EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Testing of Goods and Other Measures) Regulations 2025

The *Therapeutic Goods Act 1989* (the Act) relevantly provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act has a number of other objectives relating to controls on poisons, controls on the regulation of vaping goods, and pharmacist substitution of medicines in shortage. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Department of Health, Disability and Ageing (the Department).

Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Part 5 of the *Therapeutic Goods Regulations 1990* (the TG Regulations) provides for the procedures to be followed in relation to the handling of samples of therapeutic goods that are to be tested under Part 5, and the testing of those samples. It also provides for the appointment of analysts and official analysts to perform testing; empowers authorised persons to obtain samples in certain circumstances; specifies the testing to be performed to determine whether therapeutic goods comply with applicable standards; provides for the issuing of certificates setting out results of testing; and provides a process for review of testing results.

Part 5 applies only to a small subset of the samples of goods that the TGA tests as part of its testing program, and is limited in terms of the procedures that it prescribes for the testing of samples under that Part. It follows that currently most of the TGA's testing program is conducted outside the scope of Part 5. Further, the procedures for the sampling and testing of therapeutic goods currently set out in Part 5 are inflexible, and in some instances unclear, impacting transparency and limiting the TGA's ability to conduct urgent, novel or high-volume testing within the scope of Part 5 to support the safety of therapeutic goods used in Australia.

The *Therapeutic Goods Legislation Amendment (Testing of Goods and Other Measures) Regulations 2025* (the Amendment Regulations) repeal and replace current Part 5 of the TG Regulations to provide for clearer, more effective, and more flexible arrangements for the testing of samples of goods. In particular, the new Part 5:

- enables analysts to select a sample of goods for testing under Part 5, so that a broader range of goods may be tested under Part 5 regardless of how the samples were obtained or received
- enables testing under Part 5 for a broader range of purposes that support the administration of the regulatory scheme, such as testing to determine whether or not goods are therapeutic goods or vaping goods
- provides analysts with improved flexibility to select the appropriate tests to be performed on a sample of goods under Part 5, noting that the TGA tests an extensive range of goods as part of its testing program, and
- enables the TGA to engage an external facility to perform testing where that facility has particular expertise, capability or equipment to undertake the required testing.

The Amendment Regulations also include one minor measure not related to testing, involving amending the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to extend to 31 December 2028 the transitional arrangements relating to the classification of medical devices that are in-vitro diagnostic (IVD) companion diagnostics, to align with transitional arrangements in the European Union.

Details of the Amendment Regulations are set out in Attachment A.

The Amendment Regulations are compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

The Act specifies no conditions that need to be satisfied before the power to make the Amendment Regulations may be exercised. The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Regulations commence on 1 October 2025.

Consultation

Between June and September 2024, the TGA undertook public consultation on proposed amendments to Part 5 of the TG Regulations, including by emailing 4352 stakeholders and holding public webinars attended by 124 people. Respondents were invited to comment on 8 proposed measures which, among other things, would extend the application of Part 5 to a broader range of the TGA's testing activities; allow greater flexibility in the TGA's testing methodologies; and remove the tailored regime under which certain persons may seek review of a certificate of analysis issued in respect of a sample tested under Part 5.

The TGA received 34 responses, including from sponsors, manufacturers, health practitioners, industry organisations, and peak and professional bodies. A large majority of respondents broadly supported 7 of the proposed measures with only 15 percent or fewer respondents disagreeing with the proposed measures. The exception was the proposal to remove the provision for review of the results of the testing, which 50 percent of respondents supported, while the remaining respondents either did not support it or indicated that they were uncertain whether to support it.

In August 2024, the TGA consulted the Regulatory and Technical Consultative Forum for medical devices (RegTech) and Pathology Technology Australia (PTA) in relation to the proposed amendment to the MD Regulations that would extend the transitional arrangements for Class 3 IVD medical devices including IVD companion diagnostics. RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry, and PTA is the peak representative body for the IVD medical device industry. Both organisations supported the proposed amendment.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT A

Details of the *Therapeutic Goods Legislation Amendment (Testing of Goods and Other Measures) Regulations 2025*

Section 1 – Name

This section provides that the title of the Amendment Regulations is the *Therapeutic Goods Legislation Amendment (Testing of Goods and Other Measures) Regulations 2025*.

Section 2 – Commencement

This section provides that the Amendment Regulations commence on 1 October 2025.

Section 3 – Authority

This section provides that the Amendment Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1—Amendments relating to testing of goods

Part 1—Amendments

Therapeutic Goods Regulations 1990

The TGA's testing program plays an important role in the regulation of therapeutic goods and vaping goods in Australia. It is critical to a number of the TGA's functions, including to support and inform:

- the pre-market assessment of therapeutic goods for registration, listing or inclusion in the Australian Register of Therapeutic Goods (the Register), and batch release of vaccines for release for supply in Australia;
- post-market monitoring of therapeutic goods, whether or not those goods are in the Register or supplied subject to a relevant exemption, approval or authority—including, for example, compliance testing to ensure that such goods comply with applicable standards or the essential principles;
- the investigation of suspected offences against or contraventions of the Act or its regulations—including, for example, to determine whether goods are counterfeit therapeutic goods, a person has unlawfully dealt with vaping goods, or a person has unlawfully supplied therapeutic goods that do not comply with applicable standards; and

- regulatory decision-making—including, for example, to assist the Secretary in deciding whether or not to suspend or cancel the registration, listing or inclusion of therapeutic goods in the Register, or to require therapeutic goods to be recalled.

The testing program comprises several testing categories, including, most relevantly, programmed compliance testing and responsive testing to investigate signals (such as in response to a complaint, adverse event report, or issue identified by other areas of the TGA). The goods tested by the TGA are generally therapeutic goods or vaping goods. However, the TGA may also test goods for the purpose of ascertaining whether or not the goods are therapeutic goods or vaping goods, because in some instances this may not be clear without testing.

The TGA's Laboratories Branch is principally responsible for designing and conducting the TGA's testing program. The Laboratories Branch relevantly includes sections for biotherapeutics, biomaterials and engineering, chemistry and microbiology, and comprises Australian Public Service (APS) employees in the Department of Health, Disability and Ageing (the Department) with qualifications across a broad range of disciplines.

The TGA's Laboratories Branch is accredited by the National Association of Testing Authorities (NATA) to ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*, which is the international benchmark for which most laboratories must be accredited to be deemed technically competent to produce valid and reliable test results.

Part 5 of the Therapeutic Goods Regulations 1990

Part 5 of the *Therapeutic Goods Regulations 1990* (the TG Regulations) provides a legislative mechanism for the sampling and testing of therapeutic goods in certain circumstances. It provides for, among other matters:

- an authorised person to obtain samples in certain circumstances (regulation 24 refers);
- the appointment of analysts and official analysts to perform testing and other functions under the TG Regulations (regulation 25 refers);
- the handling of samples of therapeutic goods (regulations 26, 26A and 27 refers) before and during testing;
- the examination and testing of samples, including determining the tests to be conducted (regulations 27 and 28 refers);
- the issuing of an evidentiary certificate setting out the results of the testing (regulation 29 refers); and
- a process by which persons may, in certain circumstances, seek review of the results of the testing (regulation 30 refers).

However, Part 5 of the TG Regulations is outdated and no longer fit for purpose. One of the primary concerns with current Part 5 is that it only applies to a small portion of the TGA's testing program. Specifically, Part 5 is only enlivened in relation to samples of therapeutic goods that are:

- taken by an authorised officer from premises of a kind referred to in regulation 24 of the TG Regulations; or

- delivered by the person in relation to whom the goods are registered, listed or included in the Register, in compliance with a condition of the entry of those goods in the Register, pursuant to paragraph 28(5)(h) or subsection 41FN(2) of the Act.

The limited application of Part 5 is undesirable because the TGA not only tests samples of therapeutic goods, but also vaping goods and other kinds of goods, and test samples that it receives or obtains in a variety of ways.

The Act and its regulations provide various mechanisms by which the TGA may request or obtain samples of therapeutic goods, vaping goods and (in some cases) other kinds of goods. For example, Part 6-2 of the Act contains provisions which empower authorised persons to enter and search premises, including by consent or under a warrant, and, among other things, take samples of therapeutic goods, vaping goods or other things.

Further, departmental officers may purchase goods that are then tested. The TGA also receives samples of goods from persons who may have concerns relating to the quality, safety, efficacy or performance, or lawfulness of the goods, including from members of the public, or agencies or authorities with health or law enforcement functions such as the Australian Border Force, and state or territory health departments.

Part 5 currently does not apply to samples of goods that are obtained in such ways. In these circumstances, testing is done outside of Part 5 under express or implied statutory powers, or in the exercise of executive capacity. The power of the TGA to sample and test therapeutic goods in certain circumstances in the exercise of non-statutory executive capacity has been confirmed by the Full Court of the Federal Court in *Secretary, Department of Health and Aged Care v M House Pty Ltd* [2024] FCAFC 71 at [80]-[82] and [107].

The limited scope of Part 5 can cause uncertainty for sponsors and other stakeholders as to how their goods will be tested. For example, in relation to a medical device of a kind included in the Register, testing would currently be done under Part 5 if samples were received from the sponsor in response to a request made under subsection 41FN(2). However, if the samples of the same medical device were instead purchased by officers of the Department from a retailer, testing would be done outside of Part 5.

The intended effect of the new Part 5 is to bring a greater range of testing under the framework, increasing the consistency of the application of the framework, while recognising there may be some limited circumstances where testing outside Part 5 is appropriate.

The procedures set out in regulations 26, 26A, 27 and 28 for the sampling and testing of therapeutic goods are also unclear, and limit the TGA's ability to conduct urgent, novel or high-volume testing, such as in response to a public health crisis.

Amendments made by this Schedule

This Schedule amends the TG Regulations to:

- repeal and replace Part 5, broadly to revise and streamline the procedures in Part 5 relating to the testing of goods, and improve the clarity and functionality of other arrangements in that Part;

- prescribe analysts and other persons who test samples of goods under new Part 5 as '*protected persons*' for the purposes of section 61A (immunity from civil actions) and section 62 (protection from criminal responsibility) of the Act; and
- provide transitional arrangements relating to the introduction of new Part 5 and make a small number of other minor consequential amendments, including to introduce a new definition and repeal older definitions that are no longer needed.

The purpose of these amendments includes to:

- provide greater scope for more of the testing activities that the TGA undertakes to be performed under new Part 5;
- ensure that the TGA can engage external facilities to undertake testing where appropriate in the circumstances, including where another facility has specialised laboratory equipment or expertise, or where a surge in required testing necessitates additional testing resources;
- provide flexibility in the procedures for testing goods so the regulations will continue to operate effectively in future for the testing of new technology and novel products, and so the testing program is better able to operate effectively in a public health crisis or emergency;
- provide certainty about the testing that is undertaken under new Part 5 and the procedures that apply to that testing, such as the issuing of a certificate and the provision of that certificate to the person in relation to whom therapeutic goods are listed, registered, or included in the Register; and
- remove unnecessary definitions, provisions and processes that do not have any utility or that are duplicative.

Items [1] and [3] – Regulation 2 (definitions of *analysis* and *sample*)

Items [1] and [3] amend regulation 2 of the TG Regulations to repeal the definitions of '*analysis*' and '*sample*', respectively. These amendments are consequential to other amendments made below, and reflect that these definitions are no longer needed. The definition of analysis is repealed as that term is not used in new Part 5 – instead, the term test or testing is used, for consistency, and in reliance on a broad ordinary meaning of that term. That meaning is understood to include analysis and other testing activities such as evaluation, investigation, assessment, visual inspection and the observation of a sample of goods.

Item [2] – Regulation 2

This item amends regulation 2 of the TG Regulations to introduce a signpost definition of '*analyst*', which refers the reader to new subregulation 24(1). The definitions currently in regulation 23 are not reproduced in new Part 5 as, other than a definition of 'analyst', these definitions are no longer needed. New Part 5 does not provide for the roles of official analyst, responsible analyst or samples officer as these roles are not necessary, and are duplicative of part of the role of an analyst.

Items [4] and [5] – Subparagraph 20(b)(iv) and Paragraph 20(c)

These items amend regulation 20 of the TG Regulations to repeal paragraph (c). The effect of this amendment is to remove the condition that paragraph 20(c) imposes on the holder of a

license granted under Part 3-3 of the Act to manufacture therapeutic goods other than medical devices.

Paragraph 20(c) provides that the holder of a licence granted under Part 3-3 of the Act (the licence holder) must comply with the provisions of Part 5 in relation to the taking of samples by authorised officers. This condition complements subregulation 24(1), which relevantly provides that an authorised officer under the TG Regulations may enter the premises of a licence holder and, among other things, take samples of therapeutic goods.

Notably, however, licence holders must comply with the conditions imposed by paragraph 40(4)(b) to (d) of the Act, which require a licence holder to allow an authorised person under the Act to (among other things):

- enter, at any reasonable time, each manufacturing site covered by the licence; and
- among other things, take samples of any therapeutic goods at the site or anything at the site that relates to any therapeutic goods.

The condition in paragraph 20(c) duplicates some of the conditions imposed on licence holders by paragraphs 40(4)(b) to (d) of the Act. Consequently, and noting that new Part 5 of the TG Regulations does not contain a provision equivalent to current regulation 24, it follows that the condition currently imposed on licence holders by paragraph 20(c) is no longer necessary.

Item [6] – Part 5

This item repeals and replaces Part 5 of the TG Regulations. The provisions in new Part 5 ("Testing of goods") are set out below. Broadly, the new provisions:

- enable analysts (nominated APS employees within the Department) to select a sample of goods for testing under Part 5, with the effect that a broader range of samples may be tested under new Part 5 regardless of how the samples are obtained or received by the Department;
- allow testing under Part 5 for a broader range of purposes that support the administration of the Act, its regulations or instruments made under the Act or its regulations, including, for example, testing to determine whether or not goods are therapeutic goods or vaping goods, or whether goods comply with applicable standards contained in a legislative instrument made by the Minister under section 10 of the Act;
- provide greater flexibility for analysts to select the appropriate tests to be performed on a sample of goods under Part 5, reflecting that the TGA tests an extensive range of goods as part of its testing program, with the correct testing procedure varying accordingly, and over time as new technologies emerge and standards are updated; and
- make it clear that the TGA may engage an external facility to perform testing where that facility has particular expertise, capability or equipment to perform the required testing.

Notably, new Part 5 does not include a provision comparable to current regulation 24 (authorised officer—powers and duties). This is because there are other legislative powers, principally in the Act, that provide avenues for TGA officers to, depending on the circumstances, take or obtain samples of therapeutic goods, vaping goods or other things.

This includes in the course of certain searches under warrant conducted under Part 6-2 of the Act, on receipt from a sponsor on request from the Secretary under paragraph 28(5)(h) of the Act, by purchasing from a retailer, or by receiving the goods voluntarily from a State or Territory health authority.

Further, new Part 5 does not include equivalent provisions to regulations 26 and 26A, or subregulation 27(1), of current Part 5, which relate to the handling of samples of therapeutic goods. These provisions are not replicated in new Part 5 because they are: overly prescriptive and not always relevant to the TGA's diverse range of testing activities; do not account for the full range of goods that the TGA tests; and do not reflect all the circumstances in which samples may be received and processed by the TGA. For example, it is not practical for a samples officer to determine whether software received in digital form under subsection 41FN(2) of the Act is "appropriately fastened and sealed", which is a requirement under current subregulation 26A(1). As sample handling requirements are highly specific to the nature of the particular goods being tested, new Part 5 does not prescribe specific sample handling procedures or requirements.

New Part 5 also does not reproduce current regulation 30 of the TG Regulations, which provides a tailored regime for review of an evidentiary certificate issued under current regulation 29. Regulation 30 is not reproduced because, unlike evidentiary certificates issued under current regulation 29, certificates issued under new Part 5 do not contain statements that express a view about whether the goods tested conform to an applicable standard or, in relation to medical devices, comply with the applicable provisions of the essential principles. Rather, certificates issued under new Part 5 focus on setting out the results of the testing to which they relate and do not include a statement or view about whether or not the goods tested comply with regulatory requirements. This approach is consistent with approach under other Commonwealth, State and Territory statutory frameworks, for example section 233BA of the *Customs Act 1901* (Cth).

New Part 5 of the TG Regulations also does not include a provision comparable to current regulation 31 (payment for samples), which effectively requires the Commonwealth to pay for samples that the TGA receives or obtains for testing under current Part 5. This change aligns with the intention to significantly expand the scope of testing performed under new Part 5 and to treat samples of goods tested under Part 5 in the same way as goods tested under other provisions of the therapeutic goods legislative framework. The reasons for this include:

- **Inappropriate to pay in some cases:** There are a variety of circumstances where it would be inappropriate for the TGA to pay any person for the samples, such as where the goods have been seized under warrant on suspicion of being black market goods which were imported into or manufactured in Australia illegally.
- **Avoid double payment:** Payment to a sponsor may effectively result in a double payment, such as where the TGA has purchased the goods from retailers or been voluntarily sent the goods by a Commonwealth, State or Territory health regulator who own the goods.
- **Consistency with the regulatory framework:** Paying the sponsor of therapeutic goods in the Register (or a manufacturer who holds a manufacturing licence or conformity assessment certificate) is out of step with the broader regulatory framework which provides that sponsors of goods in the Register are subject to a range of regulatory controls which they must comply with at their own cost.
- **Accommodate non-destructive testing:** In some circumstances, samples of goods are tested in a non-destructive way, and therefore have limited to no financial impact

on sponsors. An example is where the TGA tests a sample of a kind of medical device which is software being a therapeutic good which is in an incorporeal form that is easily duplicable on a computer.

- **Avoid prohibitive costs:** Depending on the nature of the goods being tested, obtaining samples of goods may be so prohibitively expensive that the costs of compensating sponsors effectively would preclude the TGA from obtaining samples for testing purposes, or would otherwise compromise the TGA's capacity to test other goods. Either option may in turn harm public confidence in the regulatory scheme and potentially the health of patients and the broader community. An extreme example of this is a PET/CT scanner, which can cost millions of dollars per unit.

New Part 5 also does not include a provision equivalent to current regulation 32 (offences relating to analysis etc.) because offences contained in the Schedule to the *Criminal Code Act 1995* (the Criminal Code) are sufficient to cover conduct which causes harm to, obstructs, dishonestly influences or intimidates an analyst in the exercise of their powers or performance of their duties under new Part 5.

New regulation 23 – Purpose of Part 5

New subregulation 23(1) provides that new Part 5 of the TG Regulations is made for the purposes of the whole of subsection 63(1) and paragraphs 63(2)(d) and (g) of the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Paragraphs 63(2)(d) and (g) of the Act provide, respectively, that the regulations may:

- provide for the procedures to be followed in, relevantly, the testing of any of the following:
  - therapeutic goods;
  - vaping goods;
  - any kind of goods, for the purpose of ascertaining whether or not they are therapeutic goods or vaping goods; and
- make provision, relevantly, for the testing of therapeutic goods or vaping goods at the request of persons.

New subregulation 23(2) makes it clear that new Part 5 of the TG Regulations does not preclude the testing of goods other than under that Part. This reflects that new Part 5 is not intended to apply to the entire testing program of the TGA or the broader Department. New Part 5 does not cover the entire field of when therapeutic goods or vaping goods (or goods which are being tested to determine whether or not they are therapeutic goods or vaping goods) may be tested by the Department or its officers under the Act or under non-statutory powers. New Part 5 is not intended to displace or modify the non-statutory power or capacity of the Department and its officers to test or otherwise deal with any goods.

For instance, the TGA may conduct testing:

- under another provision of the Act or its regulations, such as during a search under paragraph 46A(1)(b) of the Act;

- under a commercial arrangement, such as if the TGA agreed to conduct testing for a State health regulator on a commercial basis in circumstances where the State's laboratory facilities were temporarily closed;
- at the request of the World Health Organization, or a regulatory authority of another country, for a purpose that is not related to the administration of the Act; or
- in the context of an urgent public health emergency, where it would be unacceptable from a public health perspective for testing to be delayed by the procedural requirements in Part 5.

New regulation 24 – Nomination of analysts

New subregulation 24(1) of the TG Regulations provides that an APS employee in the Department is an '*analyst*' for the purposes of performing functions and duties, or exercising powers, under this Part, if the Secretary nominates the APS employee, in writing, under this subregulation. Nominated persons will principally include APS employees within the TGA's Laboratories Branch, whose functions include the testing of therapeutic goods and vaping goods. However, the Secretary may also nominate APS employees within other parts of the TGA, or the Department more broadly, as analysts for the purposes of Part 5.

New subregulation 24(2) introduces a precondition to the exercise of the Secretary's power to nominate APS employees to perform the functions and duties, and exercise the powers, of an analyst. The Secretary (or their delegate) must be satisfied that an APS employee has the appropriate qualifications, experience or knowledge to perform those functions, duties, or powers. This supports the integrity of testing conducted under new Part 5 by ensuring the technical competency of persons performing those tests.

The scope of who may be nominated to be an analyst under subregulation 24(1) and the precondition on the exercise of the nomination power are intended to be broadly consistent with the process of appointing analysts under the current Part 5. Current subregulation 25(1) provides that the Secretary may only appoint 'a person who has appropriate qualifications and experience to be an analyst', where in practice only APS employees in the Department were appointed to this position.

It is anticipated that, in practice, most analysts will possess a relevant undergraduate, postgraduate or other higher education qualification. However, the Secretary may also nominate APS employees in the Department who, despite not possessing such a qualification, nevertheless have obtained through experience the requisite knowledge or experience to perform the functions or exercise the powers of an analyst.

New regulation 25 – Testing of samples of goods

Scope of new Part 5 of the TG Regulations

New subregulation 25(1) of the TG Regulations provides that an analyst may select a sample of goods for testing under this regulation for the purpose of the administration of the Act or regulations made under the Act, or an instrument made under the Act or those regulations, including (but not limited to) testing for any of the following purposes:

- ascertaining whether or not the goods are therapeutic goods or vaping goods;
- assessing the quality, safety, efficacy or performance of therapeutic goods or vaping goods;

- monitoring or investigating compliance or non-compliance with the Act, regulations made under the Act, or an instrument made under the Act or those regulations;
- supporting the enforcement of the Act, regulations made under the Act, or an instrument made under the Act or those regulations.

In practice, most of the TGA's testing activities are performed for a purpose relating to the administration of the Act or subordinate legislation made under the Act – usually for a purpose specified in paragraphs 25(1)(a) to (d). However, the chapeau in subregulation 25(1) makes it clear that paragraphs (a) to (d) do not constitute an exhaustive list of purposes for which testing may occur under regulation 25.

The selection of goods for testing is also not limited to therapeutic goods or vaping goods, as there may be circumstances where it is not clear whether a good is a therapeutic good or a vaping good (or both) or not, unless the good is tested to identify its nature and composition.

However, the selection of a sample of goods for testing under regulation 25 is important because there are instances where an analyst may appropriately choose not to select a sample for testing under regulation 25, such as where:

- testing under Part 5 is inappropriate because extraordinary, urgent testing is needed to be done by the TGA to address a public health emergency;
- the TGA intends to test a sample for a purpose that does not clearly relate to the administration of the legislative framework. This may include, for instance, testing the TGA performs solely for the purpose of assisting a Commonwealth, State or Territory agency in the administration of their own legislation, or testing that the TGA performs at the request of another country or an international organisation.

The selection of a sample for testing under regulation 25 is a preliminary or procedural step, which does not of itself have any substantive consequences. Depending on the results of the testing, the results may be used to inform decision-makers' considerations as to whether or not to take regulatory or enforcement action that may affect a person's rights or interests. If such action is then taken under the Act or its regulations, a regulatory decision may be subject to merits review or judicial review.

The results of laboratory testing may be used to inform or support the enforcement of the Act or its subordinate legislation, or action taken in relation to non-compliance with the Act or its subordinate legislation. It is not appropriate for a preliminary step in relation to the monitoring or investigation of compliance or non-compliance to be subject to merits review.

Consequently, the selection of goods for testing under regulation 25 is not itself subject to merits review. This is appropriate given the selection of goods for testing under regulation 25 does not affect a person's rights or interests, and is a preliminary decision that does not have substantive consequences. It is only once the testing is undertaken, and the results are known, that regulatory action may be subject to merits review – that is, the selection of a sample for testing and the testing of those goods may (or may not, depending on the results of the testing) facilitate or lead to the making of a substantive decision. This aligns with the Administrative Review Council's Guide *What decision should be subject to merits review* (see paragraphs 4.3-4.7).

The review of the preliminary and procedural decision to test a sample of goods under new regulation 25 may unnecessarily frustrate or delay the taking of important and critical

regulatory action. There are no substantive consequences to the testing of a sample of goods – it is only the action that may be taken following consideration of testing results that may have substantive consequences for a person.

Testing samples under new Part 5

New subregulation 25(2) of the TG Regulations provides that, if an analyst selects a sample of goods for testing under this regulation, the analyst must:

- test the sample, or arrange for another analyst to test the sample; or
- arrange for the sample to be tested by another appropriate person or body.

The TGA's Laboratories Branch maintains accreditation with NATA to ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. This international standard is the benchmark by which most laboratories, including those operated by comparable overseas regulators such as the United States Food and Drug Administration, must hold accreditation to be deemed technically competent to produce valid and reliable test results. For example, ISO/IEC 17025 sets out procedures for the transportation, receipt, handling and storage of test samples, which are principally designed to ensure the integrity of samples and test results relating to the same.

The TGA's accreditation to ISO/IEC 17025 requires it to maintain comprehensive Quality Management System (QMS) procedures for the methods used for testing. The methods used must be reviewed for suitability, kept up to date, and verified to ensure the required performance can be achieved. Non-standard or laboratory-developed methods are also validated to ensure the required performance can be achieved. Deviations from test methods are documented and investigated. The TGA also maintains QMS procedures in relation to the training, supervising and authorising of competent personnel to conduct those tests. As required under its accreditation, the TGA routinely reviews the integrity and suitability of its QMS procedures, which are also the subject of independent accreditation audits by NATA. The TGA conducts its testing program in accordance with these procedures, and this will continue for testing performed by analysts under new regulation 25. The testing that analysts perform includes various activities such as analysis, evaluation, investigation, assessment, visual inspection, and observation of the sample of goods or certain aspects of the sample of goods.

Under subregulation 25(2), an analyst may test the sample of goods themselves or arrange for another analyst to test the sample. This reflects that more than one analyst may perform a test on a sample of goods, multiple different analysts may test a sample, or just one analyst may complete the testing. This is a practical necessity given work or leave arrangements, the capacity of an analyst, and other factors that influence an analyst's availability to test a sample.

Alternatively, an analyst may arrange for the sample to be tested by another appropriate person or body. This enables the TGA to engage another person or body to test a sample of goods under regulation 25. This may be a particular individual, or another government department or agency, a university, a laboratory or facility that is a corporate entity. The TGA may do this in circumstances where another person or body might have specialised equipment or expertise to test the particular goods or to perform the appropriate tests. The TGA may also engage another person or body to perform testing during periods of high volumes of testing.

In order for a person or body to be appropriate, it is anticipated that ordinarily:

- a person would have, for example, relevant qualifications, experience or knowledge to conduct the relevant testing; and
- a body would have appropriate accreditation (such as with NATA to ISO/IEC 17025) and institutional knowledge or experience with the relevant testing.

However, it is appropriate to provide flexibility to analysts to determine who is appropriate to test in each case, such as to account for circumstances where novel testing is required for a new kind of therapeutic good.

Testing that is performed by an analyst or another appropriate person or body, under an arrangement for that other person or body to test the sample, is performed under subregulation 25(2).

The note to new subregulation 25(2) complements the amendments made in this Schedule to regulation 46B of the TG Regulations. Specifically, the note indicates that, pursuant to regulation 46B, the following are protected persons for the purposes of sections 61A (immunity from civil actions) and 62 (protection from criminal responsibility) of the Act:

- an analyst;
- a person who conducts a test on a sample of goods under an arrangement under paragraph 25(2)(b);
- a person assisting the analyst or other person; and
- a person with whom an arrangement is made under paragraph 25(2)(b).

Decision to not test, or to discontinue testing, under new Part 5

New subregulation 25(3) of the TG Regulations has the effect that if, after a sample of goods is selected for testing (whether or not the testing has commenced or an arrangement has been made under paragraph 25(2)(b)), an analyst decides it is no longer appropriate, possible or necessary for the sample to be tested:

- the sample is not required to be tested under regulation 25; and
- if testing of the sample has already commenced—the testing may be ceased.

This subregulation recognises that there may be instances where it may not be possible to test a sample, for example if there is a defect in the sample that is only identified after that sample has been selected for testing under regulation 25, or if a sample is not of a sufficient size to produce meaningful results. In addition, there may be circumstances in which testing of a sample of goods is no longer needed, for example if the sponsor of the goods has taken appropriate measures to remove the goods from the market or mitigate a risk of harm associated with those goods. In such cases, an analyst may decide that it is no longer appropriate, necessary or possible to test, or to continue to test, the sample under regulation 25.

Importantly, an analyst who makes such a decision in relation to a sample of goods need not be the same analyst who initially selected the sample for testing under regulation 25.

However, the power in subregulation 25(3) may only be exercised in relation to samples the testing of which is either yet to commence, or has not been finalised.

Other matters relating to testing under new Part 5

New subregulation 25(4) of the TG Regulations provides that a sample of goods may be tested under this regulation:

- regardless of how or where the sample was obtained or accessed by, or given to:
  - the Department or an analyst, or
  - another person or body as arranged under paragraph 25(2)(b), and
- whether or not the goods are registered, listed or included in the Register.

Subregulation 25(4) recognises that the TGA may receive, access or otherwise obtain samples of goods in a variety of ways, not all of which are expressly anticipated by the Act or its regulations. For example, officers of the Department may purchase samples from retailers for the purpose of ascertaining whether or not the goods are therapeutic goods or vaping goods, or goods may be provided to the TGA by a hospital for testing because of a suspected safety or quality concern.

Further, new paragraph 25(4)(b) confirms that new Part 5 may apply to goods regardless of whether those goods are in the Register. This provision is intended to clarify that new Part 5 applies to a broader range of goods, where the implementation of current Part 5 is limited to therapeutic goods in the Register.

New subregulation 25(5) provides that, to avoid doubt:

- more than one test may be conducted on a particular sample of goods – for example, a sample may be subjected to:
  - multiple tests to determine compliance with numerous requirements in an applicable standard; or
  - the same test multiple times to ascertain whether the goods continue to comply with an applicable standard over the course of the relevant shelf-life;
- more than one analyst or other person or body may test a particular sample of goods – this recognises that sometimes it may not be practical for one person to perform a test from start to finish, for example if they work part time or go on leave, or that a test may require two or more analysts to perform; and
- a particular sample of goods may be tested at more than one place – for example, the TGA may perform some tests on a sample, but the goods may then be conveyed for testing at a different facility which has the necessary equipment to perform other tests.

New subregulation 25(6) provides that a reference in this regulation to a sample of goods includes a reference to a part of a sample of goods. This is consistent with the definition of '*sample*' in current regulation 2, which is repealed.

This provision confirms that particular testing need not be done on the entire quantity of particular goods held by the TGA. For example, the TGA may hold 1,000 specimens of a medical device taken from a batch of 1,000,000. An analyst may select 500 of those specimens as a sample for testing under new subregulation 25(1). The analyst may then, under new subregulation 25(2), conduct one test on a random sample of 30 from the sample

of 500, and conduct another test on a random sample of 30 from the sample of 470 which remained after the first test.

New regulation 26 – Certificate of analyst

Analyst to issue certificate

New subregulation 26(1) provides that if a sample of goods is tested under regulation 25 (including as arranged under paragraph 25(2)(b)), an analyst must issue a certificate setting out:

- the test that was conducted; and
- the results of the testing.

The obligation to issue a certificate under this subregulation arises once testing of a sample under regulation 25 has been completed. Further, the analyst who issues the certificate may not be the analyst who selected the sample for testing under subregulation 25(1), or who tested the goods or arranged for the testing of the goods under subregulation 25(2). As outlined above, more than one analyst may be involved in the procedure for testing a sample of goods.

New subregulation 26(2) has the effect that, in addition to the information specified in paragraphs 26(1)(a) and (b), which must be included, a certificate issued under subregulation 26(1) may also set out other information relating to the sample or the testing of the sample. Such information may include, for example, a description of the sample that was tested (such as its presentation); the standards against which the sample was tested; from where the sample was obtained; and when, where or by whom the sample was tested.

Like certificates issued under current Part 5 of the TG Regulations, certificates issued by analysts under new subregulation 26(1) are intended to support and inform the TGA's regulatory decision-making and provide for procedural efficiencies in proceedings under the Act or its regulations (including proceedings for an offence against the Act or its regulations, or a contravention of a civil penalty provision) by enabling the Secretary to establish formal or technical matters of fact that are unlikely to be in dispute, or are unlikely to be disputed in a compelling way.

However, unlike certificates issued under current Part 5, certificates issued by analysts under new subregulation 26(1) are not required to contain statements that express a view about whether the goods tested conform to an applicable standard or, in relation to medical devices, comply with the applicable provisions of the essential principles. This reflects that this is a matter for a regulatory decision-maker to form a view on (including by taking into account the laboratory testing results as relevant) or, in proceedings under the Act or its regulations, such matters are appropriately for the court or jury to determine.

New subregulation 26(3) provides that the certificate may cover:

- more than one test conducted on the sample;
- tests conducted on the sample by different analysts or other persons or bodies; and
- tests conducted on the sample at different places.

This provision allows analysts to set out in one evidentiary certificate all the tests that were performed on a particular sample (or part of the sample) under regulation 25, and the results of those tests. This is so even in relation to tests that are performed by multiple analysts or persons, or at different locations. This reduces administrative burden by providing flexibility to issue one certificate in relation to a particular sample covering multiple tests, where appropriate.

Similarly, new subregulation 26(4) provides administrative flexibility by providing that more than one certificate may be issued under subregulation 26(1) in relation to a particular sample. The purpose of this provision is to make it clear that an analyst may issue separate certificates in respect of different tests performed on a sample (or part of the sample). This may be appropriate, for example, if various tests are performed on the sample for different purposes under regulation 25, and the timeframes for finalising each of those tests vary. It may also be that a sample is only selected for further testing sometime after the first test was performed. This subregulation makes it clear that separate certificates may be issued for each test that is completed.

Providing certificate to certain persons

New subregulation 26(5) provides that if the sample is of goods that are registered, listed or included in the Register, an analyst must cause a copy of the certificate to be given to the person in relation to whom the goods are so registered, listed or included.

This requirement does not apply in relation to samples of goods that are not registered, listed or included in the Register. This reflects that, in such cases, an analyst may not know, and may be unable to readily ascertain, the identity of the sponsor of the goods (for example if the goods are counterfeit goods). The term '*sponsor*' is defined in section 2 of the Act – broadly, however, a sponsor is the person responsible for, or who arranges, the importation or exportation of therapeutic goods, or the manufacture of therapeutic goods for supply in Australia. The analyst may also be unaware of the details of the person from whom the sample of goods was taken, particularly where the sample was given to the TGA by a member of the public, for instance, or another health or law enforcement agency or authority.

The obligation in current Part 5 to provide a certificate to the person from whom the goods were taken is not included in new Part 5 as there may be some circumstances where this might tip-off that person (or other persons) about potential enforcement action. In some cases, it may be in the public interest not to release the certificate to persons from whom the goods were taken. The TGA may otherwise release the certificate to other persons and bodies, including under section 61 of the Act.

Finally, while in nearly all circumstances it is anticipated that an analyst will be able to readily identify if a sample tested is of goods registered, listed or included in the Register, there may be unusual circumstances where an analyst is unable to do so, or incorrectly concludes that goods are not entered in the Register. This may occur, for example, where an analyst has tested a box of unidentifiable pills seized from an illegal dispensary, but where – in fact – some of the pills tested were registered medicines. Consequently, it is not intended that the failure to issue a copy of the certificate under subregulation 26(5) would invalidate the testing done under new Part 5 or adversely affect the evidential value of the certificate (including the operation of subregulation 26(6)).

Use of certificate in proceedings

New subregulation 26(6) has the effect that a certificate issued under subregulation 26(1) is, in the following proceedings, prima facie evidence of the matters set out in the certificate:

- proceedings for an offence against the Act;
- proceedings for a contravention of a civil penalty provision of the Act; and
- any other proceedings under the Act or regulations made under the Act (such as proceedings under Part 5A-4 of the Act in which the Secretary is seeking an injunction, or proceedings under subsection 52AAA(4) of the Act where a person seeks a declaration that a thing is not forfeited to the Commonwealth).

The reference in paragraph 26(6)(a) to an offence against the Act has the same extended meaning given to that expression in subsection 3(7) of the Act. That is, paragraph 26(6)(a) has the effect that an analyst's certificate is prima facie evidence of the matters set out in the certificate in proceedings for:

- an offence against the Act or regulations made under the Act;
- an offence against section 6 of the *Crimes Act 1914*, or section 11.1, 11.4 or 11.5 of the Criminal Code, in relation to an offence against the Act or regulations made under the Act; and
- an offence against section 136.1, 137.1 or 137.2 of the Criminal Code in relation to the Act or regulations made under the Act.

New subregulation 26(6) effectively replaces current subregulation 29(5) of the TG Regulations, with the new provision providing that the evidentiary value of an analyst's certificate applies in proceedings under not only the Act or TG Regulations, but also the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

However, minor drafting updates have also been made to make it clearer on the face of the provision that an analyst's certificate is prima facie proof of the matters set out in it. Consequently, consistent with judicial consideration of prima facie evidence provisions in other legislative contexts, it is intended that the certificate will be proof of the matters set out or stated in it sufficient to establish each matter beyond a reasonable doubt, in the absence of credible evidence tending to the contrary that engenders a reasonable doubt as to the truth of the matter.

This subregulation provides for procedural efficiencies in proceedings under the Act, TG Regulations or the MD Regulations. It does so by enabling the Secretary (including as an applicant in civil penalty proceedings under section 42Y of the Act or as a respondent in proceedings under subsection 52AAA(4) of the Act), the Crown, or a respondent, defendant or other party, to establish formal matters that are unlikely to be in dispute (including, for instance, the tests that were performed on the sample, and the standards against which the sample was tested), or are unlikely to be disputed in a compelling way, without other evidence being led about technical matters concerning testing procedures and standards.

However, as an analyst's certificate is only prima facie proof of the matters set out in it in proceedings under the Act or its regulations, the prima facie presumption may be displaced if evidence has been led or elicited (by one or more parties to the proceedings) the total effect of which gives rise to a reasonable doubt as to the matters set out in the certificate.

Document purporting to be certificate

New subregulation 26(7) provides that a document purporting to be a certificate issued under subregulation 26(1) or a copy of that certificate is, unless evidence to the contrary is adduced, taken to be such a certificate or copy and to have been duly given. This is an equivalent provision to subregulation 29(6) currently in Part 5 of the TG Regulations.

References to a sample of goods

New subregulation 26(8) provides that a reference in this regulation to a sample of goods includes a reference to a part of a sample of goods. It is intended that new subregulation 26(8) will have the same effect as new subregulation 25(5).

Items [7] and [8] – Regulation 44

These items make minor consequential amendments to regulation 44 of the TG Regulations. Specifically:

- item [7] replaces the reference to "analyse" with "test"; and
- item [8] replaces the reference to "analysis" with "testing".

The purpose of these amendments, broadly, is to mirror the terminology used in new Part 5 of the TG Regulations to consistently refer to *test* or *testing* to describe the range of activities that the TGA performs to test samples of goods.

Item [9] – Regulation 46B

This item repeals and replaces regulation 46B (protected persons) of the TG Regulations for the purposes of section 61A (immunity from civil actions) and section 62 (protection from criminal responsibility) of the Act.

Immunity from civil actions

New subregulation 46B(1) provides that, for the purposes of paragraph (ga) of the definition of '*protected person*' in subsection 61A(4) of the Act, the following kinds of persons are prescribed:

- an analyst;
- any other person who conducts a test on a sample (or part of a sample) of goods under an arrangement under paragraph 25(2)(b) of the TG Regulations – whether or not that person is a party to the arrangement; and
- a person with whom an analyst makes an arrangement under paragraph 25(2)(b) of the TG Regulations, or a person who makes the arrangement on behalf of a body.

Subsection 61A(1) of the Act provides that no civil action, suit or proceeding lies against the Commonwealth or a protected person in respect of any loss, damage or injury suffered by another person as a result of anything done—or omitted to be done—by a protected person in relation to their performance or exercise of their functions, duties or powers under the Act or regulations. This immunity extends to the purported performance or purported exercise of a protected person's functions, duties or powers under the Act or its regulations.

A '*protected person*', for the purposes of section 61A of the Act, is defined in subsection 61A(4), and relevantly includes a person of a kind prescribed by the regulations (paragraph (ga) of the definition refers). This is designed to provide flexibility by permitting the making of regulations to recognise the range of persons in relation to whom it would be important to ensure that the immunity applies, particularly new categories of persons who may be empowered to perform functions under the regulations. This ensures that such persons may be covered by the immunity without the need for an amendment to the Act.

The effect of new subregulation 46B(1) is that the statutory immunity provided by subsection 61A(1) of the Act applies to persons who are nominated as analysts under new subregulation 24(1) of the TG Regulations; persons with whom an analyst makes an arrangement under paragraph 25(2)(b) of the TG Regulations (which may include bodies corporate and other legal entities) for that person to test the goods; and the individuals who test a sample of goods under such an arrangement.

Analysts and the other persons prescribed in subregulation 46B(1) play a crucial role in the delivery of the TGA's testing program, and their work is critical to ensuring the integrity and robustness of the Department's regulatory actions with respect to therapeutic goods and vaping goods. Without the protection afforded by section 61A of the Act, analysts or other prescribed persons may be unwilling to perform functions or exercise powers under new Part 5 of the TG Regulations if they are concerned about being the subject of claims for civil liability by persons who are dissatisfied with their test results.

Importantly, however, the statutory immunity in subsection 61A(1) of the Act does not apply if the protected person's act or omission was in bad faith (subsection 61A(2) refers).

The note at the end of new subregulation 46B(1) indicates that, pursuant to paragraph (h) of the definition of '*protected person*' in subsection 61A(4) of the Act, a person assisting a person prescribed by that subregulation is also a protected person. This may include, for example, individuals who are employed by a person with whom an analyst has made an arrangement under paragraph 25(2)(b) of the TG Regulations, and whose responsibilities include receiving, handling and storing (but not testing) the samples that are the subject of the arrangement for testing of the sample.

Protection from criminal responsibility

New subregulation 46B(2) provides that, for the purposes of paragraph (b) of the definition of '*protected person*' in subsection 62(3) of the Act, the following kinds of persons are prescribed:

- a person to whom powers or functions are delegated under subsection 57(1A) of the Act;
- a person who conducts a test on a sample (or part of a sample) of goods under an arrangement under paragraph 25(2)(b) of the TG Regulations – whether or not that person is a party to the arrangement;
- a person assisting an analyst or a person mentioned in paragraph (b) of this subregulation in relation to the testing of a sample (or part of a sample) of goods under Part 5 of the TG Regulations; and
- a person with whom an analyst makes an arrangement under paragraph 25(2)(b) of the TG Regulations, or a person who makes the arrangement on behalf of a body.

As APS employees in the Department, analysts are protected persons pursuant to paragraph (a) of the definition in subsection 62(3) of the Act. This is reflected in the note at the end of new subregulation 46B(2).

Section 62 of the Act enables protected persons to obtain, possess or convey goods (or facilitate the conveyance of goods), despite such conduct ordinarily constituting an offence against a law of the Commonwealth, a state or the Australian Capital Territory or Northern Territory, for the purpose of identifying whether the Act or regulations have been complied with. A protected person for the purposes of section 62 of the Act means an APS employee in the Department, or a person of a kind prescribed by the regulations (subsection 62(3) refers).

Regulation 46B currently provides that, for the purposes of paragraph (b) of the definition of '*protected person*' in subsection 62(3) of the Act, a person to whom powers or functions are delegated under subsection 57(1A) of the Act is prescribed. New paragraph 46B(2)(a) replicates these arrangements.

In addition, new paragraph 46B(2)(b) prescribes as a protected person a person who conducts tests on a sample (or part of a sample) of goods under an arrangement under new paragraph 25(2)(b) of the TG Regulations. As section 62 of the Act otherwise does not apply to persons who conduct tests on a sample under such an arrangement, those persons may be prohibited under a law of the Commonwealth, a state or the Australian Capital Territory or Northern Territory from obtaining, possessing or conveying the sample of goods. This may particularly be the case, for instance, if the goods are, or contain, prescription medicines or a vaping substance.

Consequently, new paragraph 46B(2)(b) enables persons who conduct tests on a sample of goods as arranged under new paragraph 25(2)(b) of the TG Regulations to obtain, possess or convey (or facilitate the conveyance of) that sample, without committing an offence relating to such dealings against a law of the Commonwealth, a state or the Australian Capital Territory or Northern Territory.

New paragraph 46B(2)(c) prescribes a person assisting an analyst or person mentioned in paragraph 46B(2)(b) in relation to the testing of a sample of goods under new Part 5 of the TG Regulations. This may include, for example, samples officers who are employed by a person with whom an analyst has made an arrangement under paragraph 25(2)(b) of the TG Regulations, and whose functions include the receipt and handling (but not necessarily testing) of the samples that are the subject of that arrangement.

New paragraph 46B(2)(d) prescribes a person with whom an analyst makes an arrangement under paragraph 25(2)(b) of the TG Regulations, or a person who makes the arrangement on behalf of a body. This provision is necessary to ensure that such persons (which may include bodies corporate and other legal entities) may lawfully obtain, possess or convey the relevant goods for the purpose of giving effect to the arrangements made under paragraph 25(2)(b).

Notably, subsection 62(2) of the Act enables each of the persons prescribed as protected persons in new subregulation 46B(2) of the TG Regulations to arrange for other persons to convey (and possess for the purposes of conveyance) the sample of goods, without those other persons committing an offence against a law of the Commonwealth, a state or the Australian Capital Territory or Northern Territory.

Importantly, the protections provided by subsections 62(1) and (2) of the Act only apply in circumstances where the protected person obtains, possesses or conveys (or facilitates or arranges for the conveyance of) the relevant sample for the purpose of, or in connection with, finding out whether the Act or regulations have been complied with.

Item [10] – Subdivision D of Division 12 of Part 9

This item repeals Subdivision D of Division 12 of Part 9 of the TG Regulations, which provides for the application of amendments to Part 5 of the TG Regulations by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*, as this is no longer needed to be provided for.

Item [11] – Regulation 101

This item repeals regulation 101 of the TG Regulations, which provides for the application of amendments that were made to Part 5 of the TG Regulations by the *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024*, as this is no longer needed to be provided for.

Item [12] – Schedule 5 (table item 3, column 2, paragraph (d))

This item amends paragraph (d) in column 2 of table item 3 in Schedule 5 to the TG Regulations to omit "analysis or" from that paragraph. The effect of this amendment is that paragraph (d) now refers to samples of therapeutic goods imported, exported, manufactured or supplied for the purposes of being subject to laboratory testing procedures.

This amendment is consequential to the repeal of the current definition of '*analysis*' in regulation 2 of the TG Regulations, and reflects that the TGA performs a range of activities to test samples of therapeutic goods and vaping goods, including evaluation, investigation, assessment, visual inspection and observation.

Item [13] – Schedule 5A (table item 4, column 3, subparagraph (g)(iv))

This item amends subparagraph (g)(iv) in column 3 of table item 4 in Schedule 5A to the TG Regulations to omit "or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations" from that subparagraph. This amendment is consequential to other amendments made above, as new Part 5 does not contain a provision equivalent to current regulation 24 (authorised officers—powers and duties).

Item [14] – Schedule 5A (table item 8, column 3, subparagraph (f)(iv))

This item amends subparagraph (f)(iv) in column 3 of table item 8 in Schedule 5A to the TG Regulations to omit "or a person who is an authorised officer for a provision of Part 5 of these Regulations" from that subparagraph. This amendment is consequential to other amendments made above, as new Part 5 does not contain a provision equivalent to current regulation 24 (authorised officers—powers and duties).

Item [15] – Schedule 5A (table item 10, column 3, subparagraph (h)(iv))

This item amends subparagraph (h)(iv) in column 3 of table item 10 in Schedule 5A to the TG Regulations to omit "or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations" from that subparagraph. This amendment is consequential to other amendments made above, as new Part 5 does not contain a provision equivalent to current regulation 24 (authorised officers—powers and duties).

Item [16] – Schedule 5A (table item 11, column 3, subparagraph (g)(iv))

This item amends subparagraph (g)(iv) in column 3 of table item 11 in Schedule 5A to the TG Regulations to omit "or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations" from that subparagraph. This amendment is consequential to other amendments made above, as new Part 5 does not contain a provision equivalent to current regulation 24 (authorised officers—powers and duties).

Item [17] – Schedule 5A (table item 12, column 3, subparagraph (g)(iv))

This item amends subparagraph (g)(iv) in column 3 of table item 12 in Schedule 5A to the TG Regulations to omit "or a person who is an authorised officer for the purposes of a provision of Part 5 of these Regulations" from that subparagraph. This amendment is consequential to other amendments made above, as new Part 5 does not contain a provision equivalent to current regulation 24 (authorised officers—powers and duties).

Part 2—Application, transitional and saving provisions

Therapeutic Goods Regulations 1990

Item [18] – In the appropriate position in Part 9

This item amends Part 9 of the TG Regulations to insert new Division 28, which contains application, transitional and saving provisions relating to the Amendment Regulations. The provisions of new Division 28 are set out in detail below.

New regulation 112 (Definitions)

New regulation 112 provides that, in new Division 28 of Part 9:

- '*amending regulations*' means the Amendment Regulations; and
- '*commencement day*' means the day Division 28 commences.

New regulation 113 (Sampling and testing)

New subregulation 113(1) saves the application of current regulation 23, and (other than subregulation 25(1)) current regulations 25 to 30, to samples of therapeutic goods that are, before the commencement day, delivered to or obtained by the TGA in a manner that enlivens current Part 5 of the TG Regulations. Specifically, those provisions continue to apply to samples of therapeutic goods that, before the commencement day, are:

- taken by an authorised officer before the commencement day under current paragraph 24(1)(c) of the TG Regulations; or

- delivered before the commencement day under paragraph 28(5)(h) or subsection 41FN(2) of the Act.

This subregulation applies subject to new subregulation 113(4).

New subregulation 113(2) effectively preserves the evidentiary value of a certificate issued under current regulation 29 (certificate of responsible analyst) or current regulation 30 (review of results of examination and analysis) before the commencement day. Subject to new subregulation 113(4), it also saves the application of those provisions, as relevant, in relation to such a certificate.

New subregulation 113(3) effectively saves the definitions of '*analysis*' and '*sample*' in current regulation 2 of the TG Regulations with respect to samples of a kind referred to in new subregulation 113(1), and certificates of a kind referred to in new subregulation 113(2), respectively.

New subregulation 113(4) has the effect that, in current subregulations 25(3) to (5) and current regulations 23 and 26 to 30 (the continuing provisions), as they continue to apply because of new subregulations 113(1) and (2):

- a reference to an analyst or official analyst is taken to be a reference to an analyst nominated under new regulation 24 as in force on and after the commencement day; and
- a reference to an authorised officer is taken to be a reference to a person authorised on or after the commencement day under regulation 2A for the purposes of any provision in the TG Regulations, as if the person were also authorised to exercise powers under the continuing provisions.

New subregulation 113(5) provides that new regulations 25 and 26, as in force on and after the commencement day, apply in relation to a sample (or part of a sample) of goods that is or was obtained, accessed or given (however described) before, on or after the commencement day – other than as described in new paragraphs 113(1)(a) and (b).

New regulation 114 (Protected persons)

New subregulation 114 provides that the substitution of regulation 46B made by the Amendment Regulations applies in relation to anything done, or omitted to be done, by a person on or after the commencement day.

Schedule 2—Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Subregulations 11.54(2) and (6)

This item amends subregulations 11.54(2) and (6) of the MD Regulations to omit "26 May 2026" from those subregulations and substitute "31 December 2028". These revisions extend the transitional arrangements for amendments that were made to the MD Regulations in 2019 with respect to the classification of in-vitro diagnostic (IVD) medical devices that are companion diagnostics.

The *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (the 2019 regulations) amended the MD Regulations to, among other things, clarify that an IVD medical device or in-house IVD medical device that is intended by its manufacturer to be used as an IVD companion diagnostic is classified as a Class 3 IVD medical device or Class 3 in-house IVD medical device.

Regulation 11.54 of the MD Regulations provides transitional arrangements for the amendments in the 2019 regulations relating to the classification of IVD companion diagnostics. Subregulation 11.54(2) has the effect that sponsors and manufacturers of a kind of IVD medical device specified in subregulations 11.54(3) to (5) have until 26 May 2026 to ensure that their devices are included in the Register as a Class 3 IVD medical device or Class 3 in-house IVD medical device (as relevant) and comply with all applicable legislative requirements.

The amendments to subregulations 11.54(2) and (6) of the MD Regulations extend the transitional arrangements to 31 December 2028 to align with similar changes to the transitional arrangements for the regulation of IVD companion diagnostics in the European Union (EU). These amendments are necessary to ensure the uninterrupted supply of IVD companion diagnostics in Australia, noting that some sponsors of such devices rely on conformity assessment certificates issued by notified bodies in the EU when seeking marketing approval for their devices in Australia.

Therapeutic Goods Regulations 1990

Item [2] – Regulation 2 (definition of *mercury-added products*)

This item makes a very minor amendment to the definition of '*mercury-added products*' in regulation 2 of the TG Regulations to replace "Part 1" with "Part I". This minor amendment is editorial in nature, to accurately reference the Minamata Convention, and does not make any substantive change to the definition.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Therapeutic Goods Legislation Amendment (Testing of Goods and Other Measures) Regulations 2025

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The *Therapeutic Goods Act 1989* (the Act) relevantly provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act has a number of other objectives relating to controls on poisons, controls on the regulation of vaping goods, and pharmacist substitution of medicines in shortage. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Department of Health, Disability and Ageing (the Department).

Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Part 5 of the *Therapeutic Goods Regulations 1990* (the TG Regulations) provides for the procedures to be followed in relation to the handling of samples of therapeutic goods that are to be tested under Part 5, and the testing of those samples. It also provides for the appointment of analysts and official analysts to perform testing; empowers authorised persons to obtain samples in certain circumstances; specifies the testing to be performed to determine whether therapeutic goods comply with applicable standards; provides for the issuing of certificates setting out results of testing; and provides a process for review of testing results.

Part 5 applies only to a small subset of the samples of goods that the TGA tests as part of its testing program, and is limited in terms of the procedures that it prescribes for the testing of samples under that Part. It follows that currently most of the TGA's testing program is conducted outside the scope of Part 5. Further, the procedures for the sampling and testing of therapeutic goods currently set out in Part 5 are inflexible, and in some instances unclear, impacting transparency and limiting the TGA's ability to conduct urgent, novel or high-volume testing within the scope of Part 5 to support the safety of therapeutic goods used in Australia.

The *Therapeutic Goods Legislation Amendment (Testing of Goods and Other Measures) Regulations 2025* (the Amendment Regulations) repeal and replace current Part 5 of the TG Regulations to provide for clearer, more effective, and more flexible arrangements for the testing of samples of goods. In particular, the new Part 5:

- enables analysts to select a sample of goods for testing under Part 5, so that a broader range of goods may be tested under Part 5 regardless of how the samples were obtained or received
- enables testing under Part 5 for a broader range of purposes that support the administration of the regulatory scheme, such as testing to determine whether or not goods are therapeutic goods or vaping goods
- provides analysts with improved flexibility to select the appropriate tests to be performed on a sample of goods under Part 5, noting that the TGA tests an extensive range of goods as part of its testing program, and
- enables the TGA to engage an external facility to perform testing where that facility has particular expertise, capability or equipment to undertake the required testing.

The Amendment Regulations also include one minor measure not related to testing, involving amending the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to extend to 31 December 2028 the transitional arrangements relating to the classification of medical devices that are in-vitro diagnostic (IVD) companion diagnostics, to align with transitional arrangements in the European Union.

Human rights implications

The Amendment Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR).

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000),* the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Regulations take positive steps to promote the right to health by supporting the TGA's testing activities which is an important part of the TGA's administration of the Act and subordinate legislation made under the Act. This will, in turn, enhance the TGA's ability to:

- safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods that are used in or exported from Australia; and
- monitor compliance with and enforce the national system of controls relating to the regulation of vaping goods that are imported into, manufactured or supplied in, or exported from, Australia.

In particular, the Amendment Regulations support the TGA's testing activities by:

- allowing a broader range of samples to be tested under new Part 5 of the TG Regulations, for a broader range of purposes that support the regulation of therapeutic goods and vaping goods;

- providing greater flexibility for analysts within the Department to select the appropriate tests to be performed on a sample of goods under new Part 5 of the TG Regulations—thereby:
  - enabling analysts to refine and adopt new testing methodologies over time as new technologies emerge and standards are updated; and
  - increasing the TGA's ability to conduct urgent, novel or high-volume testing, such as in response to a public health emergency; and
- ensuring that the TGA can appropriately engage external facilities to undertake testing where necessary or desirable, including where another facility has specialised laboratory equipment or subject matter expertise, or where a surge in required testing (such as in response to a public health crisis) necessitates additional testing resources.

The Amendment Regulations also promote the right to health by ensuring the uninterrupted supply of medical devices that are IVD companion diagnostics in Australia. IVD companion diagnostics are pathology tests designed to identify the presence of specific biomarkers in a person. The purpose of detecting the presence of a biomarker—i.e., characteristics such as molecules or genes that can be used to identify or measure a pathological or physiological process such as a disease—is to identify whether a person is likely to benefit from the use of a particular medicine or biological, or whether they may be at particular risk from such a product.

In 2019, the MD Regulations were amended to clarify the classification rules that apply in relation to medical devices that are IVD companion diagnostics. The Amendment Regulations extend the transitional arrangements for those amendments to 31 December 2028 to align with similar changes to the regulation of IVD companion diagnostics in the European Union (EU). These amendments are necessary to ensure the uninterrupted supply of IVD companion diagnostics in Australia, noting that many sponsors of such devices rely on conformity assessment certificates issued by notified bodies in the EU when seeking marketing approval for their devices in Australia.

Conclusion

The Amendment Regulations are compatible with human rights because they support the right to health in Article 12 of the ICESCR as outlined above and otherwise do not raise any other human rights issues.

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