EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listing of Pharmaceutical Benefits) Instrument 2012

PB 71 of 2012

Purpose

This legislative instrument provides for the listing of pharmaceutical benefits on the Pharmaceutical Benefits Scheme (PBS). It determines the pharmaceutical benefits that are on the PBS (through declarations of drugs and medicinal preparations, and for ready-prepared benefits: determinations of forms, manners of administration and brands) and provides for related matters (responsible persons, prescribing circumstances, maximum quantities and numbers of repeats, and whether the pharmaceutical benefit is to be available generally or available only under special arrangements).

The Instrument contains:

- declarations under subsections 85(2), 85(2A), and 85(2AA) of the *National Health Act 1953* (the Act); and
- determinations under subsections 84AF(1), 84AK(2), 84AK(3), 85(3), 85(5), 85(6), 85(7), 85(8), 85A(2), 85A(2A), 88(1A), 88(1C), 88(1D) and 88(1E) of the Act.

It revokes and replaces PB 108 of 2010.

The Pharmaceutical Benefits Scheme and the powers exercised in this Instrument

Overview

Part VII of the Act is the legislative basis for the PBS under which Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) of the Act provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

Other provisions of Part VII provide for the Minister to make declarations and determinations, by legislative instrument, defining those pharmaceutical benefits and matters relating to the prescribing of those benefits. These are the powers exercised in this instrument and they are explained below.

Minister's powers - drugs and medicinal preparations, forms, manners of administration and brands

The Minister's powers to declare drugs and medicinal preparations under subsection 85(2) of the Act, and to determine forms, manners of administration and brands under subsections 85(3), (5) and (6) respectively, have been exercised in this Instrument.

Subsection 85(2) provides for the drugs and medicinal preparations to which Part VII applies. Part VII applies to the drugs and medicinal preparations declared by the Minister under paragraph 85(2)(a). Part VII also applies to certain extemporaneously-prepared medicinal preparations as a result of declarations under paragraph 85(2)(b). All of the drugs and medicinal preparations in relation to which a declaration is in force under subsection 85(2) are defined as *listed drugs*.

The Minister may not declare, under paragraph 85(2)(a), a drug or medicinal preparation to be a drug or medicinal preparation in relation to which Part VII applies unless the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended to the Minister that

it be so declared (subsection 101(4)). The new drugs and medicinal preparations which have been added to the PBS by this Instrument have been the subject of such recommendations by the PBAC to the Minister. These new drugs and medicinal preparations are listed in Attachment 2 to this Explanatory Statement.

The Minister may determine:

- the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3) of the Act);
- the manner of administration of a form of a listed drug (subsection 85(5) of the Act); and
- a brand of a pharmaceutical item (subsection 85(6) of the Act). The pharmaceutical item is the listed drug in the form with the manner of administration determined (section 84AB).

For ready-prepared pharmaceutical benefits, these declarations and determinations govern what is a *pharmaceutical benefit* under the definition of that term in subsection 84(1) of the Act. Where a drug has been declared under subsections 85(2), and a form, manner of administration and brand determined under subsections 85(3), (5) and (6) respectively, the pharmaceutical benefit is that brand of the drug in that form with that manner of administration.

For extemporaneously-prepared pharmaceutical benefits, there are no declarations of form, manner of administration or brand under subsections 85(3), (5) and (6). The pharmaceutical benefit is the drug or medicinal preparation in relation to which there is a declaration under subsection 85(2).

Minister's powers - responsible persons

The Minister may determine the responsible person for a brand of a pharmaceutical item (section 84AF of the Act). The brand must be a listed brand (i.e. a brand of a pharmaceutical item in relation to which there is a determination under subsection 85(6) in force). The responsible person must be the person who has notified the Minister that they are, or will be, the person who is, or will be, the supplier of a particular brand of a pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the responsible person for all pharmaceutical items that have that brand. These prerequisites to the exercise of the power in section 84AF have been met and the Minister's power in section 84AF to determine responsible persons has been exercised in this Instrument.

Minister's powers - prescribing of pharmaceutical benefits

The Minister's powers to determine authorised prescribers, prescribing circumstances, and maximum quantities and number of repeats that may be prescribed and related conditions, under section 88, and subsections 85(7), and 85A(2) and (2A), of the Act, respectively, have been exercised in this Instrument.

Section 88 provides for various matters relating to the prescribing of pharmaceutical benefits. Subsection 88(1) provides that, subject to Part VII, a medical practitioner is authorised to write a prescription for the supply of a pharmaceutical benefit. Other subsections of section 88 empower the Minister to determine the pharmaceutical benefits that may be prescribed by the various categories of prescribers mentioned. The prescribers and the relevant subsections are:

- participating dental practitioners (subsection 88(1A));
- authorised optometrists (subsection 88(1C));

- authorised midwives (subsection 88(1D)); and
- authorised nurse practitioners (subsection 88(1E)).

The Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit (paragraph 85(7)(b)), after determining (under paragraph 85(7)(a)) that the pharmaceutical benefit is a *relevant pharmaceutical benefit* for the purposes of section 88A. Section 88A provides that the writing of a prescription for a relevant pharmaceutical benefit is authorised only in the circumstances determined under subsection 85(7).

The Minister may determine the maximum quantity or number of units of a pharmaceutical benefit or pharmaceutical item that may be directed to be supplied, and the maximum number of occasions on which the supply may be directed to be repeated, in the one prescription (subsection 85A(2)). The determinations may be made with respect to the writing of prescriptions by persons included in a specified class of persons (i.e. particular prescribers), and the maximums may be specified for all purposes or particular purposes. The Minister may also determine conditions that must be satisfied when writing a prescription for a pharmaceutical benefit to which a determination of a maximum quantity or number of repeats applies (subsection 85A(2A)).

Minister's powers - Section 100 only supply and prescriber bag only supply

The Minister's powers in subsection 85(2A) and paragraphs 85(8)(a) and (b) of the Act in relation to section 100 only supply of pharmaceutical benefits have been exercised in this Instrument. The PBAC recommended that the new drug, human menopausal gonadotrophin, the subject of the subsection 85(2A) declaration, be made available under section 100 special arrangements.

All pharmaceutical benefits are supplied under Part VII of the Act. While most pharmaceutical benefits are generally available for supply under Part VII, some pharmaceutical benefits can, under section 85AA, only be supplied under Part VII in accordance with special arrangements under section 100 of the Act. The section 100 special arrangements are contained in separate instruments. The pharmaceutical benefits to which section 85AA applies are those to which the following Ministerial declarations or determinations relate:

- a declaration that a particular drug or medicinal preparation can only be supplied under special arrangements under section 100 (subsection 85(2A));
- a determination that a particular pharmaceutical benefit can only be supplied under special arrangements under section 100 (paragraph 85(8)(a));
- a determination that one or more of the circumstances (being circumstances determined under paragraph 85(7)(b)) in which a prescription for the supply of the pharmaceutical benefit may be written are circumstances in which the benefit can only be supplied under special arrangements under section 100 (paragraph 85(8)(b)).

Other pharmaceutical benefits can, under section 85AAA of the Act, only be supplied under Part VII under one or more of the prescriber bag provisions of the Act. The prescriber bag provisions are:

- section 93 (supplies by medical practitioners);
- section 93AA (supplies by authorised midwives); and
- section 93AB (supplies by authorised nurse practitioners).

The pharmaceutical benefits to which section 85AAA applies are those to which the following Ministerial declarations or determinations relate:

- a declaration that a particular drug or medicinal preparation can only be supplied under one or more of the prescriber bag provisions (subsection 85(2AA)); and
- a determination that a particular pharmaceutical benefit can only be supplied under one or more of the prescriber bag provisions (subsection 85(7A)).

Minister's powers - pack quantity and determined quantity

The Minister's powers to determine pack quantities and determined quantities of a listed brand of a pharmaceutical item in subsections 84AK(2) and (3) respectively, have been exercised in this instrument.

Under subsection 84AK(2) the Minister may determine, for a listed brand of a pharmaceutical item, that one or quantities or numbers of units of the pharmaceutical item is a pack quantity of the brand. Responsible persons request the Minister to determine pack quantities for each of their PBS pack sizes. The Act provides that the approved ex-manufacturer price for each brand of a particular pharmaceutical item must be agreed or determined by reference to the lowest pack quantity of any brand of the pharmaceutical item; it also provides for proportional ex-manufacturer prices for other pack quantities.

Under subsection 84AK(3) the Minister may determine, for a listed brand of a pharmaceutical item, that one or quantities or numbers of units of the pharmaceutical item is a determined quantity of the brand. A determined quantity is used when there is no appropriate maximum quantity as the basis for selecting the appropriate wholesale mark-up for working out Commonwealth payments for the supply of pharmaceutical benefits, under a number of legislative instruments.

Minister's powers - revocation of drug declarations

Subsection 101(4AAA) of the Act empowers the Minister, by legislative instrument, to revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation.

Where a revocation or variation of a subsection 85(2) declaration would have the result that a drug or medicinal preparation would cease to be a listed drug, the Minister must, under subsection 101(4AAB) of the Act, obtain the advice in writing of PBAC before making the revocation or variation. Under subsection 101(4AAC), this PBAC advice is to be tabled in Parliament with the related declaration under subsection 101(4AAA).

Recent amendments to the Act relevant to this Instrument

New subsection 85A(2A) was inserted into the Act on 1 July 2012 by the *National Health Amendment (Fifth Community Pharmacy Agreement Initiatives) Act 2012*. The Minister's power under subsection 85A(2A) is being exercised in this Instrument for the first time. This is the power to determine conditions that must be satisfied when writing a prescription for a pharmaceutical benefit to which a determination of a maximum quantity or number of repeats applies.

A number of amendments of the Act commence on the same day as this Instrument and some of the determinations in this Instrument are being made under the new provisions. The amending Act (the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*) received Royal Assent on 28 June 2012 and commences on 1 October 2012. This Instrument exercises the powers in the amended provisions in reliance on section 4 of the *Acts Interpretation Act 1901*. The powers exercised in this instrument for the first time are the

power to determine a pack quantity (subsection 84AK(2)), the power to determine a determined quantity (subsection 84AK(3)) and the power to declare that a drug is prescriber bag only (subsection 85(2AA)).

Changes to the PBS effected by this Instrument

This Instrument revokes PB 108 of 2010. Many of the matters declared and determined in this Instrument are the same as in PB 108 of 2010, as amended. Changes since the last amendment are summarised in Attachment 2.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. When recommending the listing of a medicine on the PBS, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, and agreement to final listing details.

This Instrument

Details of the provisions in this Instrument are set out in Attachment 1.

This Instrument commences on 1 October 2012.

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

ATTACHMENT 1

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* and may also be cited as PB 71 of 2012.

Section 2 Commencement

This section provides that the Instrument commences on 1 October 2012.

Section 3 Revocation

This section provides for the revocation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* (PB 108 of 2010).

Section 4 Definitions

A number of expressions used in the Instrument are defined in this section.

Section 5 Drugs and medicinal preparations to which Part VII applies

Section 5 declares, for subsection 85(2) of the Act, the drugs and medicinal preparations to which Part VII of the Act applies. These are:

(a) the drugs and medicinal preparations:
- in Schedule 1; and
- in Part 1 of Schedule 2; and

(b) medicinal preparations:
- composed of one or more drugs or medicinal preparations in Part 1 of Schedule 2; and
- composed of one or more of the drugs and medicinal preparations in Part 1 of Schedule 2 and one or more of the Additives in Part 2 of Schedule 2.

All of the drugs and medicinal preparations in relation to which a declaration under subsection 85(2) is in force are defined as *listed drugs* in subsection 84(1) of the Act.

With the exception of the drugs and medicinal preparations in Schedule 1, all the other drugs and medicinal preparations referred to are *pharmaceutical benefits*, i.e. the listed drug is the pharmaceutical benefit, because there are no determinations of form, manner of administration or brand under subsections 85(3), (5) and (6) of the Act respectively, in relation to these listed drugs. These pharmaceutical benefits are defined in section 4 of this Instrument to be *extemporaneously-prepared pharmaceutical benefits*.

However, further determinations are made in sections 6, 7 and 8 of this Instrument in relation to the drugs and medicinal preparations in Schedule 1, with the result that the *pharmaceutical benefits* in the case of the listed drugs in Schedule 1 are the brands of the drugs in the forms with the manners of administration determined. These pharmaceutical benefits, i.e. ones which have a brand determination under subsection 85(6) of the Act, are defined in section 4 of this Instrument to be *ready-prepared pharmaceutical benefits*.

Section 6 Form

This section determines, for subsection 85(3) of the Act, the allowable forms of the listed drugs in Schedule 1. The form of a drug is typically the strength and type of unit (e.g. 200 mg tablet), but may include other matters.

Section 7 Manner of administration

Subsection 7(1) determines, for subsection 85(5) of the Act, the manner of administration of the forms of the listed drugs in Schedule 1.

Subsection 7(2) determines, for paragraph 85A(2)(c) of the Act, that if a manner of administration is mentioned in Schedule 1 for a form of a listed drug, that is the only manner of administration that may be directed to be used in a prescription for a pharmaceutical benefit that has that listed drug in that form.

Section 8 Brand and responsible person

Subsection 8(1) determines, for subsection 85(6) of the Act, the brands of the pharmaceutical items in Schedule 1. The pharmaceutical items are the listed drugs in the forms with the manners of administration declared and determined in sections 5 – 7 above.

Subsection 8(2) determines, for subsection 84AF(1) of the Act, the responsible person for each brand of a pharmaceutical item in Schedule 1. Under subsection 84AF(1):

- the responsible person determined must be the person who has notified the Minister that they are, or will be, the supplier of the brand of the pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly; and
- the same person must be the responsible person for all pharmaceutical items that have a particular brand.

These preconditions have been met.

The Act imposes obligations on the responsible person in relation to price disclosure and guarantee of supply and it is the responsible person with whom price negotiations occur.

Section 9 Authorised prescriber

Subsections 9(1), (2), (3) and (4), respectively, determine the pharmaceutical benefits that may be prescribed by participating dental practitioners, authorised optometrists, authorised midwives and authorised nurse practitioners. These determinations are made for subsections 88(1A), (1C), (1D) and (1E) of the Act, respectively.

There is no determination of the pharmaceutical benefits that may be prescribed by medical practitioners. The reason for this is that subsection 88(1) of the Act authorises medical practitioners to prescribe all pharmaceutical benefits. A *Note* at the end of section 9 alerts readers to this.

Section 10 Prescription circumstances - Schedule 1

This section determines the circumstances, if any, in which a prescription for the supply of a pharmaceutical benefit may be written.

If no circumstances are determined for a pharmaceutical benefit, there are no restrictions on the prescribing of the pharmaceutical benefit by an authorised prescriber.

Where at least one circumstances code (the letter ‘C’ followed by a number) is mentioned in the Column headed ‘Circumstances’ in Schedule 1 for a pharmaceutical benefit:

- for paragraph 85(7)(a) of the Act, the pharmaceutical benefit is determined to be a relevant pharmaceutical benefit for the purposes of section 88A of the Act; and
- for paragraph 85(7)(b) of the Act, the circumstances in which a prescription for the pharmaceutical benefit may be written are the circumstances set out in Part 1 of Schedule 4 for at least one of those circumstances codes. Each circumstances code

represents one circumstance, and it is only necessary for one circumstance to be met for the prescription to be written.

Section 88A of the Act provides that the writing of a prescription for a *relevant pharmaceutical benefit* is authorised only in the circumstances determined.

Section 11 Authority required procedures

Section 12 Authority required procedures - submission of prescription

Section 13 Authority required procedures - authorisation

Section 14 Streamlined authority code

These sections set out matters relevant to Authority Required prescriptions and form part of the Minister's determination of circumstances under paragraph 85(7)(b) of the Act.

Section 11 provides that where a circumstance determined for a pharmaceutical benefit includes compliance with authority required procedures:

- a prescription for the pharmaceutical benefit must be submitted to the Chief Executive Medicare in accordance with section 12; and
- the prescription must be authorised by the Chief Executive Medicare in accordance with section 13.

The circumstances may include:

(a) Compliance with Authority Required procedures;

(b) Compliance with Written Authority Required procedures;

(c) Compliance with Telephone Authority Required procedures; or

(d) Compliance with Written or Telephone Authority Required procedures.

Section 12 sets out the procedures for submission of prescriptions to the Chief Executive Medicare in writing, by telephone and by electronic means. Where the circumstance includes 'Compliance with Authority Required procedures', the prescription may be submitted by any of these means. Where the circumstance includes compliance with a particular type of Authority Required procedures, the prescription must be submitted by the corresponding method, e.g. 'Compliance with Written Authority Required procedures' means the prescription must be submitted in accordance with paragraph (1)(a).

Section 13 sets out the methods by which the Chief Executive Medicare may authorise the prescription which has been submitted.

Section 14 applies if the circumstances determined for a pharmaceutical benefit include a Streamlined Authority Code. Subsection 14(2) provides that the requirements of section 12 are taken to be complied with, and the Chief Executive Medicare is taken to have authorised the prescription under section 13 if the authorised prescriber has:

(a) prepared and signed a prescription in accordance with one of the subparagraphs of paragraph 12 (1)(a); and

(b) written the Streamlined Authority Code on the prescription.

This section provides for a streamlined method of complying with the Authority Required procedures. There is no requirement for formal submission of the prescription and the obtaining of a prior authorisation. All that is required is for prescription to be prepared and signed in the stated manner and for the Streamlined Authority Code to be written on the prescription.

Section 15 Extended application of sections 11 to 14

Section 15 provides that sections 11 to 14 apply in relation to conditions and conditions codes as if the circumstances and circumstances codes mentioned in those sections were conditions and conditions codes. This means that the authority required provisions set out in sections 11 to 14 apply where a condition determined under section 18 or 21 of this instrument includes a requirement to comply with an authority required procedure.

Section 16 Prescription circumstances - Schedule 2

Section 16 provides for paragraph 85(7)(b) prescription circumstances for extemporaneously-prepared pharmaceutical benefits. *Extemporaneously-prepared pharmaceutical benefits* are all pharmaceutical benefits other than ready-prepared pharmaceutical benefits, i.e. they are pharmaceutical benefits which have no brand determined under subsection 85(6) of the Act. In practice there have also been no determinations of form or manner of administration in relation to these pharmaceutical benefits; there have only been declarations of the relevant drugs and medicinal preparations under subsection 85(2) – see section 5 of this Instrument. The extemporaneously-prepared pharmaceutical benefits are:

- the listed drugs in Part 1 of Schedule 2;
- medicinal preparations composed of one or more of those listed drugs; and
- medicinal preparations composed of one or more of those listed drugs and one or more of the additives in Part 2 of Schedule 2.

The circumstances set out in Part 1 of Schedule 2 for a listed drug in that Part are determined to be the circumstances for that listed drug (which itself is an extemporaneously-prepared pharmaceutical benefit) and for (other) extemporaneously-prepared pharmaceutical benefits that contain that listed drug. Where an extemporaneously-prepared pharmaceutical benefit contains more than one of those listed drugs, a prescription for the extemporaneously-prepared pharmaceutical benefit may only be written if all of the circumstances for each of the listed drugs contained in the pharmaceutical benefit are met.

Section 17 Maximum quantity - Schedule 1

This section determines, for paragraph 85A(2)(a) of the Act, with respect to the pharmaceutical benefits and authorised prescribers in Schedule 1, the maximum quantities that the authorised prescribers may, in one prescription, direct to be supplied on the one occasion.

Subsections 17(2) and (3) provide that the maximum may be the maximum:

- for all purposes;
- for particular purposes; or
- for all purposes other than particular purposes.

Where particular purposes apply, these are represented by one or more purposes codes (the letter ‘P’ followed by a number), and the purposes relating to each purposes code are set out in Part 1 of Schedule 4.

Section 18 Maximum quantity conditions - Schedule 1

This section determines, for subsection 85A(2A) of the Act, the conditions, if any, which must be satisfied when writing a prescription for the supply of a pharmaceutical benefit to which a determination of a maximum quantity under paragraph 85A(2)(a) applies; the determinations of maximum quantities are made in section 17 of this instrument.

Where a conditions code (the letter 'CN' followed by a number) is mentioned in the Column headed 'Max Quantity' in Schedule 1 for a maximum quantity for a pharmaceutical benefit, the conditions which must be satisfied when writing a prescription for the supply of the pharmaceutical benefit to which the maximum quantity applies, are the conditions set out in Part 1 of Schedule 4 for the conditions code.

Section 19 Maximum quantity - Schedule 2

This section determines, for paragraph 85A(2)(a) of the Act, the maximum quantities of extemporaneously-prepared pharmaceutical benefits that may in one prescription be directed to be supplied on any one occasion. The maximum is specified for the type of extemporaneously-prepared pharmaceutical benefit.

Section 20 Maximum number of repeats - Schedule 1

This section determines, for paragraph 85A(2)(b) of the Act, with respect to the pharmaceutical benefits and authorised prescribers in Schedule 1, the maximum number of repeats that the authorised prescribers may direct in one prescription.

Subsections 20(2) and (3), like subsections 17(2) and (3), provide that the maximum may be the maximum:

- for all purposes;
- for particular purposes; or
- for all purposes other than particular purposes.

Where particular purposes apply, these are represented by one or more purposes codes (the letter 'P' followed by a number), and the purposes relating to each purposes code are set out in Part 1 of Schedule 4.

Section 21 Maximum number of repeats conditions - Schedule 1

This section determines, for subsection 85A(2A) of the Act, the conditions, if any, which must be satisfied when writing a prescription for the supply of a pharmaceutical benefit to which a determination of a maximum number of repeats under paragraph 85A(2)(b) applies; the determinations of maximum numbers of repeats are made in section 20 of this instrument.

Where a conditions code (the letter 'CN' followed by a number) is mentioned in the Column headed 'Number of Repeats' in Schedule 1 for a number of repeats for a pharmaceutical benefit, the conditions which must be satisfied when writing a prescription for the supply of the pharmaceutical benefit to which the maximum number of repeats applies, are the conditions set out in Part 1 of Schedule 4 for the conditions code.

Section 22 Maximum number of repeats - Schedule 2

This section determines, for paragraph 85A(2)(b) of the Act, the maximum number of repeats of extemporaneously-prepared pharmaceutical benefits that may in one prescription be directed to be supplied. The maximum is specified for the type of extemporaneously-prepared pharmaceutical benefit.

Section 23 Determined Quantity

This section determines, for subsection 84AK(3) of the Act, the determined quantity, if any, for a listed brand of a pharmaceutical item.

Section 24 Pack Quantity

This section determines, for subsection 84AK(2) of the Act, the pack quantity or quantities for a listed brand of a pharmaceutical item.

Section 25 Section 100 only supply

This section determines matters relating to section 100 only supply.

All pharmaceutical benefits are supplied under Part VII of the Act. The pharmaceutical benefits supplied under Part VII may be:

- pharmaceutical benefits available for general supply only;
- pharmaceutical benefits available, or available in specified circumstances, only under special arrangements made under section 100 (i.e. section 100 only supply);
- pharmaceutical benefits available both for general supply and for supply under special arrangements made under section 100 (i.e. dual supply pharmaceutical benefits);
- pharmaceutical benefits available only under the prescriber bag provisions of the Act, namely sections 93, 93AA and 93AB (i.e. prescriber bag only supply).

The fourth category of pharmaceutical benefits is provided for in section 26 of this instrument.

This section relates to the second category of pharmaceutical benefits, i.e. pharmaceutical benefits available, or available in specified circumstances, only under special arrangements made under section 100. The section 100 only supply may relate to:

- section 100 only drugs;
- section 100 only pharmaceutical benefits; or
- section 100 only circumstances for prescribing a pharmaceutical benefit.

Subsection 25(1) declares, for subsection 85(2A) of the Act, the listed drugs that can only be supplied under special arrangements under section 100 of the Act. They are identified by the code D(100) in the column headed 'Section 100/Prescriber Bag only' in Schedule 1.

Subsection 25(2) determines, for paragraph 85(8)(a) of the Act, the pharmaceutical benefits that can only be supplied under special arrangements under section 100 of the Act. They are identified by the code PB(100) in the column headed 'Section 100/Prescriber Bag only' in Schedule 1.

Subsection 25(3) determines, for paragraph 85(8)(b) of the Act, the circumstances in which particular pharmaceutical benefits can only be supplied under special arrangements under section 100 of the Act. They are identified by the code C(100) in the column headed 'Section 100/Prescriber Bag only' in Schedule 1.

Section 85AA of the Act provides for the consequences of a declaration under subsection 85(2A) and determinations under paragraphs 85(8)(a) and (b):

- If a declaration is made under subsection 85(2A) of the Act in relation to a listed drug, then every pharmaceutical benefit that has that drug can only be supplied under Part VII in accordance with special arrangements under section 100: subsection 85AA(1) of the Act;
- If a determination is made under paragraph 85(8)(a) of the Act in relation to a pharmaceutical benefit, then that pharmaceutical benefit can only be supplied under Part VII in accordance with special arrangements under section 100: subsection 85AA(2) of the Act; and
- If a determination is made under paragraph 85(8)(b) of the Act about the circumstances in which a pharmaceutical benefit can only be supplied under special arrangements under section 100, then, in those circumstances, that pharmaceutical benefit can only be supplied under Part VII in accordance with special arrangements under section 100: subsection 85AA(3) of the Act.

Section 26 Prescriber bag only supply

This section determines matters relating to prescriber bag only supply. The prescriber bag only supply may relate to:

- prescriber bag only drugs; or
- prescriber bag only pharmaceutical benefits.

Subsection 26(1) declares, for subsection 85(2AA) of the Act, the listed drugs that can only be supplied under the prescriber bag provisions of the Act and which supplier bag provisions of the Act they may be supplied under. The drugs are identified by one or more of the codes D(MP), D(MW) or D(NP) in the column headed 'Section 100/Prescriber Bag only' in Schedule 1.

The *Note* under subsection 26(1) relates to an existing medical practitioner prescriber bag only drug, methoxyflurane. Prior to 1 October 2012, this drug was declared as a Section 100 only drug. A special arrangement under Section 100 provided for its direct supply only by medical practitioners. Methoxyflurane is covered by transitional provisions in the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*. Subitem 18(1) of Schedule 3 to that Act provides that, on and from 1 October 2012, the legislative instrument declaring methoxyflurane to be a Section 100 drug which was in force immediately before 1 October 2012 continues in force (and may be dealt with) as if it had been made under subsection 85(2AA) of the Act and declared that methoxyflurane can only be supplied under section 93 of the Act. No declaration of methoxyflurane has been made under subsection 85(2AA) of the Act in this Instrument because the transitional provisions have that effect. However, the code D(MP) has been included for the drug in Schedule 1.

Subsection 26(2) determines, for subsection 85(7A) of the Act, the pharmaceutical benefits that can only be supplied under the prescriber bag provisions of the Act and which supplier bag provisions of the Act they may be supplied under. The pharmaceutical benefits are identified by one or more of the codes PB(MP), PB(MW) or PB(NP) in the column headed 'Section 100/Prescriber Bag only' in Schedule 1.

The codes D(MP) and PB(MP) mean supply by medical practitioners under section 93 of the Act. The codes D(MW) and PB(MW) mean supply by authorised midwives under section 93AA of the Act. The codes D(NP) and PB(NP) mean supply by authorised nurse practitioners under section 93AB of the Act.

Section 85AA of the Act provides for the consequences of declarations under subsection 85(2AA) and determinations under subsection 85(7A):

- If a declaration is made under subsection 85(2AA) of the Act in relation to a listed drug, then every pharmaceutical benefit that has that drug can only be supplied under Part VII under the prescriber bag provision or provisions mentioned;
- If a determination is made under subsection 85(7A) of the Act in relation to a pharmaceutical benefit, then that pharmaceutical benefit can only be supplied under Part VII under the prescriber bag provision or provisions mentioned.
- However, if
  (a) a declaration is made under subsection 85(2AA) of the Act in relation to a listed drug; and
  (b) a determination is made under subsection 85(7A) of the Act in relation to a pharmaceutical benefit that has that drug;

  then the pharmaceutical benefit may only be supplied under Part VII under the prescriber bag provision or provisions in the subsection 85(2AA) determination and the prescriber bag provision or provisions in the subsection 85(7A) determination.

Schedule 1 Ready-prepared pharmaceutical benefits

This Schedule sets out all matters (other than matters concerning prices) relevant to the listing of ready-prepared pharmaceutical benefits on the PBS. The matters dealt with in the various columns of the Schedule, and the corresponding provisions of the Act and sections of this Instrument are set out below.

Column in Schedule 1	**Provision of the Act**	**Section of this Instrument**
Listed Drug	Subsection 85(2)	Section 5
Form	Subsection 85(3)	Section 6
Manner of Administration	Subsection 85(5)	Section 7
Brand	Subsection 85(6)	Section 8
Responsible Person	Subsection 84AF(1)	Section 8
Authorised Prescriber	Subsections 88(1A), (1C), (1D) and (1E)	Section 9
Circumstances	Paragraphs 85(7)(a) and (b)	Sections 10 - 15
Purposes	Paragraphs 85A(2)(a) and (b)	Sections 17 and 20
Maximum Quantity	Paragraph 85A(2)(a) Subsection 85A(2A)	Sections 17 and 19 Section 18
Number of Repeats	Paragraph 85A(2)(b) Subsection 85A(2A)	Sections 20 and 22 Section 21
Determined Quantity	Subsection 84AK(3)	Section 23
Pack Quantity	Subsection 84AK(2)	Section 24
Section 100 only	Subsection 85(2A), Paragraphs 85(8)(a) and (b)	Section 25
Prescriber bag supply only	Subsection 85(2AA), Paragraphs 85(7A)	Section 26

Notes to Schedule 1

There are four Notes included in Schedule 1. Notes 1 to 3 relate to the supply of certain pharmaceutical benefits under special arrangements under section 100 of the Act and note 4 relates to the supply of certain pharmaceutical benefits only under the prescriber bag provisions of the Act.

As set out in relation to section 25 of this Instrument, the pharmaceutical benefits available under special arrangements under section 100 may be:

- pharmaceutical benefits available, or available in specified circumstances, only under special arrangements made under section 100 (i.e. section 100 only); or

- pharmaceutical benefits available both for general supply and for supply under special arrangements made under section 100 (i.e. dual supply).

Subsection 100(3) of the Act enables a section 100 arrangement instrument to modify, for the purposes of the arrangement, the operation of Part VII of the Act, and regulations and other instruments made for the purposes of Part VII.

Note 1 appears only in the Authorised Prescriber column and it may appear for either a dual supply pharmaceutical benefit or a section 100 only benefit. Subsection 88(1) of the Act authorises medical practitioners to prescribe all pharmaceutical benefits. In recognition of this, the code 'MP' is included in the Authorised Prescriber column along with the codes for any other prescribers who have been authorised to prescribe the pharmaceutical benefits under section 88. *Note 1* alerts readers to the fact that the Authorised Prescribers may be modified in a section 100 arrangement instrument. The modified prescribing arrangements will only apply for supply under the specific section 100 arrangement. For instance, the section 100 arrangement instrument may modifying the authorised prescribers by providing that only a subset of medical practitioners (such as particular specialists) may prescribe certain pharmaceutical benefits under the arrangement. Alternatively, the arrangement instrument may provide for supply of the pharmaceutical benefit otherwise than on a prescription; in such a case there will be no authorised prescribers, but the persons who may supply the pharmaceutical benefits may be determined in the section 100 arrangement instrument.

Note 2 relates to dual supply pharmaceutical benefits, i.e. pharmaceutical benefits available both for general supply and for supply under special arrangements made under section 100. The matters relevant to their availability for general supply have been set out in Schedule 1. However, some of these matters may be modified in a special arrangement instrument, as provided for in subsection 100(3) of the Act. *Note 2* alerts readers to the fact that modified matters may be provided for in relation to supply under a section 100 arrangement and that these can be found in the special arrangement instrument or instruments.

Note 3 relates to certain section 100 only pharmaceutical benefits. Where possible all the matters relevant to section 100 only pharmaceutical benefits have been included in Schedule 1. However, some matters have not been determined in this Instrument and may be determined in a section 100 arrangement instrument. For instance, the maximum quantity that may be prescribed may not be a simple number, but may be a complex formula depending on a number of factors, and may be too lengthy to be included in Schedule 1. Also, a section 100 arrangement may modify the prescriber arrangements, so that although there may be limitations on the quantities that can be supplied under the section 100 arrangement, they are not maximum quantities for prescribing for paragraph 85A(2)(a) of the Act and so cannot be included in the Maximum Quantity column in Schedule 1. These maximum amounts for supply are specified in the section 100 arrangement instrument.

Note 4 relates to prescriber bag only pharmaceutical benefits. The pharmaceutical benefit may be supplied only under the particular prescriber bag provisions of the Act referred to in the column headed 'Section 100/Prescriber Bag only', i.e. it is only able to be supplied directly to patients. As it is not able to be *prescribed* as a pharmaceutical benefit, there are no authorised prescribers, or other matters concerning prescriptions (i.e. no prescription circumstances, number of repeats, or conditions relating to prescribing.

Schedule 2 Extemporaneously-prepared pharmaceutical benefits

This Schedule sets out all matters (other than matters concerning prices) relevant to the listing of extemporaneously-prepared pharmaceutical benefits on the PBS. It is divided into three Parts. The matters dealt with in each Part, and the corresponding provisions of the Act and sections of this Instrument are set out below.

Schedule Part	**Column**	**Provision of the Act**	**Section of this Instrument**
Part 1	Listed drug	Paragraph 85(2)(a) Subparagraph 85(2)(b)(i)	Subparagraph 5(1)(a)(ii) Paragraph 5(1)(b) Subsection 5(2)
	Circumstances	Paragraphs 85(7)(a) and (b)	Section 16
Part 2	Additives	Subparagraph 85(2)(b)(ii)	Subsection 5(3)
Part 3	Maximum Quantity	Paragraph 85A(2)(a)	Section 19
	Number of Repeats	Paragraph 85A(2)(b)	Section 22

Schedule 3 Responsible person codes

This Schedule relates to subsection 8(3) of the Instrument. The responsible person for each brand of a pharmaceutical item in Schedule 1 was determined in subsection 8(2) of this Instrument. The person is identified in the column headed 'Responsible Person' in Schedule 1 by a two letter code. Schedule 3 sets out the name of the responsible person and their ABN, if any, for each code.

Schedule 4 Circumstances, purposes and conditions codes

Part 1 Circumstances, purposes and conditions

Part 1 of Schedule 4 relates to sections 10, 17, 18, 20 and 21 of this Instrument.

The prescription circumstances determined in section 10 are identified in the column headed 'Circumstances' in Schedule 1 by circumstances codes. These codes and the circumstances that are represented by the codes are set out in Part 1 of Schedule 4.

The maximum quantities and number of repeats are determined in sections 17 and 20, respectively, of this Instrument and are set out in the respective columns in Schedule 1. Where these maximums have been determined for particular purposes, there are purposes codes in the column headed 'Purposes' in Schedule 1. These codes and the purposes that are represented by the codes are set out in Part 1 of Schedule 4.

The maximum quantities conditions and number of repeats conditions are determined in sections 18 and 21, respectively, of this Instrument and are identified in the respective columns in Schedule 1 by conditions codes. These codes and the conditions that are represented by the codes are set out in Part 1 of Schedule 4.

Part 2 General statement for lipid-lowering drugs

Some of the circumstances mentioned in Part 1 of Schedule 4 refer to matters in the *General Statement for Lipid-Lowering Drugs*. This Statement is set out in Part 2 of Schedule 4.

ATTACHMENT 2

SUMMARY OF CHANGES

Listed Drug Added

Carbomer with Triglyceride Lipids
Human menopausal gonadotrophin
Pazopanib

Forms Added

Bortezomib	Powder for injection 1 mg
Phenobarbitone	Injection 200 mg (as sodium) in 1 mL

Forms Deleted

Amino acids—synthetic, formula	Oral powder 400 g (Neocate Advance Tropical Flavour)
Glucose Indicator—Blood	Test strips, 50 (AgaMatrix Jazz)
Nebivolol	Tablet 1.25 mg (as hydrochloride), 28
Phenobarbitone	Injection containing phenobarbitone sodium 200 mg in 1 mL
Risedronic acid and calcium with colecalciferol	Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g with colecalciferol 22 micrograms
Verapamil	Injection containing verapamil hydrochloride 5 mg in 2 mL

Brands Added

Amoxycillin	Capsule 250 mg (as trihydrate) (Yomax 250) Capsule 500 mg (as trihydrate) (Yomax 500)
Anastrozole	Tablet 1 mg (Pharmacor Anastrozole 1)
Ceftriaxone	Powder for injection 1 g (as sodium) (Ceftriaxone Alphapharm) Powder for injection 2 g (as sodium) (Ceftriaxone Alphapharm)
Clopidogrel	Tablet 75 mg (as hydrogen sulfate) (APO-Clopidogrel)
Diltiazem	Tablet containing diltiazem hydrochloride 60 mg (Diltiazem-PS)
Famciclovir	Tablet 500 mg (Famciclovir Sandoz)
Frusemide	Tablet 20 mg (APO-Frusemide) Tablet 40 mg (APO-Frusemide)
Isotretinoin	Capsule 20 mg (Isotretinoin-PS)
Letrozole	Tablet 2.5 mg (Pharmacor Letrozole 2.5)
Levetiracetam	Tablet 250 mg (Levetiracetam Pfizer) Tablet 500 mg (Levetiracetam Pfizer) Tablet 1 g (Levetiracetam Pfizer)
Lisinopril	Tablet 5 mg (Zinopril 5) Tablet 10 mg (Zinopril 10) Tablet 20 g (Zinopril 20)
Magnesium	Tablet 37.4 mg (as aspartate dihydrate) (MagMin (PBS))

Mirtazapine	Tablet 15 mg (Mirtazapine Pfizer) Tablet 30 mg (Mirtazapine Pfizer) Tablet 45 mg (Mirtazapine Pfizer) Tablet 15 mg (orally disintegrating) (Mirtazapine Dispersible Pfizer) Tablet 30 mg (orally disintegrating) (Mirtazapine Dispersible Pfizer) Tablet 45 mg (orally disintegrating) (Mirtazapine Dispersible Pfizer)
Mycophenolic Acid	Capsule containing mycophenolate mofetil 250 mg (Cellplant) Tablet containing mycophenolate mofetil 500 mg (Cellplant)
Olanzapine	Tablet 5 mg (orally disintegrating) (STADA Olanzapine ODT) Tablet 10 mg (orally disintegrating) (STADA Olanzapine ODT)
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate) (I-Pantoprazole) Tablet (enteric coated) 40 mg (as sodium sesquihydrate) (I-Pantoprazole)
Paroxetine	Tablet 20 mg (as hydrochloride) (Paroxetine-PS)
Perindopril with Indapamide	Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg (Indosyl Combi 4/1.25)
Pioglitazone	Tablet 15 mg (as hydrochloride) (Pioglitazone Pfizer) Tablet 30 mg (as hydrochloride) (Pioglitazone Pfizer) Tablet 45 mg (as hydrochloride) (Pioglitazone Pfizer)
Quetiapine	Tablet 25 mg (as fumarate) Tablet 100 mg (as fumarate) Tablet 200 mg (as fumarate) Tablet 300 mg (as fumarate)
Risedronic Acid	Tablet containing risedronate sodium 150 mg (APO-Risedronate; Chem mart Risedronate; Terry White Chemists Risedronate)
Risedronic Acid and Calcium	Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate) (Risedronate Winthrop EC Combi)
Risedronic acid and calcium with colecalciferol	Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g with colecalciferol 22 micrograms (Risedronate Winthrop EC Combi D)

Brands Deleted

Bicalutamide	Tablet 50 mg (Bicalutamide Ranbaxy)
Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL (Ozcef) Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL (Ozcef)
Etoposide	Solution for I.V. infusion 100 mg in 5 mL vial (Hospira Pty Limited)
Famotidine	Tablet 40 mg (Pepcidine)
Gemcitabine	Powder for I.V. infusion 200 mg (as hydrochloride) (Gemcite) Powder for I.V. infusion 1 g (as hydrochloride) (Gemcite)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL (Camptosar)
Lisinopril	Tablet 5 mg (Lisinopril Ranbaxy) Tablet 10 mg (Lisinopril Ranbaxy) Tablet 20 mg (Lisinopril Ranbaxy)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate) (Zondan) Tablet 8 mg (as hydrochloride dihydrate) (Zondan)
Oxaliplatin	Powder for I.V. infusion 50 mg (Oxalatin; Oxaliplatin Link) Powder for I.V. infusion 100 mg (Oxalatin; Oxaliplatin Link)
Perindopril with Indapamide	Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg (Indopril Combi 4/1.25)

Alteration of Form Description

Listed Drug	Form
Bisacodyl	*From:* Tablets 5 mg, 200 *To:* Tablet 5 mg

Alteration of Responsible Person

Listed Drug	Form	Brand	Responsible Person
Zidovudine	Capsule 100 mg	Retrovir	*From:* GlaxoSmithKline Australia Pty Ltd (GK) *To:* ViiV Healthcare Pty Ltd (VI)
	Capsule 250 mg	Retrovir	*From:* GlaxoSmithKline Australia Pty Ltd (GK) *To:* ViiV Healthcare Pty Ltd (VI)
	Syrup 10 mg per mL, 200 mL	Retrovir	*From:* GlaxoSmithKline Australia Pty Ltd (GK) *To:* ViiV Healthcare Pty Ltd (VI)

Alteration of Maximum Quantity and Number of Repeats

Folinic acid	Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL *Max qty: From:* 5 *to:* 10*; No. of rpts: From:* 5 *to:* 2
Metronidazole	I.V. infusion 500 mg in 100 mL *Max qty: From:* 5 *to:* 10*; No. of rpts: From:* 1 *to:* 0

Addition of Responsible Person Code

BB [Blackmores Limited]

Deletion of Responsible Person Code

HE [HealthSense Products Pty. Ltd.]

Alteration of Circumstances

Listed Drug	Alteration
Bortezomib	Circumstances amended to extend availability for the treatment of patients with newly diagnosed multiple myeloma *[powder for injection 1 mg]*
Sunitinib	Circumstances amended relating to the treatment of renal cell carcinoma

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Listing of Pharmaceutical Benefits) Instrument 2012

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* revokes and replaces the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010.* This instrument determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, maximum quantities, numbers of repeats, and whether the pharmaceutical benefit is to be available only under special arrangements).

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

Tanya Plibersek
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