Cardinal Health
Global Sourcing
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cardinalhealth.com

October 8, 2018

Dear Valued Supplier,

As the pharmaceutical industry approaches the midpoint in the 10-year implementation of the Drug Supply Chain Security Act (DSCSA)[1], Cardinal Health remains committed to working with you to comply with the requirements of the law. With unit level serialization and enhanced verification on the horizon, we would like to share additional expectations for how we will exchange serialized products and data, so you can plan accordingly.

Communication of GTINs
The DSCSA requires the use of standards for identifying products and exchanging data to ensure an interoperable system. For pharmaceuticals, the GTIN-14 is the identifier that links a scan of a product barcode to the master data associated with that product, including the NDC, package size and quantity. Since the meaning of the first digit of the GTIN-14 (the packaging level) can vary from manufacturer to manufacturer, wholesale distributors need a way to identify the expected pack level or quantity when we scan your 2D barcode.

Beginning November 1, 2018, we will reject any form for a new pharmaceutical item without the required GTIN information.
For all new pharmaceutical items, we require the use of the updated HDA Standard Pharmaceutical Product Information Form published in February 2017[2]. The sections for DSCSA and GTIN product information must be filled out completely or we will not be able to add your new product to our system.

Cardinal Health will require GTIN information on existing items by March 1, 2019.
Cardinal Health supports the use of a repository to store and transmit GTIN data to downstream trading partners as it is much more efficient and less prone to errors than receiving information via spreadsheets and email. We plan to utilize Origin, the HDA GTIN repository created in partnership with ValueCentric, and we encourage manufacturers to post their data there. For more information about Origin, please visit the **Origin Product Website**.

If Origin is not a possibility for your organization, then you must submit your GTIN data to us via a Cardinal Health GTIN template. We will only be able to accept GTIN data via this template as this format allows us to mass upload to our item database. It is critical that your GTINs are properly loaded in our Master Data when we receive serialized product. Your product may be quarantined if data is not mapped appropriately.

Next steps: Update your GTIN data via Origin or use the downloadable spreadsheet provided below

- Please let us know if you plan to use Origin by sending an email to **drugtracing@cardinalhealth.com**. For more information about Origin or to submit data, visit the **Origin Product Website**.
- **If you are not using Origin -** download the pre-populated spreadsheet for your organization and send completed forms to **GMB-DUB-SupplierCleansing@cardinalhealth.com**. You can find instructions for completing the form on the second tab of the spreadsheet.

Questions about the spreadsheet?
*Contact us at **SupplierCleansing@cardinalhealth.com***

Upcoming DSCSA requirements
As a reminder, beginning November 27, 2018 manufacturers must place a unique product identifier on each package and homogeneous case.

- The FDA has clarified that a package or homogenous case is considered grandfathered if it was packaged by the manufacturer before November 27, 2018 and that trading partners may engage in transactions of grandfathered product until expiration date.
- Based on that, Cardinal Health will accept shipments after November 27, 2018 that include non-serialized product as long as it was packaged prior to that date.
- We intend to use your transaction statement as an indication that any non-serialized product received after November 27, 2018 is grandfathered. No additional documentation is expected.

The safety and security of our nation's pharmaceutical supply is one of our top priorities. We take this responsibility seriously, as a safe and reliable drug supply is central to our customers' businesses and critical to the health and well-being of patients. As a valued manufacturer partner, we recognize the efforts you are making to implement a traceability solution and we look forward to working together to establish an industry-wide, standards-based approach to comply with the DSCSA.

Please send any questions or requests for additional information to **drugtracing@cardinalhealth.com**.

Sincerely,

Dianne Pfahl
Vice President
Global Sourcing

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[1] The full text of the law, including requirements for manufacturers of pharmaceutical products, can be **found on the FDA website**.
[2] A copy of the most up to date HDA Standard Pharmaceutical Product Information form can be downloaded **here**