



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 2: Fees and charges

June 2004

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.

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Appendix 2: Fees and charges

Sponsors of medicines evaluated by the Drug Safety and Evaluation Branch (DSEB) for registration, or variation of registration, are required to pay processing and/or evaluation fees as appropriate.

Fees will vary according to the type of evaluation undertaken (new chemical entity, extension of indications, generic application etc) and are on a "per submission basis". A submission is one or more applications from the same sponsor, with the same active ingredient, submitted at the same time. A concomitant application from, or on behalf of, another sponsor is a separate submission.

The active ingredient is the therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action.

A list of fees is included in Schedule 9 of the *Therapeutic Goods Regulations*. A list of charges can be found in the *Therapeutic Goods (Charges) Regulations*. These fees may change from time to time. A detailed description of the fees and charges applicable to products evaluated by the DSEB is also available from the Therapeutic Goods Administration (TGA) website¹.

Requests for the waiving evaluation fees can only be considered within the provisions of the Orphan Drug Program.

The fee for submissions involving applications associated with different fee categories will be the maximum individual fee.

Category 1 and 2 applications: 75% of the evaluation fee is payable when the application is submitted. Payment of this part of the evaluation fee is required within two months of the sponsor being advised of the amount, or the application will lapse. Where the total fee payable for the evaluation is greater than \$100,000, the submission may be submitted without payment, and an invoice for 75% of the fee will be sent after screening. In either case, the remaining 25% of the evaluation fee is payable upon completion of the evaluation, whether approved or rejected, but only where the evaluation has been completed within the statutory time period (see Section 3.5.1 of the *Australian Regulatory Guidelines for Prescription Medicines, ARGPM*). An invoice for the remaining fee will be sent to the sponsor.

If the application is withdrawn or rejected before it is accepted for evaluation, a screening fee applies (see TGA website for details of current screening fees).

Category 3 applications: 100% of the evaluation fee, must accompany the application.

Notifications: For safety-related notifications, self-assessable notifications and other notifications, the processing fee must accompany the notification.

Annual charges: An annual charge is payable for maintaining registration in the Australian Register of Therapeutic Goods (ARTG). There are two levels of annual charges based on whether the product is of biological or non-biological origin.

The annual fee is not payable for *low volume, low value* products. To be eligible for an exemption from the annual charge, a sponsor must apply to the TGA, providing a declaration that the wholesale turnover is low volume and low value. There is a non-refundable application fee per registration or listing to apply for a declaration that a product is low volume and low value.

¹ <http://www.tga.gov.au/about/fees.htm>

Fee categories

1. New Chemical Entity

A new chemical entity is defined in Schedule 9 of the Regulations as:

1. a chemical, biological or radiopharmaceutical substance that has not previously been included in the Register; or
2. an isomer, mixture of isomers, complex of, derivative of or salt of, a registered chemical substance that, having previously been included in the Register, differs from the registered substance in having different safety or efficacy properties; or
3. a biological substance that, having previously been included in the Register, differs from the registered substance:
 - a. in having a different molecular structure; or
 - b. in deriving from source material of a different nature or from a different manufacturing process; or
4. a radiopharmaceutical substance that:
 - a. is a radionuclide or ligand that has not previously been included in the Register; or
 - b. has a coupling mechanism, linking the molecule and radionuclide, that has not previously been included in the Register; or
5. a fixed combination of active substances that have not previously been included in the Register as that fixed combination.

If a sponsor is able to show the new isomer, mixture of isomers, complex of, derivative of, or salt of a registered substance does not change the pharmacokinetics, pharmacodynamics and/or in toxicity of the moiety in a way which could change the safety/efficacy profile, the new product may be considered to be *essentially similar* and the fee level would be for a *generic product* rather than a *new chemical entity*. Should this not be the case, the application will be considered as a *new chemical entity*.

If the sponsor believes a new isomer, mixture of isomers, complex of, derivative of or salt of a registered substance to be *essentially similar*, the sponsor should first submit a preliminary document of no more than 10 pages to justify essential similarity. In case of problems, it is recommended this justification be submitted at least two months before the complete application is lodged.

2. Extension of indications

Indications in relation to therapeutic goods are defined in the Act as *the specific therapeutic uses of the goods*.

An application to extend the indications of a *generic* medicine to include a new indication is a new indication irrespective of whether the innovator has that indication or not.

3. Major variation

A major variation is defined in Schedule 9 of the Regulations as a *change to*:

1. the strength, as recorded in the entry in the Register; or
2. the dosage, the recommended dosage regimen or the maximum daily dose; or
3. the dosage form; or
4. the route of administration; or
5. the intended patient group

A change in the intended patient group refers to any application that:

- alters to the number of patients using a medicine; or

- modifies the category of patients using a medicine; but
- is not an extension of the indications or other major variation
- is not a safety related notification; or
- is not an application for the deletion of an indication.

Examples would include an application to delete a contraindication or precaution and some changes to the clinical trials section of the product information (PI).

4. New generic product

A generic medicine is defined in the Regulations as *a medicine that, in comparison to a registered medicine:*

1. *has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the registered medicine; and*
2. *has the same pharmaceutical form; and*
3. *is bioequivalent; and*
4. *has the same safety and efficacy properties.*

The concept of a generic product is usually not appropriate for biotechnology products. Applications for a new biotechnology product would normally be regarded as a new chemical entity.

Section 25A of the *Therapeutic Goods Act 1989* states that when evaluating therapeutic goods for registration, protected information about other therapeutic goods may not be used. Protected information relates to an active ingredient first registered less than 5 years previously and refers to information about the active ingredient not in the public domain. Applications for a generic version of such an active ingredient would be considered a new chemical entity.

5. Additional trade name

A trade name is defined in the Regulations *as the commercial name:*

1. *given to goods of that kind by the manufacturer; and*
2. *under which the goods are supplied.*

Three situations may occur:

- a sponsor has already registered a product under one trade name and the same sponsor is seeking to register the same product under another trade name;
- a sponsor has already registered a product under one trade name and is seeking to register the same product under another trade name on behalf of another sponsor; and
- a sponsor has already registered a product under one trade name and a second sponsor is seeking to register the same product under another trade name.

The fee for an additional trade name is restricted to the first type of application, that is, those applications in which a sponsor has already registered a product under one trade name and is seeking to register the same product under another trade name.

Applications of the second and third types, that is, where a second sponsor is involved, are applications for a new generic product.

6. Minor variation

A minor variation is defined in Schedule 9 of the *Therapeutic Goods Regulations* as *a change (other than a change that is a major variation) to:*

1. *the formulation, composition or design specification; or*
2. *the container for the goods; or*
3. *any other attribute of the goods that results in the goods being separate and distinct.*

7. Variations to a Register entry involving the evaluation of quality information (chemistry, quality control and manufacturing information), and clinical, non-clinical or bio-equivalence data, but not included in another fee category.

A Category 1 application for a variation of the entry in the register (section 9D(3) of the Act), but not included in another fee category.

8. Changes to the PI involving the evaluation of data

All amendments to the PI involving the evaluation of data and not otherwise included in a higher fee category.

9. Changes to Product Information where no evaluation is required

All amendments to the PI which are of an administrative nature (for example, new format, change of administrative information). Editorial changes to the PI are discussed in Section 4.4.5.3 of the ARGPM.

10. Changes to Consumer Medicine Information

Review of the CMI when not part of another application in another fee category.

11. Variations to a Register entry involving the evaluation of only quality (chemistry, quality control and manufacturing) information

A Category 3 application concerning changes that require TGA approval before implementation (see Section 2.5.3 of the ARGPM).

12. Notification of Self-Assessable Changes

A Category 3 application concerning self-assessable changes of the type described in Appendices 13 and 14 of the ARGPM.

13. Safety Related Notification

Safety related notifications are discussed in Section 4.4.5.1 of the ARGPM.

14. Testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program

A fee for testing and provision of advice, requested from Pharmaceutical Benefits Program, prior to listing on Pharmaceutical Benefits Listing Program.

Historical document

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Reference/Publication #