The Global Language of Business

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

Purpose

The purpose of this paper is to facilitate discussions on a globally harmonised system for pharmaceuticals traceability in India for both domestic and export products.

This paper complements a previous GS1 discussion paper for pharmaceuticals traceability for the domestic market in India[1] that explored the risks associated with proprietary systems using different technologies for the identification and traceability of medicines by local stakeholders.

It is widely recognised that global traceability is essential to combat counterfeiting across borders. The use of global standards, particularly the GS1 standards, is recommended by intergovernmental organisations (e.g., WHO) and key trade associations worldwide. The GS1 standards are already implemented by the healthcare sector in over 70 countries globally.

Issue statement and discussion

India has implemented specific export requirements for pharmaceutical products over the past 10 years, which has been aligned with the global framework for authentication and traceability of medicines. Over the years, the regulation has bolstered the integrity of medicines produced in India and enhanced market competitiveness, positioning India as a strong global player.

In response to these export requirements, global and local healthcare industries operating in India have made significant investments to equip packaging lines, train their workforce and adjust their supply chain process, to apply on their product a GS1 DataMatrix encoding a Global Trade Identification Number (GTIN), lot number, expiry date and serial number, in line with the World Health Organization (WHO) Policy Paper[2] for traceability of medicinal products and with requirements in more than 70 countries.

This alignment has ensured high level manufacturing capabilities, improved efficiency and strengthened Indian competitiveness, enabling companies to meet the growing international demand for high-quality, safe and affordable medicines. It is important to note that this also enabled India to strengthen its role as a strategic supplier of development partners, such as GAVI, the Global Fund, UNICEF, etc.

Recent withdrawal of the requirements for export pharmaceutical products, by Notice No. 44/2024-25, will have a significant impact on Indian competitiveness and on patient safety locally if a consistent and harmonised approach is not maintained.

The adoption of global standards presents a critical opportunity for India to enhance its position in the international market, improve operational efficiency, and ensure patient safety. This paper aims to highlight both the risks associated with non-alignment with the global framework defined by the WHO and the advantages of global alignment using global standards.

The risks of not aligning with global framework:

1. **Trade barriers and competitiveness:** Failure to align with the WHO Policy, in favour of a national solution, could undermine the competitiveness of Indian manufacturers by creating trade barriers. The WTO's Agreement on Technical Barriers to Trade (TBT) aims to ensure that national regulations, standards, and conformity assessment procedures do not create unnecessary obstacles to international trade. The TBT Agreement recognises the role of international standards in improving the efficiency of production and global trade. India joined the WTO in 1995.
2. **Increased complexity, costs, inefficiencies & Indian competitiveness:** Without a global traceability framework, local manufacturers may be forced to implement and adhere to two separate systems – one for domestic and another for international standards compliance. This dual requirement will lead to unnecessary complexity and increased costs, making it more difficult for manufacturers to compete globally.

[1] https://www.gs1.org/docs/healthcare/position-papers/paper-gs1-hc-india-oct2023.pdf
[2] https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products

3. **Inefficiencies in patient care:** The implementation of a national solution will have a significant impact on Indian hospitals as they will receive products imported from other countries with different traceability data than products locally manufactured. Aligning the requirements for products manufactured in India with the rest of the world, will allow any software systems throughout the supply chain (including hospitals) to recognise and decode the data captured in a barcode, reducing complexity for hospitals and healthcare professionals.
4. **Compromised patient safety:** Proprietary systems, based on the QR code encoding a URL, 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 and a fake sense of safety to patient/healthcare provider. Requirements and solutions to authenticate medicines are critical to ensure patient safety.

Insufficient integration, limited validation opportunities, and the digitalisation of healthcare in India will either be challenging to implement or incur significant costs, as the legislation for the top 300 brands only specifies the data manufacturers are required to provide, but does not outline how or where it should be made accessible. This lack of clarity makes it difficult to evaluate the utility and effectiveness of the systems in place.

Advantages of aligning with the global framework:

1. **Enhanced competitiveness:** To ensure India's global competitiveness and growth in both the domestic and export markets, aligning with the global framework for pharmaceuticals traceability using global standards will have significant positive outcomes. It will reduce supply chain complexity, costs, and security risks for all healthcare stakeholders while ensuring interoperability with systems implemented in other countries.
2. **Operational efficiency:** By harmonising domestic and export requirements with global traceability standards, Indian products will comply with both local and international regulations. This unified approach will simplify operations for manufacturers rather than navigating complex regulatory landscapes.
3. **Global interoperability:** Implementing and aligning with global standards promotes interoperability on a global scale. Integrating existing standards into the evolution of digital health will enhance healthcare professionals' and patients' access to essential digital information, including electronic product information.

Recommendation and Conclusions

As the Ministry for Health and Family welfare assumes responsibility for implementation of an authentication system for pharmaceuticals being exported, this paper's key public policy recommendation is to **align both the domestic and export pharmaceutical regulations with the global framework defined by the WHO and adopted by more than 70 countries worldwide**. By doing so, India can enhance its pharmaceutical industry's competitiveness, ensure patient safety, and improve healthcare outcomes for its population.

About GS1 Healthcare
GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare include more than 100 leading healthcare organisations worldwide.

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GS1 Global Office
Avenue Louise 523 | BE-1000 Brussels, Belgium
T +32 2 788 78 20 | **E** healthcare@gs1.org
www.gs1.org/healthcare

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