EXPLANATORY STATEMENT

Issued by Assistant Minister for Customs, Community Safety and Multicultural Affairs and Parliamentary Secretary to the Minister for Home Affairs

Customs Act 1901

Customs Legislation Amendment (Prohibited Exports and Imports) Regulations 2019

The *Customs Act 1901* (the Act) concerns customs related functions and is the legislative authority that sets out the customs requirements for the importation, and exportation, of goods to and from Australia.

Subsection 270(1) of the Act, provides, in part, that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters, which by the Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for giving effect to the Act.

Section 50 of the Act provides, in part, that the Governor-General may, by regulation, prohibit the importation of goods into Australia and that the power may be exercised by prohibiting the importation of goods absolutely or by prohibiting the exportation of goods unless specified condition or restrictions are complied with.

Section 112 of the Act provides, in part, that the Governor-General may, by regulation, prohibit the exportation of goods from Australia and that the power may be exercised by prohibiting the exportation of goods absolutely or by prohibiting the exportation of goods unless specified conditions or restrictions are complied with.

The purpose of the *Customs Legislation Amendment (Prohibited Exports and Imports) Regulations 2019* (the Amendment Regulations) is to amend the *Customs (Prohibited Exports) Regulations 1958* (the Prohibited Exports Regulations) and the *Customs (Prohibited Imports Regulations 1956* (the Prohibited Imports Regulations) in relation to drugs, to maintain the currency of controls on the importation and exportation of such substances.

The Minister for Health requested the amendments due, in part, to recent scheduling decisions by the United Nations Commission on Narcotic Drugs for the *Single Convention on Narcotic Drugs of 1961*, as amended by the 1972 Protocol, the *Convention on Psychotropic Substances of 1971* and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances1988*.

Australia as a signatory to these Conventions is obliged to impose import and export controls on substances scheduled in these Conventions. The amendments will ensure Australia's continuing compliance with these Conventions by adding the twelve newly scheduled substances to the Prohibited Exports Regulations and Prohibited Imports Regulations.

In addition, the Minister for Health requested regulation 5A of the Prohibited Imports Regulations be repealed in order to remove the import prohibition on antibiotics. The prohibition of antibiotics is no longer required for the purposes of monitoring the importation of antibiotics under regulation 5A. This is an outcome of the National Antimicrobial Research Strategy 2015-2019.

The Amendment Regulations also modernise the mechanism by which a Minister may exempt drugs from the exportation or importation prohibitions. Under regulation 10AA of the Prohibited Exports Regulations and subregulation 5(3) of the Prohibited Imports Regulations the Minister may by notice, published in the Gazette, approve the exportation or importation of a drug mentioned in the notice. New regulation 10AA of the Prohibited Exports Regulations and new subregulation 5(3) of the Prohibited Imports Regulations make it clear that such a notice is a legislative instrument and also more clearly indicate the conditions in which such approvals are subject.

The Amendment Regulations also make minor corrections in Schedule 4 and Schedule 8 of the Prohibited Imports Regulations generally repealing outdated provisions that impose an unnecessary regulatory burden, and rescheduling thalidomide and preparations containing thalidomide.

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

The Department of Health consulted with the Therapeutic Goods Administration and the Department of Home Affairs on the repeal of Regulation 5A as it poses a regulatory burden on access to prescription only medicines. As the other amendments give effect to international obligations, are of a deregulatory benefit or are minor or machinery in nature, further consultation was considered unnecessary. This accords with subsection 17(1) of the *Legislation Act 2003* (the Legislation Act) which envisages consultations where appropriate and reasonably practicable.

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

The Amendment Regulations commence on the day after registration on the Federal Register of Legislation.

OPC64239 - A

ATTACHMENT A

Details of the *Customs Legislation Amendment (Prohibited Exports and Imports) Amendment Regulations 2019*

Item 1 – Name

This section provides that the title of the Regulations is the *Customs Legislation Amendment (Prohibited Exports and Imports) Regulations 2019.*

Section 2 – Commencement

Table item 1 provides for the whole of this instrument to commence on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section sets out the authority under which the *Customs Legislation Amendment (Prohibited Exports and Imports) Regulations 2019* (the Amendment Regulations) are to be made, which is the *Customs Act 1901*.

Section 4 – Schedules

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

The instruments being amended are the *Customs (Prohibited Exports) Regulations 1958* (the Prohibited Exports Regulations) and the *Customs (Prohibited Imports) Regulations 1956* (the Prohibited Imports Regulations).

Schedule 1 – Amendments

Customs (Prohibited Exports) Regulations 1958

Item 1 - Regulation 10AA

This item repeals and substitutes regulation 10AA of the Prohibited Exports Regulations to modernise the mechanism by which the Minister may exempt drugs from the exportation prohibitions. New regulation 10AA provides that the Minister administering the *Therapeutic Goods Act 1989* may, on the recommendation of the Secretary, by legislative instrument, approve the exportation from Australia of a Schedule 8 drug that meets one or more of the criteria mentioned in, the legislative instrument. New regulation 10AA makes it clear that the approval could apply in relation to a form of a drug, or by reference to the person exporting the drug, the value or amount of the drug or the way or means of exportation of the drug.

Item 2 – 5 Part 1 of Schedule 8

Regulation 10 of the Prohibited Exports Regulations provides that the exportation from Australia of a Schedule 8 drug is prohibited unless certain circumstances apply. Schedule 8 sets out the description of those drugs the exportation of which is prohibited if specified conditions, restrictions or requirements are not complied with.

Together, items 2-10 amend the relevant parts of Schedule 8 to the Prohibited Export Regulations to implement the 2019 scheduling decisions of the United Nations Commission on Narcotic Drugs that added new substances to the *Single Convention on Narcotic Drugs of 1961* as amended by the 1972 Protocol, the *Convention of Psychotropic Substances of 1971* and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988*.

Items 2-5 ensure Australia's continuing compliance with these treaties by adding certain newly scheduled drugs to Part 1 of Schedule 8 of the Prohibited Exports Regulations

Item 6 – 9 Part 2 of Schedule 8

These items ensure Australia's continuing compliance with these treaties by adding certain newly scheduled drugs to Part 2 of Schedule 8 of the Prohibited Exports Regulations.

Item 10 – 11 Part 3 of Schedule 8

This item ensures Australia's continuing compliance with these treaties by adding the newly scheduled drugs to Part 3 of Schedule 8 of the Prohibited Exports Regulations.

Customs (Prohibited Imports) Regulations 1958

Regulation 5 of the Prohibited Imports Regulations provides the framework that controls the importation of drugs into Australia. The term *drug* is defined under Regulation to include a chemical, compound, or other substance or thing that is included in Schedule 4. Schedule 4 sets out the description of those drugs.

Item 12 - Subregulation 2(1) (definition of *Kava*)

This item amends the definition of *Kava* to specify that *kava* means a plant or part of a plant of the species *Piper methysticum* or a preparation obtained from the plan or part of the plant. This makes this definition consistent with other drugs that are plants to expressly refer to a part of a plant.

Item 13 and item 16

Item 13 repeals subregulation 2(2) of the Prohibited Imports Regulations. This item is consequential to the repeal of regulation 5A.

Item 16 makes a minor typographical amendment to the definition of *initial decision* in subregulation 5HA(1) of Customs Prohibited Imports Regulations to omit references to subregulation 5A(1), 5A(4) and 5A(6). This item is consequential to the repeal of regulation 5A.

Item 14 - Subregulation 5(3)

This item repeals and substitutes subregulation 5(3) to modernise the mechanism by which the Minister may exempt drugs from the importation prohibitions. New subregulation 5(3) provide the Minister, may on the recommendation of the Secretary, by legislative instrument, approve the importation into Australia of a drug that meets one or more of the criteria set out in new subregulation 5(3). New subregulation 5(3) makes it clear that the approval could apply in relation to a form of a drug, or by reference to the person importing the drug, the value or amount of the drug or the way or means of importation of the drug.

Item 15 – Regulations 5A and 5F

This item repeals regulation 5A of the Prohibited Imports Regulations. Regulation 5A prohibits the importations of a therapeutic substance that is an antibiotic substance unless a permission in writing to import the substance has been granted by the Secretary or an authorised person.

Regulation 5A is no longer required as the border control of antibiotics is no longer considered necessary as part of the National Antimicrobial Research Strategy 2015-2019. Repealing 5A will reduce regulatory burden on importers and delays for shortages or for time critical patients.

Item 12 also repeals regulation 5F of the Prohibited Imports Regulations. This amendment is consequential to the repeal of regulation 5A, as regulation 5F only related to regulation 5A.

Item 17 - After Regulation 10

This item inserts new item 11 into regulation 10 of the Prohibited Imports Regulations, to provide the *Customs (Prohibited Imports) (Importation of Hemp Derived Products) Approval 2018* continues in force on and from the commencement of the Amendment Regulations as if it had been made under new subregulation 5(3). This notice was made on 6 June 2018 under existing subregulation 5(3) and this transitional provision will ensure that it remains in force despite the repeal and substitution of subregulation 5(3).

Items 18 – 27 Schedule 4

Together these items implement the 2019 scheduling decisions of the United Nations Commission on Narcotic Drugs that added new substances to the *Single Convention on Narcotic Drugs of 1961* as amended by the 1972 Protocol, the *Convention of Psychotropic Substances of 1971* and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988*.

These items ensure Australia's continuing compliance with these treaties by adding the newly scheduled drugs to the Prohibited Imports Regulations

Item 29 - Schedule 8 (table item 2)

This item repeals table item 2 of Schedule 8 to the Prohibited Imports Regulations. This table item relates to certain advertising material that is misleading, false or extravagant and is unnecessary as the advertising provisions in the *Therapeutic Goods Act 1989* address these matters, therefore this item is repealed.

Item 30 - Schedule 8 (table item 10)

This item amends table item 10 of Schedule 8 to the Prohibited Imports Regulations to omit the reference to glycol or a derivative of a glycol other than propylene glycol. The reference to these products is no longer required for monitoring purposes and is therefore repealed.

This item maintains the current prohibition in relation to calamus or oil of calamus under table item 10 of Schedule 8.

Items 28 and 31 - Schedule 4 and Schedule 8 (table items 13 and 15)

Item 31 repeals table item 13 of Schedule 8 to the Prohibited Imports Regulations. Table item 13 relates to remedies for drunkenness, alcoholic habit or drug habit that historically were imposed to safeguard the community; however, it is antiquated and does not align with modern prescription only medicines used to treat these disorders. It also imposes a regulatory burden on prescription only medicines and is therefore repealed.

Item 31 repeals table item 15 of Schedule 8 to the Prohibited Imports Regulations, which applies to thalidomide and preparations containing thalidomide. Item 28 of the Amendment Regulations inserts into Schedule 4 of the Prohibited Imports Regulations new table item 224A which applies to *Thalidomide.* These amendments together enable travellers who legitimately use thalidomide under prescription to enter Australia without having to obtain import permission under regulation 5.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Customs Legislation Amendment (Prohibited Exports and Imports) Regulations 2019

The *Customs Legislation Amendment (Prohibited Exports and Imports) Regulations 2019* (the Amendment Regulations) are compatible with human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview

The Amendment Regulations amend the *Customs (Prohibited Exports) Regulations 1958* (the Prohibited Exports Regulations) and the *Customs (Prohibited Imports) Regulations 1956* (the Prohibited Imports Regulations) in relation to substances to maintain the currency of drug control measures on export from, and import into, Australia.

Regulation 10 of the Prohibited Exports Regulations provides that the exportation from Australia of a drug listed in Schedule 8 of the Prohibited Exports Regulations is prohibited unless certain circumstances apply. Schedule 8 sets out the description of those drugs the exportation of which is prohibited if specified conditions, restrictions or requirements are not complied with.

Regulation 5 of the Prohibited Imports Regulations provides the framework that controls the importation of drugs into Australia. The term drug is defined under Regulation to include a chemical, compound, or other substance or thing that is included in Schedule 4. Schedule 4 sets out the description of those drugs.

The changes implemented by the Amendment Regulations to Schedule 8 of the Prohibited Exports Regulations and Schedule 4 of the Prohibited Import Regulations are, due in part to recent scheduling decisions by the United Nations Commission on Narcotic Drugs for the *Single Convention on Narcotic Drugs of 1961*, as amended by the 1972 Protocol, *the Convention on Psychotropic Substances of 1971* and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988*. The amendments would ensure Australia's continuing compliance with these treaties by adding the newly scheduled drugs to the Prohibited Exports Regulations and the Prohibited Imports Regulations.

In addition, regulation 5A of the Prohibited Imports Regulations has been repealed in order to remove the import prohibition on antibiotics. The prohibition of antibiotics is no longer required for the purposes of monitoring the importation of antibiotics under regulation 5A. This is an outcome of the National Antimicrobial Research Strategy 2015-2019. Repealing 5A will reduce regulatory burden on importers and reduce delays for shortages or for time critical patients.

The outcome of these amendments is that exportation or importation of the listed goods would be permissible with approval from the relevant authority (in this case the Department of Health), but the illicit movement of goods would become an offence.

The Amendment Regulations also modernise the mechanism by which a Minister may exempt drugs from the exportation or importation prohibitions. Under regulation 10AA of the Prohibited Exports Regulations and subregulation 5(3) of the Prohibited Imports Regulations, the Minister may, by notice published in the *Gazette*, approve the exportation or importation of a drug mentioned in the notice.

New regulation 10AA of the Prohibited Exports Regulations provides that the Minister administering the *Therapeutic Goods Act 1989* may, on the recommendation of the Secretary, by legislative instrument, approve the exportation from Australia of a Schedule 8 drug that meets one or more of the criteria mentioned in the legislative instrument. New regulation 10AA would make it clear that the approval could apply in relation to a form of a drug, or by reference to the person exporting the drug, the value or amount of the drug or the way or means of exportation of the drug.

New subregulation 5(3) of the Prohibited Imports Regulations provides that the Minister may, on the recommendation of the Secretary, by legislative instrument, approve the importation into Australia of a drug that meets one or more of the criteria set out in new subregulation 5(3). New subregulation 5(3) makes it clear that the approval could apply in relation to a form of a drug, or by reference to the person importing the drug, the value or amount of the drug or the way or means of importation of the drug.

The Amendment Regulations also make minor corrections in Schedule 4 and Schedule 8 of the Prohibited Imports Regulations generally repealing outdated provisions that impose an unnecessary regulatory burden, and rescheduling thalidomide and preparations containing thalidomide.

Human rights implications

To the extent that the substances that have been added to Schedule 4 of the Prohibited Import Regulations are required for legitimate medical purposes by persons in Australia, this amendment may engage the right to enjoyment of the highest attainable standard of physical and mental health under Article 12 of International Covenant on Economic, Social and Cultural Rights (ICESCR). This is because access is restricted to these substances following the changes made by the Amendment Regulations. However, the restriction of access to these substances is not only necessary in order to implement Australia's international legal obligations under the international instruments discussed above, but also to protect the Australian community from the risks to health that misuse of these substances may cause.

Further, the restriction of access to these substances is balanced by the ability to obtain import permission for those substances where legitimate circumstances exists, such as medical necessity. As such, the limitation to Article 12 that this amendment may present is necessary in order to implement international legal obligations and to protect the Australian community, and

it is reasonable and proportionate as access to the substances is available where there is a legitimate need.

The Amendment Regulations also positively engage Article 12 of the ICESCR by repealing the import prohibition on antibiotics and rescheduling thalidomide and preparations containing thalidomide. The removal of this prohibition supports the right under Article 12 by giving more efficient access to antibiotics through the removal of a regulatory burden to time critical patients. It further supports the right under Article 12 by removing the regulatory burden on travellers who legitimately use thalidomide under prescription to enter Australia without having to obtain import permission.

Conclusion

The Amendment Regulations are compatible with human rights because the Amendment Regulations support Article 12 of the ICESCR and to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

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