Australian Government

Department of Health

Therapeutic Goods Administration

ACE scheme waiver guidance

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TGA Health Safety Regulation

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The Annual Charges Exemption (ACE) scheme which came into operation on 1 July 2015 provides an exemption from annual charges until a product first generates turnover. Once a product has turnover then the annual charge is payable for the relevant entry in the Australian Register of Therapeutic Goods (the Register) for that financial year and each subsequent financial year (that the good remains on the Register).

From 1 July 2015, sponsors of certain high risk therapeutic goods can seek a waiver from the annual charge (under subregulation 43AAH of the *Therapeutic Goods Regulations 1990* (the Regulations) if:

- it is not financially viable for the therapeutic good to remain on the Register if the annual charge was payable; **AND**
- it is in the interest of public health for the therapeutic good to remain on the Register.

It is the responsibility of the sponsor to provide the TGA with sufficient evidence to allow a delegate to be satisfied about both those matters.

The objective of the waiver provisions in the Regulations is to ensure the continued availability of essential therapeutic goods to the Australian public. Sponsors should note that a waiver will only be approved in **exceptional circumstances**.

See Evidence requirements for what is considered in determining financial viability and public health interests.

Note

- **If you are exempt from paying the annual charge for a financial year under the ACE scheme, then there is no need to apply for a waiver for that financial year.**
- **Under the ACE scheme, newly registered or included goods in the Register are automatically exempt from paying the annual charge until they commence turnover.**

How long is the waiver valid for?

A waiver only applies to the annual charges for the financial year for which it was granted.

Note

If you think that you qualify for a waiver for any particular financial year, you must apply for it in relation to that financial year. Any waiver given for a previous financial year is no longer applicable.

Which therapeutic goods are eligible?

- Registered medicines
- Biologicals
- Medical devices which are class IIa or higher (i.e. class IIa, class IIb, class III or AIMD)
- In-vitro diagnostic devices which are class 2 or higher (i.e. class 2, class 3 or class 4).

Applying for a waiver

A waiver will **only** be relevant if an annual charge is payable for the eligible therapeutic good in that year.

Fees

There is **no fee** associated with applying for a waiver.

When to apply

1. **New products**

   If an annual charge for your therapeutic good is payable for the financial year that it was first entered in the Register, an application for a waiver must be made before 31 December in the next financial year.

   Remember, a waiver is only relevant if you are liable to pay the annual charge in relation to that year; that is, there has been sales turnover of the goods in that year.

2. **Existing products**

   Where:

   – the good was already in the Register on the first day of the financial year (to which the charge relates), and

   – you would otherwise be liable to pay the annual charge for that good,

   you must apply during that financial year.

How to apply

To apply for a waiver, you must make an application in writing, and it **must** address both the financial viability and public health criteria referred to above. Information about what should be included in the application is set out under Evidence requirements.

You can include more than one Register entry, and entries for different types of therapeutic goods in the one application. However, the information required (see Evidence requirements) must be provided in relation to **each** entry.

When you make the application, please ensure that you:

- provide all the information that you want us to consider that is relevant to the criteria (see Evidence requirements),

- ensure that the relevant officer of your company (explained below) has signed off on your application,
- include a list of the relevant entries covered by your application (for each, ensure you include its Register entry number, the name of the product on the entry, the annual charges invoice number, and the type of therapeutic good) (see Evidence requirements for more information about what to include in your application), and
- provide an email address that we can use for associated correspondence.

What constitutes an 'application'?

An application for an entry will only be assessed if it addresses the requirements set out in the Regulations. That is, subregulations (7) and (8) of regulation 43AAH as described in the Evidence requirements. If the application does not properly address the requirements the application will not be considered.

Please note

Under regulation 43AAH, the TGA **cannot** consider information you provide after submitting your application, other than where it is provided in response to a request from us for more information.

Evidence requirements

You must provide sufficient information in your application to satisfy the criteria set out in regulation 43AAH.

All applications for waiver - financial viability

To support your claim that it **would not be financially viable** for the therapeutic goods covered by the entry to remain on the Register if the annual charge had to be paid, you **must** include the following:

1. where the entry is for a **medicine or a biological**
   - historic:
     - the number of units sold in Australia in the past two financial years (if any)
     - the unit sale price of the goods
     - the revenue from the sale of the goods in the past two financial years
     - direct costs, including for example, costs of production and distribution of the goods
   - forecast:
     - an estimate of the number of units that are likely to be sold in Australia in the year to which a waiver is being sought, and the basis of estimation
     - the proposed unit price of the goods

- § the expected revenue from the sale of the goods for the year to which a waiver is being sought
- § direct estimated costs, including for example, costs of production and distribution of the goods

2. where the entry is for a **medical device**

– a list of the medical devices covered by the entry (i.e. that could be supplied under the entry)[1]

§ historic:

the number of units of each of those medical devices (including all variants approved) sold in Australia in the past two financial years (if any)

the unit sale price of each of those medical devices (and variants where relevant)

the revenue from the sale of each of those medical devices in the past two financial years (if any)

direct costs, including for example, costs of production and distribution

§ forecast:

an estimate of the number of units, for each device covered by the entry, that are likely to be sold in Australia in the year to which a waiver is being sought, and the basis of estimation

the proposed unit price of each device

the expected revenue from the sale of each device covered by the entry for the year to which a waiver is being sought

direct estimated costs, including for example, costs of production and distribution

3. any other matter you think is relevant to the issue of financial viability of the entry.

Note

- Direct costs should be calculated as the actual direct costs rather than a transfer price used between related divisions/companies.
- The information submitted to support the claim that it would not be financially viable for a sponsor to pay the annual charge should be signed by the **Chief Financial Officer or equivalent within the business**.

[1] With the exception of Class III and Active Implantable Medical Devices, an entry in the Register is for a "kind" of medical device. This means that more than one medical device can be authorised for marketing by that entry.

All applications for waiver - public health criteria

Under regulation 43AAH(8) the TGA must take into account the following matters when considering whether it would be in the **interests of public health** for the entry to remain on the Register:

- the population who use the good(s)
- the clinical needs of that population
- the reasonable availability (or not) of therapeutic alternatives to the goods for that population
- any health risks to that population which may be associated with:
  - obtaining the therapeutic good through alternative means
  - the use of therapeutic alternatives
- the likelihood of your goods being available to that population through alternative means if the relevant entry was not on the Register.

1. Public health criteria for medicines and biologicals

If the application is for a medicine or biological, please include the following information in support of your application:

- information identifying the population[2] who uses the medicine or biological (for instance: what the size of the population is; is there widespread use but only intermittent, or only in an emergency)
- information about whether the population who uses the medicine or biological, or a subgroup of that population, have particular characteristics and/or whose health would be particularly disadvantaged if the medicine or biological was not available
  - identify any subgroup, those characteristics, and/or any such disadvantage
- information about whether the medicine or biological would be, or is likely to be, available through alternative means for that population (or population subgroup) in the relevant financial year if the entry were cancelled at your request
- information about whether any potential alternatives for that medicine or biological are on the Register and whether they are available for that population (or subgroup)
  - if so, information about what they are and what is their actual availability
- information about whether there are any specific characteristics or factors that would raise health issues for that population (or population subgroup) in **obtaining or accessing**, any such alternatives
  - if so, information about what those specific characteristics or factors are, and what the health issues are
- whether there are any specific clinical matters that raise health issues for that population (or population subgroup) in **using** any such alternatives
  - if so, information about what those clinical matters are, and what the health issues are.

[2] The population refers to the patients using the therapeutic goods, or on whom, or in relation to whom the therapeutic goods are used.

Note

1. The information submitted relating to the evidence to support the claim that it is in the interests of public health for an entry to remain on the Register should, if at all possible, be signed by a person with the relevant professional qualifications e.g. a medical professional. If it is not possible, please explain why.
2. Your application for a waiver needs to make a case that there is a public health need for the entry to remain on the Register even if the annual charge is not paid. The TGA will **not** accept material previously submitted or considered as part of any approval process for the medicine or biological (such as dossiers or evaluation reports) except to the extent that it is relevant to the criteria as described above.

2. Public health criteria for medical devices

If the application is for an entry for medical devices, please include the following information in support of your application:

- the GMDN code for the device
- the intended purpose of the device[3]
- the classification of the device
- information as to whether the device is an 'Accessory'[4] to another device
- information about whether the population[5] who uses the medical device (or the device to which it is an accessary), or a subgroup of the population, have particular characteristics and/or whose health would be particularly disadvantaged if the medical device was not available
  - identify any subgroup, those characteristics, and/or any such disadvantage
- information about whether the device would be, or is likely to be, available through alternative means to that population (or subgroup) in the relevant financial year if the relevant entry were cancelled at your request
- information about whether there are potential alternatives for that device on the Register and whether they are available for that population (or subgroup)
  - if so, information about what they are and what is their actual availability

[3] In most cases, the intended purpose of the device will provide the TGA with information about the population and clinical use of the device. Provide any additional information you think relevant in identifying the relevant population.
[4] Accessory, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab) of the *Therapeutic Goods Act 1989*, means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended (section 3 of the Act).
[5] The population refers to the patients using the medical device, or on whom, or in relation to whom, or by whom, the medical device is used. In the case of some kinds of medical devices (for instance, surgical instruments), it might include health professionals using the device.

- information about whether there are any specific characteristics or factors that would raise health issues for that population (or subgroup) in **obtaining or accessing**, any such alternatives
  - if so, information about what those specific characteristics or factors are, and what the health issues are
- whether there are any specific clinical matters that raise health issues for that population (or population subgroup) in **using** any such alternatives
  - if so, information about what those clinical matters are, and what the health issues are.

Note

1. The information submitted relating to the evidence to support the claim that it is in the interests of public health for an entry to remain on the Register should, if at all possible, be signed by a person with the relevant professional qualifications e.g. a medical professional. If it is not possible, please explain why.
2. Your application for a waiver needs to make a case that there is public health need for the entry to remain on the Register even if the annual charge is not paid. The TGA will **not** accept material previously submitted or considered as part of any approval process for the medical device (such as dossiers or evaluation reports) except to the extent that it is relevant to the criteria as described above.

Information about any waiver for the previous year

Please indicate whether you applied for a waiver in the immediately preceding financial year for the relevant entry, and if so, the outcome of the application, i.e. whether it was accepted, refused or withdrawn.

Incomplete, insufficient or incorrect information

An application that does not contain the information that addresses the criteria will not be considered by the TGA on the basis it is not an 'application'. There is no review available in this case.

Your application for a waiver needs to make a case that there is a public health need for the entry to remain on the Register. As noted above, the TGA will not accept material previously submitted or considered as part of any approval process for the products covered by the entry except to the extent that it is relevant to the criteria.

An application that does not contain sufficient information or sufficiently persuasive information to satisfy the delegate that it is in the interests of public health for the entry to remain on the Register and that it would not be financially viable if you were required to pay the annual charge may result in refusal of the waiver.

You are reminded that it is an offence under section 137.1 and 137.2 of the *Criminal Code* to provide any false or misleading information or documents in relation to this application.

Submitting your application

Completed applications should be sent to:

Email: ace.scheme@health.gov.au

Post: Regulatory Pricing and Decision Review Section
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Once your application is submitted

Once we receive a completed and signed application (including supporting information), we will review it and decide whether to grant a waiver (or not) for that financial year.

We are required to make this decision within 60 days of receiving an application that we are satisfied contains information that addresses the criteria.

What information is considered?

Apart from the matters referred to under Evidence requirements (see subregulation 43AAH(8) of the Regulations), we can take into account any other matter we consider relevant in considering whether it would be in the interests of public health for the goods to remain on the Register (subregulation 43AAH(9)).

Note

- We **cannot** consider any information you submit to us after the initial application has been made, unless provided in response to a request for further information from us.
- We **cannot** grant a waiver if the goods have been cancelled from the Register at the time the application is being considered (subregulation 43AAH(7)).

Informing you of our decision

We will provide you with written notice of our decision as soon as practicable after the decision is made.

If we refuse to waive the annual charge for an entry, the written notice will:

- set out the reasons for that decision,
- specify the date the annual charge becomes payable, and
- state that you can, within 90 days after the decision comes to your notice, apply for a review of the decision (under regulation 48 of the Regulations).

Request to cancel therapeutic good(s) that have a waiver

If, having been granted a waiver for a financial year for an entry on the Register, you request the TGA to cancel that entry, you will be required to pay the annual charge for that entry for that financial year.

In this case, we will provide you with a written notice specifying the date the annual charge(s) becomes payable. (See also below about publication.)

Publication

Information about applications that have been approved or refused will be published on the TGA website. This information would include:

- the name of the sponsor,
- the relevant Register entry number,
- the name of the goods, and
- whether the decision was to waive the annual charge or not.

We will also publish information about sponsors who, having been granted a waiver, are required to pay the annual charge because of a request they subsequently made to cancel the entry.

Later inquiries

The TGA can at any time seek information from a sponsor about any matter relating to an application to waive the annual charge for an entry in the Register (whether successful or not). It is an offence under the Therapeutic Goods Act to fail to provide the information, or to provide information that is false or misleading, in response. It is also grounds for suspension or cancellation of the entry.

Version history

Version	Description of change	Author	Effective date
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V2.0	Updated	TGA	June 2017
V3.0	Updated	TGA	June 2018

Therapeutic Goods Administration

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