

## EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health and Ageing

### *National Health Act 1953*

#### **National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2007 (No. 1)**

Section 90 of the *National Health Act 1953* (“the Act”) provides for the Secretary to approve a pharmacist to supply pharmaceutical benefits at or from particular premises.

Subsection 90(3A) of the Act requires applications to establish a new pharmacy or relocate an existing pharmacy to be referred to the Australian Community Pharmacy Authority (“the Authority”). The Authority is the body, established under section 99J of the Act, which considers applications and makes recommendations to the Secretary as to whether or not a pharmacist should be approved in respect of particular premises.

In making recommendations in relation to applications, the Authority must comply with the rules determined by the Minister under subsection 99L(1) of the Act (“the Pharmacy Location Rules”). In accordance with the *Legislative Instruments Act 2003*, all legislative instruments are subject to disallowance.

From 1 July 2006, the Minister has a discretionary power under section 90A of the Act to approve a pharmacist where the Secretary has made a decision to reject an application by a pharmacist for approval to supply pharmaceutical benefits at or from particular premises. The application must have been made on or after 1 July 2006, and the Minister must be satisfied that the application of the Pharmacy Location Rules under section 99L results in a community being left without reasonable access to pharmaceutical benefits, and that it is in the public interest to approve the pharmacist.

The *National Health (Australian Community Pharmacy Authority Rules) Determination 2006* introduced new rules under subsection 99L(1) of the Act from 1 July 2006 arising from the Fourth Community Pharmacy Agreement, which operates until 30 June 2010.

#### **Effect of Amendments**

The *National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2007 (No. 1)* (this Determination) addresses the issue of “clustering” of pharmacies which can result when pharmacists “backfill” a pharmacy in a large shopping centre or private hospital (backfilling is described below). This Determination also clarifies the intention of the Pharmacy Location Rules by requiring the applicant to have a legal right to occupy the premises at the time of application and at the time the Authority makes its recommendation; it also ensures consistency between an approval granted by the Secretary under section 90 of the Act and an approval granted by the Minister under section 90A of the Act, using his or her discretionary power.

### **Clustering of pharmacies outside large shopping centres and private hospitals**

Shopping centre “backfilling” occurs where a pharmacist relocates a pharmacy a short distance (up to 1.5km) out of a shopping centre, medical centre or private hospital and then relocates another pharmacy into the vacated site in the shopping centre, medical centre or private hospital. Most of the Pharmacy Location Rules are subject to specific distance requirements between the proposed premises and other approved premises. The distance requirements are intended to ensure that there is a well distributed network of community pharmacies in Australia. However, neither the rule relating to short relocation out of the shopping centre, medical centre or private hospital nor the rule relating to the relocation into the vacated site in the large shopping centre or private hospital, is subject to any distance requirements between the proposed premises and other approved premises. In practice, this means that pharmacies can relocate out of a shopping centre, medical centre or private hospital irrespective of other existing pharmacies in the location and can result in a “cluster” of pharmacies outside the shopping centre, medical centre or private hospital in an area which may already be well serviced by existing pharmacies. This is inconsistent with the objectives of the Pharmacy Location Rules.

This issue was addressed for pharmacists applying to relocate into a shopping centre (small or large), medical centre or private hospital after 1 July 2006, by preventing a subsequent relocation of less than 1.5km out of the shopping centre, medical centre or private hospital, unless there are exceptional circumstances. As the rules relating to relocations into small shopping centres (item 109) and medical centres (item 112) were only introduced from 1 July 2006, there is no need for this Determination to further address the issue of clustering as it has already been adequately covered from 1 July 2006.

This Determination further addresses the issue of clustering of pharmacies by requiring that, if a pharmacy is located in a large shopping centre or private hospital and an application is made to relocate that pharmacy a short distance (less than 1.5km) from the existing premises in the shopping centre or private hospital, then the proposed premises must be at least 500 metres (by straight line) from any other approved premises outside the shopping centre or private hospital.

This Determination incorporates a provision to protect the interests of those pharmacists who have made a commercial commitment (for example, a signed lease) prior to the introduction of the amendment.

### **Amendment to require legal right to occupy premises**

When a pharmacist makes an application under the Pharmacy Location Rules to establish a new pharmacy or relocate an existing pharmacy, the pharmacist is required to provide evidence of his or her legal right to occupy the proposed premises (for example, a signed lease), as well as evidence that the proposed premises can be used for the purpose of operating a pharmacy (under the applicable local, State or Territory government laws relating to land development). This Determination clarifies that this requirement must be satisfied both at the date the application is made, and on the date that the application is considered by the Authority.

### **Minister’s decision under section 90A**

If the Minister approves a pharmacist, using his or her discretionary power under section 90A, it is not clear that the approved pharmacist is subject to the requirements of Schedule 3, Part 2 of the Pharmacy Location Rules, which sets out additional requirements that apply to

certain kinds of relocations. This has caused an unintended inconsistency between an approval granted by the Secretary under section 90 and an approval granted by the Minister under section 90A of the Act. This Determination will provide consistency as the requirements of Schedule 3, Part 2 of the Pharmacy Location Rules must be met for an approval granted by the Secretary under section 90 and an approval granted by the Minister under section 90A.

Details of the amendments are provided in the Attachment.

### **Consultation**

The Department of Health and Ageing has consulted on the proposed changes with Medicare Australia, which administers the Pharmaceutical Benefits Scheme program on behalf of the Department, and the Pharmacy Guild of Australia, the body that represents the interests of community pharmacy proprietors. Both Medicare Australia and the Pharmacy Guild of Australia support the proposed changes.

This Determination comes into effect on 27 March 2007 and will apply to applications for approval considered by the Authority after that date.

### **Financial Impact Statement**

There is negligible financial impact from this Determination.

### **Regulation Impact Statement**

As this Determination has low impact on existing pharmacy businesses and does not substantially alter existing arrangements, therefore a Regulatory Impact Statement is not required.

**Details of the National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2007 (No. 1)**

**1. Name of Determination**

Subsection 1(1) provides that this Determination is called the *National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2007 (No. 1)*.

Subsection 1(2) provides that this Determination may also be referred to as Determination No. PB 30 of 2007.

**2. Commencement**

Section 2 provides that this Determination will commence on 27 March 2007.

**3. Amendment of *National Health (Australian Community Pharmacy Authority Rules) Determination 2006***

Section 3 provides that Schedule 1 of this Determination amends the *National Health (Australian Community Pharmacy Authority Rules) Determination 2006*.

**4. Application**

Section 4 provides that this Determination applies to applications considered by the Authority on or after 27 March 2007.

**Schedule 1**

[1] New item 101 broadens the introductory words in paragraph 2(a) to include applications approved by the Minister under section 90A following an application which was made to relocate a pharmacy within the same shopping centre or private hospital. This will ensure that applications under the Act are treated consistently, as applications made to the Minister to substitute the Secretary's decision rejecting an application are subject to the same requirements as applications made to the Secretary.

Item 101 applies to the relocation of an approval within the same small or large shopping centre or private hospital.

The proposed premises must be situated within the same small or large shopping centre or private hospital in which the existing premises are situated where the existing approval was granted following a recommendation by the Authority in relation to the provisions set out in items 109, 110 or 111 (that is, relating to small or large shopping centres or private hospitals) under the Pharmacy Location Rules 2006 or in accordance with the relevant provisions of previous determinations of the Pharmacy Location Rules. This ensures that, at the time the existing approval was granted, the application satisfied the requirements relevant to that kind of application.

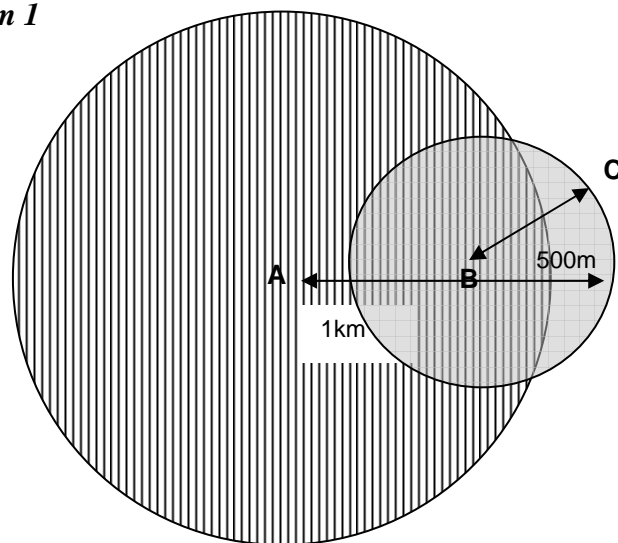
[2] New item 104 provides that, where a pharmacist seeks to relocate a pharmacy a short distance (less than 1 km) from existing premises in a large shopping centre or private hospital, the proposed premises must be at least 500 metres, in a straight line, from any other approved premises outside the shopping centre or hospital (see *Diagram 1* below). This will prevent clustering of pharmacies outside large shopping centres and private hospitals. This

restriction only applies to a pharmacist who wishes to relocate a short distance out of a large shopping centre or private hospital.

Item 104 applies to the short distance relocation of an approval. It requires that the proposed premises are no more than 1 km, in a straight line, from the existing premises. It aims to ensure flexibility for pharmacists to relocate their pharmacies within their local area.

Straight line distance measurements are to be taken at ground level, at the centre of the public entrance door of each relevant premises. If either (or both) of the premises has more than one public entrance, the distance is a reference to the shortest distance measurement in relation to the two premises.

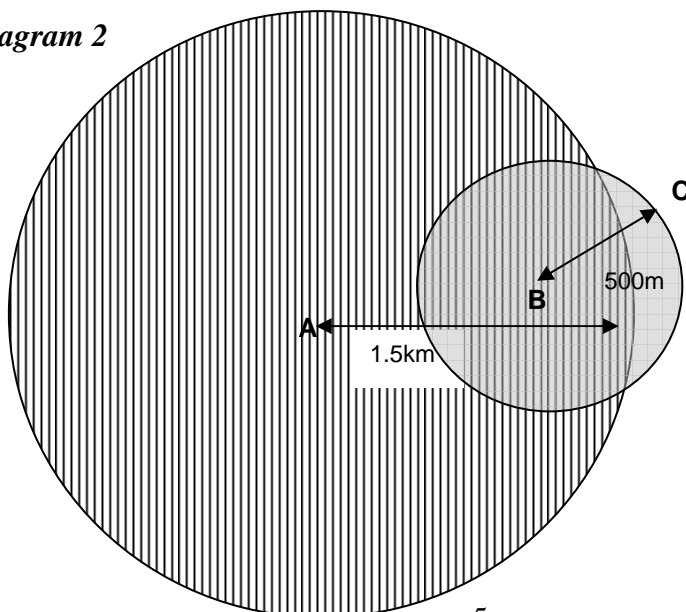
**Diagram 1**



**A** = existing premises in large shopping centre or private hospital  
**B** = proposed premises (less than 1km from existing premises)  
**C** = nearest approved pharmacy  
**B** must be at least 500 m from the nearest approved premises at **C**.

[2] New item 105 provides that, where a pharmacist seeks to relocate a pharmacy a short distance (more than 1 km and less than 1.5km) from existing premises in a large shopping centre or private hospital, the proposed premises must be at least 500 metres, in a straight line, from any other approved premises outside the shopping centre or hospital (see *Diagram 2* below). This will prevent clustering of pharmacies outside large shopping centres and private hospitals.

**Diagram 2**

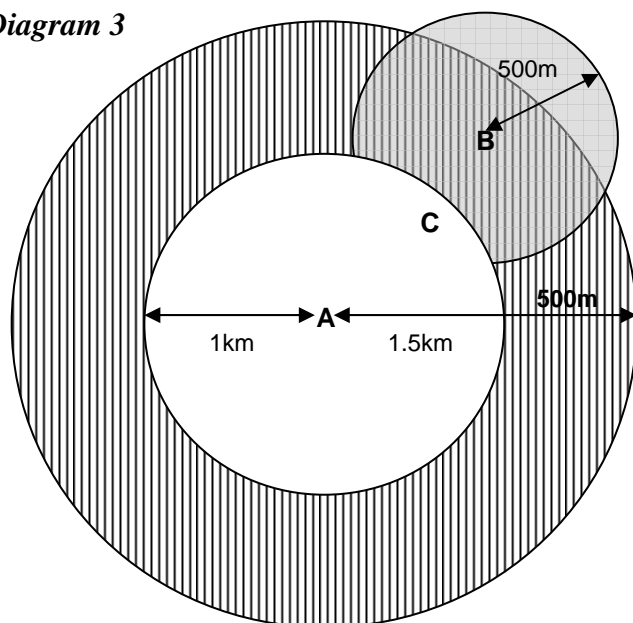


**A** = existing premises in large shopping centre or private hospital  
**B** = proposed premises (less than 1.5km from existing premises)  
**C** = nearest approved pharmacy  
**B** must be at least 500 m from the nearest approved premises at **C**.

Item 105 aims to ensure flexibility for pharmacists to relocate their pharmacies within their local area and, in some instances, to limit the clustering of pharmacies.

If the existing premises are not in a large shopping centre or private hospital, the proposed premises must be at least 500 metres, in a straight line, from any other approved pharmacy, unless the approved pharmacy is less than 1 km, in a straight line, from the existing premises (see *Diagram 3 below*).

**Diagram 3**



**A** = existing premises  
**B** = proposed premises  
**C** = nearest approved pharmacy

**B** must be at least 500 m from the nearest approved premises that is not within the 1 km of the existing premises (**A**).

In this example, **B** does not have to be 500 m from the premises at **C** because **C** is within 1 km of the existing premises (**A**).

Straight line distance measurements are to be taken at ground level, at the centre of the public entrance door of each relevant premises. If either (or both) of the premises has more than one public entrance, the distance is a reference to the shortest distance measurement in relation to the two premises.

## Schedule 2

[3] Amended item 201 provides that the legal right to occupy proposed premises and land development approval must be obtained prior to the date the application is lodged and must remain in effect on the date of the Authority's recommendation.

Schedule 2 sets out the requirements that every application must meet, regardless of whether the application involves the cancellation of an existing approval or not. As required at subparagraphs 9(a)(iii) and 9(b)(iii) of Part 2 of the Determination, an application must meet the requirements of Schedule 2.

Item 201 requires that the Authority be satisfied that the requirements at paragraphs (a), (b), (c) and (d) are met.

Paragraph (a) requires the applicant to have a legal right to occupy the proposed premises.

For example, the applicant may produce a signed lease to demonstrate that he or she is leasing or will be leasing the proposed premises, or may produce a rates notice to demonstrate that he or she owns the proposed premises.

If there is more than one pharmacist making the application, the Authority must be satisfied that each pharmacist has a legal right to occupy the proposed premises.

Paragraph (b) requires that the proposed premises can be used under the applicable local government and State/Territory laws relating to land development for the purpose of operating a pharmacy.

For example, the applicant may produce a notice from their local Council that advises that the permitted use for the proposed premises includes operating a pharmacy, or may produce evidence that confirms that the proposed premises are situated on land which is zoned for retail purposes which includes pharmacy usage.

Paragraph (c) requires that the applicant will be able to begin operating a pharmacy at the proposed premises within six months after the date the Authority makes its recommendation.

The intention of this provision is to improve timely access to the supply of pharmaceutical benefits by ensuring that pharmaceutical benefits will be supplied to the relevant community within six months of the Authority recommending approval of an applicant.

Paragraph (d) requires that the proposed premises are not directly accessible, by the public, from within a supermarket.

### **Schedule 3**

[4] New items 303, 304, 305, 306 and 307 provide that applications approved by the Minister under section 90A of the Act following an application which was rejected by the Secretary are subject to the same requirements under Schedule 3, Part 2 as approvals granted by the Secretary under section 90 of the Act. This will ensure that applications under the Act are treated consistently, as applications made to the Minister to substitute the Secretary's decision rejecting an application are subject to the same requirements as applications made to the Secretary.

Schedule 3 Part 2 applies to certain applications of the kind described in Part 1 of Schedule 1 (that is, certain applications to relocate an existing approval). As required by subparagraph 9(a)(iv) of Part 2, an application described in an item in Part 2 of Schedule 3 must meet the requirements set out in that item.

Item 303 applies to the relocation of an approval granted as a *New pharmacy (rural)* which cannot, under any circumstances, be relocated from the rural locality in which it was granted. That is, the proposed premises must be in the same rural locality as the existing premises. This requirement applies to an approval granted under item 114 or the equivalent provision of a previous determination.

This provision reflects the intention to ensure that pharmacy services are retained in rural localities by requiring that a *New pharmacy (rural)* approval stays in the rural locality in respect of which it was originally granted.

Paragraph (a) provides that the existing approval was granted as a *New pharmacy (rural)*. That is, the existing approval was granted following a recommendation by the Authority in relation to the provisions set out in item 114, or in accordance with the relevant provisions of previous determinations setting out the pharmacy location rules.

Paragraph (b) provides that the existing approval following an application of the kind mentioned in subsection 90(3AA) or 90(3AE) of the Act, that is, a change of ownership or an expansion/contraction (respectively), and that involved the cancellation of the previous approval that was granted in the manner described in paragraph (a).

If the application is of the kind mentioned in Part 1 of Schedule 1 (that is, the relocation of an existing approval) that involves the cancellation of an existing approval that was granted in the manner described in paragraph (a) or (b), the proposed premises must be in the same rural locality as the existing premises.

Item 304 also applies to the relocation of an approval granted as a *New pharmacy (rural)*. If such an approval has subsequently been relocated in accordance with the current or previous Pharmacy Location Rules, the approval still cannot, under any circumstances, be relocated from the rural locality in which it was originally granted. That is, the proposed premises must be in the same rural locality as the existing premises.

This provision reflects the intention to ensure that pharmacy services are retained in rural localities by requiring that a *New pharmacy (rural)* approval stays in the rural locality in respect of which it was originally granted.

Subparagraph (a)(i) provides that the existing approval was granted following the cancellation of an approval granted as a *New pharmacy (rural)*. That is, the existing approval was granted following a recommendation by the Authority in relation to an application of the kind described in item 303.

Subparagraph (a)(ii) provides that the existing approval was granted following the cancellation of an approval that was originally granted as a *New pharmacy (rural)*. That is, the existing approval was granted following a recommendation by the Authority in relation to an application of the kind described in this item (item 304).

Subparagraphs (a)(iii)-(iv) provide that the existing approval was granted following the cancellation of an approval that had been granted following the cancellation of an approval that had been granted as a *New pharmacy (rural)*. That is, the approval being relocated was originally granted as *New pharmacy (rural)* in accordance with the relevant provision of previous determinations of the Pharmacy Location Rules.

Paragraph (b) provides that the existing approval was granted following an application of the kind mentioned in subsection 90(3AA) or 90(3AE) of the Act, that is, a change of ownership or an expansion/contraction (respectively), and that involved the cancellation of the previous approval that was granted in the manner described in paragraph (a).

If the application is of the kind mentioned in Part 1 of Schedule 1 (that is, the relocation of an existing approval) that involves the cancellation of an existing approval that was granted in the manner described in paragraph (a) or (b), the proposed premises must be in the same rural locality as the existing premises.

Item 305 applies to the relocation of an approval granted within a small or large shopping centre, a private hospital or a large medical centre. It provides that any approval granted as a result of the provisions specifically relating to these facilities cannot subsequently undertake



a short distance relocation (see item 104 or 105) unless the Authority is satisfied there are exceptional circumstances.

The provision reflects the intention to stop the practice of “backfilling”, that is, the introduction of an additional approval in a community via a small or large shopping centre, private hospital or large medical centre. It does this by preventing approvals that have been granted within these facilities from relocating a short distance out of the facility, unless there are exceptional circumstances.

Paragraph (a) provides that the existing approval was granted following a recommendation by the Authority in relation to an application of the kind mentioned in item 109 (*Relocation to small shopping centre*), item 110 (*Relocation to large shopping centre*), item 111 (*Relocation to private hospital*) and item 112 (*Relocation to large medical centre*).

Paragraph (b) provides that the existing approval was granted following an application of the kind mentioned in subsection 90(3AA) or 90(3AE) of the Act, that is, a change of ownership or an expansion/contraction (respectively), and that involved the cancellation of the previous approval that was granted in the manner described in paragraph (a).

Paragraph (c) provides that existing approval was granted following a recommendation by the Authority in relation to an application of the kind mentioned in item 101 (*Relocation within shopping centre or private hospital*) and the previous approval was granted in the manner described in paragraph (a) or (b).

If the application is of the kind mentioned in item 104 or 105 (that is, the short distance relocation of an existing approval) that involves the cancellation of an existing approval that was granted in the manner described in paragraph (a), (b) or (c), the Authority must be satisfied that there are exceptional circumstances. An example of exceptional circumstances might include if a shopping centre is being redeveloped and all tenants must be temporarily relocated to sites outside of the centre until the redevelopment is complete and new premises are available within the centre.

Item 306 applies to the relocation of an approval granted as a *New pharmacy (general)* which cannot be relocated more than 1.5 km, in a straight line, from the premises in respect of which the approval was originally granted, that is, the existing premises. This requirement applies to an approval granted under item 113.

This provision reflects the intention to ensure that new approvals that are granted to address a community need remain in that area of need by requiring that a *New pharmacy (general)* approval stays within a 1.5 km radius of the premises in respect of which the approval was originally granted, for a period of five years.

Subparagraph (a)(i) provides that the existing approval was granted as a *New pharmacy (general)*, that is, the existing approval was granted following a recommendation by the Authority in relation to the provision set out in item 113.

Subparagraph (a)(ii) provides that the existing approval was granted following an application of the kind mentioned in subsection 90(3AA) or 90(3AE) of the Act, that is, a change of ownership or an expansion/contraction (respectively), and that involved the cancellation of the previous approval that was granted in the manner described in subparagraph (a)(i).

Paragraph (b) provides that the application is made within five years after the date the approval described at subparagraph (a)(i) was granted.

If the application is of the kind mentioned in Part 1 of Schedule 1 (that is, the relocation of an existing approval) that involves the cancellation of an existing approval that was granted in the manner described in paragraph (a), and is made within the period specified in paragraph (b), the proposed premises must be within 1.5 km, in a straight line, from the existing premises.

Item 307 also applies to the relocation of an approval granted as a *New pharmacy (general)*. If such an approval has subsequently been relocated, the approval still cannot, under any circumstances, be relocated further than 1.5 km, in a straight line, from the premises in respect of which the approval was originally granted. This applies to an approval granted under item 113.

This provision reflects the intention to ensure that new approvals that are granted to address a community need remain in that area of need by requiring that a *New pharmacy (general)* approval stays within a 1.5 km radius of the premises in respect of which the approval was originally granted, for a period of five years.

Subparagraph (a)(i) provides that the existing approval was granted following the cancellation of an approval granted as a *New pharmacy (general)*. That is, the existing approval was granted following a recommendation by the Authority in relation to an application of the kind described in item 306.

Subparagraph (a)(ii) provides that the existing approval was granted following the cancellation of an approval that was originally granted as a *New pharmacy (general)*. That is, the existing approval was granted following a recommendation by the Authority in relation to an application of the kind described in this item.

Subparagraph (a)(iii) provides that the existing approval was granted following an application of the kind mentioned in subsection 90(3AA) or 90(3AE) of the Act, that is, a change of ownership or an expansion/contraction (respectively), and that involved the cancellation of the previous approval that was granted in the manner described in subparagraph (a)(i) or (ii).

Subparagraph (b) provides that the application is made within five years after the date the approval was originally granted as a *New pharmacy (general)*.

If the application is of the kind mentioned in Part 1 of Schedule 1 (that is, the relocation of an existing approval) that involves the cancellation of an existing approval that was granted in the manner described in paragraph (a), and is made within the period specified in paragraph (b), the proposed premises must be within 1.5 km, in a straight line, from the site in respect of which the approval was originally granted as a *New pharmacy (general)*.