SHPAs Response to the National Medicines Traceability Framework (NMTF) Consultation – via online survey

Q1-14 *demographic questions*

Serialisation and data matrix codes - awareness and current use

In March 2021 the TGA released a standard for medicine serialisation (TGO 106) to provide clarity for adopters of serialisation and data matrix codes on medicines supplied in Australia. The standard sets out the requirements where TGO 106 applies and which medicines are exempt. It was released as a voluntary standard and will take effect from January 2023.

We are keen to find out where your organisation stands in relation to this standard, and whether you are implementing it already, or plan to in the near future.

Please note, TGO 106 covers medicines that are serialised or include a data matrix code that encodes the Global Trade Item Number (GTIN). Other medicines are currently out of scope.

Q15. Your organisation is:

is aware of the introduction of TGO 106 - **Yes**

has medicines in your inventory within scope for TGO 106 – **N/A**

already used product serialisation codes for medicine product management purposes before the introduction of TGO 106 – **N/A**

supports the use of TGO 106 for your relevant medicine products – **N/A**

Q16. Has your organisation identified any impediment to the adoption of TGO 106?

Yes

Comments:

Therapeutic Goods Administration should update the relevant Therapeutic Goods Orders to mandate barcoding unit dose packaging to be the standard. This would complement their regulations on improving the clarity of medication labels. The existing Therapeutic Goods Order for prescription medications contains exceptions for ‘small products’ and specific requirements for text size, so an amendment would be needed to ensure that the requirement for identification on unit doses is consistent and clear. It also must have appropriate timelines to implement.

All medications should be identified at the secondary packaging level using a GS1 DataMatrix barcode containing the GTIN, batch and expiry date of the product. Where there are two barcodes (a GS1 DataMatrix and an EAN-13 linear barcode) the GTIN must be the same in both to avoid confusion in the clinical setting.

An appropriate implementation timeline should be defined based on consultation with pharmaceutical manufacturers and other stakeholders to ensure an appropriate and streamlined transition process is undertaken.

All solution providers who need to support pharmaceutical processes in the future will need to ensure that they can effectively and accurately support these measures to ensure the benefits are realised.

Q17. Does your organisation currently track and trace medicine products as they pass through the supply chain?

In hospital inpatient settings, the use of innovative health information technology has been introduced to achieve a closed loop medication management system. At the bedside, barcode technology can be used in real time to verify a patient's identity before medication administration and to capture the care provider administering the medication. Bedside verification of medications allows nurses to check and document the medication administration to reduce administration errors.

Currently, for most Australian hospitals, verification of medication at the bedside is largely done via a visual check of the product against the prescriber's order. This is a manual task reliant on the nurse following approved procedures, checking the product label and description, eMAR (electronic Medication Administration Record) description or written order on a paper NIMC (National Inpatient Medication Chart), and interpreting the medication order correctly.

Barcode scanning of medications at the unit dose level will likely start with unambiguous identification of the product using the Global Trade Item Number (GTIN) allocated to identify this level of the product contained within the GS1 DataMatrix. In future, the barcodes may also include data related to the batch number and expiry date, which will assist in the management of medication alerts and recalls due to improved tracking and tracing of doses within hospitals. The introduction of identification and barcoding including batch number and expiry date information should start at least with secondary packaging to ensure that the end to end supply can better be managed across all processes and be introduced as part of a planned transition program. As it is a requirement for nurses to check the expiry date of the medication prior to administration, it is desirable for barcodes on unit dose packaging to include expiry date to enable digital checking of this. If the information is not able to be contained in the barcode, then it must be available visually.

In hospitals, pharmacists regularly prepare compounded medications such as intravenous solutions, parenteral nutrition and chemotherapy. Scanning of source ingredients during compounding, repackaging or labelling processes can ensure the labelled doses contain the appropriate ingredients and appropriate records be maintained for compounded medications. This improves the quality, safety and efficiency of health services delivered to patients.

The introduction of unit dose packaging identification aligns with recommendations made by the Australian Commission on Safety and Quality in Health Care and the use of unambiguous identification and barcoding aligns with the Therapeutics Goods Administration's *Therapeutic Goods Order for Prescription Medication Labelling (TG091)*11 requirements for machine-readable codes.

Q18. Does your organisation plan to implement a medicine track and trace capability as part of your day to day supply chain management?

N/A

Q20. Does your organisation, or an affiliate of your organisation, participate in medicine traceability systems implemented in other jurisdictions, for instance the European Union's European Medicines Verification System (EMVS) or the United States of America's Drug Supply Chain Security Act (DSCSA)?

No

Industry and Public Health Benefits

In the next two sections we are seeking your views on how you see an NMTF possibly benefitting your organisation and the public, and what the benefits you see are.

Please indicate your level of agreement with the following statements regarding the expected business benefits your organisation would experience from the introduction of an NMTF.

Q21. Please state if you agree (Y) or disagree (N) with the following:

An NMTF would benefit your organisation by helping:

- Ensure only authorised products, registered or approved, circulate in the legal supply chain **- Y**
- Prevent the distribution and/or dispensing of falsified, expired, prohibited or recalled products **- Y**
- Facilitate efficient and fast market recalls **- Y**
- Enable efficient inventory management **- Y**
- Identify shortages and monitor the reasons for shortages and stock outs **- Y**

Q22. Please state if you agree (Y) or disagree (N) with the following:

An NMTF could benefit public health through:

- Faster and more accurate product recalls as specific locations are known **- Y**
- Safer dispensing practices through greater automation and data matching **- Y**
- Improved pharmacovigilance **- Y**
- Rapid location of medicines within the supply chain, enhancing the ability to respond to health emergencies - **Y**
- Improved security of the medicines supply chain **- Y**
- Improved opportunities to identify counterfeit and compromised medicines **- Y**
- Provision of accurate and secure data that can be used by the supply chain to support payment reconciliation **- Y**

Industry Impact

We are aware that there would be an impact on medicine supply chain stakeholders from an NMTF. The following questions are not exhaustive but will explore areas of possible impact on your organisation. We will engage in further consultation with industry stakeholders as the framework continues to develop.

Q23. **Please indicate the expected level of impact your organisation would experience on the following business areas due to the introduction of an NMTF.**

- Organisational policy and processes – **High Impact**
- Business strategy – **High Impact**
- Workforce capability and capacity – **High Impact**
- Capital investment – **High Impact**
- Operational investment – **High Impact**
- Regulatory compliance – **High Impact**
- Information technology systems and services – **High Impact**
- Data systems and services – **High Impact**
- Logistics and distribution systems and services – **High Impact**
- Supply chain systems and services – **High Impact**

Q24. Overall, how does your organisation view the potential impact of an NMTF on your business?

Positive

Comments:

SHPA members are in support of a NMTF and the overall effect on pharmacovigilance. However, members report some concerns such as the time taken to comply with traceability scanning could see a large impact on time taken to complete dispensing tasks. An increase in pharmacy staff may be required to counterbalance

the time taken away from usual dispensary activities. In addition, the financial burden of implementing the software and hardware required could be a potential barrier for some.

Members feel that if it is an opt-in framework, then those that do opt-in carry the financial burden for those that do not.

Siloed medication funding streams across different settings increases complexity and could impede the rollout and integrity of a NMTF. For example, the same medicine used in a hospital setting, could be subject to different procurement, storage and supply settings, depending on whether it was a PBS or non-PBS medicine, if it was used in an inpatient or outpatient setting, if the medicine was used in a clinical trial or as part of a compassionate access scheme. Moreover, many PBS medicines are also listed under multiple schedules within the PBS. Whether the medicine supply occurs in a public or private hospital setting also has impacts on the funding and reimbursement of medicines. These complexities and proliferation of various medicines funding and reimbursement pathways ultimately can undermine efforts to achieve national medicines traceability.

Q25. Overall, how does your organisation view the potential regulatory burden of an NMTF on your business?

Moderate Burden

Traceability models under consideration

Three medicine traceability options have been identified as potentially suitable for an Australian NMTF, based on international traceability guidelines and systems already being developed or implemented in other jurisdictions. We are keen to identify your views regarding preferred traceability models.

Q26. **Does your organisation have a preference for the type of traceability model to be considered for an NMTF?**

Traceability models under consideration:

Full Track and Trace Model – *low preference*

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.

Point of Dispense Verification Model – *high preference*

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.

Dispersed Data Model – *low preference*

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.

Industry Support and Capacity to Transition

The next questions will explore your general support for an NMTF.

Due to the scale of the project we are interested in understanding the nature of potential investments and timings of new arrangements on medicine supply chain participants, as well as any assistance that may be required.

Q27. Does your organisation have the capability and capacity to participate in an NMTF for your medicine products?

Workforce support and funding is required for implementation of the NMTF.

Q28. Has your organisation identified a preferred approach to phase in a serialisation and/or traceability framework - for instance by medicine category or by medicine sponsor? If yes, please outline your approach.

No

Q29. Does your organisation handle medicines that would require exemptions from an NMTF?

Yes.

SAS and extemporaneously prepared medicines may be challenging to track and trace as they may not have data matrix codes.

Q30. Please indicate the expected level of assistance your organisation would broadly require to plan, initiate, implement and participate in an NMTF.

Planning and implementation assistance - High level of assistance required

Workforce capability assistance - High level of assistance required

Regulatory assistance – Some assistance required

Financial assistance - High level of assistance required

Ongoing operational assistance - Some assistance required

Q31. Are there any organisational or technological changes not mentioned previously that may need to be considered for your organisation to implement and participate in an NMTF?

No

Q32. Is there any other government assistance which your organisation might require to implement and operate an NMTF?

Yes.

Workforce funding to support the slow down in productivity. Hardware and software required to track and trace will also require funding.

Q33. Overall, how confident are you that your organisation would be able to successfully participate in a fully implemented NMTF?

Moderately Confident

Q34. Please provide any other comments relating to the proposal of an NMTF.

Overall, SHPA is in support of NMTF and SHPA members report that a NMTF would improve traceability processes and pharmacovigilance.