



Australian Government

Department of Health and Aged Care

# Community Service Obligation Operational Guidelines



October 2022

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# Introduction

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## 1 INTRODUCTION

### ***Operation of the Community Service Obligation Funding Pool***

The Community Service Obligation (**CSO**) Funding Pool arrangements were established on 1 July 2006 and continue under the current Seventh Community Pharmacy Agreement (7CPA).

The primary objective of the CSO Funding Pool is to ensure that arrangements are in place to provide all Australians with ongoing and timely access to all PBS Medicines, through Community Pharmacies.

Under the CSO Funding Pool arrangements, eligible entities, known as CSO Distributors, receive Payments from the CSO Funding Pool for supplying PBS Medicines to Community Pharmacies.

To receive these Payments, CSO Distributors must meet all of their Obligations under the CSO Deed of Agreement (**Deed**) with the Commonwealth, including the CSO Service Standards and the CSO Compliance Requirements.

### ***Operation of the National Diabetes Services Scheme***

The Sixth Community Pharmacy Agreement transferred the responsibility for distribution of National Diabetes Services Scheme (**NDSS**) Products to CSO Distributors from July 2016.

The NDSS enhances the capacity of over one million Australians with type 1, type 2, gestational and other diabetes to understand and manage their life with diabetes.

The NDSS aims to ensure people have timely, reliable and affordable access to the supplies and services they require to effectively self-manage their diabetes.

Under the Deed, CSO Distributors undertake to supply NDSS Products to Access Points in accordance with the CSO Service Standards and the CSO Compliance Obligations. In return, CSO Distributors receive Payments calculated by reference to the price of the unit of NDSS Product together with components for supply and delivery.

### ***CSO Operational Guidelines***

The Commonwealth is committed to the principles outlined in the 7CPA including implementing administrative efficiencies, simplifying reporting requirements and making other regulatory reforms to reduce the administrative burden on the CSO Distributors and reflect competitive business practices.

This document has been issued by the Commonwealth and provides advice to the CSO Administration Agency, the NDSS Administrator and CSO Distributors regarding:

- administrative matters relating to the CSO Funding Pool;
- administrative matters relating to the NDSS Distribution Services; and
- Obligations of the CSO Administration Agency, NDSS Administrator and CSO Distributors.

This document constitutes the CSO Operational Guidelines (**CSO Guidelines**) for the purpose of the Deeds.

CSO Distributors are advised to refer to their Deed for full details of all Obligations, including the context and definitions.

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Terms defined in the Deeds have the same meaning when used in the CSO Guidelines. Principal terms are also defined in Appendix H.

The Commonwealth may from time to time update the CSO Guidelines, and any revised version of the CSO Guidelines will replace the previous version. The CSO Administration Agency will notify all CSO Distributors of any revised version and a copy will also be available on the [Department of Health and Aged Care's website](#).

## **CSO Administration Agency**

The CSO Administration Agency is an independent agency that is responsible for administering the CSO Funding Pool and monitoring the performance of CSO Distributors with regard to their Obligations under the Deed, including the CSO Service Standards and CSO Compliance Requirements.

The CSO Administration Agency is an independent entity that reports to the Department. The CSO Administration Agency provides administration functions over the supply of PBS Medicines and NDSS Products. Its functions include, but are not limited to:

- assessing payment claims by the CSO Distributors in relation to PBS Medicines and allocating the CSO Funding Pool on the basis of approved claims;
- calculating only the Supply Component of Payments in relation to NDSS Distribution Services based on information from the NDSS Administrator;
- ensuring the ongoing compliance of the CSO Distributors with all of their Obligations, including the CSO Compliance Requirements and Service Standards;
- receiving and resolving Complaints;
- providing a Help Desk service for the CSO Distributors to receive information on matters such as Payments and the provision of Data and Reports;
- considering requests for additional Approved Fees or for increase to existing Approved Fees applied to the Supply of CSO Products to Distribution Points;
- analysing and investigating Data; and
- conducting site audits of the warehouses and storage facilities of CSO Distributors.

An aim of the CSO Administration Agency is to work constructively with CSO Distributors to ensure CSO Distributors understand their Obligations under the Deed and comply with these Obligations. The CSO Administration Agency is available to discuss and provide advice to CSO Distributors regarding any aspect of the administration of the CSO Funding Pool.

## **CSO Distributors**

The CSO Distributors will supply PBS Medicines and NDSS Products (collectively **CSO Products**) through Community Pharmacies and other designated Access Points (collectively **Distribution Points**).

**For PBS Medicines:** Each Month, CSO Distributors must provide the CSO Administration Agency with information, including, but not limited to:

- Product mapping information to support the Sales claimed, including:
  - PBS item code;
  - product code (PDE) and description;

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- drug name;
- form and strength;
- pack size; and
- Brand name;
- Sales data for every eligible Unit of PBS Medicine Supplied, including:
  - PDE and description;
  - relevant details of where the PBS Medicine was distributed to; and
  - volume distributed;
- data for Sales Supplied under Exclusive Supply Arrangements, noting that these Sales are not claimable for CSO purposes;
- data for Sales of PBS Medicines Supplied under Special Pricing Arrangements, which may include Sales that are not claimable for CSO purposes; and
- a report setting out the total number of Additional Charges (by type of charge) incurred by each Distribution Point, by postcode, including both Approved Fees and for fees that are not required to be approved by the CSO Administration Agency.

Additional details regarding the data provision requirements are found in Schedule 3 of the Deed.

**For NDSS Products:** Each Month, CSO Distributors must provide the CSO Administration Agency with information, including, but not limited to:

- Sales data for every eligible Unit of NDSS Product Supplied including:
  - PDE;
  - postcode (location) the NDSS Product was distributed to; and
  - volume distributed.

Once the CSO Administration Agency is satisfied that the Data submitted by the CSO Distributors is accurate and complete, the CSO Administration Agency undertakes a Monthly Payment calculation process. During this process, the CSO Administration Agency assesses whether the CSO Distributor has met all its Obligations under the Deed for each Sale of CSO Products that it has made. For PBS Medicines, the CSO Administration Agency determines the market shares across each of the CSO Distributors, and these figures are then used to determine the level of funding that each CSO Distributor will receive for that particular Month.

## ***NDSS Administrator***

The NDSS Administrator is an independent entity that reports to the Department. The NDSS Administrator cooperates in good faith with the CSO Administration Agency only in respect of NDSS Distribution Services and not PBS Medicines. Its functions for the CSO Distributors include, but are not limited to:

- liaising with CSO Distributors, to the extent permitted under the Deed, in relation to queries Distributors have about the NDSS Distribution Services;
- calculating the Direct Cost and Delivery Components of NDSS Payments based on the Units of NDSS Products Supplied and the cost of these NDSS Products;

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- providing information to the CSO Administration Agency regarding the Units of NDSS Products delivered, to enable the Agency to calculate the Supply Component;
- deducting sanctions as approved by the CSO Administration Agency;
- participating in the complaints procedure forming part of the CSO Deeds as required to properly administer the NDSS; and
- overseeing, maintaining and supporting the ordering gateway for Access Points to order and receive NDSS Products from CSO Distributors.

Each Month the NDSS Administrator will access information in relation to NDSS Products supplied during the previous Month.

***These CSO Guidelines provide administrative advice regarding the CSO Distributors' Obligations under their Deed with the Commonwealth (through the Department of Health and Aged Care)***

## 2. Compliance Requirements and Service Standards

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### 2 COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS

This chapter explains the CSO Compliance Requirements and CSO Service Standards that CSO Distributors are required to meet. The information presented has been extracted from the Deeds (see *clauses 3 and 4 of Schedule 1*).

There are three CSO Compliance Requirements and nine CSO Service Standards that must be met by CSO Distributors as part of their Obligations under the Deed.

#### **CSO Compliance Requirements**

To meet their Obligations under the CSO Compliance Requirements, CSO Distributors must:

- 1) provide a single entry point for Distribution Points to order CSO Products, receive information and resolve queries;
- 2) maintain access to established infrastructure and sufficient financial capacity to meet the CSO Service Standards and CSO Compliance Requirements; and
- 3) maintain the quality of CSO Products that they Supply, including meeting all applicable storage condition requirements, holding all necessary State and Territory licences, and complying with the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8* (1 April 2011).

#### **CSO Service Standards**

In addition to the three CSO Compliance Requirements, CSO Distributors must also meet the nine CSO Service Standards as follows:

- 1) Supply to any Distribution Point;
- 2) Supply to any Rural and Remote Pharmacy and ensure that they meet the set Threshold for Sales to Rural and Remote Pharmacies;
- 3) Supply any Brand of CSO Product (PBS Medicine and NDSS Product);
- 4) Stock in their warehouses or distribution centres at least one Brand of each:
  - a. PBS Medicine (except for PBS Medicines that are the subject of Exclusive Supply Arrangements or which are out of stock or unobtainable from the Manufacturer);
  - b. NDSS Product listed on the NDSS Product Schedule;
- 5) Supply any Low Volume PBS Medicine and ensure that they meet the set Threshold for Sales of Low Volume PBS Medicines;
- 6) Supply any PBS Medicine at or below the relevant CSO Price for that PBS Medicine;
- 7) Supply any NDSS Products at no cost to Access Points;
- 8) Not impose Prohibited Financial Imposts on Distribution Points; and
- 9) Supply any Brand of CSO Product within the Guaranteed Supply Period:
  - a. PBS Medicines within 72 hours (for products listed in the High Volume List) or 24 hours (for all other PBS Medicines) of the Regular Order Cut Off Time; and
  - b. NDSS Products within 24 hours of the Regular Order Cut Off Time.

Details of each of the CSO Compliance Requirements and CSO Service Standards are discussed in detail in the following sections.



## 2. Compliance Requirements and Service Standards

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### Requirement to provide a single entry point for Distribution Points

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

#### Requirement to provide a single entry point for Distribution Points

- 3.1 The Company must provide a single entry point through which:
  - 3.1.1 Community Pharmacies within its CSO Jurisdiction can:
    - a) order any Brand of any PBS Medicine via a single order; and
    - b) receive information or resolve any inquiries in relation to those orders of PBS Medicine;
  - 3.1.2 Access Points within its CSO Jurisdiction can:
    - a) order any NDSS Products via a single order; and
    - b) receive information or resolve any inquiries in relation to those orders.
- 3.2 Despite clause 3.1.2, the Commonwealth has approved current arrangements under which all orders for NDSS Products are placed by Access Points via an ordering gateway maintained by the NDSS Administrator.
- 3.3 The requirement set out in clause 3.1 of this Schedule does not prevent a Company from providing additional entry points for Distribution Points within its CSO Jurisdiction to, for example:
  - 3.3.1 access special pricing offers made available through a specific Manufacturer or under a specific program; and/or;
  - 3.3.2 place turnover orders.

#### How to meet this Compliance Requirement

To meet this Compliance Requirement, CSO Distributors must ensure that Distribution Points can quickly and easily order any CSO Product, receive information and resolve questions in relation to their orders via one point of access (e.g. telephone, or internet, or facsimile).

Administrative fees cannot be applied to the nominated Single Entry Point communication mechanism, i.e. a CSO Distributor cannot charge a fee for a telephone order if its single point of entry is via telephone.

## 2. Compliance Requirements and Service Standards

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### **Requirement to maintain access to established Infrastructure and sufficient financial capacity to meet the CSO Service Standards and CSO Compliance Requirements**

#### **Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS**

#### **Requirement to maintain access to established Infrastructure and sufficient financial capacity to meet the CSO Service Standards and CSO Compliance Requirements.**

3.4 The Company must maintain access to established Infrastructure and sufficient financial capacity to meet all its Obligations under this Deed.

### **How to meet this Compliance Requirement**

'Infrastructure' is a defined term in the Deed and refers to "*physical infrastructure, such as warehouses, distribution centres, and transport and logistic services*". This includes the systems that CSO Distributors use to operate this Infrastructure and provide these services.

CSO Distributors must inform the CSO Administration Agency if they experience financial difficulties, or have difficulty maintaining access to established Infrastructure for any reason, and must notify the CSO Administration Agency as soon as it is known if those difficulties are likely to impact on the CSO Distributors' ability to carry out any of their Obligations under the Deed.

CSO Distributors must also inform the CSO Administration Agency of any significant planned changes to its Infrastructure and systems, for example:

- closing a warehouse, upgrading a warehouse or opening a new site
- implementing a new enterprise resource planning (ERP) system.

For significant planned system changes, CSO Distributors must provide a risk management plan, a business continuity plan, and an implementation plan to the CSO Administration Agency. These plans must include consideration of the need:

- for a staged approach to system cutover, including running parallel systems
- for a communications strategy for Community Pharmacies
- for testing and monitoring at each stage of implementation
- to accept NDSS orders via PharmX and NDSS Connect
- to provide CSO compliance reports to the CSO Administration Agency.

## 2. Compliance Requirements and Service Standards

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### Requirement to maintain the quality of CSO Products

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement to maintain the quality of CSO Products

3.5 The Company must maintain the quality of all CSO Products that it Supplies, including meeting all applicable storage condition requirements. The Company must hold all necessary State and Territory licences and/or certificates for their warehouses and distribution centres. The Company must also comply with the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 (the Code)*, where compliance with the Code is not already mandatory under the necessary State and Territory licences and/or certificates. For the avoidance of doubt, nothing in this Deed overrides the Code or any State or Territory regulations for the handling, storage, distribution or sale of medicines or medical or surgical aids, equipment or appliances.

### How to meet this Compliance Requirement

As part of the CSO Administration Agency's monitoring and audit activities, the CSO Administration Agency will conduct checks to ensure that CSO Distributors are meeting this Compliance Requirement and, specifically, that warehouse storage conditions comply with the *Code of Good Wholesaling Practice for Medicines in schedules 2, 3, 4 and 8* (1 April 2011) and that storage conditions do not adversely impact on the quality of the CSO Products.

CSO Distributors must ensure that Distribution Points receive CSO Products that are in a fit state to be supplied to customers by ensuring that it has been maintained appropriately in accordance with approved storage requirements.

### Compliance with the Code of Good Wholesaling Practice for Medicines, April 2011

The *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4, and 8*, April 2011 (**the Code**) (at [the TGA website](#)) supersedes the November 1991 edition of the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*.

The Code is applicable to wholesalers who, for the purposes of the Code, are defined as persons or organisations including manufacturers wholesalers, manufacturers agents importers and distributors who store and or supply by wholesale medicines included in Schedules 2, 3, 4 and 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons*, or other applicable State or Territory poisons legislation.

The provisions of this Code are applied through applicable State and Territory therapeutic goods/drugs and poisons legislation, and/or State or Territory wholesaler licence arrangements.

The Code is concerned with ensuring that quality is maintained during wholesaling and it sets out appropriate standards to be applied. A principle of the Code is that policies and procedures should be in place to provide storage conditions to ensure the maintenance of quality and safety of stored medicines. In addition, policies and procedures should be in place to ensure that damaged products and products that are otherwise unsuitable for use are quarantined and accounted for. Medicines in Schedules 2, 3, 4 and 8 need to be stored and distributed in accordance with the label requirements of the manufacturer, State and Territory legislation and the Code.

The Code contains a number of principles and practice standards relating to:

- buildings and grounds;

## 2. Compliance Requirements and Service Standards

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- storage facilities;
- personnel;
- stock handling and stock control;
- transport;
- management of complaints, return of unused and /or damaged goods and product recalls;
- management of records, documentation and standard operating procedures;
- cold chain medicines;
- security arrangements and procedures; and
- additional measures for the management of controlled drugs and other goods with high illicit value.

### ***Documenting and reporting Temperature Deviation Events***

In particular CSO Distributors should note the following Practices in the Code:

#### **Practice Number 2.5**

*“If TSM (Temperature Sensitive Medicines) storage temperature is found to have deviated from the sponsor’s recommended conditions specified on the label for an extended time, the sponsor of the goods should be contacted and the suitability of the product for use resolved. The meaning of extended time is to be determined in consultation with the sponsor of the product”.*

#### **Practice Number 6.8**

*“Stock which has been damaged or otherwise deemed unsuitable for sale, temporarily or permanently, should be placed in quarantine so that it cannot be sold in error, misappropriated or stolen or leak and contaminate other goods. Quarantine may be achieved through physical isolation from saleable stock or electronically through a warehouse management system or stock control system”.*

#### **Practice Number 6.9**

*“Standard operating procedures should be in place to ensure all quarantined medicines are accounted for and are unavailable for sale”.*

#### **Practice Number 8.9**

*“If cold chain medicine storage temperature is found to have deviated from the sponsor’s recommended conditions, the sponsor of the medicines should be contacted and the suitability of the medicine for use should be resolved and the outcome recorded”.*

Medicines can become less effective or ineffective if they are not stored and distributed correctly, e.g. if they are allowed to get too hot, too cold and/or exposed to direct sunlight. The outcome following exposure to any or all of these conditions is dependent on the medicine itself. For example, for vaccines that are cold or freeze-sensitive such as pneumococcal and influenza vaccines, the loss of potency following freezing is immediate and these vaccines must not be supplied to Distribution Points. When vaccines are exposed to repeated episodes of heat, outside the sponsors recommended range, the loss of vaccine potency is cumulative and cannot be reversed.

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CSO Distributors must ensure that their storage facilities protect the PBS Medicines from deterioration, and that they store medicines in accordance with the storage conditions specified on the medicine labels and the medicines' Material Safety Data Sheets (**MSDS**) where relevant.

In practice, this requires CSO Distributors to maintain refrigerated storage areas within the range +2°C to +8°C and maintain other warehouse areas used to store PBS medicines at or below +25°C.

Due to the potential public health issues associated with the supply of unsuitable medicines, if one or more PBS Medicines are subject to a temperature excursion (outside the range specified on the medicine labels and the medicines' MSDS where relevant), except as described below, the CSO Distributor must identify and provide full details of the temperature excursion and affected stock to the CSO Administration Agency as soon as the temperature event is detected using the CSO Cold Chain and Non-cold chain Temperature Sensitive Medicine Breach Report Form at Attachment F.

The CSO Distributor will not be required to identify and report a temperature excursion where, in accordance with a risk-based approach agreed in writing with the Commonwealth through the CSO Administration Agency, the CSO Distributor has determined that:

- the temperature excursion is inside the tolerances provided for in the mean kinetic temperature (MKT) framework; and
- there is no material risk to consumer safety arising from the temperature excursion.

Note that these provisions **do not apply to cold-chain medicines**. As soon as the storage temperature for one or more cold-chain medicines is detected to be outside the range +2°C to +8°C, it must be reported to the Agency using the form provided at Attachment F.

The CSO Administration Agency may provide this temperature breach information to the Commonwealth as part of its CSO reporting obligations.

If CSO Products are found to be outside the manufacturers recommended range and Supplied to Distribution Points and/or other health organisations, the CSO Administration Agency may request the CSO Distributor to provide contact and supply details for these organisations.

### **MKT FRAMEWORK**

Mean kinetic temperature (MKT) 'is a calculated value that may be used as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature variations'.

For CSO purposes, CSO Distributors must use the MKT to monitor warehouse temperatures for temperature sensitive Medicines (**not cold-chain**), based upon the method and guidelines set out in the United States Pharmacopeia (USP), i.e. warehouse temperature should not exceed an MKT of 298.15K (25°C) or 303.15K (30°C).

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CSO Distributors must ensure that their calculation of MKT is as per the USP, using Haynes formula:

$$MKT_k = \frac{\frac{\Delta H}{R}}{-\ln \left( \frac{e^{-\frac{\Delta H}{RT_1}} + e^{-\frac{\Delta H}{RT_2}} + \dots e^{-\frac{\Delta H}{RT_n}}}{n} \right)}$$

Where:

$K$	=	degrees Kelvin (i.e. degrees Celsius + 273.15)
$\Delta H$	=	activation energy, <b>which should always be 83.144 kJ/mol</b>
$R$	=	the universal gas constant (i.e. $8.3144 \times 10^{-3}$ kJ/mol/degree)
$T_1$	=	average temperature (in degrees K) during the first 24-hour period
$T_2$	=	average temperature (in degrees K) during the second 24-hour period
$T_n$	=	average temperature (in degrees K) during the nth 24-hour period
$n$	=	the total number of temperatures recorded.

For clarity:

- The MKT is calculated over a 30-day period on a rolling basis, therefore  $n$  is 30
- Temperatures  $T_1$  to  $T_n$  represent the average temperatures during each of the 30 24-hour periods. This average daily temperature is determined by:
  - a) taking the highest and lowest recorded temperature during each 24-hour period and divide these by two; or
  - b) taking actual temperature recordings and divide these by the number of observations (arithmetic average) provided that there are at least 24 observations.

Method a) suits situations whereby temperatures are recorded manually using a min-max probe.

Method b) is more accurate and suits situations whereby temperatures are recorded and logged electronically.

- These calculations should be made for each probe, e.g. if a warehouse has 12 probes, 12 MKT calculations are required.

Subject to an MKT of not more than 298.15K (25°C) or 303.15K (30°C) being maintained, excursions are permitted, so long as the transient spike in temperature does not exceed 24 hours in duration or 40°C. **If the transient spike in temperature is above 40°C, or the duration of the excursion is longer than 24 hours, the CSO Distributor must report the temperature excursion to the Agency.**

Excursions must be reported as part of the Monthly Declaration and Exception Report (DER). The information reported must include:

- the location (i.e. warehouse) of the excursion
- a description of the excursion and explanation of why the excursion occurred
- hourly temperature readings for the period affected.

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### ***Licences and Certificates***

CSO Distributors must ensure that they, and their subcontractors, hold current State and Territory licences and/or certificates for their warehouses and distribution centres. Licence requirements differ between the States and Territories, and it is the responsibility of the CSO Distributor to ascertain whether or not it and its subcontractors are required to hold a licence. The failure of the CSO Distributor to make such enquiries may result in a Non-Performance being recorded by the CSO Administration Agency and Sanctions being applied.

The CSO Administration Agency maintains a register of all licences and certificates, and CSO Distributors are required to provide the CSO Administration Agency with copies of updates or renewals to these licences and certificates, if such updates or renewals are required under State and Territory legislation. The updated licences and certificates must be provided to the CSO Administration Agency with the Monthly Declaration and Exception Report.

## 2. Compliance Requirements and Service Standards

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### ***Service Standards***

#### **Requirement to Supply to any Distribution Point**

##### **Extract from Schedule 1 – CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS**

##### **Requirement to Supply to any Distribution Point**

- 4.1 The Company must Supply PBS Medicines to any Community Pharmacy and NDSS Products to any Access Point within its CSO Jurisdiction.
- 4.2 The Company will not be required to Supply CSO Products to any Distribution Point while that Distribution Point is a bad debtor. The Company must resume Supply as soon as the Distribution Point is no longer a bad debtor.
- 4.3 The CSO Administration Agency or the Commonwealth may by notice in writing to the Company:
  - 4.3.1 specify what constitutes a “bad debtor” for the purposes of clause 4.2; or
  - 4.3.2 direct the Company to supply a particular Distribution Point on a cash-before-delivery or cash-on-delivery basis, notwithstanding that the relevant Distribution Point may otherwise be a “bad debtor”.
- 4.4 The Company must ensure that the terms of its supply arrangements with Distribution Points do not contain any terms which are inconsistent with or contrary to the purpose or intent of the CSO Funding Pool or this Deed.

#### **How to meet this Service Standard**

CSO Distributors must Supply CSO Products to any Distribution Points except if the Distribution Point is deemed to be a bad debtor, in which case the CSO Distributor will not be required to Supply to that Distribution Point (unless the CSO Administration Agency or the Commonwealth directs otherwise).

**Note:** The Supply of PBS Medicines in Dose Administration Aids by CSO Distributors or their subcontractors lies outside the scope of the CSO Funding Pool, and cannot be claimed by CSO Distributors for funding from either the National or State based CSO Funding Pool.



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### Requirement to Supply to Rural and Remote Pharmacies

#### Extract from Schedule 1 – CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement to Supply Rural and Remote Pharmacies

- 4.5 The Company must ensure that its volume of Sales of PBS Medicines to Rural and Remote Pharmacies within its CSO Jurisdiction is not more than 10% below the Industry Average (the **Threshold**) for each Year and for each Month within each Year within the Term. For the avoidance of doubt, Sales of NDSS Products will not be taken into account for the purposes of assessing compliance with this clause 4.5.
- 4.6 The CSO Administration Agency will notify the Company of its performance against the applicable Threshold for Sales to Rural and Remote Pharmacies in each Year and Month within the Term. Sanctions may be applied if the Company fails to meet the applicable Threshold for Sales to Rural and Remote Pharmacies in any Year or Month.

### How to meet this Service Standard

Thresholds are in place to ensure that CSO Distributors supply PBS Medicines to any Community Pharmacy within their CSO jurisdiction, including Community Pharmacies in Rural and Remote Locations.

A Community Pharmacy is in a Rural and Remote Location if the location postcode for that Community Pharmacy falls within the identified range of Rural and Remote postcodes for CSO Funding Pool purposes, as listed in *Appendix A*.

The Rural and Remote Thresholds reflect the proportion of total Sales of PBS Medicines that must be supplied to Community Pharmacies in Rural and Remote Locations. These Thresholds are intended to reflect the level at which the Commonwealth is satisfied that Community Pharmacies in Rural and Remote Locations are receiving full access to PBS Medicines.

CSO Distributors must ensure that their proportion of Sales to Community Pharmacies in Rural and Remote Locations against their total CSO Sales, do not fall below specified Thresholds, i.e. do not fall more than 10% below the Industry Average.

Industry Average is defined in the Deed to be:

*“the average Sales volume of PBS Medicines, calculated to one decimal place, to Community Pharmacies by all CSO Distributors in the preceding Year, based on Data and Reports provided by CSO Distributors to the CSO Administration Agency throughout the Year. The Industry Average will:*

- (a) be calculated on the basis of Data and Reports provided by CSO Distributors for the previous Year (even if the Year preceded the Commencement Date) and as reconciled by the CSO Administration Agency;<sup>1</sup>*
- (b) apply from October to September immediately after that Year (or part thereof during the Term);*

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<sup>1</sup> Data and Reports submitted by all CSO Distributors, National and State Based, will be used to calculate the National Industry Average and the Industry Average for each State and Territory.

## 2. Compliance Requirements and Service Standards

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- (c) *be used to calculate the applicable Thresholds for Sales to Rural and Remote Pharmacies and Sales of Low Volume PBS Medicines; and*
- (d) *be used to calculate the list of High Volume PBS Medicines.”*

The Industry Average is calculated by determining the average Sales volume of PBS Medicines to Community Pharmacies by CSO Distributors under CSO arrangements. The amount derived following the application of the 10% tolerance level to the Industry Average becomes the applicable Threshold. For example, if the current Industry Average for sales to Community Pharmacies in Rural and Remote Locations is 31.3 for every 100 PBS Medicines supplied, then no less than 28.2 PBS Medicines would need to be supplied to Community Pharmacies in Rural and Remote Locations for the Threshold to be met, i.e. 28.2% of Sales made by CSO Distributors must be to Community Pharmacies in Rural and Remote Locations.

The 10% tolerance level was introduced in recognition of the difficulties faced by CSO Distributors in consistently meeting the Industry Average. As a result, CSO Distributors are considered to have satisfied their Obligations as long as Sales of PBS Medicines to Community Pharmacies in Rural and Remote Locations do not fall more than 10% below the Industry Average.

The Thresholds will be calculated following analysis of aggregated Data for the preceding year provided by each CSO Distributor. These Thresholds must be calculated by 31 August each Year, with the new Thresholds applying from October to September of the following Year.

## 2. Compliance Requirements and Service Standards

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### Calculating Rural and Remote Thresholds for State Based CSO Distributors

Due to the differing number of Rural and Remote locations between each State/Territory, a different Threshold is determined for each State/Territory. The same methodology is applied to determine the Thresholds for each individual State and Territory. Clause 4.7 of Schedule 1 of the Deed describes the process for calculating the Thresholds for State Based CSO Distributors.

#### **Extract from Schedule 1 – CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS**

- 4.7 Where the Company is a State Based CSO Distributor eligible to access the CSO Funding Pool in more than one State or Territory:
- 4.7.1 The Industry Average and applicable Threshold for Sales to Rural and Remote Pharmacies for the Company will be calculated based on Sales made by CSO Distributors in those State/s and/or Territory/ies in which the Company has been assessed as eligible to access the CSO Funding Pool. This calculation will be made by comparing:
- (a) the proportion of total Sales to Rural and Remote Pharmacies by all CSO Distributors (National and State Based) in those State/s and/or Territory/ies in which the Company has been assessed as eligible to access the CSO Funding Pool; against
  - (b) total Sales by all CSO Distributors (National and State Based) in those State/s and/or Territory/ies in which the Company has been assessed as eligible to access the CSO Funding Pool.
- 4.7.2 The performance of the Company against the applicable Threshold for Sales to Rural and Remote Pharmacies will be calculated based on the proportion of the Company's total Sales to Rural and Remote Pharmacies against the total Sales by the Company across all State/s and/or Territory/ies in which the Company has been assessed as eligible to access the CSO Funding Pool.

## 2. Compliance Requirements and Service Standards

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### Requirement to Supply any Brand of CSO Product

#### Extract from Schedule 1 – CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement to Supply any CSO Products

- 4.8 The Company must Supply any Brand of any CSO Product, where requested, to Distribution Points within its CSO Jurisdiction.
- 4.9 The Company will not be required to Supply CSO Products:
- 4.9.1 that are not available to it because of an Exclusive Supply Arrangement (details of which will be published or provided (or both) from time to time by the CSO Administration Agency);
  - 4.9.2 that are out-of-stock with the Manufacturer; or
  - 4.9.3 cannot be supplied by the Manufacturer; or
  - 4.9.4 to the extent and for the timeframe specified (but only to the extent and for the timeframe specified) in a written direction issued by the Department under clause 4.9A.
- 4.9A Where the Department determines that a Force Majeure Event has arisen, the Department may (but is not obliged to) issue a written direction to the Company requiring the Company to restrict the supply of CSO Products to the extent and for the timeframe specified in that written direction. Notwithstanding any timeframe specified in a written direction given under this clause 4.9A, the Department may revoke, vary or extend a written direction at any time. Where the circumstances of the Force Majeure Event permit, the Department will endeavour to provide the Company not less than 24 hours' prior notice of the issue, revocation, variation or extension of a written direction given under this clause 4.9A. The Company must comply with any requirements of a written direction issued under this clause 4.9A while the written direction is in force, including any data reporting requirements.

### How to meet this Service Standard

The aim of this Service Standard is to ensure that all Australians have access to their preferred Brand of CSO Product. However, a CSO Distributor is not required to Supply a CSO Product:

- that is not available to it because of an Exclusive Supply Arrangement;
- that is not available to it because the CSO Product is out-of-stock with the Manufacturer or otherwise cannot be supplied by the Manufacturer;
- which the CSO Distributor believes is intended for export; or
- which is subject to a written direction issued by the Department to the Company, in response to a Force Majeure Event.

### CSO Products intended for export

If a CSO Distributor believes an order for a CSO Product is likely to be intended for export, then the CSO Distributor is under no obligation to supply that brand. For example if a CSO Distributor had reason to believe an order for a brand of infant formula was intended for overseas, then it is not required to fulfill this order.

## 2. Compliance Requirements and Service Standards

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However if a CSO Distributor does not supply a CSO Product because it believes it is likely to be intended for export, then it is required to advise the CSO Administration Agency and provide further details each month with its monthly DER.

### **Written directions issued by the Department in response to a Force Majeure Event**

CSO Distributors may be required to assist the Department to address and monitor product shortages and issues arising from a Force Majeure Event. In these circumstances, CSO Distributors will be provided with guidance through a written direction issued under Clause 4.9A of Schedule 1 of the Deed.

This guidance may require.

- The CSO Distributor to put arrangements in place to ensure equitable supply and availability of PBS Medicines.
  - Any restriction of supply must occur on an appropriate and equitable basis, i.e. limiting of orders must not discriminate against or benefit a particular customer or type of customer, including large buying groups or banner groups
  - The approach to restricting supply should include consideration of customers' historical pattern of ordering such products and any other appropriate considerations.
- Additional supplementary data reporting in relation to activities arising from the CSO Distributor's response to a Force Majeure Event. General guidance on the scope and nature of possible supplementary data reporting is described at the end of Section 6 of these Operational Guidelines, and specific details will be provided as part of the issuance of a written direction.

## 2. Compliance Requirements and Service Standards

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### Exclusive Supply Arrangements

#### Extract from Clause 7 - Exclusive Supply Arrangements

- 7.1. The Company represents and warrants to the Commonwealth, as at the Commencement Date, that:
- 7.1.1. it has disclosed in writing to the Commonwealth details of all Exclusive Supply Arrangements to which the Company was, or its Related Entities were, a party on the ITA Publication Date;
  - 7.1.2. the list of agreements, arrangements or understandings set out Schedule 9 (**Exempt Exclusive Supply Arrangements**) fully and accurately reflects the Exclusive Supply Arrangements disclosed by the Company to the Commonwealth as being the only Exclusive Supply Arrangements to which the Company was, or its Related Entities were, a party on the ITA Publication Date; and
  - 7.1.3. it and its Related Entities have not entered into any new Exclusive Supply Arrangements, or varied or extended any Exempt Exclusive Supply Arrangements, since the ITA Publication Date.
- 7.2. The Company must not, and must procure that its Related Entities do not, at any time during the Term:
- 7.2.1. enter into any new Exclusive Supply Arrangements; or
  - 7.2.2. agree to or give effect to any material variation or amendment to any Exempt Exclusive Supply Arrangement without the prior written consent of the Commonwealth.
- 7.3. The Commonwealth may immediately Terminate this Deed under clause 26.4.4 if the Commonwealth considers that:
- 7.3.1. the Company has failed to comply (including where a Related Entity of the Company causes it to fail to comply) with the Obligations set out in clause 7.2; or
  - 7.3.2. the Company has entered into, or any of the Company's Related Entities have entered into, any new Exclusive Supply Arrangements after the ITA Publication Date and before the Commencement Date.
- 7.4. The Company must not, and must ensure that its Related Entities do not, renew, extend or allow to roll over any Exempt Exclusive Supply Arrangement listed in Schedule 9 beyond its expiry date where its expiry date is on or before 30 June 2020 and where the renewal, extension or rolling over is within the control or at the discretion (in whole or in part) of the Company or its Related Entities (or both).
- 7.5. Where the Commonwealth considers that the Company and/or its Related Entities have:
- 7.5.1. renewed, extended or allowed to roll over any Exempt Exclusive Supply Arrangement listed in Schedule 9 as having an expiry date before 30 June 2020 in circumstances where the Commonwealth also considers that the renewal, extension or rolling over was within the control or at the discretion (in whole or in part) of the Company or its Related Entities (or both); or
  - 7.5.2. continue to be a party to any Exempt Exclusive Supply Arrangements beyond 30 June 2020,
- the Commonwealth may immediately Terminate this Deed under clause 26.4.4.

## 2. Compliance Requirements and Service Standards

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An Exclusive Supply Arrangement arises where a CSO Product is not made available by the relevant Manufacturer to all CSO Distributors.

If a particular CSO Product is subject to an Exclusive Supply Arrangement, but a CSO Distributor does have access to the CSO Product, then the CSO Distributor must continue to meet its Obligations under the Deed, but will not receive Payment for Sales of that CSO Product.

The CSO Administration Agency maintains a list of the CSO Products that are currently subject to Exclusive Supply Arrangements. This list is updated on a Monthly basis based on information that the CSO Administration Agency receives from CSO Distributors. CSO Distributors must advise the CSO Administration Agency of any items that need to be added or removed from the Exclusive Supply Arrangements list for the following Month and provide supporting evidence. The CSO Administration Agency must be notified by the CSO Distributor of any additions or deletions required by the twelfth (12<sup>th</sup>) Business Day of each Month.

The CSO Administration Agency will assess the validity of the notifications and, by the last day of the Month, the CSO Administration Agency will upload the Exclusive Supply Arrangements list that will apply for the subsequent Month on the CSO Administration Agency's mapping website.

The current list of CSO Products on the Exclusive Supply Arrangements list is attached at *Appendix D* to these Guidelines.

## 2. Compliance Requirements and Service Standards

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### Stocking Requirement for CSO Products

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Stocking Requirement for CSO Products

- 4.10 The Company must hold Stock in its warehouses or distribution centres (that the Company will use to meet the CSO Service Standards) of at least one Brand of every PBS Medicine. For multi-Branded PBS Medicines, the Company must hold Stock of at least one Innovator Brand and one additional Brand which is Benchmark Priced.
- 4.11 The Company must hold Stock in its warehouse or distribution centres (that the Company will use to meet its CSO Service Standards) of at least one of each product listed on the NDSS Product Schedule.
- 4.12 The Company will not be required to hold Stock of CSO Products:
- 4.12.1 that are not available to it because of an Exclusive Supply Arrangement (details of which will be published or provided (or both) from time to time by the CSO Administration Agency);
  - 4.12.2 that are out-of-stock with the Manufacturer; or
  - 4.12.3 cannot be supplied by the Manufacturer.
- 4.13 If the Company is unable to Stock a particular CSO Product for any reason other than those mentioned in clause 4.12 of this Schedule, the Company must provide the CSO Administration Agency with an explanation as to why the CSO Product is unable to be Stocked. If the explanation, in the CSO Administration Agency's reasonable opinion, is insufficient or is not provided, this will be considered a Non-Performance of the Company's Obligations under this Deed.

### How to meet this Service Standard

A CSO Distributor must hold at least one Brand of every CSO Product in its warehouses and distribution centres.

For PBS Medicines that have more than one Brand, the CSO Distributor must keep at least one Innovator/Originator Brand and one additional Benchmark Priced Brand in stock. A list of Originator Brands for multi-Branded PBS Medicines is available on the Federal Register of Legislation (<https://www.legislation.gov.au/Series/F2015L01525>).

For NDSS Products the CSO Distributor must hold at least one of each product listed on the NDSS Product Schedule.

The Administration Agency will undertake checks as part of its monitoring and audit activities to ensure CSO Distributors stock all CSO Products in accordance with this CSO Service Standard.

This Service Standard ensures that all Australians have access to at least one Brand of their CSO Product where no Brand price premium is applicable. This obligation is central to the main objective of the CSO to ensure that arrangements are in place to provide all Australians with ongoing and timely access, through Distribution Points, to all CSO Products.

Accordingly, CSO Distributors must provide a written explanation to the Administration Agency as to why they failed to stock a CSO Product, if their reasons for failing to stock that product fall outside of the circumstances listed in clause 4 of Schedule 1 of the Deed.



## 2. Compliance Requirements and Service Standards

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### Requirement to Supply any Low Volume PBS Medicine

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement to Supply any Low Volume PBS Medicine

- 4.14 The Company must Supply any Brand of any Low Volume PBS Medicine, including in single Units, where requested.
- 4.15 The Company must ensure that its volume of Sales of Low Volume PBS Medicines within its CSO Jurisdiction is not more than 10% below the Industry Average (the **Threshold**) for each Year and for each Month within each Year within the Term.
- 4.16 The CSO Administration Agency will notify the Company of its performance against the applicable Threshold for Sales of Low Volume PBS Medicines in each Year and Month within the Term. Sanctions may be applied if the Company fails to meet the applicable Threshold for Sales of Low Volume PBS Medicines in any Year or Month.
- 4.17 Where the Company is a State Based CSO Distributor and is eligible to access the CSO Funding Pool in more than one State or Territory, the performance of the Company against the applicable Threshold for Sales of Low Volume PBS Medicines will be calculated based on the proportion of the Company's total Sales of Low Volume PBS Medicines against the total Sales of PBS Medicines (excluding NDSS Products) by that Company across all State/s and/or Territory/ies in which the Company has been assessed as eligible to access the CSO Funding Pool.

### How to meet this Service Standard

Low Volume PBS Medicines are products that are "sold by CSO Distributors to Community Pharmacies at an average rate of less than one Unit per Community Pharmacy per week, as determined by the CSO Administration Agency". The PBS Medicines that fall within this definition of Low Volume are assigned to a list of Low Volume PBS Medicines.

The Low Volume Thresholds are intended to reflect the acceptable level at which the Commonwealth is satisfied that Community Pharmacies are receiving access to Low Volume PBS Medicines.

CSO Distributors must ensure that their proportions of Low Volume PBS Medicine Sales to Community Pharmacies (measured against their total Sales), do not fall more than 10% below the Industry Average.

The Industry Average is calculated by working out the average Volume of Sales of PBS Medicines to Community Pharmacies by CSO Distributors under the CSO. The amount calculated following the application of the 10% tolerance level to the Industry Average becomes the applicable Threshold.

For example, if the National Industry Average is 19.8%, then for every 100 PBS Medicines supplied to Community Pharmacies, no less than 17.8 Low Volume PBS Medicines would need to be supplied to Community Pharmacies, i.e. 17.8% of a CSO Distributors Sales must be of Low Volume PBS Medicines.

The Low Volume list is not altered by any additions, deletions and other changes to the PBS that may occur throughout the Year.

## 2. Compliance Requirements and Service Standards

### Requirement to Supply any PBS Medicine at or below the Price to Pharmacists

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

#### Requirement to Supply any PBS Medicine at or below the Price to Pharmacists or the Claimed Price plus the Wholesale Mark-Up

- 4.18 Subject to clause 4.19, the Company must Supply any PBS Medicine, in any quantity:
- 4.18.1 if the Unit equals a Pack Quantity:
- (a) at or below the Price to Pharmacists for the Pack Quantity of the PBS Medicine Supplied; or
  - (b) if there is a Claimed Price for the Pack Quantity of the PBS Medicine Supplied, at or below the Claimed Price for the Pack Quantity plus the Wholesale Mark-Up calculated in accordance with clause 4.22; or
- 4.18.2 if the Unit does not equal a Pack Quantity:
- (a) at or below the pro-rata ex-manufacturer price for the Unit calculated in accordance with clause 4.20 plus the Wholesale Mark-Up calculated in accordance with clause 4.23; or
  - (b) if there is a Claimed Price for the Pack Quantity of the PBS Medicine, at or below the pro-rata claimed price for the Unit calculated in accordance with clause 4.21, plus the Wholesale-Mark-Up calculated in accordance with clause 4.24.
- 4.19 Any order of PBS Medicines from the High Volume List (other than Low Volume PBS Medicines) must be for at least the Minimum Order Quantity unless the Community Pharmacy agrees to pay an additional fee in accordance with this clause. If a Community Pharmacy requests the Company to Supply less than the Minimum Order Quantity of PBS Medicines from the High Volume List (other than Low Volume PBS Medicines), then in addition to any other charge provided for under this Deed, the Company may charge an additional amount deemed appropriate by the Company at their discretion for the increased service requirement. Such charges do not require the approval of the CSO Administration Agency. The Company may not charge any additional amount under this clause 4.19 until the Company and the Commonwealth have agreed the form and quantity of product for the purpose of the definition of "Shelf Pack" in clause 1.1 in this Schedule. The Company and the Commonwealth will use their respective best endeavours to agree the definition of "Shelf Pack", each party acting reasonably and in good faith. In negotiating the definition of "Shelf Pack", the Commonwealth and the Company will consider any definition of "Shelf Pack" agreed between the CSO Distributors and The Pharmacy Guild of Australia ABN 84 519 669 143.
- 4.20 For the purposes of clauses 4.18.2(a) and 4.23.2, the pro-rata ex-manufacturer price for the Unit is to be worked out proportionately from the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity of the PBS Medicine.
- 4.21 For the purposes of clauses 4.18.2(b) and 4.24.2, the pro-rata claimed price for the Unit is to be worked out proportionately from the Claimed Price for the Pack Quantity of the PBS Medicine.

## 2. Compliance Requirements and Service Standards

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### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

#### **Wholesale Mark-Up if a Unit equals a Pack Quantity and if there is a Claimed Price for a Pack Quantity of a PBS Medicine**

- 4.22 For the purposes of clause 4.18.1(b), the Wholesale Mark-Up for the Pack Quantity of the PBS Medicine is to be worked out using the methodology for calculating the wholesale mark-up for ready-prepared pharmaceutical medicines in the determination made under paragraph 98B(1)(a) of the NH Act, subject to the following:
- 4.22.1 for the purposes of identifying the appropriate wholesale mark-up formula in Step 2 of the methodology, the ex-manufacturer price for the relevant quantity is to be worked out proportionately from the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity of the PBS Medicine; and
  - 4.22.2 otherwise, the methodology is to be applied as if the Claimed Price for the Pack Quantity of the PBS Medicine were the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity.

#### **Wholesale Mark-Up if a Unit does not equal a Pack Quantity**

- 4.23 For the purposes of clause 4.18.2(a), the Wholesale Mark-Up for the Unit of the PBS Medicine is to be worked out using the methodology for calculating the wholesale mark-up for ready-prepared pharmaceutical benefits in the determination made under section 98B(1)(a) of the NH Act, subject to the following:
- 4.23.1 for the purposes of identifying the appropriate wholesale mark-up formula in Step 2 of the methodology, the ex-manufacturer price for the relevant quantity is to be worked out proportionately from the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity of the PBS Medicine; and
  - 4.23.2 otherwise, the methodology is to be applied as if the pro-rata ex-manufacturer price for the Unit calculated in accordance with clause 4.20 were the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity.

#### **Wholesale Mark-Up if a Unit does not equal a Pack Quantity and if there is a Claimed Price for a Pack Quantity of a PBS Medicine**

- 4.24 For the purposes of clause 4.18.2(b), the Wholesale Mark-Up for the Unit of the PBS Medicine is to be worked out using the methodology for calculating the wholesale mark-up for ready-prepared pharmaceutical medicines in the determination made under section 98B(1)(a) of the NH Act, subject to the following:
- 4.24.1 for the purposes of identifying the appropriate wholesale mark-up formula in Step 2 of the methodology, the ex-manufacturer price for the relevant quantity is to be worked out proportionately from the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity of the PBS Medicine; and
  - 4.24.2 otherwise, the methodology is to be applied as if the pro-rata claimed price for the Unit worked out in accordance with clause 4.21 were the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity.

## 2. Compliance Requirements and Service Standards

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### How to meet this Service Standard

#### Pricing

For each PBS Medicine, a maximum price is defined at which CSO Distributors are allowed to Supply to Community Pharmacies, i.e. CSO Distributors must Supply at or below that price. For PBS Medicines which are supplied in Pack Quantities, this maximum price is either the:

- Price to Pharmacist; or
- Claimed Price plus a Wholesale Mark-up.

For PBS Medicines which are supplied in less than Pack Quantities, the maximum price is either the:

- pro rata ex-manufacturer price plus a Wholesale Mark-Up; or
- the pro rata Claimed Price plus a Wholesale Mark-Up.

**The approved ex-manufacturer price for all PBS Medicines is available on the PBS website: <https://www.pbs.gov.au/info/industry/pricing/ex-manufacturer-price>.**

#### Price to Pharmacist

Price to Pharmacist is a defined term in the Deed and has the same meaning as in the determination under section 98B(1)(a) of the *National Health Act 1953*.

#### Claimed Price

The Claimed Price for particular Brands of pharmaceutical items is the amount specified in a determination in force under subsection 85B(3) of the NH Act.

#### Price for Unit less than Pack Quantity

CSO Distributors are allowed to claim Sales of some pack sizes that are either not listed on the Schedule of Pharmaceutical Benefits, or are not the maximum quantity listed, and therefore have no Price to Pharmacist. In such instances, CSO Distributors must Supply these products to Community Pharmacies at or below the price of such products, calculated on a proportional basis using the Approved Ex-Manufacturer Price for the maximum quantity as listed on the PBS. Where more than one listing for a product exists and each has a different maximum quantity, use the largest maximum quantity.

#### Wholesale Mark-Up

The Wholesale Mark-Up is worked out using the methodology for calculating the wholesale mark-up for ready prepared pharmaceutical benefits in the determination made under section 98B(1)(a) of the *National Health Act 1953*, on a pro rata basis if the Unit is less than a Pack Quantity.

#### Discounts and rounding

Under the Deed, PBS Medicines must be Supplied to Community Pharmacies at or below the price referred to above (**CSO Price**). **Meeting this requirement must not be dependent on Community Pharmacies obtaining conditional discounts or incentives.**

Additionally, CSO Distributors must ensure that the accounting software in use does not generate rounding up errors, e.g. \$0.01 rounding up, as this may cause the PBS Medicine to be sold above the relevant CSO Price and would therefore be a Non-Performance.

## 2. Compliance Requirements and Service Standards

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### Pricing of PBS Medicines that are not claimable for CSO Purposes

The Schedule of Pharmaceutical Benefits lists the PBS Medicines that, unless otherwise specified by the Commonwealth, are claimable by CSO Distributors, including:

- any product which is listed on both PBS general (Section 85) and RPBS (dual listed items)
- any product which is listed on both PBS general (Section 85) and PBS Section 100 (dual listed items).

PBS Medicines which **cannot** be claimed for CSO purposes, and for which CSO Distributors are therefore **not** required to supply to Community Pharmacies at or below the CSO Price or Price Per Unit, include any PBS Medicine which is listed on the RPBS only, or in PBS Section 100 only (non-dual listed items).

The exception is PBS Medicines which are subject to Exclusive Supply Arrangements. These PBS Medicines cannot be claimed for CSO purposes, however if a CSO Distributor does have access to these PBS Medicines, **the CSO Distributor must Supply these items to Community Pharmacies at or below the CSO Price, and meet all other Deed Obligations in respect of these PBS Medicines.**

## 2. Compliance Requirements and Service Standards

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### Requirement to Supply any NDSS Product at no cost to Access Points

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement to Supply any NDSS Product at no cost to Access Points

- 4.25 The Company must Supply any NDSS Product, in any quantity, at no cost to the Access Point. The Commonwealth will pay for the NDSS Distribution Services in accordance with Schedule 2.

### How to meet this Service Standard

The Commonwealth has structured the Payments for NDSS Distribution Services so that CSO Distributors receive fair compensation for the Supply of NDSS Products. Under the NDSS this compensation is paid by the Commonwealth. A CSO Distributor may not charge a Distribution Point any amount in relation to the Supply of NDSS Products or for NDSS Distribution Services.

## 2. Compliance Requirements and Service Standards

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### Requirement to not impose Prohibited Financial Imposts on Distribution Points

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement to not impose additional fees

- 4.26 Subject to clause 4.28, 4.31 and 4.40, the Company may not impose or attempt to impose fees, levies, cost recoveries or other financial imposts or trading terms (**Prohibited Financial Imposts**) on Distribution Points which are intended to, or which have the effect of, providing to the Company additional revenue or compensation for complying with its Obligations under this Deed or which are otherwise inconsistent with the purpose or intent of the CSO Funding Pool or this Deed.
- 4.27 Examples of Prohibited Financial Imposts include fees charged or levied by a CSO Distributor for:
- 4.27.1 delivery to Rural and Remote Locations or to Distribution Points in non-metropolitan areas;
  - 4.27.2 delivery within the Guaranteed Supply Period;
  - 4.27.3 providing a Daily delivery service;
  - 4.27.4 supply of a particular CSO Product; or
  - 4.27.5 ordering less than a specified minimum volume/quantity in a single order, unless that fee is expressly permitted by this Deed.
- 4.28 Despite clause 4.26, a Company can charge:
- 4.28.1 commercially acceptable fees of an accounting or accounts receivable nature (for example, fees on overdue accounts and fees for dishonoured payments) (**Approved Fees**) which have been approved by the CSO Administration Agency in writing for the purpose of this clause on or about the Commencement Date; and
  - 4.28.2 additional Approved Fees which have been approved by the CSO Administration Agency in writing after the Commencement Date.
- 4.29 Any proposed new fees or increase in Approved Fees must be approved by the CSO Administration Agency in writing.

##### How to meet this Service Standard

CSO Distributors are able to apply commercially acceptable fees of an accounting nature such as fees applied to overdue accounts or fees applied to dishonoured payments, that have been approved by the CSO Administration Agency (Approved Fees). If a CSO Distributor wishes to increase previously Approved Fees or introduce a new fee, the CSO Distributor must apply to the CSO Administration Agency for approval prior to it being applied. The CSO Administration Agency must consider the fee increase or new fee to be fully justified before it can be approved. In order to make this determination, the CSO Administration Agency needs, at a minimum, the following information:

- description of the fee and circumstances in which it will be applied;
- amount of proposed increase or new fee; and
- reason for proposed increase or new fee.

## 2. Compliance Requirements and Service Standards

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### **Fees relating to Minimum Order Quantities**

PBS Medicines on the High Volume list should be ordered by Community Pharmacies in efficient quantities. Efficient quantities are:

- for products which are not refrigerated, Shelf Packs of each product with aggregate minimum value of at least \$15.00 ex manufacturer or, where there is no Shelf Pack, Units with an aggregate minimum value of \$15.00 ex-manufacturer; and,
- for products which must be stored in refrigerated conditions, Shelf Packs of one or more products with an aggregate minimum value of at least \$150 ex manufacturer or, where there is no Shelf Pack, Units with an aggregate minimum value of at least \$150 ex-manufacturer.

An additional fee may be charged by CSO Distributors for orders of High Volume PBS Medicines which are below the Minimum Order Quantity. An additional fee may also be charged if the Community Pharmacy requires delivery faster than the Guaranteed Supply Period set out in the Deed.

These additional fees do not require the approval of the CSO Administration Agency, but must be a reasonable and a genuine cost to the CSO Distributor.

It should be noted that clause 4.19 of Schedule 1 of the Deed specifies that CSO Distributors cannot charge these additional fees *“until the Company and the Commonwealth have agreed the form and quantity of product for the purpose of the definition of “Shelf Pack” in clause 1.1 in this Schedule”*. As the “Shelf Pack” definition has not yet been agreed, CSO Distributors are currently not able to charge these fees.



## 2. Compliance Requirements and Service Standards

### Requirement to Supply any Brand of CSO Product within the Guaranteed Supply Period

#### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

##### Requirement for timely Supply

- 4.30 The Company must Supply any Brand of PBS Medicine to any Community Pharmacy within their CSO Jurisdiction and any NDSS Product to any Access Point within their CSO Jurisdiction within the Guaranteed Supply Period, unless:
- 4.30.1 the Distribution Point specifies otherwise; or
  - 4.30.2 the location of the Distribution Point is on the list of locations provided by the Commonwealth at Annexure A of Schedule 1 that falls outside the requirement to Supply CSO Product within the Guaranteed Supply Period; or
  - 4.30.3 the Company is unable to meet this Service Standard due to a Force Majeure Event, subject to the Company's compliance with clauses 4.32 and 4.33 of this Schedule.
- 4.31 Where the Guaranteed Supply Period for a PBS Medicine on the High Volume List is 72 hours, the Company must Supply any Brand of that PBS Medicine within 24 hours or 48 hours if requested by a Community Pharmacy. If a Community Pharmacy requests and the Company agrees to Supply any PBS Medicines quicker than the Guaranteed Supply Period then, in addition to any other charge provided for under this Deed, the Company may charge an additional amount deemed appropriate by the Company at their discretion for the further service requirement. Such charges do not require the approval of the CSO Administration Agency but must be notified to the CSO Administration Agency.
- 4.32 If the Company is unable to undertake its Obligations under this Deed due to a Force Majeure Event:
- 4.32.1 that Company must promptly give the CSO Administration Agency written notice of that fact, including:
    - (a) full particulars of the Force Majeure Event;
    - (b) an estimate of its likely duration;
    - (c) the Obligations affected by the Force Majeure Event and the extent of its effect on those Obligations; and
    - (d) the steps taken and to be taken to rectify it; and
  - 4.32.2 if, in the CSO Administration Agency's reasonable opinion, the written explanation is reasonable and sufficient (including because the CSO Administration Agency considers that the impacted Obligations would still not have been able to be performed even when or if the Company implemented its Business Continuity Plan), a Non-Performance will not be recorded by the CSO Administration Agency.
- 4.33 The Company upon claiming a Force Majeure Event must remove, overcome or minimise the impact of that Force Majeure Event on its operations and the performance of Obligations as quickly as possible.
- 4.34 If a Force Majeure Event that affects the Company's distribution centre, continues for more than 30 Days, either party to this Deed may immediately terminate this Deed by written notice to the other. If the Commonwealth exercises its Right under this clause, it will not be liable for compensation for termination.

## 2. Compliance Requirements and Service Standards

### Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND CSO SERVICE STANDARDS

- 4.35 The Company must develop and maintain a Business Continuity Plan that complies with the requirements at Schedule 8 to mitigate any failure to Supply to Distribution Points within the Guaranteed Supply Period.
- 4.36 A day on which the Distribution Point is closed for business, such as a Sunday or Public Holiday, will not count towards the Guaranteed Supply Period.
- 4.37 The CSO Administration Agency and/or the Commonwealth have the right, by notice in writing, to amend Annexure A of this Schedule.
- 4.38 The Company must make available a Daily delivery service to any Distribution Point within its CSO Jurisdiction as part of their standard service delivery Infrastructure, except where and to the extent:
- 4.38.1 particular Distribution Points within the Company's CSO Jurisdiction have identified that they do not need a Daily delivery service, or do not need all of their orders filled within the Guaranteed Supply Period;
  - 4.38.2 the Company's failure to meet this CSO Service Standard is a result of a Force Majeure Event and the explanation has been accepted by the CSO Administration Agency under clause 4.32.2, in which case, clauses 4.33 and 4.34 apply; or
  - 4.38.3 the Distribution Point does not have the capacity to receive deliveries on a particular Business Day.
- 4.39 The Company must provide an explanation to the CSO Administration Agency as to why it failed to make a Daily delivery service available to any Distribution Point within its CSO Jurisdiction. If, in the CSO Administration Agency's reasonable opinion, the explanation is reasonable and sufficient, a Non-Performance will not be recorded.
- 4.40 The Company may make available alternative delivery services to any Distribution Point within its CSO Jurisdiction than those specified in clause 4.38, on request by that Distribution Point. If the Company does so, in addition to any other charge provided for under this Deed the Company may charge that Distribution Point an additional amount deemed appropriate by the Company at their discretion for the increased service requirement. Such charges do not require the approval of the CSO Administration Agency.

### How to meet this Service Standard

Under the Deed, a CSO Distributor must Supply any Brand of any CSO Product to any Distribution Point within its CSO Jurisdiction within the Guaranteed Supply Period (72 hours from the Regular Order Cut Off Time for PBS Medicines on the High Volume List, and 24 hours from the Regular Order Cut Off Time for other PBS Medicines and for all NDSS Products). This CSO Service Standard must be met unless:

1. The Distribution Point specifies otherwise through the provision of a timely supply waiver;
2. The location (postcode) of the Distribution Point falls outside of the requirement to supply within the Guaranteed Supply Period; or
3. The CSO Distributor is unable to meet this Service Standard due to a Force Majeure Event.

A CSO Distributor can choose the form and content of a timely supply waiver to be agreed with the Distribution Point. However, the waiver must be in written form and must, at a minimum, explain/state the following:

- The CSO Distributor's timely supply obligations under the CSO

## 2. Compliance Requirements and Service Standards

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- The customer does not require this obligation to be met
- The customer can withdraw from this agreement at any time.

A timely supply waiver can be for a specific order or time period, or be ongoing.

A Regular Order Cut Off Time is the specified time agreed between the CSO Distributor and a Distribution Point by which orders must be lodged with the CSO Distributor. Orders received after the Regular Order Cut Off Time are considered to be received on the next Business Day.

Business Day means, in relation to the doing of action in a place, any day other than a Saturday, Sunday, or Public Holiday in that place.

### **Guaranteed Supply Period requirement - exempt postcodes**

The Deed distinguishes postcodes that fall outside of the requirement to Supply CSO Products within 72 hours / 24 hours from the Regular Order Cut Off Time, as applicable. However, under the Deed, the CSO Distributors must make all reasonable efforts to supply CSO Products within the Guaranteed Supply Period to these locations.

Postcodes that fall outside the 72 hour / 24 hour delivery requirement are listed at *Appendix B*.

## 2. Compliance Requirements and Service Standards

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### Force Majeure Event

A CSO Distributor's Obligations under this Service Standard may temporarily not be required to be met, if its failure to Supply within the Guaranteed Supply Period is due to a Force Majeure Event.

Under the Deed, a Force Majeure Event means any of the following events:

- (a) *"fire, flood, earthquake, pandemic, other natural disaster or other Act of God;*
- (b) *war or other state of armed hostilities; or*
- (c) *an emergency, that in the Commonwealth's reasonable opinion, is a national disaster or critical emergency affecting a region in which an Obligation must be performed."*

A CSO Distributor must promptly provide the CSO Administration Agency with a written notice that they are unable to meet their Obligations under the Deed due to a Force Majeure Event, and this notice should include:

- full particulars of the Force Majeure Event;
- an estimate of its likely duration;
- the Obligations affected by the Force Majeure Event and the likely extent of its effect on those Obligations; and
- the steps taken or to be taken to rectify it.

If in the CSO Administration Agency's reasonable opinion, the written explanation for non-performance due to the Force Majeure Event is reasonable and sufficient (including because the CSO Administration Agency considers that the impacted Obligations would still not have been able to be performed even when or if the Company implemented its Business Continuity Plan), a Non-Performance will not be recorded by the CSO Administration Agency.

The CSO Distributor claiming a Force Majeure Event must remove, overcome or minimise the impact of the Event on its operations and the performance of its Obligations as quickly as possible.

If a Force Majeure Event that affects a CSO Distributor's distribution centre, continues for more than 30 days, either party to the Deed may terminate the Deed by written notice to the other party. If the Commonwealth exercises its right to termination under this clause in the Deed, it will not be liable for compensation for termination.

To mitigate the effects of failing to Supply a Distribution Point within the Guaranteed Supply Period, CSO Distributors must develop, test and maintain an up-to-date Business Continuity Plan. The Business Continuity Plan must include practical activities and/or mitigating actions that will be undertaken by the CSO Distributor to continue to meet their Obligations under the Deed, when a Force Majeure Event occurs.

The Business Continuity Plan must comply with the Australian Standard 'AS/NZS 5050:2010 Business Continuity – Managing disruption-related risk' or any other format reasonable requested by the CSO Administration Agency.

## 2. Compliance Requirements and Service Standards

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### Daily Delivery Service

CSO Distributors must make available a Daily delivery service to any Distribution Point within their CSO Jurisdiction as part of their standard service delivery Infrastructure. Daily is defined in the Deed as:

*"any Business Day and also on Saturdays where a Company offers a Saturday delivery"*

The only exceptions to this CSO Service Standard are where:

1. particular Distribution Points within the CSO Distributor's CSO Jurisdiction identify that they do not need a Daily delivery service, or do not need all of their orders filled within the Guaranteed Supply Period; or
2. the CSO Distributor's failure to meet this Service Standard is a result of a Force Majeure Event.

The CSO Distributor must provide an explanation to the CSO Administration Agency as to why it failed to make a Daily delivery service available to any Distribution Point within its jurisdiction. If in the CSO Administration Agency's reasonable opinion, the explanation is reasonable and sufficient, a Non-Performance will not be recorded.

## 3. Declaration and Exception Reports

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### 3 DECLARATION AND EXCEPTION REPORTS

The CSO Administration Agency is required to monitor the performance of CSO Distributors through the analysis and investigation of Data and Declaration and Exception Reports (**DERs**), submitted Monthly and quarterly by CSO Distributors.

The DERs are tools through which CSO Distributors can demonstrate and declare their compliance with their Deed and also provide evidence for supporting claims for Payment from the CSO Funding Pool on a Monthly basis. The CSO Administration Agency uses the information in the DERs to assess whether CSO Distributors are meeting their Obligations.

#### ***Requirements to provide Data and reports***

Schedule 3 of the Deed specifies the Data and the reports that CSO Distributors are required to submit to the CSO Administration Agency. Schedule 3 requires CSO Distributors to provide:

- Data and Reports required for CSO Payments and Payments in respect of NDSS Distribution Services (*clause 1*);
- Data and Reports required for monitoring CSO Service Standards (*clause 2*); and
- Other Data and Reports (*clause 3*).

#### **Monitoring of CSO Obligations**

Clause 2 of Schedule 3 requires CSO Distributors to submit Monthly reports to the CSO Administration Agency regarding their compliance with the CSO Service Standards and other Obligations "using a standard format to be specified". The DER is this standard format. On an ongoing basis, CSO Distributors must complete and submit Monthly DERs to the CSO Administration Agency.

In completing the DERs, CSO Distributors must report any non-compliance with the Obligations under the Deed. For any material non-compliance, this should include a detailed report including background, causes and responses and impacts of the non-compliance. A summary report is sufficient for minor non-compliances.

If a CSO Distributor submits a DER which indicates non-compliance with an Obligation, the CSO Administration Agency will investigate and consider all information to determine the appropriate course of action and response. The DERs provide CSO Distributors with an opportunity to explain the reasons for any non-compliance and to provide additional information.

The DERs also provide a useful checklist to assist CSO Distributors to ensure they are meeting their Obligations under the Deed. CSO Distributors are encouraged to fully and diligently assess their organisation's compliance with each Obligation, prior to submitting each report. Failure to report any non-compliance may result in Sanctions and/or Payment Adjustments being applied.

#### **Monthly DER**

The Monthly DER requires CSO Distributors to confirm their compliance, or advice of any non-compliance, with the following Obligations under the Deed:

- Data and reports (*clauses 10, 13 and Schedule 3*) – submitting accurate and complete Data and reports within the required timeframe and required format, not editing, selecting or otherwise manipulating its Data and reports and submitting all Data and reports requested by the CSO Administration Agency;

### 3. Declaration and Exception Reports

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- CSO Compliance Requirements (*clause 3 of Schedule 1*);
- CSO Service Standards (*clause 4 of Schedule 1*);
- Notification requirements (*clause 8*) – CSO Distributors must notify the CSO Administration Agency of any Exclusive Supply Arrangements, bad debtors, CSO Products that were out of stock or could not be supplied by the Manufacturer, details of any Non-Performances notified to the CSO Administration Agency and any other event or circumstance that the CSO Distributor considers relevant to the proper administration of the CSO Funding Pool or of the NDSS Distribution Services; and
- Subcontractor requirement (*clause 19*) - CSO Distributors must advise the CSO Administration Agency if they commence supplying through a new arrangement or alter an existing arrangement involving subcontractors or other third parties.

The Monthly DER format is straightforward, with CSO Distributors simply confirming either “YES” or “NO” to whether they have met each Obligation. CSO Distributors are only required to provide additional information where they have failed to meet an Obligation, or when new or updated State or Territory licences have been obtained.

In completing the Monthly DER, CSO Distributors must report any non-compliance with their Deed. For material non-compliances, CSO Distributors must provide additional information on the background, reasons for non-compliance, their response to the non-compliance and the impacts that the non-compliance may have on the CSO. For minor non-compliances, a less detailed summary is sufficient. As part of the CSO Administration Agency’s monitoring role, if a CSO Distributor submits a DER that indicates non-compliance, the CSO Administration Agency will investigate and consider all facts to determine the appropriate course of action and response.

#### Quarterly DER

In addition to the Monthly DER, CSO Distributors are required to submit a Quarterly DER. The Quarterly DER addresses compliance with the following Obligations:

- Plans, including Business Plans, Remedial Business Plans and/or Business Continuity Plans developed in accordance with the requirements in Schedule 1, 5, 7 and/or 8 (where applicable);
- Audits and Records (*clause 16*);
- Conflict of Interest (*clause 20*);
- Confidentiality (*clause 21*);
- Privacy (*clause 22*);
- Workplace Gender Equality (*clause 5*);
- Security (*clause 5*); and
- Aboriginal and Torres Strait Islander Opportunities (*clause 5*).

## 3. Declaration and Exception Reports

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### **Frequently asked questions**

The following frequently asked questions are provided to explain the Monthly and Quarterly DERs.

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#### **1. Why do CSO Distributors have to submit Declaration and Exception Reports (DERs)?**

The requirement to submit DERs is an Obligation under the Deed.

Clause 2.1 of Schedule 3 requires CSO Distributors to:

*'submit Monthly Reports to the CSO Administration Agency against all the Obligations under this Deed using a standard format to be specified. This must be provided at the same time, and together with, the Data referred to in clause 1 of this Schedule.'*

The DER is the standard format for this reporting. The DERs also address compliance with other CSO Obligations under the Deed, such as notification requirements, and therefore provide a useful checklist to assist CSO Distributors in meeting their Obligations under the Deed.

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#### **2. When does a CSO Distributor need to submit the DER?**

The Monthly DER should be submitted to the CSO Administration Agency electronically within five Business Days of the end of each month to which the report relates (at the same time as the CSO Distributor submits its Data).

The Quarterly DER should be submitted by the last Business Day of the quarter to which it relates. Quarterly DERs are due at the end of January, April, July and October each Year.

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#### **3. What happens if a CSO Distributor reports non-compliance in the DER?**

CSO Distributors should report any non-compliance with any of their Obligations under the Deed in the DER, providing a detailed report for material non-compliances and a summary report for minor non-compliances. If a CSO Distributor submits a DER which indicates non-compliance with an Obligation, the CSO Administration Agency will investigate and consider all facts to determine the appropriate course of action and response. The DERs provide CSO Distributors with an opportunity to explain the reasons for any non-compliance and to provide any additional information.

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#### **4. Can a CSO Distributor charge a price which is above the CSO Price, if it offers a discount which reduces the actual price to at or below the CSO Price?**

Any product which is claimable under the CSO must be supplied by CSO Distributors at or below the CSO Price to Community Pharmacies. This must be independent of any discounts that may also be applicable, i.e. must not be conditional on achieving discounts or incentives. For example, pricing must be at or below the CSO Price before any conditional settlement or volume discounts are applied to an invoice.

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#### **5. What constitutes 'bad debtors' for the Monthly DER?**

CSO Distributors are required to notify the CSO Administration Agency Monthly, in their DER of "any bad debtor that the CSO Distributor will not be supplying CSO Products to" (clause 8.3.1). CSO



### 3. Declaration and Exception Reports

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Distributors should notify the CSO Administration Agency where there has been 5 days or more of non-Supply to that Distribution Point during the Month, due to it being a bad debtor.

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#### 6. What constitutes 'cannot Supply' for notification requirement in the Monthly DER?

CSO Distributors are required to notify the CSO Administration Agency Monthly, in their DER, of *"any CSO Product that the Company cannot Supply because the CSO Product is out-of-stock or cannot be Supplied by the Manufacturer"* (clause 8.3.2). Reporting against this requirement is to be provided as part of reporting against the requirement to deliver within the Guaranteed Supply Period. CSO Distributors are required to advise of all instances in which a CSO Product was not Supplied within the Guaranteed Supply Period, unless specified otherwise by a Community Pharmacy (see next FAQ for additional details).

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#### 7. What constitutes failure to meet the Guaranteed Supply Period reporting requirement in the Monthly DER?

CSO Distributors are required to deliver every CSO Product, within the Guaranteed Supply Period, unless either: 1) the postcode the Distribution Point is located in is exempt from this requirement; 2) the Distribution Point has specified otherwise; or 3) a Force Majeure Event applies.

Where the Guaranteed Supply Period for a PBS Medicine on the High Volume List is 72 hours, the CSO Distributor must Supply any Brand of that PBS Medicine within 24 hours or 48 hours if requested by a Community Pharmacy. If a Community Pharmacy requests and the CSO Distributor agrees to Supply any PBS Medicines quicker than the Guaranteed Supply Period then, in addition to any other charge provided for under the Deed, the CSO Distributor may charge an additional amount deemed appropriate by the CSO Distributor at their discretion for the increased service requirement. Such charges do not require the approval of the CSO Administration Agency, but must be notified to the CSO Administration Agency.

If during the period of reporting covered by the Monthly DER, the CSO Distributor has been advised by a Distribution Point that it does not require an order to be supplied within the Guaranteed Supply Period, then data on these instances must be reported in the Monthly DER.

CSO Distributors should report in their DER **each CSO Product** that they did not deliver within 72 hours from the Regular Order Cut Off Time (for PBS Medicines on the High Volume List or 24 hours from the Regular Order Cut Off Time (for all other CSO Products). This includes where the Manufacturer was out of stock or unable to Supply a particular CSO Product as well as the CSO Distributor being otherwise unable to provide the CSO Product within the Guaranteed Supply Period.

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#### 8. If a Distribution Point specifies that it does not require an order to be supplied within the Guaranteed Supply Period via an agreement with the CSO Distributor (timely supply waiver), what are the minimum requirements for a waiver?

CSO Distributors can choose the form and content of waivers, providing they comply with the following minimum requirements.

### 3. Declaration and Exception Reports

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Timely supply waivers must be in writing and must explain/state:

- The CSO Distributor's timely supply obligations under the CSO
- The customer does not require this obligation to be met
- The customer can withdraw from this agreement at any time.

A waiver can be for a specific order or time period, or be ongoing. As an example, the following waiver would comply.

**[CSOD name] delivery agreement**

I ...(name and position in pharmacy)

Of ...(pharmacy name)

**Understand** that under the CSO arrangements, [CSO Distributor] is required to deliver all orders within the Guaranteed Supply Period, which is:

- 72 hours from Regular Order Cut Off Time for High Volume PBS Medicines \*
- 24 hours from Regular Order Cut Off Time for all other PBS Medicines and for all NDSS Products.

**Hereby agree** that I do not require delivery within the Guaranteed Supply Period. I understand that I can withdraw from this agreement at any time by giving written notice to [CSO Distributor].

Signature ...

Date ...

\* List of High Volume PBS Medicines is published at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>

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#### 9. If nothing had previously been reported to the CSO Administration Agency in the Monthly DER because there was nothing to report, should CSO Distributors tick the 'yes' or 'no' box?

For each Obligation, CSO Distributors are asked to tick a 'yes' or 'no' box. For most Obligations, a 'yes' tick indicates compliance with the requirement, **which includes instances where there is nothing to report.**

For example a 'yes' tick would be appropriate for timely supply if the CSO Distributor had no failures to report.

## 4. Non-Performance and Sanctions

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### 4 NON-PERFORMANCE AND SANCTIONS

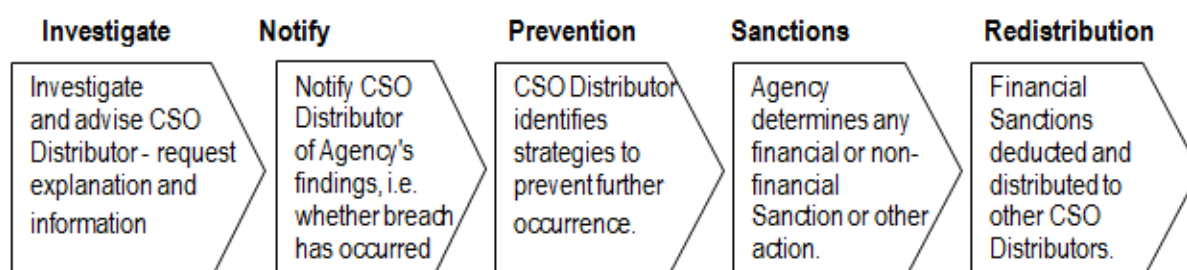
#### **Overview of Non-Performance and Sanctions process**

Non-Performance by a CSO Distributor is defined in the Deed as:

*“non-performance means a non-performance by the Company of any Obligation under this Deed, including non-compliance with the CSO Compliance Requirements and the CSO Service Standards.”*

The CSO Administration Agency monitors the performance of CSO Distributors against their Obligations by undertaking activities including Data analysis, auditing, reviewing DERs, investigating complaints and assessing progress against Business Plans, where these are in place.

Any potential or apparent Non-Performance identified will be investigated. The key steps are as follows, but these steps may vary depending on the particular circumstances:



Investigate	The CSO Administration Agency will investigate the matter. The CSO Distributor will be advised that the CSO Administration Agency has identified a potential Non-Performance or received a complaint and will be given the opportunity to explain and provide further information.
Notify	The CSO Distributor will be formally notified of the outcome of the CSO Administration Agency's investigation, i.e. whether the CSO Distributor did not meet its Obligations under the Deed, and whether a Non-Performance has occurred. CSO Distributors will have the opportunity to respond to this notification prior to any Sanctions being determined.
Prevention	Where a Non-Performance is confirmed, the CSO Distributor may be asked to identify strategies to prevent future occurrences. The CSO Administration Agency may also direct the CSO Distributor to undertake remedial action, e.g. develop or update a Business Plan.
Sanctions	Following consideration of all circumstances, the CSO Administration Agency will then determine the classification of the Non-Performance as either Major or Minor. The CSO Administration Agency will also determine whether a financial or non-financial Sanction and/or other action (for example, the submission of a Business Plan) is to be applied, and will advise the CSO Distributor accordingly. If the CSO Distributor is dissatisfied with the action taken by the CSO Administration Agency, the CSO Distributor may lodge a complaint with the CSO Administration Agency. The CSO Complaints Procedure will then be followed (see Chapter 5 of these Guidelines), i.e. an investigation conducted and the CSO Distributor advised of the outcome. If a CSO Distributor is not satisfied with the outcome of their complaint, under the Complaints Procedure, the CSO Distributor may then refer their complaint in writing to the

## 4. Non-Performance and Sanctions

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Commonwealth's Authorised Officer or the Commonwealth's nominee, within 28 days after receiving notification from the CSO Administration Agency.

**Redistribution** Any financial Sanctions will be deducted from the CSO Distributor's Payment for the relevant Month or Months, and transferred to a separate National or State Sanction Pool. The financial Sanctions money will then be distributed amongst the other CSO Distributors in the next applicable Payment period.

*Note: An exception is if financial Sanctions are applied to all National CSO Distributors in a month, the CSO Administration Agency may determine that this amount will be:*

- *permanently removed from the National CSO Funding Pool for that Year; or*
- *withheld until such time as the CSO Administration Agency determines that the National CSO Distributors have rectified the Non-Performance issue to the satisfaction of the CSO Administration Agency.*

### **Non-Performance**

The Deed differentiates between Major and Minor Non-Performances for any Obligation under this Deed, including but not limited to compliance with the CSO Compliance Requirements and Service Standards. The Deed provides the following definitions:

- **Major Non-Performance** means:
  - a Non-Performance; or
  - a series of related Minor Non-Performances,

*that, in the reasonable opinion of the CSO Administration Agency, impacts the key objectives of the CSO Funding Pool or the NDSS.*
- **Minor Non-Performance** means a Non-Performance that, in the reasonable opinion of the CSO Administration Agency, is unlikely to directly impact on the objectives of the CSO Funding Pool or NDSS on its own.

For example, a Major Non-Performance means a Non-Performance that impacts the key objectives of the CSO Funding Pool or the NDSS with consideration of the application of a financial Sanction by the CSO Administration Agency.

For example, a Minor Non-Performance means a lesser Non-Performance that is unlikely to directly impact on the CSO or NDSS key objectives on its own and may not warrant a Sanction, but would not preclude more than one successive or concurrent Minor Non-Performance resulting in a Major Non-Performance.

The CSO Administration Agency has discretion in determining whether administrative failings by CSO Distributors should be recorded as a Non-Performance. When making such a decision, the CSO Administration Agency will take into account whether the administrative failings are persistent and/or significant.

Given the broad range of potential CSO Distributor Non-Performances and the varying circumstances in which CSO Distributor Non-Performances may occur, the CSO Administration Agency will take a case-by-case approach when determining how to deal with CSO Distributor Non-Performances. A single Minor Non-Performance may not result in a Sanction, but is not precluded from contributing to a Major Non-Performance.

## 4. Non-Performance and Sanctions

The following table provides broad guidance about the types of Non-Performance that are likely to be determined as Minor and those that are likely to be determined as Major. The table provides guidance in relation to each CSO Compliance Requirement and Service Standard and certain other Obligations, but does not address all potential Non-Performances. The table provides broad guidance only.

The CSO Administration Agency retains discretion in determining whether a Non-Performance is Major or Minor, based on consideration of the particular circumstances and outcomes involved. For example, the determination may vary from the table if there are:

- exceptional or extenuating circumstances, such as a Force Majeure Event; and/or
- potentially serious adverse outcomes for a patient/consumer, as a consequence of the Non-Performance.

### Compliance Requirements and Service Standards

Obligation	Minor Non-Performance	Major Non-Performances
CR1 – Provide a single entry point for Distribution Points	-	All Non-Performances in relation to this requirement.
CR2 – Maintain access to established infrastructure and sufficient financial capacity	-	All Non-Performances in relation to this requirement.
CR3 – Maintain the Quality of CSO Products	Non-Performance (including failure to comply with the Code of Good Wholesaling Practice) which is non-systemic or isolated and which does not negatively impact the quality or safety of the CSO Products supplied.	Non-Performance (including failure to comply with the Code of Good Wholesaling Practice) which represents a systematic or ongoing issue or which negatively impacts on the quality or safety of the CSO Products supplied.
SS1 – Supply to any Distribution Point	Non-Performance which is non-systemic or isolated and which relates to a temporary or one-off circumstance.	Non-Performance which is part of a systemic or ongoing failure to meet this requirement.
SS2 – Supply to any Rural and Remote Pharmacy (and meet Rural/Remote Threshold)	-	Any failure to meet the Rural/Remote Threshold.
SS3 – Supply any Brand of CSO Product	Non-Performance which is non-systemic or isolated and which relates to a temporary or one-off circumstance.	Non-Performance which is part of a systemic or ongoing failure to meet this requirement.
SS4 – Stocking requirement for PBS Medicines	Non Performance where 20 or less PBS Medicines are not stocked in	Non Performance where more than 20 PBS Medicines are not stocked in

## 4. Non-Performance and Sanctions

Obligation	Minor Non-Performance	Major Non-Performances
	accordance with this requirement during a Month.	accordance with this requirement during a Month.
SS4 – Stocking requirement for NDSS Products	Non Performance where 10 or less NDSS Products are not stocked in accordance with this requirement during a Month.	Non Performance where more than 10 NDSS Products are not stocked in accordance with this requirement during a Month.
SS5 – Supply any Low Volume PBS Medicine (and meet Low Volume Threshold)	-	Any failure to meet the Low Volume Threshold.
SS6 – Supply any PBS Medicine at or below the relevant CSO Price	Non-Performance which is non-systemic or isolated and which relates to a temporary or one-off circumstance.	Non-Performance which is part of a systemic or ongoing failure to meet this requirement.
SS7 – Supply any NDSS Product at no cost to Access Points	Non-Performance which is non-systemic or isolated and which relates to a temporary or one-off circumstance.	Non-Performance which is part of a systemic or ongoing failure to meet this requirement.
SS8 – Not Impose Prohibited Financial Imposts on Distribution Points	Non-Performance which is non-systemic or isolated and which relates to a temporary or one-off circumstance.	Non-Performance which is part of a systemic or ongoing failure to meet this requirement.
SS9 – Timely Supply (delivery within 72/24 hours)	Non-Performance which is non-systemic or isolated and which relates to a temporary or one-off circumstance.	Non-Performance which is part of a systemic or ongoing failure to meet this requirement for a given Community Pharmacy, postcode or region.
SS9 – Timely Supply (make available a Daily delivery service)	-	Any failure to make available a Daily delivery service.

### Other Requirements and Obligations

Obligation	Minor Non-Performance	Major Non-Performances
Providing Timely and Accurate data (clauses 10.3 and 10.5) – Timeliness	Non-Performance relating to the timeliness of information/data which does not significantly impact upon the CSO Administration Agency's ability to effectively and efficiently administer the CSO Funding Pool or the NDSS Distribution Services and does not result in a significant and/or unreasonable	Non-Performance relating to the timeliness of information/data which significantly impacts upon the CSO Administration Agency's ability to effectively and efficiently administer the CSO Funding Pool or the NDSS Distribution Services or results in a significant and/or unreasonable

## 4. Non-Performance and Sanctions

Obligation	Minor Non-Performance	Major Non-Performances
	financial impact on other CSO Distributors.	financial impact on other CSO Distributors.
Providing Timely and Accurate data (clause 10.2) - Accuracy	Non-Performance relating to the accuracy of information/data which does not significantly impact upon the CSO Administration Agency's ability to effectively and efficiently administer the CSO Funding Pool or the NDSS Distribution Services and does not result in a significant and/or unreasonable financial impact on other CSO Distributors.	Non-Performance relating to the accuracy of information/data which significantly impacts upon the CSO Administration Agency's ability to effectively and efficiently administer the CSO Funding Pool or the NDSS Distribution Services or results in a significant and/or unreasonable financial impact on other CSO Distributors.
Business Plans (clause 5.1.2)	-	Any failure to meet a Business Plan milestone or KPI.
Notification Requirements (clause 8)	Non-Performance which does not significantly impact upon the CSO Administration Agency's ability to effectively or efficiently administer the CSO Funding Pool or the NDSS Distribution Services (including adequately monitoring CSO Distributors' performance) and which does not result in a significant and/or unreasonable financial impact on other CSO Distributors.	Non-Performance which significantly impacts upon the CSO Administration Agency's ability to effectively or efficiently administer the CSO Funding Pool or the NDSS Distribution Services (including adequately monitoring CSO Distributors' performance) or in a significant and/or unreasonable financial impact on other CSO Distributors.

## 4. Non-Performance and Sanctions

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### Explanation and strategies to prevent further occurrence

#### Extract from Schedule 5 - SANCTIONS

- 3.7 For the duration of the Term, CSO Distributors will be notified in writing by the CSO Administration Agency of any Non-Performance of their Obligations under this Deed and may be required to produce a statement explaining the reason/s for any identified failures and, if requested by the CSO Administration Agency, the strategy to be adopted to prevent further occurrences. The CSO Administration Agency is not obliged to seek from the Company reason/s for any identified failures or a strategy to be adopted to prevent further occurrences prior to applying a Sanction in respect of such identified failures.
- 3.8 The CSO Administration Agency may take into account any reasons and information provided by the Company, in response to this written notification, and on this basis, may deem that:
- 3.8.1 Non-Performance has not occurred and Sanctions will not apply;
  - 3.8.2 a Minor Non-Performance has occurred;
  - 3.8.3 a Major Non-Performance or a Minor Non-Performance has occurred but Sanctions will not apply; or
  - 3.8.4 a Major Non-Performance has occurred and Sanctions will apply.

As outlined in the Deed, the CSO Administration Agency will notify CSO Distributors of any potential Non-Performance and may request an explanation and further information. The provision of an explanation and strategy to prevent future similar Non-Performances will not exclude a Minor Non-Performance or Major Non-Performance from being recorded, nor will it exclude either a financial or non-financial Sanction being applied.

Where a Non-Performance is confirmed, the CSO Distributor will be formally notified and may be asked to provide details of the strategy it will implement to prevent future Non-Performance/s. The CSO Administration Agency may require the CSO Distributor to submit, comply with and report against a Business Plan that specifies the timeframe, measurable milestones and activities that the CSO Distributor will undertake to rectify the Non-Performance/s. The CSO Administration Agency may also require other remedial action by the CSO Distributor, such as financial restitution to Distribution Points where overcharging has occurred.

### Sanctions

#### Extract from Schedule 5 - SANCTIONS

- 3.9 The CSO Administration Agency has the sole discretion in determining the Sanctions to be applied. However, in the event that the Company is dissatisfied with this determination, the Company may refer this determination, in writing, to the Commonwealth's Authorised Officer or the Commonwealth's nominee. The decision made by the Commonwealth's Authorised Officer or nominee will be final and binding.

#### Extract from clause 14 - SANCTIONS

- 14.2 Where, in the CSO Administration Agency's view, the Company has failed to meet any of its Obligations under this Deed, including one or more of:



## 4. Non-Performance and Sanctions

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- 14.2.1 complying with clause 6 or the Remedial Business Plan approved by the CSO Administration Agency for the purposes of that clause;
- 14.2.2 meeting the CSO Compliance Requirements and/or the CSO Service Standards (including the applicable Thresholds for Sales to Rural and Remote Pharmacies and/or Sales of Low Volume PBS Medicines);
- 14.2.3 submitting Data and Reports in accordance with Schedule 3; and
- 14.2.4 meeting the timeframes, milestones and activities outlined in any Remedial Business Plan,

and the Non-Performance represents a Major Non-Performance, the CSO Administration Agency may apply financial or non-financial Sanctions. If the CSO Administration Agency considers it necessary to impose a financial Sanction for a Major Non-Performance, the financial Sanction provisions in Schedule 5 will be used.

- 14.3 If the CSO Administration Agency was to consider that the Company's Non-Performance was such as to warrant exclusion from the CSO Funding Pool or the NDSS, then it may recommend to the Commonwealth that the Commonwealth Terminate this Deed in accordance with clause 26.4.
- 14.4 The CSO Administration Agency will notify the Company and (in respect of any Sanctions applicable to NDSS Distribution Services, the NDSS Administrator), in writing, of any decision to apply the Sanctions, in accordance with Schedule 5, and the Month or Months to which the Sanctions apply.

As detailed in the Deed, the CSO Administration Agency has the sole discretion in determining the Sanctions to be applied if a CSO Distributor is found not to have complied with any of its Obligations under its Deed.

Where a Non-Performance has occurred, the CSO Administration Agency may:

- not apply any Sanctions;
- apply non-financial Sanctions;
- apply financial Sanctions; or
- recommend to the Department that the CSO Distributor's Deed be terminated.

The application of Sanctions does not limit the remedies available to the CSO Administration Agency and does not exclude the CSO Administration Agency from also making a Payment adjustment.

### **Determination of Sanctions**

Predetermined values for financial Sanctions have not been defined by the CSO Administration Agency or in the Deed, as each Non-Performance is considered on a case-by-case basis. However, the Deed provides guidance on the application of Sanctions for a number of specific Non-Performance issues, including failure to meet any Obligation under the Deed including CSO Compliance Requirements or CSO Service Standards, delays in submitting Monthly CSO Data and other reports, or failure to notify the CSO Administration Agency of any Exclusive Supply Arrangements in which a CSO Distributor is participating.

Sanctions may include:

- the application of a non-financial Sanction;

## 4. Non-Performance and Sanctions

- the application of a financial Sanction;
- whole or part of the CSO Monthly Payment or Payment for NDSS Distribution Services withheld until the Non-Performance is remedied;
- a reduction in Payments for the Month or Months; or
- recommendation to the Department that the CSO Distributor's Deed be terminated.

In determining whether Sanctions or other remedies are to be applied to a CSO Distributor and the value of any financial Sanction, the CSO Administration Agency will consider all relevant information and circumstances. These include, but are not limited to:

- the extent of the Non-Performance/s of Obligations under the Deed;
- the level of cooperation and assistance of the CSO Distributor in the investigation;
- the CSO Distributor's performance history;
- the scale and impact of the Non-Performance;
- any remedial action taken or planned by the CSO Distributor;
- the CSO Operational Guidelines, as amended from time to time; and
- any extenuating circumstances or other considerations, including any effects and consequences arising from a Force Majeure Event.

The Deed specifies how the CSO Administration Agency may apply Sanctions for Non-Performance issues, as follows.

### Extract from Schedule 5 – SANCTIONS

Non-Performance issue	Sanction	Remedial Obligations
7.1 Failure to meet any single CSO Compliance Requirement.	<p>The CSO Administration Agency may, after giving consideration to the extent and reasons for the Non-Performance, the Company's performance history and the CSO Operational Guidelines:</p> <ul style="list-style-type: none"><li>• decide not to apply any Sanctions.</li><li>• withhold, or determine that the NDSS Administrator should withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied to the satisfaction of the CSO Administration Agency;</li><li>• determine that no Payment will be made, or that only part Payment will be made, to the Company for the Month or Months from the commencement of the Non-Performance until the Non-Performance is remedied to the</li></ul>	<p>After notification, where directed to do so by the CSO Administration Agency, the Company must submit a written statement with information explaining the Non-Performance and the strategy to be adopted to prevent further occurrences.</p> <p>The CSO Administration Agency may require the Company to submit a formal Remedial Business Plan that specifies a timeframe, measurable milestones, and activities that the Company will undertake to rectify the Non-Performances. When approved by the CSO Administration Agency, this Remedial Business Plan will be deemed to be included in this Deed.</p>

## 4. Non-Performance and Sanctions

Non-Performance issue	Sanction	Remedial Obligations
	<p>satisfaction of the CSO Administration Agency and that such amounts not paid will be permanently forfeited by the Company; or</p> <ul style="list-style-type: none"> <li>recommend to the Commonwealth that this Deed be Terminated.</li> </ul>	
8.1 Failure to meet any single CSO Service Standard	<p>The CSO Administration Agency may, after giving consideration to the extent and reasons for the Non-Performance, the Company's performance history and the CSO Operational Guidelines:</p> <ul style="list-style-type: none"> <li>decide not to apply any Sanctions.</li> <li>withhold, or determine that the NDSS Administrator should withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied to the satisfaction of the CSO Administration Agency;</li> <li>determine that no Payment will be made, or that only part Payment will be made, to the Company for the Month or Months from the commencement of the Non-Performance until the Non-Performance is remedied to the satisfaction of the CSO Administration Agency and that such amounts not paid will be permanently forfeited by the Company; or</li> <li>recommend to the Commonwealth that this Deed be Terminated.</li> </ul>	<p>After notification, where directed to do so by the CSO Administration Agency, the Company must submit a written statement to the CSO Administration Agency with information explaining the Non-Performance and the strategy to be adopted to prevent further occurrences.</p> <p>The CSO Administration Agency may require the Company to submit a formal Remedial Business Plan that specifies a timeframe, measurable milestones, and activities that the Company will undertake to rectify the Non-Performances. When approved by the CSO Administration Agency, this Remedial Business Plan will be deemed to be included in this Deed.</p>
9.1 Delay of up to 3 Business Days to submit required Monthly Data and/or Reports.	<p>The CSO Administration Agency may:</p> <ul style="list-style-type: none"> <li>decide not to apply any Sanctions;</li> <li>withhold, or determine that the NDSS Administrator will withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied to the satisfaction of the CSO Administration Agency; or</li> <li>reduce, or determine that the NDSS Administrator will reduce, the amount of a Payment by up to 10% for each Non-Performance and that such</li> </ul>	<p>The Company must provide written advice to the CSO Administration Agency as to the reason for the delay.</p>

## 4. Non-Performance and Sanctions

Non-Performance issue	Sanction	Remedial Obligations
	amounts not paid will be permanently forfeited by the Company.	
9.2 Delay of between 3 and 14 Business Days to submit required Monthly Data and/or Reports.	<p>The CSO Administration Agency may:</p> <ul style="list-style-type: none"> <li>• decide not to apply any Sanctions;</li> <li>• withhold, or determine that the NDSS Administrator will withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied to the satisfaction of the CSO Administration Agency; or</li> <li>• reduce, or determine that the NDSS Administrator will reduce the amount of a Payment by up to 20% for each Non-Performance and that such amounts not paid will be permanently forfeited by the Company.</li> </ul>	<p>After notification, where directed to do so by the CSO Administration Agency, the Company must submit a written statement to the CSO Administration Agency with information explaining the Non-Performance and the strategy to be adopted to prevent further occurrences.</p> <p>The CSO Administration Agency may require that the Company create a formal Remedial Business Plan for achieving on-time delivery of Data and/or Reports. When approved by the CSO Administration Agency, this Remedial Business Plan will be deemed to be included in this Deed.</p>
9.3 Delay of 15 or more Business Days to submit required Monthly Data and/or Reports.	<p>The CSO Administration Agency may reduce, or determine that the NDSS Administrator will reduce, all or part of the Payment by any amount it deems appropriate or determine that no or only part Payment will be made for that Month and that such amounts not paid will be permanently forfeited by the Company.</p> <p>If this occurs on 3 or more occasions in a 12 Month period then the CSO Administration Agency may recommend to the Commonwealth that this Deed be Terminated.</p>	<p>After notification, where directed to do so by the CSO Administration Agency, the Company must submit a written statement to the CSO Administration Agency with information explaining the Non-Performance and the strategy to be adopted to prevent further occurrences.</p>
9.4 Data and/or Reports are not provided in the required format and/or are incomplete, and/or have significant errors or inaccuracies.	<p>The CSO Administration Agency may:</p> <ul style="list-style-type: none"> <li>• decide not to apply any Sanctions;</li> <li>• withhold, or determine that the NDSS Administrator will withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied to the satisfaction of the CSO Administration Agency; or</li> <li>• reduce, or determine that the NDSS Administrator will reduce, the amount of the Payment for that Month by 10% for each Non-Performance that is not remedied to the satisfaction of the CSO Administration Agency within 2 Business Days and that such</li> </ul>	<p>The Company must re-submit the Data and/or Reports in the correct format to the CSO Administration Agency within 2 Business Days of notification by the CSO Administration Agency of the Non-Performance.</p>

## 4. Non-Performance and Sanctions

Non-Performance issue	Sanction	Remedial Obligations
	amounts not paid will be permanently forfeited by the Company.	
10.1 Failure of the Company to adhere to a Remedial Business Plan that has been developed to rectify another Non-Performance issue.	<p>The CSO Administration Agency may, after giving consideration to the extent and reasons for the Non-Performance, the Company's performance history and the CSO Operational Guidelines:</p> <ul style="list-style-type: none"> <li>• decide not to apply any Sanctions.</li> <li>• withhold, or determine that the NDSS Administrator will withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied to the satisfaction of the CSO Administration Agency;</li> <li>• determine that no Payment (or that only part Payment) will be made to the Company for the Month or Months from the commencement of the Non-Performance until the Non-Performance is remedied and that such amounts not paid will be permanently forfeited by the Company; or</li> <li>• recommend to the Commonwealth that this Deed be Terminated.</li> </ul>	<p>After notification, where directed to do so by the CSO Administration Agency, the Company must submit a written statement to the CSO Administration Agency with information explaining the Non-Performance and the strategy to be adopted to prevent further occurrences.</p>
11.1 Failure to notify the CSO Administration Agency of any Exclusive Supply Arrangement in which it is participating (other than an Exempt Exclusive Supply Arrangement).	<p>The CSO Administration Agency may, after giving consideration to the extent and reasons for the seriousness of the non-disclosure, the Company's performance history and the CSO Operational Guidelines:</p> <ul style="list-style-type: none"> <li>• recalculate and/or reduce the Payments to the Company engaged in any Exclusive Supply Arrangement(s) for the Month or Months where the Exclusive Supply Arrangement was (or the Exclusive Supply Arrangements were) in place as determined by the CSO Administration Agency and that such amounts not paid will be permanently forfeited by the Company; or</li> <li>• recommend to the Commonwealth that this Deed be Terminated.</li> </ul>	<p>After notification, the Company must submit a written statement with information:</p> <ul style="list-style-type: none"> <li>• explaining the reasons for the non-disclosure;</li> <li>• providing details about when the Company became involved in or aware of any Exclusive Supply Arrangement;</li> <li>• providing details of what PBS Medicines are subject to an Exclusive Supply Arrangement; and</li> <li>• where applicable, providing evidence of when the Company entered in an Exclusive Supply Arrangement;</li> </ul> <p>within 3 Business Days of receiving this notice.</p>

## 4. Non-Performance and Sanctions

Non-Performance issue	Sanction	Remedial Obligations
11.2 Continuation of an Exempt Exclusive Supply Arrangement after its current expiry date (where that expiry date is listed in Schedule 9 as being before 30 June 2020).	<p>The CSO Administration Agency may, after giving consideration to the extent and reasons for the continuation, the Company's performance history and the CSO Operational Guidelines:</p> <ul style="list-style-type: none"> <li>recalculate and/or reduce the Payments to the Company engaged in an Exclusive Supply Arrangement(s) beyond the disclosed expiry date for the Month or Months where the Exclusive Supply Arrangement was (or the Exclusive Supply Arrangements were) in place as determined by the CSO Administration Agency and that such amounts not paid will be permanently forfeited by the Company; or</li> <li>recommend to the Commonwealth that this Deed be Terminated.</li> </ul>	<p>After notification, the Company must submit a written statement with information:</p> <ul style="list-style-type: none"> <li>explaining the reasons for the continuation; and</li> <li>providing details about when the Exclusive Supply Arrangement(s) will end,</li> </ul> <p>within 3 Business Days of receiving this notice.</p>
11.3 Continuation of Exempt Exclusive Supply Arrangements after 30 June 2020.	<p>The CSO Administration Agency may, after giving consideration to the extent and reasons for the continuation, the Company's performance history and the CSO Operational Guidelines:</p> <ul style="list-style-type: none"> <li>recalculate and/or reduce the Payments to the Company engaged in any Exclusive Supply Arrangement for the Month or Months where the Exclusive Supply Arrangement was (or the Exclusive Supply Arrangements were) in place after 30 June 2020 as determined by the CSO Administration Agency and that such amounts not paid will be permanently forfeited by the Company; or</li> <li>recommend to the Commonwealth that this Deed be Terminated.</li> </ul>	<p>After notification, the Company must submit a written statement with information:</p> <ul style="list-style-type: none"> <li>explaining the reasons for the continuation; and</li> <li>providing details about when the Exclusive Supply Arrangement(s) will end,</li> </ul> <p>within 3 Business Days of receiving this notice.</p>

### Notification

The CSO Administration Agency will notify the CSO Distributor of its decision in relation to the application of Sanctions, as specified in clause 14.4 and Schedule 5 of the Deed.

### Application of financial Sanctions

In circumstances where a CSO Distributor has already received Payment/s and the CSO Administration Agency has ascertained that the CSO Distributor did not meet one or more Obligations under the Deed in the Month/s in which the Payment/s were made, the CSO Administration Agency can exercise its right

## 4. Non-Performance and Sanctions

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to adjust the Payment/s made to the CSO Distributor in accordance with clause 11, clause 11 of Schedule 2 and clause 3 of Schedule 5 of the Deed.

The CSO Administration Agency will notify the affected CSO Distributor, in writing, of any decision to apply the financial Sanction/s, in accordance with Schedule 5, and the Month or Months to which the financial Sanction/s apply.

In cases where the CSO Administration Agency has determined that a CSO Distributor has breached its Obligations and a Non-Performance is confirmed, the CSO Distributor will be notified of the CSO Administration Agency's findings. The CSO Distributors may also be asked to identify strategies to prevent future occurrences and may be directed to take remedial action, if required.

A CSO Distributor's Payment that will be reduced under the financial Sanction regime can ask the CSO Administration Agency to take into account the potential impact of the repayments on the financial position of the CSO Distributor. However, the CSO Administration Agency retains absolute discretion in determining the timing and manner of repayments.

### ***Distribution of financial Sanctions to CSO Distributors***

#### **Extract from Schedule 5 - SANCTIONS**

- 3.10 The application of Sanctions and any distribution of the National and State Based Sanctions Pools will be calculated in accordance with the principle that a Non-Performing CSO Distributor will not be permitted to benefit unreasonably from the application of Sanctions and, in particular, the principle that a Non-Performing CSO Distributor will not be permitted to benefit from a Sanction that has been applied against it.

## 4. Non-Performance and Sanctions

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### Extract from Schedule 5 - SANCTIONS

#### 4 ARRANGEMENTS FOR THE APPLICATION OF SANCTIONS FOR NATIONAL CSO DISTRIBUTORS

- 4.1 If financial Sanctions are not applied to all National CSO Distributors in a Month, the value of the financial Sanctions applied to National CSO Distributors in that Month (the Sanctions Month) will be deducted from the National CSO Funding Pool amount for that Month and transferred to a separate National Sanctions Pool. The value of the financial Sanction applied to a National CSO Distributor in a Month will be deducted from the Payment to be made to that National CSO Distributor from the National CSO Funding Pool amount for that Month.
- 4.2 The National Sanctions Pool for the Sanctions Month will be distributed in the next applicable Payment period to those National CSO Distributors who did not incur any financial Sanctions in the Sanctions Month.
- 4.3 If the CSO Administration Agency determines that financial Sanctions should be applied to all National CSO Distributors in a Month, the CSO Administration Agency will withhold part or all of the Payment to be made to each National CSO Distributor for that Month. This amount will not be transferred to the National Sanctions Pool and the CSO Administration Agency may determine that the amount will be permanently removed from the National CSO Funding Pool for that Year or is to be withheld until such time as the CSO Administration Agency determines that the National CSO Distributors have rectified the Non-Performance issue to the satisfaction of the CSO Administration Agency. If the latter occurs, this amount will then be returned to the National CSO Distributors at the same time as the Monthly Payment due after the rectification.

The manner in which financial Sanctions relating to PBS Medicines are distributed among CSO Distributors is based on the following underlying principles:

1. A CSO Distributor will not be permitted to benefit from the Sanction that was applied against them or otherwise unreasonably profit from an application of Sanctions.
2. Any financial Sanctions applied to a National or a State CSO Distributor in a Month will be deducted from the Payments to be made to those National or State CSO Distributors from the CSO Funding Pool amount for that Month and transferred to a separate National or State Sanctions Pool.  
*Note: Where there is only one State CSO Distributor, the amount of the financial Sanction applied to the State CSO Distributor will be deducted from the Payment to be made to that State Based CSO Distributor from the CSO Funding Pool amount for that Month and transferred to the National Sanctions Pool.*
3. Any financial Sanction, related to PBS Medicines, that is applied to a CSO Distributor from the CSO Funding Pool will be allocated back to the CSO Funding Pool to ensure the total value of the CSO Funding Pool is fully distributed to CSO Distributors.  
*Note: An exception is if financial Sanctions are applied to all National CSO Distributors in a month, the CSO Administration Agency may determine that this amount will be:*
  - permanently removed from the National CSO Funding Pool for that Year; or



## 4. Non-Performance and Sanctions

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- *withheld until such time as the CSO Administration Agency determines that the National CSO Distributors have rectified the Non-Performance issue to the satisfaction of the CSO Administration Agency.*

Any financial Sanction, related to NDSS Products, that is applied to a CSO Distributor, will be reduced or withheld from the Payment to that CSO Distributor for the Month, or any Month.

## 5. Complaints

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### 5 COMPLAINTS

#### *Introduction*

As part of its role in administering the CSO Funding Pool, the CSO Administration Agency is responsible for reviewing and resolving complaints regarding:

- the performance of CSO Distributors against a CSO Compliance Requirement or Service Standard;
- any aspect of the CSO Administration Agency's administration of the CSO Funding Pool or the NDSS Administrator's calculation of Payments for NDSS Distribution Services; or
- any other issue relating to the CSO Funding Pool.

A person may make a complaint to the CSO Administration Agency raising an issue or issues about a CSO Distributor's responsibility under the CSO Funding Pool arrangements.

Complaints can be lodged:

- by consumers, Distribution Points, and any other entity regarding the performance of CSO Distributors against the Obligations in the Deeds, including the CSO Service Standards or the CSO Compliance Requirements;
- CSO Distributors about the Administration Agency's administration of the CSO Funding Pool or the NDSS Administrators calculation of Payments for NDSS Distribution Services; and
- any other expression of dissatisfaction by any entity or person about the CSO Funding Pool.

Under the Deed, a complaint is defined as *"any expression of dissatisfaction by any person about any aspect of the Company's performance against any of its Obligations under this Deed or complaints by the Company contemplated by clause 12.2"*.

The CSO Complaints Procedure outlines the process for receiving, considering and resolving complaints, and this is available on the CSO Administration Agency's website, as well as the websites of the Department, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. These web pages should also include a link to the Department's CSO web page, which provides details of the CSO arrangements including the CSO Service Standards and Compliance Requirements. The Complaints Procedure will take precedence over this Chapter of the Operational Guidelines, should any inconsistencies arise over time if the Complaints Procedure is periodically updated.

#### *Lodging a complaint*

CSO complaints must be made in writing (including electronically) and clearly specify who or what the complaint is about, and include any relevant supporting information or evidence.

Complaints can be lodged with the CSO Administration Agency by means of **CSO Product Supply Complaint Form** (Appendix G) or by mail, fax, email or hand delivery to the CSO Administration Agency Office.

## 5. Complaints

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Complainants should ensure that their complaint details:

1. Who the complaint is about;
2. What the complaint is about<sup>2</sup>;
3. Any supporting information and evidence available;
4. Whether the complainant wishes the matter to be treated as a formal complaint; and
5. Whether the complainant consents to their identity being disclosed to the subject of the complaint.

The CSO Administration Agency will use the structure of the CSO Product Supply Complaint Form for the recording of complaint information, for uniformity in the CSO Administration Agency recording of telephone and written complaints.

### **Confidentiality obligations**

Confidential and personal information may be involved in the making or resolution of a complaint. The CSO Administration Agency will handle all complaints in accordance with the relevant laws and provisions governing the maintenance of confidential and personal information. The NDSS Administrator may participate in the CSO Complaints Procedure in accordance with clause 2.2 of Schedule 4 of the Deed. The NDSS Administrator will also handle all complaints in accordance with the relevant laws and provisions governing the maintenance of confidential information.

In particular, all complaints will be handled in accordance with the Australian Privacy Principles in the *Privacy Act 1988* (Cth) (the **Privacy Act**). The Australian Privacy Principles in the Privacy Act are strict privacy safeguards that federal government agencies must obey when receiving, considering and resolving a complaint. The CSO Administration Agency is contractually obliged to comply with the Privacy Act.

The CSO Administration Agency may request further information from the complainant during the investigation of the complaint. The CSO Administration Agency may investigate a complaint even if all the information is not supplied or the complaint is withdrawn by the complainant.

The complainant may ask the CSO Administration Agency to keep all or any part of the complaint confidential ('confidential complaint information'). In that event, the CSO Administration Agency will not disclose the confidential complaint information to anyone except:

- to officers, employees, agents or advisers of the CSO Administration Agency, the NDSS Administrator, its officers, employees, agents or advisers, or the Commonwealth Department of Health and Aged Care who require the information for the purposes of investigating or reporting on or receiving reports on or advising in relation to the complaint (see further in the paragraph below);
- if required to do so by law; or
- with the written consent of the complainant.

Where consent to disclose identity is not provided, the CSO Administration Agency will not provide any information to the subject of the complaint which it could reasonably be expected would enable the subject of the complaint to ascertain the identity of the complainant.

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<sup>2</sup> Refer *CSO Compliance Requirement and CSO Service Standard* at the [CSO Administration Agency's website](#).

## 5. Complaints

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All CSO Distributors are bound by the confidentiality obligations in the Deed.

Information in relation to a complaint (including all information in the Complaints Register) may be provided by the CSO Administration Agency to the Department of Health and Aged Care. The CSO Administration Agency will identify any information that it has been asked to keep confidential and advise the Commonwealth if the complainant has asked that their identity not be disclosed. The Commonwealth will take all reasonable steps to protect this information, but complainants should note that the Commonwealth can disclose it in very limited circumstances (including, for instance, required under the *Freedom of Information Act 1982* (Cth), to avoid a Material Adverse Outcome, or where the Commonwealth is required to disclose it to other agencies or Parliamentary committees).

### ***Confidential information of the subject of a complaint***

The Commonwealth has obligations of confidentiality to each CSO Distributor under the Deed of Agreement. Any feedback given to a complainant by the CSO Administration Agency during the investigation of the complaint and information given to complainants about the outcome of the complaint will need to be consistent with and in compliance with these confidentiality obligations.

Generally, the CSO Administration Agency will provide a complainant with all relevant information, except any information that is of a commercial nature or otherwise confidential. This type of information cannot be provided without the consent of the relevant CSO Distributor.

### ***Administration Agency complaint review process***

Once a formal complaint has been lodged, the CSO Administration Agency will conduct a preliminary assessment and then advise the subject of the complaint. The CSO Administration Agency is obliged to investigate and resolve any complaints in accordance with the terms of the Deed.

The CSO Administration Agency may seek further information from the subject of the complaint or the complainant and any other relevant sources, where appropriate. This includes the ability to carry out audits of CSO Distributors for compliance with the CSO Compliance Requirements, CSO Service Standards and other obligations under their Deed.

### ***Advising parties of the outcome***

Once the investigation is completed, the CSO Administration Agency will:

- for complaints about the CSO Administration Agency's administration of the CSO Funding Pool or the NDSS Administrator's calculation of Payments for NDSS Distribution Services:
  - provide a written summary of the CSO Administration Agency's assessment of the complaint to the complainant; and
  - notify the complainant, in writing, of the action (if any) to be taken as a result of the complaint.
- for all other complaints:
  - notify the subject of the complaint, in writing, of the outcome of the complaint process (e.g., that the CSO Distributor has not complied with a CSO Service Standard) and the action (if any) to be taken as a result of the complaint; and
  - where appropriate, provide general information to the complainant about the outcome of the complaint.

## 5. Complaints

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However, for complaints about a CSO Distributor's performance against a CSO Compliance Requirement or CSO Service Standard or any other obligation under its Deed, the CSO Administration Agency must, prior to providing any information to the complainant about the outcome of the complaint, ensure that:

- the CSO Distributor is notified of, and given a reasonable opportunity to respond in writing to, any alleged Non-Performance; and
- the CSO Administration Agency takes into account the reasons and information provided prior to making a final determination in relation to Non-Performance and Sanctions.

### ***CSO Distributors' review rights***

A CSO Distributor who is dissatisfied with the action taken by the CSO Administration Agency:

- as a result of a complaint lodged about a CSO Distributor's performance against a CSO Compliance Requirement or CSO Service Standard or any other obligation under its Deed; or
- as a result of a complaint lodged by the CSO Distributor about the CSO Administration Agency's administration of the CSO Funding Pool,

may refer the complaint, in writing, to the Commonwealth's Authorised Officer or the Commonwealth's nominee within 28 days after receiving notification from the CSO Administration Agency or NDSS Administrator.

Review Requests must be lodged in hard copy, to the following address:

Assistant Secretary  
Pharmacy Branch  
Technology Assessment and Access Division  
Department of Health and Aged Care  
9<sup>th</sup> Floor, Sirius Building, GPO Box 9848  
Canberra ACT 2601  
E-mail [CSOAdmin@health.gov.au](mailto:CSOAdmin@health.gov.au)

The decision made by the Department in any review is final and binding, and there are no other review rights available to a CSO Distributor in relation to a complaint.

### ***Review Rights of Other Complainants***

Complainants who are not CSO Distributors do not have review rights under the CSO Complaints Procedure. However, complaints about any aspect of the CSO Funding Pool may be directed to the Commonwealth Ombudsman in accordance with the *Ombudsman Act 1976* (Cth).

Complaints may be made to the Commonwealth Ombudsman in writing, by phone, in person or by using the Ombudsman's online complaint form. Contact details for the Ombudsman are:

Phone: 1300 362 072 (calls from mobile phones at mobile phone rates)  
Email: [ombudsman@ombudsman.gov.au](mailto:ombudsman@ombudsman.gov.au)  
Post: GPO Box 442, CANBERRA ACT 2601  
Fax: 02 6276 0123  
Website: [www.ombudsman.gov.au](http://www.ombudsman.gov.au)

## 6. Providing Accurate and Timely Data

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### 6 PROVIDING ACCURATE AND TIMELY DATA

#### ***Introduction***

This chapter is divided into the following sections:

- Data Obligations;
- What Sales of PBS Medicines are claimable?;
- What Sales of NDSS Products are claimable?;
- PBS Monthly Data and Payments cycle;
- Funding Pool Payment Calculations;
- NDSS Monthly Data and Payment cycle;
- NDSS Payment Calculations;
- Annual reconciliation process; and
- Calculation of Low Volume and Rural and Remote Thresholds for PBS Medicines.

#### ***Data Obligations***

It is the responsibility of the CSO Distributors to ensure the accuracy and completeness of the Data that they submit to the CSO Administration Agency. To do this effectively, CSO Distributors must have appropriate systems and processes in place to ensure this occurs. If Data is provided late or is inaccurate, this may be recorded as a Non-Performance against the CSO Distributor and Sanctions and/or Payment Adjustments may be applied by the CSO Administration Agency.

The following list identifies some of the Obligations under the Deed that relate to Data requirements.

## 6. Providing Accurate and Timely Data

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### **Extracts from Clause 10 and Schedule 3 – DATA AND REPORTS**

- 10.1 The Company must provide Data to the CSO Administration Agency.
- 10.2 The Company must ensure that any Data, Reports or information provided under this Deed is accurate and complete.
- 10.3 The Company acknowledges that the timely submission of accurate and complete Data by the Company is critical to the calculation and release of Payments from the CSO Funding Pool or the making of Payments for NDSS Distribution Services.
- 10.4 The CSO Administration Agency and/or the Commonwealth has the right, by reasonable notice in writing to the Company, to alter the Data requirements in Schedule 3 at any time after the first receipt of Data from the Company, including the format of the Data to be provided by the Company in accordance with the Deed.
- 10.5 The Company must provide any additional data requested by any Administration Agency within the timeframe reasonably specified by the Administration Agency.

### **Schedule 3**

- 3.1 The Company must provide any Data and Reports sought by the CSO Administration Agency to assess and resolve Complaints by consumers, Distribution Points, Registrants and others regarding the performance of the Company against its Obligations under this Deed.
- 3.2 The Company must provide any Data and Reports sought by the CSO Administration Agency as part of a periodic assessment carried out by the CSO Administration Agency to ensure the continued achievement by the Company of the requirements for access to the CSO Funding Pool or to Payments for NDSS Distribution Services set out in this Deed.
- 3.3 The Company must provide any other Data and Reports required for activities contained within this Deed and the CSO Operational Guidelines, including audits in accordance with clause 16 of the Deed.
- 3.4 The Company must submit any Data and Reports sought by the CSO Administration Agency and/or the Commonwealth (within the reasonable timeframe required by them) in respect of CSO Products identified to be the subject of a current or anticipated shortage, including products identified through the Medicines Shortages Information Initiative administered by the Therapeutic Goods Administration.

Before claiming Sales for a product, CSO Distributors must first provide the CSO Administration Agency with the relevant Portable Data Entry (PDE) code and description for each pack size and map it to an eligible PBS code. A web-based system has been established by the CSO Administration Agency to enable CSO Distributors to provide this PDE-PBS code mapping information. It is the responsibility of CSO Distributors to ensure that they do not claim Sales of ineligible CSO Products or pack sizes. The following explains:

- What Sales of PBS Medicines are claimable?
- What Sales of NDSS Products are claimable?

### ***What Sales of PBS Medicines are claimable?***

CSO Distributors must submit Data for every Unit of PBS Medicine that they Supply. However, CSO Distributors will only receive Payments from the CSO Funding Pool for Sales in respect of which the

## 6. Providing Accurate and Timely Data

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CSO Distributor has met its Obligations under the Deed. Under the Deed, the terms Pack Quantity, PBS Medicines, Unit, and Supply are defined as follows:

**Pack Quantity (PQ):**

- (a) *in relation to a PBS Medicine, has the same meaning as in subsection 84AK(2) of the NH Act*

*Note: The Minister may determine one or more pack quantities for a brand of a pharmaceutical item under subsection 84AK(2) of the NH Act. The quantities determined are the quantities in the manufacturer's PBS packs.*

**PBS Medicines** means all items listed on the Schedule of Pharmaceutical Benefits (including items listed on the Schedule of Pharmaceutical Benefits that are supplied under Exempt Exclusive Supply Arrangements), but does not include pharmaceutical items that:

- (a) *contain a drug for which there is a declaration under paragraph 85(2A)(b) of the NH Act [section 100 drug declaration], unless specified by the Commonwealth in writing to the Company;*
- (b) *are a pharmaceutical benefit for which there is a determination under paragraph 85(8)(a) of the NH Act [section 100 only pharmaceutical benefit determination], unless specified by the Commonwealth in writing to the Company;*
- (c) *the Company cannot Supply due to an Exclusive Supply Arrangement to which the Company or any of its Related Entities are not parties; or*
- (d) *are medicines listed only for Supply under the Repatriation Schedule of Pharmaceutical Benefits.*

*Note: The Obligations mentioned in this Deed for a PBS Medicine relate to the medicine. Those Obligations do not vary based on the circumstances or purposes determined for a PBS Medicine under Part VII of the NH Act.*

**Unit** means a pack size:

- (a) *equal to a Pack Quantity;*
- (b) *which, if less than a Pack Quantity, is a factor of a Pack Quantity; or*
- (c) *which, if greater than a Pack Quantity, can be broken down to a size that equals a Pack Quantity.*

**Supply** means to obtain and deliver a CSO Product to a Distribution Point.

### CLAIMABLE PACK SIZES

Based on the definitions outlined above, a CSO Distributor is permitted to claim Sales of PBS Medicines that:

- are equal to a Pack Quantity
- if less than a Pack Quantity, can be multiplied by a whole number to equal the Pack Quantity; or
- if greater than a Pack Quantity, can be broken down to a size that equals a Pack Quantity.



## 6. Providing Accurate and Timely Data

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### NEW PBS MEDICINES

PBS Medicines are claimable one Month prior to being added to the Schedule of Pharmaceutical Benefits. CSO Distributors should ensure new items, which have been delivered, are added to their Monthly Data report.

### DELETED PBS MEDICINES

PBS Medicines are only claimable for up to one Month after they have been deleted from the Schedule of Pharmaceutical Benefits. CSO Distributors must ensure that any deleted items are removed from their Monthly Data report, prior to submitting it to the CSO Administration Agency.

The only exception to this is if a deleted PBS Medicine moves to the Supply Only schedule (see below). For CSO purposes, PBS Medicines on the Supply Only schedule are effectively not deleted and therefore must not be removed from CSO Distributors' Monthly Data reports.

### SUPPLY ONLY PBS MEDICINES

'Supply Only' rules introduced from 1 November 2020, specify that if a PBS Medicine is deleted from the PBS it may continue to be dispensed (although not prescribed), usually for a period of up to 12 months from deletion. The Supply Only schedule is published monthly on the pbs.gov.au website.

If a PBS Medicine on the Supply Only schedule is available to a CSO Distributor, then:

- The CSO Distributor must fulfil any orders received from Community Pharmacies and comply with all other CSO Services Standards relating to the supply of PBS Medicines
- Supply of these Supply Only PBS Medicines to Community Pharmacies are considered claimable Sales for the purposes of the CSO arrangements (while the PBS Medicine is listed on the Supply Only schedule).

### OVER-THE-COUNTER EXCLUSIONS

The Department, in consultation with the Agreement Oversight Committee, determines the proportion of Over the Counter (**OTC**) PBS Medicines that are excluded from the CSO Distributor Payment calculation. This list is then distributed by the CSO Administration Agency to CSO Distributors. The current OTC PBS Medicines list is attached at *Appendix E* to this document and is available on the CSO Administration Agency's PDE-PBS mapping website.

Each PBS-listed OTC Medicine has been assigned a specific percentage/proportion of Sales to be deducted for CSO purposes. This proportion of a CSO Distributor's supply of this item will be deducted in the CSO market share calculation. The CSO Administration Agency undertakes this calculation Monthly, and includes a summary of the number of units excluded, due to OTC PBS Medicines proportioning, in the Monthly Payment letter provided to each CSO Distributor.

### PBS MEDICINES UNDER EXCLUSIVE SUPPLY ARRANGEMENTS

If a particular CSO Product is subject to an Exclusive Supply Arrangement, but a CSO Distributor does have access to it, then the CSO Distributor must continue to meet its Obligations under the Deed. These Sales must be reported to the CSO Administration Agency, but the CSO Distributor will not receive Payment for Sales of that CSO Product.

### COMMUNITY PHARMACIES

CSO Distributors can only claim Sales PBS Medicines made to Community Pharmacies. Under the Deed, Community Pharmacy is defined as *'any premises which have been approved under section 90 of the NH Act from which an Approved Pharmacist conducts pharmacy business'*.

## 6. Providing Accurate and Timely Data

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A pharmacist must receive approval via Medicare Australia to supply pharmaceutical benefits from the premises. An approved Community Pharmacy will then receive a Pharmacy Approval Number (**PAN**) from Medicare Australia. A PAN consists of six characters - five numbers followed by a letter, e.g. 12345A.

### **CONFIRMATION OF COMMUNITY PHARMACY STATUS**

CSO Distributors are expected to take all possible steps to confirm customers are approved Community Pharmacies. For example, to confirm that a customer is an approved Community Pharmacy, CSO Distributors should ask the customer to provide their PAN. For a new customer, this request may be part of the new account setup.

If a customer refuses to provide their PAN, the CSO Distributor should seek written confirmation from them that they have a valid and current PAN from Medicare Australia. The CSO Distributor should inform the CSO Administration Agency if they are unable to confirm either of the above points.

The CSO Administration Agency accepts however that CSO Distributors may not be able to confirm that a PAN provided by a customer is:

- A valid PAN; and/or
- Current for the Month of sales claimed, i.e. has not been revoked.

Where a PAN has been provided as part of the Data requirements and is found to be unintentionally incorrect despite the reasonable endeavours of the CSO Distributor to obtain accurate PAN information, this will not be considered a non-performance under the Deed so long as sufficient alternative information identifying the Approved Pharmacy and confirming Community Pharmacy status (such as trading or retail name, and delivery location of the pharmacy) has been provided to the CSO Administration Agency.

To demonstrate that a CSO Distributor has applied 'reasonable endeavours', it should periodically reconfirm the PAN details for all accounts and investigates any anomalies, and in particular for older accounts.

### **NEW CUSTOMERS**

In some instances, CSO Distributors make Sales to a new Community Pharmacy prior to their obtaining a PAN. Such Sales can only be claimed for the calendar Month prior to a Community Pharmacy obtaining its PAN.

For Sales made to a Community Pharmacy which does not have a PAN, CSO Distributors can only claim such Sales if the pharmacy:

- Confirms to the CSO Distributor that it has applied for a PAN;
- Receives a PAN within the calendar Month following the Sale, and provides details of the PAN to the CSO Distributor. If a PAN is not granted to the pharmacy within the calendar Month following the Sale, the CSO Distributor must advise the CSO Administration Agency and an appropriate adjustment will be made during the annual reconciliation to ensure that only Sales made in the calendar Month before the PAN is granted are claimed; and/or
- Holds a licence to store Schedule 4 PBS Medicines (issued by their State Pharmacy Board).

## 6. Providing Accurate and Timely Data

### ***What Sales of NDSS Products are claimable?***

CSO Distributors must submit Data for every Unit of NDSS Product that they Supply. However, CSO Distributors will only receive Payments for Sales in respect of which the CSO Distributor has met its Obligations under the Deed. Under the Deed, the term Pack Quantity in relation to a Brand of an NDSS Product, means *the quantities or numbers of units of that Brand of that NDSS Product, as listed in the NDSS Product Schedule.*

### **DELETED NDSS PRODUCTS**

NDSS Products are only claimable while they are listed on the NDSS Product Schedule. CSO Distributors must ensure that any deleted items are removed from their Monthly Data report, prior to submitting it to the CSO Administration Agency.

### **NEW NDSS PRODUCTS**

NDSS Products are claimable while they are listed on the NDSS Product Schedule. CSO Distributors should ensure new items, which have been delivered, are added to their Monthly Data report.

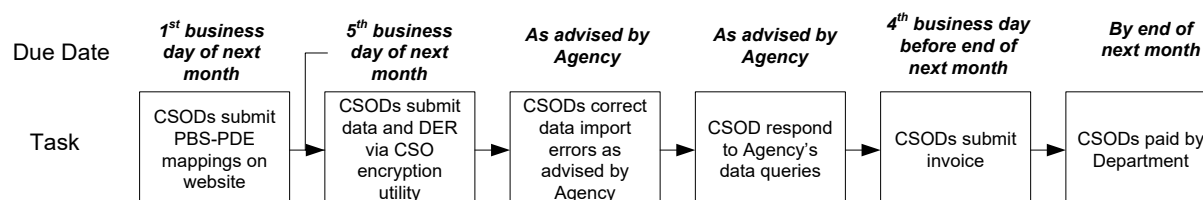
### **ACCESS POINTS**

CSO Distributors can only claim Sales for NDSS Products Supplied to Access Points.

Under the Deed, Access Point is defined as ‘any Community Pharmacy or other organisation appointed by the NDSS Administrator or the Commonwealth to supply NDSS Product to Registrants and notified in writing to the Company from time to time.’

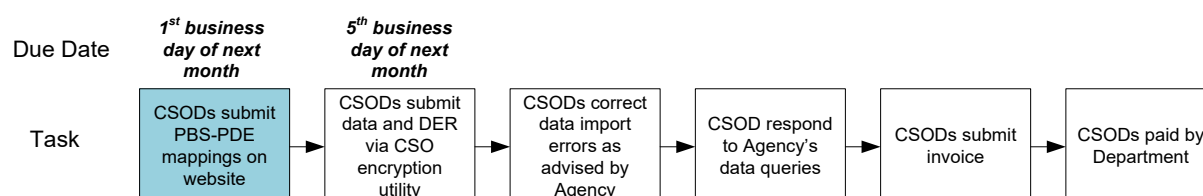
### ***PBS Monthly Data and Payment cycle***

For each Month's Sales, the following Data cycle occurs in the subsequent Month. For example for July 2020 Sales, this cycle occurs in August 2020.



The following sections describe what is required of CSO Distributors during each of the above steps.

### **PBS-PDE mappings**



Before CSO Distributors can claim Sales for a PBS Medicine, they must provide the CSO Administration Agency with a relevant product PDE code and description matching this PBS Medicine. A web-based system has been established by the CSO Administration Agency to enable CSO Distributors to provide this information.

## 6. Providing Accurate and Timely Data

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The CSO Administration Agency's PBS-PDE product code mapping website:

1. Allows CSO Distributors to provide their PDE code for a given Brand name and pack size of a PBS code (generic name and form and strength information is also listed); and
2. Provides a list of the:
  - Monthly additions to the PBS schedule. For example, the section titled '*July 2020*' contains the PBS additions for August 2020, which are claimable for CSO purposes from 1 July 2020;
  - NDSS Products listed on the NDSS Products Schedule;
  - PBS Medicines listed as Exclusive Supply;
  - PBS Medicines identified as Low Volume;
  - PBS Medicines identified as High Volume; and
  - Postcodes identified as Rural and Remote.

The CSO Administration Agency lists these additions on the mapping website by the twelfth business day to the Month prior to the item being listed on the Schedule of Pharmaceutical Benefits. All CSO Distributors are required to complete the PDE-PBS code mapping for the Monthly additions by the first Business Day of the following Month.

When using the mapping website, it is important that CSO Distributors:

Complete all fields for each record and tick the 'Confirm' box; and

Select the '*Notify CSO Agency of completion*' link once all the information has been completed and reviewed.

Only PDE codes that have been mapped to eligible PBS items will be counted towards a CSO Distributor's CSO Payment calculation each Month.

It is possible that CSO Distributors may not have a PDE code for all PBS Medicines. For example, a CSO Distributor may not have a PDE code for a product it did not intend to stock, or a product it intends to stock in future, but has not yet allocated a PDE code.

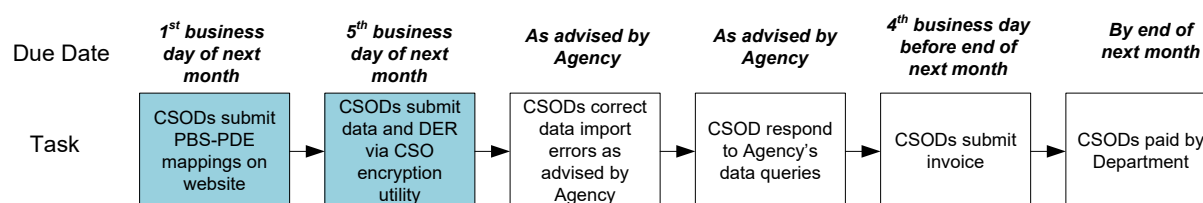
The CSO Administration Agency will consider this to be acceptable provided that the Sales Data that the CSO Distributor submits does not include that product, and that the CSO Distributor complies with their Requirement to Supply any PBS Medicines. For any Month in which a CSO Distributor claims Sales for a product for the first time, the CSO Distributor must ensure that it has provided the PDE code and description to the CSO Administration Agency before it submits its Monthly data. This information can be provided to the CSO Administration Agency via the CSO Administration Agency's mapping website.

It is the responsibility of CSO Distributors to record which PDE codes have been provided to the CSO Administration Agency and to ensure that the CSO Administration Agency is advised of any new PDE codes.

Further information regarding how to provide PBS-PDE mapping information via the CSO Administration Agency's website is available to download on the website, or can be requested from the CSO Administration Agency.

## 6. Providing Accurate and Timely Data

### Submission of Monthly Sales Data



CSO Distributors are required to submit the following information in their Monthly Sales Data, by the fifth Business Day of the subsequent Month:

1. CSO Distributor product code (PDE);
2. CSO Distributor product description;
3. Postcode the PBS Medicine was distributed to; and
4. Units sold of each medicine.

The CSO Administration Agency has established a secure electronic communication tool known as the CSO Encryption Utility (CSO EU), which allows secure encryption and transmission of electronic information between the CSO Administration Agency and a CSO Distributor. Each CSO Distributor's Monthly Sales Data is submitted via the CSO EU, in a text delimited format, either as a .txt or .csv file.

Information sent by CSO Distributors is compressed and encrypted prior to transmission and then sent via the Internet to the CSO Administration Agency. On receipt of a communication, the CSO Administration Agency transfers the content to its secure network and will then decrypt it.

Public Key Infrastructure (PKI) encryption is used to secure all electronic communications. It is essential that CSO Distributors restrict access to the CSO EU, to ensure that the key remains secure and that copies of it are not created.

CSO Distributors must ensure that:

1. All Sales included in Monthly Data submissions are only to Distribution Points and are therefore claimable;
2. The postcode reported to the CSO Administration Agency for each Sale is that of the delivery address of the Distribution Point (i.e. the physical location) and not a separate billing address, head office address or PO Box address; and
3. All Data is submitted on time.

### CSO Encryption Utility System Requirements

CSO EU system requirements are:

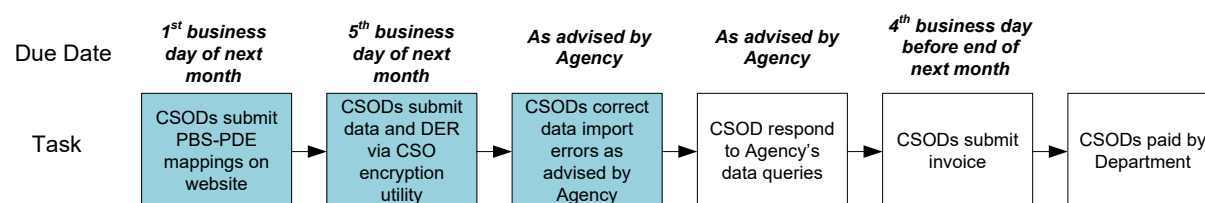
- Windows 2000 or above; and
- An Internet connection (preferably broadband).

The CSO EU also requires that both SMTP and HTTP protocols enabled on the host system. It is possible that the CSO Distributor may require its IT department to adjust the SMTP or HTTP settings on the installed computer to allow the CSO EU to operate.

## 6. Providing Accurate and Timely Data

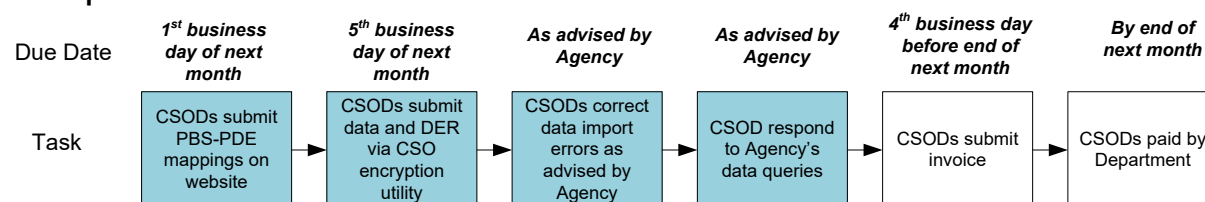
For detailed instructions on installation, testing and the submission of data using the CSO EU, please see the CSO Distributor User manual, available to download from the PDE-PBS mapping website.

### Import errors



Once the CSO Distributor has submitted the Sales Data via the CSO EU, the CSO Administration Agency will import the Data and record any errors. Errors usually occur due to a CSO Distributor claiming Sales for a product for which the CSO Administration Agency has no corresponding PBS code mapped ('mapping errors'), or Sales to invalid postcodes or products. For mapping errors, CSO Distributors are required to provide mapping details via the CSO Administration Agency's PDE-PBS mapping website. CSO Distributors are usually allowed two Business Days to provide this additional information.

### Data queries



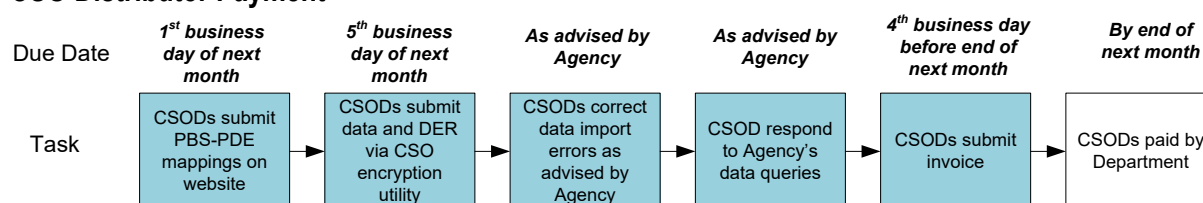
Each Month, the CSO Administration Agency requests additional information from CSO Distributors regarding their Sales Data submission. These Monthly Data queries are currently classified as either postcode queries or product queries. As well as providing additional information, CSO Distributors are asked to check and confirm that the specific postcode or product Sales queried were supplied to Community Pharmacies during the Month reported and are therefore claimable under the CSO arrangements.

CSO Distributors must ensure that they thoroughly investigate any query raised by the CSO Administration Agency and provide an accurate response. The CSO Administration Agency may conduct further investigations regarding the accuracy of the responses provided by CSO Distributors to the CSO Administration Agency's Monthly Data queries. Non-Performances will be recorded against CSO Distributors if the CSO Administration Agency's investigations identify that CSO Distributors have not thoroughly investigated the CSO Administration Agency's queries.

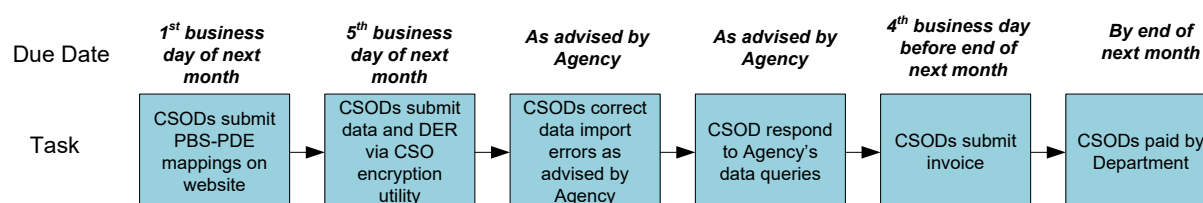
The CSO Administration Agency may request a Data resubmission from CSO Distributors if it identifies any errors which alter the total units supplied by a CSO Distributor during the Data query process.

## 6. Providing Accurate and Timely Data

### CSO Distributor Payment



Once the CSO Administration Agency has finalised Data from all CSO Distributors, payment calculations will be undertaken in accordance with Schedule 2 of the Deed. The CSO Administration Agency will then send a Payment advice letter advising CSO Distributors of their CSO Distributor Funding Pool Payment for the previous Month's Sales, and request an invoice, in accordance with Schedule 2, clause 7 of the Deed. CSO Distributors are usually given 2 Business Days to provide their invoice.



After ensuring the accuracy of the Data and the CSO Distributors' Reports provided to the CSO Administration Agency, the CSO Administration Agency must provide the Department with a Monthly Payment report, reflecting the Payments that are to be made to each CSO Distributor for each Month during the term of the Deed.

### Funding Pool Payment Calculations

The underpinning principle of the CSO Payment process is that CSO Distributors must meet the Obligations under the Deed to receive Payments from the CSO Funding Pool. This principle is set out in clause 11.6 of the Deed and means that Payments are linked to a CSO Distributor's compliance with the Obligations under the Deed.

For each Month, and as part of the CSO Payment process set out in the Deed, the CSO Administration Agency must consider a CSO Distributor's compliance with the Obligations under the Deed when determining whether to make a Payment to that CSO Distributor and how much any Payment should be.

### National Funding Pool Payment Calculations

Funding for the National CSO Funding Pool may not necessarily be evenly distributed over each Year of the Term of the Deed, and as a result the amount available for distribution to CSO Distributors in any particular Month may or may not equate to one twelfth of the total value of the CSO Funding Pool for that Year.

The amount payable to each National CSO Distributor will be based on the proportion of their volume of Sales of PBS Medicines, compared to the total volume of PBS Medicine Sales to Community Pharmacies by all National CSO Distributors (combined) for the Month. The amount available for Payment to National CSO Distributors per Month may vary to reflect the application of financial Sanctions to the total amount of Payments in a previous Month or any unspent amounts from the State based pool.

## 6. Providing Accurate and Timely Data

The CSO Administration Agency has discretion within the framework of the Deed and the CSO Operational Guidelines to determine how and when the financial Sanctions are applied. In the event that any funds allocated to the administration of the CSO Funding Pool each Year are not spent by the CSO Administration Agency, the funds will be added to the National CSO Funding Pool for the following Year. This is subject to any Payment exclusions or Payment exclusion policy and the arrangements for the application of Sanctions referred to in the Deed.

### Payment Exclusion Policy

#### Extract from Schedule 2, clause 8

- 8.1 CSO Products that are the subject of Exclusive Supply Arrangements (including Exempt Exclusive Supply Arrangements) will be excluded by the CSO Administration Agency from the calculation of total Sales of CSO Products for each CSO Distributor and will therefore not be counted for the purpose of calculating Payments from the CSO Funding Pool.
- 8.2 Sales of Excluded Over the Counter PBS Medicines will also not be included in the Payment calculation. The process for calculating the proportion of Over the Counter PBS Medicines which are excluded will be revised from time to time as determined by the Commonwealth. Once this process is finalised, CSO Distributors will be notified by the CSO Administration Agency. Excluded Over the Counter PBS Medicines will not be included in the Payments calculation from the date of the notification.

#### Example 1 – Allocation of Payment to National CSO Distributors

CSO Distributor	PBS Medicines Supplied	Payment from the National CSO Funding Pool
CSO Distributor W	6.1 million Units (24.3%)	\$3.645 million
CSO Distributor X	8.7 million Units (34.7%)	\$5.199 million
CSO Distributor Y	5.5 million Units (21.9%)	\$3.287 million
CSO Distributor Z	4.8 million Units (19.1%)	\$2.869 million
<b>All CSO Distributors</b>	<b>25.1 million Units (100.0%)</b>	<b>\$15.000 million</b>

This Payment equates to \$0.60 per Unit of PBS Medicine Sold.

### State Based Funding Pool Payment Calculations

Funding for the State Based CSO Funding Pool is apportioned across each Month and is calculated by:

Identifying the volume of PBS Medicines supplied under the CSO to Community Pharmacies by each State Based CSO Distributor; and

From this, deriving a ratio for each State that compares the volume of CSO Sales of PBS Medicines by each State Based CSO Distributor in a State to the total volume of CSO Sales of PBS Medicines by all State Based CSO Distributors across Australia.



## 6. Providing Accurate and Timely Data

The following three tables provide examples of the calculation of and allocation of State Based Funding Pool Payments.

*Example 2 – Number of PBS Medicines supplied by State Based CSO Distributors in a Month*

CSO Distributor	PBS Medicine Supplied	Percentage of CSO Sales across each State
A (Victoria)	150,000 Units	60% of Vic CSO Sales
B (Victoria)	100,000 Units	40% of Vic CSO Sales
B (South Australia)	300,000 Units	100% of SA CSO Sales
<i>Total (Victoria)</i>	250,000 Units	-
<i>Total (South Australia)</i>	300,000 Units	-
<b>Total (All)</b>	<b>550,000 Units</b>	

In the example above, CSO Distributor A supplied 60% of the total CSO Sales to Victoria, with CSO Distributor B supplying the remaining 40%. CSO Distributor B supplied 100% of the total CSO Sales to South Australia. Once the Monthly allocation of funding for CSO Distributors A and B have been determined, these proportions of CSO Sales are used to determine the level of Payment that each State Based CSO Distributor will receive.

*Example 3 – Ratio of Sales of PBS Medicines across each State*

State	Percentage of CSO Sales	Total Monthly Allocation
Victoria	45.45% (250,000/550,000)	\$127,272.73 (45.45% of \$280,000)
South Australia	54.55% (300,000/550,000)	\$152,727.27 (54.55% of \$280,000)
<b>Total</b>	<b>100%</b> <b>(550,000)</b>	<b>100%</b> <b>(\$280,000)</b>

For the purposes of the example above, the Monthly CSO Funding Pool State allocation is assumed to be \$280,000. The allocation of Monthly funding within each State Based jurisdiction is then based on the volume of Sales of PBS Medicines supplied to Community Pharmacies by each State Based CSO Distributor in a State, compared to the total volume of Sales of PBS Medicines supplied to Community Pharmacies by all State Based CSO Distributors (combined) in that State.

*Example 4 – Allocation of Payment to State Based CSO Distributors*

CSO Distributor	Payment
A	\$76,363.64 (60% of \$127,272.73)
B	\$203,636.36 (40% of \$127,272.73) + (100% of \$152,727.27)
<b>Total</b>	<b>\$280,000</b> <b>(\$203,636.36 + \$76,363.64)</b>

The amount of funding that each State Based CSO Distributor receives is then based on the proportion of CSO Sales that each CSO Distributor made in each State. In this example, CSO Distributor A would receive 60% of the \$127,272.73 allocation for Victoria, which equates to \$76,363.64.

## 6. Providing Accurate and Timely Data

CSO Distributor B would receive the remaining 40% of the allocation for Victoria, which equates to \$50,909.09, plus the full \$152,727.27 allocation for South Australia, as CSO Distributor B was the only State Based CSO Distributor operating in South Australia.

### **Calculating the National Cap**

Monthly Payments to State Based CSO Distributors are capped to ensure that the per unit Payments to any State Based CSO Distributor will not exceed that paid to National CSO Distributors for the same period. Any unspent funds from the State Based Funding Pool in any Month are added to the National Funding Pool.

*Example 5 – Total Number of PBS Medicines Distributed by all National CSO Distributors in a Month*

CSO Distributor	PBS Medicine Supplied	National Funding Pool allocation	National Cap
CSO Distributor W	6.1 million units		
CSO Distributor X	8.7 million units		
CSO Distributor Y	5.5 million units		
CSO Distributor Z	4.8 million units		
<b>Total</b>	<b>25.1 million units</b>	<b>\$15 million</b>	<b>\$0.60</b>

For the purposes of the example above, the Monthly CSO Funding Pool National Allocation is assumed to be \$15 million.

The National Funding Pool Cap is calculated as the Monthly National Funding Pool allocation divided by the total number of Units of PBS Medicines supplied by National CSO Distributors in a Month. This particular example results in a National Cap of \$0.60 per unit of PBS Medicine sold, i.e. \$15 million/25.1 million units.

If Payments to State Based CSO Distributors (which are based on the total number of units of PBS Medicines sold by all State Based CSO Distributors and divided by the Monthly State Based Funding Pool allocation), exceeds Payments calculated based on the National Cap (\$0.60 in the above example), the National Cap will apply to Payments to State Based CSO Distributors.

*Example 6 – Payment to all State Based CSO Distributors in a Month - adjusted for National Funding Pool Cap*

Total PBS Medicines Supplied	State Based Funding Pool Allocation	Payment based on National Cap of \$0.60	Actual Payment due
450,000 units	\$280,000	\$270,000	\$270,000

In the above example, the State Based Funding Pool Allocation (\$280,000) exceeds the total payment due to all State Based CSO Distributors calculated based on the National Cap of \$0.60 (\$270,000), and therefore \$270,000 would be paid, i.e. the National Cap would be applied.

## 6. Providing Accurate and Timely Data

*Example 7 – Payment to all State Based CSO Distributors in a Month - no adjustment required for National Funding Pool Cap*

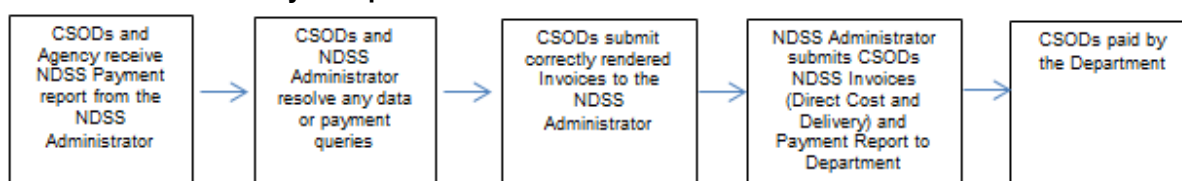
Total PBS Medicines Supplied	State Based Funding Pool Allocation	Payment based on National Cap \$0.60	Actual Payment due
550,000 units	\$280,000	\$330,000	\$280,000

In the above example, the State Based Funding Pool Allocation (\$280,000) is less than the total payment due to all State Based CSO Distributors based on the National Cap of \$0.60 (\$330,000), and therefore \$280,000 would be paid, i.e. the National Cap would not be applied.

### **NDSS Monthly Data and Payment cycle**

For each Month's Sales, the following Data cycle occurs in the subsequent Month. For example for July 2020 Sales, this cycle occurs in August 2020.

#### **Direct Cost and Delivery Component**



By the 2<sup>nd</sup> business day of the next month, the NDSS Administrator will send the CSO Distributors and the CSO Administration Agency a Payment Report on NDSS Products that were shipped by CSO Distributors as a result of orders through the NDSS system. This report will form the basis of the amount CSO Distributors are required to invoice the Department for the Direct and Delivery cost components of the distribution of NDSS products and for the CSO Administration Agency to calculate the NDSS Supply Component.

By the 4<sup>th</sup> business day of the next month, CSO Distributors should have raised any queries with the NDSS Administrator related to the Payment Report data.

By the 5<sup>th</sup> business day of the month, CSO Distributors will submit correctly rendered Invoices to the NDSS Administrator who will forward Invoices and payment Report to the Department for payment.

The Department will pay correctly rendered Invoices within 15 Business Days.

Where CSO Distributors do not agree with the Payment Report provided by the NDSS Administrator, the Distributors will raise their concerns, in the first instance, with the NDSS Administrator.

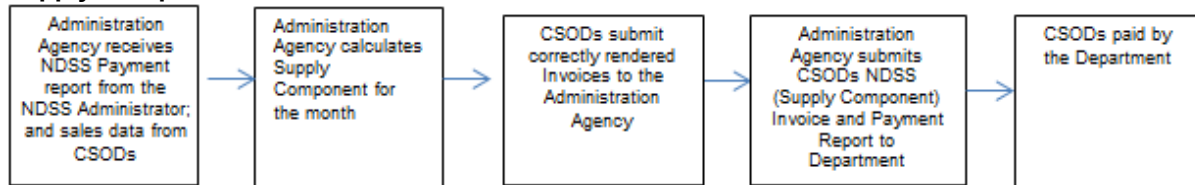
If the issue is not resolved by the NDSS Administrator by the 5<sup>th</sup> Business Day, an invoice will need to be raised by the CSO Distributor for the amount outlined in the Payment Report and the NDSS Administrator will escalate the issue to the CSO Administration Agency.

The Department will note the disputed amount under investigation and any approved changes to payment will be incorporated into the following month's invoice. If an invoice has not been raised, the Department will not make payment for that month and will carry over to the following month.

## 6. Providing Accurate and Timely Data

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### Supply Component



By the 2<sup>nd</sup> business day of the next month, the NDSS Administrator will send the CSO Administration Agency a Payment Report on NDSS products that were shipped by CSO Distributors as a result of orders through the NDSS system. This report will form the basis of the amount CSO Distributors are required to invoice the Department for the NDSS Supply Component.

The CSO Administration Agency will advise the CSO Distributors of the Invoice to be raised for the Supply Component only.

The Department will pay the Supply Component at the same time it pays the PBS Medicine Invoices.

### **NDSS Payment Calculations**

The underpinning principle of the CSO Payment process is that CSO Distributors must meet the Obligations under the Deed to receive Payments for NDSS Distribution Services. This principle is set out in clause 11.7 of the Deed and means that Payments are linked to a CSO Distributor's compliance with the Obligations under the Deed.

For each Month, and as part of the CSO Payment process set out in the Deed, the CSO Administration Agency must consider a CSO Distributor's compliance with the Obligations under the Deed when determining whether to make a Payment to that CSO Distributor and how much any Payment should be.

### **NDSS Distribution Service Payment Calculations**

Funding for the NDSS Distribution Service is dependent on demand through the NDSS and may not necessarily be evenly distributed over each Year of the Term of the Deed.

The amount payable to a CSO Distributor for NDSS Distribution Services will be based on its volume of NDSS Products Supplied to Access Points within its CSO Jurisdiction(s) for the Month, and consists of:

- The Direct Cost Component;
- The Delivery Component; and
- The Supply Component.

Payment for the Direct Cost and Delivery Components will be calculated by the NDSS Administrator, and payment for the Supply Component will be calculated by the CSO Administration Agency.

The Supply Component for each unit of NDSS Product supplied to an Access Point during a Month is an amount equal to the per Unit Payment from the CSO Funding Pool for the Supply of each Unit of PBS Medicine during that Month.

## 6. Providing Accurate and Timely Data

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*Example 8 – Calculation of Payment to CSO Distributors for the Supply Component of NDSS Distribution Services*

CSO Distributor	NDSS Products Supplied	Payment for Supply Component
W	150,000 Units	\$90,000
X	100,000 Units	\$60,000
Y	300,000 Units	\$180,000
Z	200,000 Units	\$120,000

For the purposes of the example above, the Unit Payment from the CSO Funding Pool for the Supply of a Unit of PBS Medicine in that Month is assumed to be \$0.60 (refer Example 1).

The Payment amount to CSO Distributors per Month may vary to reflect the application of financial Sanctions to the total amount of Payments in a previous Month.

The CSO Administration Agency has discretion within the framework of the Deed and the CSO Operational Guidelines to determine how and when the financial Sanctions are applied. Any financial sanctions will then be incorporated into future NDSS payments.

### ***Annual reconciliation process***

The CSO Administration Agency is required to perform an annual reconciliation of Payments made to CSO Distributors to recalculate Payment entitlements for each Month, taking into consideration Data errors and other issues that are identified after the original Payments were made.

The reconciliation is undertaken at the end of the financial Year and in conjunction with an annual assessment of each CSO Distributor's compliance with their CSO Obligations. The CSO Administration Agency begins the annual reconciliation in May each year, and requests data and other information from CSO Distributors from this time.

If necessary, CSO Distributors will be requested to resubmit their Monthly Data for the past year and ensure that all errors, such as ineligible PDE codes, Sales to locations that are not Distribution Points and other errors identified by the CSO Administration Agency throughout the Year have been addressed.

CSO Distributors are responsible for the accuracy and completeness of their Data. Sanctions and/or Payment Adjustments may be applied where the reconciliation identifies that inaccurate or incomplete Data was previously submitted, or that any Deed Obligation was not met for any Month, e.g. the Low Volume or Rural and Remote Threshold requirements.

Once the CSO Administration Agency has received reconciled Data from all CSO Distributors, it will conduct an analysis of each Month's Data for each CSO Distributor to:

Ensure Data errors detected during the Year have been corrected, both in the Months they were identified and all preceding or subsequent Months affected by that same error, where relevant;

## 6. Providing Accurate and Timely Data

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Identify where there are significant unexplained differences between the final and original Data, and ascertain the reasons for these differences;

Identify apparent anomalies and variations; and

Ensure relevant Deed Obligations were met for each Month.

Following receipt of CSO Distributors cleansed Data and completion of the CSO Administration Agency's reconciliation checks, the CSO Administration Agency will advise CSO Distributors of any adjustments to their monthly market shares and Payments for the preceding Year, by early September.

### ***Calculation of Low Volume and Rural and Remote Thresholds for PBS Medicines***

Thresholds are in place to ensure that CSO Distributors supply PBS Medicines to any Community Pharmacy within their CSO jurisdiction, including rural and remote Community Pharmacies.

The Rural and Remote Thresholds reflect the proportion of total Sales of PBS Medicines under the CSO that must be supplied to Community Pharmacies in Rural and Remote localities. These Thresholds are intended to define the level at which the Government is satisfied that Community Pharmacies in Rural and Remote areas are receiving full access to PBS Medicines.

CSO Distributors must ensure that their proportion of Sales to Rural and Remote Community Pharmacies against their total CSO Sales are not below specified Thresholds, i.e. do not fall more than 10% below the Industry Average.

The Industry Average is calculated by determining the average Sales volume of PBS Medicines to Community Pharmacies by CSO Distributors under CSO arrangements. The amount derived following the application of the 10% tolerance level to the Industry Average becomes the applicable Threshold. For example, if the current Industry Average for sales to Rural and Remote Community Pharmacies is 31.3 for every one hundred PBS Medicines supplied then no less than 28.2 PBS Medicines would need to be supplied to rural and remote pharmacies for the Threshold to be met (i.e. 28.2% of total sales must be to a rural and remote Community Pharmacy).

The 10% tolerance level was introduced in recognition of the difficulties faced by CSO Distributors in consistently meeting the Industry Average. CSO Distributors will satisfy their obligations as long as Sales of PBS Medicines to rural and remote locations under the CSO do not fall more than 10% below the Industry Average.

On an annual basis, the CSO Administration Agency examines aggregated reconciled Data for the preceding Year provided by each CSO Distributor, to determine the total Sales of all PBS Medicines by product and postcode. Those PBS Medicines that fall within the definition of Low Volume in the Deed are assigned to a list of Low Volume PBS Medicines that is *"those PBS Medicines that were sold by CSO Distributors to Community Pharmacies at an average rate of less than one Unit per Community Pharmacy per week, as determined by the CSO Administration Agency"*.

Additionally, the percentage of Sales to Rural/Remote locations for each CSO Distributor is calculated from the aggregate Data. A Rural and Remote location means a location postcode which falls within the identified range of rural and remote postcodes for CSO Funding Pool purposes (*Appendix A*).

The CSO Administration Agency then calculates the industry average Sales of Low Volume items and Sales to Rural/Remote locations and the new minimum Low Volume and Rural/Remote Thresholds are

## 6. Providing Accurate and Timely Data

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determined. The current Rural and Remote Postcodes List is provided at *Appendix A*, and the Low Volume PBS Medicine List is provided at *Appendix C*. These new minimum Thresholds are applied from October to September of the next Year. During September, CSO Distributors are advised of the new minimum Thresholds and are provided with an updated list of Low Volume PBS Medicines, an updated list of High Volume PBS Medicines and an updated list of Rural and Remote postcodes, if applicable.

These lists are also available to download from the PDE-PBS mapping website of the CSO Administration Agency.

### ***CSO Products subject to current or anticipated shortage***

The Department and/or the CSO Administration Agency may require CSO Distributors to provide additional Data and/or Reports in respect of CSO Products identified to be the subject of a current or anticipated shortage.

### **Force Majeure Events**

The provision of such Data and/or Reports may be for a limited duration, due to the need to address and monitor issues arising from a Force Majeure Event. In these circumstances, CSO Distributors will be provided with additional guidance through a written direction issued under Clause 4.9A of Schedule 1 of the Deed, as detailed in Section 2 of these Operational Guidelines.

Additional reporting may cover matters including a description of the arrangements put in place by a CSO Distributor to manage equitable access to CSO Products, including restriction limits, inventory management arrangements and stocking information.

Where the nature of the matter allows, the Department will endeavour to provide reasonable advance notice in relation to written directions issued under clause 4.9A of Schedule 1 of the Deed.

### **Ongoing critical medicines shortages**

Additionally, to further support the Department's monitoring and engagement with PBS supply chain stakeholders regarding ongoing critical medicines shortages, CSO Distributors may also be requested to provide reporting on current and/or anticipated medicines shortages identified through the Medicines Shortages Information Initiative administered by the Therapeutic Goods Administration.

Such reporting may include inventory and stocking information (including backorder information), order pattern history and information on the distribution of identified products to various locations across Australia.

In determining any requirements for additional Data or Reports, and the timeframe for complying with requests for additional reporting, the Department may consult with the CSO Distributors and consider a range of factors and circumstances, including but not limited to:

- availability of the information to the CSO Distributors; and
- whether that information is already routinely collected for related CSO Product supply purposes.

## 7. Audit Site Visits

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### 7 AUDIT SITE VISITS

As per Clause 16.4 of the Deed, the CSO Administration Agency, the Australian National Audit Office, the Auditor-General, the Australian Information Commissioner, the Commonwealth, or a nominated independent entity, may audit CSO Distributors for compliance with their Deed Obligations.

The CSO Administration Agency undertakes a range of ongoing monitoring and auditing activities, including regular site visits to CSO Distributors' head office and distribution centres. The following provides an overview of these site visits.

The audit visit typically lasts between a half day and a full day. At least two weeks prior to a scheduled audit, the CSO Administration Agency will request information from the CSO Distributor to enable the CSO Administration Agency to complete its site audit quickly and with the least possible disruption to operations.

#### ***Site Audit – Head Office***

At least once a Year, the CSO Administration Agency conducts a site audit of each CSO Distributors' head office. Head office audit visits assist the CSO Administration Agency to:

- understand and review systems and process which operate across the organisation; and
- validate a range of information and processes.

The CSO Administration Agency will pay particular attention to material Obligations when conducting the head office audit, such as:

- requirement to provide a single entry point for Distribution Points;
- requirement to Supply to any Distribution Point;
- requirement to Supply any Rural and Remote Pharmacy;
- requirement to Supply any PBS Medicine and NDSS Product;
- stocking requirement for CSO Products;
- requirement to Supply any Low Volume PBS Medicines;
- requirement to Supply any PBS Medicines at or below the CSO Price;
- requirement to Supply any NDSS Product at no cost to Access Points;
- requirement to not impose Prohibited Financial Imposts on Distribution Points;
- general Deed Obligations (clause 5);
- obligation to notify the CSO Administration Agency on matters considered relevant (clause 8); and
- obligation to provide Data as specified in Schedule 3 and clause 10.

#### ***Site Audit – Distribution Centre / Warehouse***

The warehouses used by each CSO Distributor to meet their CSO Obligations under the Deed are subject to periodic site audits by the CSO Administration Agency. Administration Agency visits to a CSO Distributor's warehouses focus on how the CSO Distributor ensures that all CSO Compliance Requirements and Service Standards are met at those particular storage facilities. Of particular focus are the:



## 7. Audit Site Visits

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- requirement to maintain access to established Infrastructure and sufficient financial capacity to meet the CSO Service Standards;
- requirement to maintain the quality of CSO Product;
- stocking requirement for CSO Products;
- requirement to Supply any PBS Medicines at or below the CSO Price;
- requirement to Supply any NDSS Product at no cost to Access Points;
- requirement for timely Supply; and
- obligation to provide Data as specified in Schedule 3 and clause 10.

CSO Distributors must ensure that they maintain the quality of all CSO Products that they Supply, including meeting all the applicable storage condition requirements as outlined in the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4, and 8*. The CSO Distributor must also ensure that it, and any subcontractors, holds all necessary State and Territory licences and/or certificates for their distribution centres. Failure to meet any of the Obligations in this Compliance Requirement may result in a Non-Performance being recorded by the CSO Administration Agency and Sanctions being applied.

Additional checks of data accuracy, which relate to both the warehouse audited and each CSO Distributors' Monthly CSO Sales data are conducted following warehouse audits.

## Appendix A: List of Postcodes defined as Rural and Remote

Please refer to separate document.

## Appendix B: List of Postcodes outside the Guaranteed Supply Period requirement

### 1 List of locations that fall outside the requirement to Supply CSO Products within the Guaranteed Supply Period

#### 1.1 The following locations fall outside the requirement to Supply CSO Products within the Guaranteed Supply Period:

Postcode	State / Territory	Community Pharmacy Location
0860	Northern Territory	TENNANT CREEK
2899	New South Wales	NORFOLK ISLAND
4871	Queensland	MORNINGTON ISLAND
4874	Queensland	WEIPA
4875	Queensland	THURSDAY ISLAND
6161	Western Australia	ROTTNEST ISLAND
6714	Western Australia	KARRATHA
6728	Western Australia	DERBY
6798	Western Australia	CHRISTMAS ISLAND

#### 1.2 The CSO Distributor must make all reasonable efforts to Supply CSO Products within the Guaranteed Supply Period to the locations listed at clause 1.1 of this Appendix. Locations listed at clause 1.1 of this Appendix should not receive a lesser standard of service than they received at the time that the relevant CSO Distributor entered into a Deed.

## Appendix C: Low Volume Thresholds

Not included in this publication.

## Appendix D: List of Exclusive Supply Arrangements for PBS Medicines

Not included in this publication.

## Appendix E: Over the Counter Proportion List

Not included in this publication.

# Appendix F: CSO Product Breach Report Form

## Cold Chain and Non-cold Chain Temperature Sensitive Medicine Breach Report Form

For Community Service Obligation (CSO) Distributors  
CSO Funding Pool-only supplied PBS Medicines

*CSO Distributors must complete this Form and Spread sheet for all instances of cold chain and temperature sensitive medicine breaches, where the medicine has not been stored in accordance with sponsor's recommended conditions for product stability integrity stated on the TGA approved product packaging, other than those breaches which are not required to be reported in accordance with the risk based approach agreed in writing between the CSO Distributor and the Commonwealth through the CSO Administration Agency:*

- *where the temperature excursion is inside the tolerances provided for in the mean kinetic temperature (MKT) framework; and*
- *there is no material risk to consumer safety arising from the temperature excursion.*

*The completed Form and spread sheet must be provided to the CSO Administration Agency as soon as the cold chain or temperature sensitive medicine breach is detected.*

Date: \_\_\_\_\_

Name of CSO Distributor: \_\_\_\_\_

Reported by CSO Distributor responsible person:

Name: \_\_\_\_\_ Position: \_\_\_\_\_

Signature: \_\_\_\_\_

Contact number: \_\_\_\_\_ email: \_\_\_\_\_

### Definitions

In this form, the following definitions apply:

**Cold chain** has the same meaning as in the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8, 1 April 2011*.

**Non-cold chain temperature sensitive medicines** has the same meaning as in the *Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8, 1 April 2011*, i.e. medicines that require controlled temperatures, such as those that must be stored at or below +25 °C.

**Warehouse temperature** means the maintenance of other warehouse areas (other than refrigerators or freezers) used to store PBS Medicines at or below 25°C (refer to the CSO *Operational Guidelines*).

# Appendix F: CSO Product Breach Report Form

## Type of breach:

(Attach additional details if needed)

Cold Chain (Refrigerator/Freezer) / Warehouse (circle as appropriate)

Below recommended temperature range ☐ Minimum Temp°C \_\_\_\_

Above recommended temperature range ☐ Maximum Temp°C \_\_\_\_

**Duration of breach:** \_\_\_\_

(Time that medicines were out of recommended temperature range)

**Date breach occurred:** \_\_\_\_

**Date breach detected:** \_\_\_\_

**Have any medicines affected by the breach been supplied to Community Pharmacies?**

**Yes/No**

Details to be provided in attached spreadsheet Table F.1

**Have / were medicines affected by the breach been quarantined?**

**Yes/No**

Details to be provided in attached Table F.1

**Has supplier / manufacturer advice been obtained / sought about the medicines suitability for use?**

**Yes/No**

Details to be provided in attached Table F.1

**Has the State / Territory pharmaceutical wholesaling licensing agency been notified of the breach?**

**Yes/No**

## Cause of breach:

(Describe the cause/event e.g. door left open, fluctuating internal temperatures, equipment failure etc. Attach additional details if needed)

\_\_\_\_

## How was the breach discovered?

(e.g. self-report, CSO Administration Agency audit, audible alarm, routine data review etc. Attach additional details if needed)

\_\_\_\_

Attached details of the medicines affected by the breach (Table F.1).

Return this completed Form and spreadsheet to the CSO Funding Pool Administration Agency **as soon as the breach is detected:**

Email: [admin@csoagency.com.au](mailto:admin@csoagency.com.au)

*The CSO Administration Agency will provide this temperature breach information to the Commonwealth Department of Health and Aged Care as part of its CSO reporting obligations, and may request from the CSO Distributor additional information including contact details of the supply recipients of any medicines affected by the temperature breach.*



# Appendix F: Breach Report Form

Table F.1 Cold Chain and Non-Cold Chain Temperature Sensitive Medicine Breach Report Form (excel spreadsheet)  
(CSO Funding Pool-only supplied medicines)

Type of breach Cold Chain (refrigerator/freezer) /Warehouse	Product description	PDE code	Supplier/ manufacturer	PBS code	Warehouse location, including State/ Territory	Quantity affected	Quantity supplied to Community Pharmacies	Quarantine status in-quarantine / released from quarantine / non quarantined	Supplier/manufacturer 'Suitability for use' advice suitable for use / not suitable for use / advice outstanding (if outstanding expected response date)	Commentary (e.g. temperature range, breach duration, other actions to date)
Select								Select	Select	
Select								Select	Select	
Select								Select	Select	
Select								Select	Select	
Select								Select	Select	
Select								Select	Select	
Select								Select	Select	
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Select								Select	Select	

# Appendix G: CSO Product Supply Complaint Form

## Appendix G: CSO Product Supply Complaint Form

### Before lodging a complaint

Before lodging a complaint, or to assist you in completing this form, it may be useful to contact the CSO Administration Agency toll free in VIC on 1300 309 213 to discuss your complaint or seek assistance.

A summary of the CSO Compliance Requirements and Service Standards CSO Distributors are required to meet has also been attached for your reference.

Complaints can be lodged with the CSO Administration Agency in writing, either electronically or in hard copy, to the following address:

Email: [admin@csoagency.com.au](mailto:admin@csoagency.com.au)  
Fax: (03) 9639 4459  
Post: Complaints Officer, CSO Funding Pool Administration Agency  
Locked Bag 32005, Collins Street East, VIC 8003

### I want to lodge a formal complaint with the CSO Administration Agency Yes No My details are:

Mr/Mrs/Ms (other): \_\_\_\_\_ First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Address: \_\_\_\_\_

Postcode: \_\_\_\_\_ State: \_\_\_\_\_

Telephone: (business hours) \_\_\_\_\_

Mobile: \_\_\_\_\_ Fax: \_\_\_\_\_ Email address: \_\_\_\_\_

### I am lodging this complaint on behalf of:

**Myself** (go to page 2 of the form)

**Another company or person** (complete the details below)

### Details of the company or person who was affected by the actions or service that you wish to complain about are:

Mr/Mrs/Ms (other) \_\_\_\_\_ First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Or company name: \_\_\_\_\_

Address: \_\_\_\_\_

Postcode: \_\_\_\_\_ State: \_\_\_\_\_

Telephone: (business hours) \_\_\_\_\_

Mobile: \_\_\_\_\_ Fax: \_\_\_\_\_ Email address: \_\_\_\_\_

Is the person or company aware you are making this complaint? **Yes No**

# Appendix G: CSO Product Supply Complaint Form

My relationship with the company or person is (for example shareholder, director business partner, family member): \_\_\_\_\_

## I want to complain about:

☐ **CSO Distributor One**

CSO Distributor Name: \_\_\_\_\_

CSO Distributor contact details (if known): \_\_\_\_\_

☐ **CSO Distributor Two**

CSO Distributor Name: \_\_\_\_\_

CSO Distributor contact details (if known): \_\_\_\_\_

**If there are more CSO Distributors you want to complain about please attach their details on a separate piece of paper to the back of this form.**

☐ **Another aspect of the CSO Funding Pool**

## My complaint is:

Use the space below to provide details of your complaint. It is useful to include what happened, when it happened and who was involved. Include as much supporting information and evidence as you can (attach any relevant documents you have to the back of this form). If you need more space, please attach a separate piece of paper to the back of this form.

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## The main issues I am concerned about are:

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# Appendix G: CSO Product Supply Complaint Form

**As a result of my complaint I want:**

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**Where this complaint is against a CSO Distributor, have you approached the CSO Distributor about this complaint? Yes No**

If yes, what was the outcome?

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**Have you complained to another organisation about the same matter? Yes No**

If yes, please give details.

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**The CSO Administration Agency will send details of this complaint to any CSO Distributor/s you have identified in your complaint asking them to provide a response to the CSO Administration Agency.**

**I agree that my identity can be released for this purpose -**

**Yes No**

You do not have to agree to the release of your identity.

**I agree that a copy of my complaint can be released for this purpose? Yes No**

You do not have to agree to release a copy of this complaint. If you select 'No', you need to advise below any information in this form that you do not want released to the subject of the complaint (e.g. your name, others names, other details about the complaint).

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# Appendix H: Glossary

## Glossary

Unless the contrary intention appears, all capitalised terms in the CSO Operational Guidelines have the following meanings.

**Access Point** means any Community Pharmacy or other organisation appointed by the NDSS Administrator or the Commonwealth to supply NDSS Product to Registrants and notified in writing to CSO Distributors from time to time.

**Act of God** means an event or occurrence, due to natural causes, that in the Commonwealth's reasonable opinion:

- a) occurs independently of human intervention;
- b) is beyond the control of the CSO Distributor;
- c) could not be foreseen by the CSO Distributor;
- d) could not have been prevented, avoided, or overcome by the CSO Distributor taking all reasonable steps; and
- e) could not reasonably have been prevented, avoided, or overcome by the CSO Distributor before the Commencement Date of the Deed.

**Additional Charge** means any CSO Approved Fees charged by a CSO Distributor to a Community Pharmacy.

**Administration Agency** means any one or more service providers contracted by the Commonwealth to administer the CSO Funding Pool. (If a new service provider is appointed to administer the CSO Funding Pool, there may be two Administration Agencies until the new service provider takes over full administration of the CSO Funding Pool from the previous service provider.) A reference to the CSO Administration Agency includes the CSO Administration Agency's Authorised Officer.

**Approved Fees** are commercially acceptable fees of an accounting or accounts receivable nature (for example, fees on overdue accounts and fees for dishonoured payments), which are charged by the Company as at the date of the Deed.

**Approved Pharmacist** has the meaning given in the section 84(1) of the *National Health Act 1953* which, at the date of this Agreement, is a person for the time being approved under section 90 of that Act and includes:

- a) a person treated as having been so approved under any provision of a law of the Commonwealth other than section 91; and
- b) except so far as subsection 90(3) is concerned – a person treated as having been so approved under section 91.

**Authorised Officer** means a person appointed by a party to act as its authorised officer for the purposes of the Deed.

**Brand** means a name, make or mark used to identify a CSO Product as from a particular Manufacturer, Wholesaler, pre-Wholesaler, CSO Distributor or other producer.

# Appendix H: Glossary

**Business Continuity Plan** means a set of documents, instructions and procedures that are regularly tested and which enable the CSO Distributor to manage risk and minimise the outage period following a critical event, so that key business activities under CSO arrangements, including the CSO Service Standards and CSO Compliance Requirements are not interrupted.

**Business Day** means, in relation to the doing of any action in a place, any day other than a Saturday, Sunday, or public holiday in that place.

**Business Plan** means a plan of action that details a timeframe, measurable milestones, and activities that will be undertaken by a CSO Distributor to rectify any other Non-Performance issue.

**Claimed Price** means the amount specified in a determination in force under subsection 85B(3) of the *National Health Act 1953*.

**Commonwealth** means the Commonwealth as represented by the Department of Health and Aged Care.

**Community Pharmacy** means any premises which have been approved under section 90 of the *National Health Act 1953* from which an Approved Pharmacist conducts pharmacy business.

**Company** means a CSO Distributor.

**Complaint** means any expression of dissatisfaction by any person about any aspect of the CSO Funding Pool.

**Complaints Procedure** means the CSO Complaints Procedure as approved by the Commonwealth.

**Confidential Information** means information which is:

- a) by its nature confidential;
- b) designated by its Discloser to be confidential;
- c) agreed by the parties to be confidential; or
- d) by its nature capable of protection at Law or in equity as confidential information,

but does not include information that:

- e) is or becomes public knowledge, other than by breach of this Deed or by any other unlawful means
- f) is in the possession of the Recipient without restriction in relation to disclosure before the date of receipt from the other party; or
- g) has been independently developed or acquired by the Recipient
- h) is required to be disclosed by Law or court order.

**CSO** means Community Service Obligation.

**CSO Compliance Requirements** means the requirements specified under the CSO arrangements.

**CSO Distributor** means an Eligible Entity that has entered into a Deed with the Commonwealth in relation to the CSO Funding Pool and the NDSS Distribution Services.

**CSO Funding Pool** means the Commonwealth funding referred to in clause 8.1 of the 7CPA.

# Appendix H: Glossary

**CSO Jurisdiction** means the jurisdiction(s), either National or State Based, in which the Company is Supplying CSO Product and is seeking to access the CSO Funding Pool.

**CSO Operational Guidelines** means the set of advice and guidelines of that name issued by the Commonwealth to the Company from time to time, in relation to the Company's Obligations under this Deed and administrative matters relating to the CSO Funding Pool and NDSS Distribution Services.

**CSO Price** means the Price to Pharmacists or the Claimed Price Plus the Wholesaler Mark-Up.

**CSO Products** means PBS Medicines and NDSS Products

**CSO Service Standards** means the standards specified under the CSO arrangements

**Daily** means on any Business Day and also on Saturdays where the Company offers a Saturday delivery.

**Data** means the data that meets the requirements specified under the CSO arrangements and that:

- a) whether or not specified, allows the CSO Administration Agency to ascertain compliance with the Deed; and/or
- b) is to be provided by the CSO Distributor to the CSO Administration Agency in the form of a Report.

**Deed** means the document between the Commonwealth and CSO Distributors including any schedules and annexures.

**Distribution Point** means:

- a) in respect of PBS Medicines, a Community Pharmacy; and
- b) in respect of NDSS Products, an Access Point.

**Eligible Entity** means any entity that has the capacity to obtain and deliver pharmaceuticals and medical or surgical aids, equipment or appliances to Distribution Points where those CSO Products are available from Manufacturers and where, further, the Commonwealth has determined the entity is eligible to participate in the CSO Funding Pool.

**Entity** has the meaning given in section 64AA of the *Corporations Act 2001* (Cth).

**Exclusive Supply Arrangement** means any agreement, arrangement or understanding under which CSO Products are not made available by the relevant Manufacturer to all CSO Distributors.

**Exempt Exclusive Supply Arrangement** means an Exclusive Supply Arrangement set out in Schedule 9 of a Deed.

**Force Majeure Event** means any of the following events:

- a) fire, flood, earthquake, pandemic, other natural disaster or other Act of God;
- b) war or other state of armed hostilities;
- c) an emergency, that in the Commonwealth's reasonable opinion is a national disaster or critical emergency, affecting a region in which an Obligation must be performed.

# Appendix H: Glossary

**Guaranteed Supply Period** means:

- a) for PBS Medicines on the High Volume List, within 72 hours from the Regular Order Cut Off Time;
- b) for all other PBS Medicines (including Low Volume PBS Medicines), within 24 hours from the Regular Order Cut Off Time; and
- c) for NDSS Products, within 24 hours from the Regular Order Cut Off Time.

**High Volume PBS Medicines** means, those PBS Medicines that were sold by CSO Distributors to Community Pharmacies at an average rate of one or more Unit per Community Pharmacy per week, calculated on the basis of Data and Reports provided by CSO Distributors and as reconciled by the CSO Administration Agency.

**Industry Average** means the average Sales volume of PBS Medicines, calculated to one decimal place, to Community Pharmacies by all CSO Distributors in the preceding Year, based on Data and Reports provided by CSO Distributors to the CSO Administration Agency throughout the Year. The Industry Average will:

- a) be calculated on the basis of Data and Reports provided by CSO Distributors for the previous Year (even if the Year preceded the Commencement Date) and as reconciled by the CSO Administration Agency;
- b) apply from October to September immediately after that Year (or part thereof during the Term);
- c) be used to calculate the applicable Thresholds for Sales to Rural and Remote Pharmacies and Sales of Low Volume PBS Medicines; and
- d) be used to calculate the list of High Volume PBS Medicines.

**Infrastructure** means physical infrastructure, such as warehouses, distribution centres, and transport and logistics services.

**ITA** means the Invitation to Apply to participate in the Community Service Obligation Funding Pool and supply NDSS Products (Health 18/19–04990) released by the Commonwealth.

**ITA Publication Date** means the 'Publish Date' for the ITA as specified for the ITA on AusTender (at <http://www.tenders.gov.au>), being 30 November 2018.

**Low Volume PBS Medicines** means, those PBS Medicines that were sold by CSO Distributors to Community Pharmacies at an average rate of less than one Unit per Community Pharmacy per week, calculated on the basis of Data and Reports provided by CSO Distributors and as reconciled by the CSO Administration Agency.

**Major Non-Performance** means a Non-Performance that, in the reasonable opinion of the CSO Administration Agency, impacts the key objectives of the CSO Funding Pool.

**Manufacturer** means

- (a) any manufacturer of CSO Products or that manufacturer's agent;
- (b) any pre-wholesaler of CSO Products; or
- (c) any other participant in the supply chain for CSO Products reasonably determined by the Commonwealth to be a 'Manufacturer' for the purposes of this Deed. For the



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avoidance of doubt, a Related Entity of the persons described in paragraph (a) and (b) of this definition may be determined by the Commonwealth to be a 'Manufacturer' for the purposes of the Deed.

**Material Adverse Outcome** means any outcome that would, in the Commonwealth's reasonable opinion, have a negative impact on the CSO Funding Pool, the 7CPA, the quality, safety or efficacy of any CSO Products or any related Commonwealth policy arrangements.

**Minimum Order Quantity**, for any order of High Volume PBS Medicines (which may include one or more types of High Volume PBS Medicines), means:

- a) for products which are not refrigerated, Shelf Packs of each product with an aggregate minimum value of at least \$15.00 ex manufacturer or, where there is no Shelf Pack, Units, with an aggregate minimum value of at least \$15.00 ex manufacturer; and
- b) for products which must be stored in refrigerated conditions, Shelf Packs of one or more products with an aggregate minimum value of at least \$150.00 ex manufacturer or, where there is no Shelf Pack, Units, with an aggregate minimum value of at least \$150.00 ex manufacturer.

**Minor Non-Performance** means a Non-Performance that, in the reasonable opinion of the CSO Administration Agency, is unlikely to directly impact on the objectives of the CSO Funding Pool on its own, but would not preclude more than one Minor Non-Performance resulting in a Major Non-Performance.

**Month** means a calendar month.

**National** includes all Australian States and Territories.

**National CSO Distributors** means CSO Distributors that Supply all Australian States and Territories.

**National CSO Funding Pool** means the Commonwealth funding made available to National CSO Distributors under the CSO arrangements.

**National Diabetes Services Scheme** or **NDSS** means the Commonwealth's scheme to ensure that persons with diabetes have timely, reliable and affordable access, on a National basis, to the supplies and services required for the effective self-management of their condition.

**National Sanctions Pool** means:

- a) the monies to be paid by National CSO Distributors to the Commonwealth, or deducted from Payments, as a result of the application of financial Sanctions under any Deed between the Commonwealth and a National CSO Distributor; and
- b) where there is only one State Based CSO Distributor, monies to be paid by that State Based CSO Distributor to the Commonwealth, or monies to be deducted from the Payment to that State Based CSO Distributor as a result of the application of financial sanctions under the Deed between the Commonwealth and the State Based CSO Distributor.

**NDSS Products** means all items listed on the NDSS Product Schedule.

**NH Act** means the *National Health Act 1953* (Cth).

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**Non-Performance** means a non-performance by the CSO Distributor of any Obligation under the CSO arrangements, including but not limited to non-compliance with the CSO Compliance Requirements and the CSO Service Standards. Each Non-Performance of an Obligation will be dealt with as a separate Non-Performance for the purpose of the Commonwealth's Rights in respect of the Non-Performance.

**Obligation** means any legal, equitable, contractual, statutory or other obligation, commitment, duty, undertaking or Liability, present or future, including the CSO Compliance Requirements and CSO Service Standards.

**Over the Counter PBS Medicines** means PBS Medicines that are provided over the counter at Community Pharmacies without a medical practitioner's prescription and those that are provided with a medical practitioner's prescription but are not dispensed.

### **Pack Quantity (PQ):**

- (a) in relation to a PBS Medicine, has the same meaning as in subsection 84AK(2) of the NH Act; and.

**Note:** The Minister may determine one or more pack quantities for a brand of a pharmaceutical item under subsection 84AK(2) of the *National Health Act 1953* (Cth). The quantities determined are the quantities in the manufacturer's PBS packs.

- (b) in relation to a Brand of an NDSS Product, means the quantities or numbers of units of that Brand of that NDSS Product, as listed in the NDSS Product Schedule.

**Payment** means a payment made to a CSO Distributor from the CSO Funding Pool under the CSO arrangements; for NDSS Distribution Services; or for the reimbursement of PharmX Costs.

**PBS Medicines** means all items listed on the Schedule of Pharmaceutical Benefits, but does not include pharmaceutical items that:

- a) contain a drug for which there is a declaration under section 85(2A)(b) of the National Health Act 1953 [section 100 drug declaration], unless specified by the Commonwealth in writing to the CSO Distributor;
- b) are a pharmaceutical benefit for which there is a determination under section 85(8)(a) of the National Health Act 1953 [section 100 only pharmaceutical benefit determination], unless specified by the Commonwealth in writing to the CSO Distributor;
- c) the CSO Distributor cannot supply due to an Exclusive Supply Arrangement; or
- d) are medicines listed only for supply under the Repatriation Schedule of Pharmaceutical Benefits.

**Note 1:** The Obligations mentioned in this Deed for a PBS Medicine relate to the medicine. Those Obligations do not vary based on the circumstances or purposes determined for a PBS Medicine under Part VII of the *National Health Act 1953*.

**Note 2:** 'PBS Medicines' does not include medicines listed only for supply under the Repatriation Schedule of Pharmaceutical Benefits.

**Price Per Unit** is determined based on the Approved Price to Pharmacist for the maximum quantity of the PBS Medicine as published in the Schedule of Pharmaceutical Benefits.

**Price to Pharmacists** has the same meaning as in the Determination under paragraph 98B(1)(a) of the NH Act.

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**Prohibited Financial Imposts** are fees, levies, cost recoveries or other financial imposts or trading terms on Distribution Points which are intended to, or which have the effect of, providing to the Company additional revenue or compensation for complying with its Obligations under the Deed or which are otherwise inconsistent with the purpose or intent of the CSO Funding Pool or the Deed.

**Quarterly** means the three Month periods from 1 July to 30 September, 1 October to 31 December, 1 January to 31 March and 1 April to 30 June.

**Regular Order Cut Off Time** means the Daily time, as agreed by the CSO Distributor and the Community Pharmacy, by which orders must be lodged with the CSO Distributor.

**Report** means a report to be provided by the CSO Distributor to the CSO Administration Agency.

**Review** means any review referred to under the CSO arrangements between the Commonwealth and CSO Distributors.

**Rural and Remote** means a location that has been defined as Rural and Remote for the purposes of the CSO Funding Pool reflected in the CSO Operational Guidelines.

**Sales** means:

- (a) total volume of sales of Units of PBS Medicines to Community Pharmacies; and
- (b) total volume of delivery of Pack Quantities of NDSS Products to Access Points,

(excluding Sales of PBS Medicines under Exclusive Supply Arrangements) within a specified period of time minus, in each case, any returns of CSO Products within that specified period of time.

**Sanctions** means the financial or non-financial sanctions as described under the CSO arrangements.

**Shelf Pack** means the form and quantity of product (if any) as agreed in writing between the Company and the Commonwealth as constituting a shelf pack.

**Single Business Entity** means the single separately registered entity that has entered into and will be held accountable for meeting Obligations under the CSO arrangements.

**7CPA** means the Seventh Community Pharmacy Agreement between The Honourable Greg Hunt, MP, Minister for Health (on behalf of the Commonwealth of Australia), the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.

**Special Pricing Arrangements** means arrangements entered into between the Commonwealth and a Manufacturer in relation to the price of PBS Medicines.

**State Based** means any, but not all, Australian States and Territories.

**State Based CSO Distributors** means CSO Distributors that Supply any, but not all, Australian States and Territories.

**State Based CSO Funding Pool** means the Commonwealth funding made available to State Based CSO Distributors under this Deed.

**Stock** means to have custody or possession of a CSO Product.

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**Supply** means to obtain (from a warehouse, distribution centre or elsewhere) and deliver a CSO Product to a Distribution Point.

**Supply Only** means a PBS Medicine that is deleted from the Schedule of Pharmaceutical Benefits but moves to the Supply Only schedule (published monthly on the pbs.gov.au website). Supply Only PBS Medicines may continue to be dispensed (although not prescribed), usually for a period of up to 12 months from deletion.

**Term** means the period, including any extended periods, under which the CSO arrangements operate under Deeds.

**Terminate this Deed** means to bring the agreement between the Commonwealth and CSO Distributors, and the parties' Rights and Obligations under it (other than their respective Rights and Obligations which have accrued up to that time or which are expressed to survive its ending), to an end.

**Threshold** means the minimum requirement for Sales volumes as specified under the CSO arrangements.

**Unit means** a pack size:

- a) equal to a Pack Quantity;
- b) which, if less than a Pack Quantity, is a factor of a Pack Quantity; or
- c) which, if greater than a Pack Quantity that can be broken down to a size that equals a Pack Quantity.

**Wholesale Mark-up**, in relation to a PBS Medicine, means the amount worked out using the methodology for calculating the wholesale mark-up for ready prepared pharmaceutical benefits in the determination made under section 98B(1)(a) of the *National Health Act 1953*, on a pro rata basis if the Unit is less than a Pack Quantity.

**Year** means a financial year from 1 July to 30 June.