EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2023 (No. 1)

PB 70 of 2023

Purpose

The purpose of this legislative instrument, made under subsection 89A(3) of the *National Health Act 1953* (the Act), is to amend the *National Health (Continued Dispensing) Determination 2022* to make changes to the pharmaceutical benefits eligible to be provided as a Continued Dispensing supply.

The *National Health (Continued Dispensing) Determination 2022* (the Principal Instrument) lists the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and provides the conditions for such a supply (a 'Continued Dispensing' supply).

The amendments made by this instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and the conditions for such a supply ('Continued Dispensing').

This instrument does not override state and territory legislation and does not apply in the external territories. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to the eligible medicines.

Amendments made by this Instrument

Schedule 1 to this instrument provides for the addition of the drug sotalol and the deletion of the drugs adefovir, cromoglycic acid, dolutegravir, efavirenz, enfuvirtide, entecavir, ertugliflozin, ertugliflozin with metformin, ertugliflozin with sitagliptin, exenatide, losartan, norethisterone with mestranol, pindolol, raltegravir, and tipranavir from the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply.

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

Consultation

This instrument affects approved pharmacists, at or from premises in respect of which the pharmacist is for the time being approved, supplying a pharmaceutical benefit. Consultation was undertaken prior to commencement of the Principal Instrument with relevant peak bodies including the Pharmaceutical Society of Australia, Australian Medical Association, Royal Australian College of General Practitioners, Consumers Health Forum, the Australian Federation of AIDS Organisations, and the Pharmacy Guild of Australia. The Department has also undertaken direct consultation with Services Australia and has consulted with state and territory Departments of Health about implementation.

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

General

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

This instrument commences on 1 August 2023.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2023 (No. 1)*

Section 1 Name

This section provides that the Instrument is the *National Health (Continued Dispensing) Amendment Determination 2023 (No. 1)* and may also be cited as PB 70 of 2023.

Section 2 Commencement

This section provides that the Instrument commences on 1 August 2023.

Section 3 Authority

This section states that this Instrument is made under subsection 89A(3) of the of the *National Health Act 1953*.

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition and deletion of drugs for the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. These changes are summarised below.

SUMMARY OF CHANGES TO THE CONTINUED DISPENSING MEASURE MADE BY THIS INSTRUMENT

Drug Added

Listed Drug

Sotalol

Drugs Deleted

Listed Drug

Adefovir

Cromoglycic acid

Dolutegravir

Efavirenz

Enfuvirtide

Entecavir

Ertugliflozin

Ertugliflozin with metformin

Ertugliflozin with sitagliptin

Exenatide

Losartan

Norethisterone with mestranol

Pindolol

Raltegravir

Tipranavir

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing) Amendment Determination 2023 (No. 1)

(PB 70 of 2023)

This legislative 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 Legislative Instrument

The *National Health (Continued Dispensing) Amendment Determination 2023 (No. 1)* (the Instrument) amends the *National Health (Continued Dispensing) Determination 2022* (the Principal Instrument) which specifies the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the *National Health Act 1953* without a prescription, and the conditions for such a supply ('Continued Dispensing').

This Instrument provides for amendments to the Special Arrangement to ensure that the Special Arrangement accurately reflects changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act, which commences on the same day.

Human rights implications

This Instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Social Security

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (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 (the Committee) 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

This Instrument advances the right to health and the right to social security by ensuring that amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Listing Instrument), that affect the pharmaceutical benefits that may be supplied as a Continued Dispensing supply, are also made in the Principal Instrument (*National Health (Continued Dispensing) Determination 2022*). This Instrument provides for the addition of the drug sotalol to the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply. It also provides for the deletion of the listed drugs adefovir, cromoglycic acid, dolutegravir, efavirenz, enfuvirtide, entecavir, ertugliflozin, ertugliflozin with metformin, ertugliflozin with sitagliptin, exenatide, losartan, norethisterone with mestranol, pindolol, raltegravir, and tipranavir from the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply.

The Listing Instrument determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based. This Instrument continues to provide the option for patients to have subsidised access to eligible PBS medicines through continued dispensing arrangements.

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 *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*. 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 in the abovementioned instruments, would not result in an unmet clinical need. The delisting of these items will not affect access to the drugs, 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 2023, these fees are up to $30.00 for general patients and $7.30 for concession card holders.

The drug cromoglycic acid was requested to be delisted from the PBS by the sponsor due to the discontinuation of the product. The PBAC considered that there were several suitable clinical alternatives and advised the delisting of cromoglycic acid would not result in an unmet clinical need.

The drug efavirenz was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug enfuvirtide was requested to be delisted from the PBS by the sponsor due to it being discontinued from manufacture. The PBAC noted the low rate of utilisation and that there were clinical alternatives available. The PBAC advised that the delisting of enfuvirtide would not result in an unmet clinical need.

The drug ertugliflozin was requested to be delisted from the PBS by the sponsor. The PBAC noted there were a moderate number of services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug ertugliflozin with metformin was requested to be delisted from the Pharmaceutical Benefits Scheme (PBS) by the sponsor. The PBAC noted the range of alternatives on the Schedule and also that the two agents would remain listed as individual products. The PBAC advised the delisting of these products would not result in an unmet clinical need.

The drug ertugliflozin with sitagliptin was requested to be delisted from the PBS by the sponsor. The PBAC noted there were a moderate number of services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug exenatide was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, available clinical alternatives and sponsor's intent to discontinue supply of the product. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug losartan was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are several alternatives on the PBS. The PBAC advised the delisting of these products would not result in an unmet clinical need.

The drug norethisterone with mestranol was requested to be delisted from the PBS by the sponsor. The PBAC noted the sponsor intends to discontinue supply in Australia. The PBAC agreed with the specialist advice that there are suitable alternatives. The PBAC advised that the delisting of this product would not result in an unmet clinical need.

The drug pindolol was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, available clinical alternatives and sponsor's intent to discontinue supply of the product. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug tipranavir was requested to be delisted by the sponsor. The PBAC noted low utilisation of tipranavir and that there are several alternatives. The PBAC considered that the delisting of tipranavir would not result in an unmet clinical need.

The drugs adefovir, dolutegravir, entecavir and raltegravir are being removed from the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply but remain listed on the Schedule of Pharmaceutical Benefits otherwise unchanged.

Conclusion

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

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