



Discussion paper on global harmonisation of the traceability system for medicines for the domestic market in India

Purpose

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

Issue statement and discussion

GS1 welcomes the initiative of the Ministry of Health and Welfare in order to improve the security of the supply chain for the pharmaceuticals domestic market and the safety of patients in India.

The current Notification requires that:

“The manufacturers of drug formulation products as specified in the Schedule H2 of the said rule, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that stores data or information legible with software application to facilitate authentication. The stored data or information shall include the following particulars, namely:

- (i) Unique product identification code,*
 - (ii) Proper and generic name of the drug,*
 - (iii) Brand name,*
 - (iv) Name and address of the manufacturer,*
 - (v) Batch number,*
 - (vi) Date of manufacturing,*
 - (vii) Date of expiry,*
- Manufacturing licence number.”*

This requirement is currently **providing a flexible framework for implementation but the lack of clear guidance**, on the type of barcode to be used and on how to access to the required data elements.

Furthermore, the size of the barcode, ending all these data elements, becomes very large and will not fit on the packaging, especially when the barcode is applied to the primary packaging level as preferably requested by the Notification. Applying the barcode on the secondary packaging level is also not a suitable alternative due to space constraints.

Last, without a defined structure to encode the data elements within the barcode, the interpretation of the data cannot be consistently ensured, and this undermines the intent of the proposed authentication requirement.



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This is leading to the use of proprietary systems for identification and barcoding of these pharmaceuticals.

For local manufacturers supplying to the Indian market only, even though a QR code based solution **may initially be perceived as a simple and cheaper solution, it will add cost and complexity in the long term** since it is not an efficient and effective system and will create issues as explained below in this document. Vendor dependencies may also limit innovations and increase the total cost of the system. In addition, due to the large size of the barcodes, many manufacturers must apply the barcodes in a manual way, which triggers higher costs as the printing equipment (i.e., inline printing often does not support such large size barcodes).

For local manufacturers exporting medicines outside of India and for global manufacturers, this leads to increasing costs by using a second completely different system for identification and authentication. These additional costs and complexity **will impact the growth and competitiveness of the Indian manufacturers and will impact medicines accessibility in India.**

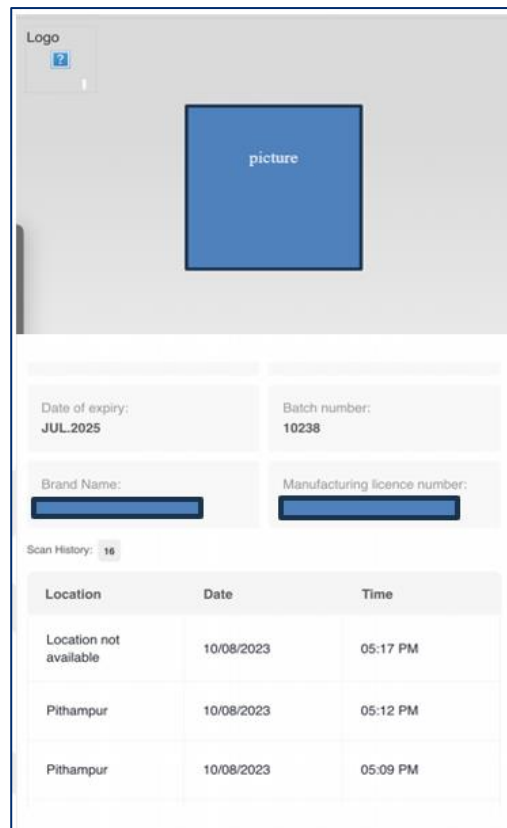
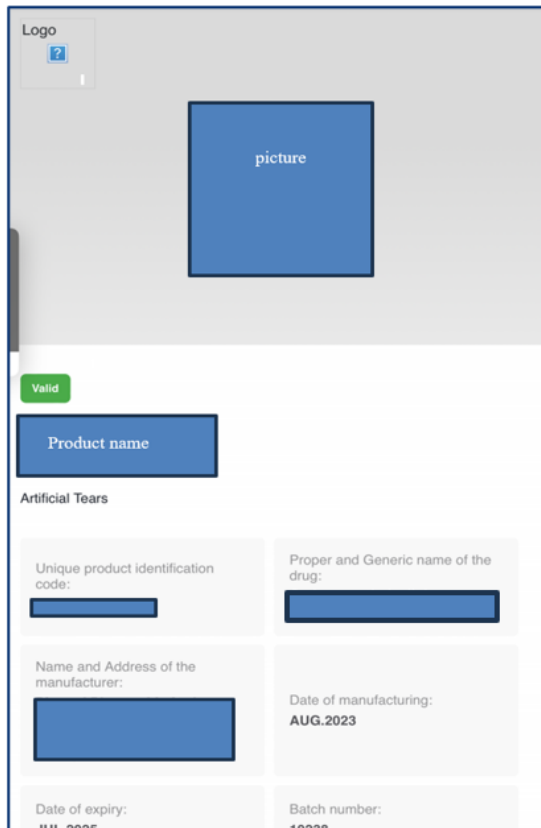
The fight against counterfeiting is a key objective of regulations around the world. Ensuring accessibility to medication is key as well to fight substandard and falsified medicines as using or reporting a counterfeited pharmaceutical product may be a challenge when no alternative else is available.

In the last years, there has been a significant growth of the use of smart phones to access online information related to pharmaceuticals (e.g., ePIL, videos). This is also the way vendors of proprietary systems are currently enabling manufacturers/MAH to implement the “Top 300 requirements” for authentication on the Indian domestic market.

Specifically, a manufacturer/MAH applies a QR code encoding a URL onto a pharmaceutical’s package which the patient/healthcare provider can scan to access an online webpage confirming – or not – the authenticity of the product.



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The pictures above display the outcome of scanning the QR code encoding a URL to implement the “Top 300” requirements using a proprietary solution. The screen is split into 2 pictures because the user must scroll on their device to see all information. The green rectangular “Valid” indicates that the product is authentic, however nothing enable to confirm that the webpage accessed is effectively the webpage of the manufacturer/MAH.

Solutions such as the one described above **do not provide a strong and robust way to detect substandard and falsified pharmaceuticals.** A QR code-based solution can undermine supply chain security by providing counterfeiters with an easy mechanism to create a false sense of authenticity.

Requirements and solutions to authenticate medicines are critical to ensure patient safety.



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In most countries today, the regulatory requirements for drug traceability are implemented using GS1 standards. The GS1 Healthcare community does **NOT recommend the use of QR codes for product identification**¹.

In practice, **four data elements encoded in a GS1 DataMatrix are sufficient**: the Global Trade Item Number (GTIN), the expiration date, batch/lot number and a serial number. Those four elements are those needed by the healthcare providers and are enabling **access to other data element in a repository/database**.

In addition, the GS1 Digital Link standards are providing a standards-based structure for the data encoded in the barcode to be linked to digital content, by scanning the barcode. The GS1 Digital Link standards work with any type of barcodes, including the GS1 DataMatrix, and the GTIN is the key used to link the packaging/product to the online content.

In India, the GS1 standards have been required for many years for the traceability of pharmaceuticals for export. Ensuring consistency in the requirements for the domestic and for export market is critical to ensure supply chain efficiency and security in India.

Consequently, the Indian regulator should consider **aligning the regulatory framework for the Indian domestic market with the requirements for export and with the global framework**. It will also be important to **ensure that the deadlines for compliance allow sufficient time for implementation by the industry**.

Conclusion

The use of GS1 standards, is recommended by inter-governmental organisations, including the WHO², as well as by key trade associations across the world. The GS1 standards and the GS1 DataMatrix are used and implemented for medicines traceability by at least 70 countries worldwide, including the Indian requirement for export.

The proprietary systems, based on the QR code encoding a URL, do not enable a strong and robust authentication of pharmaceutical products and are providing a fake sense of safety to patient/healthcare provider.

Aligning on the global framework and on the traceability system for medicines for export in India will ensure substandard and falsified medicines are effectively not dispensed to patients in India. It will reduce the complexity and cost of implementation, and as a result

¹ <https://www.gs1.org/docs/healthcare/position-papers/GS1-DataMatrix-Position-Paper-FINAL.pdf>

² <https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products>





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preserve local competitiveness and growth. It will enable interoperability within India as well with globally harmonised systems. It will also facilitate reverse logistics and post-market activities, to ultimately improve patient safety.