Reforming Australia's Therapeutic Goods Testing Regulations

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Acknowledgement of Country

In the spirit of reconciliation, the Department of Health and Aged Care 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 present today.

Welcome

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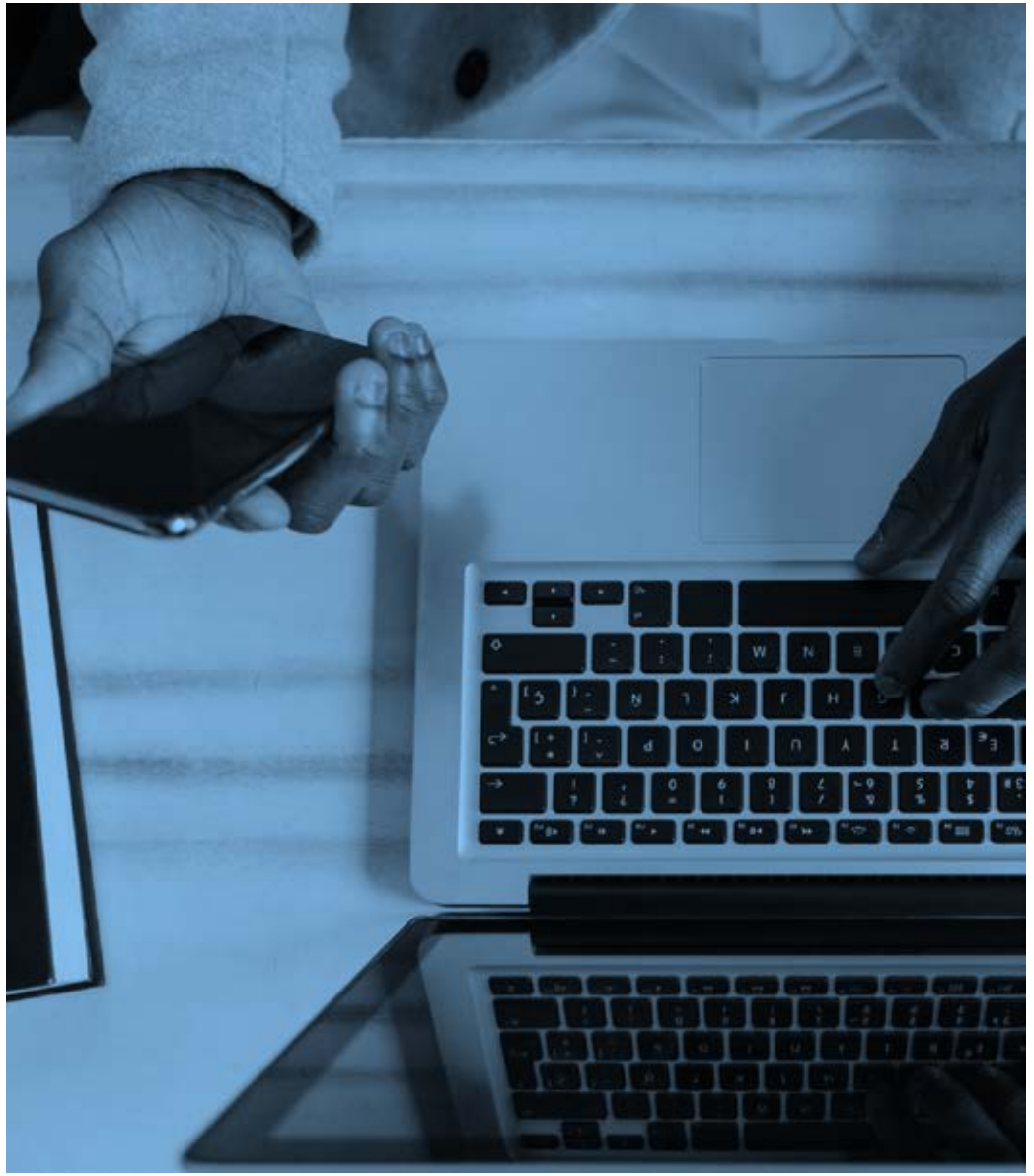

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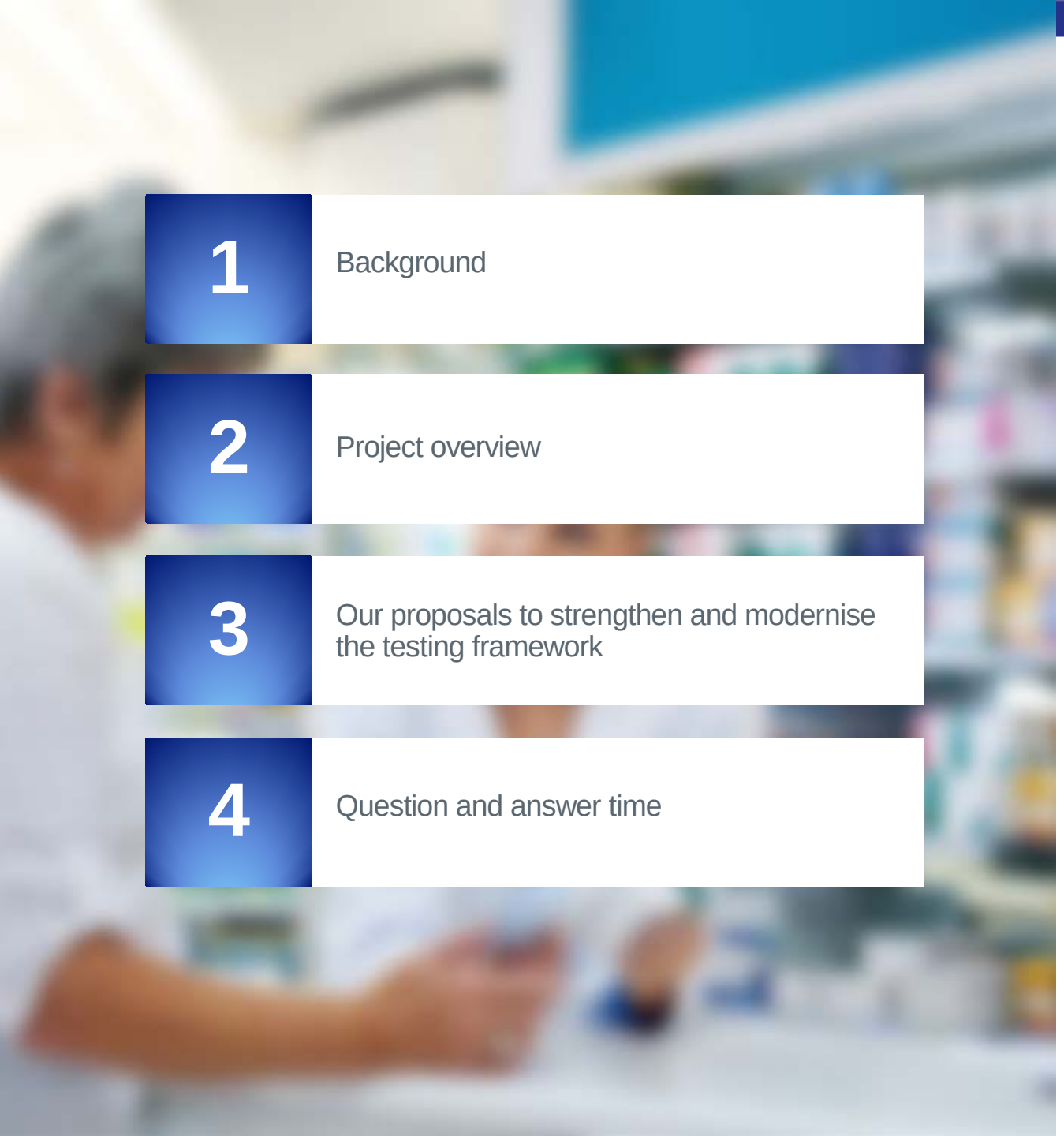


1. Background
2. Project overview
3. Our proposals to strengthen and modernise the testing framework
4. Question and answer time

What we'll cover today

Reforming Australia's Therapeutic Goods Testing Regulations

Closes 28 Aug 2024

Opened 24 Jun 2024

Contact

tgalabs.consultation@health.gov.au

1 Background

The Department of Health and Aged Care

The Department of Health and Aged Care

We work to deliver an affordable, quality health and aged care system and better health, ageing and sport outcomes for all Australians. Our vision is better health and wellbeing for all Australians, now and for future generations.

The Therapeutic Goods Administration

The Therapeutic Goods Administration

We are Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. We regulate medicines, medical devices and biologicals to help Australians stay healthy and safe.

TGA Labs

TGA Laboratories

TGA Laboratories conducts laboratory testing to assess compliance of goods with the relevant quality and performance standards. These results are used to support regulatory decisions and as necessary, compliance and enforcement action that TGA undertakes. The results provide confidence in public heath activities such as vaccination programs

***The Therapeutic Goods Act 1989* (The Act)**

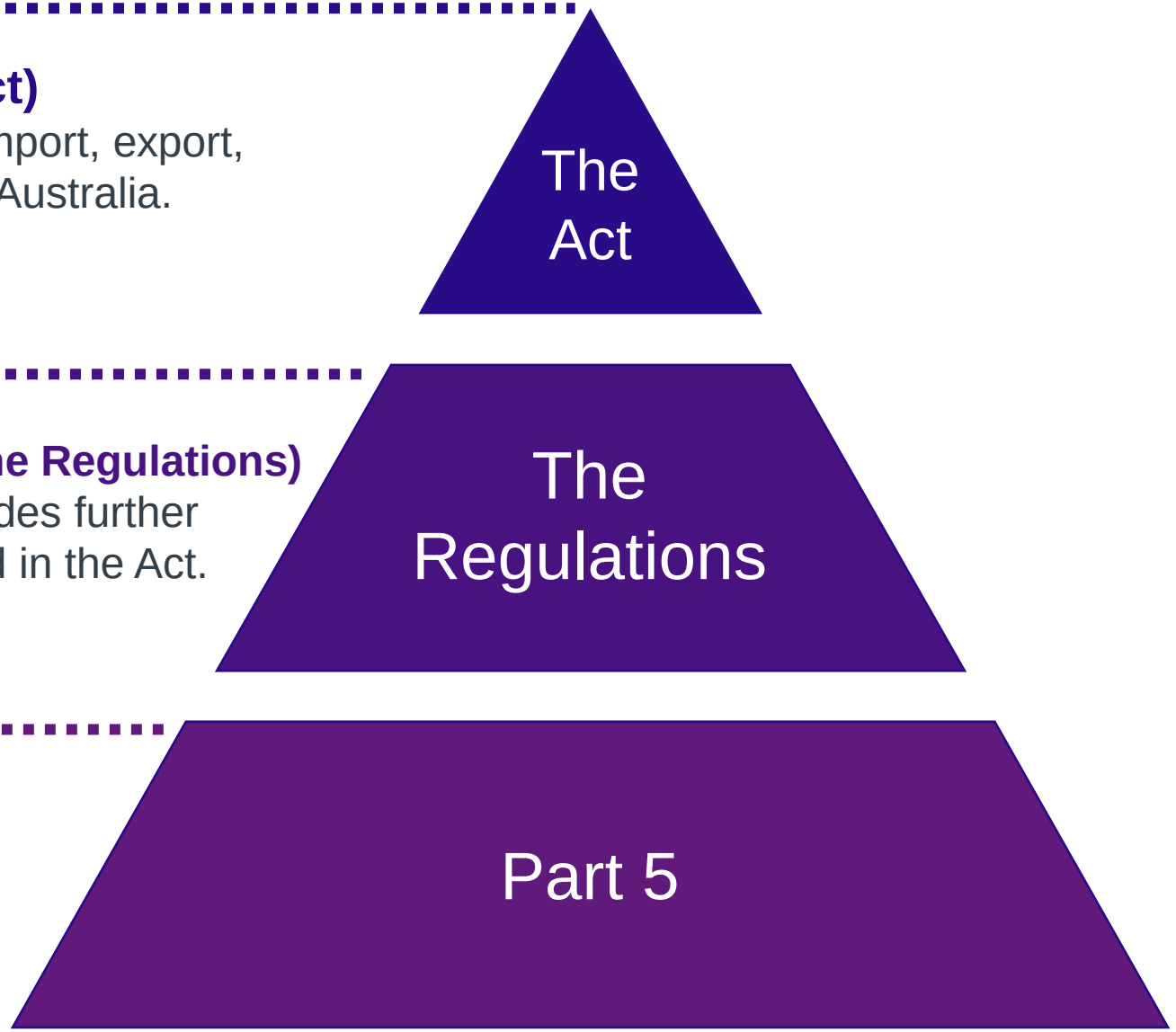
The Act sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia.

***The Therapeutic Goods Regulations 1990* (The Regulations)**

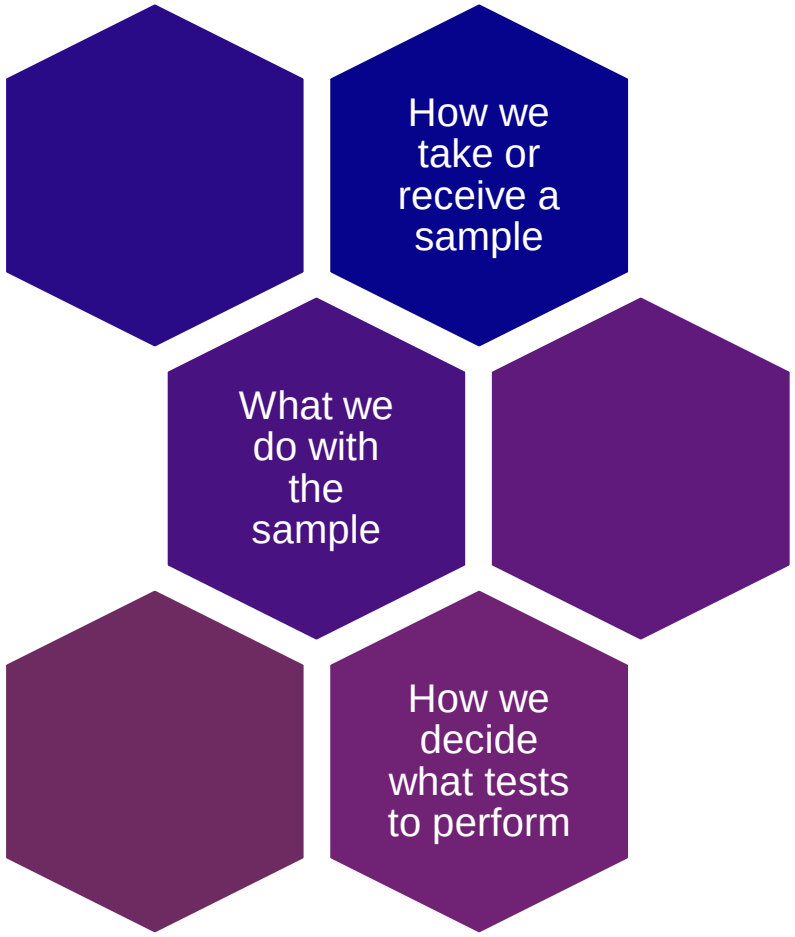
The Act is supported by the Regulations. It provides further details on *how* we must perform matters covered in the Act.

Part 5 of the Regulations

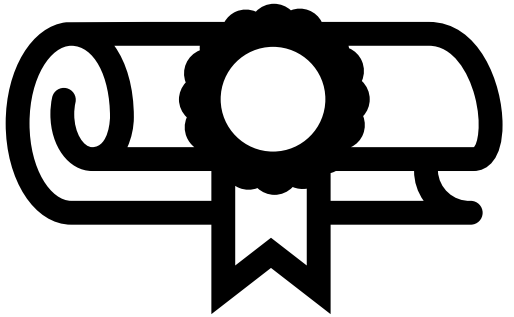
Sets out the procedures for the examination, testing and analysis of therapeutic goods. This part is designed to ensure the integrity of these test results.



Part 5 – Examination, testing and analysis of goods



Testing result



Regulation 29 certificate of responsible analyst

2 Project Overview

Alignment with the Health Regulatory Policy Framework (HRPF)

The HRPF is a high-level statement of our regulatory principles. It provides clarity and consistency around Health's approach to regulation so we can maximise our efforts to protect the health and wellbeing of all Australians.

7 We regularly monitor and review our regulation to ensure it remains fit-for-purpose

We review our regulations at appropriate intervals to ensure they remain fit-for-purpose, deliver on our desired outcomes and continue to provide public value.

This will achieve 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
- ✓ is fair, transparent and resilient

Review of Part 5

- Part 5 is a regulatory system that does not currently meet these criteria
- Our goal:
  - Contemporary, flexible and future focussed regulations
  - Reinforce high standards for quality, safety and performance of therapeutic goods

Safety for consumers and patients

Regulatory burden

Problem One. Limited application of the testing framework.

- The testing framework does not adequately align with the expanded scope of the therapeutic industry.
- The framework does not provide coverage for emerging innovations

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

- Part 5 has processes that are overly prescriptive and do not align with modern best laboratory or regulatory practice.
- There is a lack of clarity stemming from unclear processes with gaps, or duplicative information.

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

- Complex procedures for the production and use of the evidentiary certificate
- Processes are convoluted and often duplicative of other areas of the legislative framework.

Problem Four. 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.
- Staff have been exposed to inappropriate behaviour.

3

Our proposals to strengthen and modernise the testing framework

Problem 1. Limited application of the testing framework

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

Current situation

- Currently 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)
- Part 5 has undergone minimal change since enactment
- Growth in our role has introduced or expanded regulation in response to new or evolving technologies for:
  - Complementary medicines, medical devices, in-vitro diagnostic devices, vaping products

We are proposing

- Update Part 5 to cover a broader range of goods and testing activities
- **Remove the limitations** that only allow samples to be tested if taken by an authorised officer or received as a condition of entry in the Register
- Allow testing of a larger range of sample types **regardless of where or how the sample was obtained or provided to us**
- Include **all testing to assess the quality, safety or performance of a good** for supply within Australia or for export only

Problem 1. Limited application of the testing framework

Proposal 2. Revise the powers of an authorised officer

Current situation

- An authorised officer may
  - **Enter premises**, inspect and take samples from a place where therapeutic goods are kept for supply
  - 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
- This power is **limited to the premises** of:
  - Licence holders
  - Manufacturers in respect of whom a conformity assessment certificate has been issued
  - Wholesalers
  - In some cases, sponsors
- Samples taken from other premises are not eligible for testing under Part 5

We are proposing

- To adjust the powers of authorised officers in line with our proposal to broaden the testing framework
- We are proposing that authorised officers be empowered to enter the premises of:
  - All sponsors, including 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

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

Proposal 3. Make testing processes clearer and more streamlined

Current situation

- **Highly prescriptive** procedures and processes
- **No allowance for necessary and appropriate variation** to accommodate new therapeutic goods, developments and innovations, different testing methods or unique circumstances
- **Does not improve quality or integrity of the procedures**
- Often results in **unnecessary steps added** to the chain of custody for samples

We are proposing

- **Remove these procedures** from the Regulations
- Store procedures wholly within our **Quality Management System**
- Storage in QMS will allow:
  - **External review and audits** by our accreditation body (National Association of Testing Authorities)
  - **Ongoing maintenance** and upkeep of the processes
  - **Revision and expansion of procedures** as required to deal with unique circumstances or emerging technologies

TGA Laboratories maintain accreditation to ISO/IEC 17025 **General requirements for the competence of testing and calibration laboratories**

NATA DELIVERING CONFIDENCE for more than 75 years

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

Proposal 4. Improve clarity and definitions

Current situation

- Use of **vague and ambiguous language**
- **Overlapping words** like “examination, testing, analysis”
- Words that are **used inconsistently** across Part 5

We are proposing

- Update the definitions to be **clearly defined** if required beyond their ordinary meaning
- **Standardise wording** to ensure consistency of application
- Clarify that “**testing**” includes all activities such as:
  - Examination
  - Analysis
  - Evaluation
  - Observation
- Streamline duplicate analyst roles into a single role for “analyst”

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate

Proposal 5a. Simplify information in certificate of responsible analyst

Current situation

- At completion of testing, we issue a **certificate containing results** of analysis
- The certificate is also required to state whether the **goods complied with a relevant requirement** about safety, efficacy or performance
- The statement regarding compliance is based on the results of a single laboratory test, and cannot take into account a broader context of an investigation

We are proposing

- Analysts would n**ot be required to include a decision** on whether a relevant good complies with the applicable requirements
- Certificates would only contain **information relating to facts about the testing**. E.g.;
  - Information about the sampling process
  - Information about the handling of the sample
  - Results of the test applied to the sample
- Results of analysis would be **referred to a delegate of the Secretary** who may use discretion to determine the level of regulatory action required

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate

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

Current situation

- A recipient of a certificate that states “non-compliance” **may request that the results of analysis be reviewed** if evidence can be provided that the goods do comply with the relevant requirement
- Stakeholders have found Regulation 30 is extremely difficult to interpret
- These review rights **duplicate** those provided in the Act and Regulations
- If we remove the compliance decisions from the certificate, this **review process would not be necessary** as no compliance decision has been made at this point in the process

We are proposing

- We **repeal the review process** in accordance with proposal 5a
- The review process is instead **conducted further down the track**
- An example may be:
  - Sample is analysed by the laboratory
  - The sample fails the prescribed test
  - The laboratory passes this result to a delegate of the Secretary
  - The delegate investigates the matter
  - The delegate decides if the good is compliant with the relevant requirement
  - **The delegate’s decision is subject to review rights** already prescribed by the Act

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate

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

Current situation

- Subregulation 29(2) specifies that we must send a copy of the certificate to:
  - **the sponsor of the goods**, and
  - 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 **aligns closely with the current scope** of the testing framework and the powers of an authorised officer

We are proposing

- To send a copy of the certificate to the sponsor, **where the sponsor is identifiable**
- Provision of a certificate to a party other than the sponsor would be on a **case-by-case basis**
- If necessary, results could be provided to another party using the existing mechanisms for release of therapeutic goods information under the Act

Problem 3. Complex and inefficient procedures regarding the evidentiary certificate

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

Current situation

- 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"

- This wording limits the use **only to proceedings under the Act or these Regulations**
- However, our test results are often used in legal proceedings commenced under other legislation or common law

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 would also prescribe information that a certificate must, and as appropriate may record in the certificate

Problem 4. Insufficient protection for staff while performing their duties

Proposal 8. Extension of the offence to intimidate authorised officers

Current situation

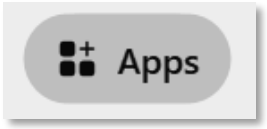
- It is an offence to molest, obstruct, try to intimidate or influence an authorised officer as they execute their powers or perform their functions under the Regulations
- Our analysts are not currently afforded the same protections

We are proposing

- To **extend the same protection** provided to authorised officers to our analysts as they execute their powers or perform their functions

How did we go?

Take a moment to complete our survey



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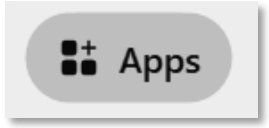

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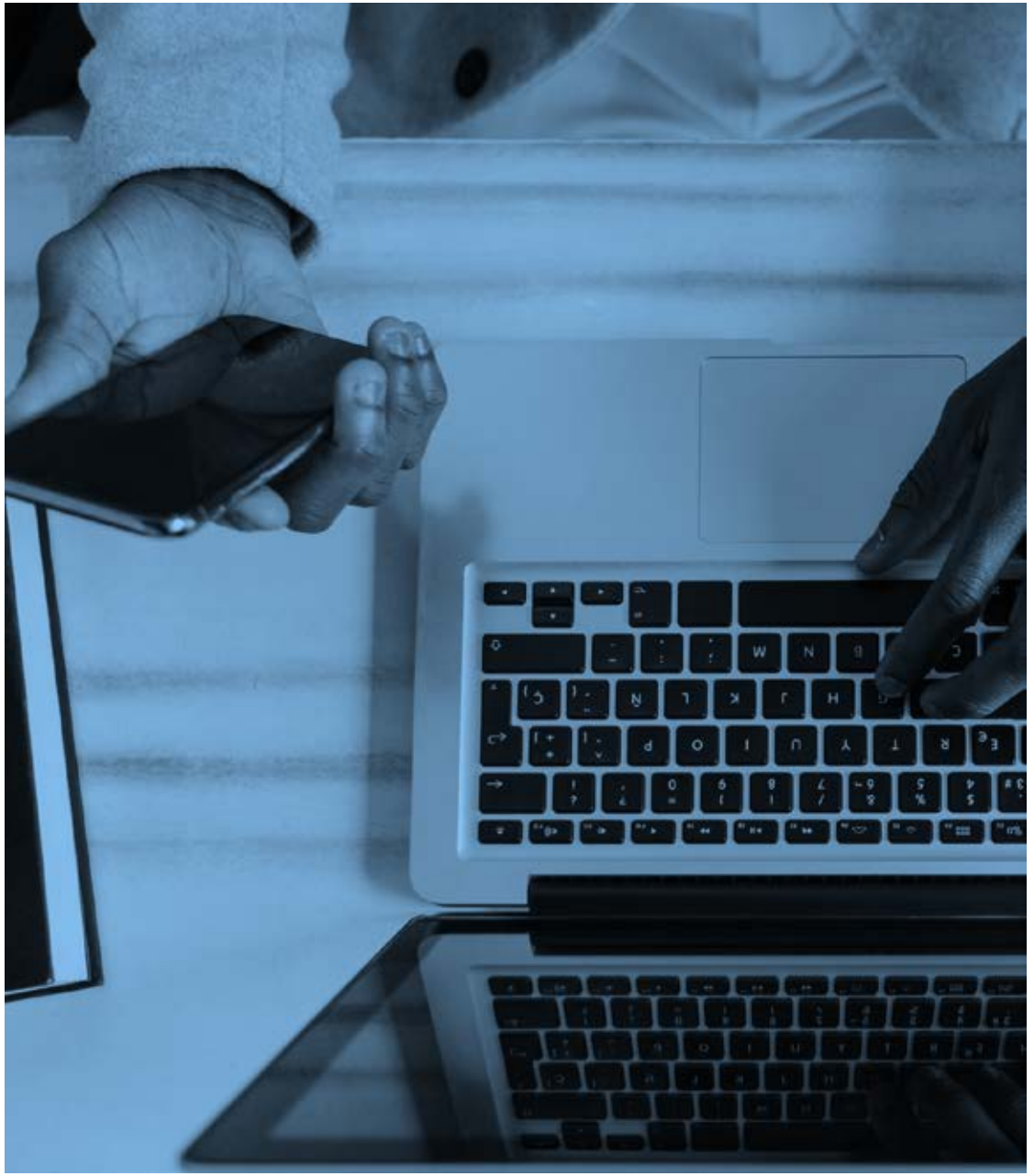

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