



Australian Government

Department of Health

Therapeutic Goods Administration

Guidance for requesting reconsideration of an initial decision

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TGA Health Safety
Regulation

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Introduction

The purpose of this document is to provide:

- information about the reconsideration by the Minister for Health (or a delegate of the Minister) of 'reviewable' initial decisions made by the Secretary of the Department of Health or their delegate (the Secretary)
- guidance on how to request reconsideration of an initial decision by the Minister for Health (the Minister) under section 60 of the [Therapeutic Goods Act 1989](#), regulation 48 of the [Therapeutic Goods Regulations 1990](#) or regulation 10.7 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

Under section 60 of the Therapeutic Goods Act, a person whose interests are affected by an initial decision made under the Act may, by notice in writing given to the Minister, request the Minister to reconsider the initial decision.

Under regulation 48 of the Therapeutic Goods Regulations, a person whose interests are affected by an initial decision made under the Regulations may, by notice in writing given to the Minister, request the Minister to reconsider the initial decision.

Under regulation 10.7 of the Medical Devices Regulations, a person whose interests are affected by an initial decision made under the Medical Devices Regulations may, by notice in writing given to the Minister, request the Minister to reconsider the initial decision.

Submitting a request for reconsideration of an initial decision **does not** incur a fee.

Subject to the [Administrative Appeals Tribunal Act 1975](#) (the AAT Act), if a person is dissatisfied with a reconsideration decision made by the Minister, an application may be made to the Administrative Appeals Tribunal (AAT) for a review of the Minister's decision by the AAT.

Submitting an application to the AAT for review of a decision upon reconsideration **may incur** a fee. Refer to the [Administrative Appeals Tribunal](#) section in this document.

Reviewable initial decisions

Only 'reviewable' initial decisions can be reconsidered by the Minister.

An initial decision made by the Secretary that is not specifically identified as a 'reviewable' initial decision, cannot be reconsidered under section 60 of the Therapeutic Goods Act, regulation 48 of the Therapeutic Goods Regulations or regulation 10.7 of the Medical Devices Regulations. A summary of [reviewable initial decisions](#) under the Act and Regulations is published on the TGA website.

The following are some examples which are not considered to be an initial decision:

- TGA advice to an applicant that an application made by the applicant was 'not effective' because the application fee had not been paid
- a proposal by the TGA to cancel an entry on the [Australian Register of Therapeutic Goods](#) (ARTG) (though the decision to cancel is an initial decision)
- informing an applicant that an application had not been made in accordance with statutory requirements (including that the information necessary to allow the application to be evaluated had not been provided).

These examples are not initial decisions because no 'decision' has been made by the Secretary by exercising their discretion under the Therapeutic Goods Act, the Therapeutic Goods Regulations

or the Medical Devices Regulations. The outcome, such as ‘the application is not effective’ is the outcome of ensuring compliance with legislation has occurred (i.e. the operation of the Therapeutic Goods Act itself).

Guidelines

Notification of an initial decision

Under the Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations, it is the usual case that notification of an initial decision must be given to a person (usually an applicant or a sponsor) in writing. In some cases, the particulars of an initial decision (such as to cancel a product from the ARTG) must also be published in the Gazette or on the [TGA website](http://www.tga.gov.au) <www.tga.gov.au> at the time the initial decision is made.

Where **written notice** of the making of an initial decision is given¹ by the Secretary to a person whose interests are affected by the decision, the notice must inform the person whether the initial decision is a ‘reviewable initial’ decision which can be reconsidered by the Minister upon request in writing.

Preparing a request for reconsideration

A person whose interests are affected by an initial decision may, by notice in writing given to the Minister, request reconsideration of the initial decision. Such requests must be made:

- if the Therapeutic Goods Act, the Therapeutic Goods Regulations or the Medical Devices Regulations require the person to be given notice in writing of the initial decision, **within 90 days after the notice is given to the person**

OR

- in any other case, within 90 days of the publication of the initial decision in the Gazette or on the [TGA website](http://www.tga.gov.au) OR within 90 days of the decision first coming to the person’s notice, **whichever is earlier**.

Important: A request for reconsideration made after the abovementioned period (i.e. 90 days) cannot be considered by the Minister.

A person whose interests are affected is advised to ensure the notification of a request for reconsideration includes the following:

- the notification should be **titled** ‘<insert name of person/company> - Request for Reconsideration Under **Section 60** of the *Therapeutic Goods Act 1989*’ or ‘<insert name of person/company> - Request for Reconsideration Under **Regulation 48** of the Therapeutic Goods Regulations 1990’ or ‘<insert name of person/company> - Request for Reconsideration Under **Regulation 10.7** of the Therapeutic Goods (Medical Devices) Regulations 2002’
- is **dated and signed** by the person requesting reconsideration

¹ In accordance with section 160 and section 163 of the [Evidence Act 1995](http://www.legislation.gov.au/austrlii/au/other/dfat/special/evidence/evidence_1995.html), written notification of an initial decision **via post** is deemed to be ‘given’ to a person within 10 business days after the date of the notice. In accordance with section 14A of the [Electronic Transactions Act 1999](http://www.legislation.gov.au/austrlii/au/other/dfat/special/electronic/electronic_1999.html), written notification **via email** of an initial decision is deemed to be ‘given’ to a person within 1 business day after the date that the notice is emailed.

- nominates an **email address** for the purposes of receiving correspondence in relation to the request for reconsideration
- a copy of the **initial decision notification letter** (or other evidence of notification)
- identifies, and describes with as much specificity as possible, **which component(s)** of the initial decision should be reconsidered and set out the **reasons why** reconsideration is requested
- any **information/documentation in support** of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested
- a description of how the person's interests are affected by the initial decision (**only applicable** if the notification of an initial decision was *not issued* to the person whose interests are affected).

It is important to ensure all information and documentation that you wish the Minister to consider is provided with your request as the Minister is **not** able to consider any information provided after the making of a request unless the information is provided in response to a request from the Minister; or (in the case of a review under section 60) the information indicates that the quality, safety or efficacy of therapeutic goods is unacceptable.

Wherever practicable, requests for reconsideration and all supporting documentation should be made available electronically via email, preferably in Adobe (with OCR) format. Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD.

Submitting a request for reconsideration

Notification of a request for reconsideration should be **given to the Minister by email to:**

[<minister.hunt.DLO@health.gov.au>](mailto:minister.hunt.DLO@health.gov.au) and copied to [<decision.review@health.gov.au>](mailto:decision.review@health.gov.au)

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Minister for Health
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Upon receipt of a request for reconsideration of an initial decision, the TGA sends a written acknowledgement to the person who requested the reconsideration to confirm that their request has been received by the Minister's office. The written acknowledgement will:

- be sent to the email address nominated within the person's request for reconsideration, and
- advise the latest date by which the outcome of the Minister's decision will be given to the person making the request.

Where the person whose interests are affected is a third party (i.e. the person was not the person to whom the initial decision was issued by the Secretary), the TGA will also notify, in writing, the person to whom the initial decision was issued by the Secretary (e.g. the registered sponsor of a product) advising that a request for reconsideration has been received. The registered sponsor of a product for which a request for reconsideration has been made by a third party will be accorded procedural fairness in the form of a right of reply. The consent of the

third party to release the particulars of their request for reconsideration to the product sponsor will be sought from the third party before any such right of reply notice is issued by the TGA.



Note:

Where a person who has made a request for reconsideration does not receive notice of the decision of the Minister on that reconsideration within 60 days after making the request², the Minister is taken to have confirmed the initial decision.

The Minister needs to consider all the relevant information (including information that was not made available to the Secretary (as the initial decision maker) which is now properly available to consider and to make a decision upon reconsideration that he or she considers is the correct decision in the circumstances. The Minister is not limited to considering issues that were raised in the request for reconsideration, nor is the Minister reviewing the 'lawfulness' of the initial decision of the Secretary or whether the initial decision of the Secretary was right or wrong.



Important:

Under the Therapeutic Goods Act, the Therapeutic Goods Regulations, or the Medical Devices Regulations, the Minister is not able to consider any information that is provided after the making of the request unless the information is provided in response to a request from the Minister; or (in relation to a reconsideration under section 60), the information indicates that the quality, safety or efficacy of therapeutic goods is unacceptable.

Reconsideration by the Minister

The Minister **must give notice** in writing of the decision upon reconsideration that includes a 'statement of reasons' (i.e. findings, references to evidence and reasons for the decision) to the person whose interests are affected, **within 60 days after making a request for reconsideration**³.

If the initial decision is one of which is required to be published in the Gazette or on the TGA website (such as a decision to cancel a product from the ARTG) and the Minister decides to 'revoke' or 'revoke and substitute' the initial decision upon reconsideration, the particulars of the decision upon reconsideration must also be published in the Gazette or on the TGA website.

Subject to the [Administrative Appeals Tribunal Act 1975](#) (the AAT Act), if a person is dissatisfied with a reconsideration decision made by the Minister, an application may be made to the Administrative Appeals Tribunal (AAT) for a review of the Minister's decision by the AAT. Refer to the section titled [Administrative Appeals Tribunal](#).

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the TGA with the appropriate delegation.

² The making of a request for reconsideration is taken to have been made on the date it is received by the Minister.

³ The making of a request for reconsideration is taken to have been made on the date it is received by the Minister. The Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations do not allow for an extension of the 60 day period in which the Minister must reconsider the initial decision.

A request for reconsideration of an initial decision by the Minister will result in one of the following outcomes:

- **confirm** the initial decision
- **revoke** the initial decision
- **revoke and substitute** the initial decision with a new decision
- **remit** the initial decision (Applies to section 60 reconsiderations only. Refer to [Section 60A – new information](#))

Confirm the initial decision

Where the decision upon reconsideration by the Minister is to ‘confirm’ the initial decision, the Minister has decided to uphold the initial decision. The initial decision therefore remains unchanged.

It is however possible that upon reconsideration the Minister may have come to the same conclusion as the initial decision of the Secretary but for different reasons. The Minister may assess evidence in support of the decision upon reconsideration differently to the Secretary or come to another conclusion on the basis of available evidence (which might be additional to what was available to the Secretary when making the initial decision).

Revoke the initial decision

Where the decision upon reconsideration by the Minister is to ‘revoke’ an initial decision (such as to cancel a product from the ARTG), the Minister has decided to **overturn the initial decision** of the Secretary (i.e. the product should remain on the ARTG). The initial decision is therefore reversed (as though the initial decision was never made).

This may be because the Minister assesses the initial decision of the Secretary as being incorrect at the time it was made and is still incorrect, or as being incorrect only in light of additional information made available to the Minister upon reconsideration of the initial decision.

Revoke and substitute the initial decision with a new decision

Where the decision upon reconsideration by the Minister is to ‘revoke and substitute’ an initial decision with a new decision, the Minister has decided to vary all or part of the initial decision of the Secretary. The initial decision is therefore partially or entirely replaced (substituted) by a new decision. For instance, the Secretary may have decided not to approve an application. The Minister’s decision does not agree – so the Secretary’s decision is revoked and the Minister substitutes it with a decision to approve the application.

Upon reconsideration of the initial decision, the Minister may decide that a variation (to one or more specific aspects) of the initial decision of the Secretary is, under certain circumstances, the correct outcome. The Minister may assess the initial decision of the Secretary as being partially or entirely incorrect at the time it was made or as being partially or entirely incorrect in light of additional information made available to the Minister upon reconsideration of the initial decision.

Section 60A – new information on review

Where an initial decision is made by the Secretary under **section 25, section 32DF, section 32DG or section 41EC** of the Act and a person whose interests are affected by the initial

decision lodges 'new' information in support of a request for reconsideration of the initial decision by the Minister, the Minister must either:

- take that information into account upon reconsideration of the initial decision

OR

- remit the matter to the Secretary for a fresh decision.

Under the Therapeutic Goods Act, 'new' information means information that was in existence at the time the Secretary made the initial decision under section 25, section 32DF, section 32DG or section 41EC of the Therapeutic Goods Act **but was not made available to the Secretary** for the purpose of making the initial decision and is information that was relevant to the making of the initial decision.

If the Minister **remits the matter to the Secretary and** the person whose interests are affected **has paid a further evaluation or conformity assessment fee** as required under the Therapeutic Goods Act, the Secretary **must make a fresh (initial) decision** under section 25, section 32DF, section 32DG or section 41EC taking into account the 'new' information, as if a fresh application had been made.

If the Minister decides to remit the request for reconsideration, the Minister must notify their decision in writing to the person whose interests are affected. If the person whose interests are affected does not receive notice in writing of the decision of the Minister to remit the matter within 60 days of the notification of a request for reconsideration being made to the Minister⁴, the Minister is taken to have confirmed the initial decision.

Withdrawing a request for reconsideration

The person who made a request for reconsideration of an initial decision can withdraw their request at any time before the reconsideration decision is made by the Minister. Withdrawal of a request for reconsideration should be notified in writing to the Minister as soon as possible.

Notification of the withdrawal of a request for reconsideration should be emailed to <minister.hunt.DLO@health.gov.au> and copied to <decision.review@health.gov.au>.

Administrative Appeals Tribunal

Introduction

The Administrative Appeals Tribunal (AAT) is a Commonwealth administrative body that reviews a wide range of decisions made by Australian Government ministers, departments, agencies and some other tribunals. The AAT takes a fresh look at a decision and, based on all the evidence before the AAT, decides the 'best or preferable decision' in the circumstances.

Notification of a decision upon reconsideration

Under the Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations, where written notice of the decision by the Minister upon reconsideration is given to a person whose interests are affected and that person is dissatisfied with the Minister's

⁴ The making of the (notification) request for reconsideration is taken to have been made on the date it is received by the Minister.

decision, they can, subject to the [Administrative Appeals Tribunal Act 1975](#) (the AAT Act), make an application to the AAT for review of the Minister's decision.

Application for review of a decision

Under the AAT Act, an application to the AAT for review of a decision upon reconsideration must be made in writing **within 28 days commencing on the day on which the decision upon reconsideration is made**, otherwise an extension of time must be sought from the AAT.

Applicants should complete the AAT online form [Application for Review of Decision \(Organisation\)](#) and submit the form via email to <generalreviews@aat.gov.au> or by regular mail to 'Administrative Appeals Tribunal, GPO Box 9955 in your capital city' or by facsimile. For more information or assistance, refer to the [AAT website](#) or contact the AAT on **1800 228 333**.

Submitting an application to the AAT for review of a decision upon reconsideration **may incur a fee**. Further information about AAT application fees is available on the [AAT website](#).

The AAT notifies the Minister as the person on whose behalf the decision upon reconsideration was made (the respondent) that an application has been received requesting review of a decision upon reconsideration made by the respondent. The respondent must then lodge a statement of reasons for the decision upon reconsideration and all documents relevant to the AAT's review of the decision upon reconsideration within 28 days of receiving the notice. These documents are referred to as 'Tribunal Documents' ('T Documents').

Note:



After an application for review of a decision upon reconsideration is made to the AAT, the TGA is unable to alter the decision upon reconsideration by variation of the decision upon reconsideration, setting aside the decision upon reconsideration or setting aside a decision upon reconsideration and making a new decision upon reconsideration in substitution for the decision upon reconsideration set aside unless the applicant and the Tribunal consent to the making of the alteration. Such an agreement refers to consent orders under section [42C of the AAT Act](#).

Shortly after the T Documents are lodged, a conference is conducted by an AAT member or Conference Registrar with both parties present. The conference aims to identify issues in dispute, to negotiate a settlement of the case or, if settlement is not possible, to prepare a matter for hearing. Normally a timetable is set by the AAT for the parties to file any additional evidence in support of their case.

Once both parties have filed their evidence it is possible that if the parties and the AAT agree, the matter can proceed to mediation. However, this is a voluntary process to be agreed by both parties. At mediation, the parties can negotiate a settlement of their case with the help of the neutral third party (the AAT). The mediator does not decide the dispute or tell the parties what to do, but helps the parties to reach an agreement. If an agreement is not reached after mediation (or alternatively if mediation is not undertaken and the matter is not resolved after a conference) the matter proceeds to a hearing. At the hearing, parties and witnesses will appear before an AAT member or members to present their case. AAT hearings are usually open to the public. At the end of the hearing, the AAT will either give its review decision immediately or will reserve its review decision, which will be provided at a later date. The review decision may be published.

Section 60A – new information on review – discretion to remit

Where a decision upon reconsideration is made by the Minister in relation to an initial decision made under **section 25, section 32DF, section 32DG** or **section 41EC** of the Therapeutic Goods Act and a person whose interests are affected by the Minister's decision applies to the AAT for review of that decision and lodges 'initial new' or 'later new' information (or both) in support of that application, the AAT may if the AAT thinks fit remit the matter to the Secretary for a fresh (initial) decision.

Note:



A person whose interests are affected by a decision upon reconsideration made by the Minister in relation to an initial decision made by the Secretary under **section 25, section 32DF, section 32DG** or **section 41EC** of the Act is, under the Act, obliged to **pay the applicable evaluation fee or conformity assessment fee** as if it is a new application, before the application can be considered.

Under the Therapeutic Goods Act, '**initial new**' information means information that was in existence at the time the Secretary made the initial decision under **section 25, section 32DF, section 32DG** or **section 41EC** of the Therapeutic Goods Act, or at the time the Minister made the decision upon reconsideration but was not made available to the Secretary for the purpose of making the initial decision or was not made available to the Minister for the purpose of making the decision upon reconsideration and is information that is relevant to the making of either of those decisions.

Under the Therapeutic Goods Act, '**later new**' information means information that was in existence at the time the Minister made the decision upon reconsideration in relation to an initial decision made by the Secretary under **section 25, section 32DF, section 32DG** or **section 41EC** of the Act, but was not made available to the Minister for the purpose of making the decision upon reconsideration and is information that is relevant to the making of that decision.

If the AAT **decides to remit the matter to the Secretary and** the person whose interests are affected **has paid a further evaluation or conformity assessment fee** as required under the Therapeutic Goods Act, the Secretary must make a fresh (initial) decision under section 25, section 32DF, section 32DG or section 41EC taking into account the 'initial new' or 'later new' information, as if a fresh application had been made.

If the AAT **decides not to remit the matter to the Secretary**, where a person whose interests are affected by a decision upon reconsideration made by the Minister applies to the AAT for review of that decision upon reconsideration and lodges 'initial new' or 'later new' information (or both) in support of that application, the AAT **cannot** consider any 'initial new' information not considered by the Minister or 'later new' information **except** where the 'initial new' or 'later new' information lodged **indicates that the quality, safety or efficacy of the therapeutic goods is unacceptable**.

The AAT **cannot remit the matter to the Secretary** for a fresh (initial) decision where a person **lodges only 'initial new' information (not 'later new' information)** to the AAT in support of their application, which was not already considered by the Minister.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication called 'TGA internal review guideline: The operation of TGA's internal review and how to apply'	Office of Regulatory Integrity	07/09/2012
V1.1	Updated the address for submission of a request for reconsideration	Therapeutic Goods Administration	20/05/2016
V2.0	Major Revision - included the guidance on how to request reconsideration of an initial decision by the Minister for Health (the Minister) under regulation 48 of the Therapeutic Goods Regulations 1990 or regulation 10.7 of the Therapeutic Goods (Medical Devices) Regulations 2002	Regulatory Pricing & Decision Review	1/11/2016
V2.1	Updated the email addresses for submission of a request for reconsideration	Regulatory Pricing & Decision Review	20/1/2017

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@health.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

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