**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH LEGISLATION AMENDMENT
(MAXIMUM DISPENSED QUANTITIES) INSTRUMENT 2024*PB 14 of 2024**

**Purpose**

The purpose of this legislative instrument is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*(PB 71 of 2012) (the Main Listing Instrument) to increase the maximum dispensed quantity (MDQ) 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.

These changes will commence on 1 March 2024, as the second of three stages of implementation of the MDQ measure. Stage 2 includes some medicines for chronic conditions such as hypothyroidism, diabetes, menopause, androgen deficiency, incontinence, prostate enlargement, epilepsy, migraine, bipolar disorder, breast cancer, prostate cancer, osteoporosis and arthritis.

This instrument applies increased maximum dispensed quantities to 238 PBS items to implement the second stage of medicines approved for listing with an increased MDQ.

**Authority**

Amendments to the Main Listing Instrument

Section 84AF of the Act enables the Minister to determine the responsible person for a brand of a pharmaceutical item. The responsible person is to be the person who has notified the Minister they are, or will be, the person who is, or will be, the supplier of a particular brand of a pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the responsible person for all pharmaceutical items that have that brand.

Section 84AK of the Act enables the Minister to determine the pack quantity for a brand of a pharmaceutical item.

Section 85 of the Act enables the Minister to:

* declare drugs and medicinal preparations to be drugs or medicinal preparations to which Part VII applies (subsection 85(2)). A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a ‘listed drug’;
* determine the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3));
* determine the manner of administration of a form of a listed drug (subsection 85(4));
* determine a brand of a pharmaceutical item (subsection 85(6));
* determine that a brand of a pharmaceutical item is to be treated as equivalent to one or more other brands of pharmaceutical items, for the purposes of paragraph 103(2A)(b) of the Act (subsection 85(6A)); and
* determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit (subsection 85(7)).

Section 85A of the Act enables the Minister to:

* determine the maximum quantity or number of units of a pharmaceutical item in a pharmaceutical benefit that may, in one prescription, be directed to be supplied to a patient on one occasion (paragraph 85A(2)(a));
* determine the maximum number of occasions on which the supply of a pharmaceutical benefit may, in one prescription, be directed to be repeated (paragraph 85A(2)(b)); and
* determine that particular conditions must be satisfied when writing a prescription for the maximum quantities and repeats (subsection 85A(2A)).

Section 88 of the Act enables the Minister to determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)) and authorised nurse practitioners (subsection 88(1E)).

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

**Background – Maximum Dispensed Quantity**

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 1 to the *National Health* *Legislation Amendment (**Maximum Dispensed Quantities) Instrument 2024* amends the listings of 238 PBS items to implement stage 2 of MDQ.

New PBS items with the increased MDQ will be 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 PBAC’s advice from December 2022, including a full list of the PBS items considered by PBAC as suitable for an increased MDQ, was published on the same day.

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 1 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 second 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 2 include PBS items for diabetes, epilepsy, osteoporosis and arthritis, 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. 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 will 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) till expiry and the new Eighth Community Pharmacy Agreement (8CPA), once effective. The Department will monitor the number and distribution of pharmacies across Australia. The ongoing impact on wholesalers will be monitored through the 7CPA until expiry, and then the 8CPA. 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.

**Commencement**

Schedule 1 commences on 1 March 2024. Schedule 1 amends the Main Listing Instrument to implement the second stage of the MDQ measure.

**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 made by Schedule 2 of 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.

The government has considered current shortages in determining the medicines included in Stage 2. Medicines have been considered suitable for implementation of the increased MDQ measure on 1 March 2024 if they have premium-free alternative brands of the same form that are substitutable by the pharmacist (based on the shortages reported to TGA in one, or more, brands, of one, or more, forms at 2 January 2024).

A full list of the medicines, including forms and PBS item codes, for which an increased MDQ will be implemented on 1 March 2024 for all brands listed on the PBS, is provided at Attachment A. The medicines and PBS item codes included in Attachment A have all been recommended by the PBAC for inclusion in the increased MDQ measure.

The PBS Schedule is part of the wider PBS managed by the Department and administered by Services Australia. As part of the consultation process the Department and Services Australia have collaborated on required information technology system changes, including to ensure that software vendors receive data outputs with sufficient time to ensure prescribing and dispensing software can be updated for the 1 March 2024 commencement of Stage 2 of the increased MDQ measure.

**Incorporation by reference**

The Instrument incorporates by reference the following legislative instruments, or provisions of the following legislative instruments:

* *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020;*
* *National Health (Pharmaceutical Benefits) (Conditions for approved pharmacists) Determination 2017;*
* *National Health (Supply of Pharmaceutical Benefits—Under Co-payment Data and Claims for Payment) Rules 2022;*
* *National Health (Listing of Pharmaceutical Benefits) Instrument 2012;*
* *National Health (Pharmaceutical Benefits) Regulations 2017.*

These instruments or relevant provisions of the instruments are all incorporated as in force from time to time and the instruments can be accessed free of charge on the Federal Register of Legislation at [www.legislation.gov.au](http://www.legislation.gov.au).

**General**

Details of the Instrument are at Attachment A.

This Instrument commences on 1 March 2024.

The human rights statement of compatibility is at Attachment B. The statement of compatibility concludes the 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*.

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

**ATTACHMENT A**

**PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH LEGISLATION AMENDMENT (MAXIMUM DISPENSED QUANTITIES) INSTRUMENT 2024**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024* andmay also be cited as PB 14 of 2024.

**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 on 1 March 2024.

**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**

This section 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 Amendments**

Schedule 1 of the Instrument amends Schedules 1 and 4 of the Main Listing Instrument to increase the maximum dispensed quantity (MDQ) for 238 PBS items. Schedule 1 will take effect on 1 March 2024. These items include some medicines for chronic conditions such as hypothyroidism, diabetes, menopause, androgen deficiency, incontinence, prostate enlargement, epilepsy, migraine, bipolar disorder, breast cancer, prostate cancer, osteoporosis and arthritis.

The MDQ is the maximum quantity or number of units of a pharmaceutical benefit that a PBS prescriber can direct to be supplied to a patient on the one occasion. The MDQ for the relevant items is currently an amount sufficient to one month’s supply. Schedule 1 will amend the entries for the relevant items in Schedule 1 of the Main Listing Instrument to include a new MDQ, sufficient for two months’ supply, along with the applicable new ‘purposes codes’ and ‘circumstances codes’.

Schedule 1 of the Instrument will also amend Schedule 4 of the Main Listing Instrument to detail, for the new purposes and circumstances codes, the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient’s condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Current listings enabling the prescription of one month’s supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

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

**Addition of Increased Maximum Dispensed Quantity**

| ***Drug*** | ***Form (strength and presentation)***  | ***Item Code*** |
| --- | --- | --- |
| acarbose | acarbose 50 mg tablet, 90 | 08188Y |
|  | acarbose 100 mg tablet, 90 | 08189B |
| alendronate with colecalciferol | alendronate 70 mg + colecalciferol 70 microgram (2800 units) tablet, 4 | 09012H |
|  | alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4 | 09183H |
| alogliptin | alogliptin 6.25 mg tablet, 28 | 02944Y |
|  | alogliptin 12.5 mg tablet, 28 | 02933J |
|  | alogliptin 25 mg tablet, 28 | 02986E |
| alogliptin with metformin | alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56 | 10033C |
|  | alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56 | 10032B |
|  | alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56 | 10035E |
| amlodipine with atorvastatin | amlodipine 10 mg + atorvastatin 80 mg tablet, 30 | 09056P |
| anastrozole | anastrozole 1 mg tablet, 30 | 08179L |
| bromocriptine | bromocriptine 2.5 mg tablet, 30 | 01443Y |
| cabergoline | cabergoline 500 microgram tablet, 8 | 08114C |
| carbamazepine | carbamazepine 100 mg/5 mL oral liquid, 300 mL | 02427R |
|  | carbamazepine 200 mg modified release tablet, 200 | 02426Q |
|  | carbamazepine 400 mg modified release tablet, 200 | 02431Y |
| carbimazole | carbimazole 5 mg tablet, 100 | 01153Q |
| ciclosporin | ciclosporin 10 mg capsule, 60 | 08657P |
|  | ciclosporin 25 mg capsule, 30 | 08658Q |
|  | ciclosporin 50 mg capsule, 30 | 08659R |
|  | ciclosporin 100 mg capsule, 30 | 08660T |
|  | ciclosporin 100 mg/mL oral liquid, 50 mL | 08661W |
| cortisone | cortisone acetate 5 mg tablet, 50 | 01246N |
|  | cortisone acetate 25 mg tablet, 60 | 01247P |
| cyproterone | cyproterone acetate 50 mg tablet, 20 | 01269T |
|  | cyproterone acetate 50 mg tablet, 50 | 01270W |
|  | cyproterone acetate 100 mg tablet, 50 | 08019C |
| dapagliflozin | dapagliflozin 10 mg tablet, 28 | 10011X |
|  | dapagliflozin 10 mg tablet, 28 | 12823X |
| dapagliflozin with metformin | dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 | 10510E |
|  | dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 | 10516L |
|  | dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 | 10515K |
| desmopressin | desmopressin acetate 200 microgram tablet, 30 | 08662X |
|  | desmopressin acetate 200 microgram tablet, 30 | 08663Y |
|  | desmopressin 120 microgram sublingual wafer, 30 | 09398P |
|  | desmopressin 240 microgram sublingual wafer, 30 | 08975J |
| dexamethasone | dexamethasone 500 microgram tablet, 30 | 01292B |
| dutasteride | dutasteride 500 microgram capsule, 30 | 05468T |
| dutasteride with tamsulosin | dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30 | 05490Y |
| empagliflozin | empagliflozin 10 mg tablet, 30 | 10206E |
|  | empagliflozin 10 mg tablet, 30 | 12918X |
|  | empagliflozin 25 mg tablet, 30 | 10202Y |
| empagliflozin with linagliptin | empagliflozin 10 mg + linagliptin 5 mg tablet, 30 | 11310G |
|  | empagliflozin 25 mg + linagliptin 5 mg tablet, 30 | 11298P |
| empagliflozin with metformin | empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 | 10626G |
|  | empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 | 10627H |
|  | empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 | 10633P |
|  | empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 | 10677Y |
| eprosartan | eprosartan 600 mg tablet, 28 | 05491B |
|  | eprosartan 600 mg tablet, 28 | 08447N |
| estradiol | estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets | 08286D |
|  | estradiol 10 microgram modified release pessary, 18 | 10203B |
|  | estradiol valerate 1 mg tablet, 56 | 01663M |
|  | estradiol 2 mg tablet, 56 | 08274L |
|  | estradiol valerate 2 mg tablet, 56 | 01664N |
| estradiol and estradiol with dydrogesterone | estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28 | 10146B |
|  | estradiol 2 mg tablet [14] (&) estradiol 2 mg + dydrogesterone 10 mg tablet [14], 28 | 08244X |
| estradiol and estradiol with norethisterone | estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 8 | 08425K |
|  | estradiol 50 microgram/24 hours patch [4] (&) estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 8 | 08426L |
| estradiol with norethisterone | estradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8 | 08427M |
| estriol | estriol 0.1% (1 mg/g) cream, 15 g | 01781R |
|  | estriol 500 microgram pessary, 15 | 01771F |
| ethosuximide | ethosuximide 250 mg/5 mL oral liquid, 200 mL | 01414K |
| everolimus | everolimus 750 microgram tablet, 60 | 08842J |
|  | everolimus 1 mg tablet, 60 | 09352F |
| exemestane | exemestane 25 mg tablet, 30 | 08506Q |
|  | exemestane 25 mg tablet, 30 | 10103R |
| glibenclamide | glibenclamide 5 mg tablet, 100 | 02939Q |
| gliclazide | gliclazide 60 mg modified release tablet, 60 | 09302N |
|  | gliclazide 80 mg tablet, 100 | 02449X |
| glimepiride | glimepiride 1 mg tablet, 30 | 08450R |
|  | glimepiride 2 mg tablet, 30 | 08451T |
|  | glimepiride 3 mg tablet, 30 | 08533D |
|  | glimepiride 4 mg tablet, 30 | 08452W |
| glipizide | glipizide 5 mg tablet, 100 | 02440K |
| hydrocortisone | hydrocortisone 4 mg tablet, 50 | 01499X |
| labetalol | labetalol hydrochloride 100 mg tablet, 100 | 01566K |
| lacosamide | lacosamide 10 mg/mL oral liquid, 200 mL | 11694L |
|  | lacosamide 10 mg/mL oral liquid, 200 mL | 12628P |
|  | lacosamide 50 mg tablet, 14 | 10293R |
|  | lacosamide 50 mg tablet, 14 | 12626M |
|  | lacosamide 100 mg tablet, 56 | 09335H |
|  | lacosamide 100 mg tablet, 56 | 12634Y |
|  | lacosamide 150 mg tablet, 56 | 09337K |
|  | lacosamide 150 mg tablet, 56 | 12627N |
|  | lacosamide 200 mg tablet, 56 | 09338L |
|  | lacosamide 200 mg tablet, 56 | 12658F |
| lamotrigine | lamotrigine 5 mg tablet, 56 | 08063J |
|  | lamotrigine 25 mg tablet, 56 | 02848X |
|  | lamotrigine 50 mg tablet, 56 | 02849Y |
|  | lamotrigine 100 mg tablet, 56 | 02850B |
|  | lamotrigine 200 mg tablet, 56 | 02851C |
| lanthanum | lanthanum 500 mg chewable tablet, 2 x 45 | 09403X |
|  | lanthanum 750 mg chewable tablet, 6 x 15 | 09404Y |
|  | lanthanum 1 g chewable tablet, 6 x 15 | 09405B |
| leflunomide | leflunomide 10 mg tablet, 30 | 05449T |
|  | leflunomide 10 mg tablet, 30 | 08374R |
|  | leflunomide 20 mg tablet, 30 | 05450W |
|  | leflunomide 20 mg tablet, 30 | 08375T |
| letrozole | letrozole 2.5 mg tablet, 30 | 08245Y |
| levetiracetam | levetiracetam 100 mg/mL oral liquid, 300 mL | 09169N |
|  | levetiracetam 250 mg tablet, 60 | 08654L |
|  | levetiracetam 500 mg tablet, 60 | 08655M |
|  | levetiracetam 1 g tablet, 60 | 08656N |
| linagliptin  | linagliptin 5 mg tablet, 30 | 03387G |
| linagliptin with metformin | linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 | 10038H |
|  | linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 | 10045Q |
|  | linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 | 10044P |
| liothyronine | liothyronine sodium 20 microgram tablet, 100 | 02318B |
| medroxyprogesterone | medroxyprogesterone acetate 5 mg tablet, 56 | 02323G |
|  | medroxyprogesterone acetate 10 mg tablet, 100 | 02722G |
|  | medroxyprogesterone acetate 10 mg tablet, 30 | 02321E |
|  | medroxyprogesterone acetate 100 mg tablet, 100 | 02725K |
|  | medroxyprogesterone acetate 200 mg tablet, 60 | 02316X |
|  | medroxyprogesterone acetate 250 mg tablet, 60 | 02727M |
|  | medroxyprogesterone acetate 500 mg tablet, 30 | 02728N |
| metformin | metformin hydrochloride 500 mg modified release tablet, 120 | 09435N |
|  | metformin hydrochloride 500 mg tablet, 100 | 02430X |
|  | metformin hydrochloride 850 mg tablet, 60 | 01801T |
|  | metformin hydrochloride 1 g modified release tablet, 60 | 03439B |
|  | metformin hydrochloride 1 g tablet, 90 | 08607B |
| methenamine | methenamine hippurate 1 g tablet, 100 | 03124K |
| methotrexate | methotrexate 50 mg/2 mL injection, 5 x 2 mL vials | 02395C |
| minoxidil | minoxidil 10 mg tablet, 100 | 02313R |
| mycophenolate | mycophenolate mofetil 250 mg capsule, 50 | 01836P |
|  | mycophenolate mofetil 250 mg capsule, 100 | 08649F |
|  | mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL | 08651H |
|  | mycophenolate 180 mg enteric tablet, 120 | 02150E |
|  | mycophenolate 360 mg enteric tablet, 120 | 02193K |
|  | mycophenolate mofetil 500 mg tablet, 50 | 08650G |
| norethisterone | norethisterone 5 mg tablet, 30 | 02993M |
| olmesartan with amlodipine | olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30 | 05293N |
|  | olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30 | 05294P |
| olmesartan with amlodipine and hydrochlorothiazide | olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30 | 02953K |
| oxcarbazepine | oxcarbazepine 60 mg/mL oral liquid, 250 mL | 08588B |
|  | oxcarbazepine 300 mg tablet, 100 | 08585W |
|  | oxcarbazepine 600 mg tablet, 100 | 08586X |
| oxybutynin  | oxybutynin 3.9 mg/24 hours patch, 8 | 09454N |
|  | oxybutynin hydrochloride 5 mg tablet, 100 | 08039D |
| perampanel | perampanel 4 mg tablet, 28 | 10162W |
|  | perampanel 4 mg tablet, 28 | 11418Y |
|  | perampanel 6 mg tablet, 28 | 10163X |
|  | perampanel 6 mg tablet, 28 | 11407J |
|  | perampanel 8 mg tablet, 28 | 10160R |
|  | perampanel 8 mg tablet, 28 | 11429M |
|  | perampanel 10 mg tablet, 28 | 10151G |
|  | perampanel 10 mg tablet, 28 | 11428L |
|  | perampanel 12 mg tablet, 28 | 10159Q |
|  | perampanel 12 mg tablet, 28 | 11409L |
| phenoxymethylpenicillin | phenoxymethylpenicillin 250 mg capsule, 50 | 01705R |
|  | phenoxymethylpenicillin 250 mg tablet, 25 | 01703P |
| phenytoin | phenytoin sodium 30 mg capsule, 200 | 01873N |
|  | phenytoin sodium 100 mg capsule, 200 | 01874P |
|  | phenytoin 30 mg/5 mL oral liquid, 500 mL | 02692Q |
|  | phenytoin 50 mg chewable tablet, 200 | 01249R |
| phosphorus | phosphorus 500 mg effervescent tablet, 100 | 02946C |
| pioglitazone  | pioglitazone 15 mg tablet, 28 | 08694N |
|  | pioglitazone 30 mg tablet, 28 | 08695P |
|  | pioglitazone 45 mg tablet, 28 | 08696Q |
| pizotifen | pizotifen 500 microgram tablet, 100 | 03074T |
| prednisolone | prednisolone 1 mg tablet, 100 | 03152X |
|  | prednisolone 5 mg tablet, 60 | 01917X |
|  | prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL | 08285C |
| prednisone | prednisone 1 mg tablet, 100 | 01934T |
|  | prednisone 5 mg tablet, 60 | 01935W |
| probenecid | probenecid 500 mg tablet, 100 | 01940D |
| propantheline | propantheline bromide 15 mg tablet, 100 | 01953T |
| propylthiouracil | propylthiouracil 50 mg tablet, 100 | 01955X |
| quinagolide | quinagolide 75 microgram tablet, 30 | 08822H |
| saxagliptin | saxagliptin 2.5 mg tablet, 28 | 10128C |
|  | saxagliptin 5 mg tablet, 28 | 08983T |
| saxagliptin with dapagliflozin | saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 | 11305B |
| saxagliptin with metformin | saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 | 10048W |
|  | saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 | 10055F |
|  | saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 | 10051B |
| sevelamer | sevelamer carbonate 800 mg tablet, 180 | 11856B |
|  | sevelamer hydrochloride 800 mg tablet, 180 | 02142R |
| sirolimus | sirolimus 1 mg/mL oral liquid, 60 mL | 08725F |
|  | sirolimus 500 microgram tablet, 100 | 08984W |
|  | sirolimus 1 mg tablet, 100 | 08724E |
|  | sirolimus 2 mg tablet, 100 | 08833X |
| sitagliptin | sitagliptin 25 mg tablet, 28 | 09180E |
|  | sitagliptin 50 mg tablet, 28 | 09181F |
|  | sitagliptin 100 mg tablet, 28 | 09182G |
| sitagliptin with metformin | sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 | 09449H |
|  | sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 | 09450J |
|  | sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 | 10090C |
|  | sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 | 09451K |
|  | sitagliptin 100 mg + metformin hydrochloride 1 g modified release tablet, 28 | 10089B |
| sodium bicarbonate | sodium bicarbonate 840 mg capsule, 100 | 09470K |
| spironolactone | spironolactone 100 mg tablet, 100 | 02340E |
| sucroferric oxyhydroxide | sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90 | 10250L |
| sulthiame | sulthiame 50 mg tablet, 200 | 02099L |
|  | sulthiame 200 mg tablet, 200 | 02100M |
| tacrolimus | tacrolimus 500 microgram capsule, 100 | 08646C |
|  | tacrolimus 500 microgram modified release capsule, 30 | 05299X |
|  | tacrolimus 750 microgram capsule, 100 | 10870D |
|  | tacrolimus 1 mg capsule, 100 | 08647D |
|  | tacrolimus 1 mg modified release capsule, 60 | 05300Y |
|  | tacrolimus 2 mg capsule, 100 | 10871E |
|  | tacrolimus 3 mg modified release capsule, 50 | 11914C |
|  | tacrolimus 5 mg capsule, 50 | 08648E |
|  | tacrolimus 5 mg modified release capsule, 30 | 05451X |
| tamoxifen | tamoxifen 20 mg tablet, 30 | 01880Y |
|  | tamoxifen 20 mg tablet, 30 | 10911G |
|  | tamoxifen 20 mg tablet, 60 | 02110C |
| teriparatide | teriparatide 250 microgram/mL injection, 2.4 mL cartridge | 12670W |
| testosterone | testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations | 10380H |
|  | testosterone 2% (23 mg/actuation) gel, 56 actuations | 11740X |
|  | testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets | 08830R |
| tiagabine | tiagabine 5 mg tablet, 50 | 08221Q |
|  | tiagabine 10 mg tablet, 50 | 08222R |
|  | tiagabine 15 mg tablet, 50 | 08223T |
| tobramycin | tobramycin 28 mg powder for inhalation, 224 capsules | 10074F |
|  | tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules | 05442K |
| topiramate | topiramate 15 mg capsule, 60 | 08371N |
|  | topiramate 25 mg capsule, 60 | 08372P |
|  | topiramate 50 mg capsule, 60 | 08520K |
|  | topiramate 25 mg tablet, 60 | 08163P |
|  | topiramate 50 mg tablet, 60 | 08164Q |
|  | topiramate 100 mg tablet, 60 | 08165R |
|  | topiramate 200 mg tablet, 60 | 08166T |
| toremifene | toremifene 60 mg tablet, 30 | 08216K |
| valproic acid | valproate sodium 200 mg/5 mL oral liquid, 300 mL | 02293Q |
|  | valproate sodium 200 mg/5 mL oral liquid, 300 mL | 02295T |
|  | valproate sodium 100 mg tablet, 100 | 02294R |
|  | valproate sodium 200 mg enteric tablet, 100 | 02289L |
|  | valproate sodium 500 mg enteric tablet, 100 | 02290M |
| vigabatrin | vigabatrin 500 mg powder for oral liquid, 60 sachets | 02668K |
|  | vigabatrin 500 mg tablet, 100 | 02667J |
| vildagliptin | vildagliptin 50 mg tablet, 60 | 03415R |
| vildagliptin with metformin | vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 | 05474D |
|  | vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 | 05475E |
|  | vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 | 05476F |
| zonisamide | zonisamide 25 mg capsule, 56 | 09388D |
|  | zonisamide 50 mg capsule, 56 | 09389E |
|  | zonisamide 100 mg capsule, 56 | 09390F |

**Documents Incorporated by Reference**

|  |  |  |
| --- | --- | --- |
| ***Listed Drug*** | ***Document incorporated*** | ***Document access*** |
| dapagliflozinempagliflozintopiramate | **Approved Product Information/Australian Product Information/TGA-approved Product Information.** 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*.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: <https://www.tga.gov.au/product-information-0> |
| dapagliflozinempagliflozin | **New York Heart Association (NYHA) classification**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 NYHA classification system is used to define the degree of heart failure.  | The NYHA classification system is available for download for free from the Heart Foundation website (contained within the heart failure clinical guidelines): <https://www.heartfoundation.org.au/Conditions/Heart-failure-clinical-guidelines>  |

**ATTACHMENT B**

**Statement of** **Compatibility with Human Rights**

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

***National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024***

**(PB 14 of 2024)**

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**

*National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024* (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 March 2024 the Principal Instrument will be amended by Schedule 1 to the Instrument to implement stage 2 of 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 Instrument are the second of three stages of implementation of the MDQ measure. Stage 2 includes some medicines for chronic conditions such as hypothyroidism, diabetes, menopause, androgen deficiency, incontinence, prostate enlargement, epilepsy, migraine, bipolar disorder, breast cancer, prostate cancer, osteoporosis and arthritis. Patients will only be eligible to receive an increased supply where their chronic condition is stable.

Current listings enabling the prescription of one month’s supply of the relevant items are not being repealed, and prescribers can continue to prescribe the lower MDQ where appropriate.

**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.

Stage 2 of the MDQ measure will be implemented on 1 March 2024 by amendments to the Principal Instrument made by the *National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024.* 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 the instrument which implemented stage 1 of the MDQ measures on 1 September 2023, which can be found on the Federal Register of Legislation at [*National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023*](https://www.legislation.gov.au/F2023L00843/asmade/text). 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 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.

Addition of new purposes and circumstances codes does not affect human rights. The new purposes and circumstances codes detail the purposes for which, and circumstances in which, the new MDQ amounts can be prescribed. These relevantly will include that the patient’s condition must be stable for the prescriber to consider the increased MDQ suitable for the patient. Any existing purposes and circumstances for the relevant items (for example that the prescription is to treat a particular condition) will continue to apply.

Implementation of the MDQ measure does not risk exacerbating any shortages of these medicines in the community as a whole. It should 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 medicine shortages were likely to be short-term as the system adjusts to a new phased model of supply.

The Therapeutic Goods Administration (TGA) works with many stakeholders to manage shortages and can take a range of actions to assist with medicine shortages. 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. Pharmacists and prescribers already manage medicine supply shortages in a number of ways on a daily basis.

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.

**Nikolai Tsyganov**

**Assistant Secretary**

**Pricing and PBS Policy Branch**

**Technology Assessment and Access Division**

**Department of Health and Aged Care**