

EXPLANATORY STATEMENT

Subject: *Therapeutic Goods Act 1989*

Restricted Medicine Specification 2011

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

Subsections 3(2A) and (2B) of the TG Act authorise the Minister for Health and Ageing (the Minister), by legislative instrument, to specify medicines and classes of medicine for the purposes of paragraphs (a) and (b), respectively of the definition of ***restricted medicine*** in subsection 3(1) of the TG Act. ***Restricted medicine*** means a medicine specified in an instrument under subsection 3(2A) or medicine included in a class of medicine specified in an instrument under subsection 3(2B).

Paragraph 23(2)(b) of the TG Act requires an application lodged under section 23 for the registration of a restricted medicine to be accompanied by a draft product information document for the medicine in the form approved by the Secretary of the Department of Health and Ageing under section 7D. An application for the registration of a restricted medicine that is not accompanied by the product information document is not an effective application under section 23 of the TG Act and will not be considered for evaluation.

A product information document in relation to therapeutic goods means a document containing information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods (subsection 3(1) of the TG Act). By reason of subparagraph 25(1)(da)(i) the product information provided by the applicant is one of the matters that is evaluated for the purpose of determining whether the medicine the subject of the application should be approved for registration in the Australian Register of Therapeutic Goods. If the decision of the Secretary or her delegate is that the medicine is to be registered, subparagraph 25(4)(d)(ia) requires that the applicant be notified in writing of the product information that is approved in relation to the medicine.

The purpose of this instrument is to specify medicines or classes of medicine for the purposes of the definition of ***restricted medicine*** in subsection 3(1). This instrument is to be cited as the *Restricted Medicine Specification 2011* and commences on the day after it is registered in the Federal Register of Legislative Instruments.

The medicines or classes of medicine that are specified as restricted medicines are set out in Schedule 1 to the instrument. The effect of the inclusion of a medicine or classes of medicine in Schedule 1 is that an applicant for registration of any of the medicines so listed is required to provide a draft product information document as part of the application for registration package.

Schedule 1 specifies medicines and classes of medicine:

- (a) that are included in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* (the Regulations) other than in item 1(b) of Part 1 and item 14; and
- (b) that contain a substance included in Schedule 3 to the current Poisons Standard.

The medicines set out in Part 1 of Schedule 10 to the Regulations include those that contain a substance mentioned in Schedules 4 (prescription only medicines), 8 (controlled drug) or 9 (prohibited substance) of the current Poisons Standard (which because they are considered high risk have restrictions on the way they can be supplied), vaccines, allergens, and immunoglobulins. Schedule 3 substances are those that can be supplied without a prescription but only by a pharmacist.

Item 1(b) in Part 1 of Schedule 10 is excluded as it refers to substances that are not mentioned in any of Schedules 4, 8 or 9 but which meet the criteria for mention in those Schedules. Were an application for registration to be made for such a substance and either at any time during the evaluation process the substance is included in any of those Schedules or the Secretary otherwise comes to the view that it would be appropriate for a product information document to be approved as part of the registration process for that medicine, the Secretary can notify the applicant to supply a product information document in the approved form. The same applies in relation to an application for a medicine that contains a substance which is not in Schedule 3 but meets the criteria for mention in Schedule 3.

Item 14 in Part 1 of Schedule 10 to the Regulations (which currently refers to therapeutic goods referred for evaluation to the Office of Prescription Medicines of the TGA) is excluded because therapeutic goods would only be referred once an application for registration has already been lodged. Item 14 could not therefore apply to a medicine at the time an application for registration for the medicine was being made.

The Restricted Medicine Specification 2011 is a legislative instrument for the purposes of the *Legislative Instruments Act 2003* (the LIA).

The requirements set out in this instrument will have minimal regulatory impact in general as they reflect the TGA's current administrative arrangements for the lodgement and approval of product information documents for prescription and other medicines.

The making of this instrument did not involve public consultation. However, the amendments to the TG Act implemented by Schedule 1A of the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*, which include provisions relating to the requirements for a product information document, involved consultation with the Generic Medicines Industry Association (GMiA) and Medicines Australia. As noted above, the requirements reflect current administrative arrangements.