Australian Government

Department of Health

Therapeutic Goods Administration

Guidance 7: Certified product details

Previously ARGPM Appendix 7: Certified product details

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 <http://www.tga.gov.au>. 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.

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The 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 <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	12/07/2013

Contents

Introduction

This guidance is intended for sponsors who are submitting the Certified Product Details (CPD) for their prescription medicine to the TGA.

7.1 What are Certified Product Details

The CPD is a summary of the formulation, quality control and shelf life for a prescription medicine.

It specifies the medicine's:

- formulation
- manufacturing process, and test methods; and
- their specifications.

The CPD is prepared by sponsors at the request of the TGA to avoid searching through large dossiers and files when conducting testing, such as:

- batch release testing to confirm consistency of manufacture of biological medicines (this is a condition of registration which is imposed on particular medicines under s. 28 of the *Therapeutic Goods Act 1989* (the Act))
- testing in response to adverse drug reactions (regulated under s. 29AA of the Act).

The TGA may request the CPD or an updated CPD:

- as a condition of registration
- as part of the process for requesting a variation to an entry in the Australian Register of Therapeutic Goods (ARTG); or
- at the TGA's discretion.

7.2 What to include in Certified Product Details

7.2.1 The CPD contents

The CPD contains:

- a covering page (which contains information that will be used by the TGA for indexing purposes)
- details of packaging
- details of formulation
- release and expiry specifications
- details of the sterilisation method
- details of the shelf life and storage conditions
- detailed descriptions of testing methodologies as appendices.

7.2.2 What to include

Include the following information in the CPD:

- detailed standard operating procedures for crucial tests for the drug substance (e.g. potency, content or impurities) and for all drug product tests, with a bookmark or hyperlink in the index.
- sufficient detail of testing methodologies so that they can be replicated by the TGA, preferably in the form of the standard operating procedure from the company's quality control laboratory.
- a list of any specialised instrumentation, such as unusual high-performance liquid chromatography (HPLC) columns or dissolution apparatus that are not specified in a default standard pharmacopoeia.
- details of the standards, controls and system suitability criteria for the test. The standards and controls should also be supplied to the TGA, if requested.
- details of how antimicrobial activity is neutralised in descriptions of sterility test methods.

Note

Each dosage form should have a separate CPD.

Different strengths and packaging may appear in the same CPD, but a separate set of specifications should be provided for each strength. Any differences should be made clear (e.g. different formulations or different tablet weights for different strengths).

A senior representative of the Australian product sponsor should sign the CPD to confirm that this sponsor takes responsibility for the accuracy of the

contents.

7.2.3 Specific requirements for biological medicines

For many biological medicines, critical tests are conducted on the drug substance and not repeated on the drug product because of low concentrations of the drug substance or interference by excipients.

Because of this, the CPD for biological medicines should contain the covering page (Parts 1 and 2) that contains the formulation, strengths, ARTG numbers, sponsor details and tracking details, as well as the following information in Part 3:

- a flow chart of the drug substance manufacturing process
- the drug substance testing procedures and release specifications
- a flow chart of the drug product manufacturing process
- the drug product testing procedures, and release and expiry specifications
- the sterilisation method(s)
- the shelf life and storage conditions
- any current exemptions under s. 14 of the Act.

7.3 How and when to provide Certified Product Details

7.3.1 How to provide the CPD

Proformas for the CPD for biological prescription medicines and chemical prescription medicines are available on the TGA website or at request to the appropriate testing email inbox.

- Provide the CPD electronically as a single Portable Document Format (PDF) document
- Include a hyperlinked index to the methodology standard operating procedures.

7.3.2 When to provide the CPD

Submit the CPD upon request by the TGA, rather than in the initial application to register a medicine, because there can be changes to make following the evaluation phase.

7.3.2.1 For applications to register biological medicines

The TGA will usually request the CPD towards the end of the evaluation of the quality data (Module 3 of the Common Technical Document (CTD)).

7.3.2.2 For applications to register chemical entities

The TGA will usually request the CPD after approval of the product(s).

Note

Ensure the CPD accurately reflect the quality data approved by the TGA.

Once the CPD has been requested, ensure it is provided in a timely manner for checking by TGA evaluators, so that an agreed version is available for any testing that may be necessary.

This is particularly important when batch release has been imposed as a condition of registration, as usually happens with biological medicines.

7.3.2.3 Other reasons for requesting a CPD

The TGA may also request the CPD if:

- a sample is to be tested
- the TGA does not already hold a copy
- the TGA's copy of the CPD is more than five years old.

The TGA reserves the right to check or recheck the CPD at any stage at its discretion.

Any discrepancies may lead to questions to the sponsor under s. 31.

Any current s. 14 exemption should be detailed in the appropriate table of the CPD. Any batch-specific exemptions need not be included.

7.4 How to update Certified Product Details

An updated CPD is normally sought following approval of a variation to change the test specifications, including deleting, changing or adding test methods or limits for results.

Related information and guidance

- Minor variations to registered prescription medicines: chemical entities
- Minor variations to registered prescription medicines: biological medicines

The TGA may request an updated CPD in other circumstances, at the TGA's discretion – for example:

- if a grandfathered product that has not previously been evaluated comes to the TGA's attention, or
- if a complaint has been made.

The CPD is not a means of introducing changes to the quality data.

Because the CPD is not necessarily checked on receipt, do not assume that the TGA has accepted information submitted in the CPD.

7.4.1 Biological medicines

When supplying an updated CPD for a biological medicine, provide a new copy of the entire document, including testing methodology, even if these details have not changed.

The new document needs to contain all current specifications and methodologies, because the superseded document will be archived.

7.4.2 Chemical entities

When supplying an updated CPD for a chemical entity, provide the updated information and a new CPD proforma, not the entire CPD document.

Therapeutic Goods Administration

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Reference/Publication #