Project background

The Department of Health is exploring changes regarding supply and reimbursement arrangements for medicines listed on the Pharmaceutical Benefits Scheme (PBS) with Special Pricing Arrangements (SPA).

AHA was engaged to assist the Department to explore, plan and implement these potential changes, applying AHA's specialist knowledge associated with the PBS and the pharmaceutical supply chain.

Activity to 30 September 2018

AHA provided a range of services to the Department regarding the development of potential changes to the PBS payment and reconciliation arrangements.

Services were provided as directed, and included:

- Attended meetings and workshops regarding the development of the amendments to the PBS payment and reconciliation arrangements by teleconference and in person as required
- Drafted documents and schematics to support the consultations and development of the amendments to the PBS payment and reconciliation arrangements as directed
- Provided advice regarding the outcomes of the stakeholder consultations and to the stakeholders about the development of the reforms as directed.

Documents produced

Schematics for five key options were drafted and further developed by AHA based on ongoing feedback:

- Model A. Pack tracking via unique ID
- Model B: Pack tracking via invoice number
- Model C: Netting off approach
- Model D: No invoice crediting (Order On-Demand)
- Model E: Reconciliation via Escrow Agent.

Other key documents produced by AHA include:

- Description of Potential SPA Supply Models
- SPA Administrator Concept of Operations.

The latest versions of the above five schematics and two documents are attached.

Face to face meetings

In total, fifteen face to face meetings and workshops were attended by AHA personnel, as detailed in the following table.

Supply Chain

Dashed lines indicate existing flows

Manufacturer supplies medicine to wholesaler at Manufacturer retail price (\$20k with unique ID)

> Manufacturer credits wholesaler (-\$20k via unique ID)

Wholesaler supplies medicine to pharmacy at retail price Wholesaler (\$20k and markup with unique ID)

> Wholesaler credits pharmacy (-\$20k via unique ID)

Pharmacy dispenses to patient

Pharmacy

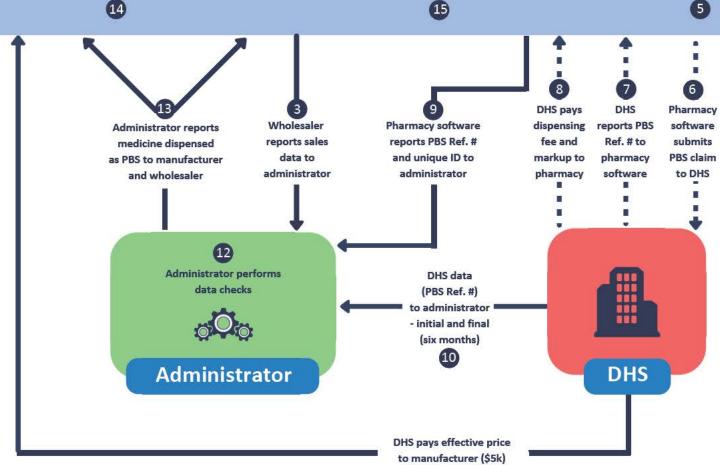
Patient

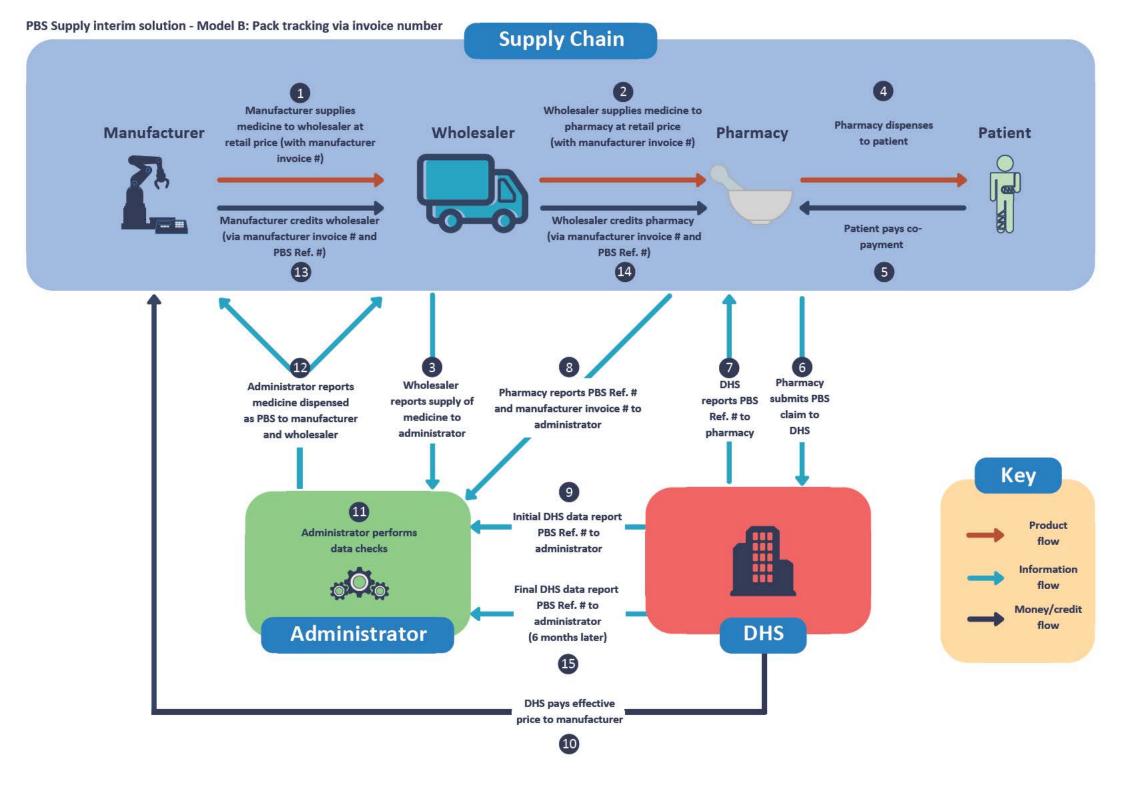
Patient pays copayment

5

Assumptions

- · All models. including this one, will be as automated as possible through systems and data flows
- The administrator will provide data on available credits
- · The six months noted in step 10 is a final audit check up to six months later by the administrator and will not delay payment





Supply Chain

Dashed lines indicate existing flows



Wholesaler supplies
Wholesaler medicine to pharmacy
at retail price
(\$20k and markup)

Wholesaler credits pharmacy

(-\$20k via PBS Ref. #)

Pharmacy

Pharmacy dispenses

macy dispenses to patient

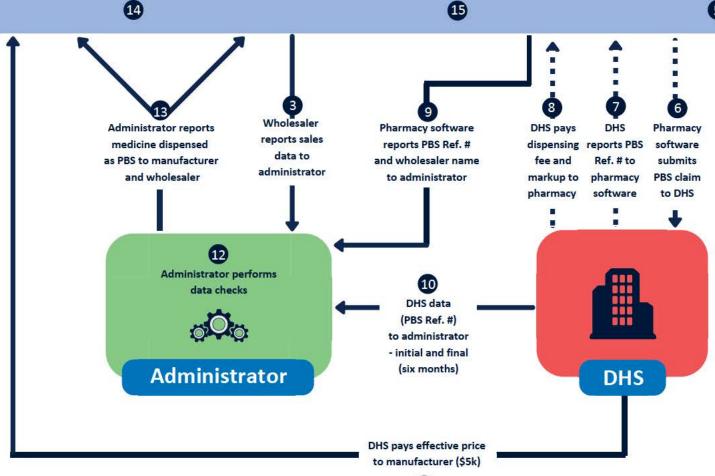
Patient

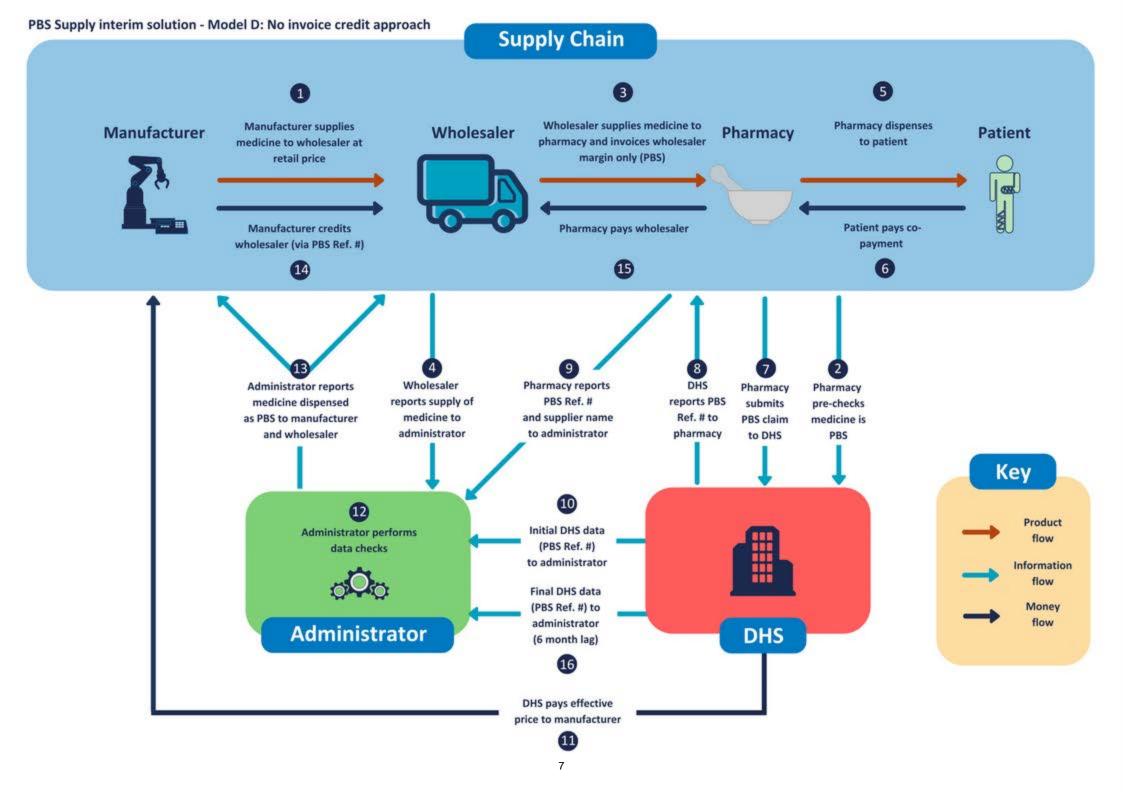
Patient pays co-



Assumptions

- All models, including this one, will be as automated as possible through systems and data flows
- The administrator will provide data on available credits
- The six months
 noted in step 10 is a
 final audit check up
 to six months later
 by the
 administrator
 and will not delay
 payment



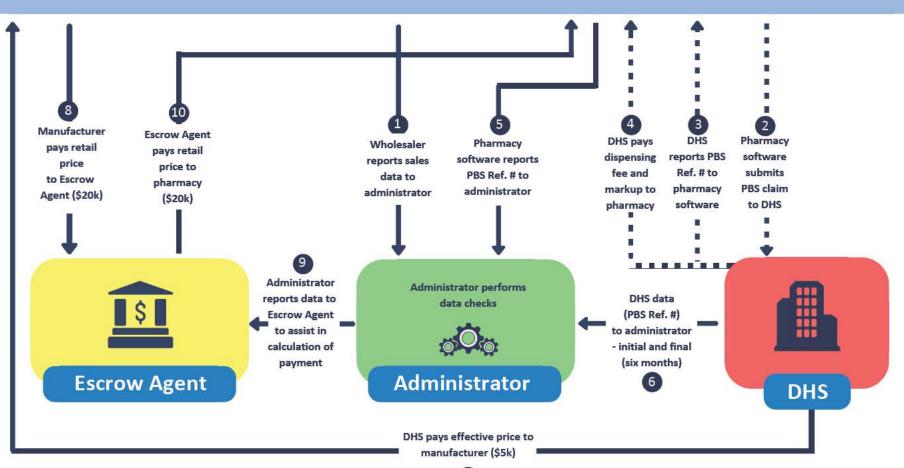


Dashed lines indicate existing flows

Supply Chain Community Manufacturer supplies Wholesaler supplies or hospital Manufacturer Wholesaler **Patient** medicine to wholesaler medicine to pharmacy Pharmacy dispenses pharmacy at retail price at retail price (\$20k) to patient (\$20k and markup) Wholesaler pays Pharmacy pays wholesaler Patient pays manufacturer (\$20k) (\$20k and markup) co-payment

Assumptions

- All models, including this one, will be as automated as possible through systems and data flows
- The administrator will provide data on available credits
- The six months
 noted in step six is
 a final audit check
 up to six months
 later by the
 administrator
 and will not delay
 payment



The attached schematics detail five potential models for managing the supply and reimbursement arrangements for SPA medicines. Models are as follows:

Invoice crediting approach

Model A: Pack tracking via Unique ID

Model B: Pack tracking via Invoice number

Model C: No pack tracking

No invoice crediting approach

Model D: No invoice crediting (Order On-Demand)

No crediting approach

Model E: Escrow.

This document describes each model to support the schematics.

Invoice crediting approach

This section describes the three invoice crediting approaches (Models A, B, C) identifying:

- · Arrangements common to all three models
- Variations associated with each model.

Arrangements common to all three potential models

Medicines are supplied through the supply chain at the retail price. If the medicine is dispensed as PBS:

- DHS pays the wholesaler mark-up value and pharmacy fees (AHI, dispensing, etc) to the claiming pharmacy, and provides a PBS reference number to the pharmacy
- DHS pays the effective price directly to the manufacturer
- A credit for the retail price (excluding wholesaler mark-up) is provided to the pharmacy by the wholesaler¹ and subsequently a credit for the retail price is provided to the wholesaler by the manufacturer. Credit requests identify the PBS reference number and Unique ID (model A), or PBS reference number and manufacturer invoice number (model B), or PBS reference number (model C).
- An administrator acts as a data exchange to receive/provide data, monitor processes and assist to resolve any issues. The Administrator receives data from:
 - Wholesalers and direct supply manufacturers: sales volumes and customer/pharmacy name

^{1 &#}x27;wholesaler' in this document includes a manufacturer that supplies via direct supply arrangements

- Pharmacies via an online portal linked to dispensing software: PBS reference number (to evidence the PBS claim), plus Unique ID (model A) or manufacturer invoice number (model B)
- Credits can be facilitated in one of two ways, as follows:
 - The Administrator advises of the credits to be provided based on data received
 - Invoicees request credits and the invoicer is able to review data in the Administrator's portal to confirm that a credit is owed.

Proposed arrangements will allow credits to be issued promptly. Processes to raise credits for pharmacies can commence within a few days of the pharmacy submitting a PBS claim as data will be readily available to wholesalers confirming the credits to be issued.

A core aims of the Administrator is to ensure that the number of credits issued by manufacturers matches the number of payments from DHS – i.e. one PBS dispense = one payment from DHS and one credit to a wholesaler or pharmacy where direct supply arrangements exist. This is to ensure manufacturers can be confident of appropriate payment for the medicines supplied.

Variations associated with each individual model

The following describes variations associated with each model. The key difference between the three models is the level of pack tracking:

- A. Pack tracking via Unique ID identifies specific packs to credit
- B. Pack tracking via Invoice number identifies manufacturer invoice relevant to the credit
- C. No pack tracking identifies that a credit is due to a specific customer for a particular product, but will not identify the specific invoice or pack.

Model A: Pack tracking via Unique ID

Under this model individual packs are tracked through the supply chain using a Unique ID affixed to each pack by the manufacturer. Manufacturers, wholesalers and pharmacies record the Unique ID of each pack purchased and supplied to their customers. The Unique ID is identified in all data provided:

- By wholesalers to the Administrator
- By pharmacies to the Administrator regarding PBS claims
- By the Administrator in data accessible by wholesalers and manufacturers.

The Unique ID is also included in all credit requests to track them through the supply chain.

Model B: Pack tracking via invoice numbers

Under this model packs are tracked through the supply chain using the manufacturer invoice number as a proxy for a Unique ID. This involves the manufacturer invoice number being affixed to the pack either by the manufacturer prior to supply, or by the wholesaler on receipt of the stock.

The manufacturer invoice number and PBS reference number are included in all credit requests to track them through the supply chain.

Model C: No pack tracking

There are no additional requirements associated with this model (above those for the *Arrangements common to all three potential models*).

The PBS reference number is included in all credit requests to track them through the supply chain.

No invoice crediting approach

Model D: No invoice crediting (Order On-Demand)

A no invoice crediting approach (Model D) has been proposed which would be the same as Model C, except:

- Stock of medicines with SPAs would not be maintained by pharmacies
- Pharmacies would purchase SPA medicines from wholesalers 'on demand', following presentation of a prescription by a patient and following the pharmacy doing a check whether the prescription/patient is PBS-eligible
- When purchasing from wholesalers the pharmacy would advise whether the medicine is PBS or non-PBS, the wholesaler will charge the pharmacy as follows:
 - PBS medicine supplied at zero cost with the invoice value representing only the wholesaler margin
 - Non-PBS medicine supplied at full retail price, including wholesaler margin.
- In general, wholesalers will not be required to provide credits to pharmacies as each medicine will be supplied by the wholesaler at the correct price
- The Administrator will be required to review wholesalers' sales to ensure that the number of units supplied at the PBS price matches the number of PBS claims – as identified by PBS reference numbers provided by pharmacies to the Administrator.

It would also be possible to combine the tracking elements of Model A (pack tracking via Unique ID) or Model B (pack tracking via invoice number) with Model D as outlined above.

Most stakeholders do not support this model, due to its potential negative impact on patient access. If pharmacies do not stock SPA medicines, patient access may be delayed.

No crediting approach

Model E: Escrow

Under this model, the complete supply chain of medicine remains unchanged from current arrangements, i.e. the existing supply, invoicing and payments methods.

The main change is that when a PBS claim is confirmed, the pharmacy receives payment (at retail price) from an Escrow Agent (rather than from DHS). The Escrow Agent is funded by manufacturers, and makes payment based on reconciled data provided by an Administrator.

Existing processes, which remain unchanged:

- The supply chain operates the same as currently, with medicines subject to SPAs supplied, invoiced and paid based upon the retail price (with no subsequent crediting required)
- Once the medicine is dispensed, the pharmacy dispensing system submits the claim to DHS via PBS Online
- DHS reports back to the pharmacy system PBS reference number, quantity and claim status

New/changed processes:

- DHS reports claims data to the Administrator PBS reference number, quantity and claim status
- For each PBS reference number with a 'payable' status, the pharmacy system reports details to the Administrator's system
- The Administrator provides reconciled claims data to the Escrow Agent
- Using this information, the Escrow Agent pays the pharmacy at the retail price (funds provided by manufacturers)
- DHS pays dispensing fee and wholesale margin to the pharmacy
- DHS pays effective price to the manufacturer.

This document describes how an Administrator may operate and interact with the supply chain under the Special Pricing Arrangements (SPA). This document is set out under the following headings:

- 1. Administrator role
- 2. Data flows
- 3. Secure online portal.

Five potential SPA supply chain models have been developed as follows:

Invoice crediting approach

Model A: Pack tracking via Unique ID Model B: Pack tracking via Invoice number

Model C: No pack tracking

No crediting approach

Model D: Order On-Demand

Model E: Escrow.

This document is focused on the invoice crediting approach (models A, B, C), however the principles described are similar for all models.

1. Administrator role

The invoice crediting approach requires manufacturers to credit wholesalers, and wholesalers to credit pharmacies, in respect of SPA medicines dispensed.

The Administrator's role is to support this through providing these organisations with access to relevant information. Supply chain parties must have visibility and certainty about what credits they should provide and/or expect to receive.

Minimum data and role

At a minimum, each supply chain party must be able identify:

- That a relevant PBS dispense has occurred, including details of the medicine
- Who should provide/receive the credit.

The Administrator will make this data available to each party via a secure online portal. This minimum information could potentially be derived from existing pharmacy reporting to DHS (with one new data field – wholesaler ID), i.e. not require new data flows from pharmacies to the Administrator.

Enhanced data and role

Many supply chain parties have expressed significant concern that the above minimum information is inadequate to allow them to efficiently manage the crediting process. Models A and B potentially address many of these concerns through pack tracking (via unique ID or invoice number), however both involve additional administration and reporting throughout the supply chain. Automation may minimise this impost, however this is unlikely to be achieved by July 2019 implementation.

Some parties propose that the Administrator provide further information and a matching or reconciliation role, to assist parties to ensure they receive/provide all appropriate credits or payments. For example to ensure pharmacies only claim credits from the wholesaler from whom

they purchased the relevant medicines dispensed. The Administrator could also assist to resolve disputes and complaints. These roles would require additional data flows from pharmacies and wholesalers to the Administrator.

An important distinction is that the Administrator's core role is to provide accurate data and information. It will not direct or have authority over any party about the credits they claim/receive from each other, which are therefore able to operate any legal commercial arrangements they agree.

2. Data flows

Existing data flows

- Pharmacy submits claim to DHS
- DHS reports to pharmacy (PBS ref #, claim status).

New data flows

- 1. DHS data to Administrator
- 2. Administrator data available to supply chain parties
- 3. Pharmacy and wholesaler data to Administrator.

New data flows are described below. Data flows to/from the Administrator will occur through a secure online data portal managed by the Administrator (refer Section 3 of this document).

2.1 DHS data to Administrator

The Administrator will receives nightly data feeds from DHS, which at a minimum will include the data on the following page (*Table 1*). No patient related data will be provided. The availability and timing of DHS data to the Administrator will largely determine the subsequent data flows to the supply chain.

This minimum information could be derived from existing pharmacy claims reporting to DHS, with the addition of one new data field – wholesaler ID. It is envisaged that pharmacies would identify the wholesaler from whom they intend to claim a credit. Conceptually this data field is similar to the existing 'chemotherapy compounder' data field reported by pharmacies for relevant claims.

DHS closes each claim after 90 days, i.e. until that time pharmacies can adjust claims via PBS online. Data to the supply chain via the portal will therefore contain any such adjustments.

Key challenges include:

- Reporting chemotherapy compounding
- Stock movement between wholesalers, suppliers and third parties
- Appropriate credit value if PBS price increases or decreases.

Table 1: DHS data to Administrator - data extract

	Claim status	Dispensing Pharmacy ID	CPN	Processing date	Date of Supply	Pay Category	Number	Code		Item code	Version ID	Supplied quantity	Supplied % of pack	PBS reference number	UPPN	S
	Payment		1806	14/03/2018	14/03/2018	Concessi onal	1363	s 47G			0	28	100%	s 47G		
	Payment		1802	16/03/2018	16/03/2018	General	153					1	100%			
e/	Payment		1802	19/03/2018	19/03/2018	General	180				0	90	100%			
e	Payment		1802	20/03/2018	20/03/2018	Concessi onal	3221				0	1	100%			
	Reject		1803	31/03/2018	31/03/2018	Concessi onal	2922				0	28	100%			
,	Cancel		1803	31/03/2018	31/03/2018	Concessi onal	2922				1	28	100%			
	Payment		1802	1/03/2018	1/03/2018	Concessi onal	1224				0	1	100%			
	Payment		1802	1/03/2018	1/03/2018	General	124				0	2	200%			
	Payment		1802	1/03/2018	1/03/2018	General	174				0	2	200%			
0	Payment		1802	1/03/2018	1/03/2018	General	174			1	2	200%				
1	Payment		1802	1/03/2018	1/03/2018	General	174				2	2	200%			

2.2 Administrator data available to supply chain parties

Approved PBS claims data will be updated daily on the portal and appropriate data subsets will be accessible by:

- Pharmacies to identify credits they are due from each wholesaler
- Wholesalers to identify credits they are due to provide to each pharmacy
 - to identify credits they are due from each manufacturer
- Manufactures to identify credits they are due to provide to each wholesaler.

Mock ups of the minimum data that will be available to pharmacies, wholesalers and manufacturers via the online portal, are provided on the following three pages (*Portal mock-up 1, 2, 3*).

Under the Escrow model (E), the Administrator will make claims data information available to the Escrow Agent, providing the basis for the Escrow Agent to pay pharmacies. Potentially, access to data subsets could also be made available to pharmacies and/or wholesalers/manufacturers.

2.3 Pharmacy and wholesaler data to Administrator

As indicated, some supply chain organisations propose that the Administrator provide further information and a matching or reconciliation role, to assist parties to ensure they receive/provide all appropriate credits or payments. For example to ensure pharmacies only claim credits from the wholesaler from whom they purchased relevant medicines dispensed.

This would require additional data flows from pharmacies and wholesalers to the Administrator.

Pharmacy data may include:

- PBS Reference number and Version ID, generated by DHS and provided to the pharmacy following submission of the relevant claim via PBS online
- Unique ID/ pack ID (models A and B)
- Wholesaler identifier (or manufacturer if direct supply), i.e. which company should provide a credit to the pharmacy (model C)
- One or two other data fields (TBC).

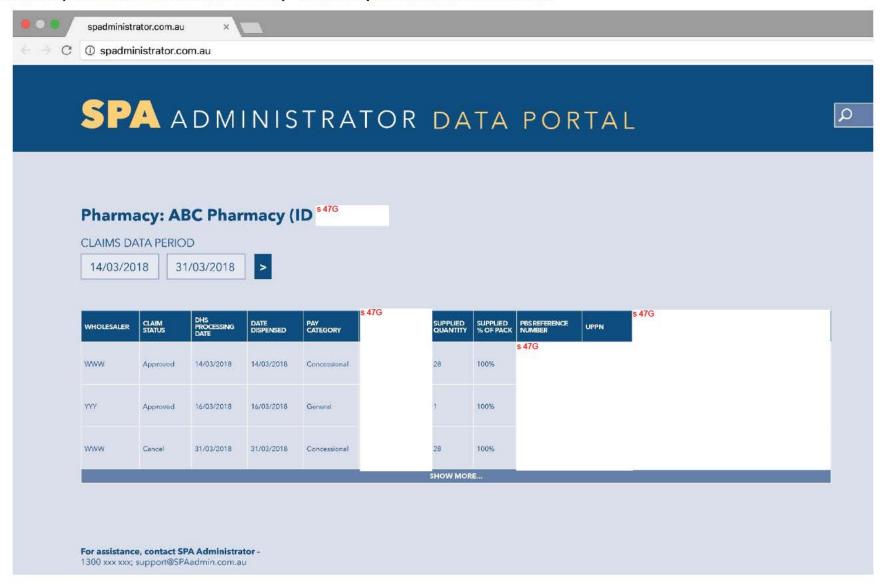
Pharmacies would submit data to evidence the PBS dispensing of SPA medicines, via the portal. The Administrator and Department of Health would work together with pharmacy software vendors to enable automatic submission of data via pharmacy software as soon as possible, to minimise the burden on pharmacy.

Under the CSO arrangements, CSO wholesalers currently submit sales data to the CSO Agency. Data is submitted monthly and is at a postcode level, i.e. it does not identify pharmacy customers.

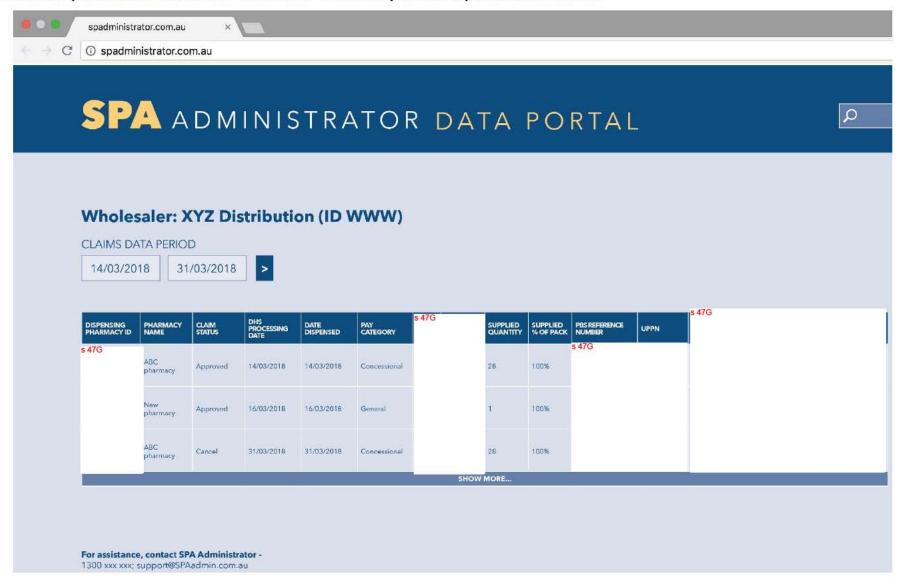
The Administrator may potentially require data:

- From all wholesalers and also from manufacturers who direct supply
- That identifies sales to each pharmacy customer
- Daily or weekly, rather than monthly.

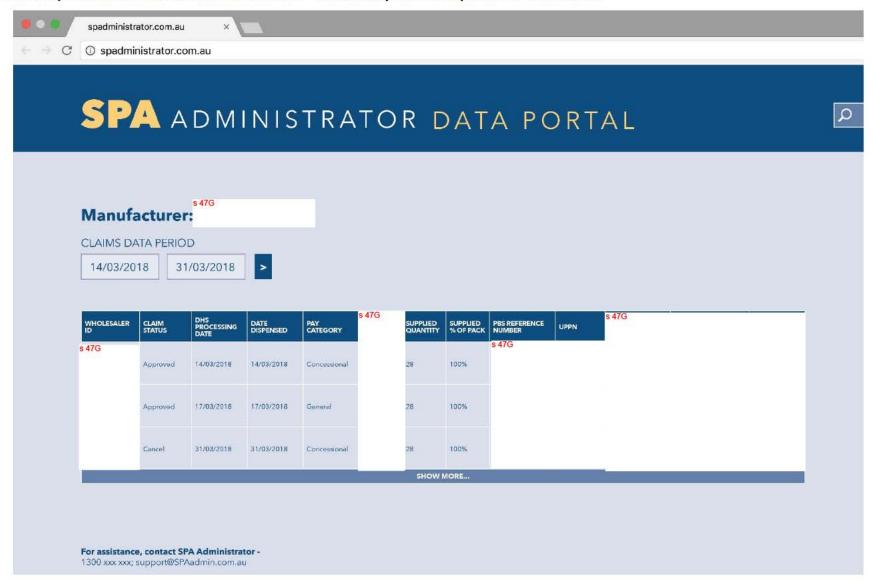
Portal mock-up 1: Data available to each Pharmacy - Credits they are due from each wholesaler



Portal mock-up 2: Data available to each Wholesalers - Credits they are due to provide to Pharmacies



Portal mock-up 3: Data available to each Manufacturer - Credits they are due to provide to Wholesalers



3. Secure online portal

The Administrator will develop and manage a secure portal to provide supply chain parties with access to appropriate data subsets. The portal may also be used for data submission by pharmacies to the Administrator, following PBS dispensing of SPA medicines.

The portal will be a simple, easy-to-use cloud-based portal accessible via computer, tablet or smartphone. Users will receive a login and password for the portal via one of two methods, depending on preference/recommendation:

- Automatic pre-registration with a login and password generated by the Administrator and sent to each pharmacy along with information about the portal. Once received, users can login and change their username and password to alternatives of their preference
- Users are invited to register for the portal and are able to nominate their preferred username and password as part of the registration process.

The Administrator will provide comprehensive support via a Help Desk contactable by e-mail or telephone.

3.1 Data available to supply chain parties

It is anticipated data will be available on the portal within one to two business days of data being received by the Administrator. This will ensure that in many cases pharmacies will be able to be credited by wholesalers prior to the original invoice becoming due.

3.2 Data submission by pharmacies

The portal will enable pharmacies to securely submit data via four potential methods, as follows:

- 1. Login to the portal and direct entry information into an online form/interface
- 2. Complete a excel/csv/xml template file, login to the portal and upload the file
- 3. Login to the portal and upload a csv or xml file generated by pharmacy software
- 4. Automated interface between portal and pharmacy software which requires no manual action by the pharmacy.

The Administrator and the Department of Health will work together with pharmacy software vendors to enable submission via methods 3 and 4 above as soon as possible, to minimise the burden on pharmacy.

No set interval or frequency is proposed for the submission of data, allowing pharmacies the flexibility to submit data according to their preferred intervals/frequencies.