Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Reforming Australia's Therapeutic Goods Testing Regulations

Consultation Paper

Version 1.0, April 2024

Confidentiality

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Introduction

The Therapeutic Goods Administration (TGA) is responsible for protecting the health and safety of the community by regulating therapeutic goods for safety, efficacy, performance, and quality. We do this through the application of the *Therapeutic Goods Act* 1989 (the Act), the *Therapeutic Goods Regulations* 1990 (the Regulations) and associated legislation.

The TGA Laboratories are responsible for delivering results on the quality and performance of therapeutic goods. The testing we conduct assesses compliance with quality and performance standards for the therapeutic goods. This testing provides the TGA, as the regulator, with scientific data to inform and support regulatory decisions and actions, ensuring the safety of therapeutic goods for Australian consumers.

Part 5 of the Regulations (Part 5) sets out procedures for examination, testing and analysis of goods to be conducted within the regulatory framework. Currently, this Part is applicable to only a subset of our sampling and testing activities.

In line with the Health Regulatory Policy Framework (HRPF), we have conducted a review of the Regulations to determine the suitability of Part 5. Our review looked to ensure Part 5 was a regulatory system that:

- is fit for purpose (i.e., is well designed for its intended outcomes)
- takes into account the latest innovations,
- is efficient to comply with and administer,
- is effective in achieving its outcomes, and
- is fair, transparent, and resilient.

Our review has concluded that Part 5 does not currently meet these criteria. We are seeking your input on proposals that aim to align Part 5 with the HRPF and enhance the Regulations to protect the health and safety of Australians, while minimising unnecessary compliance burden.

This consultation

We are committed to continuous improvement and consulting with stakeholders on proposed changes to policy and legislation.

This consultation paper outlines a number of legislative reforms we are proposing, to strengthen and modernise the legislative framework for the examination, testing, and analysis of therapeutic goods. These proposed changes aim to improve the clarity and functionality of the arrangements in Part 5.

Our goal is to ensure that the Regulations are contemporary and flexible, allowing for future development, while also reinforcing high standards of quality, safety, and performance of therapeutic goods in Australia.

We are seeking your consideration of proposed reforms to ensure this improvement activity strikes the right balance of safety for consumers/patients without imposing unnecessary regulatory burden on industry. We understand that changes to legislation can impact how businesses make decisions. Your engagement is critical to ensuring that these reforms are fit for purpose.

This consultation will close on 05 August 2024. Please submit your feedback by then.

How you can share your feedback

We are seeking your views on the proposals in this consultation paper to ensure the changes proposed to the legislation are fit for purpose. A number of questions have been posed throughout this paper, and we ask that you respond to all questions relevant to you and/or your organisation.

Written submissions are requested on or before 05 August 2024 using the CitizenSpace portal.

Any questions relating to the submission process can be directed to tgalabs.consultation@health.gov.au

Background

The role of therapeutic goods testing

Therapeutic goods can comprise a broad range of things, but are generally categorised as medicines, biologicals, or medical devices. We also regulate other therapeutic goods which do not meet the definitions of medicines, medical devices, or biologicals, such as tampons and disinfectants. Regulatory testing of therapeutic goods is an important part of safeguarding the health and well-being of the Australian public. Our laboratory testing activities provide a critically important level of support to post-market monitoring, including compliance and enforcement action, in relation to breaches of the Act and its regulations.

Our testing focuses on the quality of therapeutic goods that are used in, or exported from, Australia. For medical devices, testing can also include a device's ability to meet intended performance specifications. This testing provides the TGA, as the regulator, with scientifically robust data to support regulatory decisions and, as necessary, compliance and enforcement action.

Our Laboratories contribute to the TGA's reputation as a world-class regulator by enabling continuous improvement and building trust, supporting risk-based and data-driven regulatory practices, and promoting collaboration and engagement.

Part 5 of the Regulations

Part 5 sets out procedures for examination, testing and analysis of goods to be conducted when testing within the regulatory framework. Currently, this Part is applicable to only a subset of our sampling and testing activities. These Regulations are principally designed to ensure the integrity of test results of samples tested by the TGA for the purpose of identifying whether the goods are safe for use, and comply with important elements of the regulatory scheme, such as applicable standards.

Part 5 consists of the provisions that are outlined in Table 1 below:

Table 1. Provisions in Part 5 of the Therapeutic Goods Regulations 1990

Regulation	Description
Regulation 23	Sets out defined terms for the purposes of Part 5 of the Regulations.
Regulation 24	Sets out certain powers of authorised officers.
Regulation 25	Provides for the appointment of analysts and official analysts and sets out powers and functions of the latter.

Regulation	Description
Regulation 26	Sets out the procedure by which samples are taken by an authorised officer and forwarded for laboratory testing.
Regulation 26A	Sets out administrative processes relating to the receipt of samples that are delivered to the TGA by sponsors.
Regulation 27	Sets out administrative processes relating to the examination and testing of samples that are received by a laboratory operated by the Department.
Regulation 28	Sets out tests for determining whether a particular therapeutic good conforms with an applicable standard, or whether a particular kind of medical device complies with the essential principles.
Regulation 29	Sets out the procedure by which the analyst responsible for a sample must report the results of their examination and analysis of that sample (i.e., by issuing an evidentiary certificate).
Regulation 30	Sets out the procedure and other requirements for requesting a review of the responsible analyst's findings (i.e., if a person who is issued an evidentiary certificate under regulation 29 disputes those findings).
Regulation 31	Provides that the Commonwealth is liable to pay for samples that are taken by an authorised officer or delivered by a sponsor for testing under Part 5 of the Regulations.
Regulation 32	Provides that it is an offence to engage in certain kinds of conduct toward authorised officers while performing their duties under the Regulations, or to fail to provide information requested by an official analyst that is relevant to the testing of therapeutic goods.
Regulation 33	Requires the Secretary to ensure that each authorised officer is issued an identity card.

A key component of this testing framework is the production and issuing of a regulation 29 certificate of responsible analyst at the conclusion of testing. This certificate includes the results of the testing performed, as well as a statement about whether the goods complied with a relevant requirement for safety, efficacy, performance or quality standards. This certificate can be used in proceedings under the Act or the Regulations as evidence.

The problems identified through the review

Our review of Part 5 showed that there are gaps in our current legislative and regulatory framework for sampling and testing. We have identified a number of reform opportunities to strengthen and enhance this component of the testing framework. The problems and associated proposals outlined in this paper are intended to provide all stakeholders with increased transparency and confidence in the TGA Laboratory testing program, while allowing greater flexibility and responsiveness of the testing framework.

Your views are sought on the following four key problems and our proposals for reform:

Problem 1. Limited application of the testing framework.

The testing framework is no longer fit for purpose as it does not adequately align with the expanded scope of the therapeutic industry, or provide coverage for emerging innovations.

We are seeking to broaden the application of the testing framework to increase the scope of samples that can be tested under the framework, as well as where and how samples can be obtained, or received for testing.

Problem 2. Prescriptive processes that are inflexible, unclear and burdensome.

Part 5 has many regulations that are overly prescriptive and no longer align with modern best laboratory and regulatory practice. This will hinder future progression and innovation. There is also a lack of clarity stemming from unclear processes with gaps or duplicative information. This creates difficulties and inconsistencies for interpretation, compliance and administration.

We are seeking to clarify and streamline processes and definitions.

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate.

There are multiple complex procedures in Part 5 for the production and use of the evidentiary certificate. These procedures are convoluted and often duplicative of other areas of the legislative framework. There are multiple processes and procedures that can be improved to decrease ambiguity and increase fairness and transparency.

We are seeking to amend procedures for the requirements, release of information and reliance on evidentiary certificates.

Problem 4. Insufficient protection for staff while performing their duties.

The regulations in place to protect staff while performing their duties have a narrow scope of application which has exposed staff to inappropriate behaviour.

We are seeking to expand the provision for offences relating to intimidation of staff members in the conduct of their duties.

Preliminary Questions

Preliminary Questions

1. What is your name?
2. What is your email address?
3. Are you responding to this consultation as:
   (a) An individual
   (b) On behalf of an agency/organisation/business/statutory bod, etc.
4. If applicable, what is the name of the agency/organisation/business/statutory body, etc. that you are responding on behalf of?
5. What is your role or title?
6. Select an option that best describes who you are representing below:
   - Consumer (individual)
   - Consumer organisation
   - Government (state or territory)
   - Government (federal)
   - Healthcare professional (individual)

- Hospital
- Industry organisation or peak body
- Laboratory professional - individual
- Manufacturer (small)
- Manufacturer (medium)
- Manufacturer (large)
- Manufacturer (Australian, export only)
- Manufacturer (overseas)
- Manufacturer (Australian)
- Patient advocacy group
- Professional body
- Procurement
- Registry
- Regulatory affairs consultant
- Researcher or research organisation
- Sole trader
- Sponsor
- Third party distributor/retailer
- Third party laboratory
- Other

Problem 1. Limited application of the testing framework.

Proposal 1 – Apply Part 5 to a wider range of testing

Part 5 of the Regulations is principally designed to ensure the integrity of test results when samples are tested by the TGA Laboratories. However a major barrier to our use of Part 5 for testing activities is the narrow set of circumstances in which Part 5 may be applied. Whether or not a sample is tested under Part 5 depends on where or how the goods are obtained or provided to the TGA. Currently, Part 5 only applies in relation to samples that are:

- taken by an authorised officer under regulation 24 of the Regulations; or
- delivered by a sponsor in compliance with a condition of the entry of the relevant good in the Register (namely, under paragraph 28(5)(h) or subsection 41FN(2) of the Act).

This narrow scope is likely due to the role of the TGA at the time the Regulations were written. Part 5 of the Regulations has undergone minimal reform since enactment in 1990. Over this same period there has been expansive growth in our agency and in our role as the Australian regulator of therapeutic goods. Examples of this include the introduction of complementary medicines regulation, medical devices regulation, more comprehensive regulation of in-vitro diagnostic kits and more recently, new vaping frameworks. The laboratory testing of therapeutic goods has similarly kept pace with the introduction of these critical regulatory systems and new product categories. However, our testing activities have evolved beyond what can be captured by the outdated and stringent pathway to testing under Part 5.

In addition to the expansion of regulatory scope and products, we also perform testing on samples for critical monitoring, compliance and enforcement activities. Often testing is requested by other Commonwealth, State or Territory agencies. Samples may be purchased from a retailer by an officer of the TGA for the purpose of replicating goods as purchased by a consumer. And sometimes testing is performed at the request of agencies like Australian Border Force (ABF). Samples provided by law enforcement agencies like ABF are often not registered on the Australian Register of Therapeutic Goods (ARTG). For example, any imports suspected of containing therapeutic products are referred to the TGA and are often tested in our laboratories. A few examples of this testing include:

- Testing to determine if a good is a therapeutic good or not. In the instance of vaping goods, laboratory testing could be conducted to determine the presence or absence of the therapeutic vaping substance, nicotine.
- Testing products labelled as therapeutic goods to identify possible counterfeit products. In the instance of semaglutide, laboratory testing can confirm the presence or absence of the labelled compound, as well as the content.
- Testing an unmarked good or product with no distinguishable product name to determine the presence of prohibited substances. In the instance of botanical substances such as Traditional Chinese Medicine herbal products, laboratory testing can confirm the presence or absence of aristolochic acids.

Because this testing is performed on unregistered goods, the testing does not fall under Part 5. However the outcomes of testing may determine the product to be a therapeutic good, or a prohibited import. Results of testing of unregistered therapeutic goods are more likely to be used in court compared with registered products.

We are proposing to update Part 5 to cover a broader range of goods and testing activities, so that it more appropriately covers the scope of testing activities already undertaken as part of the laboratory testing program. We are proposing to remove the limitations within Part 5 that only allow samples to be tested if taken by an authorised officer, or received as a condition of entry. This would allow us to include testing under Part 5 for a larger range of sample types regardless of where or how the sample

was obtained or provided to the TGA. Testing under Part 5 would be intended to include all testing to assess the quality, safety or performance of a good for supply within Australia or for export only. Testing would cover all aspects of the testing activities undertaken, including examination, analysis, evaluation and observation We also propose that the testing framework in the Regulations would cover testing of goods to determine whether the goods are therapeutic goods, such as in the examples described above.

Benefits of applying Part 5 to a wider range of testing.

Expanding the application of the testing framework will provide increased consistency and transparency to the testing activities conducted by us. The principles of Part 5 are to provide a testing framework that ensures integrity of the test results. By broadening the scope of testing activities permissible under Part 5, we are able to ensure the application of a testing framework that produces reliable, consistent and easy to understand outcomes.

An example of where this sometimes does not happen is when a sample of the same product and the same batch is tested under two different pathways.

Sample One may have been requested from the sponsor under subsection 41FN(2) of the Act. Sample Two was provided to the TGA by the National Medical Stockpile.

In this instance, only Sample One is able to be tested under Part 5. At the conclusion of testing, we issue results of the testing. Sample One has a formal certificate of analyst issued under Regulation 29. Sample Two has a simple laboratory report. Both samples are found to pass the applied tests.

Often there is confusion as to why two different testing pathways were applied to the same product, from the same batch, which concluded the same result. There is no reason for this variance, other than the narrow scope of applicability currently in Part 5.

The introduction of consistent testing pathways will provide stakeholders with greater certainty around how we perform our testing and issue our results. Stakeholders will be able to turn to the Regulations to understand the sample testing and outcome process for the majority of testing activities. This increased transparency, will also increase stakeholder familiarity with the processes and outcomes of testing, as well as how our testing influences regulatory outcomes.

We do not anticipate these changes to increase regulatory burden on stakeholders or sponsors of products listed on the ARTG, as our laboratory testing program already covers testing of these samples.

The inclusion of testing activities performed at the request of law enforcement agencies will allow us to produce a regulation 29 certificate of responsible analyst. This certificate can be used as evidence where appropriate in criminal or civil court action in relation to prohibited imports, or if a good is found to be a therapeutic good that has been imported or supplied in Australia without appropriate authorisation. This will enhance public value in the work performed to protect the Australian people by identifying deficient goods, and will enable regulatory processes to take decisive action against substandard goods and remove them from the market.

Proposal 1

7. Do you agree that there is benefit to the expansion of the testing framework to provide more consistency and greater integrity to the testing activities performed?

   (a) Yes/No/Not sure

(b) Please provide a reason for your position.

8. Do you believe that this proposal will have an impact on you/your organisation?

(a) Positive impact
Negative impact
Both positive and negative impact
No impact

(b) Please provide an explanation of any anticipated impact.

(c) What alternative options, if any, do you think TGA should consider to achieve the same objectives?

Proposal 2 – Revise the powers of an authorised officer.

An authorised officer may, for the purpose of exercising powers or performing the duties of an authorised officer under regulation 24 of the Regulations, enter certain premises on which therapeutic goods are kept, inspect the place at which those goods are kept, and take samples of those goods. An authorised officer may also ask the owner of the goods, or the person apparently in charge of the goods, for information relevant to the manufacture and testing of those goods.

However, regulation 24 currently only permits authorised officers to exercise those powers and perform those duties on the premises of licence holders, manufacturers in respect of whom a conformity assessment certificate has been issued, wholesalers and, in some cases, sponsors. This means that, if a sample of a therapeutic good is taken from any other premises (e.g. in the exercise of a separate power to do so under other provisions of the Regulations or other law), that sample would be tested outside Part 5 of the Regulations. This includes, for example, most samples of unapproved goods (i.e. goods that are not entered in the Register), samples taken from, or submitted by, the National Medical Stockpile, State and Territory Health Departments, Hospitals, Pharmacies and law enforcement agencies (such as Australian Border Force or Australian Federal Police). In line with our proposal to broaden the testing framework, we are proposing to adjust the powers of authorised officers to ensure our officers have the power to enter premises for the purpose of inspecting and taking samples of goods.

We are proposing that authorised officers be empowered to enter the premises of:

- all sponsors, including the sponsors of unapproved therapeutic goods;
- all manufacturers, including those who manufacture goods that are exempt (or who are themselves the subject of an exemption) from the operation of Part 3-3 of the Act;
- wholesalers.

Benefits of revising the powers of an authorised officer.

The proposed expansion of the goods that may be tested under the Regulations regardless of where the samples were obtained or how samples were received by the TGA means that our authorised officers must have equivalent power to enter premises for the purpose of inspecting or seizing samples. The inclusion of these powers for sponsors of unapproved goods will assist in enforcement activities once the products are tested under Part 5. This will enable us to identify and manage risks to the health and safety of the Australian public.

Proposal 2

9. Please indicate your level of agreement with the statement:
"To assist in addressing issues of public health and safety, it will be beneficial to increase the scope of where samples can be obtained or how samples can be received to include:

   - *all sponsors, including the sponsors of unapproved therapeutic goods;*
   - *all manufacturers, including those who manufacture goods that are exempt (or who are themselves the subject of an exemption) from the operation of Part 3-3 of the Act;*
   - *wholesalers."*

   (a) Strongly agree
   Agree
   Neither agree nor disagree

Disagree
Strongly disagree

(b) Please provide a reason for your position.

10. Do you believe that if this change were adopted you would be newly subject to the powers and duties of an authorised officer under regulation 24?

    Yes/No/Not sure

11. Please describe any unintended consequences of this proposed change.

Problem 2. Prescriptive processes that are inflexible, unclear and burdensome.

Proposal 3 – Make testing processes clearer and more streamlined.

Part 5 sets out the procedures to be followed in relation to the handling of samples and the processes to be undertaken when examining and testing the relevant sample. Many of the sample handling and testing procedures are highly prescriptive. This creates unnecessary complexities in the relevant procedures and documents. This creates additional burden for compliance, but does not serve to improve the quality or integrity of the procedures.

Under Subregulation 26A(1), the Secretary must determine if a received sample is appropriately fastened and sealed before forwarding to the relevant laboratory for testing. Following this, a samples officer must also determine whether the sample is appropriately fastened and sealed.

A delegate of the Secretary for the purposes of 41FN(2) and 28(5)(h) is not always the same person, and can vary across different roles within the TGA. It often creates confusion and some degree of convolution if a sample arrives in the laboratories directly from a Sponsor instead of being sent directly to the delegate of the Secretary.

To enable greater consistency in this process, samples could be delivered directly to the samples officer to determine if the sample is appropriately fastened and sealed. This would increase consistency in the applied process and record keeping practices for the check.

This could also remove a step in the chain of custody, leading to better overall control of the sample lifecycle.

During examination and testing of a sample under regulation 27, conditions for storage of a sample are clear for some steps, but ambiguous for others. Storage of the sample is specified under 27(1)(b) as “under the [samples] officer’s” control. However, there is no information about storage conditions once the sample is collected by the responsible analyst.

From a practical perspective, individual testing areas are equipped with environment and access controlled sample storage rooms equivalent to those in the sample office. Storage of the sample under the control of the samples officer at all times (except when being tested) does not add any benefit or additional integrity to the chain of custody for the sample. However, it does create unnecessary burden and additional steps for the responsible analyst to arrange storage and collection in the samples office if testing occurs over multiple days.

We currently perform a broad range of testing activities on a variety of different samples, spanning all types of therapeutic goods. Having highly prescriptive processes within the legislation does not allow for necessary and appropriate variation to procedures and processes to accommodate the different types of therapeutic goods, development and innovations, different testing methods or to accommodate unique circumstances. Like in the examples above, additional steps that do not provide value become particularly laborious when we are responding to major public health incidents. This

often requires the acquisition and testing of large numbers of samples. These small steps and workarounds become exacerbated when performed thousands of times for a single project.

We are proposing to facilitate clearer, more flexible, and efficient processes and arrangements for our sampling and testing activities. We propose that the prescriptive processes dealing with the collection, handling, and storage of samples of therapeutic goods be removed from Part 5. We also propose that the unnecessary demarcation, such as for the roles and responsibilities of analysts, responsible analysts and official analysts be removed from Part 5.

We propose that these procedures should be conducted according to, and supported by, comprehensive internal Quality Management System (QMS) procedures, rather than existing within the Regulations. The TGA Laboratories maintain accreditation with the National Association of Testing Authorities (NATA) to ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. This international standard defines requirements to ensure laboratories operate competently and generate valid results. This standard is recognised nationally and internationally, with agencies such as the Food and Drug Administration's Office of Regulatory Affairs and the European Directorate for the Quality of Medicines and HealthCare's network of Official Medicines Control Laboratories being accredited.

The standard requires procedures for the transportation, receipt, handling, protection, storage, retention and disposal or return of test items to protect the integrity of the test item and to protect the interests of the laboratory and customer. The standard also requires procedures for the competency, selection, training, supervision, and authorisation of personnel.

The procedures for these matters already exist within our QMS in accordance with both the accreditation and regulation requirements. The procedures may be as expansive as required, and are not only subject to the requirements of ISO/IEC 17025. As such there will be no decrease in the integrity of these procedures. The integrity and suitability of the procedures will also be maintained by routine auditing and assessment through regular internal reviews, as well as independent, external accreditation audits conducted by NATA.

Benefits of making testing processes clearer and more streamlined.

Removing the sample handling and process requirements from the Regulations will allow us to remain flexible and contemporary for our technical and administrative processes. This is vital to ensuring that we can keep pace with the development of novel therapeutic goods, updated testing methodologies and changing Australian and international standards. The ability to remain flexible also reflects the various ways that samples can be obtained across the TGA.

By prescribing these processes wholly within the QMS, we can perform ongoing maintenance and upkeep of these processes in a way that is not possible when prescribed by the Regulations. Processes and procedures within the QMS undergo regular updates, audits and reviews internally to ensure they remain modern and fit-for-purpose. They are also subject to external reviews and audits conducted by NATA to ensure they remain compliant with accreditation requirements. The maintenance of these procedures within the QMS will allow us to ensure that we are performing our duties in an effective manner that aligns with the principles of the regulations as well as with current laboratory best practice principles.

Proposal 3

12. Do you support the proposal to prescribe these procedures wholly within the TGA Laboratories' accredited Quality Management System?
    (a) Yes/No/Not sure
    (b) Please provide a reason for your position.

(c) Please suggest alternative options for TGA to consider.

13. Do you believe that this proposal would require additional principles, safeguards or oversight mechanisms to manage these procedures?

(a) Yes/No/Not sure

(b) Please provide a reason for your position.

Proposal 4 – Improve clarity and definitions.

There is currently an overarching lack of clarity within Part 5 that is principally due to the use of vague and ambiguous language in several provisions. For example, the use of undefined, but overlapping words like ‘examination’, ‘testing’ and ‘analysis’ causes confusion and uncertainty when attempting to understand the regulatory process.

We are proposing to update the definitions to reduce confusion created by inconsistent wording and unclear definitions. These updates will ensure that words are clearly defined if required beyond their ordinary meaning and ensure that the application of these words throughout the Regulations remains consistent.

We are proposing that the meaning of ‘testing’ be clarified to include all testing activities including examination, analysis, evaluation, observation, etc. It is also proposed that unnecessary definitions be removed. This includes the duplicative roles of ‘analysts’, ‘official analysts’ and ‘responsible analysts’, which are proposed to be streamlined to a single role for ‘analysts’. This definition would also include clarification that different analysts may be responsible for performing tests on a single sample. Often it is not practical for a single analyst to be responsible for the processing of a sample from start to finish. We will also review the reference to terms like ‘laboratories’ to ensure consistency of application throughout Part 5.

Benefits of improving clarity and definitions.

The improvements proposed to increase clarity will assist all stakeholders in understanding their rights and obligations, and the procedures described in the Regulations. This will improve stakeholder and consumer confidence in the TGA testing framework and prevent issues from arising due to inconsistent or ambiguous interpretation.

Proposal 4

14. Do you agree with the proposed changes to improve clarity within the Regulations?
    (a) Yes/No/Not sure
    (b) Please provide a reason for your position.
15. Do you believe that the proposed changes to the definitions will have any impact on your ability to carry out business functions in line with the Regulations?
    (a) Positive impact
    Negative impact
    Both positive and negative impact
    No impact
    (b) Please provide an explanation of any anticipated impact.
16. Please tell us about any additional barriers to understanding Part 5 that you believe require improvements or further clarity.

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate.

Proposal 5a –Simplify information in certificate of responsible analyst

After we test samples of therapeutic goods, we include the results of the testing in a certificate. For example, a certificate of testing about a face mask product may state that the mask failed the test for fluid resistance by ISO 22609:2004 - Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected).

However, rather than just containing the results of testing, regulation 29 requires the certificate to state whether the goods complied with a relevant requirement about their quality, safety, efficacy or performance. In this example, the test result indicates that the product does not comply with applicable provisions of the Essential Principles (EP):

- The design and production of the device may compromise health and safety [EP1]; and
- The design and construction may not conform with safety principles having regard to the generally acknowledged state of the art [EP2]; and
- The device may not be suitable for the intended purpose [EP3]

Such a determination may have significant legal consequences for the supplier or manufacturer of the product. Further, it is sometimes not appropriate to make such a determination based on one set of test results, when additional material obtained during an investigation (such as information about how the goods were manufactured) may be a relevant consideration.

We are proposing that analysts would not be required to decide whether a relevant good complies with applicable requirements. Instead, we propose that the information to be included in the certificate would be limited to factual matters about the sampling and testing of the goods, as well as the results of that testing. The information contained within the certificate would be used to inform the delegate of the Secretary about the quality of the sample tested. The delegate of the Secretary would then be responsible for the decision as to whether the relevant good complies with the applicable legislative requirements.

Benefits of simplifying information in certificate of responsible analyst

The proposal to no longer include a statement in certificates about compliance with regulatory requirements will contribute to a better and fairer regulatory process applied by the TGA. We consider it to be more appropriate for a certificate to only state information related directly to the sampling and testing of the goods as well as the results of that testing. When testing samples, we often test for compliance with labelling requirements (e.g., compliance with Therapeutic Goods Order No. 92 – *Standard for labels of non-prescription medicines*). If we detect an issue with the labelling, then we must issue a certificate stating that the product is non-compliant. By removing this decision, we can instead inform the delegate of the Secretary about the results of our analysis. The delegate may then use their discretion to determine what level of regulatory action needs to be taken.

This process also reflects what occurs in practice. The results of testing are provided to other areas of the TGA and the Department to use as a signal, to investigate further, or to take enforcement or other regulatory action.

Proposal 5b – Repeal of the review process in line with proposal 5a

If a certificate has been issued to indicate a product is not compliant with a relevant requirement about quality, safety, efficacy or performance, the certificate must include a statement to say that the recipient of the certificate may ask, under regulation 30, for the results of analysis to be reviewed. A request for results to be reviewed must be accompanied by written evidence that the goods do conform with a relevant requirement about quality, safety, efficacy or performance. However, this review process is predicated on the certificate explicitly stating a legislative compliance decision.

In line with proposal 5a, the removal of compliance decisions from certificates would subsequently mean that the review rights provided for by Part 5 would no longer be necessary, as no significant regulatory decision is made in the certificate.

Analysis of stakeholder feedback and requests for guidance indicate that regulation 30 is difficult to understand and navigate. The evidence provided to the TGA has stringent, but unclear requirements, and would often require the sponsor to obtain third party evidence of compliance in a very short period of time. This can be expensive, onerous and may only be readily accessible to large, sophisticated sponsors. The effort required for compliance and administration of this regulation is not efficient and increases burden on both stakeholders and the regulator.

We are proposing to remove the regulation 30 review process from Part 5 as it will no longer be necessary. This proposal does not seek to entirely remove sponsor access to review rights, merely to remove the review rights as prescribed in Part 5. Review rights are currently provided in the Act and regulations in relation to specified regulatory decisions under the TG Act and regulations. In line with the proposal above, results of laboratory testing will be passed to a delegate of the Secretary to inform them about the quality of the sample tested. The delegate of the Secretary would then be responsible for the decision under the relevant power of the Secretary as to whether the relevant good complies with the applicable legislative requirements. The decision (that has been informed by laboratory results, if relevant) would then be subject to internal review. If an impacted stakeholder has concerns about the validity of the results informing the regulatory decision, they may still provide the decision maker with evidence that the relevant goods are compliant and request that the TGA Laboratories' results be reviewed.

Benefits of repealing the review process in line with proposal 5a

The review rights that currently exist for an administrative decision are straightforward and well characterised. These processes are familiar and straightforward for stakeholders who are affected by administrative decisions. The review rights afforded in regulation 30 are confusing, unclear and are subject to interpretation. Removal of the compliance decision from the certificates and review rights associated with the certificates, serve to make the review process straightforward and familiar, without removing the right to review for any subsequent regulatory decision.

Proposal 5

17. Would the removal of a compliance decision from certificates impact you/your organisation?

    (a) Positive impact
    Negative impact
    Both positive and negative impact
    No impact

    (b) Please provide an explanation of any anticipated impact.

18. If compliance decisions are removed from certificates, do you agree that the review process should be removed from Part 5?

    (a) Yes/No/Not sure

    (b) Please provide a reason for your position.

    (c) Please suggest alternative options for TGA to consider.

Proposal 6 – Amend the requirements for the release of a certificate of responsible analyst

Currently, subregulation 29(2) specifies that the TGA must send a copy of the certificate to:

a) The sponsor of the goods, and

b) If the sample was taken under the powers of an authorised officer, and the person from whom the sample was taken is not the sponsor of the goods – the person from whom the sample was taken.

This regulation is aligned closely with the current scope of the testing framework under Part 5 and the limited ways in which a sample may be obtained for testing.

We are proposing that regulation 29 be updated to ensure that it is mandatory for an analyst to send a copy of the certificate to the sponsor *where the sponsor is identifiable*. The proposed increased scope of testing, particularly to cover compliance testing, will mean that a sponsor is not always identifiable when goods are seized unpackaged or unmarked. In this instance, it would be impossible for a copy of the certificate to be sent to the sponsor of the goods.

We are also proposing that provision of the certificate to any other party will be on a case-by-case basis. If it is necessary to provide information to another party, this could be done using the existing mechanisms under section 61 of the Act for release of therapeutic goods information in certain circumstances. This proposal recognises that release of information to a person other than the sponsor is not always appropriate and requires more discretion than is currently provided within Part 5.

Benefits of amending the requirements for the release of a certificate of responsible analyst

There will be no impact to the supply of a certificate to the sponsor. This subregulation will remain mandatory for an analyst to comply with, but allows for instances where compliance is impossible due to the condition of the goods as received or seized. This proposal serves only to bring the subregulation in line with any updates to Part 5 that increase the scope of testing.

The release of information under section 61 of the Act, contains clear descriptions of the circumstances in which release of information is acceptable. Using this mechanism to release the certificate will provide stakeholders with greater transparency, thereby reducing confusion. It will also allow for greater discretion as it does not make the release of information mandatory.

Proposal 6

19. Please outline any concerns with the proposal to amend the requirements for the release of a certificate.

20. Do you believe that this proposal will have an impact on you/your organisation?

    (a) Positive impact
    Negative impact
    Both positive and negative impact
    No impact

    (b) Please provide an explanation of any anticipated impact, and indicate if these impacts are anticipated to be short or long term.

    (c) What alternative options, if any, do you think TGA should consider to achieve the same objectives?

(d) What other principles, safeguards or oversight mechanisms should TGA Laboratories consider if this proposal is implemented?

Proposal 7 – Increasing the reliance on the certificate of responsible analyst

Part 5 currently enables a responsible analyst to produce a certificate of results at the conclusion of testing. Subregulation 29(5) states that "In proceedings under the Act or these Regulations, [this certificate is], in the absence of evidence to the contrary, conclusive proof of the matters set out or stated in it." Due to the wording used within this subregulation, the use of this certificate is limited to only proceedings under the Act or the Regulations. However, there are a range of legal proceedings that may be commenced under other legislation or the common law to which the results of TGA Laboratories test results are also relevant. Currently, the certificate would not necessarily hold the same evidentiary value.

We are proposing to amend the wording so that a certificate produced would hold the same evidentiary value in all Court or Tribunal proceedings. To support this, we also propose that the Regulations prescribe, with greater specificity, the information that an analyst must, and as appropriate, may record in the certificate. These matters would be limited to technical and procedural matters of fact that are relevant to the testing of a sample, such as the tests performed, results of testing and any information relevant to the testing.

Benefits of increasing the reliance on the certificate of responsible analyst

As the regulator, it is critical that the TGA can take regulatory action when there is a potential risk arising from non-compliance or safety concerns. The changes proposed to the use of the certificate of results will provide additional consistency and transparency in regulatory actions and Court or Tribunal proceedings for which the certificate is presented as evidence.

This proposal is also bolstered by the additional clarity that will be provided for in the Regulations regarding the contents of the certificate.

Proposal 7

21. Do you consider it appropriate for the certificate to hold the same evidentiary value in all Court or Tribunal proceedings?
    (a) Yes/No
    (b) Please provide a reason for your position.
22. Please describe any unintended consequences of this proposal.

Problem 4. Insufficient protection for staff while performing their duties

Proposal 8 – Extension of the offence to intimidate authorised officers

Currently, subregulation 32(1)(a) is in place to protect an authorised officer as they execute their powers or perform their functions under the Regulations. This regulation makes it an offence to molest, obstruct, or try to intimidate or influence an authorised officer. The penalty for such activity is 10 penalty units (currently equal to $3,130). This subregulation is critical to ensure protection from inappropriate behaviour and should remain in place. However, despite the protection afforded to authorised officers, analysts are not afforded the same protection and have been the subject of inappropriate behaviour intended to intimidate or influence.

We are proposing that the same protection provided to authorised officers should also be extended to analysts who are exercising their powers or performing their duties under the Regulations. We propose to apply the same number of penalty units for offences against authorised officers and analysts (10 penalty units).

Benefits of extending the offence to intimidate authorised officers

Authorised officers and analysts are both required to perform duties and exercise powers under the Regulations. Performance of these duties may place both authorised officers and analysts in situations where there is an increased risk of inappropriate behaviour. Therefore, we must implement control measures for psychological hazards related to harmful behaviours such as those described in subregulation 32(1)(a). We consider that an extension of this subregulation to cover analysts is a suitable way to minimise the risk of analysts being exposed to intimidation and harmful behaviour.

Extension of the current offence to analysts will also allow the work of analysts to continue in an objective and uninhibited manner. This ensures that all laboratory testing results are a fair and accurate representation of laboratory testing. Ensuring analysts are not subject to intimidation or influence supports analysts to conduct work in a fair and impartial way, thereby increasing confidence in laboratory testing results.

Proposal 8

23. Do you agree with the proposal to extend the protections currently afforded to authorised officers to also protect analysts?
    (a) Yes/No
    (b) Please provide a reason for your position.

Post-Survey Questions

Post-Survey Questions

24. Do you agree for your information to be published? (Select option below)
    * See privacy collection notice on page 19.
    - **Publish my entire submission in full**, including my name and work title as it appears on the submission, on the TGA website. **Note:** Australian Privacy Principle 8.1 will not apply if you consent to this.
    - Only **publish my submission** on the TGA website, **do not publish** my name or work title.
    - **Only publish** my name, work title and organisation on the TGA website, **do not publish** my submission.
    - **Do not publish** my name or work title or my submission on the TGA website.
    - **Only publish some of my submission** (please specify below)
25. Please provide any other suggestions, not covered in this paper, for improvement of Part 5 of the *Therapeutic Goods Regulations 1990*.
26. What sort of guidance material would you like to see in place to assist with any updates that are made to Part 5?
27. Would you be interested in receiving future guidance material regarding any updates that are made to Part 5?
    Yes/No

Summary of Questions

Preliminary Questions

Preliminary Questions

1. What is your name?
2. What is your email address?
3. Are you responding to this consultation as:
   (a) An individual
   (b) On behalf of an agency/organisation/business/statutory bod, etc.
4. If applicable, what is the name of the agency/organisation/business/statutory body, etc. that you are responding on behalf of?
5. What is your role or title?
6. Select an option that best describes who you are representing below:
   - Consumer (individual)
   - Consumer organisation
   - Government (state or territory)
   - Government (federal)
   - Healthcare professional (individual)
   - Hospital
   - Industry organisation or peak body
   - Laboratory professional - individual
   - Manufacturer (small)
   - Manufacturer (medium)
   - Manufacturer (large)
   - Manufacturer (Australian, export only)
   - Manufacturer (overseas)
   - Manufacturer (Australian)
   - Patient advocacy group
   - Professional body
   - Procurement
   - Registry
   - Regulatory affairs consultant
   - Researcher or research organisation
   - Sole trader
   - Sponsor

- Third party distributor/retailer
- Third party laboratory
- Other

Problem 1. Limited application of the testing framework.

Proposal 1 – Apply Part 5 to a wider range of testing

Proposal 1

7. Do you agree that there is benefit to the expansion of the testing framework to provide more consistency and greater integrity to the testing activities performed?
   (a) Yes/No/Not sure
   (b) Please provide a reason for your position.
8. Do you believe that this proposal will have an impact on you/your organisation?
   (a) Positive impact
   Negative impact
   Both positive and negative impact
   No impact
   (b) Please provide an explanation of any anticipated impact.
   (c) What alternative options, if any, do you think TGA should consider to achieve the same objectives?

Proposal 2 – Revise the powers of an authorised officer.

Proposal 2

9. Please indicate your level of agreement with the statement:
   "To assist in addressing issues of public health and safety, it will be beneficial to increase the scope of where samples can be obtained or how samples can be received to include:
   - *all sponsors, including the sponsors of unapproved therapeutic goods;*
   - *all manufacturers, including those who manufacture goods that are exempt (or who are themselves the subject of an exemption) from the operation of Part 3-3 of the Act;*
   - *wholesalers."*

   (a) Strongly agree
   Agree
   Neither agree nor disagree
   Disagree
   Strongly disagree

(b) Please provide a reason for your position.

10. Do you believe that if this change were adopted you would be newly subject to the powers and duties of an authorised officer under regulation 24?

    Yes/No/Not sure

11. Please describe any unintended consequences of this proposed change?

Problem 2. Prescriptive processes that are inflexible, unclear and burdensome.

Proposal 3 – Make testing processes clearer and more streamlined.

Proposal 3

12. Do you support the proposal to prescribe these procedures wholly within the TGA Laboratories' accredited Quality Management System?
    (a) Yes/No/Not sure
    (b) Please provide a reason for your position.
    (c) Please suggest alternative options for TGA to consider.
13. Do you believe that this proposal would require additional principles, safeguards or oversight mechanisms to manage these procedures?
    (a) Yes/No/Not sure
    (b) Please provide reasons for your position.

Proposal 4 – Improve clarity and definitions.

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate.

Proposal 4

14. Do you agree with the proposed changes to improve clarity within the Regulations?
    (a) Yes/No
    (b) Please provide a reason for your position.
15. Do you believe that the proposed changes to the definitions will have any impact on your ability to carry out business functions in line with the Regulations?
    (a) Positive impact
    Negative impact

Both positive and negative impact
No impact

(b) Please provide an explanation of any anticipated impact.

16. Please tell us about any additional barriers to understanding Part 5 that you believe require improvements or further clarity?

Proposal 5a – Simplify information in certificate of responsible analyst

Proposal 5b – Relocation of the review process in line with proposal 5a

Proposal 5

17. Would the removal of a compliance decision from certificates impact you/your organisation?

(a) Positive impact
Negative impact
Both positive and negative impact
No impact

(b) Please provide an explanation of any anticipated impact.

18. If compliance decisions are removed from certificates, do you agree that the review process should be removed from Part 5?

(a) Yes/No/Not sure

(b) Please provide a reason for your position.

(c) Please suggest alternative options for TGA to consider.

Proposal 6 – Amend the requirements for the release of a certificate of responsible analyst

Proposal 6

19. Please outline any concerns with the proposal to amend the requirements for the release of a certificate.

20. Do you believe that this proposal will have an impact on you/your organisation?

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Negative impact
Both positive and negative impact
No impact

(b) Please provide an explanation of any anticipated impact, and indicate if these impacts are anticipated to be short or long term.

(c) What alternative options, if any, do you think TGA should consider to achieve the same objectives?

(d) What other principles, safeguards or oversight mechanisms should TGA Laboratories consider if this proposal is implemented?

Proposal 7 – Increasing the reliance on the certificate of responsible analyst

Proposal 7

21. Do you consider it appropriate for the certificate to hold the same evidentiary value in all Court or Tribunal proceedings?
    (a) Yes/No
    (b) Please provide a reason for your position.
22. Please describe any unintended consequences of this proposal.

Problem 4. Insufficient protection for staff while performing their duties

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Proposal 8

23. Do you agree with the proposal to extend the protections currently afforded to authorised officers to also protect analysts?
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26. What sort of guidance material would you like to see in place to assist with any updates that are made to Part 5?
27. Would you be interested in receiving future guidance material regarding any updates that are made to Part 5?
    Yes/No

Next Steps

How to make a written submission

The TGA invites written submissions in response to the detailed questions in this consultation paper. For your reference, the full list of questions is extracted at Attachment A.

Written submissions will close at 23:59, 05 August 2024.

Submissions on this consultation paper are welcome from all stakeholders, including State and Territory Health Departments, therapeutic consumers, healthcare professionals, pharmaceutical and medical device companies, distributors and retailers, peak and industry bodies, patients and patient advocacy groups, third party laboratories and legal and consulting firms.

We welcome written submissions in response to any or all of the consultation questions listed in this consultation paper. Please provide your submission through the CitizenSpace consultation hub. Please direct any questions relating to the submission process to tgalabs.consultation@health.gov.au.

What we will do with your feedback

Feedback from written submissions will be used by the Department to refine the legislative proposals described in this consultation paper. Your feedback will help us build a full picture of the impacts of these proposals. Any regulatory burden will be carefully considered alongside the benefit from the proposed changes.

After reviewing your feedback on the proposals in this consultation paper, the Department will provide advice to the Government on updates to the legislation to implement the proposals.

Responses to this consultation will be collated and published on the website as below.

Privacy collection notice

The Department is bound by the Australian Privacy Principles (APPs) in the Privacy Act. The APPs regulate how we collect, use, store and disclose personal information, and how you may seek access to, or correction of, the personal information that we hold about you.

Providing personal information in your submission is voluntary. Please refrain from including personal information of any third parties. The Department may publish your submission (including your name), unless you request that your submission remain anonymous or confidential, or we consider (for any reason) that it should not be made public. If you do not tell us that your submission is to remain anonymous or confidential, you acknowledge that by providing your submission it may be accessible to people outside Australia and that you are aware that:

- any overseas recipient(s) will not be accountable under the Privacy Act for any acts or practices of the overseas recipient in relation to the information that would breach the APPs; and
- you will not be able to seek redress under the Privacy Act if an overseas recipient handles your personal information in breach of the Privacy Act.

The Department may redact parts of published submissions, as appropriate. For example, submissions may be redacted to remove defamatory or sensitive material. Submissions containing offensive language or inappropriate content will not be responded to and may be destroyed.

Information you provide in your submission, including personal information, may be disclosed to the Commonwealth; state and territory governments and their departments and agencies; and third parties who provide services to the Department. This information may also be used to communicate with you about your submission and the consultation process.

For more information about the Department's personal information handling practices, including how you can seek access to, or correction of, personal information that the Department holds about you, or how to make a complaint if you believe that the Department has handled your personal information in a way that breaches our obligations in the APPs, please refer to the Department's privacy policy, which you can access here.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Laboratories Branch Therapeutic Goods Administration	June 2024

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