

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2020 (No. 6)*

#### **PB 55 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 drug semaglutide to the PBS. Additionally, it provides for the deletion of the listed drug prasugrel and the deletion of forms of the listed drugs aspirin, diazepam, heparin, idarubicin, levodopa with carbidopa, ondansetron, phenelzine, and whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose from the PBS. Furthermore, it provides for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs atezolizumab, brentuximab vedotin, certolizumab pegol, golimumab, granisetron, ondansetron, and trastuzumab emtansine.

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

- the addition of 18 brands and deletion of 29 brands of existing pharmaceutical items;
- the deletion of a pack size of 1 existing brand of a pharmaceutical item;
- the alteration of responsible person codes for 3 existing brands of pharmaceutical items;
- the deletion of 1 responsible person from the list of responsible persons;
- the alteration of the number of repeats applicable to 4 pharmaceutical items; and
- the alteration of the section 100/prescriber bag only code applicable to 2 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 July 2020.

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

**PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2020 (No. 6)**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 6)* and may also be cited as PB 55 of 2020.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 July 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 deletion of forms of drugs, the addition and deletion of brands, the deletion of a pack size for an existing brand, the alteration of responsible person codes for a number of pharmaceutical benefits, the deletion of a responsible person code from the list of responsible persons, the alteration of numbers of repeats, the alteration of section 100/prescriber bag only codes, 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***

Semaglutide

**Listed Drugs Deleted**

***Listed Drug***

Prasugrel

**Forms Deleted**

***Listed Drug***

Aspirin

***Form***

Tablet, dispersible, 300 mg

Diazepam

Injection 10 mg in 2 mL

Heparin

Injection 35,000 units (as sodium) in 35 mL

Idarubicin

Capsule containing idarubicin hydrochloride 5 mg

Levodopa with carbidopa

Tablet 250 mg-25 mg (USP)

Ondansetron	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL
Phenelzine	Tablet 15 mg (as sulfate) (USP)
Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose	Sachets containing oral powder 100 g, 10 (RenaStart)

## Brands Added

### Listed Drug

Listed Drug	Form and Brand
Amoxicillin	Capsule 500 mg (as trihydrate) ( <i>NOUMED AMOXICILLIN</i> )
Carbimazole	Tablet 5 mg ( <i>NeoMercazole</i> )
Celecoxib	Capsule 100 mg ( <i>Celecoxib APOTEX</i> ) Capsule 200 mg ( <i>Celecoxib APOTEX</i> )
Gliclazide	Tablet 30 mg (modified release) ( <i>Pharmacor Gliclazide MR</i> ) Tablet 60 mg (modified release) ( <i>Pharmacor Gliclazide MR</i> )
Meloxicam	Tablet 7.5 mg ( <i>MELOBIC</i> ) Tablet 15 mg ( <i>MELOBIC</i> )
Montelukast	Tablet, chewable, 4 mg (as sodium) ( <i>Montelukast Mylan</i> ) Tablet, chewable, 5 mg (as sodium) ( <i>Montelukast Mylan</i> )
Naloxone	Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule ( <i>Junalox</i> )
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate) ( <i>NOUMED PANTOPRAZOLE</i> ) Tablet (enteric coated) 40 mg (as sodium sesquihydrate) ( <i>NOUMED PANTOPRAZOLE</i> )
Risperidone	Tablet 0.5 mg ( <i>NOUMED RISPERIDONE</i> ) Tablet 1 mg ( <i>NOUMED RISPERIDONE</i> ) Tablet 2 mg ( <i>NOUMED RISPERIDONE</i> ) Tablet 3 mg ( <i>NOUMED RISPERIDONE</i> ) Tablet 4 mg ( <i>NOUMED RISPERIDONE</i> )

## Brands Deleted

### Listed Drug

Listed Drug	Form and Brand
Amoxicillin	Capsule 250 mg (as trihydrate) ( <i>Amoxycillin Ranbaxy</i> ) Capsule 500 mg (as trihydrate) ( <i>Amoxycillin Ranbaxy</i> )
Anastrozole	Tablet 1 mg ( <i>Anastrozole AN; Astzol</i> )
Bicalutamide	Tablet 50 mg ( <i>Bicalide; Bicalutamide AN</i> )
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. ( <i>Bleo 15K</i> )

Capecitabine	Tablet 150 mg ( <i>Xelocitabine</i> ) Tablet 500 mg ( <i>Xelocitabine</i> )
Clonazepam	Tablet 500 micrograms ( <i>Rivotril</i> ) Tablet 2 mg ( <i>Rivotril</i> )
Clopidogrel	Tablet 75 mg (as hydrogen sulfate) ( <i>Plavix</i> )
Cyproterone	Tablet containing cyproterone acetate 50 mg ( <i>Cyprostat - Pack Quantity: 50</i> )
Dorzolamide with timolol	Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL ( <i>DORZOLAMIDE/TIMOLOL AN 20/5</i> )
Insulin glargine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 ( <i>Lantus; Lantus SoloStar</i> )
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL ( <i>IRINOTECAN ACT</i> ) I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL ( <i>IRINOTECAN ACT</i> )
Letrozole	Tablet 2.5 mg ( <i>Letroz; Letrozole AN</i> )
Metformin	Tablet containing metformin hydrochloride 500 mg ( <i>Metformin generichealth</i> )
Mirtazapine	Tablet 30 mg ( <i>Mirtazapine GH</i> )
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL ( <i>Paclitaxel ACT</i> ) Solution concentrate for I.V. infusion 100 mg in 16.7 mL ( <i>Paclitaxel ACT</i> ) Solution concentrate for I.V. infusion 150 mg in 25 mL ( <i>Paclitaxel ACT</i> ) Solution concentrate for I.V. infusion 300 mg in 50 mL ( <i>Paclitaxel ACT</i> )
Temozolomide	Capsule 20 mg ( <i>Temozolomide Amneal</i> ) Capsule 140 mg ( <i>Temozolomide Amneal</i> )
Tobramycin	Solution for inhalation 300 mg in 5 mL ( <i>Tobramycin AN</i> )

### Deletion of Pack Quantity

<b>Listed Drug</b>	<b>Form</b>	<b>Brand Name</b>	<b>Pack Quantity</b>
Isotretinoin	Capsule 20 mg	Roaccutane	60

### Alteration of Responsible Person Code

<b>Listed Drug</b>	<b>Form.</b>	<b>Brand Name</b>	<b>Responsible Person Code</b>
Ciclesonide	Pressurised inhalation 80 micrograms per dose, 120 doses (CFC-free formulation)	Alvesco 80	<b>From:</b> AP <b>To:</b> EU
	Pressurised inhalation 160 micrograms per dose, 120 doses (CFC-free formulation)	Alvesco 160	<b>From:</b> AP <b>To:</b> EU
Tetracosactide	Compound depot injection 1 mg in 1 mL	Synaethen Depot 1 mg/1 mL	<b>From:</b> LM <b>To:</b> IX

## Deletion of Responsible Person Code

### *Responsible Person and Code*

Reckitt Benckiser (Australia) Pty Limited (RC)

## Alteration of Number of Repeats

<i>Listed Drug</i>	<i>Form</i>	<i>Number of Repeats</i>
Alectinib	Capsule 150 mg	<i>From:</i> 1 <i>To:</i> 3
Ceritinib	Capsule 150 mg	<i>From:</i> 1 <i>To:</i> 3
Crizotinib	Capsule 200 mg	<i>From:</i> 1 <i>To:</i> 3
	Capsule 250 mg	<i>From:</i> 1 <i>To:</i> 3

## Alteration of Section 100/Prescriber Bag only Code

<i>Listed Drug</i>	<i>Form</i>	<i>Section 100/Prescriber Bag only Code</i>
Idarubicin	Solution for I.V. injection containing idarubicin hydrochloride 5 mg in 5 mL	<i>From:</i> PB(100) <i>To:</i> D(100)
	Solution for I.V. injection containing idarubicin hydrochloride 10 mg in 10 mL	<i>From:</i> PB(100) <i>To:</i> D(100)

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

### *Listed Drug*

Atezolizumab  
Brentuximab vedotin  
Certolizumab pegol  
Golimumab  
Granisetron  
Ondansetron  
Trastuzumab emtansine

## Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Certolizumab pegol Golimumab	<b>Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).</b> 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 BASDAI is a widely used tool that enables measurement and evaluation of the level of disease activity in Ankylosing Spondylitis.	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>

Trastuzumab emtansine

**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG)**

**Performance Status.** 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) Amendment Instrument 2020 (No. 6)*** **(PB 55 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. 6)* 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 deletion of forms of drugs, the addition and deletion of brands, the deletion of a pack size for an existing brand, the alteration of responsible person codes for a number of pharmaceutical benefits, the deletion of a responsible person code from the list of responsible persons, the alteration of numbers of repeats, the alteration of section 100/prescriber bag only codes, 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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