Manufacturing Quality and GMP Clearance

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Session overview

- Manufacturing Quality Branch Updates
- GMP Clearance Overview
- Backlog Reduction Strategy
- Looking Ahead
- GMP Clearance Digital Transformation

Who Are We?

Health Products Regulation Group / TGA

Medical Devices and Product Quality

Manufacturing Quality Branch

GMP Clearance Section

Manufacturing Quality Branch Updates

- Publication of information on when statutory declarations should be provided. See Manufacturer statutory declarations (TGA Website)
- Manufacturing licensing decisions (grants, revocation and suspension) are now published on the TGA website instead of the Public Service Gazette. See List of licensed manufacturers in Australia (TGA Website)
- Intention to undertake public consultation on the publication of GMP inspection outcomes and GMP certificates for international manufacturers
- Planned updates to the PIC/s Guide following public consultation on Annex 6 and Annex 15 concept papers

What is GMP Clearance?

Desktop evaluation of overseas medicine manufacturers

Inspection reliance facilitated by our international agreements with overseas regulatory authorities:

- Mutual Recognition Agreements (MRA)
- Memorandum of Understandings (MoU)
- Cooperation Agreements

Why Do We Do It?

- For overseas manufactured goods to be registered or listed on the ARTG:
    - The delegate must be satisfied the manufacturing and quality control procedures are acceptable
    - Sections 25(g), 26(1)(g), 26A(3) and 26(AB)(4) of the Therapeutic Goods Act
- To support the main objectives of the Act
    - Ensuring the safety, quality, efficacy and timely supply of therapeutic goods

GMP Clearance Pathways

Two Inspection Reliance 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)

Backlog Reduction Strategy

The Backlog – July 2025

The Problem:

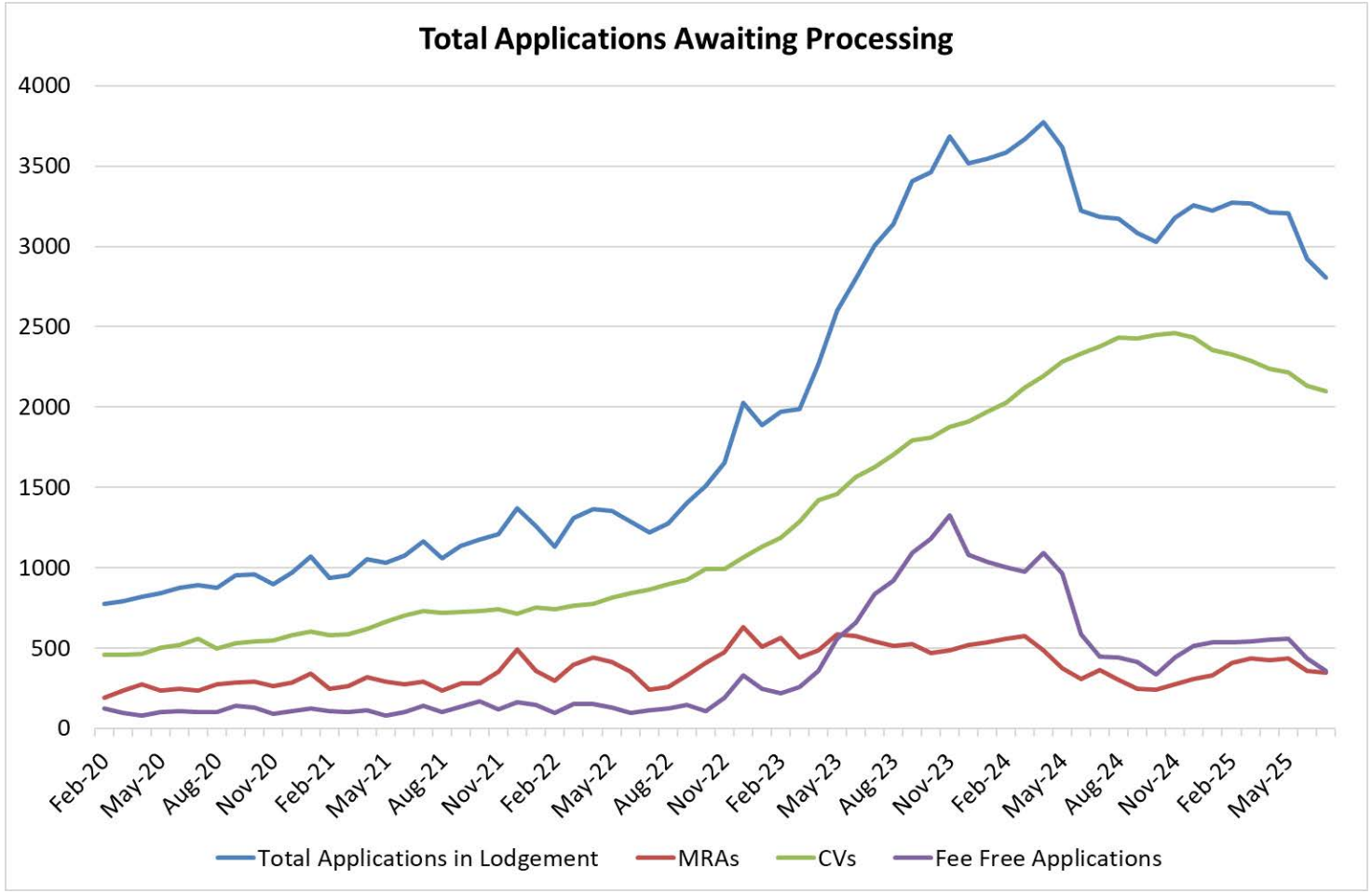
- Significant increase in applications due to COVID, travel restrictions limited new inspections

Initial mitigation strategies:

- Increase in head count, created prioritisation pathways, streamlined evaluations

Backlog:

- Peaked in Oct 2024
- Target steady state ~750 applications



Backlog Reduction Strategy Overview

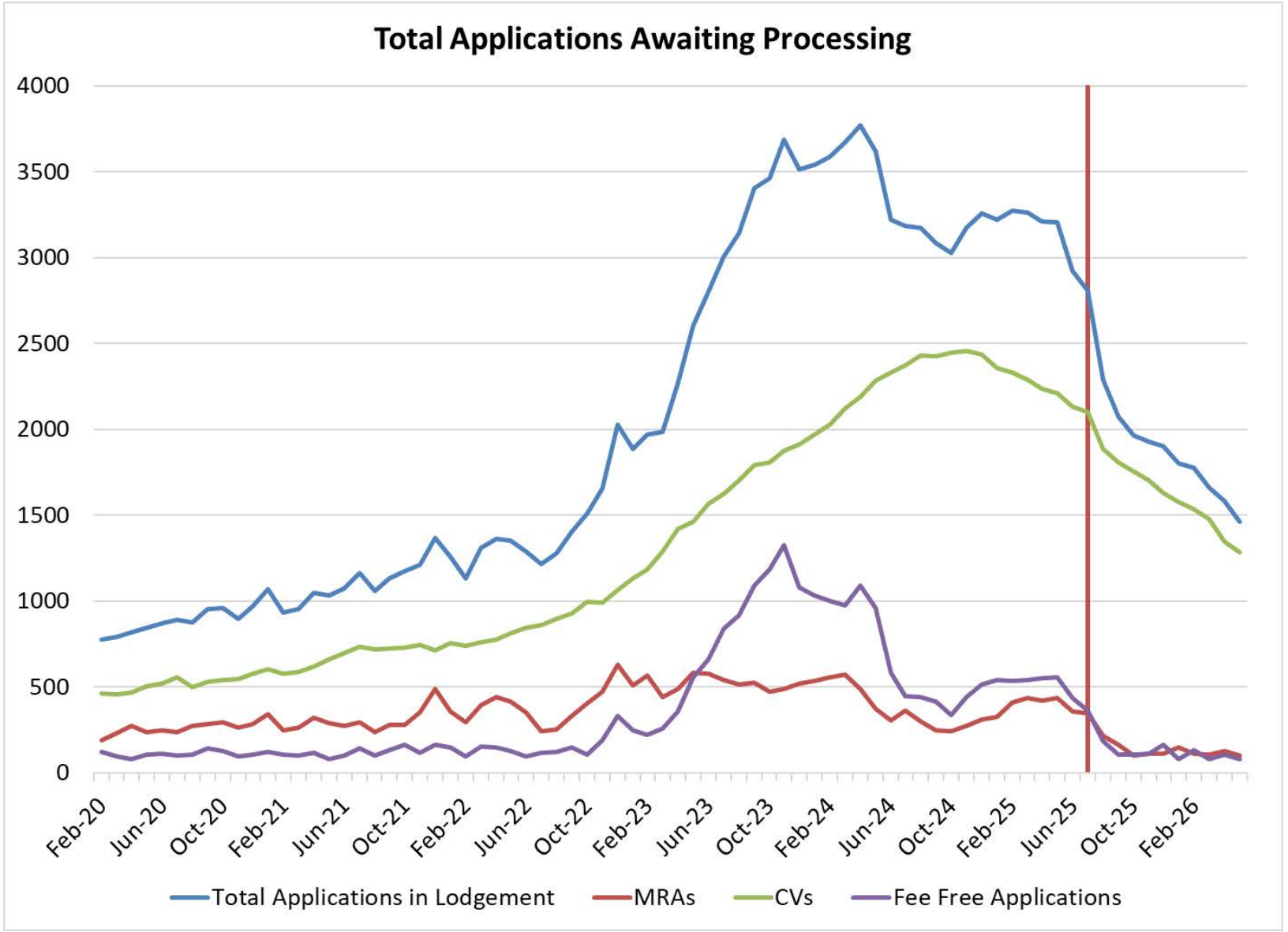
1. Automatic extension of MRA and NS API CVs

2. Abbreviated evaluations of manufacturers performing certain lower risk activities

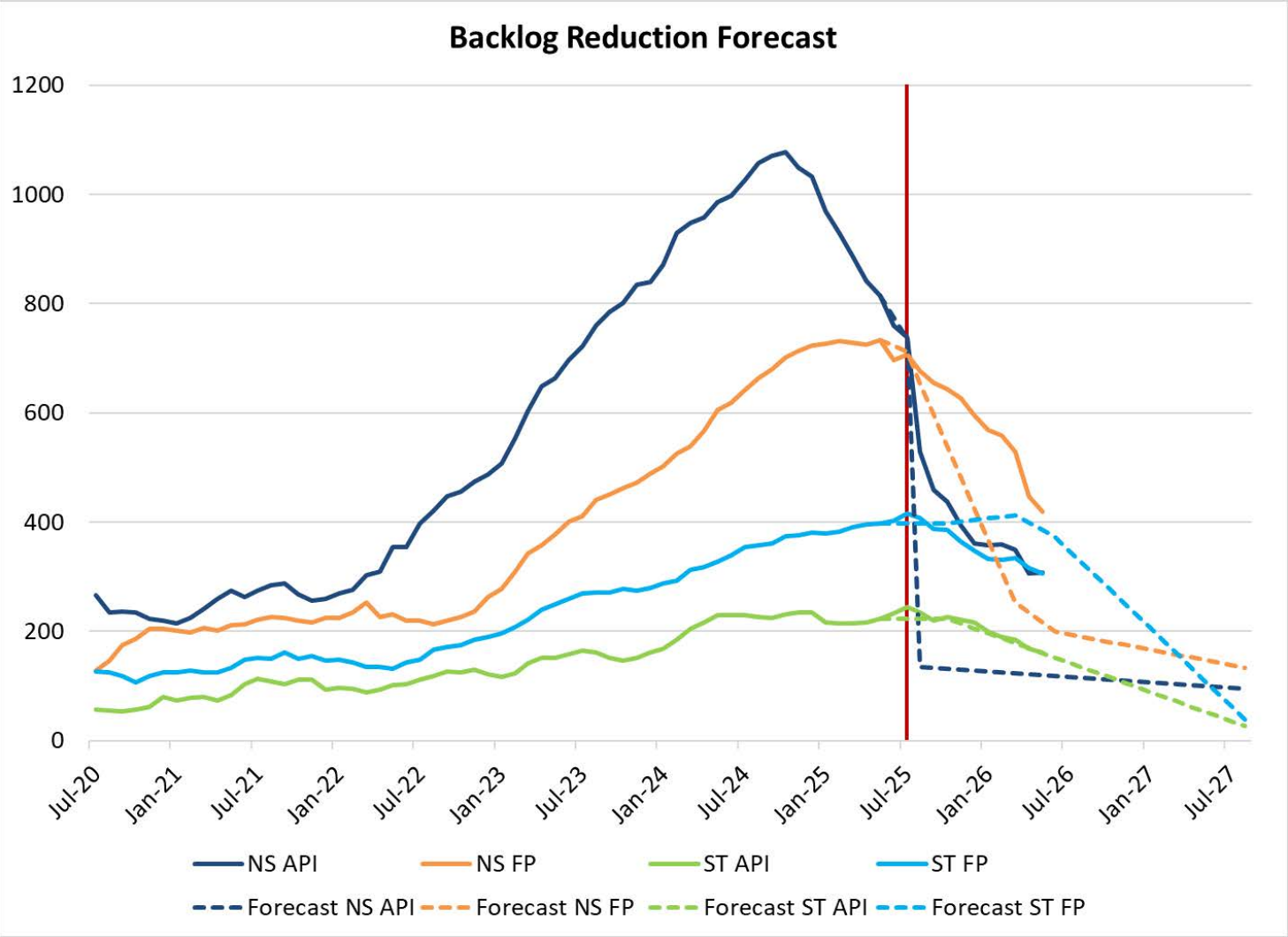
3. Ending GMP Clearance flexibilities introduced during COVID-19, specifically the GMP Clearance Questionnaire

Progress To Date

- Red line is the implementation of our strategy
- Were able to reduce the number of MRA and Fee Free Applications and maintain low volumes
- Rate of decline for CVs has increased
- Backlog currently consists of ~500 CVs above our steady state



Strategy Forecast vs Actual



- More NS API applications had newer evidence than anticipated, requiring evaluation
- More MRA applications received than anticipated
- Progress has been delayed in the NS FP queue due to training and staffing

What Worked Well

- Extended over 6,000 MRA and NS API clearances for two years
    - This has reduced the incoming volume of applications allowing us to prioritise the backlog work
- Undertaking abbreviated evaluations in certain circumstances
- Modified our training program to train our large cohort of newer evaluators
- Working closely with product evaluation areas to minimise delays to submissions

What Didn’t Go As Planned

- New inspection evidence was available for many applications
    - If newer evidence provided a longer expiry, the application remained in the queue for full evaluation
- Resources and training remains a challenge
- Continuing to receive a high volume of priority application requests

Current Focus

- Prioritising work in the NS FP queue
- Continue to train our evaluators in higher risk sterile applications
- Working with the product registration areas to minimise delays
- Continue development on digital transformation

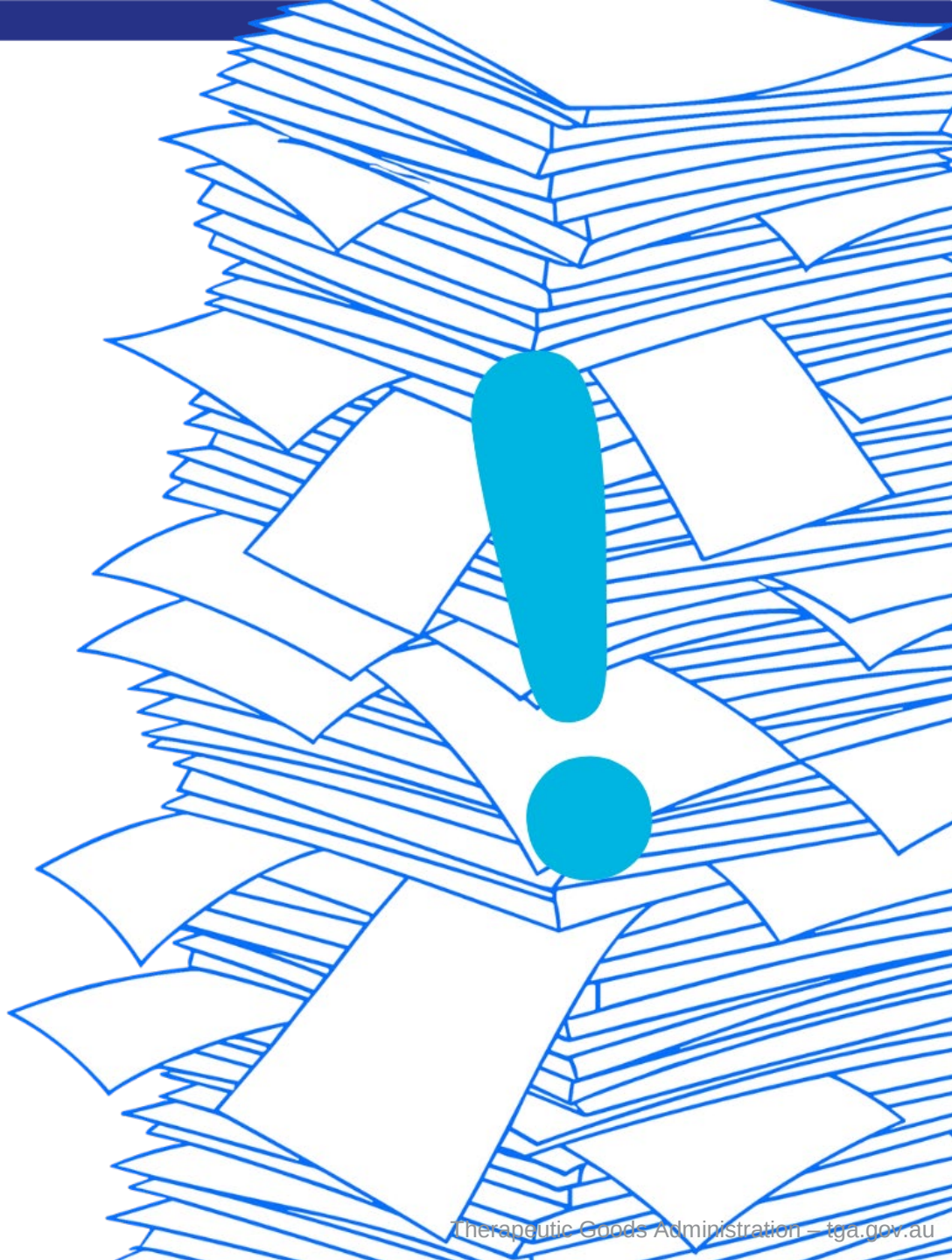
Looking Ahead

Predictable Timeframes

- Aim to make GMP Clearance timelines consistent and reliable
- Focus on being predictable, so sponsors can plan with confidence
- Keep exceptions to a minimum and avoid queue jumping
- Aiming to use a clear first-in / first-out order to have a level playing field for industry

Prioritisation Requests

- Introduced in 2023 to triage the backlog at its peak
- We’re reviewing the priority pathways (1,300+ requests over 3 years)
- High volume of requests, created lots of work managing the competing application priorities
- We will continue to publish updates to SID



What Industry Can Do

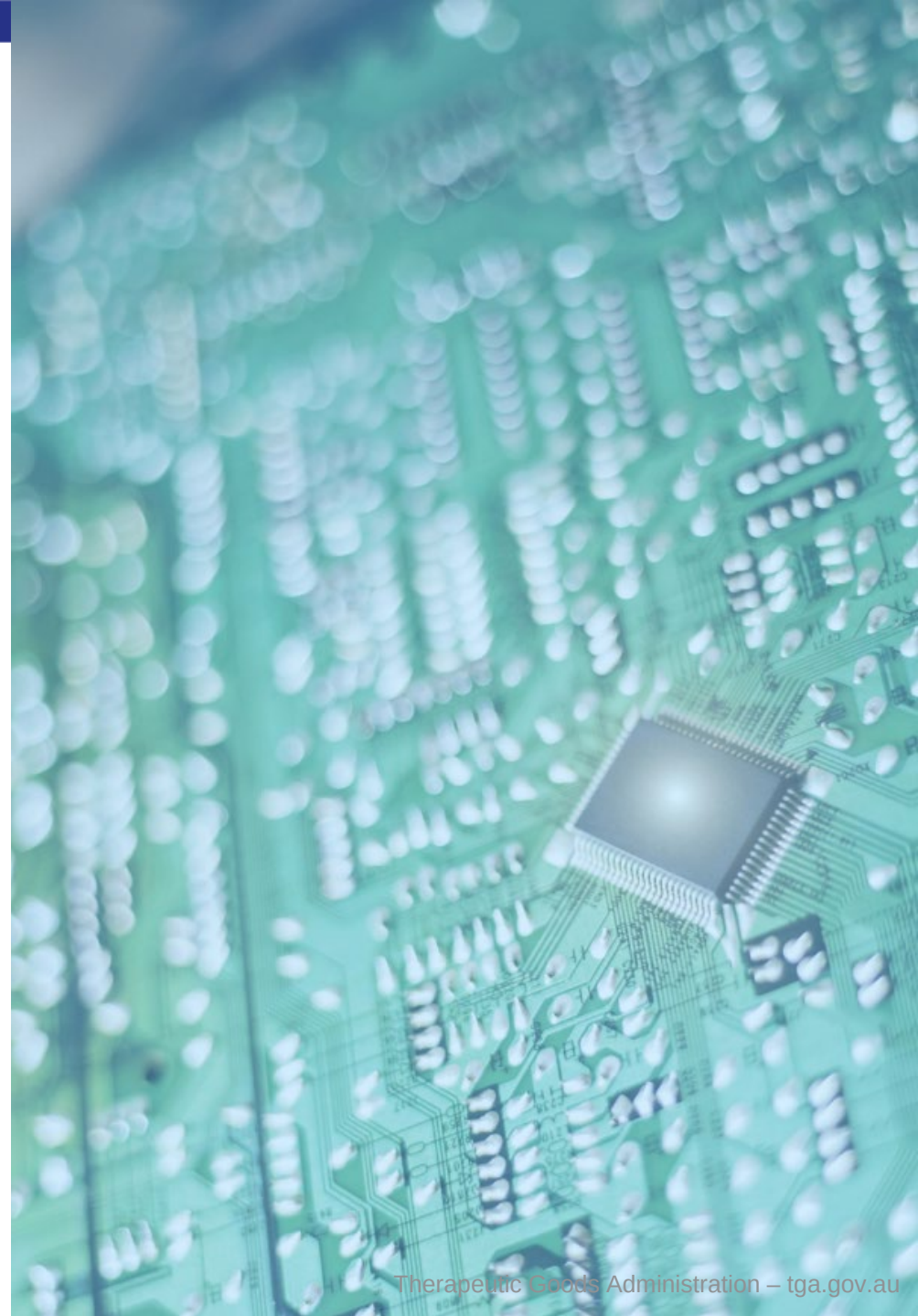
- Submit current evidence upfront and submit updated evidence when it becomes available
- Withdraw applications that are no longer required
- Continue to provide us with details of linked product submissions
- Submit a request for a GMP pre-submission meeting

GMP Clearance Digital Transformation

Overview of our digital transformation

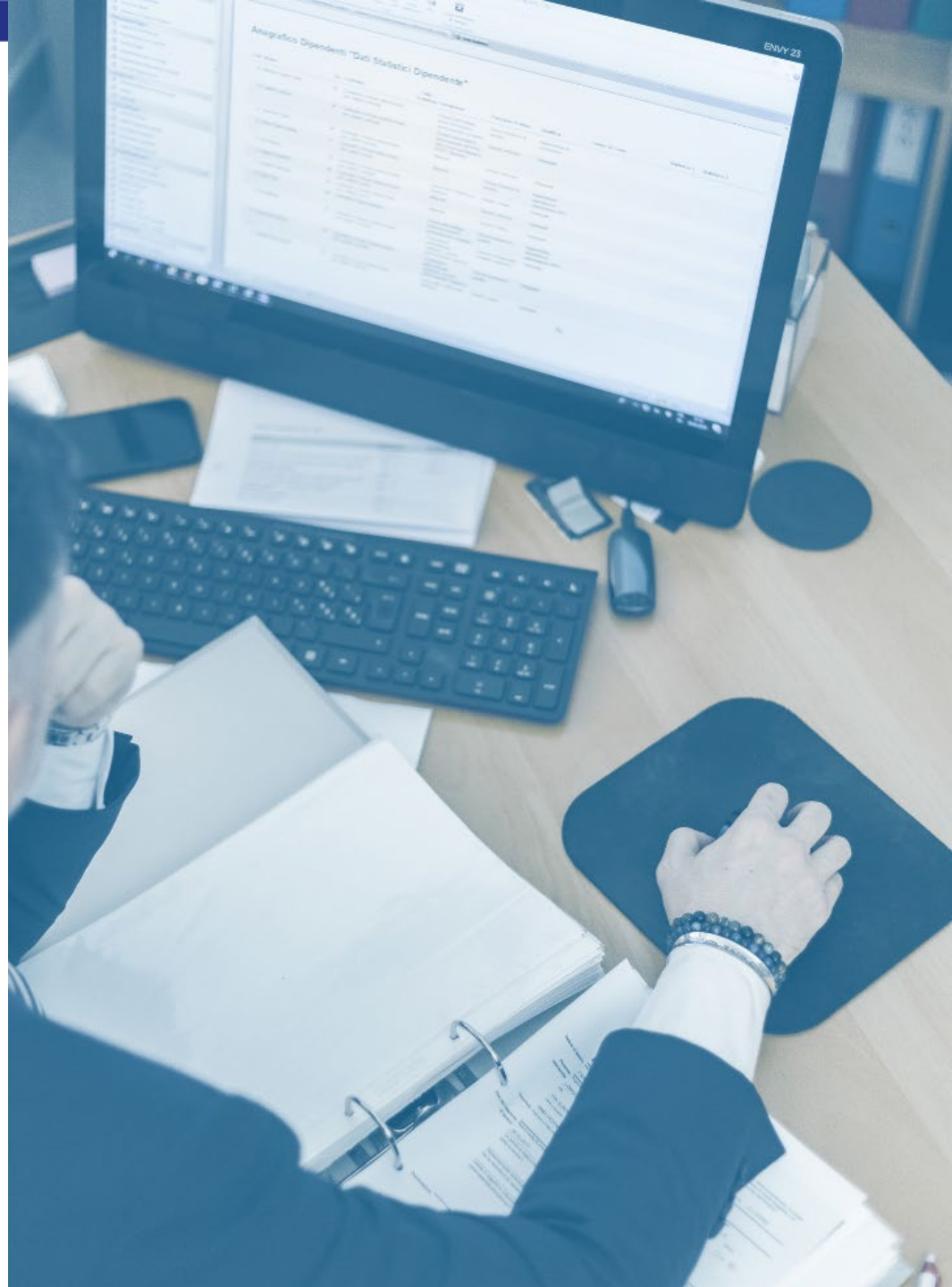
- Three parts currently being worked on
  - Internal – Case Management System
  - External – GMP Clearance Application Form
  - External – Manufacturers on the Portal

- The application form and manufacturers portal will live on Health Business Services Portal
  - New tiles for business areas will be available once they are migrated



GMP Clearance application form

- Current focus of work is designing the application form for a new GMP Clearance submission
- Other application types (variations, extensions etc) will be a later focus
- Addressing common pain points for industry and TGA



Application form improvements

- Introduction of additional sites linked to a clearance

- Combined API and FP scopes
  - Will no longer require two clearances for a single site performing activities for APIs and FPs

- Capturing new structured data
  - Can link applications to product submissions and existing ARTG entries
  - Can list secondary contact details for applications

Case Management Portal

- In the process of being configured for GMP Clearance
- Will have better visibility for sponsors over the current system
- Establishing a series of milestones throughout the process which can be seen by sponsors
- Maintaining elements of the current system such as stop clocks
- Uplifting activities performed off system to improve efficiency

Manufacturers evidence

- Manufacturers manage and update evidence directly
- Evidence is stored prior to application submission
- Sponsors link to the data via a reference key

Questions?

www.tga.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration