TGA Digital Transformation
Exploring the Beta version of the new TGA business services portal
Webinar Questions and Answers

This document captures the questions raised during the webinar held on 2 December 2025 and provides consolidated responses from the TGA Digital Transformation team.

The focus of the session was on the upcoming TGA Business Services (TBS) portal release, including changes to submissions, workflows, GMP clearance processes, and communication features.

The answers aim to clarify what is in scope for the initial release, what will be delivered in future iterations, and how industry feedback will continue to shape the system.

Please note: Some responses reflect current design intent and may evolve as development progresses.

Contents

General queries

1. Will the new eBS platform affect the information on the Australian Register of Therapeutic Goods (ARTG) Record.
   No. The planned go-live of the new TBS won't change the ARTG record.
2. Is the system cloud-based, and secure?
   Yes. The new systems are cloud-based. We meet all federal cyber security requirements.
3. I'm an agent, representing many organisations and with many logins – what will this look like for me?
   You'll register with one login in the Health Business Services Portal and from there enter the new TBS. This login gives you access to all your existing accounts. If you represent multiple organisations, you'll see a list and choose which organisation you're acting for in that session.
4. Will the portal meet web accessibility standards?
   Yes. All new systems meet web content accessibility standards.
5. What is our approach to AI and will industry be consulted?
   We're exploring safe and effective ways to use AI and improve data collection and sharing. This could help us:

   - reduce evaluation times
   - improve compliance
   - increase productivity
   - get therapeutic goods to Australians faster

   We're also improving our data assets behind the scenes so they're more efficient and accessible. We'll keep engaging with you as we progress digital transformation because your feedback is critical to shaping the products and systems we are building.

Submissions, drafts & migration

6. Will timelines and submission processes change?
   We assume that this question refers to the regulatory timeframes.

   Behind the scenes, we're improving workflows and productivity. These changes aim to:

   - speed up application processing
   - give clearer updates
   - make us more adaptable to policy changes
   - improve data accuracy
   - give you better visibility in the portal.
7. Will all my organisation's current and draft submissions be available in the new portal?
   Yes.

8. What forms and processes will be included in the new portal - submitting proprietary ingredient applications, safety reporting, medical devices?
   All forms and processes currently available in TBS will also be available in the new TBS. We also plan to make it easier, over time, to access other forms that currently sit outside the TBS menu by bringing them together in one place.

9. Will the completed submissions continue to be accessible for future reference?
   Yes. The submissions dashboard has a record of all completed submissions. You can filter by the date they were submitted.

10. Can we view timelines for previously completed submissions in the new portal?
    For new submissions, you'll see this in the progress tracker where it stays linked to that submission. The progress tracker won't reflect submissions that have already been completed. We're exploring ways to improve progress tracking across different types of submissions that are processed through different technology. We will continue improving this feature after it launches in 2026.

11. Will draft submissions from the current system automatically transfer into the new system so that I can submit it in the new system?
    Our intent is to make the transition to the new system as seamless as possible. Once the new system is live, all submissions will be made via the new system. We will communicate with industry about how this will happen prior to going live.

12. Once an application has been approved, will it still appear in the Submissions list?
    Yes.

13. Will the full contents of a submitted application be viewable after submission?
    We're still working out the best way to let you view the full contents of an application after it's been submitted. In the webinar, we showed a preview of the print-preview option. With each update, we're adding more features so you can see a snapshot of what you submitted. These improvements will be rolled out gradually across all forms.

14. Will form print previews properly show all completed fields in the new portal?
    This feature is currently in development and will be thoroughly tested to ensure user needs are effectively catered for.

15. When printing a submitted device application, will uploaded attachments be displayed?
    Uploaded attachments won't appear when you print a submitted device application in the initial release planned for mid to late 2026. After the portal goes live, we'll keep collecting feedback from industry and continue improving the system over time. We'll consider adding this feature in a future update.

16. Will naming conventions for submissions be standardised in the new system?
    We have not yet finalised naming conventions for submissions in the new system. The intention is to do so (where it makes sense) but also provide flexibility to ensure we meet the needs of a wide range of different business areas.

17. Is the planned deletion of all draft minor variation applications after 23 January 2026 linked to this new process?

    The deletion of all draft minor variation applications is related to a different project on the prescription medicine variation system and is unrelated to what was shared in the webinar. However, if you have further questions about this, please reach out to our inbox and we can pass these questions on to the relevant project team.

Workflow, tracking & visibility of progress

18. Will the portal show elapsed time and target processing timeframes for submissions?

    We are currently working through internal consultation and governance steps to agree on a consistent approach across the whole organisation. We are also looking into whether it's technically possible to display how much time has passed and the target processing time for each submission. In the future, external stakeholders will be able to track the progress of their submissions through the new TGA service layer dashboard.

19. Can additional tracking checkpoints be included, such as "assessment started" or "estimated completion"?

    What was shown on the day in the webinar is an example of the capability to adjust tracking milestones and will be subject to further development. These will be configured based on business and regulatory requirements.

20. How soon will internal progress updates appear to sponsors in the system?

    It is going to be relatively instant. As workflow steps progress in the case management system, these updates will flow directly to the portal.

21. Will related submissions be visible across all relevant TGA assessment areas?

    The submission dashboard will display a consolidated view of all submissions completed against an organisation.

22. Will users be able to export data as excel reports through the new interface, and generate reports such as submissions volumes and processing times?

    There is an export function currently in TBS with multiple export formats, this will remain in the new TBS so that users can export various reports. This will include the submission dashboard view in case users want to export a view of what submissions have been submitted. We're open to understanding where else we need to add export functionality other than replicating what is currently exportable. You can provide feedback via the survey available on our website.

23. Will withdrawn submissions or ARTG entries be visible to sponsors?

    When a submission is withdrawn, we are looking to make this visible to users via the 'Submissions' dashboard. We are still working through whether the dashboard will include historically withdrawn submissions, and for how long these should be displayed.

24. Will milestone and approval letters be visible within the portal?

We're working to improve how you access and view these documents, and this will be delivered as part of the new correspondence feature.

Correspondence will be a priority feature we develop after the November Beta release. Our aim is for all correspondence to be sent through the new system, with notifications to let you know when something needs your attention. We plan to test this feature with industry before it goes live in mid to late 2026.

Forms, form design & navigation

25. Will all online forms follow the same layout and usability standards?

Yes, wherever possible and practical, we intend to update all online forms to follow the same layout and usability standards. However, as we continue to transition, some forms will take time to be aligned to the new layout and usability standards. Additionally, some business processes may require unique features or exceptions to ensure specific regulatory/operational needs are met.

26. Will we be able to preview full application forms before starting the submission?

Each form will have guidance that will allow you to get familiar with the form and the full extent of its requirements before they begin. The website also offers guidance on completing the different submission types. Our new form's structure and questions change based upon user input, and each step in the form is validated. Because the questions depend on your input, we can't show a full preview of the form in advance.

27. Will the forms be available for view on the TGA website outside of the new portal?

The forms which are currently available on the website, will be made available in the portal through the consolidated forms menu. The forms which are currently available via the website will continue to be available via the website.

28. What forms will be replaced by online forms in the new portal?

Please note: *This question consolidates all individual questions about forms, including those about PPF, Full Category 1, Cat 3, advertising and complaint reporting forms*.

All existing forms will be available in the new TBS in their current format. Existing forms will be uplifted and improved over time. As we uplift our forms, we will continue to consult with industry during this continuous improvement process. We will make adjustments and exceptions as needed to address specific regulatory or operational requirements.

In the webinar, we showed the updated GMP clearance form as an example of how we plan to modernise forms. As we continue this process, we'll keep working with industry to ensure the forms meet all requirements.

We're starting with forms used for managing manufacturing evidence because about 75% of sponsors and agents rely on them. This includes GMP clearances, certificates and licences, device conformity assessments, and manufacturer evidence processes.

29. Where will different application types such as cancellations, adverse events and field actions be displayed?

    All application/submission types currently available within TBS will be accessible via the 'Forms Library' function in the new system.

30. Will biologicals applications be included in the Beta release?

    Our Beta release included testing of the new GMP clearance application form which includes biologicals in its scope. The application form for adding a biological to the ARTG was not in scope for this round of testing.

31. Can we preview or view an example of a variation or Category 1 application form?

    This hasn't been designed yet. However, as we develop new forms, we will consult with industry to ensure their needs and feedback are considered throughout the process.

32. Will the ARTG search visualisation tool still exist after portal changes?

    Yes.

GMP clearance – functionality & linking

33. Will documentation provided for GMP applications be visible during renewal submissions?

    We have not designed the renewal form yet. It is likely that the information about your clearance will form part of your renewal. This should make the process easier and help keep everything consistent.

34. Will GMP clearances linked to medicine applications be visible within the new portal?

    All new GMP clearances will be submitted on the portal once it goes live in mid-late 2026. We are also looking at how we can migrate information on already approved clearances to the new system.

35. Will current GMP clearance records and renewals be migrated into the new system?

    We expect to process applications already underway through the current system. Once the new portal and GMP clearance form go live, any new applications will be made within the new system. We are also looking at how we move previously granted clearances to the new system.

36. Will GMP clearances be linked to relevant medicine applications?

    The new form we are working on is designed to be better connected and provide better context for our assessors. We are working on connecting relevant medicine applications in the current prototype that we are testing with industry.

37. Will the portal enable linking between GMP clearances and related variation submissions?

    We are still in the design process for how variations will look and feel. We are working on this.

38. How will variations to existing GMP clearances be managed if the existing record stays in the old system?
    We are still in the discovery process for how variations will look and feel. We will continue to engage with stakeholders as we design the form in the future.
39. Will we be able to navigate directly from manufacturer information to related submissions?
    We are currently designing how manufacturer information will be presented in our new system. We will work through how users can best navigate to and from this information and will be testing this with users in early 2026.
40. Will selecting manufacturing sites and GMP codes be streamlined in the new portal?
    Yes. The new form will connect better with the TGA's data, which means more automatic checks and a smoother process when you're filling it out.
41. Will deleted manufacturing sites in a variation form be visible in the final form output?
    We are still in the discovery process for how variations will look and feel. We will continue to engage with stakeholders as we progress.
42. Will there be improvements for secure uploading of large GMP documents from API manufacturers?
    We are looking at ways to better involve manufacturers in the GMP clearance process to address current pain points like this. We will be consulting with industry further as we develop technical options for addressing this issue.

Communication & notifications

43. Is the aim to move all future correspondence between sponsor and TGA to be via the portal? Current modes of communication with TGA are through emails, uploading dossiers and using eBS for GMP clearance etc. Will this new system provide common platform to deal with TGA for all these activities during pre and post approval submissions?
    We're reviewing how messaging and correspondence will function across the TGA. The plan is to reduce emails and move most communication into the new system. Sometimes email will still be the right option. We'll keep working with industry and doing user testing to shape how this feature develops.
44. Which notifications and messages will appear in "My Messages"?
    My message tab functionality is in concept testing. This is the next feature targeted for delivery following the November Beta release. The intent is to have all correspondence communicated through the portal and to develop an ability to be notified if there is something waiting for your attention in the portal.
45. Will milestone and correspondence letters be sent through the portal instead of email, and will the portal automatically send email notifications when an application stage changes?
    A priority feature we're working on is adding correspondence directly into the portal. The aim is for all communication to happen through the portal, with

notifications to tell you when something needs your attention. We plan to test this with industry before the system goes live in 2026.

46. Will email- and Gov Teams-based submissions be phased out once the portal is live?
    The intention is to reduce reliance on email and Gov-Teams over time. Industry will be informed well in advance of any process changes.

47. Will the portal store email correspondence and uploaded documents for future reference?
    Yes, the new TBS will store the emails and documents you currently see in TBS. All that information will move over so you can still access it in the new system.

48. Will sponsors be able to contact the case manager directly through the portal?
    Correspondence will be a priority feature targeted for delivery following the November Beta release. Although at times you can't see who you're talking to by design, to avoid forming direct relationships in sensitive regulatory areas.

Access, roles & authentication

49. How will sponsor administrators manage user access in the new portal?
    Sponsor Administrators will be able to manage user access via self-service functionality within the new TBS portal.

50. Will roles such as drafter and financial submitter remain the same?
    We have no intent to change the roles as they currently are. The only difference will be how they interact with the portal. For example, through the login process, there will be changes to how organisation admins add contacts into the system. We will test this with industry in future Beta testing.

51. Will the portal require multi-factor authentication (MFA) or myGovID login?
    You can register for the Health Business Services portal either with your myID or an email address.

    - If you register with myID, then you can sign in to the portal using the myID app.
    - If you register with an email address, there will be a one-off ID verification step. You can then sign in to the portal with an email and password. We will be introducing MFA for this sign in option later in 2026, as required by the Australian Government's Essential Eight policy.

    Note that myID is an authentication app and is different to myGov.

52. Will users be able to customise their TGA homepage or dashboard?
    When the new portal goes live, customisations to the Health Business Services or the new TBS home pages will be limited. Although they will be tailored to only show the services that are associated with your role. Customisations have been recorded as a proposed enhancement to the currently developed functions as presented within the webinar, for consideration in a future release.

53. Will login conflicts with Australian Industrial Chemicals Introduction Scheme (AICIS) be resolved so multiple access does not cause issues?

    We need to better understand the issues being experienced to support a response as to whether they will be resolved. Please contact us to provide further details.

Portal usability & support

54. If I am partway through an application, can I return to the helpful links and supporting guidance?

    This is not something we have considered yet but is a helpful suggestion. We will take this feedback onboard as we continue to develop and improve. You will however be able to keep helpful links and supporting guidance open in a separate tab to reference as you complete the application.

55. Can I skip steps in an application and return to complete fields later?

    For the new GMP clearance application, we have designed the form in a way that each page gets validated as the user progresses. You won't be able to skip steps as the form will generate future questions and pages based on your inputs.

56. How long before inactivity signs me out of the system?

    The current time is 15 minutes, which will be monitored and reviewed, considering cyber requirements, risk assessments and business processes.

57. Will the new portal work across all major internet browsers, mobile devices and tablets?

    The new portal will work for all major browsers and responsive to device type. If you access forms in our older systems, there may be browser and mobile responsiveness limitations. These will still be best accessed via a desktop or laptop computer until they are modernised in our new TGA service environment.

58. Will there be an ability to export a copy of your application in the system?

    It depends on the submission type. Majority of the submissions will have the ability to download and export. If you have the ability to do so now, you will retain it. We intend to upgrade all submissions to have this ability to export in future updates.

File upload & system limits

59. Will the maximum file upload limit increase beyond the current 100 MB limit?

    There is a current technical limitation on 100 MB uploads, we are continuing to explore options on how to support larger file uploads and will provide further information on this once its available.

60. Will SharePoint still be required for large file uploads?

    We are currently exploring options for how we address management of large file uploads and will share further details on this as it becomes available.

61. Will file size restrictions for secure third-party document uploads be improved?
    We are currently exploring options for how we address management of large file uploads and will share further details on this as it becomes available.

System integration & connected platforms

62. Will GovTEAMS be integrated with the new portal for large file share?
    We are currently exploring options for how we address file size limits to provide an improved user experience.

63. Will payment processing be fully completed within the portal?
    We're looking at supporting some of the existing functionality in TBS where you can complete payments in the portal. We understand this is currently using a payment gateway and are looking at updating the payment gateway to enable payments to continue to be paid within the new system.

64. Will pre- and post-approval activities be managed in one shared platform?
    This is the intent, yes. However further analysis work is required to determine the timing of this. We will continue to share details on this as it becomes available.

65. Will integration include access to the Australian Register of Therapeutic Goods (ARTG) tools in future updates?
    Assuming that this means the ARTG visualisation tool, the access to it would remain through the website.

Implementation & transition

66. What services will the new system provide and when?
    You'll see benefits when the new portal goes live in mid to late 2026.

    Through the portal you can:

    - access all forms, new and existing
    - use the dashboard
    - make payments.

    We'll improve existing forms over time, starting with the GMP clearance application form.

67. When is the go-live?
    Subject to Beta testing, we are working towards releasing a production (live) version of the new TGA business services portal (the new TBS) in mid-late 2026.

68. What support will there be for go-live?
    We'll support you with demonstrations, communications, training, quick reference guides and ways to give feedback close to go-live.

69. Will the rollout be a full cut-over or will there be a transition period?
    This Beta phase of engagement supports the transition period. We will communicate extensively prior to the go live date. On day 1, you will be re-directed to the new Health Business Services portal to log in. All of the same

processes that you do today will be possible in the new portal. We won't run both concurrently as this creates data risks.

70. When will we move away from legacy systems?

    We've focused on improving the website and portal this year so you can access information easily and use a modern, flexible system. Industry will see immediate benefits through the updated Health Business Services portal and new TBS. Behind the scenes, we're planning the steps to move data from legacy systems like eBS to a cloud platform. This will support transformation, AI readiness and assist with fixing data issues with the ARTG. Business continuity is a priority. Legacy systems will stay supported until new systems are available.

71. When will medical device adverse events and market action reporting be included?

    All the reporting forms and notifications you currently use in TBS will also be available in the updated portal. For services, forms, or processes that need bigger changes, we're working in the background to plan the right order and timing for when these will be updated. We'll continue to keep industry informed as we make progress.

72. Will issues in the current portal be addressed before the transition?

    We have consulted with people across industry and heard feedback on the pain points and issues industry has identified with the current systems. Our intent is to address these in the new system, including making the portal easier to use and navigate, improving its reliability, and giving clearer visibility into the progress of submissions. We welcome industry feedback. You can provide feedback on the Beta demonstrations via the website with demo videos and accompanying surveys, or email TGADigitalStakeholders@health.gov.au.

Updates on future roll outs

73. Where can I stay up to date with TGA Digital Transformation topics?

    You can:

    - check updates on TGA.gov.au in the business services section
    - check TGA newsletters
    - subscribe by emailing TGADigitalStakeholders@health.gov.au for updates, guidance and invitations to testing
    - participate in user testing
    - watch demo videos and give feedback through surveys.

74. Are you doing another Beta round?

    We will run another Beta testing activity in the coming months as features progress through development.

75. How can sponsors support the TGA to prepare to give advice at pre-submission meetings?

    You can contact us using the information on our website.