Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Guidance for requesting reconsideration of an initial decision

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Contents

Introduction

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

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.

Therapeutic Goods Act 1989 (section 60)

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)).

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)
- subsection 26BE(3A)
- subsection 26BJ(6)
- subsection 29B(1)
- subsection 30F(2)
- section 31
- section 31A
- section 31AA
- section 31B
- subsection 32DR(1)
- section 32JA
- section 32JE
- section 32JF
- section 32JG
- section 32JH
- subsection 37(2)
- subsection 40(6)
- subsection 40B(10)
- section 41AB

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 the TGA website <https://www.tga.gov.au/> 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 Appeals Tribunal for review of the reconsideration decision (subject to the *Administrative Appeals Tribunal Act 1975*). Refer to the *Administrative Appeals 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 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.

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 on that reconsideration within 60 (calendar) days after making the request, the Minister 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 Appeals Tribunal Act 1975*, if a person is dissatisfied with a reconsideration decision made by the Minister (or delegate), an application may be made to the Administrative Appeals Tribunal (the AAT) for a review of the Minister's (or delegate's) decision by the AAT. Refer to the Administrative Appeals 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 Appeals Tribunal

The Administrative Appeals Tribunal (the 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, 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 Appeals Tribunal Act 1975* (the AAT Act), make an application to the AAT for review of the Minister's (or delegate's) reconsideration decision.

Application for review of a decision upon reconsideration

Under the *Administrative Appeals Tribunal Act 1975* (the AAT Act), an application to the Administrative Appeals Tribunal (the AAT) 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 AAT.

Applicants should complete the AAT form available on the AAT website titled '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**'. For more information or assistance, refer to the AAT website <www.aat.gov.au> or contact the AAT on **1800 228 333**.

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

The AAT 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 AAT review of the reconsideration decision. The respondent must then lodge a statement of reasons for the reconsideration decision and all documents relevant to the AAT's review of the reconsideration decision within 28 days after receiving notice regarding the application for AAT review from the AAT. These documents are referred to as 'Tribunal Documents' ('T Documents').

Note:

After an application for review of a reconsideration decision is made to the AAT, 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 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 of AAT 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 Appeals Tribunal (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 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 AAT **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 AAT **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 AAT for review of that reconsideration decision 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 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 AAT **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 AAT 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.

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
V2.2	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	Regulatory Pricing & Decision Review	1 December 2021
V2.3	Updated the email address for submission of a request for reconsideration	Regulatory Pricing & Decision Review	1 April 2022
V2.4	Updated information about initial decisions by a delegate of the Secretary under the *Therapeutic Goods Act 1989*	Regulatory Legal Services Branch	28 March 2023
V2.5	Minor editorial changes about initial decisions by a delegate of the Secretary under the *Therapeutic Goods Act 1989*	Regulatory Legal Services Branch	23 April 2023

Therapeutic Goods Administration

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