

## EXPLANATORY STATEMENT

### NATIONAL HEALTH ACT 1953

#### NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 8)

#### PB 79 of 2023

#### **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).

PB 71 of 2012 determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) 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).

This instrument commences immediately after commencement of Schedule 2 to the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (PB 57 of 2023). That instrument applies increased maximum dispensed quantities to 256 PBS items to implement the first stage of medicines approved for listing with an increased MDQ. The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 8)* (PB 79 of 2023) (the Instrument) makes a number of minor consequential changes to some of those items and also removes some items from the MDQ measure and adds other items to the measure as a result of changes to availability since the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* was made.

#### **Authority**

This Instrument is made under 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*

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.

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. Subsection 85A(2A) provides that the Minister may determine that particular conditions must be satisfied when writing a prescription for the maximum quantities and repeats.

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

Paragraph 88(1EB) provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit, allowing the benefit to be supplied only.

This legislative instrument is made pursuant to section 88 of the Act.

#### *Supplying pharmaceutical benefits*

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.

#### *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.

### **Background**

The MDQ is the maximum number or quantity of units of a pharmaceutical benefit that can be prescribed for a particular purpose for supply to a patient on the one occasion under the PBS. Currently, the MDQ for many PBS medicines used in the treatment of chronic medical conditions equates to one month's supply.

In December 2022, the PBAC considered and provided advice to the Minister for Health and Aged Care on a proposal that would improve access to PBS medicines for patients with stable, chronic medical conditions by providing prescribers the choice to prescribe an increased quantity for selected PBS medicines - two months' or three months' supply instead of the current one month's supply at each dispensing.

The PBAC considered a list of medicines from the General Schedule (section 85) of the PBS listed for use in treatment of chronic conditions for suitability for the proposal. Based on an assessment of clinical safety and ongoing cost-effectiveness, the PBAC recommended that over 300 medicines were acceptable for listing with increased MDQ. The PBAC also agreed on standard restriction wording for all medicines included in this proposal, to ensure the higher MDQ items are only prescribed to patients whose condition is stable.

Schedule 2 to the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* will amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* on 1 September 2023 to introduce the first of three stages of implementation of increased MDQ. Schedule 2 to the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* amends the listings of 256 PBS items to implement MDQ.

New PBS items with the increased MDQ are being included in the Schedule of Pharmaceutical Benefits in addition to the medicine's current PBS items that provide for one month's supply and five repeats (in general). This will facilitate prescribing of smaller quantities than the new MDQ for patients as clinically appropriate, to avoid medicine wastage and support closer clinical monitoring of patients where required.

The PBAC considered this proposal would allow clinicians to exercise greater choice to prescribe the increased MDQ if clinically appropriate and provide patients with both financial and convenience benefits. The PBAC also considered allowing either two or three months' supply for dispensing on the one occasion was safe for the list of recommended medicines and considered that the implementation of increased MDQ allowing two or three months' supply was a decision for the Australian Government.

The Minister for Health and Aged Care announced the Government's intention to implement the two-month MDQ proposal on 26 April 2023 as part of the 2023-24 Budget. The Minister, in announcing the measure, highlighted the reforms would deliver important and immediate cost of living relief to Australians with chronic health conditions. The Minister announced the Government's decision to implement the policy in three stages, with increased MDQ applied to the first set of medicines from 1 September 2023, to the second set of medicines from March 2024 and to the remaining set of medicines from 1 September 2024. Phased introduction of MDQ will allow the pharmacy sector additional time to adjust to the new practices required to implement these changes.

Implementation of the first stage of MDQ has been designed to maximise the financial and convenience benefits for the greatest number of patients and to deliver these benefits at the earliest possible opportunity. The medicines in stage 1 include many high-volume PBS items for high blood pressure and high cholesterol, chronic medical conditions that affect many Australians.

An increase in the MDQ for certain medicines used in treating chronic conditions will improve access to and affordability of PBS medicines and build on the recent PBS General Patient Co-Payment reduction to \$30 on 1 January 2023. It will also mean that patients with chronic, stable medical conditions will need to make less visits to a pharmacy and their prescriber for some common PBS medicines. It will result in reduced 'out of pocket costs' for both concessional and general patients and provide added convenience for many people. Recent public representations and discussion have indicated broad support from prescribers and consumers for the policy.

#### Evaluation of MDQ and stakeholder impacts

The Department has committed to developing a comprehensive evaluation framework that will monitor risks and provide mitigation strategies over the course of implementation. This will utilise existing data sources (including PBS claims data) to analyse uptake rates of increased MDQ items, medicine shortages, pharmacovigilance and medicine wastage.

Lower health care costs for patients and Government and maintenance of patient safety will be evaluated by reviewing the PBS statistics for MDQ PBS items. Once sufficient PBS data is available, the utilisation of the new MDQ PBS items and the quantity of medicine dispensed will be monitored and the savings for consumers will be quantified through research conducted by the PBS Post-Market Review program. These utilisation reviews would be considered by the Drug Utilisation Sub-Committee (DUSC) of the PBAC, and any concerns referred to the PBAC.

The Department's planned evaluation framework will utilise existing well-developed processes within the Therapeutic Goods Administration (TGA) and the PBS program to assess outcomes of the implementation of MDQ on patient safety, optimal use of medicines and to identify/evaluate any previously unreported adverse reactions to MDQ medicines (pharmacovigilance). The TGA will continue to monitor all spontaneous reports of adverse medicine events and will inform the Department and the PBAC of any emerging trends in adverse reactions or medicine misuse associated with these medicines.

The Department has committed to evaluating the impacts of MDQ on all affected stakeholders through existing mechanisms. The impact on the community pharmacy sector remuneration and continued participation in community pharmacy programs will be monitored through the existing Seventh Community Pharmacy Agreement (7CPA). The Department will monitor the number and distribution of pharmacies across Australia. The ongoing impact on wholesalers will be monitored through the 7CPA. Evaluation of financial impacts will be dependent on affected stakeholders providing necessary financial information at a granular level. The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.

#### **Changes to *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* made by this Instrument**

Schedule 1 to this Instrument provides for the following amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, which affect some of the drugs approved for implementation of increased MDQ in stage 1:

- updating of circumstances and purposes codes for 88 listed drugs to align the codes with those used by software systems for the prescribing, dispensing and claiming of pharmaceutical benefits. This is a technical change only and does not affect the circumstances in which increased MDQ prescribing will be allowed
- the removal of increased MDQ for 11 pharmaceutical benefits initially slated for commencement in Stage 1 but that currently have supply availability concerns
- the addition of increased MDQ for 4 pharmaceutical benefits for which supply shortages have resolved since the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* was made
- the addition of 12 brands of pharmaceutical benefits which have been newly listed on the PBS and where other brands of the benefit will be subject to increased MDQ because of the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*
- the deletion of 2 brands scheduled to be delisted from the PBS on 1 October 2023
- the addition of 156 pharmaceutical items to Supply Only arrangements.

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.

Extensive consultation took place in relation to the amendments to be made by Schedule 2 to the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* to implement stage 1 of MDQ.

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 immediately after Schedule 2 to the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*, which will commence on 1 September 2023.

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 2023 (No. 8)**

### **Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 8)* and may also be cited as PB 79 of 2023.

### **Section 2 Commencement**

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, Schedule 1 to the Instrument commences immediately after the commencement of Schedule 2 of the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (PB 57 of 2023), which will commence on 1 September 2023.

### **Section 3 Authority**

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

### **Section 4 Schedules**

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms. Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (Main Listing Instrument).

### **Schedule 1 Amendments**

The amendments in Schedule 1 involve:

- the substitution of new circumstances and purposes codes for the PBS listings for increased maximum quantity prescribing for PBS items included in Stage 1 of the MDQ measure to align the codes with those used by software systems for the prescribing, dispensing and claiming of pharmaceutical benefits. When the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* was made, the final circumstances and purposes codes to be used by software systems were not able to be generated. The substitution of the final codes does not affect the content of the circumstances in which or purposes for which prescriptions may be written for increased maximum quantity dispensing but is a minor technical change only;
- the removal of the option for increased maximum quantity prescribing for a small number of PBS items initially intended for inclusion in Stage 1 of the MDQ measure commencing on 1 September 2023.  
Since the making of the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*, supply availability concerns have arisen about these items. The Instrument will amend the Main Listing Instrument to remove the option for increased maximum quantity prescribing with effect from 1 September 2023 for these items, immediately after the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* commences;
- the inclusion of the option for increased maximum quantity prescribing for a small number of PBS items. At the time of making the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*, these items were omitted from Stage 1 of the MDQ measure because of concerns about possible supply shortages. Since then supply shortages have resolved. The Instrument will therefore amend the Main Listing Instrument to include these items in Stage 1 as originally intended;

- the removal of the option for increased maximum quantity prescribing for brands of PBS items which are scheduled to be delisted from the PBS on 1 October 2023 and are therefore unsuitable for commencement of increased maximum quantity prescribing on 1 September 2023;
- the inclusion of the option for increased maximum quantity prescribing for a small number of newly PBS-listed brands of PBS items where other brands of these items are already included in the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* for commencement of increased maximum quantity prescribing on 1 September 2023;
- the repeal of a number of PBS items from Part 1 of Schedule 1 of the Main Listing Instrument and their movement to Part 2 of Schedule 1, in other words movement to Supply Only arrangements. This means that new prescriptions for these items cannot be written, although supplies can continue to be made on existing prescriptions. The relevant PBS items all provided for the writing of prescriptions with 11 repeats of one month's supply, totalling a year's supply, for patients receiving treatment under Medicare care plans for patients with certain chronic conditions. Because these items are included in the MDQ measure, from 1 September 2023 prescribers can write a prescription for two months' supply with 5 repeats, totalling a year's supply, for suitable patients with eligible stable chronic conditions. Prescribers will retain the option to write prescriptions for one month's supply with five repeats for these PBS items.

These changes are summarised below.

### **SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME MADE BY SCHEDULE 1 OF THIS INSTRUMENT**

#### **Alteration of Circumstances and Purposes Codes**

<i>Listed Drug</i>	<i>Listed Drug</i>
Adapalene with benzoyl peroxide	Lercanidipine
Alendronic acid	Lercanidipine with enalapril
Allopurinol	Lisinopril
Amlodipine	Mesalazine
Amlodipine with atorvastatin	Metoprolol
Amlodipine with valsartan	Metoprolol succinate
Amlodipine with valsartan and hydrochlorothiazide	Moxonidine
Apixaban	Nebivolol
Atenolol	Nicorandil
Atorvastatin	Nifedipine
Baclofen	Olmesartan
Balsalazide	Olmesartan with amlodipine
Bisoprolol	Olmesartan with amlodipine and hydrochlorothiazide
Calcipotriol with betamethasone	Olmesartan with hydrochlorothiazide

Calcitriol	Pancreatic extract
Calcium	Penicillamine
Candesartan	Perindopril
Candesartan with hydrochlorothiazide	Perindopril with amlodipine
Carvedilol	Perindopril with indapamide
Chlortalidone	Potassium chloride
Clonidine	Potassium chloride with potassium bicarbonate
Clopidogrel	Pravastatin
Clopidogrel with aspirin	Prazosin
Dabigatran etexilate	Propranolol
Enalapril	Raloxifene
Enalapril with hydrochlorothiazide	Ramipril
Eplerenone	Ramipril with felodipine
Ezetimibe	Risedronic acid
Ezetimibe and rosuvastatin	Rivaroxaban
Ezetimibe with atorvastatin	Rosuvastatin
Ezetimibe with simvastatin	Sacubitril with valsartan
Febuxostat	Simvastatin
Felodipine	Spironolactone
Fenofibrate	Sulfasalazine
Fluvastatin	Telmisartan
Furosemide	Telmisartan with amlodipine
Glyceryl trinitrate	Telmisartan with hydrochlorothiazide
Hydrochlorothiazide	Thiamine
Hydrochlorothiazide with amiloride	Ticagrelor
Indapamide	Trandolapril
Irbesartan	Trandolapril with verapamil
Irbesartan with hydrochlorothiazide	Valsartan
Isosorbide dinitrate	Valsartan with hydrochlorothiazide

Isosorbide mononitrate

Verapamil



### **Increased MDQ removed due to supply availability concerns**

<b>Listed Drug</b>	<b>Form</b>
Hydralazine	Tablet containing hydralazine hydrochloride 25 mg Tablet containing hydralazine hydrochloride 50 mg
Labetalol	Tablet containing labetalol hydrochloride 100 mg
Methyldopa	Tablet 250 mg (as sesquihydrate)
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)
Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg
Probenecid	Tablet 500 mg
Quinapril	Tablet 5 mg (as hydrochloride) Tablet 10 mg (as hydrochloride) Tablet 20 mg (as hydrochloride)

### **Increased MDQ added due to the resolving of supply shortages**

<b>Listed Drug</b>	<b>Form</b>
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium)
Ezetimibe with atorvastatin	Tablet 10 mg-20 mg
Gemfibrozil	Tablet 600 mg
Isosorbide mononitrate	Tablet 120 mg

### **Brands Added**

<b>Listed Drug</b>	<b>Form and Brand</b>
Clonidine	Tablet containing clonidine hydrochloride 100 micrograms ( <i>Clonidine Lupin</i> )
Perindopril	Tablet containing perindopril arginine 2.5 mg ( <i>APX-Perindopril Arginine</i> ) Tablet containing perindopril arginine 5 mg ( <i>APX-Perindopril Arginine</i> ) Tablet containing perindopril arginine 10 mg ( <i>APX-Perindopril Arginine</i> )
Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate) ( <i>APX-Perindopril Arginine/Amlodipine 5/5</i> )

Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)  
(*APX-Perindopril Arginine/Amlodipine 5/10*)

Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate)  
(*APX-Perindopril Arginine/Amlodipine 10/5*)

Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)  
(*APX-Perindopril Arginine/Amlodipine 10/10*)

Rosuvastatin      Tablet 5 mg (as calcium) (*Blooms Rosuvastatin*)  
                          Tablet 10 mg (as calcium) (*Blooms Rosuvastatin*)  
                          Tablet 20 mg (as calcium) (*Blooms Rosuvastatin*)  
                          Tablet 40 mg (as calcium) (*Blooms Rosuvastatin*)

### Brands Deleted

**Listed Drug                      Form and Brand**

Fenofibrate                      Tablet 48 mg (*Fenofibrate Mylan*)  
     Tablet 145 mg (*Fenofibrate Mylan*)

### Supply Only – Additions

<b>Listed Drug</b>	<b>Form</b>	<b>Brand Name</b>	<b>Maximum Quantity</b>	<b>Number of Repeats</b>
Atorvastatin	Tablet 10 mg (as calcium)	<i>APO-Atorvastatin</i>	30	11
		<i>Atorvachol</i>	30	11
		<i>Atorvastatin GH</i>	30	11
		<i>Atorvastatin SZ</i>	30	11
		<i>Blooms the Chemist Atorvastatin</i>	30	11
		<i>Lipitor</i>	30	11
		<i>Lorstat 10</i>	30	11
		<i>NOUMED ATORVASTATIN</i>	30	11
		<i>Pharmacor Atorvastatin</i>	30	11
	<i>Trovas</i>	30	11	
	Tablet 20 mg (as calcium)	<i>APO-Atorvastatin</i>	30	11
		<i>Atorvachol</i>	30	11
		<i>Atorvastatin GH</i>	30	11
		<i>Atorvastatin SZ</i>	30	11
		<i>Blooms the Chemist Atorvastatin</i>	30	11
		<i>Lipitor</i>	30	11
		<i>Lorstat 20</i>	30	11
		<i>NOUMED ATORVASTATIN</i>	30	11

		<i>Pharmacor Atorvastatin</i>	30	11
		<i>Trovas</i>	30	11
Tablet 40 mg (as calcium)		<i>APO-Atorvastatin</i>	30	11
		<i>Atorvachol</i>	30	11
		<i>Atorvastatin GH</i>	30	11
		<i>Atorvastatin SZ</i>	30	11
		<i>Blooms the Chemist Atorvastatin</i>	30	11
		<i>Lipitor</i>	30	11
		<i>Lorstat 40</i>	30	11
		<i>NOUMED ATORVASTATIN</i>	30	11
		<i>Pharmacor Atorvastatin</i>	30	11
		<i>Trovas</i>	30	11
Tablet 80 mg (as calcium)		<i>APO-Atorvastatin</i>	30	11
		<i>Atorvachol</i>	30	11
		<i>Atorvastatin GH</i>	30	11
		<i>Atorvastatin SZ</i>	30	11
		<i>Blooms the Chemist Atorvastatin</i>	30	11
		<i>Lipitor</i>	30	11
		<i>Lorstat 80</i>	30	11
		<i>NOUMED ATORVASTATIN</i>	30	11
		<i>Pharmacor Atorvastatin</i>	30	11
		<i>Trovas</i>	30	11
Fenofibrate	Tablet 48 mg	<i>APO-Fenofibrate</i>	60	11
		<i>Fenofibrate Cipla</i>	60	11
		<i>Fenofibrate Mylan</i>	60	11
		<i>FENOFIBRATE RBX</i>	60	11
		<i>Fenofibrate Viatris</i>	60	11
		<i>Lipidil</i>	60	11
	Tablet 145 mg	<i>APO-Fenofibrate</i>	30	11
		<i>Blooms the Chemist Fenofibrate</i>	30	11
		<i>Fenocol</i>	30	11
		<i>Fenofibrate Cipla</i>	30	11
		<i>Fenofibrate Mylan</i>	30	11
		<i>FENOFIBRATE RBX</i>	30	11
		<i>Fenofibrate Sandoz</i>	30	11
		<i>Fenofibrate Viatris</i>	30	11
		<i>Lipidil</i>	30	11

Fluvastatin	Tablet (prolonged release) 80 mg (as sodium)	<i>Lescol XL</i>	28	11
Gemfibrozil	Tablet 600 mg	<i>Ausgem</i>	60	11
		<i>Lipigem</i>	60	11
Pancreatic extract	Capsule (containing enteric coated minimicrospheres) providing not less than 10,000 BP units of lipase activity	<i>Creon 10,000</i>	500	21
		<i>Creon 25,000</i>	200	21
		<i>Creon 35,000</i>	200	21
		<i>Creon Micro</i>	3	21
Pravastatin	Tablet containing pravastatin sodium 10 mg	<i>APO-Pravastatin</i>	30	11
		<i>APX-Pravastatin</i>	30	11
		<i>Cholstat 10</i>	30	11
		<i>Lipostat 10</i>	30	11
		<i>Pravachol</i>	30	11
		<i>Pravastatin Sandoz</i>	30	11
	Tablet containing pravastatin sodium 20 mg	<i>APO-Pravastatin</i>	30	11
		<i>APX-Pravastatin</i>	30	11
		<i>Cholstat 20</i>	30	11
		<i>Lipostat 20</i>	30	11
		<i>Pravachol</i>	30	11
		<i>Pravastatin Sandoz</i>	30	11
	Tablet containing pravastatin sodium 40 mg	<i>APO-Pravastatin</i>	30	11
		<i>APX-Pravastatin</i>	30	11
		<i>Cholstat 40</i>	30	11
		<i>Lipostat 40</i>	30	11
<i>Pravachol</i>		30	11	
<i>Pravastatin Sandoz</i>		30	11	
Tablet containing pravastatin sodium 80 mg	<i>APO-Pravastatin</i>	30	11	
	<i>APX-Pravastatin</i>	30	11	

		<i>Lipostat 80</i>	30	11
		<i>Pravachol</i>	30	11
Rosuvastatin	Tablet 5 mg (as calcium)	<i>APX-Rosuvastatin</i>	30	11
		<i>Blooms the Chemist Rosuvastatin</i>	30	11
		<i>Cavstat</i>	30	11
		<i>Crestor</i>	30	11
		<i>Crosuva 5</i>	30	11
		<i>Noumed Rosuvastatin</i>	30	11
		<i>Pharmacor Rosuvastatin 5</i>	30	11
		<i>Rosuvastatin APOTEX</i>	30	11
		<i>Rosuvastatin Lupin</i>	30	11
		<i>Rosuvastatin RBX</i>	30	11
		<i>Rosuvastatin Sandoz</i>	30	11
	Tablet 10 mg (as calcium)	<i>APX-Rosuvastatin</i>	30	11
		<i>Blooms the Chemist Rosuvastatin</i>	30	11
		<i>Cavstat</i>	30	11
		<i>Crestor</i>	30	11
		<i>Crosuva 10</i>	30	11
		<i>Noumed Rosuvastatin</i>	30	11
		<i>Pharmacor Rosuvastatin 10</i>	30	11
		<i>Rosuvastatin APOTEX</i>	30	11
		<i>Rosuvastatin Lupin</i>	30	11
		<i>Rosuvastatin RBX</i>	30	11
		<i>Rosuvastatin Sandoz</i>	30	11
	Tablet 20 mg (as calcium)	<i>APX-Rosuvastatin</i>	30	11
		<i>Blooms the Chemist Rosuvastatin</i>	30	11
		<i>Cavstat</i>	30	11
		<i>Crestor</i>	30	11
		<i>Crosuva 20</i>	30	11
		<i>Noumed Rosuvastatin</i>	30	11
		<i>Pharmacor Rosuvastatin 20</i>	30	11
		<i>Rosuvastatin APOTEX</i>	30	11
		<i>Rosuvastatin Lupin</i>	30	11
		<i>Rosuvastatin RBX</i>	30	11
		<i>Rosuvastatin Sandoz</i>	30	11

	Tablet 40 mg (as calcium)	<i>APX-Rosuvastatin</i>	30	11
		<i>Blooms the Chemist Rosuvastatin</i>	30	11
		<i>Cavstat</i>	30	11
		<i>Crestor</i>	30	11
		<i>Crosuva 40</i>	30	11
		<i>Noumed Rosuvastatin</i>	30	11
		<i>Pharmacor Rosuvastatin 40</i>	30	11
		<i>Rosuvastatin APOTEX</i>	30	11
		<i>Rosuvastatin Lupin</i>	30	11
		<i>Rosuvastatin RBX</i>	30	11
		<i>Rosuvastatin Sandoz</i>	30	11
Simvastatin	Tablet 5 mg	<i>Simvastatin Sandoz</i>	30	11
		<i>Zimstat</i>	30	11
	Tablet 10 mg	<i>APO-Simvastatin</i>	30	11
		<i>NOUMED SIMVASTATIN</i>	30	11
		<i>Simvar 10</i>	30	11
		<i>Simvastatin Sandoz</i>	30	11
		<i>Zimstat</i>	30	11
	Tablet 20 mg	<i>APO-Simvastatin</i>	30	11
		<i>Lipex 20</i>	30	11
		<i>NOUMED SIMVASTATIN</i>	30	11
		<i>Simvar 20</i>	30	11
		<i>Simvastatin Sandoz</i>	30	11
		<i>Zimstat</i>	30	11
		<i>Zocor</i>	30	11
	Tablet 40 mg	<i>APO-Simvastatin</i>	30	11
		<i>Lipex 40</i>	30	11
		<i>NOUMED SIMVASTATIN</i>	30	11
		<i>Simvar 40</i>	30	11
		<i>Simvastatin Sandoz</i>	30	11
		<i>Zimstat</i>	30	11
		<i>Zocor</i>	30	11
	Tablet 80 mg	<i>APO-Simvastatin</i>	30	11
		<i>Simvar 80</i>	30	11
		<i>Simvastatin Sandoz</i>	30	11
		<i>Zimstat</i>	30	11
Sulfasalazine	Tablet 500 mg	<i>Salazopyrin</i>	200	11
	Tablet 500 mg (enteric)	<i>Pyralin EN</i>	200	11

### Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Ezetimibe with atorvastatin	<p><b>Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance)</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>This document provides health professionals with the Australian CVD risk calculator which calculates a risk score, expressed as a percentage, which is a person's chance of having a heart attack or stroke in the next five years. This calculator has been produced by the National Vascular Disease Prevention Alliance.</p>	<p>The Risk Calculator can be accessed free of charge at <a href="https://www.cvdcheck.org.au/calculator">https://www.cvdcheck.org.au/calculator</a></p>

## 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 2023 (No. 8)*** **(PB 79 of 2023)**

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 2023 (No. 8)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) 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).

On 1 September 2023 the Principal Instrument will be amended by Schedule 2 to the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* to implement the maximum dispensed quantity (MDQ) measure. The MDQ measure increases the maximum quantity that may be prescribed to be dispensed on one occasion for certain pharmaceutical benefits, in certain circumstances, from one to two months' supply. As a result of the changes, an eligible patient can be prescribed two months' supply of a pharmaceutical benefit to be dispensed on the one occasion under the PBS.

The amendments made by the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* are the first of three stages of implementation of the MDQ measure. Stage 1 includes some medicines for chronic conditions such as cardiovascular disease, Crohn disease, gout, heart failure, high cholesterol, hypertension, osteoporosis, and ulcerative colitis. Patients will only be eligible to receive an increased supply where their chronic condition is stable.

The Instrument makes the following changes to the list of drugs approved for implementation of increased MDQ in stage 1:

- substitutes new circumstances and purposes codes for the PBS listings for increased maximum quantity prescribing for PBS items included in Stage 1 of the MDQ measure to align the codes with those used by software systems for the prescribing, dispensing and claiming of pharmaceutical benefits. When the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* was made, the final circumstances and purposes codes to be used by software systems were not able to be generated, The substitution of the final codes does not affect the content of the circumstances in which or purposes for which prescriptions may be written for increased maximum quantity dispensing but is a minor technical change only;
- removes the option for increased maximum quantity prescribing for a small number of PBS items initially intended for inclusion in Stage 1 of the MDQ measure commencing on 1 September 2023. Since the making of the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*, supply availability concerns have arisen about these items. The Instrument will amend the Principal Instrument to remove the option for increased maximum quantity prescribing with effect from 1 September 2023 for these items, immediately after the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* commences;
- includes the option for increased maximum quantity prescribing for a small number of PBS items. At the time of making the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*, these items were omitted from Stage 1 of the MDQ measure because of concerns about possible supply shortages. Since then supply shortages have resolved. The



Instrument will therefore amend the Principal Instrument to include these items in Stage 1 as originally intended;

- removes the option for increased maximum quantity prescribing for brands of PBS items which are scheduled to be delisted from the PBS on 1 October 2023 and are therefore unsuitable for commencement of increased maximum quantity prescribing on 1 September 2023;
- includes the option for increased maximum quantity prescribing for a small number of newly PBS-listed brands of PBS items where other brands of these items are already included in the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* for commencement of increased maximum quantity prescribing on 1 September 2023; and
- repeals a number of PBS listings from Part 1 of Schedule 1 of the Main Listing Instrument and moves them to Part 2 of Schedule 1, in other words movement to Supply Only arrangements. This means that new prescriptions for these items cannot be written, although supplies can continue to be made on existing prescriptions. The relevant PBS items all provided for the writing of prescriptions with 11 repeats of one month's supply, totalling a year's supply, for patients receiving treatment under Medicare care plans for patients with certain chronic conditions. Because these items are included in the MDQ measure and from 1 July 2023, prescribers can write a prescription for two months' supply with 5 repeats, totalling a year's supply, for suitable patients with eligible stable chronic conditions. Prescribers will retain the option to write prescriptions for one month's supply with five repeats for these PBS items.

## **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 Pharmaceutical Benefits Scheme (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 Schedule are evidence-based.

The MDQ measure will be implemented on 1 September 2023 by amendments to the Principal Instrument made by the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*. A detailed analysis of the human rights implications of the MDQ measure is included in the Statement of Compatibility with Human Rights in the Explanatory Statement for that instrument which can be found on the Federal Register of Legislation at [National Health Legislation Amendment \(Opioid Dependence Treatment and Maximum Dispensed Quantities\) Instrument 2023](#). However, the overall policy behind the MDQ measure is to address the affordability of medicines and the cost-of-living pressures many Australians are currently facing. The MDQ increases the amount of eligible drugs that eligible patients can receive for a single co-payment, which allows for greater patient access to these drugs, convenience and financial savings. The lowering of costs to patients is likely to have a positive impact on patient medication compliance and associated health outcomes.

Substitution of new purposes and circumstances codes does not affect human rights. These amendments are to codes only and do not affect the circumstances in which or purposes for which any of the affected PBS items can be prescribed.

Amendments to remove the option for increased maximum quantity prescribing for a small number of PBS items where supply availability concerns have arisen since the making of the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* overall promote the rights to health and social security. While the removal of the option will mean that eligible patients cannot get the benefit of an increased supply of medicines for a single co-payment, the removal of the option for increased maximum quantity prescribing ensures that the implementation of the MDQ measure does not risk exacerbating any shortages of these medicines in the community as a whole. It should nevertheless be noted that:

- before making the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* the Minister sought advice from the PBAC who noted that the number of patients and volume of medicines prescribed will not change significantly as a result of the MDQ measure and that any shortages were likely to be short-term as the system adjusts to a new phased model of supply;
- the TGA works with many stakeholders to manage shortages and can take a range of actions to assist. These actions are discussed in detail in the Statement of Compatibility with Human Rights in the Explanatory Statement for the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* but include approving the supply of overseas-registered alternative products under section 19A of the *Therapeutic Goods Act 1989*, working with key stakeholders to manage inventory, including constraining supply to enable fair distribution of stock in Australia and implementing a Serious Scarcity Substitution Instrument, which allows pharmacists to dispense certain identified substitute medicines when a medicine is in shortage; and
- pharmacists and prescribers already manage medicine supply shortages in a number of ways on a daily basis.

Amendments to extend the option of increased maximum quantity prescribing to a small number of new PBS items that have come out of shortage since the *Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* was made, and the inclusion of newly listing brands of PBS items in the MDQ measure, where other brands of the item will also be included in the measure from 1 September 2023, will promote the rights to health and social security by enabling eligible patients to receive an increased supply of these items or brands for the same co-payment. As with other PBS items included in the MDQ measure, prescribers are not required to prescribe the increased quantity and retain their capacity to use their clinical judgement about whether a patient should continue to only be dispensed one month's supply at a time.

The movement of a number of PBS listings to Supply Only arrangements will not affect the rights to health or social security. The option to prescribe a year's supply of these medicines to patients receiving treatment for chronic conditions in the form of one original one month's supply with 11 repeats has been replaced by an option to prescribe a year's supply in the form of one original supply for two months with 5 repeats. It is

unnecessary to retain the capacity to write new prescriptions for one month's supply with 11 repeats. The movement to supply ensures that existing prescriptions can be continue to be used.

Where there are many brands of a listed drug and form, then the removal of one brand from the increased MDQ measure will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The removal of brands from the increased MDQ measure 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 removal of brands from the increased MDQ measure in this instrument do not result in an unmet clinical need.

### **Conclusion**

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

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