Discussion paper on global harmonisation of the identification system for pharmaceutical products in Sri Lanka

Purpose

The purpose of this paper is to facilitate the discussions on a globally harmonised system for pharmaceuticals traceability in Sri Lanka.

Issue statement and discussion

GS1 welcomes the initiatives of the Board of the National Medicines Authority Sri Lanka to improve the security of the supply chain for pharmaceutical products and patient safety.

The "Notice", published on 15.07.2024 and amended on 13.08.2024, envisions two changes to the labelling requirements:

1. Stickers to be placed on each commercial pack indicating the wording "NMRA approved", and the retail price (applicable from the first of October 2024);

2. Product specific **QR or bar code of the manufacturer** encoding the following information (application three months after the first of September 2024):
   - The product name
   - The generic name and strength
   - Batch number
   - Date of manufacturer
   - Date of expiry
   - Name of the manufacturer and site address

While this requirement currently provides different options for implementation it may not completely support the clearly stated goal in this "Notice" to enhance protection against falsified products coming into the market.
The "Notice" lacks clear guidance on the particular type of barcode to be used and it does not include any requirement for globally unique identification of the product, which is the foundation for traceability of medical products. Based on the GS1 standards, the Global Trade Identification Number (GTIN) is used for product identification and the GS1 DataMatrix is the barcode used to capture information for medicines traceability within the WHO[1] global framework.
The utilisation of a QR Code including a large amount of information will require a sufficient space available on the commercial pack to print the barcode. If the actual commercial pack will not be able to bear this barcode, the risk to increase the cost of the product or to undermine the possibility for the patient to receive its medicine is high.

[1] https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products

In most countries today, the regulatory requirements for pharmaceutical product traceability are implemented using GS1 standards and in alignment with the global framework defined by the WHO.

In practice, for traceability, **four data elements encoded in a GS1 DataMatrix are sufficient**:

- Global Trade Item Number (GTIN),
- Expiration date
- Batch/lot number
- Serial number.

(01)19506000117843
(17)141120
(10)NYFUL01
(21)192837

These are the four elements needed by the healthcare providers and are enabling access to other data element in a repository/database.

The Global Trade Item Number (GTIN) helps identify the product and product owner. The GTIN is used as a global unique key that serves as a link to databases to provide additional product master data. Additionally, it can also be used as a key to access other data, such as registration data. By adding a batch or lot number, a link can be made to the production data, which can be used for recalls or similar purposes.
However, while this significantly improves product identification, it does not help prevent counterfeiting.

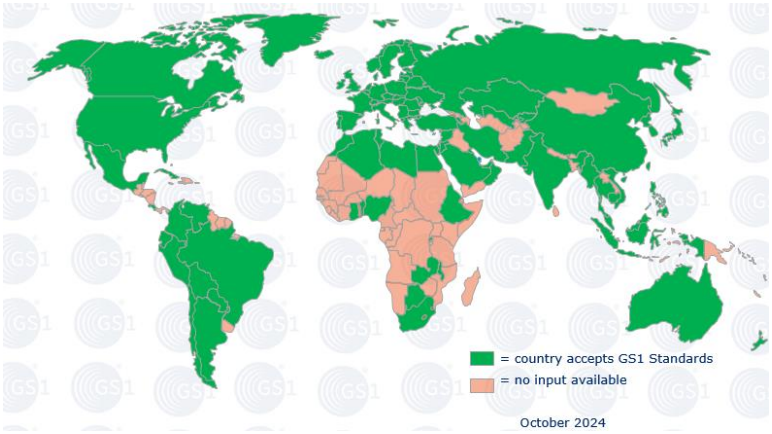
Counterfeiters can still copy the product information if it does not include a unique identifier for each individual unit.
Authentication is crucial for protecting against counterfeiting and for ensuring traceability across the supply chain. To enable product authentication, a serial number is added to distinguish each single unit. At the point of dispense the serial number is checked against a central database to verify if the serial number was previously reported as dispensed elsewhere. If the serial number has been copied or re-used, it will be detected during the authentication process. Additionally, traceability can allow supply chain events to be recorded and monitored.

The GS1 Healthcare community does **NOT recommend the use of QR codes for identification[2].**
For product identification and traceability purposes for pharmaceutical products, GS1 DataMatrix remain the data carriers of choice. It ensures the globally harmonised identification of products and facilitate implementations for all stakeholders.

It is important to mention that local solution providers have developed proprietary systems, based on the QR code encoding a URL, to support the implementation of authentication of certain pharmaceutical product supplied to the domestic market in India. This does not enable a strong and robust identification of products and **can undermine supply chain security by providing counterfeiters with an easy mechanism to create a false sense of identification and authentication. Therefore, most of global manufacturers are currently pushing against these requirements and aligning their implementation with the global framework, using the Data Matrix.[3]**

Conclusion

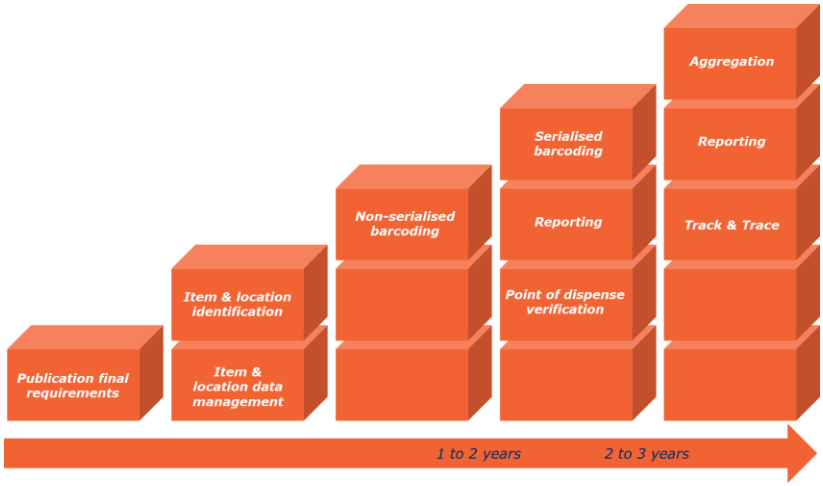
The use of GS1 standards, is recommended by inter-governmental organisations, including the WHO[4], as well as by key trade associations across the world. The international procurement agencies (IPAs) are also committed to implementing global supply chain data standards for product identification[5].
Most regulations for traceability around the world are aligned with global trends on identification and barcode application on secondary-level packaging, the GS1 standards and the GS1 DataMatrix are used and implemented for medicines traceability by at least 70 countries worldwide.



[2] https://www.gs1.org/docs/healthcare/position-papers/GS1-DataMatrix-Position-Paper-FINAL.pdf
[3] https://www.gs1.org/docs/healthcare/position-papers/paper-gs1-hc-india-oct2023.pdf
[4] https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products
[5] https://www.ghsupplychain.org/sites/default/files/2023-06/20230622%20GSTIG%20V3.0_FINAL.pdf

Summary recommendations:

- Clarify the type of barcode to be used (DataMatrix). Maintaining a reference to the possible use of the QR code can lead to the use of proprietary solutions and does not enable a strong and robust identification of products. The use of DataMatrix is more secure and standardised solution.
- Focus the requirements on the use of 4 data elements (the Global Trade Item Number (GTIN), the expiration date, batch/lot number and a serial number) encoded in a DataMatrix. These data are sufficient to fight against falsified pharmaceutical products, and it will also reduce the system's complexity.
- Align with global standards to ensure access to safe medicines and minimise shortages and avoid falsified products entering the country. Ensuring access to medicines is key, alongside fighting substandard and falsified products, as using or reporting a counterfeited product may be a challenge when no alternative is available.
- Allow sufficient time for implementation. It is important to set an achievable implementation timeframe to allow manufacturers to comply with the requirements.



Considerations for achievable timeframe to implement a traceability system