EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2021 (No. 11)

PB 120 of 2021

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 – Emergency Measures) Determination 2020* to make changes to the pharmaceutical benefits eligible to be provided as a Continued Dispensing supply.

The *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (the Principal Instrument) expands the list of 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 poisons laws. 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 listed drugs lanadelumab, and ripretinib, the addition of forms of the listed drugs high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate, and ribavirin, and the deletion of forms of the listed drugs desmopressin, imipramine, and testosterone, for 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 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 December 2021.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2021 (No. 11)*

Section 1 Name

This section provides that the Instrument is the *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2021 (No. 11)* and may also be cited as PB 120 of 2021.

Section 2 Commencement

This section provides that the Instrument commences on 1 December 2021.

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 of listed drugs, and the addition and deletion of forms of listed 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 – EMERGENCY MEASURE MADE BY THIS INSTRUMENT

Listed Drugs Added

Listed Drug
Lanadelumab
Ripretinib

Forms Added

Listed Drug	***Form***
High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate	Oral liquid 250 mL, 30 (KetoVie Peptide 4:1)
Ribavirin	Tablet 200 mg

Forms Deleted

Listed Drug	***Form***
Desmopressin	Intranasal solution containing desmopressin acetate 100 micrograms per mL, 2.5 mL dropper bottle

Imipramine	Tablet containing imipramine hydrochloride 25 mg USP
Testosterone	Capsule containing testosterone undecanoate 40 mg

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2021 (No. 11)

(PB 120 of 2021)

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 (Continued Dispensing – Emergency Measures) Amendment Determination 2021 (No. 11)* amends the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* 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').

Human rights implications

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 PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based. The pharmaceutical industry now has a nominee on the PBAC membership.

Whether there is any detriment to patients by the delisting of these drugs, and if so, how this is compatible with the right to social security

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.

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. PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from 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 and the form 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.

Patients accessing PBS subsidised medicines are usually required to pay a co-payment towards their cost. From 1 January 2021, these fees are up to $41.30 for general patients and up to $6.60 for concession card holders. These co-payments are payable for accessing all PBS subsidised medicines. The delisting of the drugs specified below is therefore unlikely to result in a negative financial impact for patients. This is due to the same maximum co-payments applying to all PBS listed medicines.

In the event of a medicine shortage, a provision under section 19A of the Therapeutic Goods Act 1989 allows for temporary approvals to be granted for the import or supply of a brand of medicine that is not registered on the Australian Register of Therapeutic Goods, which could act as a substitute for the medicine that is unavailable or in short supply. Where possible, the Australian Government works with medicine sponsors to organise PBS subsidised access to section 19A medicines, and when the shortage is resolved, the section 19A approval lapses as the medicine is no longer required and is therefore delisted without the need for consideration by the PBAC.

Considerations for forms being delisted in this instrument

Desmopressin	Intranasal solution containing desmopressin acetate 100 micrograms per mL, 2.5 mL dropper bottle	The sponsor requested the delisting of desmopressin acetate nasal drops from the PBS. The PBAC noted there were suitable alternative forms of desmopressin available on the PBS. The PBAC therefore advised that the delisting of desmopressin acetate nasal drops would not result in an unmet clinical need.
Imipramine	Tablet containing imipramine hydrochloride 25 mg USP	Section 19A delisting. Imipramine Tablet containing imipramine hydrochloride 25 mg continues to be available.
Testosterone	Capsule containing testosterone undecanoate 40 mg	The sponsor requested the delisting of testosterone undecanoate from the PBS due to low utilisation and the discontinuation of supply. The PBAC noted there were alternative forms of testosterone available on the PBS. The PBAC therefore advised that the delisting of testosterone undecanoate capsules would not result in an unmet clinical need.

Conclusion

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

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