REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020

This instrument reduces regulatory burden for certain medical devices that are intended to be used in conjunction with a prescription medicine containing nicotine for the purposes of smoking cessation.

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 *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020* (the Regulations) amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to exempt the following two kinds of medical devices from the requirement to be included in the Australian Register of Therapeutic Goods (the Register) for the purposes of section 41HA of the Act:

- medical devices intended by the person in whose name they are to be supplied to be used for the vaporisation and administration of a registered medicine (whose only active ingredient is nicotine and whose only indication relates to its use, by means of the device, for smoking cessation); and
- medical devices that are system or procedure packs comprising the medical device and registered medicine mentioned above.

The exemptions provide clarity and avoid duplication for applicants who would otherwise be required to make three separate applications for marketing approval in relation to the prescription medicine, the medical device and the system or procedure pack (containing both the medical device and the prescription medicine). The exemptions mean that applicants are only required to make one application for marketing approval, in relation to the prescription medicine.

The performance of the medical device would still be considered as part of the evaluation of the application for the registration of the prescription medicine. This is because the two components cannot be divorced from one another in the context of considering the safety and efficacy of the medicine, particularly in relation to the medicine's toxicological profile and relevant pharmacokinetics (the study of the drug absorption, distribution, metabolism and excretion).

The effect of the exemptions is that the two kinds of medical devices do not require inclusion in the Register or conformity assessment certification, which would involve consideration of the manufacturer's quality management system. However, the devices still need to comply with the essential principles (minimum benchmarks for safety and performance of medical

devices) and limited conformity assessment procedures (manufacturing benchmarks for medical devices), as these apply to exempt devices under the Act.

The exemptions are subject to various conditions, including that the person in whose name the device is to be supplied must notify the Secretary regarding adverse events, allow authorised persons to access the premises at which the device is manufactured, and provide any necessary information to the Secretary on request.

In relation to who may be an authorised person in the context of the exemption, 'authorised person' is defined in subsection 3(1) of the Act as:

- in relation to any provision of the Act or the regulations made under the Act, a person authorised by the Secretary to exercise powers under that provision; or
- in relation to a provision of Part 6-2 of the Act, a member of the Australian Federal Police, or a Customs officer exercising powers in a Customs place (within the meaning of section 183UA of the *Customs Act 1901*).

Regulation 10.1 of the MD Regulations allows the Secretary of the Department of Health (the Department) to authorise any of the following persons to exercise powers under a specified provision of the MD Regulations:

- an officer of the Department, or another Department or of an authority of the Commonwealth;
- an officer of a Department of State of a State, a Department or administrative unit of the Public Service of a Territory or an authority of a State or Territory, with functions relating to health matters.

In practice, authorised persons are principally appointed from officers of the Department and are selected for their scientific or medical expertise, or regulatory compliance background. This reflects the importance of being able to accurately identify safety and quality/performance concerns as part of post-market monitoring activities.

This is particularly important for products such as the vaporisation devices and system or procedure packs mentioned in the instrument, that are exempt from the requirement to be included in the Register and are therefore not subjected to pre-market evaluation before being able to be supplied in Australia.

The inclusion of requirements relating to allowing authorised persons to enter manufacturing premises is also a consistent condition of exemption from the requirement for kinds of medical devices to be included in the Register (items 2.10, 2.10A, 2.12 and 2.13 of Part 2 of Schedule 4 to the MD Regulations refer).

In terms of safeguards to protect information gathered by an authorised person, it is important to note that under the condition of exemption a manufacturer is only required to allow an authorised person to undertake the activities mentioned in subparagraphs (e)(i)-(iii) and that each of these relates to the manufacturer's manufacturing premises or the medical device being manufactured. This reflects that such post-market monitoring is designed to focus on device safety and the integrity of the manufacturing process, and not on a person or on personal information.

In addition, as an APP entity for the purposes of the *Privacy Act 1988*, the Department's collection, use and disclosure of any personal information would be required to be in accordance with the Privacy Act.

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 they are registered.

Consultation

Specific consultation was not undertaken in relation to the instrument, the effect of which is more in the way of a technical amendment.

However, the measure represents a natural extension of consultation that was carried out during 2020, including consultation by the Senate Select Committee on Tobacco Harm Reduction, and the debate around the regulatory status of nicotine and related products which occurred between 17 April 2020 and 18 May 2020 and was undertaken in accordance with the procedures set out in Subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990* that are to be followed in relation to a proposed amendment to the current Poisons Standard that is referred to an expert advisory committee.

The submissions to that consultation included support from peak bodies (including the Australian Medical Association (the AMA), the Society of Hospital Pharmacists of Australia (the SHPA) and the Pharmacy Guild of Australia (the Guild)) for the evaluation of e-cigarette related products that administer nicotine as part of ensuring that such products are assessed by the TGA for quality, safety and efficacy before their supply to consumers.

Specifically, during the consultation period for the scheduling delegate's invitation to make submissions on the interim decision to include nicotine (other than nicotine replacement therapies and when in tobacco prepared and packed for smoking), the Department had received a number of inquiries from potential applicants for inclusion of a vaporiser nicotine product (a device and a medicine / system or procedure pack) on the Australian Register of Therapeutic Goods (the Register). It was therefore considered appropriate to establish the exemption for the vaporiser medical devices in place before applications for such marketing approval are made.

Significantly, while the instrument exempts such devices from the requirement to be included in the Register, it only does so in relation to devices that *administer a medicine that is registered in the Register* (and system or procedure packs that contain such a device and medicine). This is in the nature of a technical exemption for two reasons. First, and most importantly, it follows from the very nature of a vaporiser product that includes both the medical device and the vaporiser medicine that the device's administration of the medicine will necessarily be properly assessed as part of the related medicine's application for registration; as the explanatory statement explains, particularly in relation to the medicine's toxicological profile and relevant pharmacokinetics. As such, the exemption is designed to reflect the feedback provided by the AMA, the SHPA and the Guild in the earlier consultation.

Second, a further consideration in relation to not undertaking specific consultation on the instrument was that if the exemption were not to be established, a person seeking to market such products in Australia would be required to make two or three separate applications, one for the medical device, one for the medicine and one for the system or procedure pack. This is unnecessary regulatory burden. It would not enhance the carrying out of the evaluation

process as required by the Act and would attract a requirement to pay a fee. The exemption is therefore designed to avoid such duplicative outcomes for sponsors, while not compromising the concerns raised in the earlier consultation to ensure the evaluation of the device for quality, safety and efficacy. The various conditions that apply to the exemption further support the safety and oversight of such products by assuring adverse event reporting, provision of information on request and authority for officers to access the manufacturing premises.

The Regulations are also to be supported by a comprehensive communication programme in relation to the effect of the exemptions on patients and health practitioners. It is also anticipated that the TGA will work with peak health bodies to provide input to clinical guidelines.

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

ATTACHMENT A

Details of the *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after they are registered.

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 (at the end of the table)
This item amends Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to introduce two new exemptions (new item 2.11A), with the effect of exempting the following two kinds of medical devices from the requirement to be included in the Australian Register of Therapeutic Goods (the Register):

- a medical device intended, by the person under whose name it is or is intended to be supplied, to be used for the vaporisation and administration to a person of a medicine that is registered in the Register, whose only active ingredient is nicotine and whose only indication relates to its use, by means of the device for smoking cessation; and
- a medical device that is a system and procedure pack consisting of a device as described above and a medicine as described above.

The principal effect of the new exemptions is to provide clarity and to minimise burden (through avoiding duplication) for sponsors seeking marketing approval for these kinds of medical devices and the associated prescription medicine, who would otherwise need to make three applications for the marketing approval of each product.

It is important to note that the exemptions do not have the effect of reducing the safety oversight of the medical devices (or the system or procedure packs containing both the medicine and the medical device) because the safety and performance of the device would be considered as part of the evaluation of the medicine. This is because the two components cannot be divorced from one another in the context of considering the safety and efficacy of the medicine, as delivered by the device.

In relation to safety and post-market surveillance, the exemptions for these devices are also subject to a number of important conditions, including for example, that:

- the device must comply with the essential principles (these are minimum benchmarks of safety and performance for medical devices, in Schedule 1 to the MD Regulations);
- the manufacturer of the device must, on request by the Secretary, provide information within 20 working days including 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 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, for example relating to malfunctions or deteriorations or any use in accordance with, or contrary to, the manufacturer's intended use 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; and
- the person under whose name the device is or is to be supplied must keep records relating to the importation or supply of the device by or on behalf of the person, and must provide this to the Secretary within 20 working days of receiving a request by the Secretary (or a longer period agreed by the Secretary).

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020

The *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) 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).

The *Therapeutic Goods (Medical Devices) Amendment (Vaporisers for Smoking Cessation) Regulations 2020* (the Regulations) amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to exempt the following two kinds of medical devices from the requirement to be included in the Australian Register of Therapeutic Goods (the Register) for the purposes of section 41HA of the Act:

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The effect of the exemptions is that the two kinds of medical devices do not require inclusion in the Register or conformity assessment certification, which would involve consideration of the manufacturer's quality management system. However, the devices still need to comply with the essential principles (minimum benchmarks for safety and performance of medical devices) and limited conformity assessment procedures (manufacturing benchmarks for medical devices), as these apply to exempt devices under the Act.

The exemptions are subject to various conditions, including that the person in whose name the device is to be supplied must notify the Secretary regarding adverse events, allow authorised persons to access the premises at which the device is manufactured, and provide any necessary information to the Secretary on request.

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 promote the right to health by reducing regulatory burden and providing clarity for industry, which will encourage industry to make the affected therapeutic goods available to Australians to assist consumers with efforts to cease smoking, while maintaining an appropriate level of safety oversight over the exempt devices.

The exempt devices will remain subject to a range of important post-market monitoring requirements in the Act, for example in relation to compliance with the essential principles (these are minimum benchmarks of safety and performance for medical devices), compliance with conformity assessment procedures (these are manufacturing standards for medical devices), applicable advertising requirements and requirements relating to the reporting of adverse event – related information involving the 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