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 officers to access the premises at which the device is manufactured, and provide any necessary information to the Secretary on request.

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

While formal consultation was not undertaken in relation to the exemptions, the exemptions are likely to be welcomed by potential applicants for inclusion in the Register to provide clarity in relation to the appropriate evaluation and assessment processes for these kinds of medical devices.

Further, submissions were made by peak health bodies (including the Australian Medical Association, the Society of Hospital Pharmacists of Australia and the Pharmacy Guild of Australia) in response to a recent invitation from the Secretary's delegate to comment on a proposed amendment to the current Poisons Standard to clarify the entry relating to nicotine for all human use as a prescription only medicine. The submissions relevantly included support for nicotine containing e-cigarettes to be included in the Register, with the effect that such products would be assessed by the TGA for quality, safety and efficacy. As Dr Omar Korshid, President of the AMA, stated in his evidence to the Senate Select Committee on Tobacco Harm Reduction, 'it will be important to ensure that products are reliable, that you can believe the quantities of nicotine and whatever other products are within their products so that both the consumer and the doctor know what is actually being ingested'.

The Regulations meet this sentiment by ensuring that the medical devices are evaluated as an inherent part of the evaluation of the prescription medicine, and that the devices will be assessed against the essential principle that requires a medical device that is intended to be used to administer medicine to be designed and produced in a way that ensures that the device is compatible with the provisions and restrictions applying to the medicine and allows that medicine to perform as intended.

The Regulations are 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:

- 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
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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 officers 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