EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2020 (No. 5)

PB 42 of 2020

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to make changes to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

Subsection 88(1) provides that a medical practitioner is authorised to prescribe a pharmaceutical benefit. Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Supplying pharmaceutical benefits

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

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

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

Variation and revocation

Unless there is an express power to revoke or vary PB 71 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 71 of 2012.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the PBAC is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

Changes to PB 71 of 2012 made by this Instrument

Schedule 1 to this Instrument provides for the addition of the listed drugs amino acid formula with carbohydrate without phenylalanine, amino acid formula with fat, carbohydrate without methionine, amino acid formula with fat, carbohydrate without phenylalanine and tyrosine, and amino acid formula with fat, carbohydrate without valine, leucine and isoleucine to the PBS and the addition of a form each of the listed drugs ferric derisomaltose, and mepolizumab. Additionally, it provides for the deletion of the listed drug oxytocin from the PBS and the deletion of a form each of the listed drugs levodopa with carbidopa, and protein formula with carbohydrate, fat, vitamins and minerals. Furthermore, it provides for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs bortezomib, budesonide with formoterol, buprenorphine, certolizumab pegol, codeine, codeine with paracetamol, fentanyl, golimumab, hydromorphone, methadone, morphine, oxycodone, oxycodone with naloxone, tapentadol, and tramadol.

Schedule 1 to this Instrument also provides for the following changes:

- the addition of 23 brands and deletion of 5 brands of existing pharmaceutical items;
- the alteration of a maximum quantity and number of repeats applicable to 1 pharmaceutical item;
- the addition of a maximum quantity and number of repeats for 14 pharmaceutical items;
- the deletion of a maximum quantity and number of repeats for 2 pharmaceutical items; and
- the addition of pack quantity for 4 pharmaceutical items.

These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

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

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

General

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 June 2020.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2020 (No. 5)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 5)* and may also be cited as PB 42 of 2020.

Section 2 Commencement

This section provides that this Instrument commences on 1 June 2020.

Section 3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

This section provides that Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition and deletion of drugs, the addition and deletion of forms of drugs, the addition and deletion of brands, the alteration, addition, and deletion of maximum quantities and numbers of repeats, the addition of pack quantities, and alterations to the circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme. These changes are summarised below.

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

Listed Drugs Added

Listed Drug

Amino acid formula with carbohydrate without phenylalanine

Amino acid formula with fat, carbohydrate without methionine

Amino acid formula with fat, carbohydrate without phenylalanine and tyrosine

Amino acid formula with fat, carbohydrate without valine, leucine and isoleucine

Listed Drugs Deleted

Listed Drug

Oxytocin

Forms Added

Listed Drug	***Form***
Ferric derisomaltose	Injection 1000 mg (iron) in 10 mL
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen

Forms Deleted

Listed Drug	*Form*
Levodopa with carbidopa	Tablet (modified release) 200 mg-50 mg
Protein formula with carbohydrate, fat, vitamins and minerals	Oral liquid 500 mL, 8 (Nutrini Peptisorb Energy)

Brands Added

Listed Drug	*Form and Brand*
Amitriptyline	Tablet containing amitriptyline hydrochloride 10 mg (*Amitriptyline Lupin*)
	Tablet containing amitriptyline hydrochloride 25 mg (*Amitriptyline Lupin*)
	Tablet containing amitriptyline hydrochloride 50 mg (*Amitriptyline Lupin*)
Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms (*Doubluts*)
Fluoxetine	Capsule 20 mg (as hydrochloride) (*BTC Fluoxetine*, *Fluoxetine APOTEX)*
Isotretinoin	Capsule 10 mg (*Isotretinoin Lupin*)
	Capsule 20 mg (*Isotretinoin Lupin*)
Montelukast	Tablet, chewable, 4 mg (as sodium) (*Montelukast Lupin*)
	Tablet, chewable, 5 mg (as sodium) (*Montelukast Lupin*)
Perindopril	Tablet containing perindopril erbumine 2 mg (*BTC Perindopril, Perindopril APOTEX*)
	Tablet containing perindopril erbumine 4 mg (*BTC Perindopril, Perindopril APOTEX*)
	Tablet containing perindopril erbumine 8 mg (*BTC Perindopril, Perindopril APOTEX*)
Risperidone	Oral solution 1 mg per mL, 100 mL (*Rixadone)*
Sevelamer	Tablet containing sevelamer carbonate 800 mg (*Sevelamer Lupin*)
Valsartan with hydrochlorothiazide	Tablet 80 mg-12.5 mg (*Dilart HCT 80/12.5*)
	Tablet 160 mg-12.5 mg (*Dilart HCT 160/12.5*)
	Tablet 160 mg-25 mg (*Dilart HCT 160/25*)
	Tablet 320 mg-12.5 mg (*Dilart HCT 320/12.5*)
	Tablet 320 mg-25 mg (*Dilart HCT 320/25*)

Brands Deleted

Listed Drug	*Form and Brand*
Ciprofloxacin	Tablet 500 mg (as hydrochloride) (*Ciprofloxacin-BW*)
Doxepin	Capsule 10 mg (as hydrochloride) (*Sinequan*)
	Capsule 25 mg (as hydrochloride) (*Sinequan*)
Metformin	Tablet containing metformin hydrochloride 1 g (*Metformin generichealth 1000*)
Terbinafine	Tablet 250 mg (as hydrochloride) (*Terbinafine GH*)

Alteration of Maximum Quantity and Number of Repeats

Listed Drug	*Form*	*Maximum Quantity*	*Number of Repeats*
Ferric derisomaltose	Injection 500 mg (iron) in 5 mL	***From:*** 2 ***To:*** 3	***From:*** 1 ***To:*** 0

Addition of Maximum Quantity and Number of Repeats

Listed Drug	*Form*	*Maximum Quantity*	*Number of Repeats*
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	2	2
	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	1	2
Certolizumab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	2	0
	Solution for injection 200 mg in 1 mL pre-filled pen	2	0
Codeine	Tablet containing codeine phosphate hemihydrate 30 mg	10	0
Codeine with paracetamol	Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg	10	0
Hydromorphone	Tablet containing hydromorphone hydrochloride 2 mg	10	0
	Tablet containing hydromorphone hydrochloride 4 mg	10	0
	Tablet containing hydromorphone hydrochloride 8 mg	10	0
Morphine	Tablet containing morphine sulfate pentahydrate 30 mg	10	0
Oxycodone	Capsule containing oxycodone hydrochloride 5 mg	10	0
	Capsule containing oxycodone hydrochloride 10 mg	10	0
	Tablet containing oxycodone hydrochloride 5 mg	10	0
Tramadol	Capsule containing tramadol hydrochloride 50 mg	10	0

Deletion of Maximum Quantity and Number of Repeats

Listed Drug	*Form*	*Maximum Quantity*	*Number of Repeats*
Codeine with paracetamol	Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg	60	0
Tramadol	Capsule containing tramadol hydrochloride 50 mg	20	2

Addition of Pack Quantity

Listed Drug	*Form*	*Pack Quantity*
Lenalidomide	Capsule 5 mg	14
	Capsule 10 mg	14
	Capsule 15 mg	14
	Capsule 25 mg	14

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Bortezomib

Budesonide with formoterol

Buprenorphine

Certolizumab pegol

Codeine

Codeine with paracetamol

Fentanyl

Golimumab

Hydromorphone

Methadone

Morphine

Oxycodone

Oxycodone with naloxone

Tapentadol

Tramadol

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) Amendment Instrument 2020 (No. 5)

(PB 42 of 2020)

This 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 Instrument

The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 5)* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Principal Instrument) which 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).

The amendments in Schedule 1 involve the addition and deletion of drugs, the addition and deletion of forms of drugs, the addition and deletion of brands, the alteration, addition, and deletion of maximum quantities and numbers of repeats, the addition of pack quantities, and alterations to the circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme.

Human rights implications

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

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

Conclusion

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

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