

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021

These Regulations support the timely availability of new COVID-19 vaccines and treatments in Australia and prescription access to certain nicotine vaping products for smoking cessation by Australians.

An object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering 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.

The purpose of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to remove an unintended barrier to accessing the provisional registration pathway for new COVID-19 vaccines and treatments in Australia, and to remove regulatory burden in relation to nicotine vaping products and conformity assessment of certain medical devices.

In particular the Regulations:

- enable new COVID-19 vaccines and treatments access to the provisional registration pathway for promising new medicines without needing to demonstrate that they represent a significant improvement in efficacy or safety compared to other COVID-19 vaccines or treatments that are fully registered in the Australian Register of Therapeutic Goods (the Register). Without this measure it is likely to be very difficult for subsequent COVID-19 vaccines or treatments to access this pathway once a COVID-19 vaccine or treatment progresses from provisional to full registration;
- reduce regulatory burden for importers, manufacturers, wholesalers and pharmacies by exempting nicotine vaping products (prescription medicines containing nicotine in solution that are vaporised, and administered by inhalation, using a vaping device, principally for smoking cessation) from inclusion in the Register when reasonably expected to be for supply to consumers under the Special Access Scheme Category B (SAS B) or Authorised Prescriber (AP) pathways. This allows importation, manufacture and supply of such products, including stocking in pharmacies, in anticipation of supply to a consumer under a prescription and SAS B approval or AP authority (the devices with which such products are to be used will also be exempt);
- reduce regulatory burden in relation to medical devices by enabling manufacturers of certain higher risk medical devices to seek conformity assessment from an Australian conformity assessment body or an overseas regulatory authority rather than only through an application to the Secretary, and remove the requirement for a mandatory audit of an application for inclusion in the Register for medical devices, for which

such an audit is currently required, if the application for such a device is supported by evidence of conformity assessment issued in accordance with the European Union's Regulation 2017/745 (for devices other than in vitro diagnostic (IVD) medical devices) or Regulation 2017/746 (for IVD medical devices); and

- make two minor amendments to clarify the operation of two exemptions.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after it is registered on the Federal Register of Legislation.

Consultation

Consultation on the measure to support access to the provisional registration pathway for new COVID-19 vaccines and treatments could not take place prior to the preparation of the Regulations. The urgency of ensuring the availability of the affected products meant that specific consultations were unable to take place.

Sponsors, pharmacy groups, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia were consulted on the proposed exemptions for certain nicotine vaping products and vaping devices in May – June 2021. Advice obtained through the consultation process was incorporated into the Regulations.

The increased flexibility for conformity assessment of certain high risk devices was consulted on in 2016 and stakeholders (including Notified Bodies) broadly supported Australian conformity assessment bodies undertaking conformity assessment for certain medical devices.

Consultation on the amendments which clarify two exemptions was not undertaken as they are minor and machinery in nature.

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

Details of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*

Section 1 – Name of the Regulations

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) 2021*.

Section 2 – Commencement

This section provides for the Regulations to commence on the day after registration on the Federal Register of Legislation.

Section 3 – Authority

The Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedules

This section gives legal effect to the amendments in the Schedules.

Schedule 1 – Amendments

Part 1—Provisional determinations—COVID-19

Therapeutic Goods Regulations 1990

Item [1] – Regulation 10L

This item makes a minor editorial amendment to regulation 10L of the *Therapeutic Goods Regulations 1990* (the TG Regulations), to accommodate the amendments that are made by item 2 below.

Item [2] – At the end of regulation 10L

Regulation 10L of the TG Regulations sets out the criteria that new prescription medicines and new indications medicines must meet in order to qualify for the provisional registration pathway under the Act. The provisional registration pathway is designed to provide a marketing approval pathway for promising new medicines, based on early clinical data, provided they meet the criteria in regulation 10L and satisfy the requirements for provisional registration in section 25 of the Act.

The criteria in regulation 10L are that:

- (a) an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;
- (b) either there are no therapeutic goods included in the Australian Register of Therapeutic Goods (the Register) that are for the treatment, prevention or diagnosis of

the same condition as the medicine (except other provisionally registered medicines) or, if there are, there is preliminary clinical data demonstrating that it is likely the medicine provides a significant improvement in efficacy or safety in comparison to those other goods;

- (c) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance; and
- (d) sufficient evidence has been provided of a plan to submit comprehensive clinical data on safety and efficacy within 6 years of provisional registration.

A concern has arisen that once a COVID-19 vaccine or treatment progresses from provisional registration to full registration in the Register, the above criteria has the effect of precluding access to the provisional registration pathway for subsequent vaccines or treatments with similar efficacy and safety (as opposed to significant improvement in efficacy or safety), or a major therapeutic advance, over fully registered vaccines or treatments that themselves reflect considerable scientific progress.

As there is a strong public health need for urgent access to a range of COVID-19 vaccines and treatments, including in particular to COVID-19 vaccines that are particularly designed to address COVID-19 variants, this item amends regulation 10L with the effect that the criteria in paragraphs (b) and (c) above do not apply in relation to an application for provisional registration of a medicine that is for the treatment or prevention of COVID-19.

This ensures that the criteria in these paragraphs do not operate as an unintended barrier to access to critical COVID-19 vaccines and treatments for Australians.

The TGA still requires and evaluates data on such a vaccine's or treatment's efficacy and safety profile once such a product progresses from the provisional determination stage to applying for provisional registration in the Register.

Part 2—Nicotine vaping products

Therapeutic Goods (Medical Devices) Regulations 2002

Therapeutic Goods Regulations 1990

Items [3], [4], [6], [7] and [8]

Nicotine vaping products are medicines containing nicotine in solution which are vaporised, and administered by inhalation, using a medical device (a “vaping device”), principally for the purposes of smoking cessation. There are currently no nicotine vaping products in the Register, and as such these products are only able to be lawfully supplied on a patient-by-patient basis in accordance with a prescription and the relevant pathways for accessing unapproved therapeutic goods under the Act, under a Special Access Scheme Category B (SAS B) approval or Authorised Prescriber (AP) authority.

While these pathways are important to ensure the lawful and safe supply of these medicines, they do not presently provide sufficient lawful authority to enable efficient and effective logistics to take the products from importation into, or manufacture in, Australia, to their subsequent supply before the point of being provided to a consumer. That is, without the amendments, it would be administratively unworkable and burdensome, particularly in light

of the reported existing users of nicotine vaping products, for any such importation, manufacture or supply chain movements to only be authorised once a prescription and SAS B approval or AP authority is in place. Noting that many patients leave filling their prescription to the last minute, the risk of the present regulatory framework is untimely supply to a patient. In turn, this may create an incentive for patients to get access to a product by otherwise than lawful means, with attendant risks to health and safety.

The amendments in this Part are designed to address such concerns and ensure a workable supply chain by, in accordance with the specified reasonable safeguard measures, authorising the bulk importation, manufacture and supply chain movement of nicotine vaping products, and the medical devices with which they are to be used, in anticipation of final supply to a consumer under a prescription and SAS B approval or AP authority. The result is that it will be lawful for pharmacies to stock nicotine vaping products on their shelves in anticipation of a prescription being required to be filled.

Item 3 amends regulation 7.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), for consistency with the approach for the nicotine vaping products when supplied on their own (item 8 below refers), and to make it clear that the exemption of the system or procedure packs is not intended to authorise any broader supply of such products in Australia in circumstances other than provided for in the new item 1.6 of Part 2 of Schedule 4 to the MD Regulations.

Item 4 amends the MD Regulations to exempt the medical devices with which the nicotine vaping products are to be used from the requirement to be included in the Register, and to similarly exempt medical devices that are system or procedure packs comprised of such a device and a nicotine vaping product.

Item 4 also requires that, for the exemption of such system or procedure packs to apply, the sponsor, manufacturer or intermediate supplier of such a pack must have a reasonable expectation that, when supplied to the ultimate consumer, the nicotine vaping product in the pack would be covered by an SAS B approval or AP authority (and, in the case of that supply to the ultimate consumer, such an approval or authority is in place). This is in order to ensure consistency with the terms of the exemption of the nicotine vaping products when supplied on their own (i.e. not in a system or procedure pack), and to ensure that the exemption of such packs does not inadvertently provide a mechanism to avoid the critical safeguard for the health of consumers that is provided by the SAS B or AP pathways being the main options for accessing such medicines.

Item 6 introduces a definition of nicotine vaping product, which principally refers to a medicine that contains nicotine in solution, is a finished product and that is intended to be vaporised, and administered for inhalation, using a vaping device.

Item 8 amends the TG Regulations to exempt the nicotine vaping products themselves from the requirement to be included in the Register, when imported into or manufactured in Australia, and reasonably expected by the sponsor or manufacturer to be supplied to the ultimate consumer in accordance with an approval under subsection 19(1) of the Act (SAS B approval) or an authority under subsection 19(5) of the Act (AP authority).

The intention is that for these exemptions to apply, the importer or manufacturer must have a reasonable expectation that the products would be supplied in accordance with one of those

pathways. Probable evidence will be required to support the expectation including, for example, that the importer or manufacturer has evidence that the intermediate supplier has agreed to supply the product to a pharmacy which is aware of its obligation, at law, to supply in accordance with a relevant SAS B approval or AP authority.

Item 7 amends regulation 12 of the TG Regulations to provide that the exemption of the nicotine vaping products in new item 5 of Schedule 5 to the TG Regulations only has effect in relation to the importation, manufacture or intermediate supply of such products as set out in new item 5. The effect of this is to further highlight that new item 5 is not intended to authorise any broader supply of such products in Australia in circumstances other than provided for in the new item 5.

Item 8 also exempts a nicotine vaping product that is supplied to a person who is not the ultimate consumer of the product, provided that the person engaging in that process reasonably expects that the products would be supplied in accordance with the SAS B or AP pathway when supplied to the ultimate consumer. This ensures the lawful movement of such nicotine vaping products within the supply chain in Australia (including the stocking of pharmacies in anticipation of prescriptions and SAS B approvals or AP authorities being in place), before the final step of supply of such a product to the consumer. The final step of supply to the consumer, in most instances by a pharmacist, would be on behalf of the prescribing health practitioner and, as such, covered by the SAS B approval or AP authority (this is why the exemptions do not cover this step).

Item [5] – Part 2 of Schedule 4 (table item 2.11A, column headed “Kinds of medical devices”)

This item makes a minor amendment to existing item 2.11A in Part 2 of Schedule 4 to the MD Regulations, which exempts vaping devices used to administer a medicine that is registered in the Register, to clarify that the administration of the medicine by such devices is specifically administration by inhalation. This is principally designed to ensure consistency in relation to the description in the MD Regulations of the operation of the kinds of medical devices that vaporise, and administer by inhalation, a related medicine.

Part 3—Conformity assessment

Therapeutic Goods (Medical Devices) Regulations 2002

Item [9] – Regulation 4.1

Paragraph 41EA(b) of the Act provides that the regulations may prescribe kinds of medical devices in respect of which a conformity assessment certificate (issued by the Secretary under section 41EE of the Act) must be issued before a valid application can be made to include such a device in the Register.

Conformity assessment certificates are one way of demonstrating that the conformity assessment procedures in Schedule 3 to the MD Regulations have been applied to a medical device. Such procedures are designed to ensure the safety and quality of the manufacturing process used by a medical device manufacturer.

Regulation 4.1 of the MD Regulations lists the kinds of medical devices for which a conformity assessment certificate is required, for the purposes of paragraph 41EA(b) of the Act, being principally devices that may pose a higher potential risk to users:

- devices containing tissues of animal origin that have been rendered non-viable (other than those that come into contact with intact skin only);
- devices containing tissues, cells or substances of microbial or recombinant origin and that are intended for use in or on the human body;
- devices incorporating stable derivatives of human blood or plasma that are liable to act on the human body in a way that is ancillary to the device;
- devices incorporating a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device;
- Class 4 in vitro diagnostic medical devices (IVDs); and
- Class 4 in-house IVDs (other than those to which the conformity assessment procedures in Part 6B of Schedule 3 to the MD Regulations have been applied).

Regulation 4.1 precludes manufacturers and sponsors of such kinds of devices from relying on the other means of demonstrating the application of the conformity assessment procedures that are recognised under the Act – principally, an Australian conformity assessment body certificate or an overseas regulator conformity assessment document.

To provide greater flexibility, and reduce regulatory burden, for affected sponsors and manufacturers, this item removes this limitation. The removal of regulation 4.1 has the effect of providing sponsors and manufacturers of affected devices with greater flexibility in relation to demonstrating the application of the conformity assessment procedures to their products, with access to additional options of relying on a conformity assessment undertaken by an Australian conformity assessment body or by an overseas regulatory authority, alongside the existing option of a conformity assessment certificate issued by the Secretary under section 41EE of the Act.

Item [10] – Subregulation 5.3(1)

This item makes a minor amendment to subregulation 5.3(1) of the MD Regulations, to reflect the introduction of the changes in item 11 below.

Item [11] – After subparagraph 5.3(1)(viii)

Most of the kinds of medical devices listed in regulation 4.1 of the MD Regulations are covered by paragraphs 5.3(1)(e) or (i) of the MD Regulations (which refer respectively to Class AIMD medical devices, and Class III medical devices that have not been assessed under the EC Mutual Recognition Agreement or EFTA Mutual Recognition Agreement), signifying for the purposes of paragraph 41FH(1)(a) of the Act that an application for inclusion in the Register for such a kind of device is to be subject to a mandatory application audit (subject to certain exemptions).

However, one kind of medical device mentioned in regulation 4.1 is not already covered by the current terms of subregulation 5.3(1) – Class 4 IVD medical devices (paragraph 4.1(e) of the MD Regulations refers). Accordingly, this item amends subregulation 5.3(1) to include a reference to such products.

Item [12] – After subregulation 5.3(2)

Under subregulation 5.3(2) of the MD Regulations, the requirement for a mandatory application audit does not apply for a kind of medical device mentioned in subregulation

5.3(1) if a conformity assessment certificate issued by the Secretary under section 41EE of the Act, or an Australian conformity assessment body certificate issued by an Australian conformity assessment body, is in place in relation to the kind of device. This is designed to reflect confidence that obtaining such a certificate is likely to signify that a device and its manufacturing process meet certain minimum benchmarks for safety and performance (including, in particular, that a relevant quality management system has been applied to the device, it complies with the essential principles, and that other certification requirements of the conformity assessment procedures set out in Schedule 3 to the MD Regulations have been met).

This item amends regulation 5.3 to introduce a new, alternative form of evidence of conformity assessment for which there is similar confidence, with the effect that, if provided in support of an application for inclusion in the Register of a kind of device mentioned in subregulation 5.3(1), the application will not be subject to a mandatory audit.

The new form of evidence is a certificate or other document of conformity assessment issued by a notified body under the European Union's Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (for medical devices other than IVD medical devices) or Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (for IVD medical devices). Notified bodies are organisations designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices (including IVD medical devices).

The European regulations referred to reflect significant reforms in relation to updating the assessing and ensuring the safety and performance of medical devices. This reform recognises that, and reduces regulatory burden for manufacturers and sponsors of such devices.

Each of the European regulations referred to are incorporated by reference in new subregulation 5.3(2AA), and each is incorporated as in force from time to time (subparagraphs 5.3(2AA)(a)(i) and (ii) refer). The legislative authority for this approach is set out in paragraph 63(4)(b) of the Act. The regulations may be freely obtained from the EUR-Lex website ([EU law - EUR-Lex \(europa.eu\)](http://eur-lex.europa.eu)).

It is also important to note that applications for inclusion in the Register that are not required to undergo a mandatory audit may be selected by the Secretary, on a discretionary basis, for audit, e.g. to verify supporting evidence or investigate new safety signals.

Part 4—Other amendments

Therapeutic Goods Regulations 1990

Item [13] – Schedule 5 (table item 9, column 2)

Item 9 of Schedule 5 to TG Regulations exempts medicines or biologicals that are starting materials used in the manufacture of therapeutic goods from the requirement to be included in the Register, except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form.

This is principally designed to reflect that, while goods that are for use as an ingredient or component in the manufacture of therapeutic goods are themselves therapeutic goods under paragraph (ii) of the definition of ‘therapeutic goods’ in subsection 3(1) of the Act, such goods are not, in most instances, intended to be required to be included in the Register.

However, item 9 incorrectly refers to such starting materials as medicines or biologicals, when in most instances they would not themselves be medicines or biologicals (as distinct from some of the goods which they may be used to manufacture).

This item therefore makes a minor amendment to item 9 to remove this error, and to clarify that the exemption in item 9 applies in relation to starting materials that are ingredients or components for use in the manufacture of therapeutic goods, except when pre-packaged for supply for other therapeutic purposes or formulated as a dosage form.

This is consistent with the focus of the regulatory scheme being on finished products, and avoids over-regulating such materials before they are used to manufacture other therapeutic goods.

Part 5—Application provisions

Therapeutic Goods (Medical Devices) Regulations 2002

Item [14] – In the appropriate position in Part 11

This item introduces new Division 11.12 and new regulation 11.58 to the MD Regulations, principally with the effect of making it clear that the new exemptions for medical devices to be used to vaporise and administer an exempt nicotine vaping product, and related system or procedure packs, apply in relation to such devices:

- that are imported or manufactured on or after the commencement of the Regulations; and
- that are supplied on or after the commencement of the Regulations, where imported or manufactured on or after that commencement.

New regulation 11.58 also makes it clear that the amendments relating to conformity assessment, to remove regulation 4.1 of the MD Regulations and reduce regulatory burden for certain devices, applies in relation to an application for the inclusion in the Register of a relevant kind of medical device that is made on or after the commencement of the Regulations.

Therapeutic Goods Regulations 1990

Item [15] – In the appropriate position in Part 9

This item introduces new Division 14 and new regulation 78 to the TG Regulations, with the effect of making it clear that the new exemptions for nicotine vaping products that are introduced by Part 2 of Schedule 1 to the Regulations, applies to such a nicotine vaping product that is imported or manufactured on or after the commencement of the Regulations, and to such a nicotine vaping product that is supplied on or after that commencement provided that importation or manufacture also occurred after commencement.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021

The *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021* (the Regulations) are 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 Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act).

The purpose of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to remove an unintended barrier to accessing the provisional registration pathway for new COVID-19 vaccines and treatments in Australia, and to remove regulatory burden in relation to nicotine vaping products and conformity assessment of certain medical devices.

In particular the Regulations:

- enable new COVID-19 vaccines and treatments access to the provisional registration pathway for promising new medicines without needing to demonstrate that they represent a significant improvement in efficacy or safety compared to other COVID-19 vaccines or treatments that are fully registered in the Australian Register of Therapeutic Goods (the Register). Without this measure it is likely to be very difficult for subsequent COVID-19 vaccines or treatments to access this pathway once a COVID-19 vaccine or treatment progresses from provisional to full registration;
- reduce regulatory burden for importers, manufacturers, wholesalers and pharmacies by exempting nicotine vaping products (prescription medicines containing nicotine in solution that are vaporised, and administered by inhalation, using a vaping device, principally for smoking cessation) from inclusion in the Register when reasonably expected to be for supply to consumers under the Special Access Scheme Category B (SAS B) or Authorised Prescriber (AP) pathways. This allows importation, manufacture and supply of such products, including stocking in pharmacies, in anticipation of supply to a consumer under a prescription and SAS B approval or AP authority (the devices with which such products are to be used will also be exempt);
- reduce regulatory burden in relation to medical devices by enabling manufacturers of certain higher risk medical devices to seek conformity assessment from an Australian conformity assessment body or an overseas regulatory authority rather than only through an application to the Secretary, and remove the requirement for a mandatory audit of an application for inclusion in the Register for medical devices, for which such an audit is currently required, if the application for such a device is supported by evidence of conformity assessment issued in accordance with the European Union's Regulation 2017/745 (for devices other than in vitro diagnostic (IVD) medical devices) or Regulation 2017/746 (for IVD medical devices); and
- make two minor amendments to clarify the operation of two exemptions.

Human rights implications

The Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. 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 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 Regulations take positive steps to support the right to health by:

- ensuring timely access to new COVID-19 vaccines and treatments for Australian consumers through the provisional registration pathway;
- enabling the appropriate importation and supply chain movements (including allowing pharmacists to hold stock in anticipation of supply to consumers under prescription and through a special access pathway for unapproved medicines), of nicotine vaping products to support smoking cessation; and
- supporting the availability of certain higher risk medical devices in Australia by removing unnecessary regulatory burden for sponsors and manufacturers of such products.

Conclusion

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

Greg Hunt, Minister for Health and Aged Care