



Executive Summary – Review of the Minimum Stockholding Requirements

Early review of the 12-month progress and outcomes



Executive summary

From 1 July 2023, certain medicines listed on the Pharmaceutical Benefits Scheme (**PBS**) referred to as '[Designated Brands](#)' are subject to a Minimum Stockholding Requirement (**MSR**). Under the MSR, companies (referred to as 'Responsible Persons' (**RPs**)) are required to hold a minimum of either four or six months of stock that is 'available for sale' in Australia by the RP. These supply buffers are intended to ensure better continuity of supply in the Australian market and allow additional time for global supply disruptions to be resolved including through identifying alternative sources of supply wherever possible.

The MSR is a component of the [Medicines Supply Security Guarantee \(MSSG\)](#), which was agreed through the [2022-2027 Strategic Agreements](#) between the Commonwealth and Medicines Australia (**MA**) and the Generic and Biosimilar Medicines Association (**GBMA**). The MSSG is designed to address the supply risks associated with lower-cost multi-branded medicines that can be more vulnerable to supply disruptions. The Agreement with the GBMA includes a commitment to review the 12-month progress and outcomes of the MSR.

[Attachment 1](#) provides background on the MSR. [Attachment 2](#) provides background on PBS Statutory Price Reductions. The [PBS Stockholding Guidelines](#) provides further detail on operational aspects such as [reporting requirements](#), [compliance obligations](#) and the process for RPs to request a [Ministerial Determination of 'another quantity'](#).

The 12-month review of the MSR

This executive summary presents the findings of a 12-month review of the implementation and early outcomes of the MSR. A further review will be undertaken at 24 months to evaluate the effectiveness of the MSR. The review was conducted through engagement with the medicines industry through:

- A detailed survey open to all PBS RPs
- A Roundtable discussion with peak bodies, including MA and the GBMA
- A joint Submission from the peak bodies.

The review developed key performance indicators (**KPIs**) to evaluate:

- Implementation progress
- Administration of the MSR
- Early compliance with the MSR
- Regulatory burden and administrative costs for industry (preliminary assessment)
- Use of stocks to mitigate shortages of designated brands (preliminary assessment)
- The effect on shortages of designated brands (preliminary assessment)
- The effect on wastage and viability (preliminary assessment).

The key findings of the review

1. **Overall, the 12-month implementation progress and early outcomes of the MSR signal that the policy has had positive impacts.** The medicines industry has made changes to increase their stock levels and early data indicates a reduction in medicine shortages of designated brands. However, a 24-month review is required to evaluate the effectiveness of the MSR, its impact on medicine shortages, as well as the regulatory impact on the medicines industry. Further improvements can be made to systems and processes to reduce administrative burden and additional guidance is required in certain areas in response to feedback from industry.

2. The department **implemented the Medicines Supply Security Guarantee (MSSG) in full** within the required timeframe.
3. The department has developed **effective processes to facilitate the implementation and operation of the MSR**. Survey feedback indicated that RPs have a good understanding of the requirements, but raised some concerns and suggested potential improvements, including:
 - a) More guidance in relation to [Ministerial determinations](#), [breach notifications](#), the [calculation of usual demand](#), and the department's approach to [non-compliance](#).
 - b) Concerns that stakeholder engagement during the development of the MSR was restricted to MA and GBMA and limited to consultation on the Guidelines rather than broader supply issues.
 - c) Strong feedback that the 12-months lead time allowed for implementation of the MSR was inadequate. Widespread feedback was that 18-24 months should have been allowed, given the time required to build up stocks.
4. The department sought feedback on its **administrative effectiveness** – how effectively the MSR is being administered:
 - a) **Departmental response times:**
 - i) the current average response time for [breach notifications](#) is 80 days. The department notes its initial administrative process to respond to breach notifications was established expecting a significantly lower number of notifications than was received in the first 9 months. The approach and processes to assess notifications are well established, with further improvements, including automation through the development of an online portal, expected to dramatically improve response times and also management of breaches.
 - ii) over 99% of applications for [Ministerial determinations](#) were processed in accordance with the timeframes published in the [PBS Stockholding Guidelines](#) (indicative outcomes were provided within 30 business days for ongoing applications and within 50 business days for the initial bulk round which opened 21 October 2022).
 - b) **Experience with reporting systems:** overall, industry was satisfied with the clarity of instructions for notifications, disclosures, and designated brands lists, but many RPs raised the issue of the breach notification process being time consuming and administratively burdensome.
5. **Administrative efficiency** – the department experienced an unexpected and significant number of breach notifications submitted by RPs. This has led to significant administrative pressures which the review proposes to address with improved systems for reporting breach notifications.
6. **Compliance with stockholding requirements:**
 - a) **Rate of compliance with MSR:** of all brands subject to the MSR, over **91%** reported a compliant stockholding for at least one month during the first 9 months,¹ **75%** were compliant for the majority of the period, and **45%** were fully compliant for the full 9-month period. On average each month, **77%** of brands had a compliant stockholding. When all quantities of stock held across all brands is aggregated, there was a **5%** increase in the total volume of stock held in Australia since the policy commenced.

¹ Two stockholding disclosure periods have elapsed to date resulting in 9 months of disclosure data available (1 July 2023 – 31 March 2024).

- b) **Reasons for non-compliance:** supply chain issues leading to non-compliance with the MSR have been identified by survey responses as well as by RPs when submitting an actual breach notification. Manufacturing capacity constraints, supply disruptions such as batch failures and quality issues, input shortages and logistic issues are all common supply chain problems.
 - c) **Actions taken by RPs to avoid non-compliance:** almost all RPs have taken some corrective actions to avoid being non-compliant with substantive stockholding requirements, including airfreighting stock, negotiating additional supplies from overseas manufacturers, increasing or bringing forward shipments, triaging orders to ensure continuity of supply to pharmacies and patients, and seeking supplies from other markets.
7. **Compliance with the [disclosure requirements](#)** was 100% during the first 9 months of the MSR.²
8. **Compliance with [breach notification requirements](#):**
- a) **Notification compliance:** during the first disclosure period, **44%** of designated brands were compliant with breach notification requirements.³ 56% of the brands that were identified as non-compliant through the stockholding disclosure did not submit a breach notification for the first period. For the second disclosure period, only **30%** of designated brands were compliant with the breach notification requirements. 70% of the brands that were identified as non-compliant through the stockholding disclosure did not submit a breach notification for the second period.
 - b) **Likely breaches resulting in Actual breaches:** approximately **35%** of reported likely breaches became actual breaches. However, significantly, **93%** of actual breach notifications were not preceded by a likely breach notification. This significant under reporting of likely breaches may be a result of the administrative burden associated with the notification process. This may also be an indication that some breaches occur unexpectedly or with minimal forewarning, meaning RPs are unable to provide a likely breach notification before the actual breach has occurred. Likely breaches are intended to provide the department valuable information about supply chain issues on the horizon and the extent to which RPs are able to take action to avoid them. At this juncture, due to the under reporting of likely breaches, it is difficult to determine the 'value-add' of likely breach notifications. It is anticipated that likely breach notification rates will increase through the establishment of the notification portal, and subsequently an evaluation of the 'value-add' of likely breach notifications can be undertaken at the 24-month review stage.
 - c) **Lodging notifications on time:** the requirement for breach notifications to be lodged as soon as practicable is not being met. **19%** of actual breach notifications were lodged within 2 days of the breach occurring, while **43%** of likely breach notifications were lodged within 2 days of forming the belief that a breach may be likely. The legal requirement is for breach notifications to be lodged 'as soon as practicable'. 2 days is a nominal figure used by the department as a starting point for assessment and in most cases is likely to align with what is 'as soon as practicable' after an RP forms a belief of a likely breach, or becomes aware of an actual breach (**notification trigger**). Notification more than 2 days after a notification trigger, is not necessarily non-compliant behaviour. However, it is more likely (depending upon particular factual circumstances), that a

² A small number of RPs made their disclosures up to 3 days late for the second disclosure period, however 100% of RPs did provide the required stockholding disclosure, and there was 100% compliance with both the timing and substance of stockholding disclosure in the first disclosure period.

³ RPs are required to lodge a likely breach notification as soon as they form a belief that they may breach the MSR, and an actual breach notification as soon as practicable after they breach the MSR.

notification made 3 or more days after a notification trigger, does not comply with the requirement to notify 'as soon as practicable'. It appears that many RPs are not lodging notifications as soon as they ought to be or could be.

- d) **Administrative burden:** feedback provided by RPs through the survey and Roundtable discussion consistently and clearly indicate that the notification process is administratively burdensome. RPs have also raised concerns about the role that likely breach notifications play.

9. Enforcement actions taken

- a) **Powers used by the Minister:** no Ministerial enforcement powers have been utilised to date, reflecting the strong compliance rates and the department's focus on encouraging compliance through education and support to RPs.
- b) **Identified non-compliance:** despite the absence of formal compliance actions, 36 RPs have been contacted regarding notification non-compliance detected from data matching of disclosure and notification records. The non-compliance varies in severity and scale, with 14 RPs identified as having submitted no breach notifications despite identified breaches (stockholding disclosure reports). Case management is ongoing and enforcement options are being considered.

10. Regulatory burden for industry

- a) **Insights from Industry responses:** Industry has, overall, taken the new requirements seriously, with many engaging additional resources and making changes to supply chains and other business practices to ensure compliance with the MSR. Early indications are that the costs of these changes may have been significant for many RPs, but we have been unable to obtain consistent information that we can be confident provides an accurate and reliable **estimate of the cost impacts of the MSR**. For this reason, we have been unable to fully evaluate regulatory burden for this review. The department will seek to improve the collection of data and evaluate these costs in more detail for the next review.

11. Changes in inventory management

- a) **Safety stock impacts:** many RPs have made significant changes to their stock levels and inventory management in response to the MSR. **64%** of survey respondents said their holdings of 'safety stocks'⁴ had increased since the introduction of the MSR. The increase in stock ranged from 2 to 20 weeks, with an average increase of **8 weeks** of stock (based on 21 RPs).

12. Effect of the MSR on [medicine shortages](#) of designated brands

- a) **Reduction in the total number and shorter duration shortages:** there was a **13%** decline (from 612 to 533) in the number of shortages of designated brands between 2022-23 and 2023-24. The number of shorter duration shortages (under 4 months) fell by **24%**. The department notes longer term shortages (greater than 200 days) increased by **57%**. Whilst noting the promising initial decline in shorter duration shortages, it is not expected that the MSR will prevent all shortages and longer-term shortages which are often symptomatic of more intractable global supply issues, will likely persist. Further evaluation through the 24-month review is required to identify and analyse the causal factors for the changes in the number of shortages and the divergence in the trend between shorter and longer duration shortages.

⁴ Safety stocks are held to manage disruptions or fluctuations in demand or supply that go beyond the normal market variability.

- b) **RP actions to reduce shortages:** Of the 26 RPs that provided responses to this question, **44%** said they draw down MSR stocks to mitigate supply chain issues, while 26% drew down safety stocks. **67%** of respondents agreed that holding additional safety stocks as required by the MSR would help in managing shortages.

13. **Effect of the MSR on wastage and viability**

- a) RPs raised some concerns regarding the risk of **wastage**, particularly associated with instances where ‘usual demand’ is higher than current or forecast demand.
- b) **Concerns about [viability](#):** 16 RPs provided relevant written responses to the survey question about factors that underlie their concerns about viability. Main pressures on viability are low margins, cost pressures, and low Australian pricing relative to more lucrative markets.
- c) **[Impact of October 2022 price increases](#):** 15 RPs provided relevant written responses to the survey question about whether the October 2022 price increases had helped with viability. The responses were generally positive, but some RPs noted that the cost of goods sold (**COGS**) has also risen, offsetting the benefits. We note that the intention of the price rise was to improve the viability of very low-price medicines, so the responses from most RPs would suggest this has been achieved.

The key issues raised in the review

[Breach notifications](#)

A consistent theme has emerged in relation to the system of breach notifications, with many RPs raising issues in relation to:

- The administrative burden of having to make so many notifications.
- The lack of flexibility for minor or transitory breaches.
- Having to submit multiple notifications for ongoing breaches which require updated information, or recurring breaches arising from an earlier supply disruption/demand shock, during the period in which an RP is working to restore their minimum stockholding and safety stocks to avoid further breaches.
- The need for greater clarity over the requirement to lodge a breach notification ‘as soon as practicable’.
- The role of likely breaches – queries were made regarding the value of the current likely breach notification process, and whether different reporting frequencies for breach notifications and stockholding disclosures might be as effective in mitigating but at a lower administrative cost.

[Guidelines and educational material](#)

Another key theme in the review was the need for better understanding of, and a stronger rationale for, some of the key elements of the MSR. The main aspects of the implementation of the MSR that need to be better articulated through updated Guidelines, are:

- **The department’s approach to compliance** – enforcement and compliance management (case management).
- **Forming a belief** – what does it mean in practical terms for making a likely breach notification.
- **As soon as practicable** – what does it mean in practical terms for making a notification.
- **Usual demand** – how are increases due to competitor out-of-stock (**OOS**) dealt with in calculating usual demand or in matters the Minister must or may take into account (in relation

to breaches), and why the calculation of usual demand does not take into account demand forecasts.

- **Ministerial Determinations** – circumstances in which determinations may be made.
- **Reasonable reason for a breach** – what constitutes a *reasonable reason* for a breach and that it is expected RPs will draw down on their stockholding in event of supply disruptions.
- **Stocks that count** – why stocks in transit and wholesaler stocks do not count toward the MSR.
- **Threshold for notifications** – why even minor breaches must be notified.

The key recommendations of the review

1. Reduce administrative burden for RPs and the department through improved systems and processes:
 - a) Develop a new **notifications portal** to automate and streamline the breach notification process. This will reduce the administrative burden on RPs, improve notification compliance rates, and improve the department's response times.
 - b) Develop an **excel notification** template as an interim solution to the notification portal.
 - c) Develop a **case management system** for managing non-compliance. This will enable the department to more comprehensively manage the assessment, response, engagement, and ongoing monitoring of a compliance case. A case management system is a necessity for effective compliance management given the considerable volume of breach notifications that the department is dealing with.
 - d) Develop a **PBS shortages data reporting tool** that converts [TGA shortages](#) information and maintains a PBS shortages database to support departmental administration.
2. Develop **additional educational guidance material** such as Fact Sheets to supplement the Guidelines which will provide a quick reference guide to support RPs' understanding of the notification and other requirements, including:
 - a) An 'MSR Compliance Fact Sheet' outlining RPs' compliance obligations, usual demand calculations, the department's risk-based compliance approach, what 'form a belief' and 'as soon as practicable' means and the threshold for notifications.
3. Consider making **updates to the [Guidelines](#)** in relation to:
 - a) Additional matters the Minister *may* consider in the event of a breach, specifically:
 - i) Taking into consideration stock in transit when assessing the likelihood that an RP will maintain adequate supply of a brand in the future.
 - ii) The impact of competitor out-of-stock on the calculation of usual demand.
 - iii) The impact of loss of contracts and adjustment of stockholding requirements.
 - iv) Allowance for difficulties in building up stocks due to lead time constraints.
 - b) Rebranding and transitioning stockholding from an old brand name to a new brand name.
 - c) Lead times afforded to RPs for when they must first hold a compliant minimum stockholding.
4. Undertake further analysis and evaluation of some important issues in the **24-month review**, including assessing the value add of likely breach notifications, assessing the regulatory burden of the MSR for RPs, and whether different reporting frequency for breach notifications and stockholding disclosures would reduce the administrative burden for RPs. **Table 1** presents a summary of all findings and recommendations.

Table 1: Summary of key findings and recommendations

KPI	Summary of findings	Recommendations
KPI 1: Timely implementation	The department met all implementation milestones.	None.
KPI 2: Effective implementation	<p>The department implemented effective processes however notes:</p> <ul style="list-style-type: none"> • RPs need more guidance on Ministerial determinations, breach notifications, calculation of usual demand, and the department’s approach to compliance. • Stakeholder engagement during policy development could be extended beyond peak bodies. • RPs required additional lead time to implement the required minimum stockholding (i.e., 12 months was insufficient). 	<p>2.1 develop additional guidance and educational material on Ministerial determinations, breach notifications, calculation of usual demand, and the department’s approach to compliance.</p> <p>2.2 ensure that future consultation design on the MSR be extended to all individual PBS RPs (consistent with the review and guidelines development).</p> <p>2.3 develop a stakeholder engagement plan and communication plan.</p> <p>2.4 consider extending lead times where necessary for RPs when brands become designated brands.</p>
KPI 3: Effective administration	<p>Overall, industry satisfaction or level of comfort with the Guidelines, instructional material, clarity of instructions for notifications, disclosures, and designated brands lists are reasonably good. 99% of Ministerial determinations were processed within the timeframes in the Guidelines. Other feedback included:</p> <ul style="list-style-type: none"> • Clarification and new educational materials required to help RP understanding of requirements. • Current manual notification process is administratively burdensome. • Ministerial determinations did not accommodate for real world logistics and RPs identified additional pressures that requires review. • RPs outlined challenges faced due to supply chains and time awaiting outcomes of a Ministerial determination application. 	<p>3.1 provide additional educational material to improve understanding of the Ministerial determinations process.</p> <p>3.2 develop a new online notification portal to automate and streamline the notification process.</p> <p>3.3 seek additional feedback to investigate matters that are not long-term practical barriers to compliance, being addressed through the non-compliance framework. The department will provide further education and guidance to RPs to assist with their understanding of how these matters may be considered/addressed through the non-compliance framework.</p> <p>3.4 provide additional guidance for industry on Ministerial determinations and the circumstances in which determinations may be made.</p> <p>3.5 update the Guidelines to provide details of the current approach to rebrands.</p> <p>3.6 provide periodic updates on MSR progress and compliance rates to industry through the Joint Oversight Committee (JOC). The department should also give further consideration to whether periodic updates should be published on the PBS website.</p>

KPI	Summary of findings	Recommendations
KPI 4: Efficient administration	During the first year of the MSR, the number and complexity of notifications and disclosures were significantly greater than anticipated.	4.1 develop a compliance case management system. 4.2 build a PBS shortages data reporting tool utilising TGA shortages information to support departmental administration.
KPI 5: Compliance with MSR	Over 92% of all designated brands held a compliant level of stockholding, four or six months of usual demand in most cases, for at least one month in the first nine months. The average rate of compliance with the MSR each month was 77% , over three quarters were compliant for most months, and 45% were compliant for the whole nine months.	5.1 update the Guidelines to provide more guidance on calculation of usual demand, allowances for difficulty in building up stocks, and consideration of stock in transit and the impact of usual demand variation as a result of competitor OOS when assessing breaches. 5.2 monitor concerns regarding wastage associated with 'usual demand' based on historical data and evaluate whether further action is required or whether existing processes are adequate at the 24-month review.
KPI 6: Compliance with disclosures	Industry was 100% compliant with the stockholding disclosure requirements.	6.1 develop an MSR Compliance Fact Sheet to supplement the Guidelines which will provide a quick reference guide to support RPs' understanding of the compliance obligations, including the disclosure obligations.
KPI 7: Compliance with notifications	56% brands in the first disclosure period and 70% of brands in the second disclosure period were identified as failing to notify of a breach of the MSR. 93% of actual breaches were not preceded by a likely breach. The majority of breaches are not being notified by RPs.	7.1 as per recommendation 3.2 . 7.2 as an interim solution to the online portal, make an Excel notification template available to all RPs. 7.3 as per recommendation 6.1 . 7.4 further assess the 'value-add' of likely breach notifications and the timing intervals of notifications and disclosures at the 24-month review.
KPI 8: Enforcement of the MSR	No Ministerial powers have been utilised to date. This reflects compliance with the stockholding requirements, and the department's focus is on encouraging compliance through education and support to RPs.	8.1 develop an MSR Compliance Fact Sheet to supplement the Guidelines which will further support RPs' understanding of the department's risk-based approach to compliance. 8.2 as per recommendation 3.2 8.3 deploy a case management system to enhance the efficiency and effectiveness of compliance assessment, management, monitoring, and finalisation.

KPI	Summary of findings	Recommendations
KPI 9: Regulatory burden (costs for industry)	<p>Many RPs have engaged additional resources and made changes to supply chains and other business practices to ensure compliance with the MSR. Early indications are that the costs of these changes may have been significant for many RPs, but we have been unable to obtain information in a consistent format for data standardisation that allows regulatory burden to be robustly evaluated.</p>	<p>9.1 as per recommendation 3.2. 9.2 seek to improve the data available on the costs of increased stockholdings in order to rigorously and consistently evaluate and monitor the regulatory burden of the MSR in future reviews.</p>
KPI 10: Management of stockholdings	<p>Many RPs have made significant changes to their stock levels and inventory management in response to the MSR. The department has been unable to obtain structured information on the costs of these changes (other than a handful of statistics presented by RPs as examples). For this reason, the 12-month review has been unable to comprehensively evaluate the costs to industry of the changes in inventory management required in order to implement the MSR, but the department will seek to do so for the 24-month review.</p>	<p>10.1 improve data collection on changes to inventory management and costs of same, to evaluate and monitor regulatory burden of MSR in future reviews.</p>
KPI 11: Designated brand shortages	<p>The early evidence shows that there was a 13% decline (from 612 to 533) in the number of shortages of designated brands since the introduction of the MSR. The number of shorter duration shortages (under 4 months) fell by 24%. This is consistent with feedback from industry through the survey about their use of MSR stocks to mitigate supply disruptions and shortages. Further evaluation through the 24-month review is required to understand the impact of the MSR on shortages.</p>	<p>11.1 as per recommendation 4.2. 11.2 as part of the 24-month review, undertake additional analysis of breach notifications and TGA shortages data to evaluate the impact of the MSR on shortages of designated brands.</p>
KPI 12: Wastage and viability	<p>The evidence about the impact of the MSR, and the October 2022 price increases, on the viability of designated brands with an AEMP <\$3.50 is inconclusive. Further analysis is required to understand the effectiveness of strategies to improve the viability of these medicines within the wider landscape affecting medicine viability, including factors that influence cost of goods sold (COGS) and global pricing arrangements.</p>	<p>12.1 solicit further feedback on whether wastage is occurring/why, and efficacy of existing processes to address this. 12.2 as per recommendation 5.2. 12.3 undertake further analysis of the factors that support the viability of medicines with an AEMP <\$3.50 for the 24-month review.</p>

Attachment 1: Background to the MSR

Medicine shortages

Global medicine shortages can interrupt the supply of medicines to Australian patients for a number of health conditions. The Therapeutic Goods Administration (**TGA**) manages medicine shortages in Australia to reduce the impact on patients wherever possible, and publishes reported shortages in the [TGA Medicine Shortage Reports Database](#). While the number of shortages has been relatively consistent since the introduction of mandatory reporting in January 2019, shortages continue to impact the health and wellbeing of people in Australia and the health professionals that support them. As of **15 July 2024**, there were **410** current and **62** anticipated medicine shortages published on the TGA website.⁵ Depending on the cause of the shortage, the TGA has a range of management actions it can take.⁶

Medicine supply chains are complex global systems involving many parties. Disruptions to supply can occur for various reasons including: manufacturing and quality issues, sudden increases in demand, pressure on prices or viability, raw material and active pharmaceutical ingredient (**API**) shortages, manufacturing problems and supply disruptions caused by geopolitical or natural/climatic events.⁷ The Organisation for Economic Co-operation and Development (**OECD**) recommends addressing the root causes – which can include pressure on costs and low profitability in generic markets – as the best way to reduce exposure to shortage risks.⁸ In 2019 and 2020, brands of over 500 PBS listed medicines experienced medium to critical impact shortages. These shortages predominantly affected low-cost (priced at \$4 or less), multi-branded medicines in the off-patent market. Multi-branded medicines represent over one third of the total number of prescriptions subsidised through the PBS.

The Department of Health and Aged Care (**the department**) administers the [National Health Act 1953 \(the Act\)](#) which regulates the subsidisation of medicines through the Pharmaceutical Benefits Scheme (**PBS**). Similar to other OECD countries, the generic medicines market is subject to a mix of price regulation and competition. In Australia, the Price Disclosure regime (Division 3CAA of the Act) can result in price reductions biannually ([Attachment 2](#)). Over time, sustained price reductions can reduce the viability of some medicines in the generic market, particularly where there are increases in production costs or other cost pressures.

A multifaceted approach combining various strategies is more effective for management of medicine shortages than a single strategy in isolation. Many OECD countries⁹ have implemented stockholding requirements as a policy tool to help mitigate the effects of sudden increases in demand and/or disruptions caused by supply chain failures.¹⁰ Australia accounts for only 2% of the global pharmaceutical market and imports over 90% of its medicines, making it more vulnerable in periods of global shortage. This highlights the role of stockholdings as a key response to managing medicine supply risks in the Australian market. Although stockholdings cannot prevent shortages that are outside the control of the medicines industry, they are designed to work in conjunction with other

⁵ This statistic includes medicines which are not listed on the PBS.

⁶ Including approving the supply of overseas-registered alternative products under section 19A of *the Therapeutic Goods Act 1989* and allowing pharmacists to dispense certain identified substitute medicines when a medicine is in shortage, by making a Serious Scarcity Substitution Instrument.

⁷ Napier, M., D. Kourouklis, A. Cole, and G. Cookson (2024), *The Dynamics of Drug Shortages*, Office of Health Economics, Research Report, London.

⁸ Quality issues, pressure on prices as well as concentration of manufacturing capacities are most frequently cited as root causes of shortages.

⁹ For example, in 2022 these included Canada, Denmark, Germany, Finland, Israel, Latvia, Lithuania, Norway, Portugal, Switzerland, and the UK. See OECD (2022), *Shortages of medicines in OECD countries*, OECD Health Working Papers No, 137, 22 March 2022.

¹⁰ OECD (2023), *Strengthening health system resilience by improving medical supply chain security: key findings and recommendations*, 34th Session of the Health Committee, OECD Conference 2-3 November 2023, pages 23-24.

strategies for managing shortages and help to ensure that Australian companies are better placed to maintain supply when global disruptions occur.

The Medicines Supply Security Guarantee

The department explored approaches to mitigate the risk of PBS medicine shortages with Medicines Australia (MA) and the Generic and Biosimilar Medicines Association (GBMA). The [Medicines Supply Security Guarantee \(MSSG\)](#) was agreed through the [2022-2027 Strategic Agreements](#) between the Commonwealth and MA and the GBMA to address the supply risks associated with lower-cost multi-branded medicines that can be more vulnerable to supply disruptions. The MSSG includes the [Minimum Stockholding Requirements \(MSR\)](#) and [improved statutory pricing mechanisms to support viability](#).

The MSSG was given effect through amendments made by the [National Health Amendment \(Enhancing the Pharmaceutical Benefits Scheme\) Act 2021 \(Cth\)](#) (the Amendment Act) and the [National Health \(Pharmaceutical Benefits\) Amendment \(2021 Measures No. 1\) Regulations 2021 \(Cth\)](#).

The Strategic Agreement with the GBMA includes a commitment to undertake a review of the progress and outcomes of the stockholding policy by 1 July 2024 or a later date by agreement¹¹. The Executive Summary presents the key findings of this review.

The Minimum Stockholding Requirements

From 1 July 2023, under Division 3CAA of the Act, RPs are required to hold a minimum of either four or six months of stock in Australia for 'Designated Brands' listed on the PBS. These supply buffers are intended to ensure better continuity of supply in the Australian market and allow additional time for global supply disruptions to be resolved including through identifying alternative sources of supply wherever possible.

A brand of a pharmaceutical item¹² is a 'designated brand' (s99ADHC) and will be subject to the minimum stockholding requirements (s99AEKA) from the date that it meets one or more of the criteria set out in s99ADHC(1) of the Act:

- the drug and manner of administration (drug/MoA) of the pharmaceutical item has been on Formulary 2 (F2) for at least 42 months and at least 30 months must have passed since the first [price disclosure](#) price reduction for any brand of the same drug/MoA (42-month clock) (s99ADHC(1)(a)) (refer to [Attachment 2](#) for a brief overview of PBS pricing).
- the AEMP of the brand is \$4 or less (s99ADHC(1)(b)).
- the AEMP of the brand has been increased on or after 1 July 2022 through a new price agreement and a determination is in force in relation to the brand under s99ADHC(2) (**designated brand determination**) (s99ADHC(1)(c)).
- the AEMP of the brand has received a price increase on 1 October 2022 under s104B of the Act (s99ADHC(1)(d)).

As of 1 July 2024, there were **2,945** designated brands across **867** pharmaceutical items that are subject to the stockholding requirements. This includes medicines to treat health conditions including high blood pressure, high cholesterol, depression, schizophrenia, Alzheimer's disease, glaucoma, nerve pain, diabetes, and infections. The department first published a list of Designated Brands on the PBS website on 1 July 2022, providing 12 months advance notice for RPs to meet the MSR from 1 July 2023. The department updates the list of designated brands on the PBS website biannually on

¹¹ The department and GBMA subsequently agreed to a review delivery date of 31 July 2024.

¹² 'Pharmaceutical item' = the combination of a drug, form and manner of administration e.g., paracetamol (drug), 500mg tablets (form), oral (manner of administration).

1 April and 1 October. The list includes details of those brands projected to become designated brands within 12 months from the publication date.

The department conducted extensive consultation with the medicines industry in the development of [PBS Minimum Stockholding Guidelines \(the Guidelines\)](#) to support industry in implementing the MSR. The Guidelines include operational aspects such as reporting requirements, compliance obligations and the process for RPs to request a [Ministerial Determination of 'another quantity'](#).

Substantive stockholding requirements

The amount of stock required to be kept to meet the MSR is set by reference to a number of months (generally either 4 or 6 months) of 'usual demand' for the brand of pharmaceutical item. Designated brands that receive a price increase are required to hold six months stock by reference to 'usual demand'. Designated brands that have not received a price increase are required to hold four months stock by reference to 'usual demand'.

'Usual demand' is the average number of packs of a brand supplied per month based on [price disclosure data](#) where available. Stock that is required to be held is based on price disclosure data¹³ in the corresponding 6-month data collection period occurring 12 months prior to each stockholding period. For example, for the stockholding period 1 April 2024 to 30 September 2024, usual demand is based on supplies in the reference period 1 April 2023 to 30 September 2023. This allows the MSR to account for any seasonal variation in demand. Where price disclosure data is not available (brands containing drugs on the F1 formulary or the Combination Drugs List (CDL), and pharmaceutical items exempt from price disclosure), PBS prescription data is utilised instead.

Under the Act, MSR stock must be 'available for sale' in Australia by the RP. This means that stocks must be physically located on shore in Australia and immediately available for sale. Stock in transit to Australia, stocks that have not yet passed customs, stocks that are in bulk storage (not yet in packaging for final sale), and stocks that have been sold from the RP to wholesalers, do not meet the legislative requirement. This is intended so that if a supply disruption occurs, stock is readily available for distribution into the local supply chain.

Ministerial determination of another quantity

The Minister has the power under the Act to make a minimum stockholding determination specifying 'another quantity'.¹⁴ Requests for Ministerial determinations of another quantity are made by RPs using the [determination request form](#). These requests may be considered appropriate where there are long term practical barriers to compliance that cannot be overcome. For example, medicines with short shelf-life (<18 months) where a 6-month stockholding may result in medicine wastage.

Determinations made by the Minister are published in the [National Health \(Minimum Stockholding\) Determination 2023](#) on the [Federal Register of Legislation](#).

Requirement to notify of likely and actual breaches

Section 99AEKD of the Act requires RPs to notify the Minister 'as soon as practicable' of a likely or actual breach of the MSR. For a likely breach, this means as soon as practicable after they 'form a belief' of a likely breach.¹⁵ For an actual breach, this means as soon as practicable after the breach has

¹³ Price disclosure data includes the number of packs of a brand which are supplied by an RP during a 6-month data collection period. Refer to ['Price disclosure' in Attachment 2: PBS Statutory Price Reductions](#) for further information.

¹⁴ This power may be exercised by the Minister or their delegate. Subsequent references to the Minister can be taken to be a reference to the Minister or their delegate.

¹⁵ 'Form a belief' means as soon as they form a commercial judgement that they are likely to breach. It is different to the technical possibility of a breach being indicated by sales or supply data, if the RP also knows that the possible breach will probably be avoided through, for example, a new shipment arriving, the release of a shipment through customs, etc. There is an element of judgement required in 'forming a belief' – depending on an RP's experience and expertise, two RPs may form a different belief in response to the same technical data.

occurred. Notifications are submitted using the [breach notification form](#) and submitted via email to pbsstockholding@health.gov.au.

Stockholding disclosures

In accordance with s99AEKF of the Act and s85C of the Regulations, RPs are required to biannually disclose the quantity of stock held on the last day of each month in each 6-month disclosure period. RPs are required to submit the required information to the Price Disclosure Data Administrator (PDDA) by the following deadlines:

- for the period 1 April – 30 September: by 11 November; and
- for the period 1 October – 31 March: by 12 May.

The first disclosure period (1 July 2023 to 30 September 2023) included stockholding disclosure data from 91 RPs for 3,044 brands. The second disclosure period from 1 October 2023 to 31 March 2024 included stockholding disclosure data from 92 RPs for 2,944 brands.¹⁶

Ministerial powers

Under s99AEKE(2) of the Act, in the event of a breach of the substantive MSR,¹⁷ the Minister¹⁸ has the powers to:

- a) de-list the medicine(s) from the PBS which do not comply with the minimum stockholding requirement and/or any other medicines which the RP has listed on the PBS; and/or
- b) refuse to list new medicines on the PBS for that RP.

When assessing a breach of the minimum stockholding requirements and determining whether to exercise their powers, the Minister *must* consider:

- a) the RP's reason for the breach and whether those reasons are, in the opinion of the Minister, reasonable
- b) whether, in the Minister's opinion, the RP will consistently maintain adequate stock of the brand in the future
- c) whether the RP has offered discounts or incentives in relation to sales of the brand
- d) whether the RP has previously breached the minimum stockholding requirement in relation to any brands for which they are the RP and if so, the reasons for the breach(es) and whether those reasons are, in the opinion of the Minister, reasonable
- e) whether the RPs for other brands of the same pharmaceutical item have breached the minimum stockholding requirements in relation to those other brands
- f) any other matter the Minister thinks is relevant.

Section 8 of the [Guidelines](#) provides more details on the factors the Minister *must* and *may* consider when determining to exercise powers under the Act.

¹⁶ The number of designated brands changes over time due to monthly updates to the PBS Schedule (new brand listings and de-listings) as well as new medicines meeting the designated brand criteria in section 99ADHC of the Act. The disclosure data also includes brands that do not meet the legislative criteria but are subject to stockholdings through a Deed of Agreement (thus, the number of brands that have disclosed stockholding data will generally be higher than the number of designated brands). The disclosure data currently includes 5 brands subject to stockholdings through a Deed of Agreement.

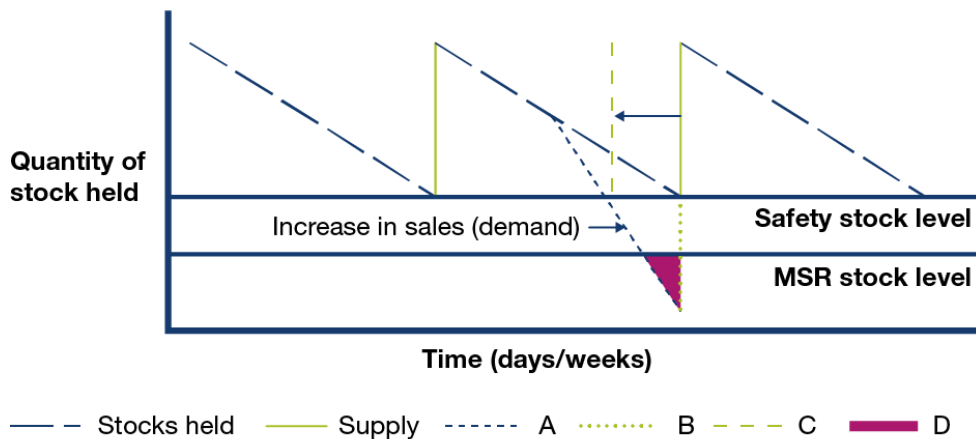
¹⁷ The substantive MSR means the requirement to keep in stock either 4 or 6 months' stock by reference to usual demand, or another quantity determined by the Minister.

¹⁸ This power may be exercised by the Minister or their delegate. Subsequent references to the Minister can be taken to be a reference to the Minister or their delegate.

The role of the MSR in mitigating shortages

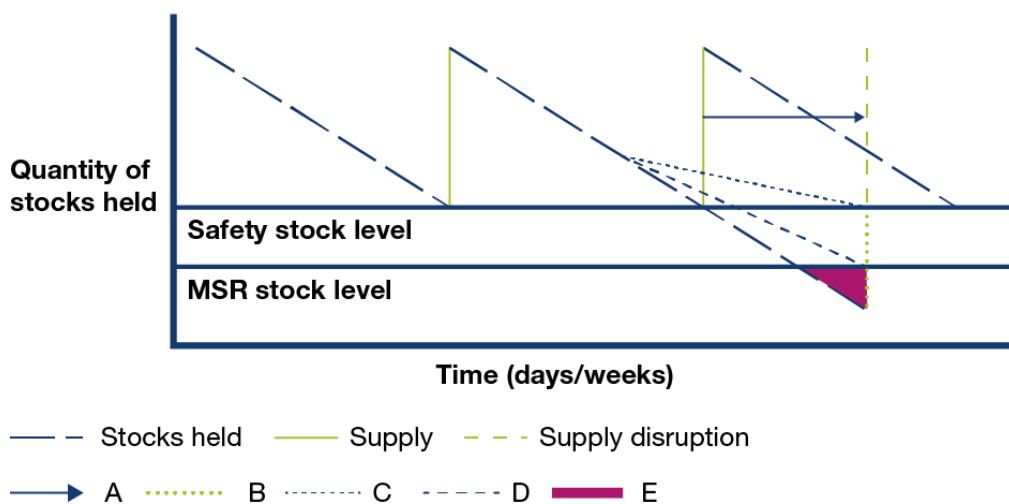
The role played by MSR stocks in mitigating potential supply shortages is shown in the figures below. Figure 1 shows how MSR stocks can help avoid a shortage in the event of a sudden surge in sales, for example, if a competitor is out of stock. Figure 2 shows how MSR stocks can help avoid a shortage in the event of a supply disruption, for example, to shipping routes, a manufacturing breakdown, or a shortage of raw materials.

Figure 1: use of MSR stocks to manage a demand increase



A spike in demand has the effect of increasing sales, meaning that stocks are drawn down more quickly than planned (shown by the dotted line A): this can either be managed by dipping into safety and/or MSR stocks (B), or by bringing forward new supplies (C). Without the MSR, there would have been a shortage (D) in which the medicine was out of stock.

Figure 2: use of MSR stocks to manage a supply disruption



A supply disruption such as that caused by a shipment delay (shown by A) can either be managed by dipping into safety/MSR stocks (B) or by rationing stock. The line C shows stock being rationed to avoid breaching safety stocks, while line D shows stock being rationed to avoid breaching the MSR. RPs may ration stock to avoid going out of stock entirely, however this results in reduced availability for patients. Without the MSR, the medicine would have been out of stock (E) or there would have been greater likelihood of rationing.

Attachment 2: PBS Statutory Price Reductions

PBS pricing

The PBS subsidy scheme for pharmaceuticals was established in 1948 and is governed by the [National Health Act 1953](#) (the Act). The PBS is a program that reimburses pharmacists for the dispensing of listed medicines. It does not directly purchase medicines or reimburse patients. Pharmaceutical items listed on the PBS are subject to a range of statutory pricing mechanisms set out in Part 7 of the Act.

The AEMP

The reimbursed price per pack of medicine is by agreement between the Government and the sponsor and is referred to as the Approved Ex-Manufacturer Price (AEMP). All brands of a pharmaceutical item¹⁹ must have the same AEMP.

Formularies

When drugs are listed on the PBS, they are allocated to one of two formularies, which then determines which pricing arrangements the drug is subject to:

- Formulary 1 (F1) is intended for single branded drugs. F1 drugs are subject to anniversary price reductions 5, 10 and 15 years after listing.
- Formulary 2 (F2) is for drugs for which there is more than one brand. F2 drugs are subject to price disclosure and guarantee of supply regulations.
- The first new brand (FNB) statutory price reduction (SPR) applies when the first new brand of a pharmaceutical item that is bioequivalent or biosimilar and has the same manner of administration as an existing pharmaceutical item is listed on the PBS.
 - When the FNB is listed for a drug that is in F1, the drug becomes multi-branded and moves from F1 to the F2 formulary and is subject to a FNB SPR which is up to 25%.

Price disclosure (PD)

Once a drug is in F2, medicine prices are subject to price disclosure. The price paid by pharmacy for a medicine may be less than the PBS reimbursement (AEMP) to the pharmacy. Price disclosure aims to ensure the prices that patients and the Australian Government pay for multi-branded medicines more closely reflects the average prices those medicines are supplied to the market.

Under Division 3B of the Act, sponsors of medicines subject to price disclosure are required to collect and submit data on sales revenue, sales volume and incentives every six months. The arrangements result in price reductions based on weighted average disclosed prices (WADPs) which can occur twice a year on either 1 April or 1 October. A price reduction for a brand may occur if the percentage difference between the current price and the WADP is greater than the prescribed threshold for the brand. The relevant thresholds include:

- For brands that are not designated brands – **10%**;
- For designated brands with an AEMP of more than \$4 – **30%**; or
- For designated brands with an AEMP of more than \$4, if there has been discounting averaging at least **12.5%** over the last 3 data collection periods including the one for which calculations are performed and there has not been a price reduction under s99ADH of the Act – **10%**.

¹⁹ Where Pharmaceutical Item is defined by the drug, the form (e.g. oral solution, pills, injectables) and the manner of administration (e.g. oral, injection).

Viability and the MSSG

There are various legislative and administrative mechanisms in place to protect medicines from an unviable price reduction occurring, including:

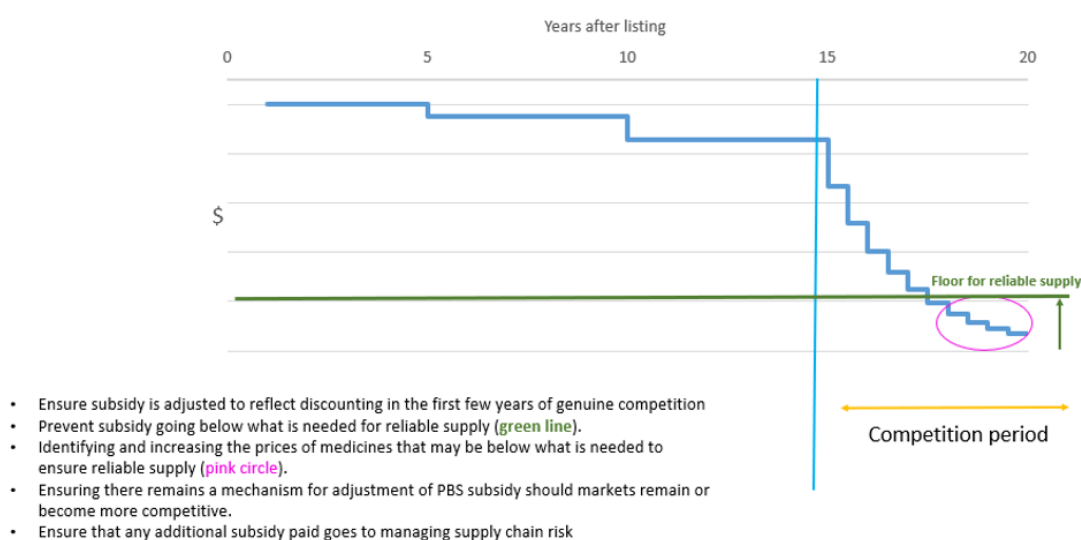
- [Ministerial discretion](#) to not apply (or to reduce) a statutory price reduction
- The [Price Disclosure Dispute Resolution process](#)
- [Exempt](#) items from statutory price reductions

However, despite the fact that price disclosure reductions occur based on average market prices, over time sustained price reductions can reduce the viability of some medicines, particularly where there are increases in production costs (or other cost pressures).

The MSSG included PBS pricing reforms to improve medicine viability for older, lower cost medicines that have been subject to sustained price reductions, including:

- a) One-off price increases on 1 October 2022 for PBS medicines with an AEMP of less than \$3.50.²⁰ The price increases aimed to address viability concerns in the multi-branded market as a root cause of supply disruptions. Approximately 950 brands of pharmaceutical items received a price increase on 1 October 2022, with an average increase to the AEMP of 44%.
- b) The continuation of the 30% price disclosure threshold test and addition of the 12.5% averaging threshold test to protect older medicines from unviable price reductions whilst ensuring price reductions still occur where there is ongoing sustained discounting in the market; and
- c) The establishment of floor price protections whereby designated brands are not subject to price reductions under the Act, unless the 30% or 12.5% price disclosure threshold is surpassed, in which case any price reduction would not reduce the AEMP any lower than \$4.

Figure 3: pricing reform objectives of the Medicines Supply Security Guarantee



²⁰ 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 and more than \$3.00 but less than \$3.50 received an increase to \$3.50.