EXPLANATORY STATEMENT

National Health Act 1953

National Health (Minimum Stockholding) Amendment Determination (No. 12) 2025

PB 159 of 2025

Authority

This instrument is made under subsection 99AEKC(2) of the *National Health Act 1953* (**the Act**).

Subsection 99AEKC(2) of the Act provides that the Minister may, by legislative instrument, make a determination of another quantity for the purposes of subparagraph 1(a)(ii) or subparagraph 1(b)(ii) of Section 99AEKC of the Act.

Subsection 33(3) of the *Acts Interpretation Act 1901* (**the Acts Interpretation Act**) provides that where an Act confers a power to make an instrument of a legislative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to amend or vary any such instrument. Subsection 4(2) of the Acts Interpretation Act provides that where an amendment to an Act will confer a power to make an instrument, the power may be exercised before commencement of the amendments as if the relevant commencement had occurred. The provisions of the instrument take effect at the commencement date (or later time specified in the instrument) (subsection 4(5) of the Acts Interpretation Act).

Unless there is an express power to revoke or vary PB 65 of 2023 cited in this Instrument and explanatory statement, subsection 33(3) of the Acts Interpretation Act is relied upon to revoke or vary PB 65 of 2023.

Changes to PB 65 of 2023 made by this Instrument

This instrument determines an 'applicable quantity' for the purposes of subsections 99AEKC(1)(a)(ii) and/or 99AEKC(1)(b)(ii) of the Act, for certain brands of pharmaceutical items which are subject to the minimum stockholding requirement in Division 3CAA of the Act.

Background

Part VII of the Act establishes the Pharmaceutical Benefits Scheme (**PBS**), which provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for the supply of drugs and medicinal preparations as pharmaceutical benefits.

On 6 September 2021 the Commonwealth entered into new 5-year Strategic Agreements with Medicines Australia (**MA**) and the Generic and Biosimilar Medicines Association (**the GBMA**) commencing on 1 July 2022. The new agreements include improved statutory price reductions under Division 3A of the Act, the introduction of floor price protections and

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stockholding requirements under the Act and the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Consultation

The determinations of 'another quantity' for the purposes of the minimum stockholding requirement for particular brands of pharmaceutical items impact pharmaceutical companies that supply medicines that are subsidised through the PBS.

MA and the GBMA were consulted in the development of PBS Minimum Stockholding Guidelines (**the Guidelines**), which provide guidance for pharmaceutical companies on the process to request a Ministerial determination for another stockholding quantity for a particular brand of pharmaceutical item, including the matters the Minister may consider relevant.

The Guidelines also outline the department's policies with respect to lead times for pharmaceutical companies to prepare to hold minimum stockholdings, and the process for the Minister to determine the applicable quantity for the minimum stockholding requirement is zero, during a period of up to 6 months prior to a brand of a pharmaceutical item delisting from the PBS. MA and the GBMA were consulted regarding those departmental policies.

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

The Act specifies no conditions that need to be satisfied before the power to make a determination by legislative instrument under subsection 99AEKC(2) of the Act may be exercised.

The *National Health (Minimum Stockholding) Amendment Determination (No. 12) 2025* is a legislative instrument for the purposes of the *Legislation Act 2003*.

The *National Health (Minimum Stockholding) Amendment Determination (No. 12) 2025* commences as set out in the Attachment.

Details of the *National Health (Minimum Stockholding) Amendment Determination (No. 12) 2025* are set out in the Attachment.

Authority: Subsection 99AEKC(2) of the
National Health Act 1953

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ATTACHMENT

Details of the proposed *National Health (Minimum Stockholding) Amendment Determination (No. 12) 2025*

Section 1 – Name

This section provides the name of this Instrument as the *National Health (Minimum Stockholding) Amendment Determination (No. 12) 2025.*

This section also provides that this Instrument may also be cited as PB 159 of 2025.

Section 2 – Commencement

This section provides that each provision of this Instrument commences as set out in the table.

Section 3 – Authority

This section states that this Instrument is made under subsection 99AEKC(2) of the Act.

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 commencing 1 January 2026

The amendments in Schedule 1 commence on 1 January 2026 and provide the quantity which is determined as the applicable quantity of a brand of pharmaceutical item for the purpose of subparagraphs 99AEKC(1)(a)(ii) and/or (1)(b)(ii) of the Act, for each brand of a pharmaceutical item which is specified in the Schedule.

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Statement of Compatibility with Human Rights

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

NATIONAL HEALTH (MINIMUM STOCKHOLDING) AMENDMENT DETERMINATION (NO. 12) 2025

This Disallowable 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 Disallowable Legislative Instrument

This legislative instrument determines an 'applicable quantity' for the purposes of subsections 99AEKC(1)(a)(ii) and/or 99AEKC(1)(b)(ii) of the *National Health Act 1953* (**the Act**), for certain brands of pharmaceutical items which are subject to the minimum stockholding requirement in Division 3CAA of the Act.

The effect of a determination of an applicable quantity is that a pharmaceutical company which would otherwise be required to hold a 4- or 6-month minimum stockholding of a brand of a pharmaceutical item, will instead be required to hold the quantity which has been determined as the applicable quantity. A determination may be effective for a specified period of time, or the time period may not be specified (in which case it is effective from when the determination commences, to when it is revoked).

Human rights implications

This legislative instrument engages the following rights:

- the right to social security under Article 9 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)
- the right to the enjoyment of the highest attainable standard of physical and mental health under Article 12 of the ICESCR.

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 (**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.

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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

Article 9 of the ICESCR recognises the right to social security. 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. The PBS is a social security measure that provides subsidised access to medicines for Australians.

This instrument ensures that medicines which are listed on the PBS and are subject to minimum stockholding requirements can still be effectively supplied on the PBS, by making appropriate adjustments to the minimum stockholding requirement where required. If these adjustments are not made where appropriate, the minimum stockholding policy would be undermined by requiring pharmaceutical companies to hold stock which is likely to be wasted, or by pharmaceutical companies not being given adequate time to prepare their supply chain to reliably meet the minimum stockholding requirements. Both circumstances would be likely to discourage pharmaceutical companies from listing medicines on the PBS, in turn impacting on Australian patients having access to subsidised medicines necessary for the proper treatment and management of common medical conditions.

Article 12(1) of the ICESCR recognises the right of all individuals to enjoy the highest attainable standard of physical and mental health. The determinations contained in this Instrument support the sustainability of the implementation of the minimum stockholding requirement for the pharmaceutical industry by providing determinations for a reduced minimum stockholding requirement where appropriate to ensure that pharmaceutical companies have the opportunity to dissipate their minimum stockholdings prior to delisting a medicine from the PBS, in order to avoid medicine wastage.

The purpose of the minimum stockholding requirement is to provide a buffer of stock which is available to be drawn down upon if required in the event of supply disruptions. This buffer is intended to allow time for supply disruptions to be resolved, and to ensure better continuity of supply for Australians. The minimum stockholding is additional stock which is held outside of the usual supply chain which otherwise consists of working stock and safety stock held by pharmaceutical companies, as well as stock held downstream by wholesalers and pharmaceutical retailers.

Where a brand is delisting from the PBS, if other brands of the same pharmaceutical item remain listed on the PBS, it is not expected that there will be any impact on patient access to appropriate medicines, as other brands remain listed on the PBS and are subject to the minimum

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stockholding requirement. Where there are no other brands available and there would be an unmet clinical need if a medicine were to delist, items are made available on the PBS Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option. It is expected that during this period of time, demand for the particular item is likely to reduce as patients transition to an alternative treatment option, and the available safety stock and working stock of the brand of the pharmaceutical item (not the previously required 4- or 6-month minimum stockholding which serves as a buffer against supply disruptions) will be adequate to meet that patient demand.

The determinations protect the right of individuals to enjoy the highest attainable standard of physical and mental health by ensuring that where determinations are made, it is for a limited period of time where appropriate, and in a quantity which is appropriate to the circumstances and supports the goal of the minimum stockholding requirements to provide security of medicines supply for Australian patients.

Conclusion

This legislative instrument is compatible with human rights.

Human rights continue to be protected by ensuring that where a determination is made for a minimum stockholding which is less than provided for by subparagraph 99AEKC(1)(a)(i) or (1)(b)(i) (as relevant), it is for a period of time and in a quantity which is appropriate to avoid medicine wastage and to support the development of secure medicine supply chains.

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