

TGA Digital Program Beta Release - November 2025



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Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

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** and will be available for access in upcoming weeks



Closed captions are available

Activate it with the speech bubble icon on the bottom left of your screen



Difficulties with sound?

Check your settings located under **Audio & Video** located top of your screen

You can also call to join the webinar on the details below.

Dial: 02 9338 2221 (+61-2-9338-2221)

Access code: 2652 255 3766



SLIDO – questions are now open

How to access and use Slido



Through the Slido application in Webex



- Click on the **Apps** icon
- Select **Slido**
- Open the **Q&A** tab to ask questions
- Live Poll (use survey tab when prompted)



Using the QR code



Scan the QR code to access Slido from your mobile device

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tga.gov.au

Purpose of the webinar

To demonstrate the beta release features and benefits for our industry stakeholders, to validate and refine before the live launch.

Presenters and Panellists:

Prof Tony Lawler

Deputy Secretary
Therapeutic Goods
Administration

Chris Bedford

First Assistant Secretary
Regulatory Practice &
Support Division

Lisa Tepper

First Assistant Secretary
Information Technology
Division

Jennifer Frisby

Assistant Secretary
Health Business
Systems Branch

Alysha Martens

Director
HPRG Digital Branch

Michael Davis

Director
HPRG Digital Branch

Provide background on the Digital Transformation program

Demonstrate the beta release features
Login > Service Layer > CMS

Q&A and Feedback



Welcome to Beta testing: Engagement & Feedback Strategy

Ongoing engagements and feedback via regular meetings with industry

Targeted testing



Facilitated user research sessions

From 27/11/2025 – 5/12/2025

Members of the **IWG and organisations representing industry** have been invited to participate in guided group feedback sessions over late November and early December

Feedback Mechanism:
Session summary report and follow up survey

OR



Independent run-through

From 27/11/2025 – 12/12/2025

This will be accessible to a **limited user cohort** for a limited time duration, enabling users to independently run-through the Beta product to provide feedback

Feedback Mechanism:
Session summary report and follow up survey

Open feedback

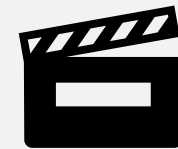


Webinar

Webinar: 2/12/2025

Live webinar which will then be accessible to the **public and all of industry** via the TGA website.

Feedback Mechanism:
Survey



Demonstration Videos

Surveys open Dec – Feb

There will be **demonstration videos** available for viewing on the website, and for internal staff.

Feedback Mechanism:
Survey

Introduction: Improving the TGA digital systems

We're **transforming** the way that industry interact with us by building a **modern, intuitive** digital platform that aims to make interactions with us **easy, seamless and efficient**

Our goal is to create a **flexible, transparent, and connected** regulatory platform that strengthens our ability to protect the health and safety of all Australians.

We are also updating our internal business processes to work alongside the improved digital platform.

Through this transformation, we will improve industry experiences, streamline interactions and make it easier to meet regulatory obligations. We aim to:

reduce **regulatory burden and costs** for businesses

respond more effectively to the needs of **industry, patients, consumers and healthcare professionals**

make more **efficient and consistent** decisions

provide **more accurate information** to health consumers

lower risks to government service delivery

Current State Challenges

With the proliferation of technology over the years, the complexity of the tech landscape has dramatically increased with persistent system errors and failures

Existing systems are not decommissioned, instead new systems enter the ecosystem.

They are poorly integrated, creating greater load on the existing systems and adding to some of the root causes of problems on reliability.

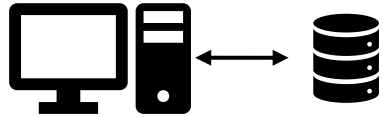
💡 Business Improvement Program (BIP)

💡 Digital Transformation Program

💡 HPRG Digital Branch

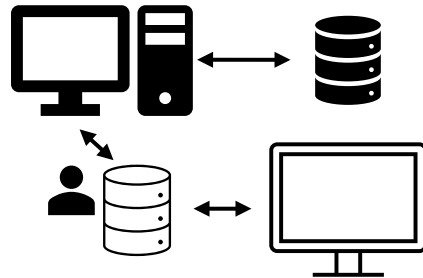
2010-2015

Monolithic systems, difficult to adapt to evolving business needs. Core systems relied on heavily for day-to-day business.



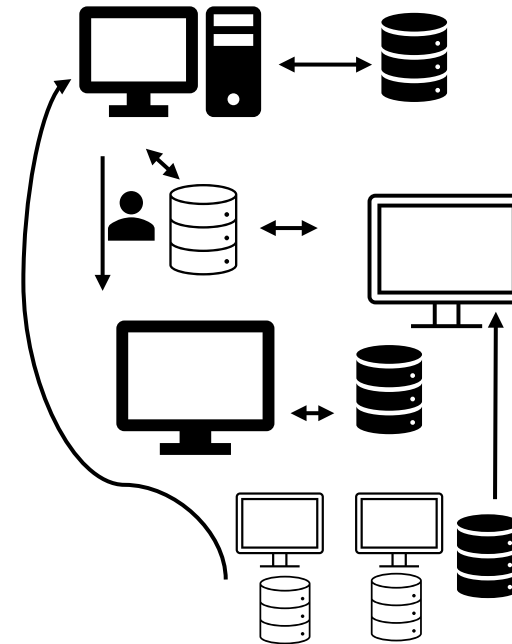
2015-2023

Introduction of more modern technology to address problems faced by industry and staff. Core systems still heavily relied on for day-to-day business.



2023-2025

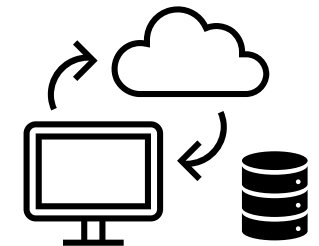
Seeking to reduce reliance on existing core systems and improve integration across systems to avoid failures.



Today

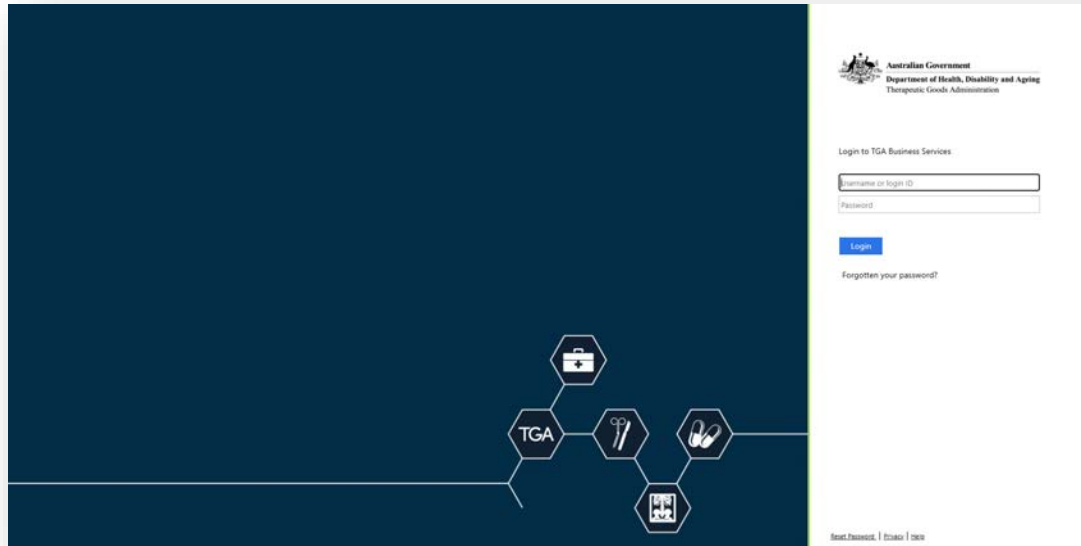
Moving from existing to new systems without impacting on business continuity.

Systems that are modern and can adapt with evolving business needs. These are delivered by a team of digital professionals that seek to provide *continuous* improvements to TGA's digital products and technical landscape.



Current State

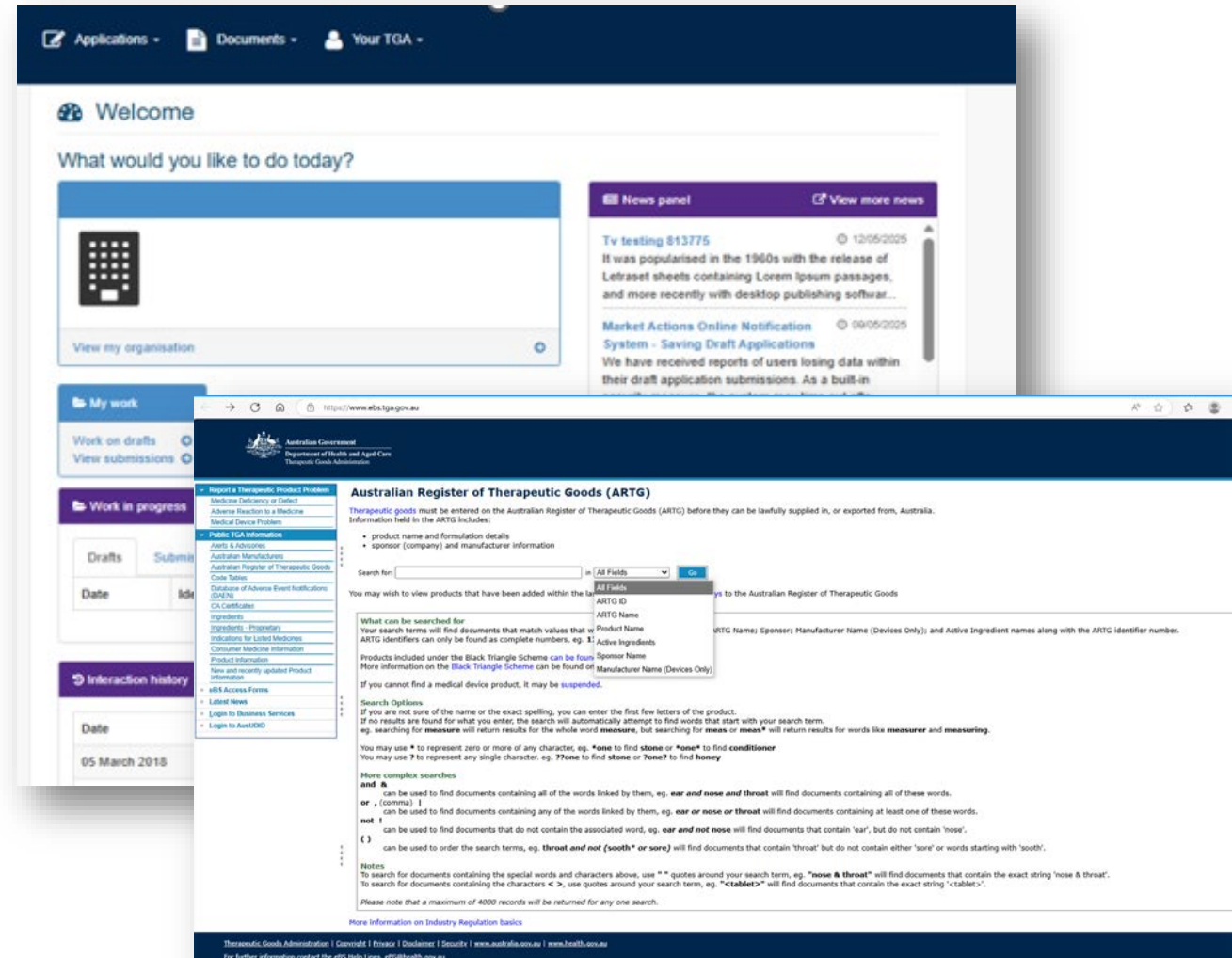
Login



“Because the thing is, you don’t do any submissions on a Friday because the system crashes on a Friday... and then sometimes on a Monday as well, you’ve got to be careful...”


– Agent, everyday user of TBS/eBS

TBS/eBS



Current State

eBS Forms



Lodge Product Information - for publication

CloseSaveValidateLodge

Identification Number:

Publication:

Sponsor:

☒ For Publication
 ☐ Not For Publication

TGA Account for Demo - Beta

Active Ingredients:

Enter the first complete word of the Active Ingredient name

Search ARTG Entries

If the product has more than one active ingredient you may refine the search by entering further names below.

Select the appropriate ARTG Entries by checking their checkboxes.

Trade Names:

Version:

Attach PDF:

1

Choose File

No file chosen

Licence Agreement:

Upload and Access Terms for Product Information (PI) and Consumer Medicine Information (CMI) documentation ("Licence") Parties
 You or Your means any legal person or entity who uploads a PI Document or CMI Document via Our eBusiness web portal
 and

☐ I accept.
 ☒ I do not accept.
 [Expand licence agreement](#)

Commencement Date:

05/11/2025

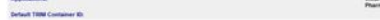
CloseSaveValidateLodge

*“Multiple pain points within the current state...user interface is **unintuitive, fragmented, inconsistent**, lacking in support materials and difficult for new staff to learn.”*

“Users manage and use multiple client ID’s, juggling browsers and time-consuming workarounds”

- What we learned from portal users

eBS (Domino)



Work Management & Decision

Task - Clearance Assessment & Decision

Work Process ID:

Work Process Manager:

Application:

Default TBM Container ID:

MPF 2025-01234-1

GMP Clearance

Clearance MP 2025-CL-00123-1 Macdonald Pharmaceuticals Ltd

Work Process Status:

Assigned To:

In Progress

LCI Assistant - 45

Task Description

In this task the assigned officer checks the outcome from the Application Review or CV outcome. They will either approve or reject the application.

Task Information

Task Specifics

Work Process Summary

Click Information

Supporting Information

Task Information

Work Process Component:

Task Status:

Planned Start:

Actual Start:

Other task comments:

MS Application

Active

Planned End:

Actual End:

Clearance Assignment's comment:

CC-00000

Clearance Application Processing's comment:

TGA + GSK (GSK)

Completion Signer = 45

Endorsement Type = GSK/GA - Germany 2024

Endorsement comments = Task received 21/03/2025. Evidence a from Eudra Gateway which is a recognised regulatory authority. Site is a site. Inspection date is 21/03/2025 which is current. All evidence checked, and CV form prepared and sent out to the site. Issue completed 21/03/2025. Therefore, application is complete.

Missing Evidence = No

Task set for submission = App - CV file

Missing file = No

Management Comment

Overdue

☐ Additional information requested (Select one of the following):

- ☐ Clarification sought
- ☐ Evidence missing (specify in custom text comment)

☐ Initial comment (Select one of the following):

- ☐ Yes
- ☐ No

☐ Score updated to MS

- ☐ New Review completed (if required)

☐ Decision on Application Completed (Select one of the following):

- ☐ Issue Clearance (no conditions)
- ☐ Issue Clearance (with conditions)
- ☐ ... Decision position statement is entered correctly into task specifics
- ☐ Not Issue (GMP Clearance)
- ☐ TGA Inspection recommended
- ☐ TGA 2025 - no entry into relevant information from CV form
- ☐ All information under 'task specifics' complete and correct
- ☐ CV Form Completed

Overdue Comments

Current (GMP or SLP or ISO Certificate)

Full Inspection Report

Regulatory Inspection History

This beta release is to demonstrate our new portal to industry and internal staff to validate and refine the systems before live launch.

HPRG Core Digital Products: Overarching November Beta Release Goals

1 EXTERNAL FACING

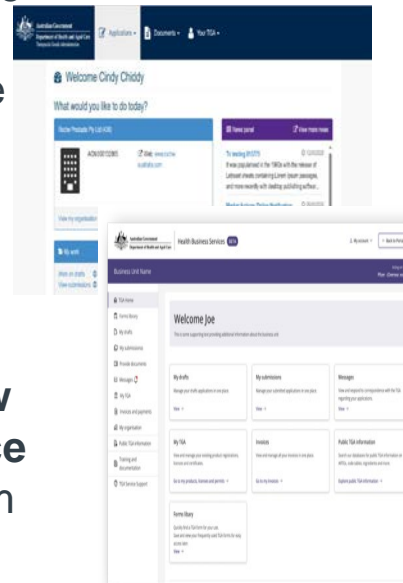
Go live with our new information architecture for the **TGA website**



2 EXTERNAL FACING

Deliver a functional beta release for the TGA showcasing:

- what will be the new **TGA Business Service (TBS) Portal**
- including the start of the new **GMP Clearance** application form (alongside a demo of a clickable Figma)



3 INTERNAL FACING

Deliver a functional beta release for the TGA showcasing:

- what will be the new **case management product**, enabling internal testers to explore the functionality in the context of a GMP clearance application case



Enhancement features – Beta for external users

These new systems will be more reliable, stable, and easier to adapt to the TGA's evolving operating environment.

Single front door	User friendly navigation	New forms library	Draft submissions	My submissions	New Dashboard	Improved reliability
All people that do business with the TGA will log in via the new Health Business Services (HBS) portal	A new landing page with improved navigation so industry can find what they need to complete interactions with the TGA	With improved search functions and the ability to bookmark frequently used forms	A clearer section to save draft submissions, view all drafts in one place, and progress drafts to submission.	To view all submissions lodged with the TGA	Real time updates on your submissions, with filters to help locate information quickly	Moving to a modern cloud-based platform improves reliability, reduces downtime and improves overall performance

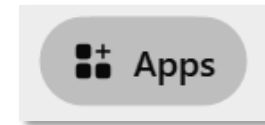
Behind the scenes, upgrades to our case management system will find efficiencies and improve productivity.



What we are about
to show you today,
is the **first major
leap** to our future
direction

How did we go?

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



Use the app in Webex



Use the QR code

Questions?

Ask us through Slido



Use the app in Webex



Use the QR code



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Next steps & how to engage with us

Demonstration videos and feedback surveys will be available on the 'business services' tab of tga.gov.au **from the 16th December**

We will continue to engage and consult with stakeholders, particularly industry, health providers, health professionals and consumers to understand their needs and issues to build a better experience for everyone.



Get in touch

You can reach out to our team with questions or suggestions.

www.tga.gov.au



Learn more

You can join our mailing distribution list for regular Program updates.

TGADigitalStakeholders@health.gov.au



Future testing & feedback

If you'd like to contribute to this work, you can sign up for our user research group.



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