The Global Language of Business

Discussion paper on global harmonisation of the identification system for medical devices for the domestic market in India

Purpose

The aim of this paper is to stimulate discussions on a globally harmonised system for the identification and traceability of medical devices, with a focus on the Indian domestic market. This paper builds upon an existing GS1 Global Office discussion paper[1] that explored the risks associated with using QR codes for the identification and traceability of medicines by local stakeholders.

Issue statement

As part of the Indian authorities' pursuance of the objective to ensure compliance with printing 2D barcodes on top-selling brands for medicines supplied on the Indian domestic market, it might be the case that the authorities are considering enlarging the scope of the requirements for the domestic market, expanding the number of the products and brands affected by the regulation and with medical devices potentially impacted. It is important to note that an official regulation with the list of additional products and possible new requirements for medical devices are not yet available.

Discussion

Recent indications to use QR codes for medical device identification and digital labelling have underscored the urgent need to assess the impact of such requirements and to highlight the importance of alignment with the global framework for Unique Device Identification (UDI) established by regulators under both the International Medical Device Regulatory Forum[2] (IMDRF) and the Global Harmonisation Work Party[3] (GHWP) frameworks.

It should be noted that, for local medical device manufacturers supplying to the Indian market only, small deviations will cause issues in the healthcare supply chain (e.g. hospitals) and even though a QR code-based solution, may initially be perceived as a simple and cheap solution, it will undoubtedly add cost and complexity in the long term as explained in this document.

Current UDI regulations around the world are focused on the implementation of a system to identify medical devices. Rather that attempting to combat counterfeiting which has been a primary goal of the various medicines track and trace regulations in place globally, medical device regulations are still focused on the foundational step of implementing a globally harmonised system to identify devices. If India were to institute anti-counterfeiting measures via a UDI based track and trace system for medical devices, it would be the among the first country to do so and should expect a significant implementation timeline for device manufacturers to make the infrastructure investments needed to comply. As mentioned above, based on current information, QR codes are not commonly used for UDI on medical devices anywhere in the world and would cause device manufacturers to either re-label products for India or manufacture India specific products.

Furthermore, for local manufacturers exporting medical devices outside of India and for global manufacturers, this may increase costs by using a second completely different system for identification and labelling of medical devices. These additional costs and added complexity **will potentially impact the growth and put at risk the both the competitiveness of Indian based manufacturers and accessibility of medical devices in India**.

In the last years, there has been a surge in the use of smart phones to access online information related to healthcare products, including medical devices (e.g. eIFUs, videos, etc…). This is also the way vendors of proprietary systems are currently enabling medicines manufacturers to implement the "Top 300 requirements" for authentication on the Indian domestic market.

Proprietary systems, based on the QR code, do not enable a strong and robust identification of medical device products and **can undermine supply chain securi-**

[1] https://www.gs1.org/docs/healthcare/position-papers/paper-gs1-hc-india-oct2023.pdf.
[2] https://www.imdrf.org/
[3] http://www.ahwp.info/

ty by providing counterfeiters with an easy mechanism to create a false sense of identification and authentication.

In many countries today, the regulatory requirements for medical device identification and traceability are implemented using GS1 standards. The GS1 Healthcare community does **NOT recommend the use of QR codes for product identification**[4] [5].

International framework

Harmonisation of requirements with global standards, is recommended by the international regulatory community, in particular, by the aforementioned IMDRF and GHWP frameworks, as well as by key trade associations across the world. Moreover, GS1 standards and GS1 barcodes are used and implemented for medical devices identification and traceability around the world.

The IMDRF Unique Device Identification (UDI) framework[6] is a globally harmonised system designed to ensure the consistent and clear identification of medical devices throughout their lifecycle.

The framework references a wide variety of data carriers, and states no particular AIDC methods should be required by a regulatory authority. It therefore, supports the use of various barcode symbologies that meet specific requirements for encoding the UDI. These specifically include **linear barcodes (code 128), two-dimensional (2D) barcodes specifically the Data Matrix** and Radio Frequency Identification (RFID) under specific conditions.

Conclusion

GS1 is requesting that the Indian regulator carefully evaluate the requirements for implementation of QR codes on medical devices. This evaluation should consider the potential for confusion among users in the healthcare supply chain, including patients and healthcare provider staff.

Given the concerns raised in this paper, the Indian regulator should consider **aligning the potential future domestic regulatory framework for medical devices with the existing global medical device framework and consider the existing UDI regulations in place and seek a globally harmonised regulation**.

GS1 recommends global alignment, and **proactive efforts are needed by user affiliates and contacts in India to share** the messages outlined in the current paper.

[4] https://www.gs1.org/sites/gs1/files/2023-12/gs1seg231205-01-for_hclt_gs1_stds_to_access_digital-content_in_hc_a4_08.pdf
[5] https://www.gs1.org/docs/healthcare/position-papers/GS1-DataMatrix-Position-Paper-FINAL.pdf
[6] https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf

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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