Manufacturing Quality Branch Updates

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Session overview

- Who we are and what we do
- Recall reforms
- Licencing, Certification and Engagement, and GMP Compliance and Enforcement
- Inspections
- GMP Clearance - Backlog reduction strategy

Manufacturing Quality Branch

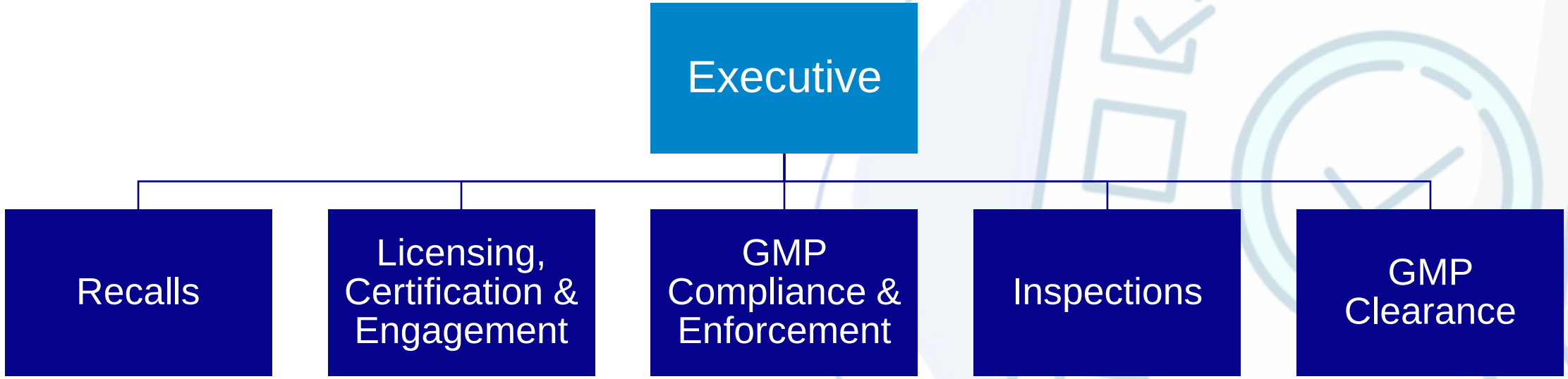
Who we are

Health Products Regulation Group (HPRG)

Therapeutic Goods Administration (TGA)

Medical Device and Product Quality Division (MDPQD)

Manufacturing Quality Branch Structure



What we do

Assists in the timely supply of therapeutic goods, ensuring they are of appropriate quality for their entire lifecycle

- GMP Inspections of domestic and overseas medicine and biological manufacturers
- Inspection Reliance evaluation of overseas medicine manufacturers
- Case-management of GMP non-compliance. Enforcement actions for GMP non-conformance.
- Recalls of all therapeutic goods (medical devices, biological products and medicines) supplied in the Australian market.
- Support for sovereign manufacturing capability

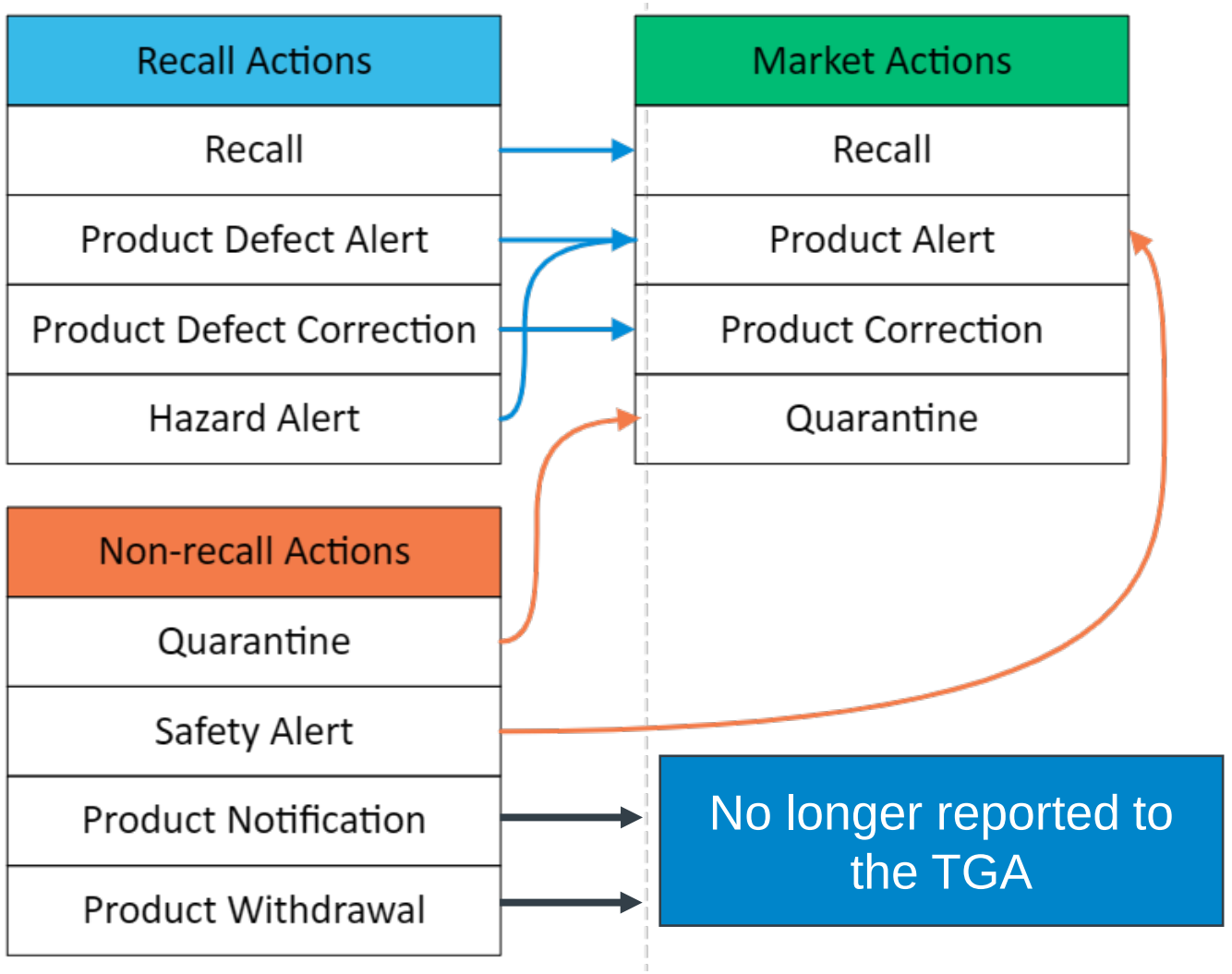
Recall Reforms

New Terminology

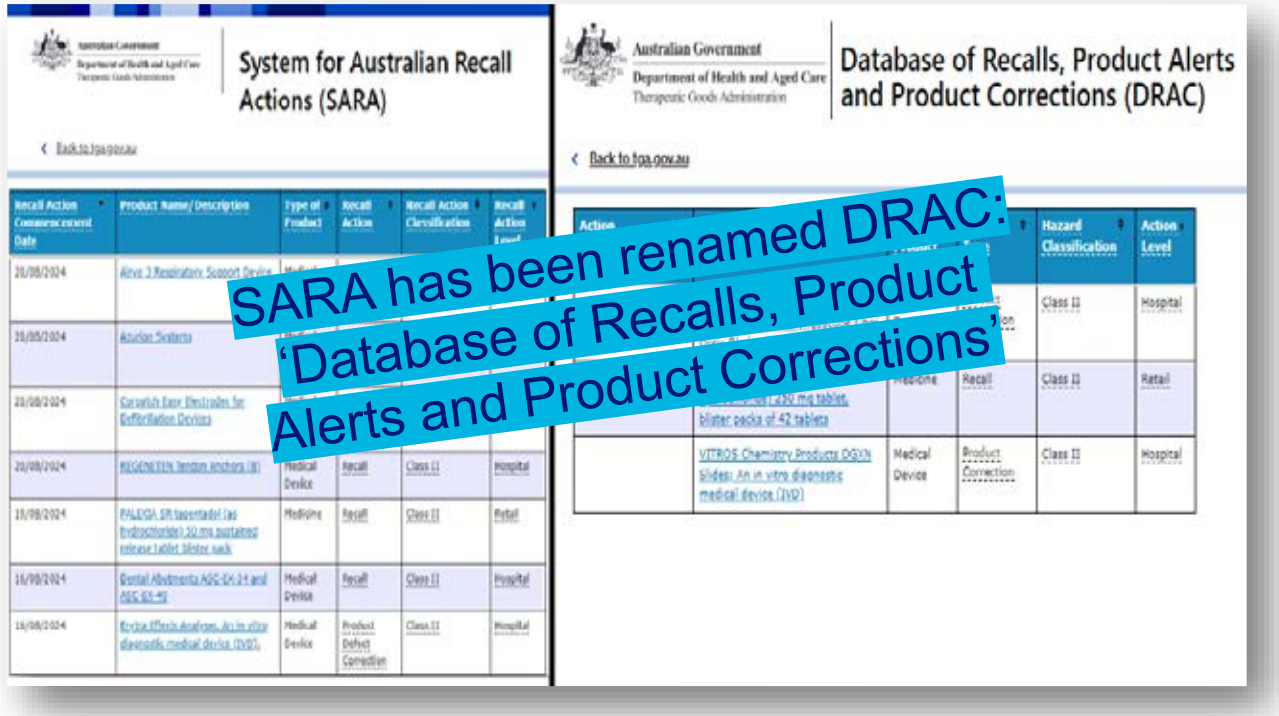
Uniform Recall Procedure for Therapeutic Goods (URPTG)

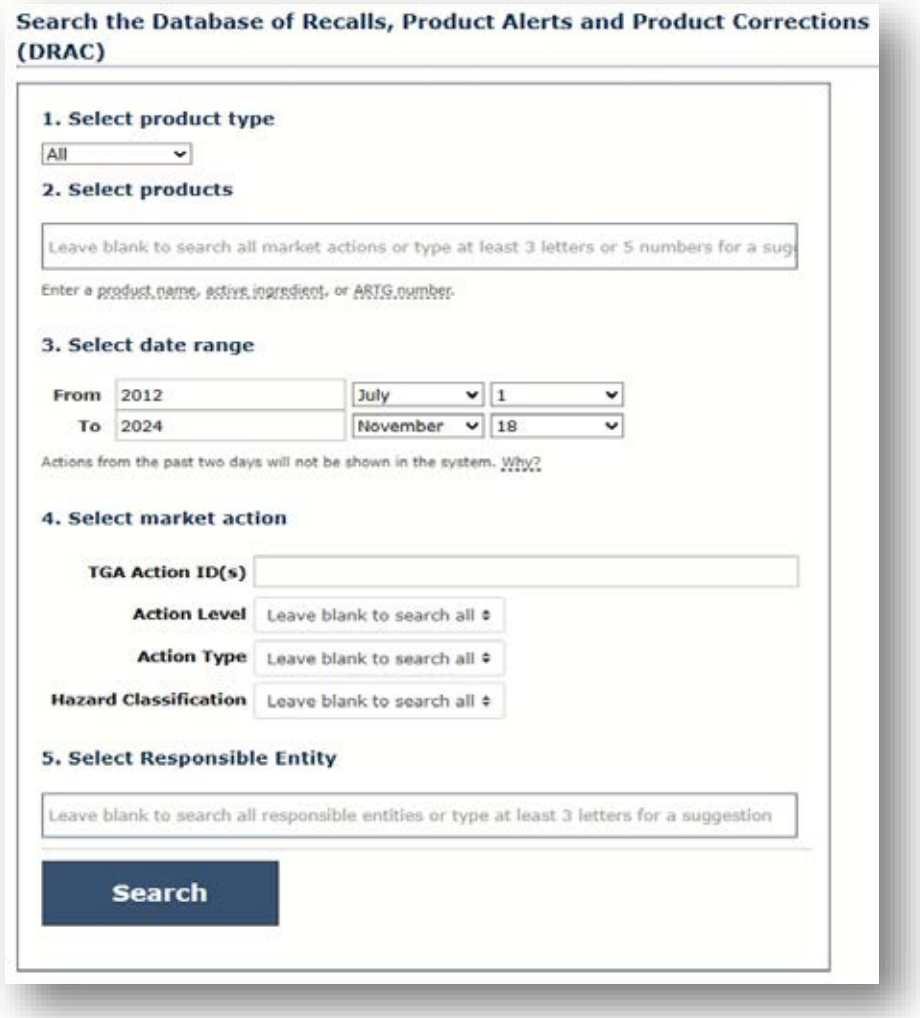
Replaced by

Procedure for recalls, product alerts and product corrections (PRAC)

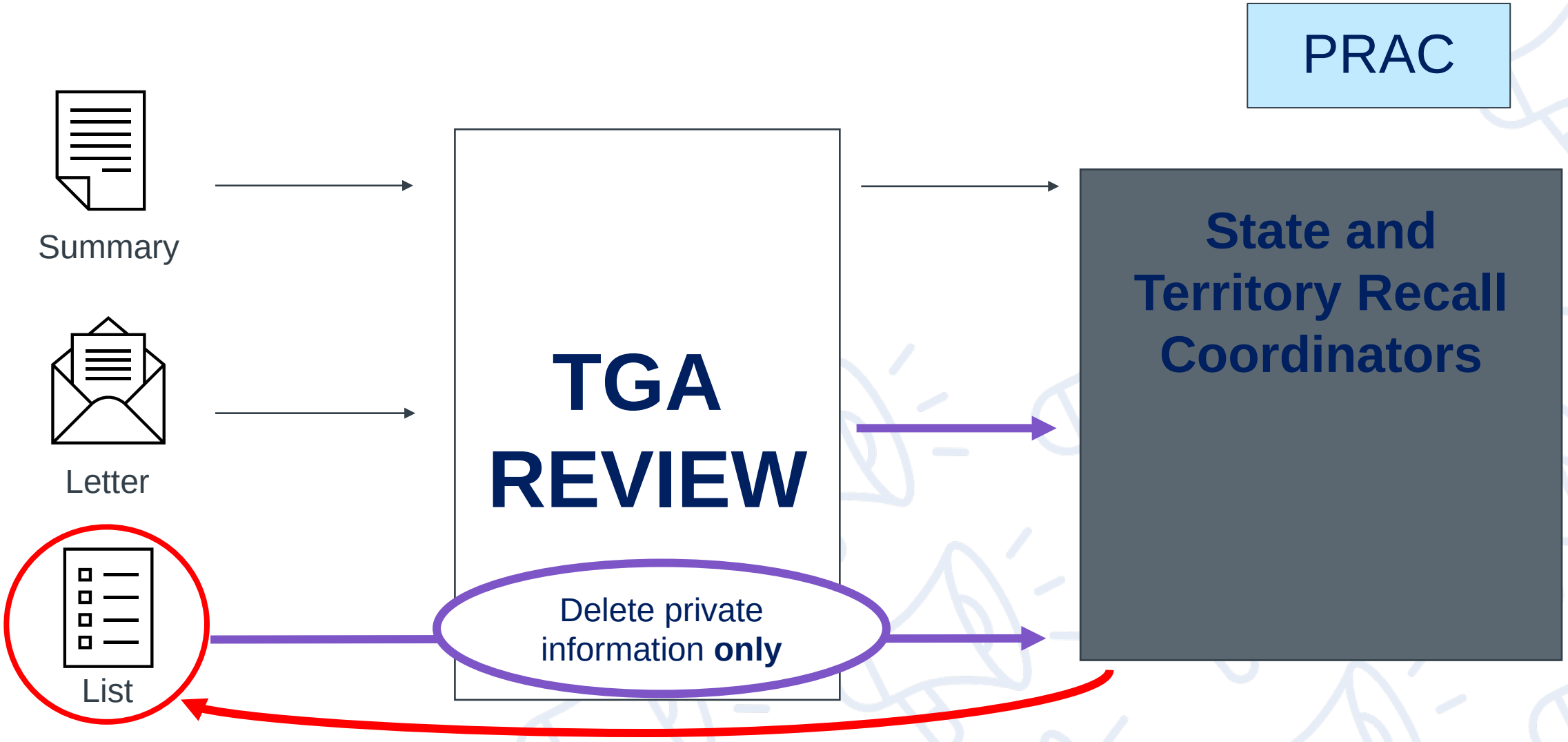


Database of Recalls, Product Alerts and Product Corrections (DRAC)





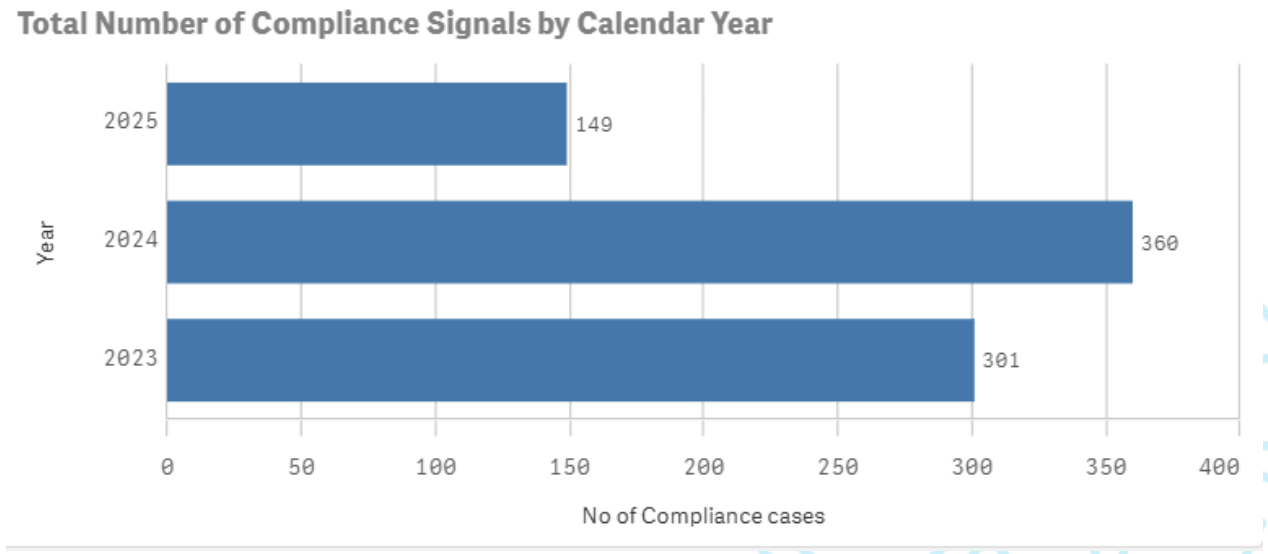
Notifying States and Territories



Licencing, Certification and Engagement

- Introduced extended validity of GMP certificates for Australian manufacturers to support export activities
- Focus on supporting domestic and overseas inspection planning

GMP Compliance and Enforcement



Inspections

- Ongoing use of ‘Surveillance Inspections’ introduced in 2024
- Industry guidance on Annex 16 “Authorised Person and Batch Release”
- Adoption of PIC/S version 17 including Annex 1 “Manufacture of Sterile Medicines”
- Development of further risk-based strategies for GMP inspections

GMP Clearance

Backlog reduction strategy

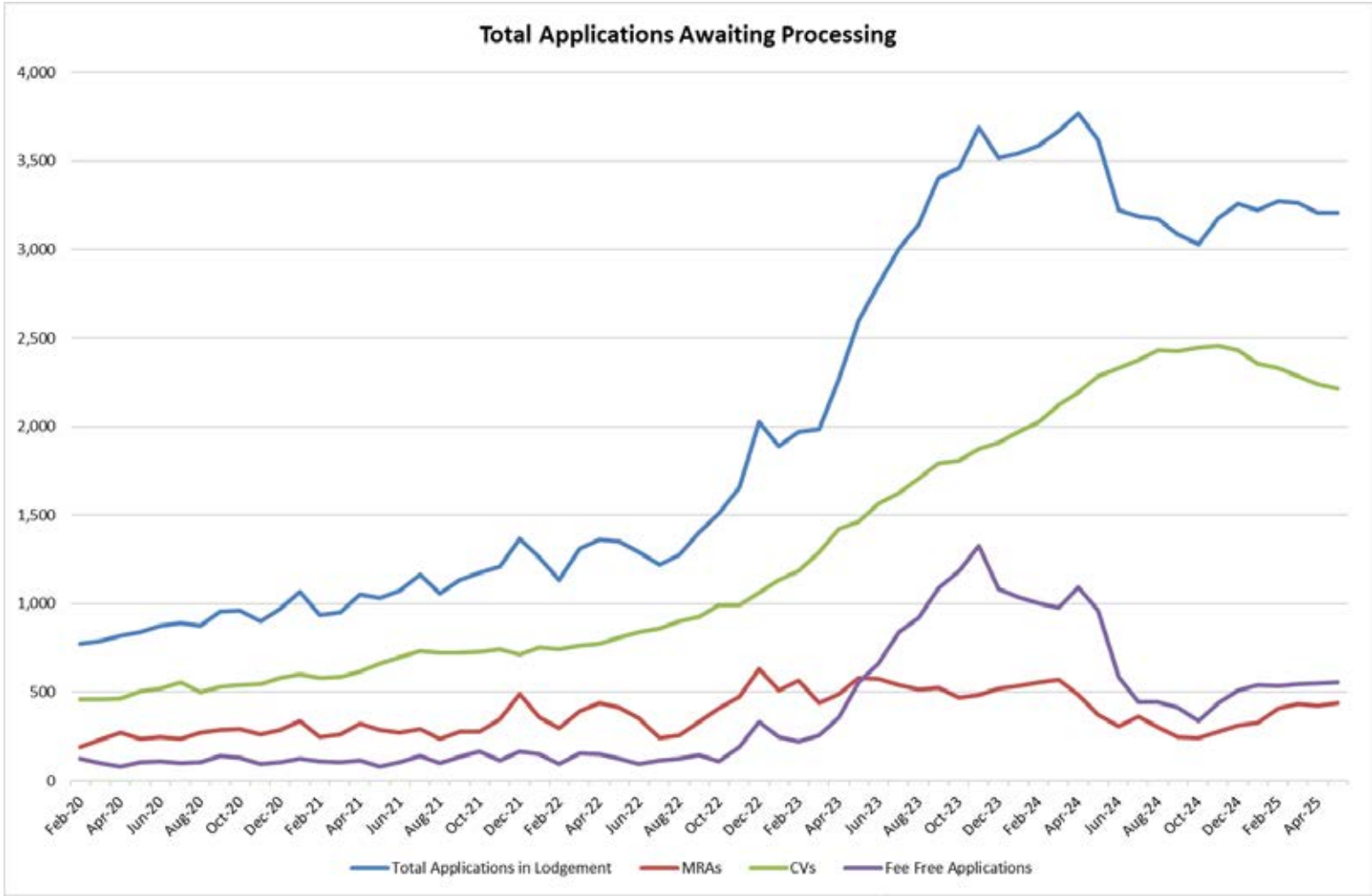
GMP clearance pathways

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

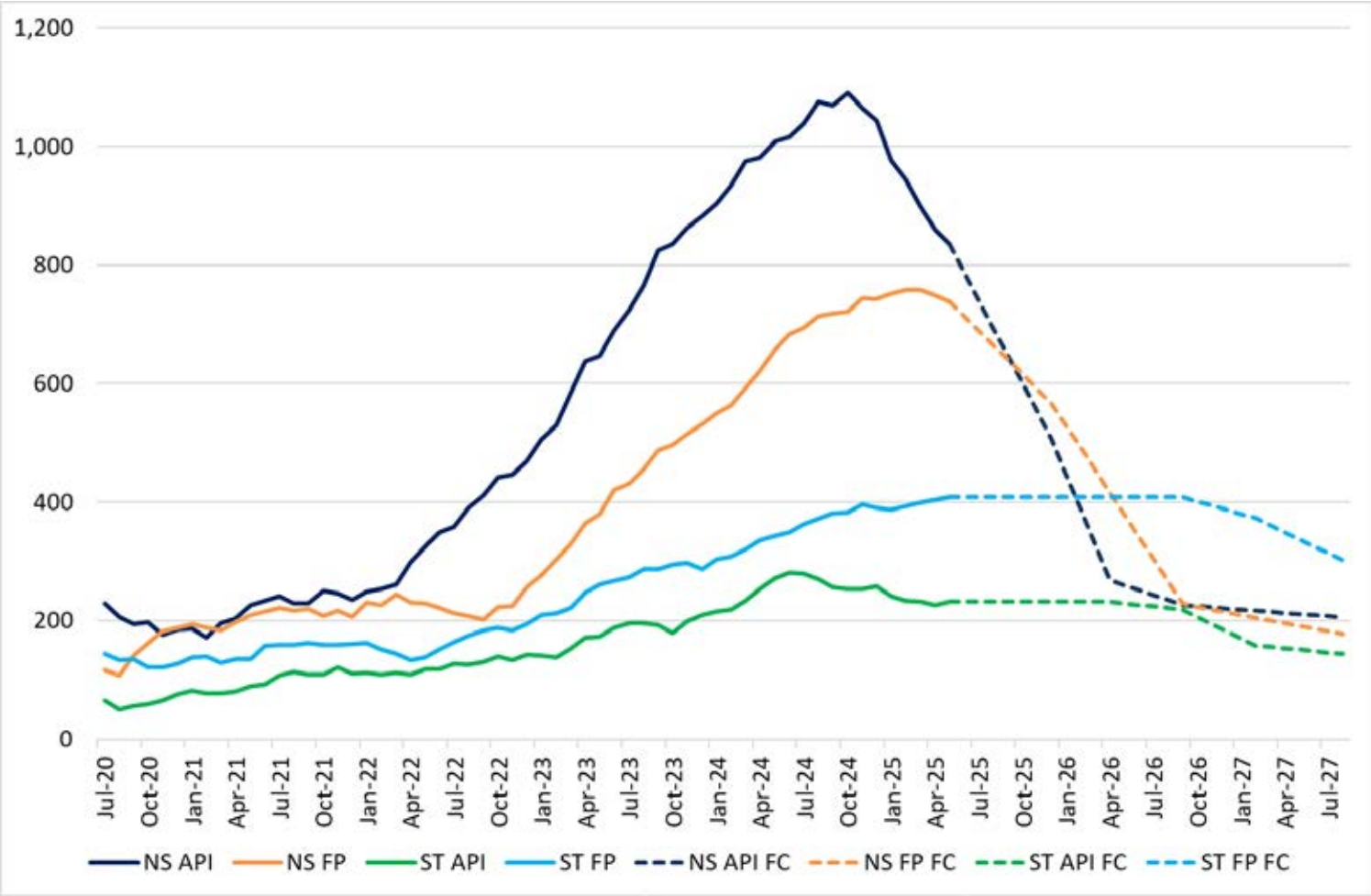
- Limited to our CV streams only (green trend)
- Peaked in October 2024 and now reducing
- Pre-pandemic ~500 CV applications on hand. This was our steady state.
- New target steady-state is ~750 CVs
- Backlog consists of ~1500 CVs



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
  - Suggested proposals are temporary measures

Backlog reduction strategy

1. Automatic extension of Mutual Recognition Agreement (MRA) and Non-sterile Active Pharmaceutical Ingredient (API) Compliance Verifications (CV)
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
- Close all 'in-train' applications
- Only evaluate new or variation applications

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

2: Abbreviated evaluations

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

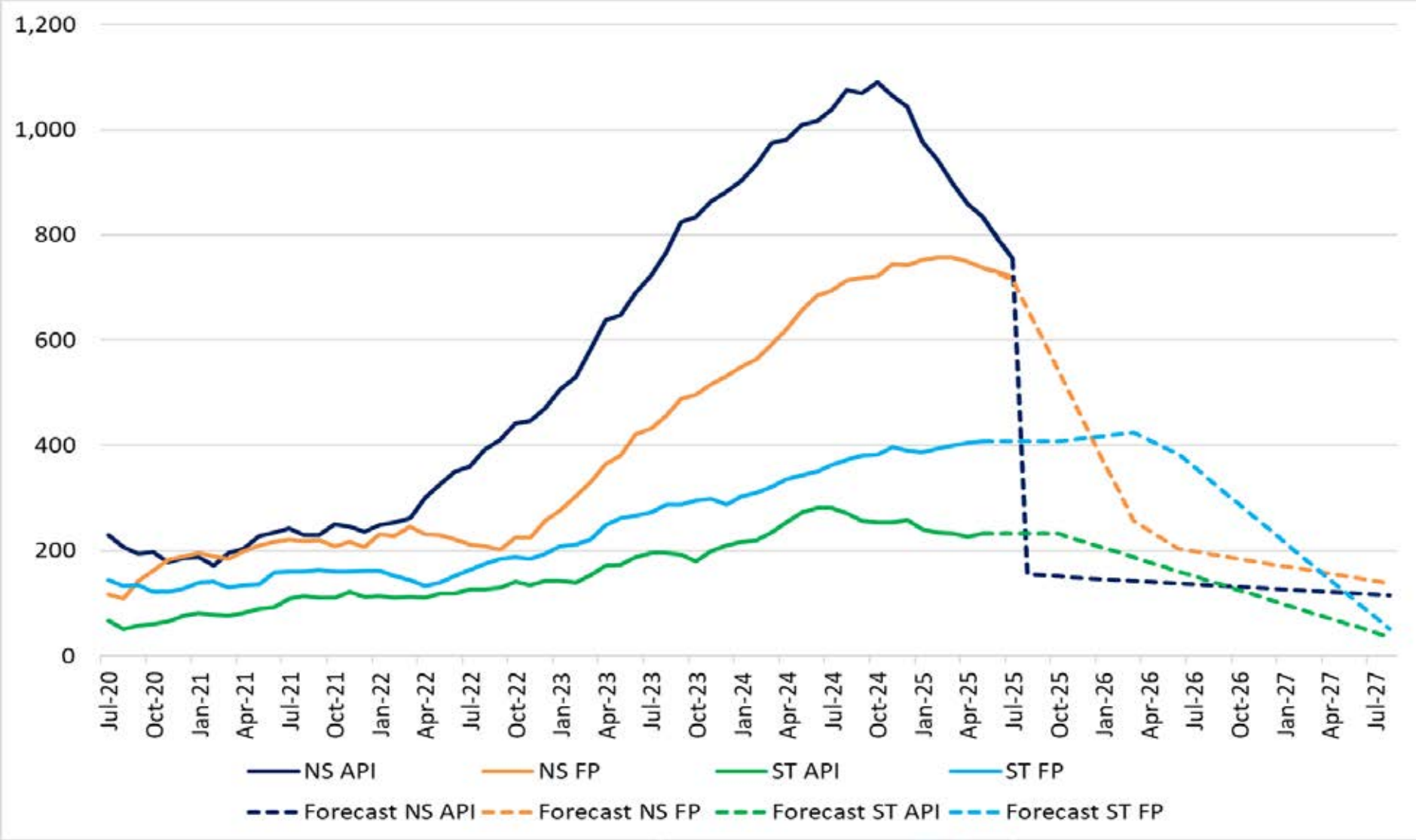
Benefits
Efficiency gains and productivity increase
Expedite backlog reduction even further
Continue to support new product registrations, listings and variations

3: Ending GMP Clearance flexibilities

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

Benefits
Remove major contributing factor to backlog creation
Provide clear guidance to industry on what acceptable evidence for inspection reliance pathways
Removes uncertainty for TGA processes

Expected outcome



Consultation and communication

- Consulted with the TGA – Industry Working Group on GMP (TIWGG)
- Web statement published on 29th May
- Webinar planned in June
- Regular progress updates on the GMP Clearance Sponsor Information Dashboard (SID)
- Encourage early engagement to discuss individual applications or supply situations case by case

Next steps

- Webinar and Q&A session in June
- Commencement on 1 July 2025
- Ongoing collaboration to manage supply and medicine shortages
- Digital transformation and reform

Therapeutic Goods Administration (TGA)

Exhibition booth **No.60**

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Therapeutic Goods Administration