



National Medicines Traceability Framework

Frequently Asked Questions

1. What is the National Medicines Traceability Framework?

The Department of Health (Health) is scoping the need to strengthen and enhance Australia's medicine supply chain through medicine package serialisation and traceability, and is seeking industry's input on potential frameworks that may achieve this.

The initiative is known as the National Medicines Traceability Framework (NMTF) and this activity follows international developments in medicine track and trace systems, and the 2020-21 Budget measure: [Improving Access to Medicines – development of Unique Identification framework for PBS medicines](#).

No specific framework design or timeframe for implementation has yet been decided, as the measure is currently in the policy development stage.

A consultation process has commenced seeking medicine supply chain stakeholder views on how the supply chain could be improved through medicine traceability technologies, and to identify preferences for traceability framework options and implementation approaches.

The results of the consultation will inform Health's NMTF policy recommendations to Government.

2. What is the rationale for an NMTF?

The introduction of medicine serialisation and traceability systems is being used more and more frequently around the world to safeguard and strengthen the integrity of medicine supply chains, enhance patient safety, and provide access to near real-time data on medicine location and movement.

Additionally, the COVID-19 health emergency has highlighted the fragility of the medicine supply chain not only in Australia, but internationally.

Without effective oversight and visibility of the movement of medicines across the supply chain, there are increased risks such as the potential for substandard medicines entering the supply chain, or of inefficiencies such as loss of inventory or expired products. These risks have the potential for affecting the supply of vital medicines to patients, which can lead to impacts on Australian patients and their health outcomes.

3. What will be the advantages of an NMTF for industry?

Health envisions that an NMTF could significantly benefit industry by enabling medicine supply chain participants to better capture inventory and transactional data. Access to this data could assist supply chain participants to improve the management of supply disruptions, medicine distribution, medicine recalls and stock levels.

4. Are other countries implementing medicine traceability frameworks?

Implementing track and trace systems for medicines is a key objective of medicines regulators around the world and many jurisdictions and countries have implemented, or are in the process of implementing, such systems. See the [World Health Organization \(WHO\) Policy paper on traceability of medical products](#).

The European Union (EU) has implemented a 'track and trace' system that verifies medicines at the point of dispense, and the United States of America (USA) is in the process of implementing standards for medicine traceability that require reporting obligations across the supply chain upon Government request.

These systems have been developed for a variety of reasons relating to protecting the integrity of the medicine supply chains and maintaining public confidence in the ability of governments and industry to guarantee supply.

5. How long is implementation of an NMTF expected to take?

Based on medicine supply chain traceability initiatives in other jurisdictions, including the USA and EU, Health expects that full implementation of an NMTF would take several years.

6. How can we be involved in the NMTF consultation?

Health's Consultation Hub NMTF survey poses a number of questions on the possible design, timing, burdens and impacts of the introduction of an NMTF.

The NMTF Consultation Hub is now open and submissions will be accepted until 28 February 2022. Please contact NMTF@health.gov.au to request access to Health's NMTF consultation hub survey.

7. What will happen next?

Following the closure of the consultation, Health will produce a findings report to inform Government options about the policy design and implementation of an NMTF. Health may also make public any NMTF submissions depending on the publication preferences selected by the respondent.
