EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health and Ageing

National Health Act 1953

National Health (Australian Community Pharmacy Authority Rules) Determination 2011
No. PB 65 of 2011

This legislative instrument determines the pharmacy location rules against which most applications made by pharmacists under section 90 of the *National Health Act 1953* (the Act) must comply. It also revokes the *National Health (Australian Community Pharmacy Authority Rules) Determination 2006* (No. PB 23 of 2006).

Section 90 of the Act provides that the Secretary may, upon application by a pharmacist, approve that pharmacist to supply pharmaceutical benefits at particular premises. The Secretary has delegated this function to the Chief Executive, Medicare.

As required under subsection 90 (3A) of the Act, an application made by a pharmacist under section 90 of the Act, must be referred to the Australian Community Pharmacy Authority (the Authority) and considered against the requirements of the pharmacy location rules (the Rules).

The legislation supporting the operation of the Rules is contained in Division 4B, Part VII of the Act. Division 4B provides for the establishment of the Authority and its functions, and that the Minister must determine the rules against which applications to be approved to supply pharmaceutical benefits under section 90 of the Act, must comply. It also provides at section 99Y that unless sooner repealed, the Division ceases to have effect at the end of 30 June 2015.

The function of the Authority is to consider applications by pharmacists for approval to supply pharmaceutical benefits at particular premises and to make recommendations to the Secretary as to whether or not such applications should be approved. In making its recommendations, the Authority must comply with the Rules determined by the Minister under section 99L in Division 4B, Part VII of the Act.

The Rules relate to the cancellation of an existing approval in respect of particular pharmacy premises (and the relocation of that approval) and the establishment of a new pharmacy approval in respect of particular premises. The Rules describe the circumstances in which the Authority must recommend that a pharmacist be approved under section 90 of the Act in respect of particular premises. The Authority must not recommend approval if the relevant criteria in the Rules are not met.

Applications for approval under section 90 of the Act for a change of pharmacy ownership or to expand or contract pharmacy premises can be approved by the Secretary without a recommendation by the Authority, therefore these kinds of applications are not subject to the Rules. However, the Secretary may, at his or her discretion, refer an application for an expansion or contraction of a pharmacy to the Authority for its recommendation (for example, if an expansion of pharmacy premises was likely to result in a pharmacy being directly accessible from within a supermarket, the Secretary may consider it necessary for the Rules to be applied).

The Secretary may only approve a pharmacist to supply pharmaceutical benefits at particular premises if the Authority has recommended that approval and the pharmacist is permitted under the relevant State or Territory law to carry on business as a pharmacist.

Consultation

In early 2010, the Department commissioned an independent review (the Review) of the Rules made by the Minister in Determination PB No. 23 of 2006.

Urbis Pty Ltd ('Urbis') undertook the Review which was completed in mid 2010. The Review considered opportunities to improve the effectiveness and efficiency of the administration of the Rules, including the application, assessment and appeal processes, the requirement for clarity regarding the Rules or their implementation and the need for flexibility in responding to current health policy reforms and the changing policy environment for community-based primary health care delivery.

Urbis consulted with 17 different organisational or individual stakeholders that have a critical interest in the Rules and also surveyed pharmacists who had previously made section 90 applications under the Rules. The stakeholders included, among others, the Pharmacy Guild of Australia ('the Guild'), the Authority, the Pharmaceutical Society of Australia, the Consumer Health Forum as well as the Department and Medicare Australia. The final report by Urbis on the findings of the Review was accepted by the Minister in October 2010 and subsequently published on the Department's website.

Soon after the Urbis Review report was published, the Department consulted with the Guild, as the representative body for Approved Pharmacists as defined under the Act and a signatory to the Fifth Community Pharmacy Agreement 2010-2015, and with the Authority and Medicare Australia. The Rules contained in this Determination were developed to reflect the findings in the Urbis Review and to address other identified anomalies.

From the time this Determination was signed by the Minister to when it commences on 18 October 2011, pharmacists are being advised about the changes to the Rules and the application process. This is being done through letters sent to pharmacies, pharmacist agents, brokers and stakeholder organisations; pharmacy journal articles; the Guild's communication channels and the Department of Health and Ageing and Department of Human Services (Medicare) websites.

The structure of Determination No. PB 65 of 2011 is at Attachment A. An explanation of the content of the Determination is at Attachment B.

This instrument is a legislative instrument for the purpose of the *Legislative Instrument Act 2003*.

Determination No. PB 65 of 2011 commences on 18 October 2011.

ATTACHMENT A

Structure of Determination No. PB 65 of 2011

Part 1: sets out the provisions that deal with the name of the Determination and its commencement, the revocation of the current determination made under subsection 99L(1), transitional arrangements, interpretation of key terms, meanings of key terms such as measurement of distances between premises and in what circumstances the Authority may consider information provided by an applicant after an application is made.

Part 2: sets out the circumstance in which the Authority must recommend that an applicant be approved and the circumstances in which the Authority must recommend that an applicant not be approved.

Schedule 1: sets out the different kinds of applications and the requirements that must be met for each kind of application.

- Part 1 sets out the kinds of applications that involve the cancellation of an existing approval in relation to particular premises (that is, an expansion or contraction of approved premises or relocation of an existing approval); and
- Part 2 sets out the kinds of applications that do not involve the cancellation of an existing approval, instead these involve the granting of a new approval.

Schedule 2: sets out the requirements that must be satisfied for every kind of application.

Schedule 3: sets out additional requirements that must be met by applications that involve the cancellation of an existing approval (these are known as relocations).

- Part 1 sets out the requirements that involve the cancellation of an existing approval and apply to every application of this kind; and
- Part 2 sets out additional requirements that apply only to certain kinds of relocations.

ATTACHMENT B

Details of the *NATIONAL HEALTH (AUSTRALIAN COMMUNITY PHARMACY AUTHORITY RULES) DETERMINATION No. PB 65 of 2011*

PART 1 – PRELIMINARY

Part 1 of the Determination sets out provisions that deal with the names of the Determination, its commencement, the revocation of the current determination made under subsection 99L(1), transition provisions and interpretation of key terms.

1. Name of Determination

Subsection 1(1) provides that the name of the Determination is the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011*.

Subsection 1(2) provides that the Determination may also be referred to as Determination No. PB 65 of 2011.

2. Commencement

Section 2 states that the Determination will commence on 18 October 2011.

3. Revocation

Section 3 revokes the previous Determination that sets out the current pharmacy location rules, that is, Determination No. PB 23 of 2006.

4. Transitional

Section 4 provides that the Determination that sets out the current pharmacy location rules as in force immediately before 18 October 2011 (Determination No. PB 23 of 2006) will apply to any application for approval made before 18 October 2011.

5. Interpretation

Subsection 5(1) defines the common terms used in the Determination. Some examples are set out below:

"facility"- means a small or large shopping centre, private hospital or large medical centre.

"gross leasable area"- for a shopping centre means the total floor area of the shopping centre excluding loading docks and car parks and for a supermarket means the total floor area of the supermarket excluding loading docks.

"large shopping centre" – means a shopping centre that:

(a) has a gross leasable area of at least 5000 m^2; and
(b) contains a supermarket that occupies a gross leasable area of at least 1000 m^2; and
(c) contains at least 50 other commercial establishments; and
(d) has customer parking facilities.

"single management" – for a shopping centre or medical centre means one or more managers that are cooperatively managing the centre (under an agreement) as a whole, for the purpose of encouraging the use of the centre as a single integrated facility. It would include managing the security, pedestrian and vehicular access, cleaning, signage, trading hours, marketing and maintenance of buildings, common areas and utilities, for the centre.

Single management does not include owners or tenants that cooperate only on particular occasions or only in relation to some (not all) of the matters described above. For example, a group of shop owners in a shopping arcade might only cooperatively manage the promotion of the arcade over the Christmas shopping period or they may cooperatively manage the arrangements for cleaning and maintenance of the arcade, however, each owner individually manages the marketing and trading hours of their own shop. In these circumstances, the requirement of single management would not be met.

"small shopping centre" – means a shopping centre that:

(a) has a gross leasable area of at least 5000 m^2; and
(b) contains a supermarket that occupies a gross leasable area of at least 2 500 m^2; 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. Reference to a *range* of food, beverages, groceries and domestic goods means that it is the type of store in which a person could do their weekly shopping from fresh food (e.g. dairy, meat, bread), pantry items, cleaning products, personal care items and other household staples (e.g. laundry pegs, plastic food wrap). Reference to the *primary business* means that the definition would not extend to a department or variety store that has a deli or café section, nor does it include a farmer's market selling a range of produce.

Note 1 and *Note 2* provide that certain terms that are not defined in this Determination, such as "Authority", "PBS prescriber" and "private hospital" have the same meaning as either in the Act or the *Health Insurance Act 1973*.

Same town

Subsection 5(2) provides that where any reference is made to the proposed premises and an approved premises being in the same town, those premises must be in the same town and postcode. For example, item 132 (*New additional pharmacy – at least 10 km*) of Schedule 1 requires that the proposed premises are in the same town as an approved premises.

Subsection 5(3) provides that where any reference is made to the proposed premises and existing premises being in the same town, those premises must be in the same town and postcode. For example, item 123 (*Relocation within the same town (10 km)*) requires that the proposed premises are in the same town as the existing premises.

6. Meanings of *approved premises* and *redundant premises*

Section 6 provides that the Authority will treat any site in respect of which it has recommended approval of a pharmacist as if it were approved premises and, in certain circumstances, if an approved pharmacist has ceased supplying pharmaceutical benefits at particular premises, the Authority will not treat that site as approved premises.

Subsection 6(1) provides that "approved premises" means premises in respect of which an approval under section 90 of the Act is in force. "Approved premises" includes premises in respect of which the Authority has recommended a pharmacist be approved, even though the pharmacist may not yet be approved to supply pharmaceutical benefits at those premises.

This means that where more than one application is received in respect of the same area, the first application to be recommended for approval by the Authority will be considered for approval by the Secretary to the Department of Health and Ageing (or their delegate). The second application will then be considered by the Authority having regard to the first application that was previously recommended for approval, even though the Secretary (or their delegate) may not yet have approved that application. The Authority's recommendation of the first application may have the effect that the second application will fail to meet the requirements of the Rules. This ensures the sustainability of approved pharmacies by avoiding an oversupply of approved pharmacies in an area that could not sustain both pharmacies if they were approved.

Subsection 6(2) provides that "redundant premises" means premises in respect of which a pharmacist is approved under section 90 of the Act if:

- the pharmacist has ceased supplying pharmaceutical benefits at those premises; and
- the Secretary (or their delegate) has agreed not to cancel the approval under section 98 of the Act; and
- that approval is the subject of an application which has been recommended for approval by the Authority (the approval is being relocated).

Disregarding "redundant premises" will ensure the community has reasonable access to pharmaceutical benefits if another pharmacist makes an application to open a pharmacy in that area. An approved pharmacist may cease supplying pharmaceutical benefits at their approved premises ("redundant premises") in preparation to relocate to new premises, with the agreement of the Secretary (or their delegate). If the redundant premises continued to be treated as approved premises it could cause delays in community access to pharmaceutical benefits in that particular area.

Note 1 is included to assist readers to understand that "approved premises" includes any reference to premises in respect of which a pharmacist has been approved by the Minister under subsection 90A(2) of the Act (the exercise of Ministerial discretion).

Note 2 is included to assist readers to understand that "approved premises" includes any reference to a person that has been granted permission by the Secretary under subsection 91(1) of the Act (to supply pharmaceutical benefits after the death of an approved pharmacist).

7. Meaning of *commercial establishment*

Section 7 makes clear that the meaning of "commercial establishment" is intended to include those premises from which businesses will provide goods and/or services to consumers. It is intended that these types of businesses would attract consumers to a shopping centre.

Subsection 7(1) describes those types of business which the term "commercial establishment" can include and that those businesses described do not need to be operating in

order to be considered "commercial establishments" for the purpose of the Authority considering an application.

Subsection 7(2) specifies those types of businesses which the term "commercial establishment" does **not** include. For example, it does not include commercial office space, or premises occupied by accountants, analysts, architects, engineers, lawyers, planners, stockbrokers, surveyors, unless the premises are occupied as a shopfront; real estate agents or insurance companies, unless the premises are occupied as a shopfront (for example a real estate agency selling or renting homes or NRMA /RACV and Medibank Private); government offices or shopfronts (other than an Australia Post or ABC shop or Medicare or Centrelink shopfronts); carwash or car parking facilities; libraries; child care facilities (unless they regularly provides services to shoppers while they shop at the centre); space used for storage; temporary selling points such as those used for sales or promotions; or ATMs or vending machines.

Subsection 7(3) provides how certain commercial establishments are counted in determining the number in a shopping centre.

Paragraph (a) provides that multiple premises occupied (or likely to be occupied) by the same business are only counted as one commercial establishment. That is, each commercial establishment must be independent of another.

Example of how subsection 7(3)(a) operates:
If a mobile phone business operates (or is likely to operate) from Shop 12 on the ground floor of a shopping centre, and the same business also operates (or is likely to operate) from Kiosk 2C on the 2nd floor, this will only be considered to be one commercial establishment.

Alternatively, two separate coffee shops of the same company that are operated separately (by different franchisees) would be considered to be independent and therefore be counted as two commercial establishments.

Paragraph (b) provides that if the commercial establishments are a shopfront for an accountant, analyst, architect, engineer, lawyer, planner, stockbroker or surveyor, the total number of these types of commercial establishments is limited to one for a small shopping centre and two for a large shopping centre.

8. Measurement of distance between premises

Section 8 describes how the measurement of distances between approved premises is to be undertaken.

Subsection 8(1) describes how a straight line distance is to be measured in respect of two premises. Measurements are to be taken at ground level, at the centre of the public entrance door of each relevant premises.

Subsection 8(2) describes how the distance of the shortest lawful access route is to be measured in respect of two premises. Measurements are to be taken at ground level, at the centre of the public entrance door of each relevant premises.

Subsection 8(3) provides that 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.

Note: measuring distances All measurements in this Determination are to be taken from the mid point at ground level of the public access door nearest to the other specified premises. The method by which measurements must be taken is specified in the relevant items, and is either straight line or shortest lawful access route.

The shortest lawful access route is one generally available to be taken between premises that could reasonably be used by average persons travelling that route. It can be by car, walking or any other legal means of travel, or a combination of these. The route can include travelling through public land such as parks and reserves. It must be one available to most members of the public rather than one catering to persons or groups with specialised needs.

9. Information to be considered by the Authority

Section 9 provides that the Authority may consider information provided in support of an application only if it was given at the time the application was made, or, if the Authority has requested the information.

PART 2 – RECOMMENDATIONS BY THE AUTHORITY

Part 2 of the Determination sets out the circumstances in which the Authority must recommend that an applicant be approved, and the circumstances in which the Authority must recommend that an applicant not be approved.

10. When the Authority must recommend approval of applicant

Section 10 states that, the Authority must recommend approval of an applicant in respect of particular premises, if the application meets the requirements specified in either paragraph 10(a) or 10(b).

Paragraph 10(a) applies to an application involving the cancellation of an existing approval (that is, a relocation).

Subparagraph 10(a)(i) provides that the application must be one of the kinds of application set out in column 2 of Part 1 of Schedule 1. These items are:

Item 121 – *Expansion or contraction*

Item 122 – *Relocation within a facility*

Item 123 – *Relocation within the same town (10km)*

Item 124 – *Short distance relocation (1 km)*

Item 125 – *Short distance relocation (more than 1 km)*

Item 126 – *Long distance relocation*

Item 127 – *Relocation to a population growth area*

Subparagraph 10(a)(ii) provides that the application must meet the requirements associated with that kind of application, as set out in column 3 the item. For example, if the application is, *Short distance relocation (1 km)*, the proposed premises must be no more than 1 km, in a straight line, from the existing premises.

Subparagraph 10(a)(iii) provides that the application must meet all the requirements of Schedule 2 and Part 1 of Schedule 3.

Subparagraph 10(a)(iv) provides that if the application is of a kind described in column 2 of Part 2 of Schedule 3 it must meet the associated requirements set out in column 3 of that Part. This relates to the relocation of certain kinds of approvals which have specific restrictions on them. For example, an approval granted following an application of the kind mentioned in item 134 of Part 2 of Schedule 1 (*New pharmacy in a facility (large shopping centre)* the pharmacy can not move out of the large shopping centre for 10 years, unless there are exceptional circumstances.

Paragraph 10(b) applies to an application that does not involve the cancellation of an existing approval (that is, a new approval).

Subparagraph 10(b)(i) provides that the application be one of the following kinds of application set out in column 2, Part 2 of Schedule 1. These items are:

Item 130 – *New pharmacy (at least 1.5km)*

Item 131 – *New pharmacy (at least 10km)*

Item 132 – *New additional pharmacy (at least 10km)*

Item 133 – *New pharmacy in a facility (small shopping centre)*

Item 134 – *New pharmacy in a facility (large shopping centre)*

Item 135 – *New pharmacy in a facility (private hospital)*

Item 136 – *New pharmacy in a facility (large medical centre)*

Subparagraph 10(b)(ii) provides that the application must meet the requirements associated with that kind of application, as set out in column 3, Part 2 of Schedule 1. For example, if the application is *New pharmacy (at least 10km)*, the proposed premises must be at least 10 km, by the shortest lawful access route, from the nearest approved premises.

Subparagraph 10(b)(iii) provides that the application must meet all the requirements of Schedule 2.

11. When the Authority must recommend applicant not be approved

Section 11 states that the Authority must recommend that an applicant not be approved if an application does not meet the requirements specified in either paragraph 10(a) or 10(b).

SCHEDULE 1 – KINDS OF APPLICATIONS, AND REQUIREMENTS IN RELATION TO THOSE APPLICATIONS

Schedule 1 sets out the different kinds of applications that may be made in relation to an existing approval (see Part 1) or a new approval (see Part 2). It also sets out the requirements relevant to each kind of application. As required by Part 2, section 10 of the Determination, the Authority must recommend that an applicant be approved if it, among other things, meets the relevant requirements set out in column 3 of Schedule 1.

SCHEDULE 1, PART 1 – Applications involving cancellation of existing approval

Part 1 of Schedule 1 applies to applications involving the cancellation of an existing approval, that is, applications to expand or contract existing premises or to 'relocate' an existing approval.

Expansion or contraction

Item 121 applies to the expansion or contraction of approved premises. It requires that the application is of the kind mentioned in subsection 90 (3AE) of the Act, and that it has been referred to the Authority under subsection 90 (3AF) of the Act.

Under subsection 90 (3AE) of the Act, the Secretary is not required to refer an application to the Authority for consideration where it relates to an expansion or contraction of approved premises. However, under subsection 90 (3AF), the Secretary may do so at his or her discretion. For example, the Secretary may decide to refer an application for an expansion of premises to the Authority for consideration if the expansion might result in the premises being directly accessible from within a supermarket, and thereby not meet the requirements set out at paragraph (d) of Item 211 of Schedule 2.

Relocation within a facility

Item 122 applies to the relocation of an approval within the same facility. A facility is defined in subsection 5(1) of this Determination as being a small or large shopping centre or private hospital or large medical centre.

Item 122 requires only that the proposed premises are situated within the same facility as the existing premises.

Relocation within the same town (10km)

Item 123 applies to the relocation of an existing approval within the same town.

Sub-item 1 requires that the proposed premises are situated in the same town in which the existing premises are situated.

Sub-item 2 requires that the proposed premises are at least 10 km, by the shortest lawful access route, from the nearest approved premises (not including the existing premises).

Short distance relocation (1 km)

Item 124 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 and, if the existing premises are in a facility, then the proposed premises must be more than 500 m from all other approved pharmacies (other than the existing premises). It aims to ensure flexibility for pharmacists to relocate their pharmacies within their local area.

Sub-item 1 requires that the proposed premises are no more than 1 km, in a straight line, from the existing premises.

Paragraph 2(a) requires that the existing premises are not in a facility.

Paragraph 2(b) requires that if the existing premises are in a facility, the proposed premises are at least 500 m, in a straight line, from all approved premises other than approved premises in the facility.

The following items, 125, 126 and 127, each contain the same provisions as those contained in items 105, 106 and 108 of Schedule 1, Part 1 of Determination No. PB 23 of 2006. However, the requirement that existed in item 108 that the proposed premises are not in a rural locality has been removed from item 127, in line with changes made to other items in this Determination to no longer require that the proposed premises are in a rural locality or are not in a rural locality (urban). The effectiveness of items 105, 106 and 108 were reviewed in the context of the Urbis Review findings and determined to be no longer relevant due to the complexity of the item and low uptake or the objective of the item for which it was first introduced, has been met.

Items 125, 126 and 127 are included in this Determination to provide pharmacists who, before 18 October 2011, have entered into a legal commitment to occupy proposed premises after 18 October 2011, the opportunity (if relevant) to apply to relocate a pharmacy under one these items before 16 April 2012.

Short distance relocation (more than 1 km)

Item 125 applies to the short distance relocation of an approval to premises which are more than 1km but no more than 1.5km, in a straight line, from the existing premises.

Sub-item 1 requires that the application is made before 16 April 2012.

Sub-item 2 requires that the proposed premises are more than 1 km but no more than 1.5 km, in a straight line, from the existing premises.

Paragraph 3(a) requires that if the proposed premises are not in a private hospital or large shopping centre, the proposed premises must be 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.

Paragraph 3(b) requires that if the existing premises are in a private hospital or large shopping centre, the proposed premises are at least 500 m, by straight line, from all approved premises other than approved premises in the private hospital or large shopping centre.

Sub-item 4 requires that the applicant had before 18 October 2011, a legal right to occupy the proposed premises on or after 18 October 2011.

Long distance relocation

Item 126 applies to the long distance relocation of an approval and requires that the proposed premises are more than 1.5 km, in a straight line, from all approved pharmacies.

Sub-item 1 requires that the application is made before 16 April 2012.

Paragraph 2(a) requires that the proposed premises are at least 1.5 km, in a straight line, from the nearest approved premises.

Paragraph 2(b) requires that if the proposed premises are less than 1.5 km away, in a straight line, from the nearest approved premises, the proposed premises must be at least 2 km, by the shortest lawful access route, from each approved premises that are within 1.5 km (in a straight line) of the proposed premises.

Sub-item 3 requires that the applicant had before 18 October 2011, a legal right to occupy the proposed premises on or after 18 October 2011.

Relocation to a population growth area

Item 127 applies to the relocation of an approval into a catchment area with a single pharmacy.

Sub-item 1 requires that the application is made before 16 April 2012.

Sub-item 2 requires that the proposed premises are at least 500 m, in a straight line, from the nearest approved premises.

Paragraph 3(a) requires that (i) the catchment area for the proposed premises contains a resident population of at least 8,000 for most of the year, and (ii) the population has grown at least 5% in each of the two years before the application was made.

Paragraph 3(b) requires that the catchment area for the proposed premises contains only one approved pharmacy.

Paragraph 3(c) requires that the applicant had before 18 October 2011 a legal right to occupy the proposed premises on or after 18 October 2011.

SCHEDULE 1, PART 2 – Applications not involving cancellation of existing approval

Part 2 of Schedule 1 deals with applications to establish a new pharmacy. These kinds of applications do not involve the cancellation of an existing approval. Five of the seven items that apply to applications to establish a new pharmacy, that is, items 132, 133, 134, 135 and 136, have, in previous determinations setting out the pharmacy location rules, required the relocation of an approval as required in Part 1 of Schedule 1.

New pharmacy (at least 1.5km)

Item 130 applies to applications for a new approval where there is a community need for the supply of pharmaceutical benefits. It aims to address community need by targeting areas which have no local pharmacy and in which there are services and attractions likely to draw a sufficient number of people requiring the supply of PBS medicines, ensuring the viability of a pharmacy in that community.

Sub-item 1 requires that the proposed premises are at least 1.5 km, in a straight line, from the nearest approved premises.

Paragraph 2(a) requires that within 500 m, in a straight line, from the proposed premises there is at least the equivalent of one full-time prescribing medical practitioner and a supermarket with a gross leasable area of at least 1000 m^2.

Note: An explanation of "the equivalent of", "full-time" and "medical practitioner" is provided at item 136, *New pharmacy in a facility (large medical centre).*

Paragraph 2(b) provides that if paragraph (a) does not apply, there is, within 500 m in a straight line from the proposed premises, a supermarket with a gross leasable area of at least 2,500 m^2.

Sub-item 3 provides that the Authority is satisfied that on the day the application is made and on the day the Authority makes a recommendation in respect of the application, the requirements of paragraph 2 (a) or (b), are met.

New pharmacy (at least 10km)

Item 131 aims to address the needs of communities isolated from existing pharmacies, such as in rural and remote areas. It requires only that the proposed premises are at least 10 km, by the shortest lawful access route, from the nearest approved premises.

New additional pharmacy (at least 10km)

Item 132 applies to applications to establish a second pharmacy in a town where there is only one approved pharmacy and the nearest other approved pharmacy is at least 10 km away by the shortest lawful access route. It aims to address community need by targeting single pharmacy towns in which there are services and attractions likely to draw a sufficient number of people requiring the supply of PBS medicines, ensuring the viability of a second pharmacy in that town.

Subparagraph 1(a) requires that the proposed premises are in the same town as an approved premises.

Subparagraph 1(b) requires that the proposed premises are at least 200 m, in a straight line, from the nearest approved premises.

Subparagraph 1(c) requires that the proposed premises are at least 10 km, by the shortest lawful access route, from any approved premises other than approved premises mentioned in paragraph (b).

Paragraph 2(a) and (b) requires that within the same town as the proposed premises there are at least the equivalent of four full-time prescribing medical practitioners and one, or a maximum of two, supermarkets with a combined gross leasable area of at least 2,500 m^2.

Note: An explanation of "same town" is provided at section 10 of Part 1 and an explanation of "the equivalent of", "full-time" and "medical practitioner" is provided at item 136, *New pharmacy in a facility (large medical centre).*

Sub-item 3 requires that the Authority is satisfied that on the day the application is made and on the day the Authority makes a recommendation in respect of the application, the requirements of paragraph 2 (a) and (b), are met.

New pharmacy in a facility (small shopping centre)

Item 133 applies to applications for a new approval in a small shopping centre. It aims to improve pharmacy access for consumers in a shopping centre that are of sufficient size and range of commercial establishments to attract a significant number of residents from the local community and surrounding areas.

Sub-item 1 requires that the proposed premises are situated in a small shopping centre. Shopping centre is defined at subsection 5(1) of Part 1 as a group of shops and associated facilities that is under single management and small shopping centre is defined as a shopping centre, that:

(a) has a total gross leasable area of at least 5,000 m^2; and

(b) contains a supermarket that occupies a gross leasable area of at least 2,500 $m^{2;}$ and

(c) contains at least 15 other commercial establishments; and

(d) has customer parking facilities.

Sub-item 2 requires that the proposed premises are at least 500 m, in a straight line, from the nearest approved premises.

Sub-item 3 requires that there are no approved premises in the shopping centre.

New pharmacy in a facility (large shopping centre)

Item 134 applies to applications for a new pharmacy in a large shopping centre. It aims to improve pharmacy access for consumers in shopping centres that are of sufficient size and range of commercial establishments to attract consumers from a larger area than that of the local community.

Sub-item 1 requires that the proposed premises are situated in a large shopping centre. Shopping centre is defined at subsection 5(1**)** of Part 1 as a group of shops and associated facilities that is under single management and large shopping centre is defined as a shopping centre, that:

(a) has a total gross leasable area of at least 5,000 m^2; and

(b) contains a supermarket that occupies a gross leasable area of at least 1,000 m^2; and

(c) contains at least 50 other commercial establishments; and

(d) has customer parking facilities.

Paragraph 2(a) requires that for a shopping centre with at least 50 but less than 100 commercial establishments, it contains no approved premises.

Paragraph 2(b) requires that for a shopping centre with at least 100 but less than 200 commercial establishments, it contains no more than one approved premises.

Paragraph 2(c) requires that for a shopping centre with at least 200 commercial establishments, it contains no more than two approved premises.

Note: commercial establishments
The provisions relating to small and large shopping centres specify that the centre must contain at least a specific number of commercial establishments. A commercial establishment is defined in Part 1 subsection 7(1), and generally means premises from which businesses will provide goods and/or services to consumers.

In considering an application under either of the shopping centre provisions, the Authority need not be satisfied that the requisite number of commercial establishments are operating within that centre, rather, the Authority must be satisfied that the centre is, or is likely to be, occupied by the requisite number of commercial establishments. In considering this, the Authority will have some discretion and may consider matters such as, how much progress has been made on fitting out the relevant premises and how soon the commercial establishments will begin operating.

New pharmacy in a facility (private hospital)

Item 135 applies to applications for a new approval in a private hospital. It aims to improve access to pharmaceutical benefits for patients of, and visitors to, the hospital which are drawn from a larger area than that of the local community.

Sub-item 1 requires that the proposed premises are situated in a private hospital.

Note: meaning of 'private hospital' -
Under subsection 3(1) of the *Health Insurance Act 1973*, 'private hospital' means:
"(a) premises that were, immediately before 1 October 1986, a private hospital (within the meaning of this section as in force at that time), other than premises in respect of which a declaration under subsection 23EA(2) is in force; and
(b) premises in respect of which a declaration under subsection 23EA(1) is in force."

'Private hospital' has the same meaning in the Act as defined in the *Health Insurance Act 1973* (see subsection 4(1A) of the Act)

Sub-item 2 requires that the private hospital does not contain an approved premises.

Sub-item 3 requires that the hospital authority is not approved under section 94 of the Act. Section 94 of the Act provides for the Minister to approve a hospital authority to supply pharmaceutical benefits to patients receiving treatment in or at that hospital. A hospital authority approved under section 94 can not supply pharmaceutical benefits to the general public.

Sub-item 4 requires that the private hospital is licensed or registered under the relevant State or Territory law:

(a) to contain at least 150 beds to provide health services to patients; or
(b) to treat or accommodate or lodge at least 150 patients at any one time.

New pharmacy in a facility (large medical centre)

Item 136 applies to applications for a new approval in a large medical centre. It aims to facilitate timely and convenient access to the supply of pharmaceutical benefits for patients of large medical centres that operate extended hours and also recognises the multidisciplinary health services that large medical centres may provide, for example, by dental practitioners or nurse practitioners approved to prescribe PBS medicines.

Sub-item 1 requires that the proposed premises are situated in a large medical centre. Large medical centre is defined at subsection 5(1) of Part 1 as a medical centre that is under single management, operates for at least 70 hours each week and has one or more prescribing medical practitioners at the centre for at least 70 hours a week.

Note: large medical centre - The intention of having a pharmacy in a large medical centre is primarily to meet the needs of medical centre patients outside normal business hours, when nearby pharmacies have closed. Irrespective of the hours that the medical centre operates or the number of medical practitioners rostered on during those hours, general practice services must be provided at the medical centre for at least 70 hours each week. If the medical centre closes for an hour over lunchtime then that hour is not counted towards the time that the medical centre is providing general practice services, as patients are unable to obtain a consultation with a medical practitioner during that hour. Where more than one medical practitioner's hours overlap, the total hours that the medical centre is providing general practice services is not the combined hours of the medical practitioners, it is instead the total hours that the centre is providing general practice services.

Sub-item 2 requires that there are no approved premises in the medical centre.

Sub-item 3 requires that the proposed premises are at least 500 m, in a straight line, from the nearest approved premises except those pharmacies approved in a small or large shopping centre or private hospital.

Sub-item 4 requires that the Authority is satisfied that there are at least 8 full-time, or equivalent, PBS prescribers practising at the centre, of which, at least 7 PBS prescribers must be prescribing medical practitioners.

Note: "PBS prescriber" and "medical practitioner"

PBS prescriber: is defined in section 84(1) of the *National Health Act 1953* as meaning a medical practitioner or a participating dental practitioner or an authorised optometrist, midwife or nurse practitioner.

Medical practitioner**:** under subsection 3(1) of the *Health Insurance Act 1973*, a 'medical practitioner' means a person registered or licensed as a medical practitioner under a State or Territory law, and does not include a person whose registration/license has been suspended or cancelled. 'Medical practitioner' has the same meaning in the Act as defined in the *Health Insurance Act 1973* (see subsection 4(1A) of the Act).

For the purpose of this Determination, the requirements associated with a *medical practitioner* require that the medical practitioner provide general practice services in the relevant community and issues prescriptions for pharmaceutical benefits (see definition of 'prescribing medical practitioner' at subsection 5(1) of Part 1).

Full-time PBS prescriber (including medical practitioner), means providing the services of a PBS prescriber for at least 38 hours each week. For example, for a medical practitioner, time spent consulting with patients at their home or in hospital is included when calculating the hours that a medical practitioner practises at a medical centre. Time spent consulting at other medical centres, working at a hospital (rostered duties), attending nursing homes and undertaking administration work for the medical centre/practice, such as staff rosters, is not counted towards the time spent practising at the medical centre/practice.

The equivalent of a full-time PBS prescriber means any number of PBS prescribers who provide the equivalent services of one full-time PBS prescriber. For example, if one part-time PBS prescriber practises 20 hours each week and another practises 18 hours each week, then they will be considered the equivalent to one full-time PBS prescriber (i.e. their combined practice hours equal 38 hours). Similarly, if one PBS prescriber practises 57 hours each week then they are considered the equivalent to one and a half full-time PBS prescribers.

Subparagraphs 5(a), (b) and (c) provide that the requirement in sub-item 4 must be satisfied at the day on which the application was made and during the 2 months before that day, and on the day the Authority makes a recommendation in respect of the application.

Sub-item 6 requires that the applicant will make all reasonable attempts to ensure that the proposed premises' hours of operation will meet the needs of patients of the medical centre. The intention of this provision is to ensure that, as far as is practicable, a majority of patients can access the pharmacy following a consultation by a doctor in that medical centre.

SCHEDULE 2 – GENERAL REQUIREMENTS

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 10(a)(iii) and 10(b)(iii) of Part 2 of the Determination, an application must meet the requirements of Schedule 2.

Item 211 requires that the Authority be satisfied that all the specified requirements are met.

Legal right to occupy proposed premises

Paragraph (a) the Authority must be satisfied that the applicant had, on the day the application was made, and has, on the day on which the Authority makes a recommendation in respect of the application, a legal right to occupy the proposed premises on or after the day the application was made. For example, the applicant may produce a 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.

Proposed premises can be used as a pharmacy and are accessible by members of the public

Subparagraph (b)(i) requires that the proposed premises, on the day the application is made and on the day on which the Authority makes a recommendation in respect of the application could be used under the applicable local government and State/Territory laws relating to land development for the purpose of operating a pharmacy. For example, this requirement would be satisfied if planning approval for the proposed pharmacy has been obtained or if this is not necessary in the State/Territory where the pharmacy would be located, the proposed premises are on land that is zoned so as to enable the operation of a pharmacy. An application to obtain building works approval or a certificate of occupancy, or similar, is not required to satisfy this requirement. However, it may be needed for compliance with requirement (c), depending on the operation of applicable State/territory land development laws.

Subparagraph (b)(ii) requires that the proposed premises would be accessible by members of the public, not just certain classes of the public. This also supports the purpose of the Pharmaceutical Benefits Scheme, which is to ensure that pharmaceutical benefits are available to the Australian community at large and not restricted to certain members of the public, such as patients of a particular medical centre.

Applicant will begin operating a pharmacy at the proposed premises within six months

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.

Proposed premises are not accessible from within a supermarket

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

Proposed premises are not approved premises at the date on which the application is made

Item 212 requires that the Authority is satisfied that on the day on which the application is made, the proposed premises are not approved premises.

SCHEDULE 3 – REQUIREMENTS FOR APPLICATIONS INVOLVING CANCELLATION OF EXISTING APPROVAL

Schedule 3 sets out requirements for an application to relocate an existing approval. As required at subparagraphs 10(a)(iii) and 10(a)(iv) of Part 2 of the determination, an application involving the cancellation of an existing approval must meet the requirements of Schedule 3.

SCHEDULE 3, PART 1 – All applications

Part 1 of Schedule 3 applies to applications involving the cancellation of an existing approval, as set out in Part 1 of Schedule 1, that is, applications to relocate an existing approval that is in force in respect of the existing premises, or applications to expand or contract premises.

Existing approval to be cancelled

Item 311 provides that the Authority must be satisfied that an approved pharmacist has requested that his or her approval be cancelled immediately before the approval in respect of the subject application is granted.

Paragraph (a) requires that the approved pharmacist (that is, either the applicant or any other pharmacist) in respect of the existing premises has requested, in writing, the cancellation of the existing approval immediately before approval in respect of the proposed premises is granted.

Paragraph (b) requires that, if the approved pharmacist in respect of the existing premises has stopping carrying on business as a pharmacist at the existing premises, the Secretary is aware of this and has agreed only to cancel the existing approval in accordance with the request made by the approved pharmacist (noted at paragraph (a)).

Period existing premises have been approved premises

Item 312 relates to the period of time the existing approval has been in force. It provides that an existing approval can not be relocated more often than once every two years, except in specified circumstances such as, temporary relocations resulting from refurbishment of premises, for relocations within the same facility, or if there are exceptional circumstances (such as, if the existing premises have been damaged by flood or fire). It aims to ensure a degree of stability in the network of approved pharmacies while still allowing some flexibility for relocations that have no impact on other pharmacies.

Where an approval is located in a facility or, in a town where the pharmacy is at least 10km from the nearest approved premises, the approval is taken to have been in force continuously from the time it is first granted in that facility or town, regardless of any subsequent relocations. That is, the two year clock that is normally reset after each relocation, will continue for as long as the approval remains in that facility or town.

Paragraph (a) requires that, on the day the application is made, one or more approvals in respect of the existing premises have been in force continuously for at least two years immediately before the day the application is made.

Paragraph (b) requires that, if paragraph (a) does not apply, one of the exceptions set out in subparagraphs (i)-(vii) is to be met.

Subparagraph (b)(i) requires that the proposed premises are situated in the same facility in which the existing premises are situated.

Subparagraph (b)(ii) requires that the existing premises are the only approved premises in a particular town and the proposed premises are situated in the same town as the existing premises.

Subparagraph (b)(iii) requires that the purpose of the application is to relocate the existing approval while the existing premises are being renovated or refurbished.

Subparagraph (b)(iv) requires that the proposed premises are renovated or refurbished premises that are substantially the same premises that were previously occupied by the pharmacy at the existing premises (operated by the applicant or the previous owner of the pharmacy).

Subparagraph (b)(v) requires that the application is the result of exceptional circumstances (for example, the existing premises may have been damaged by fire or flood).

Subparagraph (b)(vi) requires that the application involves the cancellation of an existing approval that was granted following an application for an expansion or contraction of approved premises (subsection 90 (3AE) of the Act), and the existing and previous approvals have been in force for a total of at least two years. This requirement reflects the view that if the previous approval was granted at least two years prior to the day the application is made, an expansion or contraction that has occurred since that approval was granted has no negative impact on the application.

Subparagraph (b)(vii) requires that the application is for an expansion or contraction of approved premises (subsection 90 (3AE) of the Act) and the application has been referred to the Authority under subsection 90 (3AF) of the Act. This provides that expansions or contractions of approved premises can proceed if the existing approval has been in force in respect of the existing premises for less than two years.

SCHEDULE 3, PART 2 – Particular applications

Part 2 of Schedule 3 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 10(a)(iv) of Part 2 of the Determination, an application described in an item in Part 2 of Schedule 3 must meet the requirements set out in that item.

Relocation of new pharmacy (at least 1.5km)

Item 313 applies to an application to relocate an approval which was granted following an application made under the provisions of item 130 (*New pharmacy (at least 1.5km))* of Part 2 Schedule 1. This provision reflects the intention to ensure that new approvals that are granted to address community need remain in that area of need by requiring that an approval granted following an application made under item 130, stays within a 1 km radius of the premises in respect of which the approval was originally granted, for a period of five years.

Paragraph (a) provides that the application involves the cancellation of an existing approval.

Subparagraph (a)(i) provides that the existing approval was granted following an application of the kind mentioned in item 130 of Part 2 of Schedule 1.

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 which was granted in the circumstances described in subparagraph (a)(i).

Subparagraph (a)(iii) provides that the existing approval was granted following an application of the kind set out in Part 1 of Schedule 1 (that is, a relocation of an existing approval) and that involved the cancellation of the previous approval described in subparagraphs (a)(i) or (ii).

Paragraph (b) provides that the application is made within five years after the day the approval was originally granted in the circumstances described in subparagraph (a)(i).

If the application is of the kind mentioned in Part 1 of Schedule 1 (that is a 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 km, in a straight line, from the premises at which an approval was granted following an application of the type described in subparagraph a(i).

Relocation of new pharmacy (urban)

Item 314 applies to an application to relocate an approval which was granted following an application made under the provisions of item 113, *New pharmacy (urban)* of Part 2 of Schedule 1 to Determination No. PB 23 of 2006. It provides for the requirement which applied to an approval of this type to be retained. That is, for five years from the date on which the original approval was granted, the approval can not be relocated more than 1.5 km from the premises at which it was originally granted.

Paragraph (a) provides that the application involves the cancellation of an existing approval.

Subparagraph (a)(i) provides that the existing approval was granted following an application of the kind mentioned in item 113 of Part 2 of Schedule 1 to Determination PB No. 23 of 2006.

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).

Subparagraph (a)(iii) provides that the existing approval was granted following an application of the kind set out in Part 1 of Schedule 1 of this Determination or Determination PB No. 23 of 2006 (that is, a relocation of an existing approval) and that involved the cancellation of the previous approval described in subparagraph (a)(i) or (ii).

Paragraph (b) provides that the application is made within five years after the day the approval was originally granted in the circumstances described in subparagraph (a)(i).

If the application 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 premises at which the approval was granted following an application mentioned in subparagraph (a)(i).

Relocation of new pharmacy (at least 10km)

Item 315 applies to an application to relocate an approval granted following an application made under the provisions of item 131, *New pharmacy (at least 10 km)* or item 132, *New*

additional pharmacy (at least 10 km) of Part 2 of Schedule 1 or *New pharmacy (rural)* under previous determinations. It provides that the proposed premises must be in the same town in which the original approval was granted.

Paragraph (a) provides that the existing approval was granted as *New pharmacy (at least 10km)* or *New additional pharmacy (at least 10 km)*. That is, the existing approval was granted following an application made under the provisions set out in item 131 or 132 of Part 2 of Schedule 1.

Paragraph (b) provides that the existing approval was granted as *New pharmacy (rural)*. That is, the existing approval was granted following an application made under the provisions set out in item 114 of Part 2 of Schedule 1 to Determination PB No. 23 of 2006.

Paragraph (c) provides that the existing approval was granted following a recommendation made by the Authority under the relevant provisions of previous determinations setting out the pharmacy location rules (see subparagraph (c)(i) and (ii)).

Paragraph (d) provides that the existing approval was granted following an application of the kind set out in Part 1 of Schedule 1 (that is, a relocation of an existing approval) that involved the cancellation of the previous approval described in paragraph (a), (b) or (c).

Paragraph (e) provides that the existing approval was granted following an application of the kind set out in Part 1 of Schedule 1 to Determination No. PB 23 of 2006 that involved the cancellation of the previous approval described in paragraph (b) or (c).

Paragraph (f) and (g) provides that the existing approval was granted following a recommendation made by the Authority under section 6 or 7 of Determination No. PB 8 of 2006 or under section 6 or 7 of Determination No. PB 8 of 2000 that involved the cancellation of the previous approval described in paragraph (c).

Paragraph (h) 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 paragraphs (a) to (g).

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 paragraphs (a) to (h), the proposed premises must be in the same town as the existing premises.

Relocation from a small or large shopping centre (exceptional circumstances)

Determination No. PB 23 of 2006 included a requirement in item 305 of Part 2 of Schedule 3, that if a pharmacy relocated an existing approval into a facility under one of the facility rules (small or large shopping centre, private hospital or medical centre) it could never move out of the facility unless there were exceptional circumstances. This requirement had the potential to cause problems for pharmacies located in shopping centres whereby the shopping centre landlords had a hold over the pharmacy tenant because the pharmacy was unable to move out of the centre (known as ‘rent hostages’).

Item 316 provides that a pharmacy approved as a new pharmacy in a shopping centre (under item 133 or item 134 of Part 2 of Schedule 1) can move out of the shopping centre after 10 years, unless there are exceptional circumstances. The pharmacy can move within the same facility at any time (Refer to item 122 of Part 1 of Schedule 1). A pharmacist seeking to

be approved in a shopping centre is now able to negotiate a lease with the shopping centre landlord taking into account this requirement.

Item 316 applies to an approval granted as a new pharmacy under item 133 or item 134 of Part 2 of Schedule 1 and provides that the approval can not be relocated out of the facility in which it was granted for at least 10 years, unless the Authority is satisfied that there are exceptional circumstances (for example, fire or flood). It can relocate within the same facility (Refer to item 122 of Part 1 of Schedule 1).

Subparagraph (a)(i) provides for the cancellation of an existing approval which was granted following an application of the kind mentioned under item 133 or 134 of Part 2 of Schedule 1**.**

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 if the approval was granted under the circumstances mentioned in subparagraphs (a)(i) or (ii), the approval can not be relocated from the shopping centre for at least 10 years from the date the approval was granted in the circumstance mentioned in subparagraph (a)(i), unless there are exceptional circumstances.

Relocation from a private hospital or large medical centre (exceptional circumstances)

Item 317 applies to the relocation of a pharmacy approved as a new pharmacy in a private hospital or a large medical centre under item 135 or item 136 of Part 2 of Schedule 1. It provides that the approval can not be relocated from the private hospital or large medical centre in which it was approved unless there are exceptional circumstances. The approval can be relocated within the same facility in which it was approved (Refer to item 122 of Part 1 of Schedule 1).

Paragraph (a) provides that the application involves the cancellation of an existing approval following an application of the kind mentioned in item 135 or 136 of Part 2 of Schedule 1.

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).