

# Minimum Stockholding Requirements consultation

## Overview

The Australian Government entered into Strategic Agreements with Medicines Australia (**MA**) and the Generic Biosimilar Medicines Association (**GBMA**) in July 2022. These Agreements included the Medicines Security Supply Guarantee (**MSSG**) designed to improve supply chain security for older, lower-cost, multi-branded medicines that are more vulnerable to shortages or supply disruptions.

As part of the MSSG, a Minimum Stockholding Requirement (**MSR**) requires Responsible Persons (**RPs**) to hold a minimum of either 4 or 6 months of stock in Australia for certain PBS listed medicines, referred to as '**Designated Brands** <<https://www.pbs.gov.au/info/industry/pricing/designated-brands>>'. While these measures will not prevent shortages that are outside the control of Australian companies, they will help to ensure that Australian manufacturers are better placed to maintain supply when global disruptions occur. Holding buffer stocks allows time for supply disruptions to be resolved, including through identifying alternative sources of supply (where possible).

Amendments made to *the National Health Act 1953 (Act)* by the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021 (Amendment Act)* gave effect to the MSSG reforms. The MSRs are outlined in Division 3CAA of the Act and involve:

- Substantive stockholding requirements:** RPs of 'designated brands' must hold 6 months stock by reference to 'usual demand' if the brand received a price increase on or after 1 July 2022, and 4 months stock if the brand did not receive a price increase. The stock that is kept must be available for sale in Australia by the RP (e.g., stock held by wholesalers is not counted as available for sale).
- Disclosure requirements:** twice a year RPs must disclose their quantity of stock of the designated brands kept in Australia to Australian Healthcare Associates (**AHA**). The two disclosure periods are 1 April to 30 September (disclosure due 11 November), and 1 October to 31 March (disclosure due 12 May) with disclosure being provided for the last day in each month in the disclosure period.
- Notification requirements:** RPs of designated brands are required to notify the Minister of a likely or actual breach of the MSR in accordance with s99AEKD of the Act. RPs must report an actual or likely breach of the MSR '*as soon as practicable*':
  - In the case of a likely breach, *as soon as* they form a belief that they are likely to breach the MSR in relation to a designated brand; or
  - In the case of an actual breach, *as soon as* they breach the MSR in relation to a designated brand.

The investment by the medicines industry in managing supply chain risks through the MSR has been supported by the Australian Government through:

- One-off price increases on 1 October 2022** to improve the viability of low-cost medicines in the F2 formulary. The Approved Ex-Manufacturer (AEMP) price of Brands with an AEMP of:
  - \$2.00 or less were increased to \$2.50
  - between \$2.00 and \$3.00 were increased by \$0.50.
  - more than \$3.00 but less than \$3.50 were increased to \$3.50.

Approximately 950 brands of pharmaceutical items received a price increase on 1 October 2022, with an average increase to the AEMP of 44%.

## 2. **Protective price disclosure thresholds for designated brands**

- Designated brands are protected from price disclosure reductions through thresholds which ensure that price reductions occur only where there is significant discounting in the market (the 30% threshold), or where there is sustained discounting over a period of time (the 12.5% averaging and 10% threshold).

## 3. **Floor price protections for designated brands**

- Designated brands are not subject to price reductions under Part VII of the Act other than price disclosure reductions. That is, they will not have their prices reduced as a result of an anniversary, first new brand or combination item flow-on reduction.
- Designated brands with an AEMP of more than \$4 are not subject to price disclosure reductions unless the relevant threshold is met for a price disclosure reduction to occur.
- The Act establishes a floor price of \$4 for designated brands. Designated brands with an AEMP of \$4 or less are protected from further legislated price reductions. Where a designated brand with an AEMP of more than \$4 meets the threshold for a price reduction to occur, the price reduction will not reduce the AEMP any lower than \$4.

## Why your views matter

This survey is being conducted as part of a 12-month review of the MSR to provide feedback to the Australian Department of Health and Aged Care (the Department) in relation to industry's initial experience and progress with the MSR. This feedback will form an important input to the Department's review of the MSR.

The questions in the survey are optional. The Department recognises that for some of the questions you may not have all of the information available, or there may be challenges in ascertaining some information. The Department would appreciate you completing the survey as comprehensively as possible. This will provide the best outcome in terms of the policy review and the operation of the MSR. Where you provide answers based on averages, ranges or estimates, please indicate this in the free text boxes provided.

A PDF copy of the survey is attached below to allow you to see all of the questions asked and prepare the responses in advance.

## Introduction

### 1 What is your email address?

Email address *(Required)*

## 2 Responsible Person name

Responsible person name *(Required)*

## 3 Privacy information

### Privacy and your personal information

Your personal information is protected by law. The Department is bound by the *Privacy Act 1988* and the Australian Privacy Principles (APPs).

Some of your personal information will be collected by the Department, via Citizen Space, for the purposes of conducting a consultation process in relation to the 12 month Review of the Minimum Stockholding Requirements. The Department will collect this information at the time that you provide a submission. Some of the results of the survey may be published in aggregate form so that the department can report on implementation progress and outcomes of the Minimum Stockholding Requirements, but the survey results will not be published and your responses, and any information you have provided, will remain confidential.

The *Freedom of Information Act 1982* (Cth) (*FOI Act*) gives individuals a legally enforceable right to request access to documents held by government departments. This includes documents provided in response to the consultation process in support of the MSR Review. The *FOI Act* is available here: <https://www.legislation.gov.au/Details/C2020C00366> <<https://www.legislation.gov.au/Details/C2020C00366>>

The Department has an APP privacy policy which contains information about:

- how you may access the personal information the Department holds about you and how you can seek correction of it;
- how you may complain about a breach of the APPs;
- a registered APP code that binds the Department; and
- how the Department will deal with complaints.

You can read about the APP at <https://www.health.gov.au/resources/publications/privacy-policy> <<https://www.health.gov.au/resources/publications/privacy-policy>> . You can also obtain a copy by contacting the Department by telephone on (02) 6289 1555 or freecall 1800 020 103, or by using the online enquiries form at <https://www.health.gov.au/about-us/contact-us#general-enquiries> <<https://www.health.gov.au/about-us/contact-us#general-enquiries>> .

## Information about the survey

This information is to provide you with guidance about completing the survey.

The survey has four main sections reflecting the four key themes:

experience with the MSR (this provides feedback to the Department)

inventory management (this will help the Department understand if the MSR has led to any changes in management of stocks)

implementation costs (this will help the Department understand the impacts of the MSR on RPs)

viability and shortages (this will help the Department understand whether the MSR has had any implications for medicine viability or wastage)

The survey questions are set up as:

Yes/No response

Multiple choice with 'Select all that applies'

Drop down list selection

Text field where you are asked to provide comments/responses.

In the Final section we ask you how long it took to complete the survey.

### How the survey works

The information asked in some of the questions may require you to gather information to be able to respond to these questions. **Throughout the survey there are links to various supporting documents to help you with your responses. When clicking on a hyperlink, please use a right click to open the document in a new tab. Otherwise it will take you out of the survey and the responses could be lost.**

The survey has a feature 'Save and return' which is at the bottom of each page of the survey. For this feature to work, you must have cookies enabled in your browser.

You will be asked to provide your email address to be able to save your responses and return later. Any email address that you enter in the field on the 'Save and return' page will not be stored as response data in Citizen Space. It is just used to send the email. This is so responses can remain anonymous.

After selecting 'save and send email' you will be shown the information that you can make a note of, which will allow you to return to your incomplete response whenever you choose. After you enter your email address this message will be displayed:

#### **'Your return details'**

Your return details have been sent to **info@delib.net** (delib is where the survey is hosted). You will need these details to come back, edit and submit your incomplete response.

The email will be sent from the address **no-reply@mail1.citizenspace.com** with the subject '**Your return code**'. If it doesn't appear in your inbox within a couple of minutes, please check your spam or junk folder, or make a note of the following information:

#### **Return link:**

<https://screenshots.citizenspace.com/etc/etc/etc> - as per URL received in the message.

#### **Response ID:**

ANON-6NXJ-DU8K-2 (this is just an example)

#### **Response key:**

6eb4541c9b918daeb5f5ecb80bcfec4d0b69033d (this is just an example)

#### **Close date:**

31 May 2024 (example)

Keep these details in a safe place. Anyone who knows your response ID and key will be able to read or edit your response until you submit it.

An email from Citizen Space will be sent to you with the subject line 'Your return code' followed by your Response ID. That email will contain a unique link that will allow you to return to survey any time until the survey is closed.

In case you need any assistance with troubleshooting, please contact [pbsstockholding@health.gov.au](mailto:pbsstockholding@health.gov.au) and we will assist.

## SECTION 1. Experience with the Minimum Stockholding Requirements

We are seeking to understand your experience with the implementation and administration of the new minimum stockholding requirements (MSR) and associated reporting requirements.

### **A Understanding the requirements of the MSR**

Does the information provided in the **PBS Minimum Stockholding Guidelines** <<https://www.pbs.gov.au/industry/pricing/medicines-supply-security-guarantee/Pharmaceutical-Benefits-Scheme-Minimum-Stockholding-Guidelines-published-21-Oct-2022.pdf>> (the Guidelines) and on the **Medicines Supply Security Guarantee** <<https://www.pbs.gov.au/info/industry/pricing/medicines-supply-security-guarantee>> webpage assist you in understanding the following (tick all that apply):

*Please select all that apply*

- Stock that counts towards the MSR (i.e., stock which is in Australia and available for sale by the RP)
- Designated brand criteria
- Usual demand
- Breach notification requirements
- Disclosure requirements
- None of the above

**B How would you rate your understanding of the MSR?**

Please select one that applies

*Please select only one item*

- I do not understand the MSR
- I understand some, but not all aspects of the MSR. I need further clarification
- I fully understand the MSR

Please provide more information about the aspects of the MSR that need further clarification

**C Are there any areas of the MSR where you would like more information? (tick all that apply)**

*Please select all that apply*

- Breach notification requirements
- Disclosure requirements
- Ministerial determination of another quantity
- Calculation of 'usual demand'
- No more information required
- Other area more information is required

Please discuss which areas of the MSR you would like more information about, and why

**D Have you requested advice from the Department about the MSR?**

*Please select only one item*

- Yes
- No

**E If you answered yes to D, what was the average number of days taken by the Department to provide you with advice and information in relation to:**

Breach notifications

Stockholding disclosures

Stockholding requirements

**F** If you answered yes to D, was this advice and information timely?

*Please select only one item*

- Yes  
 No

If 'No' above, did this affect your ability to report breach notifications on time?

*Please select only one item*

- Yes  
 No

If 'No' above, did this affect your ability to make stockholding disclosures on time?

*Please select only one item*

- Yes  
 No

If 'No', did it affect your ability to meet the stockholding requirements?

*Please select only one item*

- Yes  
 No

**G** If you answered yes in D, has the advice provided by the Department been useful or helpful in relation to meeting reporting requirements for (tick all that apply):

*Please select all that apply*

- Breach notifications  
 Disclosures using the Price Disclosure Submission Utility (PDSU)  
 Stockholding requirements  
 Was not helpful

How could the Department improve its advice in relation to the above?

## H Meeting implementation timeframes

In July 2022 industry was made aware that the MSR was commencing from 1 July 2023 through updates to the PBS website and through email communications to RPs.

Was 12 months enough time for you to implement the changes or adjust your business practices where necessary to meet the requirements?

Please select only one item

- Yes  
 No

If 'No', how long was required? e.g. how much time should have been allowed to prepare and why? Were different timeframes required for different medicines, manufacturers, or countries of manufacture? Please identify reasons for different timeframes required, and what the implications of the time constraint were.

Section 5.1 of the Guidelines outlines the lead times afforded to RPs to prepare to meet the MSR where a brand becomes a designated brand. For example, 6 months lead time following a price increase, approximately 4 months lead time following a price reduction (\$4 or less), and up to 12 months lead time for brands that meet the 42 month clock.

Are these lead times adequate to prepare to meet the MSR?

Please select only one item

- Yes  
 No

If 'No', how long is required?

Please describe any challenges you experienced in implementing the changes required by the MSR?

The designated brands list is updated bi-annually on 1 April and 1 October each year, on the PBS website ([Designated Brands](https://www.pbs.gov.au/info/industry/pricing/designated-brands) <<https://www.pbs.gov.au/info/industry/pricing/designated-brands>> ). Do you find bi-annual updates to the designated brand list timely?

Please select only one item

- Yes  
 No

Do you find the designated brand list user friendly?

Please select only one item

- Yes  
 No

If No, why?

## I Consultation

The MSR was developed through consultation with Medicines Australia (MA) and the Generic Biosimilar Medicines Association (GBMA) through the Strategic Agreements which were signed in September 2021. In June 2022, the Department undertook a consultation and engagement process with all RPs with brands listed on the PBS for the development of the PBS Minimum Stockholding Guidelines. The Guidelines were reviewed by MA and GBMA prior to publication.

Acknowledging this consultation, do you consider there was adequate consultation on the new requirements?

*Please select only one item*

Yes

No

If 'No', what could have been done differently.

**J** How much additional work, in excess of that required for your usual stock monitoring and management arrangements, is involved in reporting to the Department?

Actual and likely breach notifications

Total hours required (e.g. if multiple staff are involved, please add up their total combined hours spent on this task) to lodge each likely breach notification

Average salary costs (including on-costs) per hour for staff required to lodge each breach notification

**More information**

Time required to lodge a breach notification refers only to the time required to do the paperwork - filling out the forms and lodging them.

Before lodging a notification, the information required for the notification has to be prepared. Time required to prepare a notification includes the time taken to collect, collate and analyse the data that goes into the breach notification.

Making a distinction between time required to lodge the breach notification, and the time required to prepare the information that goes into the notification:

Total hours required (e.g. if multiple staff are involved, please add up their total combined hours spent on this task) to prepare the data for each breach notification.

For likely breach

For actual breach

Average salary costs (including on-costs) per hour for staff required to prepare the notification data

For likely breach

For actual breach

Stockholding disclosures using the PDSU

Total hours required (e.g. e.g. if multiple staff are involved, please add up their total combined hours spent on this task) to lodge each stockholding disclosure

Average salary costs per hour required to lodge each stockholding disclosure

Making a distinction between the time required to lodge the stockholding disclosure through the PDSU facility, and the time required to prepare the data that goes into the disclosure:

How many hours were required to prepare the data on stocks held during each reporting period.

For no-breach/fully compliant with stockholding requirements

For non-compliance or breach of the stockholding requirements

What were the average salary costs per hour to prepare the data on stocks held



## K Your experience with the MSR reporting systems

### Clarity of instructions or information

Are the instructions included on the **breach notification form** <<https://www.pbs.gov.au/industry/pricing/medicines-supply-security-guarantee/Notification-Form-for-likely-or-actual-breach-of-minimum-stockholding-requirement.pdf>> on how to complete and submit a notification clear?

Please select only one item

- Yes  
 No

If No, how this could be improved? (please provide your feedback)

Are the instructions on how to complete and submit stockholding disclosures through the PDSU facility clear?

Please select only one item

- Yes  
 No

If No, how could the process for submitting stockholding disclosures be improved? (please provide your feedback)

### Changes to your internal processes

We are seeking to understand how you may have had to modify internal processes for monitoring stocks, in order to be able to notify the Department 'as soon as practicable' of a likely or actual breach, and to be able to meet the stockholding disclosure requirements.

Have you engaged any additional resources solely for purposes of meeting the reporting requirements for the MSR?

Please select only one item

- Yes  
 No

Please provide more information about the additional resources required

Did you have to modify your company's internal processes in order to meet the breach notification requirements (reporting likely or actual breaches 'as soon as practicable')?

Please select only one item

- Yes  
 No

Please provide further information about changes that were required internally to be able to report breach notifications?

Did you have to modify internal processes for monitoring stocks, in order to be able make stockholding disclosures?

Please select only one item

- Yes
- No

If yes, please describe what changes were required internally to be able to report stockholding disclosures

Updated notifications:

Have you ever needed to revise a notification already submitted?

Please select only one item

- Yes
- No

If Yes, what was the reason? (select all that apply)

Please select all that apply

- Made a mistake
- New information available
- Resolution of actual or likely breach
- Other

If Other, please describe

How easy was it to provide this update?

Scale of 1 to 5

Please select only one item

- 1 Hard
- 2. Moderately hard
- 3. Neutral
- 4. Moderately easy
- 5. Easy

Do you have any internal processes in place to identify where updates to a notification are required?

Please select only one item

- Yes
- No

Ministerial Determination of another quantity:

A determination may be made at the discretion of the Minister to address long term practical barriers to compliance that cannot be overcome, e.g., for short shelf-life medicines (<18 months) where meeting the minimum stockholding requirement may result in medicine wastage (or additional wastage). The Minister may also make a determination for zero stock to be held, up to six months prior to a designated brand delisting from the PBS to allow the RP to run down its minimum stockholding. These questions are seeking your experience with the determinations.

What has been your experience with the determination process?

If you have had a determination made as a result of short shelf life, are you satisfied that the determination of the lower quantity will reduce the risk of additional medicine wastage due to the MSR?

Have you had an experience where a determination was not made that you thought should have been? Please explain

Noting the intent of determination, are there reasons other than short shelf-life where you believe a determination should be considered? Please explain.

## L Calculating stocks held

We are seeking to understand the internal processes required to calculate stock that is 'available for sale' and that counts for the purposes of the MSR. For example, how do you exclude stock that is currently being warehoused but has been sold and is not 'available for sale'.

Please describe what is required internally to be able to calculate stocks or make stockholding disclosures

## M Reasons for non-compliance

Have you been non-compliant with either the breach notification or stockholding disclosure requirements?

*Please select only one item*

- Yes  
 No

If you were non-compliant with breach notification requirements, was this because you:

*Please select all that apply*

- Did not understand the requirements  
 Did not have time  
 Other (such as resourcing constraints)

Please provide more information to support your answer above

If you were non-compliant with the stockholding disclosure requirements, was this because you:

*Please select all that apply*

- Did not understand the requirements  
 Did not have time  
 Other

Please provide more information to support your answer above

If you were non-compliant with the 4- or 6-month minimum stockholding requirements, was this because you:

*Please select all that apply*

- Did not understand the requirements  
 Did not have time to build up stocks  
 Faced supply chain or manufacturing problems  
 Other (please specify below)

Please provide more information to support your answer above

If you answered 'faced supply chain or manufacturing problems' above, were these because of:

Please select all that apply

- Global allocation issues (unable to get stock)
- Manufacturing issues (such as capacity constraints, machinery breakdowns)
- Transit issues
- Active Pharmaceutical Ingredients (API) availability
- Excipient availability
- Raw material availability
- Warehousing or storage issues
- Production scheduling
- Trade or customs issues
- Packaging issues
- Quality issues
- Product recall
- Shortage of competitor product which resulted in an unexpected increase in demand
- Other issues

Please provide more information in relation to any of the above

If you were non-compliant with the stockholding requirements, did you take any steps to mitigate or overcome these issues?

Please select only one item

- Yes
- No

If 'Yes', please describe any steps you took to mitigate or overcome these issues and why those steps were not sufficient to avoid non-compliance?

If you did not take steps to mitigate these issues can you please provide more information why not?

If you were unable to hold the required level of stock because of supply chain or manufacturing issues, did you:

Please select all that apply

- Draw down MSR stocks
- Draw down safety stocks
- Change your use of cycle stocks
- None of the above
- Other

If you drew down MSR or safety stocks or changed the use of cycle stocks, please describe by how much and for how long

If you did not draw down MSR or safety stocks or change the use of cycle stocks, please explain why not. How did you manage the shortfall?

## N Have you had any questions or concerns about the calculation of usual demand or usual PBS demand?

### More information

Minimum stockholding requirements for designated brands that are subject to price disclosure, are based on the calculation of usual demand using price disclosure data in accordance with s85b of the Regulations (see section 2.2 of the [Guidelines](https://www.pbs.gov.au/industry/pricing/medicines-supply-security-guarantee/Pharmaceutical-Benefits-Scheme-Minimum-Stockholding-Guidelines-published-21-Oct-2022.pdf) <<https://www.pbs.gov.au/industry/pricing/medicines-supply-security-guarantee/Pharmaceutical-Benefits-Scheme-Minimum-Stockholding-Guidelines-published-21-Oct-2022.pdf>> for more information).

Determinations of minimum stockholding requirements for designated brands that have not been subject to price disclosure are based on the calculation of usual PBS demand using PBS dispensing data.

Have you had any concerns about the calculation of usual demand?

*Please select only one item*

- Yes (usual demand)
- Yes (usual PBS demand)
- No

Please outline your concerns

## SECTION 2: Inventory management:

We are seeking to understand your business-as-usual inventory management and how that may have changed as a result of the MSR.

It is expected that RPs will hold inventories comprising cycle stocks, safety stocks, and MSR stocks.

Cycle stocks are defined as stocks held to manage normal monthly demand by meeting projected demand between planned shipments.

Safety stocks are defined as stocks held to manage disruptions or fluctuations in demand or supply that go beyond the normal market variability.

MSR stock is the stock held to meet the minimum stockholding requirements. It is stock that is available for sale in Australia and held in addition to safety stocks.

### A Safety stocks

Before the introduction of the MSR, did you hold safety stocks?

*Please select only one item*

- Yes
- No

If 'Yes', how much safety stock did you hold expressed as the equivalent of 'number of weeks' of stock

If you did not hold safety stock, how did you manage supply disruptions or sudden changes in demand?

## B How do you determine how much stock to hold as safety stocks?

This question is seeking information on the business factors that influence how much safety stock should be held to manage supply risks such as price risks, demand shocks, expectation about shortages, and the costs of building up and holding stocks.

For example, how does the number of weeks of safety stocks held for each medicine differ depending on the characteristics of the supply chain (such as time required to order additional stock)?

How do you determine how much safety stock to hold?

Has the amount of safety stock you hold changed since the introduction of the MSR?

*Please select only one item*

- Yes  
 No

If Yes, have safety stocks:

*Please select only one item*

- Increased  
 Decreased

If safety stocks have increased or decreased, by how much (expressed as weeks of supply). Please explain why they increased or decreased.

Have your total stocks held (safety stocks plus MSR stocks) increased since the introduction of the MSR?

*Please select only one item*

- Yes  
 No

If total stocks increased, by how much (expressed as weeks of supply). Please explain why they increased

If your total stocks have not increased, please explain why not

### C How are safety stocks managed?

We are seeking to understand whether the use of safety stock varies depending on the brand, for example because of supply chain timing.

Does your use of safety stocks differ by brand?

*Please select only one item*

- Yes  
 No

Please describe or explain why and how the use of safety stocks differ according to brand.

Has the management of safety stocks changed since the introduction of the MSR? Please provide more information.

### D The cost of holding safety stocks

We are seeking to understand the pre-MSR cost of holding safety stocks

Cost of safety stock as a percentage of cost of goods (COGS)

Cost of safety stock as a percentage of average ex-manufacturer price (AEMP)

Please explain how the above costs were calculated



## E The effect of safety stocks on medicine shortages

Do you think safety stocks help reduce the severity or length of a shortage?

*Please select only one item*

- Yes  
 No

Please provide more information to support your answer

Does the answer above depend on the designated brand? Please provide more information.

Has your ability to manage unexpected market fluctuations changed as a result of having to hold additional stocks under the MSR?

*Please select only one item*

- Yes  
 No

Please provide more information to support your answer

## F Cycle stocks

Before the introduction of the MSR, how much cycle stock did you hold (expressed as the equivalent of 'number of weeks' of stock)?

How do you determine how much stock to hold as cycle stocks?

Has the amount of cycle stock you hold changed since the introduction of the MSR?

*Please select only one item*

- Yes  
 No

If yes, how much have cycle stocks changed expressed as number of weeks

Please provide more information on whether the management of cycle stocks has changed, and in what way

## G Cost of holding cycle stocks

Cost of cycle stocks as a percentage of the cost of goods (COGS)

Cost of cycle stocks as a percentage of average ex-manufacturer price (AEMP)

Please explain how the above estimates were calculated and provide more information, e.g. does the cost of cycle stock vary by brand?

## H Inventory management

What type of inventory management system do you use?

*Please select all that apply*

- A manual warehouse management system
- An electronic or automated warehouse management system
- A real-time inventory management system
- Other

If Other, please specify

Has your inventory management changed since the introduction of the MSR?

*Please select only one item*

- Yes
- No

If yes, please provide information about how your inventory management system has changed as a result of the MSR

How do you undertake stocktakes? Do you:

*Please select all that apply*

- Physically count stocks
- Estimate stocks
- Other

If Other, please provide more information

How regularly are stocktakes done?

*Please select all that apply*

- Once a week
- Once a month
- Once a quarter
- Twice a year
- Annually
- Bi-annually
- Other

How do you store/warehouse your product? Do you:

*Please select all that apply*

- Use your own warehousing facility?
- Use a 3PL/4PL provider?
- Other

If other, please provide more information

### I Effect of the MSR on supply chains

We are seeking to understand whether the MSR has led to any changes in supply chains.

Has the requirement to hold additional stocks under the MSR led to:

*Please select all that apply*

- Any changes in your ability to negotiate allocations from global suppliers?
- Any increase in production levels for particular medicines?

Please provide more information to support your answer above

Has the requirement to hold additional stocks under the MSR led to:

*Please select all that apply*

- Changes in the frequency of shipments/imports
- Changes in the size of shipments
- Changes in production/ordering patterns such as size/frequency of batch manufacture, utilisation of campaign manufacturing, size of MOQs, etc.
- Changes in suppliers
- Changes in 3PL provider
- Changes in transit times
- Changes in supply/lead time

Please provide more information as needed for any of the above answers

### SECTION 3. Cost of meeting the new requirements:

In addition to the administrative costs of reporting notifications and disclosures covered in Section 1(J) above, the Department is also seeking to understand the implementation costs of the stockholding requirements themselves on your business.

#### Related information

Administrative costs are the costs of preparing and lodging your notifications and disclosures. The implementation costs we are seeking here are the costs you may have incurred in modifying your business practices in order to comply with the MSR requirements.

## A Costs of implementing the new requirements

What are the costs of buying additional stocks to meet the minimum stockholding requirements (please specify the units used, e.g. cost per pack, cost per weeks supply)

What are the holding costs of those additional stocks (e.g. costs of warehousing, insurance, labour, transport, depreciation, inventory shrinkage, damaged or spoiled inventory, obsolescence or shelf life issues) incurred as a result of the MSR. Please indicate whether this cost is per brand or as a total across your designated brand portfolio and specify the units used (e.g. cost per pack, cost per weeks supply)

What are the opportunity costs (e.g. costs of deferred sales) incurred as a result of the minimum stockholding requirement. Please indicate whether this cost is per brand or as a total across your designated brand portfolio and specify the units used (e.g. cost per pack, cost per weeks supply)

Have there been any costs resulting from the changes to the supply chain (e.g. costs of sourcing extra supplies, changing the frequency of shipments, finding new/additional sources or suppliers)?

*Please select only one item*

- Yes  
 No

Can you show the costs of these supply chain changes expressed as:

Cost as a percentage of COGS

Cost as a percentage of AEMP?

Do these costs vary by brand? Please provide more information

## B Cost of additional storage capacity

Have you acquired additional storage capacity in order to comply with the MSR?

Please select only one item

- Yes  
 No

How did you acquire it?

Please select all that apply

- Building new capacity  
 Through contracting with a 3PL  
 Leasing additional capacity  
 By rearranging existing storage capacity

How much additional storage capacity have you acquired?

By building a new capacity (please define capacity units)

Through contracting with a 3PL provider (define capacity units)

By leasing or renting additional capacity (define capacity units)

By rearranging existing storage capacity - please define the capacity units and provide more information

We are seeking information about the costs of this additional storage capacity. Please provide relevant information in the response lines below. Please define capacity units.

Building costs (amortised capital costs plus operating costs per unit of capacity)

Leasing or renting costs (cost per unit of capacity)

Costs of rearranging existing storage capacity (cost per unit of capacity)

## C Do the costs of holding stocks in accordance with the stockholding requirements vary by designated brand?

Please provide information or data about how stockholding costs vary by brand

## SECTION 4. The Medicines Supplies Security Guarantee (MSSG)'s impact on the viability of medicines:

The MSSG was designed to improve the security of supply for older, very low cost, multi-branded medicines through a range of reforms. These reforms include the implementation of the MSR which has been supported by Government through one-off price increases for approximately 950 brands on 1 October 2022 for medicines priced less than \$3.50.

**A** Did you have viability concerns about medicines priced below \$3.50 prior to the MSSG?

*Please select only one item*

- Yes  
 No

If 'Yes', please tell us about what made these medicines unviable?

**B** Do you agree that lower cost medicines can be more susceptible to supply disruptions?

*Please select only one item*

- Yes  
 No

Please explain your answer

**C** Did the October 2022 price increase improve the viability of your low-cost medicine/s priced less than \$3.50?

*Please select only one item*

- Yes  
 No

Please explain why/why not

Do you have any other feedback in relation to the MSSG?

**D** What percentage of the additional revenue from the price increases were (please express as a percentage):

Used to fund additional stockholding

Used to fund additional storage capacity

Used to fund additional production

Used to fund improved supply chain timing e.g. more frequent shipping

Passed onto customers through increased discounts

Retained as increased margins without investing any additional revenue in supply chain security measures

Other

Please explain 'Other'

**E** If the 1 October 2022 price increases had not occurred, would your company have considered delisting these brand/s from the PBS as a result of viability concerns?

Please provide more information about the factors that would lead to delist, whether you did delist, and if not, why not

**F** Are there other measures that could improve the viability of medicines to improve supply security?

Please provide details



**G** Has the new MSR raised any issues in relation to viability? Can you explain or provide details:

Can you please explain or provide more details

FINAL SECTION.

How long has it taken you to complete this survey?

Time taken to complete survey

*Please select only one item*

- Less than 1 hour
- Between 1 and 4 hours
- Between 4 and 8 hours
- More than 1 day
- More than 5 days

Thank you for your response to this survey. The survey results will assist the Department of Health and Aged Care undertake the 12-month review of the implementation and outcomes of the Minimum Stockholding Requirements.