Australian Government

Department of Health

Towards a National Medicines Traceability Framework

Consultation Paper

November 2021

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	NMTF@health.gov.au	November 2021

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Vision

Imagine a national system which can identify where a package of medicine is and where it has been.

This system would strengthen the security and efficiency of the medicine supply chain by allowing inventory management and assurance in real time, improving the efficiency of recalls and responses to shortages. It would also further improve Australia's strong regulatory standing and interoperability in an increasingly complex and growing global market.

This is the vision of a national medicine traceability framework (the Framework) being explored by the Department of Health (Health) in response to the 2020-21 Budget Measure: Improving Access to Medicines – development of Unique Identification framework for PBS medicines.

Why we are consulting with you

We are consulting with key medicine supply chain stakeholders to help us shape the Framework policy, determine feasible framework designs and implementation approaches, gauge industry appetite and readiness to operate within such a framework, and confirm the expected benefits and impact a framework may have on businesses.

While potential medicine traceability options are outlined in this paper no specific framework design or timeframe for implementation has yet been decided, as we are currently in the initial consultation stage of the project.

Your feedback will inform Health's framework policy recommendations to Government and will ensure that your viewpoint has been considered. We will engage in further consultation with industry stakeholders as the Framework policy design progresses.

The following references are particularly relevant in providing context for our current consultation:

- Better healthcare: a vision for use of data matrix codes and medicines traceability, Therapeutic Goods Administration (TGA), July 2020
- Recommendations on Common Technical Denominators for T&T Systems to Allow for Interoperability, International Coalition of Medicines Regulatory Authorities (ICMRA), August 2021
- Standard for serialisation and data matrix codes on medicines: Guidance for Therapeutic Goods Order (TGO) 106, TGA, March 2021
- The World Health Organization Policy paper on traceability of medical products, 2021, World Health Organization (WHO), March 2021.

A glossary and list of references and further reading are provided at the end of this document.

Sustaining a world class health system

Australia's medicine supply chain is critical infrastructure which sustains the health outcomes of all Australians

In Australia, the Australian Government subsidises the cost of medicines through the Pharmaceutical Benefits Scheme (PBS) as part of the National Medicines Policy. In the 2019-2020 financial year total government PBS expenditure was $12.7 billion in benefits paid[1], with estimates indicating PBS expenditure will increase to over $14.3 billion per annum by 2023-24.[2]

While Australia is internationally considered to have a high medicines regulatory standard, there is limited transparency to Government on the volume, location, or consumption of medicines across the supply chain. Additionally, there is no central repository of medicine supply chain information to facilitate pharmacovigilance, assist in the identification of potential fraud activities, or to provide a national view of medicines within the supply chain to better detect or respond to medicine shortages, recalls and wastage.

Australia is reliant on the importation of over 90% of its medicines[3] and thus is more at risk of medicine shortages than other countries and jurisdictions with larger local medicine markets. This creates a further imperative to strengthen the visibility, management and interoperability of the national medicine supply chain and align regulatory frameworks with international standards to help mitigate medicine supply risks and costs.

Additionally, the COVID-19 health emergency has highlighted the fragility of the medicine supply chain both internationally and within Australia. A 2020 senate inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade[4] identified that the pandemic has exposed the vulnerability of the Australian medical and pharmaceutical supply chain, which is considered critical infrastructure.[5]

Many independent research reports, including the references listed in this paper, discuss the global take-up of national medicine traceability systems, the rational and motivation for their introduction, and the potential supply chain, public health, and regulatory benefits resulting from their implementation.

Health is seeking comments from Australian medicine supply chain stakeholders on the development of a medicines traceability framework, including possible implementation approaches and architecture options.

Potential benefits of medicine traceability

In its March 2021 Policy paper on traceability of medical products,[1] WHO notes:

'Traceability technologies ... offer the technical possibility to trace medical products along the supply chain – from final stage manufacture to the point of dispensing, or the ultimate place where the medical product is administered to a patient – with a view to strengthening the near real-time monitoring of the integrity of a given pack. There is global recognition that traceability systems can be leveraged as useful tools to ensure the integrity and improve the efficiency of supply chains. Traceability may not be able to completely block falsified medical products from entering the supply chain but implemented alongside the considerations contained in this policy paper, it can minimise the risk and allow for earlier detection and response'.

[1] Annual Report 2019-20 - Services Australia

[2] 2020–21 Health Portfolio Budget Statements

[3] Medicine shortages in Australia – what are we doing about them?

[4] Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade

[5] Critical Infrastructure Centre

WHO further stated that:

'The successful implementation of a traceability system can facilitate strengthened supply chain integrity and efficiency, with the ability to trace where a product has been at any given moment. Near real-time information and appropriate data access can provide visibility of products and can expedite regulatory responses to safeguard patients and the supply chain, including by:

1. *Ensuring only authorised products, registered or approved, circulate in the legal supply chain;*
2. *Preventing the distribution and/or dispensing of falsified, expired, prohibited or recalled products;*
3. *Facilitating efficient and fast market recalls;*
4. *Enabling efficient inventory management at all levels; and*
5. *Identifying shortages and monitoring the reasons for shortages and stock outs.*

Traceability systems can help prevent the entry of falsified medical products into regulated supply chains, detect any falsified medical products that are circulating in-country, and assist regulators to respond quickly and proportionately to any substandard and falsified incidents that are detected.

These potential opportunities, if realised, can offset the costs of traceability systems. The hidden costs of not investing in traceability in preparedness for resilient supply chains may end up being considerably higher'.

TGA's 2020, *Better healthcare: a vision for use of data matrix codes and medicines traceability* paper highlights potential benefits of a 'medicines track and trace system' that align with those listed by WHO. These benefits are placed in a context of 'health professionals wanting better electronic systems to improve patient safety', that are 'integrated' to provide better automation and at-call information, which would help reduce medication errors and adverse events.

TGA's 2020 *traceability vision* further noted that 'any future track and trace system in Australia must be globally aligned, using common fundamental components to ensure interoperability' and that 'the identification, capture and sharing of information about a medicine and its movement throughout the supply chain must be in a globally recognised format and language'.

TGA's 2020 Better healthcare paper identifies that the ultimate benefits of a traceability system will depend on the track and trace model chosen, and could include:

- *Visibility of product status (e.g. recalled, expired)*
- *Reduced risk of substandard, falsified and counterfeit medicines entering the legitimate supply chain and being dispensed to patients*
- *Improved pharmacovigilance and monitoring of treatment outcomes*
- *Efficient and targeted recall management*
- *Real-time visibility of product numbers and locations in the supply chain, which may assist during medicine shortages and also help prevent them*
- *Coordinated strategic management of shortages, with all stakeholders easily identifiable*
- *Improved inventory management, including both forwards and reverse logistics*
- *Efficient payment and payment monitoring*
- *Robust reimbursement processes*
- *Assurance of authenticity, increasing trust and confidence in Australian medicines.*

TGA notes that a 'fully interoperable' track and trace system could result in new linkages across health data sets that would allow 'information in currently siloed health systems to be aligned so that the valuable health data from each can be viewed as one dataset. The detection of trends and anomalies, not recognisable with a single system, becomes possible. These new insights can

support better health polices, earlier detection of medicine problems and ultimately better health outcomes for Australians'.

Elements of a medicine traceability framework

The ICMRA 2020 'track and trace' paper strongly endorses the principle of the use of 'internationally agreed standards that allow for interoperability' when implementing a medicine traceability framework. The paper provides technical recommendations which focus on interoperability rather than individual system design. Architectural features that allow for system interoperability such as identifiers of products, standards, data elements and information exchange are discussed in detail in Section 5.

In March 2021, following extensive industry consultation, TGA released TGO 106, a *standard for serialisation and data matrix codes for medicines*. This standard, which sets out requirements for adopters of serialisation and data matrix codes on medicines supplied in Australia, is a fundamental and enabling component of a national medicine traceability framework.

A serialised medicine is one where each unit bears a unique identifier, allowing the unit to be identified distinctly within its batch. The combination of a product identifier (GTIN) and serial number creates a globally unique character chain for the unit. A definition of serialisation is provided in Section 4 of TGO 106.

At a concept level a national medicines traceability framework would include the following elements:

1. Identification of industry participants operating across the Australian medicine supply chain and how and when they are required to interact with the Framework.
2. A traceability infrastructure that would allow supply chain participants to verify, track and upload data on medicine products as they pass from one participant to another across the supply chain. This infrastructure would be:
    a. *standardised*, in that it would provide a specification of how traceability information would be collected,
    b. *extensible*, in that it would have the capacity to receive increasing amounts and types of information as its scope expands after an initial rollout, and
    c. *interoperable*, in that it would allow other data systems, for instance a manufacturer's specific electronic supply chain data system, to connect and share information with the Framework.
3. A serialisation standard for uniquely identifying medicines, and
4. availability of a near-real time data repository for collecting and accessing traceability information.

Importantly, a national medicines traceability framework would not include the requirement to collect individual personal information resulting from the dispensing of medicines. The framework is only concerned with data relating to the traceability of medicines through the Australian supply chain.

Traceability models

The majority of economies with existing traceability systems have clearly stated, specific regulatory objectives. (GS1 2018, p-6)

There are several medicine traceability models already being implemented around the globe, which can be considered in determining the framework most suitable for the Australian medicine supply chain.

The role of the regulator

In considering which traceability options may be most applicable to an Australian framework there is alignment across independent international bodies - WHO (2021), ICMRA (2020) and GS1(2018) – that the '**track and trace**' and '**point of dispense verification**' are the two main medicine traceability approaches in common use.

There is also agreement across WHO, ICMRA and GS1 that it is the national regulator's role to define the traceability model, 'taking into account many considerations including the operational details of their specific medical product supply chain, complexity, implementation and operational costs, and the ability to address the problems faced. The traceability regulation should identify the model selected'. [6]

As the regulator of a possible framework, Health must identify the most appropriate traceability model, including the frequency of medicine verification, which will support the intended public health benefits and medicine regulatory outcomes.

WHO (2021, p-17) comments that 'regulators can specify clearly in their traceability regulation the frequency of verification, in particular with respect to the point of dispense vs full track and trace verification, based on the maturity of the local supply chain, the capability of the stakeholders to efficiently fulfil the verification requirements, their objective and the cost implications'.

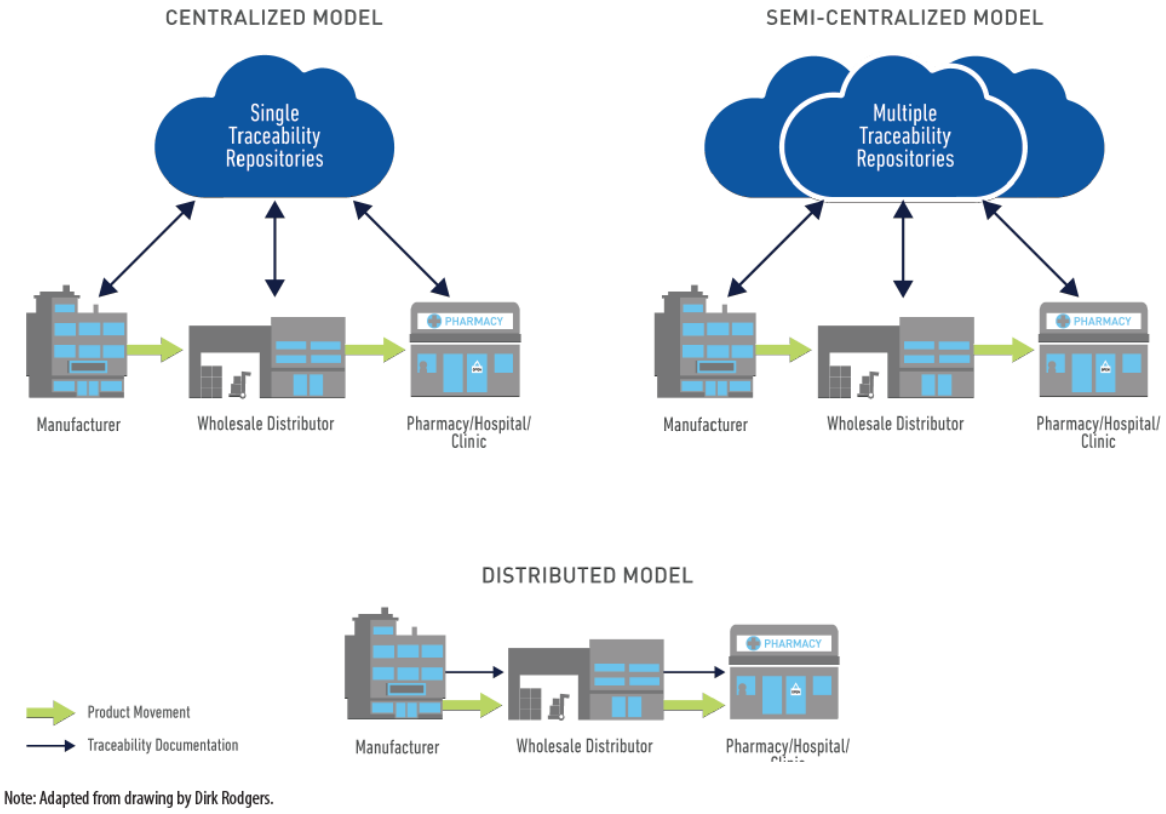
Verification *is a technique that allows stakeholders, patients and/or regulatory or enforcement agencies to check the likely authenticity and authorisation of products within the supply chain or, under regulations that allow it, in the hands of patients. Each traceability model (see Fig. 1) offers one or more ways to implement the verification of the product identifiers and/or production identifiers (unit-level unique identifiers).*

In the ***centralised model****, where all traceability data are stored in a single database or repository, verification can be performed by national regulatory authorities, members of the supply chain, health care professionals and/or patients communicating with the central repository to verify the identifiers.*

In the ***semi-centralised model****, where traceability data are spread among a small number of repositories, verification can be performed by communicating with one of the regional repositories.*

In the ***distributed model****, where each member of the supply chain holds its own traceability data, verification can be performed by communicating with the original manufacturer. Owing to the frequency of verification required in most cases, these communications should be standardized, web-based messages between systems. (WHO. 2021, p-15)*

Figure 1. The three primary traceability models are differentiated by where the traceability data are stored and how verifications are performed (from WHO. 2021 p-16).



Full Track and Trace model

*With the Full **Track and Trace system**, the manufacturer (or sponsor) is required to uniquely and unequivocally identify the product. The manufacturer and all stakeholders of the supply chain are reporting information about this product and its movements throughout the supply chain—up to the point when these products reach points of dispense.*

The advantage of this model relies on detecting in real time, a product's 'irregularities' and, upon detection, ensuring an effective recall and management of inventory. Likewise, it provides visibility of the entire, end-to-end product supply chain.

The main disadvantage of a Full Track and Trace system is its complexity as it involves a large number of stakeholders in the supply chain that will often need to allocate resources to support the system's operation. (GS1 2018)

Point of Dispense Verification model

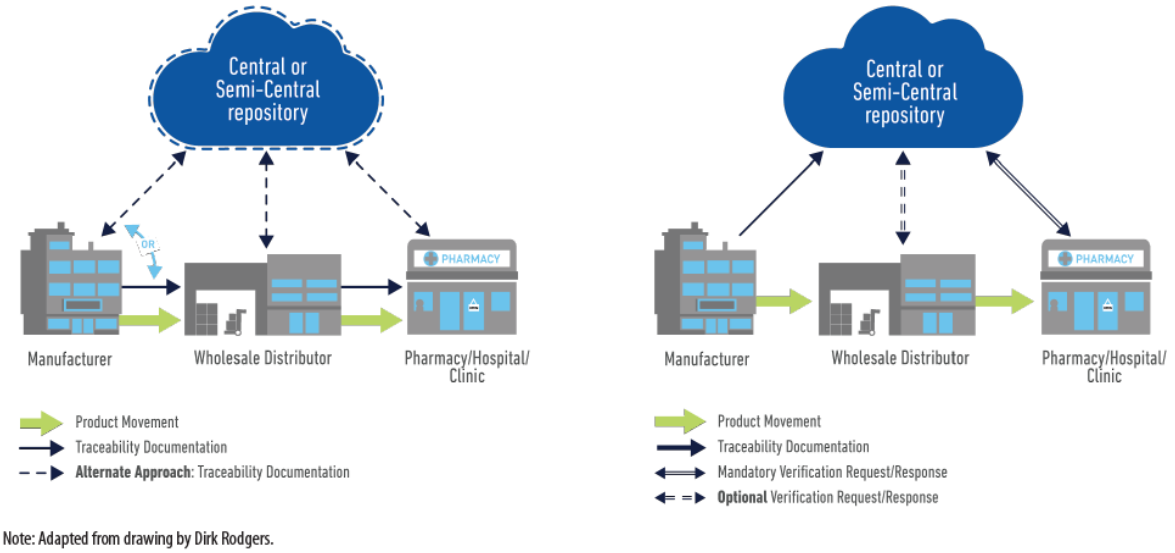
*The **Point of Dispense Verification system** exempts stakeholders in the middle of the legal supply chain (e.g. wholesalers) from providing information for the majority of transactions, while the manufacturer/sponsor is required to uniquely and unequivocally identify the product and share this information through a database.*

Prior to the dispensation in pharmacies or healthcare institutions, the serial number on the package of the medical product, in combination with the GS1 Global Trade Item Number® (GTIN®), is validated by comparing it with the information provided by the product manufacturer/sponsor.

The main advantage of a Point of Dispense system is that it involves less parties and is thus easier to implement. On the other hand, the main drawback of this system is that the detection of any abnormalities occurs at the time of dispensation and such detection is subject to the effective validation of the product at this single and last point in the supply chain. In addition, it does not provide the side benefits of a full traceability system such as detecting where counterfeit products enter the legitimate supply chain.

With both models, intermediate measures can be taken such as a point of dispensing check with random risk-based checks at wholesalers, or phased implementation per product type or stakeholder. (GS1 2018)

Figure 2. The two main medicine traceability models adopted across global jurisdictions. Full track and trace is shown on the left with solid black lines and the alternate approach shown in dashed black lines. Point of dispense verification is shown on the right (from WHO. 2021 p-18).



Note: Adapted from drawing by Dirk Rodgers.

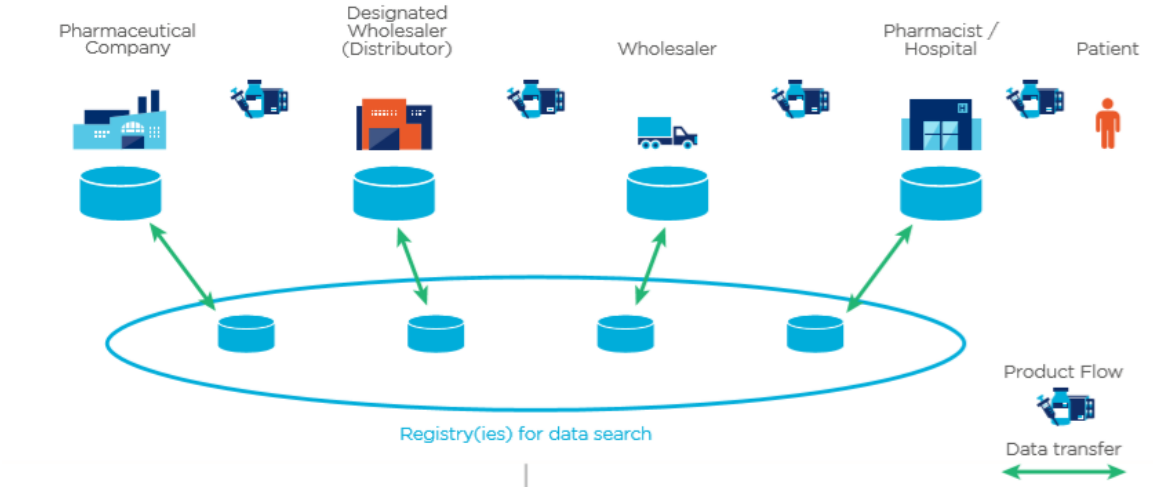
Traceability options under consideration

Three medicine traceability options have been identified as potentially suitable for Australia, based on international traceability guidelines and systems already being developed or implemented in other jurisdictions.

1. Dispersed Data Model

This option establishes serialisation of in-scope medicines, but only requires reporting obligations for suspect products on request by the Government and leaves implementation and data management and control in the hands of businesses. This type of system has been adopted by the United State of America (USA) and is outlined in the case studies at the end of this document. There is no centralised data repository in this system, and consequently Government is reliant on supply chain participants to report medicines information themselves or upon request (e.g. counterfeit or substandard medications).

Option 1. The data and medicines product flow in a decentralised medicines supply chain with serialisation (from GS1. 2018).[7]



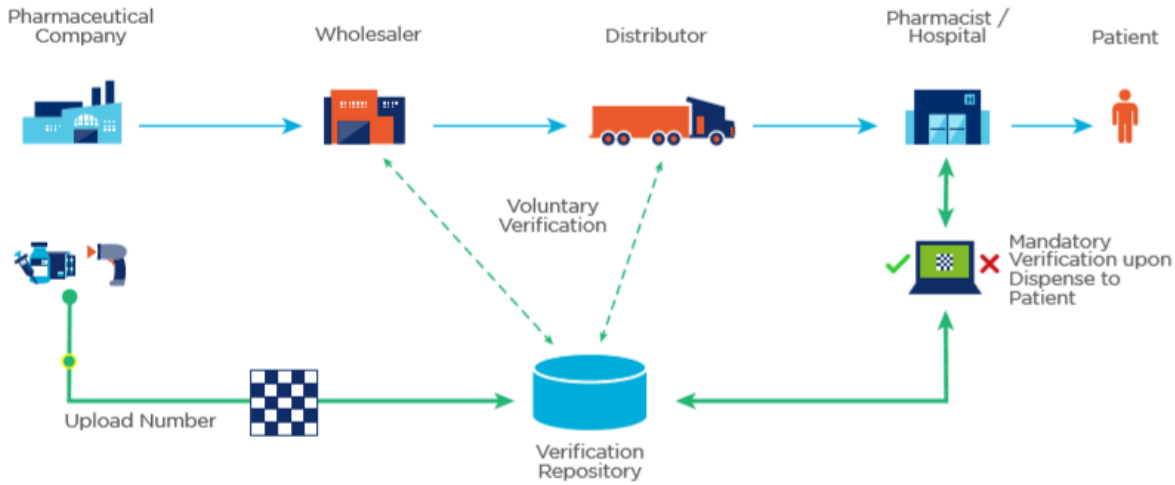
2. Point of Dispense Verification Model

This option encompasses serialisation of in-scope medicines with a point of dispense verification system. This essentially means that the manufacturer would scan in the unique identifier of a medicine, which would upload data into a centralised data repository as it enters the supply chain. A verification or 'check-out' would occur once the medicine is dispensed to a patient. Whatever happens in between manufacture and dispense is not required to be reported or captured.

This type of system has been adopted by the European Union (EU), which was also outlined in the case studies section at the end of this document. This centralised data repository enables the transmission and collection of data/information on the movement of medicines into and out of the supply chain and allows ready availability of that data to health agencies and governments.

[7] GS1 Healthcare Road Map

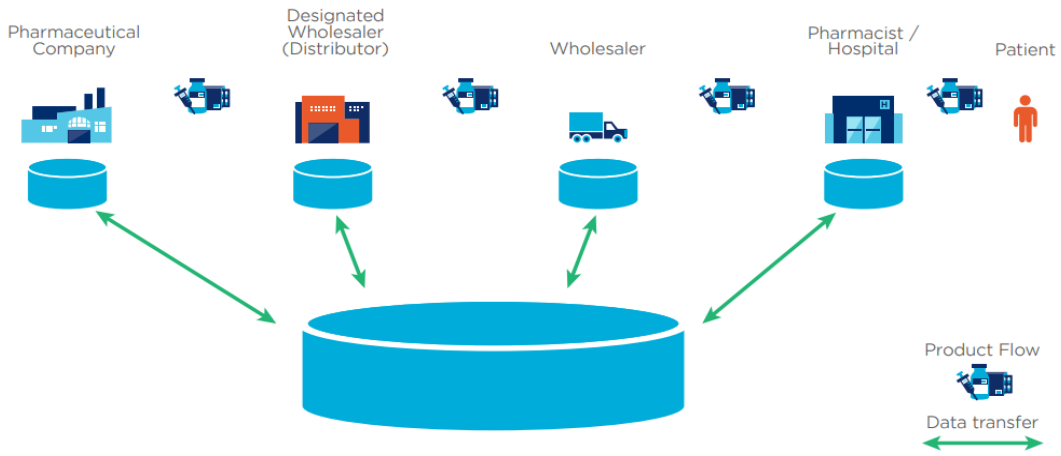
Option 2. The data flow in a medicines supply chain with serialisation and federated traceability at the point of dispense (from GS1 2018).



3. Full Track and Trace Model

Under this option data capture would occur at each point of the medicines supply chain, filling the gaps between manufacture and dispense of medicines. This option encompasses serialisation of all in-scope medicines with a fully capable track and trace system and centralised data repository that is managed by the Government. Verification of medicines occurs throughout the supply chain in an end-to-end manner.

Option 3. Potential data flow in a medicines supply chain with serialisation and federated full track and trace framework (from GS1. 2018).



Comparison of options

Table 1. Comparison of traceability options.

Option	Serialisation mandated for in-scope medicines	Centralised Data Repository	Components of Framework
Dispersed Data Model	Yes	No	No central data repository. Businesses manage their own data (not real-time). Reporting obligations only for certain products following government request.
Point of Dispense Verification Model	Yes	Yes	Centralised data repository with a reporting obligation at the point of dispense only.
Full Track and Trace Model	Yes	Yes	Centralised data repository owned and operated by the Government for full traceability of medicines throughout the supply chain.

Framework options and potential benefits

This analysis is based on qualitative criteria for the likelihood levels (low, moderate and high) that key medicine supply chain activities are strengthened and improved.

Table 2. The likelihood of potential benefits with each framework option.

Potential Benefits	Status quo	Dispersed data model	Point of dispense verification model	Full track and trace model
Increased efficiency of medicine recalls	Low	Moderate	Moderate	High
Improved pharmacovigilance	Low	Moderate	Moderate	High
Enhanced and timely inventory management	Low	Low	Moderate	High
Improved national and international system interoperability and data harmonisation	Low	Moderate	High	High

Implementation approaches

As discussed earlier, a national medicines traceability framework would require a standardised and interoperable traceability architecture that would allow supply chain participants to verify the entry and exit of medicines across their business, with this information being stored and accessed from a data repository.

Based on medicine supply chain traceability initiatives in other jurisdictions, including the USA and EU, we expect that full implementation of a framework would take several years.

Given the broad scope of the initiative a medicines traceabilty framework could be implemented in a variety of different ways:

- using different medicine groups, sponsors, and/or manufacturers, e.g. starting with PBS listed medicines or specific manufacturers already serialising their medicines
- gradually increasing traceability data capture and functionality, or
- starting with a point of dispense verification, and gradually increasing the number of verification points towards achieving a full track and trace system.

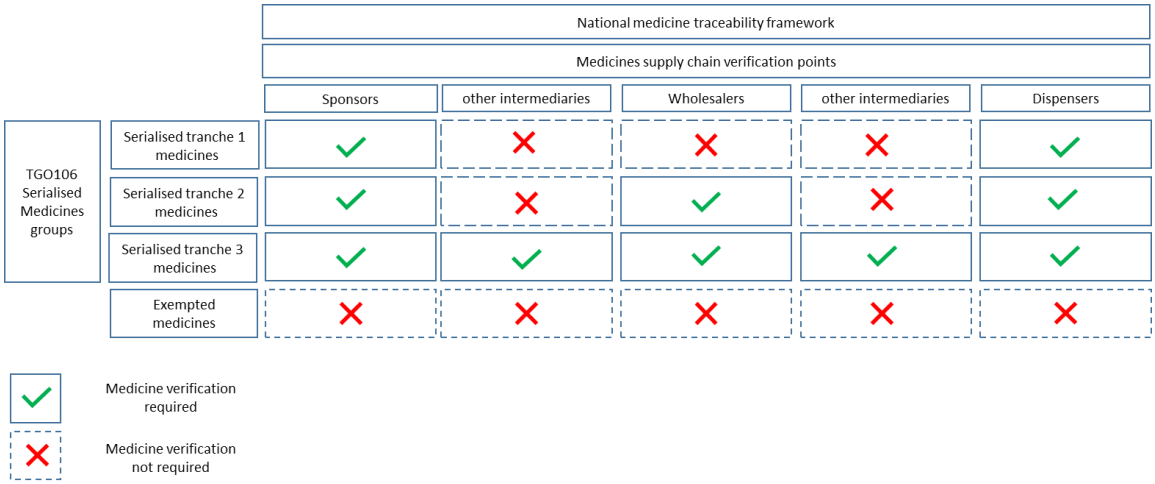
For example, in Figure 3 the transit of in-scope 'tranche 1' medicines are verified only by 'Sponsor' and 'Dispenser' supply chain participants. Tranche 1 medicines pass through other participants without need of verification. This is similar to the operation of a 'point of dispense verification' model.

In contrast, the transit of in-scope 'tranche 3' medicines are verified by all participants along the medicine supply chain, similar to a 'full track and trace' model.

Medicines that are excluded from the scope of the Framework are not required to be verified by any supply chain participant, as depicted in the last row of Figure 3.

Additionaly, as the Framework is intended to be standardised and interoperable, any medicines that meet the requirements of the framework could potentially use the system.

Figure 3. Depicts the possible options for a phased approach to medicine traceability, across medicine serialisation, medicine traceability, and supply chain participants.



Traceability case studies

The following two case studies from the EU and USA provide examples of both a centralised government controlled federated data repository network, and a company specific decentralised system.

The European Union Falsified Medicines Directive

The European Union Falsified Medicines Directive 2011/62/EU1 was adopted by the European Council and the European Parliament and was published on 1 July 2011. The new rules became applicable on 9 February 2019, and require:

- *All prescription medicine in the EU market to carry a unique identifier (UI) and anti-tampering device (ATD)*
- *Marketing Authorisation Holders – MAH (medicine sponsors in the Australian context) must sign contracts to provide UI data to the National Medicines Verification Organisations (NMVO – a centralise data repository in each EU member state) in member states where they market their product*
- *MAHs must also connect to the European Medicines Verification Organisation (EMVO), a central data repository for the EU*
- *Manufacturers and importation authorisation holders must update production lines to include UI and ATD from the applicable data*
- *Wholesalers and distributors must update their computer systems to allow connection to NMVOs to verify and decommission UIs from 9 February 2019*

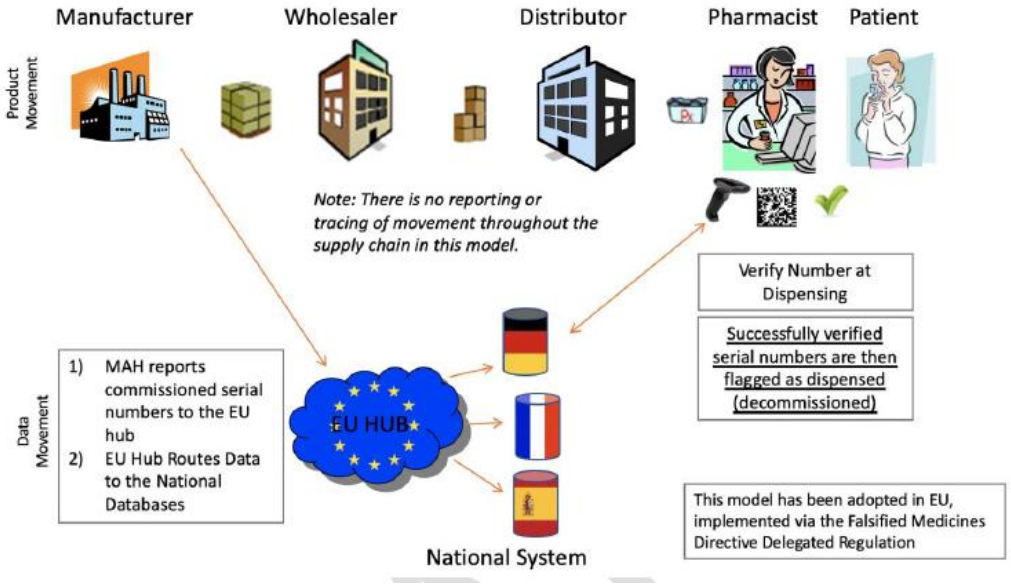
Community pharmacies, hospital pharmacies and healthcare institutions when receiving or dispensing medicines must:

1. *verify the safety features on the medicine pack, and*
2. *decommission the medicine UI by connecting to the NMVO.*

To do so efficiently they are also required to purchase scanners to read the UI and upgrade software to connect to the repository system.

The EU model is a federated track and trace system with national centralised data repositories, as well as an EU wide centralised data repository that aims to allow medicines to only be dispensed once a UI and ATD are verified, and the UI is then decommissioned once the medicine is dispensed.

Figure 4. The EU model, central hub, multiple national repositories, not full track and trace (from ICMRA. 2020 p-35).



The United States Drug Quality and Security Act (DQSA)

Essentially the US model establishes standards for medicine traceability systems across a supply chain, and requires reporting obligations for suspect products, but leaves implementation, data management, and data control in the hands of individual companies within and across the supply chain.

Whilst perhaps less costly and burdensome for government to establish, it also presents significantly less opportunities to government for access to supply chain data with which to leverage a range of key benefits.

The DQSA was enacted by the US Congress on 27 November 2013. While some requirements commenced from November 2014 and into 2015, full implementation is not required until 2023. The US model does not involve a centralised data repository. Instead it is aimed at enhancing the safety and security of the medicine supply chain in the US by:

- *Establishing a system for third-party logistic provider reporting to the Food and Drug Administration (FDA),*
- *Establish a system for wholesale drug distributor reporting to the FDA and public database with licensing information*
- *Develop regulations establishing standards for licensing of wholesale drug distributors,*
- *Develop regulations establishing standards for licensing of third-party logistic providers, creating standards and regulation for system attributes necessary to enable secure tracing at the medicine package level,*
- *Develop standards and regulation for interoperable data exchange to enhance secure tracing of medicine at the package level, and*
- *Develop regulations to establish enhanced drug distribution security systems for interoperable electronic tracing of product at the package level.*

Consultation questions and next steps

Health is seeking initial feedback from medicine supply chain stakeholders on our proposal to develop a national medicines traceability framework.

Our consultation survey asks questions on the possible design, timing, burdens and impacts which a Framework may introduce.

Further consultations will follow as the policy development progresses.

Our initial consultation will commence in November 2021 and will close in February 2022.

Please contact NMTF@health.gov.au if you wish to access the NMTF consultation survey on Health's Consultation Hub and/or make a written submission.

The question topics of our national medicines traceability framework (NMTF) survey include your:

- *organisational details*
- *current capability and capacity to serialise medicine products*
- *current capability and capacity to track and trace medicine products*
- *alignment with potential public health and business benefits of a NMTF*
- *preferred model(s) for a NMTF*
- *assessment of the potential business impact and burden of participating in a NMTF*
- *assessment of the broad timeframe required for implementing a NMTF*
- *preferred NMTF implementation approach(s), and*
- *assessment of any government assistance that may be required to participate in a NMTF.*

Following completion of our initial consultation, Health will compile and analyse the feedback to produce a findings report. This findings report will be published and will inform Government decisions about the preferred framework design and implementation options and further industry engagement.

Glossary

Critical infrastructure – those physical facilities, supply chains, information technologies and communication networks which, if destroyed, degraded or rendered unavailable for an extended period, would significantly impact the social or economic wellbeing of the nation.

DataMatrix – a DataMatrix is a data matrix code formatted in accordance with the Global Standards 1 (GS1) General Specifications.

Data matrix code – a data matrix code is a type of two-dimensional code that can be read by a scanner. It is a small square or rectangle with two solid edges, two dotted edges and pixelated light and dark areas within the matrix. There are no fixed shapes within the matrix.

For the purposes of TGO 106, QR codes are not considered data matrix codes.

Full Track and Trace Systems – systems that allow full traceability of the product transaction and/or other supply chain events from beginning to end of its supply chain, including agents in the middle e.g. distributors.

Global Trade Item Number (GTIN) – a GTIN can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain.

Interoperability – the ability of track and trace systems to exchange information and make use of the information received from other systems.

Primary pack – Primary pack has the same meaning as in the *Therapeutic Goods Act 1989* where it is defined as 'the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.'

Primary pack is different to primary packaging. The primary pack may be what others refer to as 'primary packaging' or 'secondary packaging', depending on the product.

The primary pack as defined in the Act is usually secondary packaging in GS1 and Good Manufacturing Practice (GMP) guidance.

Sometimes the primary pack is also primary packaging, such as a bottle of capsules with no further packaging.

Primary packaging – Primary packaging, as used in GS1 and GMP guidance, is the packaging which directly contacts the medicine (injection vial, tablet blister and so forth). The *Therapeutic Goods Act 1989* refers to this as the container.

Serialisation – the processes and results of defining, assigning, and affixing unique serial numbers to product packaging at any level.

Serialised medicines – a serialised medicine is one where each unit bears a unique identifier, allowing the unit to be identified distinctly within its batch. This typically is achieved through a serial number applied to the unit. The combination of product number (GTIN) and serial number creates a globally unique character chain for the unit.

Supply chain – two or more companies that buy and/or sell products, starting with the manufacturer and ending with the entity that supplies or administers the products to the end patient.

Supply chain participants – medicine supply chain members including manufacturers/sponsors; distributors/wholesalers; retailers; community and hospital pharmacies; logistics and transport companies; public and private hospitals; residential aged care; industry peak bodies; state/territory/Australian government.

Supply chain stakeholders – companies, including non-government organisations and aid agencies, that participate in the supply chain of medical products, including but not limited to, manufacturers, third-party logistics providers, importers, distributors, wholesale distributors, logistics companies, pharmacies, hospitals, clinics, etc.

TGO 106 – Therapeutic Goods Order 106, which outlines the standard for serialised medicines in Australia

Trace – the ability to know where a product has been within a supply chain prior to its current location.

Traceability – the capability to trace something. In some cases, it is interpreted as the ability to verify the history, location, or application of an item by means of documented recorded identification.

Traceability system – a systematic implementation of a traceability model.

Track – the ability to know where a product is right now.

Track and Trace – a model that attempts to track and trace products through a supply chain.

A full glossary of relevant terms is listed in the referenced WH0 2021 and ICMRA 2020 *background papers*.

References and Further Reading

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