**PBS Minimum Stockholding Requirements**

**Ministerial determination request form**

1. **Basis for application for a minimum stockholding determination of ‘another quantity’:**

[ ]  Short shelf-life

[ ]  Other reasons – summarise reason in a sentence or less (further details are given below or in an attachment) Click or tap here to enter text.

1. **Basic details:**
	1. Drug, form, Manner of Administration (MoA) and brand to have alternate quantity: Click or tap here to enter text.
	2. Responsible Person of brand: Click or tap here to enter text.
	3. Authorised representative contact information:
		1. Name: Click or tap here to enter text.
		2. Contact phone number: Click or tap here to enter text.
		3. Email address: Click or tap here to enter text.
	4. First date brand is subject to minimum stockholding requirements: Click or tap to enter a date.
	5. Shelf life (life time) of brand per ARTG entry: Click or tap here to enter text.

*Note: where a brand may have a different shelf-life depending on final packaging, specify the shelf life for each form of packaging, which form of packaging is used and why, as well as the applicable shelf life.*

* 1. Additional information regarding shelf life: Click or tap here to enter text.
1. **Another quantity details:**
	1. Proposed other quantity:
		1. Choose an item. months of ‘usual demand’; or
		2. Click or tap here to enter text. packs of the brand to be held each month.
	2. If you have requested ‘another quantity’ by number of packs:
		1. How many packs of the brand have you sold on average per month, in the last 12 months? Click or tap here to enter text.
		2. If less than 12 months sales data is available or sales data is unavailable[[1]](#footnote-1), please provide details of your past sales history and projected average monthly sales. Click or tap here to enter text.
2. **Manufacturing lead times/supply chain information**

*If manufacturing lead times/supply chain timing is a factor in the request (e.g., for a product with a short shelf-life), please provide the information requested below. Please ensure that sufficient information is included to allow the Department to assess what steps the Responsible Person has taken to ensure supply chain and inventory management best practice is used by the Responsible Person to facilitate compliance with the minimum stockholding requirements to the extent possible within any fixed constraints (e.g., the shelf-life of a product).*

* 1. 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[[2]](#footnote-2). Specify time in weeks/months.

Click or tap here to enter text.

* 1. What steps have been taken or will be taken to improve and optimise supply chain timing?

Click or tap here to enter text.

* 1. If the brand is manufactured overseas, please indicate whether it is transported by air or sea, and the transit time.

[ ] Air freight

[ ] Sea freight

Click or tap here to enter text.

* 1. Provide details of any expiry constraints imposed by wholesaler/other purchaser
	(e.g., minimum 9 months shelf life remaining when received by wholesaler)

Click or tap here to enter text.

If **minimum order quantities** are a relevant constraint in your request, provide details of:

* 1. What the minimum order quantity is, and the reason for the minimum order quantity (e.g., technical batch size or production run size).

Click or tap here to enter text.

* 1. How many months/weeks of ‘usual demand’ the minimum order quantity equates to.

Click or tap here to enter text.

* 1. Briefly explain the constraint caused by the minimum order quantity (e.g., specify the quantity of stock which may be at risk of write-off and why).

Click or tap here to enter text.

* 1. What steps have been taken or will be taken to reduce the impact of the minimum order quantity (e.g., outcome of negotiation with manufacturer, streamlined logistics to reduce shipping times)?

Click or tap here to enter text.

* 1. Provide any other relevant information regarding manufacturing lead times/supply chain timing not addressed above.

Click or tap here to enter text.

1. **Security of supply**

For **all** applications, please provide the following information in relation to security of supply:

* 1. Average quantity and number of months of stock currently held for the brand by reference to ‘usual demand’.

Click or tap here to enter text.

* 1. Size, frequency and transit mode (air/sea) of incoming shipments (e.g., *‘monthly shipment arriving by sea comprising 6 weeks of ‘usual demand’’*).

Click or tap here to enter text.

* 1. Outline your existing processes, or processes which you will implement, to ensure continuity of supply. Where processes are yet to be implemented, provide details of the timeframe for implementation and review.

Click or tap here to enter text.

* 1. Your visibility of stock throughout the supply chain (e.g., during manufacture, packaging, between ordering and dispatch from overseas manufacturing, in transit). Provide details of your capacity to monitor the quantity in stock, progression relative to estimated time/schedule.

Click or tap here to enter text.

* 1. How much advance notice would you typically receive of a supply disruption, and what are the typical lead times for you to respond to common causes of disruptions (e.g., batch failure, requirement to rebook transport for a sea shipment due to administrative error)?

Click or tap here to enter text.

* 1. Have there been any supply disruptions for this brand in the last 12 months? If so, please briefly describe the disruption, which brand(s) were impacted, and the impact on supply (e.g., *‘Shortage of API for the drug Asclepius, impacted on X, Y, Z brands. Orders were rationed by the overseas manufacturer for 6 months whilst they sourced alternative supply. We obtained the balance of our usual ordering quantities from another manufacturer and there was no impact on supply.’*)

Click or tap here to enter text.

* 1. How long does it take you to acquire and bring in additional supply to Australia in response to a sudden increase in demand (e.g. out-of-stock of a competitor, sudden increase in consumer purchases)?

Click or tap here to enter text.

1. **Supporting information**

[ ]  I have attached a comprehensive and complete explanation of the reasons for requesting a minimum stockholding determination.

*Explanations should include:*

* *an outline of reasons why the Responsible Person is requesting a minimum stockholding determination and why the Responsible Person cannot comply with the minimum stockholding requirement that would apply in the absence of a minimum stockholding determination;*
* *details of any factors and assumptions underpinning the Responsible Person’s reasons for requesting a minimum stockholding determination;*
* *why the Responsible Person otherwise submits a minimum stockholding determination should be made; and*
* *why the Responsible Person considers the proposed reduced stockholding level is appropriate.*

[ ] I have attached the following documents to this request:

Click or tap here to enter text.

[ ] I have not attached any additional documents to this request.

*Note: Responsible Persons should be prepared to provide supporting documents if requested by the Department, to validate the information and submissions made. A non-exhaustive list of documents which may be submitted as supporting evidence is provided at Section 6.3 of the Pharmaceutical Benefits Scheme Minimum Stockholding Guidelines.*

[ ]  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:** Click or tap here to enter text.

**Date:** Click or tap to enter a date.

**Note: Please submit your completed request form with supporting documentation to** **pbsstockholding@Health.gov.au** **Any submission that is incomplete, or without supporting documentation may have delayed processing and result in a delayed determination outcome.**

**PBS Minimum Stockholding Requirements (Ministerial determination request form)**

**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 (authorised representative), contact phone number and email address, as well as any personal information in further email correspondence relevant to this request form.

The department collects your personal information for the purpose of contacting you to discuss your request for a Ministerial determination. This may include seeking clarification or further information.

If you do not or are unable to provide your personal information the department will not be able to communicate/notify the outcome of the Minister’s (or their delegate’s) decision on your determination request.

**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](http://www.health.gov.au/internet/main/publishing.nsf/Content/privacy-policy). 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
1. This might be the case for new brand listings, or brands which have transferred between responsible persons and where the current responsible person does not have previous sales data. [↑](#footnote-ref-1)
2. I.e., stock which is kept by the Responsible Person in Australia and is available for sale by the Responsible Person. See s99AEKB of the Act and Section 3 of the PBS Minimum Stockholding Guidelines. [↑](#footnote-ref-2)