

## Approval to supply PBS medicines at a community pharmacy

Any premises that is approved under the relevant State/Territory law to operate as a pharmacy, is able to have prescription medicines dispensed at those premises. However, only those pharmacy premises that are also approved by the Commonwealth, under section 90 of the *National Health Act 1953* (the Act), can operate as a community pharmacy to dispense prescription medicines subsidised under the Pharmaceutical Benefits Scheme (PBS).

As at 30 June 2018 there were 5,723 approved pharmacies in Australia.

All applications for approval to supply PBS medicines at particular pharmacy premises must be made to the Secretary of the Department of the Health (the Secretary). The Secretary has delegated his power, under section 90 of the Act, to specified officers in the Department of Human Services (DHS) (the Secretary's delegate).

The Secretary's delegate must refer all applications involving the establishment of a new pharmacy, or relocation of an existing pharmacy, to the Australian Community Pharmacy Authority (the Authority). The Authority assesses those applications against the requirements of the Pharmacy Location Rules (the Rules) and makes recommendations as to whether or not each application should be approved. Refer to [section 2 and 3](#) for more details regarding the Authority and the Rules.

If a pharmacy is not approved, as a result of its failure to meet the requirements of the Rules, a request can be made to you to approve the pharmacy using your Ministerial discretion power.

### 1. Ministerial Discretion to Approve a Pharmacist

The Fourth Community Pharmacy Agreement provided for an amendment to the Act to give the Minister for Health the power to approve a pharmacist to supply PBS medicines at particular premises.

As Minister for Health, you have the discretionary power to substitute the Secretary's decision, not to approve a pharmacist, with a decision to approve a pharmacist to supply PBS medicines at particular premises.

The intention of your discretionary power is to provide flexibility to respond on an individual and timely basis in unique circumstances where the application of the Rules (refer to [section 2](#)) results in an unforeseen and anomalous situation and a community is left without reasonable access to pharmacy services.

The Act provides that a pharmacist can only request you to exercise your discretionary power after an application has been considered by the Authority (refer to [section 3](#)) and rejected by the Secretary's delegate in DHS.

A pharmacist can lodge a request with the Department of Health, seeking the exercise of your discretionary power, within 30 days of notification by the Secretary's delegate that the application was rejected.

Subsection 90A(2) of the Act provides that

*“the Minister may substitute for the Secretary’s decision a decision approving the pharmacist for the purpose of supplying pharmaceutical benefits at the particular premises if the Minister is satisfied that:*

- (a) The Secretary’s decision will result in a community being left without reasonable access to pharmaceutical benefits supplied by an approved pharmacist; and*
- (b) It is in the public interest to approve the pharmacist.”*

Under the Act, ‘reasonable access’ means access that, in the opinion of the Minister is reasonable and, ‘community’ means a group of people that, in the opinion of the Minister, constitutes a community. ‘Access’ is not defined in the Act and it may be appropriate to refer to the *Macquarie Concise Dictionary*: *‘The act or privilege of coming, admittance, approach, the way, means, or opportunity of approach’.*

Section 90D of the Act provides that you may write to any other person advising of the request and invite comments on, or information or documents relevant to, the request within a specified period. Several officers in the Department have delegation to perform this function on your behalf. However, under the secrecy provisions specified in section 135A of the Act, further details related to a particular Ministerial Discretion request cannot be divulged to a third party.

**A flow chart outlining the Ministerial Discretion process, including reference to relevant provisions under the Act, is at the end of this attachment.**

#### *Principles of administrative law*

When making your decision you should be aware that the following principles of administrative law will apply and may (if not followed) leave your decision subject to judicial scrutiny:

- if you take into account factors that ought not to have been taken into account (irrelevant considerations);
- if you fail to take into account factors (relevant considerations) that ought to have been taken into account; or
- if your decision is so unreasonable that no reasonable person would have made that decision.

#### *Relevant considerations*

The matters to which you may have regard in deciding whether a community has reasonable access to the supply of pharmaceutical benefits by an approved pharmacist, and if the approval of a pharmacist is in the public interest, include:

- i the objectives of the Rules as provided in the Sixth Community Pharmacy Agreement;
- ii the policy underlying the Rules;
- iii the reasons why the pharmacist’s application did not meet the requirements of the Rules;
- iv the characteristics and demographics of the community to which the pharmacist proposes to supply pharmaceutical benefits;
- v the community’s current level of access to the supply of pharmaceutical benefits by an approved pharmacist and whether that access is ‘reasonable’; and
- vi any other relevant factors.

### *Irrelevant considerations*

The commercial interests of the pharmacist making the request, or of any other party, are not generally considered to be relevant.

### *Right of Appeal*

The applicant and affected third parties can appeal decisions made by the Authority and/or the Minister.

Under section 13(1) of the *Administrative Decisions Judicial Review Act 1977* (ADJR Act), any "aggrieved party" may seek a Statement of Reasons in relation to your decision. If the stated reasons for your decision do not satisfy the parties, they may choose to exercise further legal options.

If an application by a pharmacist for approval to supply PBS medicines is rejected by the Secretary's delegate in Department of Human Services, after consideration by the Authority, the pharmacist may either appeal the decision to the Administrative Appeals Tribunal (AAT) for an independent review of the Authority's decision, or request the exercise of your discretionary power to approve the pharmacist to supply PBS medicines at the particular premises. A pharmacist can also request you exercise your discretionary power following an unsuccessful appeal to the AAT.

An aggrieved party may appeal a decision to the Federal Court.

## **2. The Pharmacy Location Rules (the Rules)**

The Rules have been established under the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011*.

The Rules allow pharmacists to make application for approval to supply PBS medicines at particular pharmacy premises. There are 14 rules, each applicable to certain circumstances, including the relocation of an existing approved pharmacy (up to 1km), the establishment of a new pharmacy in a facility, such as a large medical centre, shopping centre or private hospital; and for the establishment of an additional pharmacy in a rural/urban locality. Applicants choose to apply under the rule which best suits their circumstances.

Each rule sets out strict location-based criteria that must be satisfied before the Authority can recommend that the pharmacist can be approved.

The specific overall objectives of the Rules are to ensure:

- All Australians have reasonable access to PBS medicines;
- A commercially viable and sustainable network of community pharmacies dispensing PBS medicines;
- Improved efficiency through increased competition between pharmacies;
- Improved flexibility to respond to the community need for pharmacy services;
- Increased local access to community pharmacies for persons in rural and remote regions of Australia; and
- Continued development of an effective, efficient and well-distributed community pharmacy network in Australia.

### **3. Australian Community Pharmacy Authority (the Authority)**

The Secretary's delegate may grant approval to a pharmacist to supply PBS medicines at particular pharmacy premises subject to the application being referred to the Authority, and the Authority recommending the pharmacist be approved because it was satisfied that the application met all requirements of the Rules (refer to section 2).

The Authority is an independent statutory authority established under s99J of the Act. The Authority comprises six members. All members are appointed by the Minister for Health except the departmental member, who is appointed by the Secretary. Members appointed by the Minister are appointed for up to a two-year term and are eligible for reappointment for a further term.

The Authority meets monthly to assess applications against the requirements of the Rules and makes recommendations as to whether an applicant should be approved. Following each meeting, the Authority's secretariat, located in the Department of Health, informs DHS in writing of the decision made by the Authority in respect of each application. DHS in turn advises each applicant of the outcome.

## MINISTER'S DISCRETIONARY POWER OVERVIEW

