

# EXPLANATORY STATEMENT

## *National Health Act 1953*

### *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*

#### *PB 26 of 2024*

#### **Purpose and operation**

The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing 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).

#### **Background**

The PBS is a central feature of Medicare, Australia's universal health care system which helps Australians with the cost of their health care. Part VII of the *National Health Act 1953* (Act) is the legislative basis of the PBS by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians. The 2024 Listing Instrument is a component of the PBS.

Commencing 1 April 2024, the 2024 Listing Instrument sets out the pharmaceutical benefits that may be supplied to patients at Government-subsidised prices under the PBS. The drugs or medicinal preparations and, where relevant, forms, manners of administration and brands making up pharmaceutical benefits are declared or determined under subsections 85(2), (3), (5) and (6) of the Act, respectively.

The 2024 Listing Instrument replaces the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (2012 Listing Instrument), which sunsets on 1 April 2024.

#### **Authority**

The 2024 Listing Instrument is made under the following sections of the *National Health Act 1953* (the Act):

- 84AF (determination of the responsible person for a brand of pharmaceutical item);
- 84AK (determination of pricing quantities, pack quantities and determined quantities of listed brands of pharmaceutical items);
- 85 (various declarations and determinations relating to listing of pharmaceutical benefits on the PBS including the drugs, forms of drugs, manners of administration and brands of pharmaceutical benefits, restrictions on how pharmaceutical benefits may be supplied under the PBS and circumstances in which a prescription for a pharmaceutical benefit can be written);
- 85A (determination of maximum quantities of pharmaceutical items and maximum repeats that may be directed in a prescription by classes of persons);

- 88 (determination of the pharmaceutical benefits that different classes of PBS prescribers are authorised to prescribe).

## **Consultation**

The Department has consulted extensively internally and with Services Australia and the Department of Veterans' Affairs.

Some practical implementation issues regarding the submission of prescription details versus the prescription itself have been raised by Services Australia where submissions are made via the post rather than electronically. The Department has built in additional time for the changes to be implemented to allow for the required system changes to occur following the remake of the PBS Listing Instrument to address this issue and reduce any negative impacts caused by the change to the process for some parties.

## **General**

The 2024 Listing Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

The 2024 Listing Instrument commences on 1 April 2024.

Details of the 2024 Listing Instrument are set out in **Attachment A**. Part 1 of Attachment A outlines the general operation of the 2024 Listing Instrument. Part 2 of Attachment A details changes to medicine listings, such as the addition and deletion of listed drugs, forms of listed drugs, and brands of pharmaceutical benefits, the alteration of a maximum quantity for a pharmaceutical benefit, the alteration of responsible person codes for brands of pharmaceutical benefits, the addition of a pack quantity for a pharmaceutical benefit, the addition and deletion of responsible persons from the list of responsible persons and the alteration of circumstances in which a prescription may be written for a number of listed drugs.

The 2024 Listing Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

**Details of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024***

**Part 1—Preliminary**

**Section 1 – Name**

Section 1 provides that the name of the instrument is the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument). The instrument may also be cited as PB 26 of 2024.

**Section 2 – Commencement**

Section 2 provides that the 2024 Listing Instrument commences on 1 April 2024.

**Section 3 – Authority**

Section 3 provides that the 2024 Listing Instrument is made under sections 84AF, 84AK, 85, 85A and 88 of the *National Health Act 1953*.

**Section 4 – Simplified outline**

Section 4 contains a simplified outline of the 2024 Listing Instrument to assist readers.

**Section 5 – Definitions**

Section 5 sets out the definitions for the 2024 Listing Instrument.

*Terms with the same meaning as in the Act, Part VII of the Act or the Health Insurance Act*

The following terms used in the 2024 Listing Instrument have the same meaning as in Part VII of the Act:

- authorised midwife;
- authorised nurse practitioner;
- authorised optometrist;
- brand, of a pharmaceutical item;
- listed drug;
- participating dental practitioner;
- pharmaceutical benefit;
- pharmaceutical item.

A note to section 5 provides that a number of expressions used in the instrument, including “Chief Executive Medicare” and “hospital”, are defined in the Act. These two terms are defined in subsection 4(1) of the Act.

A second note to section 5 provides that under subsection 4(1A) of the Act, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning that it would have if used in that Act. This includes terms such as “medical practitioner” and “Medicare benefit” (both defined in subsection 3(1) of the *Health Insurance Act 1973*).

#### *Codes used in the 2024 Listing Instrument*

The Schedules to the 2024 Listing Instrument use a number of codes to indicate where a medicine is subject to certain rules around prescribing the medicine for the purposes of the PBS, relevantly defined as:

- circumstances code - meaning the letter “C” followed by a number;
- conditions code - meaning the letters “CN” followed by a number;
- purposes code - meaning the letter “P” followed by a number;
- streamlined authority code – meaning the words “Streamlined Authority Code” followed by a number;
- variation code - meaning the letter “V” followed by a number. This is a new definition inserted as a result of new subsections 15(5), 16(5) and new Part 2 of Schedule 4 (discussed later in this explanatory statement).

#### *Terms “ready-prepared pharmaceutical benefit” and “extemporaneously-prepared pharmaceutical benefit”*

The term “ready-prepared pharmaceutical benefit” means a pharmaceutical benefit that is mentioned in a table in Schedule 1 to the 2024 Listing Instrument. Ready-prepared pharmaceutical benefits are listed on the PBS with reference to the drug, the form of that drug, the manner of administration of the form of that drug, and the brand of that drug in that form with that manner of administration (see sections 6 to 9).

The term “extemporaneously-prepared pharmaceutical benefit” means a pharmaceutical benefit that either is a listed drug mentioned in column 1 of the table in Part 1 of Schedule 2 to the instrument, or contains such a listed drug. Extemporaneously-prepared pharmaceutical benefits are listed on the PBS with reference to the drug only (see section 6).

#### *Other select terms*

The term “authorised prescriber”, of a pharmaceutical benefit, means a PBS prescriber who is authorised under section 12 of the 2024 Listing Instrument to write a prescription for the supply of the benefit.

The term “General statement for drugs for the treatment of hepatitis C” means the statement set out in Schedule 6 to this instrument.

The term “GP Management Plan” means a comprehensive written plan for the treatment of a patient:

- that is prepared by a medical practitioner; and
- for the preparation of which a Medicare benefit is payable; and
- that includes a description of the patient’s health care needs, management goals, actions to be taken by the patient, and treatment and services the patient is likely to need.

The term “Medicare Benefits Schedule” means:

- the “table”, within the meaning of subsection 3(1) of the *Health Insurance Act 1973*; or
- any determination made under subsection 3C(1) of that Act.

The table is currently made up of the *Health Insurance (General Medical Services Table) Regulations 2021*, *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020* and the *Health Insurance (Pathology Services Table) Regulations 2020* and contains the majority of Medicare Benefits Schedule (MBS) items. Determinations made under subsection 3C(1) of the *Health Insurance Act 1973* create MBS items that are not already included in the table.

The term “palliative care patient” means a patient with an active, progressive, far advanced disease for whom the prognosis is limited and the focus of care is the quality of life.

The term “Team Care Arrangements” means arrangements that:

- are coordinated by a medical practitioner; and
- the coordination of which a Medicare benefit is payable for; and
- following consultation with collaborating providers, are documented in a plan that includes a description of the treatment and service goals for the patient, the treatment and services that all collaborating providers will provide, and the actions to be taken by the patient.

The definitions in section 5 of the 2024 Listing Instrument are substantially the same as the definitions in section 4 of the 2012 Listing Instrument. Most of the definitions added refer the reader to defined terms in Part VII of the Act. The drafting of some of the definitions has been improved and certain definitions removed where these are no longer required.

Commonwealth Acts referenced in section 5 are incorporated as in force from time to time.

## **Part 2—Pharmaceutical benefits**

Part 2, in conjunction with Schedules 1 and 2 to this instrument, sets out the pharmaceutical benefits that are on the PBS and does this through declarations of drugs and medicinal preparations and, for ready-prepared pharmaceutical benefits, determinations of form, manners of administration and brands. It also determines the responsible person for a listed brand of pharmaceutical benefit and schedule equivalent brands of pharmaceutical item.

## **Section 6 – Drugs and medicinal preparations to which Part VII of the Act applies (Act s 85(2))**

Paragraph 85(2)(a) of the Act empowers the Minister to declare the drugs and medicinal preparations in relation to which Part VII of the Act applies. This includes the power to declare a class of drugs or medicinal preparations to which Part VII of the Act applies.

The Minister may not declare, under paragraph 85(2)(a) of the Act, 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 (see subsection 101(4) of the Act). The new drugs and medicinal preparations which have been added to the PBS by the 2024 Listing Instrument have been the subject of such recommendations by the PBAC to the Minister. These new drugs and medicinal preparations are listed in Part 2 of Attachment A.

#### Declaration of drugs and medicinal preparations for ready-prepared pharmaceutical benefits

Subsection 6(1) of the 2024 Listing Instrument declares drugs and medicinal preparations for the purposes of ready-prepared pharmaceutical benefits.

Subsection 6(1) of the 2024 Listing Instrument provides that Part VII of the Act applies to a drug or medicinal preparation mentioned in the column of a table in Schedule 1 to this instrument headed “Listed Drug”.

For these drugs and medicinal preparations, there are then determinations made by the Minister in sections 7, 8, and 9 of the instrument concerning the form of that drug, the manner of administration of that drug in that form, and the brand of that drug in that form with that manner of administration.

#### Declaration of drugs and medicinal preparations for extemporaneously-prepared pharmaceutical benefits

Subsections 6(2) and 6(3) of the 2024 Listing Instrument declare drugs and medicinal preparations for the purposes of extemporaneously-prepared pharmaceutical benefits. There are no determinations of form, manner of administration or brand in relation to these listed drugs and medicinal preparations.

Paragraphs 6(2)(a) and 6(2)(b) of the 2024 Listing Instrument are made for the purposes of paragraph 85(2)(a) of the Act. Paragraph 6(2)(a) provides that Part VII of the Act applies to a drug or medicinal preparation mentioned in column 1 of the table in Part 1 of Schedule 2 to the 2024 Listing Instrument. Paragraph 6(2)(b) provides that Part VII of the Act applies to a medicinal preparation composed of one or more drugs or medicinal preparations mentioned in column 1 of the table in Part 1 of Schedule 2.

Subsection 6(3) of the 2024 Listing Instrument is made for the purposes of paragraph 85(2)(b) of the Act. Paragraph 85(2)(b) empowers the Minister to declare that Part VII of the Act applies to medicinal preparations composed of one or more of the drugs and medicinal preparations declared under paragraph 85(2)(a) and one or more additives declared by the Minister.

Subsection 6(3) provides that Part VII of the Act applies to:

- the class of drugs and medicinal preparations consisting of each drug and medicinal preparation mentioned in column 1 of the table in Part 1 of Schedule 2 to the 2024 Listing Instrument (see paragraph 6(3)(a)); and
- additives mentioned in the table in Part 2 of Schedule 2 to the 2024 Listing Instrument (see paragraph 6(3)(b)).

A note to subsection 6(3) states that Part VII of the Act applies to medicinal preparations composed of one or more of the drugs and medicinal preparations included in the class

mentioned in paragraph 6(3)(a) of the instrument and one or more additives mentioned in paragraph 6(3)(b) of the instrument.

Section 6 corresponds to section 5 of the 2012 Listing Instrument.

### **Section 7 – Form or forms of a listed drug (Act s 85(3))**

Section 7 determines, for the purposes of subsection 85(3) of the Act, the form or forms of each listed drug in Schedule 1 to the 2024 Listing Instrument. The form is set out in the column of the table in Schedule 1 headed “Form”.

Section 7 corresponds to section 6 of the 2012 Listing Instrument.

### **Section 8 – Manner of administration of a form of a listed drug (Act s 85(5))**

Section 8 determines, for the purposes of subsection 85(5) of the Act, the manner of administration of the forms of the listed drugs in Schedule 1. The manner of administration is set out in the column of the table in Schedule 1 headed “Manner of Administration”.

Section 8 corresponds to section 7 of the 2012 Listing Instrument.

### **Section 9 – Brand of a pharmaceutical item (Act s 85(6))**

Section 9 determines, for the purposes of subsection 85(6) of the Act, the brands of the pharmaceutical items in Schedule 1 to this instrument.

Where the Minister has declared or determined a drug or medicinal preparation, a form of that drug and a manner of administration of that form of the drug, then the drug in that form with that manner of administration is a pharmaceutical item (see section 84AB of the Act). The “brand” of a pharmaceutical item is defined by section 84 of the Act to mean:

- the trade name under which the person who is or will be the responsible person supplies the pharmaceutical item; or
- if there is no trade name—the name of the person who is or will be the responsible person.

The brand of a pharmaceutical item is set out in the column of the table in Schedule 1 headed “Brand”.

Section 9 corresponds to subsection 8(1) of the 2012 Listing Instrument.

### **Section 10 – Responsible person for a brand of a pharmaceutical item (Act s 84AF(1))**

Subsection 84AF(1) of the Act provides that the Minister may, by legislative instrument, determine the responsible person for a brand of a pharmaceutical item. The responsible person is the person who has notified the Minister that they are, 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 a particular brand.

The Act imposes obligations on the responsible person in relation to matters such as compliance with any applicable obligations under price disclosure (see Division 3B of the Act), guarantee of supply (see Division 3C of the Act) and minimum stockholding requirements (see Division 3CAA of the Act). It is also the responsible person with whom price negotiations occur.

Section 10 of the 2024 Listing Instrument provides that, for the purposes of subsection 84AF(1) of the Act, the responsible person for a brand of a pharmaceutical item mentioned in Schedule 1 is the person represented by the code mentioned in relation to the brand in the column of the table in Schedule 1 headed “Responsible Person”. Schedule 3 of the 2024 Listing Instrument identifies the person represented by a code.

Section 10 corresponds to subsections 8(2), 8(3) and 8(4) of the 2012 Listing Instrument.

### **Section 11 – Schedule equivalents of brands of pharmaceutical items (Act s 85(6A))**

Under subsection 85(6A) of the Act, if the Minister determines a brand of a pharmaceutical item under subsection 85(6) of the Act the Minister may, by legislative instrument, determine that, for the purposes of paragraph 103(2A)(b) of the Act, the brand is to be treated as equivalent to one or more other brands of pharmaceutical items. Subsection 103(2A) of the Act is an exception to the offence provision in subsection 103(2) of the Act.

Paragraph 103(2)(a) of the Act makes it an offence for a pharmacist to supply anything other than the pharmaceutical benefit that is directed to be supplied in a prescription presented to the pharmacist.

Section 11 of the 2024 Listing Instrument provides that, for the purposes of subsection 85(6A) of the Act, a brand of a pharmaceutical item included in a schedule equivalent group in the table in Schedule 5 is, for the purposes of paragraph 103(2A)(b) of the Act, to be treated as equivalent to every other brand of a pharmaceutical item that is included in that same schedule equivalent group.

This means that where a prescription directs the supply of a pharmaceutical benefit (the prescribed benefit) that is mentioned in a schedule equivalent group in Schedule 5, a pharmacist may supply any of the other pharmaceutical benefits in the group without committing an offence under paragraph 103(2)(a) provided that:

- the prescriber had not indicated in the prescription that only the prescribed pharmaceutical benefit may be supplied;
- the Schedule of Pharmaceutical Benefits states that the prescribed pharmaceutical benefit and the other pharmaceutical benefit are equivalent;
- the other pharmaceutical benefit is a listed brand of pharmaceutical item;
- supplying the other pharmaceutical benefit would not contravene an applicable State or Territory law.

The determination of schedule equivalence supports brand substitution at the point of supply without the need for a new prescription, for example where the prescribed pharmaceutical benefit is out of stock or to promote the use of generic alternatives.



Section 11 of this instrument corresponds to section 8A of the 2012 Listing Instrument. The 2012 Listing Instrument used three mechanisms to identify pharmaceutical benefits determined to be treated as equivalent under subsection 85(6A) – the inclusion of the letters ‘a’ or ‘b’ against brands of a pharmaceutical item to be treated as equivalent (known as “a-flagging” and “b-flagging”) and also the specification of schedule equivalent groups in Schedule 5 of the 2012 Listing Instrument.

The 2024 Listing Instrument no longer uses a-flagging and Schedule 5 is the sole location for details of the schedule equivalent groups.

### **Part 3—Prescription of pharmaceutical benefits**

#### **Division 1—Authorised prescribers and prescription circumstances**

##### **Section 12 – Authorised prescribers (Act s 88)**

Section 88 of the Act enables the Minister to determine the pharmaceutical benefits that, subject to Part VII of the Act, are authorised to be prescribed by medical practitioners, participating dental practitioners, authorised optometrists, authorised midwives and authorised nurse practitioners.

In accordance with subsection 12(1) of the 2024 Listing Instrument, the column of the table in Part 1 of Schedule 1 headed “Authorised Prescriber” identifies the classes of prescribers who can write a prescription for the supply of the benefit as follows:

- if the initials “MP” are mentioned – medical practitioners;
- if the initials “PDP” are mentioned - participating dental practitioners;
- if the initials “AO” are mentioned - authorised optometrists;
- if the initials “MW” are mentioned - authorised midwives;
- if the initials “NP” are mentioned - authorised nurse practitioners.

Subsection 12(2) of the 2024 Listing Instrument provides that a medical practitioner is authorised to write a prescription for the supply of an extemporaneously-prepared pharmaceutical benefit (i.e. a pharmaceutical benefit that is a listed drug mentioned in Schedule 2 or that contains such a drug).

Section 12 corresponds to sections 9 and 9A of the 2012 Listing Instrument.

##### **Section 13 – Prescription of ready-prepared pharmaceutical benefits in certain circumstances (Act s 85(7))**

Under subsection 85(7) of the Act the Minister may, by legislative instrument, determine that a particular pharmaceutical benefit is to be a relevant pharmaceutical benefit for the purposes of section 88A of the Act and the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written.

Section 88A of the Act provides that where a pharmaceutical benefit is determined under subsection 85(7) of the Act to be a relevant pharmaceutical benefit, the writing of a

prescription for the supply of the benefit is authorised under Part VII of the Act only in circumstances specified in the determination.

Section 13 of the 2024 Listing instrument provides:

- if a circumstances code (i.e. the letter C followed by a number) is mentioned in the column of the table in Part 1 of Schedule 1 headed “Circumstances” in relation to a pharmaceutical benefit, the benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act; and
- the circumstances mentioned in the column of the table in Part 1 of Schedule 4 headed “Circumstances and Purposes” for the relevant circumstances code are circumstances in which a prescription for the supply of the pharmaceutical benefit may be written; and
- if the column of the table in Part 1 of Schedule 4 headed “Authority Requirements” in relation to the circumstances code is not blank, it is part of the circumstances that the writing of the prescription must be authorised by the Chief Executive Medicare in accordance with section 19 of the 2024 Listing Instrument.

The circumstances in which a particular pharmaceutical benefit can be prescribed can be complex. A particular pharmaceutical benefit may also be able to be prescribed in many different circumstances. The same circumstance could also apply to many different pharmaceutical benefits (for example different brands of the same pharmaceutical item). The use of circumstances codes in Part 1 of Schedule 1, along with detailed specification of the content of those codes in Schedule 4, keeps the 2024 Listing Instrument a manageable size.

Section 13 corresponds to section 10 of the 2012 Listing Instrument.

#### **Section 14 – Prescription of extemporaneously-prepared pharmaceutical benefits in certain circumstances (Act s 85(7))**

Section 14 of the 2024 Listing Instrument outlines, for the purposes of subsection 85(7) of the Act, the circumstances in which a prescription can be written for the supply of extemporaneously-prepared pharmaceutical benefits mentioned in Schedule 2 to the instrument.

Subsection 14(1) provides:

- if circumstances are mentioned in column 2 of an item in the table in Part 1 of Schedule 2, the listed drug in column 1 of that item is a relevant pharmaceutical benefit for the purposes of section 88A of the Act and an extemporaneously-prepared pharmaceutical benefit that contains the listed drug is also a relevant pharmaceutical benefit;
- the circumstances are the circumstances under which a prescription for the supply of the listed drug, or a prescription for the supply of a pharmaceutical benefit that is a relevant pharmaceutical benefit only because it contains the listed drug, can be written.

Subsection 14(2) provides that if a pharmaceutical benefit contains 2 or more listed drugs (the “component drugs”) mentioned in column 1 of an item in Part 1 of Schedule 2 that are

relevant pharmaceutical benefits, then, for the purposes of paragraph 85(7)(b) of the Act, a prescription for the supply of the pharmaceutical benefit may be written only if the circumstances mentioned in column 2 of the table in Part 1 of Schedule 2 for every component drug exist.

Section 14 corresponds to section 16 of the 2012 Listing Instrument.

## **Division 2—Maximum quantities and repeats**

### **Section 15 - Maximum quantity (number of units)—ready-prepared pharmaceutical benefits (Act s 85A(2)(a), (2A) and (3A))**

Subsection 15(1) outlines that section 15 determines three matters affecting the writing of prescriptions for the supply of ready-prepared pharmaceutical benefits having a pharmaceutical item by authorised prescribers for the benefit.

#### Determination of maximum number of units

Paragraph 85A(2)(a) of the Act provides that the Minister may determine the maximum quantity or number of units of a pharmaceutical item (if the pharmaceutical benefit has a pharmaceutical item) or otherwise a pharmaceutical benefit that may, in one prescription, be directed to be supplied on the one occasion. The Minister may determine the maximum quantity or number of units for all purposes or for particular purposes.

Subsection 15(2) of the 2024 Listing Instrument provides that, if only one number of units is mentioned in the column of the table in Part 1 of Schedule 1 headed “Maximum Quantity” (the “maximum quantity column”), in relation to brands of a pharmaceutical item and a kind of authorised prescriber, that number is the maximum number of units of a pharmaceutical item that can be prescribed by that kind of authorised prescriber for all purposes.

If more than one number of units is mentioned in the maximum quantity column then subsection 15(3) sets out the rules regarding the maximum number of units for that pharmaceutical item. It provides:

- where a purposes code (i.e. the letter P followed by a number) is mentioned in the column of the table in Part 1 of Schedule 1 headed “Purposes” in relation to the number of units, that number is the maximum number of units of the pharmaceutical item for that kind of authorised prescriber for the purposes mentioned in the table in Part 1 of Schedule 4 for that purposes code (see paragraph 15(3)(a)); and
- where no purposes code is mentioned in relation to the number of units, that number is the maximum number of units of the pharmaceutical item for that kind of authorised prescriber for all purposes, other than purposes to which paragraph 15(3)(a) applies (see paragraph 15(3)(b)).

For example, a pharmaceutical item might have maximum quantities of 8 units and 12 units for the brands of the pharmaceutical item, with a purposes code only specified for the 12 units. In that case, the relevant authorised prescriber(s) can write a prescription for up to 8 units of pharmaceutical benefits containing the pharmaceutical item for all purposes *other than* the purposes outlined in the purposes code for the maximum number of 12 units.

The content of purposes codes is outlined in Part 1 of Schedule 4 to the 2024 Listing Instrument.

#### Conditions for writing a prescription for the maximum number of units

Subsection 85A(2A) of the Act relevantly provides the Minister may determine that particular conditions must be satisfied when writing a prescription to which a determination under paragraph 85A(2)(a) applies (i.e. a determination by the Minister about the maximum quantity or number of units).

Subsection 15(4) provides that, if the maximum quantity column includes a conditions code (i.e. the letters CN followed by a number) together with the maximum number of units, it is a condition when writing a prescription to which that maximum applies that writing the prescription must be authorised by the Chief Executive Medicare in accordance with section 19.

#### Rules for authorising variation of maximum number of units

Regulations made for subsection 85A(3) of the Act provide the Minister with the power to authorise the variation of the application of a determination regarding the maximum number of units of a pharmaceutical item that a PBS prescriber may direct to be supplied on the one occasion. The relevant provisions are in the *National Health (Pharmaceutical Benefits) Regulations 2017*. Subsection 85A(3A) of the Act provides that the Minister may also determine rules that must be applied when deciding whether to vary the maximum number of units.

Decisions whether to vary the maximum number of units in relation to a particular prescription are made by delegates in Services Australia.

Subsection 15(5) of the 2024 Listing Instrument will apply where the column of the table in Part 1 of Schedule 1 headed “Variations” includes a variation code (i.e. the letter V followed by a number) in relation to a maximum number of units. In that case, the rules mentioned in the column of the table in Part 2 of Schedule 4 headed “Variation Rules” in relation to the variation code must be applied when deciding whether to authorise a variation of that maximum number of units (to the extent that those rules relate to the number of units).

A note to subsection 15(5) of the instrument outlines that variation rules can also relate to the maximum number of repeats.

Subsection 15(5) is a new provision intended to more accurately reflect that binding rules about the variation of maximum numbers of units that can be prescribed for supply on one occasion are not part of the general circumstances for writing a prescription determined for subsection 85(7) of the Act. These variation rules are now identified in a separate Part 2 of Schedule 4 to this instrument. In the 2012 Listing Instrument these rules were outlined in Part 1 of Schedule 4 to that instrument but it is more appropriate for these rules to be outlined in a separate part of Schedule 4.

Apart from the previously mentioned new provision in subsection 15(5), section 15 corresponds to section 17 and section 18 of the 2012 Listing Instrument.

## **Section 16 - Maximum number of repeats—ready-prepared pharmaceutical benefits (Act s 85A(2)(b), (2A) and (3A))**

Subsection 16(1) outlines that section 16 determines three matters affecting the writing, by authorised prescribers, of prescriptions for the supply of ready-prepared pharmaceutical benefits having a pharmaceutical item.

### Determination of maximum number of repeats

Paragraph 85A(2)(b) of the Act provides that the Minister may determine the maximum number of occasions on which the supply of a pharmaceutical benefit may, in one prescription, be directed to be repeated. The Minister may determine the maximum number of repeats for all purposes or for particular purposes.

Subsection 16(2) of the 2024 Listing Instrument provides that, if only one number is mentioned in the column of the table in Part 1 of Schedule 1 headed “Number of Repeats” (the “repeats column”), in relation to the pharmaceutical benefit and a kind of authorised prescriber, that number is the maximum number of occasions that a supply of the pharmaceutical benefit can be directed in one prescription by an authorised prescriber for all purposes.

Subsection 16(3) sets out the rules regarding the maximum number of repeats where more than one number is mentioned in the repeats column. It provides:

- where a purposes code is mentioned in the column of the table in Part 1 of Schedule 1 headed “Purposes” in relation to the number of repeats, that number is the maximum number of repeats of the pharmaceutical item for that kind of authorised prescriber for the purposes mentioned in the table in Part 1 of Schedule 4 for that purposes code (see paragraph 16(3)(a)); and
- where no purposes code is mentioned in relation to the number of repeats, that number is the maximum number of repeats of the pharmaceutical item for that kind of authorised prescriber for all purposes other than purposes to which paragraph 16(3)(a) applies (see paragraph 16(3)(b)).

### Conditions for writing a prescription for the maximum number of repeats

Subsection 16(4) sets out conditions that must be satisfied by an authorised prescriber when writing a prescription directing the maximum number of repeats for a pharmaceutical benefit. It provides that, if the repeats column includes a conditions code together with the maximum number of repeats, it is a condition when writing a prescription to which that maximum applies that writing the prescription must be authorised by the Chief Executive Medicare in accordance with section 19.

### Rules for authorising variation of maximum number of repeats

Regulations made for subsection 85A(3) of the Act provide the Minister with the power to authorise the variation of the application of a determination regarding the maximum number of repeats of a pharmaceutical benefit that a PBS prescriber may direct to be supplied in a prescription. The relevant provisions are in *the National Health (Pharmaceutical Benefits) Regulations 2017*. Subsection 85A(3A) of the Act provides that the Minister may also

determine rules that must be applied when deciding whether to vary the maximum number of repeats.

Decisions whether to vary the maximum number of repeats in relation to a particular prescription are made by delegates in Services Australia.

Subsection 16(5) of the 2024 Listing Instrument provides that if the column of the table in Part 1 of Schedule 1 headed “Variations” includes a variation code in relation to a maximum number of repeats, the rules mentioned in the column of the table in Part 2 of Schedule 4 headed “Variation Rules” in relation to the variation code must be applied when deciding whether to authorise a variation of that maximum number of repeats (to the extent that those rules relate to the number of repeats).

A note to subsection 16(5) mentions that variation rules can also be made that relate to the maximum number of units.

Subsection 16(5) is a new provision intended to more accurately reflect that binding rules about the variation of maximum numbers of repeats are not part of the general circumstances for writing a prescription determined for subsection 85(7) of the Act. These variation rules are now identified in a separate Part 2 of Schedule 4 to this instrument. In the 2012 Listing Instrument these rules were outlined in Part 1 of Schedule 4 to that instrument but it is more appropriate for these rules to be outlined in a separate part of Schedule 4.

Apart from the previously mentioned new provision in subsection 16(5), section 16 corresponds to section 20 and section 21 of the 2012 Listing Instrument.

### **Section 17 - Maximum quantity—extemporaneously-prepared pharmaceutical benefits (Act s 85A(2)(a))**

Section 17, made for the purposes of paragraph 85A(2)(a) of the Act, provides for the maximum quantity of an extemporaneously-prepared pharmaceutical benefit in Part 3 of Schedule 2 to the instrument.

The maximum quantity of an extemporaneously-prepared pharmaceutical benefit, of a type mentioned in column 1 of an item in the table in Part 3 of Schedule 2, that may be directed to be supplied on any one occasion is the quantity mentioned in column 2 of the item. Only medical practitioners are authorised to prescribe extemporaneously-prepared pharmaceutical benefits.

Section 17 corresponds to section 19 of the 2012 Listing Instrument.

### **Section 18 - Maximum number of repeats—extemporaneously-prepared pharmaceutical benefits (Act s 85A(2)(b))**

Section 18, made for the purposes of paragraph 85A(2)(b) of the Act, provides for the maximum number of occasions that the supply of an extemporaneously-prepared pharmaceutical benefit may be directed to be supplied in one prescription.

The maximum number of occasions that an extemporaneously-prepared pharmaceutical benefit of a type mentioned in column 1 of an item in the table in Part 3 of Schedule 2 may

directed to be supplied in one prescription is the number mentioned in column 3 of the item. Only medical practitioners are authorised to prescribe extemporaneously-prepared pharmaceutical benefits.

Section 18 corresponds to section 22 of the 2012 Listing Instrument.

### **Division 3—Authorisation of prescriptions**

#### **Section 19 - Authority required procedures**

Section 19 sets out the procedures (called “authority required procedures”) that prescribers must follow to receive authorisation from the Chief Executive Medicare to write a prescription for the supply of certain pharmaceutical benefits.

Subsection 19(1) provides that the section applies if either of the following include a requirement for a prescription for a pharmaceutical benefit to be authorised by the Chief Executive Medicare:

- the circumstances under paragraph 85(7)(b) of the Act in which a prescription for the supply of the pharmaceutical benefit may be written apply (see paragraph 13(c)); or
- the conditions under subsection 85A(2A) of the Act for writing a prescription for the supply of the pharmaceutical benefit (see subsections 15(4) and 16(4)).

Subsection 19(2) provides that the authorised prescriber requesting authority to write a prescription must provide details of the proposed prescription to the Chief Executive Medicare.

Subsection 19(3) provides that, if the column of the table in Part 1 of Schedule 4 headed “Authority Requirements” contains the statement “Compliance with Written Authority Required procedures”, the details of the proposed prescription must be provided in writing.

Subsection 19(4) provides that, if the Chief Executive Medicare gives authority to write the prescription, the Chief Executive Medicare must allot a number to the prescription and tell the authorised prescriber that number.

#### Streamlined authority required

Subsection 19(5) provides that, if the column of the table in Part 1 of Schedule 4 headed “Authority Requirements” includes a streamlined authority code (i.e. the words “Streamlined Authority Code” followed by a number), writing the prescription is taken to have been authorised by the Chief Executive Medicare.

Notes to subsections 19(4) and 19(5) refers the reader to section 40 and section 41 of the *National Health (Pharmaceutical Benefits) Regulations 2017*. Those provisions set out requirements to write the number allocated by the Chief Executive Medicare or the streamlined authority code (where applicable) on the prescription.

## Changes to authority required procedures from 2012 Listing Instrument

The process for seeking authorisation to write a prescription in new section 19 differs from current sections 11 to 15 of the 2012 Listing Instrument as follows:

- the prescriber submits details of a proposed prescription to the Chief Executive Medicare (in practice their delegates within Services Australia) rather than submitting the prescription itself or a copy of the prescription;
- drafting about the different channels a prescriber can use to submit details of the proposed prescription to Services Australia has been simplified in order to make these administrative processes more adaptable to rapid technology change. Where needed, information about authority application channels will be provided to prescribers on Services Australia's normal communication platforms as well as via administrative notes published in the online PBS schedule;
- as Services Australia will now receive details of proposed prescriptions rather than prescriptions that have already been finalised by the prescriber, provisions requiring the prescriber to alter a prescription where requested by the Minister are now redundant and have been omitted;
- prescribers can no longer ask for the prescription to be sent on to the patient once authorised.

The move to requiring prescribers to seek authorisation of a proposed prescription before it is finalised improves alignment of processes with the Act.

Section 24 of this instrument (discussed below) contains a transitional provision giving prescribers an additional 3-month period in which to transition from the authority required procedures in the 2012 Listing Instrument to those in section 19 of the 2024 Listing Instrument.

### **Part 4—Quantities of pharmaceutical items**

#### **Section 20 - Pack quantity (Act s 84AK(2))**

Subsection 84AK(2) of the Act provides that the Minister may, by legislative instrument, determine for a listed brand of a pharmaceutical item that one or more quantities or numbers of units of the pharmaceutical item is a pack quantity of the brand.

Section 20 of the 2024 Listing Instrument provides that, for the purposes of subsection 84AK(2) of the Act, a number of units of a pharmaceutical item mentioned in the column of a table in Schedule 1 headed "Pack Quantity" in relation to a brand of the pharmaceutical item is a pack quantity of the brand.

The pack quantity or quantities determined for a listed brand of pharmaceutical item is relevant because the lowest pack quantity of any listed brand of a pharmaceutical item is the pricing quantity for all brands of the pharmaceutical item. The approved ex-manufacturer price (AEMP) of a listed brand is set by reference to its pricing quantity, with a proportional ex-manufacturer price for other pack quantities of the brand.

Section 20 corresponds to section 24 of the 2012 Listing Instrument.



## **Section 21 - Determined quantity (Act s 84AK(3))**

Subsection 84AK(3) of the Act provides that the Minister may, by legislative instrument, determine for a listed brand of a pharmaceutical item that one or more quantities or numbers of units of the pharmaceutical item is a determined quantity of the brand of the pharmaceutical item.

Section 21 of the 2024 Listing Instrument provides that, for the purposes of subsection 84AK(3) of the Act, a number of units of a pharmaceutical item mentioned in the column of a table in Schedule 1 headed “Determined Quantity”, in relation to a brand of the pharmaceutical item, is a determined quantity of the brand.

Most brands of pharmaceutical item do not have a determined quantity. A determined quantity may be set when maximum quantity or number of units has been determined for a pharmaceutical item for the purposes of paragraph 85A(2)(a) of the Act. A number of legislative instruments generally use the maximum quantity for brands of a pharmaceutical item as the basis for calculating certain mark-ups used in calculating Commonwealth payments for the supply of pharmaceutical benefits, but provide for the determined quantity to be used where no maximum quantity applies.

Section 21 corresponds to section 23 of the 2012 Listing Instrument.

## **Part 5—Supply of pharmaceutical benefits**

### **Section 22 - Listed drugs and pharmaceutical benefits that can only be supplied under the prescriber bag provisions (Act s 85(2AA) and (7A))**

Sections 93, 93AA and 93AB of the Act enable medical practitioners, authorised midwives and authorised nurse practitioners to supply certain pharmaceutical benefits to patients. No prescription is required for supplies made under sections 93, 93AA or 93AB. Supplies of pharmaceutical benefits under these arrangements are known as “prescriber bag” supplies and enable relevant practitioners to quickly supply appropriate medicines to patients for emergency use. Only medical practitioners and authorised nurse practitioners are currently able to make prescriber bag supplies.

#### Drugs that can only be supplied under prescriber bag provisions

Subsection 85(2AA) of the Act provides that if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended that a listed drug should only be able to be supplied under one or more of the prescriber bag provisions, the Minister must make a declaration to that effect.

Subsection 22(1) of the 2024 Listing Instrument has effect that where one or more of the codes “D(MP)”, “D(MW)” and “D(NP)” is mentioned in the column of a table in Schedule 1 headed “Section 100/Prescriber Bag only” (the “section 100/prescriber bag only column”) in relation to a listed drug, the drug can only be provided under the prescriber bag provisions. If:

- the code “D(MP)” is mentioned – the drug can be supplied under section 93 of the Act by medical practitioners; and

- the code “D(MW)” is mentioned – the drug can be supplied under section 93AA of the Act by authorised midwives; and
- the code “D(NP)” is mentioned – the drug can be supplied under section 93AB of the Act by authorised nurse practitioners.

#### Pharmaceutical benefits that can only be supplied under prescriber bag provisions

Subsection 85(7A) of the Act provides that the Minister may determine that a particular pharmaceutical benefit can only be supplied under one or more of the prescriber bag provisions.

Subsection 22(2) of the 2024 Listing Instrument has effect that where one or more of the codes “PB(MP)”, “PB(MW)” and “PB(NP)” is mentioned in the section 100/prescriber bag only column in relation to a pharmaceutical benefit, the benefit can only be provided under the prescriber bag provisions. If:

- the code “PB(MP)” is mentioned – the pharmaceutical benefit can be supplied under section 93 of the Act by medical practitioners; and
- the code “PB(MW)” is mentioned – the pharmaceutical benefit can be supplied under section 93AA of the Act by authorised midwives; and
- the code “PB(NP)” is mentioned – the pharmaceutical benefit can be supplied under section 93AB of the Act by authorised nurse practitioners.

A note to section 22 directs the reader to subsection 85AAA(3) of the Act for information regarding the interaction between a declaration under subsection 85(2AA) of the Act in relation to a drug and a declaration under subsection 85(7A) of the Act in relation to a pharmaceutical benefit that has the drug.

Section 22 corresponds to section 26 of the 2012 Listing Instrument.

#### **Section 23 - Listed drugs and pharmaceutical benefits that can only be supplied under special arrangements (Act s 85(2A) and (8))**

Section 100 of the Act enables the Minister to make, by legislative instrument, special arrangements for or in relation to providing that an adequate supply of pharmaceutical benefits will be available, to persons living in isolated areas, where the pharmaceutical benefits can be more conveniently or efficiently supplied under the special arrangement or to persons who are receiving treatment in circumstances in which pharmaceutical benefits available for ‘general supply’ are inadequate for that treatment.

Under the Act the Minister can determine that certain drugs or pharmaceutical benefits may only be supplied under special arrangements. The Minister can also determine that a pharmaceutical benefit can only be supplied under a special arrangement in certain circumstances only.

#### Drugs that can only be supplied under special arrangements

Subsection 23(1) is made for the purposes of subsection 85(2A) of the Act which provides that the Minister must declare that a listed drug can only be supplied under special

arrangements if the PBAC has made a recommendation to that effect under subsection 101(4AAD) of the Act.

Subsection 23(1) provides that a listed drug can be supplied only under special arrangements if the code “D(100)” is mentioned in the section 100/prescriber bag only column in relation to the drug.

#### Pharmaceutical benefits that can only be supplied under special arrangements

Subsection 23(2) is made for the purposes of paragraph 85(8)(a) of the Act which provides that the Minister may determine that a particular pharmaceutical benefit (other than a pharmaceutical benefit that has a drug covered by subsection 85(2A)) can be supplied only under special arrangements.

Subsection 23(2) provides that a ready-prepared pharmaceutical benefit can only be supplied under special arrangements if the code “PB(100)” is mentioned in the section 100/prescriber bag only column in relation to the pharmaceutical benefit.

#### Pharmaceutical benefits that can only be supplied under special arrangements in certain circumstances

Subsection 23(3) is made for the purposes of paragraph 85(8)(b) of the Act which provides that the Minister may determine that one or more of the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written are circumstances in which the benefit can be supplied under special arrangements.

Subsection 23(3) provides that if the code “C(100)” is mentioned in the section 100/prescriber bag only column in relation to both a pharmaceutical benefit and a circumstances code, the circumstances mentioned in the table in Schedule 4 for the circumstances code are circumstances in which the pharmaceutical benefit can only be supplied under special arrangements.

Section 23 corresponds to section 25 of the 2012 Listing Instrument.

### **Part 6—Application, saving and transitional provisions**

#### **Section 24 – Transitional provision – authorisation of prescriptions**

Section 24 contains a transitional provision regarding the authorisation of prescriptions by the Chief Executive Medicare.

Subsection 24(1) provides that the section applies in relation to prescriptions for the supply of pharmaceutical benefits written before 1 July 2024.

Subsection 24(2) provides that despite the repeal of the 2012 Listing Instrument, which will occur on 1 April 2024:

- an authorised prescriber may submit a prescription to the Chief Executive Medicare in accordance with section 12 of that instrument as in force immediately before 1 April 2024; and

- the Chief Executive Medicare may authorise the prescription in accordance with section 13 of that instrument as in force immediately before 1 April 2024; and
- if the Chief Executive Medicare authorises the prescription, writing the prescription is taken to have been authorised in accordance with section 19 of the 2024 Listing Instrument.

Subsection 24(3) provides that if the Chief Executive Medicare authorises a prescription under subsection 13(1), (1A) or (1B) of the 2012 Listing Instrument, as in force immediately before 1 April 2024, the prescriber is not required to comply with paragraphs 40(1)(i) or 41(3)(a) of the *National Health (Pharmaceutical Benefits) Regulations 2017* in relation to the prescription. Those provisions would ordinarily require the prescriber to write the authority approval number allotted by the Chief Executive Medicare on the prescription or medication chart prescription.

Section 24 is intended to allow prescribers a period to adjust to new arrangements for requesting authorisation.

## **Schedule 1—Ready-prepared pharmaceutical benefits**

### Part 1 Ready-prepared pharmaceutical benefits

Part 1 of Schedule 1 to the instrument deals with matters relevant to the listing of ready-prepared pharmaceutical benefits on the PBS. The matters dealt with in the various columns in Part 1 of Schedule 1, and the corresponding provisions of the Act and sections of the 2024 Listing Instrument are set out below.

<b><u>Column in Part 1 of Schedule 1</u></b>	<b><u>Provision of the Act</u></b>	<b><u>Section of this Instrument</u></b>
Listed Drug	Subsection 85(2)	Section 6
Form	Subsection 85(3)	Section 7
Manner of Administration	Subsection 85(5)	Section 8
Brand	Subsection 85(6)	Section 9
Responsible Person	Subsection 84AF(1)	Section 10
Authorised Prescriber	Section 88	Section 12
Circumstances	Subsection 85(7)	Section 13
Purposes	Paragraphs 85A(2)(a) and (b)	Sections 15 and 16
Maximum Quantity	Paragraph 85A(2)(a) Subsection 85A(2A)	Section 15
Number of Repeats	Paragraph 85A(2)(b) Subsection 85A(2A)	Section 16
Variation	Subsection 85A(3A)	Sections 15 and 16
Pack Quantity	Subsection 84AK(2)	Section 20
Determined Quantity	Subsection 84AK(3)	Section 21

Section 100/ Prescriber bag only	Subsection 85(2AA) Subsection 85(2A) Subsection 85(7A) Subsection 85(8)	Sections 22 and 23
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### Notes to Part 1 of Schedule 1

There are three notes included after Part 1 of Schedule 1.

Note 2 relates to dual supply pharmaceutical benefits, i.e. pharmaceutical benefits available both for general supply and for supply under special arrangements. “Note 2” is used in Part 1 of Schedule 1 to flag where a pharmaceutical benefit may be covered by a special arrangement. The Note provides that matters relevant to the availability of the pharmaceutical benefit for general supply have been set out in Schedule 1. However, section 100 of the Act provides that the Act and instruments made under it, including the 2024 Listing Instrument, apply subject to any special arrangement. Note 2 also informs readers that modified matters may be provided for in relation to supply under a special arrangement instrument and that where the benefit is supplied under the special arrangement the modified matters will apply.

Note 3 relates to pharmaceutical benefits that may only be supplied under special arrangements, either in all circumstances or in the circumstances mentioned in an item in Schedule 1. “Note 3” is used in Part 1 of Schedule 1 to flag where a matter has not been determined for a pharmaceutical benefit in the 2024 Listing Instrument. These matters may be determined in a special arrangement instrument. The types of matters that most typically may be determined in a special arrangement rather than in the 2024 Listing Instrument are the circumstances in which a prescription for the pharmaceutical benefit may be written, the purposes for which certain maximum quantities or numbers of units of the benefit may be prescribed and those quantities or numbers of units, and the maximum number of times a single prescription can direct the supply of the benefit. 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.

“Note 4” is used in Part 1 of Schedule 1 to indicate pharmaceutical benefits that may only be supplied under one or more of the prescriber bag provisions. The note informs readers that the pharmaceutical benefit may only be supplied under the particular prescriber bag provisions referred to in the column headed ‘Section 100/Prescriber Bag only’ and it is not able to be prescribed as a pharmaceutical benefit. Note 4 also refers readers to a legislative instrument made under the prescriber bag provisions (on 1 April 2024, the *National Health (Prescriber Bag Supplies) Determination*).

### Part 2 Ready-prepared pharmaceutical benefits for supply only

Part 2 of Schedule to the 2024 Listing Instrument sets out the ready-prepared pharmaceutical benefits available for supply only. It declares or determines matters for sections 6 to 10 and 20 to 23 of the 2024 Listing Instrument.

A PBS prescription cannot be written for the supply of the pharmaceutical benefits in Part 2 of Schedule 1 but these benefits may still be supplied under the PBS where a prescription for their supply was written prior to their removal from Part 1 of Schedule 1 (or in certain

circumstances where the Act enables supply without a prescription, such as under continued dispensing arrangements).

## **Schedule 2—Extemporaneously-prepared pharmaceutical benefits**

This Schedule sets out matters relevant to the listing of extemporaneously-prepared pharmaceutical benefits on the PBS. It determines matters for sections 6, 14, 17 and 18 of the 2024 Listing Instrument.

Part 1 of Schedule 2 sets out the listed drugs that are or may be contained in extemporaneously-prepared pharmaceutical benefits as well as matters relating to circumstances in which a prescription may be written for the supply of those benefits.

Part 2 of Schedule 2 sets out the additives that may be contained in extemporaneously-prepared pharmaceutical benefits.

Part 3 of Schedule 2 sets out the maximum quantities and numbers of repeats for certain types of extemporaneously-prepared pharmaceutical benefits.

## **Schedule 3—Responsible persons**

This Schedule sets out the name of the responsible person and their ABN (if any) for each code used to identify the responsible person for a brand of pharmaceutical item in Schedule 1. It is made for the purposes of section 10 of the 2024 Listing Instrument.

## **Schedule 4—Circumstances, purposes, conditions and variations**

### Part 1 Circumstances, purposes and conditions

Part 1 of Schedule 4 relates to sections 13, 15, 16, 19 and 23 of the 2024 Listing Instrument.

The table in Part 1 provides detailed content for the circumstances codes, purposes codes and conditions codes appearing in the “Circumstances”, “Purposes” and “Conditions” columns, respectively, in Schedule 1 for ready-prepared pharmaceutical benefits.

- The circumstances are the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written (see section 13). The circumstances may include a requirement that the Chief Executive Medicare authorises the writing of the prescription;
- The purposes are the purposes for which a prescriber may direct that a maximum quantity of the pharmaceutical benefit may be directed to be supplied on one occasion (see section 15) and/or purposes for which a prescriber may include the maximum number of occasions a single prescription can direct the supply of the pharmaceutical benefit (see section 16);
- The conditions are the conditions that must be satisfied when writing a prescription for maximum quantity or maximum number of repeats (see sections 15 and 16). The conditions may also include a condition that the Chief Executive Medicare has authorised the writing of the prescription.

### *Authority required procedures*

Where the column headed “Authority Requirements (part of Circumstance; or Conditions)” (“authority required column”) includes a streamlined authority code, writing of the prescription is taken to have been authorised by the Chief Executive Medicare (see section 19). Under sections 40 and 41 of the *National Health (Pharmaceutical Benefits) Regulations 2017*, the streamlined authority code is required to be written on the prescription.

Where the authority required column contains the statement “Compliance with Written Authority Required Procedures”, the details of the proposed prescription must be provided to the Chief Executive Medicare in writing (see section 19).

The content of the “Circumstances and Purposes” column may also set out requirements relating to authority required procedures including requirements for requests for authorisation by the Chief Executive Medicare to be accompanied by specified documents or information or for requests to be made using particular channels. This may also have the effect that the authority application must be made in writing.

Part 1 of Schedule 4 also outlines, for the purposes of subsection 23(3) of the 2024 Listing Instrument, the circumstances in which a pharmaceutical benefit may only be supplied under a section 100 arrangement.

## **Part 2 Variation rules**

Part 2 of Schedule 4 relates to subsections 15(5) and 16(5) of the 2024 Listing Instrument.

The Part sets out the details of rules identified by variation codes in Part 1 of Schedule 1 that must be applied by the Minister (or their delegate) when making a decision whether to vary the application of a determination under subsection 85A(2)(a) or (2)(b) of the Act regarding the maximum number of units of a ready-prepared pharmaceutical benefit that can be directed to be supplied on the one occasion and/or the maximum number of times a single prescription can direct the supply of a ready-prepared pharmaceutical benefit.

The content of these rules was previously included in Schedule 4 of the 2012 Listing Instrument.

## **A note on documents incorporated by reference into Schedule 4**

There are various documents incorporated by reference into Schedule 4 to the 2024 Listing Instrument. All Commonwealth Acts and legislative instruments are incorporated as in force from time to time. All other documents are incorporated as in force at the date the 2024 Listing Instrument commences (i.e. 1 April 2024), except where the 2024 Listing Instrument expressly refers to a version of the document that predates 1 April 2024.

## **Schedule 5—Schedule equivalent groups of brands of pharmaceutical items**

Schedule 5 contains a table that sets out schedule equivalent groups and the brands of pharmaceutical items included in the groups, for the purposes of section 11.

A brand of a pharmaceutical item included in a schedule equivalent group in the table can be treated as equivalent to each other brand of a pharmaceutical item included in that schedule equivalent group, for the purposes of paragraph 103(2A)(b) of the Act.

### **Schedule 6—General statement for drugs for the treatment of hepatitis C**

Some of the circumstances and purpose mentioned in Schedule 4 to the 2024 Listing Instrument require that a patient meets the criteria set out in the General statement for drugs for the treatment of hepatitis C, for example circumstances relating to glecaprevir with pibrentasvir. This Statement is set out in Schedule 6.



SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME  
MADE BY THIS INSTRUMENT

**Drug Added**

*Listed Drug*

Inclisiran

**Drugs Deleted**

*Listed Drug*

Abacavir with lamivudine and zidovudine

Fosamprenavir

Tropisetron

**Forms Added**

*Listed Drug*

*Form*

Ethosuximide

Capsule 250 mg (s19A)

Teriparatide

Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen

**Forms Deleted**

*Listed Drug*

*Form*

Lopinavir with ritonavir

Tablet 100 mg-25 mg

Methylprednisolone

Powder for injection 40 mg (as sodium succinate)

Morphine

Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 20 mg per sachet

Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 30 mg per sachet

Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 60 mg per sachet

Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 100 mg per sachet

Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 200 mg per sachet

## Brands Added

<i>Listed Drug</i>	<i>Form and Brand</i>
Azithromycin	Tablet 500 mg (as dihydrate) ( <i>Azithromycin Viatris</i> )
Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL ( <i>Cefaclor SUN</i> )
	Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL ( <i>Cefaclor SUN</i> )
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg ( <i>Fenac EC</i> )
	Tablet (enteric coated) containing diclofenac sodium 50 mg ( <i>Fenac EC</i> )
Fluticasone propionate with salmeterol	Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses ( <i>Salflumix Easyhaler 250/50</i> )
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses ( <i>Salflumix Easyhaler 500/50</i> )
Fosaprepitant	Powder for I.V. infusion 150 mg ( <i>FOSAPREPITANT MEDSURGE</i> )
Imatinib	Tablet 100 mg (as mesilate) ( <i>Imatinib Sandoz</i> )
	Tablet 400 mg (as mesilate) ( <i>Imatinib Sandoz</i> )
Irbesartan	Tablet 75 mg ( <i>Blooms Irbesartan</i> )
	Tablet 150 mg ( <i>Blooms Irbesartan</i> )
	Tablet 300 mg ( <i>Blooms Irbesartan</i> )
Methyldopa	Tablet 250 mg (as sesquihydrate) ( <i>Hydopa</i> )
Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg ( <i>ARX-MYCOPHENOLATE</i> )
Olanzapine	Tablet 7.5 mg ( <i>APO-OLANZAPINE</i> )
Pomalidomide	Capsule 1 mg ( <i>Pomalidomide Sandoz</i> )
	Capsule 2 mg ( <i>Pomalidomide Sandoz</i> )
Pramipexole	Tablet containing pramipexole dihydrochloride monohydrate 125 micrograms ( <i>APO-Pramipexole</i> )
	Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms ( <i>APO-Pramipexole</i> )
Quetiapine	Tablet 25 mg (as fumarate) ( <i>APX-QUETIAPINE</i> )
	Tablet 200 mg (as fumarate) ( <i>APX-QUETIAPINE</i> )
	Tablet 300 mg (as fumarate) ( <i>APX-QUETIAPINE</i> )

Tenofovir with emtricitabine      Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (*TENOFOVIR/EMTRICITABINE 300/200 ARX*)

### Brands Deleted

<i>Listed Drug</i>	<i>Form and Brand</i>
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg ( <i>Fenac 25</i> ) Tablet (enteric coated) containing diclofenac sodium 50 mg ( <i>Fenac</i> )
Erythromycin	Capsule 250 mg (containing enteric coated pellets) ( <i>Eryc</i> )
Glimepiride	Tablet 1 mg ( <i>Aylide 1</i> ) Tablet 2 mg ( <i>Aylide 2</i> ) Tablet 3 mg ( <i>Aylide 3</i> ) Tablet 4 mg ( <i>Aylide 4</i> )
Lurasidone	Tablet containing lurasidone hydrochloride 40 mg ( <i>Ardix Lurasidone</i> ) Tablet containing lurasidone hydrochloride 80 mg ( <i>Ardix Lurasidone</i> )
Pregabalin	Capsule 75 mg ( <i>Pregabalin GH</i> ) Capsule 150 mg ( <i>Pregabalin GH</i> )
Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg ( <i>Stemzine</i> )
Risperidone	Tablet 1 mg ( <i>Risperidone generichealth</i> ) Tablet 2 mg ( <i>Risperidone generichealth</i> ) Tablet 3 mg ( <i>Risperidone generichealth</i> )
Vinorelbine	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL ( <i>Navelbine</i> )
Voriconazole	Tablet 200 mg ( <i>Vfend</i> )

### Alteration of Maximum Quantity

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Circumstances Code</i>	<i>Maximum Quantity</i>
Choriogonadotropin alfa	Solution for injection 250 micrograms in 0.5 mL pre-filled pen	<i>Ovidrel</i>	C14096	<b>From: 1 To: 4</b>

### Alteration of Responsible Person Code

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Responsible Person</i>
Ambrisentan	Tablet 5 mg	<i>PULMORIS</i>	<b>From: YC To: XT</b>

	Tablet 10 mg	<i>PULMORIS</i>	<b>From:</b> YC <b>To:</b> XT
Bevacizumab	Solution for I.V. infusion 100 mg in 4 mL	<i>Abevmy</i>	<b>From:</b> AF <b>To:</b> SZ
	Solution for I.V. infusion 400 mg in 16 mL	<i>Abevmy</i>	<b>From:</b> AF <b>To:</b> SZ
Candesartan	Tablet containing candesartan cilexetil 4 mg	<i>Atacand</i>	<b>From:</b> AP <b>To:</b> LM
	Tablet containing candesartan cilexetil 8 mg	<i>Atacand</i>	<b>From:</b> AP <b>To:</b> LM
	Tablet containing candesartan cilexetil 16 mg	<i>Atacand</i>	<b>From:</b> AP <b>To:</b> LM
	Tablet containing candesartan cilexetil 32 mg	<i>Atacand</i>	<b>From:</b> AP <b>To:</b> LM
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg	<i>Atacand Plus 16/12.5</i>	<b>From:</b> AP <b>To:</b> LM
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg	<i>Atacand Plus 32/12.5</i>	<b>From:</b> AP <b>To:</b> LM
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg	<i>Atacand Plus 32/25</i>	<b>From:</b> AP <b>To:</b> LM
Carbamazepine	Tablet 100 mg	<i>Carbamazepine Sandoz</i>	<b>From:</b> SZ <b>To:</b> NM
	Tablet 200 mg	<i>Carbamazepine Sandoz</i>	<b>From:</b> SZ <b>To:</b> NM
Ciclosporin	Capsule 25 mg	<i>Cyclosporin Sandoz</i>	<b>From:</b> SZ <b>To:</b> NM
	Capsule 50 mg	<i>Cyclosporin Sandoz</i>	<b>From:</b> SZ <b>To:</b> NM
	Capsule 100 mg	<i>Cyclosporin Sandoz</i>	<b>From:</b> SZ <b>To:</b> NM
Clindamycin	Capsule 150 mg (as hydrochloride)	<i>Clindamycin LU</i>	<b>From:</b> LV <b>To:</b> XT
Fenofibrate	Tablet 145 mg	<i>Fenocol</i>	<b>From:</b> YC <b>To:</b> XT
Ferric carboxymaltose	Injection 500 mg (iron) in 10 mL	<i>Ferinject</i>	<b>From:</b> VL <b>To:</b> CS
	Injection 1000 mg (iron) in 20 mL	<i>Ferinject</i>	<b>From:</b> VL <b>To:</b> CS
Mefenamic acid	Capsule 250 mg	<i>FEMIN</i>	<b>From:</b> LI <b>To:</b> XT
Paracetamol	Tablet 500 mg	<i>Febridol</i>	<b>From:</b> EA <b>To:</b> XT

Ripretinib	Tablet 50 mg	<i>Qinlock</i>	<b>From:</b> TS <b>To:</b> ZB
Trastuzumab	Powder for I.V. infusion 150 mg	<i>Ogivri</i>	<b>From:</b> AF <b>To:</b> SZ
Vinorelbine	Capsule 20 mg (as tartrate)	<i>Velabine</i>	<b>From:</b> LI <b>To:</b> XT
	Capsule 30 mg (as tartrate)	<i>Velabine</i>	<b>From:</b> LI <b>To:</b> XT

### **Addition of Pack Quantity**

<b>Listed Drug</b>	<b>Form</b>	<b>Brand Name</b>	<b>Pack Quantity</b>
Paracetamol	Tablet 665 mg (modified release)	<i>Parapane OSTEO</i>	192

### **Addition of Responsible Person**

#### **Responsible Person and Code**

Specialised Therapeutics Pm Pty Ltd (*ZB*)

### **Deletion of Responsible Person**

#### **Responsible Person and Code**

Amneal Pharmaceuticals Pty Ltd (*EA*)

Luminarie Pty Ltd (*LV*)

Cipla Australia Pty Ltd (*YC*)

### **Alteration of Circumstances in Which a Prescription May be Written**

#### **Listed Drug**

Acalabrutinib	Mecasermin
Alirocumab	Methotrexate
Avelumab	Niraparib
Cemiplimab	Obeticholic acid
Certolizumab pegol	Olaparib
Daratumumab	Ondansetron
Empagliflozin	Pembrolizumab
Evolocumab	Secukinumab
Fluticasone propionate with salmeterol	Selinexor
Gilteritinib	Tebentafusp
Golimumab	Upadacitinib

Lacosamide

### Supply Only – Additions

<i>Listed Drug</i>	<i>Form</i>
Estradiol	Transdermal patches 2 mg, 4 Transdermal patches 3.8 mg, 4 Transdermal patches 5.7 mg, 4 Transdermal patches 7.6 mg, 4
Paraffin with retinol palmitate	Eye ointment, compound, containing liquid paraffin, light liquid paraffin, wool fat, white soft paraffin and retinol palmitate, 5 g
Somatropin	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)

### Supply Only – Deletions

<i>Listed Drug</i>	<i>Form</i>
Hydralazine	Tablet containing hydralazine hydrochloride 25 mg Tablet containing hydralazine hydrochloride 50 mg
Sterculia with frangula bark	Granules 620 mg-80 mg per g, 500 g
Triglycerides, medium chain	Oral liquid 225 mL, 15 (K.Quik)
Triglycerides - medium chain, formula	Sachets containing oral powder 16 g, 30 (MCT Pro-Cal)

### Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Acalabrutinib Alirocumab Certolizumab pegol Evolocumab Golimumab Inclisiran Secukinumab Tebentafusp Upadacitinib	<b>Approved Product Information/Australian Product Information/TGA-approved Product Information.</b> The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i> . This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: <a href="https://www.tga.gov.au/product-information-0">https://www.tga.gov.au/product-information-0</a>

<p>Certolizumab pegol Golimumab Secukinumab Upadacitinib</p>	<p><b>Assessment of Spondyloarthritis International Society (ASAS) criteria</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The document is a self-described handbook on the clinical assessment of spondyloarthritis, with a focus on axial spondyloarthritis. Box 4 and 8, plus Table 2 within the document specifically give the clinician guidance in forming a diagnosis of non-radiographic axial spondyloarthritis.</p>	<p>The ASAS criteria are available for download for free from the ASAS group website: <a href="https://www.asas-group.org/wp-content/uploads/2020/07/ASAS-handbook.pdf">https://www.asas-group.org/wp-content/uploads/2020/07/ASAS-handbook.pdf</a></p> <p>The published literature reference is:</p> <p>Sieper J et al. The Assessment of SpondyloArthritis international Society (ASAS) handbook: a guide to assess spondyloarthritis. <i>Ann Rheum Dis</i> 2009; 68; ii1-ii44</p>
<p>Certolizumab pegol Golimumab Secukinumab Upadacitinib</p>	<p><b>Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The BASDAI is a widely used tool that enables measurement and evaluation of the level of disease activity in Ankylosing Spondylitis.</p>	<p>The BASDAI is available for download for free from the Services Australia website: <a href="http://www.servicesaustralia.gov.au">www.servicesaustralia.gov.au</a></p>
<p>Alirocumab Evolocumab Inclisiran</p>	<p><b>Dutch Lipid Clinic Network Score (DLCNS).</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The DLCNS is a validated set of criteria used to categorise the likelihood of a patient having Familial Hypercholesterolaemia, by evaluating family history of premature cardiovascular disease (CVD) in first degree relatives, the patient's own CVD history, their untreated lipid levels and physical signs such as the presence of tendon xanthomata or arcus cornealis prior to the age of 45.</p>	<p>The DLCNS is available for download for free from the Royal Australian College of General Practitioners website: <a href="https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Red%20Book/Appendix-2B.pdf">https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Red%20Book/Appendix-2B.pdf</a></p>
<p>Niraparib Olaparib</p>	<p><b>Gynaecologic Cancer InterGroup (GCIG) guidelines/GCIG CA-125 response criteria.</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The GCIG guidelines/GCIG CA-125 response criteria are a set of criteria for defining response and progression of ovarian cancer.</p>	<p>The GCIG guidelines/GCIG CA-125 response criteria are available for download for free in references from the Oxford University Press website: <a href="https://academic.oup.com/jnci/article/96/6/487/2606756">https://academic.oup.com/jnci/article/96/6/487/2606756</a></p>
<p>Acalabrutinib</p>	<p><b>International workshop on chronic lymphocytic leukemia (iwCLL) guidance.</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to</p>	<p>The iwCLL guidance is available for download for free from the Blood Journal website: <a href="https://ashpublications.org/blood/article/131/25/2745/37141/iwCLL-">https://ashpublications.org/blood/article/131/25/2745/37141/iwCLL-</a></p>

paragraph 14(1)(b) of the *Legislation Act 2003*.

This document provides health professionals with guidance on various aspects of management of CLL/SLL. Notably, two of these are:

- (1) when to treat versus when to monitor the patient without therapy – see ‘Indications for treatment’ section; and
- (2) recognising progressive disease – see ‘Definition of response, relapse, and refractory disease’ section.

[guidelines-for-diagnosis-indications-for](#)

The published literature reference is:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

Niraparib  
Olaparib

**The Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.**

The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*.

The RECIST guidelines are a tool used widely for defining when tumours in cancer patients respond, stabilise and/or progress during treatment.

The RECIST guidelines are available for download for free from the RECIST Working Group website: <https://recist.eortc.org/>

Alirocumab  
Evolocumab  
Inclisiran

**Thrombolysis in Myocardial Infarction (TIMI) risk score.**

The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*.

The TIMI score quantifies the risk of having or dying from a heart-related event in the next 14 days.

The TIMI risk score is available for download for free from the Journal of the American Medical Association website <https://jamanetwork.com/journals/jama/fullarticle/192996>

Cemiplimab

**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.**

The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*.

The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient’s daily living abilities, by evaluating a patient’s level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.).

The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: <https://ecog-acrin.org/resources/ecog-performance-status>



## 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 2024*

(PB 26 of 2024)

This Disallowable 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 Disallowable Legislative Instrument

The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* replaces the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* which sunsets on 1 April 2024. 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, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

This instrument also incorporates a number of changes to medicine listings that are scheduled to take effect on 1 April 2024 (see Analysis).

#### Human rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

##### *The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

##### *The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and

health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

## Analysis

The Instrument advances the right to health and the right to social security by providing a new drug, new forms and brands of existing listed drugs, and ensuring the deletion of drugs, forms and brands of listed drugs, does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of these human rights 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 Schedule are evidence-based. The Instrument includes the addition of 1 new drug, 2 new forms of existing drugs, and the addition of 24 new brands across 24 existing forms, which allows for greater patient access to these drugs.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with this Instrument and will be tabled with any subsequent monthly amendments to this Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of drugs and forms of drugs in the abovementioned instrument would not result in an unmet clinical need, except where indicated for a particular drug or form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been/will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are \$31.60 for general patients and \$7.70 for concession card holders.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

The drug abacavir with lamivudine and zidovudine (Trizivir) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug estradiol in the forms transdermal patches 2 mg, 4 (Climara 25), transdermal patches 3.8 mg, 4 (Climara 50), transdermal patches 5.7 mg, 4 (Climara 75), and transdermal patches 7.6 mg, 4 (Climara 100) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of these products would not result in an unmet clinical need. These items will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access these items pending transition to an alternative treatment option.

The drug fosamprenavir (Telzir) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are suitable alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug hydralazine (Alphapress 25, Alphapress 50) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the importance of hydralazine in the management of hypertension, especially in urgent situations and in renal disease, and advised the delisting of these products may result in an unmet clinical need. The Department sought to retain these products in line with this advice, however the sponsor indicated retention was not viable due to financial reasons and wished to proceed with the delisting. This item was available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug lopinavir with ritonavir in the form tablet 100 mg-25 mg (Kaletra) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug methylprednisolone in the form powder for injection 40 mg (as sodium succinate) (Methylpred) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are suitable alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug morphine in the forms sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 20 mg per sachet (MS Contin Suspension 20 mg), sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 30 mg per sachet (MS Contin Suspension 30 mg), sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 60 mg per sachet (MS Contin Suspension 60 mg), sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 100 mg per sachet (MS Contin Suspension 100 mg), and sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 200 mg per sachet (MS Contin Suspension 200 mg) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year. However, it considered that this may be due to supply issues and the inability to access these items rather than demand in clinical practice. The PBAC advised the delisting of these products may result in an unmet clinical need and requested that the Department seek to retain these products if possible. The sponsor was approached however requested to proceed with its delist request, advising that the products had been deregistered from the Australian Register of Therapeutic Goods and discontinued.

The drug paraffin with retinol palmitate (VitA-POS) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the moderate number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug somatropin in the form solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative) (NutropinAq) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug sterculia with frangula bark in the form granules 620 mg-80 mg per g, 500 g (Normacol Plus) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the substantial number of services in the previous year and that the product has been discontinued from supply. The

PBAC noted this product is the only bulk-forming laxative listed on the PBS Schedule and that no suitable PBS-subsidised pharmaceutical alternative is available. The PBAC advised the delisting of this product may result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 4 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug triglycerides, medium chain in the form oral liquid 225 mL, 15 (K.Quik) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and that there are no suitable alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain this product in line with this advice, however the sponsor indicated retention is not viable due to financial reasons and wished to proceed with the delisting. This item was available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug triglycerides - medium chain, formula in the form sachets containing oral powder 16 g, 30 (MCT Pro-Cal) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and that there are no suitable alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain this product in line with this advice, however the sponsor indicated retention is not viable due to financial reasons and wished to proceed with the delisting. This item was available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug tropisetron (Tropisetron-AFT) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

### **Conclusion**

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

**Nikolai Tsyganov**  
**Assistant Secretary**  
**Pricing and PBS Policy Branch**  
**Technology Assessment and Access Division**  
**Department of Health and Aged Care**