Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Requesting the Minister for Health to reconsider our initial decision

Guidance about how to request reconsideration of 'reviewable' initial decisions by the Minister for Health.

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On this page

Purpose

The main purpose of this document is to provide:

- Information about which decisions are reviewable initial decisions under the *Therapeutic Goods Act 1989* (the Therapeutic Goods Act), *Therapeutic Goods Regulations 1990* (the Therapeutic Goods Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Device Regulations)
- Guidance on how to request reconsideration of a reviewable initial decision
- Information about the reconsideration process.

Under section 60 of the Therapeutic Goods Act, a person whose interests are affected by an 'initial decision' made under that Act, may 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 those Regulations, may 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 those Medical Devices Regulations, may 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 Review Tribunal Act 2024*, if a person is dissatisfied with a reconsideration decision made by the Minister, an application may be made to the Administrative Review Tribunal (the ART) for a review of the Minister's decision. Refer to the Administrative Review Tribunal section.

Legislation

Therapeutic Goods Act 1989

Therapeutic Goods Regulations 1990

Therapeutic Goods (Medical Devices) Regulations 2002

Administrative Review Tribunal Act 2024

Reviewable initial decisions

The only decisions that are reviewable initial decisions and can therefore be reconsidered by the Minister (or a delegate of the Minister), are those 'initial decisions' of the Secretary (or an authorised person) specified in section 60 of the Therapeutic Goods Act, regulation 48 of the Therapeutic Goods Regulations or regulation 10.7 of the Medical Devices Regulations.

In order to be eligible to request reconsideration under section 60 of the Therapeutic Goods Act, a person must be someone whose interests are affected by a reviewable initial decision. Further, in some cases, the Therapeutic Goods Act provides that only certain persons are entitled to request reconsideration of a decision (section 60(2AA)-(2D)).

Therapeutic Goods Act 1989 (section 60)

An initial decision can only be reconsidered under section 60 of the Therapeutic Goods Act if it is a decision of the Secretary (or their delegate):

- refusing to make, or refusing to vary or repeal, a declaration under section 7 upon an application made under subsection 7(2); or
- under subsection 7C(3); or
- under section 9C, 9D or 9F; or
- refusing to grant, or imposing conditions on a grant of, a consent under section 14 or 14A; or
- under Part 3-2 (registration and listing of therapeutic goods), other than a decision under paragraph 26BE(4)(a), or a decision under subsection 26BJ(8), to make a recommendation; or
- under Part 3-2A (biologicals); or
- under Part 3-3 (manufacturing of therapeutic goods); or
- under subsection 41BD(3); or
- under Part 4-4 (conformity assessment certificates); or
- under Part 4-5 (including medical devices in the Register), other than:
    - a decision under section 41FH (selecting applications for auditing); or

    - a decision about which aspects of the matters referred to in paragraphs 41FI(1)(a) and (b) to consider in auditing an application under Subdivision C of Division 1 of Part 4-5; or
- under Part 4-6 (suspension and cancellation from the Register); or
- under Part 4-7 (exempting medical devices from inclusion in the Register); or
- under Part 4-9 (public notification and recovery of medical devices); or
- refusing to grant, or imposing conditions on a grant of, a consent for the purposes of section 41MA or 41MAA (non-compliance with essential principles); or
- under section 42DF, 42DH or 42DI or subsection 42DV(1) or (2).

A decision under the Act to give a notice to a person requiring that person to give information or produce documents to the Secretary is ***not*** an 'initial decision', and therefore cannot be the subject of a request for reconsideration under section 60. Examples include decisions made under:

• subsection 25AA(1B)	• section 32JA
• subsection 26BE(3A)	• section 32JE
• subsection 26BJ(6)	• section 32JF
• subsection 29B(1)	• section 32JG
• subsection 30F(2)	• section 32JH
• section 31	• subsection 37(2)
• section 31A	• subsection 40(6)

• section 31AA	• subsection 40B(10)
• section 31B	• section 41AB
• subsection 32DR(1)	

A decision made under Part 4-8 of the Act, which includes a request for information under section 41JA of the Act, is not an initial decision and cannot be the subject of a request for reconsideration under section 60. Other kinds of decisions that are not reviewable initial decisions include:

- refusal of an application (and notice to an applicant of this) because *the application has not passed preliminary assessment*
- notifying an applicant that *an application has not been made in accordance with statutory requirements* (including that the information necessary to allow the application to be assessed has not been provided)
- notifying an applicant that an application made by the applicant was 'not effective', for example, because the application fee has not been paid
- scientific advice from the TGA about aspects of quality, safety or efficacy of medicine
- informing a sponsor that it is *proposed* to suspend or cancel a kind of device included in the Australian Register of Therapeutic Goods.

Therapeutic Goods Regulations 1990 (regulation 48)

In order to be eligible to request reconsideration under regulation 48 of the Therapeutic Goods Regulations, a person must be someone whose interests are affected by a reviewable initial decision. Further, in some cases, the Therapeutic Goods Regulations provide that only certain persons are entitled to request reconsideration of a decision (regulation 48(2AA)).

A decision can only be reconsidered under regulation 48 of the Therapeutic Goods Regulations if it is a decision made under:

- subregulation 10C(3), (5) or (6);
- subparagraph 16J(1)(b)(ii);
- paragraph 16L(3)(b);
- paragraph 16M(1)(b);
- subparagraph 16R(1)(b)(ii);
- subregulation 16T(1);
- subregulation 22(8);
- paragraph 43AAH(4)(b);
- regulation 45;
- regulation 45AA.

Therapeutic Goods (Medical Devices) Regulations 2002 (regulation 10.7)

In order to be eligible to request reconsideration under regulation 10.7 of the Medical Device Regulations, a person must be someone whose interests are affected by a reviewable initial decision. Further, in some cases, the Medical Device Regulations provide that only certain persons are entitled to request reconsideration of a decision (regulation 10.7(3A)-(3B)).

A decision can only be reconsidered under regulation 10.7 of the Medical Device Regulations if it is a decision under:

- subparagraph 4.3C(1)(b)(ii);
- subregulation 4.3E(1);

- subregulation 4.10(2);
- the following provisions (about conformity assessment body determinations):
    - subregulation 4A.6(1);
    - subparagraph 4A.7(3)(a)(i) or (ii);
    - subregulation 4A.7(5);
    - regulation 4A.20;
    - subregulation 4A.22(3);
    - subregulation 4A.23(1);
    - subregulation 4A.26(1);
    - subregulation 4A.27(1);
    - subregulation 4A.28(1);
    - subregulation 4A.29(1);
- subparagraph 5.4B(1)(b)(ii);
- subregulation 5.4D(1);
- the following provisions (about conformity assessment body determination assessment fees):
    - regulation 9.1C;
    - subregulation 9.1D(1);
    - subregulation 9.1F(2);
- paragraph 9.4(2)(a);
- subregulation 9.5(1).

Notification of an initial decision

Under the Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations, notification of an initial decision must generally 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 Australian Register of Therapeutic Goods (ARTG) (the Register)) must also be published in the Gazette or on our website at the time the initial decision is made.

Where **written notice** of the making of an initial decision is given by the Secretary (or an authorised person) to a person whose interests are affected by the decision, the notice must inform the person that the initial decision is a reviewable initial decision and that the person may seek a reconsideration by the Minister and, if dissatisfied with the reconsideration decision, make an application to the Administrative Review Tribunal for review of the reconsideration decision (subject to the *Administrative Review Tribunal Act 2024*). Refer to the Administrative Review Tribunal section.

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 (calendar) days after the notice is given to the person**

OR

- in any other case, within 90 (calendar) days of the publication of the initial decision in the Gazette or on the TGA website OR within 90 (calendar) days of the decision first coming to the person's notice, **whichever is earlier**.

> ***Important:*** *The Minister cannot consider a request for reconsideration made after the abovementioned legislated timeframe of 90 days.*

A request for reconsideration is usually submitted by email. Persons preparing a request for reconsideration are advised to ensure the request addresses the following matters:

- the email '**Subject**' field should state:
  - '<*insert name of person/company making request*> - Request for Reconsideration Under **Section 60** of the *Therapeutic Goods Act 1989*'; or
  - '<*insert name of person/company making request*> - Request for Reconsideration Under **Regulation 48** of the *Therapeutic Goods Regulations 1990*'; or
  - '<*insert name of person/company making request*> - Request for Reconsideration Under **Regulation 10.7** of the *Therapeutic Goods (Medical Devices) Regulations 2002*';
- attach a copy of the initial decision notification letter (or other evidence of notification);
- attach or include a dated and signed statement by the person requesting reconsideration that 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;
- attach or include any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested;

- nominate an email address for the purposes of receiving correspondence in relation to the request for reconsideration.

NOTE: If the notification of an initial decision was not issued to the person who is proposing to seek reconsideration, the request for reconsideration must also include a description of how the person's interests are affected by the initial decision. As noted, in certain cases, the therapeutic goods legislation specify that only certain persons are entitled to request reconsideration of an initial decision. Refer to the 'Reviewable Initial Decisions' section.

Important:

It is important to ensure all information and documentation that you wish the Minister to consider is provided in your email requesting reconsideration. Under the therapeutic goods legislation, the Minister is not able to consider any information that is provided by, or on behalf of, the person making the request after the making of the reconsideration request unless the information is provided in response to a request from the Minister; or (in relation to a reconsideration under section 60) it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Submitting a request for reconsideration

All requests for reconsideration should be **given to the Minister by email** to 'decision.review@health.gov.au'.

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "... - Email 1 of 3", "... - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Upon receipt of an email requesting reconsideration of an initial decision, the TGA sends a written acknowledgement to the person who requested the reconsideration to confirm that their request had been received. The written acknowledgement will:

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

Note:

Where a person whose interests are affected has made a request for reconsideration and does not receive notice of the decision of the Minister on that reconsideration within 60 (calendar) days after making the request[1], the Minister is taken to have confirmed the initial decision.

Important:

As noted in the 'Preparing a request for reconsideration' section, it is important to ensure all information and documentation that you wish the Minister to consider is provided in your email requesting reconsideration. Under the therapeutic goods legislation, the Minister is not able to consider any information that is provided by, or on behalf of, the person making the request after the making of the request for reconsideration 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 may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the TGA with the appropriate delegation.

The Minister (or delegate) **must give notice** in writing of the decision upon reconsideration to the person whose interests are affected, **within 60 (calendar) days after making a request for reconsideration**[2]. The notice will include, amongst other things, a 'statement of reasons' for the reconsideration decision setting out the findings, referring to the evidence or other material on which those findings were based and the reasons for the decision.

Note:

Where a person whose interests are affected has made a request for reconsideration and does not receive notice of the decision of the Minister (or delegate) on that reconsideration within 60 (calendar) days after making the request, the Minister (or delegate) is taken to have confirmed the initial decision.

The Minister (or delegate) will consider all relevant information, including information that was not available to the initial decision maker, in making a decision upon reconsideration. The Minister (or delegate) is not limited to considering issues that were raised in the request for reconsideration, nor is the Minister (or delegate) reviewing the 'lawfulness' of the initial decision of the Secretary or whether the initial decision of the Secretary was right or wrong. The Minister's (or delegate's) focus is what is the correct decision on the material before him or her.

A request for reconsideration of an initial decision by the Minister (or delegate) will result in one of the following outcomes, that is, the Minister (or delegate) will:

- **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 the Section 60A - New information on review - discretion of Minister to remit section).

It is open to the Minister (or delegate) to make a new decision in terms not requested by the person requesting reconsideration. For example, if a person requests that a decision to cancel a product from the Australian Register of Therapeutic Goods (ARTG) (the Register) be revoked (with the effect that lawful supply of the product can resume), the Minister (or delegate) could decide to revoke the cancellation

and substitute it with a decision to impose a condition, relating to the supply of the product, on the inclusion of the product in the Register.

Confirm the initial decision

Where the decision upon reconsideration by the Minister (or delegate) is to 'confirm' the initial decision, the Minister (or delegate) has decided to uphold the initial decision. The initial decision therefore remains unchanged.

It is however possible that upon reconsideration, the Minister (or delegate) may have come to the same conclusion as the initial decision of the Secretary but for different reasons. The Minister (or delegate) 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 the evidence available to the Secretary when making the initial decision).

Revoke the initial decision

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

A decision to revoke an initial decision may be in light of additional information made available to the Minister (or delegate) upon reconsideration of the initial decision. Alternatively, the revocation decision may be made without there being substantial additional information, on the basis that the Minister (or delegate) considers it is the correct outcome for the case.

Revoke and substitute the initial decision with a new decision

Where the decision upon reconsideration by the Minister (or delegate) is to 'revoke and substitute' an initial decision with a new decision, the Minister (or delegate) has decided to vary all or part of the initial decision of the Secretary. The initial decision is therefore partially or entirely substituted (replaced) by a new decision. For instance, the Secretary may have decided not to approve an application. If the Minister's (or delegate's) view is that the correct decision is to approve the application, the Minister (or delegate) can revoke the Secretary's decision and substitute it with a decision to approve the application.

Although the Minister (or delegate) has assessed that the correct decision is to overturn the initial decision and substitute another decision, this may be in light of additional information being made available to the Minister (or delegate) upon reconsideration of the initial decision. Alternatively, the substituted decision may be made without there being substantial new information, on the basis that the Minister (or delegate) considers that is the correct outcome for the case.

Other matters

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 Australian Register of Therapeutic Goods (ARTG) (the Register)) and the Minister (or delegate) 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 Review Tribunal Act 2024*, if a person is dissatisfied with a reconsideration decision made by the Minister (or delegate), an application may be made to the Administrative Review Tribunal (the ART) for a review of the Minister's (or delegate's) decision by the ART. Refer to the Administrative Review Tribunal section.

Section 60A - New information on review – discretion of Minister to remit

Where an initial decision is made by the Secretary under **section 25**, **section 32DF**, **section 32DG** or **section 41EC** of the Therapeutic Goods Act and a person whose interests are affected by the initial decision, provides 'new' information (referred to under the Therapeutic Goods Act as 'initial new information') in support of a request for reconsideration of the initial decision by the Minister (or delegate), the Minister (or delegate) must either:

- take that information into account upon reconsideration of the initial decision; or
- remit the matter to an authorised delegate for a fresh decision.

Under the Therapeutic Goods Act, **'new'** information (i.e. '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 but was not made available to the Secretary for the purpose of making the initial decision and is information that is relevant to that decision.

If the Minister (or delegate) remits the matter to an authorised delegate and the person whose interests are affected has paid a further evaluation or conformity assessment fee as required under the Therapeutic Goods Act, the authorised delegate 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 (or delegate) decides to remit the request for reconsideration, the Minister (or delegate) must notify their decision to do so in writing to the person who made the request. If the person who made the request for reconsideration does not receive notice in writing of the decision of the Minister (or delegate) to remit the matter within 60 (calendar) days of the making of the request for reconsideration [3], the Minister (or delegate) 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 (or delegate). Withdrawal of a request for reconsideration should be notified in writing as soon as possible.

All notifications of a withdrawal of a request for reconsideration should be **given by email to** 'decision.review@health.gov.au'.

Administrative Review Tribunal

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

In accordance with the Therapeutic Goods Act, the Therapeutic Goods Regulations and the Medical Devices Regulations, where written notice of the decision by the Minister (or delegate) upon reconsideration is given to a person whose interests are affected and that person is dissatisfied with the Minister's (or delegate's) decision, the person can, subject to the *Administrative Review Tribunal Act 2024* (the ART Act), make an application to the ART for review of the Minister's (or delegate's) reconsideration decision.

Prior to 14 October 2024, merits review of administrative decisions was undertaken by the Administrative Appeals Tribunal (AAT). All cases that were before the AAT immediately prior to 14 October 2024 were automatically transferred to the new Tribunal. If you are an applicant or another party to a case before the AAT immediately prior to 14 October 2024, you do not need to do anything.

For more information see: Transition to the Administrative Review Tribunal | Administrative Appeals Tribunal (aat.gov.au)

Application for review of a decision upon reconsideration

Information about the ART review process, including how to apply and fees payable, can be found at the ART website

Under the *Administrative Review Tribunal Act 2024* (the ART Act), an application to the Administrative Review Tribunal (the ART) for review of a decision upon reconsideration must be made in writing **within 28 days after the day on which notice of the reconsideration decision is given**, otherwise an extension of time must be sought from the ART.

The ART notifies the Minister (referred to as the respondent) as the person who made the reconsideration decision or, as is more commonly the case, on whose behalf the delegate made the reconsideration decision that an application has been received requesting ART review of the reconsideration decision. The respondent must then lodge a statement of reasons for the reconsideration decision and all documents relevant to the ART's review of the reconsideration decision within 28 days after receiving notice regarding the application for ART review from the ART. These documents are referred to as 'Tribunal Documents' ('T Documents').

Note:

After an application for review of a reconsideration decision is made to the ART, the TGA is unable to vary the reconsideration decision, set aside the reconsideration decision or set aside the reconsideration decision and substitute a new decision, unless the Tribunal remits the decision to the TGA under s 85 of the ART Act. Alternatively, if the parties to a proceeding for review of a decision reach agreement then the Tribunal may make a decision in accordance with those terms under s 103 ART Act. Further information about procedures to these reviews can be found on the ART website.

Section 60A - New information on review - discretion of ART to remit

Where a reconsideration decision is made by the Minister (or delegate) 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 (or delegate's) decision applies to the Administrative Review Tribunal (the ART) for review of that decision and lodges 'initial new' or 'later new' information (or both) in support of that application, the ART may if the ART thinks fit, remit the matter to an authorised person for a fresh (initial) decision.

Note:

A person whose interests are affected by a reconsideration decision made by the Minister (or delegate) 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 matter can be considered afresh.

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 but was not made available to the Secretary for the purpose of making the initial decision and is information that is relevant to that initial decision.

Under the Therapeutic Goods Act, '**later new**' information means information that was in existence at the time the Minister (or delegate) made the reconsideration decision 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 (or delegate) for the purpose of making the reconsideration decision and is information that is relevant to that reconsideration decision.

If the ART decides to remit the matter to an authorised delegate and the person whose interests are affected has paid a further evaluation or conformity assessment fee as required under the Therapeutic Goods Act, the authorised person 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 (or both as the case may be), as if a fresh application had been made.

If the ART decides not to remit the matter to an authorised delegate, where a person whose interests are affected by a reconsideration decision made by the Minister (or delegate) applies to the ART for review of that reconsideration decision and lodges 'initial new' or 'later new' information (or both) in support of that application, the ART cannot consider any 'initial new' information not considered by the Minister (or delegate) 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 ART cannot remit the matter to an authorised delegate for a fresh (initial) decision where a person lodges only 'initial new' information (and not any 'later new' information) to the ART in support of their application, where that ‘initial new’ information was already considered by the Minister (or delegate) in making the reconsideration decision.

Footnotes

1. The making of the request for reconsideration is taken to have been made on the date it is received by the Minister.
2. The making of the 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 (calendar) day period in which the Minister must reconsider the initial decision.
3. The making of the request for reconsideration is taken to have been made on the date it is received by the Minister.

Topics: Regulatory compliance Therapeutic goods regulation

Page history

14 October 2024
Updated information reflecting the abolition of the Administrative Appeals Tribunal and the establishment of the Administrative Review Tribunal

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27 April 2023
Minor editorial changes about initial decisions by a delegate of the Secretary under the *Therapeutic Goods Act 1989*

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30 March 2023
Updated information about initial decisions by a delegate of the Secretary under the *Therapeutic Goods Act 1989*

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1 April 2022
Updated the email address for submission of a request for reconsideration

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1 December 2021
Incorporate reviewable initial decisions made by a delegate of the Secretary under the *Therapeutic Goods Act 1989,* the *Therapeutic Goods Regulations 1990* or the *Therapeutic Goods (Medical Devices) Regulations 2002* (previously a separate webpage on the TGA website).
Updated instructions for submitting a request for reconsideration

20 January 2017
Updated the email addresses for submission of a request for reconsideration

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1 November 2016
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*

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20 May 2016
Updated the address for submission of a request for reconsideration

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7 September 2012
Original publication called 'TGA internal review guideline: The operation of TGA's internal review and how to apply'