



805-1268.



**The Hon Tanya Plibersek MP  
Minister for Health  
Minister for Medical Research**

The Hon John Murphy MP  
Chair  
Standing Committee on Petitions  
Parliament House  
CANBERRA ACT 2600

Dear Mr Murphy

Thank you for your letter of 20 June 2013 (ref. 805/1268) inviting my response to a petition submitted to the Standing Committee on Petitions, requesting that I exercise Ministerial Discretion to approve an additional pharmacy in Leeton, New South Wales.

Before I can decide whether or not to exercise my discretionary power under section 90A of the *National Health Act 1953* (the Act), a formal request must be made by a pharmacist. A request may be made only if the pharmacist's application, under section 90 of the Act, for approval to supply Pharmaceutical Benefits Scheme (PBS) medicines at particular pharmacy premises, has been rejected because it failed to satisfy the criteria specified in the Pharmacy Location Rules (the Rules). The criteria in the Rules aim to ensure access for all Australians to a well distributed network of community pharmacies, including in rural and remote areas.

The discretionary power is designed to address exceptional circumstances where there are unintended consequences of the Rules. I can only exercise my discretionary power to approve a pharmacist under the Act if I am satisfied that a decision to not approve a pharmacist will result in a community being left without reasonable access to PBS medicines, and it is in the public interest to do so.

I have recently received a request from a pharmacist seeking that I exercise my discretionary power to approve an additional pharmacy in Leeton. The terms of the petition will be taken into account during my consideration of the request.

Enclosed is a fact sheet on the process of the Australian Community Pharmacy Authority, the Pharmacy Location Rules and Ministerial Discretion, for your information.

Once again, thank you for writing.

Yours sincerely

**Tanya Plibersek**

15.7.13

Encl

## **Fact Sheet - Australian Community Pharmacy Authority, the Pharmacy Location Rules and the Ministerial Discretion power**

### **Australian Community Pharmacy Authority**

All applications to supply Pharmaceutical Benefits Scheme (PBS) medicines at particular pharmacy premises made under section 90 of the *National Health Act 1953* (the Act) are considered by the Australian Community Pharmacy Authority (the Authority).

The Authority is an independent statutory authority established under s99J of the Act.

The Authority meets monthly to assess applications against the requirements of the Pharmacy Location Rules (the Rules) and recommends whether or not an applicant should be approved to supply PBS medicines.

Applications must be made to Medicare (within the Department of Human Services), before being referred to the Authority.

There are three types of decisions the Authority can make in relation to each application – recommend approval, not recommend approval or defer a decision on the application to the next meeting subject to further evidence being provided.

Following each meeting, the Authority's Secretariat informs Medicare in writing of the decision made by the Authority in respect of each application. Medicare in turn advises the applicant of the outcome. If the Authority has recommended that an application not be approved, the Authority will also advise the applicant and include reasons for the decision.

### **The Pharmacy Location 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 establish a new or relocate an existing approved pharmacy.

The Rules set out strict location-based criteria that must be satisfied before the Authority can recommend that the pharmacist can be approved.

There are 11 Rules, each applicable to certain circumstances, including the establishment of pharmacies in large medical centres, shopping centres and rules for additional pharmacies in rural and urban contexts. Applicants choose to apply under the Rule which best suits their circumstances.

The specific overall objectives of the Rules are to ensure:

- All Australians have 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.

### **Ministerial Discretion to approve a pharmacist**

The aim of the Ministerial Discretion provision of the Act is to address any unintended consequences of the Rules.

A pharmacist can only request the Minister to exercise her discretionary power after an application has been considered by the Authority and rejected by the Secretary's delegate. A pharmacist is able to lodge a request for the Minister to exercise her discretionary power within 30 days of notification of the Secretary's decision to reject the application.

Under subsection 90A(2) of the *National Health Act 1953* (the Act), the Minister may only exercise her discretionary power if she is satisfied that:

- (a) the decision by the Secretary's delegate 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, the Minister has **three months** from the date the request is received to decide whether or not to consider the request. During this period, the Minister (or the Department acting on behalf of the Minister) may seek additional information from the pharmacist making the request, or from any other party.

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

If the Minister decides to consider a request, she has a further **three months** (after making that decision) to decide whether or not to exercise the discretionary power. During this period, the Minister (or the Department acting on behalf of the Minister) may seek additional information from the pharmacist making the request, or from any other party.

If the Minister exercises her discretion, she substitutes the delegate's decision with a decision to approve the applicant to supply pharmaceutical benefits at the premises.

Medicare is then able to issue an approval number to the applicant, who will liaise with Medicare about the date when they will open their pharmacy.

Details of individual applications for Ministerial Discretion can not be divulged to any third party as they are covered under the secrecy provisions in section 135A of the Act.