EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Medicines Advisory Statements Specification 2014

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) is responsible for administering the Act.

The Therapeutic Goods Medicines Advisory Statements Specification (the 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, medicines other than medicines mentioned in Part 1 of Schedule 10 to the Regulations.

As Part 1 of Schedule 10 lists prescription medicines, and a number of medicines such as radiopharmaceuticals and medical gases that are not usually supplied directly to consumers, the main kinds of medicines required to comply with the Specification are medicines *other than* such products.

The Specification commenced on the day after it was registered on the Federal Register of Legislative Instruments.

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 medicine for the purposes of paragraph 3(5)(ca) of the Act.

The Specification is principally based on the TGA document the Required Advisory Statements for Medicine Labels (the RASML), incorporating amendments (or 'updates') 1, 2, 3 and 4 to that document.

The requirement for medicines to comply with the RASML in relation to including warning statements on their labels has been in place for some time, under Therapeutic Goods Order 69 (TGO 69), which is a standard determined by the Minister under section 10 of the Act.

Replacing the reference to particular editions of the RASML in TGO 69 to a reference to the Specification is intended to support the streamlining of requirements relating to the inclusion of advisory statements on medicine labels (Therapeutic Goods Order 69D will, separately, amend TGO 69 to refer instead to the Specification rather than to particular editions of the RASML in relation to advisory statements).

In particular, this will permit TGO 69 to refer (relevantly) to the Specification as in force from time to time, rather than, as has been the case previously, having to update TGO 69 each time a new edition of the RASML is proposed to be adopted.

In addition, it is also important to note that medicines mentioned in Part 1 of Schedule 10 to the Regulations – which are comprised of prescription medicines and medicines such as medical gasses, radiopharmaceuticals and dialysis solutions - will not be required to comply with the Specification.

The exclusion of these products from the need to comply with the Specification reflects that access to prescription medicines is controlled by registered medical practitioners, and the transmission of information on the potential benefits and risks of a medicine is intrinsic to the consultation between a patient and their prescriber. Further, the risk-benefit profile of such medicines may vary considerably from patient to patient.

In relation to radiopharmaceuticals and the like, these are not, in most cases, supplied directly to consumers, but rather are principally utilised in a treatment setting such as a hospital.

These medicines have previously been within the scope of medicines required to comply with TGO 69, however, administratively the requirement to do so (for the reasons noted above) was never enforced.

For other medicines, the requirement to include appropriate advisory statements on the medicine label is important to assist consumers to be informed about significant information relating to the safety of the medicines and to help consumers to make informed decisions about selecting and using these medicines.

Advisory statements are principally designed to address specific risks related to the use of a medicine that have been identified via pharmacovigilance activities, testing, adverse event reports or other new scientific or clinical information.

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 approval of new substances for inclusion in listed medicines, 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.

For the first 18 months after the Specification commences, medicine sponsors will only be required to comply in respect of their medicine labels with Schedule 1 of the Specification. Schedule 1 consists of the current edition of the RASML, which is dated September 2008 and incorporates amendments to that document up to "Update 4".

Only after that initial 18 month period has expired will sponsors have to comply with Schedule 2 of the Specification. Sponsors may, however, elect to comply with Schedule 2 during that initial 18 month period if they wish to do so.

Schedule 2 principally consists of the RASML as amended by "Update 5" and "Update 6" of that document, which were provided for public comment to industry in 2009 and 2011, respectively.

As Schedule 2 incorporates the adoption of Updates 5 and 6 of the RASML, it includes a number of new advisory statements, and a number of amendments to existing advisory statements. For example, as a result of international concerns about reports of adverse events in infants, Update 6 included a new statement for medicines containing choline salicylate, advising users not to exceed the recommended dose.

Schedule 2 also contains some additional advisory statements which the TGA required sponsors of cough and cold medicines to include on their medicine labels as a condition of registration in 2012.

In 2007 – 2009, each of the regulatory authorities in the USA, Canada, the United Kingdom, New Zealand and Australia reviewed the safety and efficacy of OTC cough and cold medicines for children under 2 years of age and concluded that these medicines should not be used for children in that age group. In 2009 the TGA published a comprehensive review of the safety and efficacy of over-the counter medicines containing one or more of the 22 medicine substances listed below for the treatment of symptoms of cough and cold in children:

- **Antihistamines:** brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine, triprolidine;
- **Antitussives:** codeine, dextromethorphan, dihydrocodeine, pentoxyverine, pholcodine;
- **Mucolytics/expectorants:** bromhexine, guaiphenesin, ipecacuanha, senega and ammonia;
- **Decongestants:** phenylephrine, pseudoephedrine, oxymetazoline, xylometazoline.

In February 2012 the TGA published proposed advisory statements arising from this review, in relation to cough and cold medicines for use in children.

Schedule 2 also includes advisory statements for medicines containing a number of particular active ingredients.

In 2012 and 2013, following recommendations from the Advisory Committee on Medicines Scheduling, and the Advisory Committee on Non-prescription Medicines, the TGA proposed new advisory statements for loperamide, fexofenadine, famciclovir, loratadine, desloratadine, azelastine and *Kunzea ambigua*. Apart from *Kunzea ambigua*, all of these statements were proposed in relation to down-scheduling of the medicines.

CONSULTATION

Updates 5 and 6 of the RASML were published in draft form on the TGA's website (www.tga.gov.au), and comments from industry were invited (via direct contact with relevant peak industry bodies), in July-August 2009 (in relation to Update 5) and in February- May 2011 (in relation to Update 6). A total of 22 submissions were received.

Following that consultation, Update 6 was revised to incorporate some of the feedback received from industry in that regard. A response from the TGA to industry's comments was published on the TGA website in October 2011.

In February 2012, the TGA sought comments from interested parties on proposed advisory statements for cough and cold medicines for use in children. This followed reviews between 2007-2009 by regulatory authorities in the USA, Canada, the United Kingdom, New Zealand and Australia of the safety and efficacy of over-the-counter cough and cold medicines for children under two years of age. A large number of submissions were received in relation to that request for comment, and the TGA subsequently published a response summarising its consideration of each of the submissions.

In 2012 and 2013, the TGA published requests for submissions in relation to proposed advisory statements for loperamide, fexofenadine, famciclovir, loratadine, desloratadine, azelastine and *Kunzea ambigua*. The TGA considered the submissions and published its conclusions on the respective consultation web-pages.

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

In addition, the Therapeutic Goods Committee (TGC) was consulted in relation to Update 5 at its October 2009 and in relation to Update 6 at its 6 April 2011 meeting. The TGC was consulted in relation to the Specification (and the proposal to refer to it rather than to particular editions of the RASML in TGO 69) at its meeting in August 2013. At the latter meeting, the TGC was supportive of the new arrangements relating to the Specification and TGO 69.

The Specification is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

In relation to compatibility with human rights, it is considered that the Specification 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*, and a Statement of Compatibility setting that out in further detail is set out below.

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

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

Medicines Advisory Statements Specification 2014

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 Bill/Legislative Instrument

The *Medicines Advisory Statements Specification 2014* is made by the Minister under subsection 3(5A) of the *Therapeutic Goods Act 1989* (the Act), and specifies, for the purposes of paragraph 3(5)(ca) of the Act, advisory statements that are required to be set out on the label of prescribed kinds of medicines (principally, medicines *other than* prescription medicines or certain medicines used predominantly in a hospital setting, e.g. radiopharmaceuticals). The requirement for affected medicines to include appropriate advisory statements on their labels is intended to help consumers to be aware of important information relating to the safety of these medicines, and to assist them to make informed decisions about selecting and using these medicines.

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.

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