



# Fact Sheet – Minimum Stockholding Requirement Notifications

Last updated: 27 August 2025

## Purpose

This Fact Sheet outlines Responsible Persons' requirements to notify the Minister for Health and Aged Care (the **Minister**) of likely and actual breaches of the minimum stockholding requirements (the **MSR**).

## The Notification Requirements

Under the [National Health Act 1957](#) (the **Act**), the Responsible Person for a designated brand subject to the MSR is required to notify the Minister of any likely or actual breach of the MSR in accordance with section 99AEKD of the Act.

## What notification do I need to submit?

There are two categories of notifications:

- Likely breach notification - must be submitted if a Responsible Person forms the belief that they are likely to breach the MSR
- Actual breach notification - must be submitted when a Responsible Person breaches the MSR

## When do I need to submit a notification?

All notifications must be submitted **as soon as practicable**:

- in the case of a likely breach, after the Responsible Person forms the belief that they are likely to breach the requirements; or
- in the case of an actual breach, after a breach of the minimum stockholding requirement has occurred in relation to a designated brand.

In both cases, the Department treats the term 'practicable' as meaning the time needed to undertake the ordinary business processes necessary to submit the mandatory information required for a notification being the processes required to collect, confirm and authorise the information. The Department acknowledges it is not usually practicable for these processes to be undertaken outside of normal business hours – such as the weekend or on public holidays.

The requirement to notify the Minister relates to each individual likely and actual breaches. Responsible Persons must not aggregate notifications of likely or actual breaches or implement processes resulting in periodic notification reporting (i.e. monthly or quarterly submissions).

The Department expects Responsible Persons to have business and compliance management processes in place to ensure timely compliance with all notification requirements. The Department's risk-based response to actual breaches considers the Responsible Person's overall MSR compliance, including compliance with the notification requirements. Where there is a delay in making a



notification, Responsible Persons will be required to provide the reasons for the delay. These reasons:

- will form part of the Department’s assessment of the Responsible Person’s compliance with the notification requirements; and
- may form part of the Minister’s considerations when deciding whether to de-list a brand or to take any other action in response to a breach of the MSR.

## What is meant by ‘form the belief’?

Responsible Persons are expected to monitor stock levels and forecast supply and demand in conjunction with implementing best practice inventory and supply chain management. Where these processes cause the Responsible Person to **form the belief** that a breach of the MSR is more likely than not, the Responsible Person must submit a likely breach notification to the Minister.

Importantly, a Responsible Person must include in their considerations for submitting a notification whether their controls and mitigation strategies are likely to impact the likelihood of the breach.

For example, where an active pharmaceutical ingredient (API) shortage is reported by a supplier and the Responsible Person has arrangements in place to access an alternative API source in time to avoid a breach, a notification would not be required if the Responsible Person will continue to meet supply schedules and maintain stockholding levels at the required amount. However, where the Responsible Person might not be able to access an alternative API source in time, a notification should be made, even if the breach is not inevitable.

## What information should be included in a notification?

To facilitate notifications being made **as soon as practicable**, a Responsible Person can submit an initial notification which includes basic information. This initial notification should:

- Provide the details of the designated brand
- Inform the Minister of the likely or actual breach
- Set out the reasons for the likely or actual breach
- Indicate the anticipated duration and extent (volume of stock) of the likely or actual breach

Responsible Persons are strongly encouraged to provide the additional information sought in the second part of the notification form when that information is available. This additional information includes:

- Current business activities to facilitate compliance
- Corrective actions taken or planned to address the breach

A notification is a Responsible Person’s opportunity to provide all relevant information to assist the Department to monitor supply issues and assess the risks of breaches of the MSR. This process assists the Department to recommend to the Minister the appropriate compliance approach.



## When to update a notification

Where the initial basic information, as listed above, changes, a Responsible Person must submit an update to reflect this change. Responsible Persons are strongly encouraged to submit an update under the following circumstances:

- Resolution of the breach – the stockholding level returns to compliance
- The lowest anticipated stockholding level changes
- The approximate date that the lowest stockholding level is likely to be reached changes
- The anticipated resolution date changes

## What happens if I breach the MSR?

In the event of a breach of the MSR, the Minister may assess the breach and take such action(s) as is considered appropriate to correct the identified non-compliance, as covered in the [Compliance with the Minimum Stockholding Requirements Fact Sheet](#).

Information provided with a notification of a likely or actual breach may be taken into account by the Minister in deciding what action to take, if any. As such, it is important Responsible Persons ensure that notifications, including updates, are provided in a timely, full and frank manner. This will ensure the Department's assessment and the Minister's decisions are based on all available information and a proportionate response is applied to breaches.

Responsible Persons are encouraged to engage in compliance activities honestly, clearly and accurately. The Department undertakes compliance checks to identify non-compliance with the notification requirements. Criminal penalties can apply for breaches of the notification requirements.

## How do I Submit a notification?

From 9 April 2025, all **new** notifications can be submitted via the [Stockholding Breach Notification Portal](#) (the Portal) on the *Price Disclosure and Stockholding Notification System*. If a likely breach notification submitted via the Portal becomes an actual breach, Responsible Persons can utilise the 'upgrade' option within the likely breach form to simply and quickly close the likely breach and create a new actual breach notification for submission.

Current versions of the PDF and excel format notification forms continue to be available on the [PBS minimum stockholding requirements website](#). Previously submitted PDF and Excel notifications will not be available for Responsible Persons to access via the Portal. Where a Responsible Person is submitting an update to a previously submitted PDF or excel notification (including resolution information) Responsible Persons should submit this information in the PDF or Excel notification form/s and email [pbsstockholding@health.gov.au](mailto:pbsstockholding@health.gov.au).



## Key Resources

- [National Health Act 1953 \(Cth\)](#)
- [National Health \(Pharmaceutical Benefits\) Regulations 2017 \(Cth\)](#)
- [PBS Stockholding Guidelines](#)
- [Minimum Stockholding Requirement Webpage](#)
- Stockholding Breach Notification Portal – User Guides
  - [Review a breach notification](#)
  - [Submit a breach notification](#)
  - [Update a breach notification](#)
  - [Manage user access](#)
  - [Access the portal](#)
- [Quantity of stock to be held – Fact Sheet](#)
- [Determinations of Another Quantity – Fact Sheet](#)
- [Compliance with the Minimum Stockholding Requirements – Fact Sheet](#)
- [Executive Summary of the MSR Review](#)
- [pbsstockholding@health.gov.au](mailto:pbsstockholding@health.gov.au) for all questions you may have regarding this Fact Sheet.