Australian Government
Department of Health
Therapeutic Goods Administration

Guidance 8: Product information

Previously ARGPM Appendix 8: Product information

Version 1.0, July 2013

TGA Health Safety Regulation

Check the TGA website for up-to-date guidance

The most up-to-date information about prescription medicine registration in Australia is on the TGA website. Now that guidance is presented in a series of web pages, updates are likely to be more common than in the past. If you subscribe to the TGA guidelines email alert service, you will be emailed every time the TGA web guidance is updated.

TGA web pages are dated, and can be printed.

A PDF format is being provided during the transition between the former version of the ARGPM (Australian Regulatory Guidelines for Prescription Medicines) and the new web format. Please note that information in the PDF should not be relied upon to be up-to-date.

Contents

8.1 What is product information

The PI is a document associated with a medicine that contains technical information relating to its safe and effective use, including:

- the characteristics of the active ingredient
- indications, contraindications and precautions
- adverse reactions that may occur
- relevant clinical trials
- dosage and storage.

The PI:

- includes scientific and technical information about the risks and benefits of the medicine to support its use for the indications for which it is approved.
- informs medical practitioners, pharmacists and other health professionals about the safe and appropriate prescribing and dispensing of the medicine.
- assists healthcare professionals to provide patient education about the medicine to support high-quality and safe clinical care.

Note

The PI must not contain promotional material.

8.2 What therapeutic goods require Product Information

PI applies to all restricted medicines, and any other medicines for which a PI is required.

Restricted medicines include:

- all medicines in Schedules 4 and 8 of the Poisons Standard regulated as prescription medicines
- medicines that contain a substance in Schedule 3 of the Poisons Standard that are only available from a pharmacy
- a medicine contained in a therapeutic good mentioned in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 (other than in items 1(b) and 14).

8.3 What are the requirements for Product Information

The PI is required to be submitted to the TGA for approval before the medicine can be registered.

The form for providing PI has been approved by the Secretary under subs. 7D(1) of the *Therapeutic Goods Act 1989* (the Act).

For restricted medicines

This form is to be submitted to the TGA with the application to register a restricted medicine in order for the application to be effective under paragraph 23(2)(ba) of the Act.

The submission dossier will only be 'effective' for the purposes of subs. 23(2) of the Act if it is accompanied by a PI form that includes the information:

- under the headings
- in the order specified in the form (see paragraph 23(2)(ba) of the Act).

Consideration is not given to the content of the draft PI at this stage but to the form in which it is provided.

For other medicines

This form is required be completed and submitted for evaluation if it is requested by the TGA under subparagraph 25(1)(da)(ii) of the Act.

The content of the PI is considered as part of the evaluation of the submission under subs. 25(1) after the application has been accepted (see paragraph 25(1)(da) of the Act).

Note for all Product Information

The final PI is the version:

- approved and
- notified to the applicant in the subs. 25(4) letter.

Once approved, the PI cannot be changed without the further approval of the Secretary.

8.3.1 Applications for a new ARTG entry for a restricted medicine

Applications under s. 23 of the Act that require a new Australian Register of Therapeutic Goods (ARTG) entry for a restricted medicine must include a draft PI in Module 1.3.1 of the application dossier.

This includes applications for certain types of variations to prescription medicines that result in the creation of a separate and distinct good (as defined in s. 16(1) of the Act).

These include:

- new chemical entity (NCE)
- new fixed combination product
- new generic product
- new route of administration
- new formulation
- additional indication
- change in dosage, dose regimen or maximum daily dose
- change in patient group
- new dose strength
- changes to the pharmaceutical, nonclinical or clinical information in a PI that are not consistent with changes under s. 9D of the Act.

8.3.2 Applications for a new ARTG entry for other higher risk medicines

The Secretary can also require that other higher risk medicines have approved PIs, where appropriate.

In these cases, sponsors will be advised in writing during the pre-submission phase to include a draft of the PI in Module 1.3.1 of the submission dossier using the form approved by the Secretary under s. 7D of the Act.

If the new medicine is approved, the new PI will be approved under subs. 25(4) and subs. 25AA(1) of the Act.

8.3.3 For a request to make a variation to an ARTG entry under s. 9D of the Act

A request to make a variation to an ARTG entry under s. 9D may require a consequential change to the PI. If this is the case, any amendments to the PI will be approved at the same time as approval of the variation to the ARTG entry. Sponsors therefore need to submit a draft amended PI with their request.

Any amendments to the PI are approved under subs. 25AA(4) of the Act. These changes include:

- where the PI contains information that is incomplete or incorrect
- where the only effect of the variation would be to reduce the class of persons for whom the goods are suitable; or to add a warning, or precaution, that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy
- where the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used. Examples of these changes include:
  - additional/changes in pack sizes
  - changes in shelf life and/or storage conditions
  - changes to the container
  - additional/change in trade name
  - change to product specifications
  - other changes to the PI that do not require a new ARTG entry, such as amending a clinical trial description.

Related information and guidance

- Variations to prescription medicines - excluding variations requiring the evaluation of clinical or bioequivalence data

8.4 How is Product Information supplied to consumers

Sponsors have an obligation to upload the current approved PI to the TGA website within two weeks of its approval. This allows consumers and health professionals to access the PI at any time.

The PI may also be published on the sponsor's website.

- *For medicines for parenteral use* - the PI is supplied as a package insert.
- *For self-administered parenterals* - the Consumer Medicine Information (CMI) may also be included as the package insert with the PI.
- *For other dosage forms* - the PI may also be required to be included as a package insert, on a case-by-case basis, as a condition of registration for that product.

Note

Marketed and non marketed versions of PIs for new products will not be approved by the TGA. The single PI should state if some of the products included in the PI are not marketed.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	01/07/2013

Therapeutic Goods Administration

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Reference/Publication #