Recommendations on a harmonized implementation of traceability system using GS1 standards in China

Disclaimer: The scope of following Recommendations is pharmaceuticals and does not pertain to medical devices.

Executive Summary

Following the suspension of the CFDA national electronic drug monitoring system last year, the industry is looking for a globally harmonised solution to implement product identification and a traceability system.

GS1 Healthcare recommends transitioning from the Chinese Electronic Drug Monitoring Code (EDMC) to the GS1 system, and integrate with the Drug Standard Code, as follows:

1- A transition from the EDMC to the GS1 identification system: Global Trade Item Number (GTIN) with the relevant Application Identifiers for Batch/Lot, Expiration and Serial Number (as needed).

2- A transition from linear barcodes to two-dimensional barcodes (GS1 DataMatrix) to adapt to the increased amount of information in the barcode system and ensure speed/security in production.

3- A mapping of the Drug Standard Code with the GS1 identification system. The Drug Standard Code can be accessed via a database with the GTIN as the unique product code encoded in the barcode.

It is important to note that in order to improve the traceability system, in addition to the coding, the use of the relevant GS1 and global standards for data sharing, also need to be considered.

The relevant stakeholders are committed to work with CFDA in defining an appropriate timeframe for transition and implementation of these recommendations.

GS1 Healthcare – representing all their global members – requests the respective Chinese authorities to collaborate with both local and international stakeholders in order to establish clear and explicit guidance for the usage of global standards and systems involved in accordance with the above recommendations as the ideal solution to ensure traceability and interoperability both in China and around the world.

Purpose

This paper provides recommendations on the implementation of a traceability system for pharmaceutical products in China using GS1 standards. The move to

global standards will enhance the competitiveness of both Chinese and global manufacturers by reducing the complexity of production and the cost of traceability. It will reinforce China's commitment to patient safety based on globally traceable medicines.

Background

On 20 February 2016, CFDA published an announcement suspending its national Electronic Drug Monitoring System. It has been announced that the Electronic Drug Monitoring System will no longer be updated after 1 March 2017.

In order to further strengthen the quality management of drug distribution and to ensure drug safety, CFDA issued the newly amended Good Supply Practice for Pharmaceutical Products (GSP) on 20 July 2016. In the new GSP, companies are required to build a track and trace system to enable the traceability of their pharmaceutical products.

On 27 September 2016, CFDA published opinions encouraging food and drug manufacturing and operating companies to improve the traceability system. These opinions explicitly recommend that manufacturers of pharmaceuticals and medical devices identify their products using a unique identifier.

Lastly, on 20 January 2017, CFDA published a new notice advising the use of a specific Drug Standard Code of 14 digits to be utilised for drug traceability purposes.

Problem Statement

In the absence of requirements and a timeframe from CFDA in regard to the implementation of the national traceability system for drugs in China, the Healthcare industry in China is looking for the most suitable solution for a future drug identification and traceability system in China.

In most countries today with existing or upcoming implementations, such as those in Argentina, Europe, South Korea, Turkey and the U.S.A., the regulatory requirements for drug traceability are implemented using GS1 standards. In practice, the GS1 GTIN is encoded within a GS1 DataMatrix together with an expiration date, a batch/lot number and a serial number.

More than 40 standards based on the GS1 system, and compatible with global standards, have been developed and widely adopted throughout China over the past 20 years in various industry sectors. These sectors include retail, logistics, and healthcare, as well as in many government departments.

In the Healthcare sector alone, nearly 8000 pharmaceutical manufacturers are using GS1 standards in China today, and more than 160 hospitals have successfully implemented traceability systems for medical devices by adopting

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GS1 standards since 2006[1]. Today, most of the over the counter (OTC) drugs are already identified and marked with GS1 standards.

Recommendations

The following recommendations would apply to the secondary and applicable logistical packaging levels to ensure traceability and supply chain efficiency.

GS1 Healthcare recommends a transition to GS1 standards in China in order to ensure harmonisation and alignment with healthcare regulations around the world. GS1 Healthcare recommends:

1- A transition from the EDMC to the GS1 identification system: Global Trade Item Number (GTIN) with the relevant Application Identifiers for Batch/Lot, Expiration and Serial Number (as needed).

According to the GS1 rules, serial numbers (when required) would be generated and assigned by the manufacturers on a per GTIN basis. A randomised serialisation is recommended. The inclusion of expiration date and lot number will be of great benefit for pharmacies and hospitals to better control their inventory and improve patient safety.

2- A transition from linear barcodes to two-dimensional barcodes (GS1 DataMatrix) to adapt to the increased amount of information in the barcode system and ensure speed/security in production.

3- A mapping of the Drug Standard Code with the GS1 identification system. The Drug Standard Code can be accessed via a database with the GTIN as the unique product code encoded in the barcode.

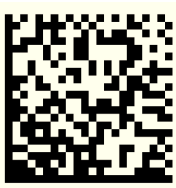
It is important to note that in order to improve the traceability system, in addition to the coding discussed above, the use of relevant GS1 and global standards for data sharing will also be needed.

The relevant stakeholders are committed to work with CFDA in defining an appropriate timeframe for transition and implementation of these recommendations. The usage of well-known widely used global standards and clear specifications for coding and reporting, communicated in a timely manner, will support a seamless implementation and quick adoption.

GS1 Healthcare acknowledges that initial investments to switch the scanners and printers and systems to accommodate the transition to the recommended harmonised approach will be needed. However this will reduce the total cost in the

[1] Based on notice published by Shanghai FDA and Shanghai HFPC

long term as the traceability system for China will be aligned with the global traceability framework.



Recommendation from GS1 Healthcare: use of GS1 GTIN with relevant AIs captured into a GS1 DataMatrix

Conclusions

The GTIN and attributes encoded in a GS1 data carrier, usually a GS1 DataMatrix barcode, provide the basis for unambiguous identification of pharmaceutical products globally and enables traceability across all the supply chain.

GS1 DataMatrix is a 2-dimensional (2D) bar code that efficiently allows the encoding and marking of a greater amount of data within a smaller space and that provides error detection and correction capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label.

In addition, the GS1 standards enable manufacturers, distributors and providers to share accurate, standardised and synchronised traceability data electronically. Thus, the GS1 System of standards builds a global and secure framework for end-to-end traceability systems.

To ensure China's global competitiveness, growth and future prosperity, alignment on a suite of global standards as outlined will have a significant and positive outcome. This will enable a reduction in supply chain complexity, in cost and in risk for all stakeholders while enhancing the potential for much desired supply chain optimisation and interoperability, with the ultimate result of improving patient safety and clinical outcomes.

References:

- Discussion paper on global harmonization of the traceability system for drugs with globally harmonised barcodes: http://www.gs1.org/sites/default/files/docs/healthcare/gs1_global_china_ph_discussion_paper_final.pdf
- GS1 Healthcare: http://www.gs1.org/healthcare