Addendum to Healthcare Distribution Alliance Comments on Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act

81 Fed. Reg. 64175 (Sept. 19, 2016); Dkt. No. FDA-2016-N-2673

DGFT Requirements for Indian Export Products

Drug serialization requirements imposed by India's Directorate General of Foreign Trade (DGFT) apply to products manufactured in India for exportation to foreign markets, including the U.S. Beginning in 2016, DGFT requires manufacturers and exporters of finished drug products to include a "unique and universal" product identifier and bar code on the product packaging.[1] DGFT also requires manufacturers and exporters in India to maintain data showing their products' movement in the supply chain, capturing the product identifier from outer packaging labels down through patient-level packaging.

HDA members anticipate significant challenges to the supply chain once the U.S. requirement for product identifier takes effect in November 2017, unless supply chain partners – potentially with FDA's assistance – develop a strategy to assure compliance with both countries' requirements without adding logistical complexity. U.S. wholesale distributors have been working on a number of fronts to resolve the supply chain issues that could result from the two countries' requirements.

One core underlying issue is that a single Global Trade Identification Number (GTIN) likely cannot conform to both the GS1-India GTIN standard and the GS1-U.S. GTIN standard. While the NDC number is embedded in the U.S. GTIN, GS1-India has established different, incompatible standards for Indian GTINs. Without a shared resolution, we anticipate that, beginning in November 2017, many shipments of drug products from India to the U.S. will include both an Indian GTIN and a U.S. GTIN. This situation conflicts with GS1 standards and with the concept of a "unique identifier."

Moreover, in an effort to absolutely ensure compliance with Indian requirements, some manufacturers currently shipping pallets or cases from India are placing two different GS1-India format GTINs and barcodes on the shipment, to account for differing interpretations of the Indian requirement.

U.S. wholesale distributors face serious logistical hurdles in processing shipping containers that display two or more different GTINs and barcodes.[2] Automated systems cannot distinguish the GTIN and barcode that should be scanned. At present, some U.S. wholesale distributors are manually cross-referencing information when presented with multiple barcodes.

We suggest that FDA consider whether such uses of multiple GTINs and barcodes also may increase the time required for such products to be processed at U.S. ports of entry. An increase in import holds could slow the delivery of needed pharmaceuticals to patients.

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[1] DGFT Pub. Not. 52/2015-2020 (Jan. 5, 2016). Implementation is phased for smaller manufacturers.

[2] Some finished drug products labeled for the U.S. market are shipped directly from a foreign manufacturing location to an exclusive wholesale distributor in the U.S. Up to 40 percent of finished prescription drug products in the U.S. market–billions of units–are manufactured in India.

While limited exemptions to the Indian requirements are available, U.S. wholesale distributors are reliant on manufacturers to apply for and obtain such exemptions. India allows manufacturers to request exemptions through Pharmexcil, the Pharmaceutical Export Promotions Council of India, if the intended country of import has traceability requirements, as the U.S. does. While we believe that Pharmexcil has begun issuing exemptions, Pharmexcil has not provided written guidance regarding the exemptions process, so several aspects remain unclear. For instance, it is not clear whether exemptions are time-limited or must be renewed, and it is not clear whether manufacturers can request a blanket exemption for all of their products that are to be exported to the U.S.

It is essential to U.S. wholesale distributors that manufacturers obtain exemptions from the Indian requirements, such that only the DSCSA serialization requirements apply to the secondary and primary packaging levels, and that manufacturers treat the pallet level as tertiary for the purposes of the DGFT requirements. U.S. wholesale distributors would be unable to use a single system to implement the two countries' requirements because of the conflicting GTIN standards and because the packaging levels defined by India's requirements do not align well with the packaging used in distributing pharmaceuticals in the U.S. Instead, in the absence of such exemptions, we believe that U.S. wholesale distributors would have to establish two parallel systems for product tracing: one scan would link the product to the GS1-India format GTIN and the packaging level as defined by DGFT, while another scan would link the product to the U.S. product identifier and standard U.S. packaging nomenclature. Such duplication would have a detrimental effect on the provision of prescription drugs by increasing, possibly substantially, the time required to move products through the distribution chain, and ultimately to patients. It also would increase the risk of data errors, further slowing provision of products to patients while suppliers and distributors correct those errors.

HDA requests FDA's assistance in clarifying with Indian officials and supply chain partners that, if the Indian manufacturer treats the exported pallet as the tertiary packaging for the purposes of meeting India's requirements, and obtains Indian exemptions for all packaging levels other than tertiary, drug products intended for the U.S. market can meet both countries' requirements without adding unnecessary confusion and complexity to the supply chain.