DRAFT FOR DISCUSSION

PHARMAC TE PĀTAKA WHAIORANGA

1. BACKGROUND

Pharmac needs to implement more complex funding and procurement decisions in the Pharmaceutical Schedule. We need to be more integrated with health sector partners, and to be able to support the development of new models of care. Change is needed and we identified possible pathways forward that we wish to explore further …

Introduction

Pharmac helps people to live better, healthier lives by deciding which medicines, and related products are available to New Zealanders in a way that is affordable and accessible. Our purpose is to deliver the best health outcomes from the Government's investment in medicines and medical devices.

Pharmac is a Government health agency and our identity in te reo Māori, Te Pātaka Whaioranga ('the storehouse of wellbeing'), sums up the part we play in managing and safeguarding something that is valuable to all New Zealanders.

Pharmac's legislative objective is set out in the New Zealand Public Health and Disability Act 2000 – 'to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided'.

Pharmac is also becoming more involved in hospital medical devices through negotiating national contracts. In future, we will decide which medical devices are available for people under the care of public hospitals and we are preparing for this change.

Medicines

Every year Pharmac makes more medicines available for more New Zealanders. We play an active role in keeping New Zealanders healthy by funding medicines (including vaccines) and related products. New Zealanders benefit from Pharmac's work when they get a prescription filled at the pharmacy, when they're vaccinated for free or when they receive medicines in a public hospital. In the 2019/20 financial year, around 3.8 million New Zealanders benefited from funded medicines.

Pharmac manages a fixed budget held by District Health Boards (DHBs), the Combined Pharmaceutical Budget. We aim to get the best health outcomes from the budget which includes funding as many new good value medicines as we can. We take steps to reduce the costs of some already funded medicines, so we can use the money to fund more medicines for more New Zealanders.

Hospital medical devices

Pharmac works hard to make sure we get the best health outcomes possible from our investments for all New Zealanders. Our scope has been expanded to include hospital medical devices and Pharmac will eventually be required to manage spending within a fixed budget. We are preparing for this by building a list of medical devices for DHBs to use, including things like cotton swabs, orthopaedic implants and dialysis machines. We are also negotiating contracts for terms like price and supply continuity to ensure consistency across DHBs.

As our role in hospital medical devices grows, we will apply many of the same principles we use for our medicines work however, as medical devices are not the same as medicines, we are also working out where we need to do things differently.

Managing the Schedule of medicines and devices

The Pharmaceutical Schedule is a list of medicines and devices that we manage on behalf of the Crown, and this list changes each month as a result of procurement or funding decisions.

However, the Schedule is more than just the list of medicines that are funded, or devices that are contracted for. It also has an infrastructure of rules, restrictions and funding mechanisms that give us the tools with which to manage that list, The Schedule is itself but one part of a broader set of IT systems and regulatory instruments that relate to pharmaceuticals in New Zealand.

Some of the key components of the Schedule management systems are:

- The coding standards, terminology and categorisation used for products listed in the Schedule.
- The 'business rules' that we use in the Schedule to establish whether or not a particular pharmaceutical will be funded for a particular person, such as targeting criteria and general funding restriction.
- The degree to which the Schedule interacts with, and depends on, other sector IT systems in order for our funding or procurement decisions to be given effect.
- The channels through which we communicate Schedule information to end-users, including which 'products' we produce for people to access the Schedule.
- The business processes and conventions relating to how we operationalise funding or procurement decisions within the Schedule, including how often we can make these changes.

Current state of our infrastructure

The Schedule has grown in both size and scope in response to Pharmac's expanded role, but the supporting infrastructure and IT systems architecture has not changed significantly during the last two decades.

In order to be able to implement new and innovative approaches to our management of pharmaceuticals, we need to revise systems and processes such that they enable, rather than constrain, our ability to make those changes.

We need the Schedule to better accommodate our expanded functions, and develop new business rules and improved business processes, while at the same time continuing to improve how we manage our older functions.

We need to incorporate advances in technology and information standards into the Schedule, not only to help us manage the Schedule better, but more importantly to help provide real benefits to patient care, such as reducing the risk of errors.

We need to move away from having the Schedule and its related systems being managed in an episodic way (e.g. around a monthly publishing cycle), and move towards a real-time environment where we can publish changes in the Schedule to the sector far more rapidly.

Our drivers for change in the Schedule systems

Pharmac's expanded responsibility means that we will need to implement new and more complex funding and procurement decisions in the Pharmaceutical Schedule in the coming years.

In addition, the health sector landscape continues to change. We need to be more integrated with health sector partners, and to be able to support the development of new models of care.

While the Schedule has expanded over the years in response to Pharmac's expanded role, the supporting infrastructure and IT systems have not changed significantly during the last two decades.

We need a significant rework of the Schedule from a systems perspective, to ensure that it meets the needs of both Pharmac and the wider health system.

Schedule systems options considered

We have identified a pathway from the current state through several potential options for the Schedule systems.

This document focuses on our near-term options, namely:

- OPTION 1: Current state
- OPTION 2: Publisher of enhanced Schedule – this is the "base camp" option that is required to move to the other identified options
- OPTION 2A: Publisher / manager of exceptions – this builds on Option 2 by adding online exception processing for special authorities, waivers, and NPPAs.

Note that these options do not represent policy but are being presented for further exploration of feasibility and costs.

2. CURRENT STATE

The Schedule system includes multiple data stores and interfaces. The Schedules are managed in separate systems with different data standards with many manual interventions …

The Schedules use …

- Pharmacode data from the Pharmacy Guild
- NZ Universal List of Medicines (NZULM) and NZ Medicines Terminology (NZMT) data from the NZULM

Medical devices Schedule …

- 140,000 medical devices so far – potentially 250,000
- Incomplete and missing data (e.g., GTINs)
- Basic database with little analysis capability

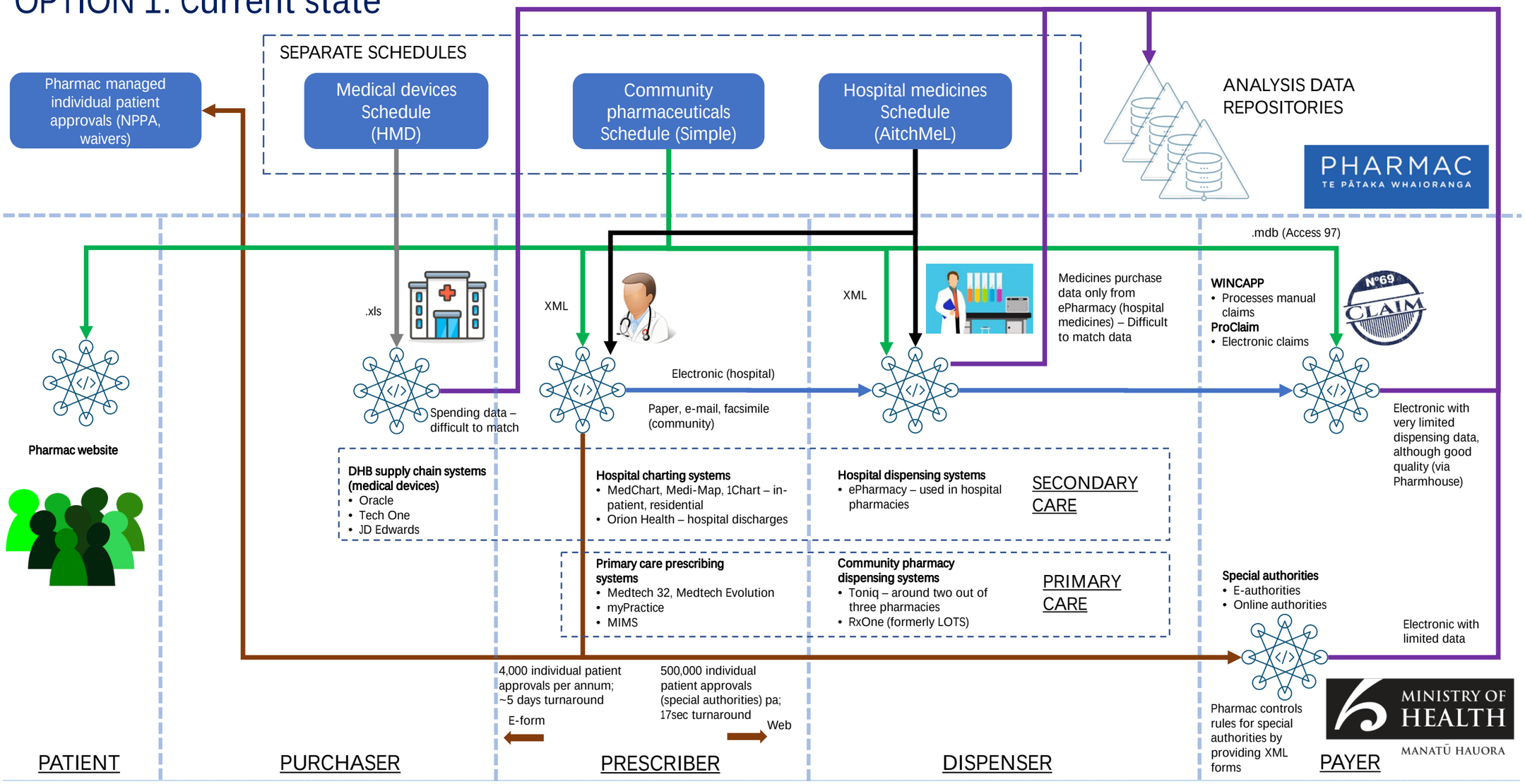
Hospital medicines and community pharmaceuticals Schedules …

- Episodic management of Schedules
- Patchy clinical advice included
- Data structures do not provide for future requirements (e.g., new roles, new types of components in the Schedule)
- Separate Schedules for historical reasons
- Making changes is very manual
- Limited dispensing data
- Limited medical device supply chain data
- Limited approvals data
- No patient and diagnosis data
- Systems are ageing and fragile
- High dependency on key personnel
- Much manual work required to deliver monthly Schedules

Business analytics in data repositories for …

- Special Authority data from Ministry
- Pharmhouse (subsidy claims) data from the Ministry
- Hospital medicines purchase data from ePharmacy
- Medical devices purchase data from DHBs

OPTION 1: Current state



2. CURRENT STATE (CONT'D)

The Schedule management system manages community pharmaceuticals, hospital medicines, and medical devices in secondary care. It connects to the Health Sector Agreements and Payments System and the Health Systems Catalogue. Individual patient approvals for exceptions are managed by the Ministry and Pharmac …

Community pharmaceuticals

Pharmac manages a Community Pharmaceutical Schedule through a dedicated system (SiMPle) that supports management and publishing of the Schedule. The Schedule is published in web format, pdf, XML for importing into sector systems, and Access 97 for use by the Ministry of Health Health Sector Agreements and Payments system (HSAAP).

The Schedule data enables prescribers to prescribe the right medicines, dispensers to dispense them, and the Ministry of Health to pay pharmacists for valid medicines.

Pharmac purchases some products directly and warehouses these for distribution. This is currently confined to vaccines other than flu vaccines.

Hospital medicines

Pharmac manages hospital medicines in a way analogous to community pharmaceuticals. It has a separate Schedule system (AitchMel). The hospital medicines Schedule is provided to DHBs and imported into their pharmacy systems.

Health Sector Agreements and Payments System

The Health Sector Agreements and Payments (HSAAP) system operated by the Ministry of Health manages the payment of pharmacies for prescribed drugs covered under the community pharmaceuticals Schedule. The medicines approval and payments aspect is one part of the wider HSAAP that the Ministry uses for claims and payments.

Medical devices in secondary care

Pharmac manages the 140,000 current medical devices (expected to rise to 250,000) in a basic database (HMD) and distributes them in Excel format. The medical device is sparse with not all fields consistently filled in (e.g., GTINs are often missing).

The medical device file is provided to DHBs for importation into their own logistics systems.

Health System Catalogue

The secondary health sector has developed a Health System Catalogue (HSC) to enable hospitals to purchase medical devices and other products and services where there are national contracts in place. This will be the mechanism by which Pharmac can manage the procurement of medical devices for secondary care. The HSC programme will also deliver a repository of Spend Data to enable analysis of what has been procured.

Hospital clinicians effectively prescribe medicines for patients that are then fulfilled from hospital stock.

Individual patient approvals

Clinician approvals for community medicines (e-special authorities, online special authorities) – in these cases specific patient criteria must be met for access to the medicines; a clinician certifies that these conditions have been met for the specific medicine and authority number is generated that the pharmacy can then use for the claim. No human intervention is required in the workflow. Note that special authorities are currently managed by the Ministry of Health.

Waivers – if a person's clinical circumstances meet the spirit or intent of Special Authority criteria, but not the technical requirements, Pharmac can consider a waiver application from a clinician. If a waiver application is approved, a special authority number is generated to support the pharmacy claim. Note that waivers are managed by Pharmac

Named Patient Pharmaceutical Assessment (NPPA) – Pharmac uses the NPPA process to consider whether to fund a treatment for an individual patient whose clinical circumstances are exceptional. If a NPPA application is approved, a special authority number is generated to support the pharmacy claim. Note that NPPAs are managed by Pharmac.

Data analysis

Pharmac collects data from the sector to support its mission. The key sources are:

- Special Authority data from Ministry
- Pharmhouse (subsidy claims) data from the Ministry
- Hospital medicines purchase data from ePharmacy in the DHBs
- Medical devices purchase data from DHBs

Key statistics
1,000 dispensers
10,000 prescribers
70,000,000 dispensings per annum
500,000 clinical special authorities per annum – These are individual patient approvals initiated by a prescriber that can be automatically approved by the Schedule Management System – These make up around half of the cost of dispensings but represent less than 5% of the transactions
5,000 special authorities pa requiring intervention (NPPAs, waivers)
2,500 medicines
250,000 medical devices

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3. FUTURE OPTIONS

Option 2 proposes key changes focused on resolving Pharmac's internal issues. It integrates the Schedules on modern platforms and upgrades the data standards. It is the baseline ("base camp") for other options to build upon …

Key changes from present

- Modern systems architecture with technology on current releases – Cloud-based as per Cabinet directives
- Published rules in machine processable form – extended rules showing more of rules as explicit rather than implicit
- Unifies the Schedule with single listing for each product and single set of rules – combines devices, community pharmaceuticals, and hospital medicines
- Category structure based on WHO ATC and UNSPSC and data structure fully based on SNOMED CT – GTINs linked through NZULM
- Improved data warehouse platform with integrated data
- Consistent data use across hospital medicines, – devices, and community pharmaceuticals

Transitional requirements

- Will need to retain conversion to current formats to allow existing sector systems to operate while they transition to using common data standards

What remains the same

- Individual patient approval management remains largely with Ministry of Health
- processing special authorities with waivers and NPPAs continuing through Pharmac on existing systems

Schedule data sent to the sector
Sector data flows
Data gathered from the sector
Clinical exceptions

OPTION 2: Publisher of enhanced Schedule ("Base camp")

This option is the necessary baseline for any future development

Pharmac managed exceptions (NPPA, waivers)

Existing system (MAD)

Integrated devices and medicines Schedule

Format conversions for rules sent out to sector)

INTEGRATED DATA REPOSITORY

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Device and medicines usages

.mdb (Access 97) – transition only

Pharmac website

.xls

XML

XML

Consistent data

Electronic (hospital)

Paper, e-mail, facsimile (community)

Medicines purchase data only from ePharmacy (hospital medicines) – Difficult to match data

Electronic (hospital)

Paper, e-mail, facsimile (community)

WINCAPP
- Processes manual claims

ProClaim
- Electronic claims

Electronic with very limited dispensing data, although good quality (via Pharmhouse)

DHB supply chain systems (medical devices)
- Oracle
- Tech One
- JD Edwards

Hospital charting systems
- MedChart, Medi-Map, 1Chart – in-patient, residential
- Orion Health – hospital discharges

Hospital dispensing systems
- ePharmacy – used in hospital pharmacies

SECONDARY CARE

Primary care prescribing systems
- Medtech 32, Medtech Evolution
- myPractice
- MIMS

Community pharmacy dispensing systems
- Toniq – around two out of three pharmacies
- RxOne (formerly LOTS)

PRIMARY CARE

Special authorities
- E-authorities
- Online authorities

Electronic with limited data

4,000 individual patient approvals per annum; ~5 days turnaround

E-form

500,000 individual patient approvals (special authorities) pa; 17sec turnaround

Web

Existing systems

Pharmac controls rules for special authorities by providing XML forms

MINISTRY OF HEALTH MANATŪ HAUORA

PATIENT | PURCHASER | PRESCRIBER | DISPENSER | PAYER

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3. FUTURE OPTIONS (CONT'D)

Option 2A builds on Option 2 and has Pharmac taking over special approvals from the Ministry of Health and starting to gather clinician provided data related to these exceptions – note this is an option for consideration only and no agreement has been made to transfer special approvals …

Key additional changes for option 2a

- Special authorities move from Ministry of Health to Pharmac management
- Redesigned system for manual management (e.g. in case of current NPPA, waivers) to support enhanced workflow and management
- Gathering of and storage clinician provided data to support exceptions and analysis

Transitional requirements

- Will need to retain conversion to current formats to allow existing sector systems to operate

What remains the same

- Limited dispensing data

OPTION 2A: Publisher / manager of exceptions

This option provides the opportunity to expand the exceptions management infrastructure into the full publisher /authoriser environment

Schedule data sent to the sector
Sector data flows
Data gathered from the sector
Clinical exceptions

5,000 individual patient authorities per annum requiring manual intervention; ~5 days turnaround

Electronic workflow to manage manual interventions for individual patient authorities

Individual patient authorities

500,000 individual patient approvals pa based on clinician recommendation – no manual intervention required

Integrated devices and medicines Schedule

Clinician provided data

Clinical data gathered to enable analysis and further approvals

INTEGRATED DATA REPOSITORY

PHARMAC TE PĀTAKA WHAIORANGA

Device and medicines usages
Clinical usage regarding exceptions

Approval tokens for payment sent to MoH

XML Schedule

WINCAPP
- Processes manual claims

ProClaim
- Electronic claims

Nº69 CLAIM

Dispenser checks individual patient approval

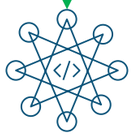
Medicines purchase data available from ePharmacy uses consistent coding to aid analysis

XML Schedule

Prescriber requests or authorises individual patient approval

XML Schedule

XML Schedule



Pharmac website

Standardised description of devices to make analysis simpler

Electronic (hospital)

Paper, e-mail, facsimile (community) – Includes approval # in case of exceptions

Electronic (hospital)

Paper, e-mail, facsimile (community) – Includes approval # in case of exceptions

Electronic with very limited dispensing data, although good quality (via Pharmhouse)

MINISTRY OF HEALTH MANATŪ HAUORA

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Hospital dispensing systems
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PRIMARY CARE

PATIENT | PURCHASER | PRESCRIBER | DISPENSER | PAYER

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3. FUTURE OPTIONS (CONT'D)

Implementing options 2 and 2A requires new datasets, Pharmac facing applications, sector facing applications, and interfaces …

Schedule management systems

A high level view of the systems required is shown opposite. It describes them in terms of:

- The Pharmac data sets that must be managed to support the Schedule and management of exceptions.
- The Pharmac applications needed by Pharmac users to manage the information and workflows.
- The sector facing applications that enable usage of the Schedule data.

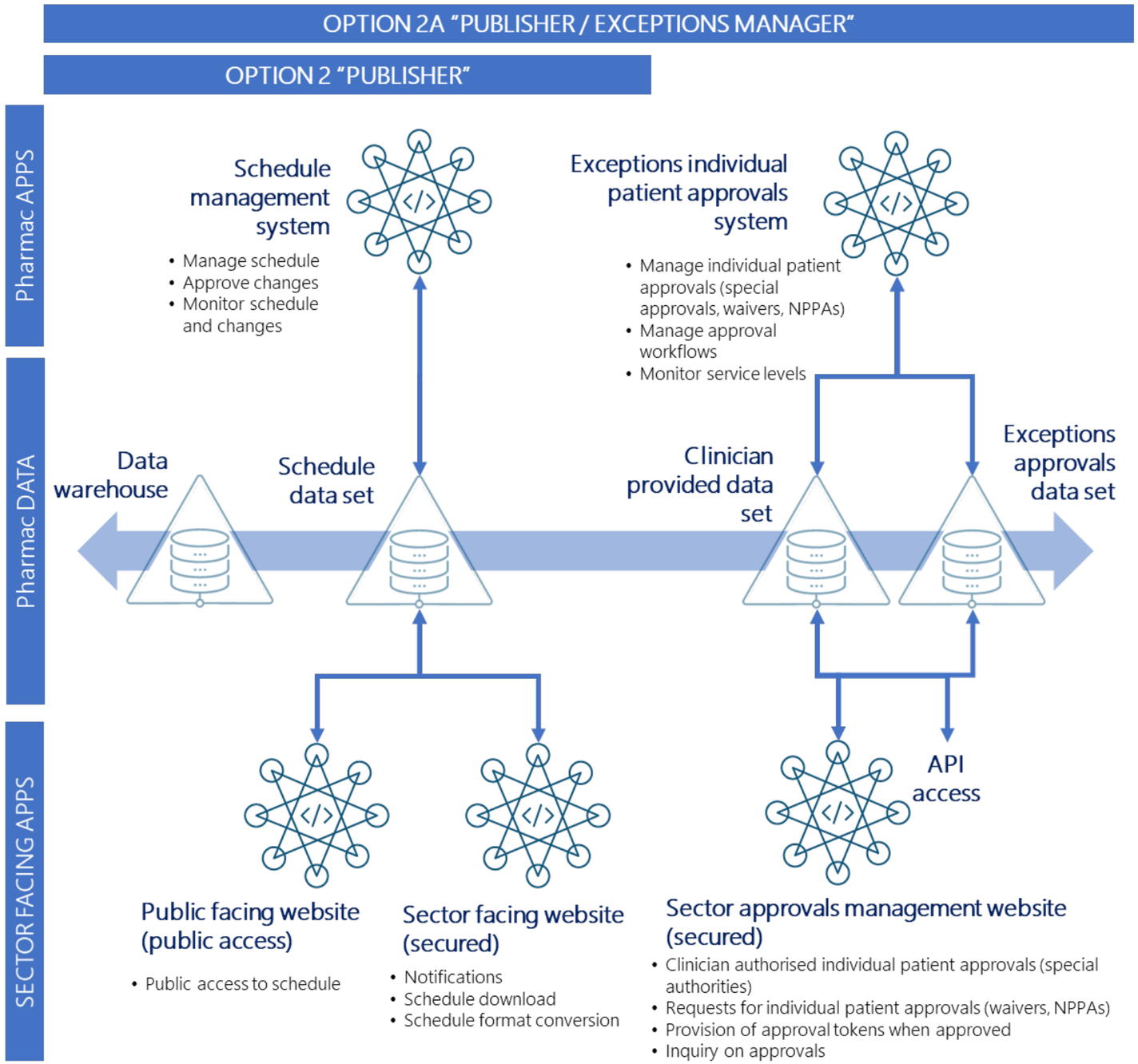
Option 2 Publisher / manager of exceptions

Option 2 includes the core Schedule data set, Schedule management system, data warehouse, public facing website, and sector-facing website.
Option 2 replaces the existing functionality with a standards based, sustainable system with increased automation and data integrity.

Option 2A Publisher / manager of exceptions

Option 2A adds the exceptions management systems and data to support automation of special authorities, waivers, and NPPAs. This replaces existing Ministry of Health systems (special authorities) and Pharmac systems (waivers, NPPAs).

Note that there is no agreement as yet to move special authorities from the Ministry to Pharmac.



3. FUTURE OPTIONS (CONT'D)

The datasets will be a major upgrade from the current state. The Pharmac applications will reduce manual intervention through increased automation. The sector applications will provide improved web-based access to services ...

Data sets

There are four main data sets that we expect to maintain, each with different structures, purposes and origins.

- The *Schedule data set* will contain all of the funding rules and criteria that define (a) which products are listed in the Schedule, and (b) the provisions under which they are listed.
- A *clinical criteria data set* will contain all of the clinician provided patient information that we collect through the process of determining patients' conformity with access criteria through the individual patient approval process.
- An *exception approvals data set* will hold information on the individual patient approvals (approved and rejected).

A data warehouse will hold copies of all the operational data including the data collected from the sector.

- The *transactions data set in the data warehouse* will hold all the information on pharmaceutical transactions (e.g., dispensing events) that is collected from the sector as well as the Schedule, clinician provided information, and individual patient approvals.

The Pharmaceutical Schedule and its associated systems will form part of a connected health sector infrastructure. We need to have system and data interoperability with other systems that form the New Zealand health sector IT infrastructure.

The key standards we will follow to enable interoperability are:

- New Zealand Universal List of Medicines and New Zealand Formulary
- Medical Device Terminology and Identification Standards
- SNOMED CT
- GS1 Standards (including UNSPSC, GTIN, and GLN)
- WHO ATC standards.

More information on these standards can be found in the glossary.

The current medical devices and medicines Schedules can be seen at www.pharmac.govt.nz.

Pharmac applications

A Schedule management system to enable Pharmac staff to manage and maintain the Schedule data set. This will need to support a wider base of users drafting Schedule changes (and a control process for finalising such changes), although some tasks will be managed by specialist users (such as crafting new case elements). It will also need to support greater automation for handling the scale involved in medical device listings.

An individual patient approvals system for the management of the approvals for specific patient circumstances outside of the general rules (currently special authorities, NPPAs, and waivers). This will include a workflow management system for the exceptions requiring manual interventions (e.g. waivers, NPPAs). It will also allow the overall exceptions data and sector facing functionality to be managed.

There will also be interfaces to the contracts system to enable new medicines and devices to be loaded into the Schedule.

Sector applications

A *sector individual patient approval* application for health practitioners to provide the information needed to support exceptions. This will include the current special authorities whereby a clinician certifies that the exception is valid (currently special authorities managed by the Ministry – these require no manual intervention by Pharmac). It will also include those exceptions requiring manual intervention (e.g. NPPAs and waivers). This will need to be a secure site with user authentication and authorisation.

A public facing website giving full access to the Schedule of medicines and devices and the rules of access. The key functions will include:

- Schedule access and download
- Other information such as alerts, key changes, etc.

The current website is expected to be the basis for the new Schedule information. This can be seen at www.pharmac.govt.nz.

A sector facing website providing the functionality needed for prescribers and dispensers and others to perform their functions. This will need to be a secure site with user authentication and authorisation. The key functions will include:

- Notifications
- Schedule download
- Any special Schedule format conversions that will be needed to maintain compatibility with existing sector systems.

Interfaces

The interfaces include:

- Interfaces to support the data standards – these interfaces access other master data sets to enable the Schedule to be structured
- Interfaces to provide data to the sector
- Interfaces to collect data from the sector.

There will also be internal interfaces to other Pharmac systems, including the contracts system for loading contract information into the Schedule.

KEY INTERFACES	2	2A
DATA STANDARDS		
Medicine data from NZ Universal List of Medicines (NZULM info.nzulm.org.nz)	✓	✓
Unique product identifier pharmacode data from the Pharmacy Guild (www.pgnz.org.nz/about-us-1/pharmacode)	✓	✓
GS1 data sets including GTINs and Global Location Numbers (www.gs1nz.org)	✓	✓
Clinical terminology data (SNOMED CT browser.ihtsdotools.org)	✓	✓
Health measurement standards (LOINC loinc.org)	✓	✓
NZ health provider index (HPI) (www.health.govt.nz/our-work/health-identity/health-provider-index)	✓	✓
NZ National Health Index(NHI) data (www.health.govt.nz/our-work/health-identity/national-health-index)	✓	✓
INFORMATION PROVIDED TO SECTOR		
Schedule updates (in appropriate formats) – Public facing website and sector facing website	✓	✓
Individual patient approval authorisation tokens to prescribers as proof of approval – sector approvals management website		✓
Individual patient approval authorisation tokens to Ministry payments system as proof to the payments system that the claim from the dispense can be paid – sent directly to payments systems	✓	✓
INFORMATION RECEIVED FROM SECTOR		
Hospital medicines purchase data from e-Pharmacy system used by hospitals	✓	✓
Medical devices purchase data from DHB supply chain systems and/or Health Systems Catalogue spend data.	✓	✓
Ministry claims and payment data (currently Pharmhouse system data)	✓	✓
Ministry processed special authorities	✓	
Ministry exceptions approved by Pharmac that have been processed	✓	✓
Ministry master list of prescriber and dispenser login IDs and security tokens	✓	✓

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4. SCHEDULE DATA SET

The Schedule data set will need to store data about devices and medicines and the core rules for pricing, dispensing, and reimbursement …

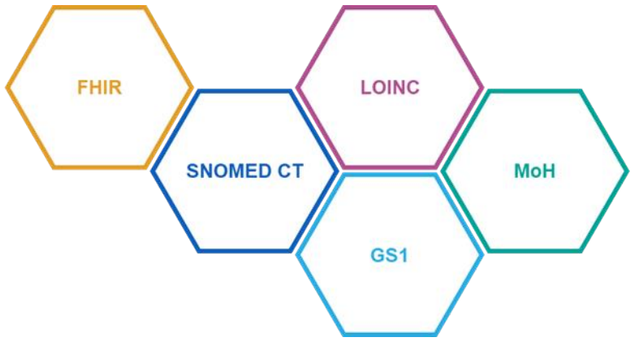
Introduction

This page presents a high level view of how we expect the Schedule database to be constructed. It is provided to give an indication as to the expected complexity.

Whereas we currently have three separate Schedules for community pharmaceuticals, hospital medicines, and medical devices, in the future we will manage all these through a single, integrated dataset using common data standards.

Core standards

The Schedule and its associated systems are to be built on a foundation of established health sector information standards that fall into five broad domains.

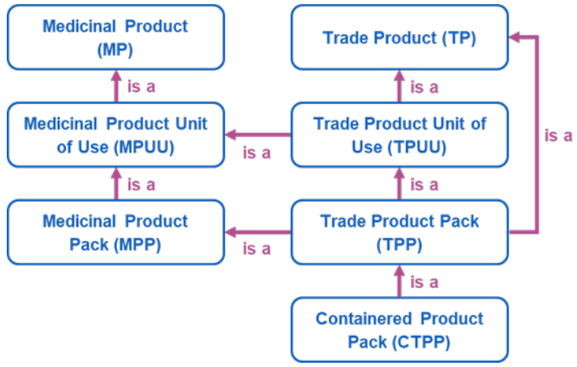


Note that the standards include FHIR (Fast Healthcare Interoperability Resources). This is a messaging standard managed by HL7, and is already in use across the New Zealand health sector. FHIR will need to be used for connection with clinical systems, but perhaps not in connection with all systems that connect to the Schedule infrastructure.

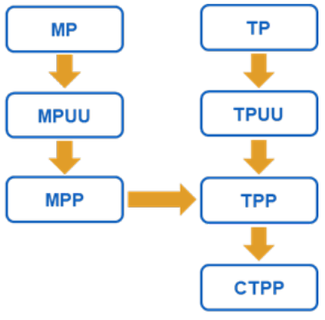
(See the glossary for details of the standards.)

Structure

The Schedule will identify products using the NZMT SNOMED CT identifiers, and will use the relationships within the NZMT model as illustrated below.



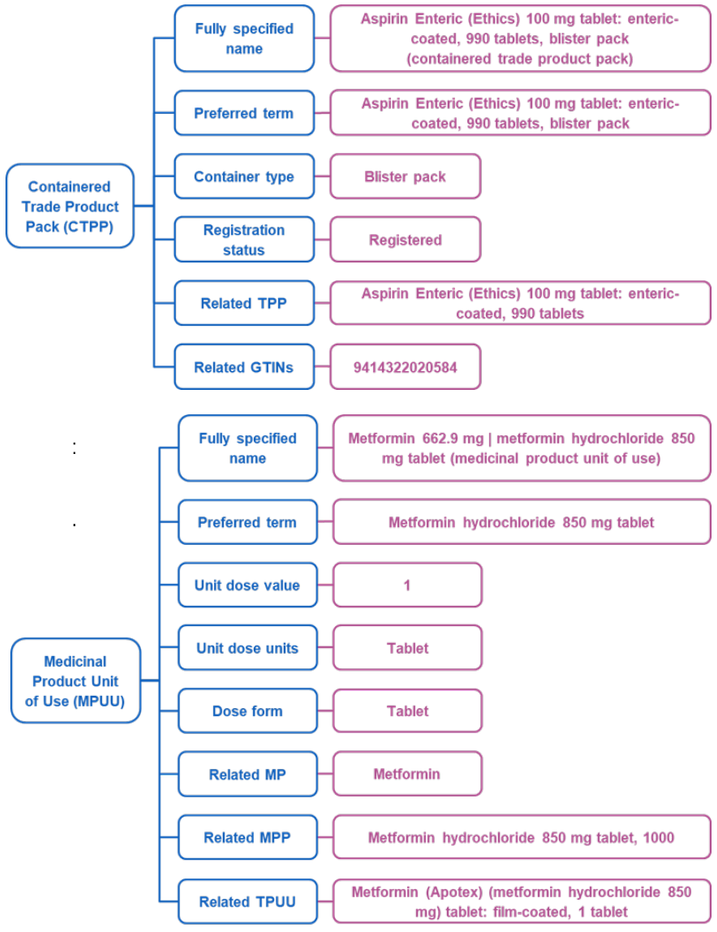
Funding-related transactions will be managed at the Containered Product Pack (CTPP) level, although funding rules will need to be able to sit at any level of the NZMT model, and cascade downwards. This means that criteria would be able to be set, for example, for all formulations of a particular chemical (medicinal product) or just of one brand (trade product). The inheritance rules will need to operate as follows.



Core product data

Every listed product will have a set of core information that is relevant across multiple funding situations. There is a small set of product attributes that are important for us to be aware of but are not determined by Pharmac. They are managed externally and will be echoed in the Schedule (generally sourced though the NZULM).

Here are examples of the kind of information we will need to store for Containered Product Packs am Medicinal Product Unit of Use.



We will also want to capture production information on products (e.g. dates, batch numbers, serial numbers), to understand the NZ-wide inventory levels and manage recalls. This information might not be consistently available for some time.

Note that GS1 barcodes can include key production information, including the batch number, expiration date and serial number, alongside the GTIN (either in a linear barcode or a data matrix), although this is not currently universally used within medicines or medical devices.

5. SCHEDULE RULES

The Schedule data set will need to store the core rules for pricing, prescribing, and dispensing. This will need to be in human readable, and as far as possible machine readable form so that prescribers, dispensers, and the payment agency (currently Ministry of Health) all operate on the same rules …

Introduction

The Schedule contains rules for prescribing and funding medicines and devices.

In Options 2 and 2A, Pharmac will be the publisher of these rules. This means that it must define and publish the rules in a way that makes it easy for other organisations to interpret – both in human readable and digital form. However, for both these options, Pharmac will not need to digitally interpret the rules outside of the limited cases covered by individual patient approvals that can be processed automatically (i.e. special authorities).

This page outlines some of the rules criteria we will need to store in the Schedule.

Pricing and reimbursement

For most products the price will be set in the Schedule and reimbursed accordingly. However, for some products the price will be more variable and therefore not fixed in the Schedule. Accordingly, it will contain one of the following:

- The price and subsidy for a pack
- A flag to indicate that the product has a variable price, meaning that it is set in a contract, but the actual price can vary from order to order (e.g. tiered pricing) – DHB users would need to be able to view the pricing Schedules for these products, as sourced from the contracts database
- A flag to indicate that the product is funded at actual price, meaning the pricing is unknown and set by the supplier for each order.

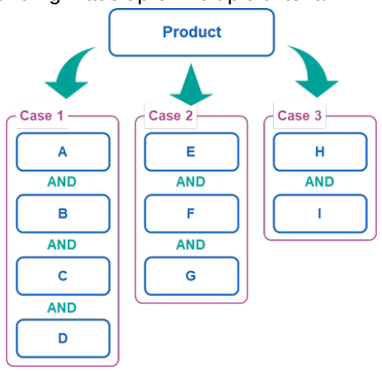
There are certain products for which we will want to pay a claimant for more than is exactly required to fill a dispensing, either because it is impractical to dispense the exact amount required (i.e. half of an inhaler), or there is a significant financial risk from being left with unused part-packs of expensive medicines. Accordingly, for each product listed in the Schedule, we will need to specify if:

- The amount supplied is to be rounded up to a set multiple of units (as defined either by multiples of MPUU) or fractions of a pack, or
- The claimant may submit wastage claims for subsequently discarded product, or
- Neither provision applies.

Prescribing

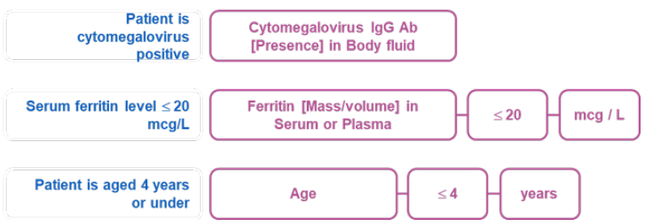
Funding criteria

We will seek to target particular groups of patients using clinical and non-clinical criteria, setting limits on the amount of a product that can be funded, and requiring that certain health services be used to access a product. Historically, criteria have been assigned directly to a product. In the future, we need to establish one or more cases for each funded product, each case being a different path to achieve funding made up of multiple criteria.



Clinical criteria

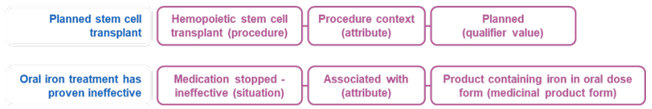
If funding is targeted to a particular population, the clinical criteria will be described in terms of disease staging, laboratory results and demographic features, etc. These criteria will be able to be expressed using SNOMED CT and LOINC, to support improved analytics of pharmaceutical usage.



Circumstance criteria

Targeting criteria often include more than simply defining the clinical condition. We often require that a product is funded for a population but only when some other situation applies – e.g. another treatment has not been successful, the patient has had surgery, or an outbreak has occurred.

These circumstantial criteria can often be bespoke and convoluted, meaning that the difficulty of clinically coding these criteria – and the reduced value in doing so – means that we will likely need to manage some criteria as free text, although many will also be constructed using SNOMED CT and LOINC.



Dispensing

Frequency

Products dispensed through community pharmacies will need to have dispensing frequency requirements attached to them, outlining whether the prescription should, by default, be dispensed (a) all-at-once, (b) in 30 day lots, or (c) some other specified amount.

Dispensing rules will also need to provide for a patient to receive dispensings in different frequencies, based on their individual circumstances (such as being in a residential care facility or living in a remote area.

Service rules

We will also need to be able to specify any health service requirements through which people will access funding, which may include:

- Dispensing by a particular type of claimant (pharmacy etc)
- Prescription by a particular type of prescriber
- Provision through a particular facility type (e.g. public hospital, hospice)
- Use of a particular form type (e.g. prescription, imprest order).

5. SCHEDULE RULES (CONT'D)

The Schedule data and rules will be distributed to the sector for prescribing (clinicians), dispensing (pharmacies), and payment (Ministry of Health) …

Introduction

The current Schedule management is based on a paper publishing paradigm that has been updated to enable electronic operation.

The new Schedule will be electronically based.

Community pharmaceuticals

The table on the right summarises the key changes we anticipate in the new community pharmaceuticals process. This process is currently the most complex of the processes and so the other key processes are described in terms of how they differ from community pharmaceuticals.

- The Schedule will be developed electronically, directly in the database. There will be no interim process to develop templated documents describing the rules.
- The electronic Schedule changes will be developed in a development and test environment so that the impact of the changes can be tested.
- Changes will be able to be selectively moved to production to support incremental publishing.
- Prescribers and dispensers will continue to download the Schedule as currently occurs.
- Individual patient approvals will be enhanced and managed completely by Pharmac. A single website will allow all current types of approvals (special authorities, waivers, and NPPAs) to be initiated.
- Pharmac will retain the information provided for approvals so that subsequent approvals for the same patient can be streamlined. It will also use this information to refine its rules and processes.

Hospital medicines

Hospital medicines will operate in a similar manner to Community Pharmaceuticals.

- The Hospital Medicines Schedule will be managed in a combined Schedule database – there will no longer be separate systems as currently takes place.
- The Schedule publishing will occur as for Community Pharmaceuticals.
- There is no prescriber step for Hospital Medicines. The hospital clinicians are "trusted".
- The dispenser and payer steps require no changes in the Pharmac processes.

Medical devices

Currently a medical devices Schedule is published for use by the DHBs. This Schedule allows DHBs to use the contracts negotiated by Pharmac. As yet, there are no rules for use of the devices. The Schedule is therefore only used at purchase time by DHBs – there is no (as yet) prescriber or dispenser processes.

Medical devices will be part of the new combined Schedule. It is likely that rules will develop over time.

Community pharmaceuticals process changes

PROCESS		CURRENT	FUTURE (OPTION 2A)
PHARMAC	Prepare Schedule	• Schedule changes are developed as set of structured rules in a templated Schedule document over extended period of time • Changes are approved based on final document	• Schedule changes are made directly in the database in a development and test environment • The data and rules can be tested as they are developed
	Convert for usage	• Schedule changes are applied to the Schedule database over a period of days by analysts • There is some back and forth ensuring that rules are being applied as intended, and can in fact be applied as intended	• -
	Publish to users	• The Schedule document is published as a pdf – typically once a month • The Schedule data is available to downloaded in XML format to prescriber, dispensing, and payment systems	• The changes to the Schedule are selectively transferred to production so they are available to the sector • No separate Schedule pdf will be produced – the Schedule will be directly readable and downloadable from the website
PRESCRIBER	Download Schedule	• Download updated electronic Schedule from website	
	Apply rules	• Rules applied in prescriber's own prescribing system • Clinicians can initiate special authority, waiver, or NPPA if a patient does not meet the prescriber rules – authorisation token # provided back by Pharmac	• Rules applied in prescribers own prescribing system • Clinicians can initiate individual patient approval request through single online system or through their own prescriber system if a patient does not meet the prescriber rules – authorisation token # provided back by Pharmac
DISPENSER	Download Schedule	• Download updated electronic Schedule from website	
	Apply rules	• When dispenser receives prescription, they check validity against the rules • If individual patient approval, they will check the authorisation token # against the website	
PAYER	Download Schedule	• Download updated electronic Schedule from website • Any changes in rule types require programming	• Download updated electronic Schedule from website • Any changes in rule types managed through rules engine
	Apply rules	• Rules applied on a transaction by transaction based	

6. INDIVIDUAL PATIENT APPROVALS

Under Option 2A, individual patient approvals (currently special authorities, waivers, NPPAs) would be integrated to a single web portal …

Introduction

Currently, the Ministry processes special authorities and Pharmac processes waivers and NPPAs, i.e. those approvals that require manual intervention.

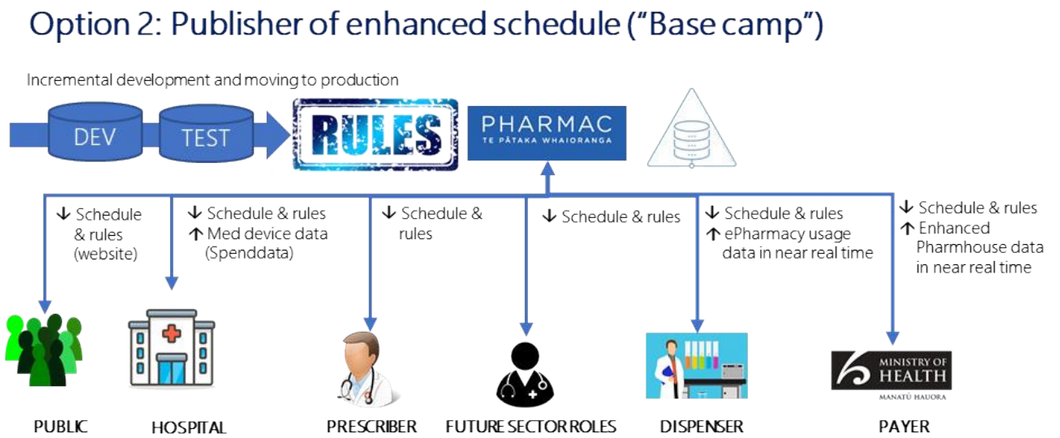
Under Option 2A, Pharmac would become responsible for all the current individual patient approvals. (Note that there is not agreement for this to occur.)

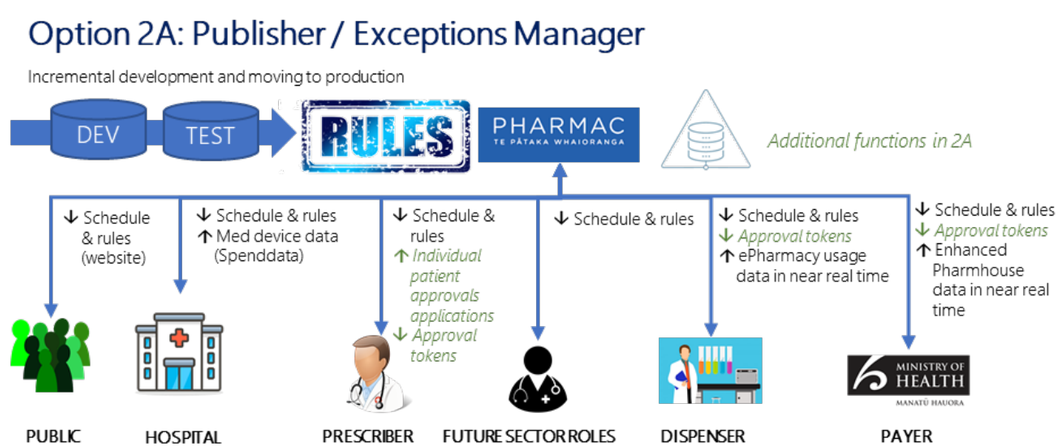
Future processes under Option 2A

Under option 2A:

- All individual patient approvals will go through a single sector web portal. This will enable simple transactions that are automatically approved (e.g. the current special authorities) and the more complex transactions requiring additional information and attachments.
- Pharmac will now start collecting clinician provided patient data. It is likely that any NHIs will be encrypted. This will enable Pharmac to preserve patient privacy while enabling subsequent approvals and longitudinal analysis. (Full privacy analysis will be required.)

The table opposite summarises the key changes between the current environment and the proposed future under option 2A.





Individual patient approvals processes

Approval types	CURRENT	FUTURE (OPTION 2A)
Clinician approvals for community medicines (500,000 pa) Currently E-special authorities, online special authorities. In these cases specific patient criteria must be met for access to the medicines; a clinician certifies that these conditions have been met for the specific medicine and authority number is generated that the pharmacy can then use for the claim. No human intervention is required in the workflow.	• Clinician certifies that clinical prerequisites are met through online webform or through electronic document sent to Ministry of Health • Prescriber systems may support close integration with special authorities • Authorisation token # provided	• Single portal website for all individual patient approvals • Clinician provides information depending upon type of approval requested • Clinician will be able to incrementally develop complex applications and save them • If approval can be made immediately with no human intervention (e.g. in current case of special authorities), this occurs • If human assessment is required, this will be managed through a workflow system at Pharmac • APIs will be provided to enable industry systems to directly access the system
Waivers (<5,000 pa) If a person's clinical circumstances meet the spirit or intent of Special Authority criteria, but not the technical requirements, Pharmac can consider a waiver. If a waiver application is approved, a special authority number is generated to support the pharmacy claim.	• Document templates must be downloaded and completed by the prescriber and additional documentation added as appropriate • These are submitted to Pharmac electronically • Pharmac manages a workflow process to approve these • Prescribers are notified by email of the result	
Named Patient Pharmaceutical Assessment (NPPA) (< 5,000 pa) Pharmac uses the NPPA process to consider whether to fund a treatment for an individual patient whose clinical circumstances are exceptional. If a NPPA application is approved, a special authority number is generated to support the pharmacy claim.		

7. GLOSSARY *This glossary explains the key terms and abbreviations used in this document …*

Community Pharmaceutical Schedule The New Zealand Pharmaceutical Schedule is a list of the prescription medicines and therapeutic products subsidised by the Government.

DMN Decision Model and Notation. A way of describing decision rules. See www.omg.org/dmn.

Dispenser An organisation (generally a pharmacy or pharmacist) that can dispense medicines that have been prescribed.

E-Pharmacy The pharmacy dispensing system used by hospitals and provided by DXC.

FHIR Fast Healthcare Interoperability Resources. A messaging standard managed by HL7, and already in use across the New Zealand health sector.

GLN Global location Number. A GS1 standard for a 13 digit number used to identify physical locations such as factories, farms, orchards, warehouses etc.

GS1 GS1 defines key data standards for products and suppliers. See www.gs1nz.org.

GTIN Global Trade Item Number. A GS1 standard for a unique identifier for a product.

Hospital Medicines The Hospital Medicines (HML) Schedule specifies medicines that may be used in DHB hospitals, along with any access conditions that apply.

HPI Health Provider Index. Unique identifier for health providers in New Zealand.

HSAAP The Health Sector Agreements and Payments (HSAAP) system managed by the Ministry of Health manages the payment of pharmacies for prescribed drugs covered under the community pharmaceuticals Schedule. The medicines approval and payments aspect is one part of the wider HSAAP that the Ministry uses for claims and payments.

HSC Health System Catalogue. Will enable hospitals to purchase medical devices and other products and services where there are national contracts in place from a single approved catalogue. The HSC programme will also deliver a repository of Spend Data to enable analysis of what has been procured.

LOINC The international standard for identifying health measurements, observations, and documents. See loinc.org.

Medical Devices Medical devices are products and equipment that are generally used on, in or by a person for a diagnostic or therapeutic purpose. They include consumable and durable products, implantables, and complex equipment – everything from a cotton swab to an orthopaedic implant and a home dialysis machine. DHBs can use any medical device they prefer – they are not limited to medical devices listed by Pharmac. However, if the DHB wishes to use a device that is listed in the Pharmac addendum, then the DHB must use Pharmac's contract for that device.

NHI National Health Index. Unique identifier for any person access health or disability services in New Zealand.

NPPA Pharmac uses its Named Patient Pharmaceutical Assessment (NPPA) process to consider whether to fund a treatment for an individual patient whose clinical circumstances are exceptional. (see pharmac.govt.nz/medicine-funding-and-supply/make-an-application/nppa-applications)

NZMT The New Zealand Medicines Terminology. A coding and naming system provided by the NZ Ministry of Health for use in the NZ health sector. It provides a unique name and number for every medicinal product available in New Zealand. The NZMT is part of the NZ Universal List of Medicines (NZULM).

NZULM New Zealand Universal List of Medicines. It is the standard source of commonly-used information about medicines and the primary naming and coding database for medicines in the NZ health sector. It is used in most medical and pharmacy software. It was first officially released for use in 2011, and is free to use. See info.nzulm.org.nz.

PCT Hospital medicines that are claimed through the Schedule in a similar process to community pharmaceuticals. Previously related to Pharmaceutical Cancer Treatments, but now includes a wider range of products for other conditions.

Pharmacode The Pharmacy Guild developed Pharmacode® in the late 1970s and early 1980s to enable all pharmacies to purchase items from New Zealand pharmaceutical suppliers using a unique product identifier. See www.pgnz.org.nz/about-us-1/pharmacode.

Pharmhouse The data warehouse managed by the Ministry of Health for recording and analysing pharmacy claim and payment transactions.

Prescriber A clinician who is able to prescribe medicines to a patient.

Schedule The term used in this document to mean the Schedule of medicines and devices that Pharmac manages for the sector.

SNOMED CT SNOMED CT is a system of clinical terminology that comprises over 350,000 concepts and 1,200,000 terms for clinical findings, disorders, procedures, substances, medicines, devices and other concepts related to health and social care. See browser.ihtsdotools.org.

Special Authorities A Special Authority is an application process in which a prescriber requests government subsidy on a Community Pharmaceutical for a particular person. Once approved, the prescriber is given a Special Authority number which must appear on the prescription. The Special Authority number can provide access to subsidy or waive certain restrictions otherwise present on the Community Pharmaceutical.

UNSPSC United Nations Standard Products and Services Code®. Managed by GS1 US. A standard for efficient, accurate classification of products and services.

Waiver if a person's clinical circumstances meet the spirit or intent of Special Authority criteria, but not the technical requirements, Pharmac can consider a waiver. If a waiver application is approved, a special authority number is generated to support the pharmacy claim.

WHO ATC World Health Organisation Anatomical Therapeutic Chemical Classification System. A drug classification system that classifies the active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.