



Medicine Shortages Strategies to mitigate supply chain disruptions

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Therapeutic Goods Administration

Overview

- *TGA's role in managing medicine shortages*
- *Reasons for shortages*
- *What sponsors and manufacturers can do to prepare*
- *Summary*



A question for you

Scan the QR code and select:
POLL – Question No.1



Slido Question 1

What is the biggest supply chain challenge for your organisation?

Mandatory reporting of shortages

Medicine shortage:

A medicine is in '**shortage**' if its supply in Australia will not, or will not likely, meet the demand for it at any time in the next 6 months, for all the patients in Australia who take it or who may need to take it.

- Since Jan 2019, sponsors of all Australian registered prescription medicines and a limited number of over-the-counter medicines must report shortages and discontinuations to the TGA
- All current shortages and discontinuations are published on the Medicine Shortage Reports Database
- Downloadable csv files for active and archived shortage reports

TGA's Medicine Shortage Reports Database

Browse ALL shortages and discontinuations

[Click here to display only CRITICAL medicine shortages and discontinuations](#)

Search Results

- Export active shortage reports
- Export archived shortage reports

amoxicillin

Enter an active ingredient or trade name

Current (25)

Anticipated (3)

Resolved (3)

Discontinuations (2)

Current shortages

Sort by: Updated date | Active ingredient | Trade name | Therapeutic class

amoxicillin trihydrate

Updated 16-02-2023

APO-AMOXICILLIN amoxicillin (as trihydrate) 500 mg capsule blister pack
AUST R: 208144

Expected supply: 24 Mar 2023

Availability: Unavailable

Management action: A TGA web alert is available

at: <https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/antibiotics-shortages> A Serious Scarcity Substitution Instrument for oral amoxicillin medicines has been implemented. Further information is at: <https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/substitution-allowed-address-shortage-amoxicillin> Unregistered products have been approved for supply under Section 19A. See the website: <https://www.tga.gov.au/ws-s19a-index> and search for the active ingredient.

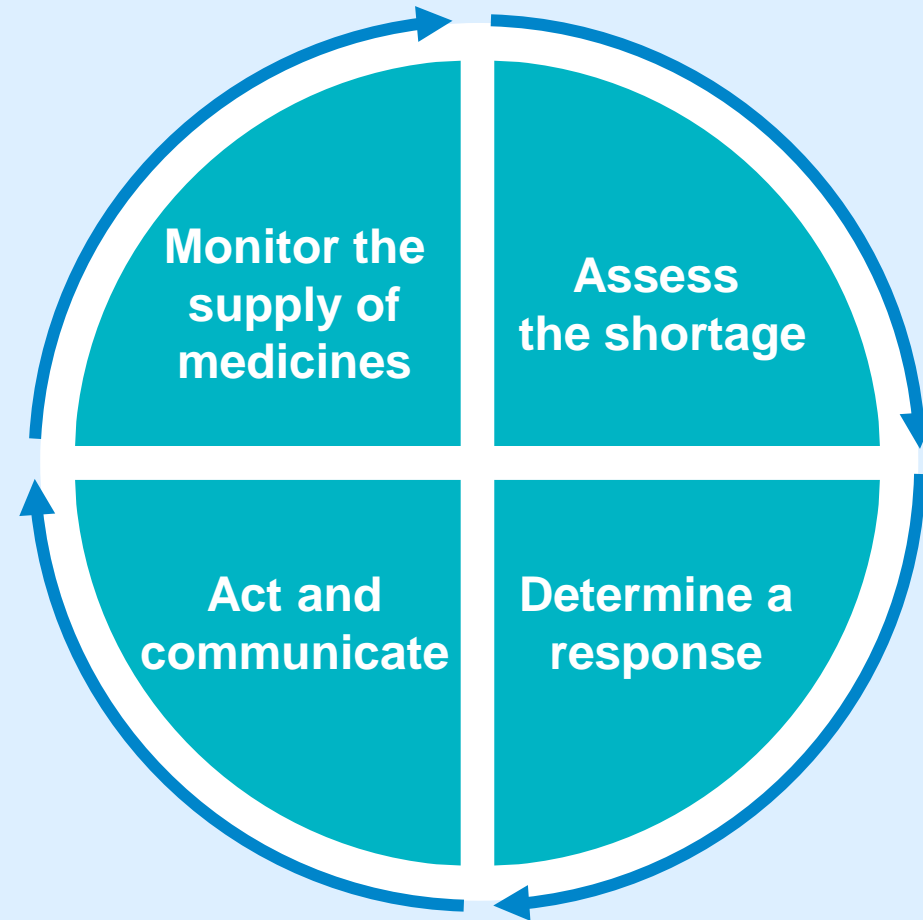
The role of the TGA in Medicine Shortages



Our Goal

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

To facilitate continual access of medicines, where possible.



Our shortage management activities

Inventory Management



Work with pharmaceutical companies to:

- **Constrain**
- **Bring forward or increase orders**

Prevent stockpiling and facilitate equitable distribution of stock

Approve overseas-registered products to fill supply gaps (Section 19A Approvals)

Prescribing



Work with medical colleges and professional organisations to **develop joint statements** and **endorse clinical guidelines**

Recommend temporary **changes to PBS** prescribing rules

Dispensing



Allow community pharmacists to substitute specific medicines without prior approval from the prescriber via **Serious Scarcity Substitution Instruments (SSSIs)**

Communication



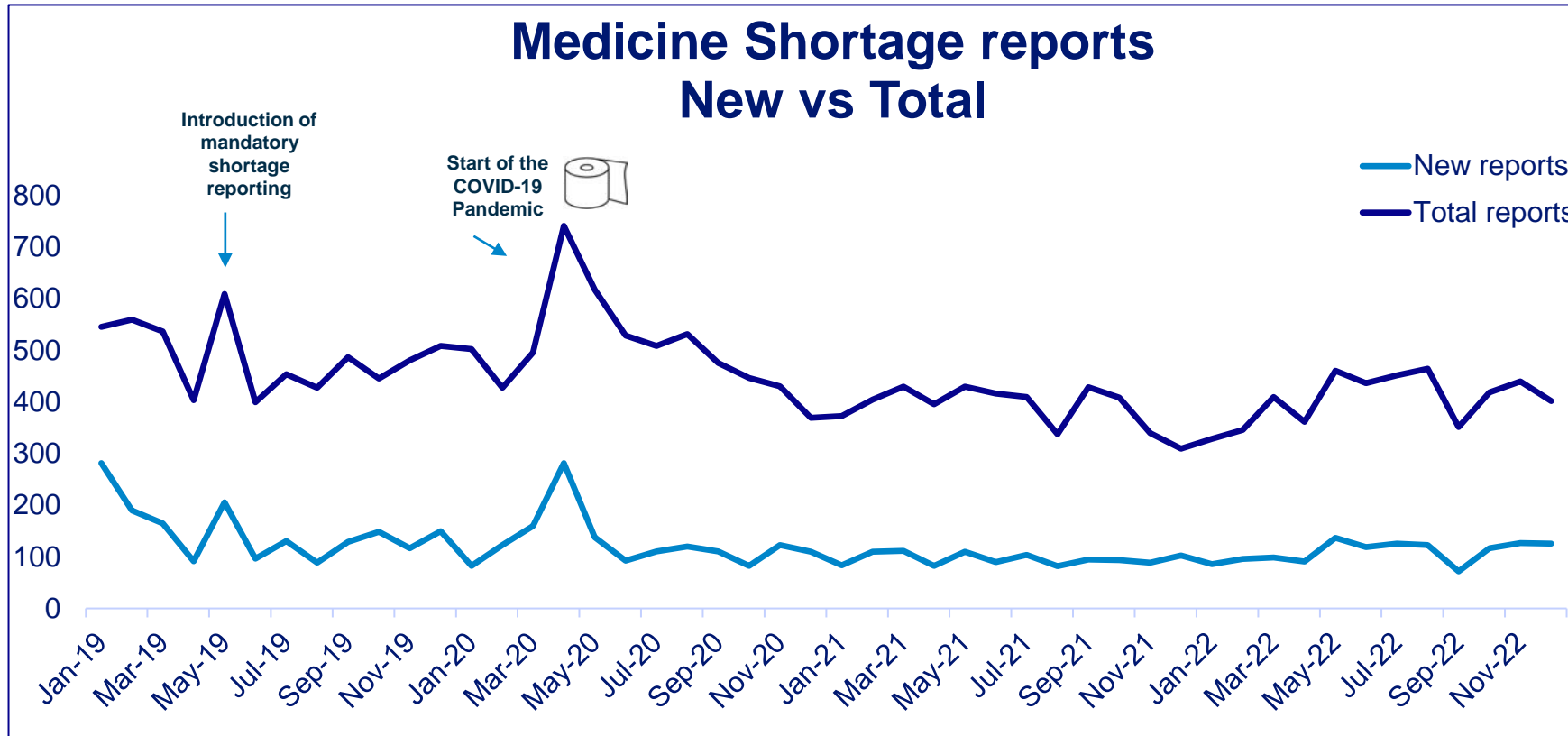
Publish shortages information on the TGA website

Coordinate consistent **shortage information** for health professionals and consumers

E.g. Alerts to subscription list, PHNs, communication to consumer groups, etc

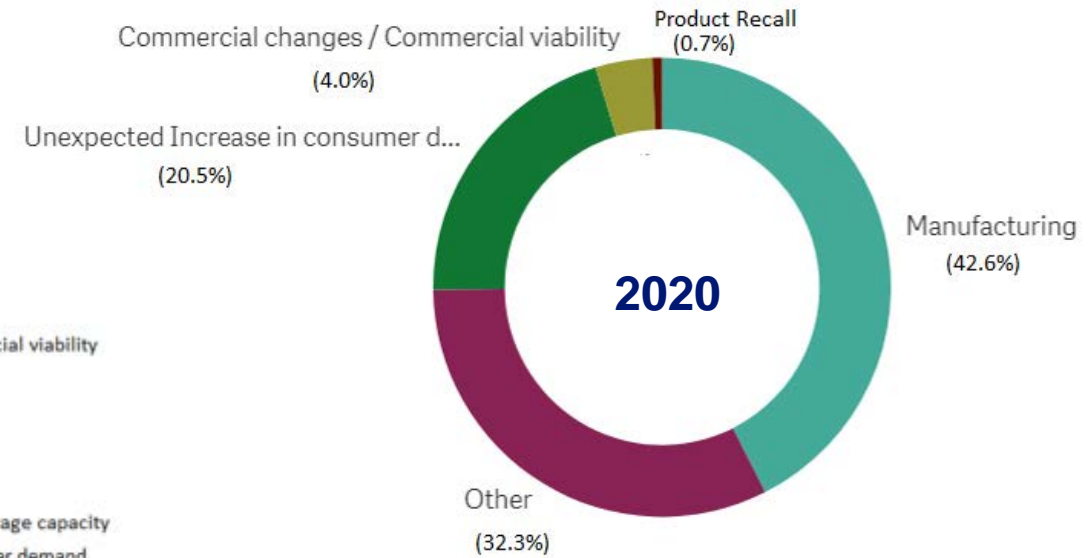
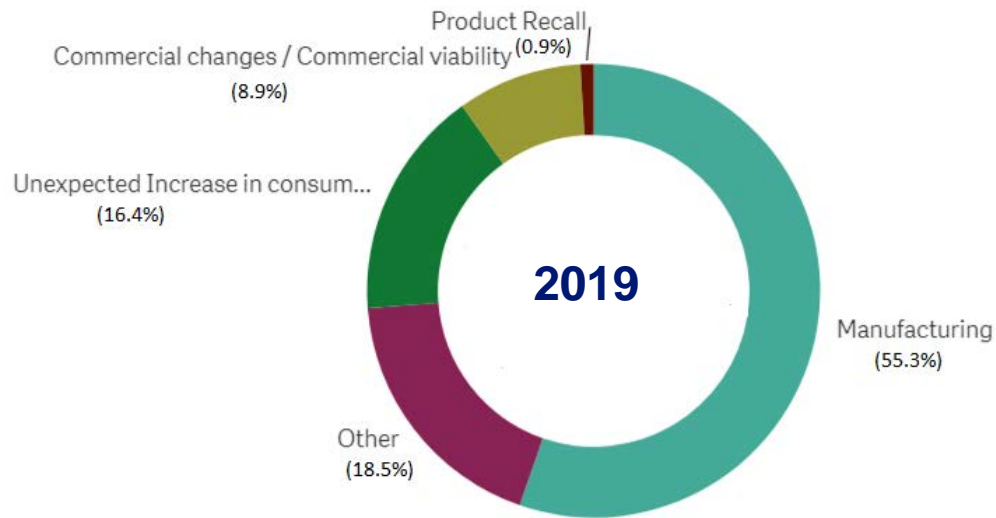
Impact of COVID-19 on medicine shortages

The COVID-19 pandemic has highlighted supply chain issues and changed the way signals are received and shortages are managed

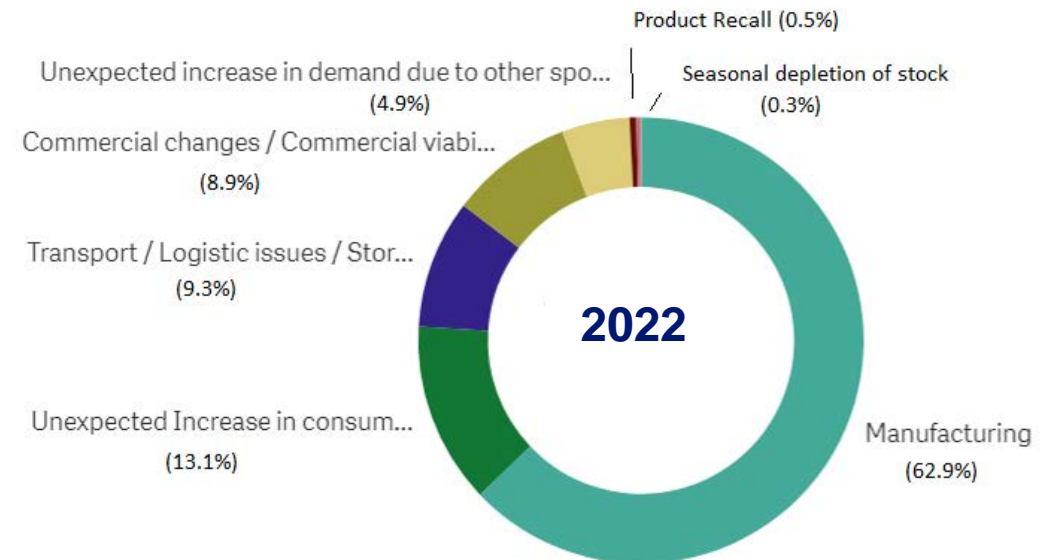
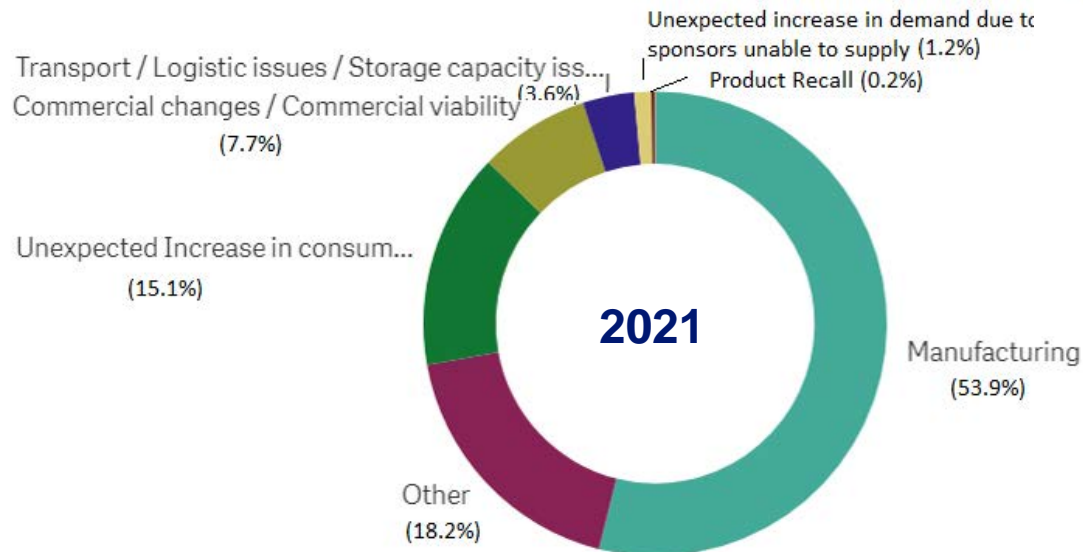


- **Consistent** number of new and total reports
- **Increased** complexity of shortages
- **Increased** supply monitoring
- **Increased** engagement
- **Increased** methods used in managing shortages

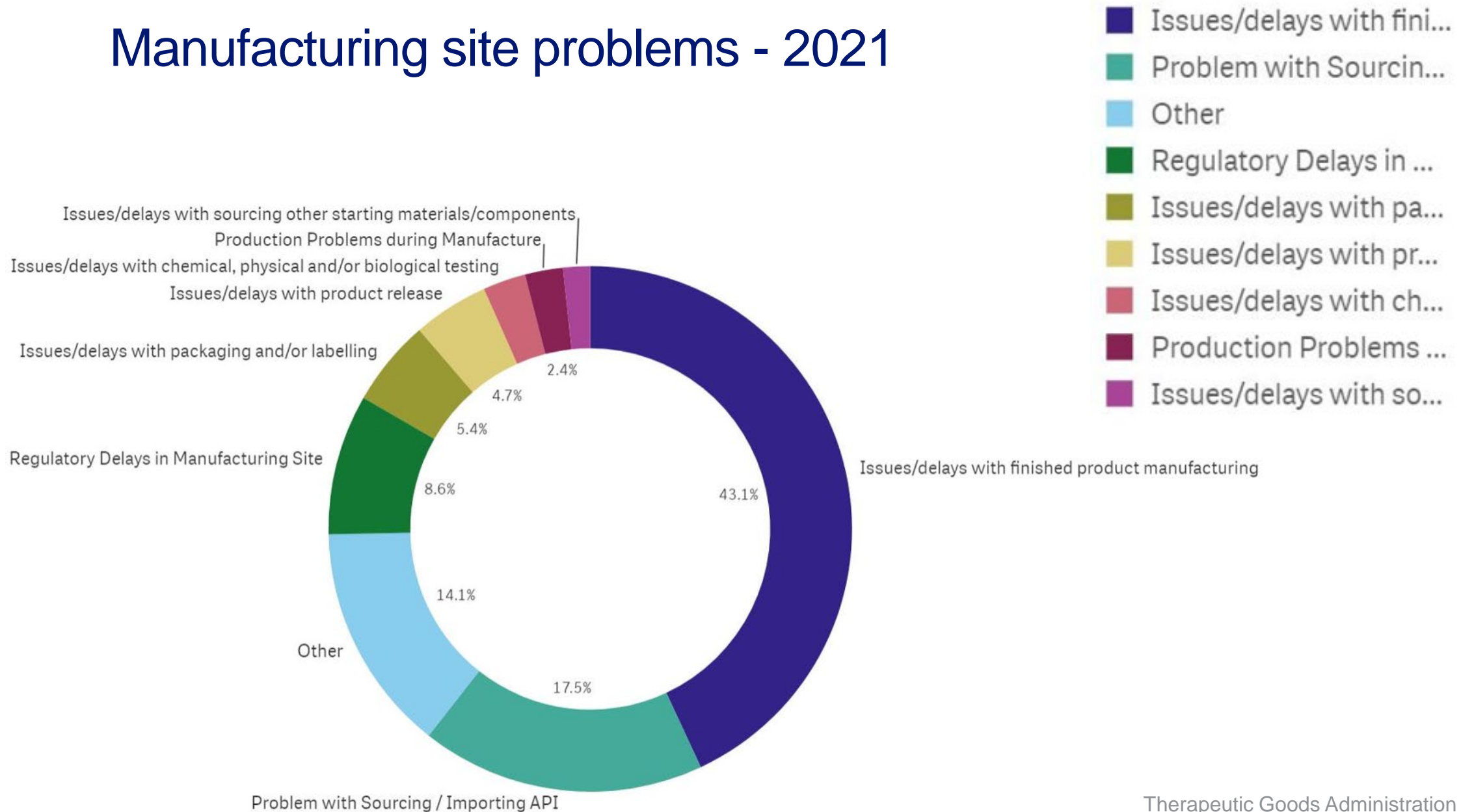
Shortage Reasons – manufacturing #1



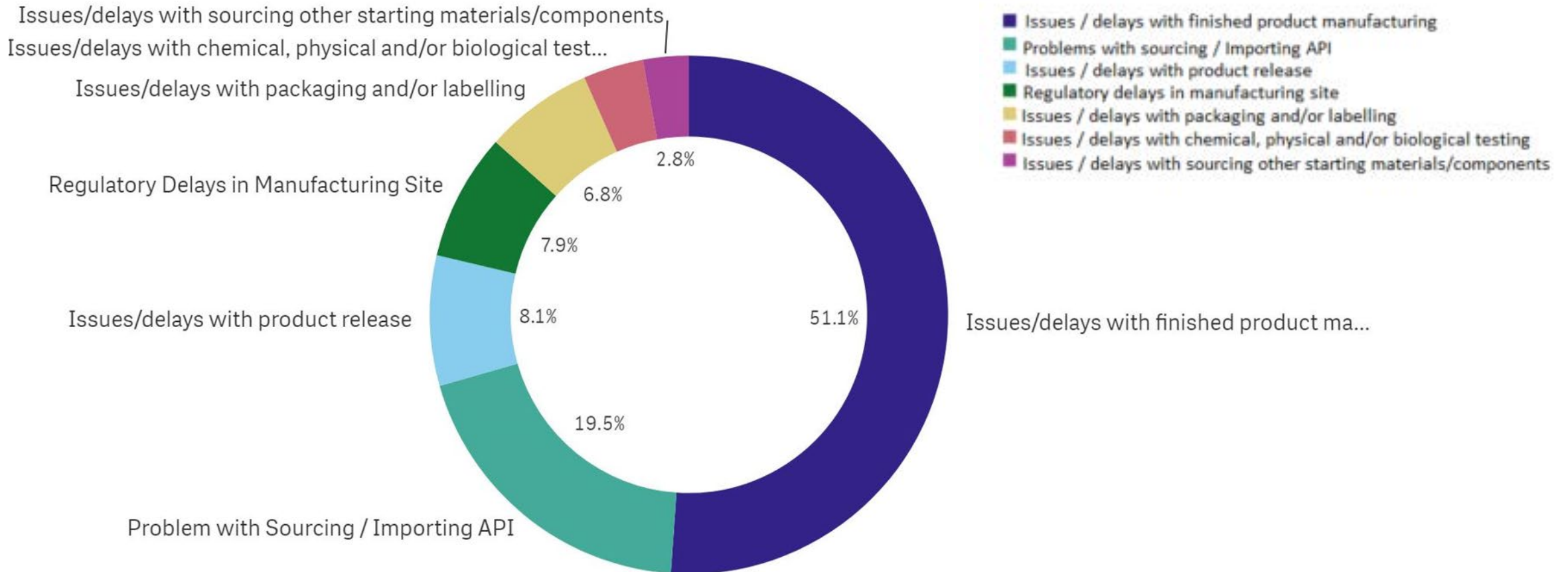
- Commercial changes / Commercial viability
- Manufacturing
- Other
- Product Recall
- Seasonal depletion of stock
- Transport / Logistic issues / Storage capacity
- Unexpected increase in consumer demand
- Unexpected increase in demand due to other sponsors unable to supply



Manufacturing site problems - 2021



Manufacturing site problems - 2022



What sponsors and manufacturers can do to mitigate supply chain vulnerabilities.



Know your medicines

Consider:

- market share
- indications (including off-label)
- alternatives (exact, similar and appropriate) and their availability
- patient groups
- relevant health professional groups



Keep dossiers up to date

Maintain GMP clearance

- most critical to pivot quickly

Where possible, consider:

- Align Australian products with those made overseas
- Add new manufacturing sites



Optimise processes



supply and demand monitoring



demand forecasts



aim for early detection and communication of issues



consider mapping supply chain and developing contingencies



Contact TGA medicine shortages team as early as possible

Contact us even if you're not sure if the shortage will eventuate and before mandatory reporting timeframe

TGA can help with:

- supply constraints
- stakeholder engagement
- consistent communication
- clinical advice and conservation measures
- expediting assessments of regulatory applications
- need for emergency or direct supply?
- pharmacy substitution



Focus on the goal - minimise patient impact



Put patients at the centre of planning

Regulatory pathways to assist with supply

To minimise shortage impact, the TGA can consider a range of regulatory options:

- Section 19A approvals to import and supply overseas-registered medicines during a shortage
- Section 14/14A consent – if the Australian goods don't meet a standard
- Regulatory submissions:
 - Category 3 applications: new manufacturing site, shelf life extension, etc.
 - GMP applications
 - Section 23 applications for new medicines

Contrast Media Shortage – Case Study

- Chinese manufacturing site affected by lockdowns
- Wide usage for diagnoses of many serious conditions = many stakeholders
- Freight difficulties – heavy and expensive
- Extensive management

Sponsor Contingencies

- Alternative manufacturing site already been included on ARTG
- International test methods already approved for some lines – quickly adapted to other presentations
- Identification of highest volume products – focussed regulatory approvals and production to these

What you can do to help
mitigate shortages.



Summary

Act now:

- Prepare as much as possible in advance
- Consider supply risk of each medicine
- Optimise processes and consider contingencies

If you face a shortage:

- Contact medicine shortages team as early as possible and before communicating externally
- Consider patient impact
- Consider regulatory options to increase supply – ARTG or overseas goods
- Mobilise resources
- Consider need for direct/emergency supply
- Communicate

A question for You

Scan the QR code and select:
POLL – Question No.2



Slido Question 2

What is the first step you will take after this Forum to strengthen your supply chains and help with continued patient access?

Website and link references

TGA medicine shortages hub	https://www.tga.gov.au/hubs/medicine-shortages
Medicine shortage reports database	https://www.tga.gov.au/safety/shortages/medicine-shortage-reports-database
Section 19A: Guidance for industry	https://www.tga.gov.au/publication/section-19a-guidance-industry
Section 19A approvals database	https://www.tga.gov.au/resources/section-19a-approvals
Serious Scarcity Substitution	https://www.tga.gov.au/serious-scarcity-substitution-instruments-sssis
Instruments (SSSIs)	https://www.tga.gov.au/serious-scarcity-substitution-instruments-sssis
Medicine shortage alerts	https://www.tga.gov.au/safety/shortages/medicine-shortage-alerts/trulicity-dulaglutide-shortage

Participate in the Q&A

Verbal questions:

Raise your hand to ask a verbal question. A member of the GMP Forum staff will provide a roaming microphone.

Written questions:

Scan the QR code below or click the link in your calendar to access Slido via your mobile device. You can submit your question, and vote on other questions submitted.





Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Coming up next in this room



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GMP for Advanced Therapy Medicinal Products (ATMP)