Australian Government

Department of Health

Ministerial Discretion Guidelines

June 2021

An electronic version of these Guidelines can be obtained from the Department of the Health website: https://www1.health.gov.au/internet/main/publishing.nsf/Content/pharmaceutical-benefits-scheme-approved-supplier-guides-and-forms

Disclaimer

These Guidelines are designed as a general guide for pharmacists making a request for approval by the Minister for Health and Aged Care under section 90A of the *National Health Act 1953* (Act). It should not be used as a basis for legal interpretation or as a definitive reference.

For more precise and detailed information please consult the relevant sections in the Act and the Explanatory Memorandum.

The Minister and the Australian Government accept no responsibility arising from use of, or reliance on, this document.

Enquiries

Information relating to the Ministerial Discretion process is available on the Department's website or by sending an email to 90Apharmacy@health.gov.au.

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DEFINITIONS

In these Guidelines:

- "Act" means the *National Health Act 1953*;
- "AAT" means the Administrative Appeals Tribunal;
- "application" means an application made under section 90 of the Act for approval to supply pharmaceutical benefits at particular premises which is referred to the Authority to determine whether the requirements of the Pharmacy Location Rules have been met;
- "Authority" means the Australian Community Pharmacy Authority established under section 99J of the *National Health Act 1953* to perform functions under section 99K of the Act;
- "Department" means the Department of Health;
- "Discretionary power" means the discretionary power provided to the Minister for Health and Aged Care under subsection 90A(2) of the Act;
- "Minister" means the Minister for Health and Aged Care;
- "pharmaceutical benefits" means drugs or medicinal preparations for which benefits will be paid by the Commonwealth, in accordance with Part VII of the Act;
- "Pharmacy Location Rules" means the rules determined by the Minister under section 99L of the Act;
- "Request" means a request to the Minister under section 90B of the Act that the Minister exercise the power under subsection 90A(2) of the Act;
- "Secretary" means the Secretary of the Department of Health or their delegate, as the Secretary's responsibilities concerning the approval of pharmacists have been delegated to designated officers within the Department.

1 INTRODUCTION

1.1 The Guidelines

The purpose of these Guidelines is to assist a pharmacist who is considering making a request to the Minister, for approval to supply pharmaceutical benefits at particular pharmacy premises.

A summary of the legislative provisions relevant to the Minister's discretionary power is at Appendix 1.

A flowchart showing the decision-making process is at Appendix 2.

1.2 The Pharmacy Location Rules

The Act provides that the Secretary may approve a pharmacist to supply pharmaceutical benefits at particular premises. The Secretary may only approve a pharmacist if:

a) the Authority has recommended the application be approved; and

b) the pharmacist is permitted under the relevant State or Territory law in which the premises are situated, to carry on a pharmacy business.

In making its recommendations to the Secretary, the Authority must comply with the Pharmacy Location Rules.

1.3 The Minister's discretionary power

The Minister's discretionary power under subsection 90A(2) of the Act only arises in situations where a pharmacist has not been approved by the Secretary to supply pharmaceutical benefits at particular premises, because the requirements of the Pharmacy Location Rules were not met.

The discretionary power enables the Minister to approve a pharmacist to supply pharmaceutical benefits at particular premises in circumstances where the Minister is satisfied that:

a) the Secretary's decision will result in a community[1] being left without reasonable access[2] to pharmaceutical benefits supplied by an approved pharmacist; and

b) it is in the public interest to approve the pharmacist.

The intention of the discretionary power is to enable the Minister to respond on an individual and timely basis in circumstances where the application of the Pharmacy Location Rules has resulted in a community being left without reasonable access to the supply of pharmaceutical benefits and it is in the public interest to grant approval.

When determining whether these two criteria are met, the Minister will have regard to the individual circumstances of each case. The circumstances in which the commercial interests of the pharmacist making the request, or of any other party, are relevant to these criteria are

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[1] *community* means a group of people that, in the opinion of the Minister, constitutes a community; and

[2] *reasonable access*, in relation to the supply of pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister is reasonable.

likely to be limited. The purpose of the legislative scheme is 'not concerned with minimising competition in the pharmaceutical industry but with reducing the Commonwealth's financial burden in providing pharmaceutical benefits while maintaining an acceptable level of community service'.[3]

The Minister's discretionary power cannot be delegated to another person. Any decision regarding the exercise of the discretionary power must be made by the Minister personally.

The Department has responsibility for managing all aspects of requests made to the Minister.

2 MAKING A REQUEST

2.1 When a request can be made to the Minister

The Minister can only consider a request if the Secretary has made a decision not to approve the pharmacist because the application failed to meet the requirements of the Pharmacy Location Rules.

If the pharmacist has initiated proceedings before the AAT or a federal court in respect of a decision by the Secretary not to approve the application, those proceedings must be finalised (i.e. discontinued, withdrawn or dismissed) before a request to the Minister can be made. If such a proceeding is initiated after a request is made, then the request will be taken to have been withdrawn.

2.2 Making a request on the approved form

A request must:

- be made on the approved form
- include all relevant attachments and
- be lodged via the PBS Approved Suppliers Portal PBSApprovedSuppliers.

The request form can be downloaded from the Department's website.

2.3 Making a request on behalf of a pharmacist

If the pharmacist/s making the request is being represented by another person/company a letter of authority, signed and dated by all applicant pharmacist(s), appointing the other person/company to act on behalf of the pharmacist/s in respect of the request, must be provided.

2.4 Timing

A request must be made:

a) Within 30 calendar days after the day the pharmacist is notified of the Secretary's decision to reject an application by the pharmacist (i.e. within 30 calendar days after the day the pharmacist receives the Secretary's letter (see Appendix 3)), or

b) if the pharmacist has applied to the AAT for review of the Secretary's decision - within 30 calendar days after the day:

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[3] *Kong v Minister for Health* (2014) 227 FCR 215, [97], [179], [183]; *Pharmacy Restructuring Authority v Martin* (1994) 53 FCR 589, 597.

(i) the pharmacist is given a copy of the AAT's decision affirming the Secretary's decision, or

(ii) the application has been discontinued, withdrawn or dismissed

c) if the pharmacist has sought an order from a federal court in respect of the Secretary's decision or a decision of the AAT affirming the Secretary's decision – within 30 calendar days after the day:

(i) the court has made an order affirming the Secretary's decision or the AAT's decisions, as the case requires, or

(ii) the court proceeding has been discontinued, withdrawn or dismissed.

When calculating the 30 day time period, the day specified in paragraphs (a) to (c) above will not be included (eg, if a pharmacist receives the Secretary's letter notifying the pharmacist of their decision on 2 August, the 30 day time period begins on 3 August)[4]. If the 30 day time period ends on a Saturday, Sunday or a public holiday in the Australian Capital Territory (ACT), then the request will still fall within the 30 day time period if it is made on the next day that is not a Saturday, Sunday or public holiday in the ACT[5].

A request will be treated as 'made' when it is received by the Department in Canberra via the PBS Approved Suppliers Portal PBSApprovedSuppliers. The time when the request is received will be determined according to Australian Eastern Standard Time or Australian Eastern Daylight Time as observed in the ACT.

Please note: In order to ensure your application is processed within the legislated timeframe, the Department strongly encourages applicant pharmacists to submit their request as soon as practicable after receiving the notice of decision. This is particularly important if the applicant pharmacist's application is found to be invalid in the first instance.

2.5 Mandatory and supporting documents

Mandatory documents

The following documents must be included with the request:

a) a copy of either:

- the letter from the Secretary notifying the pharmacist of the decision to reject the pharmacist's application for approval to supply pharmaceutical benefits (see sample at Appendix 3), or
- the order or decision of the AAT/ a federal court affirming the decision of the Secretary, or
- the notice that the proceeding in the AAT/ a federal court is discontinued, withdrawn or dismissed.

[4] *Interpretation Act 1901* s 36(1)(6))

[5] *Acts Interpretation Act 1901* s 36(2) and (3)(a)

Supporting documents

The following should also be provided in support of the request:

a) evidence of the pharmacist's legal right to occupy the proposed premises

b) evidence that the proposed premises could be used for the operation of a pharmacy under applicable local government and State and Territory laws relating to land development

c) evidence that the proposed premises would be accessible by members of the public (and not restricted to certain members of the public, such as patients of a particular medical centre)

d) a brief summary of the request, including:

- the reason/s the Authority did not recommend the application be approved (refer to the letter from the Authority's secretariat advising the reasons why the application did not satisfy the requirement/s of the Pharmacy Location Rules)
- the applicant's submissions about why the decision of the Secretary to reject the application by the pharmacist to supply pharmaceutical benefits at the proposed premises, will result in a community being left without reasonable access to the supply of pharmaceutical benefits by an approved pharmacist
- the applicant's submissions about why it is in the public interest for the Minister to approve the pharmacist to supply pharmaceutical benefits at the proposed premises

e) a discussion about the community and surrounding area including:

- a description of the area/community in which the proposed pharmacy premises is located
- details about the distance between the proposed pharmacy and other approved pharmacies in the surrounding area
- information about access to the supply of pharmaceutical benefits at other pharmacies and reasons why that may not be considered reasonable
- any relevant geographical or other features in the area surrounding the proposed pharmacy premises that would affect a particular community's access to the supply of pharmaceutical benefits at other approved pharmacies (for example, an unbroken railway line or a large body of water)
- any demographics that may be relevant, including particular subsets of the community for whom local pharmacy access may differ from that of the general population (ensure that the source of any information, such as population data, is properly cited).

3 PROCESSING REQUESTS

3.1 Assessing validity of a request

Upon receipt of a request, the Department will assess the request to determine whether it is valid, specifically if the request:

a) is one for which the discretionary power is available (paragraph 2.1 refers)

b) has been made on the approved form (paragraph 2.2 refers)

c) has been made within the required timeframe (paragraph 2.5 refers)

d) is made in the same name and for the same premises as the rejected application, and

e) includes all of the attachments (paragraph 2.6 refers).

Each request will be issued with an identification number. This identification number will allow the pharmacist making the request, the Department and the Minister to monitor the progress of the request.

The Department will advise the pharmacist making the request, in writing within ten (10) working days of receipt of the request, if the request is valid or invalid.

If the request is valid, the Department will prepare a submission for the Minister's consideration, which will include the request, a summary of the request, and any further information received from the applicant or a third party in response to a notice from the Minister (paragraphs 3.2 and 4.4 refer).

If the request is invalid, the Department will advise the pharmacist in writing, including the reasons why the request is invalid. The pharmacist is then able to resubmit their request to the Department, provided the resubmitted request is made within the 30 day time period as specified above. Please note: In order to ensure your request is processed within the legislative timeframe, the Department strongly encourages all applicant pharmacists to resubmit their request (including the completed request form) via the PBS Approved Suppliers Portal as soon as practicable within the 30 day time period as specified above.

The legislation does not allow for requests to be accepted that are not made within the legislative timeframe.

3.2 Consulting third parties

The Minister (or the Department on behalf of the Minister) may, at any time during the process, seek information from any other party.

The Department will normally allow fourteen (14) days for any other party to provide comments or information relevant to the request.

Any comments provided should be limited to addressing the two criteria referred to in paragraph 1.3 above, or any specific information requested in the notice.

If the information requested of any other party is not provided within the specified timeframe, the Minister is not required to take any further action to obtain the information.

The Minister is not required to (but may) consider any further information provided if it is received outside of the specified timeframe.

Any third party that provided comment on a request will be advised in writing of the Minister's decision after the applicant has been notified of the decision.

4 STAGE 1 – DECIDING WHETHER TO CONSIDER A REQUEST

4.1 Timeframe to decide whether to consider a request

The Minister has three months from the date a valid request is received, in which to decide whether or not to consider the request (stage 1 in the process).

The Minister is not under any legal obligation to consider a request and cannot be compelled to do so. If the Minister does not make a decision within the three month period, they will be taken to have decided not to consider the request.

4.2 Departmental submission (stage 1) to the Minister

The Department will provide the Minister with a submission, which will include the request, a summary of the request, research undertaken by the Department and any further information received from the applicant or a third party in response to a notice issued by the Minister (or the Department acting on behalf of the Minister) (paragraphs 3.2 and 4.4 refer).

4.3 If the Minister decides not to consider a request

If the Minister decides not to consider a request, the Department will advise the pharmacist who made the request, of the Minister's decision in writing, as soon as practicable after the decision (not to consider the request) was made. This includes circumstances where no decision has been made and the Minister is taken to have decided not to consider the request (paragraph 4.1 refers).

The effect of the Minister's decision to not consider the request is that the decision of the Secretary to reject the pharmacist's application for approval to supply pharmaceutical benefits, stands. The pharmacist may then consider seeking a review of the Secretary's decision by the AAT or Federal Court, if they have not already done so.

4.4 If the Minister decides to consider a request

If the Minister decides to consider a request (stage 1), the Department will advise the pharmacist who made the request, of the Minister's decision in writing, as soon as practicable after that decision was made.

The Minister (or the Department acting on behalf of the Minister) may also decide to seek additional information from the pharmacist making the request, or any other third party.

If the information requested of the pharmacist making the request is not provided within the specified timeframe, the Minister may treat the request as having been withdrawn.

5 STAGE 2 – DECIDING WHETHER TO APPROVE A REQUEST

5.1 Timeframe to decide whether to approve a request

The Minister has three months, after deciding to consider a request, in which to decide whether or not to exercise the discretionary power to approve the request (stage 2 in the process).

The Minister is not under any legal obligation to exercise the discretionary power to approve a pharmacist to supply pharmaceutical benefits at particular premises, and cannot be compelled to do so. If the Minister does not make a decision within the three month period, the Minister is taken to have decided not to exercise the discretionary power.

5.2 Departmental submission (stage 2) to the Minister

The Department will provide the Minister with a submission, which will include the request, a summary of the request, research undertaken by the Department and any further information received from the applicant or a third party in response to a notice issued by the Minister (or the Department acting on behalf of the Minister) (paragraphs 3.2 and 4.4 refer).

5.3 If the Minister decides not to approve a request

If the Minister decides not to approve a request (stage 2), the Department will advise the pharmacist who made the request, of the Minister's decision in writing, as soon as practicable after that decision was made.

This includes circumstances where no decision has been made and the Minister is taken to have decided not to approve the request (paragraph 5.1 refers). Any third party that provided comment on a request will be advised of the Minister's decision in writing after the pharmacist who made the request has been notified of the decision.

The effect of the Minister's decision to not approve a request is that the decision of the Secretary to reject the pharmacist's application for approval to supply pharmaceutical benefits, stands. The pharmacist may then consider seeking a review of the Secretary's decision by the AAT or Federal Court, if they have not already done so.

5.4 If the Minister decides to approve a request

If the Minister decides to exercise the discretionary power, the Minister's decision substitutes the decision of the Secretary to reject the pharmacist's application for approval to supply pharmaceutical benefits, with a decision to approve the pharmacist to supply pharmaceutical benefits at the proposed premises.

As soon as practicable after the Minister's decision was made, the Department will notify the pharmacist and the Secretary of the Minister's decision. The Secretary will allocate an approval number to the pharmacist before the pharmacist is then advised in writing of the approval number and the associated administrative processes to be undertaken.

Any third party that provided comment on a request will be advised of the Minister's decision in writing after both the pharmacist who made the request and the Secretary have been notified of the decision.

Appendix 1

LEGISLATION

The Act sets out the legislative basis for the Minister's discretionary power.
Sections 90A - 90E set out the:

i. power to approve a pharmacist to supply Pharmaceutical Benefits Scheme (PBS) medicines at particular premises (section 90A);

ii. circumstances in which the discretionary power is/is not available (section 90A);

iii. conditions that must be satisfied in order for the discretionary power to be exercised (section 90A);

iv. non-compellable nature of the discretionary power (section 90A(5));

v. the form in which a request must be made (subsection 90B(2));

vi. timeframe in which requests must be made (subsection 90B(3));

vii. timeframe in which the Minister will make a decision about whether to consider a request (subsection 90B(4) and 90B(5));

viii. procedures for advising pharmacists of decisions made by the Minister (subsection 90B(6));

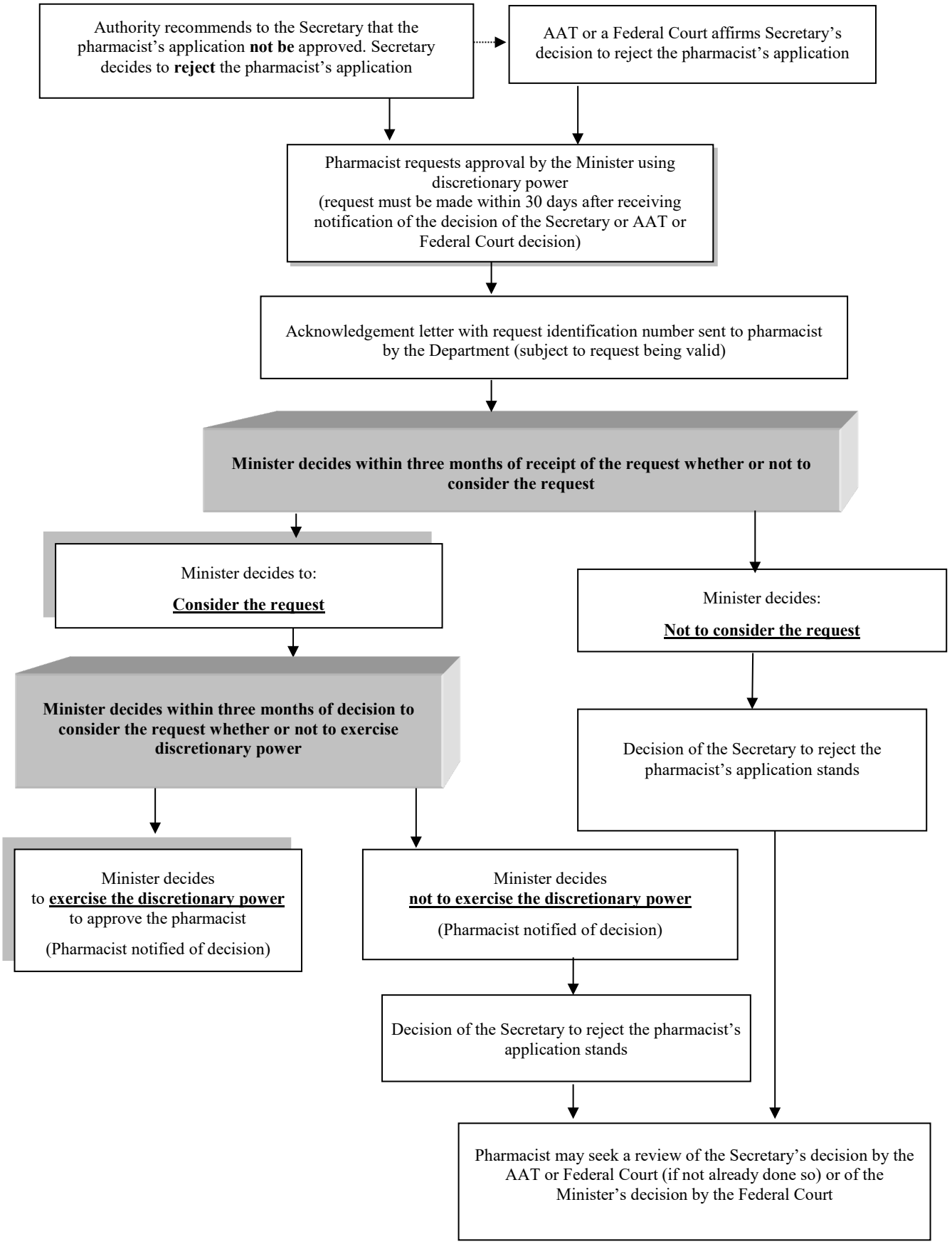
ix. arrangements for dealing with requests where the applicant has sought a review of the decision of the Secretary's delegate (section 90C);

x. arrangements for seeking further information from an applicant (or any other person) to assist in making a decision about a request (section 90D); and

xi. conditions of approval and rights and obligations of approved pharmacists (section 90E).

Appendix 2

MINISTER'S DISCRETIONARY POWER FLOWCHART



Appendix 3

Australian Government
Department of Health

Reference: [application number]

[Applicant Title First Name Surname]
[Applicant Company]
[Applicant address]

Dear [Applicant(s)]

Notification of decision

As the Delegate of the Secretary of the Department of Health (Department), I am writing to inform you that on [date], the Australian Community Pharmacy Authority (Authority) made a recommendation to not approve your application to supply pharmaceutical benefits at [address of proposed premises].

Under section 90(3B) of the *National Health Act 1953* (Act), unless the Authority has recommended the grant of an approval, I have no discretion other than to refuse to grant approval.

Decision
As a Delegate of the Secretary of the Department, under section 90(3B) of the Act, I reject your application to supply pharmaceutical benefits at the above premises.

Review of decisions
Under section 105AB(7) of the Act, an application may be made to the Administrative Appeals Tribunal (AAT) for a review of a decision of the Secretary under section 90 of the Act rejecting an application under that section. Information about making an application to the AAT, including the applicable fees and options for fee waiver refunds, is available at www.aat.gov.au.

If you have any questions, please email to **pbsapprovedsuppliers@health.gov.au** and a departmental officer will contact you.

Yours sincerely

Delegate of the Secretary of the Department of Health
[Date]