



Fact Sheet – Compliance with the Minimum Stockholding Requirements

Last updated: 27 August 2025

Purpose

This Factsheet outlines compliance with the minimum stockholding requirement (**MSR**) under Division 3CAA of Part VII of the [National Health Act 1953 \(the Act\)](#) and the [National Health \(Pharmaceutical Benefits\) Regulations 2017 \(the Regulations\)](#).

A glossary for **defined terms** is appended to this Factsheet.

The Requirements

Under the Act, a **Responsible Person** for a **designated brand** must do the following to meet the MSR:

1. **Stockholding** – Keep at least the applicable quantity of stock available for sale in Australia;
2. **Notification** – Notify the Minister where they believe there is likely to be or there is an actual breach of the stockholding requirement; and
3. **Disclosure** – Disclose stockholding levels twice a year.

Non-compliance with the MSR

A Responsible Person will be non-compliant if they fail to meet any of the three requirements outlined above. In the event of a breach of the stockholding requirement, the Minister may assess the breach and take such action(s) as they consider appropriate, including:

- de-listing from the PBS the medicine(s) which do not comply with the MSR and/or any other medicines which the Responsible Person has listed on the PBS; and/or
- refusing to list new medicines on the PBS for that Responsible Person.

Under the Act, the Minister must consider the reasons for the breach when determining to exercise the powers outlined above. Section 8 of the [PBS Minimum Stockholding Guidelines \(Guidelines\)](#) provides more details on the factors the Minister must and may consider when determining to exercise these powers.

A Responsible Person's failure to comply with the notification or stockholding disclosure requirements is a criminal offence and the Department may refer the contravention for prosecution.

Approach to non-compliance

The Department is guided by best practice principles to manage instances of non-compliance with the MSR. These shape the design and approach of the Department's MSR framework that:

1. **Is underpinned by data and information:** the Department monitors notifications and disclosure of information provided by Responsible Persons to understand the reasons for breaches, including the issues and sector





conditions that may be impacting specific compliance by specific Responsible Persons and overall industry compliance. The Department will assess each breach and critically evaluate the information and evidence which is put forward by the Responsible Person. The Department may consider other sources of information and data that could be relevant (for example, TGA medicine shortages information).

- 2. Considers risks:** the Department undertakes a risk-based approach to managing non-compliance. Where alleged or apparent non-compliance occurs, compliance or enforcement action is intended to be proportionate to the assessed risk of the non-compliance to the regulatory framework.



Before the Minister can exercise their powers in response to a breach by a Responsible Person of the MSR, the Minister is required to consider the following matters:

- the Responsible Person's reasons for the breach;
- whether, in the Minister's opinion, those reasons are reasonable;
- whether, in the Minister's opinion, the Responsible Person will consistently maintain adequate stock levels in the future;
- whether the Responsible Person has offered discounts or incentives in relation to sales of the designated brand;
- whether the Responsible Person has previously breached the MSR and, if so, the Responsible Person's reasons for the breach and whether, in the Minister's opinion, those reasons were reasonable; and
- whether the Responsible Persons for other brands of the same pharmaceutical items have breached the MSR in relation to those other brands.

The Department may consider non-compliance more serious and higher risk where:

- the conduct is unreasonable, deliberate, negligent, brazen and/or clearly not in line with the intention of the legislation;
- the Responsible Person maintains its opposed view to the Department's position on the non-compliance, and a voluntary improvement in regulatory/compliance behaviour or compliance with regulatory obligations cannot be practicably reached;
- there is reason to be concerned about future non-compliant behaviour; or the entity fails to demonstrate a willingness to achieve complete compliance.

Where the assessed risk is higher, the Department may request that the Responsible Person undertake specific additional stockholding reporting or provide evidence of mitigation actions – such as a corrective action plan/plan for continuous improvement. Where corrective action/s fail to address the identified non-compliance, and does not mitigate the risk/s, the Department may issue warning letters to the Responsible Person. Severe or unmitigated risks may result in consideration of the use of the Minister's powers, including de-listing or refusing to list the Responsible Person's brand(s) on the PBS.

- 3. Engages with Responsible Persons and seeks to improve outcomes:** the Department engages with Responsible Persons to build compliance, fostering





communication and collaboration to support industry's understanding of the expectations, consequences and best practices that can be adopted to drive high rates of compliance. Upon completing a risk assessment of the Responsible Person's non-compliance, the Department may engage with the Responsible Person to manage the non-compliance. This process involves the Responsible Person directly and will firstly seek to establish the facts. It is underpinned by the principle of returning the Responsible Person to compliance.

Key Resources

- [National Health Act 1953 \(Cth\)](#)
- [National Health \(Pharmaceutical Benefits\) Regulations 2017 \(Cth\)](#)
- [PBS Stockholding Guidelines](#)
- [Minimum Stockholding Requirement Webpage](#)
- [Quantity of stock to be held – Fact Sheet](#)
- [Determinations of Another Quantity – Fact Sheet](#)
- [Minimum Stockholding Requirement Notifications – Fact Sheet](#)
- [Executive Summary of the MSR Review](#)
- pbsstockholding@health.gov.au for all questions you may have regarding this Fact Sheet.

Glossary

Designated Brands

Designated brands are brands of pharmaceutical items that meet one of four criteria under section 99ADHC of the Act. A brand becomes a 'designated brand' and subject to minimum stockholding requirements if it meets any of the following criteria:

- the drug and manner of administration has been on Formulary 2 for at least 42 months with 30 months since the first price disclosure reduction;
- its approved ex-manufacturer price (AEMP) is \$4 or less;
- it (or another brand of the same pharmaceutical item) received a price increase after July 1, 2022, through a new price agreement, and the Minister has determined it to be a designated brand; or
- it had an AEMP less than \$3.50 before being subject to a price increase under section 104B on 1 October 2022.

More information on designated brand criteria is available at section 2 of the Guidelines.

Responsible Person

The [Responsible Person](#) is the person or corporation with a registered ABN that is or will be the supplier of a particular brand of a medicine on the PBS.

Disclosure

In accordance with section 99AEKF of the Act and section 85C of the Regulations, Responsible Persons are required to biannually disclose the quantity of stock held on the last day of each month in each 6-month disclosure period. Responsible Persons are required to submit the required information to the Price Disclosure Data Administrator (PDDA) by the following deadlines:



- for the period 1 April – 30 September: by 11 November; and
- for the period 1 October – 31 March: by 12 May.

Notification

Section 99AEKD of the Act requires Responsible Persons to notify the Minister ‘as soon as practicable’ of a likely or actual breach of the MSR. For a likely breach, this means as soon as practicable after they ‘form a belief’ of a likely breach. For an actual breach, this means as soon as practicable after the breach has occurred.