Johnson & Johnson SUPPLY CHAIN

August 10, 2017

Dear Valued Customer,

The Johnson & Johnson Family of Companies is focused on ensuring the integrity and safety of our products. We embrace product identification and traceability because of its benefits to our patients, customers, and the industry.

Health Authorities from more than 45 countries around the world have issued rules requiring pharmaceutical manufacturers to uniquely identify their products with a global identifier and a serial number. Regulations have been published in the **United States** the **European Union** and **Brazil**.

Although the specifics of each country's regulation may differ, the purpose is to enhance the safety of the pharmaceutical supply chain through improved visibility to make identification and traceability of pharmaceutical products easier, thereby helping to protecting patient safety through improved supply integrity.

The Johnson & Johnson Family of Companies is committed to complying with these regulations to ensure we can continue to deliver critical medicines to the doctors, nurses, and patients around the globe who depend on us. We are also committed to working with our customers and trading partners to help ensure the integrity of our supply chain. This will provide our customers and patients with the added benefit of a more secure and safe supply chain.

The Johnson & Johnson Supply Chain organization has established a dedicated team, focused on meeting the milestones set by the health authorities around the world. Our standard for product identification is GS1 and the GS1 Global Trade Identification Number (GTIN) is the standard identifier.

We realize that you may have more specific questions about serialization, so we've prepared a selection of Frequently Asked Questions (FAQs) which follow. However, if you have other questions beyond these, please forward your questions to the Johnson & Johnson Serialization/Traceability mailbox at: JNJSerialize@its.jnj.com.

Sincerely,

Mike Rose
Vice President, Supply Chain Visibility
Johnson & Johnson Supply Chain

Johnson & Johnson SUPPLY CHAIN

Frequently Asked Questions

1. **What is Serialization and Traceability?**

   Health Authorities around the world have issued regulations requiring pharmaceutical manufacturers to uniquely identify their products with a global identifier and a serial number. Serialization requires that package labels of applicable products (predominately pharmaceuticals) carry a unique identifier and serial number, a 2D barcode and other identifying information about the package, case or pallet.

   Traceability is the ability to track and trace products throughout the supply chain from manufacturing to dispensing to a patient. This requires aggregating individual serialized units into cartons or cases and pallets. Serialization establishes an electronic record of each individual unit and creates a hierarchy that identifies individual units, the cases containing them, and the pallets that contain the case.

2. **How does Serialization and Traceability affect pharmaceutical companies?**

   Today more than 45 countries have laws in place requiring serialization of pharmaceutical products. Health Authorities in many of these countries have issued specific regulations and compliance dates by which applicable pharmaceutical product labels must include a serial number, a product identifier, a 2D data matrix and other information.

   Johnson & Johnson's pharmaceutical companies are committed to meeting the serialization and track and trace requirements from these countries and others as they appear.

3. **What are some key regulatory milestones for Serialization and Traceability?**

   Compliance dates vary by country.

4. **What is the standard identifier for pharmaceutical products from The Johnson & Johnson Family of Companies?**

   Our standard for product identification is GS1. The GS1 Global Trade Item Number or GTIN will be on our pharmaceutical products.

Johnson & Johnson SUPPLY CHAIN

5. **What will change on the product labels as a result of serialization?**

   The labels of our individual pharmaceutical packages will have a 2D data matrix barcode. The 2D barcode will contain a set of standard data elements: GTIN, serial number, expiry and batch. These same data elements will be displayed in human readable format on the label. Additional data elements may be present on the labels to meet country-specific requirements.

6. **When a customer places an order, will anything change?**

   No. Customers can continue to use the product catalog numbers from the Johnson & Johnson companies to place orders.

7. **Will the invoice or packing slip look any different with serialization?**

   No. The look of the invoice and packing slip will remain the same.

8. **Who should I contact if I have a question about a serialized product that I purchased?**

   Continue to contact the Customer Service Center regarding all product-related questions.

9. **Who do I contact if I have a general question regarding serialization and traceability?**

   Send your question to the Johnson & Johnson Serialization/Traceability mailbox at: JNJSerialize@its.jnj.com

August, 2017

Complying with the United States of America Drug Quality and Security Act Title II: Drug Supply Chain Security Act (DSCSA)

The Johnson & Johnson Family of Companies is focused on ensuring the integrity and safety of our products. We embrace product identification and traceability because of its benefits to our patients, customers, and the industry. The Johnson & Johnson Supply Chain (JJSC) organization has a dedicated team focused on serializing pharmaceutical products as required by health authority regulations around the world. In the United States (U.S.) our distribution affiliate, JOM Pharmaceutical Services, Inc. is working to comply with these regulatory requirements.

The Drug Quality and Security Act

In the U.S. the Drug Quality and Security Act (DQSA) was passed into law on November 27, 2013. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), has a number of key provisions spanning a ten year implementation period. Below is a summary of the major milestones of the DSCSA. JJSC is committed to meeting the FDA's compliance deadlines for each milestone.

Lot Level Tracing and Verification

JJSC has met the requirement set forth by the DSCSA for lot level tracing and verification for January 1, 2015. This provision of the law requires manufacturers to transmit transaction history, statement, and information to customers (wholesalers, distributors, etc.) in paper and electronic format. The DSCSA also requires that by November 27, 2017 manufacturers have systems and processes in place to exchange this information electronically. JJSC is reviewing solutions to ensure lot level is exchanged electronically to all necessary trading partners.

Serialization

Manufacturers are required to serialize all prescription pharmaceutical products sold in the U.S. by November 27, 2017, although the FDA recently issued a draft guidance effectively allowing for an additional year. This means that applicable pharmaceutical product labels must include a standardized numerical identifier including a National Drug Code (NDC) and serial number encoded in a 2D data matrix bar code.

JJSC has made significant progress in updating internal and external packaging lines, product labeling and in preparing our distribution network.

Unit Level Track and Trace

Track and Trace (or traceability) is the ability to track products throughout the supply chain from manufacturing to dispensing to a patient. This requires aggregating individual serialized units into cartons or cases and pallets. Serialization with aggregation establishes an electronic record of each individual unit and creates a hierarchy that identifies individual units, the cases containing them, and the pallets that contain the case.

The law requires a staged implementation of an interoperable, electronic tracing of products by November 27, 2023, including the use of the serialized product identifier by all stakeholders (re-packagers, wholesalers and pharmacies) at the unit level. Throughout JJSC, progress has already been made in updating packaging lines to allow for product aggregation and in preparing distribution centers to receive traceable products.

Frequently Asked Questions

1. **Where can I learn more about the Drug Quality and Security Act (DQSA) and obtain more information regarding Title II: Drug Supply Chain Security Act (DSCSA)?**

   http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/

2. **What is Serialization?**

   Serialization is the application of a unique identifier to product labeling. The unique identifier is applied in human readable format as well as a machine readable 2d matrix at the each, case, and pallet level.

3. **What is Traceability?**

   Traceability is the ability to track and trace products throughout the supply chain from manufacturing to dispensing to a patient. This requires aggregating individual serialized units into cartons or cases and pallets. Serialization with aggregation establishes an electronic record of each individual unit and creates a hierarchy that identifies individual units, the cases containing them, and the pallets that contain the case.

4. **Are there specific products distributed by JOM Pharmaceutical Services, Inc. that are impacted by DSCSA?**

   `Product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing.

   Per the definition in the DSCSA, all Janssen Pharmaceuticals, Inc., Janssen Therapeutics a division of Janssen Products, LP, and Janssen Biotech, Inc. products distributed by JOM Pharmaceutical Services, Inc. on the list below are impacted.

   http://jom.com/products.html

5. **What will change on the product labels as a result of serialization?**

   Going forward, our product labels will contain a serialization identifier. The package will display a Global Trade Identification Number (GTIN), a unique serial number, lot code, and expiry date in both a readable text and a 2D matrix barcode.

6. **When a customer places an order, will anything change?**

   No. Customers can continue to purchase products by NDC number.

For other questions, please email us at: JNJSerialize@its.jnj.com or JOM Pharmaceutical, Inc. customer support at (800) 631-5273.

Johnson & Johnson SUPPLY CHAIN

August, 2017

Complying with Brazil's ANVISA Regulation for Serialization and Traceability

The Johnson & Johnson Family of Companies is focused on ensuring the integrity and safety of our products. We embrace product identification and traceability because of its benefits to our patients, customers, and the industry. Johnson & Johnson's Supply Chain organization has a global team dedicated to complying with pharmaceutical serialization and traceability regulations required by health authorities around the world.

ANVISA, Brazil's national health surveillance agency, instituted regulation RDC/54 in 2013, requiring serialization and track and trace of all pharmaceutical products produced, imported and distributed in Brazil. For Johnson & Johnson companies in Brazil, this includes products from pharmaceutical, medical device and consumer companies.

ANVISA requires the placement of a unique identification number (Johnson & Johnson Supply Chain's standard is GS1's Global Trade Identification Number - GTIN) on the label of each carton, shipping box* and pallet, along with associated product and serial numbers. Aggregation of serial numbers is required allowing products to be tracked from manufacture to the patient.

The Johnson & Johnson companies in Brazil have implemented ANVISA's serialization and track and trace regulations. Brazil packaging operations have updated lines for serialization and aggregation and distribution centers are prepared to receive traceable products.

Learn more about the ANVISA regulation on the ANVISA website. For other questions, please email us at: JNJSerialize@its.jnj.com

*For shipping box labels, Johnson & Johnson intends to promote market adoption of the GS1-128 format replacing DUN -14, along with other companies in the industry. The DUN -14 will be maintained during the transition period, to avoid any problems in the supply chain.

August, 2017

Complying with the European Union's Falsified Medicines Directive

The Johnson & Johnson Family of Companies is focused on ensuring the integrity and safety of our products. We embrace product identification and traceability because of its benefits to our patients, customers, and the industry. Johnson & Johnson's Supply Chain organization has a dedicated global team focused on implementing identification and traceability of pharmaceutical products as required by health authorities around the world.

The European Union's Falsified Medicines Directive (FMD) 20011/62/EU was published in 2011 and contains measures to increase security of medicinal supply chain in Europe.* As defined by the European Committee on the Environment, Public Health and Food Safety, "Falsified medicines" are:

> *"Fake medicines that pass themselves off as real, authorized medicines. Falsified medicines might contain ingredients, including active ingredients, which are of bad quality or in the wrong dose…" Read more here.*

The delegated Regulation to the Falsified Medicines Directive (FMD) was published on February 9, 2016. The regulation defines a set of requirements which include:

- Authentication and verification of drugs through the supply chain starting with serialization by manufacturers and verification at the point of dispense. Under the Regulation, intermediaries, such as wholesalers must perform verification on a risk basis.
- The inclusion of a "safety feature" on each individual package which consists of a unique identifier (serial number) and tamper evident feature.
- The establishment, management and accessibility of a central European data repository (European Hub) and National Verification Systems that connect to it for international data exchange.

These requirements must be met by pharmaceutical manufacturers selling their products in the European Economic Area (EEA) by February 9, 2019 although Belgium, Greece and Italy have the option of deferring the application of the rules by an additional period of up to six years.

Johnson & Johnson Supply Chain is committed to comply with the delegated Regulation of the Falsified Medicines Directive and meeting each major milestone. An EU based team is working hard to prepare for the implementation of the FMD's requirements to insure compliance by February 2019.

Learn more about the Falsified Medicines Directive on the European Commission's website. For other questions, please email us at: JNJSerialize@its.jnj.com

**The European Economic Area includes the European Union, Iceland, Liechtenstein and Norway. Switzerland has also expressed its' intention to implement this directive.*

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