GMP Clearance: Compliance Verification (CV) backlog reduction strategy

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Acknowledgement of Country

In the spirit of reconciliation, the Department of Health, Disability and Ageing acknowledges the Traditional Custodians of country throughout Australia and their connections to land, sea and community.

We pay our respect to their Elders past and present and extend that respect to all Aboriginal and Torres Strait Islander peoples today

Welcome

Housekeeping

This webinar is being recorded for and will be published for access in the upcoming weeks.

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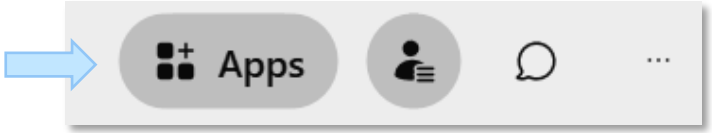

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- Live Poll (use survey tab when prompted)

Using the QR code

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Webinar overview

- Background
- Automatic GMP clearance extensions
- Abbreviated evaluations
- Ending COVID-19 GMP Clearance flexibilities
- How industry can help
- Next steps

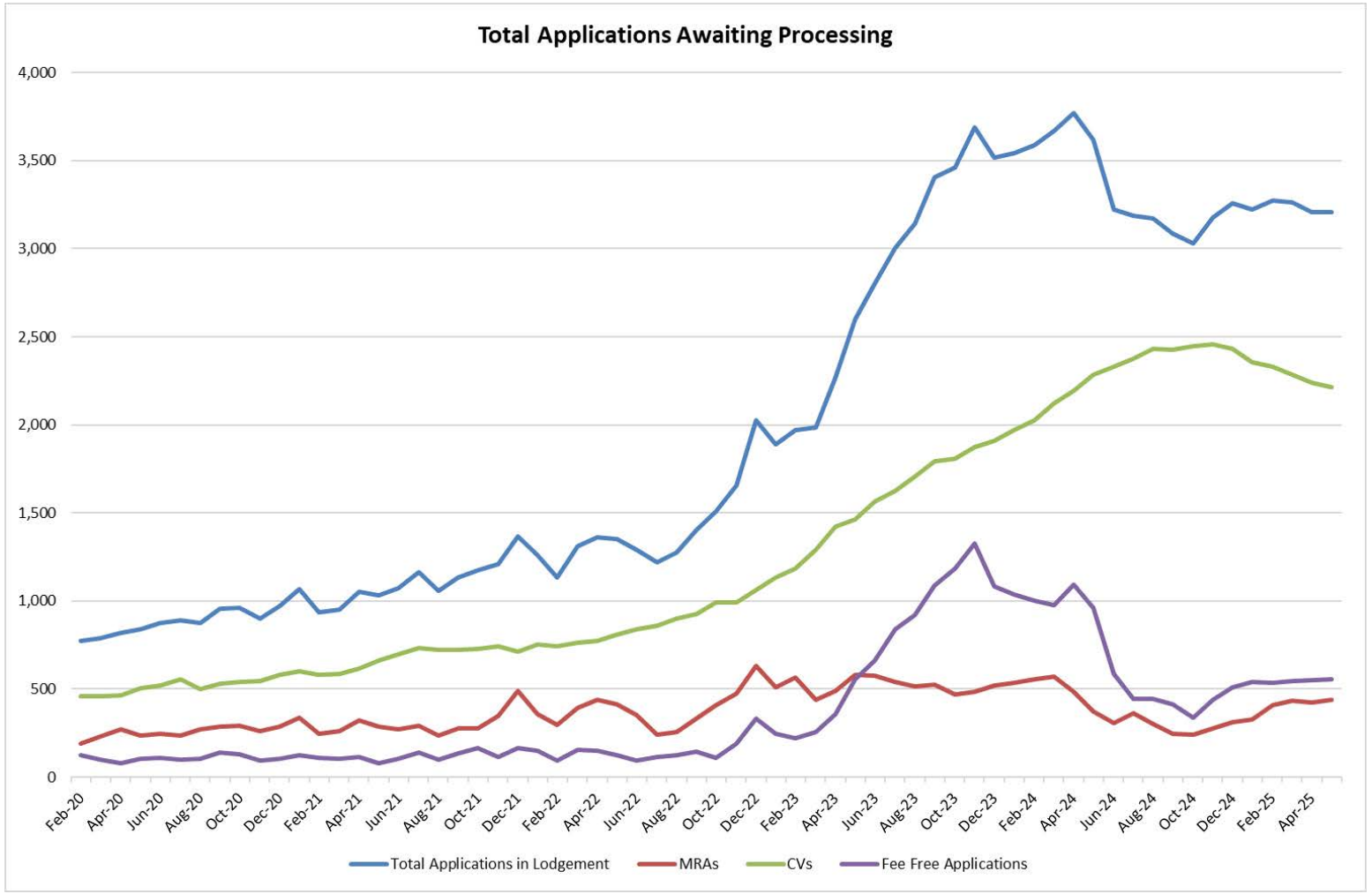
GMP clearance pathways

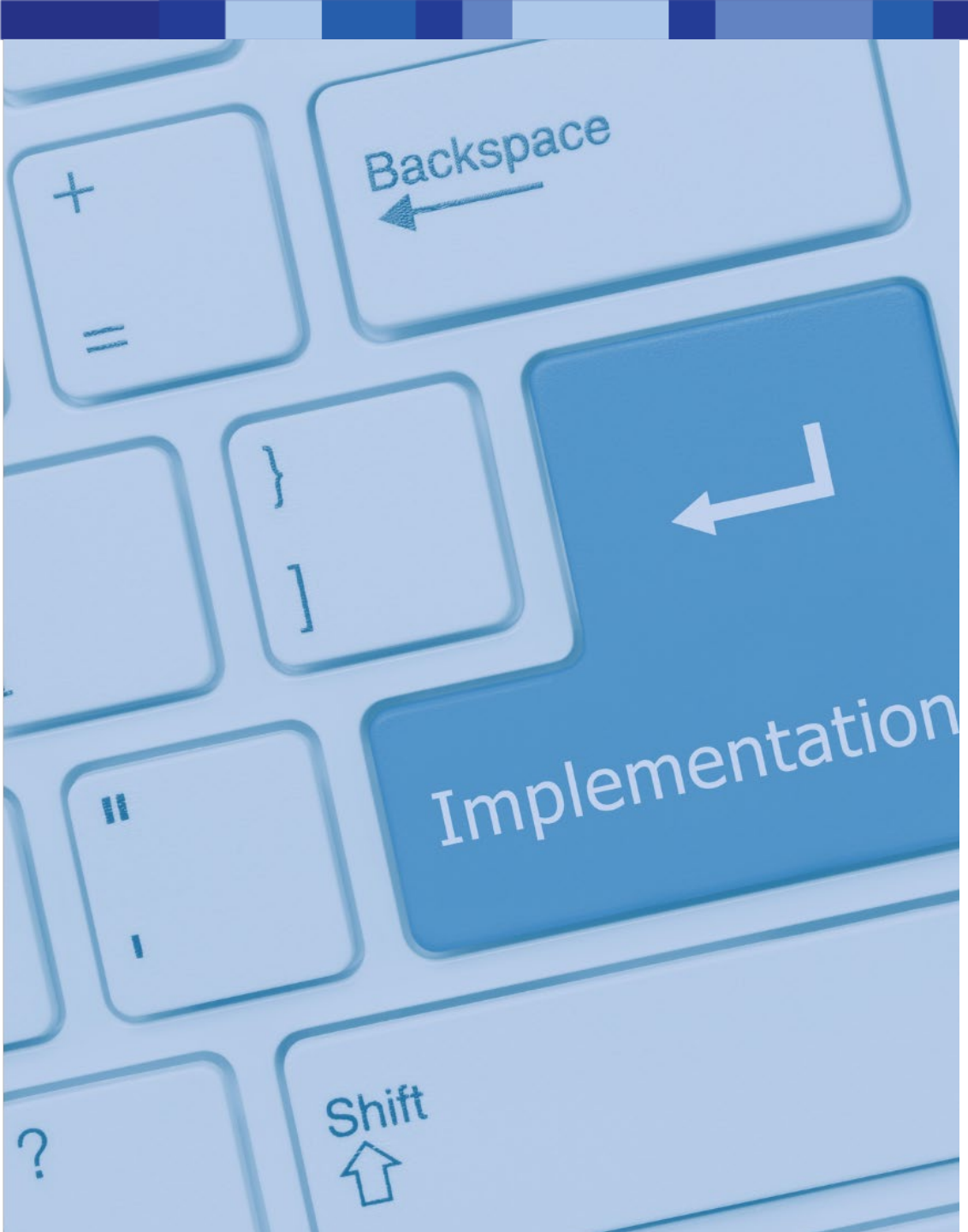
Two pathways

1. Mutual Recognition Agreement (MRA)
2. Compliance Verification (CV)
    - Non-sterile Active Pharmaceutical Ingredient (NS API)
    - Non-sterile Finished Product (NS FP)
    - Sterile Active Pharmaceutical Ingredient (ST API)
    - Sterile Finished Product (ST FP)

The backlog

- Limited to our CV streams only (green trend)
- Peaked in October 2024 and now reducing
- Pre-pandemic ~500 CV applications on hand. This was our steady state.
- New target steady-state is ~750 CVs
- Backlog consists of ~1500 CVs

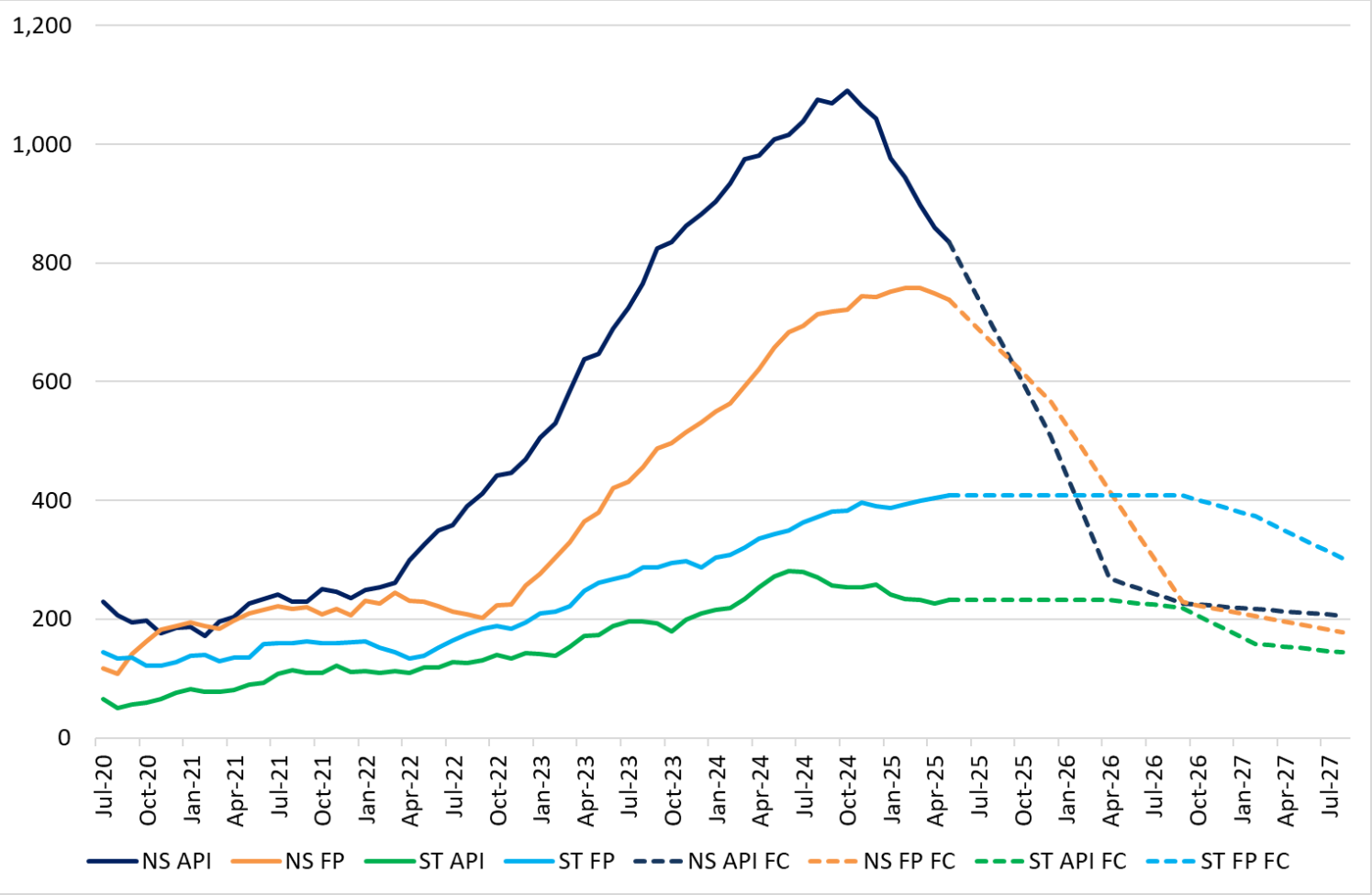




Strategies employed to date

- Recruitment and training:
  - Increase from 23 FTE to 41 FTE
  - Streamlined training program
- Created prioritisation pathways
- Streamlined evaluation processes
- Signed new international agreements
- MRA Bulk extensions
- Increased Industry reporting

With no additional actions…



2 – 2.5 years to steady state

- Forecast is based on current

  staffing levels and training plan
- Streams are tackled as:
  - evaluators are trained
  - other streams come under control
- Timeline is too long and affecting:
  - timely supply of medicines
  - Australian business

Considerations to expedite reduction

- Broad range of options considered
- All considerations were risk based, evidence-based and data driven incorporating:
  - Current data / historic trends / modelling forecasts
  - Risks – GMP compliance, market access & supply
  - Effect on time taken to reduce the backlog and return to predictable output
  - Some proposals are temporary measures

Targeted consultation with TGA Industry Working Group on GMP (TIWGG)

Backlog reduction strategy

1. Automatic extension of Mutual Recognition Agreement (MRA) and Non-sterile Active Pharmaceutical Ingredient (API) Compliance Verification (CV) applications

2. Abbreviated evaluations of manufacturers performing certain lower risk activities

3. Ending GMP Clearance flexibilities introduced during COVID-19, specifically the GMP Clearance Questionnaire

1: Extensions of MRA and NS API CV

- Extend already approved GMP Clearances expiring in the next 2 financial years for a period of 2 years
- Extensions will incorporate existing staggered expiry dates
- Close all 'in-train' applications where applicable
- Only evaluate new or variation applications

Benefits
Significant reduction in regulatory burden
Reduction of ~2700 applications per year
Free-up ~6 GMP evaluators for higher risk streams
Expedite backlog reduction by ~12 months
Continue to support new product registrations, listings and variations

Lodgement

MI-2025-CL-12345 (v2)

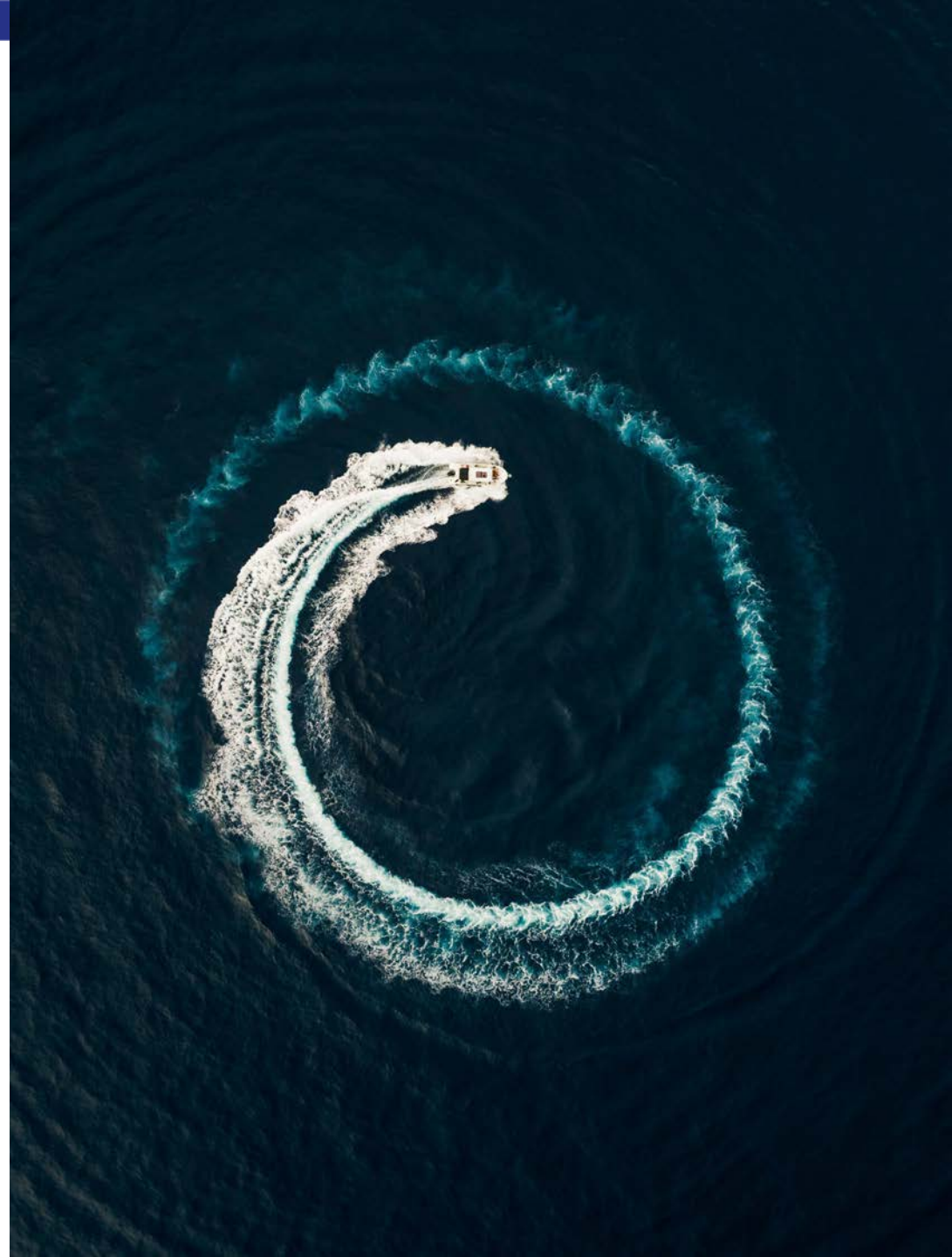
2. Close all correlating applications no longer required

3. Evaluate new evidence or variations to scope

Repository

MI-2025-CL-12345 (v1)

1. Extend all MRA & NS-API expiring in the next two FY



Example Scenarios

1. MRA / NS API CV GMP clearance expiring **prior** to 1 July 2025
   - Submit your normal extension applications
   - 2-year validity will be applied from 1 July

2. MRA / NS API CV GMP clearance expires within the first few weeks of July.
   - No need for extension applications
   - Sites that expire during first few weeks of July will get captured
   - Only contact us if this will affect a regulatory submission (i.e. CAT 3)

2: Abbreviated evaluations

- Apply to lower risk sites in typically assigned to higher risk streams
  - Testing laboratories
  - Secondary packaging / storage sites
  - Cell banking facilities
- Applies to ~15% of applications

Benefits
Efficiency gains and productivity increase
Expedite backlog reduction even further
Continue to support new product registrations, listings and variations

3: Ending GMP Clearance flexibilities

- Return to pre-pandemic business rules
- Evidence should be not more than 3 years old
- Global inspections returning to pre-pandemic numbers and frequency

Benefits
Remove major contributing factor to backlog creation
Return to clear guidance on what is acceptable evidence for inspection reliance pathways
Removes uncertainty and duplication for TGA processes (i.e. parallel GMP Certification & GMP Clearances)

Example Scenarios

1. Sponsor wants to submit a GMP clearance for a new site after 1 July 25. This is required for a category 1 (CAT1) submission intended to be lodged in November 25.
    - Most recent inspection by a Recognised Regulatory Authority (RRA) - November 2019
    - Sponsor liaises with the manufacturer and confirms no more recent evidence is available

    Sponsor should submit a GMP certification application for a TGA inspection flagging the CAT1 submission dates

Example Scenarios

2. Sponsor wants to submit a GMP Clearance for a new sterile finished product manufacturer. This is required to submit a category 3 (CAT3) variation to add this site as an alternative manufacturer replacing their existing supplier who is ceasing operations.
    - Most recent inspection by a Recognised Regulatory Authority (RRA) - December 2021
    - Sponsor liaises with the manufacturer and confirms no more recent evidence is available

    Sponsor should discuss specific situation together with relevant areas of TGA (i.e. GMP Clearance, Medicine shortages, Product regulatory area).

Refresher – How to use Slido
Questions are now open!

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Using the QR code

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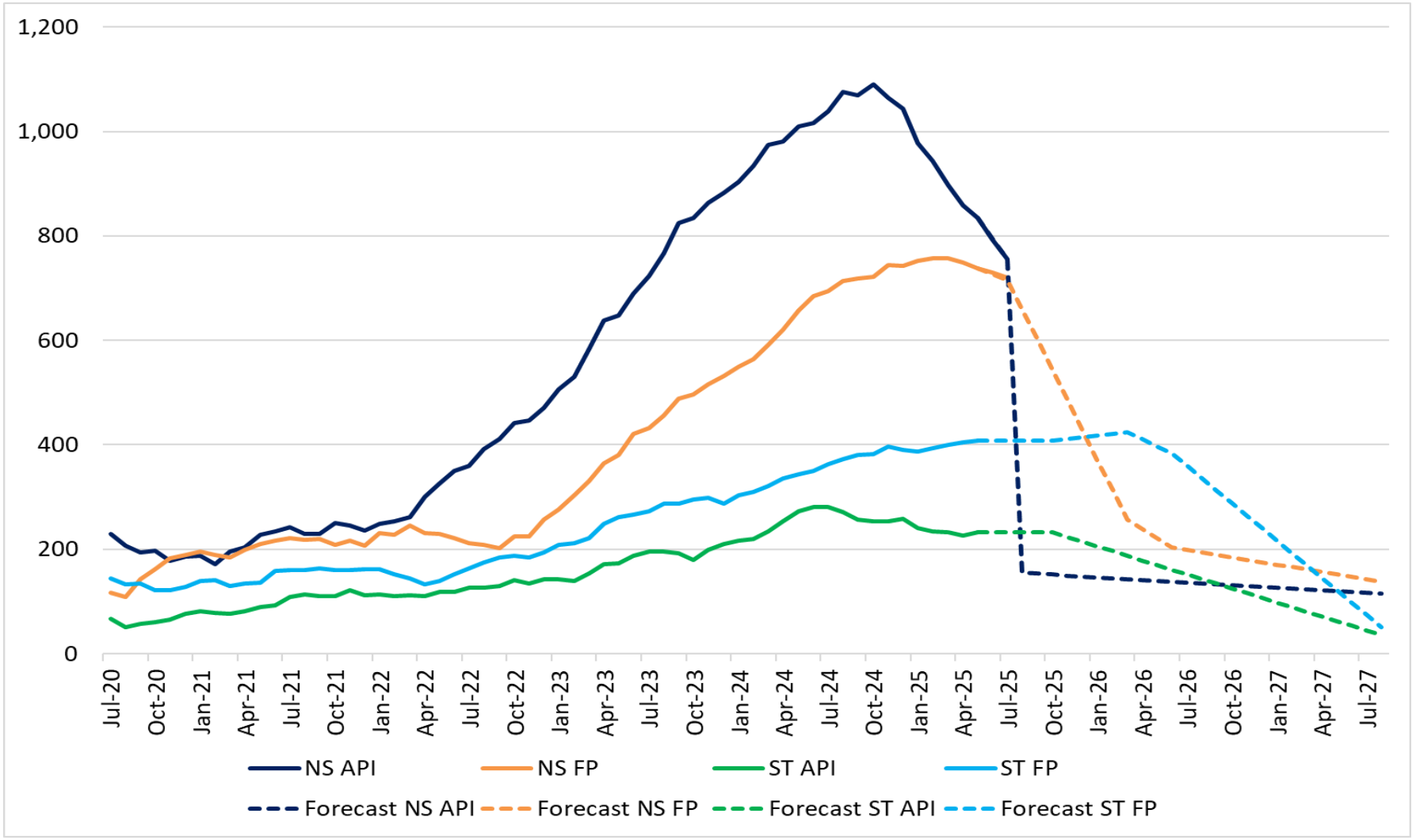
Expected outcome



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Progress reporting and Communication

- All backlog reduction strategy notifications will be published on TGA website
- Regular progress updates will be provided via:
  - Sponsor Information Dashboard (SID)
  - TGA-Industry Working Group on GMP (TIWGG)
- Encourage early engagement with all relevant areas of TGA to discuss individual applications or supply situations case by case
- Please contact us with any questions **before** submitting your applications

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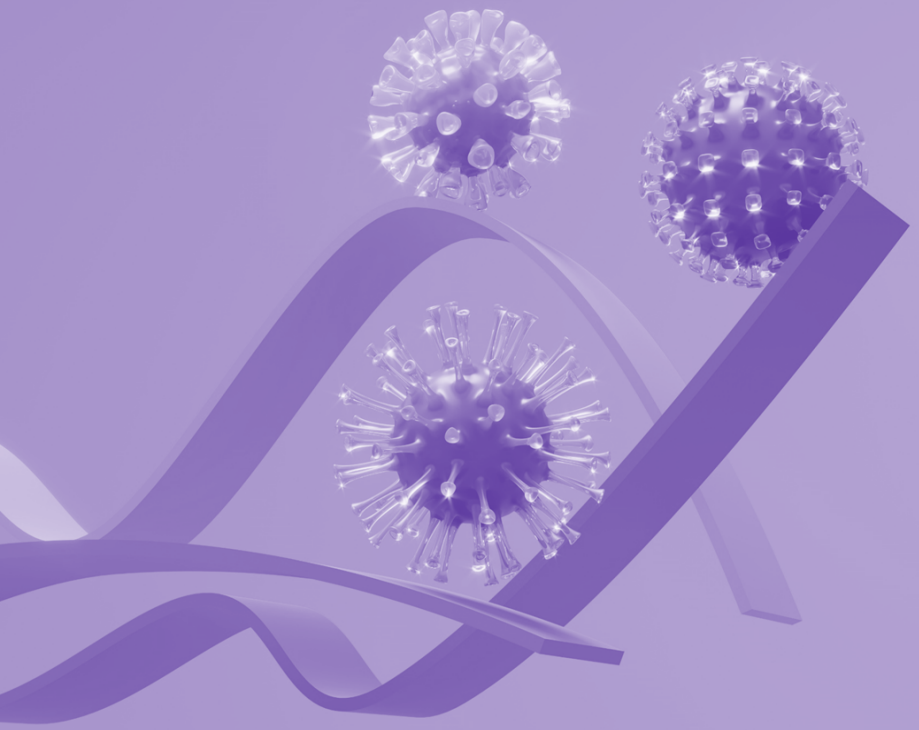

How industry can help

- Regularly review your tBS portal and application status
- Maintain the validity of your GMP Clearance(s)
- Request re-instatements rather than submit ‘new’ applications
- Only request prioritisation when it is really required
- Provide all required information upfront when requesting prioritisation or arrange meeting with all relevant areas of the TGA
- Where possible, use letters of access to clearance
- Encourage your manufacturers to provide you with LoA to evidence
- Pro-actively provide updated inspection information when available

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Recent updates

In May 2025, we published updates to our information resources on the following topics:

- Health Canada agreement on GMP inspections (Extra-jurisdictional inspections)
- Adoption of Annex 16 of the PIC/S Guide to GMP “Authorised Person and Batch Release”
- Correct use of Letters of Access (LoA)

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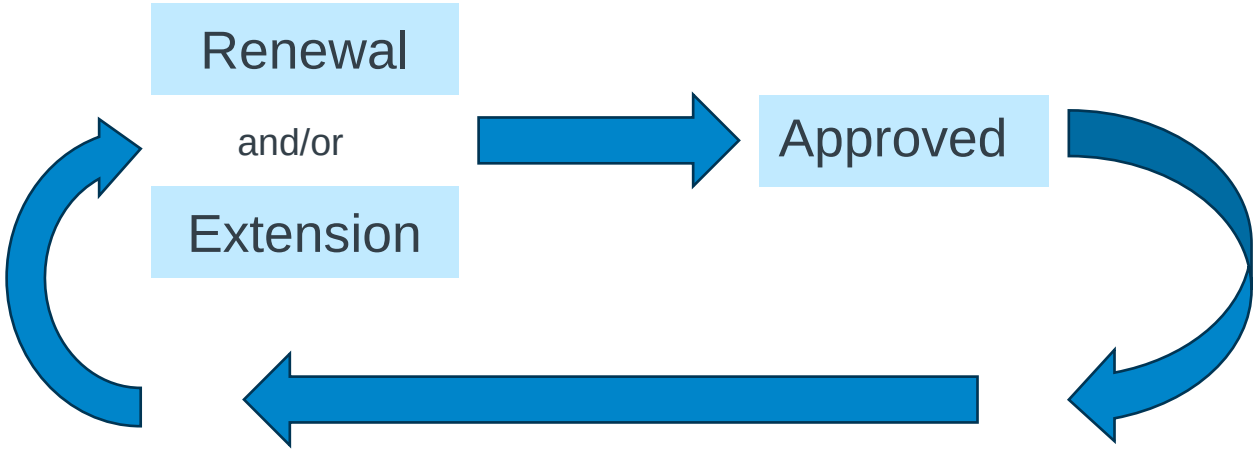
Letters of Access (LoA)



- There are 2 main types of Letters of Access (LoA)
  1. LoA to Clearance
  2. LoA to Evidence
- Sponsors need to ensure there is no ambiguity on the type of LoA to be used
- Where LoA to clearance is used, Sponsors need to ensure it clearly identifies the unique application number. This relates to a specific stage in the life-cycle of the parent application.

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Next steps

- Commencement on 1 July 2025
- Notifications and progress reporting through the website
- Ongoing collaboration to manage supply chain issues and potential medicine shortages
- Digital transformation and reform

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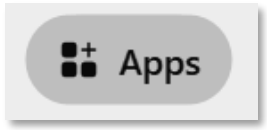
How did we go?

Take a moment to complete our survey, and we'll be back with your shortly for Q&A



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Questions?

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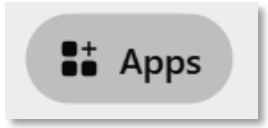

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Department of Health, Disability and Ageing, TGA

Websites & Link References

How to obtain GMP clearance through inspection reliance	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medicine/good-manufacturing-practice-gmp/overseas-manufacturers/how-obtain-gmp-clearance-through-inspection-reliance
GMP clearance Sponsor Information Dashboard (SID)	https://www.tga.gov.au/how-we-regulate/manufacturing/gmp-clearance-sponsor-information-dashboard-sid
GMP Clearance: Backlog reduction strategy commencing 1 July 2025	https://www.tga.gov.au/news/news/gmp-clearance-backlog-reduction-strategy-commencing-1-july-2025
Updated GMP clearance information	https://www.tga.gov.au/news/news/updated-gmp-clearance-information

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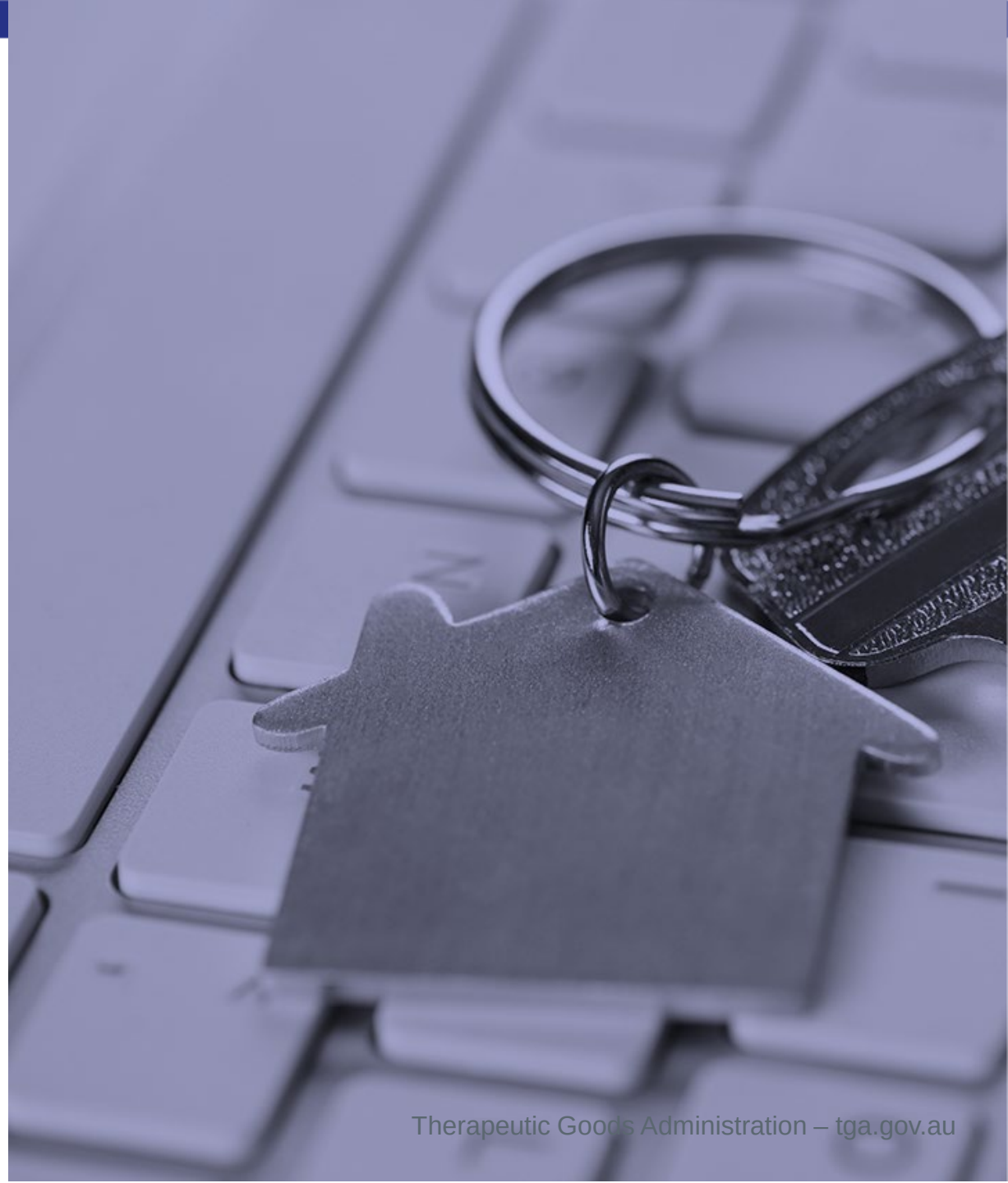
GMP Clearance team

GMPclearance@health.gov.au



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