Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 8: Product information

May 2011

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

Appendix 8: Product information

1 Introduction

The product information document contains technical information about the medicine such as the characteristics of the active ingredient, its indications and contraindications, a description of clinical trials relevant to the indications, precautions, adverse reactions that may occur from the use of the medicine, dosages and storage, and other information relating to the safe and effective use of the medicine.

The purpose of a product information document is to assist medical practitioners, pharmacists and other health professionals in prescribing and dispensing the medicine, and to assist them to provide patient education about the medicine to support high quality and safe clinical care. The product information document is to present a scientific, objective account of the medicine's usefulness and limitations as shown by the data supporting the application. It is to be devoid of promotional material.

2 Form

As a part of an application to register a 'restricted medicine', a draft product information document must be lodged in a form approved by the secretary under section 7D of the *Therapeutic Goods Act 1989* (the Act). This is the Form for providing product information for a restricted medicine or other medicine in relation to which the secretary requires product information to be provided.

Restricted medicines are defined in the *Restricted Medicine Specification 2011* and include prescription medicines (see Schedules 4 and 8 of the current Poisons Standard) and medicines only available from a pharmacist (Schedule 3 of the current Poisons Standard). The secretary can also require other higher risk medicines to have approved product information where appropriate. The form for the product information and the Restricted Medicine Specification 2011 can be found on the TGA website.

For applications to register a new medicine covered by the Restricted Medicine Specification, the application must include a draft product information document in the approved form. The document must be included in module 1 of the submission dossier (module 1.3.1). Applications for products which already have an approved product information document but will result in a new entry on the ARTG, also must include a draft product information document with the submission dossier.

For applications to register a new medicine not covered by the Restricted Medicine Specification, the applicant will, if appropriate, be given notice in writing that a product information document is to be included with the submission dossier. This notice will be given after consideration of the pre-submission planning form in the pre-submission phase. The product information document must be included in module 1 of the submission dossier (module 1.3.1).

Applications to vary an entry on the ARTG or change the conditions to which the inclusion of the medicine is subject, and require a change to the existing product information must include a draft product information document in module 1 of the submission dossier (module 1.3.1).

After registration, the product information must not be changed without TGA approval.

The product information is supplied as a package insert for products for parenteral use. For self-administered parenterals, the consumer medicine information (CMI) may be included as the package insert with the product information.

The product information on radiopharmaceuticals advises users to observe the National Health and Medical Research Council (NHMRC) *National guidelines for waste management in the health industry* (1999).[1]

[1] The NHMRC has handed responsibility for review of the Radiation Health Series publications to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The Radiation Health Committee of ARPANSA is progressively reviewing the series and republishing as part of ARPANSA's Radiation Protection Series.

Therapeutic Goods Administration

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