Clarifying Statement
on
White Paper Regarding Implementing India's Drug Serialization and Traceability Requirements to Advance Patient Safety and Support Global Trade

In May 2017, RxGPS and the Indian Council for Research on International Economic Relations (ICRIER) published a white paper entitled *Implementing India's Drug Serialization and Traceability Requirements to Advance Patient Safety and Support Global Trade* (the White Paper). The White Paper captured discussion and recommendations resulting from the 3 March, 2017 *Stakeholder Consultation on Drug Serialization and Traceability in India* hosted by ICRIER and RxGPS in New Delhi.

The White Paper provides twelve recommendations to aid India in achieving its dual goal of remaining a leader in the global pharmaceutical market and advancing supply chain security for the benefit and protection of patients. The White Paper has been well-received, but it has also raised some additional questions. This Clarifying Statement is intended to clarify several points in the White Paper.

1. Indian regulators have set requirements and specifications for implementation of serialization, but they do not establish "standards."

The White Paper makes reference to Indian standards for serialization and Indian identifiers (*e.g.*, pp. 3–4). Indian regulators have, in fact, established detailed requirements and specifications for serialization and traceability by regulation or guideline. Some of those requirements and specifications reference GS1 standards[1]; however, the requirements and specifications are not themselves standards.

2. The GS1 global system of standards for barcoding and data exchange are the only commonly accepted standards for pharmaceutical barcoding and data exchange.

As explained in Principle 5 of the White Paper, global standards should be implemented fully and without variation. Country-specific variations defeat the purpose of global standards. Principle 5 is not intended to encourage use of standards for barcoding and data exchange other than the GS1 global system of standards. The pharmaceutical industry has widely agreed for many years that the GS1 global system of standards for barcoding and data exchange are the appropriate standards for the pharmaceutical industry.

3. Terminology regarding packaging levels is used by stakeholders in multiple ways, which can cause confusion.

As defined in the Indian regulations for exports, the *primary package* is the level of packing that is in direct contact with the product (e.g., blister card or vial). The *secondary package* is a level

[1] Implementation Guidelines for Coding & Labelling Pharmaceuticals and Drugs Using Global Supply Chain Standards to Meet Directorate General of Foreign Trade's (DGFT) Authentication, Track and Trace Requirements, Version 1.3.

of packaging that may contain one or more primary packages, or a group of primary packages containing a single item. The *tertiary package* is the shipper containing one or more secondary packs.

GS1 General Specifications, however, include slightly different definitions of primary and secondary packaging. According to the GS1 General Specifications, the primary packaging is the first level of packaging for the product marked with a data carrier (*i.e.*, GS1 DataMatrix) either on the packaging or on a label affixed to the packaging. The secondary packaging is a level of packaging marked with a data carrier that may contain one or more primary packages or a group of primary packages containing a single item. The GS1 General Specifications do not define tertiary packaging; however, industry generally understands that tertiary packaging can be the logistical unit intended by the manufacturer to be shipped, such as the shipper, carton, case, pallet, or tote that contains one or more primary/secondary levels of packaging. However, the tertiary level can be a trade item.

The primary, secondary, and tertiary package terminology is distinct from the terminology commonly used in trade. Units of trade are typically referred to as saleable units, cases (homogenous or mixed), bundles, pallets, etc. These two sets of terms do not always align in the same manner. The salable unit, for example, is the smallest container of package intended by the manufacturer to be sold to a pharmacy. In practice, the saleable unit could be a pill bottle (which is a primary package), a carton containing a blister strip (which is a secondary package), or even a ten-pack of individual vials that could be dispensed to a patient. The salable unit is based on the manufacturer's intent. Similarly, multiple levels of trade items[2] (*e.g.*, case, bundle, pallet) could be the tertiary package at various times during the distribution process, but only one trade item should be considered tertiary at a given point in time.

The terms primary package, secondary package, tertiary package, and saleable unit are used in this manner throughout the White Paper.

[2] A "trade item" is any item upon which there is a need to retrieve predefined information and that may be priced, or ordered, or invoiced at any point in any supply chain.