



Fact Sheet – Ministerial Determinations of Another Quantity

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Purpose

This Factsheet outlines the process and matters that may be considered by the Minister for Health and Aged Care when making a determination of ‘another quantity’ for the purposes of the minimum stockholding requirement (**MSR**) under Division 3CAA of Part VII of the [National Health Act 1953](#) (**the Act**).

The Requirements

The Act imposes a requirement for **Responsible Person** to keep a minimum stockholding of 4 or 6 months’ stock (by reference to usual demand) for **designated brands**, unless the Minister makes a determination ascertaining ‘another quantity’ (**a Ministerial determination**) which will apply for the purposes of the MSR.

Ministerial determinations of another quantity

Responsible Persons can apply for a Ministerial determination in relation to a designated brand. On receipt of such an application, the Minister may have regard to any matters that they consider relevant when deciding whether it is appropriate to make a Ministerial determination (and if relevant, what quantity is determined).

Ministerial determinations may be used to address long-term, practical barriers to compliance that cannot be overcome. For example, for medicines with a short-shelf life where it may not be feasible to comply with the 4 or 6-month MSR without giving rise to a risk of wastage of medicine. See [below](#) for further information regarding how an application based upon short shelf-life might be considered.

Each application is assessed, and a decision made, on a case-by-case basis. In assessing whether a brand can comply with the MSR, the Minister may consider actions that a Responsible Person could take to improve their ability to hold a compliant stockholding.

Responsible Persons may make further applications at any time, including if a final decision has been made, or if a brand has been subject to, and previously complied with, the MSR but now cannot.



How to apply for a Ministerial determination

The application form can be downloaded [here](#). Once completed, the form should be submitted by email to pbsstockholding@health.gov.au, together with any supporting documents and/or further submissions.

Responsible Persons should ensure that they are familiar with and address (as relevant) the matters outlined in Section 6 of the [PBS Minimum Stockholding Guidelines \(the Guidelines\)](#).

Ministerial determination outcomes

The Department works towards providing indicative and final outcomes for routine Ministerial determination applications in accordance with the timeframes below:

| Indicative Ministerial determination outcome | Closing date for RP to submit additional information | RP notified of final Ministerial determination outcome |
|--|--|---|
| 30 business days from application submission | 10 business days after indicative outcome provided | 20 business days after closing date for RP to submit additional information |

Timeframes for other types of Ministerial determination applications in connection with the MSR (such as for new brands) are provided in Section 6.1 of the Guidelines.

Responsible Persons may provide additional information in response to an indicative outcome, for consideration by the Minister (or their delegate) when a final decision is made. Responsible Persons are encouraged to use this opportunity to respond to any matters identified in the indicative outcome, or to provide additional information in support of earlier submissions.

Assessing an application based on short shelf-life

For applications based on short shelf-life, the Minister will generally use the factors outlined in Figure 1 and Figure 2 to consider whether compliance with the MSR is likely to result in wastage of stock.

Figure 1: Step 1 - Maximum warehousing period before wastage

$$\text{Maximum warehousing period before wastage} = (\text{Shelf-life}) \text{ minus } (\text{Supply lead-time to RP}^1) \text{ minus } (\text{Commercial shelf-life requirement}^2)$$

¹ The supply lead time information requested is 'supply chain time from when the brand is packaged by the manufacturer or packaging facility to when it meets the criteria to be counted towards the Responsible Person's minimum stockholding requirement' (i.e., stock which is available for sale by the Responsible Person in Australia). If shelf-life runs from an earlier time in the production process or there is any other supply chain timing information relevant to available shelf-life and the risk of wastage of stock, Responsible Persons are encouraged to provide details of this in their application.

² Responsible Persons often have contractual requirements with customers, for a brand to have a certain amount of shelf-life remaining when received by the wholesaler/pharmacy. The Department recognises that this helps to ensure that adequately dated medicines are available to patients.



Using information provided in the Responsible Person's application, the calculation outlined in Figure 1 may be performed to determine the maximum period the Responsible Person can warehouse stock before it has passed its commercial shelf-life requirement.

Figure 2: Step 2 – Peak stock level

$$\text{Peak stock level} = \text{Minimum stockholding} + \text{safety stock}^3 + \text{cycle stock}^4$$

Then, a peak stock level is calculated in accordance with Figure 2 using information provided by the Responsible Person. If a Responsible Person does not specify their safety stock and cycle stock quantities, an allowance will generally be made for 1 month safety stock and 1 month cycle stock.

Step 3 – Determining wastage

If the peak stock level (step 2) is greater than the maximum warehousing period before wastage (step 1), the Department may recommend the Minister determine a reduced stockholding quantity.

Worked Example

Applying the above steps to a worked example:

Step 1 - Maximum warehousing period before wastage

$$\text{Maximum warehousing period before wastage} = (\text{Shelf-life}) \text{ minus } (\text{Supply lead-time to RP}) \text{ minus } (\text{Commercial shelf-life requirement})$$

Where the shelf-life = 18 months; supply lead time = 3 months; and commercial shelf-life = 9 months:

$$\text{Maximum warehousing period before wastage} = 18 - 3 - 9 = 6 \text{ months.}$$

Step 2 – Peak stock level

$$\text{Peak stock level} = \text{Minimum stockholding} + \text{safety stock} + \text{cycle stock}$$

Where the minimum stockholding requirement = 6 months; safety stock = 1 month; and cycle stock = 1 month:

$$\text{Peak stock level} = 6 + 1 + 1 = 8 \text{ months.}$$

Step 3 – Determining wastage

As the peak stock level (8 months) is greater than the maximum warehousing period before wastage (6 months), it is expected that wastage would be induced to meet the MSR.

In this example, the Department may recommend that the Minister determine 'another quantity' of 4 months as the minimum stockholding requirement for the brand. This would result in a lower peak stock level of 6 months, which is equal to the maximum warehousing period before wastage.

³ Safety stock is stock held by Responsible Persons for utilisation where there is demand variation and supply disruptions (such as minor transit delays), so that compliance with the MSR can be maintained.

⁴ Cycle stock is the inventory purchased to meet expected demand between shipments.



Other factors

- If a Responsible Person has minimum order quantities (**MOQs**) resulting in higher levels of cycle stock for a brand, the Minister may consider what attempts a Responsible Person has made to reduce the MOQs to facilitate compliance.
- Where there is pre-existing obsolescence because of short shelf-life and MOQs, the risk of additional wastage (rather than total wastage) that might result will generally be considered.
- Responsible Persons are expected to improve supply chains and business practices where necessary to facilitate compliance. Determinations may not be recommended if supply chain or business practices can be improved (e.g., by reducing supply lead times or increasing shipment frequency).
- Ministerial determinations are made in a quantity and for the period that the Minister considers appropriate. A determination may be made for a limited period which allows time for a Responsible Person to improve their supply chain timing, and the determination may then either be revoked or replaced with a higher (but still reduced) ongoing stockholding requirement that accounts for those expected improvements. Responsible Persons may provide additional information regarding their capacity to improve supply chain timing, when responding to an indicative outcome. Responsible Persons may also submit a further application for a Ministerial determination if they have not been able to make improvements to facilitate compliance to the extent expected when a final outcome was previously provided.

Barriers to compliance other than short shelf-life

Short or medium-term difficulty meeting the MSR is managed through the non-compliance framework. For more information, please refer to the *Compliance with the Minimum Stockholding Requirements – Fact Sheet*. Ministerial determinations for a limited time are generally not recommended as a response to a short- or medium-term barrier to compliance.

Examples of short- or medium-term barriers include (but are not limited to):

- demand variation (refer to the Quantity of Stock to be held – Fact Sheet for more information);
- global supply constraints/disruptions; and
- transition of manufacturing facilities.

Prior to a brand delisting from the PBS, the Minister will generally make a determination of zero as the applicable quantity for a period of up to 6 months prior to delisting, as set out in section 4.4 of the Guidelines. No application is required for these determinations.

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 Kept – Fact Sheet](#)
- [Compliance with the Minimum Stockholding Requirements – Fact Sheet](#)
- [Minimum Stockholding Requirement Notifications – Fact Sheet](#)
- [Executive Summary of the MSR Review](#)



Australian Government

Department of Health and Aged Care



- pbsstockholding@health.gov.au for questions regarding this Fact Sheet.