

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020

This instrument reduces regulatory burden for certain medical devices that are software, supports the safe use of certain prescription medicines and makes other minor amendments.

The 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 principal purpose of the *Therapeutic Goods Legislation Amendment (2020 Measures No.2) Regulations 2020* (the Regulations) is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to reduce regulatory burden for lower risk medical devices that are clinical decision support system software, by exempting them from the requirement to be included in the Australian Register of Therapeutic Goods (the Register), subject to a small number of principally safety-related conditions.

Such software can perform a broad range of functions to facilitate and support health professionals in clinical practice. Examples include software that compares a patient's symptoms and test results with clinical practice guidelines to recommend further tests or investigations, or software that calculates the volume of intravenous fluids for a burns patient based on certain information including the surface area of the burn.

The Regulations also amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to extend the end date of the current fee waiver period for medicines that are prescription opioids, from 31 December 2020 to 31 December 2021, to continue reforms designed to support the safe use of these products.

The Regulations also make a small number of more minor amendments to the TG Regulations to update the order and spelling of some active ingredients, and improve the clarity and consistency of the basis of the eligibility for listing in the Register of assessed listed medicines (these are listed medicines that are evaluated by the Secretary of the Department of Health for their efficacy claims).

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 the day after the instrument is registered, except for items 1 and 2 of Schedule 1 which commence on 25 February 2021.

Consultation

In relation to consultation:

- the TGA consulted publicly on the scope of the regulation of software-based medical devices between 25 March 2020 and 13 May 2020, including in relation to whether clinical decision support systems should be exempted under, or excluded from, the therapeutic goods regulatory scheme. Forty-eight submissions were received, including from sponsors, industry representative bodies such as the Medical Software Industry Association (MSIA), the Australian Healthcare and Hospitals Association and health professional bodies such as the Australian Medical Association (AMA), the Royal Australian College of Surgeons (RACS) and the Royal Australian College of General Practitioners (RACGP). There was broad support for exempting or excluding the kinds of clinical decision support systems identified in the proposed Regulations, but some concern (including from the AMA) about the risk of over-reliance on health professionals to mitigate problems with such software. Follow-up discussions, including to address such concerns, were held with the MSIA, the RACGP, AMA, RACS, Telstra Health, the Royal College of Pathologists of Australasia and the Consumer Health Forum. The proposed Regulations address the concerns raised during the consultation through the inclusion of a number of conditions designed to make it clear that sponsors of such products are responsible for the safety and effective functioning of their software, in order for the exemption to apply;
- the TGA undertook targeted consultation in September 2019 with prescription medicine sponsors on the implementation of reforms designed to support the safe use of prescription opioids, with broad support for the introduction of the fee waivers that are now in place for such products in September 2020 the TGA undertook further consultation with industry representative bodies Medicines Australia, the Generic and Biosimilar Medicines Association and Consumer Healthcare Products Australia on the proposed extension of the end date for the current fee waivers from 31 December 2020 to 31 December 2021, with unanimous support for the proposed extension.

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

Details of the Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020* (the Regulations).

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after they are registered, except for items 1 and 2 of Schedule 1, which commence immediately after the commencement of Schedule 2 to the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019*.

Section 3 – Authority

This section provides that the 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 this 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

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – Part 2 of Schedule 4 (table item 2.14)

The *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (the 2019 Amendments) included a number of reforms relating to the regulation of personalised medical devices, which were to commence on 25 August 2020.

The *Therapeutic Goods Legislation Amendment (2020 Measures No.1) Regulations 2020* (the 2020 Amendments) included amendments to the 2019 Amendments, and to the MD Regulations, to delay the commencement of the personalised medical devices reforms to 25 February 2021 to reflect the impact of the public health emergency caused by the outbreak of the disease known as coronavirus disease 2019 (COVID-19).

One of the measures introduced by the 2019 Amendments, that will commence on 25 February 2021, is a new, specific exemption from inclusion in the Register for patient-matched medical devices (this will be new item 2.14 in Part 2 of Schedule 4 to the MD Regulations).

Inadvertently, a reference in new item 2.14 to a requirement for sponsors of such devices to provide certain information to the Secretary by 25 February 2021 was not updated in the 2020 Amendments.

Accordingly, this item (taken together with section 2) amends item 2.14 immediately after it commences, to replace the reference to 25 February 2021 with a reference to 25 August 2021 to reflect that it was not intended for sponsors to have to provide the required information on the same day as the exemption commences but, rather, to have a period of 6 months before they would be required to provide it to the Secretary.

Item 2 – Part 2 of Schedule 4 (at the end of the table)

This item amends Part 2 of Schedule 4 to the MD Regulations to introduce a new exemption (item 2.15) from the requirement to be included in the Australian Register of Therapeutic Goods (the Register) for medical devices that are certain kinds of clinical decision support software.

Principally, the kinds of clinical decision support software that will be exempted by proposed new item 2.15 in Part 2 of Schedule 4 are those that are:

- intended by their manufacturer to be for the sole purpose of providing or supporting a recommendation to a health professional about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and
- not intended by their manufacturer to directly process or analyse a medical image or signal from another medical device; and
- not intended by their manufacturer to replace a health professional's clinical judgement in relation to making a clinical diagnosis or treatment decision.

The exemption of these kinds of devices is subject to a number of important conditions, with the effect that if the conditions are not complied with, the devices will not be covered by the exemption. The conditions include in particular, for example, that:

- the device must comply with the essential principles (these are minimum benchmarks of safety and performance for medical devices, and are set out in Schedule 1 to the MD Regulations);
- the manufacturer of the device must, on request by the Secretary, provide information within 20 working days on whether the device complies with the essential principles, whether the conformity assessment procedures have been applied to the device and whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990* (the TG Regulations); and
- the manufacturer or sponsor of the device must provide information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act (this relates to kinds of adverse events-related information, including for example information relating to any malfunction or deterioration in the characteristics of a medical device and any use in accordance with, or contrary to, the use intended by the manufacturer that might lead or might have led to the death or serious deterioration of the health of a patient or user of the device), within specified timeframes according to the seriousness of the event or occurrence to which the information relates.

Therapeutic Goods Regulations 1990

Items 3–8 – Subregulation 12B(1B) (table items 10, 11 and 18, after table item 42, table item 47, 73 and 74 and after table item 78)

These items make minor amendments to the list of active ingredients for medicines in subregulation 12B(1B) of the TG Regulations, to correct the order of a small number of ingredients and to update the spelling of two ingredients (cholecalciferol and cyclosporin) to reflect the current approach.

Item 9 – Paragraph 45(7)(b)

Concerns have arisen in recent years over the safe use of prescription medicines that are pharmaceutical opioids. These products are now responsible for more deaths and poisoning hospitalisations in Australia than illegal opioids such as heroin.

In its report *Opioid harm in Australia: and comparisons between Australia and Canada*, released on 9 November 2018, the Australian Institute of Health and Welfare indicated that every day in Australia nearly 150 hospitalisations and 14 emergency department admissions involve opioid harm, and 3 people die from drug-induced deaths involving opioid use (a copy of the report is available for free at <https://www.aihw.gov.au/reports/illicit-use-of-drugs/opioid-harm-in-australia/contents/summary>).

To help reduce the harm associated with prescription opioid use, the TGA undertook a public consultation on prescription opioids in 2018, for which a total of 98 submissions were received, with feedback indicating strong and consistent support from all stakeholders for a regulatory response. Following that consultation, the TGA established the Opioid Regulatory Advisory Group (ORAG), which included representatives from a range of health professional and consumer organisations, to provide independent, expert advice on this issue.

Through the above consultation and support of ORAG, a number of actions were identified to help address problems associated with prescription opioids, including the use of smaller pack sizes for the treatment of acute pain following injury or surgery to avoid or reduce the risk of addiction and reduce the number of unused opioids that may be circulating in the community. Another identified action was the use of relevant warning statements on products, including a boxed warning at the start of the product information and consumer medicine information for such products, alerting consumers and health professionals to the potential for harmful and hazardous use of these products.

To complement these measures, the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* amended the TG Regulations to introduce a fee waiver mechanism for certain kinds of requests by sponsors to vary the entry in the Register for their prescription opioid medicines.

Subregulation 45(7) of the TG Regulations made it clear that the Secretary must waive a fee prescribed in Schedule 9 to the TG Regulations in relation to a request by a sponsor of a prescription opioid under subsections 9D(2) or (3) of the Act to vary the entry in the Register for their medicine if:

- the request is made in the period beginning on the commencement of new subregulation 45(7) (19 December 2019) and ending at the end of 31 December 2020; and
- the request is made solely for an opioid reform purpose, as described in new subregulation 45(8) of the TG Regulations, or for an opioid reform purpose made for an associated variation of product information purpose as described in subregulation 45(9) of the TG Regulations.

Subregulation 45(8) of the TG Regulations sets out that a request for a variation to an entry in the Register for a prescription opioid will be for an opioid reform purpose if it is made:

- under subsection 9D(2) of the Act, to either add a warning or precaution in relation to the goods that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy, or to reduce the class of persons for whom the goods are suitable; or
- under subsection 9D(3) of the Act, to introduce a smaller pack size for the goods.

Subregulation 45(9) of the TG Regulations sets out that an opioid reform request will be for an associated variation of product information request if it is made:

- under subsection 9D(3) of the Act; and
- paragraphs 9D(3)(b)-(c) are satisfied in relation to the request; and
- the request is made for the purpose of varying product information in relation to the prescription opioid, so that the product information is in the form approved under section 7D of the Act in relation to that product.

These measures are designed principally to encourage sponsors of prescription opioids to submit requests to vary the entries in the Register for their products to introduce smaller pack sizes or to add appropriate warning statements or reduce the class of persons for whom their products are suitable.

In light of these important benefits, this item amends paragraph 45(7)(b) of the TG Regulations to extend the period in which this fee waiver applies in relation to such requests, by changing the end date from 31 December 2020 to 31 December 2021, in order to continue to encourage such action to support the safer use of prescription opioids in Australia.

Item 10 – Schedule 4 (table item 8, paragraph (d))

Item 8 of Schedule 4 to the TG Regulations provides the basis for the eligibility for listing in the Register of medicines that are able to access the assessed listing pathway for marketing approval. These are listed medicines that are evaluated by the Secretary under section 26AE of the Act in relation to their efficacy claims.

This item replaces paragraph (d) of item 8 with a new paragraph (d) that reflects minor changes to improve the clarity and consistency with the Act of the description in paragraph (d) of the kinds of indications that assessed listed medicines may have (without changing the scope of the paragraph or of item 8).

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020

The *Therapeutic Goods Legislation Amendment (2020 Measures No. 2) Regulations 2020* (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) and subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989*.

The principal purpose of the Regulations is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to reduce regulatory burden for lower risk medical devices that are clinical decision support system software, by exempting them from the requirement to be included in the Australian Register of Therapeutic Goods (the Register), subject to a small number of principally safety-related conditions.

Such software can perform a broad range of functions to facilitate and support health professionals in clinical practice. Examples include software that compares a patient's symptoms and test results with clinical practice guidelines to recommend further tests or investigations, or software that calculates the volume of intravenous fluids for a burns patient based on certain information including the surface area of the burn.

The Regulations also amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to extend the end date of the current fee waiver period for medicines that are prescription opioids, from 31 December 2020 to 31 December 2021, to continue reforms designed to support the safe use of these products.

Concerns have arisen in recent years over the safe use of prescription medicines that are pharmaceutical opioids. These products are now responsible for more deaths and poisoning hospitalisations in Australia than illegal opioids such as heroin.

In its report *Opioid harm in Australia: and comparisons between Australia and Canada*, released on 9 November 2018, the Australian Institute of Health and Welfare indicated that every day in Australia nearly 150 hospitalisations and 14 emergency department admissions involve opioid harm, and 3 people die from drug-induced deaths involving opioid use (a copy of the report is available for free at <https://www.aihw.gov.au/reports/illicit-use-of-drugs/opioid-harm-in-australia/contents/summary>).

To help reduce the harm associated with prescription opioid use, the TGA undertook a public consultation on prescription opioids in 2018, for which a total of 98 submissions were received, with feedback indicating strong and consistent support from all stakeholders for a regulatory response. Following that consultation, the TGA established the Opioid Regulatory Advisory Group (ORAG), which included representatives from a range of health professional and consumer organisations, to provide independent, expert advice on this issue.

Through the above consultation and support of ORAG, a number of actions were identified to help address problems associated with prescription opioids, including the use of smaller pack sizes for the treatment of acute pain following injury or surgery to avoid or reduce the risk of addiction and reduce the number of unused opioids that may be circulating in the community. Another identified action was the use of relevant warning statements on products, including a boxed warning at the start of the product information and consumer medicine information for such products, alerting consumers and health professionals to the potential for harmful and hazardous use of these products.

To complement these measures, the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* amended the TG Regulations to introduce a fee waiver mechanism (until 31 December 2020) for certain kinds of requests by sponsors to vary the entry in the Register for their prescription opioid medicines - principally to encourage sponsors of prescription opioids to submit requests to vary the entries in the Register for their products to introduce smaller pack sizes or to add appropriate warning statements or reduce the class of persons for whom their products are suitable.

In light of these important benefits, these Regulations amend the TG Regulations to extend the period in which this fee waiver applies in relation to such requests, by changing the end date from 31 December 2020 to 31 December 2021, in order to continue to encourage such action to support the safer use of prescription opioids in Australia.

The Regulations also make a small number of more minor amendments to the TG Regulations to update the order and spelling of some active ingredients, and improve the clarity of the basis of the eligibility for listing in the Register of assessed listed medicines (listed medicines evaluated by the Secretary for their efficacy claims).

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 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 Regulations take positive steps to promote the right to health by reducing regulatory burden for, and supporting the availability of, clinical decision support system software of the kind that is exempted by the Regulations. The Regulations also take positive steps to promote the right to health by supporting reforms to improve the safe use of prescription opioids by extending the current fee waiver for key safety-related variations for 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