Australian Government
Department of Health, Disability and Ageing

Pharmaceutical Benefits Scheme Minimum Stockholding Guidelines

August 2025

Contents

Section 1. Introduction

These guidelines support the implementation of minimum stockholding requirements to help secure the supply of medicines in Australia

Increasingly, global medicine shortages are interrupting supply of medicines that are the mainstay of treatment for some of the most prevalent health conditions in the Australian community. In 2019 and 2020, medicines supplied by manufacturers for $4 or less per pack were the most susceptible to shortages.

Amendments made to the *National Health Act 1953* (**the Act**) by the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021* (**the Amendment Act**) give effect to the commitments in the new Strategic Agreements with the medicines industry, which includes minimum stockholding requirements. The minimum stockholding requirements are designed to help protect Australian patients, pharmacists, and prescribers from the impact of global medicines shortages. While these measures will not prevent shortages that are outside of the control of Australian companies, they will help to ensure that Australian manufacturers are better placed to continue supply when global disruptions occur. Greater buffers will allow time for supply disruptions to be resolved and ensure better continuity of supply for Australians, including through identifying alternative sources of supply (where possible).

From 1 July 2023, the Act imposed a requirement for Responsible Persons (**RP**s) to keep in stock in Australia, 4 or 6 months of 'usual demand' for brands which meet one of the criteria in s99ADHC of the Act. Details of the legal requirements are specified in the Act and in the *National Health (Pharmaceutical Benefits) Regulations 2017*[1] (**Regulations**).

The investment by the medicines industry in managing supply chain risk through the minimum stockholding requirements is supported by the Australian Government through one-off price increases on 1 October 2022 and floor price protections for low-cost medicines.

The purpose of this guideline document is to assist RPs to comply with the minimum stockholding requirements outlined in Part VII, Division 3CAA of the Act, which commences on 1 July 2023.

These guidelines summarise compliance requirements for RPs and provide additional supporting detail. Specifically:

- Section 2: Scope of minimum stockholding requirements describes the criteria that determine which brands will be subject to the requirements.
- Section 3 Keeping a brand in stock in Australia details what types of stock will count towards satisfying the minimum stockholding requirements.
- Section 4 Quantity of stock required to be kept describes how minimum stockholding requirements are determined with reference to usual demand or via Ministerial determination of 'another quantity'.
- Section 5 Lead times discusses the timelines under which RPs will prepare to meet minimum stockholding requirements and stockholding disclosure requirements.

[1] As amended by the *National Health (Pharmaceutical Benefits) Amendment (2021 Measures No. 1) Regulations 2021*.

- Section 6 Ministerial determination of 'another quantity' describes how RPs can request a Ministerial determination for another stockholding quantity for a particular brand, including the matters the Minister may consider relevant.
- Section 7 Reporting and monitoring describes the disclosure of stockholding levels and the notifications that RPs are required to provide regarding likely or actual breaches of stockholding requirements.
- Section 8 Management of breaches describes what RPs are required to do if minimum stockholding and reporting requirements have been breached, and the measures and penalties that may apply.

These Guidelines are intended to provide general guidance to RPs in relation to the minimum stockholding requirements under the Act and Regulations. The Guidelines are not intended to be, and should not be treated as, legal or professional advice, and RPs should seek their own legal and professional advice where appropriate. Nothing in the Guidelines in any way limits the operation of either the Act or Regulations or affects or fetters any function or power of the Minister or any other person or body under the Act and Regulations.

Section 2. Scope of minimum stockholding requirements

Section 2.1. Criteria for designated brands to be subject to stockholding requirements

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

The criteria are:

- The drug and manner of administration (**drug/MoA**) of the pharmaceutical item has been on Formulary 2 (**F2**) for at least 42 months (defined in s99ADHC(6)) and at least 30 months must have passed since the first price disclosure price reduction[2] for any brand of the same drug/MoA (**42-month clock**) (s99ADHC(1)(a)). A drug/MoA will be taken to have been on F2 for at least 42 months if at the end of the previous data collection period, the drug/MoA has been on F2 for at least 42 months, and on a day at least 42 months before the end of the previous data collection period, the drug/MoA was multi-branded (s99ADHC(6)); or
- The approved ex-manufacturer price (**AEMP**) of the brand is $4 or less (s99ADHC(1)(b)); or
- The AEMP of a brand of a pharmaceutical item has been increased on or after 1 July 2022 through a new price agreement and a determination[3] is in force in relation to the brand under s99ADHC(2) (**designated brand determination**)(s99ADHC(1)(c)); or
- The AEMP of the brand has received a price increase on 1 October 2022 under s104B of the Act (i.e. before 1 October 2022 the drug was on F2, and the brand of pharmaceutical item had an AEMP less than $3.50 (s99ADHC(1)(d)).

Brands that meet at least one of the criteria above are referred to as 'designated brands'.

Regardless of whether it meets any of the above criteria, a brand will not be a designated brand and will not be subject to the minimum stockholding requirements if:

- The drug in the pharmaceutical item is included in Schedule 2 of the current Poisons Standard by reference to a quantity or amount of the drug; and
- The quantity or amount of the drug in a pack of the brand is equal to or greater than the quantity or amount specified in Schedule 2.

A brand which receives temporary approval under s19A of the *Therapeutic Goods Act 1989* will be subject to the minimum stockholding requirement and stockholding disclosure requirements if the brand otherwise meets the criteria in s99ADHC.

[2] Refer to the PBS Price Disclosure Guidelines and the Designated brand website for further information.
[3] Determinations will be made for all brands of the pharmaceutical item that are PBS listed at the time that the price increase occurred, as well as to any new brands of the pharmaceutical item that subsequently list on the PBS after the price increase has occurred.

Section 2.2. Minimum stockholding requirements and 'usual demand'

The volume of stock required to be held by RPs to satisfy minimum stockholding requirements is determined as follows:

- If the AEMP of a designated brand has not been increased on or after 1 July 2022, its minimum stockholding requirement will be 4 months of 'usual demand'; or
- if the AEMP of a designated brand has been increased on or after 1 July 2022, its minimum stockholding requirement is 6 months of 'usual demand'; or
- if the Minister determines 'another quantity' under s99AEKC(2) (**minimum stockholding determination**), the minimum stockholding requirement will be that quantity (see Section 6).

'Usual demand' calculations are based on price disclosure data where available. Where price disclosure data is not available, the Minister may make a determination based upon 'usual PBS demand' (see Section 4.4). See Section 4 below for further detail as to how 'usual demand' is calculated.

Section 2.3. Lists of designated brands subject to minimum stockholding requirements published biannually

The department publishes two lists of designated brands on 1 April and 1 October of each year, in line with Price Disclosure (**PD**) data collection periods:

1. **Current list of designated brands:** This list identifies brands subject to stockholding requirements as at the date of publishing, and their required minimum stockholding level (i.e. 4 months or 6 months of 'usual demand' or an amount determined by a minimum stockholding determination).
2. **Projected list of designated brands:** This list identifies brands that will meet the 42-month clock criteria (s99ADHC(1)(a) of the Act) and be subject to stockholding requirements 6 or 12 months after the projected list is published, i.e. from the following 1 April or 1 October. The list will also include the required minimum stockholding level (i.e. 4 months or 6 months of 'usual demand').

The projected list of designated brands may not be a comprehensive forward view of brands that will meet the other criteria of a 'designated brand' and be subject to minimum stockholding requirements in 12 months. It may not, for example, include all brands with a price increase after 1 July 2023 by agreement, brands subject to statutory price reductions which bring their AEMP to $4 or less, or the newly listed brands of existing pharmaceutical items, for which the department will not have 12 months of forward visibility. For further detail on notice of stockholding requirements, please see Exhibit 10.

Section 2.4. Notices to be provided by the department/Price Disclosure Data Administrator (PDDA)

In addition to the publication by the department of the lists referred to above, notices will be sent to RPs for designated brands as follows:

a) 12 months prior to a brand meeting the s99ADHC(1)(a) criteria[4], the PDDA will notify the RP that the brand is approaching the 42-month clock and will be subject to minimum stockholding requirements once that criteria is met.

b) Following a price increase (ss99ADHC(1)(c) or 99ADHC(1)(d) of the Act), the department will initially advise the RP of stockholding requirements which will be effective 6 months from the date the price increase takes effect (i.e. when designated brand determination is effective, as well as any minimum stockholding determination).

The PDDA will also send routine notifications of future stockholding requirements for the brand as follows:

c) By 7 June and 7 December, a forward notification to the RP advising the quantity calculated as 'usual demand'[5] for the reference period just ended, in respect of each brand of a pharmaceutical item subject to price disclosure and minimum stockholding requirements. The department's intention is that this notification should simply serve as a confirmation for the RP, as using their own reported volumes in accordance with PD requirements, the RP is able to calculate what this amount will be prior to the notification.

   (For example by 7 December 2023 the RP will be provided with a forward notification of a brand's minimum stockholding requirement for the period 1 April 2024 to 30 September 2024 (based on 'usual demand' in the reference period 1 April 2023 to 30 September 2023).)

d) On the last business day of each reporting period, an initial reminder email to the RP confirming which brands are designated brands for the reporting period which is ending, and the quantity of 'usual demand' which was required to be kept for each designated brand during that period.

[4] The s99ADHC(1)(a) criteria is met by brands for which the drug and manner of administration of the brand's pharmaceutical item has been on F2 for at least 42 months and at least 30 months have passed since the first price disclosure price reduction for any brand with the same drug and manner of administration (see section 2.1 above).
[5] 'Usual demand' for a brand is calculated in accordance with s85B of the Regulations. If RPs have any questions about the calculation of the 'usual demand' they can enquire with the PDDA or the department. If RPs dispute the PD volume data that is used to calculate 'usual demand' they can raise a dispute through the PD Dispute Resolution Administrative Process. Note that 'usual demand' may be subject to change as a result of a dispute outcome.

Section 3. Keeping a brand in stock in Australia

To meet the minimum stockholding requirement the RP for the brand must keep in stock in Australia at least the applicable quantity of the brand. If a quantity of the brand is not available for sale in Australia by the RP, that quantity of the brand is taken not to be kept in stock.

The minimum stockholding requirement is an ongoing obligation once a brand is a designated brand. Although disclosure is made of stock levels on the last day of each month (see Section 7.1 below), the minimum stockholding requirement must be met at all times.

The department considers that for the brand to be both kept in stock in Australia, and available for sale in Australia by the RP, it must satisfy the following criteria:

i. The stock is physically located onshore in Australia.

ii. The stock has cleared customs in Australia.

iii. The stock is in saleable form. This requires all manufacturing, quality control, packaging, release for supply, and any other pre-sale checks to be complete, with no further modifications necessary before sale.

iv. No permission, release, or other intervention from someone other than the RP is required before the stock can be sold.

Stock in transit

Stock that is in transit to Australia does not count towards the stockholding requirement as it is not physically located onshore in Australia and is not 'available for sale in Australia by the Responsible Person'.[6] Stock in transit therefore cannot be used to immediately supply the Australian market where there is a market disruption or an unexpected increase in demand and does not serve as a true 'supply buffer' which is the intention of the stockholding requirements. The Minister may consider stock being in transit (including when considering whether the RP is likely to maintain adequate supply of the brand in the future) where a breach of the stockholding requirements occurs. This is further outlined in Section 8.2.

Stock sold to wholesalers

If stock has been sold to a wholesaler, it will not be considered to be 'available for sale in Australia by the Responsible Person' because it is subject to release or other intervention by the wholesaler before the stock can be sold to another entity. The stock cannot be simultaneously available for sale by the wholesaler and the RP, and cannot be sold again by the RP until an arrangement is made with the wholesaler to make it 'available for sale' again by the RP. This approach ensures that the minimum stockholding is additional stock above and beyond what is held down-stream from RPs in the supply chain. Stock that has been sold to wholesalers has been supplied into the supply chain and therefore does not serve as a true 'supply buffer' which is the intention of the stockholding requirements.

If stock remains in the possession of an RP but:

- has been ordered by a wholesaler; and
- is under a commercial sale agreement between the RP and the wholesaler; and
- cannot be released from the commercial sale agreement and sold to another entity without the permission, release or other intervention by the wholesaler;

[6] s99AEKB of the Act.

then the stock would also not be considered to be 'available for sale in Australia by the Responsible Person' and as a result will not count towards the minimum stockholding requirements.

The stock available in wholesalers may be relevant when the Minister considers whether to utilise powers where a breach in the stockholding requirements occur. This is further outlined in Section 8.2.

Stock sold on consignment

If stock is sold by an RP to a wholesaler on consignment (i.e. where the RP is the consignor and the wholesaler is the consignee), the stock would not be considered to be 'available for sale in Australia by the Responsible Person' if the permission, release or intervention from the wholesaler (or someone other than the RP) is required before the stock can be sold to another entity. As a result, in these circumstances, the stock will not count towards the minimum stockholding requirements. If the wholesaler (as consignee) has agreed a standing permission for the RP to move stock around and remove it from sale by the consignee, stock will not become available for sale by the RP until the RP has exercised that right with respect to particular stock.

If the RP holds stock that is being sold on consignment (i.e. the RP is the consignee), this stock may count towards the RP's minimum stockholding requirement so long as they meet the other required criteria.

Stock held by third-party logistics providers

Stock which is kept by the RP at a third-party logistics provider's premises and/or orders fulfilled through a third-party logistics provider will count towards the RP's minimum stockholding requirement for the brand, where it otherwise meets the criteria above. Stock will not fall outside the criteria just because action needs to be taken by a third-party logistics provider to fulfil a purchase order placed with the RP.

Multi-branded pharmaceutical items kept by the same RP

An RP which has multiple brands of the same pharmaceutical item must satisfy the minimum stockholding requirements for each brand and cannot count stock of one brand towards meeting the minimum stockholding requirement for another brand.

Brands kept in multiple packaging types

Where an RP has a brand of pharmaceutical item which is packaged using different packaging types (e.g. blister packs and bottles), both types of packaging can be counted towards meeting the RP's minimum stockholding requirement if the packaged stock meets the criteria otherwise to be counted. The RP will have to disclose the number of packs in stock and the number or quantity of units in a pack for each of the different packaging types (e.g. 200 packets containing 20 capsules in each pack, and 100 bottles containing 30 capsules in each bottle).

Section 4. Quantity of stock required to be kept

As discussed in Section 2.2, the quantity of stock that is required to be kept by an RP is set by reference to the 'usual demand' for the brand of pharmaceutical item. 'Usual demand' is defined in s85B of the Regulations as follows:

> *[T]he **usual demand** for a brand of a pharmaceutical item for a month in a data collection period for that brand is the number of packs of the brand supplied during the data collection period (the **reference period**) before the previous data collection period for the brand, divided by the number of months in the reference period.*

Usual demand is expressed as a number of packs, with the pack size equal to the pricing quantity for the brand. See Section 3 above for how the total quantity of stock held by an RP is calculated, where stock is held in pack sizes other than the pricing quantity.

For brands of pharmaceutical items subject to minimum stockholding requirements, RPs are required to keep in stock 4 or 6 months' 'usual demand', depending on whether the AEMP of the brand has been increased on or after 1 July 2022 (s99AEKC of the Act). Where other brands of a pharmaceutical item have received a price increase on or after 1 July 2022 and a brand which subsequently lists is determined as a designated brand, the Minister will generally make a determination of 6 months usual demand/usual PBS demand for that brand.

'Usual demand' calculations are based on price disclosure data where available, unless there is a minimum stockholding determination of a different amount. This Section expands on how 'usual demand' is calculated in various circumstances, including:

- Demand variation
- Changes in pricing quantity between the reference period and the current period (Section 4.1)
- Variations in the length of the reference period and associated availability of PD data (Section 4.2)
- Determination of 'another quantity' in instances where reference period data is not available (Section 4.3)
- When a brand is approved to be de-listed (Section 4.4)
- When a brand subsequently re-lists following de-listing (Section 4.5).

Section 4.1. Demand Variation

Usual demand in the reference period may be different to the RP's forecasted sales for the stockholding period. This may occur for a variety of reasons including:

- Inflated demand in the reference period due to a competitor being out-of-stock
- Reduced demand in the stockholding period due to loss of a significant supply contract
- Reduced demand in the reference period due to a medicine shortage.

The calculation of usual demand does not take into account future demand forecasts as these will vary between RPs and are likely to be subject to interpretation and commercial considerations. Basing usual demand calculations on historical supply volumes provided through price disclosure (or PBS dispensing

volumes) provides a rational, concrete and consistent approach for the minimum stockholding requirements to be calculated. Under section 99AEKB of the Act, the RP must comply with the applicable quantity calculated under the Act and Regulations despite this potentially being different from forecasted sales.

In some situations (e.g. if a medicine has short shelf-life or if the magnitude of demand variation is large enough), an RP might be at risk of wasting stock by complying with the MSR. Substantial demand variation is dealt through the department's approach to non-compliance. If an RP anticipates that compliance with the MSR will result in wastage, it should notify the department, and include the following information to facilitate any later assessment by the Minister of whether the reasons for a breach by the RP of the MSR are reasonable:

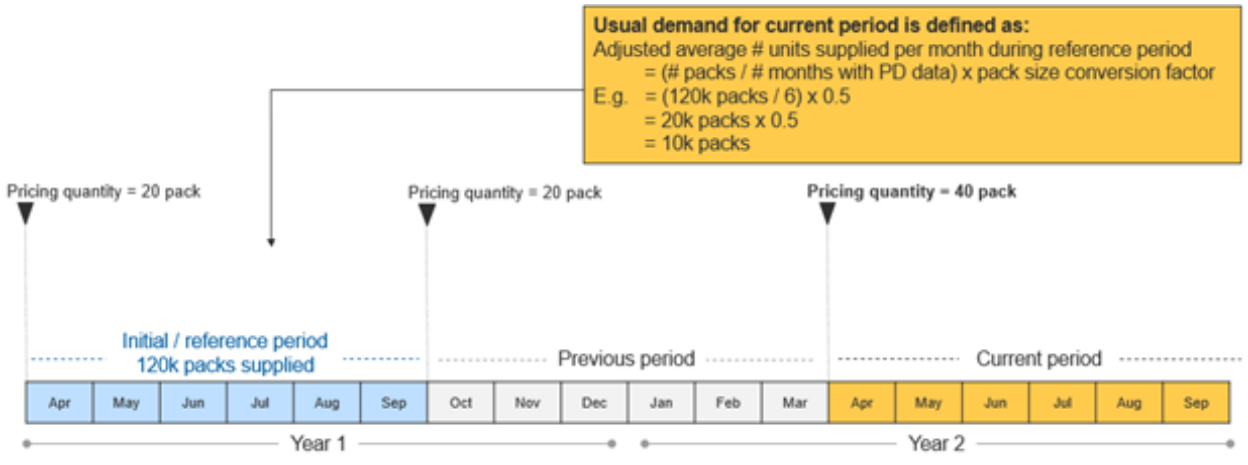
- The cause for inflated demand in the reference period or for reduced demand in the stockholding period
- Shelf-life of the brand
- Forecasted demand expressed as a number of packs per month
- The forecasted quantity of wastage if the minimum stockholding requirement were complied with
- Details of the quantity of stock that can be held in the stockholding period without inducing wastage.

RPs are encouraged to contact the department (pbsstockholding@health.gov.au) if they are, or will be, impacted by major changes to the RP's forecasted demand, such as a contract loss that impacts their entire portfolio of brands.

Section 4.2. Calculation of 'usual demand' when pricing quantity changes between the reference period and current period

Where the pricing quantity changes between the start of the reference period and the commencement of the period in which stock is required to be held, for the purposes of calculating 'usual demand' the number of packs is adjusted in proportion to the change in pack size (see Exhibit 1Exhibit 1).

Exhibit 1: Calculation of 'usual demand' when pricing quantity changes



Section 4.3. Calculation of 'usual demand' when there are variations in the length of the reference period and associated availability of PD data

In practice, there may be variations in the availability of PD data from the reference period to determine 'usual demand'. The following 4 scenarios describe how the department will use reference period PD data to determine 'usual demand' for a given brand:

1. **Scenario 1 – no PD data is available for the reference period:** For a brand which was not listed on the PBS during the reference period (e.g. a new generic brand), the 'usual demand' for the brand is taken to be zero (under s85B(3) of the Regulations). The brand will have a minimum stockholding requirement once there is a reference period in which the brand was listed, and so 'usual demand' can be calculated for that reference period (see Exhibit 2).

2. **Scenario 2 – 6 months of PD data is available for the reference period: '**Usual demand' is the average number of packs of the brand supplied per month in the reference period (see Exhibit 3).

3. **Scenario 3 – less than 6 months of PD data is available for the reference period**: 'Usual demand' is the average number of packs of the brand supplied per month in the shortened reference period. This may apply, for example, if a brand became subject to price disclosure after the start of a given data collection period, or a brand has previously exited the market and then re-listed during the reference period (see Exhibit 4).

4. **Scenario 4 – more than 6 months of PD data is available for the reference period: '**Usual demand' is the average number of packs of the brand supplied per month in the longer reference period. This may apply, for example, if a brand has moved to F2 and has an initial data collection period longer than 6 months, or if a brand is newly listed on F2 and there are already other brands of the same drug/MoA) (**related brands**) on F2 which are in an initial data collection period longer than 6 months. The brand's initial data collection period will end when the data collection period of the related brands ends. Therefore, the initial data collection period, and first reference period, could be greater than 6 months (see Exhibit 5). 'Usual demand' will be calculated once there have been subsequent data collection periods and the completed initial data collection period is the data collection period before the previous data collection period (i.e. the reference period).

Further information regarding initial data collection periods is available in Section 5.5 of the Price Disclosure Guidelines.

Where, for any reason, 'usual demand' cannot be calculated using PD data, the Minister may make a minimum stockholding determination (see Section 4.3 and Section 6).

Where a brand is supplied under a s19A temporary approval and is PBS listed, it may be a designated brand and subject to minimum stockholding requirements if it meets one of the criteria to be a designated brand. A s19A product will not have 'usual demand' able to be calculated until there is PD data available in the reference period. This means that the quantity required to be kept in stock by the RP of the s19A brand will be taken to be zero until there is sufficient PD data for 'usual demand' to be calculated in the reference period. It will generally take between 7 – 12 months from the date of PBS listing for PD data to be available for a s19A product to have 'usual demand' calculated for it to be subject to a stockholding. RPs of s19A products are able to request that a stockholding determination of zero is made up to 6 months prior to the s19A approval expires and the product delists from the PBS (see Section 4.4).

Exhibit 2: Usual demand cannot be calculated when PD data is not available for the reference period

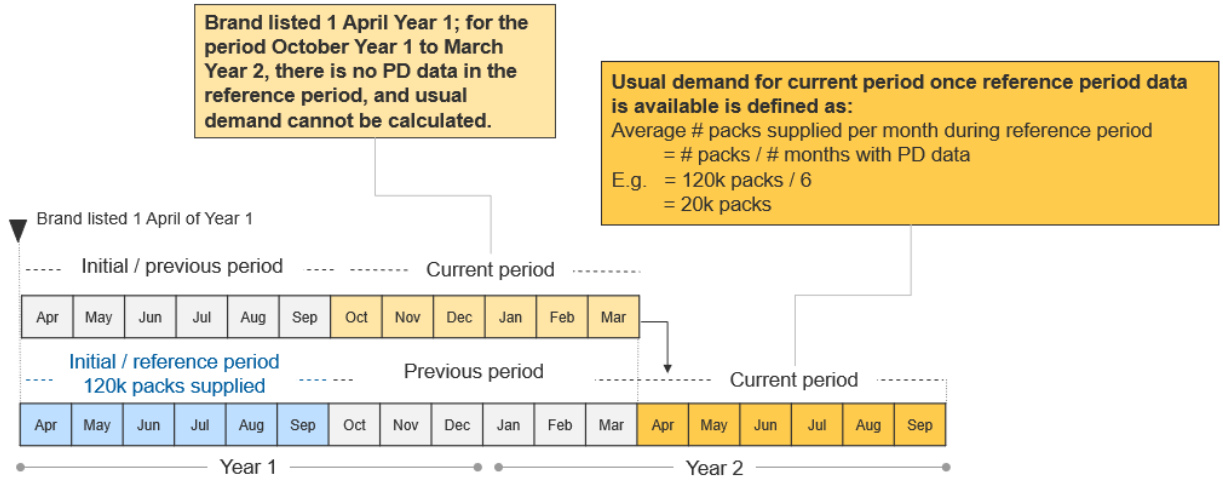


Exhibit 3: Calculation of 'usual demand' when 6 months of PD data is available for the reference period

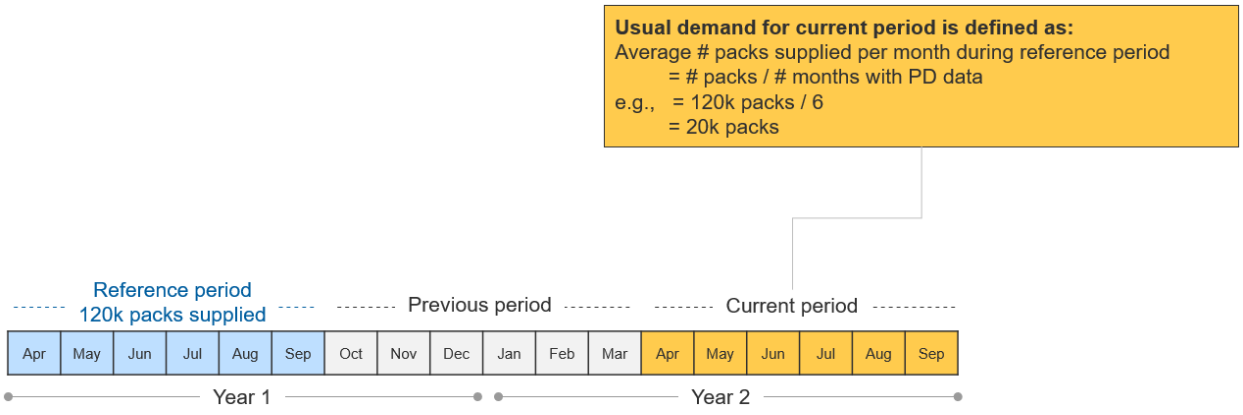


Exhibit 4: Calculation of 'usual demand' when less than 6 months of PD data is available for the reference period

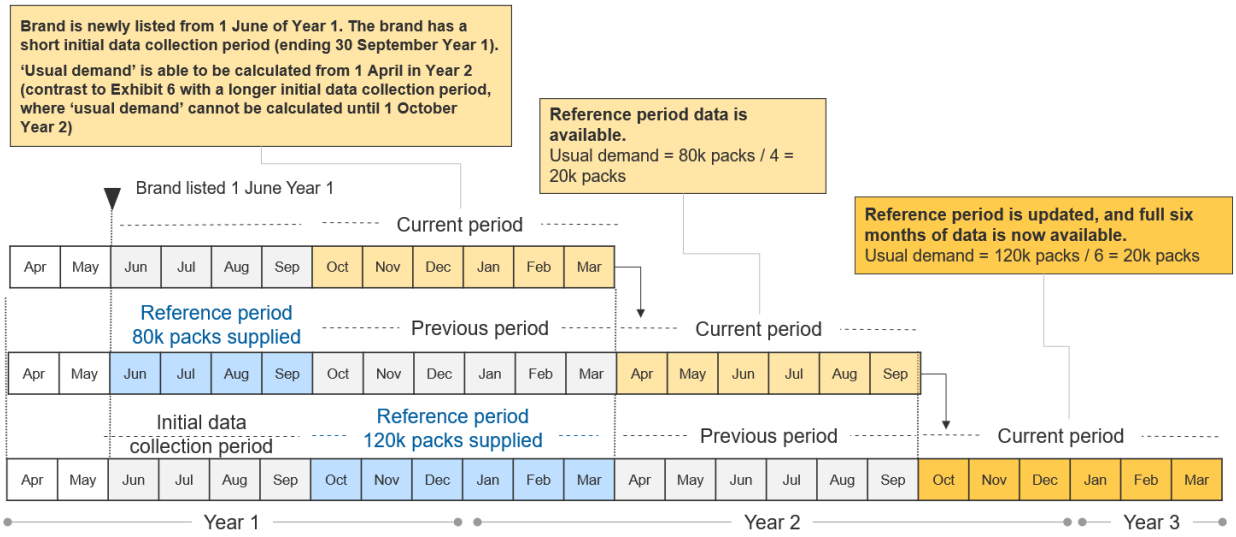


Exhibit 4 (continued): Calculation of 'usual demand' when less than 6 months of PD data is available for the reference period

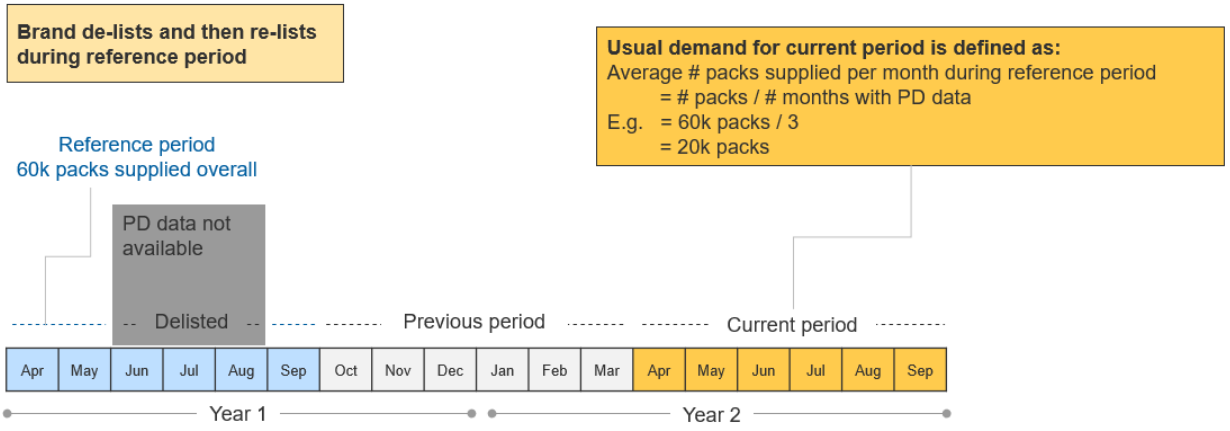
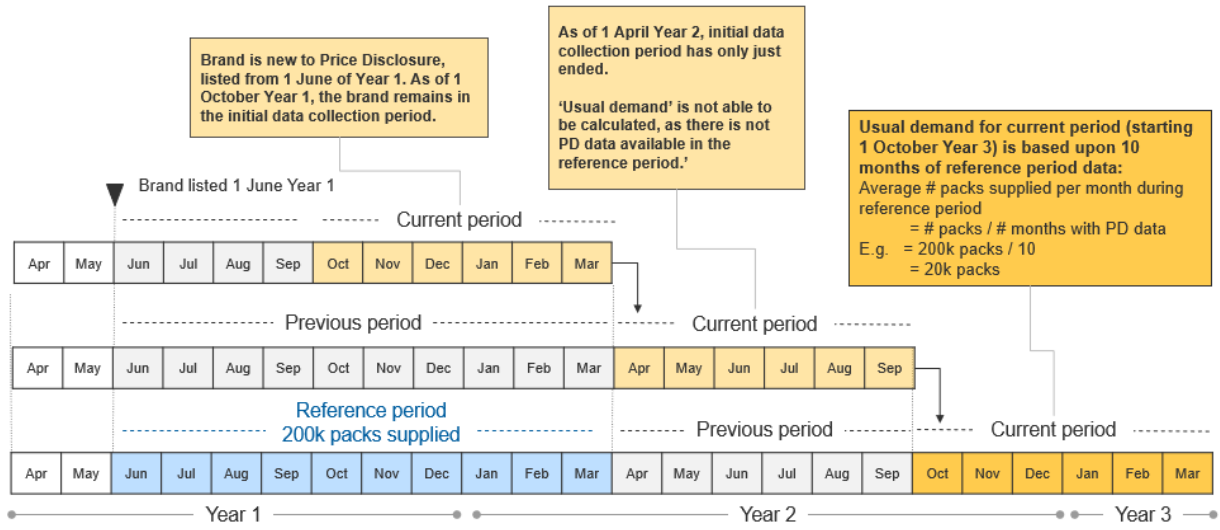


Exhibit 5: Calculation of 'usual demand' when more than 6 months of PD data is available for the reference period



Section 4.4. Determination of 'usual PBS demand' where PD data for the reference period is not available

Where PD data for the reference period is not available to calculate 'usual demand' (e.g. because the brand is not subject to price disclosure), the Minister may make a minimum stockholding determination (s99AEKC(2) of the Act; see Section 6 of these Guidelines). This may apply, for example, when a designated brand is listed on the F1 formulary, the administrative combination drugs list (**CDL**) or a brand is listed on the F2 formulary but exempt from PD. In making such a determination, the Minister may take into account PBS prescription volume data (based on the date of supply) for the reference period and adopt a similar methodology to that used to calculate 'usual demand'. This is referred to as 'usual PBS demand'. See Exhibit 6 for details. Prior to the Minister making a minimum stockholding determination, the department will provide RPs with details of the determination to be made (with reference to 'usual PBS demand') and the basis for any calculations, and provide RPs with the opportunity to seek clarification.

Once there is PD data available to calculate 'usual demand', the determination may be revoked and the RP will be required to hold stock of the 'usual demand' calculated in accordance with Section 4.2 above and the transition diagram in Exhibit 7 below. This may apply, for example, when a designated brand has recently moved from F1 or the CDL to F2, or a brand on F2 that is exempt from PD ceases to be exempt.

Exhibit 6: Minimum stockholding determination of 'usual PBS demand' based on PBS prescription volume data

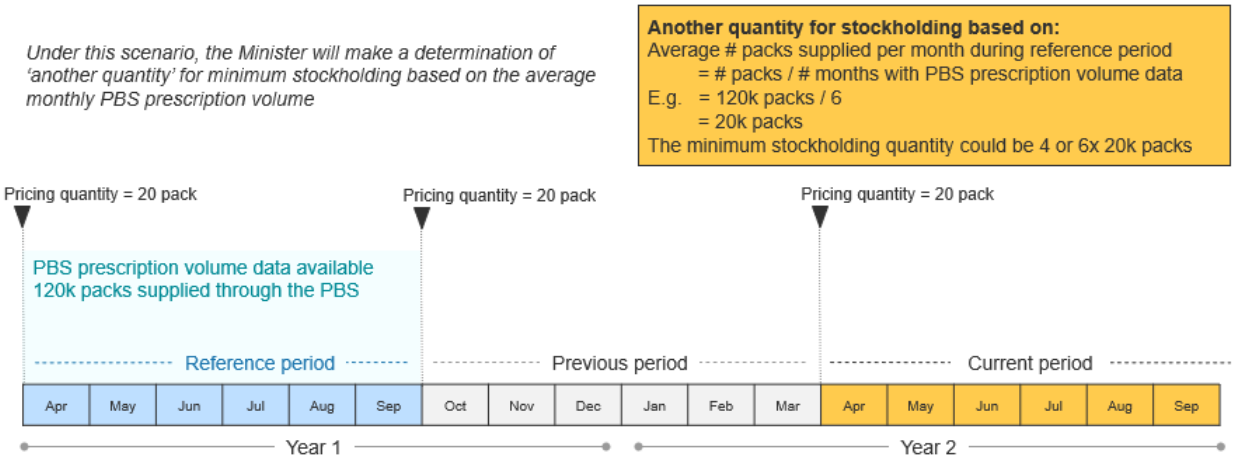
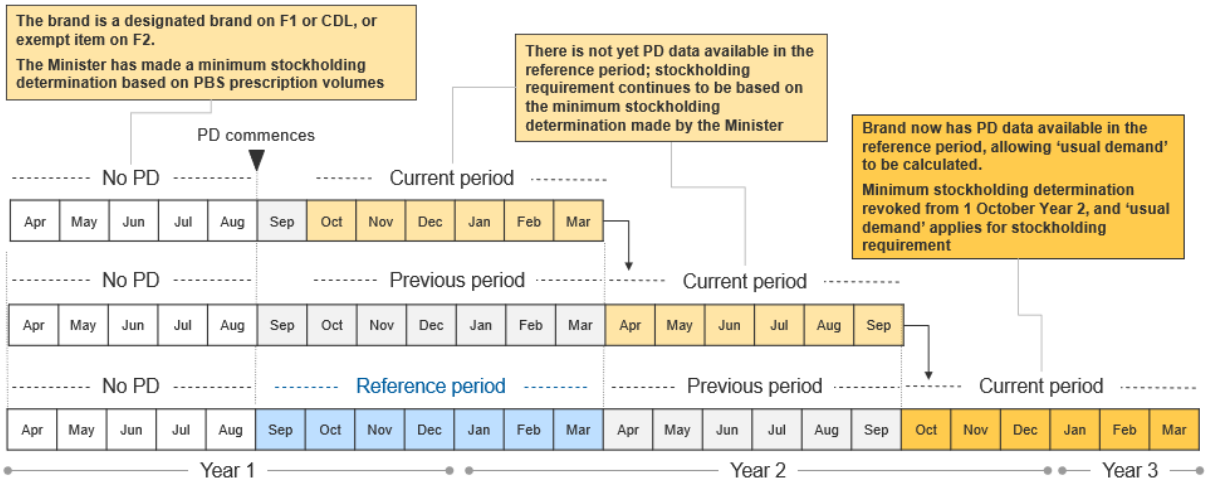


Exhibit 7: Transition from minimum stockholding determination of 'usual PBS demand' to calculation of 'usual demand'



When the Minister makes a minimum stockholding determination of 'usual PBS demand' the determination will be effective from a future date which provides the RP with time to prepare to hold the required quantity of stock (see Section 5.2).

Designated brands listed on F1 or the CDL or which are exempt items on F2 will usually have PBS prescription volume data in the reference period to assist the Minister in making a minimum stockholding determination of 'usual PBS demand' as outlined above.

For a newly listed brand for which there is no PD data or PBS prescription volume data for the reference period, neither 'usual demand' nor 'usual PBS demand' (as relevant) can be calculated. The quantity

required to be kept in stock by the RP will be taken to be zero until there is data for 'usual demand'/'usual PBS demand' to be calculated for the reference period. This will be the case for new generic brand listings for example. Once data is available, RPs will be notified of the quantity calculated as usual demand/usual PBS demand.

Section 4.5. Minimum stockholding requirements leading up to de-listing

An application by an RP for a brand to be de-listed may arise under two scenarios:

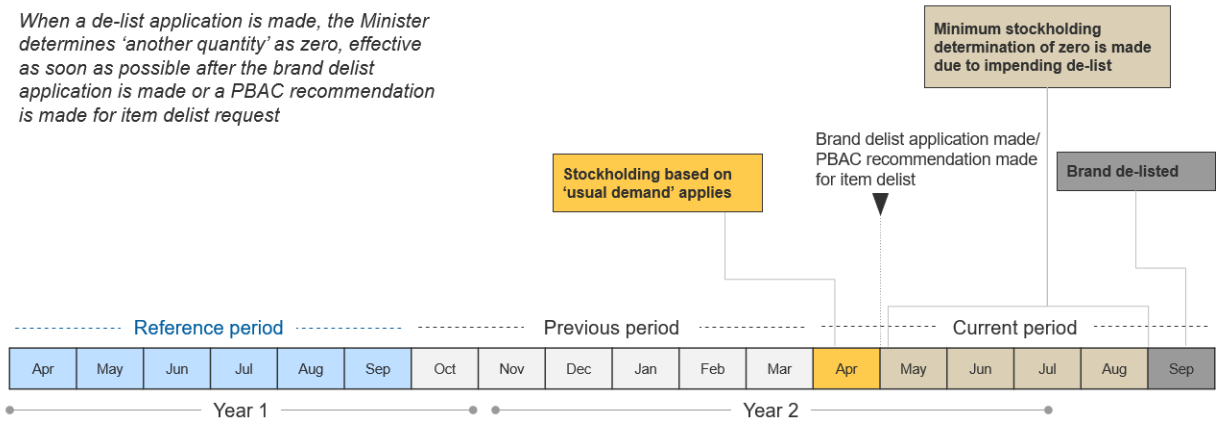
1. **Brand deletion:** If the brand is one of several brands of the pharmaceutical item listed, then Pharmaceutical Benefits Advisory Committee (**PBAC**) advice is generally not required for the de-listing request.
2. **Item deletion:** If the brand is the only brand of the pharmaceutical item listed, PBAC advice is generally required before the brand is de-listed. Where delisting applications are submitted for all brands of a pharmaceutical item, PBAC advice may be required before those brands are delisted.

More detail is available on the PBS website regarding these two scenarios. Note that if a brand delists, the RP is required to provide PD data and stockholding disclosure (see Section 7.1) up to the date of delisting.

For a brand deletion, the Minister will make a minimum stockholding determination that specifies that the applicable quantity is zero as soon as possible after the date that the de-listing application is received by the department (however any determination will not be effective any earlier than 6 months prior to the proposed delisting date). For an item deletion (in the circumstances above), the Minister will await the PBAC advice (where applicable) and the outcome of the de-listing application before making a minimum stockholding determination for the brand. When an item is approved to de-list from the PBS, the Minister will make a minimum stockholding determination that specifies that the applicable quantity is zero, effective from as soon as possible after the date approval is given to de-list (see Exhibit 8**)**. These determinations are made of the Minister's own volition. It is not necessary for an RP to apply for these determinations at the same time that the RP applies to delist a brand.

Where the quantity calculated as usual demand or usual PBS demand is zero for any stockholding period prior to when a brand is expected to delist from the PBS, it is not necessary to also make a minimum stockholding determination. RPs will be notified by email where this applies.

Exhibit 8: De-listing of a brand resulting in minimum stockholding determination specifying applicable quantity of zero



Section 4.6. 'Usual demand' calculated when a brand subsequently re-lists following de-listing

If a brand de-lists as stated in Section 4.4 an RP may apply for the brand to be re-listed at a later date.

'Usual demand' for a brand in this scenario is determined based upon any available PD data for the brand from the relevant reference period (see Exhibit 9).

Note that the Minister may make a minimum stockholding determination for re-listed brands where, for any reason, 'usual demand' cannot be calculated. Prior to the Minister making a minimum stockholding determination, the department will provide RPs with details of the determination to be made, the basis for any calculations, and the opportunity to seek clarification.

Exhibit 9: Calculation of 'usual demand' based on reference period data when a brand de-lists and then re-lists

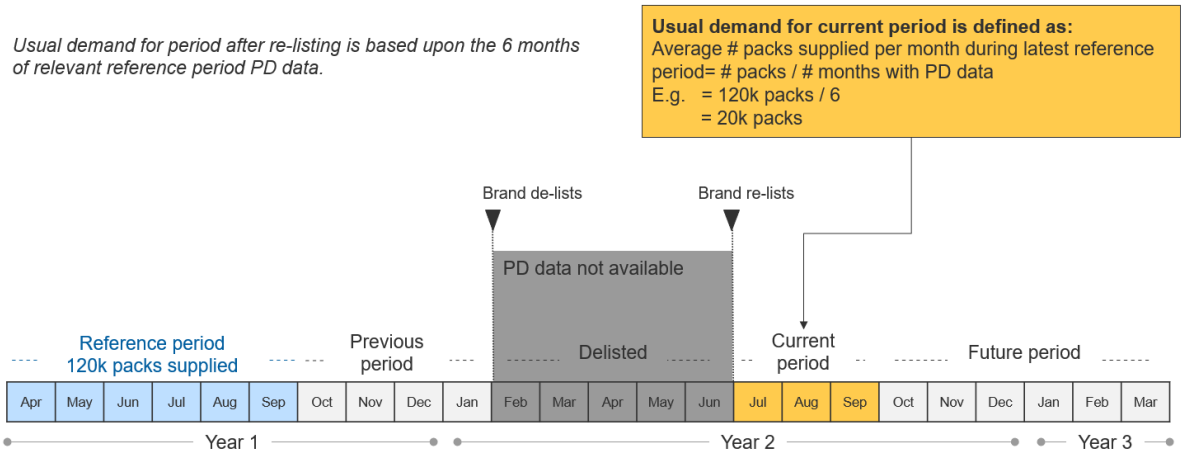
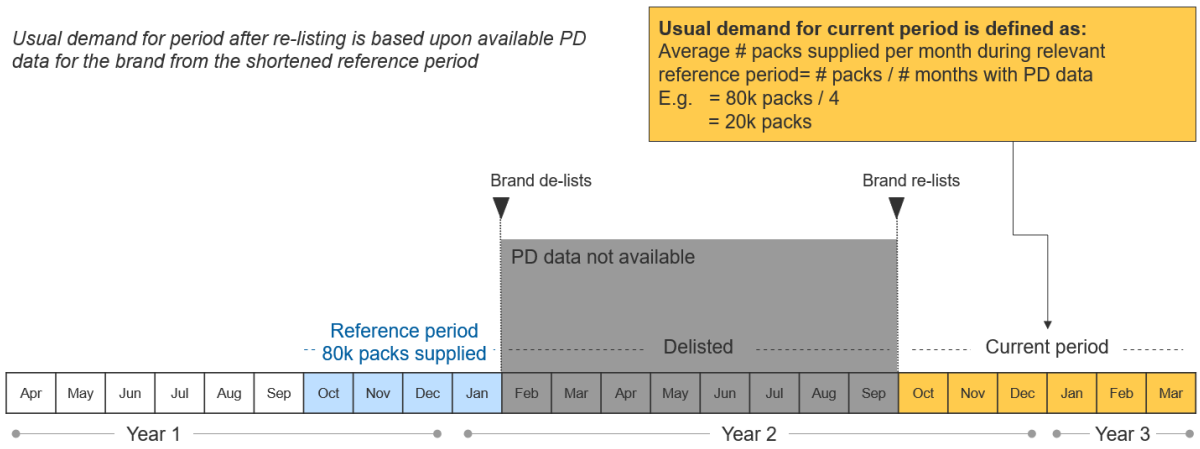
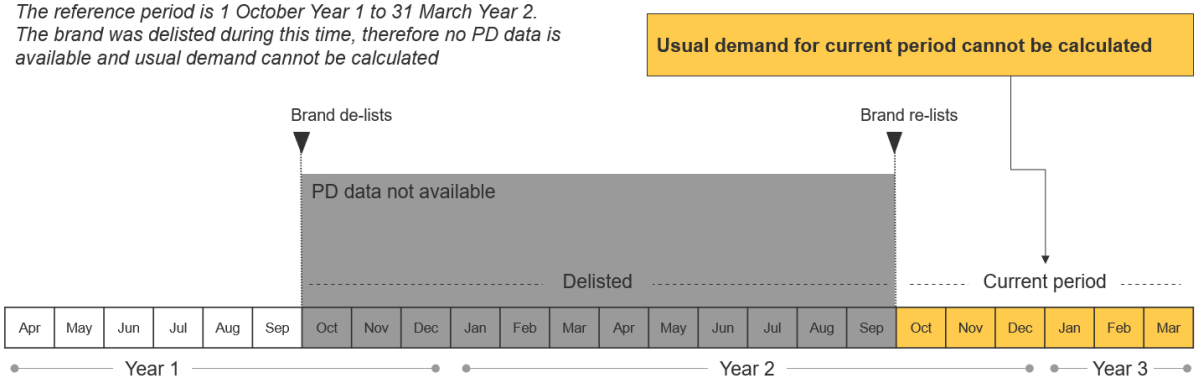


Exhibit 9 (continued): Calculation of 'usual demand' based on reference period data when a brand de-lists and then re-lists





Section 4.7. Rebranding

Where an RP changes the trade name of a designated brand of pharmaceutical item, it is necessary for an RP to transition their minimum stockholding from holding stock of the old trade name, to holding stock of the new trade name. This is facilitated differently depending upon whether or not there is a period of dual PBS listing in which the old trade name and the new trade name are separately determined as brands under s85(6) of the Act.

Variation of brand (no dual listing)

The Minister may vary a determination of a brand under s85(6) of the Act by amending the name of the brand. This is generally described as an 'Alteration of Brand Name' in the Explanatory Statement to the relevant amending instrument (see *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*). In such cases, the brand under the new name continues to be treated, under the Act, as the same brand as prior to the variation.

Example:

Asclepius Entecavir, a brand of a pharmaceutical item, is rebranding to the trade name *Entecavir Asclepius*. Effective 1 August 2025, the determined brand *Asclepius Entecavir* is varied to *Entecavir Asclepius*.

The brand as determined from 1 August 2025 (*Entecavir Asclepius*) will be treated as the same as prior to the variation (*Asclepius Entecavir*).

Usual demand is calculated by reference to PD data disclosed for supply of the old trade name and the new trade name as relevant in the reference period. Usual PBS demand is calculated by reference to PBS dispensing volumes for dispensing of the old trade name and the new trade name as relevant in the reference period.

Provided that the stock otherwise meets the requirements to be counted for the purposes of the minimum stockholding requirement (see Section 3 above):

- In the period prior to 1 August 2025, stock branded as *Asclepius Entecavir* will be counted towards the RP's minimum stockholding.
- From 1 August 2025 onwards, stock branded as *Entecavir Asclepius* will be counted towards the RP's minimum stockholding.

RPs will generally receive a courtesy email from the department after the determined brand has been varied. This email serves as confirmation of the minimum stockholding requirements which continue to apply to the brand (as varied).

Dual listing

RPs may request that both the old trade name and the new trade name are listed on the PBS at the same time. This facilitates more flexible timing for an RP to transition from selling stock of the old trade name to stock of the new trade name. It also facilitates stock which is held downstream in the supply chain being dispensed as a pharmaceutical benefit, during the time where there may be stock in the market of both the old trade name and the new trade name.

During the period of dual listing, each trade name is determined as a separate brand of pharmaceutical item under s85(6) of the Act. The minimum stockholding requirement in s99AEKB necessitates that an RP keep the applicable quantity of the brand (i.e. each separate brand) of pharmaceutical item in stock in Australia. Although the Minister may determine 'another quantity' as the minimum stockholding requirement for a brand, stock of one brand will not be counted towards compliance with the minimum stockholding requirement of another brand. This means that (if not for the approach outlined below) stock of the brand *Asclepius Entecavir* would only be counted towards compliance with the minimum stockholding requirement for the brand *Asclepius Entecavir*, and stock of the brand *Entecavir Asclepius* would only be counted towards compliance with the minimum stockholding requirement for the brand *Entecavir Asclepius*. As for newly listed brands, there is a delay before PD data is available in the reference period for a brand. In these circumstances, there would be a period of time in which the RP was not required to hold stock for the new brand, but where they were required to continue to meet the minimum stockholding requirement for the old brand in full.

To facilitate transitioning of minimum stockholdings where there is a rebrand which occurs by way of a period of dual listing, the department will generally recommend the following staged approach:

1. *Combined stockholding under Deed terms*
   Whilst the old and new brands are both listed on the PBS, Deeds between the Commonwealth and RPs provide for a combined nominal minimum stockholding requirement, calculated based upon the combined PD data (or PBS dispensing data) of both brands during the reference period. Further details in relation to the Deed process are provided below.
2. *Combined stockholding as a result of a Ministerial determination*
   Once the old brand delists, a Ministerial determination is made in relation to the new brand which calculates an 'applicable quantity' for the combined minimum stockholding requirement in the same manner, based on the data of both brands during the reference period. This determination remains in place until there is no longer any supply of the old brand in the reference period.
3. *Minimum stockholding based upon PD data for new brand only*
   After the above Ministerial determination is revoked, the minimum stockholding requirement for the new brand reverts to being calculated based upon PD data or PBS dispensing data (as applicable) for the new brand only during the reference period. Where the old brand was subject to a 6-month stockholding requirement as a result of a price increase, an ongoing determination is generally made for a 6-month minimum stockholding for the new brand.

For Stage 1 above, RPs are requested to sign a separate Deed[7] in relation to each rebranding exercise (old brand and new brand), which provides for a combined minimum stockholding requirement which is calculated with reference to sales (or PBS dispensing) of both the old brand and the new brand during the reference period. An RP may satisfy the combined minimum stockholding requirement under the Deed through holding stock of the old brand and/or the new brand without any restriction on how that stockholding is composed (provided that the total minimum stockholding requirement is met for both brands combined). Provided that the RP is compliant with the Deed, the department will recommend that the Minister not take any action under section 99AEKE for what would otherwise be a breach of the minimum stockholding requirement for the old brand (as the RP starts to run down their stock).

When the RP submits applications via HPP to list the new brand and to delist the old brand (with a period of dual listing), it is expected that the RP will indicate a rebrand is occurring and provide details of both the old brand and the new brand. This facilitates the department linking the two applications for processing as a rebrand. The department routinely monitors delisting applications for designated brands. Where the department identifies a request for dual listing of a designated brand, the PBS Minimum Stockholding Requirements team will contact the RP to arrange for execution of a Deed as outlined above.

Example of transition between stages:

The following is an example of a typical process where rebranding occurs by way of a period of dual listing. Rebranding in certain circumstances may follow a different process where required under legislation or to reflect the discretion of the Minister in exercising their powers.

The new brand (*Entecavir Asclepius*) has listed effective 1 October 2025. The old brand (*Asclepius Entecavir*) will delist from the PBS effective 1 July 2026. Last sales of the old brand are on 31 December 2025. The brands are subject to a 4-month minimum stockholding requirement. The last data collection period in which there is PD data for the old brand is the period 1 October 2025 to 31 March 2026.

Reference period	***Stockholding period***	***Status of old brand and new brand***	***Stockholding requirement***
1 October 2024 to 31 March 2025	1 October 2025 to 31 March 2026	Both the old and new brands are listed. Last sales of the old brand occur during this stockholding period/data collection period. The combined stockholding requirement is effectively based on PD data for the old brand only (as the new brand was not listed during this reference period).	4 months combined stockholding pursuant to Deed. Combined stockholding can be satisfied with stock of both the old and new brands added together.

[7] If multiple rebrands are identified at the same time, each set of an old brand and new brand may be listed in a schedule within the same Deed to reduce the administrative burden of signing individual Deeds.

1 April 2025 to 30 September 2025	1 April 2026 to 30 September 2026	Both the old and new brands are listed. The old brand will delist during this stockholding period. 1 April 2026 to 30 September 2026 is the *'data collection period in which zero packs of the old brand are disclosed'*. There is PD data for the old brand in this reference period. There is not yet PD data for the new brand.	<u>From 1 April 2026 to 30 June 2026:</u> 4 months combined stockholding pursuant to Deed. <u>From 1 July 2026 to 30 September 2026:</u> *Asclepius Entecavir* has delisted effective 1 July 2026. For *Entecavir Asclepius*, stockholding is based on Ministerial Determination of '*4 months stock by reference to usual demand of both Asclepius Entecavir and Entecavir Asclepius added together*'.
1 October 2025 to 31 March 2026	1 October 2026 to 31 March 2027	Only the new brand remains listed. There is PD data for both the old and new brands during the reference period. 1 October 2026 to 31 March 2027 is *'the data collection period which is subsequent to the data collection period in which zero packs of the old brand are disclosed'*, and 31 March 2027 is the last day of that data collection period.	*Entecavir Asclepius* remains subject to stockholding based on Ministerial Determination of '*4 months stock by reference to usual demand of both Asclepius Entecavir and Entecavir Asclepius added together*'. By 11 November 2026, the RP has submitted PD data for the data collection period ending 30 September 2026, from which it is apparent that zero packs have been disclosed for the old brand. In response to this, the department will recommend to the Minister that the Ministerial Determination already made should be revoked effective 1 April 2027 (being the '*day after the last day of the data collection period which is subsequent to the data collection period in which zero packs of the old brand are disclosed'*).
1 April 2026 to 30 September 2026	1 April 2027 to 30 September 2027	Only the new brand remains listed. There is no PD data for the old brand during the reference period.	Ministerial determination is revoked effective 1 April 2027. *Entecavir Asclepius* is subject to a 4-month minimum stockholding, with the applicable quantity 4 months 'usual demand' based on PD data for *Entecavir Asclepius* only (s99AEKC(1)(a)(i)).

Section 5. Lead times

The department recognises the need for RPs to have time to prepare for and implement the minimum stockholding requirements. Where possible and appropriate, the department will provide RPs with advance notice that brands will be subject to the minimum stockholding requirement and the applicable quantity that must be kept in stock to satisfy the minimum stockholding requirement (such as via the projected list of designated brands; see Section 2.3).

Designated brands are subject to the minimum stockholding requirement and stockholding disclosure requirements from the date that the brand becomes a designated brand. In some cases, RPs will have lead times before they are subject to the minimum stockholding requirement and stockholding disclosure requirements. The remainder of this Section provides details of indicative lead times in different scenarios (summarised in Exhibit 10).

Section 5.1. Lead time for designated brands with an AEMP of $4 or less

Brands which list on the PBS with an AEMP of $4 or less will be designated brands immediately from when the brand lists on the PBS. Newly listed brands have a lead time before there is price disclosure data or PBS dispensing data in the reference period to calculate usual demand/usual PBS demand (see Section 5.3).

The AEMP of a brand could reduce to $4 or less as a result of a statutory price reduction (e.g. an anniversary price reduction, first new brand price reduction or a combination flow-on price reduction), or a PD price reduction. A brand will be a designated brand from the date the AEMP is reduced to $4 or less.

For PD price reductions, indicative outcomes are published on the PBS pricing website in late June for 1 October price reductions and in late December for 1 April price reductions. RPs of a brand which becomes a designated brand as a result of a PD price reduction will be required to comply with stockholding disclosure requirements from the date it becomes a designated brand, and will be required to comply with minimum stockholding requirements as follows:

- where PD data is available for the relevant reference period, the RP for the designated brand will be required to hold 4 months of 'usual demand' from the date the price reduction is effective[8].
- if PD data for the reference period is not available, 'usual demand' cannot be calculated. The RP for the designated brand will be required to hold 4 months stock of 'usual demand' once PD data is available in the reference period to calculate 'usual demand' (see Section 4.1 above) or may be required to hold 'another quantity' determined by the Minister.

Where the RP is unable to meet the minimum stockholding requirement for a brand's first stockholding period following a short lead time after a PD price reduction, these circumstances may be considered when the Minister assesses the breach of minimum stockholding requirements.

[8] For example, a brand which has been on F2 since 1 July 2020 and has a price reduction to $4.00 effective 1 April 2024, will have PD data available for the reference period 1 April 2023 to 30 September 2024 and will be required to hold 4 months of 'usual demand' effective 1 April 2024.

This might be the case for example where a brand with PD data available in the reference period is subject to a PD price reduction which is notified in late June for a 1 October reduction date and the brand's RP would be required to hold 4 months of 'usual demand' from 1 October. If the brand had a lead time which required 4 months for the RP to bring additional stock into Australia, the RP might be non-compliant for the month of October, but compliant from November onwards. However, if the brand did not yet have PD data available in the reference period, the RP would have additional time to prepare and the lead-time should not impact on the RP's ability to comply once 'usual demand' could be calculated.

Any efforts made to become compliant as soon as possible with minimum stockholding requirements may also be considered. Further information on the assessment can be found in Section 8. The RP must comply with the usual requirements (see Section 7.2) to provide notification of a likely breach of the minimum stockholding requirement as well as any actual breach.

Where applicable, anniversary price reductions occur annually on 1 April for drugs on F1, and indicative AEMPs are published on the PBS website on 1 August in the previous year. If an anniversary price reduction would reduce the AEMP of a pharmaceutical item having a drug on F1 to $4 or less, the RP for the designated brand will be required to comply with stockholding disclosure requirements from the date the brand becomes a designated brand. As drugs in F1 are not subject to price disclosure, PD data for the reference period will not be available, but the Minister may make a minimum stockholding determination for another quantity based on PBS prescription volumes for that period.

If a first new brand price reduction reduces the AEMP of a pharmaceutical item to $4 or less, the RP of the existing brand which will be affected by a reduction will be notified by the department within five business days from the department receiving the application to list the new brand. As PD data for the reference period will not be available (because the existing brand was previously on F1), the Minister may make a minimum stockholding determination for another quantity based on PBS prescription volumes for that period. Any such determination will be effective from a future date which allows 6 months' notice to be given of the quantity of stock the RP must hold.

Section 5.2. Lead time for designated brands as a result of a price increase

The application and approval process for a price increase to a PBS-listed product is described on the PBS website ('Requesting a change to an existing price').

Where a price increase is agreed on or after 1 July 2022, any designated brand determination (s99ADHC(1)(c)(ii) and (2) of the Act) that is made will be effective from 6 months after the date the price increase is effective. A minimum stockholding determination may also be made if required (e.g. where PD data is not available for the reference period to calculate 'usual demand'), see Section 4.3 above and Section 6 below.

Determinations will generally be made for:

- all brands of the pharmaceutical item that are PBS listed at the time that the price increase occurred
- any new brands of the pharmaceutical item that subsequently list on the PBS after the price increase, with any such determination effective from 6 months after the new brand lists. A determination of 6 months' usual demand or 6 months' usual PBS demand may also be made, effective from 6 months after the new brand lists.

Section 5.3. Lead times in other circumstances

As 'usual demand' is calculated based upon PD data submitted during the reference period, which is the 'data collection period before the previous data collection period', outside of the above scenarios, RPs for designated brands will have the opportunity in the usual course to prepare for the minimum stockholding requirements.

For example:

- Where a new generic brand lists on F2 and immediately meets the 42-month clock criteria (s99ADHC(1)(a) of the Act), it will be a designated brand with stockholding disclosure and minimum stockholding requirements. As 'usual demand' is based upon PD data submitted in the 'data collection period before the previous data collection period', the brand will have a period of at least 7 months before there is data available for 'usual demand' to be calculated. This provides lead time for the RP to prepare for compliance with the quantity it will be required to keep in stock in the future once 'usual demand' can be calculated based on reference period disclosure (though the brand will be subject to the stockholding disclosure requirements immediately). Similarly, a s19A product will not have 'usual demand' able to be calculated until there is PD data available in the reference period, so will have 7-12 months to prepare for compliance.
- Where there is variation in 'usual demand', the RP will have at least 6 months of forward visibility over changes to the quantity it will be required to keep in stock, due to the 6-month lag between the end of the reference period and the beginning of the current period.

Exhibit 10: When brands become subject to the minimum stockholding requirement and stockholding disclosure requirements, RPs will have lead times to prepare

Criterion	Scenario	Applicable quantity for minimum stockholding*	Timeline for compliance with stockholding disclosure and minimum levels	Lead time for RP
Brand meets the 42-month clock: • Drug has been on F2 for at least 42 months, and • At least 30 months have passed since the first PD reduction for a related brand	Brand is already listed on F2	4 months	Immediate from when brand meets 42-month clock	12 months
	Brand is newly listed on F2	4 months	Immediate from when brand meets 42-month clock (but usual demand zero until PD data in reference period to calculate 'usual demand')	7+ months
The AEMP of the designated brand of the pharmaceutical item is $4 or less	Brand receives a statutory price reduction to AEMP of $4 or less	4 months	Disclosure immediate from when AEMP becomes $4 or less. Minister will determine 'another quantity' effective from a date which allows 6 months notice.	6 months
	Brand receives a PD price reduction to AEMP of $4 or less	4 months	Immediate from when AEMP becomes $4 or less (but usual demand zero until PD data in reference period to calculate 'usual demand')	3 months
	Brand is newly listed with AEMP of $4 or less	4 months	Immediate from when brand lists (but usual demand/usual PBS demand zero until PD data/PBS dispensing data in reference period to calculate 'usual demand'/'usual PBS demand')	7+ months
A brand of the pharmaceutical item has had a price increase on or after 1 July 2022 and the brand is subject to a designated brand determination		6 months	Immediate from date designated brand determination (and minimum stockholding determination if applicable) is effective	6 months
The AEMP for the item has been increased under s104B of the Act on 1 October 2022 Before 1 October 2022: • Drug was on F2, and • Brand of pharmaceutical item had an AEMP less than $3.50		6 months	Immediate from 1 July 2023	12 months from 1 July 2022

*By reference to usual demand/usual PBS demand unless the Minister determines another quantity

Section 6. Ministerial determination of 'another quantity'

Section 99AEKC(2) of the Act provides that the Minister may make a minimum stockholding determination specifying 'another quantity' that RPs must keep in stock to satisfy the minimum stockholding requirements. A minimum stockholding determination is made at the discretion of the Minister, and may be made of the Minister's own volition, or in response to an application made by an RP. The quantity in a minimum stockholding determination may be a specified number of months stock by reference to the 'usual demand' for the brand, or other parameters such as 'usual PBS demand' (for brands without price disclosure data to calculate usual demand) or a fixed number of packs.

It is a matter for the Minister to determine whether it is appropriate in the circumstances to make a minimum stockholding determination and what quantity is determined. As noted at Section 4.3 above, prior to the Minister making a minimum stockholding determination of their own volition, the department will provide RPs with details of the determination to be made and the basis for any calculations, and provide RPs with the opportunity to seek clarification.

This Section provides detail on the process by which RPs may submit a request for a determination to be made, and guidance on the matters the Minister may consider relevant when considering a request made by an RP. This Section also provides details of the process for an RP to be notified of the outcome of their Ministerial determination application.

Section 6.1. RPs can request the Minister make a determination of 'another quantity'

RPs may submit a request for a minimum stockholding determination under the relevant requested timelines below (see also: Exhibit 11 and Exhibit 12):

i. Routine timeframes for applications to be considered and outcomes provided are outlined in Exhibit 11.

ii. RPs seeking urgent assessment of an application following a price increase or price reduction which satisfies the criteria specified in s99ADHC(1)(b) and (c) of the Act[9] (see Section 2.1) or brands that are a new generic brand listing[10], may submit an application per the timeframes outlined in Exhibit 12. Applications in these circumstances which are not submitted by the relevant closing date, will be considered in line with the timeframes in Exhibit 11.

These timeframes may be extended over the December/January period to account for Departmental closedown and reduced staffing levels. RPs will be notified where delayed outcomes are expected.

[9] Section 99ADHC(1)(b): the approved ex-manufacturer price (**AEMP**) of the brand is $4 or less; s99ADHC(1)(c): the AEMP of a brand of the same pharmaceutical item 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**)

[10] Where the new brand listing is for a drug/MoA which meets the s99ADHC(1)(a) criteria or the new brand listing has an AEMP of $4 or less, the new generic brand which listed will be a designated brand immediately on listing, but 'usual demand' for the 4-month minimum stockholding requirement cannot be calculated until there is PD data available in the reference period. (see Section 4.2 above).

Exhibit 11: Routinely submitted applications

Ministerial determination applications close	Indicative Ministerial determination outcomes	Closing date for RPs to submit additional information	RPs notified of final Ministerial determination outcomes
No closing date – applications may be submitted at any time	*30 business days*	*10 business days*	*20 business days*

Exhibit 12: Urgent applications[11]

Minimum stockholding determination applications for brands subject to price increases/reductions and new brands listed after 1 July 2023

Date the price increase takes effect, date First New Brand reduction takes effect, date indicative Anniversary price reduction is published[a], or date the new generic brand lists in the schedule	Ministerial determination applications close	Indicative Ministerial determination outcome	Additional information due	Final Ministerial determination outcome
	10 business days	*20 business days*	*5 business days*	*10 business days*

[a] 1 August annually

Minimum stockholding determination requests must be submitted via email to pbsstockholding@health.gov.au. RPs must complete the application form available on the PBS website, and submit it via email together with any supporting documents. In the future, requests are to be submitted through the Health Products Portal (**HPP**), RPs will be advised when this functionality is available.

The department has responsibility for managing all aspects of processing requests made to the Minister. The department will provide the Minister with any submissions together with a summary of the request and a recommendation in relation to the exercise of discretion. All submissions, documents and information provided for requests for Ministerial determinations will be handled consistently with the *National Health Act 1953* and the *Privacy Act 1988*. Giving false or misleading information is a serious offence. Providing false or misleading documents is also an offence.

Applications for Ministerial determinations will be cost recovered under the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022*.

In the event that the s19A medicine is listed for a long enough period for a minimum stockholding quantity based on 'usual demand' to be calculated from PD data in the reference period, s19A medicines do not have any cost recovery fees applicable and there is no fee for the RP of a s19A medicine to make an application for a Ministerial determination. (See Section 4.2 in relation to 'usual demand' for s19A medicines).

[11] The department will endeavour to work to these reduced timeframes but cannot guarantee that reduced timeframes will always be met.

Section 6.2. The Minister may consider a range of matters in regard to determinations

This Section provides guidance on the types of information and matters that might be considered relevant to the Minister's exercise of discretion to make a minimum stockholding determination. The Minister has discretion to consider any matters that they consider relevant. This guidance does not limit the Minister's powers, nor fetter the Minister's discretion, under the Act.

Ministerial determinations may be used to address long-term, practical barriers to compliance that cannot be overcome. For example, one of the matters the Minister may consider relevant is the shelf-life of the brand and the Minister's assessment of the feasibility for the RP to ensure that the brand has a viable shelf-life remaining when on-sold from the RP to wholesalers/retailers and/or consumers. Section 6.3 provides further detail about the assessment of applications for lower stockholding quantities based on short shelf life.

Short or medium-term difficulty meeting the MSR is managed through the non-compliance framework. Ministerial determinations for a limited time are generally not used as a response to a short- or medium-term barrier to compliance. For more information about the non-compliance framework please refer to Section 8.3.

Examples of short- or medium-term barriers include (but are not limited to):

- Demand variation
- Global supply constraints/disruptions
- Transition of manufacturing facilities.

Prior to a brand delisting from the PBS, the Minister will generally make a determination of zero as the applicable quantity for a period of up to 6 months prior to delisting, as set out in Section 4.4. No application is required for these determinations.

When submitting a request for the Minister to make a minimum stockholding determination, RPs should specify the quantity they are seeking to be determined as the applicable quantity. This amount can be a specified number of months of stock by reference to 'usual demand', or by reference to a number of packs of the brand.

Section 6.3. Assessing applications based on short shelf-life

For applications based on short shelf-life, the Minister will generally use the factors outlined in Exhibit 13 and Exhibit 14 to consider whether compliance with the MSR is likely to result in wastage of stock.

Exhibit 13: Step 1 – Maximum warehousing period before wastage

Maximum warehousing period before wastage = *(Shelf-life) minus (Supply lead-time to RP[12]) minus (Commercial shelf-life requirement[13])*

Using information provided in the RP's application, the calculation outlined in Exhibit 13 may be performed to determine the maximum period the RP can warehouse stock before it has passed its commercial shelf-life requirement.

Exhibit 14: Step 2 – Peak stock level

Peak stock level = *Minimum stockholding + safety stock[14] + cycle stock[15]*

Then, a peak stock level is calculated in accordance with Exhibit 14 using information provided by the RP. If an RP does not specify their safety stock and cycle stock quantities, an allowance will generally be made for 1 month safety stock and 1 month cycle stock.

Step 3 – Determining wastage

If the peak stock level (Step 2) is greater than the maximum warehousing period before wastage (Step 1), the department may recommend the Minister determine a reduced stockholding quantity.

Worked Example

Applying the above steps to a worked example:

Step 1 – Maximum warehousing period before wastage

Maximum warehousing period before wastage = *(Shelf-life) minus (Supply lead-time to RP) minus (Commercial shelf-life requirement)*
Where the shelf-life = 18 months; supply lead time = 3 months; and commercial shelf-life = 9 months:
Maximum warehousing period before wastage = 18 – 3 – 9 = 6 months.

[12] The supply lead time information requested is *'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'* (i.e. stock which is available for sale by the RP in Australia). If shelf-life runs from an earlier time in the production process or there is any other supply chain timing information relevant to available shelf-life and the risk of wastage of stock, RPs are encouraged to provide details of this in their application.
[13] RPs often have contractual requirements with customers, for a brand to have a certain amount of shelf-life remaining when received by the wholesaler/pharmacy. The department recognises that this helps to ensure that adequately dated medicines are available to patients.
[14] Safety stock is stock held by RPs for utilisation where there is demand variation and supply disruptions (such as minor transit delays), so that compliance with the MSR can be maintained.
[15] Cycle stock is the inventory purchased to meet expected demand between shipments.

Step 2 – Peak stock level

Peak stock level *= Minimum stockholding + safety stock + cycle stock*
Where the minimum stockholding requirement = 6 months; safety stock = 1 month; and cycle stock = 1 month:
Peak stock level = 6 + 1 + 1 = 8 months.

Step 3 – Determining wastage

As the peak stock level (8 months) is greater than the maximum warehousing period before wastage (6 months), it is expected that wastage would be induced to meet the MSR.

In this example, the department may recommend that the Minister determine 'another quantity' of 4 months as the minimum stockholding requirement for the brand. This would result in a lower peak stock level of 6 months, which is equal to the maximum warehousing period before wastage.

Other factors

- If an RP has minimum order quantities (**MOQs**) resulting in higher levels of cycle stock for a brand, the Minister may consider what attempts an RP has made to reduce the MOQs to facilitate compliance.
- Where there is pre-existing obsolescence because of short shelf-life and MOQs, the risk of additional wastage (rather than total wastage) that might result will generally be considered.
- Where the minimum stockholding requirement is based on usual PBS demand (and thus does not represent the whole of market demand for the brand), the extent to which this reduces the risk of wastage to hold a 4 or 6 month stockholding (based on usual PBS demand rather than usual demand) will generally be considered.
- RPs are expected to improve supply chains and business practices where necessary to facilitate compliance. Determinations may not be recommended if supply chain or business practices can be improved (e.g. by reducing supply lead times or increasing shipment frequency).
- Ministerial determinations are made in a quantity and for the period that the Minister considers appropriate. A determination may be made for a limited period which allows time for an RP to improve their supply chain timing, and the determination may then either be revoked or replaced with a higher (but still reduced) ongoing stockholding requirement that accounts for those expected improvements. RPs may provide additional information regarding their capacity to improve supply chain timing, when responding to an indicative outcome. RPs may also submit a further application for a Ministerial determination if they have not been able to make improvements to facilitate compliance to the extent expected when a final outcome was previously provided.

Section 6.4. RPs should provide supporting evidence

RPs should provide a comprehensive and complete explanation of their reasons for requesting a minimum stockholding determination, including why they cannot comply with the minimum stockholding requirement that would apply in the absence of a minimum stockholding determination. RPs should provide evidence and documentation that supports their request, including details of any factors and assumptions underpinning their reasons for requesting a minimum stockholding determination, why it is appropriate for

the Minister to make a minimum stockholding determination and why the proposed reduced stockholding level is appropriate. Potential information and documentation could include, but is not limited to:

a) Manufacturer reports and/or Therapeutic Goods Administration (**TGA**) reports outlining characteristics of the pharmaceutical item, including its shelf-life

b) Wholesaler/retailer contracts specifying shelf-life contractual obligations

c) Internal reports and analysis on manufacturing performance and outlook

d) Third-party correspondence on supply chain conditions (e.g. availability assessment of shipping/air freight)

e) Analysis or reports outlining typical supply chain steps and lead-time for that RP and the brand

f) Reports outlining a brand's packaging arrangements including contracts with local/offshore third parties

g) Any other reports outlining feasibility of meeting minimum stockholding requirements whilst maintaining viable shelf-life

h) Details of how the RP will ensure continuity of supply based on an alternative stockholding level.

RPs should not omit any matters without which the information provided would be misleading. As noted above, giving false or misleading information, and producing false or misleading documents, is an offence.

It is not necessary for all matters listed above to be addressed in a request for a minimum stockholding determination, nor is it necessary for the Minister to consider all of these matters when deciding whether or not to make such a determination, or the quantity to determine. It remains open to RPs to submit any other reasons why the Minister should make a determination and determine a specific quantity, where that matter is not listed above.

Section 6.5. Opportunity to provide additional information before final outcome; determinations may apply to all brands of an item

Release of assessment outcome

In response to an application for the Minister to make a minimum stockholding determination the department will, in accordance with the timeframes outlined in Exhibit 11 and Exhibit 12:

i. Notify the RP of the indicative decision initially via email or HPP (depending on submission method)

ii. Where the indicative Ministerial decision is not to make a minimum stockholding determination, or to make a minimum stockholding determination in a different quantity to that sought by the RP, provide a summary of reasons for the indicative decision and give the RP an opportunity to provide further information to the Minister before a final decision is made

iii. Notify the RP of the final outcome.

As noted, a minimum stockholding determination is a decision made by the Minister. Until such a determination is made, no statements by the department should be interpreted as a guarantee that a request for a minimum stockholding determination will be approved, or that a particular quantity will be determined.

If a minimum stockholding determination is not made following an application by an RP (or the determination is made in a different quantity to that sought by the RP), then ‘usual demand’ or ‘another quantity’ determined by the Minister will be the applicable quantity of stock which the RP is required to hold.

The fact that an application has been made by the RP previously does not alter the requirement for the RP to hold the applicable quantity of stock to comply with their minimum stockholding requirement, or to notify the department of a likely or actual breach of the minimum stockholding requirements.

Section 7. Disclosure and Notifications

RPs subject to stockholding requirements must comply with separate disclosure and notification requirements:

1. Biannual stockholding disclosures must be made in accordance with s99AEKF of the Act and s85C of the Regulations.
2. If a breach of the minimum stockholding requirements is likely to occur, or actually occurs, the RP must notify the Minister as set out in s99AEKD of the Act.

In this section, disclosure and notification requirements are discussed in detail. Section 8 discusses how to manage compliance with the requirements and the department's approach to monitoring and enforcing compliance with the legislative framework. All submissions, documents and information provided for stockholding disclosures and notifications will be handled consistently with the *National Health Act 1953* and the *Privacy Act 1988*.

Section 7.1. Disclosure requirements

RPs for designated brands subject to the minimum stockholding requirement are required to comply with the stockholding disclosure requirements set out in s99AEKF of the Act and s85C of the Regulations. The Act sets out the general stockholding disclosure requirements and penalties for non-compliance. Section 85C of the Regulations prescribes the information required to be disclosed, how that information must be provided and timeframes in which disclosure must be made.

a) Required information for stockholding disclosure

For each brand of a pharmaceutical item which is subject to the minimum stockholding requirement, RPs must report biannually on the quantity of the brand of pharmaceutical item kept in stock in Australia. RPs must provide the prescribed information for the two periods from 1 April to 30 September and 1 October to 31 March of the following year.

RPs must provide the following information16 in relation to the quantity of the brand kept in stock in Australia:

i. Start and end dates of the period to which the information relates;

ii. Name of the brand;

iii. Name of the RP;

iv. Name of the drug in the pharmaceutical item;

v. Form of the drug, including its strength;

vi. Manner of administration of the form of the drug;

vii. Number or quantity of units in a pack (the number of tablets in a pack, for example); and

[16] Fields (i) to (vii) are prepopulated in the PDSU for each brand an RP is required to report for, and these pre-populated fields are presented to the RP following the end of a data collection period. The RP is required to provide the number of packs held in stock at the end of each month in the period; and confirm that the complete data including prepopulated information is true and correct. Where the brand is sold in packs of other sizes, the RP will be able to separately enter the pack size and number of packs held in stock at the end of each month in the period, for any other pack sizes.

viii. Number of packs held in stock at the end of each month in the period.

The RP should ensure the quantities reported as held in stock capture only the stock that counts towards meeting the RP's minimum stockholding requirement (see Section 3). Disclosure must be provided for each period that a brand is a designated brand, regardless of:

i. Whether the brand was only a designated brand for part of that period described above;

ii. Whether the brand has a determination of 'zero' as the applicable quantity in effect; or

iii. If it is no longer listed on the PBS at the time that stockholding disclosure is required to be made.

RPs are expected to have robust systems in place, including an inventory management system, that are able to provide an accurate report at the end of each month. RPs must ensure that the amount of stock recorded in the system accurately reflects the physical stock on hand. RPs' systems must also be able to distinguish stock which is kept in stock in Australia – counting towards the RP's applicable quantity for their minimum stockholding requirement – from stock which does not meet the stockholding definition.

Where a consent is provided under section 14 of the Therapeutic Goods Act 1989, if there is no change in the trade name17 under which the pharmaceutical item is supplied, then the stock may be counted towards the RP's minimum stockholding requirement where it otherwise meets the criteria in s99AEKB. If there is a change of trade name, the differently branded stock will not be reported for disclosure purposes and is not counted towards the RP meeting their minimum stockholding requirement.

All methodologies, detailed transactional records, analysis and any other materials relating to stockholding disclosure, must be kept for two years from the end of the stockholding period to which those records relate. For example, records relating to the reference period 1 April 2024 to 30 September 2024 on which 'usual demand' is calculated for the stockholding period 1 April 2025 to 30 September 2025 must be retained until 30 September 2027.

b) When to submit a disclosure

RPs are required to provide the required information by the following deadlines:

i. For the period 1 April – 30 September: by 11 November; and

ii. For the period 1 October – 31 March: by 12 May.

For brands that become subject to the minimum stockholding requirement during these windows RPs are required to make disclosures by the next reporting deadline. For example, for a brand that becomes subject to the minimum stockholding requirement on 1 July, its RP is required to make disclosures by 11 November of that year.

Note: where 11 November or 12 May fall on a day that is not a business day, the deadline for the disclosure will be the next business day[18].

[17] Under s84 of the Act, 'brand' of a pharmaceutical item means:
(a) the trade name under which the person who is or will be the responsible person supplies the pharmaceutical item; or
(b) if there is no trade name – the name of the person who is or will be the responsible person.

[18] Business day means a day other than a Saturday, Sunday or a public holiday.

c) How to submit a disclosure

The required information must be submitted to the PDDA through the Price Disclosure Submission Utility (**PDSU**). RPs will have access to the PDSU through the existing price disclosure processes or will be provided with access to the PDSU prior to the first reporting window in which they are required to meet the stockholding disclosure requirements. The stockholding disclosure requirements must be met for all brands subject to the minimum stockholding requirement, regardless of whether the brand remains subject to the minimum stockholding requirement at the time the disclosures are required to be made.

Section 7.2. Notification requirements

The RP for a designated brand subject to the minimum stockholding requirement must notify the Minister of likely and actual breaches of the minimum stockholding requirements in accordance with s99AEKD of the Act.

RPs need to have effective forecasting and stock management practices to manage compliance with the minimum stockholding requirements, including systems to also enable timely identification of likely and actual breaches. All notifications must be submitted 'as soon as practicable':

i. In the case of a likely breach, after the RP forms the belief that they are likely to breach the minimum stockholding requirement; or
ii. In the case of an actual breach, after a breach of the minimum stockholding requirement has occurred in relation to a designated brand.

The department acknowledges that submitting a compliant notification may include processes to collect, confirm and authorise relevant information. In considering whether a notification has been provided 'as soon as practicable', it is not expected that RPs will undertake this work outside of normal business hours (such as the weekend or on public holidays). However, it is expected that RPs will avoid any delay and prioritise these processes to an extent which allows for the notification to be submitted 'as soon as practicable'.

The requirement to notify the Minister relates to each individual likely or actual breach. RPs must not aggregate notifications of likely or actual breaches or implement processes resulting in periodic notification reporting (i.e. monthly or quarterly submissions) which are separated by periods of time. In these circumstances, the department considers that the RP has not met the requirement to make a notification 'as soon as practicable'.

If an RP has multiple brands with a likely breach or an actual breach required to be notified, the RP must submit a notification for each brand that is likely to breach or has actually breached.

The department has published a Factsheet on the PBS website to assist industry to understand the notification requirements and expectations – Fact Sheet – Minimum Stockholding Requirement Notifications.

a) Required information in a notification

To facilitate notifications being made as soon as practicable, an RP can submit an initial notification which includes basic brand and breach information. This initial notification should:

i. Provide the details of the designated brand

ii. Inform the Minister of the likely or actual breach

iii. Set out the reason(s) for the likely or actual breach

iv. Indicate the anticipated duration and extent (volume of stock) of the likely or actual breach

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

i. Corrective actions taken by the RP, including:

- what actions are and/or were being taken to maintain or restore stock to the required level (Exhibit 15 provides examples of actions RPs could take); and
- outcomes of any investigations into cause of breach/likely breach and evidence of corrective actions taken thus far;

ii. Suitability of RP's existing business activities:

- existing processes the RP takes to forecast demand;
- existing processes the RP takes to manage and monitor supply chain and storage facilities; and
- any prior risk assessment made of supply chain and any applicable steps taken to mitigate those risks.

The RP may submit the first part of a notification whilst they are in the process of attempting to mitigate a supply disruption, or whilst they are gathering further information, but the notification must be provided '*as soon as practicable*' and not be delayed whilst further action, investigation or information-gathering is completed.

A notification is an RP's opportunity to provide all relevant information to assist the department to monitor supply issues and assess the risks of breaches. This process assists the department to recommend the appropriate compliance approach to the Minister.

Where the basic information initially provided in Part 1 of a PDF, Excel or Portal notification changes, an RP must submit an update to the submitted notification to reflect this change. RPs are strongly encouraged to submit an update under the following circumstances:

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

The department may seek information to enable an assessment of whether the notification has complied with the requirement that a notification be made *'as soon as practicable'*, especially where the department identifies an apparent delay in submitting the notification. The department encourages RPs to include this information when submitting or updating a notification.

Example – In the case of a likely breach, this could include information about when and how the RP became aware of any matters on which the belief was formed, and supporting evidence can include, but is not limited to:

- *dated internal communication notifying of breach/causative factor to breach or likely breach;*
- *dated third-party communication to RPs notifying of causative factor to breach or likely breach; and*

- *dated third-party reports assessing causative factors for breach or likely breach.*

To enable this assessment in the case of an actual breach, the RP should specify the date on which the breach occurred and supporting evidence can include, but is not limited to:

- *dated internal communications notifying of the breach;*
- *stock records indicating the minimum stockholding requirement was satisfied up to the date of breach.*

RPs should provide a complete explanation of their reasons for the breach or belief of a likely breach (as appropriate). Information which is provided with a notification of a likely breach and/or an actual breach may be taken into account by the Minister in deciding what action to take following an actual breach arising from the circumstances the subject of the notification. The information which is provided may inform the Minister's consideration of:

a) The RP's reasons for the breach and whether those are in the Minister's opinion reasonable (s99AEKE(3)(a)); and

b) Whether, in the Minister's opinion, the RP will consistently maintain adequate stock levels of the brand of the pharmaceutical item in the future (s99AEKE(3)(b)).

Information which is provided may also be taken into account by the Minister in deciding what action to take following any future breaches arising in other circumstances. The information which is provided may inform the Minister's consideration of:

a) Whether, in the Minister's opinion, the RP will consistently maintain adequate stock levels of the brand of the pharmaceutical item in the future (s99AEKE(3)(b)); and

b) The RP's reasons for any previous breach(es) and whether those reasons were, in the Minister's opinion, reasonable (s99AEKE(3)(d)).

b) When to notify a likely breach

An RP subject to the minimum stockholding requirement must report a likely breach of the minimum stockholding requirement as soon as practicable after they '*form the belief*'[19] they are likely to breach the minimum stockholding requirement.

Examples – instances that may lead an RP to form a belief that they are likely to breach their minimum stockholding requirement include, but are not limited to:

Scenario 1. Disruption to the production of an active ingredient.

Scenario 2. A market competitor, with significant market share, goes out of stock for an extended period of time. The RP subsequently absorbs a significant amount of additional demand and is required to draw down upon their existing stockholding to continue supply to Australian consumers. In these circumstances, the Minister would expect to be notified of a likely breach as soon as the RP became aware of increased demand for their brand due to a competitor going out of stock (i.e. the RP is expected to notify the Minister at the point they have indication of increased demand on their brand e.g. increased number of purchase orders to RP from wholesaler)[20].

Scenario 3. Where Scenario 2 arises, the RP may be subject to a temporary period of inflated demand which will lead to their minimum stockholding requirement being elevated significantly above their usual requirement.

[19] To '*form the belief*' a breach is likely **does not require** that a breach is inevitable, simply that a breach is likely.
[20] Where this factor is cited by the RP, the department notes the expectation that RPs plan their supply chain and stockholding levels to comply with their minimum stockholding requirements, and to account for some disruptions in the market. In considering whether an 'out-of-stock' is a reasonable reason for a breach, the Minister may consider whether the out-of-stock episode was of a significant market share, for a long period of time.

The RP should provide notification of any expected challenges they face in meeting the future increased minimum stockholding requirement. Information provided may include:

- *the length of time the competitor was out of stock;*
- *changes in market share; and*
- *the degree to which 'usual demand' has increased.*

The Minister would expect to be notified of a likely breach by the end of the reference period with the increased 'usual demand' figures (e.g. by 11 November for the period 1 April to 30 September or by 12 May for the period 1 October to 31 March). In most instances notification of future difficulty meeting the minimum stockholding requirement would be a separate notification to the notification which is made at the time of the likely breach referred to in Scenario 2. If the RP has been able to maintain their minimum stockholding whilst responding to the shortage (i.e. the RP has not made a notification as outlined in Scenario 2), they should still submit a notification with respect to any anticipated future difficulty meeting their minimum stockholding requirement due to the temporary period of inflated demand.

RPs are expected to monitor stock levels and forecast supply and demand in conjunction with implementing best practice inventory and supply chain management. The department expects in most circumstances an RP will form the belief of a likely breach prior to an actual breach eventuating. Where these processes cause the RP to form the belief that a breach of the MSR is more likely than not, the RP must submit a likely breach notification to the Minister. Importantly, an RP must include in their considerations for submitting a notification whether their controls and mitigation strategies are likely to impact the likelihood of the breach.

Example – An active pharmaceutical ingredient (API) shortage is reported by a supplier.

Scenario 1. The RP has arrangements in place to access an alternative API source in time to avoid a breach – a likely breach notification would not be required if the RP expects to meet supply schedules and maintain stockholding levels at the required amount.

Scenario 2. The RP is not able to access or is unsure if it can access an alternative API source in time to maintain original production schedule or a varied production schedule which is likely to avoid a breach – a likely breach notification should be made, even if the breach is not inevitable.

The RP may '*form the belief*' that they are likely to breach the minimum stockholding requirement based on several separate events. If the RP makes a notification and then a separate event subsequently occurs which may **also** cause a 'likely breach', the reasons submitted for the likely breach must be updated or added. Where this event causes a separate breach to be likely, a separate notification must be submitted.

Example

Scenario 1. A batch failure occurs and then a delayed shipment prolongs the initial likely breach, with no intervening resolution. The RP can update the initial notification by adding an additional 'reason' for the likely breach and updating the expected resolution date and lowest anticipated stockholding information reflecting the delayed shipment.

Scenario 2. A batch failure occurs which the RP believes will cause a breach in March and then a month later a delayed shipment occurs which the RP believes is likely to cause a separate breach in October. Each separate period that a breach is likely to occur requires a separate 'likely breach' notification.

Where a notification has been made of a 'likely breach', and the breach eventuates, the RP must still submit a notification for the actual breach.

RP should always update information provided to the department if there are further developments or to correct any inaccuracy in the initial notifications, including where the RP has avoided the breach.

c) When to notify of an actual breach

An RP must notify a breach of the minimum stockholding requirement *'as soon as practicable*' after an actual breach of the minimum stockholding requirement occurs.

An RP must provide separate notifications for each instance of a likely breach or actual breach including where stock levels fluctuate above and below the minimum stockholding requirement. Conversely, if an RP has a stock level which continuously does not meet minimum stockholding requirements for a prolonged period, the single notification of likely breach, followed by a single notification of actual breach will suffice[21].

Example

A market competitor with significant market share is experiencing supply issues, causing higher demand on an RP's designated brand. The RP is unable to adjust production orders in the short term. Although stockholding levels return to the required level with each replenishment, the higher demand causes the stockholding to fall below the requirement between deliveries. At each point the RP forms the belief of the likely breach or a further actual breach occurs, a separate notification must be submitted.

d) How to submit a notification

RPs can submit likely and actual breach notifications to the Minister via the Price Disclosure and Stockholding Notification Portal (**the Portal**). You can find more information on how to access the Portal and how to submit and update a notification on the Portal Resources page. The Resources page includes user guides, a step-by-step video on how to use the Portal and links to relevant department materials, including factsheets.

Where an RP is submitting an update to a previously submitted PDF or Excel notification (including resolution information),[22] RPs can provide updates and resolution information for these breaches using the pro-forma templates available on the PBS Minimum Stockholding Requirements website. These notifications can be submitted to the Minister via the PBS Stockholding inbox pbsstockholding@health.gov.au. If an RP makes a submission and does not use the published and approved pro-forma template the submission may not meet system and legislative requirements and may require resubmission.

As outlined in section 7.2(a), to facilitate notifications being made *as soon as practicable*, an RP can submit only Part 1 of the initial notification which includes basic information. RPs are strongly encouraged to provide the additional information sought in Part 2 of the notification form when that information is available (either as part of the initial notification or as an update).

The department may request further information from RPs via the Portal. Registered RP users will be notified of any requests via their registered email address. RPs can respond by providing the requested information or clarification via the original notification within the Portal. Failure to respond or provide requested information within requested timeframes may result in escalated compliance action.

e) Actual breach following a likely breach notification

An RP who has submitted a notification of a likely breach is also required to submit a separate notification in the event of an actual breach subsequently occurring (see Section 7.2(b)). If a likely

[21] An RP should always update information provided to the department if there are further developments or to correct any inaccuracy in the initial notifications.
[22] RPs cannot access previously submitted PDF and Excel notifications via the Portal.

breach notification submitted via the Portal becomes an actual breach, Responsible Persons should 'upgrade' the likely breach form to simply and quickly close the likely breach and create a new actual breach notification for submission. Where an RP does not '*upgrade*' a likely breach to an actual breach, and starts the notification process by submitting an actual breach notification, the Portal will prompt the RP to explain why a likely breach notification was not submitted.

f) Failure to comply with the stockholding breach notification requirements

Failure to fully comply with the notification requirements in s99AEKD of the Act is an offence. RPs will breach the notification requirements where they fail to notify the Minister of a likely or actual breach, provide notification late or provide an incomplete notification. Assessment and penalties for breaches of the notification requirements are discussed in Section 8.

Concurrent medicine shortage reports to the Therapeutic Goods Administration (TGA)

If an RP has simultaneously reported a medicine shortage to the TGA, the RP may provide a copy of that report and refer to it for additional information. However, the RP must still complete basic notification information in Part 1 of the notification. Where the RP provides a notification to the department, the RP remains responsible for separately complying with any notification requirements to the TGA, and compliance with the TGA's regulatory requirements.

The originals of any documents which are provided as supporting evidence for a notification or relied upon in providing a notification, must be kept for two years from when the notification is made. The RP must also keep all methodologies, detailed transactional records, analyses and any other documents relating to the notification for two years from when the notification is made.

Information provided by an RP under s99AEKD(1) or s99AEKD(2) may be disclosed to the TGA. Sharing of this information with the TGA (which, while operating independently is part of the department), will assist in the proactive management of potential shortages of medicines by the department and the TGA, and will assist in assessment of policies and procedures.

Other uses of notification data

The department may use notification data for other purposes, including for policy evaluation purposes. Where the department uses a notification for such other purposes that involves sharing with third parties (for example peak bodies), the department will remove all identifying information from the notification before doing so or comply with the requirements in the Act if a notification is to be shared with a third party without redaction.

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Exhibit 15: Best practice includes preventative, reporting and mitigation actions before and during a breach

Best practice includes preventative, reporting and mitigation actions

Time period:	Ongoing basis	Stockholding breach likely	Stockholding breach occurs
Preventative actions	• **Monitor** all elements of supply chain including production lines, warehousing, freight and customs • **Manage supply** to tightly align with demand cycles • Efficiently **troubleshoot** disruptions to maintain supply • **Prospective procuring** of freight space for Australian stock • **Forecast demand** of pharmaceuticals; track actual demand and adjust forecasts as necessary	• **Maintain and monitor** data to generate warning of upcoming breach • **Take remedial actions** to secure supply chain and production capacity in order to avoid actual breach • Take actions to **fast-track supply chain** (e.g., air freight) • **Source supply** of medicines that meet the minimum stockholding requirement: - Source further supply from within own supply chain - Source short-term contract manufacturing onshore • **Source alternate supply** of medicines that do not meet the minimum stockholding requirement: - Sourcing substitute brands from own portfolio - Purchasing excess supply from another RP	• **Comply** with any investigation or non-compliance activity from Department of Health • **Undertake investigations** to understand cause of breach • **Directly address causative factors** to ensure no repeat cases
Reporting actions	• **Maintain and audit** own data on stockholding volumes • **File required disclosures**	• **Notify** Minister of likely breach as soon as practicable • **Outline** a full and complete report of causative factors and other reasons for likely breach	• **Notify** Minister of actual breach as soon as practicable • **Outline** a full and complete report of causative factors and other reasons for likely breach
Mitigating actions	• Ensure supply volume **maintains required buffer** above the minimum stockholding requirement to absorb disruptions	• **Undertake investigations** to understand cause of likely breach • **Directly address causative factors** to limit breach and ensure no repeat cases	• **Take remedial actions** to secure supply chain and production capacity in order to avoid actual breach • Take actions to **fast-track supply chain** (e.g., air freight) • **Source supply** of medicines that meet the minimum stockholding requirement: - Source further supply from within supply chain - Source short-term contract manufacturing onshore • **Source alternate supply** of medicines that do not meet the minimum stockholding requirement: - Sourcing substitute brands from own portfolio - Purchasing excess supply from another RP

Section 8. Managing Compliance

This Section discusses three breaches of the Act:

1. Breach of minimum stockholding requirements (s99AEKE(1));
2. Breach of requirement to notify the Minister of an actual or likely breach (s99AEKD(3)); and
3. Breach of the stockholding disclosure requirements (s99AEKF(3)).

Criminal penalties may apply for breach of the notification requirements or stockholding disclosure requirements.

In the event of a breach of the minimum stockholding requirement, the Minister may assess the breach and take such action(s) as they consider appropriate.

This Section provides recommendations for actions that RPs may take to avoid these breaches, and outlines the factors considered when assessing each breach, the types of evidence that may be considered and the actions available to the Minister in the event of a breach of the minimum stockholding requirement.

Section 8.1. Department approach to non-compliance

The department is guided by best practice principles to assess and manage instances of non-compliance with the MSR. These shape the design and approach of the department's compliance framework that:

i. **Is underpinned by data and information:** the department monitors notifications and disclosure of information provided by RPs to understand the reasons for breaches, including the issues and sector conditions that may be impacting specific compliance by specific RPs and overall industry compliance. The department will assess each breach and critically evaluate the information and evidence which is put forward by the RP. The department may consider other sources of information and data that could be relevant (for example, TGA medicine shortages information).

ii. **Considers risks:** the department undertakes a risk-based approach to managing non-compliance. Where alleged or apparent non-compliance occurs, compliance or enforcement action is intended to be proportionate to the assessed risk of the non-compliance to the regulatory framework.

Before the Minister can exercise their powers in response to a breach by an RP, the Minister must consider the matters outlined in Section 8.2 b) and may also consider the matters in Section 8.2 c).

The department may consider non-compliance more serious and higher risk where:

- the conduct is unreasonable, deliberate, negligent, brazen and/or clearly not in line with the intention of the legislation;
- the RP maintains its opposed view to the department's position on the non-compliance, and a voluntary improvement in regulatory/compliance behaviour or compliance with regulatory obligations cannot be practicably reached;
- there is reason to be concerned about future non-compliant behaviour; or the RP fails to demonstrate a willingness to achieve complete compliance.

Where the assessed risk is higher, the department may request that the RP undertake specific additional stockholding reporting or provide evidence of mitigation actions – such as a corrective action plan/plan for

continuous improvement. Where corrective action(s) fail to address the identified non-compliance, and does not mitigate the risk(s), the department may issue warning letters to the RP. Severe or unmitigated risks may result in the department recommending for the Minister to use their powers, including de-listing or refusing to list the RP's brand(s) on the PBS.

iii. **Engages with RPs and seeks to improve outcomes:** the department engages with RPs to build compliance, fostering communication and collaboration to support Industry's understanding of the expectations, consequences and best practices that can be adopted to drive high rates of compliance. Upon completing a risk assessment of the RP's non-compliance, the department may engage with the RP to manage the non-compliance. This process involves the RP directly and will firstly seek to establish the facts. It is underpinned by the principle of returning the RP to compliance.

Section 8.2. Suggested actions for Responsible Persons to achieve compliance with legislation

Exhibit 15 outlines the actions RPs could take to ensure they meet their obligations under the Act. They are intended as a guide only, and do not contain all aspects of good business practice. The actions suggested do not guarantee adherence to the legislated requirements. Suggested actions are shown for application on an ongoing basis, when a stockholding breach is likely and when a stockholding breach occurs. It is expected that RPs will assess and monitor their supply chain and stock levels on an ongoing basis to allow them to meet their minimum stockholding requirements, receive timely notification of any supply chain disruptions, and take prompt and effective action to respond to supply disruptions if they occur.

In the event of a likely breach, an RP is required to provide notification *as soon as practicable* in accordance with s99AEKD(1), is expected to take action to assess the causative factors for the likely breach, and respond appropriately. This should include addressing any causative factors which contribute to the risk of future breaches of the minimum stockholding requirement.

The suggested actions in the event of a likely breach or an actual breach are also expected to mitigate the impact of any breach (i.e. the duration of any out-of-stock and/or period of reduced supply).

Section 8.3. Breaches of the minimum stockholding requirement

If an RP breaches the minimum stockholding requirement, s99AEKE of the Act applies. Breaches to the minimum stockholding requirement may be assessed and managed by the Minister. RPs may be asked to:

- comply with investigations undertaken by the department;
- address reasonable compliance actions imposed by the department (designed to assist RPs to comply with regulation); and
- support the maintenance of access to pharmaceutical stock for Australian consumers.

This Section describes the factors the Minister must and may consider when assessing a breach and determining whether to exercise their powers under s99AEKE(2) of the Act. Guidance is provided on the types of information that an RP can provide, and which the department or the Minister may request when assessing breaches of the minimum stockholding requirement. The Minister may also take into account

any other matter that they consider relevant. This guidance does not limit the Minister's powers, nor fetter the Minister's discretion, under the Act.

a) Minister's powers under s99AEKE

If an RP breaches the minimum stockholding requirement, the Minister may:

i. De-list from the PBS the brand(s) which do not comply with the minimum stockholding requirement (s99AEKE(2)(a)) and/or any other listed brands of the RP (s99AEKE(2)(b)); and/or

ii. Refuse to list new brands of the same Responsible Person (s99AEKE(2)(c)); and/or

iii. If the only listed brand would be a brand of the RP, refuse to make declarations or determinations under ss85(2), (3) or (5) in relation to the pharmaceutical item (s99AEKE(2)(d)).

b) Factors the Minister *must* consider

When assessing a breach of the minimum stockholding requirements and determining whether to exercise their powers under s99AEKE(2), the Minister must consider:

i. The RP's reason for the breach and whether those reasons are, in the opinion of the Minister, reasonable;

ii. Whether, in the Minister's opinion, the RP will consistently maintain adequate stock[23] of the brand in the future;

iii. Whether the RP has offered discounts or incentives in relation to sales of the brand;

iv. 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;

v. Whether the RPs for other brands of the same pharmaceutical item have breached the minimum stockholding requirements in relation to those other brands; and

vi. Any other matter the Minister thinks relevant.

What constitutes a 'reasonable' reason (s99AEKE(3)(a)) for a breach?

It is expected that RPs will draw down on their stockholding where this is necessary to maintain supply to patients following a significant supply disruption. Without limiting the discretion of the Minister under s99AEKE, reasons that *may* be considered reasonable by the Minister include but are not limited to:

i. Significant manufacturing or quality issues such as a product recall

ii. Significant supply chain disruptions such as an API or medicine shortage

iii. Whether there has been a shortage of another medicine which has resulted in significant demand shift to the RP's brand.

[23] While it is a matter for the Minister to form a view about, the department would expect the Minister to consider that an RP will consistently maintain '*adequate stock'* in the future if the RP will meet the minimum stockholding requirement. In some circumstances the Minister may consider that *'adequate stock'* is maintained for a period of time even if the minimum stockholding requirement is not met.

A reason given for a breach may be considered less reasonable where it arises from circumstances that were within the discretion or control of the RP to impact, influence or mitigate, and which the RP could be expected to have foreseen.

c) Factors the Minister *may* consider:

When assessing a breach of the minimum stockholding requirements, the Minister may consider:

i. Whether the RP has fully complied with the breach notification requirements under s99AEKD at the time of likely breach as well as when the breach occurred;

ii. The volume of stock below required minimum stockholding level;

iii. The length of time the RP did not comply with the brand's minimum stockholding requirement;

iv. The number of different items from the RP's portfolio involved in breach;

v. Whether there has been a shortage of another medicine which has resulted in significant demand shift to the RP's brand (this includes but is not limited to medicine substitution through a Serious Scarcity Substitution Instrument (SSSI));

vi. Whether there has been a loss of a significant supply contract for the RP;

vii. Any corrective actions taken by the RP to limit the impact of and/or resolve the breach;

viii. The volume of stock held by wholesalers or other customers of the RP, may be taken into account to determine whether there is sufficient stock in the whole of the supply chain to ensure adequate supply to patients while the RP takes all reasonable steps to replenish its own stockholdings; and

ix. The impact of any significant unexpected order(s) by wholesalers or other customers of the RP on the RP's stockholding, which were not foreseeable nor projected by the RP and which occurred inside the lead-time for the RP to obtain additional stock to maintain minimum stockholdings.

d) Evidence the Minister may consider

An initial notification from an RP may contain limited information, and the department will engage with the RP to highlight where further information is required. RPs should ensure that they provide a complete explanation, having regard to the factors the Minister must consider when assessing a breach and determining whether to exercise their power under s99AEKE(2).

RPs should provide relevant evidence and documentation required to support any claims they make in relation to these factors, including full details in relation to those factors and assumptions underpinning their reasons. An explanation will not necessarily be extensive (depending upon the circumstances) but should nonetheless be complete and be supported by appropriate evidence.

The Minister may consider the following documentation and information in relation to each factor:

i. The RP's reason for the breach and whether those reasons are reasonable:

- dated internal communication notifying of breach/causative factor to breach or likely breach;

- dated third-party communication to the RP notifying of causative factors for breach or likely breach;
- dated third-party reports assessing causative factors for breach or likely breach;
- third-party correspondence on supply chain conditions (e.g. availability assessment of shipping/air freight);
- analysis outlining supply chain disruptions from usual performance;
- internal reports and analysis on manufacturing performance and outlook;
- market reports outlining the RP's exits from relevant market;
- market reports outlining the market shares of RPs for a given pharmaceutical item;
- evidence of prolonged supply chain lead-times which interfere with compliance with stockholding requirements in a brand's first stockholding period, or substantially interfere with the RP responding to demand variation such as following an Out Of Stock (**OOS**) by another RP;
- TGA Medicine Shortage reports for competitor brands; and
- correspondence and/or contractual evidence which shows a loss of a significant supply contract for the RP.

ii. Whether the RP will consistently maintain adequate stock levels in the future:

- evidence of the required stock being held by the RP but not in a form that meets the stockholding definition (e.g. bulk storage with sufficient packaging materials on hand and packaging facilities to quickly release bulk product in retail form);
- stock records indicating the minimum stockholding requirement was satisfied up to the date of breach;
- assessment of the causative factors of a breach and the outcomes of any investigation into the cause of the breach;
- evidence of corrective actions which are designed to address the cause of a breach;
- whether the RP has an action plan to avoid future breaches;
- adherence to an existing action plan;
- evidence of suitable resources to maintain required stock levels;
- evidence of suitable systems to monitor all elements of the supply chain including production lines, warehousing, freight and customs;
- evidence of ability to accurately forecast demand for brands;
- evidence of the quantity of stock which is in transit and the timing for arrival/an RP's expected return to compliance; and
- evidence of pre-booked freight capacity to Australia and within Australia.

iii. Whether the RP has offered discounts or incentives in relation to sales of the brand during the reporting period:

- discounts and incentives offered for the brand; and
- contracts with wholesalers.

iv. Whether the RP has previously breached the minimum stockholding requirement and if so, the reasons for the breach(es) and whether those reasons are reasonable:

- stock records indicating the minimum stockholding requirement was satisfied up to the date of breach;
- notifications and evidence provided with respect to previous breach(es); and
- any additional information and evidence provided by the RP with respect to previous breach(es).

v. Whether an RP for other brands of the same item has breached the minimum stockholding requirement in relation to those other brands:

- the department does not expect RPs to provide any additional information or documentation on this point. The department will provide the Minister with details of any actual breach notifications which it receives for other brands of the same pharmaceutical item.

If the Minister considers the impact of significant unexpected order(s) by wholesalers or other customers of the RP (see Section 8.2(c)(vii) above), the following may assist the Minister in considering that factor:

- Details of the usual ordering patterns of the customer who placed the unexpected order, and evidence that orders by that customer leading to the breach were significantly outside of the usual ordering pattern and of a magnitude which was causative of the breach;
- Details of the RP's anticipated sales projections and any variance from those projections as a result of the unexpected order;
- If the order was part of a tender or other prior contractual arrangement, details of when the RP first responded to the tender, or commenced contract negotiations with the customer, and details of whether the unexpected order was foreshadowed in the tender, contractual arrangements and/or negotiations;
- Evidence that the significant unexpected order was made inside of the lead time of the brand;
- Details of the supply chain lead time for the brand;
- Details of actions taken by the RP to procure additional stock (within or outside of the usual lead time of the brand) and/or improve supply chain timing in order to maintain minimum stockholdings;
- Details of the RP's planned replenishment schedule and anticipated and actual stock levels for 12 months prior to the breach, clearly indicating the impact of the significant unexpected order(s).

Any previous notifications and supporting documents which have been provided by the RP (whether for the brand which is in breach, or relating to a previous breach or likely breach), will be available for consideration by the Minister in deciding whether to exercise their power in response to a breach of the minimum stockholding requirement.

Section 8.4. Breaches of the notification requirements

As discussed in Section 7.2, RPs are required to notify the Minister regarding likely or actual breaches of the minimum stockholding requirement.

Breaches of the notification requirements may be assessed and managed by the department. RPs may be requested to participate in a breach investigation. The instances when a breach occurs and potential penalties that may apply are as follows:

a) RPs are required to notify the Minister of likely and actual breaches

An RP commits an offence if they are subject to the minimum stockholding requirement and fail to give the Minister written notice which:

i. Informs the Minister that they believe they are likely to breach or that they have breached the minimum stockholding requirement for a particular brand of a pharmaceutical item;

ii. Sets out the reasons for that belief or breach; and

iii. Is given as *soon as practicable* after the RP *forms the belief* or the breach occurs,

A notification is required if the RP *forms the belief* a breach is likely. If that likely breach eventuates in an actual breach, a separate notification must be made. Separate notifications are also required for likely breaches arising in different circumstances or at different times. Where there is an ongoing supply disruption and the RP has periods of breach followed by compliance, notifications are required for each breach even if the breaches arise from the single initial instigating event. Where an RP remains in breach for a period of time, the single notification of likely breach, followed by a single notification of actual breach, will suffice but may be updated as necessary (see Section 7.2 above).

Further information on notification requirements is covered in Section 7.2, including the information and evidence that may be appropriate to submit to show that the notification which is given is compliant.

b) Notification non-compliance may impact breach risk assessment

The department's assessment of any individual likely or actual breach considers the relevant RP's compliance history, including if the RP has and continues to submit required notifications. An RP's assessed failure to comply with the notification requirements may result in an escalated compliance response.

c) Penalties may apply in the event of breaches of the breach notification requirements

The criminal penalty for failing to comply with the breach notification requirements is 60 penalty units (s99AEKD(3) of the Act). Depending upon the circumstances of a breach, the department will consider whether it is appropriate to refer the matter to the Commonwealth Director of Public Prosecutions.

Section 8.5. Breaches of the stockholding disclosure requirements

As discussed in Section 7.1, RPs are required under s99AEKF of the Act to disclose the quantity of the brand kept in stock in Australia for each designated brand. This disclosure assists the Minister to ensure

compliance with the minimum stockholding requirement. Failure to fully comply with the stockholding disclosure requirements is an offence under s99AEKF of the Act. Breaches to disclosure requirements may be assessed and managed by the department. RPs may be requested to participate in a breach investigation.

The instances when a breach occurs and the penalties that may apply are as follows:

a) RPs are required to disclose complete and accurate information

An RP commits an offence if they are required to provide stockholding disclosure and fail to:

i. Submit the information; and/or

ii. Provide all required information; and/or

iii. Provide the required information within the legislated timeline under s85C of the Regulations.

As noted above giving false or misleading information and producing false or misleading documents is an offence.

b) Failure to comply with the stockholding disclosure requirements

If the RP becomes aware that it will act or has acted in a non-compliant manner then it should advise the PDDA and the department immediately in writing. If verbal notification is provided, it should immediately be followed by written confirmation (for example, via email to pbsstockholding@health.gov.au). The department or the PDDA (acting on behalf of the department) will then advise the RP as to the course of action the RP will need to take to minimise the impact of the non-compliance.

c) Penalties may apply in the event of breaches of stockholding disclosure requirements

The criminal penalty for failing to comply with the stockholding disclosure requirements is 60 penalty units (s99AEKF(3) of the Act). Depending upon the circumstances of a breach, the department will consider whether it is appropriate to refer the matter to the Commonwealth Director of Public Prosecutions.

Section 9. Revision History

Version	2.0
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All information in this publication is correct as at August 2025