**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MAXIMUM DISPENSED QUANTITIES SEPTEMBER UPDATE) INSTRUMENT 2024***

**PB 85 of 2024**

**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 2024* (PB 26 of 2024) to make changes to the pharmaceutical benefits listed for the purposes of the Pharmaceutical Benefits Scheme (PBS), and related matters. This legislative instrument includes changes to increase the maximum dispensed quantity (MDQ) for certain pharmaceutical benefits, in certain circumstances, from one to two months’ supply, as the third of three stages of implementation of the MDQ measure. 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 *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (2024 Listing Instrument) determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) through declarations of drugs and medicinal preparations, and for ready-prepared benefits: 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).

These changes will commence on 1 September 2024.

Stage 3 of the MDQ measure includes some medicines for chronic medical conditions such as acne, anxiety disorders, asthma, chronic obstructive pulmonary disease (COPD), constipation, depression, dry eyes, gastro-oesophageal reflux disease (GORD), glaucoma and Parkinson disease.

This instrument applies increased maximum dispensed quantities to 302 PBS items to implement Stage 3 of medicines approved for listing with an increased MDQ.

**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*

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.

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 and subsection 100(2) of the Act.

*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 26 of 2024 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 26 of 2024.

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)).

**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.

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. Stage 1 of the MDQ measure was implemented 1 September 2023, Stage 2 was implemented on 1 March 2024 and Stage 3 will be implemented 1 September 2024.

Schedule 1 to the *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024* amends the listings of 302 PBS items to implement Stage 3 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.

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. 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 data is available.

The Department’s 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 impact on the community pharmacy sector remuneration and continued participation in community pharmacy programs will be monitored through the Eighth Community Pharmacy Agreement (8CPA). The Department will monitor the number and distribution of pharmacies across Australia. The ongoing impact on wholesalers will be monitored through the 8CPA. The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.

**Changes to PB 26 of 2024 made by this Instrument**

Schedule 1 to this Instrument provides for the addition to the PBS Schedule of the drug migalastat, and forms of the listed drugs amoxicillin with clavulanic acid, azithromycin, budesonide, and tiotropium. It also provides for deletion of the listed drug fosinopril with hydrochlorothiazid, and the form of the listed drug methylprednisolone, and the the alteration of circumstances in which prescriptions may be written for the supply of 118 listed drugs.

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

* the addition of 264 pharmaceutical items for the maximum dispensed quantity (MDQ) measure
* the addition of 223 brands of existing pharmaceutical items
* the deletion of 42 brands of existing pharmaceutical items
* the deletion of a maximum quantity and number of repeats for an existing pharmaceutical item
* the alteration of responsible person codes for 3 brands of existing pharmaceutical items
* the addition of 2 responsible persons for the list of responsible persons
* the deletion of 2 responsible persons for the list of responsible persons
* the addition of 2 pharmaceutical items covered under Supply Only arrangements
* the deletion of 2 pharmaceutical items covered under 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.

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

Consistent with the approach taken for implementation of Stages 1 and 2 of the increased MDQ measure, the government has considered current shortages in determining the medicines included in Stage 3. Medicines have been considered suitable for implementation of the increased MDQ measure on 1 September 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 1 July 2024).

A minor adjustment has been made to this implementation approach for Stage 3. The PBAC recommended 60-day prescription option for  PBS items that are in shortage in the lead up to 1 September 2024, have also been considered suitable for implementation where other PBS items of the same drug:

* have been listed in Stages One or Two; or,
* will be listed in Stage Three of 60-day prescriptions on 1 September 2024.

This is intended to eliminate confusion for prescribers where certain forms (e.g some strengths) of a medicine are available for 60-day prescriptions and others are not.

A full list of the medicines, including forms and PBS item codes, for which an increased MDQ will be implemented on 1 September 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 September 2024 commencement of Stage 3 of the increased MDQ measure.

**General**

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

This Instrument commences on 1 September 2024.

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

**ATTACHMENT**

**PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MAXIMUM DISPENSED QUANTITIES SEPTEMBER UPDATE) INSTRUMENT 2024***

**Section 1 Name of Instrument**

This section provides that the name of the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024* and may also be cited as PB 85 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 September 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 2024 Listing Instrument to increase the maximum dispensed quantity (MDQ) for 302 PBS items. Schedule 1 will take effect on 1 September 2024. These items include some medicines for chronic conditions such as acne, anxiety disorders, asthma, chronic obstructive pulmonary disease (COPD), constipation, depression, dry eyes, gastro-oesophageal reflux disease (GORD), glaucoma and Parkinson disease

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 2024 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 2024 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.

The amendments in Schedule 1 also involve the addition and deletion of listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the deletion of a maximum quantity and number of repeats for a form of a listed drug, the addition and deletion of responsible persons for the list of responsible persons, the alteration of the responsible persons for existing brands, the addition and deletion of pharmaceutical benefits covered under Supply Only arrangements, and the alteration of 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 SCHEDULE 1 OF THIS INSTRUMENT**

**Addition of Increased Maximum Dispensed Quantity**

| ***Drug*** | ***Form (strength and presentation)*** | ***30-day Item Code*** | ***60-day Item Code*** |
| --- | --- | --- | --- |
| Aclidinium | Powder for oral inhalation in breath actuated device 322 micrograms (as bromide) per dose, 60 doses | 10124W | 14539F |
| Aclidinium with formoterol | Powder for oral inhalation in breath actuated device containing aclidinium 340 micrograms (as bromide) with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 10565C | 14410K |
| Amantadine | Capsule containing amantadine hydrochloride 100 mg | 03016R | 14486K |
| Apomorphine | Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL | 12142C | 14375N |
|   | Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen | 12133N | 14309D |
|   | Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen | 12137T | 14485J |
|   | Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe | 12319J | 14377Q |
|  | Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL | 12306Q | 14407G |
| Beclometasone with formoterol and glycopyrronium | Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses | 12468F | 14310E |
| Beclometasone with formoterol | Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose,120 dose | 12183F | 14376P |
|  | Pressurised inhalation containing beclometasone dipropionate 200 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 13205B | 14538E |
| Beclometasone | Pressurised inhalation in breath actuated device containing beclometasone dipropionate 100 micrograms per dose, 200 doses (CFC-free formulation) | 08409N | 14514X |
|   | Pressurised inhalation containing beclometasone dipropionate 100 micrograms per dose, 200 doses (CFC-free formulation) | 08407L | 14541H |
|   | Pressurised inhalation in breath actuated device containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation) | 08408M | 14378R |
|   | Pressurised inhalation containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation) | 08406K | 14540G |
| Betaxolol | Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL | 02825Q | 14425F |
|   | Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL | 05544T |
| Bimatoprost with timolol | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL | 05558M | 14317M |
|   | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL | 09464D |
|   | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30 | 10107Y | 14351H |
|   | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30 | 10108B |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL | 05551E | 14315K |
|   | Eye drops 300 micrograms per mL, 3 mL | 08620Q |
|   | Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30 | 10046R | 14422C |
|   | Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30 | 10053D |
| Bisacodyl | Suppositories 10 mg, 10 | 01260H | 14447J |
|   | Suppositories 10 mg, 12 | 01258F | 14305X |
|   | Tablet 5 mg | 01259G | 14446H |
| Brimonidine | Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL | 05298W | 14496Y |
|   | Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL | 05563T |
|   | Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL | 05534G | 14497B |
|   | Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL | 08351M |
| Brimonidine with timolol | Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL | 05535H | 14491Q |
|   | Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL | 08826M |
| Brinzolamide with brimonidine | Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL | 10536M | 14423D |
|   | Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL | 10547D |
| Brinzolamide with timolol | Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL | 03438Y | 14495X |
|   | Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL | 05562R |
| Brinzolamide | Eye drops 10 mg per mL, 5 mL | 05540N | 14321R |
|  | Eye drops 10 mg per mL, 5 mL | 08483L |
| Budesonide | Nebuliser suspension 500 micrograms in 2 mL single dose units, 30 | 02065Q | 14438X |
|   | Nebuliser suspension 1 mg in 2 mL single dose units, 30 | 02066R | 14469M |
|   | Powder for oral inhalation in breath actuated device 100 micrograms per dose, 200 doses | 02070Y | 14331G |
|   | Powder for oral inhalation in breath actuated device 200 micrograms per dose, 200 doses | 02071B | 14503H |
|   | Powder for oral inhalation in breath actuated device 400 micrograms per dose, 200 doses | 02072C | 14470N |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | 10015D | 14467K |
|   | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | 12089G | 14535B |
|   | Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 08796Y | 14440B |
|   | Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 12101X | 14437W |
|   | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 10018G | 14468L |
|   | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 12082X | 14436T |
|   | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 08625Y | 14439Y |
|   | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 11273H | 14434Q |
|   | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 12093L | 14365C |
|   | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 11301T | 14435R |
|  | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 13258T | 14398T |
| Budesonide with glycopyrronium and formoterol | Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses | 12672Y | 14536C |
| Cabergoline | Tablet 1 mg | 08393R | 14516B |
|   | Tablet 2 mg | 08394T | 14543K |
| Carbamazepine | Tablet 100 mg | 02422L | 14509P |
|   | Tablet 200 mg | 01706T | 14338P |
| Carbomer-980 | Eye gel 2 mg per g, single dose units 0.6 mL, 30 | 05504Q | 14420Y |
|   | Eye gel 2 mg per g, single dose units 0.6 mL, 30 | 08578L |
|   | Eye gel 2 mg per g, 10 g | 05503P | 14385D |
|   | Eye gel 2 mg per g, 10 g | 08384G |
| Carmellose sodium | Eye drops containing carmellose sodium 5 mg per mL, 10 mL | 11852T | 14319P |
|   | Eye drops containing carmellose sodium 5 mg per mL, 10 mL | 11853W |
|   | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30 | 02338C | 14522H |
|   | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30 | 05506T |
|   | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30 | 02324H | 14452P |
|   | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30 | 05505R |
| Ciclesonide | Pressurised inhalation 160 micrograms per dose, 120 doses (CFC-free formulation) | 08854B | 14348E |
|   | Pressurised inhalation 80 micrograms per dose, 120 doses (CFC-free formulation) | 08853Y | 14312G |
| Citalopram | Tablet 10 mg (as hydrobromide) | 08702B | 14313H |
|   | Tablet 20 mg (as hydrobromide) | 08220P | 14490P |
|   | Tablet 40 mg (as hydrobromide) | 08703C | 14518D |
| Colestyramine | Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50 | 02967E | 14477Y |
| Desvenlafaxine | Tablet (extended release) 100 mg (as succinate) | 09367B | 14545M |
|   | Tablet (modified release) 100 mg | 10231L | 14489N |
|   | Tablet (modified release) 100 mg (as benzoate) | 10245F | 14384C |
|   | Tablet (extended release) 50 mg (as succinate) | 09366Y | 14451N |
|   | Tablet (modified release) 50 mg (as benzoate) | 10234P | 14418W |
|   | Tablet (modified release) 50 mg | 10241B | 14383B |
| Dextran-70 with hypromellose | Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL | 05520M | 14521G |
|   | Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL | 01509K |
| Diltiazem | Capsule (controlled delivery) containing diltiazem hydrochloride 180 mg | 01312C | 14564M |
|   | Capsule (controlled delivery) containing diltiazem hydrochloride 240 mg | 01313D | 14508N |
|   | Capsule (controlled delivery) containing diltiazem hydrochloride 360 mg | 08480H | 14565N |
|   | Tablet containing diltiazem hydrochloride 60 mg | 01335G | 14479C |
| Dorzolamide with timolol | Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL | 05542Q | 14386E |
|   | Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL | 08567X |
| Dorzolamide | Eye drops 20 mg (as hydrochloride) per mL, 5 mL | 05541P | 14524K |
|   | Eye drops 20 mg (as hydrochloride) per mL, 5 mL | 08488R |
| Doxycycline | Capsule 100 mg (as hyclate) (containing enteric coated pellets) | 10777F | 14443E |
|   | Tablet 100 mg (as hyclate) | 10779H | 14480D |
|   | Tablet 100 mg (as monohydrate) | 10781K | 14511R |
|   | Capsule 50 mg (as hyclate) (containing enteric coated pellets) | 02707L | 14484H |
|   | Tablet 50 mg (as hyclate) | 02711Q | 14307B |
|   | Tablet 50 mg (as monohydrate) | 09106G | 14513W |
| Entacapone | Tablet 200 mg | 08367J | 14542J |
| Eprosartan with hctz | Tablet 600 mg eprosartan (as mesilate) with 12.5 mg hydrochlorothiazide | 08624X | 14337N |
| Erythromycin | Capsule 250 mg (containing enteric coated pellets) | 10780J | 14409J |
| Escitalopram | Tablet 10 mg (as oxalate) | 08700X | 14349F |
|   | Tablet 10 mg (as oxalate) | 09432K | 14519E |
|   | Tablet 20 mg (as oxalate) | 08701Y | 14415Q |
|   | Tablet 20 mg (as oxalate) | 09433L | 14416R |
|   | Oral solution 20 mg (as oxalate) per mL, 15 mL | 10181W | 14546N |
| Esomeprazole | Capsule (enteric) 20 mg (as magnesium) | 10343J | 14510Q |
|   | Capsule (enteric) 20 mg (as magnesium) | 11687D | 14303T |
|   | Capsule (enteric) 20 mg (as magnesium) | 12275C | 14537D |
|   | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | 11692J | 14444F |
|   | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | 12287Q | 14481E |
|   | Capsule (enteric) 40 mg (as magnesium) | 10331R | 14405E |
|   | Capsule (enteric) 40 mg (as magnesium) | 12290W | 14445G |
|   | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | 12283L | 14512T |
|  | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | 03401B | 14373L |
|  | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | 08600P | 14308C |
| Estradiol with noresthisterone  | Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 | 08428N | 14336M |
| Fluoxetine | Capsule 20 mg (as hydrochloride) | 01434L | 14548Q |
| Fluticasone furoate with umeclidinium and vilanterol | Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 11379X | 14346C |
|   | Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 12917W | 14382Y |
| Fluticasone furoate with vilanterol | Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 11124L | 14379T |
|   | Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 11129R | 14345B |
| Fluticasone furoate | Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms per dose, 30 doses | 11719T | 14515Y |
|   | Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms per dose, 30 doses | 11729H | 14380W |
| Fluticasone propionate with salmeterol | Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | 08430Q | 14413N |
|   | Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | 08431R | 14449L |
|   | Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | 08432T | 14450M |
|   | Pressurised inhalation containing fluticasone propionate 50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | 08517G | 14414P |
|   | Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | 08518H | 14544L |
|   | Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | 08519J | 14311F |
| Fluticasone propionate | Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) | 08516F | 14487L |
|   | Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses | 08147T | 14412M |
|   | Pressurised inhalation containing fluticasone propionate 125 micrograms per dose, 120 doses (CFC-free formulation) | 08345F | 14347D |
|   | Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses | 08148W | 14381X |
| Fluticasone propionate with formoterol | fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations | 10007Q | 14343X |
|   | fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations | 10008R | 14344Y |
|   | fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations | 02827T | 14411L |
| Fluvoxamine | Tablet containing fluvoxamine maleate 50 mg | 08512B | 14488M |
|   | Tablet containing fluvoxamine maleate 100 mg | 08174F | 14314J |
| Formoterol | Powder for oral inhalation in breath actuated device containing formoterol fumarate dihydrate 6 micrograms per dose, 60 doses | 08239P | 14547P |
|   | Powder for oral inhalation in breath actuated device containing formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 08240Q | 14517C |
|   | Capsule containing powder for oral inhalation containing formoterol fumarate dihydrate 12 micrograms (for use in Foradile Aerolizer) | 08136F | 14419X |
| Glyceryl trinitrate  | Transdermal patch 36 mg | 08028M | 14478B |
|   | Transdermal patch 54 mg | 08119H | 14335L |
|   | Transdermal patch 18 mg | 08027L | 14371J |
| Glycopyrronium | Capsule containing powder for oral inhalation 50 micrograms (as bromide) (for use in Breezhaler) | 10059K | 14417T |
| Hyaluronate sodium | Eye drops containing sodium hyaluronate 1 mg per mL, 10 mL | 02181T | 14354L |
|   | Eye drops containing sodium hyaluronate 1 mg per mL, 10 mL | 02184Y |
|   | Eye drops containing sodium hyaluronate 2 mg per mL, 10 mL | 02171G | 14494W |
|   | Eye drops containing sodium hyaluronate 2 mg per mL, 10 mL | 02253N |
| Hydrocortisone  | Tablet 20 mg | 01500Y | 14476X |
| Hypromellose | 0.3% w/v eye drops, 10 mL (preservative free) | 11842G | 14492R |
|   | 0.3% w/v eye drops, 10 mL (preservative free) | 11849P |
|   | Eye drops 3 mg per mL, 10 mL | 11625W | 14318N |
|   | Eye drops 3 mg per mL, 10 mL | 11634H |
|   | Eye drops 5 mg per mL, 15 mL | 05517J | 14320Q |
|   | Eye drops 5 mg per mL, 15 mL | 02956N |
| Indacaterol with glycopyrronium | Capsule containing powder for oral inhalation indacaterol 110 micrograms (as maleate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler) | 10156M | 14504J |
| Indacaterol with glycopyrronium with mometasone | Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 136 micrograms (for use in Breezhaler) | 12295D | 14399W |
|   | Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 68 micrograms (for use in Breezhaler) | 12298G | 14471P |
| Indacaterol with mometasone | Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 127.5 micrograms (for use in Breezhaler) | 12289T | 14333J |
|   | Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 260 micrograms (for use in Breezhaler) | 12279G | 14441C |
|   | Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 62.5 micrograms (for use in Breezhaler) | 12269R | 14332H |
| Indacaterol | Capsule containing powder for oral inhalation 150 micrograms (as maleate) (for use in Breezhaler) | 05134F | 14334K |
|   | Capsule containing powder for oral inhalation 300 micrograms (as maleate) (for use in Breezhaler) | 05137J | 14368F |
| Lansoprazole | Capsule 15 mg | 08198L | 14448K |
|   | Tablet 15 mg (orally disintegrating) | 09331D | 14374M |
|   | Capsule 30 mg | 02241Y | 14340R |
|   | Capsule 30 mg | 11669E | 14302R |
|   | Capsule 30 mg | 12284M | 14304W |
|   | Tablet 30 mg (orally disintegrating) | 09478W | 14342W |
|   | Tablet 30 mg (orally disintegrating) | 11697P | 14406F |
|   | Tablet 30 mg (orally disintegrating) | 12276D | 14339Q |
| Latanoprost with timolol | Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL | 05553G | 14350G |
|   | Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL | 08895E |
| Latanoprost  | Eye drops 50 micrograms per mL, 2.5 mL | 05552F | 14453Q |
|   | Eye drops 50 micrograms per mL, 2.5 mL | 08243W |
| Levodopa with benserazide | Capsule containing levodopa 50 mg with 12.5 mg benserazide (as hydrochloride) | 02227F | 14388G |
|   | Capsule containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) | 02225D | 14387F |
|   | Capsule containing levodopa 200 mg with 50 mg benserazide (as hydrochloride) | 02226E | 14551W |
|   | Tablet containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) | 02229H | 14455T |
|   | Tablet containing levodopa 200 mg with 50 mg benserazide (as hydrochloride) | 02228G | 14428J |
|   | Dispersible tablet containing levodopa 50 mg with 12.5 mg benserazide (as hydrochloride) | 08218M | 14356N |
|   | Dispersible tablet containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) | 08219N | 14552X |
|   | Capsule containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) (sustained release) | 02231K | 14525L |
| Levodopa with carbidopa and entacapone | Tablet 50 mg-12.5 mg (as monohydrate)-200 mg | 08797B | 14456W |
|   | Tablet 100 mg-25 mg (as monohydrate)-200 mg | 08798C | 14554B |
|   | Tablet 150 mg-37.5 mg (as monohydrate)-200 mg | 08799D | 14357P |
|   | Tablet 200 mg-50 mg (as monohydrate)-200 mg | 09292C | 14457X |
|   | Tablet 75 mg-18.75 mg (as monohydrate)-200 mg | 09344T | 14498C |
|   | Tablet 125 mg-31.25 mg (as monohydrate)-200 mg | 09345W | 14527N |
| Levodopa with carbidopa | Tablet 100 mg-25 mg (as monohydrate) | 01242J | 14427H |
|   | Tablet 250 mg-25 mg (as monohydrate) | 01245M | 14454R |
|  | Tablet (modified release) 200 mg-50 mg (as monohydrate) | 01255C | 14322T |
| Macrogol 3350 | Powder for oral solution 510 g | 03416T | 14341T |
| Macrogol 3350 | Sachets containing powder for oral solution 13.125 g with electrolytes, 30 | 08612G | 14408H |
| Mianserin | Tablet containing mianserin hydrochloride 10 mg | 01627P | 14366D |
|   | Tablet containing mianserin hydrochloride 20 mg | 01628Q | 14505K |
| Minocycline | Tablet 50 mg (as hydrochloride) | 01616C | 14483G |
| Mirtazapine | Tablet 15 mg (orally disintegrating) | 08855C | 14369G |
|   | Tablet 15 mg | 09365X | 14507M |
|   | Tablet 30 mg (orally disintegrating) | 08856D | 14370H |
|   | Tablet 30 mg | 08513C | 14473R |
|   | Tablet 45 mg (orally disintegrating) | 08857E | 14475W |
|   | Tablet 45 mg | 08883M | 14561J |
| Moclobemide | Tablet 150 mg | 01900B | 14560H |
|   | Tablet 300 mg | 08003F | 14442D |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | 08627C | 14526M |
|   | Tablet, chewable, 5 mg (as sodium) | 08628D | 14553Y |
| Nizatidine | Capsule 150 mg | 01505F | 14306Y |
|   | Capsule 300 mg | 01504E | 14372K |
| Omeprazole | Tablet 10 mg (as magnesium) | 08332M | 14432N |
|   | Capsule 20 mg | 01327W | 14559G |
|   | Capsule 20 mg | 11682W | 14464G |
|   | Capsule 20 mg | 12281J | 14465H |
|   | Tablet 20 mg | 08333N | 14364B |
|   | Tablet 20 mg (as magnesium) | 09110L | 14397R |
|   | Tablet 20 mg (as magnesium) | 11677N | 14557E |
|   | Tablet 20 mg | 11683X | 14533X |
|   | Tablet 20 mg (as magnesium) | 12270T | 14363Y |
|   | Tablet 20 mg | 12272X | 14558F |
| Oxcarbazepine | Tablet 150 mg | 08584T | 14562K |
| Pantoprazole | Tablet (enteric coated) 20 mg (as sodium sesquihydrate) | 08399C | 14501F |
|   | Sachet containing granules 40 mg (as sodium sesquihydrate) | 09424B  | 14466J |
|   | Sachet containing granules 40 mg (as sodium sesquihydrate) | 11678P | 14500E |
|   | Sachet containing granules 40 mg (as sodium sesquihydrate) | 12282K | 14395P |
|   | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | 08008L | 14330F |
|   | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | 11681T | 14362X |
|   | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | 12277E | 14394N |
| Paraffin | Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g | 05522P | 14493T |
|   | Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g | 1750D |
|   | Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g | 05523Q | 14353K |
|   | Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g | 1754H |
|  | Eye drops containing liquid paraffin, glycerol, tyloxapol, poloxamer-188, trometamol hydrochloride, trometamol, cetalkonium chloride, 10 mL (preservative free) | 12612T | 14352J |
| Paroxetine | Tablet 20 mg (as hydrochloride) | 02242B | 14367E |
| Perfluorohexyloctane | Eye drops, 3 mL | 11439C | 14424E |
|   | Eye drops, 3 mL | 11446K |
| Pilocarpine | Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL | 02595N | 14355M |
|   | Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL | 05536J |
|   | Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL | 02596P | 14523J |
|   | Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL | 05537K |
|   | Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL | 02598R | 14550T |
|   | Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL | 05538L |
| Polyethylene glycol 400 with propylene glycol | Eye drops 4 mg-3 mg per mL, 15 mL | 05524R | 14421B |
|   | Eye drops 4 mg-3 mg per mL, 15 mL | 8676P |
|   | Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30 | 13100L | 14520F |
|   | Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30 | 13113E |
| Pramipexole | Tablet containing pramipexole dihydrochloride monohydrate 1 mg | 09153R | 14532W |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg | 03420B | 14360T |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg | 05143Q | 14556D |
|   | Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms | 09152Q | 14329E |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg | 03421C | 14460C |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg | 05145T | 14461D |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms | 03418X | 14324X |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg | 03422D | 14325Y |
|   | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms | 03419Y | 14459B |
| Pyridostigmine | Tablet containing pyridostigmine bromide 10 mg | 02724J | 14392L |
|   | Tablet containing pyridostigmine bromide 180 mg (modified release) | 02608G | 14462E |
|   | Tablet containing pyridostigmine bromide 60 mg | 01959D | 14529Q |
| Rabeprazole | Tablet containing rabeprazole sodium 10 mg (enteric coated) | 08507R | 14502G |
|   | Tablet containing rabeprazole sodium 20 mg (enteric coated) | 08508T | 14433P |
|   | Tablet containing rabeprazole sodium 20 mg (enteric coated) | 11670F | 14463F |
|   | Tablet containing rabeprazole sodium 20 mg (enteric coated) | 12286P | 14396Q |
| Rasagiline | Tablet 1 mg (as mesilate) | 01952R | 14458Y |
| Reboxetine | Tablet 4 mg (as mesilate) | 08583R | 14474T |
| Riluzole | Tablet 50 mg | 08664B | 14393M |
|   | Oral suspension 50 mg per 10 mL, 300 mL | 11662T | 14429K |
| Rotigotine | Transdermal patch 4.5 mg | 02385M | 14327C |
|   | Transdermal patch 9 mg | 02384L | 14326B |
|   | Transdermal patch 13.5 mg | 02410W | 14431M |
|   | Transdermal patch 18 mg | 11140H | 14359R |
| Safinamide | Tablet 100 mg | 11666B | 14528P |
|   | Tablet 50 mg | 11656L | 14391K |
| Salmeterol | Powder for oral inhalation in breath actuated device 50 micrograms (as xinafoate) per dose, 60 doses | 08141L | 14328D |
| Selegiline | Tablet containing selegiline hydrochloride 5 mg | 01973W | 14430L |
| Sertraline | Tablet 100 mg (as hydrochloride) | 02237R | 14506L |
|   | Tablet 100 mg (as hydrochloride) | 08837D | 14404D |
|   | Tablet 50 mg (as hydrochloride) | 02236Q | 14400X |
|   | Tablet 50 mg (as hydrochloride) | 08836C | 14403C |
| Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Enemas 3.125 g-450 mg-45 mg in 5 mL, 12 | 02091C | 14534Y |
| Soy lecithin | Eye spray 10 mg per mL, 10 mL | 05545W | 14426G |
|   | Eye spray 10 mg per mL, 10 mL | 09448G |
| Teriparatide  | Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen | 14093R | 14482F |
| Testosterone | Transdermal cream 50 mg per mL, 50 mL | 10378F | 14563L |
| Tetrabenazine | Tablet 25 mg | 01330B | 14390J |
| Tiotropium | Capsule containing powder for oral inhalation 13 micrograms (as bromide) (for use in Zonda device) | 11892X | 14555C |
|   | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler) | 08626B | 14361W |
|  | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler) | 14576E | 14574C |
|   | Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) | 10509D | 14499D |
|   | Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) | 11043F | 14323W |
|   | Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) | 11629C | 14531T |
| Tiotropium with olodaterol | Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses | 10557P | 14530R |
| Tranylcypromine | Tablet 10 mg (as sulfate) | 02444P | 14401Y |
| Travoprost with timolol | Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL | 05555J | 14316L |
|   | Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL | 09057Q |
| Travoprost | Eye drops 40 micrograms per mL, 2.5 mL | 05554H | 14549R |
|   | Eye drops 40 micrograms per mL, 2.5 mL | 08597L |
| Umeclidinium  | Powder for oral inhalation in breath actuated device 62.5 micrograms (as bromide) per dose, 30 doses | 10187E | 14389H |
| Umeclidinium with vilanterol | Powder for oral inhalation in breath actuated device containing umeclidinium 62.5 micrograms (as bromide) with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 10188F | 14358Q |
| Venlafaxine | Capsule (modified release) 150 mg (as hydrochloride) | 08302Y | 14402B |
|   | Capsule (modified release) 75 mg (as hydrochloride) | 08301X | 14472Q |

**Drug Added**

|  |
| --- |
| ***Listed Drug*** |
| Migalastat |

**Drug Deleted**

|  |
| --- |
| ***Listed Drug*** |
| Fosinopril with hydrochlorothiazid |

**Form Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Amoxicillin with clavulanic acid | Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A) |
| Azithromycin | Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL (S19A) |
| Budesonide | Capsule (enteric) 3 mg |
| Tiotropium | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler) |

**Form Deleted**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Methylprednisolone | Powder for injection 40 mg (as sodium succinate) (S19A) |

**Brand Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form and Brand*** |
| Acamprosate | Tablet (enteric coated) containing acamprosate calcium 333 mg *(ACAMPROSATE-WGR)* |
| Aciclovir | Tablet 200 mg *(ACICLOVIR-WGR)* |
|  | Tablet 800 mg *(ACICLOVIR-WGR)* |
| Alendronic acid | Tablet 70 mg (as alendronate sodium) *(ALENDRONATE-WGR)* |
| Allopurinol | Tablet 100 mg *(ALLOPURINOL-WGR)* |
|  | Tablet 300 mg *(ALLOPURINOL-WGR; APO-ALLOPURINOL)* |
| Amisulpride | Tablet 100 mg *(AMISULPRIDE-WGR)* |
|  | Tablet 200 mg *(AMISULPRIDE-WGR)* |
|  | Tablet 400 mg *(AMISULPRIDE-WGR)* |
| Amitriptyline | Tablet containing amitriptyline hydrochloride 10 mg *(AMITRIPTYLINE-WGR)* |
|  | Tablet containing amitriptyline hydrochloride 25 mg *(AMITRIPTYLINE-WGR)* |
| Amlodipine | Tablet 5 mg (as besilate) *(AMLODIPINE-WGR)* |
|  | Tablet 10 mg (as besilate) *(AMLODIPINE-WGR)* |
| Amoxicillin | Capsule 500 mg (as trihydrate) (AMOXICILLIN-WGR) |
|  | Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL *(AMOXICILLIN-WGR)* |
| Amoxicillin with clavulanic acid | Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(AMOXICILLIN/CLAVULANIC ACID-WGR 500/125)* |
|  | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)*(AMOXICILLIN/CLAVULANIC ACID-WGR 875/125)* |
| Anastrozole | Tablet 1 mg *(ANASTROZOLE-WGR)* |
| Aripiprazole | Tablet 10 mg *(ARIPIPRAZOLE-WGR)* |
|  | Tablet 15 mg *(ARIPIPRAZOLE-WGR)* |
|  | Tablet 20 mg *(ARIPIPRAZOLE-WGR)* |
|  | Tablet 30 mg *(ARIPIPRAZOLE-WGR)* |
| Atenolol | Tablet 50 mg *(ATENOLOL-WGR)* |
| Atorvastatin | Tablet 10 mg (as calcium) *(ATORVASTATIN-WGR)* |
|  | Tablet 20 mg (as calcium) *(ATORVASTATIN-WGR)* |
|  | Tablet 40 mg (as calcium) *(ATORVASTATIN-WGR)* |
|  | Tablet 80 mg (as calcium) *(ATORVASTATIN-WGR)* |
| Azathioprine | Tablet 25 mg *(AZATHIOPRINE-WGR)* |
|  | Tablet 50 mg *(AZATHIOPRINE-WGR)* |
| Azithromycin | Tablet 500 mg (as dihydrate) *(AZITHROMYCIN-WGR)* |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL *(BIMATOPROST-WGR)* |
| Bisoprolol | Tablet containing bisoprolol fumarate 2.5 mg *(BISOPROLOL-WGR)* |
|  | Tablet containing bisoprolol fumarate 5 mg *(BISOPROLOL-WGR)* |
|  | Tablet containing bisoprolol fumarate 10 mg *(BISOPROLOL-WGR)* |
| Candesartan | Tablet containing candesartan cilexetil 4 mg *(CANDESARTAN-WGR)* |
|  | Tablet containing candesartan cilexetil 8 mg *(CANDESARTAN-WGR)* |
|  | Tablet containing candesartan cilexetil 16 mg *(CANDESARTAN-WGR)* |
|  | Tablet containing candesartan cilexetil 32 mg *(CANDESARTAN-WGR)* |
| Candesartan with hydrochlorothiazide | Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg *(CANDESARTAN HCTZ-WGR 16/12.5)* |
|  | Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg *(CANDESARTAN HCTZ-WGR 32/12.5)* |
|  | Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg *(CANDESARTAN HCTZ-WGR 32/25)* |
| Carvedilol | Tablet 6.25 mg *(CARVEDILOL-WGR)* |
|  | Tablet 12.5 mg *(CARVEDILOL-WGR)* |
|  | Tablet 25 mg *(CARVEDILOL-WGR)* |
| Cefalexin | Capsule 500 mg (as monohydrate) *(CEPHALEXIN-WGR)* |
| Celecoxib | Capsule 100 mg *(CELECOXIB-WGR)* |
|  | Capsule 200 mg *(CELECOXIB-WGR)* |
| Ciclosporin | Capsule 25 mg *(CICLOSPORIN-WGR)* |
|  | Capsule 50 mg *(CICLOSPORIN-WGR)* |
|  | Capsule 100 mg *(CICLOSPORIN-WGR)* |
| Ciprofloxacin | Tablet 250 mg (as hydrochloride) *(CIPROFLOXACIN-WGR)* |
|  | Tablet 500 mg (as hydrochloride) *(CIPROFLOXACIN-WGR)* |
|  | Tablet 750 mg (as hydrochloride) *(CIPROFLOXACIN-WGR)* |
| Clindamycin | Capsule 150 mg (as hydrochloride) *(CLINDAMYCIN-WGR)* |
| Clomipramine | Tablet containing clomipramine hydrochloride 25 mg *(CLOMIPRAMINE-WGR)* |
| Clopidogrel | Tablet 75 mg (as besilate) *(CLOPIDOGREL-WGR)* |
| Desvenlafaxine | Tablet (modified release) 50 mg *(DESVENLAFAXINE-WGR XR)* |
|  | Tablet (modified release) 100 mg *(DESVENLAFAXINE-WGR XR)* |
| Diazepam | Tablet 2 mg *(DIAZEPAM-WGR)* |
|  | Tablet 5 mg *(DIAZEPAM-WGR)* |
| Diclofenac | Tablet (enteric coated) containing diclofenac sodium 25 mg *(DICLOFENAC-WGR)* |
|  | Tablet (enteric coated) containing diclofenac sodium 50 mg*(DICLOFENAC-WGR)* |
| Donepezil | Tablet containing donepezil hydrochloride 5 mg *(DONEPEZIL-WGR)* |
|  | Tablet containing donepezil hydrochloride 10 mg *(DONEPEZIL-WGR)* |
| Doxycycline | Tablet 50 mg (as hyclate) *(DOXYCYCLINE-WGR)* |
|  | Tablet 100 mg (as hyclate) *(DOXYCYCLINE-WGR)* |
| Enalapril | Tablet containing enalapril maleate 5 mg *(ENALAPRIL-WGR)* |
|  | Tablet containing enalapril maleate 10 mg *(ENALAPRIL-WGR)* |
|  | Tablet containing enalapril maleate 20 mg *(ENALAPRIL-WGR)* |
| Entecavir | Tablet 0.5 mg (as monohydrate) *(ENTECAVIR-WGR)* |
|  | Tablet 1 mg (as monohydrate) *(ENTECAVIR-WGR)* |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) *(ESOMEPRAZOLE-WGR)* |
|  | Tablet (enteric coated) 40 mg (as magnesium trihydrate) *(ESOMEPRAZOLE-WGR)* |
| Exemestane | Tablet 25 mg *(EXEMESTANE-WGR)* |
| Ezetimibe | Tablet 10 mg *(EZETIMIBE-WGR)* |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg (EZETIMIBE/SIMVASTATIN-WGR 10/10) |
|  | Tablet 10 mg-20 mg (EZETIMIBE/SIMVASTATIN-WGR 10/20) |
|  | Tablet 10 mg-40 mg (EZETIMIBE/SIMVASTATIN-WGR 10/40) |
|  | Tablet 10 mg-80 mg (EZETIMIBE/SIMVASTATIN-WGR 10/80) |
| Famciclovir | Tablet 250 mg *(FAMCICLOVIR-WGR)* |
|  | Tablet 500 mg *(FAMCICLOVIR-WGR)* |
| Fenofibrate | Tablet 48 mg *(FENOFIBRATE-WGR)* |
|  | Tablet 145 mg *(FENOFIBRATE-WGR)* |
| Fluvoxamine | Tablet containing fluvoxamine maleate 50 mg *(FLUVOXAMINE-WGR)* |
|  | Tablet containing fluvoxamine maleate 100 mg *(FLUVOXAMINE-WGR)* |
| Furosemide | Tablet 20 mg *(FUROSEMIDE-WGR)* |
|  | Tablet 40 mg *(FUROSEMIDE-WGR)* |
| Gabapentin | Capsule 300 mg *(GABAPENTIN-WGR)* |
|  | Capsule 400 mg *(GABAPENTIN-WGR)* |
| Glimepiride | Tablet 1 mg *(GLIMEPIRIDE-WGR)* |
|  | Tablet 2 mg *(GLIMEPIRIDE-WGR)* |
|  | Tablet 3 mg *(GLIMEPIRIDE-WGR)* |
|  | Tablet 4 mg *(GLIMEPIRIDE-WGR)* |
| Imatinib | Capsule 100 mg (as mesilate) *(ARX-IMATINIB)* |
| Irbesartan | Tablet 75 mg *(IRBESARTAN-WGR)* |
|  | Tablet 150 mg *(IRBESARTAN-WGR)* |
|  | Tablet 300 mg *(IRBESARTAN-WGR)* |
| Irbesartan with hydrochlorothiazide | Tablet 150 mg-12.5 mg *(IRBESARTAN HCTZ-WGR 150/12.5)* |
|  | Tablet 300 mg-12.5 mg *(IRBESARTAN HCTZ-WGR 300/12.5)* |
|  | Tablet 300 mg-25 mg *(IRBESARTAN HCTZ-WGR 300/25)* |
| Isosorbide mononitrate | Tablet 60 mg (sustained release) *(ISOSORBIDE MR-WGR)* |
| Isotretinoin | Capsule 10 mg *(ISOTRETINOIN-WGR)* |
|  | Capsule 20 mg *(ISOTRETINOIN-WGR)* |
| Ivabradine | Tablet 5 mg (as hydrochloride) *(IVABRADINE-WGR)* |
| Lamotrigine | Tablet 25 mg *(LAMOTRIGINE-WGR)* |
|  | Tablet 50 mg *(LAMOTRIGINE-WGR)* |
|  | Tablet 100 mg *(LAMOTRIGINE-WGR)* |
|  | Tablet 200 mg *(LAMOTRIGINE-WGR)* |
| Latanoprost | Eye drops 50 micrograms per mL, 2.5 mL *(LATANOPROST-WGR)* |
| Leflunomide | Tablet 10 mg *(LEFLUNOMIDE-WGR)* |
|  | Tablet 20 mg *(LEFLUNOMIDE-WGR)* |
| Lercanidipine | Tablet containing lercanidipine hydrochloride 10 mg *(LERCANIDIPINE-WGR)* |
|  | Tablet containing lercanidipine hydrochloride 20 mg *(LERCANIDIPINE-WGR)* |
| Letrozole | Tablet 2.5 mg *(LETROZOLE-WGR)* |
| Levetiracetam | Tablet 250 mg *(LEVETIRACETAM-WGR)* |
|  | Tablet 500 mg *(LEVETIRACETAM-WGR)* |
|  | Tablet 1 g *(LEVETIRACETAM-WGR)* |
| Levonorgestrel with ethinylestradiol | Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets *(LEVETH 150/30 ED)* |
| Lisinopril | Tablet 5 mg *(LISINOPRIL-WGR)* |
|  | Tablet 10 mg *(LISINOPRIL-WGR)* |
|  | Tablet 20 mg *(LISINOPRIL-WGR)* |
| Lurasidone | Tablet containing lurasidone hydrochloride 40 mg *(LURASIDONE-WGR)* |
|  | Tablet containing lurasidone hydrochloride 80 mg *(LURASIDONE-WGR)* |
| Meloxicam | Capsule 7.5 mg *(MELOXICAM-WGR)* |
|  | Capsule 15 mg *(MELOXICAM-WGR)* |
|  | Tablet 7.5 mg *(MELOXICAM-WGR)* |
|  | Tablet 15 mg *(MELOXICAM-WGR)* |
| Metformin | Tablet (extended release) containing metformin hydrochloride 500 mg *(METFORMIN-WGR XR)* |
|  | Tablet (extended release) containing metformin hydrochloride 1 g *(METFORMIN-WGR XR)* |
|  | Tablet containing metformin hydrochloride 500 mg *(METFORMIN-WGR)* |
|  | Tablet containing metformin hydrochloride 850 mg *(Diaformin Viatris; METFORMIN-WGR)* |
|  | Tablet containing metformin hydrochloride 1 g *(Diaformin Viatris)* |
| Metoclopramide | Tablet containing 10 mg metoclopramide hydrochloride (as monohydrate) *(METOCLOPRAMIDE-WGR)* |
| Metoprolol | Tablet containing metoprolol tartrate 50 mg *(METOPROLOL-WGR)* |
|  | Tablet containing metoprolol tartrate 100 mg *(METOPROLOL-WGR)* |
| Mirtazapine | Tablet 15 mg *(MIRTAZAPINE-WGR)* |
|  | Tablet 30 mg *(MIRTAZAPINE-WGR)* |
|  | Tablet 45 mg *(MIRTAZAPINE-WGR)* |
| Moclobemide | Tablet 150 mg *(MOCLOBEMIDE-WGR)* |
|  | Tablet 300 mg *(MOCLOBEMIDE-WGR)* |
| Modafinil | Tablet 100 mg *(MODAFINIL-WGR)* |
| Montelukast | Tablet, chewable, 5 mg (as sodium) *(Montelukast Viatris)* |
| Moxonidine | Tablet 200 micrograms *(MOXONIDINE-WGR)* |
|  | Tablet 400 micrograms *(MOXONIDINE-WGR)* |
| Olanzapine | Tablet 5 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)* |
|  | Tablet 10 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)* |
|  | Tablet 15 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)* |
|  | Tablet 20 mg (orally disintegrating) *(OLANZAPINE ODT-WGR)* |
| Olmesartan | Tablet containing olmesartan medoxomil 20 mg *(OLMESARTAN-WGR)* |
|  | Tablet containing olmesartan medoxomil 40 mg *(OLMESARTAN-WGR)* |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) *(APO-OLMESARTAN/AMLODIPINE 20/5; OLMESARTAN AMLODIPINE-WGR 20/5)* |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) *(OLMESARTAN AMLODIPINE-WGR 40/10)* |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) *(OLMESARTAN AMLODIPINE-WGR 40/5)* |
| Olmesartan with hydrochlorothiazide | Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg *(OLMESARTAN HCTZ-WGR 20/12.5)* |
|  | Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg *(OLMESARTAN HCTZ-WGR 40/12.5)* |
|  | Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg *(OLMESARTAN HCTZ-WGR 40/25)* |
| Ondansetron | Tablet 4 mg (as hydrochloride dihydrate) *(ONDANSETRON-WGR)* |
|  | Tablet 8 mg (as hydrochloride dihydrate) *(ONDANSETRON-WGR)* |
|  | Tablet (orally disintegrating) 4 mg *(ONDANSETRON ODT-WGR)* |
|  | Tablet (orally disintegrating) 8 mg *(ONDANSETRON ODT-WGR)* |
| Oxazepam | Tablet 30 mg *(OXAZEPAM-WGR)* |
| Pantoprazole | Tablet (enteric coated) 20 mg (as sodium sesquihydrate) *(PANTOPRAZOLE-WGR)* |
|  | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *(PANTOPRAZOLE-WGR)* |
| Paroxetine | Tablet 20 mg (as hydrochloride) *(PAROXETINE-WGR)* |
| Perindopril | Tablet containing perindopril arginine 2.5 mg *(Perindopril Arginine-WGR)* |
|  | Tablet containing perindopril arginine 5 mg *(Perindopril Arginine-WGR)* |
|  | Tablet containing perindopril arginine 10 mg *(Perindopril Arginine-WGR)* |
|  | Tablet containing perindopril erbumine 2 mg *(PERINDOPRIL-WGR)* |
|  | Tablet containing perindopril erbumine 4 mg *(PERINDOPRIL-WGR)* |
|  | Tablet containing perindopril erbumine 8 mg *(PERINDOPRIL-WGR)* |
| Perindopril with indapamide | Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg *(PERINDOPRIL/INDAPAMIDE-WGR 4/1.25)* |
| Pioglitazone | Tablet 15 mg (as hydrochloride) *(ARX-PIOGLITAZONE)* |
| Posaconazole | Tablet (modified release) 100 mg *(POSACONAZOLE-WGR)* |
| Pravastatin | Tablet containing pravastatin sodium 10 mg *(PRAVASTATIN-WGR)* |
|  | Tablet containing pravastatin sodium 20 mg *(PRAVASTATIN-WGR)* |
|  | Tablet containing pravastatin sodium 40 mg *(PRAVASTATIN-WGR)* |
| Pregabalin | Capsule 25 mg *(PREGABALIN-WGR)* |
|  | Capsule 75 mg *(PREGABALIN-WGR)* |
|  | Capsule 150 mg *(PREGABALIN-WGR)* |
|  | Capsule 300 mg *(PREGABALIN-WGR)* |
| Prochlorperazine | Tablet containing prochlorperazine maleate 5 mg *(PROCHLORPERAZINE-WGR)* |
| Propranolol | Tablet containing propranolol hydrochloride 10 mg*(PROPRANOLOL-WGR)* |
|  | Tablet containing propranolol hydrochloride 40 mg*(PROPRANOLOL-WGR)* |
| Rabeprazole | Tablet containing rabeprazole sodium 10 mg (enteric coated)*(RABEPRAZOLE-WGR)* |
|  | Tablet containing rabeprazole sodium 20 mg (enteric coated)*(RABEPRAZOLE-WGR)* |
| Ramipril | Capsule 10 mg *(RAMIPRIL-WGR)* |
|  | Tablet 1.25 mg *(RAMIPRIL-WGR)* |
|  | Tablet 2.5 mg *(RAMIPRIL-WGR)* |
|  | Tablet 5 mg *(Ramipril Viatris; RAMIPRIL-WGR)* |
|  | Tablet 10 mg *(RAMIPRIL TABS-WGR)* |
| Rasagiline | Tablet 1 mg (as mesilate) *(RASAGILINE-WGR)* |
| Risedronic acid | Tablet containing risedronate sodium 35 mg *(RISEDRONATE-WGR)* |
| Risperidone | Oral solution 1 mg per mL, 100 mL *(Risperidone Lupin)* |
| Rizatriptan | Tablet (orally disintegrating) 10 mg (as benzoate) *(RIZATRIPTAN ODT-WGR)* |
| Rosuvastatin | Tablet 5 mg (as calcium) *(APO-ROSUVASTATIN; ROSUVASTATIN-WGR)* |
|  | Tablet 10 mg (as calcium) *(ROSUVASTATIN-WGR)* |
|  | Tablet 20 mg (as calcium) *(ROSUVASTATIN-WGR)* |
|  | Tablet 40 mg (as calcium) *(ROSUVASTATIN-WGR)* |
| Roxithromycin | Tablet 150 mg *(ROXITHROMYCIN-WGR)* |
|  | Tablet 300 mg *(ROXITHROMYCIN-WGR)* |
| Sertraline | Tablet 50 mg (as hydrochloride) *(SERTRALINE-WGR)* |
|  | Tablet 100 mg (as hydrochloride) *(SERTRALINE-WGR)* |
| Sotalol | Tablet containing sotalol hydrochloride 80 mg *(SOTALOL-WGR)* |
|  | Tablet containing sotalol hydrochloride 160 mg *(SOTALOL-WGR)* |
| Sumatriptan | Tablet 50 mg (as succinate) *(SUMATRIPTAN-WGR)* |
| Telmisartan | Tablet 40 mg *(TELMISARTAN-WGR)* |
|  | Tablet 80 mg *(TELMISARTAN-WGR)* |
| Telmisartan with hydrochlorothiazide | Tablet 40 mg-12.5 mg *(TELMISARTAN HCTZ-WGR 40/12.5)* |
|  | Tablet 80 mg-12.5 mg *(TELMISARTAN HCTZ-WGR 80/12.5)* |
|  | Tablet 80 mg-25 mg *(TELMISARTAN HCTZ-WGR 80/25)* |
| Temazepam | Tablet 10 mg *(TEMAZEPAM-WGR)* |
| Terbinafine | Tablet 250 mg (as hydrochloride) *(TERBINAFINE-WGR)* |
| Topiramate | Tablet 25 mg *(TOPIRAMATE-WGR)* |
|  | Tablet 50 mg *(TOPIRAMATE-WGR)* |
|  | Tablet 100 mg *(TOPIRAMATE-WGR)* |
|  | Tablet 200 mg *(TOPIRAMATE-WGR)* |
| Tramadol | Capsule containing tramadol hydrochloride 50 mg *(TRAMADOL-WGR)* |
|  | Tablet (sustained release) containing tramadol hydrochloride 100 mg *(TRAMADOL-WGR SR)* |
|  | Tablet (sustained release) containing tramadol hydrochloride 150 mg *(TRAMADOL-WGR SR)* |
|  | Tablet (sustained release) containing tramadol hydrochloride 200 mg *(TRAMADOL-WGR SR)* |
| Trimethoprim | Tablet 300 mg *(TRIMETHOPRIM-WGR)* |
| Valaciclovir | Tablet 500 mg (as hydrochloride) *(VALACICLOVIR-WGR)* |
| Venlafaxine | Capsule (modified release) 37.5 mg (as hydrochloride) *(VENLAFAXINE XR-WGR)* |
|  | Capsule (modified release) 75 mg (as hydrochloride) *(VENLAFAXINE XR-WGR)* |
|  | Capsule (modified release) 150 mg (as hydrochloride) *(VENLAFAXINE XR-WGR)* |

**Brands Deleted**

|  |  |
| --- | --- |
| ***Listed Drug***  |  ***Form and Brand***  |
| Amlodipine | Tablet 5 mg (as besilate) *(BTC Amlodipine)* |
| Amoxicillin with clavulanic acid | Tablet 10 mg (as besilate) *(BTC Amlodipine)* |
| Amoxicillin with clavulanic acid | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(AlphaClav Duo Forte)* |
| Atorvastatin | Tablet 10 mg (as calcium) *(Blooms the Chemist Atorvastatin)* |
|  | Tablet 20 mg (as calcium) *(Blooms the Chemist Atorvastatin)* |
|  | Tablet 40 mg (as calcium) *(Blooms the Chemist Atorvastatin)* |
| Candesartan | Tablet 80 mg (as calcium) *(Blooms the Chemist Atorvastatin)* |
| Candesartan | Tablet containing candesartan cilexetil 4 mg *(Blooms the Chemist Candesartan)* |
| Tablet containing candesartan cilexetil 8 mg *(Blooms the Chemist Candesartan)* |
| Candesartan with hydrochlorothiazide | Tablet containing candesartan cilexetil 16 mg *(Blooms the Chemist Candesartan)* |
| Tablet containing candesartan cilexetil 32 mg *(Blooms the Chemist Candesartan)* |
| Candesartan with hydrochlorothiazide | Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg *(Blooms the Chemist Candesartan HCTZ 32/12.5)* |
| Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg *(Blooms the Chemist Candesartan HCTZ 32/25)* |
| Capecitabine | Tablet 500 mg *(Capecitabine-DRLA)* |
| Clopidogrel | Tablet 75 mg (as besilate) *(BTC Clopidogrel)* |
| Escitalopram | Tablet 10 mg (as oxalate) *(Blooms the Chemist Escitalopram)* |
| Fenofibrate | Tablet 20 mg (as oxalate) *(Blooms the Chemist Escitalopram)* |
| Fenofibrate | Tablet 145 mg *(Blooms the Chemist Fenofibrate)* |
| Fluoxetine | Capsule 20 mg (as hydrochloride) *(BTC Fluoxetine)* |
| Glimepiride | Tablet 1 mg *(Amaryl)* |
| Granisetron | Concentrated injection 3 mg (as hydrochloride) in 3 mL *(Granisetron Kabi)* |
| Irbesartan | Tablet 75 mg *(Avapro; Blooms the Chemist Irbesartan)* |
|  | Tablet 150 mg *(Blooms the Chemist Irbesartan)* |
| Leflunomide | Tablet 10 mg *(Arabloc)* |
| Lercanidipine | Tablet containing lercanidipine hydrochloride 10 mg *(BTC Lercanidipine)* |
|  | Tablet containing lercanidipine hydrochloride 20 mg *(BTC Lercanidipine)* |
| Olanzapine | Tablet 2.5 mg *(NOUMED OLANZAPINE)* |
|  | Tablet 5 mg *(NOUMED OLANZAPINE)* |
|  | Tablet 7.5 mg *(NOUMED OLANZAPINE)* |
|  | Tablet 10 mg *(NOUMED OLANZAPINE)* |
| Perindopril | Tablet containing perindopril erbumine 2 mg *(BTC Perindopril)* |
|  | Tablet containing perindopril erbumine 4 mg *(BTC Perindopril)* |
|  | Tablet containing perindopril erbumine 8 mg *(BTC Perindopril)* |
| Pregabalin | Capsule 75 mg *(Blooms The Chemist Pregabalin)* |
| Rosuvastatin | Tablet 5 mg (as calcium) *(Blooms the Chemist Rosuvastatin)* |
|  | Tablet 10 mg (as calcium) *(Blooms the Chemist Rosuvastatin)* |
|  | Tablet 20 mg (as calcium) *(Blooms the Chemist Rosuvastatin)* |
|  | Tablet 40 mg (as calcium) *(Blooms the Chemist Rosuvastatin)* |
| Venlafaxine | Capsule (modified release) 75 mg (as hydrochloride) *(Blooms the Chemist Venlafaxine XR)* |
|  | Capsule (modified release) 150 mg (as hydrochloride) *(Blooms the Chemist Venlafaxine XR)* |

**Deletion of Maximum Quantity and Number of Repeats**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Maximum Quantity*** | ***Number of Repeats*** |
| Colestyramine | Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50 | 2 | 11 |

**Alteration of Responsible Person Code**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Responsible Person*** |
| Haloperidol decanoate | I.M. injection equivalent to 50 mg haloperidol in 1 mL ampoule | Haldol decanoate | From: JC | To: IX |
|  | I.M. injection equivalent to 150 mg haloperidol in 3 mL ampoule | Haldol decanoate | From: JC | To: IX |
| Oxycodone | Tablet containing oxycodone hydrochloride 5 mg | Mayne Pharma Oxycodone IR |  From: YN |  To: SZ |

**Addition of Responsible Person**

|  |
| --- |
| ***Responsible Person and Code*** |
| AMICUS THERAPEUTICS PTY LTD *(FT)* |
| WAGNER PHARMACEUTICALS PTY LTD *(WG)* |

**Deletion of Responsible Person**

|  |
| --- |
| ***Responsible Person and Code*** |
| Medis Pharma Pty Ltd *(ZP)* |
| Apotex Pty Ltd *(JB)* |

**Supply Only – Additions**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Budesonide with formoterol | Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses |
| Triglycerides, long chain with glucose polymer | Oral liquid 250 mL, 18 (ProZero) |

**Supply Only – Deletions**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Bisacodyl | Enemas 10 mg in 5 mL, 25 |
| Ketoconazole | Cream 20 mg per g, 30 g |

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

|  |
| --- |
| ***Listed Drug*** |
| Adalimumab | Hypromellose with dextran  |
| Alectinib | Indacaterol |
| Amantadine | Indacaterol with glycopyrronium |
| Beclometasone | Indacaterol with glycopyrronium and mometasone |
| Beclometasone with formoterol | Indacaterol with mometasone |
| Beclometasone with formoterol and glycopyrronium | Lansoprazole |
| Betaxolol | Larotrectinib |
| Bimatoprost | Latanoprost |
| Bimatoprost with timolol | Latanoprost with timolol |
| Bisacodyl | Levodopa with benserazide |
| Brigatinib | Levodopa with carbidopa |
| Brimonidine | Levodopa with carbidopa and entacapone |
| Brimonidine with timolol | Lorlatinib |
| Brinzolamide | Macrogol 3350 |
| Brinzolamide with brimonidine | Mianserin |
| Brinzolamide with timololDorzolamide with timolol | Migalastat |
| Budesonide | Minocycline |
| Budesonide with formoterol | Pyridostigmine |
| Budesonide with glycopyrronium and formoterol | Rabeprazole |
| Cabergoline | Rasagiline |
| Cabozantinib | Reboxetine |
| Carbomer | Mirtazapine |
| Carmellose | Moclobemide |
| Carmellose with glycerin | Montelukast |
| Ceritinib | Nizatidine |
| Ciclesonide | Omeprazole |
| Citalopram | Pantoprazole |
| Colestyramine | Paraffin |
| Crizotinib | Paroxetine |
| Desvenlafaxine | Perfluorohexyloctane |
| Diltiazem | Pilocarpine |
| Dorzolamide | Polyethylene glycol 400 with propylene glycol |
| Doxycycline | Pramipexole |
| Entacapone | Riluzole |
| Entrectinib | Rotigotine |
| Eprosartan with hydrochlorothiazide | Safinamide |
| Erythromycin | Salmeterol |
| Escitalopram | Secukinumab |
| Ganciclovir | Selegiline |
| Gemfibrozil | Sertraline |
| Esomeprazole | Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate |
| Esomeprazole and clarithromycin and amoxicillin | Soy lecithin |
| Fluoxetine | Sulfasalazine |
| Fluticasone furoate  | Teriparatide |
| Fluticasone furoate with umeclidinium and vilanterol | Testosterone |
| Fluticasone furoate with vilanterol | Tetrabenazine |
| Fluticasone propionate | Tiotropium |
| Fluticasone propionate with formoterol | Tiotropium with olodaterol |
| Fluticasone propionate with salmeterol | Trabectedin |
| Fluvoxamine | Tranylcypromine |
| Formoterol | Trastuzumab |
| Fosinopril with hydrochlorothiazide | Trastuzumab deruxtecan |
| Glycopyrronium | Trastuzumab deruxtecan  |
| Hyaluronic acid | Trastuzumab emtansine |
| Hypromellose | Travoprost |
| Hypromellose  | Travoprost with timolol |
| Hypromellose with carbomer 980 | Umeclidinium |
| Hypromellose with carbomer 980  | Valganciclovir |
| Hypromellose with dextran | Venlafaxine |

**Documents Incorporated by Reference**

|  |  |  |
| --- | --- | --- |
| ***Listed Drug*** | ***Document incorporated*** | ***Document access*** |
| Cabozantinib | **International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma**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 International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma is a tool used to predict survival in patients with metastatic renal cell carcinoma who are treated with systemic therapy. | The IMDC Risk Model is available for download for free from the MDCalc website: www.mdcalc.com/calc/3008/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma  |
| Cabozantinib | **Response Evaluation Criteria in Solid Tumours (RECIST) guidelines**The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*.The RECIST guidelines are a tool used widely for defining when tumours in cancer patients respond, stabilise and/or progress during treatment. | The RECIST guidelines are available for download for free from the RECIST Working Group website: https://recist.eortc.org/ |
| AlectinibBrigatinibCabozantinibCeritinibCrizotinibEntrectinibLorlatinib | **World Health Organisation (WHO) / Eastern Cooperative Oncology Group (ECOG) Performance Status Grading system**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*.Performance status quantifies the general well-being and ability to perform activities of daily life of a patient affected by cancer.The grading runs in whole numbers from 0 to 5, with grade 0 representing perfect health and 5 representing death.It is also known as the Eastern Cooperative Oncology Group (ECOG) score, or as the Zubrod score. | Medical text books and literature. Scientific journals that reference:Oken MM et al. 1982. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol* 5:649-655The ECOG-ACRIN Cancer Research Group publishes the scale on the following website:https://ecog-acrin.org/resources/ecog-performance-status/ |

**Diagnostic tools referenced in the Instrument**

*The following standard medical diagnostic tools are referenced in the Instrument but are not intended to incorporate a document by reference.*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Diagnostic tool*** | ***Purpose and use in the Instrument*** | ***Reason this reference does not serve to incorporate a document*** |
| Cardiac MRI  | Migalastat | It is a magnetic resonance imaging technology used for non-invasive assessment of the function and structure of the cardiovascular system. | Cardiac MRI is used to diagnose a wide range of heart conditions. These include Left ventricular hypertrophy shown in cardiac related Fabry disease. |
| Echocardiogram  | Migalastat | It is an ultrasound test that checks the structure and function of your heart. An echocardiogram uses sound waves to create pictures of the heart. This common test can show blood flow through the heart and heart valves. | The test can help a health care provider diagnose heart conditions such as Left ventricular hypertrophy shown in cardiac related Fabry disease.  |
| Hidradenitis Suppurativa Clinical Response (HiSCR) | Adalimumab Secukinumab | The HiSCR is used to assess/determine an adequate response to a particular biological medicine for the treatment of Hidradenitis Suppurativa. HiSCR is defined as a ≥ 50% reduction in inflammatory lesion count (abscesses + inflammatory nodules), and no increase in abscesses or draining fistulas when compared with baseline. | Assessing the validity, responsiveness and meaningfulness of the Hidradenitis Suppurativa Clinical Response (HiSCR) as the clinical endpoint for hidradenitis suppurativa treatment. |

**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 (Maximum Dispensed Quantities September Update) Instrument 2024***

**(PB 85 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**

The *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) Instrument 2024*(the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) (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 2024 the Principal Instrument will be amended by Schedule 1 to this Instrument to implement Stage 3 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 third of three stages of implementation of the MDQ measure. Stage 3 includes some medicines for chronic conditions such asacne, anxiety disorders,asthma, chronic obstructive pulmonary disease (COPD), constipation, depression, dry eyes, gastro-oesophageal reflux disease (GORD), glaucoma and Parkinson disease

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 Instrument advances the right to health and the right to social security by providing new drugs, forms and brands of existing listed drugs, and ensuring the deletion of drugs, forms and brands of listed drugs does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of 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 Instrument includes the addition of a new drug, the addition of 4 new forms of existing drugs, and the addition of 223 new brands across existing forms, which allows for greater patient access to these drugs.

Stage 3 of the MDQ measure will be implemented on 1 September 2024 by amendments to the Principal Instrument made by the *National Health (Listing of Pharmaceutical Benefits) Amendment (Maximum Dispensed Quantities September Update) 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*. 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.

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

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

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

The drug bisacodyl in the form enemas 10 mg in 5 mL, 25 (Bisalax) was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are alternative products available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug budesonide with formoterol in the form pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses (Symbicort Rapihaler 50/3) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug fosinopril with hydrochlorothiazide (Fosetic 20/12.5) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug ketoconazole (Nizoral 2% Cream) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the sponsor’s plans to discontinue manufacture of Nizoral 2% cream and that there are alternative products available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug methylprednisolone in the form powder for injection 40 mg (as sodium succinate) (S19A) (Solu-Medrone) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of methylprednisolone in the form powder for injection 40 mg (as sodium succinate) with diluent. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 March 2024. Patient access has not been affected by this delisting, as the approved form of the drug is now available and remains PBS-subsidised and accessible for patients.

The drug triglycerides, long chain with glucose polymer in the form oral liquid 250 mL, 18 (ProZero) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are alternatives on the PBS, however the alternatives may not be suitable for all patients. The PBAC advised the delisting of these products may result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment.

**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**