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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 Sixth Community Pharmacy Agreement (Sixth Agreement).

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.

The Sixth Agreement also transferred the responsibility for distribution of NDSS Products to CSO Distributors.

Operation of the National Diabetes Services Scheme

The National Diabetes Services Scheme (**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.

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.

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 Sixth Agreement 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 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
- the Obligations of the 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.

2. Compliance Requirements and Service Standards

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 Administration Agency will provide any revised versions of the CSO Guidelines to all CSO Distributors.

Administration Agency

The 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 Administration Agency is an independent entity that reports to the Department. The 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;
- maintaining the CSO IT System;
- analysing and investigating Data; and
- conducting site audits of the warehouses and storage facilities of CSO Distributors.

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

- Mapping information to support the sales claimed each Month including:
 - PBS item code;
 - product code (**PDE**) and item description;
 - drug name;
 - form and strength;
 - pack size; and
 - brand name;
- Sales data for every eligible Unit of PBS Medicine Supplied including:
 - PDE;
 - postcode (location) the PBS Medicine was distributed to; and

2. Compliance Requirements and Service Standards

- volume distributed; 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 Administration Agency.

For NDSS Products: Each Month, CSO Distributors must provide the 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 Administration Agency is satisfied that the Data submitted by the CSO Distributors is accurate and complete, the Administration Agency undertakes a Monthly Payment calculation process. During this process, the 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 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.

An aim of the 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 Administration Agency is available to discuss and provide advice to CSO Distributors regarding any aspect of the administration of the CSO Funding Pool.

NDSS Administrator

The NDSS Administrator is an independent entity that reports to the Department. The NDSS Administrator cooperates in good faith with the 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;
- 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.

2. Compliance Requirements and Service Standards

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

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

2. Compliance Requirements and Service Standards

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 Compliance Requirements and seven 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:

- 1) Supply to any Distribution Point and ensure that they meet the set Threshold for Sales of PBS Medicines to Distribution Points in Rural and Remote Locations;
- 2) Supply any brand of CSO Product (PBS Medicine and NDSS Product);
- 3) 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;
- 4) Supply any Low Volume PBS Medicine and ensure that they meet the set Threshold for Sales of Low Volume PBS Medicines;
- 5) Supply any PBS Medicine at or below the relevant CSO Price for that PBS Medicine;
- 6) Supply NDSS Products at no cost to Access Points; and
- 7) 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

Requirement to provide a single entry point for Distribution Points

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND 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 order any Brand of any PBS Medicine, and receive information or resolve any inquiries in relation to those orders; and
 - 3.1.2 Access Points within its CSO Jurisdiction can order any NDSS Products and receive information or resolve any inquiries in relation to those orders.
- 3.2 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:
- 3.2.1 access special pricing offers made available through a specific Manufacturer or under a specific program; and/or;
 - 3.2.2 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.

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 SERVICE STANDARDS

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

- 3.3 The Company must maintain access to established Infrastructure and sufficient financial capacity to meet all its Obligations under the 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*".

CSO Distributors must inform the Administration Agency if they experience financial difficulties, or have difficulty maintaining access to established Infrastructure for any reason, and must notify the 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.

2. Compliance Requirements and Service Standards

Requirement to maintain the quality of CSO Products

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS

Requirement to maintain the quality of CSO Products

3.4 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 Administration Agency's monitoring and audit activities, the 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 <http://www.tga.gov.au/pdf/manuf-medicines-cgwp-schedule2-3-4-8.pdf>) 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.

2. Compliance Requirements and Service Standards

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

- buildings and grounds;
- 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

2. Compliance Requirements and Service Standards

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.

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 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 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.

The 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 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).

2. Compliance Requirements and Service Standards

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)
- ΔH = activation energy, **which should always be 83.144 kJ/mol**
- R = the universal gas constant (i.e. 8.3144×10^{-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:
 - taking the highest and lowest recorded temperature during each 24-hour period and divide these by two; or
 - 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 Administration Agency and Sanctions being applied.

The Administration Agency maintains a register of all licences and certificates, and CSO Distributors are required to provide the 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 Administration Agency with the Monthly Declaration and Exception Report.

Service Standards

Requirement to Supply to any Distribution Point

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND 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, including in Rural and Remote Locations.
4.2	The Company will not be required to Supply PBS Medicines to any Community Pharmacy while that Community Pharmacy is a bad debtor. The Company must resume Supply as soon as the Community Pharmacy is no longer a bad debtor.
4.3	The Administration Agency and/or the Commonwealth has the right, by notice in writing, to clarify or change the exception to the requirement to Supply to any Community Pharmacy in clause 4.2 of this Schedule.
4.4	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. NDSS Products are <u>not included</u> towards the Threshold.
4.5	On this basis:
4.5.1	the 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; and
4.5.2	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.
4.6	Where the Company is a State Based CSO Distributor eligible to access the CSO Funding Pool in more than one State or Territory:
4.6.1	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

2. Compliance Requirements and Service Standards

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.

4.6.2 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.

How to meet this Service Standard

CSO Distributors must Supply CSO Products to any Distribution Points except if a Community Pharmacy is deemed to be a bad debtor, in which case the CSO Distributor will not be required to supply PBS Medicines to that Community Pharmacy.

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.

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 Administration Agency throughout the Year. For the first Year of the Term of this Deed, the Industry Average will be calculated on the basis of data and reports provided by those Eligible Entities who were eligible to access the CSO arrangements under the Sixth Agreement. For the following Years of this Deed, the Industry Average will:

2. Compliance Requirements and Service Standards

- (a) *be calculated on the basis of Data and Reports provided by CSO Distributors for the previous Year and as reconciled by the Administration Agency;¹*
- (b) *apply from October to September of the subsequent Year;*
- (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 one hundred 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.

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 4.6 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 SERVICE STANDARDS

- 4.6 Where the Company is a State Based CSO Distributor eligible to access the CSO Funding Pool in more than one State or Territory:
- 4.6.1 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

¹ 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

(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.

4.6.2 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.

Requirement to Supply any CSO Product

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS

Requirement to Supply any CSO Product

4.7 The Company must Supply any Brand of any CSO Product, where requested, to Distribution Points within its CSO Jurisdiction. This means the Company must obtain any Brand of CSO Product and deliver it to Distribution Points within its CSO Jurisdiction if that Brand has been requested.

4.8 The Company will not be required to Supply CSO Products that are not available to it because of an Exclusive Supply Arrangement, or CSO Products that are out-of-stock with the Manufacturer or cannot be supplied by the Manufacturer.

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, CSO Distributors are not required to Supply CSO Products that are out of stock with the Manufacturer, cannot be supplied by the Manufacturer, or are subject to an Exclusive Supply Arrangement.

Exclusive Supply

An Exclusive Supply Arrangement arises when a CSO Product is not made available by a 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 it, 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 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 Administration Agency receives from CSO Distributors. CSO Distributors must advise the Administration Agency of any items that need to be added or removed from the Exclusive Supply list for the following Month and provide supporting evidence. The Administration Agency must be notified by the CSO Distributor of any additions or deletions required by the twelfth (12th) Business Day of each Month.

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

2. Compliance Requirements and Service Standards

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

Stocking Requirement for CSO Products

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS	
Stocking Requirement for CSO Products	
4.9	For PBS: The CSO Distributor must hold Stock in its warehouses or distribution centres (the warehouses or distribution centres that the CSO Distributor will use to meet the CSO Service Standards) of at least one Brand of every CSO Product. For multi-Branded PBS Medicines, the CSO Distributor must hold Stock of at least one Innovator Brand and one additional Brand which is Benchmark Priced.
4.10	For NDSS: The CSO Distributor must hold Stock in its warehouses or distribution centres (the warehouses or distribution centres that the CSO Distributor will use to meet the CSO Service Standards) of at least one of each product listed on the NDSS Product Schedule, as updated monthly by the Department.
4.11	The CSO Distributor will not be required to hold Stock of CSO Products that are not available to it because of an Exclusive Supply Arrangement, or CSO Product that are out-of-stock with the Manufacturer or cannot be supplied by the Manufacturer.
4.12	If a CSO Distributor is unable to Stock a particular CSO Product for any reason other than those mentioned in clause 4.11 of this Schedule, the CSO Distributor must provide the Administration Agency with an explanation as to why the CSO Product is unable to be Stocked. If the explanation, in the Administration Agency's reasonable opinion, is insufficient or is not provided, this will be considered a Non-Performance of the CSO Distributor'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 Brand and one additional Benchmark Priced Brand in stock.

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.

2. Compliance Requirements and Service Standards

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 in Schedule 1 of the Deed.

2. Compliance Requirements and Service Standards

Requirement to Supply any Low Volume PBS Medicine

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS	
Requirement to Supply any Low Volume PBS Medicine	
4.12	The Company must Supply any Brand of any Low Volume PBS Medicine, including in single Units, where requested.
4.13	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.
4.14	On this basis:
4.14.1	the 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; and
4.14.2	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.
4.15	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 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". 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 (as defined on page 10 of this document) 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.

2. Compliance Requirements and Service Standards

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

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

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS

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

- 4.16 Subject to clause 4.17, the Company must Supply any PBS Medicine, in any quantity:
- 4.16.1 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;
- 4.16.2 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 4.18 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 4.19, plus the Wholesale-Mark-Up calculated in accordance with clause 4.24.
- 4.17 Any order of PBS Medicines from the High Volume List must be for at least the Minimum Order Quantity. . If a Community Pharmacy requests a Company to Supply less than the Minimum Order Quantity of PBS Medicines from the High Volume List , 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 Administration Agency. The Company may not charge any additional amount under this clause 4.17 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.
- 4.18 For the purposes of clauses 4.16.2(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.
- 4.19 For the purposes of clauses 4.16.2(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.
- 4.20 The Company is able to apply existing commercially acceptable fees of an accounting nature, such as fees applied for overdue accounts or fees applied for dishonoured payments. However, the Company must ensure that its trading terms and other agreements with Community Pharmacies do not circumvent or are otherwise inconsistent with their Obligations under this Deed, and must not apply fees that circumvent or are otherwise inconsistent with their Obligations under this Deed.
- 4.21 The Company must refer new fees and increases to existing commercially acceptable fees to

2. Compliance Requirements and Service Standards

the Administration Agency for consideration and approval. Before approving any new fee or increase, the Administration Agency must be satisfied that a new or increased fee is fully justified.

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 4.16.1(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 benefits 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 4.16.2(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 paragraph 98B(1)(a) of the N H 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 4.18 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 4.16.2(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 benefits in the determination made under paragraph 98B(1)(a) of the N H 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 4.16 were the Approved Ex-Manufacturer Price or Proportional Ex-Manufacturer Price for the Pack Quantity.

2. Compliance Requirements and Service Standards

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

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.

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:

2. Compliance Requirements and Service Standards

- 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:

- a product which is listed on the RPBS only, or in PBS Section 100 only (non-dual listed items); and
- PBS Medicines that are subject to Exclusive Supply Arrangements.

The only exception is if a CSO Distributor does have access to an Exclusive Supply PBS Medicine, e.g. where they are solely responsible for distributing this PBS Medicine. While Sales of such PBS Medicines cannot be claimed for CSO purposes, the CSO Distributor must Supply these PBS Medicines to Community Pharmacies at or below the CSO Price, and meet all other Deed Obligations in respect of these items.

Fees

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 Administration Agency. If a CSO Distributor wishes to increase previously approved fees or introduce a new fee, the CSO Distributor must apply to the Administration Agency for approval prior to it being applied. The 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 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.

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 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 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 for orders of High Volume PBS Medicines which are below the Minimum Order Quantity. The ability of the CSO Distributor to charge this additional fee is conditional on the CSO Distributor and the Commonwealth agreeing on what constitutes a "shelf pack". An additional fee may also be charged if the Community Pharmacy requires delivery faster than the Guaranteed Supply Period set out in the Deed.

Additional fees must be reasonable and a genuine cost to CSO Distributors.

2. Compliance Requirements and Service Standards

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

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND 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, Annexure C.

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 NDSS Products or NDSS Distribution Services.

Requirement for timely Supply

Extract from Schedule 1 - CSO COMPLIANCE REQUIREMENTS AND SERVICE STANDARDS

Requirement for timely Supply

- 4.27 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:
- 4.27.1 the Distribution Point specifies otherwise; or
 - 4.27.2 the location of the Distribution Point is on the list of locations provided by the Commonwealth at Annexure B of this Schedule, that falls outside the requirement to Supply CSO Product within the Guaranteed Supply Period; or
 - 4.27.3 the Company is unable to meet this Service Standard due to a Force Majeure Event.
- 4.28 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 Administration Agency.
- 4.29 If the Company is unable to undertake its Obligations under this Deed due to a Force Majeure Event:
- 4.29.1 that Company must promptly give the 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
 - 4.29.2 if, in the Administration Agency's reasonable opinion, the written explanation is

2. Compliance Requirements and Service Standards

reasonable and sufficient, a Non-Performance will not be recorded by the Administration Agency.

- 4.30 The Company claiming a Force Majeure Event must remove, overcome or minimise the impact of that Force Majeure Event on its operations and the performance of its Obligations as quickly as possible.
- 4.31 If a Force Majeure Event that affects a 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.
- 4.32 The Company must develop and maintain a Business Continuity Plan that complies with the requirements at Schedule 7 to mitigate any failure to Supply to Distribution Points within the Guaranteed Supply Period.
- 4.33 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.
- 4.34 The Administration Agency and/or the Commonwealth has the right, by notice in writing, to amend Annexure A and Annexure B of this Schedule.
- 4.35 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:
- 4.35.1 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; or
 - 4.35.2 the Company's failure to meet this Service Standard is a result of a Force Majeure Event and the explanation has been accepted by the Administration Agency under clause 4.29.2, in which case, clauses 4.30 and 4.31 apply.
- 4.36 The Company must provide an explanation to the 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 Administration Agency's reasonable opinion, the explanation is reasonable and sufficient, a Non-Performance will not be recorded.
- 4.37 The Company may make available alternative delivery services to any Distribution Point within its CSO Jurisdiction than those specified in clause 4.35, 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 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 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;
2. The location (postcode) of the Distribution Point falls outside of the requirement to supply within the Guaranteed Supply Period; or

2. Compliance Requirements and Service Standards

3. The CSO Distributor is unable to meet this Service Standard due to a Force Majeure Event.

A Regular Order Cut Off Time is the specified time agreed between the CSO Distributor and a Distribution Point. 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*.

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 emergency or critical emergency affecting a region in which an Obligation must be performed."*

A CSO Distributor must promptly provide the 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 Administration Agency's reasonable opinion, the written explanation for non-performance due to Force Majeure is reasonable and sufficient, a Non-Performance will not be recorded by the Administration Agency.

The CSO Distributor claiming a Force Majeure Event must remove, overcome and 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.

2. Compliance Requirements and Service Standards

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.

A Business Continuity Plan is a set of documents, instructions and procedures developed by a CSO Distributor 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 the Deed, including those that enable compliance with the CSO Service Standards and CSO Compliance Requirements, are not interrupted. 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 Administration Agency.

Daily Delivery Service

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

3. Declaration and Exception Reports

3 DECLARATION AND EXCEPTION REPORTS

The 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 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 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 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 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 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 8, 11 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 Administration Agency;

3. Declaration and Exception Reports

- CSO Compliance Requirements (*clause 3 of Schedule 1*);
- CSO Service Standards (*clause 4 of Schedule 1*);
- Notification requirements (*clause 7*) – CSO Distributors must notify the 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 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 17*) - CSO Distributors must advise the 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 Administration Agency’s monitoring role, if a CSO Distributor submits a DER that indicates non-compliance, the Administration Agency will investigate and consider all facts to determine the appropriate course of action and response.

The Monthly DER should be submitted electronically to the Administration Agency within five Business Days of the end of each Month to which the report relates (and at the same time as the Data submission).

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, 6 and/or 7 (where applicable);
- Audits and Records (*clause 14*);
- Conflict of Interest (*clause 18*);
- Confidentiality (*clause 19*);
- Privacy (*clause 20*);
- Workplace Gender Equality (*clause 6*);
- Security (*clause 6*); and
- Aboriginal and Torres Strait Islander Opportunities (*clause 6*).

3. Declaration and Exception Reports

Frequently asked questions

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

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 Administration Agency against all the Obligations under this Deed using a standard format to be specified. This will 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.

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

The Monthly DER should be submitted to the 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.

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 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.

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.

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

CSO Distributors are required to notify the Administration Agency Monthly, in their DER of "any bad debtor that the CSO Distributor will not be supplying CSO Products to" (clause 7.3.1). CSO Distributors

3. Declaration and Exception Reports

should notify the 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.

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

CSO Distributors are required to notify the Administration Agency Monthly, in their DER, of *"any CSO Product that the CSO Distributor cannot Supply because the CSO Product is out-of-stock or cannot be Supplied by the Manufacturer"* (clause 7.3.2). 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).

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 Administration Agency, but must be notified to the 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.

8. If nothing had previously been reported to the 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. 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 Exclusive Supply Arrangements if the CSO Distributor had no such arrangements to report.

4. Non-Performance and Sanctions

4 NON-PERFORMANCE AND SANCTIONS

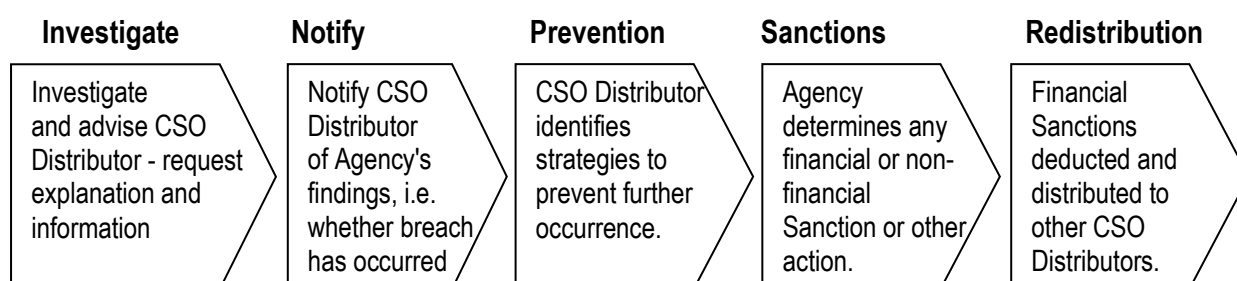
Overview of Non-Performance and Sanctions process

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 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 Administration Agency will investigate the matter. The CSO Distributor will be advised that the 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 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 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 Administration Agency will then determine the classification of the Non-Performance as either Major or Minor. The 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 Administration Agency, the CSO Distributor may lodge a complaint with the 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

4. Non-Performance and Sanctions

then refer their complaint in writing to the Commonwealth's Authorised Officer or the Commonwealth's nominee, within 28 days after receiving notification from the 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.

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 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 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 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 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 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 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.

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.

4. Non-Performance and Sanctions

The 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; and/or
- potentially serious adverse outcomes for a patient/consumer, as a consequence of the Non-Performance.

	Minor Non-Performance	Major Non-Performances
Compliance Requirements and Service Standards		
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 Product	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.
SS1 – Supply to any Distribution Point (Rural/Remote Threshold)	-	Any failure to meet the Rural/Remote Threshold.
SS2 – Requirement to Supply any 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.
SS3 – Stocking requirement for PBS Medicines	Non Performance where 20 or less PBS Medicines are not stocked in accordance with this requirement during a Month.	Non Performance where more than 20 PBS Medicines are not stocked in accordance with this requirement during a Month.

4. Non-Performance and Sanctions

	Minor Non-Performance	Major Non-Performances
Compliance Requirements and Service Standards		
SS3 – 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.
SS4 – Supply any Low Volume PBS Medicine	-	Any failure to meet the Low Volume Threshold.
SS5 – Supply any PBS Medicine at or below the Price to Pharmacists or the Claimed Price plus Wholesale Mark-Up	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.
SS6 – 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.
SS7 – Timely Supply (7/24 hour delivery requirement)	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.
SS7 – Timely Supply (make available a daily delivery service)	-	Any failure to make available a daily delivery service.
Other Requirements and Obligations		
Providing Timely and Accurate data (Clauses 8.3 and 8.5) – Timeliness	Non-Performance relating to the timeliness of information/data which does not significantly impact upon the 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 timeliness of information/data which significantly impacts upon the 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.

4. Non-Performance and Sanctions

	Minor Non-Performance	Major Non-Performances
Compliance Requirements and Service Standards		
Providing Timely and Accurate data (Clause 8.2) - Accuracy	Non-Performance relating to the accuracy of information/data which does not significantly impact upon the 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 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 6.1.2)	-	Any failure to meet a Business Plan milestone or KPI.
Notification Requirements (Clause 7)	Non-Performance which does not significantly impact upon the 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 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.

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 Administration Agency of any Non-Performance of their Obligations under this Deed and will be required to produce a statement explaining the reason/s for any identified failures and, if requested by the Administration Agency, the strategy to be adopted to prevent further occurrences.
3.8	The Administration Agency will take into account the reasons and information provided by a 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 Major Non-Performance or a Minor Non-Performance has occurred but Sanctions will not apply; or
3.8.3	a Minor Non-Performance or a Major Non-Performance has occurred and Sanctions will apply.

As outlined in the Deed, the Administration Agency will notify CSO Distributors of any potential Non-Performance and will 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

4. Non-Performance and Sanctions

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 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 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 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 12 - SANCTIONS	
12.2	Where, in the Administration Agency's view, the Company has failed to meet any of its Obligations under this Deed, including one or more of: 12.2.1 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); 12.2.2 submitting Data and Reports in accordance with Schedule 3; and 12.2.3 meeting the timeframes, milestones and activities outlined in any Remedial Business Plan, and the Non-Performance represents a Major Non-Performance or is a second or further occurrence of a Minor Non-Performance, the Administration Agency may apply financial or non-financial Sanctions. If the Administration Agency considers it necessary to impose a financial Sanction for a Non-Performance, the financial Sanction provisions in Schedule 5 will be used.
12.3	If the 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 24.4.
12.4	The 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.
12.5	For the avoidance of doubt, before any Sanction is applied, the Company will be notified of, and given reasonable opportunity to respond in writing to, any alleged Non-Performance in accordance with Schedule 5.

4. Non-Performance and Sanctions

As detailed in the Deed, the 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 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 Administration Agency and does not exclude the Administration Agency from also making a Payment adjustment.

Determination of Sanctions

Predetermined values for financial Sanctions have not been defined by the 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 Administration Agency of any Exclusive Supply Arrangements in which a CSO Distributor is participating.

Sanctions may include:

- the application of a non-financial Sanction;
- 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 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.

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

4. Non-Performance and Sanctions

Extract from Schedule 5 – SANCTIONS	
Non-Performance issue	Sanction
6.1 Failure to meet any single CSO Compliance Requirement.	The 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: ▪ decide not to apply any Sanctions. ▪ reduce or withhold, or determine that the NDSS Administrator should reduce or withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied. ▪ determine that no Payment will be made to the Company for the Month or Months until the Non-Performance is remedied. ▪ recommend to the Commonwealth that the CSO Distributor Deed be Terminated.
7.1 Failure to meet any single CSO Service Standard	The 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: ▪ decide not to apply any Sanctions. ▪ reduce or withhold, or determine that the NDSS Administrator should reduce or withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied. ▪ determine that no Payment will be made to the Company for the Month or Months until the Non-Performance is remedied. ▪ recommend to the Commonwealth that the CSO Distributor Deed be Terminated.
8.2 Delay of up to 3 Business Days to submit required Monthly Data and/or Reports.	The Administration Agency may: ▪ decide not to apply any Sanctions; ▪ reduce, or determine that the NDSS Administrator will reduce, the amount of a Payment by up to 10% for each Non-Performance; or ▪ 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.
8.3 Delay of between 3 and 14 Business Days to submit required Monthly Data and/or Reports.	The Administration Agency may: ▪ decide not to apply any Sanctions; ▪ impose, or determine that the NDSS Administrator will impose, a reduction in Payment of up to 20% for each Non-Performance; or ▪ 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.

4. Non-Performance and Sanctions

Extract from Schedule 5 – SANCTIONS	
Non-Performance issue	Sanction
8.4 Delay of 15 or more Business Days to submit required Monthly Data and/or Reports.	The Administration Agency may reduce or withhold, or determine that the NDSS Administrator will reduce or withhold, all or part of the Payment by any amount it deems appropriate or determine that no Payment will be made for that Month. If this occurs on 3 or more occasions in a 12 Month period then the Administration Agency may recommend to the Commonwealth that this Deed be Terminated.
8.5 Data and/or Reports are not provided in the required format and/or are incomplete, and/or have significant errors or inaccuracies.	The Administration Agency may: ▪ decide not to apply any Sanctions; ▪ 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 within 2 Business Days; or ▪ 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.
9.1 Failure of a Company to adhere to a Remedial Business Plan that has been developed to rectify another Non-Performance issue.	The 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: ▪ decide not to apply any Sanctions. ▪ reduce or withhold, or determine that the NDSS Administrator will reduce or withhold, all or part of the Payment to the Company until such a time as the Non-Performance is remedied. ▪ determine that no Payment will be made to the Company for the Month or Months until the Non-Performance is remedied. ▪ Recommend to the Commonwealth that this Deed be Terminated.
10.1 Failure to notify the Administration Agency of any Exclusive Supply Arrangement in which it is participating.	The 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: ▪ recalculate and/or reduce, or determine that the NDSS Administrator will 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 in place.

Notification

The Administration Agency will notify the CSO Distributor of its decision in relation to the application of Sanctions, as specified in clauses 12.4 and 12.5 and Schedule 5 of the Deed.

Application of financial Sanctions

In circumstances where a CSO Distributor has already received Payment/s and the 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 Administration Agency can exercise its right to

4. Non-Performance and Sanctions

adjust the Payment/s made to the CSO Distributor in accordance with clause 9, clause 11 of Schedule 2 and clause 3 of Schedule 5 of the Deed.

The 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 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 Administration Agency's findings and given the opportunity to respond. 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 Administration Agency to take into account the potential impact of the repayments on the financial position of the CSO Distributor. However, the 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.

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.

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. Where financial Sanctions are applied to all National or all State CSO Distributors in a Month, the Administration Agency will withhold all or part of the Payment to be made to each National or each State CSO Distributor for that Month. The amount will be withheld until such time as

4. Non-Performance and Sanctions

the Administration Agency determines that the CSO Distributor has rectified the Non-Performance issue. The amount will then be returned to the CSO Distributor the Month after the issue is rectified.

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

5 COMPLAINTS

Introduction

As part of its role in administering the CSO Funding Pool, the 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 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 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 10.2" (clause 2).*

The CSO Complaints Procedure outlines the process for receiving, considering and resolving complaints, and this is available on the 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 Administration Agency by means of **CSO Product Supply Complaint Form** (Appendix G) or by mail, fax, email or hand delivery to the Administration Agency Office.

5. Complaints

Complainants should ensure that their complaint details:

1. Who the complaint is about;
2. What the complaint is about²;
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 Administration Agency will use the structure of the CSO Product Supply Complaint Form for the recording of complaint information, for uniformity in the 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 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 Administration Agency is contractually obliged to comply with the Privacy Act.

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

- to officers, employees, agents or advisers of the Administration Agency, the NDSS Administrator, its officers, employees, agents or advisers, or the Commonwealth Department of Health 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 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.

² Refer *CSO Compliance Requirement or CSO Service Standard* at CSO Administration Agency at: www.ahaconsulting.com.au

5. Complaints

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 Administration Agency to the Department of Health. The 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 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 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 Administration Agency will conduct a preliminary assessment and then advise the subject of the complaint. The Administration Agency is obliged to investigate and resolve any complaints in accordance with the terms of the Deed.

Extract from clause 12 – SANCTIONS
12.5 For the avoidance of doubt, before any Sanction is applied, the Company will be notified of, and given reasonable opportunity to respond in writing to, any alleged Non-Performance in accordance with Schedule 5.

The 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 Administration Agency will:

- for complaints about the 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 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.

5. Complaints

- 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.

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 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 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 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 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 Administration Agency of the action to be taken.

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

Assistant Secretary
Pharmaceutical Access Branch
Department of Health
GPO Box 9848
CANBERRA ACT 2601

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:

5. Complaints

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

6. Providing Accurate and Timely Data

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 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 Administration Agency.

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

Extracts from clause 8 and Schedule 3 – DATA AND REPORTS	
8.1	The Company must provide Data to the Administration Agency.
8.2	The Company must ensure that any Data, Reports or information provided under this Deed is accurate and complete.
8.3	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 and the making of Payments for NDSS Distribution Services.
8.4	The 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 but not limited to the format of the Data to be provided by the Company in accordance with the Deed.
8.5	The Company must provide any additional data requested by the Administration Agency or NDSS Administrator within the timeframe reasonably specified by the Administration Agency or NDSS Administrator.
Schedule 3	
3.1	The Company must provide any Data and Reports sought by the Administration Agency to assess and resolve Complaints by consumers, Distribution Points, Registrants and others

6. Providing Accurate and Timely Data

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 Administration Agency as part of a periodic assessment carried out by the 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 14 of the Deed and Reviews of the CSO Funding Pool and NDSS arrangements referred to in clause 13 of the Deed

Before claiming Sales for a product, CSO Distributors must first provide the 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 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 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; and.*

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, 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; or*
- (d) *medicines listed only for Supply under the Repatriation Schedule of Pharmaceutical Benefits.*

6. Providing Accurate and Timely Data

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:

- (e) equal to a Pack Quantity;
- (f) less than a Pack Quantity; or
- (g) greater than a Pack Quantity, that 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
- less than a Pack Quantity; or
- greater than a Pack Quantity, that can be broken down to a size that equals a Pack Quantity.

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 Administration Agency.

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.

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 Administration Agency to CSO Distributors. The current OTC PBS Medicines list is attached at *Appendix E* to this document and is available on the 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 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.

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

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 Administration Agency if they are unable to confirm either of the above points.

The 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.

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 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).

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, as the pack quantity of the brand of the NDSS Product.*

Deleted NDSS Products

NDSS Products are only claimable for up to one Month after they have been removed from 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 Administration Agency.

6. Providing Accurate and Timely Data

New NDSS Products

NDSS Products are claimable one Month prior to being added to the NDSS Product Schedule. CSO Distributors should ensure new items, which have been delivered, are added to their Monthly Data report.

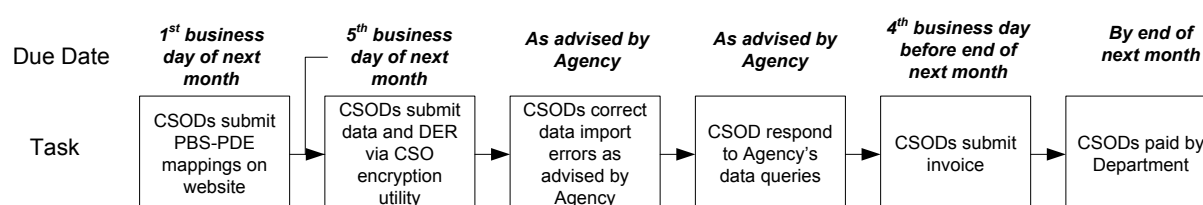
Access Points

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.’*

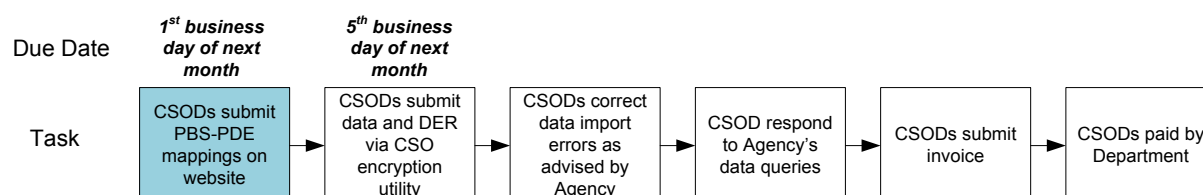
PBS Monthly Data and Payment cycle

For each Month's Sales, the following Data cycle occurs in the subsequent Month. For example for July 2016 Sales, this cycle occurs in August 2016.



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 Administration Agency with a relevant product PDE code and description matching this PBS Medicine. A web-based system has been established by the Administration Agency to enable CSO Distributors to provide this information.

The Administration Agency's PDE-PBS 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 2016’* contains the PBS additions for August 2016, which are claimable for CSO purposes from 1 July 2016;
 - NDSS Products listed on the NDSS Products Schedule;

6. Providing Accurate and Timely Data

- 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 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.

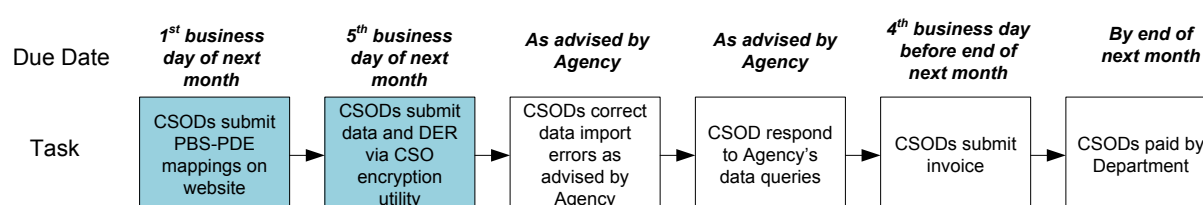
It is possible that CSO Distributors may not have a PDE code for all PBS Medicines. For example, a CSO Distributor may not have a PDE code for a product it did not intend to stock, or a product it intends to stock in future, but has not yet allocated a PDE code.

The 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 Administration Agency before it submits its Monthly data. This information can be provided to the Administration Agency via the Administration Agency's mapping website.

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

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

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;

6. Providing Accurate and Timely Data

2. CSO Distributor product description; and
3. Units sold, by postcode.

The 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 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 Administration Agency. On receipt of a communication, the 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 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

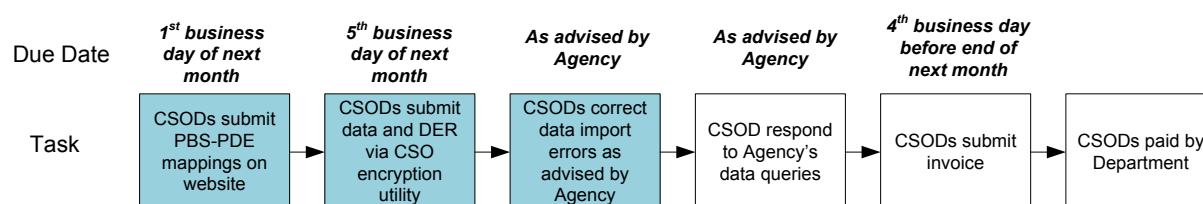
CSO EU system requirements are:

- 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.

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

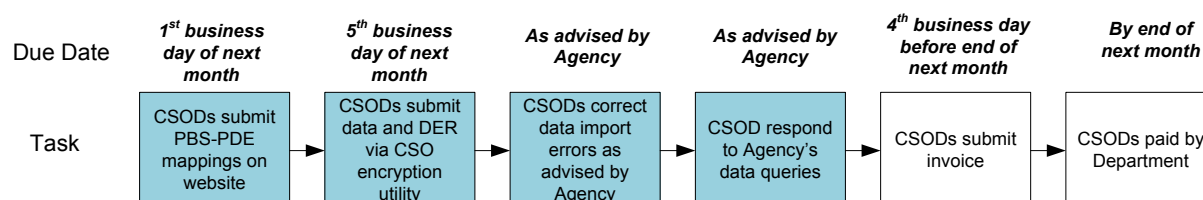


Once the CSO Distributor has submitted the Sales Data via the CSO EU, the Administration Agency will import the Data and record any errors. Errors usually occur due to a CSO Distributor claiming Sales for a product for which the Administration Agency has no corresponding PBS code mapped ('mapping

6. Providing Accurate and Timely Data

errors'), or Sales to invalid postcodes or products. For mapping errors, CSO Distributors are required to provide mapping details via the Administration Agency's PDE-PBS mapping website. CSO Distributors are usually allowed two Business Days to provide this additional information.

Data queries

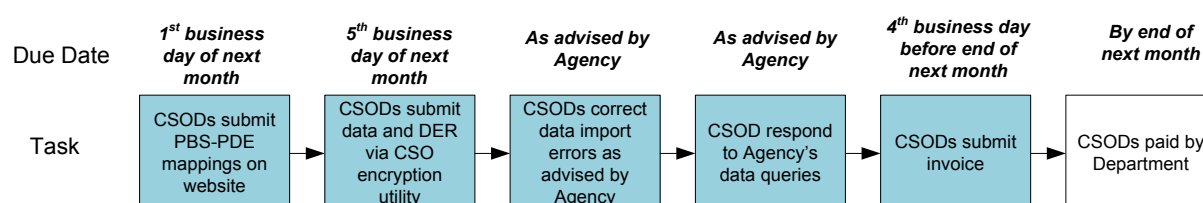


Each Month, the Administration Agency requests additional information from CSO Distributors regarding their Sales Data submission. These Monthly Data queries are currently classified as either postcode queries or product queries. As well as providing additional information, CSO Distributors are asked 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.

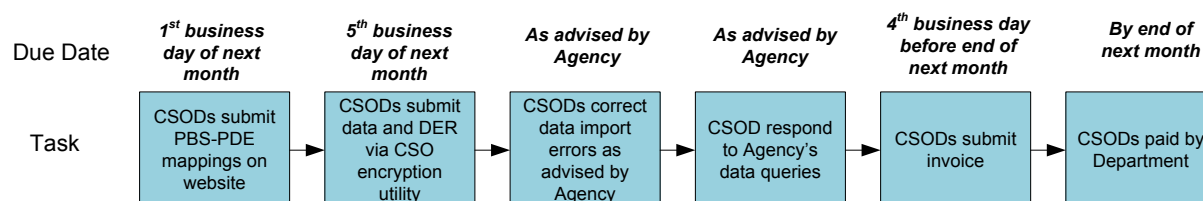
CSO Distributors must ensure that they thoroughly investigate any query raised by the Administration Agency and provide an accurate response. The Administration Agency may conduct further investigations regarding the accuracy of the responses provided by CSO Distributors to the Administration Agency's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

The 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.

CSO Distributor Payment



Once the Administration Agency has finalised Data from all CSO Distributors, payment calculations will be undertaken in accordance with Schedule 2 of the Deed. The 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.



6. Providing Accurate and Timely Data

After ensuring the accuracy of the Data and the CSO Distributors' Reports provided to the Administration Agency, the 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 9.5 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 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.

The 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 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.

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
All CSO Distributors	25.1 million Units (100.0%)	\$15.000 million

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

6. Providing Accurate and Timely Data

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.

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
CSO Distributor A (Victoria)	150,000 Units	60% of Vic CSO Sales
CSO Distributor B (Victoria)	100,000 Units	40% of Vic CSO Sales
CSO Distributor 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	-
<i>Total (All)</i>	<i>550,000 Units</i>	

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)
<i>Total</i>	<i>100%</i> <i>(550,000)</i>	<i>100%</i> <i>(\$280,000)</i>

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.

6. Providing Accurate and Timely Data

Example 4 – Allocation of Payment to State Based CSO Distributors

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

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.

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		
Total	25.1 million units	\$15 million	\$0.60

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.

6. Providing Accurate and Timely Data

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	\$279,000	\$279,000

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 (\$279,000), and therefore \$279,000 would be paid, i.e. the National Cap would be applied.

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

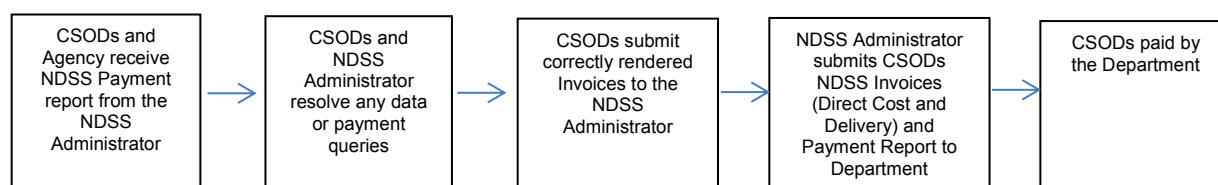
Total PBS Medicines Supplied	State Based Funding Pool Allocation	Payment based on National Cap \$0.60	Actual Payment due
550,000 units	\$280,000	\$341,000	\$280,000

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 (\$341,000), 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 2016 Sales, this cycle occurs in August 2016.

Direct Cost and Delivery Component



By the 2nd 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 4th 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 5th 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

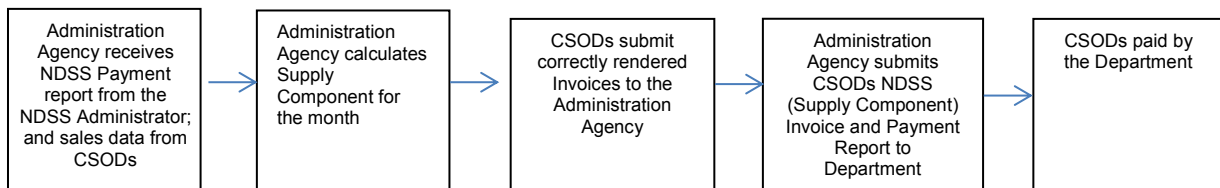
6. Providing Accurate and Timely Data

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 5th 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.

Supply Component



By the 2nd 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 9.5 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

6. Providing Accurate and Timely Data

- 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 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.

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
CSO Distributor W	150,000 Units	\$90,000
CSO Distributor X	100,000 Units	\$60,000
CSO Distributor Y	300,000 Units	\$180,000
CSO Distributor 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 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 Administration Agency begins the annual reconciliation in May 2016, 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 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.

6. Providing Accurate and Timely Data

Once the 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;
- 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 Administration Agency's reconciliation checks, the 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 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"*.

6. Providing Accurate and Timely Data

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 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 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 and an updated list of Rural and Remote postcodes, if applicable.

These lists are also available to download from the PDE-PBS mapping website.

7. Audit Site Visits

7 AUDIT SITE VISITS

As per Clause 14.4 of the Deed, the Administration Agency, the Australian Audit Office, the Auditor-General, the Privacy Commissioner, the Australian Information Commissioner, the Commonwealth, or a nominated independent entity, may audit CSO Distributors for compliance with their Deed Obligations.

The 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 Administration Agency will request information from the CSO Distributor to enable the 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 Administration Agency conducts a site audit of each CSO Distributors' head office. Head office audit visits assist the Administration Agency to:

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

The 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 PBS Medicine and NDSS Product;
- 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;
- general Deed Obligations (clause 6);
- obligation to notify the Administration Agency on matters considered relevant (clause 7); and
- obligation to provide Data as specified in Schedule 3 and clause 8.

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 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:

- 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;
- requirement to Supply any PBS Medicines at or below the CSO Price;
- requirement to Supply any NDSS Product at no cost to Access Points;

7. Audit Site Visits

- requirement for timely Supply; and
- obligation to provide Data as specified in Schedule 3 and clause 8.

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 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 Annexure. 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: Exclusive Supply List

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 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 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

The CSO Administration Agency will provide this temperature breach information to the Commonwealth Department of Health 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	
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Select								Select	Select	
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 Administration Agency in writing, either electronically or in hard copy, to the following address:

Email: <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: _____

Appendix G: CSO Product Supply Complaint Form

As a result of my complaint I want:

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?

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

If yes, please give details.

The 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 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 1 July 2011.

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 Administration Agency includes the Administration Agency's Authorised Officer.

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 this 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.

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.

Appendix H: Glossary

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.

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,
- e) but does not include information that:
- f) is or becomes public knowledge, other than by breach of this Deed or by any other unlawful means
- g) is in the possession of the Recipient without restriction in relation to disclosure before the date of receipt from the other party; or
- h) has been independently developed or acquired by the Recipient.

CSO means Community Service Obligation.

CSO Compliance Requirements means the requirements specified under the CSO arrangements

CSO Distributor means a Wholesaler that has been engaged by the Commonwealth to provide services to access the CSO Funding Pool and has entered into a Deed with the Commonwealth. A reference to the CSO Distributor includes the CSO Distributor that is a party to this Deed, the CSO Distributor's Authorised Officer, and any officers, employees, subcontractors, and agents of the CSO Distributor, where the context so requires.

CSO Funding Pool means the Commonwealth funding made available to CSO Distributors and under the CSO arrangements of the Fifth Agreement and the Sixth Agreement.

Appendix H: Glossary

CSO Jurisdiction means the jurisdiction, either National or State Based, in which the CSO Distributor is accessing the CSO Funding Pool.

CSO Operational Guidelines means the set of advice and guidelines of that name issued by the Commonwealth to the CSO Distributor from time to time and approved by the Commonwealth from time to time, in relation to a CSO Distributor's Obligations under the CSO arrangements and administrative matters relating to the CSO Funding Pool.

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 any day between Monday and Saturday that a CSO Distributor operates for trading (with the exception of Public Holidays), provided the Distribution Point has access to deliveries each weekday and also on Saturdays where a CSO Distributor 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 Administration Agency to ascertain compliance with the Deed; and/or
- b) is to be provided by the CSO Distributor to the 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.

Exclusive Supply Arrangement means any arrangement under which PBS Medicines are not made available by the Manufacturer to all CSO Distributors, as recorded in the Exclusive Supply Arrangement list in the CSO Operational Guidelines and as amended from time to time.

Fifth Agreement means the Fifth Community Pharmacy Agreement between the Australian Government and the Pharmacy Guild of Australia.

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.

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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 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 Administration Agency throughout the Year. For the first Year of the Term of this Deed, the Industry Average will be calculated on the basis of data and reports provided by those Wholesalers who were eligible to access the CSO arrangements under the Sixth Agreement. For the following Years of this Deed, the Industry Average will:

- a) be calculated on the basis of Data and Reports provided by CSO Distributors for the previous Year and as reconciled by the Administration Agency;
- b) apply from October to September of the subsequent Year; and
- 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.
- e) .

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

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 Administration Agency.

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

Manufacturer means the manufacturer of CSO Product or the manufacturer's agent or pre-Wholesaler (i.e. an extension of the manufacturer as reasonably determined by the Commonwealth).

Material Adverse Outcome means any outcome that would, in the Commonwealth's reasonable opinion, have a negative impact on the CSO Funding Pool, the Fifth Agreement, the Sixth Agreement, 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:

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- a) for products which are not refrigerated, shelf packs 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 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 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 Sanctions Pool means 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. Where there is only one State Based CSO Distributor, and that State Based CSO Distributor incurs a financial Sanction in a Month, the National Sanctions Pool will also include 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.

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

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

Non-Performance means a non-performance by the CSO Distributor of any Obligation under the CSO arrangements, including but not limited to 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.

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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.

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) 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.

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 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.

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Sales means total volume of sales of Units of PBS Medicines to Community Pharmacies within a specified period of time minus 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.

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.

Sixth Agreement means the Sixth Community Pharmacy Agreement between The Honourable Sussan Ley, MP, Minister for Health and Minister for Sport on behalf of the Commonwealth of Australia and the Pharmacy Guild of Australia.

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.

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

Term means the period, including any extended period, under which the CSO arrangements operate under the Sixth Agreement.

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, by one party (**terminating party**) giving the other a notice which:

- a) identifies the particular provision of this Deed pursuant to which the terminating party is purporting to act;
- b) gives brief particulars of the circumstances or events on which the terminating party relies; and
- c) is expressed to Terminate this Deed from a time specified in the notice.

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) less than a Pack Quantity; or
- c) 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

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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.

Wholesaler means any entity that has the capacity to obtain and deliver pharmaceuticals to Approved Pharmacists.

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