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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2017

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Minister for Sport, the Honourable Greg Hunt MP)

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2017

OUTLINE

The Therapeutic Goods (Charges) Amendment Bill 2017 (the Bill) amends the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).

These amendments support the implementation of an important recommendation of the Expert Panel Review of Medicines and Medical Devices Regulation (the Review), which relates to allowing Australian corporations to appraise the suitability of the manufacturing process for, and the safety and performance of, medical devices (Review recommendation 15), by enabling regulations to be made prescribing an annual charge for a conformity assessment body determination.

Section 41EWA of the *Therapeutic Goods Act 1989* (the TG Act), introduced by the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017*, enables regulations to make provision for, and in relation to, empowering the Secretary to make conformity assessment body determinations in respect of Australian corporations. The effect of such a determination, once made, will be to allow such bodies to undertake conformity assessments of manufacturers of medical devices in Australia.

The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 amends the TG Act to make it clear that an annual conformity assessment body determination charge is payable by the Australian corporation that is the subject of such a determination, and to set out related arrangements such as when such charges become payable. As such, there is a need to now also amend the Charges Act to enable regulations to be made to specify the relevant amount for such a charge.

Annual charges are designed in particular to ensure that the Department of Health (through the Therapeutic Goods Administration (the TGA)) is able to, in accordance with the Australian Cost Recovery Guidelines, recover the costs of its post-market monitoring activities that it undertakes as part of administering the TG Act. The introduction of an annual charge for Australian conformity assessment bodies reflects that the TGA will also undertake such monitoring of these bodies to ensure the safety and performance of the devices assessed by them. Such monitoring may include, for example, conducting inspections, and having a particular focus on adverse event monitoring for devices for which the new bodies have undertaken a conformity assessment.

The Bill also makes a small number of other, minor, amendments to the Charges Act to:

- ensure that if the Secretary suspends a conformity assessment body determination, the obligation for the conformity assessment body to pay an annual charge would continue during the suspension period. (The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 includes amendments that would enable regulations to provide for, and in relation to, suspending such determinations); and
- support Review recommendations 3 and 10 in relation to establishing a new approval pathway (to be known as provisional registration) for prescription

medicines using early clinical data to allow for the faster availability of promising new medicines. The amendments ensure that the annual charges prescribed in relation to provisionally registered goods will also apply to provisionally registered goods entered in the Australian Register of Therapeutic Goods (the Register) by Commonwealth officers in accordance with a corresponding State law.

Financial Impact Statement

The regulation of Australian conformity assessment bodies will create administration costs for the Government. The imposition of a charge prescribed in the Regulations in respect of a conformity assessment body determination will provide for the recovery of direct costs of the administration of the framework relating to Australian conformity assessment bodies by the Commonwealth.

Statement of Compatibility with Human Rights

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

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 2017

The Therapeutic Goods (Charges) Amendment Bill 2017 (the Bill) is 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 Bill

The Bill amends the *Therapeutic Goods (Charges) Act 1989* (the Charges Act), principally to support the implementation of a key recommendation of the Expert Panel Review of Medicines and Medical Devices (the Review) - enabling Australian corporations to appraise the suitability of the manufacturing process for, and the safety and performance of, medical devices (Review recommendation 15).

In particular, the Bill enables regulations to be made prescribing an annual charge for Australian corporations that are covered by a conformity assessment body determination made by the Secretary. (Section 41EWA of the *Therapeutic Goods Act 1989* (the TG Act) enables regulations to make provision for, and in relation to, empowering the Secretary to make conformity assessment body determinations in respect of Australian corporations).

The purpose of annual charges is to ensure that the Department of Health (through the Therapeutic Goods Administration (the TGA)) is able to, in accordance with the Australian Cost Recovery Guidelines, recover the costs of its post-market monitoring activities that it undertakes as part of administering the TG Act. The introduction of an annual charge for Australian conformity assessment bodies reflects that the TGA will also undertake such monitoring of these bodies, for example, by conducting inspections, in order to ensure the quality of the manufacturing processes, and the safety and performance of the devices, assessed by such bodies.

The Bill also makes a small number of minor amendments to the Charges Act to:

- ensure that if the Secretary suspends a conformity assessment body determination, the obligation for the conformity assessment body to pay an annual charge would continue during the period of any such suspension. (The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 includes amendments that would enable regulations to provide for, and in relation to, suspending such determinations); and

- clarify that annual charges prescribed in relation to provisionally registered goods will also apply to any provisionally registered goods entered in the Register by Commonwealth officers in accordance with a corresponding State law. (The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 introduces a new approval pathway (to be known as provisional registration) for prescription medicines using early clinical data to allow for the faster availability of promising new medicines.)

Conclusion

As the Bill does not make any changes to the Charges Act other than those outlined above, and as those measures would not appear to engage any of the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act* 2011, the Bill would appear to be compatible with human rights as it does not engage any of the applicable rights or freedoms.

The Honourable Greg Hunt MP, the Minister for Health and Minister for Sport

NOTES ON SECTIONS

Section 1 – Short title
This section provides that the Bill, once enacted, may be cited as the *Therapeutic Goods (Charges) Amendment Act 2017*.

Section 2 - Commencement
This section sets out the manner in which the provisions contained in the Bill will commence. Sections 1, 2 and 3 will commence on the day the Bill receives Royal Assent.

Schedule 1 to the Bill will commence at the same time as Schedule 5 to the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2017* commences. The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 provides that Schedule 5 to that Bill commences on the later of 1 January 2018 and the day after that Bill receives Royal Assent.

Under this section, however, if Schedule 5 to the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2017* does not commence at all, then the provisions in Schedule 1 to the Bill will also not commence.

Section 3 - Schedules
This section provides that each Act specified in a Schedule to the Bill will be amended or repealed as provided for under the items in the Schedule concerned, or will otherwise take effect according to the terms of that item.

SCHEDULE 1 - Amendments

Item 1
This item amends the title of the Charges Act, to include a reference to the imposition of annual charges on the making of conformity assessment body determinations.

Item 2
This item introduces a new subsection 3(3) to the Charges Act, to make it clear that for the purposes of the Charges Act, if a suspension of a conformity assessment body determination has effect at any time under regulations made for the purposes of Part 4-4A of the TG Act, such a determination will be taken to still be in force for the period of the suspension. (The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 includes measures that would amend section 41EWA of the TG Act (located in Part 4-4A) to enable regulations to provide for, and in relation to, suspending such determinations).

This is designed to ensure that if the Secretary suspends a conformity assessment body determination, the obligation for the conformity assessment body to pay an annual charge would continue during any such suspension, and is consistent with the current situation for therapeutic goods that are suspended from the Register under subsections 3(1A), (1B) and (2) of the Charges Act. It is necessary because suspension is temporary and does not result in a reduction to the usual regulatory work required to be undertaken by the TGA in relation to the determination.

Item 3

This item introduces a new subsection 4(2A) to the Charges Act, with the effect of introducing an annual charge (of such amount as is prescribed in regulations for the purposes of the new provision) in respect of a conformity assessment body determination that is in force at any time during a financial year.

Item 4

This item makes a minor amendment to introduce a new subsection 4(3A) to the Charges Act, to ensure that any annual charges prescribed in relation to provisionally registered goods under existing subsection 4(1) of the Charges Act will also apply to any provisionally registered goods entered in the Register by Commonwealth officers in accordance with a corresponding State law.

The Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017 includes amendments to the TG Act to introduce a new pathway for promising new medicines (to be known as provisional registration), and annual charges for these products are expected to be prescribed for the purposes of existing subsection 4(1) of the Charges Act.

A corresponding State law is defined in subsection 3(1) of the TG Act as a State law declared by the regulations to correspond to the TG Act or the regulations, including such a law as amended from time to time (regulation 3 of the *Therapeutic Goods Regulations 1990* lists a number of State and Territory Acts for this purpose).

Item 5
This item amends subsection 5(2) of the Charges Act to make it clear that regulations made under the Charges Act may prescribe different annual charges in relation to conformity assessment body determinations of different kinds.

Item 6
This item provides that the amendments made by this Schedule apply in relation to the financial year in which this item commences, and to each later financial year.