharmacy use



# Collaboration

## COLLABORATION with EXTERNAL stakeholders

If you need support from other organisations the TGA can help you to:

 **Connect** with relevant stakeholders

 **Facilitate** meetings

 **Expedite** activities



*ARA: Australian Rheumatology Association;  
MAWG: TGA Medicines Availability Working Group (incl. health states and territories)*

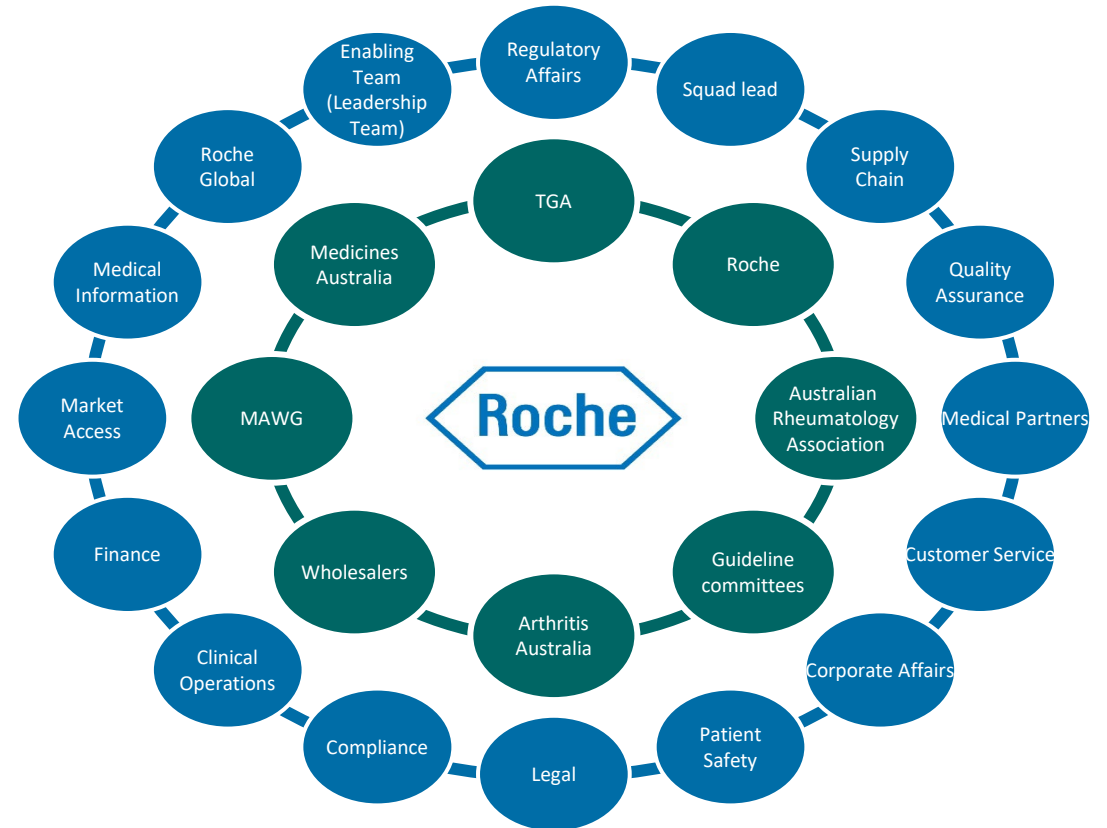
# COLLABORATION with INTERNAL stakeholders

Ensure management efficiency by:


**Drawing expertise from all parts of the business**


**Sharing information**


**Working closely**





# Patient-centred approach

# Patient-centred approach



-  **Involve patient groups**
-  **Communication plan**
-  **Own the shortage**
-  **Consistent messaging**



# Summary of key actions



# Summary of key actions

## Inventory Management



Wholesaler constraints applied

Requesting additional stock

Model availability

Expiry date extension of tocilizumab IV (covid-19 use)

## Prescribing



Clinical guidance for arthritis and COVID-19

Provided guidance to clinical trials

Temporary changes to PBS prescribing rules

## Dispensing



Developed ordering instructions for pharmacists

Serious Scarcity Substitution Instrument (SSSI) for PFS and ActPen

Approval of overseas tocilizumab products

Emergency stock (single units) delivered to pharmacies

## Communication




Coordinated and consistent messaging

Consumer information sheets

Information webinars for prescribers and consumers

# How have we changed the way we manage shortages?

 **Involvement with relevant clinical groups**

 **Multiple new management actions**

 **Targeted communication**



# What can sponsors do when facing a critical shortage?



**1** Optimise internal processes



**2** Patient-centred approach



**3** Act early







# Questions





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