

# National Health (Australian Community Pharmacy Authority Rules) Determination 2006

#### National Health Act 1953

I, TONY ABBOTT, Minister for Health and Ageing, make this Determination under subsection 99L (1) of the *National Health Act 1953*.

Dated 21 June 2006

## TONY ABBOTT Minister for Health and Ageing

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### Part 1 Preliminary

#### 1 Name of Determination

- (1) This Determination is the National Health (Australian Community Pharmacy Authority Rules) Determination 2006.
- (2) This Determination may also be cited as Determination No. PB 23 of 2006.

#### 2 Commencement

This Determination commences on 1 July 2006.

#### 3 Revocation

The Pharmaceutical Benefits Determination under subsection 99L (1) made by the Minister on 6 January 2006, also known as Determination No. PB 8 of 2006, is revoked.

#### 4 Application

This Determination applies in relation to the consideration, by the Authority, of an application made on or after 1 July 2006.

#### 5 Transitional

The Pharmaceutical Benefits Determination under subsection 99L (1) made by the Minister on 6 January 2006, also known as Determination No. PB 8 of 2006, as in force immediately before 1 July 2006, continues to apply in relation to the consideration, by the Authority, of an application made before 1 July 2006.

#### 6 Interpretation

(1) In this Determination:

Act means the National Health Act 1953.

application means an application under section 90 of the Act.

*Note* This Determination divides applications for approvals in respect of proposed premises into 2 classes:

- applications that involve the cancellation of an existing approval (see Part 1 of Schedule 1); and
- applications that do not involve the cancellation of an existing approval (see Part 2 of Schedule 1).

approved premises means premises in respect of which an approval granted under section 90 of the Act is in force.

*Note 1* Under paragraph 90E (b) of the Act, references in the Act to an approval granted under section 90 of the Act include references to an approval treated as having been granted under section 90 by paragraph 90E (a) of the Act.

*Note* 2 Under paragraph 91 (7) (c) of the Act, references in the Act to an approval granted under section 90 of the Act include references to an approval treated as having been granted under section 90 by paragraph 91 (7) (a) of the Act.

*commercial establishment* has the meaning given by section 7.

existing approval has the meaning given by paragraph 9 (a).

existing premises has the meaning given by paragraph 9 (a).

large medical centre means a medical centre:

- (a) that is under single management; and
- (b) that operates for at least 55 hours each week.

*large shopping centre* means a shopping centre that:

- (a) has a gross leasable area of at least 5 000 m<sup>2</sup>; and
- (b) contains a supermarket that occupies at least 1 000 m<sup>2</sup>; and
- (c) contains at least 30 other commercial establishments; and
- (d) has customer parking facilities.

**PhARIA** means the Pharmacy Access/Remoteness Index of Australia for 2006/07, prepared by the National Centre for Social Applications of GIS, University of Adelaide, for the Department of Health and Ageing.

pharmacy has the meaning given by subsection 90 (3AB) of the Act.

*prescribing medical practitioner* means a medical practitioner who provides general practice services to the community in which he or she practises, including the issuing of prescriptions for pharmaceutical benefits.

*proposed premises*, in relation to an application, means the premises at or from which an applicant proposes to supply pharmaceutical benefits.

*rural locality* means a locality classified as category 2, 3, 4, 5 or 6 in the PhARIA.

*shopping centre* means a group of shops and associated facilities that is under single management.

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single management, for a shopping centre or medical centre:

- (a) means management of the centre as a whole:
  - (i) by 1 manager, or by 2 or more managers working cooperatively under an agreement; and
  - (ii) to encourage use of the centre as a single integrated facility; and
  - (iii) including management of the following matters for the centre:
    - (A) security;
    - (B) pedestrian and vehicular access;
    - (C) cleaning;
    - (D) signage;
    - (E) trading hours;
    - (F) marketing;
    - (G) maintenance of buildings, common areas and utilities; and
- (b) does not include independent owners or tenants of premises in a building or centre that cooperate:
  - (i) on particular occasions; or
  - (ii) in relation to some but not all of the matters mentioned in subparagraph (a) (iii) in relation to the building or centre.

#### small shopping centre means a shopping centre that:

- (a) has a gross leasable area of at least 5 000 m<sup>2</sup>; and
- (b) contains a supermarket that occupies at least 2 500 m<sup>2</sup>; and
- (c) contains at least 15 other commercial establishments; and
- (d) has customer parking facilities.

*supermarket* means a retail store or market the primary business of which is the sale of a range of food, beverages, groceries and other domestic goods.

*Note 1* **Authority** and **pharmaceutical benefit** are defined in subsection 84 (1) of the Act. **Pharmacist** and **Secretary** are defined in subsection 4 (1) of the Act.

Note 2 **Medical practitioner** and **private hospital** are defined in subsection 3 (1) of the *Health Insurance Act 1973* and have the same meaning in the Act as in the *Health Insurance Act 1973* — see subsection 4 (1A) of the Act.

- (2) In this Determination, in each reference to the nearest approved premises, *approved premises*:
  - (a) includes premises in respect of which the Authority has recommended an applicant be approved under section 90 of the Act; and
  - (b) does not include approved premises if the Authority is satisfied that:
    - (i) the approved premises are existing premises in relation to an application; and
    - (ii) the Authority has recommended that the applicant in respect of the application be approved under section 90 of the Act in respect of the proposed premises in relation to the application; and

- (iii) the pharmacist approved in respect of the existing premises has requested, in writing, that, if the applicant is to be approved in respect of the proposed premises, the existing approval will be cancelled immediately before the approval is granted; and
- (iv) the pharmacist approved in respect of the existing premises has ceased to carry on business as a pharmacist at the approved premises; and
- (v) the Secretary:
  - (A) is aware of the cessation and of the reasons for it; and
  - (B) has agreed to cancel the existing approval only in accordance with a request of the kind mentioned in subparagraph (iii).
- (3) In working out the number of commercial establishments in a shopping centre, 2 or more commercial establishments occupied by, or likely to be occupied by, 1 business are counted as 1 commercial establishment.
- (4) For paragraph (a) of item 302 in Schedule 3, an existing approval in respect of existing premises in a large shopping centre, a private hospital or a rural locality is taken to have been in force for at least 2 years if the pharmacy operating from the existing premises has operated from premises in that large shopping centre, private hospital or rural locality for at least 2 years.

#### 7 Commercial establishments

- (1) In this Determination, subject to subsection (2):
  - commercial establishment means premises:
  - (a) in a shopping centre; and
  - (b) occupied by, or likely to be occupied by:
    - (i) a shop where goods, food or beverages are sold retail; or
    - (ii) a bar, café, restaurant or takeaway; or
    - (iii) a business that provides services to customers.
- (2) For subsection (1), *commercial establishment* does not include:
  - (a) commercial office space; or
  - (b) premises occupied by an accountant, analyst, architect, engineer, lawyer, planner, real estate agent, stockbroker or surveyor; or
  - (c) premises occupied by an insurance company, agent or broker, unless the premises are occupied as a shopfront for an insurance company; or
  - (d) a council office or government or statutory corporation office or shopfront, other than an Australia Post or Australian Broadcasting Corporation shop or a Medicare shopfront; or
  - (e) a library; or
  - (f) a kindergarten or preschool; or

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- (g) a child care centre or child minding facility, unless the centre or facility is regularly available for use by customers of the shopping centre while the customers are at the shopping centre; or
- (h) a storeroom or storage area; or
- (i) a temporary selling point; or
- (j) an automatic teller machine or automatic dispensing machine.

#### 8 Measurement of distance between premises

- (1) In this Determination, a reference to the distance between 2 premises in a straight line is a reference to the distance, measured in a straight line, from the centre, at ground level, of the public entrance of the first premises to the centre, at ground level, of the public entrance of the second premises.
- (2) In this Determination, a reference to the distance between 2 premises by the shortest lawful access route is a reference to the distance, measured by following the shortest lawful access route between the 2 premises, from the centre, at ground level, of the public entrance of the first premises to the centre, at ground level, of the public entrance of the second premises.
- (3) If either premises has more than 1 public entrance, a reference to the distance between the 2 premises is a reference to the shortest such measurement that can be made in relation to the 2 premises.

### Part 2 Recommendations by the Authority

#### 9 When Authority must recommend approval of applicant

The Authority must recommend that an applicant be approved under section 90 of the Act in respect of particular premises if:

- (a) for an application that involves the cancellation of an approval (the *existing approval*) that is in force in respect of approved premises (the *existing premises*):
  - (i) the application states that it is of a kind mentioned in column 2 of an item of Part 1 of Schedule 1; and
  - (ii) the requirements set out in column 3 of that item are met; and
  - (iii) the requirements set out in Schedule 2 and Part 1 of Schedule 3 are met; and
  - (iv) for an application described in column 2 of an item of Part 2 of Schedule 3 the requirement set out in column 3 of that item is met; and
- (b) for an application to which paragraph (a) does not apply:
  - (i) the application states that it is of a kind mentioned in column 2 of an item of Part 2 of Schedule 1; and
  - (ii) the requirements set out in column 3 of that item are met; and
  - (iii) the requirements set out in Schedule 2 are met.

#### 10 When Authority must recommend applicant not be approved

The Authority must recommend that an applicant not be approved under section 90 of the Act in respect of particular premises if a requirement that, under paragraph 9 (a) or (b), applies in relation to the application is not met.

# Schedule 1 Kinds of applications, and requirements in relation to those applications

(section 9)

## Part 1 Applications involving cancellation of existing approval

Item	Kind of application	Requirements
101	Relocation within	1. The proposed premises are in the same large or small shopping centre or private hospital as the existing premises.
101		
		of 1995 made on 14 December 1995; or  (viii) in accordance with section 7 of Determination No. PB 6 of 1995 made on 2 May 1995; or
		(ix) in accordance with paragraph 3 (eaa) or (eab) of Determination No. PB 9 of 1993 made on 8 July 1993; or
		(x) in accordance with paragraph 3 (eaa) or (eab) of Determination No. PB 6 of 1993 made on 22 April 1993; or
		(b) following an application:
		(i) of a kind mentioned in subsection 90 (3AA) or (3AE) of the Act; and
		(ii) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in paragraph (a).

Item	Kind of application	Requirements		
102 Relocation within rural locality		1. The proposed premises are in the same rural locality as the existing premises.		
		2. The proposed premises are at least 10 km, by the shortest lawful access route, from the nearest approved premises other than the existing premises.		
103	Expansion or	The application:		
	contraction	(a) is of the kind mentioned in subsection 90 (3AE) of the Act; and		
		(b) has been referred to the Authority under subsection 90 (3AF) of the Act.		
104	Short distance relocation (1 km)	The proposed premises are no more than 1 km, in a straight line, from the existing premises.		
105	Short	The proposed premises:		
	distance relocation	(a) are more than 1 km, but not more than 1.5 km, in a straight line, from the existing premises; and		
`	(more than 1 km)	(b) are at least 500 m, in a straight line, from all approved premises other than approved premises that are no more than 1 km, in a straight line, from the existing premises.		
106	Long	The proposed premises are:		
	distance relocation	(a) at least 1.5 km, in a straight line, from the nearest approved premises; or		
		(b) if paragraph (a) does not apply — at least 2 km, by the shortest lawful access route, from each approved premises that is within 1.5 km, in a straight line, from the proposed premises.		
107	Relocation to	1. The proposed premises are in a rural locality.		
	rural locality (additional pharmacy)	2. Either:		
		(a) the proposed premises are at least 200 m, in a straight line, from the nearest approved premises; or		
		(b) the proposed premises are within 200 m, in a straight line, of the nearest approved premises, and:		
		(i) the Authority is satisfied that there is a genuine barrier to access between the proposed premises and each approved premises that is within 200 m, in a straight line, of the proposed premises; and		
		(ii) the proposed premises are at least 200 m, by the shortest lawful access route, from each approved premises that is within 200 m, in a straight line, of the proposed premises.		
		3. The Authority is satisfied that:		
		(a) the resident population of the catchment area for the proposed premises is, for most of the year, at least 8 000; and		

Item	Kind of application	Requirements
		(b) there is the equivalent of at least 4 full-time prescribing medical practitioners practising in the catchment area for the proposed premises; and
		(c) the catchment area for the proposed premises contains 1 approved premises; and
		(d) the pharmacy operating from the approved premises mentioned in paragraph (c) has not, in the 3 years before the date the application is made, been involved in an amalgamation with a pharmacy that had operated from other approved premises in the same rural locality, other than an amalgamation that occurred on or after 1 July 2006.
108	Relocation to	1. The proposed premises are not in a rural locality.
	urban locality	2. Either:
	(additional pharmacy)	(a) the proposed premises are at least 500 m, in a straight line, from the nearest approved premises; or
		(b) the proposed premises are within 500 m, in a straight line, from the nearest approved premises, and:
		(i) the Authority is satisfied that there is a genuine barrier to access between the proposed premises and each approved premises that is within 500 m, in a straight line, of the proposed premises; and
		(ii) the proposed premises are at least 500 m, by the shortest lawful access route, from each approved premises that is within 500 m, in a straight line, of the proposed premises.
		3. The Authority is satisfied that:
		(a) the resident population of the catchment area for the proposed premises:
		(i) is, for most of the year, at least 8 000; and
		(ii) has grown at least 5% in each of the 2 years before the date the application is made; and
		(b) the catchment area for the proposed premises contains 1 approved premises.
109	Relocation to	1. The proposed premises are in a small shopping centre.
	small shopping	2. Either:
	centre	(a) the proposed premises are at least 500 m, in a straight line, from the nearest approved premises; or
		(b) the proposed premises are within 500 m, in a straight line, from the nearest approved premises, and:
		(i) the Authority is satisfied that there is a genuine barrier to access between the proposed premises and each approved premises that is within 500 m, in a straight line, of the proposed premises; and

Item	Kind of application	Requirements
		(ii) the proposed premises are at least 500 m, by the shortest lawful access route, from each approved premises that is within 500 m, in a straight line, of the proposed premises.
		3. There are no approved premises in the shopping centre.
110	Relocation to	1. The proposed premises are in a large shopping centre.
	large shopping	2. There are:
	centre	(a) for a shopping centre that contains at least 30, but fewer than 100, commercial establishments — no approved premises in the shopping centre; or
		(b) for a shopping centre that contains at least 100, but fewer than 200, commercial establishments — no more than 1 approved premises in the shopping centre; or
		(c) for a shopping centre that contains at least 200 commercial establishments — no more than 2 approved premises in the shopping centre.
111	Relocation to private hospital	1. The proposed premises are in a private hospital.
		2. There are no approved premises in the private hospital.
		3. The hospital authority for the private hospital is not approved under section 94 of the Act.
		4. The private hospital is registered or licensed, under the law of the State or Territory in which the private hospital is located:
		(a) to contain at least 150 beds to provide health services to patients; or
		(b) to treat, accommodate or lodge at least 150 patients at any one time.
112	Relocation to	1. The proposed premises are in a large medical centre.
	large medical centre	2. Either:
		(a) the proposed premises are at least 500 m, in a straight line, from the nearest approved premises; or
		(b) the proposed premises are within 500 m, in a straight line, from the nearest approved premises, and:
		(i) the Authority is satisfied that there is a genuine barrier to access between the proposed premises and each approved premises that is within 500 m, in a straight line, of the proposed premises; and
		(ii) the proposed premises are at least 500 m, by the shortest lawful access route, from each approved premises that is within 500 m, in a straight line, of the proposed premises.

Item	Kind of application	Requirements
		3. The Authority is satisfied that:
		(a) on the date the application is made and for the 6 months before that date, the equivalent of at least 8 full-time prescribing medical practitioners have been practising at the centre; and
		(b) the applicant will make all reasonable attempts to ensure that the operating hours of the proposed premises will meet the needs of the patients of the medical centre.

# Part 2 Applications not involving cancellation of existing approval

Item	Kind of application	Requirements
113	New pharmacy (general)	1. The proposed premises are at least 1.5 km, in a straight line, from the nearest approved premises.
		2. The Authority is satisfied that:
		(a) the resident population of the catchment area for the proposed premises is, for most of the year, at least 3 000; and
		(b) there is the equivalent of at least 1 full-time prescribing medical practitioner practising in the catchment area for the proposed premises.
114	New	The proposed premises:
	pharmacy (rural)	(a) are in a rural locality; and
		(b) are at least 10 km, by the shortest lawful access route, from the nearest approved premises.

## Schedule 2 General requirements

(section 9)

Item	Requirement
201	The Authority is satisfied that:
	(a) the applicant has a legal right to occupy the proposed premises; and
	(b) the proposed premises can, under the applicable local government and State or Territory laws relating to land development, be used for the purpose of operating a pharmacy; and
	(c) within 6 months after the date on which the Authority makes a recommendation in respect of the application, the applicant will be able to begin operating a pharmacy at the proposed premises; and
	(d) the proposed premises are not directly accessible by the public from within a supermarket.

# Schedule 3 Requirements for applications involving cancellation of existing approval

(section 9)

#### Part 1 All applications

#### Item Requirement

- The Authority is satisfied that:
  - (a) the pharmacist approved in respect of the existing premises has requested, in writing, that, if an approval is to be granted in respect of the proposed premises, the existing approval will be cancelled immediately before the approval is granted; and
  - (b) if the pharmacist approved in respect of the existing premises has ceased to carry on business as a pharmacist at the existing premises, the Secretary:
    - (i) is aware of the cessation and of the reasons for it; and
    - (ii) has agreed to cancel the existing approval only in accordance with a request of the kind mentioned in paragraph (a).
- The Authority is satisfied that:
  - (a) on the date the application is made, 1 or more approvals in respect of the existing premises have been in force for a total of at least 2 years; or
  - (b) if paragraph (a) does not apply:
    - (i) the proposed premises are in the same private hospital or large shopping centre as the existing premises; or
    - (ii) the existing premises are the only approved premises in a particular rural locality, and the proposed premises are in the same rural locality; or
    - (iii) the purpose of the application is to allow the pharmacy operated by the applicant at the existing premises to move to the proposed premises while the existing premises are renovated or refurbished; or
    - (iv) the proposed premises are renovated or refurbished premises that are the same, or substantially the same, premises previously occupied by the pharmacy operated by the applicant or by the previous owner of the pharmacy; or
    - (v) there are exceptional circumstances; or
    - (vi) both:
      - (A) the application involves the cancellation of an existing approval that was granted following an application of the kind mentioned in subsection 90 (3AE) of the Act; and
      - (B) the existing approval, and the approval the cancellation of which was involved in the application for the existing approval, have been in force for a total of at least 2 years; or

#### Item Requirement

- (vii) the application:
  - (A) is of the kind mentioned in subsection 90 (3AE) of the Act; and
  - (B) has been referred to the Authority under subsection 90 (3AF) of the Act.

Note See subsection 6 (4) in relation to paragraph (a).

### Part 2 Particular applications

Item	Description of application	Requirement	
303	An application involving the cancellation of an existing approval in respect of existing premises in a rural locality, the existing approval for which was granted:	The proposed premises are in the same rural locality	
	(a) following a recommendation by the Authority:	as the existing	
	(i) in relation to an application of the kind mentioned in item 114 of Schedule 1; or	premises.	
	(ii) under paragraph 5 (b) of Determination No. PB 8 of 2006 made on 6 January 2006; or		
	(iii) under paragraph 5 (b) of Determination No. PB 8 of 2000 made on 11 July 2000; or		
	(b) following an application:		
	(i) of a kind mentioned in subsection 90 (3AA) or (3AE) of the Act; and		
	<ul><li>(ii) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in paragraph (a).</li></ul>		
304	An application involving the cancellation of an existing approval in respect of existing premises in a rural locality, the existing approval for which was granted:	The proposed premises are in the same rural locality	
	(a) following a recommendation by the Authority:	as the existing	
	(i) in relation to an application described in item 303; or	premises.	
	(ii) in relation to an application described in this item; or		
	(iii) under section 6 or 7, and in accordance with section 9, of Determination No. PB 8 of 2006 made on 6 January 2006; or		
	(iv) under section 6 or 7, and in accordance with section 9, of Determination No. PB 8 of 2000 made on 11 July 2000; or		
	(b) following an application:		
	(i) of a kind mentioned in subsection 90 (3AA) or (3AE) of the Act; and		
	(ii) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in paragraph (a).		

Item	Description of application	Requirement
305	An application of the kind mentioned in item 104 or 105 of Schedule 1 involving the cancellation of an existing approval in respect of existing premises in a private hospital, small or large shopping centre or large medical centre, the existing approval for which was granted:	The Authority is satisfied that there are exceptional circumstances.
	(a) following a recommendation by the Authority in relation to an application of the kind mentioned in item 109, 110, 111 or 112 of Schedule 1; or	
	(b) following an application:	
	(i) of a kind mentioned in subsection 90 (3AA) or (3AE) of the Act; and	
	(ii) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in paragraph (a); or	
	(c) following a recommendation by the Authority in relation to an application:	
	(i) of the kind mentioned in item 101 of Schedule 1; and	
	<ul><li>(ii) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in paragraph (a).</li></ul>	
306	An application:	The proposed
	(a) involving the cancellation of an existing approval in respect of existing premises, the existing approval for which was granted:	premises are not more than 1.5 km in a straight line
	<ul><li>(i) following a recommendation by the Authority in relation to an application of the kind mentioned in item 113 of Schedule 1; or</li></ul>	from the existing premises.
	(ii) following an application:	
	(A) of a kind mentioned in subsection 90 (3AA) or (3AE) of the Act; and	
	(B) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in subparagraph (i); and	
	(b) that is made within 5 years after the date on which the approval granted following a recommendation by the Authority mentioned in subparagraph (a) (i) was granted.	

Item	Description of application	Requirement
307	An application:  (a) involving the cancellation of an existing approval in respect of existing premises, the existing approval for which was granted:  (i) following a recommendation by the Authority in relation to an application described in item 306; or  (ii) following a recommendation by the Authority in relation to an application described in this item; or  (iii) following an application:  (A) of a kind mentioned in subsection 90 (3AA) or (3AE) of the Act; and  (B) that involved the cancellation of an approval granted following a recommendation by the Authority mentioned in subparagraph (i) or (ii); and	The proposed premises are not more than 1.5 km in a straight line from the premises in respect of which the approval mentioned in paragraph (b) of column 2 was granted.
	(b) that is made within 5 years after the date on which an approval in respect of premises in the catchment area in which the existing premises are located was first granted following a recommendation by the Authority in relation to an application of the kind mentioned in item 113 of Schedule 1.	