



PBS Minimum Stockholding Requirements

Notification Form for likely or actual breach of minimum stockholding requirement

Notification requirements and timing of notifications

Responsible Persons (**RPs**) for brands subject to the minimum stockholding requirement are required to notify the Minister of likely or actual breaches of that requirement in accordance with s99AEKD of the *National Health Act 1953* (**the Act**).

This form is designed to:

- i) facilitate RPs giving the Minister written notice in the event of a likely or actual breach of the minimum stockholding requirement for a brand in accordance with s99AEKD(1) or (2) (as applicable);
- ii) allow the Department to assess whether, in the event of a likely or actual breach, an RP has provided a written notice that complies with s99AEKD(1) or (2) (as applicable);
- iii) provide the Minister with information relevant to the matters which the Minister **must** consider under s99AEKE(3) as well as matters the Minister **may** wish to consider¹ in deciding whether or not it is appropriate to take action under s99AEKE(2) for a breach of the minimum stockholding requirement in relation to a brand; and
- iv) provide information that may be taken into account by the Minister in deciding what action to take following any **additional** breaches, in the future, of the minimum stockholding requirement (s99AEKE(3)(d)).

In the case of a likely or actual breach of the minimum stockholding requirement RPs are required to:

1. Complete and submit the '**Notification to Minister**' section of this form:
 - i) for a likely breach – **as soon as practicable** after the RP forms a belief that it is likely to breach the minimum stockholding requirement for a brand; or
 - ii) for an actual breach – **as soon as practicable** after a breach of the minimum stockholding requirement occurs for a brand.
2. Complete and submit the '**Supporting Information**' section of this form:
 - i) for a likely breach or actual breach – **no later than two weeks** after Notification to Minister is made.

Only notifications completed in this form will be accepted, other forms including verbal and/or email are not accepted as a complete notification.

For further detail on notification requirements and management of breaches, see Sections 7.2 and 8 of the [Pharmaceutical Benefits Scheme Minimum Stockholding Guidelines](#) (**the Guidelines**), respectively.

Instructions for completion

1. On the next page, complete checkbox for the Type of Submission, and fill in date Notification was made if relevant.
2. Complete the relevant portions of the form for each type of submission/resubmission:
 - a. Submitting Notification to Minister and Supporting Information – complete all parts of the form **except** for Part 4.
 - b. Submitting Notification to Minister **only** – complete Parts 1, 2 and 5.
 - c. Resubmission providing 'Supporting Information' – complete Parts 1A and 1B to identify the submission. Then complete Parts 2, 3 and 5.
 - d. Resubmission updating information previously provided – ensure that Parts 1A and 1B are completed to identify the submission, then complete any sections for which you wish to provide updated information.
 - e. Provision of Resolution Information following resolution of a likely breach or actual breach (not used where a likely breach progresses to an actual breach) – complete Parts 1A **and** 1B to identify the submission. Then complete Part 4A **or** 4B.
3. Each time this form is provided (including if you are correcting or updating information previously provided), you **must** complete and sign the Declaration and signature at Part 6.

Note: You must obtain consent when providing another individual's personal information in your notification/submission, and evidence of consent must be provided to the Department upon request

¹ Matters which the Minister **may** wish to consider are outlined at Section 8.2(c) of the [Pharmaceutical Benefits Scheme Minimum Stockholding Guidelines](#).

Type of Notification

- This submission includes a 'Notification to Minister' **and** 'Supporting Information'.
- This submission is a 'Notification to Minister' **only** – 'Supporting Information' will be completed and provided within two weeks of this date.
- This is a resubmission providing 'Supporting Information' **or** updating information previously provided in relation to the 'Notification to Minister' made on
(enter date Notification was made)
- This form provides Resolution Information for a likely breach which has resolved without proceeding to an actual breach, or for an actual breach which has resolved. This form relates to the 'Notification to Minister' made on
(enter date Notification was made)

Part 1 – Notification to Minister

Date notification is made

This is a written notice to the Minister that the RP

- believes that it is likely to breach** s99AEKB (the minimum stockholding requirement) in relation to the brand outlined below.
- has breached** s99AEKB (the minimum stockholding requirement) in relation to the brand outlined below.

Part 1A – Responsible Person details

Name of Responsible Person (RP)

Authorised Representative contact information

Name	
<input type="text"/>	
Phone number	Email
<input type="text"/>	<input type="text"/>

Part 1B – Brand information

Brand

Drug

Form

Manner of administration

Pack quantity details (Optional)

If the brand is supplied in multiple pack sizes, indicate whether supply of all or some of the pack sizes is impacted. If only some pack sizes are impacted, indicate which pack sizes are/are not impacted and why.

Part 1C – For likely breach

When it is anticipated the minimum stockholding requirement will be breached for the brand

Date the RP formed the belief of a likely breach

What are your reasons for believing a breach is likely to occur?

Part 1D – For actual breach

Date actual breach occurred

Date the RP became aware that the actual breach occurred

What are the reasons that an actual breach has occurred?

Part 1E – For likely or actual breach

What is the anticipated duration of the likely or actual breach?

Part 2 – Acknowledgements for RP to complete (as relevant)

- (Check box – must complete) An updated form will be provided to the Department as soon as possible if any information provided in this form changes, including but not limited to:
- when the likely breach is anticipated to occur
 - anticipated duration of the likely or actual breach
 - anticipated lowest stockholding level and/or date lowest stockholding level will be reached
 - if there is a material change in corrective action and/or expected outcome of corrective action(s) in the case of an actual breach.

Check one only

- If a **likely breach** has resolved without eventuating in an actual breach, an updated form will be provided to advise when it resolved and how.
Note: if a likely breach becomes an actual breach, a separate notification must be submitted to notify of the actual breach of the minimum stockholding requirement. See Section 7.2(a) of the Guidelines.
- Following resolution of an **actual breach**, an updated form will be provided with the dates the breach started and resolved, duration of breach, and actual stock levels.

Part 3 – Supporting Information

This portion of the form may be completed and submitted at the same time as the Notification to Minister **only if** this will not cause any delay in submitting the Notification to Minister. In all other cases, the Supporting Information must be completed and submitted **no later than two weeks** after Notification to Minister is made.

Part 3A – Notification has been submitted ‘as soon as practicable’

For a likely breach – Provide information about when and how the RP became aware of any matters on which it formed a belief it was likely to breach the minimum stockholding requirement (e.g. notification of a significant supply disruption). This could include a timeline of events and the RP’s belief over time regarding their ability to maintain compliance with their minimum stockholding requirements.

For a likely or an actual breach, if the date that the RP notified the Minister is not the same date as it formed the belief of a likely breach, or the breach occurred – Provide information about why it was not practicable to notify sooner.

For an actual breach, where the Notification to the Minister is provided on the same date that the breach occurred – No further information is required.

The information provided above will be used to assess whether the Notification has been made as soon as practicable after the RP formed the belief that there would be a likely breach, or as soon as practicable after the actual breach occurred. RPs are **not required** to attach supporting evidence to confirm that notification has been made ‘as soon as practicable’. RPs should be prepared to provide supporting documents if requested by the Department to allow the Department to verify the information provided or to assess whether the notification has been made as soon as practicable. Potential evidence that may be provided includes, but is not limited to:

- Dated internal communication notifying of breach/causative factor to breach or likely breach.
- Dated third-party communication to RPs notifying of causative factor to breach or likely breach.
- Dated third-party reports assessing causative factors for breach or likely breach.
- Stock records indicating the minimum stockholding requirement was satisfied up to the date of breach.

Part 3B – Summary information

Current stockholding level of brand (months of usual demand)²

Anticipated lowest stockholding level (months of ‘usual demand’), and approximate date that the lowest stockholding level is likely to be reached³

Approximate date

DD / MM / YYYY

For actual breach only – Expected resolution date for breach

DD / MM / YYYY

² If only some pack sizes are impacted, please also provide details of current stock composition (number of packs of each pack size) and the number of months of coverage this represents for each pack size.
³ If only some pack sizes are impacted, please also provide details of anticipated stock composition (number of packs of each pack size) at the anticipated lowest stockholding level.

Part 3C – Current business activities to facilitate compliance with minimum stockholding requirement

Provide information addressing the suitability of your existing business activities to facilitate compliance and to avoid a breach of the minimum stockholding requirement.

Where relevant, this should include (as outlined in section 7.2(b) of the Guidelines):

- Existing processes to forecast demand.
- Existing processes to manage and monitor supply chain and storage facilities.
- Any prior risk assessment made of the brand's supply chain and any applicable steps taken to mitigate those risks.

You may wish to explain why your existing business activities were not sufficient to avoid a likely breach or actual breach. Do not include corrective actions in response, these will be addressed below under Part 3D – Corrective actions.

Part 3D – Corrective actions which will be taken (or are in progress/completed) in response to the likely or actual breach

Give details of the corrective actions that have been or will be taken to respond to the cause of the breach or likely breach, and to maintain or restore stock to the required minimum stockholding level.

Examples of potential actions are set out in Exhibit 15 of the Guidelines and include:

- Undertake investigations to understand cause of likely breach.
- Directly address causative factors to limit potential breach and ensure no repeat cases.
- Source further supply from within supply chain.
- Source short-term contract manufacturing onshore.
- Sourcing substitute PBS listed brands from own portfolio.
- Purchasing excess supply of the same pharmaceutical item from another RP that is PBS listed.
- Increasing stock levels of different pack sizes of the same pharmaceutical item (if PBS listed).

Give details of the outcomes of any investigations into the cause of the breach/likely breach

Where a likely breach became an actual breach, please provide details (and supporting evidence) to explain why the corrective actions taken were not sufficient to avoid the breach.

Part 4 – Resolution Information

Please ensure that the Responsible Person details and Brand information at Parts 1A and 1B are completed.

Then complete Part 4 following resolution of a likely or actual breach.

If a likely breach has proceeded to an actual breach, then Part 4 will be completed following resolution of the actual breach. It is not required to be completed to indicate the progression from a likely breach to an actual breach.

Part 4A – Information to be provided after resolution of a likely breach

Date likely breach was resolved

How the likely breach was resolved

Part 4B – Information to be provided after resolution of an actual breach

Breach start date

Breach resolution date

Duration below the required stockholding quantity (weeks/months)

Lowest stockholding level during actual breach⁴

Date the lowest stockholding level occurred

How the breach was resolved

(e.g. new shipment arrived on [date] to restore required minimum stockholding level)

If the actual resolution date differs from any expected resolution date earlier provided, please explain why the date changed (e.g. early estimate updated following confirmation of production availability)

⁴ If only some pack sizes were impacted, please also provide details of stock composition (number of packs of each pack size) at the lowest stockholding level.

Part 5 – Documents provided

- I have attached the following **additional** documents to support the claims made in this form, and to assist in assessing the breach.

List of supporting documents

- No **additional** documents are attached to/provided with this form.

Note: RPs should be prepared to provide supporting documents if requested by the Department, to validate the information and submissions made.

*In relation to actual breaches, RPs should be proactive in providing the Department with information and documents which are relevant to the factors that the Minister must and may consider when assessing a breach and determining whether to exercise their power under s99AEKE(2). A list of the documentation and information which the Minister may wish to consider in relation to each factor is provided at Section 8.2(d) of the Guidelines. **If you intend to provide further supporting documents at a later stage (after provision of the Supporting Information portion of the form), please indicate below what further documents will be provided and when.***

- I intend to provide additional documents which are not yet available. I intend to provide the following documents by the dates outlined below.

List of documents and when they will be provided by

Part 6 – Declaration and signature (compulsory)

- I acknowledge giving false or misleading information is a serious offence and that providing false or misleading documents is also an offence. I have not omitted any matters without which the information provided would be misleading.

Signed

Name

Date

DD / MM / YYYY

Note: Please submit your completed form together with any supporting documentation to pbsstockholding@Health.gov.au

PBS Minimum Stockholding Requirements (Notification of likely or actual breach of minimum stockholding requirement)

APP 5 Notice

Your personal information is being collected by the Department of Health and Aged Care (**the department**). The personal information which is being collected consists of your name (as authorised representative of a responsible person), contact phone number and email address, as well as any personal information in further email correspondence relevant to this notification form. The department collects your personal information for the purpose of contacting you to discuss the notification you have provided. This may include seeking clarification or further information. If information you provide is shared with the Therapeutic Goods Administration (TGA), this may include personal information which you have provided. If you do not or are unable to provide your personal information the department will not be able to communicate directly with you regarding this notification.

Access to and correction of your personal information

The department's privacy policy contains information about how you may access and seek correction of personal information about you that is held by the department.

Privacy complaints

The department's privacy policy contains information about how you may complain about a breach of the Australian Privacy Principles or the Australian Government Agencies Privacy Code and how the department will deal with complaints.

Overseas disclosure of your personal information

We will not disclose your personal information to any overseas recipients.

Further information

You can read the department's privacy policy [here](#). You can obtain a copy of the APP privacy policy by contacting the department using the contact details set out at the end of this notice.

Contact details

If you wish to contact the department about a privacy-related matter, including questions about this notice, please contact the department's Privacy Officer by one of the following methods:

- **Post**

Privacy Officer
Department of Health
23 Furzer Street
WODEN ACT 2606

- **Email**

privacy@health.gov.au

- **Telephone**

02 6289 1555