Errata for GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2

1. eventTime

In *The Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline R1.2*, the eventTime population rule was incorrectly published with a guidance to populate the eventTime of the transaction event to **match** the date and time of the corresponding *Shipping* event. However, to allow for sequencing and avoid potential issues when there are multiple transaction events for a *Shipping* event, it is important for the eventTime to **precede** the date and time. While a discrepancy in the published version of *The Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline R1.2* was identified by the RxSecureSupplyChain workgroup, it was decided by the workgroup to correct this in practice and publish the correction in the next release of the implementation guideline, R1.3.

Element	Usage	Туре	Value	Reason				
Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline R1.3								
eventTime	Required	Timestamp	Date and time of event. This should precede the date and time of the corresponding Shipping event. Note: When sharing the same event across trading partners, the event time should be the same across all trading partners. Although EPCIS provides for millisecond precision, the event time may be expressed with less precision and is recommended¹ to be provided in no more than second precision to ensure systems across all systems in the supply chain are properly sequencing events.	EPCIS standard definition For purposes of DSCSA, the shipping business transaction detail event time precedes the shipping date (when bizStep = shipping).				

Clarification on eventTime:

The Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline R1.2 and R1.3 normative reference is EPCIS release 1.2 (2016)

- the <xsd:element name="eventTime" type="xsd:dateTime"/>.
- eventTime defined as xsd:dateTime which requires a time zone specifier per EPCIS 1.2.

9.5 Schema for core event types

The following is an XML Schema (XSD) for the Core Event Types data definition module. This schema imports additional schemas as shown in the following table:

Namespace	Location Reference	Source
urn:epcglobal:xsd:1	EPCglobal.xsd	Section <u>9.3</u>
http://www.unece.org/cefact/ namespaces/StandardBusinessD ocumentHeader	StandardBusinessDocumentHeader.xsd	UN/CEFACT web site; see Section <u>9.2</u>

In addition to the constraints implied by the schema, any value of type xsd:dateTime in an instance document SHALL include a time zone specifier (either "Z" for UTC or an explicit offset from UTC).

¹ The RxSecureSupplyChain workgroup recommends that eventTime precision not exceed seconds. However, it is acceptable for a trading partner to generate, record, and consistently share events with eventTime in greater precision than seconds. Trading partners receiving events from upstream trading partners with eventTime precision greater than seconds shall not reject events with greater precision than seconds. Trading partners shall maintain and store the eventTime value with the same degree of precision as received from upstream trading partners.

2. netContentDescription

In <u>The Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability</u> <u>Implementation Guideline R1.2</u>, netContentDescription is required data element.

Even with it being a required data element, It SHOULD be applied contextually instead of needing to precisely match the regulatory filing. This is due to the variable lengths of regulatory filings and character limits of systems, as the netContentDescription may not match the regulatory filing word for word because of the need for abbreviations and truncation.

EPCIS events should not be rejected based on these differences.

Element	Usage	Туре	Value			
CURRENT						
netContentDescription	Required	String	The prescribed, regulated or generic product name or denomination that describes the true nature of the product and is sufficiently precise to distinguish it from other products according to country specific regulation. For DSCSA, this should exactly match the regulatory filing for the product.			
CORRECTED						
netContentDescription	Required	String	The prescribed, regulated or generic product name or denomination that describes the true nature of the product and is sufficiently precise to distinguish it from other products according to country specific regulation. For DSCSA, this should match as closely as is possible to the regulatory filing for the product			

3. Archived Documents

Since the release of <u>Applying GS1 System of Standards for DSCSA and Serialized Interoperable</u>
<u>Traceability Implementation Guideline R1.2</u>, some documents referenced in the guideline have been archived. These documents are:

- The Practice of Inference in the U.S. Pharmaceutical Supply Chain
- Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria

If you have any questions related to the material covered in these documents, please reach out to gs1usdscsa@gs1us.org.