EXPLANATORY STATEMENT

**Select Legislative Instrument No. 86, 2015**

*Therapeutic Goods (Charges) Act 1989*

*Therapeutic Goods (Charges) Amendment (2015 Measures No. 1) Regulation 2015*

The *Therapeutic Goods (Charges) Act 1989* (the Charges Act) imposes annual charges on the registration, listing and inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods. The Therapeutic Goods Administration (TGA), which is part of the Department of Health, is responsible for administering the Charges Act.

Section 4 of the Charges Act provides that annual charges of such amounts as are prescribed are payable in respect of therapeutic goods on the Register, as well as in respect of manufacturing licences, that are in force at any time within a financial year. In addition, under subsection 4(1A) of the Charges Act, where one or more therapeutic goods are “grouped” and each of the “grouped” therapeutic goods is covered by a single registration number, a single annual charge as is prescribed will apply for maintaining all the registered goods covered under the same group.

Subsection 5(1) of the Charges Act provides that the Governor-General may make regulations, not inconsistent with the Charges Act, prescribing the amounts of charges. Under subsection 5(2) of the Charges Act, the Governor-General may prescribe different levels of charges for different classes of goods or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

The purpose of the Regulation is to amend the Therapeutic Goods (Charges) Regulations 1990 (the Charges Regulations) to:

* increase most annual charges by 2.12 per cent for the financial year 2015-16; and
* provide for different amounts of annual charges for goods of a kind mentioned in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 that are not biologics - these goods are more often described as “prescription chemical medicines”.

The 2.12 per cent increase for 2015-16 applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register - this encompasses registered goods, listed goods, biologicals and medical devices.

In applying these increases, the following rounding policy has been applied:

* for charge items that are less than $10,000 - to the nearest $5; and
* for charge items that are greater than or equal to $10,000 - to the nearest $100.

Chemical prescription medicines and higher risk medical devices (class IIa, IIb, III and AIMD devices) are subject to the 2.12 per cent increase, but are also be subject to reductions in their annual charges.

These reductions are intended to complement recent amendments to the Therapeutic Goods Regulations 1990 (the TG Regulations) that will, from 1 July 2015, replace the current scheme for exemptions from annual charges (under which a sponsor’s turnover for their goods must be no more than 15 times the relevant annual charge to qualify for an exemption) with revised arrangements based on exemptions applying automatically so long as the sponsor’s turnover for the relevant goods is zero.

The reduced charges for higher risk devices are in Schedule 1 to the Regulation, and the reduced charges for prescription chemical medicines are in Schedule 2.

The 2.12 per cent increase is based on an assessment of the TGA’s budget outlook for 2015-16, and is a smaller increase than would have applied had the indexation used to calculate adjustments to TGA fees and charges in previous years (based on the Wage Price Index (50 per cent) and the Consumer Price Index (50 per cent)) been applied – this would have delivered a 2.5 per cent increase. The 2.12 per cent increase ensures the TGA is able to continue to recover its costs of administering the *Therapeutic Goods Act 1989* (the TG Act).

In relation to the amendments in Schedule 2, prescription chemical medicines must be registered under Part 3-2 of the TG Act to be marketed in Australia. Where such a medicine comes within the definition of a “new chemical entity” in Part 1 of Schedule 9 to the TG Regulations, higher fees are payable for the evaluation of an application for its registration. Higher fees are also payable for the evaluation of applications for extensions of indications and for “major variations” (as defined in Part 1 of Schedule 9 to the TG Regulations).

Both extensions of indications and major variations in relation to prescription medicines result in the creation of separate and distinct goods by reason of subsection 16(1) of the TG Act. “Major variations” include a change to the intended patient group for a medicine. Unless “grouped”, an extension of indication and a change to the intended patient group are registered under separate registration numbers by reason of subsection 27(2) of the TG Act.

Under the Regulation, the annual charge for prescription chemical medicines that are new chemical entities, or that are extensions of indications or involve a change to an intended patient group (whether grouped or not), is a higher amount until the 8th anniversary of the registration of the medicine has passed. A lower amount is payable thereafter, unless an extension of indication or change in intended patient group is grouped in which case the higher amount would again become payable.

The annual charge for prescription chemical medicines that have the same active ingredients but are separate and distinct from a medicine already on the Register by reason of subsection 16(1) of the TG Act (but are not extensions of indications or a change to the intended patient group) is determined by reference to:

* the amount of charge payable in relation to the medicine already on the Register; and
* whether or not a medicine that is an extension of indication or change to the intended patient group had been grouped with the prescription chemical medicine.

The imposition of different amounts of annual charge on different types of prescription chemical medicines is intended to broadly reflect the commitment of resources by the TGA to the post-market monitoring of those types of medicines.

All prescription chemical medicines that contain specified active ingredients that require particular post-market monitoring (e.g. thalidomide) will be charged a higher amount for so long as the medicine remains on the Register. The amount of the annual charge applicable for prescription chemical medicines that are registered as generic medicines, and on all other chemical prescription medicines, will be the lower amount.

The higher amount for the financial year 2015-16 will be the annual charge for prescription chemical medicines for the 2014-15 financial year plus 2.12 per cent, minus 5 per cent. The lower amount for financial year 2015-16 will be the annual charge for prescription medicines for the 2014-15 financial year plus 2.12 per cent, minus 23 per cent.

Details of the Regulation are set out in the Attachment.

The Charges Act does not specify conditions that would need to be met before the powers under the Act to make the Regulation may be exercised.

The Regulation would be a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulation commences on 1 July 2015.

**Consultation**

The TGA was asked during meetings with peak industry bodies in October and November 2014 to review the levels of annual charges for generic prescription medicines, particularly in light of evidence that such products may require less pharmacovigilance compared with innovator medicines that are often newer to the market. A proposal for a 2 tiered annual charge, with higher and lower amounts for chemical prescription medicines, was discussed with peak bodies at bilateral meetings in early March 2015, followed by a targeted information session with some sponsors in late March. Further discussions were held with Medicines Australia and the Generic Medicines Industry Association on the detail of the 2 tier annual charge proposal in April 2015. Industry is generally supportive of the new arrangements.

Consultation on proposals to increase fees and charges was also undertaken with peak bodies at bilaterals in early March 2015. Some attendees raised concerns about the TGA’s capacity to absorb cost increases with a lower-than-CPI increase - overall, however, the lower increase was welcomed. Following bilaterals, the TGA wrote to industry bodies with the final proposed rate of 2.12 per cent.

Authority: Subsection 5(1) of the

*Therapeutic Goods (Charges) Act 1989*.

**ATTACHMENT**

**Details of the *Therapeutic Goods (Charges) Amendment (2015 Measures No. 1) Regulation 2015***

Section 1 – Name of Regulation

This section provides that the title of the Regulation is the *Therapeutic Goods (Charges) Amendment (2015 Measures No. 1) Regulation 2015.*

Section 2 – Commencement

This section provides for the Regulation to commence on 1 July 2015.

Section 3 – Authority

This section provides that the Regulation is made under the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).

# Section 4 – Schedule

# This section provides that each instrument that is specified in a Schedule to the Regulation is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulation has effect as provided for under that item.

Schedule 1 – Annual charges for 2015-16

**Item 1 - Table of amendments to the Therapeutic Goods (Charges) Regulations 1990**

Item 1 sets out a table of amendments to provisions of the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations).

The effect of these amendments - with the exception of the proposed amendments in items 15 and 16 of the table, and prescription chemical medicines - is to increase all annual charges for therapeutic goods and manufacturing licences by 2.12 per cent, subject to the TGA’s rounding policy.

The amendments in items 15 and 16 reduce annual charges for 2015-16 for higher risk medical devices - class IIa, IIb, III and AIMD devices – by 2.88 per cent.

This reduction has been calculated on the basis of a reduction of 5 per cent, and the general increase of 2.12 per cent.

The 5 per cent reduction reflects that as a result of recent changes to the Therapeutic Goods Regulations 1990 (the TG Regulations) to replace the current low turnover scheme for annual charge exemptions with revised arrangements based on sponsors being exempt for so long as the turnover for the relevant goods is zero, sponsors with low, but some, turnover will not qualify for the revised exemption.

The annual charges for prescription chemical medicines for 2015-16 are also reduced, and the new figures for 2015-16 for these products are set out in Schedule 2.

Item 24 of the table makes an amendment to the note to subregulation 3(3) of the Charges Regulations.

This note refers to the fact that under regulation 43AAJ of the TG Regulations, the annual charge for a manufacturing licence under Part 3-3 of the *Therapeutic Goods Act 1989* (the TG Act) (other than a licence to manufacture human blood and blood components) payable by a person whose wholesale turnover of goods in a financial year is not more than $90 500, is half the amount mentioned in subregulation 3(2) of the Charges Regulations. Subregulation 3(2) of the Charges Regulations lists annual charges for manufacturing licences.

Item 24 of the table replaces the current reference in this note to the amount of $90 500 with a reference to the updated amount of $92 400, for 2015-16. This ensures consistency with changes to the TG Regulations, which include an amendment to regulation 43AAJ of the TG Regulations to increase the wholesale turnover threshold mentioned above, from $90 500 to $92 400.

Schedule 2 – Annual charges for goods that are not biologics

**Items 1 and 2 – Paragraph 3(1)(a)**

These items make minor, editorial changes to paragraph 3(1)(a) of the Charges Regulations for accuracy, and for consistency with the amendments made by items 3 to 7.

**Item 3 - Paragraph 3(1)(b)**

Paragraph 3(1)(b) of the Charges Regulations currently specifies the annual charge payable for the registration of prescription medicines that are biologics (most often described as prescription biological medicines), and for prescription medicines that are not biologics (i.e. most often, and hereinafter, described as prescription chemical medicines).

As item 8 introduces a new regulation 4 to the Charges Regulations that identifies the annual charges payable for the registration of goods that are prescription chemical medicines, item 3 introduces a new paragraph 3(1)(b) to the Charges Regulations that just specifies the annual charge payable from 1 July 2015 for prescription medicines that are biologics.

The amount specified in this regard reflects the 2.12 per cent increase to TGA fees and charges for 2015-16.

**Item 4 – At the end of subregulation 3(1)**

This item makes a minor amendment to add a note at the end of subregulation 3(1) of the Charges Regulations to indicate that annual charges for prescription chemical medicines are in new regulation 4.

**Item 5 – Paragraph 3(1A)(a)**

This item makes a minor, editorial change to paragraph 3(1A)(a) of the Charges Regulations for accuracy, and consistency with the amendments made by items 3, 4, 6 and 7.

**Item 6 – Paragraph 3(1A)(b)**

Paragraph 3(1A)(b) of the Charges Regulations currently specifies the annual charge payable for the registration of grouped prescription medicines that are biologics, and for grouped prescription chemical medicines.

As item 8 introduces a new regulation 4 to the Charges Regulations that identifies the annual charges payable for the registration of grouped prescription chemical medicines, item 6 introduces a new paragraph 3(1)(b) to the Charges Regulations that just specifies the annual charge payable from 1 July 2015 for grouped prescription medicines that are biologics.

The amount specified in this regard reflects the 2.12 per cent increase to TGA fees and charges for 2015-16.

**Item 7 – At the end of subregulation 3(1A)**

This item makes a minor amendment to add a note at the end of subregulation 3(1A) of the Charges Regulations to indicate that annual charges payable for the registration of grouped prescription chemical medicines are in new regulation 4.

**Item 8 – At the end of the Regulations**

This item introduces a new regulation 4 to the Charges Regulations that sets out the annual charge payable for the registration of prescription chemical medicines, and grouped prescription chemical medicines, if the registration is in force at any time during the financial year to which the charge relates (the charge year) (subregulation 4(1) refers).

**Higher amount and lower amount – subregulation 4(2)**

Under new subregulations 4(2), the higher amount will be payable for the registration of prescription chemical medicines if any of the circumstances described in new subregulations 4(3) - (8) apply.

If none of those subregulations apply in relation to the registration of prescription chemical medicines, or any prescription chemical medicines that are grouped, in a particular financial year, the lower amount will be payable for that year.

The imposition of the two different levels of annual charge broadly reflects the need for the TG to commit resources to the post-market monitoring of these types of medicines.

The circumstances in which the higher amount will apply for the registration of a prescription chemical medicine for a charge year are outlined below.

**Medicines containing specified active ingredients – subregulation 4(3)**

This subregulation covers prescription chemical medicines that contain any of six specified active ingredients - thalidomide, leflunomide, lenalidomide, mifepristone, clozapine or isotretinoin. Such medicines will attract the higher amount for each charge year while entered in the Register, irrespective of the number of years they have been entered, because of the serious nature of the adverse events that may be associated with the use of these ingredients. Ongoing high level monitoring and intervention is required to ensure that these risks are reduced for users of such medicines.

**New chemical entities, extensions of indications and new intended patient groups – subregulation 4(4)**

This subregulation covers prescription chemical medicines registered on or after 1 July 2015, that have been registered for less than 8 years as at 1 July in the charge year and that either:

* are new chemical entities (as defined in Part 1 of Schedule 9 to the TG Regulations – relevantly, this term covers for example new chemical or radiopharmaceutical substances not previously included in a medicine in the Register, and isomers, derivatives or salts of an already-known chemical or radiopharmaceutical substance); or
* are separate and distinct from another registered medicine because of an extension of an indication (other than an extension of an indication to which regulation 16G of the TG Regulations applies) or a change to the intended patient group (within the meaning of paragraph (e) of the definition of ‘major variation’ in subclause 1(1) of Schedule 9 of the TG Regulations).

Collectively, medicines in either of the above categories are defined as ‘relevant goods’ in proposed subregulation 4(9)).

The post-market monitoring required in relation to ensuring the safety of prescription chemical medicines in these categories is more intensive than would be required for medicines that have been in the market for longer, due to the limited use of medicines in these categories in relevant populations.

If such medicines have passed the 8th anniversary of their registration as at 1 July in the charge year, they would no longer come within subregulation 4(4). Provided they were not, at that point, covered by any of the circumstances described in subregulations (5) to (8), they would then move to the lower amount of annual charge.

**Medicines whose ‘parent goods’ have been registered for less than 8 years – subregulation 4(5)**

This subregulation covers prescription chemical medicines registered on or after 1 July 2015 that are not relevant goods (as described above) and whose ‘parent goods’ have been registered for less than 8 years as at 1 July in the charge year.

Under subregulation 4(9) a prescription chemical medicine will be ‘parent goods’, in relation to another medicine if:

* the prescription chemical medicine is relevant goods (as described above); and
* is registered before the other medicine; and
* has the same active ingredient (or, in the case of multiple active ingredients, the same active ingredients in the same quantities) as the other medicine; and
* at the time the registration of the other medicine commenced, the other medicine is registered to the same sponsor as the prescription chemical medicine or a person authorised by that sponsor.

This subregulation covers registered chemical prescription medicines that are separate and distinct goods from other registered chemical prescription medicines by reason of subsection 16(1) of the TG Act provided they are not relevant goods.

Thus medicines covered by proposed subregulation 4(5) includes those that are ‘clones’ (i.e. a different name) of a parent medicine (i.e. that is either a new chemical entity, new extension of indication or a new intended patient group) that have been registered for less than 8 years. Subregulation 4(5) also covers new dosage forms or different strengths of such a parent medicine.

As such, the same post-market considerations applying to the parent product for the first 8 year period of the parent’s registration equally applies to these new products. Thus, under this subregulation, if the ‘clone’ of the parent medicine was registered 4 years after the registration of the parent medicine, then the annual charge payable for the clone will be the higher amount only for so long as the annual charge for the parent was the higher amount (subject to the application of other subregulations such as 4(6)).

**Grouped medicines as a result of extensions of indications or changes to intended patient group – subregulation 4(6)**

This subregulation covers prescription chemical medicines that as at 1 July in the charge year are grouped (i.e. there is more than one prescription chemical medicine that has the same registration number by reason of subsection 27(2) of the TG Act) in certain circumstances. These circumstances are that one or more of the grouped prescription chemical medicines are relevant goods (as described above) and were grouped on or after 1 July 2015 and that as at 1 July in the charge year, it has been less than 8 years since each of those relevant goods was registered.

Because the grouping of the relevant goods must have occurred on or after 1 July 2015 and the grouping must have occurred before 1 July in the charge year, this subregulation only applies if the charge year is 2016-17 or later.

**Entries before 1 July 2015 – goods that are not grouped therapeutic goods – subregulation 4(7)**

This subregulation is a transitional provision in that it applies to chemical prescription medicines that were registered as at 1 July 2015. This subregulation covers prescription chemical medicines that are not grouped and, as at 1 July of the charge year, have been registered for less than 8 years.

For medicines to come within subregulation 4(7), the sponsor of the medicine must also (immediately before 1 July 2015) be the only person in relation to whom any goods with the same active ingredient or, in the case of a chemical prescription medicine with multiple active ingredients, any goods with the same active ingredients in the same quantitative amounts, are registered.

These are prescription chemical medicines already registered at the commencement of this Regulation, in relation to which there are no similar goods registered to any other sponsor at that time, and that have been registered for less than 8 years at the start of the charge year.

**Entries before 1 July 2015 – goods that are grouped therapeutic goods – subregulation 4(8)**

This is a transitional provision that applies to prescription chemical medicines that were registered and grouped as at 1 July 2015. This subregulation covers prescription chemical medicines that are grouped and that, as at 1 July in the charge year, the first of the prescription chemical medicines to be grouped has been registered for less than 8 years.

For medicines to come within subregulation 4(8), the sponsor of the medicine must also (immediately before 1 July 2015) be the only person in relation to whom any goods with the same active ingredient as the grouped goods or, in the case of a medicine with multiple active ingredients, any goods with the same active ingredients in the same quantitative amounts as the grouped goods, are registered.

These are prescription chemical medicines that are already registered – and grouped – at the commencement of this Regulation, in relation to which there are no similar goods registered to any other sponsor at that time, and where the first registered prescription chemical medicines has been registered for less than 8 years at the start of the charge year.

**Definitions – subregulation 4(9)**

Subregulation 4(9) defines a number of key terms for the purposes of these amendments.

These include defining the higher amount of annual charge payable for chemical prescription medicines under the proposed amendments - $3,835 for 2015-16, and the corresponding lower amount - $3, 110 for 2015-16.

Theses amount represent the current annual charge for prescription chemical medicines for 2014-15, with the following changes:

* for the higher amount – minus 5 per cent;
* for the lower amount – minus 23 per cent; and
* in both cases, plus 2.12 per cent.

Subregulation 4(9) also defines parent goods, and relevant goods, in the manner outlined above.

**Statement of Compatibility with Human Rights**

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

***Therapeutic Goods (Charges) Amendment (2015 Measures No.1)) Regulation 2015***

This legislative instrument 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 Legislative Instrument**

The *Therapeutic Goods (Charges) Amendment (2015 Measures No.1) Regulation 2015* (the Amendment Regulation) is made under subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).

The Amendment Regulation amends the Therapeutic Goods (Charges) Regulations 1990 to provide for different (lower) amounts of annual charges for prescription chemical medicines from 1 July 2015, to reduce charges for medical devices that are Class IIa or above and to increase charges for all therapeutic goods, and manufacturing licences, by 2.12 per cent for 2015-16.

The Amendment Regulation introduces two different annual charge amounts for prescription chemical medicines. Prescription chemical medicines that are new chemical entities, or that result from an extension of indications or a change to an intended patient group, would pay a higher amount until the 8th anniversary of their entry in the Register. After that time, provided no further indications or patient groups are added, they would pay a lower amount. If such medicines contain any of six specified active ingredients that require particular post-market monitoring (e.g. thalidomide), they would pay the higher amount for so long as they remain in the Register. With some exceptions, all other prescription chemical medicines, such as generics, would pay the lower amount. The imposition of the different amounts principally reflects the commitment of resources by the TGA to the post-market monitoring of these medicines.

By reducing charges for such medicines and for higher risk medical devices, the Amendment Regulation is intended to provide an offset for the introduction of new arrangements under which sponsors are exempt from paying annual charges for so long as the turnover of their goods remains at zero. The overall 2.12 per cent increase for all annual charges (including such medicines and devices) principally reflects the TGA’s budget outlook for 2015-16.

**Human rights implications**

As the Amendment Regulation does not introduce any changes to the Principal Regulations other than to implement the changes mentioned above, it does not engage any of the applicable rights or freedoms.

**Conclusion**

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

**Fiona Nash, Assistant Minister for Health**