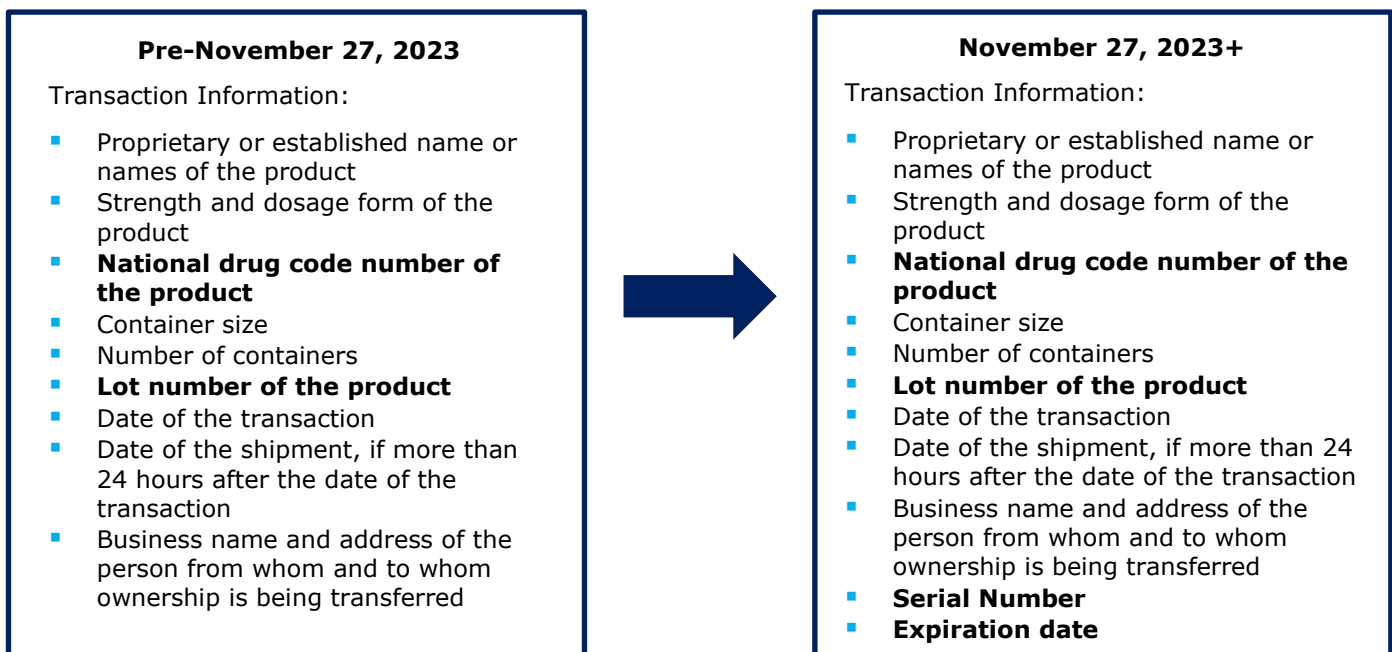


## Best Practice Guidance for Transition Inventory for November 2023 DSCSA Requirements

As of November 27, 2023, the final implementation phase of the Drug Supply Chain Security Act (DSCSA) goes into effect. Focusing on serialized item-level traceability, this phase requires transaction information and transaction statements to be exchanged in a secure, interoperable, electronic manner. The transaction information shall include the product identifiers, including serial number and expiration date, at the package level for each package included in the transaction.



With this final phase of requirements, all products governed by DSCSA that are sold must have TI/TS at the serialized unit level. Since the regulatory requirements prior to November 27, 2023, required only lot-level traceability, this affects inventory that has moved from the manufacturer into the pharmaceutical supply chain. We refer to this inventory as "Transition Inventory". Unless the U.S. FDA provides an exemption for this Transition Inventory, trading partners<sup>1</sup>, predominantly wholesale distributors, must present this Transition Inventory to outbound shipments with serialized data that was not received at the time of receipt due to the current regulatory requirements at that time. This Transition Inventory may be in stock at the time of the regulation change or received due to a saleable return.

An identified method to continue the distribution and use of this Transition Inventory is for the trading partner holding this inventory to capture the serialized data through barcode scanning and to use that Electronic Product Code (EPC) data to create a *Commissioning* event. This should mitigate the issue of missing serialized data at the lowest sellable unit. There are business benefits of operationally having a consistent process for exchanging serialized information. The approach laid below shows how serialized commissioning events can be created for the lowest saleable units by the purchasing party who previously received lot-level traceability data for the respective product. This approach enables a consistent process and system approach as well as facilitates the management of overage exceptions and enhances reconciliation of returned products

<sup>1</sup> Those who own products received prior to November 27, 2023, but who are not the manufacturer and are only in possession of lot-level data are defined as trading partners in the scope of this guidance. Manufacturers are not in the scope of this guidance.

A trading partner will most likely use the picking process for the preparation of an outbound shipment to capture and create this data, but it can occur any time after receipt of the product and prior to shipment. This allows the serialized level data for the product inventory to be captured and shared to downstream trading partners using established systems and processes for DSCSA compliance.

### Populating a Commissioning Event

A *Commissioning* event should be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Population Rules for Transition Inventory
<b>eventTime</b>	Required	Timestamp	Date and time of event.	This reflects the date the <i>Commissioning</i> event is captured and created by the trading partner who is creating the serialized data for the Transition Inventory received under lot level traceability.
<b>eventTimeZone Offset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition.
<b>recordTime</b>	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition.
<b>epcList</b>	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. If more than one EPC is included, they should all have the same value for ILM D attributes defined below or should all require these attributes to be omitted. EPCs having different values for these attributes should be shared in different Commissioning events.	Captured through scanning the product unit.  Recommend unpacking a container to capture and create a <i>Commissioning</i> event only for the lowest sellable serialized units physically packed in that container.
<b>action</b>	Required	String	ADD	EPCIS standard definition.
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition.
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the disposition value "active" is always used with the bizStep "commissioning."
<b>readPoint</b>	Optional*  Highly recommended as Required for this use case	URI	EPC Pure Identity URI for the GLN of the location at which the event took place.	The GLN (SGLN) value of the trading partner holding the inventory, may be provided as the (corporate) entity GLN value, in place of the physical location of the inventory as decided by the business.
<b>bizLocation</b>	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event.	The GLN (SGLN) value of the trading partner holding the inventory, may be provided as the (corporate) entity GLN value, in place of the physical location of the inventory as decided by the business.



<b>bizTransaction List</b>	Omitted	List of biz transactions	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Omitted in <i>Commissioning</i> events as there are no relevant business transactions to share.
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### Commissioning Event Instance/Lot Master Data (ILMD) Attributes

In addition to the EPCIS standard fields shown above, the following Instance/Lot Master Data (ILMD) attributes are also included in a *Commissioning* event.

Element	Usage	Type	Value
<b>lotNumber</b>	Conditional	String	The lot or batch number for all of the EPCs in the epclist of the ObjectEvent.
<b>itemExpirationDate</b>	Conditional	Date	The expiration date for all of the EPCs in the epclist of the ObjectEvent, formatted as an xsd:date.

- ✔ **Note:** Verification for a saleable return on this Transition Inventory may need to be direct to the source, the manufacturer, due to the change in traceability requirements during the product’s lifespan.
- ✔ **Note:** This can only be used for the lowest sellable serialized units and recommend unpacking a container to capture and create a *Commissioning* event only for those lowest sellable serialized units.
- ✔ **Note:** This method should only pertain to this Transition Inventory. Once this Transition Inventory is exhausted then this practice will cease.

This method will enable the progression of the product and identification of this transition inventory by the timestamp and GLN of the readPoint and bizLocation used in the *Commissioning* event.



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