



Australian Government

**Department of Health,
Disability and Ageing**

Ministerial Discretion Guidelines 2025

An electronic version of the Guidelines is available on the Department of Health, Disability and Ageing's website

Disclaimer

These Guidelines are a general guide only for pharmacists making a request for approval by the Minister for Health and Ageing under section 90A of the National Health Act 1953 (Act).

The Guidelines should not be used as a basis for legal interpretation or as a definitive reference. For more 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 the use of, or reliance on, this document.

Contact

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DEFINITIONS

In these Guidelines:

- “Act” means the *National Health Act 1953*;
- “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;
- ART” means the Administrative Review Tribunal;
- “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, Disability and Ageing;
- “Discretionary power” means the discretionary power provided to the Minister under subsection 90A(2) of the Act;
- “Minister” means the Minister for Health and Ageing;
- “pharmaceutical benefits” means drugs or medicinal preparations for which benefits will be paid by the Commonwealth, in accordance with Part VII of the Act;
- “Rules” means the Pharmacy Location 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, Disability and Ageing 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

These Guidelines provide information for pharmacists who are considering making a request to the Minister for approval to supply pharmaceutical benefits at a 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 requires that any application from a pharmacist seeking approval to supply pharmaceutical benefits at a particular premises, by establishing a new pharmacy, or relocating an existing pharmacy approved to supply pharmaceutical benefits, is to be considered by the Authority against the requirements of the Rules. The Authority can only recommend to the Secretary that an application be approved if the Authority is satisfied the relevant requirements of the Rules are met. The Secretary can only approve a pharmacist to supply pharmaceutical benefits at a particular premises 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.

1.3 The Minister's discretionary power

The Minister's discretionary power under subsection 90A(2) of the Act only applies if a pharmacist makes a request under section 90B, where that pharmacist has not been approved by the Secretary to supply pharmaceutical benefits at particular premises because the requirements of the Rules were not met.

Under the Act, the Minister can only approve a pharmacist to supply pharmaceutical benefits at particular premises where the Minister is satisfied:

- i. the Secretary's decision will result in a community¹ being left without reasonable access² to pharmaceutical benefits supplied by an approved pharmacist; and
- ii. it is in the public interest to approve the pharmacist.

When making a decision, the Minister will consider the individual circumstances of each request against these two criteria. Commercial interests are generally not considered as 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

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.

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

The Minister's discretionary power cannot be delegated to another person, that is, only the Minister can make a decision under the discretionary powers.

The department manages 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 that relates to a decision by the Secretary to reject an application because it failed to meet the requirements of the Rules.

If the pharmacist has begun proceedings before the ART or a federal court in respect of the Secretary's decision, the proceedings must be finalised (i.e. discontinued, withdrawn or dismissed) before a request to the Minister can be made. If a proceeding is started after a request is made, the request will be deemed withdrawn.

2.2 Timeframe for making a request

A request must be made within the legislated timeframe, that is:

- (a) within 30 calendar days after the day the pharmacist receives the Secretary's Notice of Decision (Notice) to reject an application by the pharmacist (A sample Notice is at Appendix 3), or
- (b) if the pharmacist has applied to the ART for review of the Secretary's decision, within 30 calendar days after the day:
 - i. the pharmacist is given a copy of the ART'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 ART 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 ART's decisions, as the case requires, or
 - ii. the court proceeding has been discontinued, withdrawn or dismissed.

When calculating the 30 day period, the day specified in paragraphs (a) to (c) above will not be included, for example, if a pharmacist receives the Notice on 2 August, the 30 day period begins on 3 August⁴.

If the 30 day period ends on a Saturday, Sunday or a public holiday in the Australian Capital Territory (ACT), the request will still fall within the 30 day time period if it is made on the next business day in the ACT⁵.

A request is considered 'made' when it is received by the department via the [PBS Approved Suppliers Portal](#). The date and time will be recorded according to Australian Eastern Standard Time or Australian Eastern Daylight Time as observed in the ACT.

Please note: The department encourages pharmacists to submit their request as soon as practicable after receiving the Notice. This is particularly important if the pharmacist's request is found to be invalid (paragraph 2.4). Invalid applications may be returned to the pharmacist for resubmission. The resubmitted request must still be made within the 30 day period and be found to be valid to progress to the Minister.

⁴ *Acts Interpretation Act 1901 s 36(1)(6))*

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

2.3 How to make a request

There is no fee for making a request.

A request must:

- be made on the 'Request for Ministerial Approval to supply pharmaceutical benefits at a particular premises' form available on the department's website at www.health.gov.au/pbsapprovesuppliers; and
- include supporting information and evidence; and
- be submitted via the PBS Approved Suppliers Portal at <https://pbsapprovesuppliers.health.gov.au/>.

Required documents

A copy of one of the following documents must be included with the request:

- the Secretary's Notice (see sample at Appendix 3), or
- the order or decision of the ART/federal court affirming the decision of the Secretary, or
- the notice confirming the proceeding in the ART/federal court has been discontinued, withdrawn or dismissed.

Please note, if the applicant/s wishes to appoint an authorised person to act on their behalf, a letter of authority signed and dated by the applicant/s must be included in the request. The department will only correspond with the authorised person for all matters relating to the request.

Supporting documents

The following should also be provided:

- (a) a summary of the request (**no more than 3 pages**) that includes:
 - 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 Rules)
 - a statement outlining why the pharmacist believes the Secretary's decision will result in a community being left without reasonable access to the supply of pharmaceutical benefits by an approved pharmacist
 - a statement outlining why the pharmacist believes it is in the public interest for the Minister to approve the pharmacist to supply pharmaceutical benefits at the proposed premises
- (b) information about the community and surrounding area in which the proposed premises is located including:
 - a description of the community and surrounding area
 - distances between the proposed pharmacy and other approved pharmacies in the surrounding area
 - the current arrangements for the supply of pharmaceutical benefits at other pharmacies and reasons why it may not be considered reasonable for the community
 - any relevant geographical or other features in the surrounding area that would affect the 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 relevant demographics, including subsets of the community for whom local pharmacy access may differ from the general population (information sources, such as population data, must be clearly cited).

- (c) an Australian Securities and Investments Commission (ASIC) company extract/s dated no earlier than 3 months prior to the request being made, where a request is being made by a pharmacist organisation/s,
- (d) evidence of the pharmacist's legal right to occupy the proposed premises
- (e) evidence 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
- (f) evidence the proposed premises would be accessible by members of the public (and not restricted to certain members of the public, for example, being accessible only by patients of a particular medical centre)
- (g) a timeframe and fit out schedule for the proposed premises to be open and trading, if approved, noting that where the Minister grants approval the pharmacist is treated as approved under s90 of the Act in respect of those premises, on the day the Minister's decision is made. It is therefore expected the pharmacist will be ready to trade as soon as possible in should approval be granted.

2.4 Processing requests

Validity check

The department will not process a request that has not been submitted via the PBS Approved Suppliers Portal.

Each request received via the Portal will be given an identification number that will allow the pharmacist, the department and the Minister to monitor the progress of the request.

The department will then assess a request to determine if it is valid. Only valid requests will be progressed to the Minister. For a request to be considered valid, it must:

- (a) be one for which the discretionary power is available (paragraph 2.1)
- (b) be made within the required timeframe (paragraph 2.2)
- (c) be made on the approved form (paragraph 2.3)
- (d) be in the same name and for the same premises as the rejected application, and
- (e) include all the required documents (paragraph 2.3).

Within ten (10) working days of receiving the request, the department will advise the pharmacist in writing if the request is valid or invalid.

If the request is valid, the department will prepare a submission for the Minister, which will include the request, the department's summary of the request, and any further information received from the pharmacist or a third party in response to a notice from the Minister (paragraph 2.5).

If the request is invalid, the department will advise the pharmacist in writing, including the reasons the request is invalid. The pharmacist can resubmit their request provided it is received within the 30-day period as specified in paragraph 2.2. The department will assess the resubmitted request and advise the pharmacist if it is valid or invalid.

Requests made outside the legislated timeframe cannot be accepted, regardless of the circumstances.

2.5 Seeking additional information (section 90D notice)

Under section 90D of the Act, the Minister (or the department on behalf of the Minister) may, at any time during the process, issue a notice in writing to the pharmacist or other parties, such as approved pharmacists in the surrounding area, seeking information that is relevant to the request and/or to the two criteria referred to in paragraph 1.3.

Additional information from the pharmacist

The information requested must be provided within the time specified in the notice otherwise the request may be treated as withdrawn in accordance with subsection 90D(2) of the Act. The Minister is not required to take any action to obtain the information if it is not received.

Additional information from third parties

The Minister is not required to seek comment from surrounding pharmacists, however, in general, the department will write to surrounding pharmacies to advise a request has been made and to invite comment against the 2 criteria specified in paragraph 1.3. The department is not required to and cannot guarantee it will notify all the approved pharmacies within the area of the proposed premises.

The identity of the pharmacist making the request will not be disclosed, only the location of the proposed premises.

The Minister is not required to consider information received after the time specified in the notice. The Minister is also not required to consider unsolicited submissions, that is, submissions received from third parties that were not invited to provide comment.

Any third party that was invited to and provided comment will be advised of the Minister's decision after the pharmacist has been notified. Third parties who believe they are affected by the Minister's decision may be able to seek a review by a federal court. It is recommended they seek independent legal advice before proceeding.

Natural justice

Where either the applicant pharmacist or a third party has made negative claim/s relating to the request or the operations of an approved pharmacist, the department will write to the pharmacist outlining the claims made and providing an opportunity to respond. The claims made and the pharmacist's response will be included in the department's submission to the Minister.

2.6 Department's submission 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 pharmacist or a third party in response to a notice issued by the Minister or the department acting on behalf of the Minister (paragraphs 2.3, 2.4, 2.5).

3 MINISTER'S DECISION

3.1 Timeframe for the Minister's decision

The Minister has four (4) months from the date a valid request is received to decide whether to approve or not approve the request. However, the Minister is not under any legal obligation to consider a request and cannot be compelled to do so. If a decision is not made within the 4 month period, the request will be deemed to be not approved.

Request not approved

If the Minister decides not to approve a request, the department will advise the pharmacist of the Minister's decision in writing, as soon as practicable after the 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.

Where the Minister decides not to approve the request, the Secretary's decision to reject the pharmacist's application stands. The pharmacist may then consider seeking a review of the Secretary's decision by the ART or Federal Court if they have not already done so.

The pharmacist may also seek review of the Minister's decision in the Federal Court. It is recommended they seek independent legal advice before proceeding.

If the Minister decides not to approve a request, the pharmacist may not make another request to the Minister for the same premises within 12 months of making the original request.

Request approved

If the Minister decides to approve a request, the Secretary's decision to not approve the pharmacist will be substituted with the Minister's decision to approve the pharmacist.

Following the Minister's decision, the Secretary will allocate an approval number to the pharmacist, and the pharmacist will be asked to request a deactivation of the approval until the pharmacist can provide evidence they are permitted under the relevant State or Territory law to carry on business as a pharmacist at the proposed premises, and they are ready to trade from the premises. Once evidence of this has been provided to the department, the approval can be activated and claims to supply pharmaceutical benefits can be made.

An approval granted by the Minister is treated the same as an approval granted under section 90 of the Act. That is, the approved pharmacist has the same rights and obligations as any other approved pharmacist. The pharmacist must also comply with any conditions the Minister has attached to the approval.

If a pharmacist subsequently wishes to relocate the pharmacy, they must submit an application for consideration by the Authority against the requirements of the Rules.

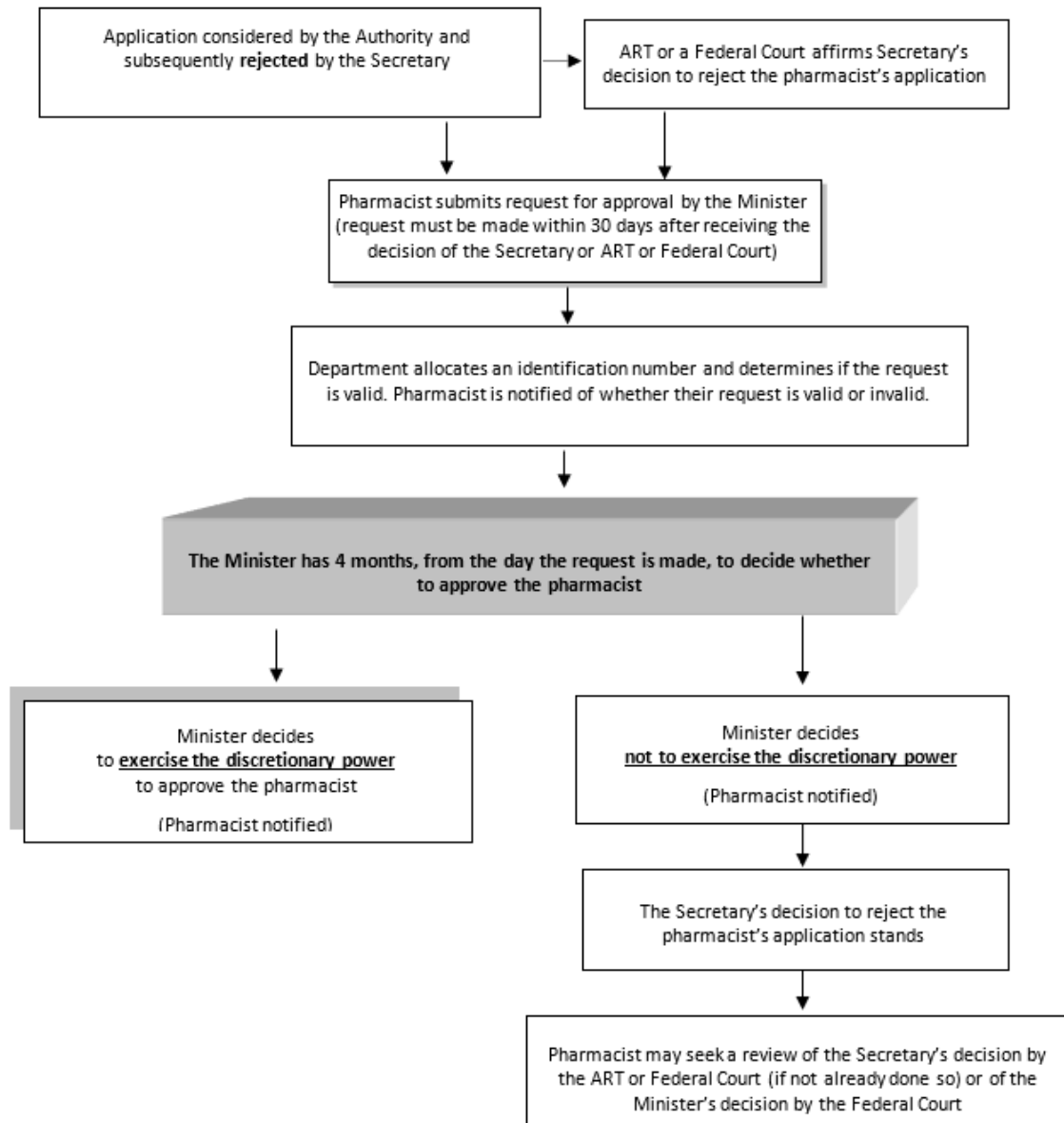
Appendix 1 LEGISLATION

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. the form in which a request must be made (subsection 90B(2));
- v. timeframe in which requests must be made (subsection 90B(3));
- vi. timeframe in which the Minister will make a decision about a request (subsection 90B(5));
- vii. procedure for advising pharmacists of decisions made by the Minister (subsection 90B(6));
- viii. arrangements for dealing with requests where the applicant has sought a review of the decision of the Secretary or their delegate (section 90C), or the same applicant makes a request for the same location within 12 months;
- ix. arrangements for seeking further information from an applicant pharmacist (or any other person) to assist in making a decision about a request (section 90D); and
- x. conditions of approval and rights and obligations of approved pharmacists (section 90E).

Appendix 2 MINISTER'S DISCRETIONARY FLOWCHART

MINISTER'S DISCRETIONARY POWER FLOWCHART



Appendix 3 SAMPLE LETTER



Australian Government

**Department of Health,
Disability and Ageing**

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, Disability and Ageing (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 Review Tribunal (ART) 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 ART, including the applicable fees and options for fee waiver refunds, is available at www.art.gov.au.

If you have any questions, please email pbsapprovesuppliers@health.gov.au.

Yours sincerely

Delegate of the Secretary of the Department of Health, Disability and Ageing

[Date]