National Health (Pharmaceutical Benefits) Regulations 1960

Statutory Rules 1960 No. 17 as amended

made under the

National Health Act 1953

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Part 1 Preliminary

Division 1.1 Interpretation

1 Name of Regulations [see Note 1]

These Regulations are the *National Health (Pharmaceutical Benefits) Regulations 1960*.

2 Commencement

These Regulations shall come into operation on 1 March 1960.

3 Repeal and saving

(1) The National Health (Pharmaceutical Benefits) Regulations (comprising Statutory Rules 1956, Nos. 54 and 75; 1957, Nos. 25 and 52; 1958, Nos. 23 and 42; and 1959, Nos. 4, 28 and 64) are repealed.

(2) A prescription or repeat authorization duly written before the commencement of these Regulations in accordance with the regulations repealed by this regulation shall be deemed, for the purposes of these Regulations, to be duly written in accordance with these Regulations.

(3) The repeal of the regulations made by subregulation (1) does not affect the power of a Committee of Inquiry established under Division 2 of Part VIII of the Act to inquire into and report, as provided in regulation 19 of the regulations so repealed, on the prescribing before the commencement of these Regulations by a medical practitioner in the circumstances specified in that regulation and, where a Committee of Inquiry has so reported before the commencement of these Regulations or so reports after the commencement of these Regulations, the medical practitioner is liable to repay to the Commonwealth the amount payable under that regulation as if the repealed regulations were still in force.

4 Transitional

The National Health (Pharmaceutical Benefits) Regulations as in force immediately before 1 January 1999 continue to apply to a prescription made out in duplicate, the duplicate being marked with the word 'Duplicate'.

5 Interpretation

(1) In these Regulations, unless the contrary intention appears:

applicable amount has the same meaning as in Part VII of the Act.

approved electronic communication means an electronic communication of a kind approved in writing by the Secretary under regulation 5E for the purposes of the provision in which the expression is used.

approved hospital means a hospital the governing body of which is an approved hospital authority.

approved hospital authority means a hospital authority approved under section 94 of the Act.

approved information technology requirements means information technology requirements of a kind approved in writing by the Secretary under regulation 5F for the purposes of the provision in which the expression is used.

approved medical practitioner means a medical practitioner approved under section 92 of the Act.

approved pharmacist has the meaning given by subsection 84 (1) of the Act.

Note The definition in subsection 84 (1) of the Act provides that ***approved pharmacist*** means a person for the time being approved under section 90 of the Act and includes certain other persons described in that definition. Under paragraph 91 (7) (a) of the Act, a person granted permission to supply pharmaceutical benefits under subsection 91 (1) of the Act is to be treated as if the person is approved under section 90 of the Act as an approved pharmacist. 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.

approved supplier has the same meaning as in Part VII of the Act.

authorised midwife has the meaning given by subsection 84 (1) of the Act.

authorised nurse practitioner has the meaning given by subsection 84 (1) of the Act.

authorised optometrist has the meaning given by subsection 84 (1) of the Act.

authority prescription means a prescription that prescribes a pharmaceutical benefit and that has been authorised:

(a) in accordance with subregulation 13 (5); or

(b) under authority required procedures that are part of the circumstances determined by the Minister for paragraph 85 (7) (b) of the Act for the pharmaceutical benefit.

Note A determination under subsection 85 (7) of the Act contains procedures that are called 'authority required procedures' that are part of the circumstances determined by the Minister for paragraph 85 (7) (b) of the Act and that only apply to certain pharmaceutical benefits specified in the determination.

brand, for a pharmaceutical item, means a brand of the pharmaceutical item within the meaning of subsection 84 (1) of the Act.

Commonwealth price has the same meaning as in Part VII of the Act.

concessional beneficiary has the same meaning as in Part VII of the Act.

concessional benefit prescription has the same meaning as in Part VII of the Act.

concession card has the same meaning as in Part VII of the Act.

concession card prescription has the same meaning as in Part VII of the Act.

dependant, in relation to a concessional beneficiary, has the same meaning as in Part VII of the Act.

drug in a pharmaceutical item has the same meaning as in Part VII of the Act.

electronic communication has the meaning given by subsection 5 (1) of the *Electronic Transactions Act 1999*.

electronic order form means a form that is approved in writing by the Secretary under subparagraph 16 (1) (b) (ii) for the purposes of lodging an order under paragraph 16 (1) (b).

electronic prescription means a prescription that is prepared and submitted:

(a) in accordance with approved information technology requirements (if any), by means of an approved electronic communication; and

(b) in accordance with a form approved by the Secretary under sub-subparagraph 19 (1) (a) (iia) (B).

entitlement card has the same meaning as in Part VII of the Act.

entitlement card prescription has the same meaning as in Part VII of the Act.

information technology requirements has the meaning given by subsection 5 (1) of the *Electronic Transactions Act 1999*.

Medicare Australia/DVA copy, for a paper-based prescription, means the duplicate of the prescription on which appear the words 'Medicare Australia/DVA copy'.

medicare number has the same meaning as in Part VII of the Act.

optometrist has the meaning given by subsection 84 (1) of the Act.

out-patient medication has the same meaning as in Part VII of the Act.

paper-based prescription means a prescription, including an authority prescription, that is prepared in duplicate in accordance with subparagraph 19 (1) (a) (i), (ii) or (iii).

participating dental practitioner has the same meaning as in Part VII of the Act.

PBS prescriber has the meaning given by subsection 84 (1) of the Act.

pharmaceutical benefit has the same meaning as in Part VII of the Act.

pharmaceutical item has the same meaning as in Part VII of the Act.

pharmaceutical item has a drug has the same meaning as in Part VII of the Act.

pharmacist/patient copy, for a paper-based prescription, means the original of the prescription on which appear the words 'pharmacist/patient copy'.

prescription means a paper-based prescription or an electronic prescription.

public hospital has the same meaning as in Part VII of the Act.

public hospital authority has the same meaning as in Part VII of the Act.

ready-prepared pharmaceutical benefit means a pharmaceutical benefit in respect of which a determination made under subsection 85 (6) of the Act is in force.

record form has the same meaning as in Part VII of the Act.

relevant entitlement period has the same meaning as in Part VII of the Act.

repatriation pharmaceutical benefit has the same meaning as in Part VII of the Act.

responsible person has the same meaning as in Part VII of the Act.

the Act means the *National Health Act 1953*.

(2) In these Regulations, unless the contrary intention appears, a reference to prescribing or to the writing of a prescription shall be read as a reference to the writing of a prescription for the supply of a pharmaceutical benefit under Part VII of the Act.

(3) In these Regulations, unless the contrary intention appears:

(a) a reference to the holder of a concession card or an entitlement card shall be read as a reference to a person who is, by virtue of section 84G of the Act, to be taken to be a holder of the card;

(aa) a reference to the original holder of a concession card is a reference to the person to whom a concession card has been issued under section 84DA of the Act;

(b) a reference to the original holder of an entitlement card shall be read as a reference to the person to whom an entitlement card has been issued under section 84E of the Act; and

(c) a reference to a member of the family of a person shall be read as a reference to a person who is a member of that family within the meaning of section 84B of the Act.

Division 1.2 Application of Regulations to electronic prescriptions and electronic orders

5A Preparing electronic prescriptions

A reference in these Regulations to writing or preparing a prescription, a repeat authorisation or a deferred supply authorisation, whether the expression ***writing***, ***preparing*** or any other expression is used, is taken to include:

(a) for an electronic prescription — writing or preparing the prescription by means of an electronic form approved by the Secretary under sub-subparagraph 19 (1) (a) (iia) (B) for the purposes of writing an electronic prescription; and

(b) for a repeat authorisation that relates to an electronic prescription — writing or preparing the authorisation by means of an electronic form authorised by the Secretary under subparagraph 26 (1A) (a) (i) for the supply of a pharmaceutical benefit under an electronic prescription; and

(c) for a deferred supply authorisation that relates to an electronic prescription — writing or preparing the authorisation by means of an electronic form authorised by the Secretary under paragraph 26A (2) (a) for deferring the supply of a pharmaceutical benefit under an electronic prescription.

5B Date when a prescription is written or a pharmaceutical benefit is prescribed

A reference in these Regulations to the day or date on which a prescription is written by a PBS prescriber or the day or date on which a pharmaceutical benefit is prescribed is, in relation to an electronic prescription, the day or date on which the prescription is signed by the PBS prescriber.

5C Requirement to give information in writing

(1) If, under these Regulations, a person is required to write information on a prescription, a repeat authorisation, a deferred supply authorisation or an order form, that requirement is taken to have been met in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form, if the person gives the information:

(a) in accordance with approved information technology requirements (if any); and

(b) by means of an approved electronic communication.

(2) This regulation applies to a requirement to write information on a prescription, a repeat authorisation, a deferred supply authorisation or an order form, whether the expression ***write***, ***certify***, ***endorse, identify***, ***indicate***, ***mark***, ***specify***, ***state***, or any other expression is used.

5D Requirement to give a prescription

If, under these Regulations, a prescription is required to be given or presented to an approved pharmacist or an approved medical practitioner for the purpose of supplying a pharmaceutical benefit to the person for whom the prescription was written, that requirement is taken to have been met in relation to an electronic prescription if:

(a) the person who will receive the pharmaceutical benefit (whether or not for the person's own use) requests the pharmacist or practitioner to supply the pharmaceutical benefit; and

(b) the pharmacist or practitioner consents, within the meaning of subsection 5 (1) of the *Electronic Transactions Act 1999*, to the prescription being given or presented, in accordance with approved information technology requirements (if any), by means of an approved electronic communication; and

(c) the prescription is accessible by the pharmacist or practitioner.

5E Approval of kinds of electronic communications

The Secretary may, in writing, approve a kind of electronic communication for 1 or more of the following purposes:

(a) preparing or submitting an electronic prescription;

(b) giving information, for the purposes of these Regulations, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;

(c) giving or presenting an electronic prescription to an approved pharmacist or an approved medical practitioner under these Regulations;

(d) submitting an electronic prescription to the Minister in accordance with paragraph 13 (2) (b);

(e) lodging an order with an approved pharmacist to obtain a pharmaceutical benefit for the purpose of section 93 of the Act;

(f) submitting a receipt for a pharmaceutical benefit received under paragraph 16 (1) (b);

(g) giving an acknowledgment under these Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription;

(h) doing any other thing that is required or permitted to be done for the purposes of these Regulations.

5F Approval of information technology requirements

The Secretary may, in writing, approve information technology requirements for 1 or more of the following purposes:

(a) preparing and submitting an electronic prescription;

(b) giving information, for the purposes of these Regulations, in relation to an electronic prescription, an authorisation that relates to an electronic prescription or an electronic order form;

(c) giving or presenting an electronic prescription to an approved pharmacist or an approved medical practitioner under these Regulations;

(d) lodging an order with an approved pharmacist to obtain a pharmaceutical benefit for the purpose of section 93 of the Act;

(e) submitting a receipt for a pharmaceutical benefit received under paragraph 16 (1) (b);

(f) giving an acknowledgment under these Regulations for the supply of a pharmaceutical benefit under an electronic prescription or an authorisation that relates to an electronic prescription;

(g) doing any other thing that is required or permitted to be done for the purposes of these Regulations.

Part II Approvals under Part VII of the Act

8 Application for approval to be in approved form

The Minister, in the case of a hospital authority, and the Secretary, in the case of a pharmacist or medical practitioner, may refuse to entertain an application for approval under Part VII of the Act unless the application:

(a) in the case of an application for approval of a pharmacist — is in accordance with a form approved in writing by the Secretary;

(b) in the case of an application for approval of a hospital authority — is in accordance with a form approved in writing by the Secretary; and

(c) in the case of an application for approval of a medical practitioner — is in accordance with a form approved in writing by the Secretary.

8AA Application for approval as authorised optometrist, authorised midwife or authorised nurse practitioner

The following applications must be made in a form acceptable to the Secretary:

(a) an application for approval as an authorised optometrist under subsection 84AAB (1) of the Act;

(b) an application for approval as an authorised midwife under subsection 84AAF (1) of the Act;

(c) an application for approval as an authorised nurse practitioner under subsection 84AAJ (1) of the Act.

8A Numbering of approvals

(1) If the Secretary approves:

(a) a dental practitioner under section 84A of the Act; or

(aa) an optometrist under section 84AAB of the Act; or

(ab) an eligible midwife under section 84AAF of the Act; or

(ac) an eligible nurse practitioner under section 84AAJ of the Act; or

(b) a pharmacist under section 90 of the Act; or

(c) a medical practitioner under section 92 of the Act;

he or she may allot a number to that approval.

(1A) If the Secretary grants permission to a person to supply pharmaceutical benefits under subsection 91 (1) of the Act, he or she may allot a number to the approval that, under paragraph 91 (7) (a) of the Act, is treated as having been granted to the person under section 90 of the Act.

(1B) If the Minister substitutes for a decision of the Secretary to which section 90A of the Act applies a decision approving a pharmacist for the purpose of supplying pharmaceutical benefits at or from particular premises, the Minister may allot a number to that approval.

(2) If the Minister approves a hospital authority under section 94 of the Act he or she may allot a number to that approval.

9 Certain requirements to be met after cancellation etc of approval

(1) If the approval of an approved pharmacist is suspended, revoked or cancelled, the pharmacist must not, in any way, indicate that he or she has been, or is, approved to supply pharmaceutical benefits.

Penalty: 1 penalty unit.

(2) An offence against subregulation (1) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

Part IIAAA Formularies, co-marketed brands and therapeutic groups

9AAC Co-marketed brands

For subsection 84AE (4) of the Act, the listed brands of a pharmaceutical item specified in columns 2 and 3 of an item in Schedule 3 are co-marketed brands.

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Part IIAA Safety net concession cards

9AA Safety net concession card

(1) For the purposes of paragraph 84DA (3) (b) of the Act, the following particulars are prescribed in relation to an application under subsection 84DA (1) or (2) of the Act:

(a) the full name of the applicant;

(b) the residential address of the applicant;

(c) the full name of each person who is a member of the applicant's family;

(d) the relationship of each person referred to in paragraph (c) to the applicant;

(e) the date on which the application is made;

(f) the medicare number of the applicant.

(2) For the purposes of paragraph 84DA (3) (b) of the Act, the following documents are prescribed in relation to an application under subsection 84DA (1) or (2) of the Act:

(a) record forms issued to the applicant or to a member of the applicant's family that:

(i) record the value of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication supplied to the applicant, or to a member of the applicant's family, during the relevant entitlement period to which the application relates; and

(ii) bear a statement signed by the applicant declaring that the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication recorded in the form were so supplied;

(b) in respect of any other pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication so supplied, any document that establishes the value of that pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication.

9AB Additional concession cards

(1) A person whose concession card has been lost, stolen, damaged or destroyed may apply for an additional concession card to the Secretary.

(2) A person who is a holder of a concession card, other than a person referred to in subregulation (1), may apply for an additional concession card to:

(a) the Secretary; or

(b) where the original concession card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority — that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority.

(3) An application under subregulation (1) or (2) for an additional concession card must:

(a) be in accordance with the form approved by the Secretary; and

(b) set out:

(i) the full name of the applicant; and

(ii) the residential address of the applicant; and

(iii) the full name of each person (other than the applicant) who is a member of the family of the original holder of the concession card and the relationship of that person to the original holder; and

(iv) the number (if known to the applicant) of any other concession card held by a member of the family of the original holder of the concession card; and

(v) if the application is made under subregulation (1) — the number (if known to the applicant) of the concession card that the applicant holds; and

(vi) the medicare number of the applicant; and

(c) be signed and dated by the applicant; and

(d) be accompanied by the original concession card unless the application is made under subregulation (1).

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(4) Where, on an application to a person for the issue of an additional concession card, the person is satisfied, having regard to:

(a) the matters contained in the application; and

(b) any other relevant matters;

that an additional concession card should be issued to the applicant, the person must issue an additional concession card to the applicant.

9AC Replacement concession cards

(1) An original holder of a concession card may apply for the issue of a replacement card.

(2) An application under subregulation (1) must:

(a) be made, in accordance with the form approved by the Secretary, to:

(i) the Secretary; or

(ii) where the original concession card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority — that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority; and

(b) set out:

(i) the full name of the applicant; and

(ii) the residential address of the applicant; and

(iii) the full name of any new family member and his or her relationship to the applicant; and

(iv) the medicare number of the applicant; and

(c) be signed and dated by the applicant; and

(d) be accompanied by the original concession card unless the application is made to the Secretary.

(3) Where, on an application to a person for the issue of a replacement card, the person is satisfied, having regard to:

(a) the matters contained in the application; and

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(b) any other relevant matters;

that:

(c) the applicant is the original holder of the concession card to which the application relates; and

(d) each person identified in the application in accordance with subparagraph (2) (b) (iii) became, after the issue of that concession card and during the relevant entitlement period in respect of which that card was issued, a member of the original card holder's family;

the person must issue a replacement concession card to the applicant.

9AD Refusal to issue additional or replacement concession cards

(1) Where an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority makes:

(a) a decision under regulation 9AB refusing to issue an additional concession card; or

(b) a decision under regulation 9AC refusing to issue a replacement concession card;

the applicant may apply to the Secretary under subregulation 9AB (2) or regulation 9AC for the issue of the additional concession card or replacement concession card, as the case requires.

(2) Where the Secretary makes:

(a) a decision under regulation 9AB refusing to issue an additional concession card; or

(b) a decision under regulation 9AC refusing to issue a replacement concession card;

the Secretary must, by notice in writing, inform the applicant of the making of, and reasons for, the decision.

(3) A notice under subregulation (2) must include a statement to the effect:

(a) that an application may be made, subject to the *Administrative Appeals Tribunal Act 1975*, by or on behalf of a person whose interests are affected by the decision, to

the Administrative Appeals Tribunal for review of the decision; and

(b) that a person whose interests are affected by the decision may, except where subsection 28 (4) of that Act applies, request a statement under section 28 of that Act.

(4) A failure to comply with subregulation (3) in relation to a decision does not affect the validity of the decision.

9AE Review of decisions

An application may be made to the Administrative Appeals Tribunal for review of a decision of the Secretary:

(a) refusing to issue an additional concession card under regulation 9AB; or

(b) refusing to issue a replacement concession card under regulation 9AC.

9AF Prescribed offices (Act s 84DA (5))

For the purposes of subsection 84DA (5) of the Act, each office specified in Schedule 1 is a prescribed office.

Part IIA Pharmaceutical benefits entitlement cards

9A Pharmaceutical benefits prescription record forms

(1) For the purposes of paragraph 84D (3) (b) of the Act, the following particulars of the person to whom a record form is issued are prescribed particulars:

(a) the Christian or given names and the surname of the person;

(b) the address of the person.

(2) For the purposes of subsection 84D (4) of the Act, the following particulars of a person who is a member of the family of a person to whom a record form is issued are prescribed particulars:

(a) the Christian or given names and the surname of the person;

(b) the relationship of the person to the person to whom the record form is issued.

(4) For the purposes of paragraph 84D (7) (c) of the Act, the following particulars in relation to the supply of a pharmaceutical benefit or repatriation pharmaceutical benefit are prescribed:

(a) the code number set out in relation to that pharmaceutical benefit or repatriation pharmaceutical benefit in the Schedule of Pharmaceutical Benefits published by the Department;

(b) the number allotted under regulation 8A to the approval of the approved pharmacist, approved medical practitioner or approved hospital authority supplying the pharmaceutical benefit or repatriation pharmaceutical benefit;

(c) the maximum value of the pharmaceutical benefit or repatriation pharmaceutical benefit for safety net purposes.

(4A) For the purposes of paragraph 84D (11) (c) of the Act, the following particulars in relation to the supply of out-patient medication are prescribed:

(a) particulars that identify the medication;

(b) particulars that identify the public hospital at which the medication was supplied;

(c) the applicable amount.

(5) The maximum value of a pharmaceutical benefit for safety net purposes is:

(a) if the price of the pharmaceutical benefit is charged under paragraph 87 (2) (a), (b) or (c) of the Act:

(i) the price mentioned for the prescription in the relevant paragraph of subsection 87 (2) of the Act as in force when the price is charged; or

(ii) if the price charged is less than the amount mentioned in subparagraph (i) — the amount of the price charged; or

(b) if the price of the pharmaceutical benefit is charged under paragraph 87 (2) (e) of the Act:

(i) the price mentioned for the prescription in paragraph 87 (2) (e) of the Act as in force when the price is charged; or

(ii) if the agreed price, within the meaning of subsection 84C (6) of the Act as in force when the price is charged, of the pharmaceutical benefit is less than the amount mentioned in subparagraph (i) — the amount of the agreed price; or

(iii) if the price charged is less than the amount mentioned in subparagraph (i) and less than the agreed price mentioned in subparagraph (ii) — the amount of the price charged.

(6) The maximum value of a repatriation pharmaceutical benefit for safety net purposes is the amount charged for the benefit in accordance with a scheme referred to in subsection 91 (1) of the *Veterans' Entitlements Act 1986*.

9B Pharmaceutical benefits entitlement card

(1) For the purposes of paragraph 84E (3) (b) of the Act, the following particulars are prescribed in relation to an application under subsection 84E (1) or (2) of the Act:

(a) the full name of the applicant;

(b) the residential address of the applicant;

(c) the full name of each person who is a member of the applicant's family;

(d) the relationship of each person referred to in paragraph (c) to the applicant;

(e) the date on which the application is made;

(f) the medicare number of the applicant.

(2) For the purposes of paragraph 84E (3) (b) of the Act, the following documents are prescribed in relation to an application under subsection 84E (1) or (2) of the Act:

(a) record forms issued to the applicant or to a member of the applicant's family that:

(i) record the value of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication supplied to the applicant, or to a member of the applicant's family, during the relevant entitlement period to which the application relates; and

(ii) bear a statement signed by the applicant declaring that the pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication recorded in the forms were so supplied;

(b) in respect of any other pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication so supplied, any document that establishes the value of that pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication.

9BA Prescribed offices for the purposes of subsection 84E (5) of the Act

For the purposes of subsection 84E (5) of the Act, each office specified in Schedule 1 is a prescribed office.

9C Additional entitlement cards

(1) A person whose entitlement card has been lost, stolen, damaged or destroyed may apply for an additional entitlement card to the Secretary.

(2) A person who is a holder of a entitlement card, other than a person referred to in subregulation (1), may apply for an additional entitlement card to:

(a) the Secretary; or

(b) where the original entitlement card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority — that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority.

(3) An application under subregulation (1) or (2) for an additional entitlement card must:

(a) be in accordance with the form approved by the Secretary; and

(b) set out:

(i) the full name of the applicant; and

(ii) the residential address of the applicant; and

(iii) the full name of each person (other than the applicant) who is a member of the family of the original holder of the entitlement card and the relationship of that person to the original holder; and

(iv) the number (if known to the applicant) of any other entitlement card held by a member of the family of the original holder of the entitlement card; and

(v) if the application is made under subregulation (1) — the number (if known to the applicant) of the entitlement card that the applicant holds; and

(vi) the medicare number of the applicant; and

(c) be signed and dated by the applicant; and

(d) be accompanied by the original entitlement card unless the application is made under subregulation (1).

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(4) Where, on an application to a person for the issue of an additional entitlement card, the person is satisfied, having regard to:

(a) the matters contained in the application; and

(b) any other relevant matters;

that an additional entitlement card should be issued to the applicant, the person must issue an additional entitlement card to the applicant.

9D Replacement entitlement cards

(1) An original holder of a entitlement card may apply for the issue of a replacement card.

(2) An application under subregulation (1) must:

(a) be made, in accordance with the form approved by the Secretary, to:

(i) the Secretary; or

(ii) where the original entitlement card was issued by an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority — that approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority; and

(b) set out:

(i) the full name of the applicant; and

(ii) the residential address of the applicant; and

(iii) the full name of any new family member and his or her relationship to the applicant; and

(iv) the medicare number of the applicant; and

(c) be signed and dated by the applicant; and

(d) be accompanied by the original entitlement card unless the application is made to the Secretary.

(3) Where, on an application to a person for the issue of a replacement card, the person is satisfied, having regard to:

(a) the matters contained in the application; and

(b) any other relevant matters;

that:

(c) the applicant is the original holder of the entitlement card to which the application relates; and

(d) each person identified in the application in accordance with subparagraph (2) (b) (iii) became, after the issue of that entitlement card and during the relevant entitlement period in respect of which that card was issued, a member of the original card holder's family;

the person must issue a replacement entitlement card to the applicant.

9E Refusal to issue additional or replacement entitlement cards

(1) Where an approved pharmacist, approved medical practitioner, public hospital authority or approved hospital authority makes:

(a) a decision under regulation 9C refusing to issue an additional entitlement card; or

(b) a decision under regulation 9D refusing to issue a replacement entitlement card;

the applicant may apply to the Secretary under subregulation 9C (2) or regulation 9D for the issue of the additional entitlement card or replacement entitlement card, as the case requires.

(2) Where the Secretary makes:

(a) a decision under regulation 9C refusing to issue an additional entitlement card; or

(b) a decision under regulation 9D refusing to issue a replacement entitlement card;

the Secretary must, by notice in writing, inform the applicant of the making of, and reasons for, the decision.

(3) A notice under subregulation (2) must include a statement to the effect:

(a) that an application may be made, subject to the *Administrative Appeals Tribunal Act 1975*, by or on behalf of a person whose interests are affected by the decision, to

the Administrative Appeals Tribunal for review of the decision; and

(b) that a person whose interests are affected by the decision may, except where subsection 28 (4) of that Act applies, request a statement under section 28 of that Act.

(4) A failure to comply with subregulation (3) in relation to a decision does not affect the validity of the decision.

9F Review of decisions

An application may be made to the Administrative Appeals Tribunal for review of a decision of the Secretary:

(a) refusing to issue an additional entitlement card to a person under regulation 9C; or

(b) refusing to issue a replacement entitlement card to a person under regulation 9D.

Part III Pharmaceutical benefits

13 Variation of application of determination of maximum number of repeats or maximum number or quantity of units

(1) For the purposes of subsection 85A (3) of the Act, the Minister is authorised to vary, in accordance with subregulation (5), in relation to a person included in the class of persons to whom this regulation applies, the application of the determinations in force under paragraph 85A (2) (a) or (b) of the Act.

(2) This regulation applies to a person in respect of whom a practitioner submits a prescription that is not in accordance with a determination in force under paragraph 85A (2) (a) or (b) of the Act:

(a) to the Secretary, in one of the forms specified in paragraph (3) (a); or

(b) to the Minister, using a method specified in paragraph (3) (b).

(3) A prescription submitted under subregulation (2) must:

(a) in the case of a prescription submitted to the Secretary — be prepared and signed by the practitioner:

(i) in a form approved in writing by the Secretary and completed by the practitioner in ink in his or her own handwriting; or

(ii) in a form, prepared by means of a computer, that is in accordance with the form approved by the Secretary under subparagraph (i); or

(iii) in a form, prepared by means of a computer, approved in writing for the purpose by the Secretary and in the format approved in writing by the Secretary; or

(iiia) in a form approved in writing by the Secretary under sub-subparagraph 19 (1) (a) (iia) (B) for the purposes of writing an electronic prescription; or

(iv) by a method approved in writing by the Secretary; or

(b) in the case of a prescription submitted to the Minister — be submitted by the practitioner giving the Minister details of the prescription that has been prepared and signed by the practitioner in accordance with paragraph (a):

(i) by telephone; or

(ii) by means of an approved electronic communication.

(4) For the purposes of paragraph (2) (a), a prescription that has been prepared and signed by the practitioner in accordance with paragraph (3) (a) is taken to have been submitted by him or her if it is submitted by one of his or her employees.

(5) A variation under subregulation (1) in relation to a person may be made:

(a) if a paper-based prescription is submitted in accordance with a form specified in subparagraph (3) (a) (i), (ii) or (iii) or by a method approved under subparagraph (3) (a) (iv) — by the Minister signing his or her authorisation of the prescription on it and:

(i) if the Minister requires the practitioner to alter the prescription — by returning it to the practitioner for alteration before the practitioner gives it to the person in respect of whom it was prepared; or

(ii) in any other case:

(A) by returning it to the practitioner; or

(B) if requested by the practitioner — by sending it to the person in respect of whom it was prepared; or

(aa) if an electronic prescription is submitted in accordance with a form approved under subparagraph (3) (a) (iiia) — by the Minister signing his or her authorisation of the prescription on the electronic prescription and:

(i) if the Minister requires the practitioner to alter the prescription — by returning it, including by means of an electronic communication, to the practitioner for alteration before the practitioner gives it to the person in respect of whom it was prepared; or

(ii) in any other case:

(A) by returning it, including by means of an electronic communication, to the practitioner; or

(B) if requested by the practitioner — by making the prescription accessible by the person in respect of whom it was prepared or by an approved pharmacist for the purpose of supplying a pharmaceutical benefit to the person in respect of whom the prescription was prepared; or

(b) if a prescription is submitted in accordance with paragraph (2) (b) by telephone — orally, at the time the Minister is given details of the prescription; or

(c) if a prescription is submitted in accordance with paragraph (2) (b) by means of an electronic communication — by the Minister sending his or her authorisation, by electronic communication, to the practitioner.

(6) If the Minister makes a variation in accordance with paragraph (5) (b) or (c):

(a) the Minister must tell the practitioner, orally or by electronic communication, the number that has been allotted to the authorised prescription; and

(b) the practitioner must:

(i) mark that number on the prescription; and

(ii) retain, for 1 year from the date on which the variation was made:

(A) if the prescription is a paper-based prescription — a copy of the prescription; or

(B) if the prescription is an electronic prescription — the electronic prescription.

(7) For subparagraph (6) (b) (ii), the date on which the Minister makes a variation in relation to a person in respect of whom a practitioner submits an electronic prescription is:

(a) if the electronic prescription was submitted in accordance with paragraph (5) (b) — the date on which the Minister

tells the practitioner the number that has been allotted to the authorised prescription; and

(b) if the electronic prescription was submitted in accordance with paragraph (5) (c) — the date on which the Minister sends, by means of an electronic communication, his or her authorisation of the prescription to the practitioner.

(8) In this regulation:

practitioner means any of the following:

(a) an authorised optometrist;

(b) a medical practitioner;

(c) an authorised midwife;

(d) an authorised nurse practitioner.

Part IV Supply of pharmaceutical benefits by medical practitioners, authorised midwives and authorised nurse practitioners

14 Meaning of *practitioner*

In this Part:

practitioner means any of the following:

(a) a medical practitioner;

(b) an authorised midwife;

(c) an authorised nurse practitioner.

15 Practitioners not authorised under sections 93 and 93AA of the Act

A practitioner who is practising his or her profession on a ship is not authorised to supply pharmaceutical benefits under section 93 or 93AA of the Act.

16 Obtaining benefits by practitioners under sections 93 and 93AA of the Act

(1) For sections 93 and 93AA of the Act, a practitioner who is not an approved medical practitioner may obtain a pharmaceutical benefit only if he or she lodges with an approved pharmacist:

(a) an order, in duplicate, signed by the practitioner, in accordance with a form approved in writing by the Secretary; or

(b) an order, in accordance with subregulation (1A), that is:

(i) signed by the practitioner; and

(ii) in accordance with an electronic form approved in writing by the Secretary.

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(1A) For paragraph (1) (b), an order is lodged with an approved pharmacist if:

(a) it is lodged in accordance with any approved information technology requirements and by an approved electronic communication; and

(b) the practitioner, or an agent of the practitioner, who will receive the pharmaceutical benefit asks the approved pharmacist to supply the pharmaceutical benefit under the order; and

(c) the approved pharmacist consents, within the meaning of subsection 5 (1) of the *Electronic Transactions Act 1999*, to the order being lodged, in accordance with any approved information technology requirements and by an approved electronic communication; and

(d) the order is accessible by the approved pharmacist.

(2) A practitioner who is not an approved medical practitioner may obtain a pharmaceutical benefit under subregulation (1) only once in a calendar month.

(3) A practitioner, or an agent of a practitioner, who receives a pharmaceutical benefit under subregulation (1), must:

(a) prepare a receipt for the benefit supplied, using the part of the order form identified for that purpose, that includes the following information:

(i) the date of supply of the benefit;

(ii) if the benefit is received by an agent of the practitioner — the agent's address; and

(b) if the order is lodged in accordance with paragraph (1) (a) — give the receipt to the approved pharmacist supplying the benefit; and

(c) if the order is lodged in accordance with paragraph (1) (b):

(i) submit the receipt, in accordance with any approved information technology requirements and by an approved electronic communication; and

(ii) ensure the receipt is accessible by the approved pharmacist supplying the benefit.

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17 Supply of pharmaceutical benefits by approved pharmacists under sections 93 and 93AA of the Act

(1) An approved pharmacist commits an offence if:

(a) he or she supplies a pharmaceutical benefit on an order lodged under regulation 16; and

(b) neither of the following circumstances applies:

(i) the pharmacist knows the practitioner whose signature appears on the order;

(ii) if he or she does not know the practitioner, the pharmacist:

(A) is given the full name and address of the practitioner by the person who lodged the order; and

(B) if the practitioner is a medical practitioner — is given the medical registration number of the practitioner by the person who lodged the order; and

(C) for any other practitioner — is given the number allotted to the approval for the practitioner by the Secretary under subregulation 8A (1) by the person who lodged the order; and

(D) writes on the order form the details mentioned in sub-subparagraphs (A), (B) and (C).

Penalty: 0.4 penalty units.

(2) An offence against subregulation (1) is an offence of strict liability.

18 Payment for pharmaceutical benefits supplied under sections 93 and 93AA of the Act

An approved pharmacist who has supplied a pharmaceutical benefit to a practitioner under section 93 or 93AA of the Act on an order lodged under regulation 16 and in accordance with these Regulations is entitled to payment from the Commonwealth for the supply of the pharmaceutical benefit at

the rate and subject to the conditions determined by the Minister and applicable at the time of the supply.

18A Benefits obtained by approved medical practitioners for the purposes of section 93

(1) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purpose of section 93 of the Act by lodging with an approved pharmacist an order under regulation 16.

Penalty: 0.2 penalty units.

(2) An approved medical practitioner commits an offence if he or she obtains a pharmaceutical benefit for the purpose of section 93 of the Act more than once in each month.

Penalty: 0.2 penalty units.

(3) An approved medical practitioner who obtains a pharmaceutical benefit for the purpose of section 93 of the Act must give a notice to the Secretary that he or she has obtained the benefit.

Penalty: 0.2 penalty units.

(4) For subregulation (3), the notice must be:

(a) in a form authorised by the Secretary; and

(b) signed and dated by the practitioner.

(5) An approved medical practitioner who gives a notice to the Secretary under subregulation (3) must retain a copy of the notice for at least 1 year from the date on which he or she gives the notice to the Secretary.

Penalty: 0.2 penalty units.

(6) An offence against subregulation (1), (2), (3) or (5) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

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(7) An approved medical practitioner who:

(a) obtains a pharmaceutical benefit for the purpose of section 93 of the Act in accordance with these Regulations; and

(b) gives a notice to the Secretary under subregulation (3) about the benefit; and

(c) gives the Secretary a claim in accordance with a form made available by the Secretary to approved medical practitioners for that purpose; and

(d) completes the claim form in accordance with directions on that form;

is entitled to payment from the Commonwealth in respect of the pharmaceutical benefit at the rate applicable for the supply of the same benefit on an order under regulation 16.

Part V Prescriptions and supply

19 Writing of prescriptions

(1) A prescription, including an authority prescription, is duly written only if a PBS prescriber:

(a) prepares the prescription:

(i) in duplicate, by handwriting the prescription in ink on a prescription form:

(A) that is as nearly as practicable 18 centimetres long by 12 centimetres wide; and

(B) on which appears the name and address of the PBS prescriber and, subject to subregulation (4), the letters 'PBS'; and

(C) on the original of which appear the words 'pharmacist/patient copy'; and

(D) on the duplicate of which appear the words 'Medicare Australia/DVA copy'; or

(ii) in duplicate, by means of a computer on a prescription form:

(A) that is as nearly as practicable 18 centimetres long by 12 centimetres wide; and

(B) on which appears the name and address of the PBS prescriber and, subject to subregulation (4), the letters 'PBS'; and

(C) on the original of which appear the words 'pharmacist/patient copy'; and

(D) on the duplicate of which appear the words 'Medicare Australia/DVA copy'; and

(E) that is approved in writing for the purpose by the Secretary; or

(iia) by means of a form:

(A) on which appear the name and address of the PBS prescriber and the letters 'PBS'; and

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(B) that is approved in writing by the Secretary for the purpose of writing an electronic prescription; or

(iii) by another method approved in writing by the Secretary; and

(aa) signs the prescription after it is prepared; and

(b) for an authority prescription — writes on it:

(i) the authority approval number allotted by the Chief Executive Medicare, unless the prescription is to be posted or delivered to the Chief Executive Medicare for authorisation; or

(ii) the streamlined authority code mentioned in the Declaration under subsection 85 (2), or the Determination under sections 85, 85A and 88, of the Act for the pharmaceutical benefit, and its circumstances or purpose, being prescribed; and

(c) specifies on the prescription the date on which the prescription is written and signs the prescription; and

(ca) for a participating dental practitioner, authorised optometrist, authorised midwife or authorised nurse practitioner — states in the prescription the number allotted to his or her approval under regulation 8A; and

(d) states in the prescription the name of the person for whom the pharmaceutical benefit is to be supplied and the address of that person; and

(e) identifies in the prescription the pharmaceutical benefit by such particulars as are necessary to identify the pharmaceutical benefit; and

(f) states in the prescription:

(i) the quantity or number of units of the pharmaceutical benefit to be supplied; and

(ii) if the supply of the benefit is to be repeated — the number of times it is to be repeated; and

(g) if the pharmaceutical benefit to be supplied is not a ready-prepared pharmaceutical benefit — indicates in the prescription the manner in which the pharmaceutical benefit is to be administered; and

(h) if, under regulation 24, the medical practitioner, authorised midwife or authorised nurse practitioner directs in the prescription the supply on the one occasion of a quantity or number of units of a pharmaceutical benefit exceeding the quantity or number of units that could otherwise be prescribed — writes on the prescription 'Reg 24' or 'Regulation 24'.

Note Paragraph 105 (b) of the Act empowers regulations to be made about the writing of prescriptions.

(2) However, a prescription will not be taken to be duly written by the PBS prescriber if it provides for the supply of a pharmaceutical benefit to:

(a) a person if the PBS prescriber has written, on the same day, another prescription for the supply of the same or an equivalent pharmaceutical benefit to the person; or

(b) more than 1 person.

(4) For the purposes of sub-subparagraphs (1) (a) (i) (B) and (1) (a) (ii) (B), a prescription form that was printed before 1 June 1996 may contain the letters 'NHS' instead of the letters 'PBS'.

(5) For subparagraphs (1) (a) (ii), (iia) and (iii), a prescription must not be prepared using a computer program that operates, or may operate, to indicate on a prescription by default, for the purpose of subsection 103 (2A) of the Act, that only the brand of pharmaceutical benefit specified in the prescription is to be supplied.

19A Prescribed matters (Act s 84AA (1), (1A), (2) and (3))

(1) For the purposes of subsections 84AA (1), (1A), (2) and (3) of the Act, the following information is prescribed:

(a) in relation to a person who is a concessional beneficiary:

(i) information that the person is a concessional beneficiary; and

(ii) the number specified on a card held by the person (being a card issued by the Commonwealth) as being an entitlement number (however described) in relation to the person;

(b) in relation to a person who is a holder of a concession card:

(i) information that the person is the holder of a concession card; and

(ii) the number of the card;

(ba) in relation to a person who is a holder of an entitlement card:

(i) information that the person is the holder of an entitlement card; and

(ii) the number of the card;

(c) in relation to a person who is a dependant of a concessional beneficiary:

(i) information that the person is a dependant of a concessional beneficiary; and

(ii) the number specified on a card held by that concessional beneficiary (being a card issued by the Commonwealth) as being an entitlement number (however described) in relation to the person.

(2) For the purposes of subsections 84AA (1) and (1A) of the Act, prescribed information shall be written or marked on a prescription by making:

(a) in accordance with a form approved by the Secretary for the purposes of this subregulation, provision on the prescription for the supply of that information; or

(b) where the Minister has, by notice in writing published in the *Gazette*, given his or her consent to that effect — an endorsement on the prescription in a form that, immediately before the commencement of this regulation, was a prescribed form for the purposes of section 84AA of the Act as then in force;

and inserting:

(c) in the case of information that the person to whom the prescription relates is a concessional beneficiary or a dependant of a concessional beneficiary — a tick or a cross in the square provided on the prescription for the supply of such information in relation to the person;

(da) in the case of information that the person to whom the prescription relates is a holder of a concession card or an entitlement card — a tick or a cross in the square provided on the prescription for the supply of such information in relation to the person; and

(e) in a case where the information is the entitlement number referred to in subparagraph (1) (a) (ii), (1) (b) (ii), (1) (ba) (ii) or (1) (c) (ii) (as the case may be) in relation to the person to whom the prescription relates — the letters and digits forming that number, in the appropriate sequence, in the squares provided on the prescription for the supply of such information.

(2A) For a prescription to which subsection 84AA (1) or (1A) of the Act applies, subregulations (1) and (2) do not apply if:

(a) the claim for a payment from the Commonwealth in relation to the supply of the pharmaceutical benefit to which the prescription relates is made under the Claims Transmission System, within the meaning of section 99AAA of the Act; and

(b) the claim includes the card number that, under subregulation (1) would, except for this subregulation, be required.

(3) For the purposes of subsections 84AA (2) and (3) of the Act, prescribed information shall be communicated to a pharmacist orally or in writing.

19B Restriction on using PBS and NHS forms

(1) A person commits an offence if:

(a) he or she writes a prescription on a form bearing the letters ‘PBS’, ‘NHS’ or ‘N. H. S’; and

(b) the prescription is not written in accordance with, or for a purpose authorised by, these Regulations; and

(c) the letters ‘PBS’, ‘NHS’ or ‘N. H. S’ (as the case may be) are not clearly struck out, or obliterated.

Penalty: 0.4 penalty units.

(2) An offence against subregulation (1) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

20 Recovery of cost of pharmaceutical benefits prescribed for persons not entitled or in excessive quantities

(1) If a Committee of Inquiry established under Division 2 or Division 2AA of Part VIII of the Act reports that, in its opinion:

(a) a medical practitioner:

(i) before 1 April 1987 — prescribed a pharmaceutical benefit, as specified in the report, otherwise than in a circumstance prescribed in relation to that pharmaceutical benefit by subregulation 14 (2) of these Regulations as in force on the date on which he or she prescribed the pharmaceutical benefit; or

(ii) on or after 1 April 1987 — prescribed a pharmaceutical benefit, as specified in the report, otherwise than in a circumstance specified in relation to that pharmaceutical benefit in a declaration under subsection 85 (2) of the Act, being a declaration as in force on the date on which the medical practitioner prescribed the pharmaceutical benefit; or

(aa) a participating dental practitioner prescribed a pharmaceutical benefit:

(i) that is referred to in the report; and

(ii) that is not in accordance with a circumstance specified in relation to that pharmaceutical benefit in a declaration, under subsection 85 (2) of the Act, that was in force on the date on which the pharmaceutical benefit was prescribed; or

(b) a medical practitioner or participating dental practitioner has prescribed a quantity or number of units of a pharmaceutical benefit that is greater, to an extent specified in the report, than the quantity or number of units of that pharmaceutical benefit that could reasonably

have been necessary for the proper medical or dental treatment of the person in respect of whose medical or dental treatment the prescription was written;

the medical practitioner or participating dental practitioner is liable to repay to the Commonwealth such amount (if any) as is determined by the Minister, being an amount not exceeding the cost to the Commonwealth of:

(c) in the circumstances specified in paragraph (a) — the quantity or number of units of the pharmaceutical benefit supplied upon the prescription; or

(d) in the circumstances specified in paragraph (b) — the excess quantity or number of units of the pharmaceutical benefit supplied upon the prescription.

(2) An amount that a medical practitioner or participating dental practitioner is liable to repay under subregulation (1) is recoverable as a debt due to the Commonwealth in a court of competent jurisdiction.

21 Supply of pharmaceutical benefit on first presentation of prescription

(1) An approved pharmacist or an approved medical practitioner must not supply a pharmaceutical benefit to a person on the first presentation of a prescription for the supply of that benefit to the person, unless:

(a) subject to regulations 22, 26 and 26A, the prescription is:

(i) written in accordance with these Regulations; and

(ii) given to the pharmacist or practitioner; and

(aa) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written; and

(b) the pharmacist or practitioner writes on the prescription (including, for a paper-based prescription, both the original and the duplicate):

(i) the pharmacist's or practitioner's name and approval number under regulation 8A; and

(ii) a number that identifies the prescription.

(2) An approved hospital authority must not supply a pharmaceutical benefit to a person on the first presentation of a prescription for the supply of that benefit to that person, unless:

(a) subject to regulations 22, 26 and 26A, the prescription is:

(i) written in accordance with these Regulations; and

(ii) given to the pharmacist or practitioner; and

(aa) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written; and

(b) the prescription (including, for a paper-based prescription, both the original and the duplicate) is marked, for the hospital authority, with:

(i) the hospital authority's name and approval number under regulation 8A; and

(ii) a number that identifies the prescription.

(3) In this regulation, a reference to the first presentation of a prescription is taken to mean, in relation to an electronic prescription, the first occasion when the prescription is accessed by an approved pharmacist or an approved medical practitioner for the purpose of supplying a pharmaceutical benefit to the person for whom the prescription was written.

22 Supply of pharmaceutical benefits before surrender of written prescription

(1) Subject to this regulation, a pharmaceutical benefit may be supplied to a person, in a case of urgency, by an approved pharmacist before the prescription for that pharmaceutical benefit is given to the pharmacist if:

(a) a PBS prescriber advises the pharmacist of the details of the prescription; or

(b) the PBS prescriber has written and signed a prescription that is sent by facsimile transmission service to the pharmacist by:

(i) the PBS prescriber; or

(ii) a person under the control of the PBS prescriber.

(2) If:

(a) the prescribing of a pharmaceutical benefit under subregulation (1) is subject to a condition that an authority for the prescription is to be obtained from:

(i) the Minister and the Chief Executive Medicare; or

(ii) either of those persons; and

(b) the PBS prescriber informs an approved pharmacist or approved medical practitioner that the PBS prescriber has been notified by the Minister or the Chief Executive Medicare (by oral or other means) that an authority will be given; and

(c) the PBS prescriber complies with subregulation (1);

the approved pharmacist or approved medical practitioner may supply the pharmaceutical benefit.

(3) A PBS prescriber referred to in subregulation (1) must ensure that, for a paper-based prescription, the original and a duplicate of the prescription are received by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

(3AA) A PBS prescriber referred to in subregulation (1) must ensure that, for an electronic prescription, the prescription is accessible by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

(3A) An offence against subregulation (3) or (3AA) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

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(4) A PBS prescriber who has communicated with an approved pharmacist or approved medical practitioner under subregulation (2) must ensure that, for a paper-based prescription, the original and a duplicate of the prescription are received by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

(4AA) A PBS prescriber who has communicated with an approved pharmacist or approved medical practitioner under subregulation (2) must ensure that, for an electronic prescription, the prescription is accessible by the relevant pharmacist or medical practitioner no later than 7 days after the day on which the benefit was supplied.

Penalty: 0.2 penalty units.

(4A) An offence against subregulation (4) or (4AA) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

(5) This regulation does not apply to a pharmaceutical benefit the prescription for which is required to be in writing by or under a law of the State or Territory of the Commonwealth in which the premises of the approved pharmacist are situated.

24 Circumstances in which quantity of repeated supply can be directed to be supplied on one occasion

(1) A medical practitioner may, in pursuance of subsection 88 (6) of the Act, instead of directing a repeated supply of a pharmaceutical benefit in accordance with Part VII of the Act, direct in a prescription the supply on one occasion of a quantity or number of units of the pharmaceutical benefit allowable under that subsection if he or she is satisfied that:

(a) the maximum quantity or number of units applicable in relation to the pharmaceutical benefit under a determination of the Minister under section 85A of the Act is insufficient for the medical treatment of the person for whom the prescription is written;

(b) that person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to that person's place of residence; and

(c) that person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions.

(2) For subsection 88 (6B) of the Act, an authorised midwife or authorised nurse practitioner may, instead of directing a repeated supply, direct in a prescription the supply on 1 occasion of a quantity or number of units of the pharmaceutical benefit allowable under subsection 88 (6A) of the Act if he or she is satisfied that:

(a) the maximum quantity or number of units applicable for the pharmaceutical benefit under a determination under section 85A and subsection 88 (1D) or (1E) of the Act is insufficient for the treatment of the person for whom the prescription is written; and

(b) the person requires the pharmaceutical benefit for the treatment of a chronic illness or is residing in a place remote from the approved pharmacist nearest to the person's place of residence; and

(c) the person could not, without great hardship, obtain the required quantity or number of units of the pharmaceutical benefit by means of repeated supplies on separate occasions.

25 Repeated supplies of pharmaceutical benefits

(1) A pharmaceutical benefit shall not be supplied a number of times greater than the number specified in the prescription.

(2) Subregulation (3) applies to a pharmaceutical benefit in relation to which:

(a) the Minister determines, under paragraph 85A (2) (b) of the Act, that the maximum number of occasions on which the supply of the benefit may, in 1 prescription, be directed to be repeated is more than 4; and

(b) the Minister determines, under paragraph 85A (2) (c) of the Act, that the manner of administration that may, in a prescription, be directed to be used in relation to the benefit is administration otherwise than by application to the eye.

(3) A pharmaceutical benefit to which this subregulation applies may be supplied to the person in respect of whom the prescription for the supply of the benefit was written if:

(a) the supplier of the benefit reasonably believes that the person has not received a supply of the pharmaceutical benefit, or of another brand of that benefit, in the period of 20 days immediately preceding the day on which it is to be supplied to the person; or

(b) the supplier of the benefit:

(i) reasonably believes that a supply of the pharmaceutical benefit that was previously supplied to the person has been destroyed, lost or stolen; and

(ii) writes the words 'immediate supply necessary':

(A) for a paper-based prescription — on the Medicare Australia/DVA copy; or

(B) for an electronic prescription — on the prescription; and

(iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires; or

(c) the supplier of the benefit:

(i) reasonably believes that, having regard to the person's circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person; and

(ii) writes the words 'immediate supply necessary':

(A) for a paper-based prescription — on the Medicare Australia/DVA copy; or

(B) for an electronic prescription — on the prescription; and

(iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires.

(4) A pharmaceutical benefit other than a benefit to which subregulation (3) applies may be supplied to the person in respect of whom the prescription for the supply of the benefit was written if:

(a) the supplier of the benefit reasonably believes that the person has not received a supply of the pharmaceutical benefit, or of another brand of that benefit, in the period of 4 days immediately preceding the day on which it is supplied to the person; or

(b) the supplier of the benefit:

(i) reasonably believes that a supply of the pharmaceutical benefit that was previously supplied to the person has been destroyed, lost or stolen; and

(ii) writes the words 'immediate supply necessary':

(A) for a paper-based prescription — on the Medicare Australia/DVA copy; or

(B) for an electronic prescription — on the prescription; and

(iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires; or

(c) the supplier of the benefit:

(i) reasonably believes that, having regard to the person's circumstances, the supply of the benefit is necessary, without delay, for the treatment of the person; and

(ii) writes the words 'immediate supply necessary':

(A) for a paper-based prescription — on the Medicare Australia/DVA copy; or

(B) for an electronic prescription — on the prescription; and

(iii) signs the Medicare Australia/DVA copy or the electronic prescription, as the case requires.

26 Repeat authorisations

(1) Subregulation (1A) applies if:

(a) an approved pharmacist, or an approved medical practitioner, or an approved hospital authority supplies a pharmaceutical benefit under:

(i) a Medicare Australia/DVA copy of a paper-based prescription that contains a direction to supply the benefit more than once; or

(ii) a pharmacist/patient copy of a paper-based prescription to which is attached a deferred supply authorisation that contains a direction to supply the benefit more than once; or

(iii) a pharmacist/patient copy of a paper-based prescription to which is attached a repeat authorisation that contains a direction to supply the benefit more than once; or

(iv) an electronic prescription:

(A) that contains a direction to supply the benefit more than once; or

(B) to which is attached or linked, by electronic means, a deferred supply authorisation that contains a direction to supply the benefit more than once; or

(C) to which is attached or linked, by electronic means, a repeat authorisation that contains a direction to supply the benefit more than once; and

(b) subsequent supplies of the pharmaceutical benefit can be made under the prescription at the time of supply under paragraph (a).

(1A) The approved pharmacist, approved medical practitioner or approved hospital authority must:

(a) on or before supplying the pharmaceutical benefit:

(i) prepare a repeat authorisation in accordance with a form (including a paper-based or an electronic form) authorised by the Secretary for the supply of the pharmaceutical benefit; and

(ii) if the prescription for the benefit is written on an authority prescription — mark the number of the authority prescription on the repeat authorisation; and

(iii) if the prescription for the benefit is a paper-based prescription — attach the repeat authorisation to the pharmacist/patient copy and give the repeat authorisation and pharmacist/patient copy to the person to whom the pharmaceutical benefit is supplied; and

(iv) if the prescription for the benefit is an electronic prescription — attach or link, by electronic means, the repeat authorisation to the electronic prescription and ensure that the person to whom the pharmaceutical benefit is supplied:

(A) is given a print-out of the repeat authorisation and prescription; or

(B) is able to access the repeat authorisation and prescription; and

(b) for the supply of the pharmaceutical benefit on the first occasion — mark on the repeat authorisation:

(i) the name and address of the approved supplier; and

(ii) the approval number given to the approved supplier under regulation 8A; and

(iii) the identifying number given to the prescription by the approved supplier; and

(iv) if the pharmaceutical benefit is a substitute benefit for the purposes of subsection 103 (2A) of the Act — the brand name of the substitute benefit; and

(c) for the supply of the pharmaceutical benefit on a subsequent occasion — mark on the repeat authorisation:

(i) the date on which the most recent supply was made; and

(ii) the identifying number given to the prescription under subparagraph (b) (iii).

Penalty: 0.2 penalty units.

(1B) An offence against subregulation (1A) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

(2) An approved pharmacist, approved medical practitioner or approved hospital authority is not authorised to supply a pharmaceutical benefit upon presentation of only the pharmacist/patient copy of a paper-based prescription unless:

(a) the approved pharmacist, approved medical practitioner or approved hospital authority is given a repeat authorisation or a deferred supply authorisation that:

(i) is related to that pharmacist/patient copy by a number or numbers; and

(ii) indicates that the pharmaceutical benefit to be supplied has not been supplied for the number of times directed in the prescription; and

(b) there is written on the repeat authorisation or deferred supply authorisation the approval number given to the supplier under regulation 8A; and

(c) the date of supply of the benefit is on or before the first anniversary of the date on which the prescription was written.

(3) Where a pharmaceutical benefit is supplied by an approved hospital authority in the circumstances set out in subregulation (1), the approved hospital authority shall cause the requirements of subregulations (1), (1A) and (2) to be complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the pharmaceutical benefit is supplied.

26A Deferred supply authorisations

(1) Where a prescription contains a direction to supply more than 1 pharmaceutical benefit, the approved pharmacist, approved medical practitioner or approved hospital authority to whom the prescription is presented may, at the request of the person for whom the prescription is written, defer the supply of one or more of the pharmaceutical benefits.

(2) An approved pharmacist, approved medical practitioner or approved hospital authority that defers the supply of a pharmaceutical benefit must:

(a) prepare a deferred supply authorisation, on and in accordance with a form (including a paper-based or an electronic form) authorised by the Secretary, in respect of each pharmaceutical benefit the deferral of the supply of which is requested; and

(b) mark on the deferred supply authorisation prepared by him the number allotted to his or her approval under regulation 8A; and

(c) if the prescription is a paper-based prescription:

(i) mark on the original and duplicate of the prescription, across the wording relating to the pharmaceutical benefit the supply of which is being deferred, the words 'original supply deferred'; and

(ii) attach the deferred supply authorisation prepared by the pharmacist, medical practitioner or hospital authority to the pharmacist/patient copy; and

(iii) give the authorisation and pharmacist/patient copy to the person for whom the prescription is written at the same time as the benefit on the original prescription is supplied; and

(d) if the prescription is an electronic prescription:

(i) mark on the prescription, in relation to the pharmaceutical benefit the supply of which is being deferred, the words 'original supply deferred'; and

(ii) attach or link, by electronic means, the deferred supply authorisation prepared by the pharmacist, medical practitioner or hospital authority to the prescription; and

(iii) give a print-out of the deferred supply authorisation and prescription to the person to whom the pharmaceutical benefit is supplied or ensure that the deferred supply authorisation and prescription are accessible by that person.

(3) Where an approved hospital authority defers the supply of a pharmaceutical benefit in the circumstance set out in

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subregulation (1), the authority shall cause the requirements of subregulation (2) to be complied with by the medical practitioner or pharmacist by whom, or under whose direct supervision, the other pharmaceutical benefit to which the prescription refers is supplied.

27 Presentation of prescriptions in trading hours

(1) An approved pharmacist shall, at all times, keep prominently displayed at each of the premises in respect of which he or she is approved, so as to be readily visible to persons who enter the premises, a notice setting out the normal trading hours during which services for the supply of pharmaceutical benefits are available.

(2) Subject to regulation 28, a person is entitled to be supplied with a pharmaceutical benefit from an approved pharmacist during normal trading hours only.

28 Presentation of urgent prescriptions

(1) A prescription for the supply of a pharmaceutical benefit marked 'Urgent', that marking being initialled, in the case of a paper-based prescription, by the medical practitioner, participating dental practitioner, authorised midwife or authorised nurse practitioner writing the prescription, may be presented at any time to an approved pharmacist at the premises in respect of which he or she is approved.

(2) An approved pharmacist must supply a pharmaceutical benefit as soon as practicable if:

(a) a prescription is presented to the pharmacist under subregulation (1); and

(b) any charge lawfully demanded for the prescription is paid.

Penalty: 0.2 penalty units.

(3) An offence against subregulation (2) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

(4) It is a defence to a prosecution for an offence against subregulation (2) if the pharmacist had a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in subregulation (4) (see section 13.3 of the *Criminal Code*).

30 Special charge for delivery

When a pharmaceutical benefit is supplied by delivery at or to a place other than premises in respect of which the approved pharmacist is approved or the premises at which an approved medical practitioner carries on his or her practice, as the case may be, the pharmacist or medical practitioner may make a special charge equal to the cost of delivery.

31 Receipt of pharmaceutical benefit

(1) Subject to subregulation (3), a person who receives a pharmaceutical benefit (whether or not for the person's own use) from an approved pharmacist, approved medical practitioner or an approved hospital authority must:

(a) write on the prescription, repeat authorisation or deferred supply authorisation for the benefit an acknowledgment that the person has received the benefit; and

(b) write the date of supply of the benefit; and

(c) if the benefit is not for the person's own use — the person's address.

Penalty: 0.2 penalty units.

(1A) If a person is required to write an acknowledgment in accordance with subregulation (1) for the supply of a pharmaceutical benefit under an electronic prescription, or an authorisation that relates to an electronic prescription, that requirement is taken to have been met if:

(a) the acknowledgment is given, in accordance with approved information technology requirements (if any), by means of an approved electronic communication; or

(b) the person writes the acknowledgment on a print-out of the electronic prescription or the authorisation that relates to an electronic authorisation.

(1B) If a person writes an acknowledgment in accordance with paragraph (1A) (b), the approved pharmacist, approved medical practitioner or approved hospital authority must write on the electronic prescription, or the authorisation that relates to an electronic prescription, that the person has written the acknowledgment on a print-out of the prescription or authorisation.

Penalty: 0.2 penalty units.

(2) An approved pharmacist, approved medical practitioner or approved hospital authority must not demand an acknowledgment of the supply of a pharmaceutical benefit to a person if the pharmacist, medical practitioner or hospital authority has not supplied the benefit to that person.

Penalty: 0.2 penalty units.

(3) If it is not practicable for an approved pharmacist, approved medical practitioner or approved hospital authority to obtain an acknowledgment in accordance with subregulation (1) for the supply of a pharmaceutical benefit, the pharmacist, medical practitioner or hospital authority must certify on the prescription:

(a) the date on which the supply was made; and

(b) the reason why it was not practicable to obtain the acknowledgment.

Penalty: $20.

(4) An offence against subregulation (1), (2) or (3) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

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Part VI Miscellaneous

32 Retention of prescriptions etc

(1) If an approved pharmacist, approved medical practitioner, or approved hospital authority supplies a pharmaceutical benefit (other than a supply of a dangerous drug) he or she must:

(a) if the benefit was supplied under a paper-based prescription or an order lodged under paragraph 16 (1) (a) — retain the forms mentioned in subregulation (2) in his or her possession for at least 1 year from the date of supply; or

(b) if the benefit was supplied under an electronic prescription or an order lodged under paragraph 16 (1) (b) — retain the forms mentioned in subregulation (2) for at least 1 year from the date of supply.

Penalty: 0.2 penalty units.

(2) For subregulation (1), the following forms are specified:

(a) in the case of supply upon a prescription not bearing instructions to supply the pharmaceutical benefit more than once:

(i) for a paper-based prescription — the pharmacist/ patient copy; or

(ii) for an electronic prescription — the electronic prescription;

(b) in the case of supply upon a prescription bearing instructions to supply the pharmaceutical benefit more than once, if it is supplied on the last occasion on which supply is authorised:

(i) for a paper-based prescription — the pharmacist/ patient copy in respect of which repeat authorisations were issued; or

(ii) for an electronic prescription — the electronic prescription and the repeat authorisation;

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(c) in the case of supply under section 93 of the Act:

(i) for a paper-based prescription — the duplicate of the order lodged under regulation 16, or the notification form mentioned in subregulation 18A (3), as the case requires; or

(ii) for an electronic prescription — the electronic order form or the notification form mentioned in subregulation 18A (3), as the case requires.

(3) An offence against subregulation (1) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

(4) In this regulation:

dangerous drug means a drug or medicinal preparation in respect of which the law of the State or Territory in which the prescription is written provides that a pharmacist who dispenses that drug or medicinal preparation, or who dispenses it on the last of a number of occasions of supply indicated in a prescription for its supply, must take possession of the prescription and cancel it or deliver it to the authority administering that law.

33 Proper stocks to be kept

(1) An approved pharmacist must, as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits, or to use as ingredients of pharmaceutical benefits.

Penalty: 0.2 penalty units.

(2) An offence against subregulation (1) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

35 Standards of composition and purity of pharmaceutical benefits and additives

(1) If:

(a) under the *Therapeutic Goods Act 1989*, a drug, medicine or substance must be of a particular standard of composition or purity; and

(b) the drug, medicine or substance is to be supplied as a pharmaceutical benefit;

the standard of composition or purity of the drug, medicine or substance is the standard for the purposes of the Act.

(2) If:

(a) under the *Therapeutic Goods Act 1989*, a drug, medicine or substance must be of a particular standard of composition or purity; and

(b) the drug, medicine or substance is used as an additive in another drug, medicine or substance (in this subregulation called 'the finished product'); and

(c) the finished product is to be supplied as a pharmaceutical benefit;

the standard of composition or purity of the drug, medicine or substance used as an additive is the standard for the purposes of the Act.

36 Labelling of pharmaceutical benefits — full cost

(1) A pharmaceutical benefit supplied by an approved supplier must be labelled with the words 'full cost' followed by the full cost of the pharmaceutical benefit.

(2) Subregulation (1) does not apply to:

(a) an approved supplier to which section 99AAB of the Act applies; or

(b) an approved hospital authority; or

(c) a pharmaceutical benefit obtained under subsection 93 (2) or 93AA (2) of the Act; or

(d) a pharmaceutical benefit to which subsection 99 (2A), (2AB) or (2B) of the Act applies.

(3) For this regulation, the ***full cost*** of a pharmaceutical benefit is the sum of:

(a) the Commonwealth price of the pharmaceutical benefit within the meaning given by Part VII of the Act; and

(b) the special patient contribution charged under subsection 87 (2A) of the Act.

Note The special patient contribution is an amount calculated under subsection 85B (2) of the Act.

37 Surrender of forms

(1) The Secretary may, by notice in writing served on a person, require that person to surrender to the Secretary or to a person specified in the notice, within a time specified in the notice, any forms that have been supplied to that person by or on behalf of the Commonwealth under or for the purpose of Part VII of that Act or these Regulations and that are in the possession of the person.

(2) A person upon whom a notice is served in pursuance of subregulation (1) shall comply with that notice.

Penalty: 0.2 penalty units.

(3) An offence against subregulation (2) is an offence of strict liability.

Note For ***strict liability***, see section 6.1 of the *Criminal Code*.

Part VIA Price reductions

Division 1 General

37A Definitions for Part VIA

In this Part:

adjusted approved ex-manufacturer price has the meaning given by subsection 99ADB (1) of the Act.

approved price to pharmacists has the meaning given by subsection 98B (3) of the Act.

data collection period has the meaning given by subregulation 37EC (1).

disclosure cycle has the meaning given by subregulation 37EB (1).

interim supplementary disclosure cycle means the disclosure cycle mentioned in paragraph 37EB (2) (b).

listed, for a brand of a pharmaceutical item, means determined under subsection 85 (6) of the Act.

main disclosure cycle means a disclosure cycle mentioned in paragraph 37EB (2) (a).

price disclosure requirements has the meaning given by section 99ADC of the Act.

reporting period means a reporting period mentioned in regulation 37J or 37JA for a brand of a pharmaceutical item.

supplementary disclosure cycle A means a disclosure cycle mentioned in paragraph 37EB (2) (c).

supplementary disclosure cycle B means a disclosure cycle mentioned in paragraph 37EB (2) (d).

37B Listed brands of pharmaceutical items, reduction days and percentages

For section 99ACK of the Act, the listed brands of pharmaceutical items, the reduction days for those brands and

percentages for those brands that are mentioned in Schedule 5 are prescribed.

37C Adjusted approved price to pharmacists

For subsection 99ADB (2) of the Act, the adjusted approved price to pharmacists of a brand of a pharmaceutical item is worked out as follows:

(a) if the adjusted approved ex-manufacturer price of the brand is $930.06 or less — by multiplying the adjusted approved ex-manufacturer price by 1.0752 and rounding the result to the nearest cent (rounding 0.5 cents upwards);

(b) in any other case — by adding $69.94 to the adjusted approved ex-manufacturer price.

37D Approved ex-manufacturer price — general

For subsection 99ADB (3) of the Act, the approved ex-manufacturer price of a brand of a pharmaceutical item (other than a listed brand of a pharmaceutical item to which regulation 37DA applies) is worked out as follows:

(a) if the approved price to pharmacists of the brand is $1 000 or less — by dividing the approved price to pharmacists by 1.0752 and rounding the result to the nearest cent (rounding 0.5 cents upwards); or

(b) in any other case — by taking $69.94 from the approved price to pharmacists.

37DA Approved ex-manufacturer price — listed brand having same drug and manner of administration as listed brand already subject to price disclosure requirements and prior disclosure cycle

(1) This regulation applies to a brand of pharmaceutical item (the ***relevant brand***) to which regulation 37F applies if the circumstances mentioned in subregulation 37F (3) apply.

Note Regulation 37F applies to listed brands of pharmaceutical items that have the same drug and manner of administration as listed brands that are already subject to price disclosure requirements.

(2) For subsection 99ADB (3) of the Act, the method for working out the approved ex-manufacturer price of the relevant brand on the last day of the data collection period for the brand in the prior disclosure cycle is as follows:

(a) if the reference price of the brand on the day is $1 000 or less — by dividing the reference price for the relevant brand by 1.0752 and rounding the result to the nearest cent (rounding 0.5 cents upwards); or

(b) in any other case — by taking $69.94 from the reference price for the relevant brand.

Note The price worked out under this subregulation is used to work out the weighted average disclosed price for the brand in the prior disclosure cycle in step 11 of regulation 37G.

(3) For subregulation 37DA (2), the ***reference price*** for a relevant brand is the sum of the following amounts:

(a) the approved price to pharmacists on the relevant day; and

(b) any amount that the Act would have required to be deducted from the approved price to pharmacists if the relevant brand had been a listed brand on and after the last day of the data collection period for the brand in the prior disclosure cycle to and including the relevant day.

(4) In this regulation:

prior disclosure cycle has the meaning given by subregulation 37F (3).

relevant day has the meaning given by paragraph 37F (1) (a).

Division 2 Weighted average disclosed price

37DB Application

For subsection 99ADB (6) of the Act, this Division:

(a) prescribes the method for determining the weighted average disclosed price of a listed brand of a pharmaceutical item; and

(b) provides for matters that are relevant to that method.

Note The method is set out in regulation 37G.

37E Weighted average disclosed price — information

(1) This regulation deals with how information provided under the price disclosure requirements may be used with the method in regulation 37G for determining the weighted average disclosed price of a listed brand of a pharmaceutical item.

(2) To use the method for a brand of a pharmaceutical item (a ***particular brand***), all the information required under the price disclosure requirements must have been provided for the whole of the data collection period for at least 1 brand (the ***reported brand***) of a pharmaceutical item that has the same drug and manner of administration as the particular brand.

(3) To avoid doubt, the method can be used for determining the weighted average disclosed price of the particular brand, even if:

(a) the reported brand is not the particular brand; or

(b) the particular brand is the only reported brand.

(4) If the information provided by a responsible person under the price disclosure requirements for a reporting period is incomplete, the information may be disregarded in making a determination of the weighted average disclosed price of the brand or every brand of every pharmaceutical item with the same drug and manner of administration.

Note For reporting periods, see regulations 37J and 37JA.

37EA Disclosure cycles and data collection periods for listed brands of pharmaceutical items — general

Regulations 37EB to 37F set out matters about disclosure cycles and data collection periods to be used for the method in regulation 37G for determining the weighted average disclosed price~~s~~ of a listed brand~~s~~ of pharmaceutical item~~s~~.

Note Section 99ADA of the Act provides that Division 3B (Price disclosure) of Part VII of the Act does not apply to brands of exempt items.

37EB Disclosure cycles

(1) For the purposes of determining the weighted average disclosed price of a listed brand of pharmaceutical item there are several kinds of ***disclosure cycles*** during which:

(a) information is provided in compliance with price disclosure requirements; and

(b) data is processed; and

(c) a reduction day occurs.

(2) For these Regulations, the kinds of disclosure cycles are as follows:

(a) main disclosure cycles;

(b) the interim supplementary disclosure cycle;

(c) supplementary disclosure cycles A;

(d) supplementary disclosure cycles B.

Note 1 Regulations 37ED and 37F set out when a brand of pharmaceutical item is in a particular cycle. Regulations 37EG and 37EH set out when a brand of pharmaceutical item moves from a supplementary disclosure cycle to a main disclosure cycle.

Note 2 For transitional arrangements, see Part 2 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 5).*

(3) There is only 1 interim supplementary disclosure cycle.

37EC Data collection periods

(1) In each disclosure cycle, there are ***data collection periods*** for which information about brands of pharmaceutical items must be provided in compliance with price disclosure requirements.

(2) In a disclosure cycle:

(a) there is only 1 data collection period for each brand of a pharmaceutical item; and

(b) all brands of pharmaceutical items that have the same drug and manner of administration have the same data collection period; and

(c) the data collection periods for brands of pharmaceutical items that have different drugs, or that have the same drug with a different manner of administration, can commence on different days; and

(d) all data collection periods in the disclosure cycle end on the same day.

37ED Listed brand having a drug and manner of administration not subject to price disclosure requirements before relevant day — first disclosure cycle and beginning of data collection period for brand

(1) This regulation applies to a listed brand of a pharmaceutical item (the ***relevant brand***) if:

(a) the price disclosure requirements first apply under section 99ADD of the Act for the relevant brand on a day (the ***relevant day***); and

(b) no requirement to comply with the price disclosure requirements has arisen under the Act before the relevant day for:

(i) the relevant brand; or

(ii) any other listed brand of any pharmaceutical item having the same drug and manner of administration as the relevant brand.

(2) The relevant brand is in a main disclosure cycle if the relevant day for the brand is:

(a) between 2 June and 1 October in a year (both dates inclusive); or

(b) 1 December 2010.

(3) The relevant brand is in the interim supplementary disclosure cycle if the relevant day for the brand is between 2 December 2010 and 1 June 2011 (both dates inclusive).

(4) Except where subregulation (3) applies, the relevant brand is in a supplementary disclosure cycle A if the relevant day for the brand is between 2 October in a year and 1 February in the next year (both dates inclusive).

(5) Except where subregulation (3) applies, the relevant brand is in a supplementary disclosure cycle B if the relevant day for the brand is between 2 February and 1 June in a year (both dates inclusive).

(6) The data collection period for the relevant brand in the first disclosure cycle for the brand begins on the relevant day.

Note The data collection period for a brand in the main disclosure cycle and to which section 99ADJ of the Act applies begins on 1 December 2010 and ends at the end of 30 September 2011.

37EE End dates for data collection periods for relevant brands covered by regulation 37ED

(1) The data collection period for a relevant brand in a main disclosure cycle ends at the end of 30 September in the year after the year in which the relevant day for the brand occurs.

(2) The data collection period for a relevant brand in the interim supplementary disclosure cycle ends at the end of 31 May 2012.

(3) The data collection period for a relevant brand in a supplementary disclosure cycle A ends:

(i) if the relevant day for the brand is between 2 October in a year and 31 December in the year (both dates inclusive) — at the end of 31 January in the second year after the year in which the relevant day for the brand occurs; and

(ii) if the relevant day for the brand is between 1 January in a year and 1 February in the year (both dates inclusive) — at the end of 31 January in the year after the year in which the relevant day for the brand occurs.

(4) The data collection period for a relevant brand in a supplementary disclosure cycle B ends at the end of 31 May in the year after the year in which the relevant day for the brand occurs.

Note For how a listed brand moves from a supplementary disclosure cycle to a main disclosure cycle, see regulations 37EG and 37EH.

(5) In this regulation:

relevant brand has the meaning given by subregulation 37ED (1).

relevant day has the meaning given by paragraph 37ED (1) (a).

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37EF Subsequent main disclosure cycle —subsequent data collection periods

A subsequent data collection period for a brand in a subsequent main disclosure cycle:

(a) begins on 1 October of the year in which the previous data collection period in the previous main disclosure cycle for the brand ended; and

(b) ends at the end of 30 September in the following year.

37EG Listed brand moving from supplementary disclosure cycle A to main disclosure cycle

(1) This regulation applies to a listed brand of a pharmaceutical item if:

(a) the brand is in a supplementary disclosure cycle A; and

(b) the data collection period in the supplementary disclosure cycle ends at the end of 31 January in a year.

(2) The brand moves to a main disclosure cycle on 1 February in the year.

(3) The data collection period for the brand in the main disclosure cycle:

(a) begins on 1 February in the year; and

(b) ends at the end of 30 September in the next year.

37EH Listed brand moving from interim supplementary disclosure cycle and supplementary disclosure cycle B to main disclosure cycle

(1) This regulation applies to a listed brand of a pharmaceutical item if:

(a) the brand is in:

(i) the interim supplementary disclosure cycle; or

(ii) a supplementary disclosure cycle B; and

(b) the data collection period in the disclosure cycle ends at the end of 31 May in a year.

(2) The brand moves to a main disclosure cycle on 1 June in the year.

(3) The data collection period for the brand in the main disclosure cycle:
  (a) begins on 1 June in the year; and
  (b) ends at the end of 30 September in the next year.

37F Listed brand having same drug and manner of administration as listed brand already subject to price disclosure requirements — disclosure cycle and beginning of data collection period for brand

(1) This regulation applies to a listed brand of a pharmaceutical item (the ***relevant brand***) if:
  (a) the price disclosure requirements first apply under section 99ADD of the Act for the relevant brand on a day (the ***relevant day***); and
  (b) both on and before the relevant day, the price disclosure requirements apply for any other listed brand of any pharmaceutical item having the same drug and manner of administration (the ***other brand***) as the relevant brand.

(2) If the end of a data collection period for a disclosure cycle (the ***relevant disclosure cycle***) for the other brand is after the relevant day, then:
  (a) the relevant brand is in the relevant disclosure cycle; and
  (b) the relevant brand joins the data collection period for the other brand on the relevant day.

(3) If the other brand is in both the relevant disclosure cycle and a disclosure cycle (the ***prior disclosure cycle***) before the relevant disclosure cycle, and the relevant day is before the reduction day for the other brand in the prior disclosure cycle, then the relevant brand:
  (a) is also in the prior disclosure cycle; and

(b) is in the data collection period for the other brand for the purposes of calculating the weighted average disclosed price for the relevant brand.

Note Although data is not required to be provided for the relevant brand for the prior disclosure cycle, a weighted average disclosed price is determined for the relevant brand using the method in regulation 37G. Regulation 37DA provides a method for working out the approved ex-manufacturer price on the last day of the data collection period in the prior disclosure cycle.

37G Weighted average disclosed price

(1) This regulation sets out the method for determining the weighted average disclosed price of:

(a) a listed brand of a pharmaceutical item; and

(b) every listed brand of every pharmaceutical item having the same drug and manner of administration;

for the data collection period for the brands in a disclosure cycle.

Step 1

(2) Add up the sales revenue for the brand, excluding sales to public hospitals (as disclosed under the price disclosure requirements) for the data collection period for the brand in the disclosure cycle.

(3) However, for a first reporting period to which subregulation 37J (3) or (4) applies:

(a) if subregulation 37J (3) applies to the reporting period — exclude the sales revenue for the brand for the first month of the first reporting period if the brand was not a listed brand immediately before the relevant day mentioned in paragraph 37ED (1) (a); or

(b) if subregulation 37J (4) applies to the reporting period — exclude the sales revenue for the brand for the first month of the first reporting period.

Step 2

(4) From the amount worked out under step 1, take away the incentives for the brand (as disclosed under the price disclosure requirements) for the data collection period for the brand in the disclosure cycle, to give the net revenue for the data collection period in the disclosure cycle.

Step 3

(5) Add up the adjusted volume of the brand sold for the data collection period for the brand in the disclosure cycle (the volume of the brand sold, based on the number of packs sold, is disclosed under the price disclosure requirements).

(6) However, for a first reporting period to which subregulation 37J (3) or (4) applies:

(a) if subregulation 37J (3) applies to the reporting period — exclude the adjusted volume of the brand sold in the first month of the first reporting period if the brand was not a listed brand immediately before the relevant day mentioned in paragraph 37ED (1) (a); or

(b) if subregulation 37J (4) applies to the reporting period — exclude the adjusted volume of the brand sold in the first month of the first reporting period.

Step 4

(7) Work out the disclosed price for the brand by dividing the net revenue for the brand by its adjusted volume.

Step 5

(8) Work out the price percentage difference for the brand (expressed as a percentage to 2 decimal places) by:

(a) subtracting its disclosed price from its applicable approved ex-manufacturer price; and

(b) dividing that amount by its applicable approved ex-manufacturer price.

Step 6

(9) Work out the adjusted price percentage difference for the brand (expressed as a percentage to 2 decimal places) as follows:

(a) if the price percentage difference for the brand is less than zero, the adjusted price percentage difference is equal to zero; and

(b) if the price percentage difference for the brand is equal to or greater than zero, the adjusted price percentage difference is equal to the price percentage difference.

Step 7

(10) Repeat steps 1 to 6 for every brand of the pharmaceutical item.

Step 8

(11) Work out the weighted average percentage difference for the pharmaceutical item as follows:

(a) for each brand of the pharmaceutical item — multiply its adjusted volume by its adjusted price percentage difference; and

(b) add up the amounts worked out in paragraph (a); and

(c) add up the adjusted volume for each brand of the pharmaceutical item; and

(d) divide the amount worked out in paragraph (b) by the amount worked out in paragraph (c).

Step 9

(12) Repeat steps 1 to 8 for every pharmaceutical item having the same drug and manner of administration.

Step 10

(13) Work out the weighted average percentage difference (expressed as a percentage to 2 decimal places) for every brand of every pharmaceutical item having the same drug and manner of administration in the following way:

(a) for each pharmaceutical item — multiply the percentage worked out in step 8 by:

(i) the PBS volume of the pharmaceutical item, as recorded by the Department; and

(ii) the applicable approved ex-manufacturer price for the brands of the pharmaceutical item;

(b) for each pharmaceutical item — multiply the PBS volume of the pharmaceutical item by the applicable approved ex-manufacturer price for the brands of the pharmaceutical item;

(c) add up the amounts worked out for each pharmaceutical item under paragraph (a);

(d) divide the amount worked out under paragraph (c) by the sum of the amounts worked out under paragraph (b).

Step 11

(14) The weighted average disclosed price for every brand of every pharmaceutical item having the same drug and manner of administration is the applicable approved ex-manufacturer price for the brands, reduced by the percentage worked out under step 10.

(15) In this regulation:

adjusted volume, of a listed brand of a pharmaceutical item that is sold, is the volume worked out as if the pack sizes in which the brand was sold were equivalent to:

(a) a maximum quantity of the pharmaceutical item that is determined under paragraph 85A (2) (a) of the Act; or

(b) if no maximum quantity of the pharmaceutical item is determined under paragraph 85A (2) (a) of the Act — an agreed quantity for a brand of the pharmaceutical item.

agreed quantity has the same meaning as in Division 3B of Part VII of the Act.

Division 3 Price disclosure requirements

37H Price disclosure requirements — content of information for reporting periods

(1) For paragraph 99ADC (1) (a) of the Act, the information to be provided for the supply of a listed brand of a pharmaceutical item for a reporting period is:

(a) the name of the responsible person; and

(b) the name of the drug in the pharmaceutical item; and

(c) the brand; and

(d) the form of the drug, including its strength; and

(e) the manner of administration of the form of the drug; and

(f) the number or quantity of units in a pack (for example, the number of tablets per pack); and

(g) the period to which the information relates; and

(h) for each period to which the information relates:

(i) the sales revenue for the brand, excluding sales to public hospitals (expressed in Australian dollars, excluding GST and rounded to the nearest whole dollar, rounding 50 cents upwards); and

(ii) the volume of the brand sold, based on the number of packs sold; and

(i) the kind of incentives (if any) given for the brand for the reporting period; and

(j) the value of the incentives given for the brand for the reporting period (expressed in Australian dollars, excluding GST and rounded to the nearest whole dollar, rounding 50 cents upwards).

Note 1 The form issued by the Department for responsible persons to provide the information may include a list of different kinds of incentives (for example, rebates or cash backs) and the responsible person would fill in the values for the kind of incentives for which information is being provided.

Note 2 For transitional arrangements, see Part 2 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 5).*

(2) However, for the first reporting period to which subregulation 37G (3) or (6) applies, the information mentioned in paragraph (1) (h) for the first month of the reporting period must be provided separately.

(3) If an incentive is given over a period of time or indirectly for a brand, the value of the incentive for the brand for the reporting period is the value apportioned to the brand for the reporting period.

Note No methodology is prescribed for apportioning the value of incentives for a brand for a period. However, the methodology used by a responsible person should be reasonable and documented.

(4) If information must be provided under paragraph (1) (h), it must not also be provided under paragraph (1) (i) or (j).

(5) The information must relate to the period from the beginning of the reporting period to the end of the reporting period.

(6) For this regulation, ***incentives*** includes anything given as an incentive to take supply of the brand, whether given:

(a) before the supply of the brand, but on condition of taking supply; or

(b) at the time of the supply of the brand; or

(c) at a later date; or

(d) over a period of time; or

(e) directly for the brand; or

(f) indirectly for the brand (for example, for a group of brands or other products).

37HA Price disclosure requirements — prescribed person

(1) For paragraph 99ADC (1) (a) of the Act, the information must be provided by the responsible person to Australian Healthcare Associates Pty Ltd, ABN 82 072 790 848.

(2) However, if the responsible person receives written notice from the Department to provide the information to the First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing, the information must be provided to that person.

37I Price disclosure requirements — manner and form

(1) For paragraph 99ADC (1) (b) of the Act, the information mentioned in regulation 37H must be provided by completing a form approved by the Secretary.

(2) The completed form must:

(a) include all the statements and information required by the form; and

(b) be signed (or authorised for electronic transmission) by a person who is authorised by the responsible person to provide the information.

37J Price disclosure requirements — information and reporting periods

(1) For paragraph 99ADC (1) (c) of the Act, the information mentioned in regulation 37H must be provided within 6 weeks after the end of each reporting period for the brand of the pharmaceutical item.

(2) Subject to subregulations (3) to (6) and regulation 37JA, a reporting period for a brand of a pharmaceutical item is:

(a) the period of 6 months ending at the end of 31 March of each year and 30 September of each year; and

(b) each successive period of 6 months in which the brand is subject to the price disclosure requirements.

(3) However, the first reporting period for a relevant brand to which regulation 37ED applies:

(a) begins on the relevant day mentioned in regulation 37ED for the relevant brand; and

(b) ends at the end of the first of the following dates to happen after the relevant day:

(i) 31 March;

(ii) 30 September.

(4) Also, the first reporting period for a relevant brand in the relevant disclosure cycle mentioned in regulation 37F to which that regulation applies:

(a) begins on the relevant day mentioned in regulation 37F; and

(b) ends at the end of:

(i) if the other brand mentioned in regulation 37F is in the interim supplementary disclosure cycle or a supplementary disclosure cycle A or supplementary disclosure cycle B — the reporting period for the other brand; or

(ii) in any other case — the first of the following dates to happen after the relevant day:

(A) 31 March;

(B) 30 September.

(5) Also, the first reporting period in the data collection period in the first main disclosure cycle for a brand of a pharmaceutical item to which regulation 37EG applies:

(a) begins on 1 February in the year the brand moves to the main disclosure cycle; and

(b) ends at the end of 31 March in the year.

(6) Also, the first reporting period in the data collection period in the first main disclosure cycle for a brand of a pharmaceutical item to which regulation 37EH applies:

(a) begins on 1 June in the year the brand moves to the main disclosure cycle; and

(b) ends at the end of 30 September in the year.

Note For transitional arrangements, see Part 2 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 5).*

37JA Price disclosure requirements — additional reporting periods

(1) Subregulation (2) applies if:

(a) a listed brand of a pharmaceutical item is in a supplementary disclosure cycle A; and

(b) the data collection period in the supplementary disclosure cycle ends at the end of 31 January in a year.

(2) Another reporting period in that data collection period begins on 1 October in the year before the year and ends at the end of 31 January in the year.

(3) Subregulation (4) applies if:

(a) a listed brand of a pharmaceutical item is in a supplementary disclosure cycle B; and

(b) the data collection period in the supplementary disclosure cycle ends at the end of 31 May in a year.

(4) Another reporting period in that data collection period begins on 1 April in the year and ends at the end of 31 May in the year.

(5) Subregulation (6) applies if:

(a) a listed brand of a pharmaceutical item is in the interim supplementary disclosure cycle; and

(b) the data collection period in the disclosure cycle ends at the end of 31 May 2012.

(6) Another reporting period in that data collection period begins on 1 April 2012 and ends at the end of 31 May 2012.

Note For transitional arrangements, see Part 2 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 5).*

Division 4 Price reduction day

37K Price reduction — prescribed reduction day

For subsection 99ADH (2) of the Act, the reduction day is 1 April, 1 August or 1 December in any year.

Part 7 Arrangements of the Pharmaceutical Benefits Advisory Committee

38 Interpretation

In this Part:

Chairperson means the Chairperson appointed under regulation 39.

Committee means the Pharmaceutical Benefits Advisory Committee established under section 100A of the Act.

Drug Utilisation Sub-Committee means the sub-committee of that name established under section 101A of the Act.

Economics Sub-Committee means the sub-committee of that name established under section 101A of the Act.

member means a member of the Committee.

38A Appointments to Committee — nominating bodies (Act s 100B (1A))

(1) For paragraph 100B (1A) (a) of the Act, the following consumer organisations are prescribed:

(a) the Consumers' Health Forum of Australia;

(b) the Australian Federation of AIDS Organisations;

(c) the Australian Consumers' Association.

(2) For paragraph 100B (1A) (b) of the Act, the following professional associations of health economists are prescribed:

(a) the Australian Health Economics Society Inc;

(b) the Economic Society of Australia Inc.

(3) For paragraph 100B (1A) (c) of the Act, the following professional associations of pharmacists are prescribed:

(a) the Pharmacy Guild of Australia;

(b) the Pharmaceutical Society of Australia;

(c) the Society of Hospital Pharmacists of Australia.

(4) For paragraph 100B (1A) (d) of the Act, the following professional associations of medical practitioners are prescribed:

(a) the Australian Medical Association Limited;

(b) the Royal Australian College of General Practitioners;

(c) the Australian Divisions of General Practice Limited;

(d) the Doctors Reform Society — Australia Inc;

(e) the Australian Federation of Medical Women Inc.

(5) For paragraph 100B (1A) (e) of the Act, the following professional associations of clinical pharmacologists are prescribed:

(a) the Royal Australasian College of Physicians;

(b) the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.

(6) For paragraph 100B (1A) (f) of the Act, the following professional associations of specialists are prescribed:

(a) the Australian Medical Association Limited;

(b) the Royal Australasian College of Physicians;

(c) the Committee of Presidents of Medical Colleges.

38B Number of nominations for appointment (Act s 100B (1B))

For subsection 100B (1B) of the Act, each body prescribed for subsection 100B (1A) of the Act must be asked to nominate at least 3 persons for selection for appointment as members of the Committee.

39 Chairperson

The Minister must appoint one of the members of the Committee as the Chairperson of the Committee.

40 Resignation

(1) The Chairperson of the Committee may resign as Chairperson by notice in writing given to the Minister.

(2) A member of the Committee may resign from the Committee by notice in writing given to the Minister.

41 Presiding member

(1) The Chairperson must preside at any meeting of the Committee at which he or she is present or, under subregulation 42 (3), is taken to be present.

(2) If the Chairperson is absent from a meeting, the members attending the meeting must elect a member to preside at that meeting.

42 Meetings of the Committee

(1) The Chairperson may, at any time, by notice in writing to all members, convene a meeting of the Committee at the time and place set out in the notice.

(2) For the purposes of subregulation (1), the Chairperson and members of the Committee may:

(a) attend a meeting in person; or

(b) participate in a meeting by telephone or closed circuit television.

(3) If the Chairperson, or a member, participates in a meeting in accordance with paragraph 2 (b), he or she is taken to be present at the meeting.

(4) The Committee must keep minutes of its meetings.

43 Quorum

At a meeting of the Committee, a quorum is the number of members who constitute a majority of the membership of the Committee.

44 Voting

(1) At a meeting of the Committee, the Chairperson and other members present each have a deliberative vote.

(2) A matter requiring a decision at a meeting must be determined by a majority of the votes of the Chairperson and other members present and voting.

(3) If an equal number of votes is cast for and against a matter at a meeting:

(a) the Chairperson, or the member elected under subregulation 41 (2) to preside at the meeting, may exercise a casting vote; and

(b) if the Chairperson or that member declines to exercise a casting vote — the matter is resolved in the negative.

(4) Decisions of the Committee must be recorded in the minutes of the meeting.

45 Disclosure of pecuniary interests by Chairperson and members

(1) The Chairperson must tell the Minister in writing, as soon as practicable after the beginning of each financial year, of all direct or indirect pecuniary interests that the Chairperson has, or proposes to acquire, in a business or in a body corporate carrying on a business that could conflict with that person's duties as Chairperson.

(2) Each member must tell the Minister in writing, as soon as practicable after the beginning of each financial year, of all direct or indirect pecuniary interests that the member has, or proposes to acquire, in a business or in a body corporate carrying on a business that could conflict with that person's duties as a member.

(3) If the Chairperson or a member does not have an interest of the kind mentioned in subregulation (1) or (2) respectively, he or she must give a statement to that effect to the Minister.

(4) If the Chairperson, or the presiding member, has a direct or indirect pecuniary interest in a matter that is to be considered at a meeting, the Chairperson or the presiding member:

(a) must disclose the interest to the members present at the meeting; and

(b) must not take part in the meeting during the consideration of that matter unless the members present at the meeting agree that the Chairperson or the presiding member may take part in the meeting.

(5) If the Chairperson, or the presiding member, is precluded from taking part in a meeting or part of a meeting because of the operation of paragraph (4) (b), the members present must elect one of the members present to act in the place of the Chairperson or the presiding member for the duration of the Committee's consideration of the matter.

(6) If a member (other than the Chairperson or the presiding member) has a direct or indirect pecuniary interest in a matter that is to be considered at a meeting, the member:

(a) must disclose the interest to the Chairperson, or the presiding member, at the commencement of the meeting; and

(b) must not take part in the meeting during the consideration of that matter unless the Chairperson, or the presiding member, allows the member to take part in the meeting.

(7) The following matters must be recorded in the minutes of a meeting:

(a) a disclosure made under subregulation (4) or (6);

(b) an agreement under paragraph (4) (b);

(c) the consent of the Chairperson, or the presiding member, under paragraph (6) (b).

(8) In this regulation, ***presiding member*** means, in relation to a meeting of the Committee, a member elected under subregulation 41 (2) to preside at the meeting.

46 Resolutions without a formal meeting

If a majority of the members of the Committee sign a document that includes a statement that they are in favour of a resolution in the terms set out in the document, the resolution is taken to have been passed at a meeting of the Committee:

(a) on the day on which the document is signed; or

(b) if the members sign the document on different days — on the day on which the document is signed by the member who completes the majority.

47 Reports and recommendations

(1) A report or a recommendation made to the Minister by the Committee as part of its consideration of a matter must be in writing.

(2) If:

(a) the members are not unanimous in agreeing to a report or a recommendation; and

(b) a member who is not part of the majority asks the Chairperson to include, as part of the report or recommendation:

(i) a statement that the members are not unanimous; or

(ii) an explanation of the opinion of the member; or

(iii) a separate report or recommendation made by the member;

the report or recommendation must include the matter requested by the member.

48 Remuneration for chair and members of sub-committees

For paragraph 140 (a) of the Act, the fees and allowances payable to the chair and members of the Drug Utilisation Sub-Committee and the Economics Sub-Committee are the amounts that are payable to the chair and members of professional committees under Schedule B to the Remuneration Tribunal Determination 2010/11: *Remuneration and Allowances for Holders of Part-Time Public Office*.

Schedule 3 Co-marketed brands

(regulation 9AAC)

Column 1	Column 2				Column 3			
Item	Listed brand of pharmaceutical item				Listed brand of pharmaceutical item			
	Brand	Drug	Form	Manner of administration	Brand	Drug	Form	Manner of administration
1	Avapro	Irbesartan	Tablet 75 mg	Oral	Karvea	Irbesartan	Tablet 75 mg	Oral
2	Avapro	Irbesartan	Tablet 150 mg	Oral	Karvea	Irbesartan	Tablet 150 mg	Oral
3	Avapro	Irbesartan	Tablet 300 mg	Oral	Karvea	Irebesartan	Tablet 300 mg	Oral
4	Iscover	Clopidogrel	Tablet 75 mg (as hydrogen sulfate)	Oral	Plavix	Clopidogrel	Tablet 75 mg (as hydrogen sulfate)	Oral

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Schedule 5 Listed brands of pharmaceutical items, reduction days and percentages

(regulation 37B)

Item	Listed brand of pharmaceutical item				Reduction days	Percentage
	Brand	Drug	Form	Manner of administration		
1	Nexium	Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	1) 1 August 2008 2) 1 August 2011 3) 1 August 2014 4) 1 August 2018	1) 4% 2) 7% 3) 7% 4) 7%
	Nexium	Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral		
2	Zoton	Lansoprazole	Capsule 15 mg	Oral	1) 1 August 2008 2) 1 August 2009 3) 1 April 2010	1) 5% 2) 5% 3) 15%

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Item	Listed brand of pharmaceutical item				Reduction days	Percentage
	Brand	Drug	Form	Manner of administration		
3	Somac	Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Oral	1) 1 August 2008 2) 1 April 2010	1) 4% 2) 21%
	Somac	Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral		
4	Pariet	Rabeprazole	Tablet (enteric coated) containing 10mg rabeprazole sodium	Oral	1) 1 August 2008 2) 1 August 2011 3) 1 August 2014 4) 1 August 2018	1) 4% 2) 7% 3) 7% 4) 7%
	Pariet	Rabeprazole	Tablet (enteric coated) containing 20mg rabeprazole sodium	Oral		
5	Zanidip	Lercanidipine	Tablet 10 mg	Oral	1) 1 August 2008 2) 1 December 2010	1) 4% 2) 21%
	Zanidip	Lercanidipine	Tablet 20 mg	Oral		

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Schedule 6 Prescribed offices for subsections 84DA (5) and 84E (5) of the Act

(regulations 9AF and 9BA)

1. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
SYDNEY NSW 2000

2. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
MELBOURNE VIC 3000

3. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
BRISBANE QLD 4000

4. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
PERTH WA 6000

5. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
ADELAIDE SA 5000

6. Pharmaceutical Benefits Scheme
Claims Section

Department of Human Services
GPO Box 9826
HOBART TAS 7000

7. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
CANBERRA ACT 2600

8. Pharmaceutical Benefits Scheme
Claims Section
Department of Human Services
GPO Box 9826
DARWIN NT 0800

Notes to the *National Health (Pharmaceutical Benefits) Regulations 1960*

Note 1

The *National Health (Pharmaceutical Benefits) Regulations 1960* (in force under the *National Health Act 1953*) as shown in this compilation comprise Statutory Rules 1960 No. 17 amended as indicated in the Tables below.

For all relevant information pertaining to application, saving or transitional provisions *see* Table A.

Table of Instruments

Year and number	Date of notification in *Gazette* or FRLI registration	Date of commencement	Application, saving or transitional provisions
1960 No. 17	29 Feb 1960	1 Mar 1960	
1960 No. 90	28 Oct 1960	1 Nov 1960	—
1960 No. 102	19 Dec 1960	R. 1: 1 Feb 1961 R. 2: 1 Jan 1961	—
1961 No. 59	28 Apr 1961	1 May 1961	—
1961 No. 137	27 Oct 1961	1 Nov 1961	—
1962 No. 34	18 Apr 1962	1 May 1962	—
1962 No. 101	31 Oct 1962	1 Nov 1962	—
1962 No. 114	24 Dec 1962	1 Jan 1963	—
1963 No. 34	26 Apr 1963	1 May 1963	—
1963 No. 69	12 Aug 1963	12 Aug 1963	—
1963 No. 107	31 Oct 1963	1 Nov 1963	—
1964 No. 12	30 Jan 1964	1 Feb 1964	—
1964 No. 57	30 Apr 1964	1 May 1964	—
1964 No. 135	30 Oct 1964	1 Nov 1964	—
1965 No. 51	30 Apr 1965	1 May 1965	—
1965 No. 151	28 Oct 1965	1 Nov 1965	—
1965 No. 152	28 Oct 1965	1 Nov 1965	—
1966 No. 80	28 Apr 1966	1 May 1966	—
1966 No. 144	27 Oct 1966	1 Nov 1966	—
1967 No. 67	1 June 1967	1 June 1967	—
1967 No. 116	31 Aug 1967	1 Sept 1967	—
1967 No. 158	30 Nov 1967	1 Dec 1967	—

Table of Instruments

Year and number	Date of notification in *Gazette* or FRLI registration	Date of commencement	Application, saving or transitional provisions
1968 No. 44	28 Mar 1968	1 Apr 1968	—
1968 No. 76	11 July 1968	11 July 1968	—
1968 No. 88	1 Aug 1968	1 Aug 1968	—
1968 No. 146	29 Nov 1968	1 Dec 1968	—
1969 No. 44	27 Mar 1969	1 Apr 1969	—
1969 No. 107 *(a)*	31 July 1969	1 Aug 1969	—
1969 No. 185 *(a)*	28 Nov 1969	1 Dec 1969	—
1970 No. 39 *(a)*	25 Mar 1970	1 Apr 1970	—
1970 No. 94 *(a)*	30 July 1970	1 Aug 1970	—
1970 No. 119	4 Sept 1970	7 Sept 1970	—
1970 No. 186 *(a)*	27 Nov 1970	1 Dec 1970	—
1971 No. 44 *(a)*	1 Apr 1971	1 Apr 1971	—
1971 No. 101 *(a)*	30 July 1971	1 Aug 1971	—
1971 No. 136	25 Oct 1971	1 Nov 1971	—
1971 No. 154 *(a)*	26 Nov 1971	1 Dec 1971	—
1972 No. 32 *(a)*	16 Mar 1972	1 Apr 1972	—
1972 No. 121 *(a)*	28 July 1972	1 Aug 1972	—
1972 No. 205 *(a)*	30 Nov 1972	1 Dec 1972	—
1973 No. 15 *(a)*	1 Feb 1973	1 Feb 1973	—
1973 No. 57 *(a)*	22 Mar 1973	1 Apr 1973	—
1973 No. 139 *(a)*	26 July 1973	1 Aug 1973	—
1973 No. 229 *(a)*	29 Nov 1973	1 Dec 1973	—
1974 No. 37 *(a)*	29 Mar 1974	1 Apr 1974	—
1974 No. 126 *(a)*	30 July 1974	1 Aug 1974	—
1974 No. 222 *(a)*	27 Nov 1974	1 Dec 1974	—
1975 No. 50 *(a)*	1 Apr 1975	1 Apr 1975	—
1975 No. 148 *(a)*	31 July 1975	1 Aug 1975	—
1975 No. 209 *(a)*	21 Nov 1975	1 Dec 1975	—
1976 No. 84 *(a)*	24 Mar 1976	R. 3: 1 Apr 1976 Remainder: 24 Mar 1976	—
1976 No. 150 *(a)*	26 July 1976	1 Aug 1976	—
1976 No. 195	14 Sept 1976	14 Sept 1976	—
1976 No. 255 *(a)*	1 Dec 1976	1 Dec 1976	—
1977 No. 39 *(a)*	28 Mar 1977	1 Apr 1977	—
1977 No. 125 *(a)*	29 July 1977	1 Aug 1977	—
1977 No. 221 *(a)*	24 Nov 1977	1 Dec 1977	—
1978 No. 47 *(a)*	29 Mar 1978	1 Apr 1978	—

Table of Instruments

Year and number	Date of notification in *Gazette* or FRLI registration	Date of commencement	Application, saving or transitional provisions
1978 No. 142 *(a)*	27 July 1978	1 Aug 1978	—
1978 No. 153	24 Aug 1978	24 Aug 1978	—
1978 No. 245 *(a)*	30 Nov 1978	1 Dec 1978	—
1979 No. 51 *(a)*	30 Mar 1979	1 Apr 1979	—
1979 No. 55	2 Apr 1979	2 Apr 1979	—
1979 No. 144 *(a)*	31 July 1979	1 Aug 1979	—
1979 No. 250 *(a)*	30 Nov 1979	1 Dec 1979	—
1980 No. 69 *(a)*	31 Mar 1980	1 Apr 1980	—
1980 No. 213 *(a)*	29 July 1980	1 Aug 1980	—
1980 No. 338 *(a)*	28 Nov 1980	1 Dec 1980	—
1981 No. 52 *(a)*	31 Mar 1981	1 Apr 1981	—
1981 No. 212 *(a)*	31 July 1981	1 Aug 1981	—
1981 No. 218	14 Aug 1981	14 Aug 1981	—
1981 No. 345 *(a)*	30 Nov 1981	1 Dec 1981	—
1982 No. 69	19 Mar 1982	19 Mar 1982	—
1982 No. 76 *(a)*	31 Mar 1982	1 Apr 1982	—
1982 No. 179 *(a)*	30 July 1982	1 Aug 1982	—
1982 No. 334 *(a)*	30 Nov 1982	1 Dec 1982	—
1982 No. 372	31 Dec 1982	1 Jan 1983	—
1983 No. 28 *(a)*	31 Mar 1983	1 Apr 1983	—
1983 No. 102	15 July 1983	15 July 1983	—
1983 No. 116 *(a)*	29 July 1983	1 Aug 1983	—
1983 No. 292	30 Nov 1983	1 Dec 1983	—
1984 No. 50 *(a)*	30 Mar 1984	1 Apr 1984	—
1984 No. 148	11 July 1984	11 July 1984	—
1984 No. 169 *(a)*	31 July 1984	1 Aug 1984	—
1984 No. 342 *(a)*	30 Nov 1984	1 Dec 1984	—
1985 No. 32 *(a)*	1 Apr 1985	1 Apr 1985	—
1985 No. 184 *(a)*	1 Aug 1985	1 Aug 1985	—
1985 No. 320 *(a)*	29 Nov 1985	1 Dec 1985	—
1986 No. 38 *(a)*	27 Mar 1986	1 Apr 1986	—
1986 No. 194 *(a)*	31 July 1986	1 Aug 1986	—
1986 No. 319	31 Oct 1986	31 Oct 1986	—
1986 No. 320 *(a)*	31 Oct 1986	1 Nov 1986	—
1986 No. 391	22 Dec 1986	22 Dec 1986	—
1987 No. 47	31 Mar 1987	1 Apr 1987	—
1987 No. 262	12 Nov 1987	12 Nov 1987	—
1987 No. 279	30 Nov 1987	1 Dec 1987	—

Table of Instruments

Year and number	Date of notification in *Gazette* or FRLI registration	Date of commencement	Application, saving or transitional provisions
1988 No. 56	29 Apr 1988	1 May 1988	—
1989 No. 330 *(b)*	30 Nov 1989	Rr. 1, 2 and 8: 1 Dec 1989 Remainder: 1 Jan 1990	—
1990 No. 226	12 July 1990	1 Aug 1990	—
1990 No. 267	21 Aug 1990	1 Aug 1990	—
1990 No. 337	31 Oct 1990	1 Nov 1990	—
1990 No. 338	31 Oct 1990	1 Nov 1990 (*see* r. 1)	—
1990 No. 437	21 Dec 1990	21 Dec 1990	—
1991 No. 1	22 Jan 1991	22 Jan 1991	—
1991 No. 474	23 Dec 1991	1 Jan 1992	—
1992 No. 226	10 July 1992	10 July 1992	—
1994 No. 348	18 Oct 1994	Rr. 7–9: 1 Jan 1995 R. 21.2: 1 Dec 1994 Remainder: 1 Nov 1994	—
1996 No. 70	31 May 1996	1 June 1996	—
1998 No. 374	22 Dec 1998	1 Jan 1999	—
2000 No. 369	20 Dec 2000	1 Jan 2001 (*see* r. 2)	—
2001 No. 68	12 Apr 2001	12 Apr 2001	—
2002 No. 9	21 Feb 2002	21 Feb 2002	—
2002 No. 239	11 Oct 2002	1 Feb 2003	—
2002 No. 344	20 Dec 2002	Rr. 1–3 and Schedule 1: 20 Dec 2002 Remainder: 1 Aug 2003	—
2003 No. 193	31 July 2003	1 Aug 2003	—
2004 No. 389	23 Dec 2004	13 Jan 2005 (*see* r. 2)	—
2005 No. 207	19 Sept 2005 (*see* F2005L02673)	1 Oct 2005 (*see* r. 2)	—
2006 No. 121	2 June 2006 (see F2006L01614)	1 July 2006	—
2006 No. 200	28 July 2006 (*see* F2006L02405)	1 Mar 2007	—
2007 No. 160	25 June 2007 (*see* F2007L01518)	1 July 2007	—
2007 No. 225	24 July 2007 (*see* F2007L02206)	1 Aug 2007	—
2008 No. 54	14 Apr 2008 (*see* F2008L00583)	15 Apr 2008	—
2008 No. 116	20 June 2008 (*see* F2008L01021)	21 June 2008	—

Table of Instruments

Year and number	Date of notification in *Gazette* or FRLI registration	Date of commencement	Application, saving or transitional provisions
2009 No. 195	30 July 2009 (*see* F2009L02523)	31 July 2009	—
2010 No. 49	25 Mar 2010 (*see* F2010L00568)	26 Mar 2010	—
2010 No. 115	7 June 2010 (*see* F2010L01069)	8 June 2010	—
2010 No. 231	21 July 2010 (*see* F2010L01979)	Rr. 1–3 and Schedule 1: 22 July 2010 Schedule 2: 1 Nov 2010	—
2010 No. 295	25 Nov 2010 (*see* F2010L02950)	26 Nov 2010	—
2010 No. 296	26 Nov 2010 (*see* F2010L02953)	1 Dec 2010	Rr. 4–7, 9 and 10 R. 8 (am. by 2012 No. 56, Sch. 1 [item 1])
as amended by			
2012 No. 56	20 Apr 2012 (*see* F2012L00902)	21 Apr 2012	—
2010 No. 327	9 Dec 2010 (*see* F2010L03077)	10 Dec 2010	—
2011 No. 29	16 Mar 2011 (*see* F2011L00427)	17 Mar 2011	—
2011 No. 120	30 June 2011 (*see* F2011L01364)	1 July 2011	—
2012 No. 55	20 Apr 2012 (*see* F2012L00901)	21 Apr 2012	—

(a) The form of introductory words used to make Statutory Rules 1986 No. 320 was as follows:

'WHEREAS it is provided by subsection 101 (4) of the *National Health Act 1953* that a drug or medicinal preparation that was not a pharmaceutical benefit under that Act immediately before the commencement of that subsection shall not be prescribed as a pharmaceutical benefit in accordance with section 85 of that Act unless the Pharmaceutical Benefits Advisory Committee has recommended to the Minister that it be so prescribed:

'AND WHEREAS the Pharmaceutical Benefits Advisory Committee has recommended to the Minister that each of the following drugs or medicinal preparations be prescribed as a pharmaceutical benefit under section 85 of that Act, namely:

(a) Indapamide;

(b) Insulin Neutral, Human (Synthetic);

(c) Insulin Zinc Suspension, Human (Synthetic);

(d) Insulin Zinc Suspension (Crystalline), Human (Synthetic);

(e) Oestrogens — Conjugated;

(f) Piroxicam;

(g) Polygeline; and

(h) Silver Sulphadiazine:

'AND WHEREAS it is desirable, amongst other things, to prescribe each of those drugs or medicinal preparations as a pharmaceutical benefit under that section:

'NOW THEREFORE I, the Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, hereby make the following Regulations under the *National Health Act 1953*.'

The form of introductory words used to make Statutory Rules 1969 Nos. 107 and 185, 1970 Nos. 39, 94 and 186, 1971 Nos. 44, 101 and 154, 1972 Nos. 32, 121 and 205, 1973 Nos. 15, 57, 139 and 229, 1974 Nos. 37, 126 and 222, 1975 Nos. 50, 148 and 209, 1976 Nos. 84, 150 and 255, 1977 Nos. 39, 125 and 221, 1978 Nos. 47, 142 and 245, 1979 Nos. 51, 144 and 250, 1980 Nos. 69, 213 and 338, 1981 Nos. 52, 212 and 345, 1982 Nos. 76, 179 and 334, 1983 Nos. 28 and 116, 1984 Nos. 50, 169 and 342, 1985 Nos. 32, 184 and 320, 1986 Nos. 38, 194 and 320 was similar to the form set out above.

(b) Disallowed by the Senate on 22 December 1989.

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Part 1	
Heading to Part I	rep. 2006 No. 200
Heading to Part 1	ad. 2006 No. 200
Division 1.1	
Heading to Div 1.1	ad. 2006 No. 200
R. 1	rs. 1998 No. 374
R. 2	am. 1977 No. 39
R. 3	rep. 1976 No. 195
R. 4 (renumbered r. 3)	am. 1977 No. 39 1998 No. 374
R. 4	ad. 1998 No. 374
R. 5	am. 1960 No. 90; 1976 No. 195; 1977 No. 39; 1979 Nos. 55 and 250; 1981 No. 218; 1982 No. 372; 1983 No. 102; 1986 Nos. 319 and 391; 1988 No. 56; 1990 No. 437; 1991 Nos. 1 and 474; 1992 No. 226; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2002 Nos. 239 and 344; 2004 No. 389; 2005 No. 207; 2006 No. 200; 2007 No. 225; 2008 No. 54; 2010 Nos. 231 and 296
Division 1.2	
Div. 1.2 of Part 1	ad. 2006 No. 200
R. 5A	ad. 2006 No. 200
R. 5B	ad. 2006 No. 200 am. 2008 No. 54
R. 5C	ad. 2006 No. 200
R. 5D	ad. 2006 No. 200
R. 5E	ad. 2006 No. 200
R. 5F	ad. 2006 No. 200
R. 6	am. 1977 No. 39; 1991 No. 474 rep. 1994 No. 348
R. 7	am. 1977 No. 39 rep. 1984 No. 148
Part II	
Heading to Part II	am. 1979 No. 55; 1982 No. 69; 1986 No. 91 rs. 2008 No. 54
Heading to r. 8	rs. 2001 No. 68
R. 8	am. 1977 No. 39 rs. 1981 No. 218 am. 1982 No. 69; 1986 No. 391; 1988 No. 56; 1994 No. 348; 1996 No. 70; 2001 No. 68

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 8AA	ad. 2008 No. 54 rs. 2010 No. 231
R. 8A	ad. 1979 No. 55 rs. 1981 No. 218 am. 1982 No. 69; 1986 No. 391; 1988 No. 56; 2004 No. 389; 2006 No. 121; 2008 No. 54; 2010 No. 231
R. 9	am. 1967 No. 158; 1977 No. 39; 1986 No. 391; 1994 No. 348 rs. 2002 No. 9
Part IIAAA	
R. 9AAA	ad. 2007 No. 225 rep. 2010 No. 296
R. 9AAB	ad. 2007 No. 225 rep. 2010 No. 296
R. 9AAC	ad. 2007 No. 225
R. 9AAD	ad. 2007 No. 225 rep. 2010 No. 49
Part IIAA	
Part IIAA	ad. 1991 No. 1
R. 9AA	ad. 1991 No. 1 am. 1991 No. 474; 1992 No. 226; 1994 No. 348; 2002 No. 344
R. 9AB	ad. 1991 No. 1 am. 1992 No. 226; 1994 No. 348; 2002 No. 344
R. 9AC	ad. 1991 No. 1 am. 1992 No. 226; 1994 No. 348; 2002 No. 344
R. 9AD	ad. 1991 No. 1 am. 1992 No. 226
R. 9AE	ad. 1991 No. 1
Heading to r. 9AF	rs. 2002 No. 344
R. 9AF	ad. 1991 No. 1 am. 1994 No. 348; 2002 No. 344
Part IIA	
Part IIA	ad. 1986 No. 319
R. 9A	ad. 1986 No. 319 am. 1990 Nos. 226, 267 and 338; 1991 No. 474; 1992 No. 226; 2002 No. 344
R. 9B	ad. 1986 No. 319 rs. 1990 No. 437 am. 1991 No. 474; 1992 No. 226; 2002 No. 344
R. 9BA	ad. 1987 No. 262 am. 1994 No. 348; 2002 No. 344

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 9C	ad. 1986 No. 319 am. 1990 No. 226 rs. 1990 No. 437 am. 1992 No. 226; 2002 No. 344
R. 9D	ad. 1986 No. 319 am. 1990 No. 226 rs. 1990 No. 437 am. 1992 No. 226; 2002 No. 344
R. 9E	ad. 1986 No. 319 am. 1990 No. 226 rs. 1990 No. 437 am. 1992 No. 226
R. 9F	ad. 1986 No. 319
Part III	
Heading to Part III	am. 1979 No. 250
R. 10	am. 1967 No. 158; 1977 No. 39 rep. 1987 No. 47
Rr. 11, 12	am. 1977 No. 39 rep. 1987 No. 47
R. 13	am. 1965 No. 152; 1977 No. 39; 1979 No. 55 rs. 1988 No. 56 am. 1996 No. 70; 2003 No. 193; 2006 No. 200; 2008 No. 54; 2010 No. 231
R. 14	am. 1965 No. 152; 1968 No. 44; 1977 No. 39; 1979 Nos. 55 and 250; 1980 No. 338; 1981 No. 52 rep. 1987 No. 47
Part IV	
Heading to Part IV	rs. 1979 No. 250; 2010 No. 231
R. 14	ad. 2010 No. 231
R. 15	rs. 1963 No. 69 am. 1994 No. 348; 2004 No. 389 rs. 2010 No. 231
R. 16	am. 1963 No. 69; 1977 No. 39; 1986 No. 391; 1988 No. 56; 1994 No. 348; 2002 No. 344; 2006 No. 200 rs. 2010 No. 231
R. 17	am. 1967 No. 158; 1977 No. 39; 1986 No. 391 rs. 2002 No. 9 am. 2006 No. 200 rs. 2010 No. 231
R. 18	am. 1963 No. 69; 1977 No. 39; 1986 No. 391; 2006 No. 200 rs. 2010 No. 231

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 18A	ad. 1963 No. 69 am. 1967 No. 158; 1977 No. 39; 1986 No. 391; 1988 No. 56; 1994 No. 348 rs. 2002 No. 9
Part V	
R. 19	rs. 1960 No. 90 am. 1965 No. 152; 1971 No. 136; 1974 No. 126; 1977 No. 39; 1978 No. 153; 1979 No. 55; 1982 No. 372; 1986 No. 391; 1987 Nos. 47 and 279; 1988 No. 56; 1991 No. 474; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2002 Nos. 239 and 344; 2004 No. 389; 2005 No. 207; 2006 No. 200; 2007 No. 160; 2008 No. 54; 2010 No. 231; 2011 No. 120
Note to r. 19 (1)	ad. 2008 No. 54
Heading to r. 19A	rs. 2001 No. 68
R. 19A	ad. 1971 No. 136 rep. 1976 No. 84 ad. 1983 No. 102 am. 1986 Nos. 319 and 391; 1990 No. 437; 1991 No. 1; 2001 No. 68; 2002 No. 344; 2004 No. 389; 2006 No. 200
R. 19B	ad. 1988 No. 56 am. 1991 No. 474 rs. 2002 No. 9
R. 20	am. 1977 No. 39; 1979 No. 55; 1981 No. 218; 1987 No. 47; 1994 No. 348
R. 21	am. 1960 No. 90; 1965 No. 152; 1977 No. 39; 1978 No. 153; 1979 No. 55; 1981 No. 52; 1985 No. 320; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56; 1998 No. 374 rs. 1994 No. 348 am. 2006 No. 200
R. 22	am. 1967 No. 158; 1977 No. 39; 1979 No. 55; 1986 No. 391; 1987 No. 47; 1988 No. 56; 1994 No. 348; 2002 No. 9; 2005 No. 207; 2006 No. 200; 2008 No. 54; 2011 No. 120
R. 23	am. 1960 No. 90 rs. 1965 No. 152 am. 1977 No. 39; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56 rep. 1994 No. 348
R. 24	am. 1977 No. 39; 1979 No. 55; 1986 No. 319; 2004 No. 389; 2010 No. 231
R. 25	am. 1990 No. 337; 1994 No. 348; 1998 No. 374; 2001 No. 68; 2005 No. 207; 2006 No. 200

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 26	am. 1965 No. 152; 1968 No. 76; 1977 No. 39; 1978 No. 153; 1979 No. 55; 1981 Nos. 52 and 218; 1982 No. 372; 1983 No. 102; 1985 No. 320; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56; 1990 No. 437; 1991 Nos. 1 and 474; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2001 No. 68; 2002 No. 9; 2005 No. 207; 2006 No. 200
R. 26A	ad. 1978 No. 153 am. 1979 No. 55; 1981 No. 218; 1982 No. 372; 1983 No. 102; 1986 Nos. 319 and 391; 1988 No. 56; 1990 No. 437; 1991 Nos. 1 and 474; 1994 No. 348; 1996 No. 70; 1998 No. 374; 2001 No. 68; 2004 No. 389; 2006 No. 200
R. 27	am. 1977 No. 39; 1986 No. 391; 1988 No. 56; 1994 No. 348; 2004 No. 389
R. 28	am. 1967 No. 158; 1977 No. 39; 1979 No. 55; 1986 No. 391; 2002 No. 9; 2004 No. 389; 2006 No. 200; 2010 No. 231
R. 29	am. 1967 No. 158 rs. 1976 No. 195 rep. 1986 No. 319
R. 30	am. 1986 No. 391; 1994 No. 348; 2004 No. 389
R. 31	am. 1960 No. 90; 1965 No. 152; 1967 No. 158; 1977 No. 39; 1983 No. 102; 1986 Nos. 319 and 391; 1987 No. 47; 1988 No. 56; 1990 No. 437; 1991 No. 1 rs. 1994 No. 348 am. 2002 No. 9; 2006 No. 200
Part VI	
R. 32	am. 1965 No. 152; 1967 No. 158; 1977 No. 39; 1978 No. 153; 1986 No. 391; 1994 No. 348; 1996 No. 70; 1998 No. 374 rs. 2002 No. 9 am. 2002 No. 344; 2006 No. 200
R. 33	am. 1967 No. 158; 1977 No. 39; 1986 No. 391 rs. 2002 No. 9
R. 34	am. 1977 No. 39; 1979 No. 55; 1986 No. 391; 1988 No. 56 rep. 1994 No. 348
R. 35	am. 1962 No. 34; 1964 Nos. 57 and 135; 1969 No. 107; 1977 No. 39; 1987 No. 47 rs. 1994 No. 344
R. 36	am. 1977 No. 39; 1994 No. 338 rep. 1996 No. 70 ad. 2002 No. 344 am. 2010 No. 231
R. 37	am. 1967 No. 158; 1977 No. 39; 1988 No. 56; 2002 No. 9

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Part VIA	
Division 1	
Heading to Div. 1 of Part VIA	ad. 2010 No. 296
R. 37A	ad. 2007 No. 225 am. 2010 No. 296
R. 37B	ad. 2007 No. 225
R. 37C	ad. 2007 No. 225
Heading to r. 37D	rs. 2010 No. 296
R. 37D	ad. 2007 No. 225 am. 2008 No. 116; 2010 No. 296
R. 37DA	ad. 2010 No. 296
Division 2	
Heading to Div. 2 of Part VIA	ad. 2010 No. 296
R. 37DB	ad. 2010 No. 296
R. 37E	ad. 2007 No. 225 am. 2010 No. 296
Note to r. 37E (4)	rs. 2010 No. 296
R. 37EA	ad. 2010 No. 296
R. 37EB	ad. 2010 No. 296
R. 37EC	ad. 2010 No. 296
R. 37ED	ad. 2010 No. 296
R. 37EE	ad. 2010 No. 296
R. 37EF	ad. 2010 No. 296
R. 37EG	ad. 2010 No. 296
R. 37EH	ad. 2010 No. 296
R. 37F	ad. 2007 No. 225 am. 2008 No. 116 rs. 2010 No. 296
R. 37G	ad. 2007 No. 225 rs. 2010 No. 296
Division 3	
Heading to Div. 3 of Part VIA	ad. 2010 No. 296
R. 37H	ad. 2007 No. 225 rs. 2010 No. 296
R. 37HA	ad. 2008 No. 116 rs. 2011 No. 29 am. 2012 No. 55
R. 37I	ad. 2007 No. 225 am. 2010 No. 296

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
R. 37J	ad. 2007 No. 225 rs. 2010 No. 296
R. 37JA	ad. 2010 No. 296
Division 4	
Heading to Div. 4 of Part VIA	ad. 2010 No. 296
R. 37K	ad. 2009 No. 195 am. 2010 No. 296
Part 7	
Part 7	ad. 1994 No. 348
R. 38	ad. 1994 No. 348 am. 2000 No. 369; 2009 No. 195
R. 38A	ad. 2000 No. 369 am. 2001 No. 68
R. 38B	ad. 2000 No. 369
R. 39	ad. 1994 No. 348
R. 40	ad. 1994 No. 348 rs. 2000 No. 369
R. 41	ad. 1994 No. 348
R. 42	ad. 1994 No. 348
R. 43	ad. 1994 No. 348
R. 44	ad. 1994 No. 348 am. 1996 No. 70
R. 45	ad. 1994 No. 348 am. 1996 No. 70
R. 46	ad. 1994 No. 348
R. 47	ad. 1994 No. 348
R. 48	ad. 1994 No. 348 rep. 2000 No. 369 ad. 2009 No. 195 am. 2010 Nos. 115 and 327
Schedule 1	ad. 2007 No. 225 rep. 2010 No. 296
Schedule 2	ad. 2007 No. 225 rep. 2010 No. 296
Schedule 3	
Schedule 3	ad. 2007 No. 225
Schedule 4	ad. 2007 No. 225 rep. 2010 No. 49

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Schedule 5	
Schedule 5	ad. 2007 No. 225 rs. 2008 No. 116 am. 2010 Nos. 49 and 295
Schedule 6	
Schedule 1	ad. 2002 No. 344 am. 2005 No. 207
Renumbered Schedule 6	2007 No. 225
Schedule 6	rs. 2011 No. 120
Heading to Schedule	ad. 1994 No. 348 rep. 2002 No. 344
Heading to The Schedules	rep. 1977 No. 39
Heading to First Schedule	rep. 1977 No. 39
Heading to Schedule 1	ad. 1977 No. 39 rep. 1987 No. 47
First Schedule	rs. 1960 No. 90 am. 1961 No. 59 rs. 1961 No. 137; 1962 Nos. 34 and 101 am. 1963 No. 34 rs. 1963 No. 107 am. 1964 No. 12 rs. 1964 Nos. 57 and 135; 1965 No. 51 am. 1965 No. 151 rs. 1966 No. 80 am. 1966 No. 144 rs. 1967 No. 67 am. 1967 No. 116 rs. 1967 No. 158 am. 1968 Nos. 44, 88 and 146; 1969 No. 44 rs. 1969 No. 107 am. 1969 No. 185; 1970 Nos. 39, 94 and 186 rs. 1971 Nos. 44 and 101 am. 1971 No. 154 rs. 1972 No. 32 am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57 rs. 1973 No. 139 am. 1973 No. 229; 1974 No. 37 rs. 1974 No. 126 am. 1974 No. 222; 1975 No. 50 rs. 1975 No. 148 am. 1975 No. 209 rs. 1976 No. 84 am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 1	rs. 1977 No. 125 am. 1977 No. 221; 1978 Nos. 47 and 142 rs. 1978 No. 245 am. 1979 No. 51

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
	rs. 1979 No. 144 am. 1979 No. 250; 1980 Nos. 69 and 213 rs. 1980 No. 338 am. 1981 No. 52 rs. 1981 No. 212 am. 1981 No. 345; 1982 No. 76 rs. 1982 No. 179 am. 1982 No. 334; 1983 No. 28 rs. 1983 No. 116 am. 1983 No. 292; 1984 Nos. 50, 169 and 342 rs. 1985 Nos. 32 and 184 am. 1985 No. 320; 1986 No. 38 rs. 1986 No. 194 am. 1986 No. 320 rep. 1987 No. 47
Heading to Second Schedule	rep. 1977 No. 39
Heading to Schedule 2.....	ad. 1977 No. 39 rep. 1987 No. 47
Second Schedule.....	rs. 1960 No. 90; 1961 Nos. 59 and 137; 1962 Nos. 34 and 101 am. 1962 No. 114; 1963 No. 34 rs. 1963 No. 107; 1964 Nos. 57 and 135; 1965 No. 51 am. 1965 No. 151 rs. 1966 Nos. 80 and 144; 1967 No. 67 am. 1967 No. 116 rs. 1967 No. 158 am. 1968 Nos. 44, 88 and 146; 1969 No. 44 rs. 1969 Nos. 107 and 185 am. 1970 Nos. 39, 94 and 186 rs. 1971 Nos. 44 and 101 am. 1971 No. 154 rs. 1972 No. 32 am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57 rs. 1973 No. 139 am. 1973 No. 229; 1974 No. 37 rs. 1974 No. 126 am. 1974 No. 222; 1975 No. 50 rs. 1975 No. 148 am. 1975 No. 209 rs. 1976 No. 84 am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 2.....	am. 1977 No. 39 rs. 1977 No. 125 am. 1977 No. 221; 1978 Nos. 47 and 142 rs. 1978 No. 245 am. 1979 No. 51 rs. 1979 No. 144 am. 1979 No. 250; 1980 Nos. 69 and 213

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
	rs. 1980 No. 338 am. 1981 No. 52 rs. 1981 No. 212 am. 1981 No. 345; 1982 No. 76 rs. 1982 No. 179 am. 1982 No. 334; 1983 No. 28 rs. 1983 No. 116 am. 1983 No. 292; 1984 Nos. 50, 169 and 342 rs. 1985 Nos. 32 and 184 am. 1985 No. 320; 1986 No. 38 rs. 1986 No. 194 am. 1986 No. 320 rep. 1987 No. 47
Heading to Third Schedule .	rep. 1977 No. 39
Heading to Schedule 3.....	ad. 1977 No. 39 rep. 1987 No. 47
Third Schedule.....	rs. 1960 No. 90 am. 1960 No. 102 rs. 1961 Nos. 59 and 137; 1962 Nos. 34 and 101 am. 1962 No. 114; 1963 No. 34 rs. 1963 No. 107 am. 1964 No. 12 rs. 1964 Nos. 57 and 135; 1965 Nos. 51 and 151; 1966 Nos. 80 and 144; 1967 No. 67 am. 1967 No. 116 rs. 1967 No. 158 am. 1968 Nos. 44, 88 and 146; 1969 No. 44 rs. 1969 No. 107 am. 1969 No. 185; 1970 Nos. 39, 94 and 186 rs. 1971 Nos. 44 and 101 am. 1971 No. 154 rs. 1972 No. 32 am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57 rs. 1973 No. 139 am. 1973 No. 229; 1974 No. 37 rs. 1974 No. 126 am. 1974 No. 222; 1975 No. 50 rs. 1975 No. 148 am. 1975 No. 209 rs. 1976 No. 84 am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 3.....	rs. 1977 No. 125 am. 1977 No. 221; 1978 Nos. 47 and 142 rs. 1978 No. 245 am. 1979 No. 51 rs. 1979 No. 144 am. 1979 No. 250; 1980 Nos. 69 and 213 rs. 1980 No. 338 am. 1981 No. 52

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
	rs. 1981 No. 212 am. 1981 No. 345; 1982 No. 76 rs. 1982 No. 179 am. 1982 No. 334; 1983 No. 28 rs. 1983 No. 116 am. 1983 No. 292; 1984 Nos. 50, 169 and 342 rs. 1985 Nos. 32 and 184 am. 1985 No. 320; 1986 No. 38 rs. 1986 No. 194 am. 1986 No. 320 rep. 1987 No. 47
Heading to Fourth Schedule	rep. 1977 No. 39
Heading to Schedule 4	ad. 1977 No. 39 rep. 1987 No. 47
Fourth Schedule	rs. 1961 No. 137; 1962 Nos. 34 and 101; 1963 No. 107; 1964 Nos. 57 and 135; 1965 No. 51; 1966 No. 80 am. 1966 No. 144 rs. 1967 Nos. 67, 116 and 158; 1969 No. 107 am. 1969 No. 185; 1970 Nos. 39 and 186 rs. 1971 Nos. 44 and 101; 1972 No. 32 am. 1973 No. 57 rs. 1973 No. 139 am. 1973 No. 229 rs. 1974 No. 126 am. 1974 No. 222; 1975 No. 50 rs. 1975 No. 148; 1976 No. 84
Schedule 4	rs. 1977 No. 125 am. 1978 No. 142 rs. 1978 No. 245 am. 1979 No. 51 rs. 1979 No. 144; 1980 No. 338 am. 1981 No. 52 rs. 1981 No. 212; 1982 No. 179; 1983 No. 116 am. 1983 No. 292 rs. 1985 Nos. 32 and 184; 1986 No. 194 am. 1986 No. 320 rep. 1987 No. 47
Heading to Fifth Schedule	rep. 1977 No. 39
Heading to Schedule 5	ad. 1977 No. 39 rep. 1987 No. 47
Fifth Schedule	rs. 1960 No. 90 am. 1960 No. 102 rs. 1961 Nos. 59 and 137; 1962 Nos. 34 and 101 am. 1962 No. 114; 1963 No. 34 rs. 1963 No. 107 am. 1964 No. 12

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
	rs. 1964 Nos. 57 and 135; 1965 Nos. 51 and 151; 1966 Nos. 80 and 144; 1967 Nos. 67, 116 and 158; 1968 No. 44 am. 1968 No. 88 rs. 1968 No. 146 am. 1969 No. 44 rs. 1969 No. 107 am. 1969 No. 185 rs. 1970 Nos. 39 and 94 am. 1970 Nos. 119 and 186 rs. 1971 Nos. 44, 101 and 154; 1972 No. 32 am. 1972 Nos. 121 and 205; 1973 Nos. 15 and 57 rs. 1973 No. 139 am. 1973 No. 229; 1974 No. 37 rs. 1974 No. 126 am. 1974 No. 222; 1975 No. 50 rs. 1975 No. 148 am. 1975 No. 209 rs. 1976 No. 84 am. 1976 Nos. 150 and 255; 1977 No. 39
Schedule 5	am. 1977 No. 39 rs. 1977 No. 125 am. 1977 No. 221; 1978 Nos. 47 and 142 rs. 1978 No. 245 am. 1979 No. 51 rs. 1979 No. 144 am. 1979 No. 250; 1980 Nos. 69 and 213 rs. 1980 No. 338 am. 1981 No. 52 rs. 1981 No. 212 am. 1981 No. 345; 1982 No. 76 rs. 1982 No. 179 am. 1982 No. 334; 1983 No. 28 rs. 1983 No. 116 am. 1983 No. 292; 1984 Nos. 50, 169 and 342 rs. 1985 Nos. 32 and 184 am. 1985 No. 320; 1986 No. 38 rs. 1986 No. 194 am. 1986 No. 320 rep. 1987 No. 47
Heading to Sixth Schedule	rep. 1977 No. 39
Heading to Schedule 6	ad. 1977 No. 39 rep. 1994 No. 348
Schedule 6	am. 1977 No. 39 rs. 1981 No. 218 am. 1984 No. 148 rep. 1994 No. 348

Table of Amendments

ad. = added or inserted am. = amended rep. = repealed rs. = repealed and substituted

Provision affected	How affected
Heading to Schedule 7.....	rs. 1991 No. 1 rep. 1994 No. 348
Schedule 7.....	ad. 1983 No. 102 rep. 1986 No. 319 ad. 1987 No. 262 rep. 1994 No. 348

Table A Application, saving or transitional provisions

Select Legislative Instrument 2010 No. 296

Part 2 Transitional

4 Definitions for Part 2

In this Part:

data collection period has the meaning given by subregulation 37EC (1) of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

disclosure cycle has the meaning given by subregulation 37EB (1) of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

first transitional disclosure cycle has the meaning given by subregulation 6 (2).

former Regulations means the *National Health (Pharmaceutical Benefits) Regulations 1960* as in force immediately before 1 December 2010.

main disclosure cycle means a main disclosure cycle mentioned in paragraph 37EB (2) (a) of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

pharmaceutical item has the meaning given by subregulation 5 (1) of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

price disclosure requirements has the meaning given by subsection 99ADC (1) of the *National Health Act 1953* as in force immediately before 1 December 2010.

reporting period has the same meaning as in regulation 37A of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

second transitional disclosure cycle has the meaning given by subregulation 6 (3).

third transitional disclosure cycle has the meaning given by subregulation 6 (5).

5 Transitional — listed brand subject to price disclosure and annual reporting period ends before 1 December 2010

(1) This regulation applies to a listed brand of a pharmaceutical item if:

(a) the price disclosure requirements applied for the listed brand, or any other listed brand of any pharmaceutical item having the same drug and manner of administration as the listed brand, before 1 December 2010; and

(b) the annual reporting period under regulation 37J of the former Regulations for at least 1 of the listed brands mentioned in paragraph (a) ended before 1 December 2010.

(2) The former Regulations apply to the listed brand until the end of the reduction day for the brand under section 99ADH of the former Act.

(3) However, if before the end of the reduction day mentioned in subregulation (2) the listed brand is in any of the following disclosure cycles, regulation 6 applies to the brand for those cycles:

(a) the first transitional disclosure cycle;

(b) the second transitional disclosure cycle;

(c) the third transitional disclosure cycle.

(4) In this regulation:

former Act means the *National Health Act 1953* as in force immediately before 1 December 2010.

6 Transitional — listed brand subject to price disclosure and annual reporting period does not end before 1 December 2010 — data collection period

(1) This regulation and regulation 7 apply to a listed brand of a pharmaceutical item if:

(a) the price disclosure requirements applied for the listed brand, or any other listed brand of any pharmaceutical item having the same drug and manner of administration as the listed brand, before 1 December 2010; and

(b) the annual reporting period under regulation 37J of the former Regulations for at least 1 of the listed brands mentioned in paragraph (a) began on 1 of the following dates (the ***relevant date***) and did not end before 1 December 2010:

(i) 1 January 2010;

(ii) 1 May 2010;

(iii) 1 September 2010.

(2) The disclosure cycle (the ***first transitional disclosure cycle***), and the data collection period, for:

(a) a listed brand to which subparagraph (1) (b) (i) applies; and

(b) any other listed brand of pharmaceutical item having the same drug and manner of administration as the listed brand mentioned in paragraph (a);

begins on 1 January 2010.

(3) The disclosure cycle (the ***second transitional disclosure cycle***), and the data collection period, for:

(a) a listed brand to which subparagraph (1) (b) (ii) applies; and

(b) any other listed brand of pharmaceutical item having the same drug and manner of administration as the listed brand mentioned in paragraph (a);

begins on 1 May 2010.

(4) The data collection periods in the first transitional disclosure cycle and the second transitional disclosure cycle end at the end of 30 September 2011.

(5) The disclosure cycle (the ***third transitional disclosure cycle***), and the data collection period, for:

(a) a listed brand to which subparagraph (1) (b) (iii) applies; and

(b) any other listed brand of pharmaceutical item having the same drug and manner of administration as the listed brand mentioned in paragraph (a);

begins on 1 September 2010.

(6) The data collection periods in the third transitional disclosure cycle end at the end of 31 January 2012.

7 Transitional — listed brand subject to price disclosure and annual reporting period does not end before 1 December 2010 — reporting period and information

(1) For the first transitional disclosure cycle, the quarterly reporting period under regulation 37J of the former Regulations that began on 1 October 2010 is taken to be a reporting period that ends at the end of 31 March 2011.

(2) For the second transitional disclosure cycle, the information that must be provided for the quarterly reporting period under regulation 37J of the former Regulations that began on 1 August 2010 must be provided within 2 months after the end of that reporting period.

(3) For the second transitional disclosure cycle, the quarterly reporting period under regulation 37J of the former Regulations that began on 1 November 2010 is taken to be a reporting period that ends at the end of 31 March 2011.

(4) For the third transitional disclosure cycle:

(a) the quarterly reporting period under regulation 37J of the former Regulations that began on 1 September 2010 is taken to be a reporting period that ends at the end of 31 March 2011; and

(b) the last reporting period in the data collection periods for that disclosure cycle begins on 1 October 2011 and ends at the end of 31 January 2012.

(5) The information about incentives to be provided for the listed brand under paragraphs 37H (1) (i) and (j) of the *National Health (Pharmaceutical Benefits) Regulations 1960* for the reporting period ending at the end of 31 March 2011 must include information about incentives mentioned in those paragraphs for the period beginning on the relevant date for the brand and ending at the end of 31 March 2011.

(6) In this regulation:

relevant date has the meaning given by paragraph 6 (1) (b).

8 Transitional — listed brand having same drug and manner of administration as listed brand already subject to price disclosure requirements — first reporting period for brand in third transitional cycle

(1) This regulation applies to a listed brand of a pharmaceutical item (the ***relevant brand***) if:

(a) the price disclosure requirements first apply under section 99ADD of the Act for the relevant brand on a day (the ***relevant day***); and

(b) both on and before the relevant day, the price disclosure requirements apply for any other listed brand of any pharmaceutical item having the same drug and manner of administration (the ***other brand***) as the relevant brand; and

(c) the other brand is in the third transitional cycle.

(2) The first reporting period for the relevant brand:

(a) begins on the relevant day; and

(b) ends at the end the first of the following days to occur after the relevant day:

(i) 31 March 2011;

(ii) 30 September 2011;

(iii) 31 January 2012.

(3) If the first reporting period for the relevant brand ends on 31 January 2012, information about sales revenue and adjusted volume for the relevant brand for the first month of the first reporting period is excluded when using the method set out in regulation 37G of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

9 Transitional — listed brand moving from first or second transitional disclosure cycle to main disclosure cycle

(1) This regulation applies if:

(a) regulation 6 applies to a listed brand of a pharmaceutical item; and

(b) the brand is in the first transitional disclosure cycle or the second transitional disclosure cycle.

(2) The brand moves to a main disclosure cycle on 1 October 2011.

(3) The data collection period for the brand in the main disclosure cycle:

(a) begins on 1 October 2011; and

(b) ends at the end of 30 September 2012.

10 Transitional — listed brand moving from third transitional disclosure cycle to main disclosure cycle

(1) This regulation applies if:

(a) regulation 6 applies to a listed brand of a pharmaceutical item; and

(b) the brand is in the third transitional disclosure cycle.

(2) The brand moves to a main disclosure cycle on 1 February 2012.

(3) The data collection period for the brand in the main disclosure cycle:

(a) begins on 1 February 2012; and

(b) ends at the end of 30 September 2013.

(4) The first reporting period in the data collection period for the brand in the main disclosure cycle:

(a) begins on 1 February 2012; and

(b) ends at the end of 31 March 2012.