**EXPLANATORY STATEMENT**

**Medicines Advisory Statements Specification 2016**

*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) is responsible for administering the Act.

The Medicines Advisory Statements Specification 2016 (the 2016 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 2016 Specification are medicines *other than* such products.

The 2016 Specification commences on 1 January 2016.

**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 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.

The advisory statements set out in the 2016 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 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.

The Medicines Advisory Statements Specification 2016 (the 2016 Specification) is intended to succeed the previous Specification.  The previous Specification is the Medicines Advisory Statements Specification 2014 (which commenced on 12 June 2014) (the 2014 Specification), as amended in May 2015 by the Medicines Advisory Statements Amendment Specification 2015 (No.1).

The 2016 Specification is principally based on the TGA document the Required Advisory Statements for Medicine Labels (the RASML).

Currently, the 2014 Specification (as amended earlier this year), requires that for the first 18 months after it commenced on 12 June 2014, 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 1, dated September 2008. After that initial 18 month period, sponsors must then comply with Schedule 2 of the 2014 Specification. Schedule 2 principally consists of RASML 2 – being, 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. Under the 2014 Specification, however, sponsors have the option of electing to comply with Schedule 2 during that initial 18 month period, if they wish to do so.

On 12 December 2015, the initial 18 month period from the commencement of the 2014 Specification will end, with the effect that medicine sponsors would, under the 2014 Specification, only have the option of complying with Schedule 2 of that instrument in relation to their medicine labels after that date.

The 2016 Specification, however, gives sponsors the option, for the first 18 months after its commencement on 1 January 2016, of complying either with RASML 2 (i.e. the version of the RASML currently set out in Schedule 2 of the 2014 Specification) as set out in Schedule 1 of the 2016 Specification, or new RASML 3, which is set out in Schedule 2 of the Specification.

RASML 3 incorporates a number of new changes as compared with RASML 2. These changes, which were canvassed with industry on various dates during the period November 2013 and October 2015, consist of amendments to advisory statements for a number of substances, as well as the introduction of a number of new advisory statements for substances not previously included in the 2014 Specification, as follows:

* cimetidine, famotidine, nizatidine and ranitidine – corrected advisory statement;
* metoclopramide - new advisory statements;
* diclofenac, flurbiprofen, ibuprofen, ketoprofen, mefenamic acid and naproxen (non-steroidal anti-inflammatory drugs [NSAIDs]) for oral use - additional advisory statement;
* esomeprazole - new advisory statements;
* methoxamine, naphazoline, oxymetazoline, phenylephrine, tetrahydrozoline, tramazoline, tymazoline and xylometazoline in nasal decongestant preparations for topical use - additional advisory statements;
* ammonium salts, bromhexine, codeine, dextromethorphan, dihydrocodeine, guaifenesin, ipecacuanha, pentoxyverine, pholcodine, and senega and ammonia in cough medicines for oral use -additional advisory statement;
* chloramphenicol, propamidine, dibromopropamidine and sulfacetamide for ophthalmic use - new advisory statements;
* *Euphausia superba* oil (Krill Oil) in Listed Medicines – new advisory statement.

**CONSULTATION**

Public comment was invited on the proposed amendments in relation to these substances, as follows:

* cimetidine, famotidine, nizatidine and ranitidine – the invitation to comment in relation to this correction was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 1 October 2015, and closed on 29 October 2015;
* metoclopramide - the invitation to comment in relation to this new requirement was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 10 March 2015, and closed on 7 April 2015 - Submissions and TGA response were published on the TGA website on 13 May 2015;
* diclofenac, flurbiprofen, ibuprofen, ketoprofen, mefenamic acid and naproxen (non-steroidal anti-inflammatory drugs [NSAIDs]) for oral use - the invitation to comment in relation to this change was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 4 February 2015, and closed on 18 March 2015 - Submissions and TGA response were published on the TGA website on 11 June 2015;
* esomeprazole - the invitation to comment in relation to this requirement for the newly down-scheduled medicines was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 12 September 2014, and closed on 10 October 2014 -Submissions and TGA response were published on the TGA website on 2 December 2014;
* methoxamine, naphazoline, oxymetazoline, phenylephrine, tetrahydrozoline, tramazoline, tymazoline and xylometazoline in nasal decongestant preparations for topical use - the invitation to comment in relation to this change was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 28 March 2014, and closed on 5 May 2014 - Submissions and TGA response were published on the TGA website on 9 September 2014;
* ammonium salts, bromhexine, codeine, dextromethorphan, dihydrocodeine, guaifenesin, ipecacuanha, pentoxyverine, pholcodine, and senega and ammonia in cough medicines for oral use - the invitation to comment in relation to this change was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 28 March 2014, and closed on 5 May 2014 - Submissions and TGA response were published on the TGA website on 9 September 2014;
* chloramphenicol, propamidine, dibromopropamidine and sulfacetamide for ophthalmic use - the invitation to comment in relation to this new requirement for these medicines was advertised on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) from 22 November 2013, and closed on 10 January 2014 - Submissions and TGA response were published on the TGA website on 4 March 2014;

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

A number of submissions were received in each case. A clear majority of submissions supported the proposals, with suggestions for rewording being proposed in some cases – 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 new statement for *Euphausia superba* oil (Krill Oil) in listed medicines, as the inclusion of this statement on the label of relevant medicines has been a condition of listing for these medicines since June 2015. This current condition of listing requires that all listed medicines containing this ingredient are labelled with the warning ‘Contains crustacean shellfish’ or ‘Derived from seafood’ (as advised in the TGA eBusiness Services News on 29 April 2015). The new requirement in the RASML No. 3 is identical to the requirement of this condition of listing as currently in force, and therefore does not involve any new requirements for the labels of medicines containing this ingredient.

The 2016 Specification is a legislative instrument for the purposes of the *Legislative Instruments 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 2016**

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 2016* (the 2016 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). 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 *Medicines Advisory Statements Specification 2016* (the 2016 Specification) is intended to succeed the previous Specification - the previous Specification is the Medicines Advisory Statements Specification 2014 (which commenced on 12 June 2014) (the 2014 Specification), as amended by the *Medicines Advisory Statements Amendment Specification 2015 (No.1*).

Under the 2014 Specification, medicine sponsors must comply with Schedule 1 of that Specification in relation to the labels of their products for the first 18 months after it commenced on 12 June 2014. Schedule 1 of that Specification consists of the edition of the TGA document the ‘Required Advisory Statements for Medicine Labels’ (RASML) cited as RASML 1, dated September 2008. After that initial 18 month period, sponsors must then comply with Schedule 2 of the 2014 Specification. Schedule 2 principally consists of RASML 2 – being, the RASML as amended by “Update 5” and “Update 6” of that document, which were released for public comment in 2009 and 2011, respectively. Sponsors may, however, comply with Schedule 2 during that initial 18 month period if they wish to do so.

On 12 December 2015, the initial 18 month period from the commencement of the 2014 Specification ends, with the effect that sponsors will only have the option of complying with Schedule 2 of the 2014 Specification in relation to their medicine labels after that date.

The 2016 Specification, however, gives sponsors the option of complying either with RASML 2 (i.e. the version of the RASML currently in Schedule 2 of the 2014 Specification), or new RASML 3, in the first 18 months after its commencement on 1 January 2016.

RASML 3 incorporates a number of new changes compared with RASML 2. These changes, which were canvassed with industry on various dates between November 2013 and October 2015, consist of amendments to existing advisory statements, and the introduction of number of new advisory statements for substances not previously included in the 2014 Specification.

**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.

**Mary McDonald, delegate of the Minister for Health**