EXPLANATORY STATEMENT

Medicines Advisory Statements Specification 2017

Subsection 3(5A), Therapeutic Goods Act 1989

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

The *Medicines Advisory Statements Specification 2017* (the 2017 Specification) is made by the Minister under subsection 3(5A) of the Act, and has the effect of specifying, for the purposes of paragraph 3(5)(ca) of the Act, advisory statements that are required to be set out on the label of medicines that are included in a class of medicines prescribed by the regulations.

Under regulation 3AA of the *Therapeutic Goods Regulations 1990* (the Regulations), such medicines are, principally, over the counter (OTC) medicines and registered complementary medicines.

Regulation 3AA has the effect that, principally, the Specification does not apply to medicines mentioned in Part 1 of Schedule 10 to the Regulations - principally prescription medicines, radiopharmaceuticals and medical gases (the exclusion of prescription medicines reflects that access to prescription medicines is controlled by medical practitioners, and information about the potential benefits and risks of a medicine is part of the consultation between prescriber and patient - and the exclusion of radiopharmaceuticals and medical gases reflects that these products are not usually supplied directly to consumers), or to listed complementary medicines that comply with the permissible ingredients determination for such medicines made by the Minister under section 26BB of the Act (the exclusion of these listed medicines reflects that relevant requirements for such products form part of the section 26BB determination, and avoids duplication in that regard).

The 2017 Specification repeals the previous two existing specification instruments - the *Medicines Advisory Statements Specification 2014*, and the *Medicines Advisory Statements Specification 2016.*

The 2017 Specification commences on 1 July 2017.

BACKGROUND

Subsection 3(5) of the Act sets out a number of circumstances in which the presentation of therapeutic goods is considered to be unacceptable for the purposes of the Act including, for example, where the presentation of a therapeutic good states or suggests that the goods have ingredients, components or characteristics that they do not have, or where the label of the goods does not declare the presence of a therapeutically active ingredient.

One of these circumstances is, at paragraph 3(5)(ca) of the Act, where the therapeutic goods in question are medicines that are included in a class of medicine prescribed by the Regulations for the purposes of that paragraph, and where the medicine's label does not

contain the advisory statements specified under subsection 3(5A) of the Act in relation to the medicine.

Subsection 3(5A) of the Act authorises the Minister to make a legislative instrument specifying advisory statements in relation to medicines for the purposes of paragraph 3(5)(ca) of the Act.

The main kinds of medicines required to comply with the Specification are over the counter medicines and registered complementary medicines. Prescription medicines and medicines such as radiopharmaceuticals and medical gases (that are not usually supplied directly to consumers), are not within the scope of the instrument, and nor are listed complementary medicines (i.e. medicines that are listed in the Register under section 26A of the Act) provided they comply with the requirements of the permissible ingredients determination made by the Minister in respect of such products under section 26BB of the Act.

The advisory statements set out in the 2017 Specification are designed to address specific risks related to the use of medicines that have been identified via pharmacovigilance activities, testing, adverse event reports or other scientific or clinical information. Having advisory statements on medicine labels ensures that consumers are informed about these risks.

The need for new advisory statements to be included on the labels of relevant medicines may arise for a number of reasons, including the entry of new medicines into the market, the identification of new risks associated with particular medicines and "down-scheduling" of medicines in the Poisons Standard.

"Down-scheduling" refers to where the Secretary moves a medicine from a higher risk schedule of the Poisons Standard to a lower risk schedule, meaning an affected product may then be more widely available for self-selection by consumers. Consequently, there may be a need in such circumstances for advisory statements to help consumers to self-select in an informed manner and to use such medicines safely and effectively.

The *Medicines Advisory Statements Specification 2017* (the 2017 Specification) is intended to succeed the previous Specification. The previous Specification is the *Medicines Advisory Statements Specification 2016* (which commenced on 1 January 2016) (the 2016 Specification). When the 2016 Specification was made, the *Medicines Advisory Statements Specification 2014* was inadvertently not repealed at that time, so the 2017 Specification also repeals that earlier instrument.

The 2017 Specification is principally based on the TGA document the Required Advisory Statements for Medicine Labels (the RASML).

Currently, the 2016 Specification requires that for the first 18 months after it commenced on 1 January 2016, medicine sponsors must comply with Schedule 1 of that Specification in respect of the labels of their products. Schedule 1 of that Specification consists of the edition of the RASML cited as RASML 2, – being, the RASML dated September 2008 as amended by "Update 5" and "Update 6" of that document, which were provided for public comment to industry in 2009 and 2011, respectively. After that initial 18 month period, sponsors must then comply with Schedule 2 of the 2016 Specification. Schedule 2 principally consists of RASML 3, being the RASML 2, as amended by the changes that were provided for public comment between January 2014 and October 2015. Under the 2016 Specification, however, sponsors have the option of electing to comply with Schedule 2 during the initial 18 month period, if they wish to do so.

On 1 July 2017, the initial 18 month period from the commencement of the 2016 Specification will end, with the effect that medicine sponsors would, under the 2016 Specification, only have the option of complying with Schedule 2 of that instrument in relation to their medicine labels after that date.

The 2017 Specification (which repeals the 2016 Specification), however, gives sponsors the option, for the first 18 months after its commencement on 1 July 2017, of complying either with RASML 3 (i.e. the version of the RASML currently set out in Schedule 2 of the 2016 Specification) as set out in Schedule 1 of the 2017 Specification, or new RASML 4, which is set out in Schedule 2 of the 2017 Specification.

The version of RASML No. 3 set out in Schedule 1 of the 2017 Specification will be identical to the version of RASML No. 3 set out in Schedule 2 of the 2016 Specification, except for a small number of changes or removal of entries, as follows:

- the entries for codeine in oral cough-and-cold medicines will be amended by removing the requirement for the statement '*If [coughing / symptoms] persist(s), consult your doctor or pharmacist*'. This statement was to be a new requirement in RASML No. 3, under Schedule 2 of the 2016 Specification, from 1 July 2017. However, medicines containing codeine will be up-scheduled to Schedule 4 of the SUSMP (Prescription Only Medicines) from 1 February 2018, and (as explained above) the Specification does not apply to prescription medicines. Not including this new statement in the 2017 Specification means that the requirements for codeine in RASML No. 3 and RASML No. 4 will be the same as those currently in RASML No. 2 (set out in Schedule 1 of the 2016 Specification). This should minimise disruption for sponsors in relation to labelling changes necessary for their products as part of the re-scheduling of these medicines to Prescription Only;

- entries that only apply to listed complementary medicines (medicines listed under section 26A of the Act) have been removed, as the relevant requirements are now included in the determination made by the Minister under subsection 26BB(1) of the Act, and the Specification does not apply to listed medicines that are compliant with that determination;
- the entries for chemical substances acetone, chromates, hydrofluoric acid, potassium hydroxide, sodium hydroxide, zinc chloride and zinc sulfate have been removed, as the requirements that are currently in RASML 3 for these substances are identical to those currently in force in the Poisons Standard for these substances, and there are no medicines currently approved for supply in Australia that contain any of these substances as active ingredients;

RASML 4 incorporates a number of new changes as compared with RASML 3. These changes, which were provided for public comment during the period October 2016 to February 2017, consist of additional advisory statements for the following substances:

- diclofenac, flurbiprofen, ibuprofen, ketoprofen, mefenamic acid and naproxen - these are non-steroidal anti-inflammatory drugs (NSAIDs) for oral use; and
- paracetamol and ibuprofen, when present in combination with each other, in medicines for oral use.

RASML 4 also incorporates a small number of minor, editorial changes that do not affect requirements for the labels of any currently registered products – these would consolidate 7 current entries for aspirin into 3 entries, and update the names of two substances as part of the TGA's ongoing reforms to update ingredient names to the most current international terminology.

CONSULTATION

Public comment was invited on the proposed amendments in RASML 4, as follows:

- consultation: Non-steroidal anti-inflammatory drugs: proposed additional advisory statement (NSAIDs for oral use: diclofenac, flurbiprofen, ibuprofen, ketoprofen, mefenamic acid and naproxen) - the invitation to comment in relation to this change was advertised on the TGA website (www.tga.gov.au) from 11 October 2016, and closed on 22 November 2016 - Submissions and TGA response were published on the TGA website on 13 February 2017; and
- consultation: Paracetamol and ibuprofen: advisory statements for medicines - the invitation to comment in relation to this change was advertised on the TGA website (www.tga.gov.au) from 11 October 2016, and closed on 22 November 2016 - Submissions and TGA response were published on the TGA website on 13 February 2017.

These consultations were consistent with the level of consultation agreed between the TGA and industry for the updating of the RASML.

Two submissions were received in each case. The submissions supported the proposals, with suggestions for rewording – as explained in the associated 'Submissions and TGA response' advice that was published on the TGA website in each case.

Public consultation was not held in regards to the removal of requirements, or in regards to the editorial changes, as these changes in the RASML No. 3 and RASML No. 4 do not involve any changes that would increase existing requirements for the labels of medicines containing these ingredients.

The 2017 Specification is a legislative instrument for the purposes of the *Legislation Act 2003*.

SUPPLEMENTARY MATERIAL - STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

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

Medicines Advisory Statements Specification 2017

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 *Medicines Advisory Statements Specification 2017* (the 2017 Specification) is made by the Minister under subsection 3(5A) of the *Therapeutic Goods Act 1989*, and sets out advisory statements required to be included on labels of prescribed kinds of medicines (mainly, those *other than* prescription medicines or certain medicines used mostly in hospitals, e.g. radiopharmaceuticals, or listed complementary medicines). These advisory statements are intended to help consumers be aware of important safety information, and to assist them to make informed decisions on medicine selection and safe use.

The 2017 Specification commences on 1 July 2017 and is intended to succeed the previous Specification - the previous Specification is the *Medicines Advisory Statements Specification 2016*, which commenced on 1 January 2016 (the 2016 Specification). The 2017 Specification also repeals the *Medicines Advisory Statements Specification 2014*, the repeal of which was inadvertently not included in the 2016 Specification.

Under the 2016 Specification, medicine sponsors must comply with Schedule 1 of that Specification (cited as 'RASML 2') in relation to the labels of their products for the first 18 months after it commenced on 1 January 2016. After that initial 18 month period, sponsors must then comply with Schedule 2 of the 2016 Specification (cited as 'RASML 3'), being the RASML 2 as amended by the changes that were provided for public comment between January 2014 and October 2015. Under the 2016 Specification, however, sponsors have had the option of electing to comply with RASML 3 during the initial 18 month period, if they wish to do so.

On 1 July 2017, the initial 18 month period from the commencement of the 2016 Specification ends, with the effect that sponsors would only have had the option of complying with RASML 3 in relation to their medicine labels after that date.

The 2017 Specification, however, gives sponsors the option of complying either with RASML 3 (as set out in Schedule 1 of the 2017 Specification) or new RASML 4 (set out in Schedule 2 of the 2017 Specification), in the first 18 months after its commencement on 1 July 2017.

The version of RASML 3 set out in Schedule 1 of the 2017 Specification will be identical to the version of RASML 3 set out in Schedule 2 of the 2016 Specification, except for some changes that involve removal of inappropriate requirements (including in particular in relation to the entries for codeine - in the context that from February 2018 medicines containing codeine will be prescription medicines and therefore not subject to the 2017 Specification).

RASML 4 incorporates a number of new changes compared with RASML 3. These changes, which were canvassed with industry between October 2016 and February 2017, consist of introduction of a new advisory statement for a number of substances already included in the 2016 Specification, and some new advisory statements for two existing substances, when present in a combination that is not included in the 2016 Specification.

On 1 January 2019 the initial 18 month period from the commencement of the 2017 Specification will end, with the effect that sponsors will only have the option of complying with RASML 4 in relation to their medicine labels after that date.

Human rights implications

This legislative instrument 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.

Larry Kelly, delegate of the Minister for Health