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Environmental Monitoring focus

With articles from R. Vijayakumar, Majmaah University, Tim Sandle, Bio Products Laboratory and Anastasia Petropoulou, University Hospital Bristol's NHS Foundation Trust

Towards a more robust pharmaceutical supply chain

A comparison of track and trace requirements in the EU and US by Kathleen M. Sanzo and Jacqueline Berman at Morgan Lewis, and Jacob Gifford Head from Thomas More Chambers

Spectroscopy focus

With contributions from Koen De Smet, Tom Van Den Kerkhof and Anke Prudic from Janssen, and University of Cambridge scientists Daniel Markl, Michael T. Ruggiero and Axel Zeitler

Pharmaceutical packaging and product Identifiers – US requirements coming in 2017

Kathleen M. Sanzo and Jacqueline Berman Morgan Lewis

Since passage of the Drug Supply Chain and Security Act (DSCSA) of 2013, Section 582 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. § 360eee-1), pharmaceutical product manufacturers have been implementing systems and processes to track and trace drug product through the drug supply chain in the US. The first of these requirements relating to providing transaction documentation, much like a passport, which trails the product throughout its passage through the US, became effective in 2015.

Starting 27th November 2017, manufacturers of pharmaceuticals[1] distributed in the US will be required to include on each product package a product identifier that carries the product's standardised numerical identifier (SNI)[2] to allow the product to be traced from the manufacturing line to the final consumer. The identifier must be a standardised graphic in both human readable form, and on a machine-readable internationally recognised data carrier such as a barcode. The elements in the product identifier must include: an SNI; product lot number and expiration date of the product.

The identifier must be affixed to each package and homogeneous case of product. Label changes that are made to package labels *solely* to incorporate the product identifier may be submitted to FDA in the product's annual report.

Purchasers of pharmaceutical products (e.g., wholesalers, retail and specialty pharmacy) eventually will be prohibited from engaging in a "transaction" under the FFDCA unless the product has an appropriate identifier. This prohibition becomes effective in 2018 (repackagers), 2019 (wholesalers) and 2020 (dispensers).

Once the product identifiers are created, they must become part of the transaction history, which will eventually only be provided electronically. Failure to affix a product identifier to a covered drug product will cause the drug product to be misbranded under the FFDCA; any distribution of a "misbranded" drug is a prohibited act[3]. Further, issues with the product identifiers may cause a product to be considered a "suspect" product, necessitating an investigation by the manufacturer or downstream purchaser.

Moreover, between 2017 and 2020, depending on whether a trading partner is a manufacturer, repackager, wholesale distributor or dispenser, trading partners must have systems in place to verify the SNI of "suspect products."

Footnotes

1. The DSCSA applies to brand and generic prescription drugs in finished dosage form but not to over-the-counter drug products, blood products or components, homeopathic drugs or medical gas is or certain IV solutions. FFDCA § 581(13)
2. SNI is a set of numbers or characters composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters. FFDCA § 581(20)
3. FFDCA §§ 301(4), 502(cc)

EXPERT VIEW

EU Falsified Medicines Directive: the time for serialisation is now, not 2019

The EU Falsified Medicines Directive (FMD) outlines complex new track and trace regulations that will start in February 2019 and apply to those who manufacture, distribute or dispense medications in the European Union and other countries following EU FMD regulations. To ensure supply to one of the largest global markets, now is the time for pharmaceutical companies, their CMO/CPO and 3PL partners to fully understand the extensive serialisation, compliance reporting, verification and other requirements to ensure full FMD compliance.

The FMD track and trace regulations include multiple, diverse rules for all stages of the product, distribution and dispensation lifecycle, including: serialisation; compliance reporting and verification of safety features

A poll conducted by TraceLink in early 2016 found that most companies (78% of those surveyed) were actively researching, building or deploying their EU FMD compliance solution. Additionally, 84% of respondents expect to deploy a solution by 2017, conveying a collective industry understanding that preparations for serialisation and managing compliant serialised product internally and across their supply network are complex, and there are benefits to implementing a solution sooner rather than later, allowing companies to better address issues in a timely manner.

Today, companies are already utilising TraceLink's EU compliance module to communicate product master data and product pack data to the EU Hub, testing readiness for serialisation and compliance requirements under the EU FMD nearly three years in advance of the February 2019 deadline. To date, the TraceLink Life Sciences Cloud has processed over 3,100 compliance documents for 6.3 million units of product in the EU, South Korea and India.

Three years may seem like a lot of preparation time. But if companies wait to implement a full serialisation and compliance plan with resource requirements and realistic timelines, there will be significant risk to their business operations.

To learn more about the EU FMD requirements and discuss how to take advantage of this lead time and best determine the full scale and scope of your business requirements for serialisation, stop by the Sharp Packaging/TraceLink booth #3L56, Hall 3 at CPhI 2016.

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