



The Global Language of Business

Brazilian Medicine Traceability using GS1 EPCIS Part 1

Implementation Guide

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1 Introduction Purpose of this Document

This document intends to help the implementation of the international GS1 EPCIS standard, with extensions needed to ensure full adherence to the standards set by ANVISA in RDC54 / 2013 and IN6 / 2014 for companies who wish to use this in their events communication systems between the links of the pharmaceutical chain.

1.1 Who Will Use this Document?

This document is intended for Brand Owners, Distributors, Manufacturers, Retailers, Solution Providers, 3PL and any other entity who have decided to use GS1 standards to comply with the Brazilian Regulation for Traceability.

The guidance and EPCIS extensions included in this document are based on the regulations published by ANVISA in RDC54 / 2013 and IN6 / 2014, plus the lessons learnt from the international implementations of traceability.

1.2 Provide feedback and get involved

GS1 standards create a common foundation for business by uniquely identifying, accurately capturing and automatically sharing vital information about products, locations, assets and more. Businesses can also combine different GS1 standards to streamline business processes such as traceability. The GS1 System and architectural components shall not be dependent upon any type of payment of royalties, fees or other considerations to third parties.

The GS1 Standards are made with the market to the market so get involved with the GS1 working groups that maintain this guideline and the related GS1 Standards. Review and provide feedback on the GS1 Standards and on this guide based upon your own experience. You can provide your feedback sending an e-mail to Patricia Amaral (patricia.amaral@gs1br.org) or you can participate of the GS1Brasil Healthcare Working Group meeting.

2 Overview Of The GS1 Standards Used

GS1 Standards support the information needs of end users interacting with each other in supply chains, specifically the information required to support the business processes through which supply chain participants interact. The subjects of such information are the real-world entities that are part of those business processes. Real-world entities include things traded between companies, such as products, parts, raw materials, packaging, and so on. Other real-world entities of relevance to trading partners include the equipment and material needed to carry out the business processes surrounding trade such as containers, transport, machinery; entities corresponding to physical locations in which the business processes are carried out; legal entities such as companies, divisions; service relationships; business transactions and documents; and others. Real-world entities may exist in the tangible world, or may be digital or conceptual. Examples of physical objects include a consumer electronics product, a transport container, and a manufacturing site (location entity). Examples of digital objects include an electronic music download, an eBook, and an electronic coupon. Examples of conceptual entities include a trade item class, a product category, and a legal entity.

This section introduces GS1 Standards that will be used through this guideline. If you need more information about those Standards, you just need to contact your local GS1 member organization.

2.1 GLOBAL LOCATION NUMBER (GLN)

A Global Location Number (GLN) is used to identify any location that needs to be unique for use in the supply chain. The GLN makes possible the unique and unambiguous identification of physical locations and parties used in the supply chain.

GLN can identify a *functional entity* (e.g., a hospital pharmacy), a *physical entity* (e.g., a warehouse or nursing station) or a *legal entity* (e.g., a health system corporation). Each GLN contains attributes [e.g., name, address, location type (e.g., ship to, bill to, deliver to)] to ensure the correct identification of a unique location in the world.

2.2 GLOBAL TRADE ITEM NUMBER (GTIN)

A Global Trade Item Number (GTIN) is used to identify any item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be priced, ordered, or invoiced at any point in any supply chain. A separate, unique GTIN is required whenever any of the pre-defined characteristics of an item are different in any way that is relevant to the trading process

The brand owner, the organization that owns trade item specifications of the trade item regardless of where and by whom it is manufactured, is normally responsible for the allocation of the Global Trade Item Number (GTIN).

2.3 SERIAL SHIPPING CONTAINER CODE (SSCC)

The SSCC (Serial Shipping Container Code) is used for the identification of logistic units. To each individual logistic unit is allocated a unique number, which remains the same for the life of the logistic unit. When assigning an SSCC, the rule is that an individual SSCC number must not be reallocated within one year of the shipment date from the SSCC assignor to a trading partner. However, prevailing regulatory or industry organization specific requirements may extend this period. In principle, the SSCC provides a unique reference number that can be used as the key to access information regarding the logistic unit in computer records.

2.4 GS1 DATA CARRIERS

A data carrier is a mean of representing data in machine-readable form. Data carriers that are endorsed are eight: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags [i.e., GS1 Electronic Product Code (EPC®)-enabled radio frequency identification tags (EPC/RFID Tags)].

2.5 GS1 APPLICATION IDENTIFIERS

Application Identifiers (AIs) are special identifiers positioned within barcodes to indicate the element data they precede. AIs are presented with two, three or four numeric digits. For instance, AI "01" is

used for GTIN. This means that, when an AI "01" appears in the encoded content of a barcode, the next 14 digits are the GTIN digits. There are around 100 different kinds of AIs to encode several element data within the barcode. Each GS1 Identification Number has a corresponding AI.

In order to enable supply chain partners on sharing relevant information encoded in a barcode, secondary information are also represented, such as the GS1 AIs "10" (batch/lot number), "17" (expiration date) and "21" (serial number), which are typically used in Healthcare for track and trace purposes.

2.6 ELECTRONIC PRODUCT CODE

The Electronic Product Code is designed to facilitate business processes and applications that need to manipulate visibility data – data about observations of physical objects. The EPC is a universal identifier that provides a unique identity for any physical object. The EPC is designed to be unique across all physical objects in the world, over all time, and across all categories of physical objects. It is expressly intended for use by business applications that need to track all categories of physical objects, whatever they may be.

By contrast, seven GS1 identification keys defined in the GS1 General Specifications can identify categories of objects (GTIN), unique objects (SSCC, GLN, GIAI, GSRN), or a hybrid (GRAI, GDTI) that may identify either categories or unique objects depending on the absence or presence of a serial number. (Two other keys, GINC and GSIN, identify logical groupings, not physical objects.) The GTIN, as the only category identification key, requires a separate serial number to uniquely identify an object but that serial number is not considered part of the identification key.

There is a well-defined correspondence between EPCs and GS1 keys. This allows any physical object that is already identified by a GS1 key (or GS1 key + serial number combination) to be used in an EPC context where any category of physical object may be observed. Likewise, it allows EPC data captured in a broad visibility context to be correlated with other business data that is specific to the category of object involved and which uses GS1 keys.

2.7 EPC INFORMATION SERVICES (EPCIS)

The EPC Information Services (EPCIS) is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers.

The goal of EPCIS is to enable disparate applications to create and share visibility event data, both within and across enterprises. Ultimately, this sharing is aimed at enabling users to gain a shared view of physical or digital objects within a relevant business context.

2.8 CORE BUSINESS VOCABULARY (CBV)

The Core Business Vocabulary (CBV) specifies the structure of vocabularies and specific values for the vocabulary elements to be utilized in conjunction with GS1 EPCIS for data sharing both within and across enterprises. Designed to ensure a common understanding of data semantics, the use of the CBV is critical to the interoperability of EPCIS implementations.

2.9 GLOBAL ELECTRONIC PARTY INFORMATION REGISTRY (GEPiR)

GEPiR (Global Electronic Party Information Registry) is a unique, internet-based service that gives access to basic contact information for companies that are members of GS1. These member companies use GS1's globally unique numbering system to identify their products, physical locations, or shipments.

2.10 OBJECT NAMING SERVICES (ONS)

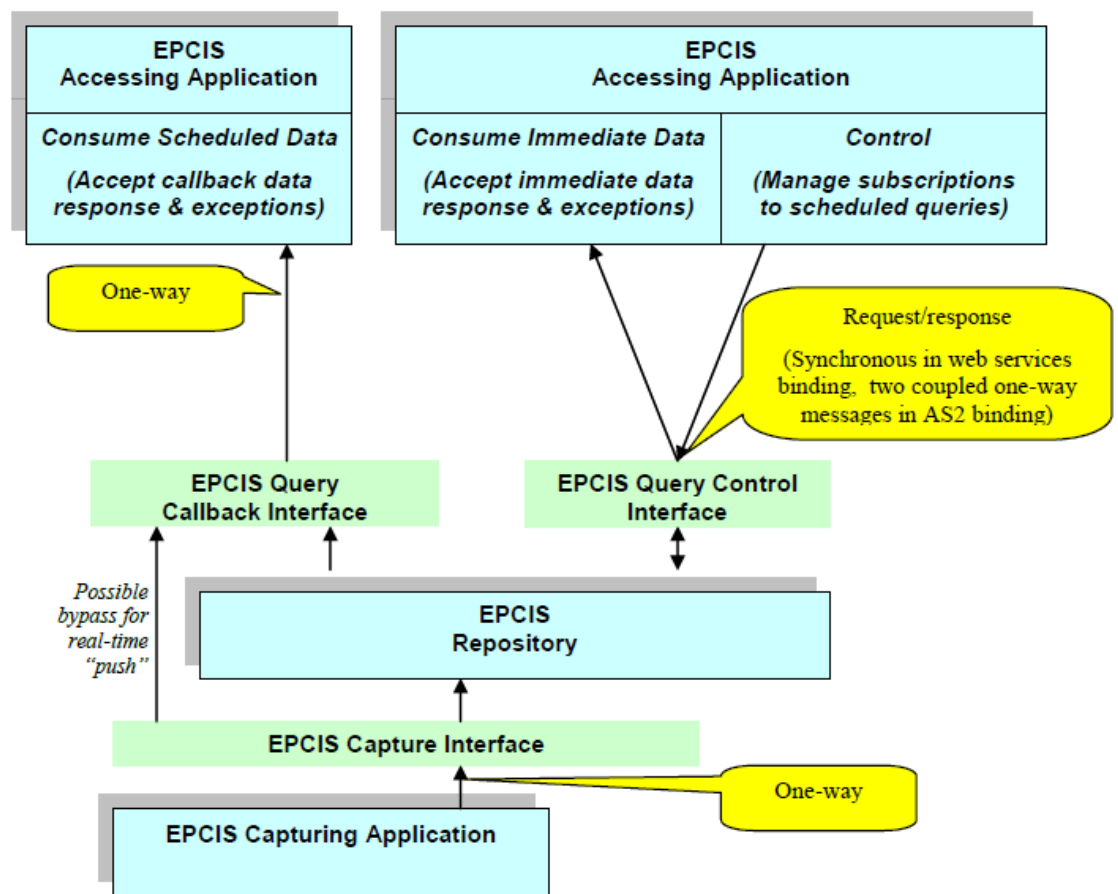
GS1's Object Name Service (ONS) is a lookup service, which uses the Internet's existing Domain Name System (DNS) to resolve information about a GS1 Identification Key. ONS takes a GS1 Key as input, and returns as output the URL of an EPCIS service (or other service) designated by the issuer of the GS1 Key in question.

3 EPCIS Standard

The EPCIS standard defines:

- A **data model** for visibility event data along with an accompanying concrete syntax for visibility data using the eXtensible Markup Language (XML); and
- Open, standardised **interfaces** that allow for seamless integration of well-defined services in inter-company environments as well as within companies. There are two interfaces defined in the EPCIS standard:
 - A **capture interface** through which visibility event data conforming to the EPCIS data model may be delivered from capturing applications to EPCIS-aware business applications; and
 - A **query interface** through which EPCIS event data may be requested by and delivered to a business application or a trading partner.

Bellow there is a example of how both interfaces act together with a consuming application.



Standard interfaces are defined in the EPCIS standard to enable visibility event data to be captured and queried using a defined set of service operations and associated data standards, all combined with appropriate security mechanisms that satisfy the needs of user companies. In many or most cases, this will involve the use of one or more persistent databases of visibility event data, though elements of the Services approach could be used for direct application-to-application sharing without persistent databases.

EPCIS is intended to be used in conjunction with the GS1 Core Business Vocabulary (CBV) standard [CBV1.1]. The CBV standard provides definitions of data values that may be used to populate the data structures defined in the EPCIS standard. The use of the standardized vocabulary provided by the CBV standard is critical to interoperability and critical to provide for querying of data by reducing the variation in how different businesses express common intent. Therefore, applications should use the CBV standard to the greatest extent possible in constructing EPCIS data.

3.1 Anatomy of an EPCIS Event

The information in an EPCIS event records the essentials of what happened during a step of a business process in which physical or digital objects were handled, expressed via the four dimensions of *what*, *where*, *when*, and *why*. This section looks in detail at one EPCIS event for a specific business process step to show exactly how those four dimensions are populated.

The following sections discuss the information content of these data dimensions in more detail.

3.1.1 The *What* Dimension

The What dimension of an EPCIS event identifies the physical or digital objects that were involved in the event. As explained in the GS1 General Specifications and the GS1 Tag Data Standard, trade items are identified using a GTIN, a GTIN plus batch/lot number, or a GTIN plus a serial number. Pallets or logistics units are identified with an SSCC. Other GS1 object identifiers include GDTI for documents, GIAI for individual assets, GRAI for returnable assets, GSRN for services, GCN for coupons, and CPID for components or parts. The *Where* Dimension

3.1.2 The *When* Dimension

The When dimension of an EPCIS event says when the event took place. There are three data elements that are part of this dimension:

- Event Time: The date and time at which the event took place.
- EventTime can be formatted as YYYY-MM-DDThh:mm:ss[timezone indicator]. Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.
- To indicate UTC, the letter Z is added directly after the time component. For example, 2015-06-30T09:30:10Z represents date and time in UTC timezone.

Alternatively, an offset from UTC time can be specified by including a positive or negative time behind the time in the form of ±[hh]:[mm]. For example, 2015-05-30T09:30:10-06:00 represents date and time with 6 hours behind UTC.

- Event Time Zone Offset: The time zone in effect at the place and time of the event. This is useful when an application wants to display the event time using the local time; for example, if a package is shipped from California to Brussels, the event time zone offset can be used to display the ship date/time in US Pacific time and the receiving date/time in Central Europe time.

EventTimeZoneOffset can be formatted as ±[hh]:[mm]. The value of this field SHALL be a string consisting of the character '+' or the character '-', followed by two digits whose value is within the range 00 through 14 (inclusive), followed by a colon character ':', followed by two digits whose value is within the range 00 through 59 (inclusive), except that if the value of the first two digits is 14, the value of the second two digits must be 00.

For example, the value +05:30 specifies that where the event occurred, local time was five hours and 30 minutes later than UTC (that is, midnight UTC was 5:30am local time).

- Record Time: The date and time when the EPCIS event was recorded into an EPCIS repository. Unlike all other fields in the EPCIS event, the record time is not filled in when the event is captured nor does it describe anything about the business step taking place during the event. Record Time is a bookkeeping mechanism that helps when querying an EPCIS repository; with the record time you can tell whether an event returned from a query is a new event since the time of your last query.

RecordTime can be formatted as YYYY-MM-DDThh:mm:ss[timezone indicator]. Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.

3.1.3 The *Where* Dimension

The Where dimension of an EPCIS event captures where the event physically took place and/or where things are following the event.

EPCIS events allow for two location types, readPoint and businessLocation. The readPoint is the location where the event took place. The businessLocation is the location where the object(s) is now

considered to reside until a subsequent event takes place. Locations may be identified using a GS1 Global Location Number (GLN), a GLN plus an extension, an industry identifier other than GLN or using geo-coordinates.

For example, a box may be scanned as it passes through a door portal. The portal it passes through may be the point in which the event is captured. Someone may be physically standing there reading it through the door, or there may be a door portal reader capturing the event. This would be the readPoint. After the boxes passes through the portal, it now sits in a particular location. This location where the box now sits would be the businessLocation. Locations can be identified at a very fine level of granularity (a specific bin in a specific spot in a warehouse), in which case a GLN plus an extension may be necessary. If a location is described at a more general level (a building), a GLN may suffice. It is important to understand how locations will be identified for the purposes of capturing visibility data.

Note, it is vitally important that the master data about locations are synchronized between internal systems or trading partners so when EPCIS refers to location using a GLN or SGLN, one can be assured that all concerned understand the location in the same way.

3.1.4 The Why Dimension

The Why dimension of an EPCIS event describes the business context in which the event took place. It can include any combination of the following data elements:

- **Business Step:** identifies what was taking place from a business perspective at the time of the event; that is, what step of a business process was occurring. Examples include "commissioning", "creating_class_instance", "inspecting", "packing", "picking", "shipping", "retail_selling." The GS1 Core Business Vocabulary (CBV) Standard,
- **Disposition:** identifies the business condition subsequent to the event of the physical or digital objects named in the What dimension. Example dispositions include "active", "in_progress", "in_transit", "expired", "recalled", "retail_sold" and "stolen." The GS1 CBV includes a list of standard Disposition values.
- **Business Transaction List:** identifies one or more particular business transactions that are relevant to an event. A business transaction is identified by a pair of identifiers: one identifier that says what type of business transaction is referenced, and a second identifier that names the particular business transaction of that type. Examples of business transaction types are list of standard business transaction type values.
- **Source List and Destination List:** is used to provide additional business context when an EPCIS event is part of a business transfer of ownership, responsibility or custody. As with business transactions, a source or destination is identified by a pair of identifiers: the type of the source or destination and an identifier of the source or destination of that type. The GS1 distinguishes three standard source/destination types: "owning_party", "possessing_party", "location".

3.1.5 EPCIS Event Types

The four dimensions that describe what is happening to an object in the physical or virtual world are captured in one of four types of an "EPCIS Event". The following is a high level summary of EPCIS event types.

- **ObjectEvent:** represents an event that happened to one or more physical or digital objects. For example shipping or receiving a pallet using the pallet's SSCC. This is the simplest type of event, as well as the most commonly used.
- **AggregationEvent:** represents an event that happened to one or more objects that are physically aggregated together or disaggregated from each other. For example, aggregating cases onto a pallet, or removing cases from a pallet. This is the next most common type of event after ObjectEvent, and these two event types together will cover the vast majority of events in a typical business process.
- **TransformationEvent:** represents an event in which input objects are fully or partially consumed and output objects are produced, such that any of the input objects may have contributed to all of the output objects. For example, consider mixing batter and chocolate chips into cookie dough, then baking the dough into a batch of cookies. Once the ingredients are "transformed",

the resulting product is packaged and labelled with an EAN or UPC that represents “consumer package of chocolate chip cookies” and can be scanned at retail.

- TransactionEvent: represents an event in which one or more objects become associated or disassociated with one or more identified business transactions. For example, linking the pallet and cases of chocolate chip cookies to a commercial invoice.

3.1.6 Actions

The Action type says how an event relates to the lifecycle of the entity being described. For example, AggregationEvent is used to capture events related to aggregations of objects, such as cases aggregated to a pallet. Throughout its life, the pallet load participates in many business process steps, each of which may generate an EPCIS event. The action field of each event says how the aggregation itself has changed during the event: have objects been added to the aggregation, have objects been removed from the aggregation, or has the aggregation simply been observed without change to its membership? The action is independent of the bizStep (of type BusinessStepID) which identifies the specific business process step in which the action took place.

The Action type is an enumerated type having three possible values:

- ADD: The entity in question has been created or added to.
- OBSERVE: The entity in question has not been changed: it has neither been created, added to, destroyed, or removed from.
- DELETE: The entity in question has been removed from the traceability system or stopped been tracked.

3.1.7 EPCIS Fields

Every EPCIS is composed by the same fields but they should be filed in a specific way on each moment of the supply chain. This section will describe all the fields and each use case will explain how to use the fields in his scenery.

ELEMENT	DESCRIPTION	TYPE
eventTime	The date and time at which the event occurred.	dateTime
eventTimeZoneOffset	The time zone offset in effect at the time and place the event occurred, expressed as an offset from UTC.	String
recordTime	Date and time the event was recorded in an EPCIS repository	dateTime
parentID	EPC of the outer container in EPC Pure Identity URI format.	URI
childEPCs	EPC(s) of the item(s) being packed into the parent in EPC Pure Identity URI format.	List of URI
epcList	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 extensions defined below, or should all require these extensions to be omitted. EPCs having different values for these extensions should be shared in different <i>Commissioning</i> events.	List of URI
action	The Action field of an ObjectEvent describes the event's relationship to the lifecycle of the objects and their identifiers named in the event. EPCIS standard action definition for Commissioning is ADD.	String
bizStep	CBV standard definition defining the business step of which this event was a part	URI
disposition	CBV standard definition: the disposition value “active” is always used with the bizStep “commissioning.”	URI
readPoint	EPC Pure Identity URI for the GLN of the location at which the event took place.	URI

ELEMENT	DESCRIPTION	TYPE
bizLocation	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. This can also be represented as URI for alternate Brazil identifiers such as CNPJ number of the location at which the event took place. http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	URI
bizTransactionList	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. Can be Omitted in <i>Commissioning</i> events unless there are relevant business transactions to share	List of biz transactions
sourceList	An unordered list of Source elements that provide context about the originating endpoint of a business transfer of which this event is a part. Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type <code>urn:epcglobal:cbv:sdt:owning_party</code> whose value is the EPC Pure Identity URI for the GLN of the transferring party. If the ship-from GLN is different from the transferring party's GLN, sourceList shall also include a second source of type <code>urn:epcglobal:cbv:sdt:location</code> whose value is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	List of sources
destinationList	An unordered list of Destination elements that provide context about the terminating endpoint of a business transfer of which this event is a part. Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include destination of type <code>urn:epcglobal:cbv:sdt:owning_party</code> whose value is the EPC Pure Identity URI for the GLN of transfer-to party.	List of destinations

3.1.8 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in EPCIS event to attend to Brazilian Regulation. This section will describe all the fields and each use case will explain how to use the fields in this section.

The root schema for the EPCIS Brazil extensions is,

https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd.

ELEMENT	DESCRIPTION	TYPE
eventID	Per the schema published by ANVISA, reportable event attributes include a unique event instance identifier that consists of 12 characters, from '0' to '9' or 'A' to 'Z' (lower case are prohibited). Such characters correspond to digits in hexatrigesimal system (base 36). To maintain uniqueness across issuing companies, eventId URI will contain the issuingParty and the eventIdValue	URI
declaringParty	Business Entity is the responsible party who will originally report the event taking place. This can either be sGLN or a URI for alternate Brazil identifiers such as CNPJ number of the location at which the event took place.	URI

ELEMENT	DESCRIPTION	TYPE
	http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	
carrierParty	Used to capture the carrier, a business service provider who transports the drug product by any means of conveyance (by truck, auto, ship, railroad, etc). This can either be sGLN or a URI for alternate Brazil identifiers such as CNPJ number of the location at which the event took place. http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	URI
natureOfMovement	Used to capture specific movement types required by ANVISA PURCHASE_SALE TRANSFERENCE DONATION RETURN COLLECTION FREE_SAMPLE	String
expectedNumUnits	Identifies the expected number of units inside the Nota Fiscal (invoice)	Integer
expectedNumUnitUOM	Denotes the package level associated with the value in expectedNumUnits ITEM, BUNDLE, CASE, PALLET	Integer
postRecoveryBatch	Updated batch number for the recovered unit	String
Reason	Motive or reason statement for the event taking place	String
retractionFlag	Flag to indicate whether event record is being retracted because it is incorrectly recorded. retractionFlag is not set when the event is first recorded. When an error has been detected in a previously recorded event, the erroneous record is retracted by re-recording the same event with the retractingFlag set to true .	Boolean
replacementEventID	Event instance identifier of the replacement event record. This is OMITTED when an event is declared as invalid and no replacement event is issued to correct the invalid information. replacementEventID is required for correction events that are intended to issue and report corrected information.	URI
retractionReason	Reason statement explaining the nature of the error detected in a previously reported event. retractionReason shall be OMITTED for an ordinary event wherein the retractionFlag is false or omitted. retractionReason shall be included when retractionFlag is true. retractionReason is required for reporting a rectification event to ANVISA.	String

3.1.9 EPCIS Extension Elements

The EPCIS standard provides for data elements not specified in the standard to be included in EPCIS events as extensions. This is done by including additional XML elements just before the closing tag for an event, where those XML elements are in an XML namespace other than the EPCIS namespace.

This EPCIS guideline also provides for specific ILM data elements defined by this guideline. These ILM data elements are also in an XML namespace other than the EPCIS namespace.

All extensions and ILM elements defined in this guideline are defined in the following XML namespace:

<http://epcis.gs1br.org/hc/ns>

All XML illustrations in this guideline use the prefix "gs1brhc" to denote this XML namespace. This means that an extension and an ILMD element would look like this:

```
<epcis:EPCISDocument xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns" ...>
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>...</eventTime>
        ...
        <bizTransactionList>
          ...
        </bizTransactionList>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

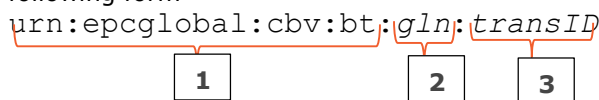
3.1.9.1 Extending Business Transaction Types

The EPCIS standard provides for a business transaction to be identified by a pair of identifiers, the "business transaction identifier" (hereinafter "BTI") that names a particular business transaction, and an optional "business transaction type" (hereinafter "BTT") that says what kind of business transaction the identifier denotes (purchase order, invoice, etc.).

When using a standard business transaction type, the value of the business transaction type attribute shall be a URI consisting of the prefix **urn:epcglobal:cbv:bt:** followed by one of the predefined business transaction type listed in section 7.3.2 of the Core Business Vocabulary. When needed, additional business transaction types can be defined using the URI form, <http://epcis.gs1br.org/hc/btt/new-business-transaction-type>

The business transaction identifier can be defined either as GLN-based URI or a custom alternate identifier based URI.

A GLN-based URI used as a business transaction identifier in all EPCIS event types has the following form



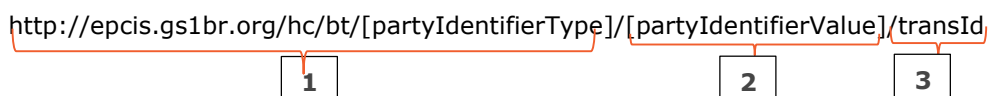
The GLN-Based URI consists of the following:

1. Prefix String urn:epcglobal:cbv:bt
2. GLN – 13 digit Global Location Number representing the business party responsible for the business transaction identifier
3. transID – Business Transaction Identifier that is unique within the business party entity represented by the GLN

An HTTP URL for non-GLN based business identifier has the following format:

http://[Subdomain.]Domain/**/bt/transID

For Brazil, the URI for a CNPJ based transaction identifier has the following form:



A non-GLN based URI consists of the following:

1. URI business transaction prefix issued with specified Party Identifier Type (i.e. CNPJ)
2. Party Identifier Value
3. transId – Business Transaction Identifier that is unique within the business party entity represented by the CNPJ

*** Note: URI business transaction prefix + Party Identifier Value together defines a business transaction field element issued with a given Party Identifier Type

The following are various bizTransaction usage examples to illustrate how a bizTransaction field can be captured using a combination of pre-defined or custom business transaction type and pre-defined or custom business transaction identifier.

Example of business transaction element using a pre-defined business transaction type, invoice and a GLN-based transaction identifier.

```
<bizTransaction type="urn:epcglobal:cbv:btt:inv">  
  urn:epcglobal:cbv:bt:0300011111116:A123  
</bizTransaction>
```

Example of business transaction element using a pre-defined business transaction type, invoice and a CNPJ-based transaction identifier.

```
<bizTransaction type="urn:epcglobal:cbv:btt:inv">  
  http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/A123  
</bizTransaction>
```

Example of business transaction element using new business transaction type, delivery with a GLN-based transaction identifier.

```
<bizTransaction type="http://epcis.gs1br.org/hc/btt/delivery">  
  urn:epcglobal:cbv:bt:0300011111116:456  
</bizTransaction>
```

Example of business transaction element using new business transaction type, delivery with a CNPJ-based transaction identifier.

```
<bizTransaction type="http://epcis.gs1br.org/hc/btt/delivery">  
  http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/456  
</bizTransaction>
```

3.1.9.3 Utilizing Business Transaction to convey Brazilian Nota Fiscal information

Local Brazil business practices require exchange of key documents to conduct business and comply with government regulations. For example, a nota fiscal is a statutory tax document required to accompany any movement of goods.

When trading partners exchange information when shipping, receiving or importing goods, nota fiscal details such as nota fiscal document number, transaction fiscal series code, and CNPJ identifier for the associated business party will be conveyed in the message exchange. To support this requirement, the EPCIS business transaction list structure will be utilized and extended to define a nota fiscal business transaction type.

The following describes the recommended make-up of the bizTransaction structure for conveying nota fiscal information in the EPCIS event.

1. Define new business transaction type called **<http://epcis.gs1br.org/hc/btt/notafiscal>**
2. Define the business transaction identifier using the following formatting convention:
`http://epcis.gs1br.org/hc/bt/[partyIdentifierType]/[partyIdentifier]/[notaFiscalDocumentNumber].[notaFiscalSeriesCode]`

partyIdentifierType can be one of the following: gln or one of the local Brazil identifiers such as cnpj, cpf, cnes, professionalReg, entityAbroad

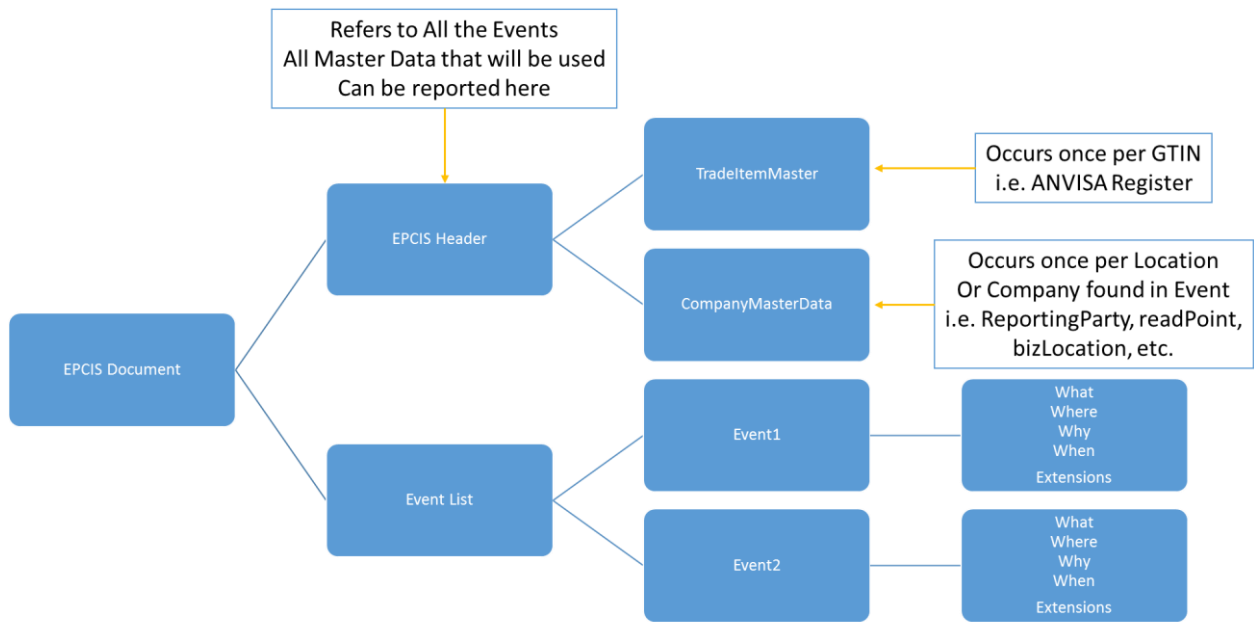
Below shows the resulting nota fiscal business transaction identifier given a set of example parameters:

- partyIdentifierType = cnpj
- partyIdentifier = 72934568000190
- notaFiscalDocumentNumber = 987654321
- notaFiscalSeriesCode = 99999999
- Resulting nota fiscal business transaction identifier
- **`http://epcis.gs1br.org/hc/bt/cnpj/72934568000190/987654321.99999999`**

Assembling the 2 custom defined business transaction components, the resulting bizTransaction field definition takes the following form:

```
<bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">  
  http://epcis.gs1br.org/hc/bt/cnpj/72934568000190/987654321.99999999  
</bizTransaction>
```

3.1.10 Structure of EPCIS Event Messages for Serialized Item-Level Traceability



3.1.10.1 Master Data Extension

Master data is included in the EPCIS Header of an EPCIS document within the masterData extension. The content of this extension is a VocabularyList element that conforms to the EPCIS Master Data Schema.

Company Elements

Each company element has an ID that is the EPC Pure Identity Pattern URI corresponding to the party identifier. The attributes are defined below:

Element	Usage	Type	Value
identifierType	Optional	String	Company Identifier Types such <i>CNPJ, CPF, CNES, PROFESSIONALREG, ENTITYABROAD, SGLN</i>
companyName	Required	String	
street1	Required	String	The first line of the street address.
street2	Optional	String	The second line of the street address.
city	Required	String	The city.
stateOrRegion	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The CEP or other postal code.
country	Required	String	The country using the standard three-letter country codes specified in ISO 3166-1 alpha-3:1974.
latitude	Optional	Decimal	The latitude of the address represented as decimal value (10,6). Although the pair of latitude and longitude values is optional, both values should be included since latitude is used together with longitude to specify a location.
longitude	Optional	Decimal	The longitude of the address represented as decimal value (10,6) Although the pair of latitude and longitude values is optional, both values should be included since latitude is used together with longitude to specify a location.

Since shared master data information are listed once in the EPCIS header extensions, the EPCIS event detail content is streamlined to reduce the size of the message payload for the messages exchanged between trading partners.

3.1.10.2 Fileset Pagination Extension

Since the size of data exchanges between Brazil supply chain links is limited to 512KB, a fileset pagination extension will be included in the EPCIS header to enable the sending party to convey the expected number of total files that will be transmitted and received by the receiving party.

filesetPagination structure has the following elements:

Element	Usage	Type	Value
filesetIdIdentifier	Optional	Integer	Numeric identifier assigned to the file set unifying the various instances of files that have been split due to size constraints.
instance	Optional	Integer	The current instance file number This value can be between 1 and the value in <i>total</i> element
total	Optional	Integer	The total number of files in the fileset

To uniquely group the split file messages together, **filesetIdIdentifier from the filesetPagination construct** will be kept the same for each file in the split file set.

For example, if the sender splits the message into 5 files, the following shows how **filesetIdIdentifier** ties together the first and second of the five files getting transmitted:

This is an example of transmitting file 1 of 5 in fileset 100

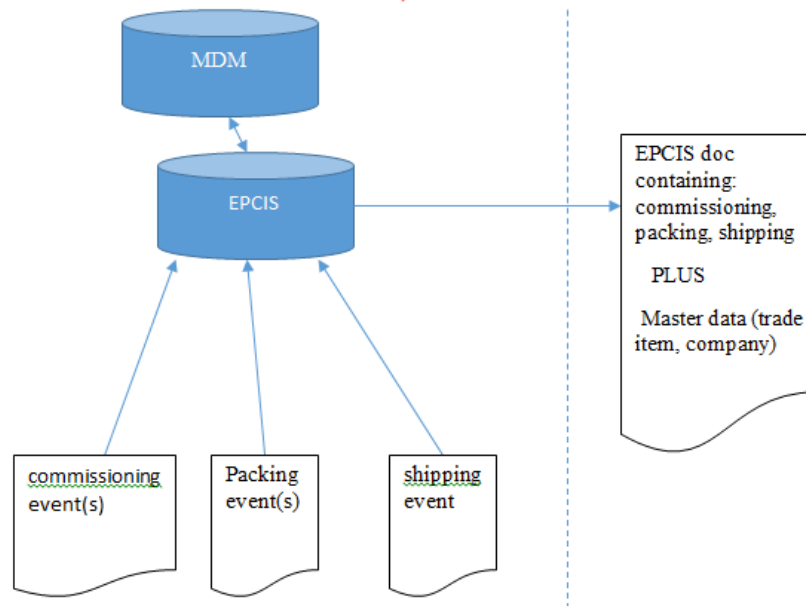
```
<gs1brhc:filesetPagination>
  <gs1brhc:filesetIdIdentifier>100</gs1brhc:instance>
  <gs1brhc:instance>1</gs1brhc:instance>
  <gs1brhc:total>5</gs1brhc:total>
</gs1brhc:filesetPagination>
```

This is an example of transmitting file 2 of 5 in fileset 100

```
<gs1brhc:filesetPagination>
  <gs1brhc:filesetIdIdentifier>100</gs1brhc:instance>
  <gs1brhc:instance>2</gs1brhc:instance>
  <gs1brhc:total>5</gs1brhc:total>
</gs1brhc:filesetPagination>
```

3.1.10.3 Usage of EPCIS Header for Communications Across Systems

It should be noted that EPCIS header extensions are not required when internally capturing EPCIS events for storing in an event repository. At time of event capture, EPCIS repository draws from Master Data Management (MDM) systems or profiles to provide the necessary trade item and company master business context. However, when EPCIS events are exchanged with trading partners, master data can either be provided in the EPCIS header extension sections or retrieved from industry master data repositories such as Global Location Number (GLN) Registry or Global Data Synchronization Network (GDSN).



Event specific sections describe and list the fields for adequately capturing the EPCIS events for trade partner exchanges and for enabling ANVISA government reporting. These EPCIS events will be collected together to form EPCIS XML message content with EPCIS Header extensions to fulfill various business scenarios, which will be included in Part II of this guideline as a supplementary material.

3.1.10.4 Example of utilizing EPCIS Header for Brazil requirements

The following illustrates the use of EPCIS Header for conveying message level details such as sender, receiver, file split page identification. The example also demonstrates how EPCIS Header can be utilized to streamline the sharing of company master details relevant to all the EPCIS events contained in the EPCIS message.

```
<EPCISHeader>
  <sbdh:StandardBusinessDocumentHeader>
    <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
    <sbdh:Sender>
      <sbdh:Identifier
Authority="SGLN">urn:epc:id:sgln:789123.111110.0</sbdh:Identifier>
    </sbdh:Sender>
    <sbdh:Receiver>
      <sbdh:Identifier
Authority="CNPJ">http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</sbdh:Identifier>
    </sbdh:Receiver>
    <sbdh:DocumentIdentification>
      <sbdh:Standard>EPCglobal</sbdh:Standard>
      <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
      <sbdh:InstanceIdentifier>517055050</sbdh:InstanceIdentifier>
      <sbdh:Type>Events</sbdh:Type>
      <sbdh:CreationDateAndTime>2015-06-30T18:14:27.574-
04:00</sbdh:CreationDateAndTime>
    </sbdh:DocumentIdentification>
  </sbdh:StandardBusinessDocumentHeader>
  <!--Example showing how to indicate that this file contains first of set of 3
files that will be transmitted
```



```

    by sender to receiver. 1 of 3 filesetPagination was arbitrarily chosen --
>
<gslbrhc:filesetPagination>
  <gslbrhc:filesetIdentifier>103</gslbrhc:filesetIdentifier>
  <gslbrhc:instance>1</gslbrhc:instance>
  <gslbrhc:total>3</gslbrhc:total>
</gslbrhc:filesetPagination>
<gslbrhc:masterData>
  <epcis:md:VocabularyList>
    <Vocabulary type="urn:epcglobal:epcis:vtype:SourceDest">
      <VocabularyElementList>
        <VocabularyElement id="urn:epc:id:sgln:789123.111110.0">
          <attribute
id="http://epcis.gslbr.org/hc/mda/identifierType">SGLN</attribute>
          <!-- Example of when the id is a CNPJ
          <VocabularyElement
id="http://epcis.gslbr.org/hc/cnpj/loc/12345678000195">
            <attribute
id="http://epcis.gslbr.org/hc/mda/identifierType">CNPJ</attribute>
            -->
            <attribute id="http://epcis.gslbr.org/hc/mda/companyName">Pharma
LLC</attribute>
            <attribute id="http://epcis.gslbr.org/hc/mda/street1">1456 Av.
Conceição Vieira</attribute>
            <attribute id="http://epcis.gslbr.org/hc/mda/street2">Room
378</attribute>
            <attribute
id="http://epcis.gslbr.org/hc/mda/city">Pinheiros</attribute>
            <attribute
id="http://epcis.gslbr.org/hc/mda/stateOrRegion">SP</attribute>
            <attribute
id="http://epcis.gslbr.org/hc/mda/postalCode">72230001</attribute>
            <attribute id="http://epcis.gslbr.org/hc/mda/country">BRA</attribute>
            <attribute id="http://epcis.gslbr.org/hc/mda/latitude">-
44.467762</attribute>
            <attribute id="http://epcis.gslbr.org/hc/mda/longitude">-
4.043813</attribute>
          </VocabularyElement>
          <VocabularyElement id="urn:epc:id:sgln:789123.111111.0">
            <!-- Example of when the id is a CNPJ
            <VocabularyElement
id="http://epcis.gslbr.org/hc/cnpj/loc/12345678000276">
              <attribute
id="http://epcis.gslbr.org/hc/mda/identifierType">CNPJ</attribute>
              -->
              <attribute id="http://epcis.gslbr.org/hc/mda/companyName">Pharma LLC
DC</attribute>
              <attribute id="http://epcis.gslbr.org/hc/mda/street1">1456 Av.
Conceição Vieira</attribute>
              <attribute id="http://epcis.gslbr.org/hc/mda/street2">Room
500</attribute>
              <attribute
id="http://epcis.gslbr.org/hc/mda/city">Pinheiros</attribute>
              <attribute
id="http://epcis.gslbr.org/hc/mda/stateOrRegion">SP</attribute>
              <attribute
id="http://epcis.gslbr.org/hc/mda/postalCode">72230001</attribute>
              <attribute id="http://epcis.gslbr.org/hc/mda/country">BRA</attribute>
              <attribute id="http://epcis.gslbr.org/hc/mda/latitude">-
44.467762</attribute>
              <attribute id="http://epcis.gslbr.org/hc/mda/longitude">-
4.043813</attribute>
            </VocabularyElement>
            <VocabularyElement
id="http://epcis.gslbr.org/hc/cnpj/loc/87654321000198">

```

```

        <attribute
id="http://epcis.gslbr.org/hc/mda/identifiertype">CNPJ</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/companyname">3PL
Headoffice XYZ123</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street1">7890 Av.
Conceição Vieira</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street2">Room
378</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/city">Pinheiros</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/stateorregion">SP</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/postalcode">72230001</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/country">BRA</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/latitude">-
44.467764</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/longitude">-
4.043815</attribute>
    </VocabularyElement>
    <VocabularyElement id="urn:epc:id:sgln:863662.100100.0">
    <!-- Example of when ID is a CNPJ
    <VocabularyElement
id="http://epcis.gslbr.org/hc/cnpj/loc/86256136000182">
        <attribute
id="http://epcis.gslbr.org/hc/mda/identifiertype">CNPJ</attribute>
        -->
        <attribute id="http://epcis.gslbr.org/hc/mda/companyname">
Carrier Enviou Chegou LTDA
        </attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street1">3587 Av. Pacheco
Nobre</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street2">Room
378</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/city">Anápolis</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/stateorregion">GO</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/postalcode">72320355</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/country">BRA</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/latitude">-
44.467768</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/longitude">-
4.043819</attribute>
    </VocabularyElement>
    <VocabularyElement
id="http://epcis.gslbr.org/hc/cnpj/loc/11223344000186">
        <attribute
id="http://epcis.gslbr.org/hc/mda/identifiertype">CNPJ</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/companyname">
Hospital Pharmacy ABC123
        </attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street1">31122 Av.
Conceição Vieira</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street2">Room
378</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/city">Pinheiros</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/stateorregion">SP</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/postalcode">72230001</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/country">BRA</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/latitude">-
44.467768</attribute>

```

```
        <attribute id="http://epcis.gslbr.org/hc/mda/longitude">-
4.043819</attribute>
        </VocabularyElement>
    </VocabularyElement
id="http://epcis.gslbr.org/hc/cnpj/loc/11223344000348">
        <attribute
id="http://epcis.gslbr.org/hc/mda/identififierType">CNPJ</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/companyName">
            Hospital Pharmacy ABC DC
        </attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street1">1127 Av.
Conceição Vieira</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/street2">Room
987</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/city">Pinheiros</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/stateOrRegion">SP</attribute>
        <attribute
id="http://epcis.gslbr.org/hc/mda/postalCode">72230001</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/country">BRA</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/latitude">-
44.467762</attribute>
        <attribute id="http://epcis.gslbr.org/hc/mda/longitude">-
4.043832</attribute>
        </VocabularyElement>
    </VocabularyElementList>
</Vocabulary>
</epcismd:VocabularyList>
</gslbrhc:masterData>
</EPCISHeader>
```

4 Data Format for EPCIS

The Electronic Product Code is a universal identifier for any physical object. It is used in information systems that need to track or otherwise refer to physical objects. Within computer systems, including electronic documents, databases, and electronic messages, the EPC takes the form of an Internet Uniform Resource Identifier (URI). This URI is called the "Pure Identity EPC URI." The following is an example of a Pure Identity EPC URI:

```
urn:epc:id:sgtin:0614141.112345.400
```

There is a well-defined relationship between EPCs and GS1 keys. For each GS1 key that denotes an individual physical object (as opposed to a class), there is a corresponding EPC. This correspondence is formally defined by conversion rules specified in GS1 Tag Data Standard Section 7, which define how to map a GS1 key to the corresponding EPC value and vice versa. The well-defined correspondence between GS1 keys and EPCs allows for seamless migration of data between GS1 key and EPC contexts as necessary.

This section intends to show how to translate the GS1 Keys used in the Brazilian Traceability Model into EPC URI Format.

4.1 GTIN

In the GS1 System, products, cases and kits are identified with the Global Trade Item Number (GTIN). GTIN is a globally unique, standards-based, identification number for trade items. When a manufacturer assigns ("allocates") a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These product description attributes define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 Standards specify the list of attributes that must be defined for each GTIN, as well as the permissible values.

4.1.1 ASSIGNING GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). In the the Brazilian Market the most used are GTIN-13 and GTIN-14. The choice of format is related to point of sale scanning:

- Assign a GTIN-13 to pharmaceuticals products that will be scanned at point of sale.
- Assign a GTIN-14 to pharmaceuticals that will not be scanned at point of sale.

4.1.2 CREATING A GTIN-13

Each GTIN-13 is a numerical string comprising three distinct segments. The three segments within a GTIN-13 are:

- **GS1 Company Prefix:** A specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-13 identifiers. GS1 Company Prefixes vary in length depending on the company/organization's needs
- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The Item Reference varies in length as a function of the GS1 Company Prefix length. (Refer to the GS1 General Specifications and the GTIN Allocation Rules for the Healthcare Sector for additional information)
- **Check Digit:** A one-digit number calculated from the first 12 digits of the GTIN-13 used to ensure data integrity. The check digit calculator can be found at [http://www.gs1.us.org/solutions/services/tools/check digit calculator](http://www.gs1.us.org/solutions/services/tools/check%20digit%20calculator).

4.1.3 CREATING A GTIN-14

Each GTIN-14 is a numerical string comprising four distinct segments. It is important to state that the GTIN-14 is based on a GTIN-13 of a Trade Item. The four segments within a GTIN-13 are:

- **GS1 Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8. (The number "0" is used in this position as a fill character when a GTIN-13 is written in 14-digit format.)

- Packaging specialists must review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product. This ensures that there is a unique GTIN on every packaging level, which is imperative to preserve the uniqueness of each GTIN.
- GS1 Company Prefix: A specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-14 identifiers. GS1 Company Prefixes vary in length depending on the company/organization's needs
- Item Reference: A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The Item Reference varies in length as a function of the GS1 Company Prefix length. (Refer to the GS1 General Specifications and the GTIN Allocation Rules for the Healthcare Sector for additional information)
- Check Digit: A one-digit number calculated from the first 13 digits of the GTIN-14 used to ensure data integrity. The check digit calculator can be found at <http://www.gs1.us.org/solutions/services/tools/check-digit-calculator>.

4.1.4 CODING A GTIN-13 INTO A GS1 DATAMATRIX

The GS1 DataMatrix is a two dimensional (2D) symbology that allows codification with the use of Application Identifiers (AI), a series of information such as: product identification (GTIN), expiration date, batch, serial number, etc. The RDC 54/2013 states that the Datamatrix bar code symbol should encode at least the following data that makes up the IUM (Unique Medicine Identifier):

- I - ANVISA medicine registry number;
- II - Serial number;
- III - Expiration Date;
- IV - Batch Number.

Although the GTIN is not mandatory in RDC 54/2013, it will be combined with the Unique Medicine Identifier (IUM) due to market requirements, as shown below:



If you need more information there is a specific guide to support medicine codification that can be found on GS1 Brazil website.

4.1.5 GTIN DATA FORMAT FOR EPCIS

Within the EPCIS, GTIN + serial number must be stored in EPC URI format. The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC). The SGTIN EPC is based on a 14-digit GTIN. Therefore, GTIN-13s will first need to be converted to a 14-digit number by adding two leading zeros. (An example of the conversion is provided below).

- General syntax:

`urn:epc:id:sgtin:CompanyPrefix.ItemReference.SerialNumber`

- Example:

`urn:epc:id:sgtin:0614141.112345.400806`

To find the EPC URI corresponding to the combination of a GTIN-13 and a serial number, first convert the GTIN-13 to a 14-digit number by adding one leading zero characters. The leading zero will serve as the Indicator Digit as shown below:

Example: Converting a GTIN13 + Serial Number into an EPC URI Format:

GTIN-13	789836741 001 5
GTIN-13 in 14-digit format	0 789836741 001 5
Serial Number	1234567890123
Corresponding Barcode Human Readable Text	(01) 0 789836741 001 5
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 789836741.0001. 1234567890123

4.1.6 DATA STORAGE OPTIONS

GTIN and serial number are assigned as separate data elements, but are saved together as an SGTIN in EPCIS. Users have several options for how to store GTIN + serial number in databases:

- 2 fields = GTIN field and Serial Number field
- 1 field = One field containing serialized GTIN in EPC URI format
- 3 fields = GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in table below:

Field	Data Format
GTIN	<ul style="list-style-type: none"> ■ 14 digits ■ text field (not numeric)
Serial Number	<ul style="list-style-type: none"> ■ 1-20 characters ■ text field (not numeric)
Serialized GTIN EPC URI	<ul style="list-style-type: none"> ■ 33-52 characters: <ul style="list-style-type: none"> □ 17 characters for "urn:epc:id:sgtin:" □ 13 characters for the GTIN (without the Check Digit) □ 1-20 characters for the serial number □ 2 periods (".") ■ text field (not numeric)

4.2 SSSC

In the GS1 System, logistics units such as cases, pallets and totes are identified with the Serial Shipping Container Code (SSCC). The SSCC is an 18-digit, globally unique, standards-based, identification number for logistics units. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

According to RDC54/2013 – Article 9: "The transport packaging should contain an identifier code in which all IUM that make up the package are listed."

For this function, the use of the SSCC (Serial Shipping Container Code) is recommended.

4.2.1 CREATING A SSCC

Suppliers are responsible for assigning (allocating) SSCCs to their logistics units. Each SSCC is a numerical string comprising four distinct segments. The four segments within an SSCC are:

- Extension Digit: The Extension Digit has no defined logic. It is available to the company to increase the capacity of the Serial Reference. The field consists of a numeric value from 0 to 9.
- GS1 Company Prefix: A specific representation of a GS1 Company Prefix that serves as the foundation for generating SSCC identifiers. GS1 Company Prefixes vary in length depending on the company/organization's needs
- Serial Reference: A number assigned by the holder of the GS1 Company Prefix to uniquely identify a logistic unit. This segment is the "serial" part of the number assigned one-by-one by the company to create a globally unique SSCC. The Serial Reference varies in length as a function of the GS1 Company Prefix length.
- Check Digit: A one-digit number calculated from the first 17 digits of the SSCC used to ensure data integrity. The check digit calculator can be found at <http://www.gs1.us.org/solutions/services/tools/check-digit-calculator>.

4.2.2 CODING A SSCC INTO A GS1-128

The GS1-128 bar code symbology (data carrier) is recommended to encode static and dynamic (variable) information and is ideally suited to the needs of identifying transport packaging for traceability. This is where information regarding the product, batch, expiration date and SSCC will be inserted, using the AI (Application Identifiers) structure. An example of the SSCC coded into a GS1-128 is show below:



If you need more information there is a specific guide to support medicine codification that can be found on GS1 Brazil website.

4.2.3 SSCC DATA FORMAT FOR EPCIS

Within the EPCIS, SSCCs must be stored in EPC URI format. The EPC URI format for an SSCC is the SSCC EPC.

- General syntax:
`urn:epc:id:sscc:CompanyPrefix.SerialReference`
- Example:
`urn:epc:id:sscc:0614141.1234567890`

Below you can see an example of how to code an SSCC into the EPC format:

Example: Converting a SSCC into an EPC URI Format:

SSCC	0 789836741 0000025 1
Corresponding Barcode Human	(00) 0 789836741 0000025 1
Readable Text	
Corresponding SSCC-EPC URI	urn:epc:id:sscc: 789836741.00000025

4.2.4 DATA STORAGE OPTIONS

When storing SSCCs in databases, these can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

- 1 field = SSCC
- 1 field = SSCC in EPC URI format
- 2 fields = SSCC field and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below:

Field	Data Format
SSCC	<ul style="list-style-type: none"> ■ 14 digits ■ text field (not numeric)
SSCC URI	<ul style="list-style-type: none"> ■ 1-20 characters ■ text field (not numeric)

4.3 GLN

In the GS1 System, parties and locations are identified with the Global Location Number (GLN). The GLN is a 13-digit, globally unique, standards-based, identification number for legal entities, functional entities, and physical locations. Each company is responsible for assigning (allocating) GLNs to its own parties and locations. When a user assigns a GLN, they define a prescribed set of data about the party/location to which that GLN relates (e.g., street address, floor, etc.). These GLN attributes define master data about the party/location (e.g., name, address, class of trade, etc.), which help to ensure that each GLN is specific to one, very precise location within the world. The GLN and its associated attributes are then saved in a database or exchange through the header of the EPC message.

Use of GLN Extensions is optional. Sub-locations can be identified by assigning a unique GLN to the sub-location, or by using a GLN Extension with the location’s GLN. There is no rule for when to assign a new GLN versus when to use a GLN Extension. However, GS1 has identified the following Best Practices to assist companies in making this decision:

- For sub-locations that will never be used as an address (e.g., shelf, door, etc.), use GLN Extensions in order to conserve GLNs.
- For sub-locations where the identifier will be used for purposes other than EPCIS events (e.g., EDI), assign a unique top-level GLN to that sub-location.

4.3.1 CREATING A GLN

Each GLN is a numerical string comprising three distinct segments. The three segments within a GLN are:

- **GS1 Company Prefix:** A specific representation of a GS1 Company Prefix that serves as the foundation for generating GLN identifiers. GS1 Company Prefixes vary in length depending on the company/organization’s needs
- **Location Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a Location. The Item Reference varies in length as a function of the GS1 Company Prefix length. (Refer to the GS1 General Specifications and the GLN Allocation Rules for the Healthcare Sector for additional information)
- **Check Digit:** A one-digit number calculated from the first 12 digits of the GLN used to ensure data integrity.

4.3.2 GLN DATA FORMAT FOR EPCIS

Within the EPCIS, GLNs must be stored in EPC URI format. The EPC URI format for a GLN (with or without Extension) is the Serialized Global Location Number EPC (SGLN EPC).

- General syntax:

`urn:epc:id:sgtin:CompanyPrefix.LocationReference.Extension`

■ Example:

urn:epc:id:sgln:0614141.112345.0

Below you can see an example of how to code an GLN into the EPC format:

Example: Converting a SSCC into an EPC URI Format:

GLN	789836741 001 5
Corresponding Barcode Human Readable Text	(414) 789836741 001 5
Corresponding GLN-EPC URI	urn:epc:id:gln: 789836741. 001.0

4.3.3 DATA STORAGE OPTIONS

When storing SGLNs in databases, these can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing a GLN with extension in databases:

- 2 fields = GLN field and GLN Extension field
- 1 field = One field containing GLN + extension in EPC URI format
- 3 fields = GLN field, GLN Extension field, and field containing GLN +extension in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below:

Field	Data Format
GLN	<ul style="list-style-type: none"> ■ 13 digits ■ text field (not numeric)
GLN Extension	<ul style="list-style-type: none"> ■ 1-20 characters ■ text field (not numeric)
SGLN EPC URI	<ul style="list-style-type: none"> ■ 31-50 characters: <ul style="list-style-type: none"> □ 16 characters for "urn:epc:id:sgln:" □ 12 characters for the GLN (no Check Digit) □ 1-20 characters for the GLN extension □ 2 periods ('.') ■ text field (not numeric)

5 Regulatory Information

5.1 Application to the ANVISA RDC 54/2013

For the purposes of this guideline, the RDC 54/2013 can be viewed as a two-milestone implementation over three years.

- The first milestone, at December 10th 2015, defines that all supply chain participants get involved in a pilot exercise of at least 3 (three) batches of pharmaceutical products serialized and tracked with complete traceability technology implemented. The traceability information required for these batches involves the end-to-end movement of goods, from the manufacturing plant, including transaction between subsidiaries, until the sales or administration point, that can be understood as a hospital, drug store, physician handling free samples, and others. The responsibility to report the traceability information to Anvisa resides with the Industry and an alignment of assumptions and approach is required with all other supply chain participants to make this pilot phase happen.
- The second RDC 54/2013 milestone, ending on December 10th 2016, requires that all supply chain participants have already in place the processes and technology to support the serialization and traceability of all pharmaceutical products which are commercialized in Brazil having an ANVISA sanitary register. All movement of goods need to be registered by all these participants, including subsidiaries, within their information systems, and it is the Industry responsibility to consolidate all this information and fulfill Anvisa expected reporting requirements. Anvisa defines the Datamatrix as the mechanism to identify serialized pharmaceutical products and leaves with the Industry the responsibility to create, own and maintain a traceability solution that will connect all the supply chain participants in a specific IT solution. The use of GS1 Identification Numbers, Application Identifiers, and Data Carriers (barcodes and RFID tags) are covered in the guide for medicine codification.

Both milestones consider that trading partners will share chain-of-custody data in a manner that allows for serialized item traceability back to the product origin (the manufacturer). The expanded use of EPCIS events for serialized item traceability are covered in Part 5 of this document.

It is important to mention that Anvisa expects all registered pharmaceutical products manufactured after December 10th, 2016 to be serialized and tracked, meaning that inventory available in any supply chain participant will be commercialized normally until a complete inventory turnover occurs. All supply chain participants will need to create and maintain processes and mechanisms to ensure both serialized and non-serialized products can co-exist for a certain amount of time.

5.2 Item level application

5.2.1 Unique Medicine Identifier (IUM)

IUM is a terminology defined by Anvisa representing the identification of a single product, with the purpose of traceability. The IUM is a series of numeric characters, alphanumeric characters or special characters, created through identification and coding standards, allowing for unique and unambiguous identification of each unit of a specific medication.

The IUM gives the condition for a medicine to be located anywhere within the participants of the chain of pharmaceutical products.

Pharmaceutical companies, 3PLs, Wholesale Distributors, doctors and pharmacies, are those participants and belong to Brazilian pharmaceutical production chain.

Anvisa makes it clear that the product registration owner is responsible for the generation of the IUM (Unique Drug Identifier) in all pharmaceutical products commercialized in the country. The IUM is composed by:

- Anvisa Drug registration number (13 digits)
- Serial Number (13 random numerical digits, non-repetitive)
- Expiration date (MM/YY format)

- Lot Number

Note: In agreement Brazilian Pharmaceutical industry, has agreed to include the GTIN international standard within the Datamatrix. The GTIN code will be placed in the Datamatrix before the IUM.

Having the mandatory information above applied to a product does not replace any other existing regulation. An example is the manufacturing date, which is also mandatory in human readable form according to the RDC 71/2009.

Supply chain participants will then be identifying pharmaceutical products with a GTIN in GS1 Standards, Drug Registration Code, Serial Number, Expiration Date and Lot Number, and marking product identifiers on products in both machine-readable (e.g., datamatrix) and human-readable format.

It is also worthwhile to say that a unique identification needs to be present in the secondary and tertiary packaging levels. In cases where the secondary packaging does not exist, the identification needs to be present in the primary packaging.

The current version of this guideline provides the basics on how to share change-of-custody information at the serialized item level. Future versions of this guideline will provide information on how to manage in a mixed environment, and provide specific guidance on exception processing and additional forward and reverse logistics events.

5.2.2 Definitions (DataMatrix)

Data Matrix code is a two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or numeric data, and are mostly used for commercial applications.

The advantages of using DataMatrix is that it can carry much more information than a classic linear bar code symbol such as lot number, expiry date, a unique serial number and even the GTIN code which allows better traceability. Indeed, 2D matrix bar code symbols capture the largest amount of data in by far the smallest footprint.

5.2.3 Difference between trade item and logistic unit

Trade item: Trade item is any item (product or service) which is traded between a supplier and a buyer. The Trade item can be ordered and invoiced based on a trading agreement and can also be identified by a Global Trade Item Number (GTIN). The GTIN is used for the unique identification of trade items worldwide.

Logistic unit: Logistic unit is a composition of one or more trade items, which are to be delivered by transport and/or stored to fulfill a trade agreement

5.3 Traceability through the supply chain

Using EPCIS, the Shipping event is used to record a transfer of custody. Therefore, this guideline integrates RDC 54/2013 requirements for the electronic exchange of transaction information for each sale into the EPCIS Shipping event (including Transaction Information, Transaction History, and Transaction Statement). Trading partners can use this event to record and exchange RDC 54/2013 item-level information at each sale/transfer of custody. Key points:

- Transfer of custody is recorded in the Shipping event. Each trading partner records and exchanges a Shipping event for each sale/transfer of custody.
- Events will be captured at the item-level and associated with a GTIN.
- Shipping events can be captured at the unit, bundle, case, pallet or other levels, and will be associated with an SSCC.
- From a traceability perspective according to the RDC 54/2013, any product movement between different legal entities (CNPJs), including subsidiaries, needs to be tracked, even if these legal entities are branches of the same company.
- All transactions with any product serialized need to be tracked as well, such as internal consumption, destruction, donations, and others, just to name a few.

- Companies will determine for themselves how they will capture/enter that data into their Shipping events (e.g., have system prompt shipping staff to enter that data manually; create a product identifier/datamatrix for each item and have shipping staff scan that datamatrix for each case in the outbound delivery to record the data electronically; etc.).

5.4 Industry Transition to RDC 54/2013 e I.N. 6

Anvisa expects from the pharmaceutical supply chain participants the evidences that they were able to deliver what is expected from the 2 (two) different milestones as described above.

Both milestones consider serialization and traceability capabilities, in this way differing from other countries like US where serialization and traceability are handled separately from an implementation timing perspective.

The processes, technology and challenges of making a product unique using the serialization concepts and tracking it through an IT solution is well understood by the industry and also with a comprehensive amount of information available all over the internet, by discussion groups and vendors with available expertise. However, implementing an interoperable solution that integrates all supply chain participants in a region or country, consolidating goods movements with comprehensive reporting features is still a big challenge as it is not just about using communication mechanisms (ie. EPCIS standards) but having to deal with different regulators approaches, supply chain participants not willing to share traceability data as it may be used for different commercial purposes, lack of IT and Internet necessary infrastructure in some parts of the world, and other challenges.

MoH authorities from Turkey and Argentina created their own database solution where supply chain agents are required to upload their traceability events, whereas in Brazil it is up to the industry to figure out the end-state solution out. Distributors, wholesalers and retailers are normally not willing to share traceability events as this practice could expose how they exactly to they handle inventory, sales and channels, among other commercial information. It is natural thus to imagine that it takes a lot of effort and time to put all these agents together and build alignment and consensus towards a robust end-state solution.

Another important aspect of the transition between the pharmaceutical market current state in Brazil and supply chains with serialization and traceability capabilities is to consider a smooth and clear approach with final customers. Communication for example needs to be planned in advance for a scenario where non-serialized products will co-exist with serialized ones, with clear rules on how to correctly identify a counterfeit and diverted product.

What is being shared above is only a small portion of what all supply chain participants will need to take into consideration during the implementation of the Brazilian solution to comply with the RDC 54/2013.

5.4.1 Eventual penalties to non-compliant supply chain participants

The law that provides details about actions that can be taken by the government on non-compliant behaviors is the Law 6437/77. Different penalties are defined depending on the severity of the action, such as:

- Warning
- Fines
- Apprehension of products
- Manufacturing and/or sales suspension
- Product registration cancellation
- Establishment interdiction

There are defined different levels of non-compliant behaviors or faults, what are the MoH authority approaches around analysis and decisions, communication method, among many other details that can be found at the following link:

http://www.planalto.gov.br/ccivil_03/leis/L6437.htm

Based on a scenario where all supply chain participants will be eventually interconnected, exchanging a number of different track and trace events, it is not hard to imagine that any reporting solution will easily identify participants that are not in compliance with the requirements determined by the RDC 54/2013.

6 EPCIS XMLs for Data Exchange

6.1 Implementation Procedure #1 Commissioning

Commissioning is the process of associating an object (e.g., bottle, case, tote, pallet, etc.) with an EPC (i.e., an identifier representing a GTIN / Serial Number, SSCC, etc.). The EPC may be encoded in a data carrier (i.e., a barcode or EPC/ RFID tag) and applied to the object during this step, or the data carrier may have been previously encoded.

6.1.1 Pre-Requisite

The EPC of the object being commissioned has been applied to the object and is ready to be activated and associated to the product.

6.1.2 When Would I Use This?

This will be used to capture the production of serialized products associating the EPCs to the serialized products. This facilitates reporting of serialized batch production by the registration holder.

6.1.2.1 Field Definitions

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

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epcList	urn:epc:id:sgtin: <i>CompanyPrefix</i> .ItemReference.SerialNumber OR urn:epc:id:sscc: <i>CompanyPrefix</i> .SerialReference	Required	Because the extensions below are event-level extensions, they should be the same for all EPCs in the event.
action	ADD	Required	EPCIS standard definition
bizStep	urn:epcglobal:cbv:bizstep:commissioning	Required	CBV standard definition
disposition	urn:epcglobal:cbv:disp:active	Required	CBV standard definition

ELEMENT	MASK	USAGE	NOTE
readPoint	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension OR http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required	EPCIS standard definition
bizTransactionList		Optional	CBV standard definition

6.1.2.1.1 ILMD Elements

Instance/Lot Master Data (ILMD) is data that describes a specific instance of a physical or digital object, or a specific batch/lot of objects that are produced in batches/lots. ILMC consists of a set of descriptive attributes that provide information about one or more specific objects or lots. ILMC for a specific object is defined when the object comes into existence. Therefore, ILMC may only be included in ObjectEvents with action ADD

ELEMENT	DESCRIPTION	TYPE	MASK	USAGE
ANVISARegistrationNumber	13 digit Medication Record Number registered with ANVISA. For drugs, the first digit is always 1.	String	1584682484853	Conditional
lotNumber	The lot or batch number for all of the EPCs in the epclList of the ObjectEvent.	String		Conditional
expirationDate	The expiration date for all of the EPCs in the epclList of the ObjectEvent, formatted as an xsd:date.	Date		Conditional
manufacturingDate	The manufacturing date of the product Although not required by ANVISA reporting, this is required for Brazil trading partner exchanges	Date		Conditional
packagingLevel	Package Type of product units which can be PALLET, CASE (for SHIPPER/TOTE), BUNDLE, ITEM	String		Required

6.1.2.1.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in a Commissioning event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Required

ELEMENT	MASK	USAGE
	or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.1.2.1.3 Commissioning Object Event Rules

The following table lists the applicable commissioning extension and ILM D elements based on the commissioned object type and whether a logistical transport identifier such as GS1 SSCC or local transport serial number is assigned to the commissioned object.

Extension Element	ITEM	BUNDLE	(Homogeneous) CASE	(Heterogeneous) CASE	PALLET
Event Id	Required	Required	Required	Required	Required
Declaring Party	Required	Required	Required	Required	Required
ANVISA_Registration_Number	Required	Optional	Optional	N/A	N/A
Lot Number	Required	Optional	Optional	N/A	N/A
Expiration Date	Required	Optional	Optional	N/A	N/A
Manufacturing Date	Required	Optional	Optional	N/A	N/A
Packaging Level	Required	Required	Required	Required	Required

- All of the EPCs within a single *Commissioning* event should belong to only one of the categories defined in the table above. Multiple *Commissioning* events should be used for EPCs belonging to different categories.

6.1.3 How To's? (Example XML)

6.1.3.1 XML Example Showing Commissioning of Serialized Items

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer produces and commissions serialized items -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-06-29T15:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-29T15:12:16Z</eventTime>
        <recordTime>2015-06-29T15:12:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
    
```



```

<epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
<epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
<epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
</epcList>
<action>ADD</action>
<bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
<disposition>urn:epcglobal:cbv:disp:active</disposition>
<readPoint>
  <id>urn:epc:id:sgln:789123.111111.0</id>
</readPoint>
<bizLocation>
  <id>urn:epc:id:sgln:789123.111111.0</id>
  <!-- Example showing use of local identifier -->
  <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
</bizLocation>
<!-- bizTransaction documents are optional for production event but an example
is provided here to show use of production order document -->
<bizTransactionList>
  <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
    urn:epcglobal:cbv:bt:7891231111107:CCC8
  </bizTransaction>
  <!-- Example showing use of local identifier -->
  <!--when using CNPJ
    <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
      http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/CCC8
    </bizTransaction> -->
</bizTransactionList>
<extension>
  <ilmd>
    <gs1brhc:ANVISARegistrationNumber>1584682484853</gs1brhc:ANVISARegistrationNumber>
    <gs1brhc:expirationDate>2016-03-15</gs1brhc:expirationDate>
    <gs1brhc:manufacturingDate>2015-03-15</gs1brhc:manufacturingDate>
    <gs1brhc:packagingLevel>ITEM</gs1brhc:packagingLevel>
  </ilmd>
</extension>
<!-- Lot Number is added as a commissioning event extension instead of
having this part of the ilmd. This is in consideration of the Recovery event which
enables batch number to be later updated as part of Recovery event notification -->
<gs1brhc:lotNumber>A123</gs1brhc:lotNumber>
<!-- eventID Format:
  <gs1brhc:eventID>
    http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]
  </gs1brhc:eventID>-->
<!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
<gs1brhc:eventID>
  http://epcis.gs1br.org/hc/eventid/gln/7891231111114/8MP56CWMAMRV
</gs1brhc:eventID>
<!--when using CNPJ
  <gs1brhc:eventID>
    http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/8MP56CWMAMRV
  </gs1brhc:eventID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!-- Example showing use of local identifier -->
<!--when using CNPJ
  <gs1brhc:declaringParty>
    http://epcis.gs1br.org/hc/cnpj/loc/12345678000195
  </gs1brhc:declaringParty> -->
</ObjectEvent>
</EventList>

```

```
</EPCISBody>
</epcis:EPCISDocument>
```

6.1.3.2 XML Example of Commissioning Logistical Unit (Shipper) with SSCC

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer produces and commissions logistical unit with SSCC -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-06-29T16:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-29T15:13:16Z</eventTime>
        <recordTime>2015-06-29T15:13:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:789123.01234567892</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:789123.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:789123.111111.0</id>
          <!-- Example showing use of local identifiers -->
          <!--when using CNPJ
            <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
        </bizLocation>
        <!-- bizTransaction documents are optional for production event but an
          example is provided here to show use of production order document -->
        <bizTransactionList>
          <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
            urn:epcglobal:cbv:bt:7891231111107:CCC8
          </bizTransaction>
          <!-- Example showing use of local identifier -->
          <!--when using CNPJ
            <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
              http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/CCC8
            </bizTransaction> -->
        </bizTransactionList>
        <extension>
          <ilmd>
            <gs1brhc:packagingLevel>CASE</gs1brhc:packagingLevel>
          </ilmd>
        </extension>
        <!-- eventID Format:
          <gs1brhc:eventID>
            http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]
          </gs1brhc:eventID>-->
        <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
        <gs1brhc:eventID>
          http://epcis.gs1br.org/hc/eventid/gln/7891231111114/SR7XCYPH6GJI5
```

```

</gs1brhc:eventID>
<!--when using CNPJ
  <gs1brhc:eventID>
    http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/SR7XCYH6GJI5
  </gs1brhc:eventID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!-- Example showing use of local identifier -->
<!--when using CNPJ
  <gs1brhc:declaringParty>
    http://epcis.gs1br.org/hc/cnpj/loc/12345678000195
  </gs1brhc:declaringParty> -->
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.1.4 Mapping of EPCIS Commissioning Event to ANVISA Production Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Producao/ Production	Producao/Evento/CabecalhoEvento/tipoEvento	Commissioning	Assign value based on bizStep For bizStep = commissioning, set corresponding value for Producao/Production
	Producao/Evento/CabecalhoEvento/idInstanciaEvento	Commissioning	gs1brhc:eventID
	Producao/Evento/CabecalhoEvento/dataHorarioRegistro	Commissioning	recordTime
	Producao/Evento/CabecalhoEvento/dataHorarioOcorrencia	Commissioning	eventTime
	choice: Producao/Evento/declarante/CPF	Commissioning	gs1brhc:declaringParty
	choice: Producao/Evento/declarante/CNPJ	Commissioning	gs1brhc:declaringParty
	choice: Producao/Evento/declarante/CNES	Commissioning	gs1brhc:declaringParty
	choice: Producao/Evento/declarante/registroProfissional	Commissioning	gs1brhc:declaringParty
	choice: Producao/Evento/declarante/entidadeExterior	Commissioning	gs1brhc:declaringParty
	Producao/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Producao/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Producao/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	Producao/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Producao/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as Producao/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	Producao/IUM/numeroRegistroMedicamentoAnvisa	Commissioning	gs1brhc:ANVISARegistrationNumber
	Producao/IUM/numeroSerial	Commissioning	epcList
	Producao/IUM/dataValidade	Commissioning	gs1brhc:expirationDate
	Producao/IUM/numeroLote	Commissioning	gs1brhc:lotNumber

6.2 Implementation Procedure #2 Packing

Packing denotes a specific activity within a business process that includes putting an object (e.g., individuals, inners, cases, pallets, etc.) into a larger container (e.g., cases, totes, pallets, etc.) usually for the purposes of storing or shipping. Aggregation of one unit to another occurs at this point

6.2.1 Pre-Requirement

The Electronic Product Codes (EPCs) of the container (parent EPC) and the contained objects (child EPCs) have been commissioned.

6.2.2 When Would I Use This?

This will be used to capture aggregation events facilitating reporting of the transportation package event.

6.2.2.1 Field Definitions

A *Packing* event should be an EPCIS Aggregation Event populated as follows:

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
parentID	urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition

ELEMENT	MASK	USAGE	NOTE
childEPCs	urn:epc:id:sgtin:CompanyPrefix.ItemReference.SerialNumber	Required	EPCIS standard definition
action	ADD	Required	EPCIS standard definition
bizStep	urn:epcglobal:cbv:bizstep:packing	Required	CBV standard definition
disposition	urn:epcglobal:cbv:disp:in_progress	Required	CBV standard definition
readPoint	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required	EPCIS standard definition

6.2.2.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in a *Packing* event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.2.3 How To's? (Example XML)

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer ships to hospital pharmacy -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
```

```

schemaVersion="1.1" creationDate="2015-06-30T15:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcisschemas/GS1-
BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <!-- Packing multiple ITEMS into CASE -->
      <AggregationEvent>
        <eventTime>2015-06-30T15:14:16Z</eventTime>
        <recordTime>2015-06-30T15:14:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sscc:789123.01234567892</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
        </childEPCs>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:789123.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:789123.111111.0</id>
          <!-- Example showing use of local identifier -->
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
        </bizLocation>
        <!-- eventID Format:
          <gs1brhc:eventID>
            http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:eventID>--
          >
          <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
          <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/7891231111114/QDVRNLESW7A</gs1brhc:ev
            entID>
          <!--when using CNPJ
          <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/QDVRNLESW7A</gs1brhc:
            eventID> -->
          <gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
          <!-- Example showing use of local identifier -->
          <!--when using CNPJ
          <gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</gs1brhc:declaringParty> --
          >
        </AggregationEvent>
      </EventList>
    </EPCISBody>
  </epcis:EPCISDocument>

```

6.2.4 Mapping of EPCIS Packing Event to ANVISA Transportation Package Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
EventoEmbalagemTransporte/Transportation Package	EventoEmbalagemTransporte/Evento/CabecalhoEvento/tipoEvento	Packing	Assign value based on bizStep For bizStep = packing, set corresponding value for EventoEmbalagemTransporte/Transportation Package Event
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/idInstanciaEvento	Packing	gs1brhc:eventID
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/dataHorarioRegistro	Packing	recordTime
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/dataHorarioOcorrencia	Packing	eventTime
	choice: EventoEmbalagemTransporte/Evento/declarante/CPF	Packing	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/CNPJ	Packing	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/CNES	Packing	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/registroProfissional	Packing	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/entidadeExterior	Packing	gs1brhc:declaringParty
	EventoEmbalagemTransporte/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	EventoEmbalagemTransporte/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	EventoEmbalagemTransporte/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	EventoEmbalagemTransporte/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	EventoEmbalagemTransporte/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as EventoEmbalagemTransporte/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	EventoEmbalagemTransporte/tipoEventoEmbalagemTransporte	Packing	Assign value based on bizStep For packing, set corresponding value for (Aggregation)
	EventoEmbalagemTransporte/idEmbalagemTransporte	Packing	parentID

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	EventoEmbalagemTransporte/idEmbalagemContida	Packing	childEPCs

6.3 Implementation Procedure #3 Shipping

Shipping is the process of initiating the transfer of an object from one trading partner to another. A data carrier (i.e., a barcode or EPC/RFID tag) may have been read during this process. Only the outermost containers in the packaging hierarchy are included.

6.3.1 Pre-Requirement

The Electronic Product Codes (EPCs) of the objects being shipped or transferred have already been commissioned. Outermost container in the packaging hierarchy has been commissioned and aggregation event(s) have been recorded to reflect the packaging hierarchy.

6.3.2 When Would I Use This?

This will be used to capture the event of transferring an object from one business entity to another facilitating reporting of a movement transfer event.

6.3.2.1 Field Definitions

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

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epcList	urn:epc:id:sgtin: <i>CompanyPrefix.ItemReference.Serial Number</i> or urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition
action	OBSERVE	Required	EPCIS standard definition
bizStep	urn:epcglobal:cbv:bizstep:shipping	Required	CBV standard definition
disposition	urn:epcglobal:cbv:disp:in_transit	Required	CBV standard definition. The disposition value "in_transit" is always

ELEMENT	MASK	USAGE	NOTE
			paired with the bizStep "shipping" for forward logistics.
readPoint	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Omitted	EPCIS standard definition
bizTransactionList	See Section 3.1.7.3 for details on how to extend bizTransactionList to include nota fiscal business transaction information.	Required	EPCIS standard definition
sourceList		Required	EPCIS v1.1 standard definition
destinationList		Required	EPCIS v1.1 standard definition

6.3.2.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in a *Shipping* event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
carrierParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
natureOfMovement		Required
expectedNumUnits		Optional
expectedNumUnitUOM		Optional
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.3.3 How To's? (Example XML)

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer ships to hospital pharmacy -->
```

```

<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-06-30T18:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcisschemas/GS1-
  BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-30T18:13:16Z</eventTime>
        <recordTime>2015-06-30T18:13:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:789123.01234567892</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:789123.111111.0</id>
        </readPoint>
        <bizTransactionList>
          <bizTransaction type="urn:epcglobal:cbv:btt:inv">
            urn:epcglobal:cbv:bt:7891231111107:195A2369845109
          </bizTransaction>
          <!--when using CNPJ
            <bizTransaction type="urn:epcglobal:cbv:btt:inv">
              http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/195A2369845109
            </bizTransaction -->
          <bizTransaction
            type="urn:epcglobal:cbv:btt:po">http://epcis.gs1br.org/hc/bt/cnpj/11223344000186/XYZ567</bizTransacti
            on>
          <bizTransaction
            type="http://epcis.gs1br.org/hc/btt/delivery">http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/456
          </bizTransaction>
          <!-- Format for defining nota fiscal information in business transaction
            <bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">
              http://epcis.gs1br.org/hc/bt/[partyIdentifierType]/[partyIdentifier]/[notaFiscalDocumentNumber].[notaFiscal
              SeriesCode]
            </bizTransaction -->
          <bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">
            http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/987654321.99999999
          </bizTransaction>
        </bizTransactionList>
        <extension>
          <sourceList>
            <source type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:789123.111110.0</source>
            <!--when using CNPJ <source
              type="urn:epcglobal:cbv:sdt:owning_party">http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</source>
            -->
          </sourceList>
          <destinationList>
            <!--when using CNPJ -->
          <destination
            type="urn:epcglobal:cbv:sdt:owning_party">http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</destinati
            on>
  
```

```

<!--when using sGLN <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:643278.100001.0</destination> -->
<!--when using CNPJ <destination
type="urn:epcglobal:cbv:sdt:owning_party">http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</destinati
on> -->
</destinationList>
</extension>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</g
s1brhc:eventID>-->
<!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/7891231111114/5E1MR1YXNUU2</gs1brhc:eve
ntID>
<!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/5E1MR1YXNUU2</gs1brhc:e
ventID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</gs1brhc:declaringParty> --
>
<gs1brhc:carrierParty>urn:epc:id:sgln:863662.100100.0</gs1brhc:carrierParty>
<!--when using CNPJ
<gs1brhc:carrierParty>http://epcis.gs1br.org/hc/cnpj/loc/86256136000182</gs1brhc:carrierParty> -->
<gs1brhc:natureOfMovement>PURCHASE_SALE</gs1brhc:natureOfMovement>
<gs1brhc:expectedNumUnits>3</gs1brhc:expectedNumUnits>
<gs1brhc:expectedNumUnitUOM>ITEM</gs1brhc:expectedNumUnitUOM>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.3.4 Mapping of EPCIS Shipping Event to ANVISA Movement/Delivery Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Movimentacao/Movement	Entrega/Evento/Cabecalho Evento/tipoEvento	Shipping	Assign value based on bizStep For bizStep = 'shipping', set corresponding value for Movimentacao/Movement or Entrega/Delivery
	Entrega/Evento/Cabecalho Evento/idInstanciaEvento	Shipping	gs1brhc:eventID
	Entrega/Evento/Cabecalho Evento/dataHorarioRegistro	Shipping	recordTime
	Entrega/Evento/Cabecalho Evento/dataHorarioOcorrencia	Shipping	eventTime
	choice: Entrega/Evento/declarante /CPF	Shipping	gs1brhc:declaringParty
	choice: Entrega/Evento/declarante /CNPJ	Shipping	gs1brhc:declaringParty

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	choice: Entrega/Evento/declarante/CNES	Shipping	gs1brhc:declaringParty
	choice: Entrega/Evento/declarante/registroProfissional	Shipping	gs1brhc:declaringParty
	choice: Entrega/Evento/declarante/entidadeExterior	Shipping	gs1brhc:declaringParty
	Entrega/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Entrega/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Entrega/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Entrega/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Entrega/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added Entrega/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	Entrega/tipoEntrega	Shipping	gs1brhc:natureofMovement
	choice: Entrega/receptor/CPF	Shipping	destinationList
	choice: Entrega/receptor/CNPJ	Shipping	destinationList
	choice: Entrega/receptor/CNES	Shipping	destinationList
	choice: Entrega/receptor/registroProfissional	Shipping	destinationList
	choice: Entrega/receptor/entidadeExterior	Shipping	destinationList
	Entrega/receptor/nome	Shipping	http://epcis.gs1br.org/hc/mda/companyName
	Entrega/receptor/endereco	Shipping	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Entrega/receptor/municipio	Shipping	http://epcis.gs1br.org/hc/mda/city
	Entrega/receptor/UF	Shipping	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Entrega/receptor/Pais	Shipping	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as Entrega/receptor/CEP	Shipping	http://epcis.gs1br.org/hc/mda/postalCode
	choice: Entrega/transportadora/CPF	Shipping	gs1brhc:carrierParty
	choice: Entrega/transportadora/CNPJ	Shipping	gs1brhc:carrierParty

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	choice: Entrega/transportadora/CNES	Shipping	gs1brhc:carrierParty
	choice: Entrega/transportadora/registroProfissional	Shipping	gs1brhc:carrierParty
	choice: Entrega/transportadora/entidadeExterior	Shipping	gs1brhc:carrierParty
	Entrega/transportadora/nome	Shipping	http://epcis.gs1br.org/hc/mda/companyName
	Entrega/transportadora/endereco	Shipping	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Entrega/transportadora/municipio	Shipping	http://epcis.gs1br.org/hc/mda/city
	Entrega/transportadora/UF	Shipping	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Entrega/transportadora/Pais	Shipping	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as Entrega/transportadora/CEP	Shipping	http://epcis.gs1br.org/hc/mda/postalCode
	choice: Entrega/idEmbalagem/idEmbalagemTransporte	Shipping	epcList
	choice: Entrega/IUM	Shipping	See mapping below for each IUM element
	Entrega/IUM/numRegistroMedicamentoAnvisa	Shipping	look-up gs1brhc:ANVISARegistrationNumber from commissioning event based on epcList listed on Shipping event
	Entrega/IUM/numSerial	Shipping	look-up and derive serial number from epcList of the from commissioning event based on epcList listed on Shipping event
	Entrega/IUM/dataValidade	Shipping	look-up gs1brhc:expirationDate from commissioning event based on epcList listed on Shipping event
	Entrega/IUM/numLote	Shipping	look-up gs1brhc:lotNumber from commissioning event based on epcList listed on Shipping event

6.4 Implementation Procedure #4 Receiving

Receiving is the process of completing the transfer of an object from one trading partner to another. Receiving may be recorded in one of two ways:

3. Only the outermost containers in the packaging hierarchy are included in the *Receiving* event, in which case the full hierarchy inferred from prior *Packing* events is inferred to have been received, or

4. One or more inner levels of hierarchy are declared explicitly in one or more *Receiving* events, in which case inference is only used for inner levels not declared explicitly (or not at all if all levels are declared explicitly)

If the *Receiving* event is to be recorded using the first method (i.e., where only the outermost containers are included in the *Receiving* event), the *Receiving* event should be an EPCIS Object Event populated as specified below. If the *Receiving* event is to be recorded using the second method (i.e., where hierarchy is declared explicitly), share as many *Receiving* Events as needed to express the hierarchy. Each event should be an EPCIS Aggregation Event where the epList fields with Parent ID and Child EPCs express the hierarchy and all other fields (including the action and the extensions) are as specified below.

6.4.1 Pre-Requirement

A shipping event capturing objects to be received Electronic Product Codes (EPCs) transfer has already been recorded in the system.

6.4.2 When Would I Use This?

This will be used to capture the event of receiving the object(s) being transferred from one business entity to another. Receipt completes the movement transfer process that will be reported.

6.4.2.1 Field Definitions

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

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epcList	urn:epc:id:sgtin: <i>CompanyPrefix.ItemReference.SerialNumber</i> OR urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition See the discussion above regarding receiving options.
action	OBSERVE	Required	EPCIS standard definition
bizStep	urn:epcglobal:cbv:bizstep:receiving	Required	CBV standard definition

ELEMENT	MASK	USAGE	NOTE
disposition	urn:epcglobal:cbv:disp:in_progress	Required	CBV standard definition
readPoint	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required	EPCIS standard definition
bizTransactionList	See Section 3.1.7.3 for details on how to extend bizTransactionList to include nota fiscal business transaction information.	Required	EPCIS standard definition
sourceList		Required	EPCIS v1.1 standard definition
destinationList		Required	EPCIS v1.1 standard definition

- To help in later matching *Shipping* and *Receiving* events, if possible, use the same values found in your trading partner's *Shipping* event for sourceList and destinationList in your *Receiving* event.

6.4.2.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in a Receiving event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
carrierParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
natureOfMovement		Required
expectedNumUnits		Optional
expectedNumUnitUOM		Optional
retractionFlag	true or false	Conditional

ELEMENT	MASK	USAGE
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.4.3 How To's? (Example XML)

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Hospital pharmacy receives shipment from manufacturer -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-06-30T19:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcischemas/GS1-
  BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-30T19:10:16Z</eventTime>
        <recordTime>2015-06-30T19:10:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:789123.01234567892</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:643278.100002.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:643278.100002.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
        </bizLocation>
        <bizTransactionList>
          <bizTransaction type="urn:epcglobal:cbv:btt:inv">
            urn:epcglobal:cbv:bt:7891231111107:195A2369845109
          </bizTransaction>
          <!--when using CNPJ
            <bizTransaction type="urn:epcglobal:cbv:btt:inv">
              http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/195A2369845109
            </bizTransaction> -->
          <bizTransaction
            type="urn:epcglobal:cbv:btt:po">http://epcis.gs1br.org/hc/bt/cnpj/11223344000186/XYZ567</bizTransaction>
          </bizTransaction>
          <bizTransaction
            type="http://epcis.gs1br.org/hc/btt/delivery">http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/456</bizTransaction>
          </bizTransaction>
          <!-- Format for defining nota fiscal information in business transaction
            <bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">
              http://epcis.gs1br.org/hc/bt/[partyIdentifierType]/[partyIdentifier]/[notaFiscalDocumentNumber].[notaFiscal
              SeriesCode]
            </bizTransaction> -->
          <bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">
  
```



```

http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/987654321.99999999
</bizTransaction>
</bizTransactionList>
<extension>
<sourceList>
<source type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:789123.111110.0</source>
<!--when using CNPJ <source
type="urn:epcglobal:cbv:sdt:owning_party">http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</source>
-->
</sourceList>
<destinationList>
<destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:643278.100001.0</destination>
<!--when using CNPJ <destination
type="urn:epcglobal:cbv:sdt:owning_party">http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</destinati
on> -->
</destinationList>
</extension>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</g
s1brhc:eventID>-->
<!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/JB6J8MWPIPX4</gs1brhc:even
tID>
<!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/JB6J8MWPIPX4</gs1brhc:ev
entID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
<!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> --
>
<gs1brhc:carrierParty>urn:epc:id:sgln:863662.100100.0</gs1brhc:carrierParty>
<!--when using CNPJ
<gs1brhc:carrierParty>http://epcis.gs1br.org/hc/cnpj/loc/86256136000182</gs1brhc:carrierParty> -->
<gs1brhc:natureOfMovement>PURCHASE_SALE</gs1brhc:natureOfMovement>
<gs1brhc:expectedNumUnits>3</gs1brhc:expectedNumUnits>
<gs1brhc:expectedNumUnitUOM>ITEM</gs1brhc:expectedNumUnitUOM>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.4.4 Mapping of EPCIS Receiving Event to ANVISA Movement/Receipt Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Movimentacao/Movement	Recebimento/Evento/CabecalhoEvento/tipoEvento	Receiving	Assign value based on bizStep For bizStep = 'receiving', set corresponding value for Movimentacao/Movement or Recebimento/Receipt
	Recebimento/Evento/CabecalhoEvento/idInstanciaEvento	Receiving	gs1brhc:eventID

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	Recebimento/Evento/CabeçalhoEvento/dataHorarioRegistro	Receiving	recordTime
	Recebimento/Evento/CabeçalhoEvento/dataHorarioOcorrencia	Receiving	eventTime
	choice: Recebimento/Evento/declarante/CPF	Receiving	gs1brhc:declaringParty
	choice: Recebimento/Evento/declarante/CNPJ	Receiving	gs1brhc:declaringParty
	choice: Recebimento/Evento/declarante/CNES	Receiving	gs1brhc:declaringParty
	choice: Recebimento/Evento/declarante/registroProfissional	Receiving	gs1brhc:declaringParty
	choice: Recebimento/Evento/declarante/entidadeExterior	Receiving	gs1brhc:declaringParty
	Recebimento/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Recebimento/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Recebimento/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Recebimento/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Recebimento/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added Recebimento/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	Recebimento/tipoRecebimento	Receiving	gs1brhc:natureofMovement
	choice: Recebimento/remetente/CPF	Receiving	sourceList
	choice: Recebimento/remetente/CNPJ	Receiving	sourceList
	choice: Recebimento/remetente/CNES	Receiving	sourceList
	choice: Recebimento/remetente/registroProfissional	Receiving	sourceList
	choice: Recebimento/remetente/entidadeExterior	Receiving	sourceList
	Recebimento/remetente/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Recebimento/remetente/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	Recebimento/remetente/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Recebimento/remetente/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Recebimento/remetente/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added Recebimento/remetente/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	choice: Recebimento/transportadora/CPF	Receiving	gs1brhc:carrierParty
	choice: Recebimento/transportadora/CNPJ	Receiving	gs1brhc:carrierParty
	choice: Recebimento/transportadora/CNES	Receiving	gs1brhc:carrierParty
	choice: Recebimento/transportadora/registorProfissional	Receiving	gs1brhc:carrierParty
	choice: Recebimento/transportadora/entidadeExterior	Receiving	gs1brhc:carrierParty
	Recebimento/transportadora/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Recebimento/transportadora/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Recebimento/transportadora/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Recebimento/transportadora/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Recebimento/transportadora/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added Recebimento/transportadora/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	choice: Recebimento/idEmbalagem/idEmbalagemTransporte	Receiving	epcList
	choice: Recebimento/IUM	Receiving	See mapping below for each IUM element
	Recebimento/IUM/numRegistroMedicamentoAnvisa	Receiving	look-up gs1brhc:ANVISARegistrationNumber from commissioning event based on epcList listed on Receiving event
	Recebimento/IUM/numSerial	Receiving	look-up and derive serial number from epcList of the from commissioning event based on epcList listed on Receiving event
	Recebimento/IUM/dataValidade	Receiving	look-up gs1brhc:expirationDate from commissioning event based on epcList listed on Receiving event

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	Recebimento/IUM/numLote	Receiving	look-up gs1brhc:lotNumber from commissioning event based on epclList listed on Receiving event

6.5 Implementation Procedure #5 Inspecting

Inspecting is the process of reviewing objects to address potential physical or documentation defects. The outcome of the inspection activity is recorded in the disposition of the event.

6.5.1 Pre-Requisite

The Electronic Product Codes (EPCs) of the objects being inspected have been commissioned.

6.5.2 When Would I Use This?

This will be used to capture the event of verifying the objects as part of the inspection of the goods received from a product shipment or transfer. This is used especially for the verification of the contents of transportation package received with the inspection outcome captured and reported as an inspecting event.

6.5.2.1 Field Definitions

An Inspecting event should be an EPCIS Object Event populated as follows:

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epclList	urn:epc:id:sgtin: <i>CompanyPrefix</i> .ItemReference. <i>SerialNumber</i> or urn:epc:id:sscc: <i>CompanyPrefix</i> .SerialReference	Required	EPCIS standard definition
action	OBSERVE	Required	EPCIS standard definition
bizStep	urn:epcglobal:cbv:bizstep:inspecting	Required	CBV standard definition

ELEMENT	MASK	USAGE	NOTE
disposition	Assign disposition value of urn:epcglobal:cbv:disp:in_progress when inspected product is in acceptable state. Assign disposition value of urn:epcglobal:cbv:disp:damaged when inspected product is impaired in its usefulness and/or reduced in value due to a defect. Assign disposition value of urn:epcglobal:cbv:disp:expired when inspected product is past expiration date.	Required	CBV standard definition
readPoint	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required	EPCIS standard definition
bizTransactionList		Optional	EPCIS standard definition

6.5.2.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in an Inspection event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
reason		Conditional
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.5.3 How To's? (Example XML)

6.5.3.1 XML Example of Positive Inspection Outcome

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Hospital pharmacy inspects products shipped by the manufacturer.
Product inspection is part of business product receipt process with the outcome of the inspection
determining whether product will be put away into inventory or quarantined for further analysis.
Example shows positive outcome of inspection with disposition of "in_progress" -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-06-30T19:11:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-30T19:10:16Z</eventTime>
        <recordTime>2015-06-30T19:10:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:789123.01234567892</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:643278.100002.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:643278.100002.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
        </bizLocation>
        <!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]/</gs1brh
c:eventID>-->
        <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/HXM2IXQMhJ76</gs1brhc:eventID>
        <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/HXM2IXQMhJ76</gs1brhc:eventID
> -->
        <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
        <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>

```

6.5.3.2 XML Example of Negative Inspection Outcome Discovering Damage

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Hospital pharmacy inspects products shipped by the manufacturer.
Product inspection is part of business product receipt process with the outcome of the inspection
determining whether product will be put away into inventory or quarantined for further analysis.
Example shows negative outcome of inspection with disposition of "damaged" -->

```

```

<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-06-30T19:12:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-30T19:11:16Z</eventTime>
        <recordTime>2015-06-30T19:11:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:789123.01234567892</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
        <disposition>urn:epcglobal:cbv:disp:damaged</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:643278.100002.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:643278.100002.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
        </bizLocation>
        <!-- eventID Format:
        <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:
        c:eventID-->
        <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

        <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/W8Z2DTIJXJ1D</gs1brhc:eventID>
        <!--when using CNPJ
        <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/W8Z2DTIJXJ1D</gs1brhc:eventID>
        -->
        <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
        <!--when using CNPJ
        <gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
        <gs1brhc:reason>Product dropped in warehouse and damaged</gs1brhc:reason>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
  
```

6.5.3.3 XML Example of Negative Inspection Outcome Discovering Expired Products

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<!-- Example scenario: Hospital pharmacy inspects products shipped by the manufacturer.
```

Product inspection is part of business product receipt process with the outcome of the inspection determining whether product will be put away into inventory or quarantined for further analysis.

Example shows negative outcome of inspection with disposition of "expired" -->

```

<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-06-30T19:15:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
  
```



```

<eventTime>2015-06-30T19:14:18Z</eventTime>
<recordTime>2015-06-30T19:14:18Z</recordTime>
<eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
<epcList>
  <epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
</epcList>
<action>OBSERVE</action>
<bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
<disposition>urn:epcglobal:cbv:disp:expired</disposition>
<readPoint>
  <id>urn:epc:id:sgln:643278.100002.0</id>
</readPoint>
<bizLocation>
  <id>urn:epc:id:sgln:643278.100002.0</id>
  <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
</bizLocation>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentiferType]/[partyIdentifier]/[eventIdValue]</gs1brhc:
eventID>-->
  <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/SRVFDBAE89D6</gs1brhc:eventID>
  <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/SRVFDBAE89D6</gs1brhc:eventID
> -->
  <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
  <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
  <gs1brhc:reason>Expired Product</gs1brhc:reason>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.5.4 Mapping of EPCIS Inspecting Event to ANVISA Transportation Package Notification Message for Verification of Content

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
EventoEmbalagemTransporte/Transportation Package	EventoEmbalagemTransporte/Evento/CabecalhoEvento/tipoEvento	Inspecting	Assign value based on bizStep For bizStep = inspecting, set corresponding value for EventoEmbalagemTransporte/Transportation Package Event for conveying Verification of Content
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/idInstanciaEvento	Inspecting	gs1brhc:eventID
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/dataHorarioRegistro	Inspecting	recordTime
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/dataHorarioOcorrencia	Inspecting	eventTime
	choice: EventoEmbalagemTransporte/Evento/declarante/CPF	Inspecting	gs1brhc:declaringParty

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	choice: EventoEmbalagemTransporte/Evento/declarante/CNPJ	Inspecting	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/CNES	Inspecting	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/registroProfissional	Inspecting	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/entidadeExterior	Inspecting	gs1brhc:declaringParty
	EventoEmbalagemTransporte/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	EventoEmbalagemTransporte/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	EventoEmbalagemTransporte/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	EventoEmbalagemTransporte/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	EventoEmbalagemTransporte/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as EventoEmbalagemTransporte/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	EventoEmbalagemTransporte/tipoEventoEmbalagemTransporte	Inspecting	Assign value based on bizStep Assign corresponding value for (Verification of Content) when bizStep = inspecting
	EventoEmbalagemTransporte/idEmbalagemTransporte	Inspecting	epcList Inspection event will be recorded for each EPC including the parent transport package identifier and the child contained transport package identifier or child IUM
	EventoEmbalagemTransporte/idEmbalagemContida	Inspecting	epcList Inspection event will be recorded for each EPC including the parent transport package identifier and the child contained transport package identifier or child IUM

6.6 Implementation Procedure #6 Unpacking

Unpacking denotes a specific activity within a business process that includes removing an object (e.g., individuals, inners, cases, pallets, etc.) from a larger container (e.g., cases, totes, pallets,

etc.) – usually for the purposes of storing or shipping. Unpacking is the reverse of packing, and the Unpacking EPCIS event disaggregates specific aggregation relationships created by Packing events.

6.6.1 Pre-Requirement

The Electronic Product Codes (EPCs) of the container (parent EPC) and the contained objects (child EPCs) have been commissioned and previously packed into a larger container.

6.6.2 When Would I Use This?

This will be used to capture disaggregation events facilitating reporting of the transportation package event.

6.6.2.1 Field Definitions

An *Unpacking* event should be an EPCIS Aggregation Event populated as follows:

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
parentID	urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition
childEPCs	urn:epc:id:sgtin: <i>CompanyPrefix.ItemReference.SerialNumber</i>	Optional	EPCIS standard definition
action	DELETE	Required	EPCIS standard definition
bizStep	urn:epcglobal:cbv:bizstep:unpacking	Required	CBV standard definition
disposition	urn:epcglobal:cbv:disp:in_progress	Required	CBV standard definition
readPoint	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i>	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> <i>or</i>	Required	EPCIS standard

ELEMENT	MASK	USAGE	NOTE
	<i>http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber</i>		definition

6.6.2.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in an *Unpacking* event.

ELEMENT	MASK	USAGE
eventID	<i>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</i> with <i>eventIdValue</i> formatted as [A-Z0-9]{12}	Required
declaringParty	<i>urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension</i> <i>or</i> <i>http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber</i>	Required
retractionFlag	true or false	Conditional
replacementEventID	<i>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</i> with <i>eventIdValue</i> formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.6.3 How To's? (Example XML)

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer's 3PL warehouse unpacks an item from a case
3PL Headquarters is sending message to Manufacturer -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-07-01T15:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcisschemas/GS1-
BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <!-- Unpacking single ITEM from CASE -->
      <AggregationEvent>
        <eventTime>2015-07-01T15:14:18Z</eventTime>
        <recordTime>2015-07-01T15:14:18Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sscc:789123.01234567892</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
        </childEPCs>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:unpacking</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:543212.100002.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:543212.100002.0</id>
        </bizLocation>
        <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
  
```

```

</bizLocation>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:eventID-->
<!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/5432121000020/KXC861YJE9YW</gs1brhc:eventID>
<!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/87654321000279/KXC861YJE9YW</gs1brhc:eventID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:543212.100001.0</gs1brhc:declaringParty>
<!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/87654321000198</gs1brhc:declaringParty> -->
>
</AggregationEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.6.4 Mapping of EPCIS UnPacking Event to ANVISA Transportation Package Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
EventoEmbalagemTransporte/Transportation Package	EventoEmbalagemTransporte/Evento/CabecalhoEvento/tipoEvento	Unpacking	Assign value based on bizStep For bizStep = unpacking, set corresponding value for EventoEmbalagemTransporte/Transportation Package Event
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/idInstanciaEvento	Unpacking	gs1brhc:eventID
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/dataHorarioRegistro	Unpacking	recordTime
	EventoEmbalagemTransporte/Evento/CabecalhoEvento/dataHorarioOcorrencia	Unpacking	eventTime
	choice: EventoEmbalagemTransporte/Evento/declarante/CPF	Unpacking	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/CNPJ	Unpacking	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/CNES	Unpacking	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/registroProfissional	Unpacking	gs1brhc:declaringParty
	choice: EventoEmbalagemTransporte/Evento/declarante/entidadeExterior	Unpacking	gs1brhc:declaringParty

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	EventoEmbalagemTransporte/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	EventoEmbalagemTransporte/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	EventoEmbalagemTransporte/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	EventoEmbalagemTransporte/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	EventoEmbalagemTransporte/Evento/declarante/Paises	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as EventoEmbalagemTransporte/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	EventoEmbalagemTransporte/tipoEventoEmbalagemTransporte	Unpacking	Assign value based on bizStep For unpacking, set corresponding value for (Disaggregation)
	EventoEmbalagemTransporte/idEmbalagemTransporte	Unpacking	parentID
	EventoEmbalagemTransporte/idEmbalagemContida	Unpacking	childEPCs

6.7 Implementation Procedure #7 End of Life (Finishing) Events

The finishing event is the last event of a tracking object of medicine in this case. The finishing event according to the regulation have 4 types: Dispensation, Stolen, Misplaced, Disposal and Loss of Product Value. For more information on how to use each event and when to use please consult ANVISA.

6.7.1 Pre-Requisite

The Electronic Product Codes (EPCs) of the objects being dispensed have been commissioned.

6.7.2 When Would I Use This?

The following instructions are not normative, but came from a agreement of interpretation within the Working Group.

1. Pharmaceutical Product Dispensing

This will be used to capture the dispensation event of the object to consumers or final patient. Tracking this event enables detection of counterfeit dispensing of duplicated serialized products. Recording of dispensation occurs within the dispensing party system since it is considered to be expected happy path not warranting an event reporting to ANVISA nor the registration holder.

2. Finishing Event – Stolen/Misplaced Products

This will be used to capture and report the event of discovering that serialized commissioned object(s) under custody is (are) missing due to theft or misplacement.

3. Finishing Event – Loss of Product Value and Product Expiration

This is used to capture the inspection outcome and report the loss of product value due to damage or product expiration.

4. Finishing Event – Disposal

This is used to capture both the removal of the serialized identification of the object and its physical destruction. This facilitates the reporting of the disposal of the serialized object.

6.7.2.1 Field Definitions

A finishing event resulting in product disposal should be an EPCIS Object Event populated as follows:

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epcList	urn:epc:id:sgtin: <i>CompanyPrefix.ItemReference.SerialNumber</i> <i>OR</i> urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition
action	See Section 6.7.2.2 for the recommended value for particular end of Life (Finishing event)	Required	EPCIS standard definition
bizStep	See Section 6.7.2.2 for the recommended value for particular end of Life (Finishing event)	Required	CBV standard definition
disposition	See Section 6.7.2.2 for the recommended value for particular end of Life (Finishing event)	Required	CBV standard definition
readPoint	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i>	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> <i>or</i> http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required	EPCIS standard definition
bizTransactionList		Optional	EPCIS standard definition

6.7.2.2 End of Life (Finishing) Event Value Combinations for Action, BizStep and Disposition

The following table characterizes each end of life(finishing) event with the recommended combination set of EPCIS action, bizStep and disposition values.

FINISHING TYPE	EPCIS action	EPCIS bizStep	EPCIS disposition
Pharmaceutical Product Dispensing (Full/Complete)	OBSERVE	http://epcis.gs1br.org/hc/bizstep/dispensing	http://epcis.gs1br.org/hc/disp/dispensed
Pharmaceutical Product Dispensing (Partial)	OBSERVE	http://epcis.gs1br.org/hc/bizstep/dispensing	http://epcis.gs1br.org/hc/disp/partial
Finishing Event – Misplaced Products	OBSERVE	urn:epcglobal:cbv:bizstep:inspecting	http://epcis.gs1br.org/hc/disp/misplaced
Finishing Event – Stolen Products	OBSERVE	urn:epcglobal:cbv:bizstep:inspecting	urn:epcglobal:cbv:disp:stolen
Finishing Event – Loss of Product Value	OBSERVE	urn:epcglobal:cbv:bizstep:inspecting	urn:epcglobal:cbv:disp:damaged
Finishing Event – Loss of Product Value due to Expiration	OBSERVE	urn:epcglobal:cbv:bizstep:inspecting	urn:epcglobal:cbv:disp:expired
Finishing Event – Disposal	DELETE	urn:epcglobal:cbv:bizstep:destroying	urn:epcglobal:cbv:disp:destroyed

6.7.2.3 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in a End of Life.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
reason		Required
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.7.3 How To's? (Example XML)

6.7.3.1 XML Example of Full Dispensing to Consumer or Final Patient

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<!-- Example scenario: Hospital pharmacy dispenses product received from manufacturer. -->
```

<!-- Since a dispensing event is recorded only at the dispensing unit's system, the dispensing event shown below is

sent from dispensing pharmacy location to the dispensing corporate office for the purpose of illustrating use of EPCIS header content. Typically, the dispensing event will only be stored in the dispensing unit system

-->

```
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-07-01T16:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-07-01T16:12:16Z</eventTime>
        <recordTime>2015-07-01T16:12:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>http://epcis.gs1br.org/hc/bizstep/dispensing</bizStep>
        <disposition>http://epcis.gs1br.org/hc/disp/dispensed</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:643278.100002.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:643278.100002.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
        </bizLocation>
        <!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:eventID>-->
        <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/U1B24SS20UTK</gs1brhc:eventID>
        <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/U1B24SS20UTK</gs1brhc:eventID>
-->
        <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
        <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

6.7.3.2 XML Example of Partial Dispensation to Consumer or Final Patient

```
<?xml version="1.0" encoding="UTF-8"?>
```

<!-- Example scenario: Hospital pharmacy PARTIALLY dispenses product received from manufacturer. -->

<!-- Since a dispensing event is recorded only at the dispensing unit's system, the dispensing event shown below is

sent from dispensing pharmacy location to the dispensing corporate office for the purpose of illustrating use of EPCIS header content. Typically, the dispensing event will only be stored in the dispensing unit system

-->


```

<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-07-01T16:15:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-07-01T16:15:20Z</eventTime>
        <recordTime>2015-07-01T16:15:20Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>http://epcis.gs1br.org/hc/bizstep/dispensing</bizStep>
        <disposition>http://epcis.gs1br.org/hc/disp/partial</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:643278.100002.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:643278.100002.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/11223344000267</id> -->
        </bizLocation>
        <!-- eventID Format:
        <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:
        c:eventID>-->
        <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

        <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/UF60LQ9HYS2Y</gs1brhc:eventID>
        <!--when using CNPJ
        <gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/UF60LQ9HYS2Y</gs1brhc:eventID>
        -->
        <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
        <!--when using CNPJ
        <gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
  
```

6.7.3.3 XML Example of Stolen Product

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Hospital pharmacy performs inventory cycle count and
  discovers a product is missing/stolen.
  Example shows negative outcome of inspection with disposition of "stolen"
  Example shows how a stolen event observation can be sent by hospital pharmacy to distributor (previous
  link) -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-07-01T18:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
  
```

```

<ObjectEvent>
  <eventTime>2015-07-01T18:09:19Z</eventTime>
  <recordTime>2015-07-01T18:09:19Z</recordTime>
  <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
  <epcList>
    <epc>urn:epc:id:sscc:789123.01234567892</epc>
  </epcList>
  <action>OBSERVE</action>
  <bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
  <disposition>urn:epcglobal:cbv:disp:stolen</disposition>
  <readPoint>
    <id>urn:epc:id:sgln:643278.100002.0</id>
  </readPoint>
  <!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIDValue]</gs1brhc:eventID-->
  <!-- Note: the party generating the eventID will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/E8I2W99WKZ60</gs1brhc:eventID>
  <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/E8I2W99WKZ60</gs1brhc:eventID>
-->
  <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
  <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
  <gs1brhc:reason>StolenCargo</gs1brhc:reason>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>
  
```

6.7.3.4 XML Example of Loss of Product Value

```
<?xml version="1.0" encoding="UTF-8"?>
```

<!-- Example scenario: Hospital pharmacy discovers serialized product in inventory as damaged. Product inspection may be part of the business product receipt process with the outcome of the inspection determining whether product will be put away into inventory or quarantined for further analysis. Discovery of

damaged product may occur for serialized product in inventory. Consequently, in this example, damaged product is returned to the manufacturer.

Example shows negative outcome of inspection with disposition of "damaged"

Example shows how a damaged event observation can be sent by hospital pharmacy to manufacturer (registration holder)-->

```

<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-07-01T19:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-07-01T19:09:20Z</eventTime>
        <recordTime>2015-07-01T19:09:20Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.10000000000003</epc>
        </epcList>
        <action>OBSERVE</action>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
  
```

```

<bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
<disposition>urn:epcglobal:cbv:disp:damaged</disposition>
<readPoint>
  <id>urn:epc:id:sgln:643278.100002.0</id>
</readPoint>
<bizLocation>
  <id>urn:epc:id:sgln:789123.111111.0</id>
  <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
</bizLocation>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:eventID>-->
  <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/ZKCXOIZUQDXH</gs1brhc:eventID>
  <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/ZKCXOIZUQDXH</gs1brhc:eventID>
> -->
  <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
  <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
  <gs1brhc:reason>Product dropped in warehouse and damaged</gs1brhc:reason>
  </ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>
  
```

6.7.3.5 XML Example of Loss due to Product Expiration

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Hospital pharmacy discovers serialized product in inventory as expired
  Product inspection may be part of the business product receipt process with the outcome of the inspection
  determining whether product will be put away into inventory or quarantined for further analysis. Discovery
  of
  expired product may occur for serialized product in inventory. Consequently, in this example,
  expired product is returned to the manufacturer.
  Example shows negative outcome of inspection with disposition of "expired"
  Example shows how a expired event observation can be sent by hospital pharmacy to manufacturer
  (registration holder) -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-07-01T16:15:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
  <EventList>
  <ObjectEvent>
  <eventTime>2015-07-01T16:09:20Z</eventTime>
  <recordTime>2015-07-01T16:09:20Z</recordTime>
  <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
  <epcList>
  <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
  </epcList>
  <action>OBSERVE</action>
  <bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
  <disposition>urn:epcglobal:cbv:disp:expired</disposition>
  
```

```

<readPoint>
  <id>urn:epc:id:sgln:643278.100002.0</id>
</readPoint>
<bizLocation>
  <id>urn:epc:id:sgln:789123.111111.0</id>
  <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
</bizLocation>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:eventID>-->
  <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/6432781000025/IUDJC1CA8IJP</gs1brhc:eventID>
  <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/11223344000267/IUDJC1CA8IJP</gs1brhc:eventID> -
->
  <gs1brhc:declaringParty>urn:epc:id:sgln:643278.100001.0</gs1brhc:declaringParty>
  <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/11223344000186</gs1brhc:declaringParty> -->
  <gs1brhc:reason>Expired Product</gs1brhc:reason>
  </ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.7.3.6 XML Example of Disposal

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Product is destroyed at 3rd Party Destruction facility
  In this example, manufacturer sent the damaged product to 3rd Party for destruction -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-07-01T16:17:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1
  https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-07-01T14:09:30Z</eventTime>
        <recordTime>2015-07-01T14:09:30Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:destroying</bizStep>
        <disposition>urn:epcglobal:cbv:disp:destroyed</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:776523.122335.0</id>
        </readPoint>
        <!-- Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</gs1brhc:eventID>-->
          <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
          <!-- Change party once readPoint is assigned -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/7765231223354/2850VOYJD3FV</gs1brhc:eventID>

```

```

<!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/54612389000236/2850VOYJD3FV</gs1brhc:eventID>
-->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</gs1brhc:declaringParty> -->
<gs1brhc:reason>Destroy Damaged Product</gs1brhc:reason>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.7.4 Mapping of EPCIS End of Life (Finishing) Event to ANVISA Finishing Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Finalizacao/Finishing	Finalizacao/Evento/CabecalhoEvento/tipoEvento	Dispensing Inspecting Destroying	Assign value based on bizStep and set corresponding value for Finalizacao/Finishing
	Finalizacao/Evento/CabecalhoEvento/idInstanciaEvento	Dispensing Inspecting Destroying	gs1brhc:eventID
	Finalizacao/Evento/CabecalhoEvento/dataHorarioRegistro	Dispensing Inspecting Destroying	recordTime
	Finalizacao/Evento/CabecalhoEvento/dataHorarioOcorrencia	Dispensing Inspecting Destroying	eventTime
	choice: Finalizacao/Evento/declarante/CPF	Dispensing Inspecting Destroying	gs1brhc:declaringParty
	choice: Finalizacao/Evento/declarante/CNPJ	Dispensing Inspecting Destroying	gs1brhc:declaringParty
	choice: Finalizacao/Evento/declarante/CNES	Dispensing Inspecting Destroying	gs1brhc:declaringParty
	choice: Finalizacao/Evento/declarante/registroProfissional	Dispensing Inspecting Destroying	gs1brhc:declaringParty
	choice: Finalizacao/Evento/declarante/entidadeExterior	Dispensing Inspecting Destroying	gs1brhc:declaringParty
	Finalizacao/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Finalizacao/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Finalizacao/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Finalizacao/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Finalizacao/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
should be added to schema as	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode	

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	Finalizacao/Evento/declarante/CEP		
	Finalizacao/tipoFinalizacao	Dispensing Inspecting Destroying	Assign based on combination of bizStep and disposition. There are five types of finishing: 1. Dispensation (for bizStep = dispensing and disposition = dispensed) 2. Exit (for bizStep = dispensing and disposition = partial) 3. Misplacement (for bizStep= inspecting and disposition = stolen or misplaced) 4. Loss (for bizStep = inspecting with either disposition = damaged OR disposition = expired) 5. Disposal (for bizStep = destroying and disposition = destroyed)
	Finalizacao/IUM/numeroRegistroMedicamentoAnvisa	Dispensing Inspecting Destroying	look-up gs1brhc:ANVISARegistrationNumber from commissioning event based on epclist listed on Dispensing/Inspecting/Destroying event
	Finalizacao/IUM/numeroSerial	Dispensing Inspecting Destroying	look-up and derive serial number from epclist of the commissioning event based on epclist listed on Dispensing/Inspecting/Destroying event
	Finalizacao/IUM/dataValidade	Dispensing Inspecting Destroying	look-up gs1brhc:expirationDate from commissioning event based on epclist listed on Dispensing/Inspecting/Destroying event
	Finalizacao/IUM/numeroLote	Dispensing Inspecting Destroying	look-up gs1brhc:lotNumber from commissioning event based on epclist listed on Dispensing/Inspecting/Destroying event
	Finalizacao/motivo	Dispensing Inspecting Destroying	gs1brhc:reason

6.8 Implementation Procedure #8 Importing

An *importation* event is recorded when a drug produced abroad is nationalized. The importation incorporates properties of production and movement. In an importation, a foreigner manufacturer (or intermediate) sends the drug to Brazil, but the existence of the drug is only acknowledged by the SNCM from the moment that it is nationalized by the importer, who is the first link by which, indeed, the drug transits.

The importation has movement properties because the drug is moved from an organization (foreigner manufacturer) to another (importer); however, the foreigner manufacturer is **not** considered in the context of SNCM, pharmaceutical products chain link, and it is not responsible for

registering information in the SNCM. Its data are neither recorded in the SNCM; the registration of importation in the SNCM begins from the information from the carrier in charge of delivering the newly nationalized drug at the importer's facilities.

6.8.1 Pre-Requisite

The Electronic Product Codes (EPCs) of the imported objects have been previously commissioned, with relevant aggregation event(s) recorded to reflect the packaging hierarchy.

6.8.2 When Would I Use This?

This will be used to capture and report the event of importing an object from a foreign entity into local importer facilities.

6.8.2.1 Field Definitions

A finishing event resulting in product disposal should be an EPCIS Object Event populated as follows:

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epcList	urn:epc:id:sgtin: <i>CompanyPrefix.ItemReference.SerialNumber</i> OR urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition
action	OBSERVE	Required	EPCIS standard definition
bizStep	http://epcis.gs1br.org/hc/bizstep/importing	Required	
disposition	urn:epcglobal:cbv:disp:in_progress	Required	CBV standard definition
readPoint	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i>	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> or	Required	EPCIS standard definition

ELEMENT	MASK	USAGE	NOTE
bizTransactionList	http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber See Section 3.1.7.3 for details on how to extend bizTransactionList to include nota fiscal business transaction information.	Required	EPCIS standard definition

6.8.2.2 Field Extensions

In addition to the EPCIS standard fields shown above, the following extension is also included in a Importation event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Required
declaringParty	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
carrierParty	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
expectedNumUnits		Optional
expectedNumUnitUOM		Optional
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.8.3 How To's? (Example XML)

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Registration holder imports products from foreign manufacturer entity into local importer warehouse via carrier -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-07-01T20:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcischemas/GS1-BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-07-01T14:20:16Z</eventTime>
        <recordTime>2015-07-01T14:20:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:789123.01234567892</epc>
        </epcList>
      </ObjectEvent>
    </EventList>
  </EPCISBody>

```



```

<action>OBSERVE</action>
<bizStep>http://epcis.gs1br.org/hc/bizstep/importing</bizStep>
<disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
<readPoint>
  <id>urn:epc:id:sgln:789123.111111.0</id>
</readPoint>
<bizLocation>
  <id>urn:epc:id:sgln:789123.111111.0</id>
  <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
</bizLocation>
<bizTransactionList>
  <bizTransaction type="urn:epcglobal:cbv:btt:bol">
    urn:epcglobal:cbv:bt:8636621001007:567BOL89012
  </bizTransaction>
  <!--when using CNPJ
    <bizTransaction type="urn:epcglobal:cbv:btt:bol">
      http://epcis.gs1br.org/hc/bt/cnpj/86256136000182/567BOL89012
    </bizTransaction> -->
  <bizTransaction type="http://epcis.gs1br.org/hc/btt/delivery">
    http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/897
  </bizTransaction>
  <!-- Format for defining nota fiscal information in business transaction
    <bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">

http://epcis.gs1br.org/hc/bt/[partyIdentifierType]/[partyIdentifier]/[notaFiscalDocumentNumber].[notaFiscal
SeriesCode]
  </bizTransaction> -->
  <bizTransaction type="http://epcis.gs1br.org/hc/btt/notafiscal">
    http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/987654321.88888888
  </bizTransaction>
</bizTransactionList>
<!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</g
s1brhc:eventID>-->
  <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/7891231111114/VJVBB4KUQMSQ</gs1brhc:eve
ntID>
  <!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/VJVBB4KUQMSQ</gs1brhc:e
ventID> -->
  <gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
  <!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</gs1brhc:declaringParty> --
>
  <gs1brhc:carrierParty>urn:epc:id:sgln:863662.100100.0</gs1brhc:carrierParty>
  <!--when using CNPJ
<gs1brhc:carrierParty>http://epcis.gs1br.org/hc/cnpj/loc/86256136000182</gs1brhc:carrierParty> -->
  <gs1brhc:expectedNumUnits>3</gs1brhc:expectedNumUnits>
  <gs1brhc:expectedNumUnitUOM>ITEM</gs1brhc:expectedNumUnitUOM>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.8.4 Mapping of EPCIS Importation Event to ANVISA Importation Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Importacao/Importation	Importacao/Evento/CabecalhoEvento/tipoEvento	Importing	Assign value based on bizStep For bizStep = importing set corresponding value for Importacao/Importation
	Importacao/Evento/CabecalhoEvento/idInstanciaEvento	Importing	gs1brhc:eventID
	Importacao/Evento/CabecalhoEvento/dataHorarioRegistro	Importing	recordTime
	Importacao/Evento/CabecalhoEvento/dataHorarioOcorrencia	Importing	eventTime
	choice: Importacao/Evento/declarante/CPF	Importing	gs1brhc:declaringParty
	choice: Importacao/Evento/declarante/CNPJ	Importing	gs1brhc:declaringParty
	choice: Importacao/Evento/declarante/CNES	Importing	gs1brhc:declaringParty
	choice: Importacao/Evento/declarante/registroProfissional	Importing	gs1brhc:declaringParty
	choice: Importacao/Evento/declarante/entidadeExterior	Importing	gs1brhc:declaringParty
	Importacao/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Importacao/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Importacao/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Importacao/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Importacao/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as Importacao/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	choice: Importacao/transportadora/CPF	Importing	gs1brhc:carrierParty
	choice: Importacao/transportadora/CNPJ	Importing	gs1brhc:carrierParty
	choice: Importacao/transportadora/CNES	Importing	gs1brhc:carrierParty
	choice: Importacao/transportadora/registroProfissional	Importing	gs1brhc:carrierParty
	choice: Importacao/transportadora/entidadeExterior	Importing	gs1brhc:carrierParty

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	Importacao/transportadora/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Importacao/transportadora/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Importacao/transportadora/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Importacao/transportadora/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Importacao/transportadora/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as Importacao/transportadora/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	choice: Importacao/idEmbalagem/idEmbalagemTransporte	Importing	epcList
	choice: Importacao/IUM	Importing	See mapping below for each IUM element
	Importacao/IUM/numRegistroMedicamentoAnvisa	Importing	look-up gs1brhc:ANVISARegistrationNumber from commissioning event based on epcList listed on importing event
	Importacao/IUM/numSerial	Importing	look-up and derive serial number from epcList of the commissioning event based on epcList listed on importing event
	Importacao/IUM/dataValidade	Importing	look-up gs1brhc:expirationDate from commissioning event based on epcList listed on importing event
	Importacao/IUM/numLote	Importing	look-up gs1brhc:lotNumber from commissioning event based on epcList listed on importing event

6.9 Implementation Procedure #9 Recovery

Recovery is the process of a total or partial incorporation of previous batches of proven quality, to another batch in a defined step of the production.

6.9.1 Pre-Requisite

Recovery of rejected products should be exceptional and pertain only to serialized items that have already been reported in a Production Event, which initiated the informational traceability process; a recovered batch should receive a new batch number.

The reprocessing or recovery is allowed only if the quality of the final product is not affected.

6.9.2 When Would I Use This?

A Recovery event is recorded by a registration holder link (and only by it) when a drug associated to a serialized item is subjected to a special recovery procedure. The event of the Recovery type was modeled based on the requirements of good manufacturing practices for pharmaceutical products.

6.9.2.1 Field Definitions

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

ELEMENT	MASK	USAGE	NOTE
eventTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
recordTime	YYYY-MM-DDThh:mm:ss[<i>timezone indicator</i>] Valid timezone indicators are "Z" for UTC, or ±[hh]:[mm] to indicate timeoffset from UTC.	Required	EPCIS standard definition
eventTimeZoneOffset	±[hh]:[mm]	Required	EPCIS standard definition
epcList	urn:epc:id:sscc: <i>CompanyPrefix.SerialReference</i>	Required	EPCIS standard definition
Action	OBSERVE	Required	EPCIS standard definition
bizStep	http://epcis.gs1br.org/hc/bizstep/recovering	Required	CBV standard definition
disposition	urn:epcglobal:cbv:disp:in_progress	Required	CBV standard definition
readPoint	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Optional	EPCIS standard definition
bizLocation	urn:epc:id:sgln: <i>CompanyPrefix.LocationReference.Extension</i> or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required	EPCIS standard definition
bizTransactionList		Optional	EPCIS standard definition

6.9.2.2 Field Extension Fields

In addition to the EPCIS standard fields shown above, the following extension is also included in a Recovery event.

ELEMENT	MASK	USAGE
eventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]	Required

ELEMENT	MASK	USAGE
declaringParty	with eventIdValue formatted as [A-Z0-9]{12} urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension or http://epcis.gs1br.org/hc/cnpj/loc/CNPJNumber	Required
postRecoveryBatch		Required
reason		Required
retractionFlag	true or false	Conditional
replacementEventID	http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue] with eventIdValue formatted as [A-Z0-9]{12}	Conditional
retractionReason		Conditional

6.9.3 How To? (Example XML)

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Recovery -->
<!-- In this scenario, the manufacturer reworks the defective product, assigns a new batch and sends
recovery message to the 3PL -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-07-02T15:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcischemas/GS1-
BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-07-02T15:11:21Z</eventTime>
        <recordTime>2015-07-02T15:11:21Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>http://epcis.gs1br.org/hc/bizstep/recovering</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:789123.111112.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:789123.111112.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000357</id> -->
        </bizLocation>
        <!-- eventID Format:
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]</g
s1brhc:eventID-->
        <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->

<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/gln/7891231111121/AROA98AW9I8K</gs1brhc:even
tID>
    
```

```

<!--when using CNPJ
<gs1brhc:eventID>http://epcis.gs1br.org/hc/eventid/cnpj/12345678000357/AROA98AW9I8K</gs1brhc:ev
entID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!--when using CNPJ
<gs1brhc:declaringParty>http://epcis.gs1br.org/hc/cnpj/loc/12345678000195</gs1brhc:declaringParty> --
>
<gs1brhc:postRecoveryBatch>RW1234</gs1brhc:postRecoveryBatch>
<gs1brhc:reason>Printing of defective datamatrix label</gs1brhc:reason>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.9.4 Mapping of EPCIS Recovering Event to ANVISA Recovery Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Recuperacao/Recovery	Recuperacao/Evento/CabecalhoEvento/tipoEvento	Recovery	Assign value based on bizStep For bizStep = recovering set corresponding value for Recuperacao/Recovery
	Recuperacao/Evento/CabecalhoEvento/idInstanciaEvento	Recovery	gs1brhc:eventID
	Recuperacao/Evento/CabecalhoEvento/dataHorarioRegistro	Recovery	recordTime
	Recuperacao/Evento/CabecalhoEvento/dataHorarioOcorrencia	Recovery	eventTime
	choice: Recuperacao/Evento/declarante/CPF	Recovery	gs1brhc:declaringParty
	choice: Recuperacao/Evento/declarante/CNPJ	Recovery	gs1brhc:declaringParty
	choice: Recuperacao/Evento/declarante/CNES	Recovery	gs1brhc:declaringParty
	choice: Recuperacao/Evento/declarante/registroProfissional	Recovery	gs1brhc:declaringParty
	choice: Recuperacao/Evento/declarante/entidadeExterior	Recovery	gs1brhc:declaringParty
	RecuperacaoEvento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Recuperacao/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Recuperacao/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Recuperacao/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Recuperacao/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	should be added to schema as Recuperacao/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	Recuperacao/iumAnterior/numRegistroMedicamentoAnvisa	Recovery	look-up gs1brhc:ANVISARegistrationNumber from commissioning event based on epclist listed on Recovery event
	Recuperacao/iumAnterior/numSeria	Recovery	look-up and derive serial number from epclist of the commissioning event based on epclist listed on Recovery event
	Recuperacao/iumAnterior/dataValidade	Recovery	look-up gs1brhc:expirationDate from commissioning event based on epclist listed on Recovery event
	Recuperacao/iumAnterior/numLote	Recovery	look-up gs1brhc:lotNumber from commissioning event based on epclist listed on Recovery event
	Recuperacao/numLoteNovo	Recovery	gs1brhc:postRecoveryBatch
	Recuperacao/motivo	Recovery	gs1brhc:reason

6.10 Implementation Procedure #10 Rectification

A rectification event is recorded when an error was detected in the previous record of a given event and it will be either declared as invalid or it will be replaced by an event with the correct data.

There are two ways to make a rectification:

1. To declare the invalidity of an event: To be performed when an event that did not occur was wrongly recorded. This event will not be replaced by any other, and should only be ignored when only information declared as true is wanted.
2. Replace an event: To be performed when an event that occurred was recorded, but with one or more incorrect information. In such case, a replacer event, containing the correct information is recorded, and the rectification associates the replacer event to the original event, indicating that the first substitutes the last one. An event instance can only be replaced by another event instance of the SAME type.

6.10.1 Pre-Requisite

An invalid event for the affected Electronic Product Codes (EPCs) of the objects being rectified have been previously recorded with the erroneous information.

6.10.2 When Would I Use This?

Since the fidelity of historical information of events registered in SNCM is forbidden to be updated or removed from the SNCM database, the rectification event is a mechanism to correct any errors detected.

6.10.2.1 Field Definitions

There is no independent separate rectification event structure defined. To streamline the correction process, a rectification event mirrors the structure of the event that is being rectified.

Each EPCIS event that is reported to ANVISA has been designed to have 3 Conditional extension fields (**retractionFlag**, **replacementEventID**, **retractionReason**) that will be populated to signal retraction of the invalid event.

- Initially, an event is recorded without populating the 3 conditional extension fields (**retractionFlag**, **replacementEventID**, **retractionReason**)
- Upon detecting an error on a previously recorded event, the declaringParty decides either to declare an event sufficiently invalid or to replace the event with correct information.
- When an event is declared as invalid only, the declaringParty will create and record an identical event augmented with **retractionFlag** field set to **true** and **retractionReason** field **filled in** with reason statement explaining the error.
- When an invalid event is replaced by another event, then the declaringParty will create and record an identical event augmented with **retractionFlag** field set to **true**, **replacementEventID** assigned with the **eventId** associated with the **replacement event**, and the **retractionReason** field **filled in** with reason statement explaining the error.

6.10.3 How To? (Example XML)

Step1: Display the initial Commissioning event that has been previously recorded and consequently identified to be invalid. (Note the absence of the 3 conditional rectification fields(**retractionFlag**, **replacementEventID**, **retractionReason**) in the commission event XML).

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer produces and commissions serialized items -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-06-29T15:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcisschemas/GS1-
  BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-29T15:12:16Z</eventTime>
        <recordTime>2015-06-29T15:12:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:789123.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:789123.111111.0</id>
          <!-- Example showing use of local identifier -->
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
        </bizLocation>
        <!-- bizTransaction documents are optional for production event but an example
          is provided here to show use of production order document -->
        <bizTransactionList>
```



```

<bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
  urn:epcglobal:cbv:bt:7891231111107:CCC8
</bizTransaction>
<!-- Example showing use of local identifier -->
<!--when using CNPJ
  <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
    http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/CCC8
  </bizTransaction> -->
</bizTransactionList>
<extension>
  <ilmd>
    <gs1brhc:ANVISARegistrationNumber>1584682484853</gs1brhc:ANVISARegistrationNumber>
    <gs1brhc:expirationDate>2016-03-15</gs1brhc:expirationDate>
    <gs1brhc:manufacturingDate>2015-03-15</gs1brhc:manufacturingDate>
    <gs1brhc:packagingLevel>ITEM</gs1brhc:packagingLevel>
  </ilmd>
</extension>
<!-- Lot Number is added as a commissioning event extension instead of
  having this part of the ilmd. This is in consideration of the Recovery event which
  enables batch number to be later updated as part of Recovery event notification -->
<gs1brhc:lotNumber>A123</gs1brhc:lotNumber>
<!-- eventID Format:
  <gs1brhc:eventID>
    http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]
  </gs1brhc:eventID>-->
<!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
<gs1brhc:eventID>
  http://epcis.gs1br.org/hc/eventid/gln/7891231111114/8MP56CWMAMRV
</gs1brhc:eventID>
<!--when using CNPJ
  <gs1brhc:eventID>
    http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/8MP56CWMAMRV
  </gs1brhc:eventID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!-- Example showing use of local identifier -->
<!--when using CNPJ
  <gs1brhc:declaringParty>
    http://epcis.gs1br.org/hc/cnpj/loc/12345678000195
  </gs1brhc:declaringParty> -->
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

Step2: Create and record the replacement event for erroneous commissioning event.

Note the recordTime, expirationDate and eventId fields in this event record, which is intending to replace the previously recorded event in Step1.

```

<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Manufacturer produces and commissions serialized items -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
  xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
  schemaVersion="1.1" creationDate="2015-07-03T15:14:27.574-04:00"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcischemas/GS1-
  BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>

```

```

<EventList>
  <ObjectEvent>
    <eventTime>2015-06-29T15:12:16Z</eventTime>
    <recordTime>2015-07-03T15:12:16Z</recordTime>
    <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
    <epcList>
      <epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
      <epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
      <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
    </epcList>
    <action>ADD</action>
    <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
    <disposition>urn:epcglobal:cbv:disp:active</disposition>
    <readPoint>
      <id>urn:epc:id:sgln:789123.111111.0</id>
    </readPoint>
    <bizLocation>
      <id>urn:epc:id:sgln:789123.111111.0</id>
      <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
    </bizLocation>
    <!-- bizTransaction documents are optional for production event but an example
      is provided here to show use of production order document -->
    <bizTransactionList>
      <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
        urn:epcglobal:cbv:bt:7891231111107:CCC8
      </bizTransaction>
      <!--when using CNPJ
        <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
          http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/CCC8
        </bizTransaction> -->
    </bizTransactionList>
    <extension>
      <ilmd>
        <gs1brhc:ANVISARegistrationNumber>1584682484853</gs1brhc:ANVISARegistrationNumber>
        <gs1brhc:expirationDate>2017-03-15</gs1brhc:expirationDate>
        <gs1brhc:manufacturingDate>2015-03-15</gs1brhc:manufacturingDate>
        <gs1brhc:packagingLevel>ITEM</gs1brhc:packagingLevel>
      </ilmd>
    </extension>
    <!-- Lot Number is added as a commissioning event extension instead of
      having this part of the ilmd. This is in consideration of the Recovery event which
      enables batch number to be later updated as part of Recovery event notification -->
    <gs1brhc:lotNumber>A123</gs1brhc:lotNumber>
    <!-- eventID Format:
    <gs1brhc:eventID>
      http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]
    </gs1brhc:eventID-->
    <!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
    <gs1brhc:eventID>
      http://epcis.gs1br.org/hc/eventid/gln/7891231111114/L2GJCH8DGAWJ
    </gs1brhc:eventID>
    <!--when using CNPJ
    <gs1brhc:eventID>
      http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/L2GJCH8DGAWJ
    </gs1brhc:eventID> -->
  </ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

Step3: Construct the augmented mirrored copy of the invalid Commissioning event showing the population of the 3 conditional rectification fields(**retractionFlag, replacementEventID, retractionReason**).

Note that the eventId in Step3 is the same as eventId in Step1 while replacementEventID is the same as eventId in Step2. The recordTime differs from Step1 reflecting that this retraction event is recorded after discovery of error.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Example scenario: Rectification event of a previously commissioning event reported by manufacturer
who produced and commissioned serialized items -->
<epcis:EPCISDocument xmlns:epcis="urn:epcglobal:epcis:xsd:1"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:epcismd="urn:epcglobal:epcis-masterdata:xsd:1" xmlns:gs1brhc="http://epcis.gs1br.org/hc/ns"
schemaVersion="1.1" creationDate="2015-06-29T15:14:27.574-04:00"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 https://www.gs1br.org/healthcare/epcischemas/GS1-
BR-EPCglobal-epcis-1_1.xsd">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2015-06-29T15:12:16Z</eventTime>
        <recordTime>2015-07-03T15:15:16Z</recordTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000001</epc>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000002</epc>
          <epc>urn:epc:id:sgtin:789123.0012345.1000000000003</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:789123.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:789123.111111.0</id>
          <!--when using CNPJ <id>http://epcis.gs1br.org/hc/cnpj/loc/12345678000276</id> -->
        </bizLocation>
        <!-- bizTransaction documents are optional for production event but an example
is provided here to show use of production order document -->
        <bizTransactionList>
          <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
            urn:epcglobal:cbv:bt:7891231111107:CCC8
          </bizTransaction>
          <!-- Examples showing use of local identifiers -->
          <!--when using CNPJ
          <bizTransaction type="urn:epcglobal:cbv:btt:prodorder">
            http://epcis.gs1br.org/hc/bt/cnpj/12345678000195/CCC8
          </bizTransaction> -->
        </bizTransactionList>
        <extension>
          <ilmd>
            <gs1brhc:ANVISARegistrationNumber>1584682484853</gs1brhc:ANVISARegistrationNumber>
            <gs1brhc:expirationDate>2016-03-15</gs1brhc:expirationDate>
            <gs1brhc:manufacturingDate>2015-03-15</gs1brhc:manufacturingDate>
            <gs1brhc:packagingLevel>ITEM</gs1brhc:packagingLevel>
          </ilmd>
        </extension>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</EPCISDocument>
```

```

</extension>
<!-- Lot Number is added as a commissioning event extension instead of
having this part of the ilmd. This is in consideration of the Recovery event which
enables batch number to be later updated as part of Recovery event notification -->
<gs1brhc:lotNumber>A123</gs1brhc:lotNumber>
<!-- eventID Format:
<gs1brhc:eventID>
http://epcis.gs1br.org/hc/eventid/[partyIdentifierType]/[partyIdentifier]/[eventIdValue]
</gs1brhc:eventID>-->
<!-- Note: the party generating the eventId will be the same as the party in the readPoint -->
<gs1brhc:eventID>
http://epcis.gs1br.org/hc/eventid/gln/7891231111114/8MP56CWMAMRV
</gs1brhc:eventID>
<!--when using CNPJ
<gs1brhc:eventID>
http://epcis.gs1br.org/hc/eventid/cnpj/12345678000276/8MP56CWMAMRV
</gs1brhc:eventID> -->
<gs1brhc:declaringParty>urn:epc:id:sgln:789123.111110.0</gs1brhc:declaringParty>
<!--when using CNPJ
<gs1brhc:declaringParty>
http://epcis.gs1br.org/hc/cnpj/loc/12345678000195
</gs1brhc:declaringParty> -->
<gs1brhc:retractionFlag>true</gs1brhc:retractionFlag>
<gs1brhc:replacementEventID>
http://epcis.gs1br.org/hc/eventid/gln/7891231111114/L2GJCH8DGAWJ
</gs1brhc:replacementEventID>
<gs1brhc:retractionReason>Incorrect expiration date was previously recorded and being updated.
</gs1brhc:retractionReason>
</ObjectEvent>
</EventList>
</EPCISBody>
</epcis:EPCISDocument>

```

6.10.4 Mapping of various EPCIS Events to ANVISA Rectification Notification Message

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
Retificacao/Rectification	Retificacao/Evento/CabecalhoEvento/tipoEvento	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	Assign value based on bizStep
	Retificacao/Evento/CabecalhoEvento/idInstanciaEvento	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing	gs1brhc:eventID

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
		Destroying Importing Recovering Rectification	
	Retificacao/Evento/Cabecal hoEvento/dataHorarioRegis tro	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	recordTime
	Retificacao/Evento/Cabeca lhoEvento/dataHorarioOco rrencia	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	eventTime
	choice: Retificacao/Evento/declara nte/CPF	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:declaringParty
	choice: Retificacao/Evento/declara nte/CNPJ	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:declaringParty
	choice: Retificacao/Evento/declara nte/CNES	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:declaringParty

ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
	choice: Retificacao/Evento/declarante/registroProfissional	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:declaringParty
	choice: Retificacao/Evento/declarante/entidadeExterior	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:declaringParty
	Retificacao/Evento/declarante/nome	EPCIS Header	http://epcis.gs1br.org/hc/mda/companyName
	Retificacao/Evento/declarante/endereco	EPCIS Header	http://epcis.gs1br.org/hc/mda/street1 http://epcis.gs1br.org/hc/mda/street2
	Retificacao/Evento/declarante/municipio	EPCIS Header	http://epcis.gs1br.org/hc/mda/city
	Retificacao/Evento/declarante/UF	EPCIS Header	http://epcis.gs1br.org/hc/mda/stateOrRegion
	Retificacao/Evento/declarante/Pais	EPCIS Header	http://epcis.gs1br.org/hc/mda/country
	should be added to schema as Retificacao/Evento/declarante/CEP	EPCIS Header	http://epcis.gs1br.org/hc/mda/postalCode
	Retificacao/tipoRetificacao	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	<p>There are 2 types of Rectification 1 - Event Invalidity Statement 2 - Event Substitution</p> <p>If gs1brhc:retractionFlag is set to true and gs1brhc:replacementEventID is NULL, then set the Rectification type to 1 for Event Invalidity Statement</p> <p>If gs1brhc:retractionFlag is set to true and gs1brhc:replacementEventID is NOT NULL, then set the Rectification type to 2 for Event Substitution</p>
	Retificacao/idInstanciaEventoSubstituida	Commissioning Packing Unpacking Shipping Receiving	eventId of the event that is being declared as invalid which may also be replaced by another event with corrected information.

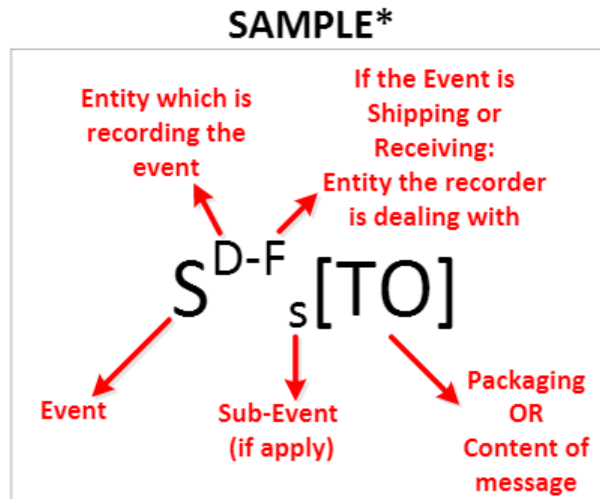
ANVISA Event	ANVISA Field Name	EPCIS Event	EPCIS Field Name
		Inspecting Dispensing Destroying Importing Recovering Rectification	when querying the event repository, an invalid event record can be identified as records with gs1brhc:retractionFlag set to true
	Retificacao/idInstanciaEventoSubstituidora	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:replacementEventID
	Retificacao/motivo	Commissioning Packing Unpacking Shipping Receiving Inspecting Dispensing Destroying Importing Recovering Rectification	gs1brhc:retractionReason

7 Choreographies

This section will show the main choreographies that will appear during the pilot implementation of the Brazilian traceability regulation. This choreographies are independent of the repository model the concern only the events and his generation. This section will continue to grow as the use cases continue to appear during the implementations.

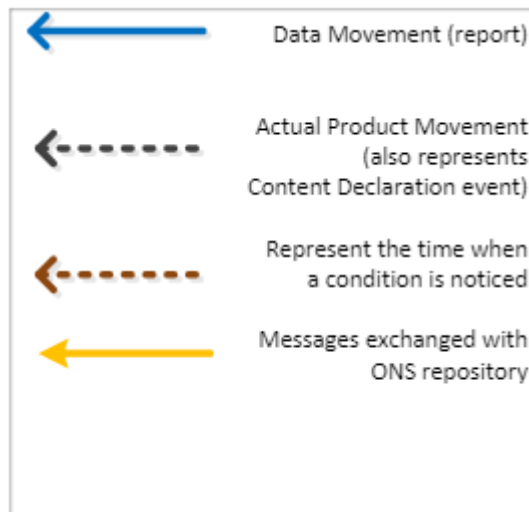
7.1 Conventions

To simplify the process to describe de choreographies it was created a nomenclature to help the process. Each event is described as the following:



*Events in green color represent events that are not mandatory to be at the Repository.

The flow of information and of goods will use the following notation:



The following events have to be recorded through the supply chain, according to the regulation:


```

C := Commissioning
    p:= production (Produção)
    i:= import (Importação)
P:= Packing (Agregação)
S:= Shipping (Entrega)
    s:= sales-purchasing (compra-venda)
    t:= transfer (transferência)
    d:= donation (doação)
    r:= return (devolução)
    f:= free-sample (amostra grátis)
    i := inventory adjustment
R:= Receiving (Recebimento)
    Note: Apply the same subindex as before
I:= Inspecting (Verificação Conteúdo)
U:= Unpacking
E:= End-of-useful-life
    d := dispensation (dispensação)
    r := rule-out (baixa)
    m:= misplace (extravio)
    l := loss (perda)
    disc:= discard (descarte)
    i := inventory adjustment
Recov:= Recovery (Recuperação)
Corr:= Correction (Retificação)
    i:= invalid event
    r:= replace event
D:= Event Statement (Declaração de Eventos)
O:= Message exchanged with ONS repository
    q:= query to ONS
    r:= response from ONS
    
```

Following are the levels of package:

```

TI := Minimum Trading Unit
CA:= Case
PA:= Pallet
TO := Tote
    
```

These are the contents to use in the ONS query:

```

KeyID:= GS1 Key ID (f. ex: GTIN, GLN)
    p:= previous
    m:= manufacturer
NAPTR:= Information related to the queried KeyID
    
```

The entities involved into the supply chain are listed below:

M:= Manufacturer (Fabricante/Importador)
DC:= Distribution Center (Centro de Distribuição)
D:= Wholesaler (Distribuidor)
F:= Drugstore (Farmácia)
H:= Hospital/Basic Health Unit
R:= Drug Company Salesman (Representante)
P:= Doctor (Médico)
E:= Entity (generic placeholder that represents any link of the supply chain)
Pat:= Public, Patient
DH:=Hospital Distribution Center (CD do Hosp.)

Notes:

1. Dataflow (coreography) for Donation is the same as Basic (Until Hospital or Drugstore), just change the subindex of the Shipping/Receiving events.
2. Dataflows (coreographies) for End-of-Life (dispense, rule-out, misplace, loss, discard) are the same, just change the subindex of the End-of-Life event.
3. The events in green color are not defined as mandatory by Anvisa regulation, but are required for operational purposes.
4. In the case of Shipping Events reported forward (Content Declaration), they should be sent with Commissioning and Packaging events, so the receiver part can infer the content of the package. (See green events in the Basic-Drugstore coreography). In other coreographies, the same applies (even if there is no explicit mention).
5. The pallet (and other high-level packages) cannot be repeated. Because the receiving partner will send an "inspecting" event at the higher-level (and the Manufacturer will link that event to the hierarchy previously informed)

7.2 Choreography #1 Content Declaration

When the manufacturer is ready to send a Pallet to the Distribution Center, it should locally register a Shipping Event and send that Shipping Event to the Distribution Center Information System. Along with the Shipping Event, the whole hierarchy should be sent to the Distribution Center Repository in order to inform the TI and packaging that are being recorded.

7.2.1 Pre-Requisite

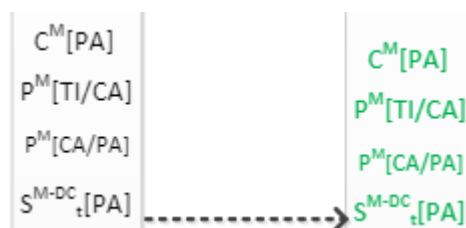
Product is ready to be shipped to the next link in the supply chain.

7.2.2 When Would I Use This?

This choreography is used every time a shipping event occurs, regardless the origin or the destination.

7.2.3 How To?

Coreography example:



Description of events:

Symbol:	S ^{M-DC} _t [PA]
---------	-------------------------------------

Description:	Shipping happening at the Manufacturer Company, with destination a Distribution Center as part of a transfer. The packaging form is a Pallet.
Trigger:	After the Fiscal Invoice is generated
Comments:	

Symbol:	$C^M[TI]$ $C^M[CA]$ $C^M[PA]$ $P^M[TI/CA]$ $P^M[CA/PA]$
Description:	Events representing Producing actions (Commissioning and Aggregation)
Trigger:	Should be sent along with the Shipping Event
Comments:	

7.3 Choreography #2 Inspecting and Receiving

When the destination receives a shipping event from the sender it needs to return information of inspect and receive the product. The destination or the origin can be any link of the supply chain.

7.3.1 Pre-Requisite

Physical receipt of the product.

7.3.2 When Would I Use This?

This choreography is used every time a receiving event occurs, regardless the origin or the destination.

7.3.3 How To?

Coreography example:



Description of events:

Symbol:	$I^{DH}[TO]$ $R^{DH-D}_s[TO]$
Description:	Events representing inspecting and receiving
Trigger:	Physical receipt
Comments:	

Symbol:	$S^{D-DH}_s[TO]$
Description:	Shipping happening at the Distribution Center to the Hospital Distribution Center as part of a sale. The packaging form is a Tote
Trigger:	Product checkout at Distribution Center
Comments:	Distribution Center also can be another Hospital Distribution Center, a Hospital or a Drugstore. Anyone local that can shipping a product to a Hospital Distribution Center.

7.4 Choreography #3 Unpacking

When the destination of a previous shipping event receives the product, it must be stored. The product packaging needs to be converted to the minimum trading unit before the store process.

7.4.1 Pre-Requisite

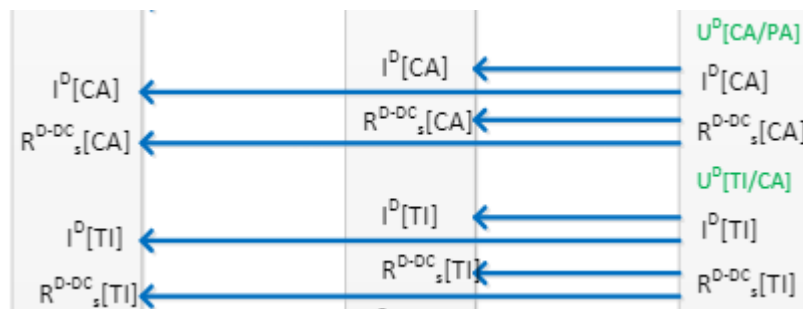
Receiving and inspecting the product.

7.4.2 When Would I Use This?

This choreography is used every time a product needs to be converted to another packing.

7.4.3 How To?

Coreography example:



Description of events:

Symbol:	$U^D[CA/PA]$ $I^D[CA]$ $R^{D-DC}_s[CA]$ $U^D[TI/CA]$ $I^D[TI]$ $R^{D-DC}_s[TI]$
Description:	Events representing unpacking.
Trigger:	After receiving the product and before the store the product.
Comments:	

7.5 Choreography #4 Packing and Shipping

When a supply chain link needs to send product to next link and this product is in the minimum trading unit.

7.5.1 Pre-Requisite

Receiving, inspecting, unpacking and store product at the shipping origin.

7.5.2 When Would I Use This?

This choreography is used every time a shipping event occurs, regardless the origin or the destination. This choreography is used for locals that redistribute products to another link of the supply chain.

7.5.3 How To?

Coreography example:



Description of events:

Symbol:	$S^{DH-H}_t[TO]$
Description:	Shipping happening at the Hospital Distribution Center to the Hospital as part of a transfer. The packing form is a Tote.
Trigger:	Product checkout at Hospital Distribution Center
Comments:	

Symbol:	$P^{DH}[TI/TO]$
Description:	Events representing Packing
Trigger:	Should be sent along with the Shipping Event
Comments:	

7.6 Choreography #5 End of Life

When any link of supply chain needs to rule-out the minimum trade unit by any reason. The event should be sent to show that the minimum trade unit does not exist anymore.

7.6.1 Pre-Requisite

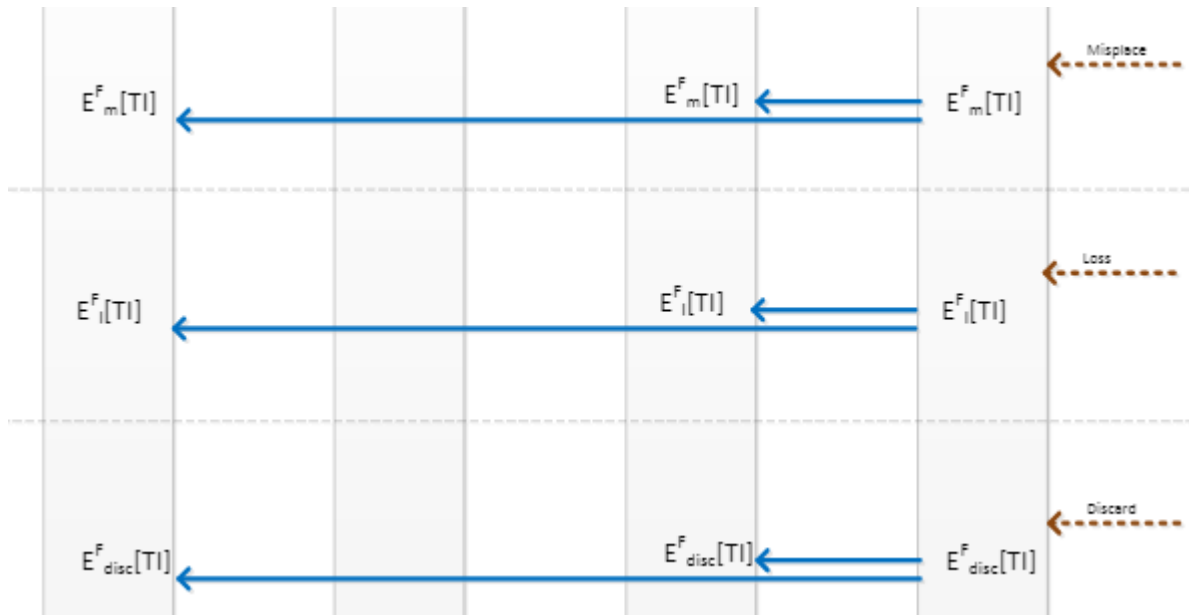
Receiving, inspecting, unpacking and store product.

7.6.2 When Would I Use This?

This choreography is used every time a rule-out event occurs, regardless the origin or the destination.

7.6.3 How To?

Coreography example:



Note: According with ANVISA’s Technical Note (SNCM – 01/2015), the dispensation and rule-out events doesn’t need to be reported back to previous links (or the manufacturer).

Description of events:

Symbol:	$E_m^F[TI]$
Description:	End-of-useful-life happening at the Drugstore to the Wholesaler. The packaging form is a Minimum Trading Unit
Trigger:	When a Minimum Trade Unit is rule-out
Comments:	This same choreography is to be used for events: Misplace, Loss and Discard. In this specific choreography the shown dispensation unit is a Pharmacy, but it applies to any dispensation unit.

7.7 Choreography #6 Product Return

After an end-of-life event a product can return to the supply chain.

7.7.1 Pre-Requisite

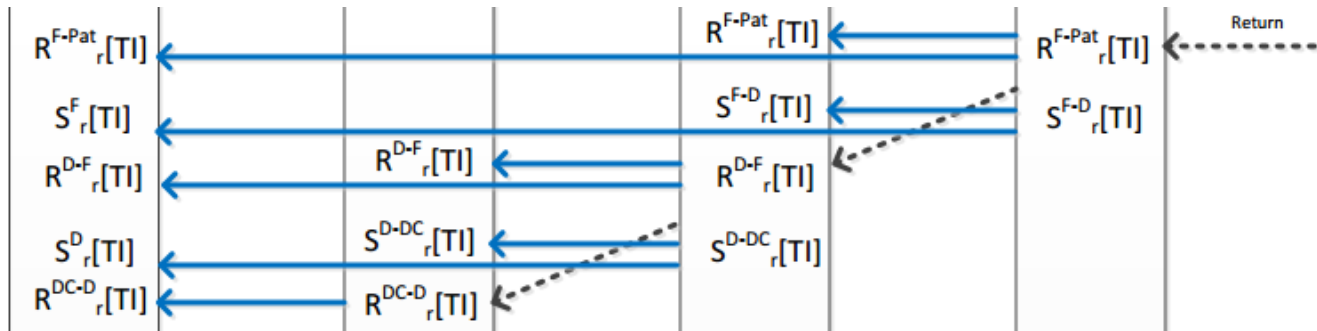
Previous sent of an end-of-life event for the product.

7.7.2 When Would I Use This?

This choreography is used every time a return event occurs, regardless the origin or the destination.

7.7.3 How To?

Coreography example:



Description of events:

Symbol:	$R^{F-Pat}_r[TI]$
Description:	Event representing a return event from the patient to the Drugstore.
Trigger:	Physical return of the product.
Comments:	

7.8 Choreography #7 Recovery

When the Drugstore recovers the Minimum Trade Unit. The event should be sent to the Wholesaler and the Manufacturer to show that the Minimum Trade Unit was a recovery event.

7.8.1 Pre-Requisite

Drugstore recovers the Minimum Trade Unit.

7.8.2 When Would I Use This?

This choreography is used every time a recovery event occurs, regardless the origin or the destination.

7.8.3 How To?

Coreography example:



Description of events:

Symbol:	$Recov^F[TI]$
Description:	A recovery event happening at the Drugstore to the Wholesaler. The packaging form is a Minimum Trading Unit
Trigger:	When a Minimum Trade Unit was recovered
Comments:	

7.9 Choreography #8 Drug Salesman Delivering Free-samples to the Doctor

When the Drug Company Salesman is ready to send the Minimum Trading Unit to the Doctor, it should locally register a Shipping Event and send that Shipping Event to the Doctor Information System. Along with the Shipping Event, the whole hierarchy should be sent to the Distribution Center Repository in order to inform the TI and packaging that are being recorded.

7.9.1 Pre-Requisite

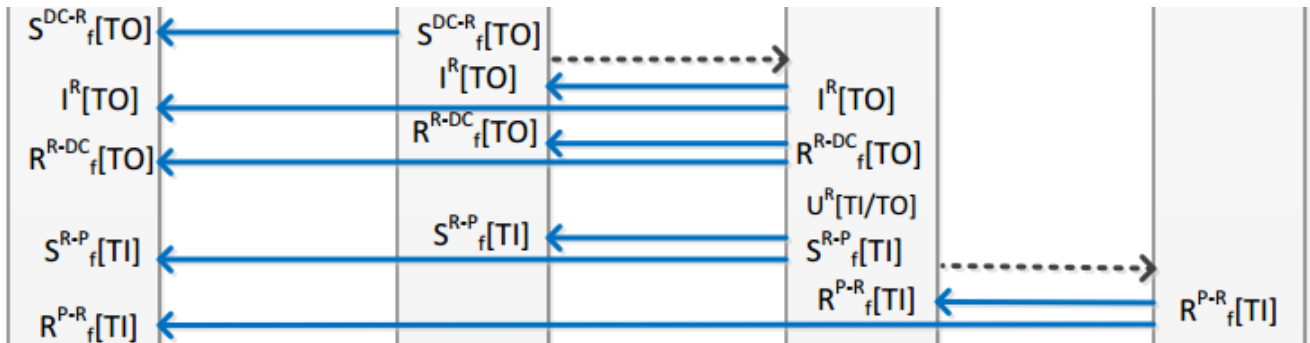
Drug Company Salesman is ready to send the Minimum Trading Unit to the Doctor.

7.9.2 When Would I Use This?

This choreography is used every time a salesman representative deliver free-samples to a Doctor.

7.9.3 How To?

Coreography example:



Description of events:

Symbol:	$S^{R-P}_f[TI]$
Description:	Shipping happening at the Drug Company Salesman to the Doctor. The packaging form is a Minimum Trading Unit
Trigger:	
Comments:	

Symbol:	$I^R[TO]$ $R^{R-DC}_f[TO]$ $U^R[TI/TO]$
Description:	Events representing Free Sample actions (Shipping)
Trigger:	Should be sent along with the Shipping Event
Comments:	

7.10 Choreography #9 ONS Queries and Responses

This choreography explains the procedure to be executed in case the entity must report an event to an external information system (Repository), if that entity doesn't know the URL of that destination repository. The EPCIS still doesn't exist inside GS1 Brazil, however it will be implemented if the market needs it.

7.10.1 Pre-Requisite

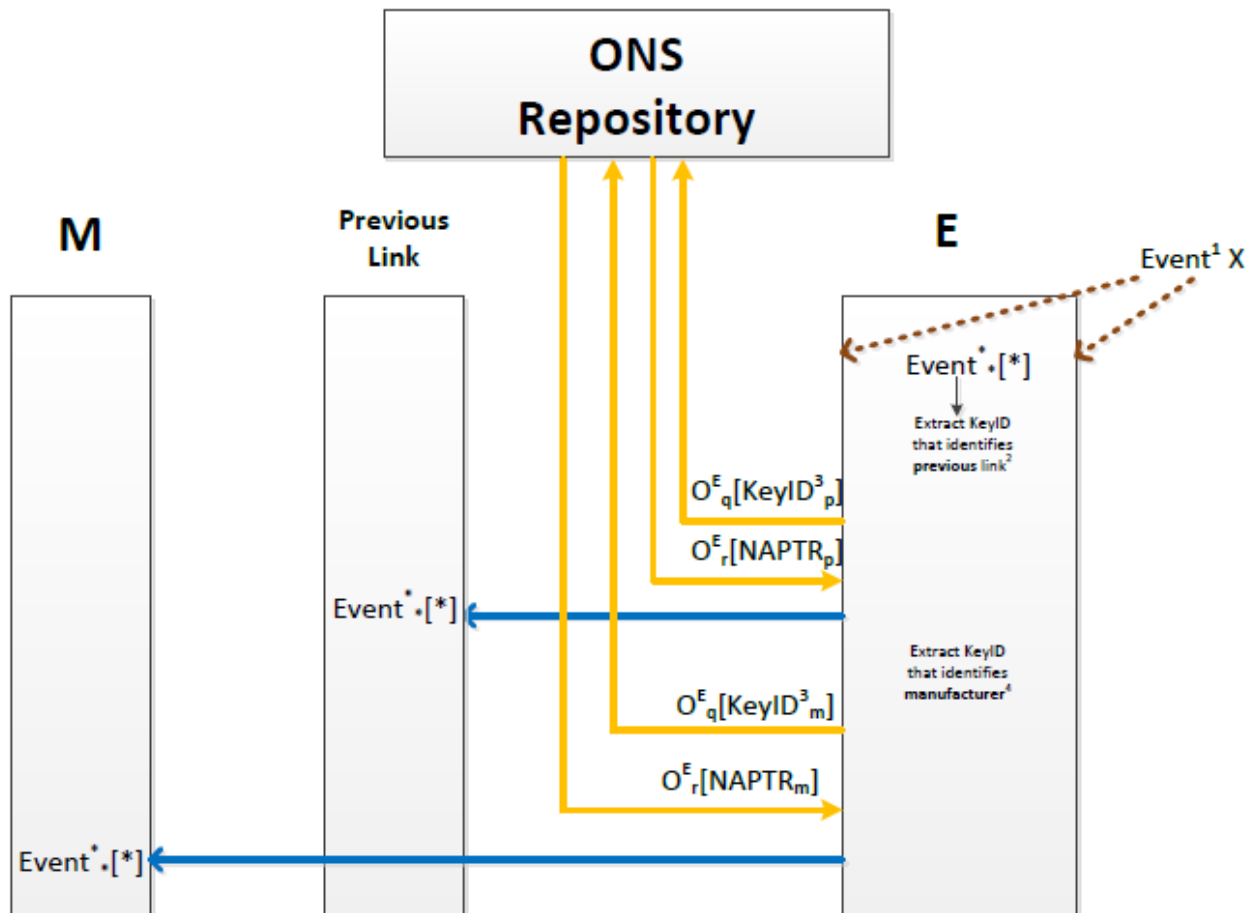
The entity must report an event to an external information system.

7.10.2 When Would I Use This?

This choreography is used when the sender Entity does not know the URL of the destination entity.

7.10.3 How To?

Coreography representation:



This choreography explains the procedure to be executed in the case the entity must report an event to an external information system (Repository), if that entity doesn't know the URL of that destination repository.

Notes:

1. Event X represents any event that must be stored in the own Information System/ Repository and that also requires to be reported to an external Information System/Repository; usually to the previous link and to the manufacturer. The event can be generated both by a downstream or an upstream entity.
2. Extracting the ID of the previous link should be done by querying the own repository (traceability information of the item)
3. The KeyID to be used should be the GLN
4. The GLN of the manufacturer should be extracted from GTIN information of the event

Description of events:

Symbol:	$O_q^E[KeyID_p]$
Description:	A query event is happening at the Entity level to the ONS to discover the URL of the previous entity. The KeyID should be the GLN identification.
Trigger:	

Comments:	
Symbol:	$O_r^E[\text{KeyID}_p]$
Description:	A response event from ONS is happening to the Entity with all information related to the queried KeyID from previous entity.
Trigger:	
Comments:	
Symbol:	$O_q^E[\text{KeyID}_m]$
Description:	A query event is happening at the Entity level to the ONS to discover the URL of the Manufactory entity. The KeyID should be the GLN identification.
Trigger:	
Comments:	
Symbol:	$O_r^E[\text{KeyID}_m]$
Description:	A response event from ONS is happening to the Entity with all information related to the queried KeyID from Manufactory entity.
Trigger:	
Comments:	

7.11 Choreography #10 Authentication, Compression and Signing AS2 Implementation

For EPCIS files authentication, compression and signing, the AS2 Protocol is recommended.

AS2 is an open, free and widely used protocol to provide multiple systems communication. It provides strong authentication, signing and compression methods (based on public and private keys digital certificates).

7.11.1 Pre-Requisite

Each party that needs to communicate EPCIS data shall establish a public/private key pair and a corresponding X.509 public key certificate. This will be used to authenticate the party and to secure communications using AS2.

Two parties who wish to communicate EPCIS data with each other must first establish trust by exchanging their X.509 certificates. This is typically done in an offline procedure in which each party takes steps to verify the identity of the party providing the certificate.

The exchange of certificates establishes bi-directional trust between the parties. Therefore, it is not necessary for either party's certificate to be signed by a certificate authority (CA). CA Certificates can be used but that is not mandatory. The exchange of certificates establishes trust even with self-signed certificates and that practice is widely used in EDI systems implementations.

7.11.2 When Would I Use This?

Any time your EPCIS repository receives a call for an event communication.

7.11.3 How To?

When one party sends EPCIS data to another, it shall use the AS2 protocol to deliver the data, where the payload of the AS2 message is an EPCIS Document conforming to the specifications in this guideline.

The AS2 protocol is specified in RFC 4130:

<http://www.ietf.org/rfc/rfc4130.txt>

AS2 offers many different options and adjustable parameters to control security. To conform to this guideline, all parties shall follow the GS1 EDIINT AS1 and AS2 Transport Communication Guidelines:

<http://www.gs1.org/ediint-as1-and-as2-transport-communication-guidelines>

Specifically, a party shall follow all "requirements" given in Section 5.4 of the above guideline and should follow all "recommendations" given in Section 5.5 of the above guideline, with the following modifications:

- Requirement 2: parties shall use a 256-bit symmetric key or greater, using the AES algorithm (the guideline's recommendation of 128 bits and 3DES is considered obsolete).
- Requirements 3 and 4: the length of the public/private key shall be 2048 bits or greater (the guideline's recommendation of 1024 bits is considered obsolete)
- Requirement 5: Use SHA256 since SHA1 has been deprecated
- Recommendation 8: this is not applicable to AS2 and may be ignored
- Recommendation 9: for large EPCIS messages, the use of compression is strongly encouraged

Note that Recommendation 6 states that HTTP is preferred to HTTP+TLS/SSL (also known as HTTPS). This is because AS2 itself provides end-to-end authentication, encryption, and integrity checking, and so transport-level security is not necessary.

7.11.3.1 AS2 Header

The AS2 Header includes "From" and "To" fields to identify the sender and recipient of the message. It is recommended to populate these fields with the same identifiers used in the <sbdh:Identifier> fields of the EPCIS Standard Business Document Header (SBDH):

- For GS1 Associates:

```
<sbdh:Sender>
<sbdh:Identifier Authority="SGLN"> urn:epc:id:sgln:789123.111110.0 </sbdh:Identifier>
</sbdh:Sender>
```

- Therefore, AS2 Sender (AS2 From) = urn:epc:id:sgln:789123.111110.0

```
<sbdh:Receiver>
<sbdh:Identifier Authority="SGLN"> urn:epc:id:sgln:789123.111110.0 </sbdh:Identifier>
</sbdh:Receiver>
```

- Therefore, AS2 Receiver (AS2 To) = urn:epc:id:sgln:789123.111110.0

- For non-GS1 Associates:

```
<sbdh:Sender>
<sbdh:Identifier Authority="CNPJ"> http://epcis.gs1br.org/hc/cnpj/loc/11223344000186
</sbdh:Identifier>
</sbdh:Sender>
```

- Therefore, AS2 Sender (AS2 From) = http://epcis.gs1br.org/hc/cnpj/loc/11223344000186

```
<sbdh:Receiver>
<sbdh:Identifier Authority="CNPJ"> http://epcis.gs1br.org/hc/cnpj/loc/11223344000186
</sbdh:Identifier>
</sbdh:Receiver>
```

- Therefore, AS2 Receiver (AS2 To) = http://epcis.gs1br.org/hc/cnpj/loc/11223344000186

8 Reference Documents

Documents used to build this guide were officially published and have a well defined governance model.

Document	Source	Link
EPC Information Services (EPCIS) Version 1.1 Specification	GS1	http://www.gs1.org/sites/default/files/docs/epc/epcis_1_1-standard-20140520.pdf
Core Business Vocabulary 1.1 (CBV)	GS1	http://www.gs1.org/sites/default/files/docs/epc/cbv_1_1-standard-20140520.pdf
Implementation Guideline - Applying GS1 Standards to U.S. Pharmaceutical Supply Chain	GS1	http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/dscsa/implementation-guide
GS1 General Specifications	GS1	http://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf
Healthcare Supply Chain Integrity enabled by EPCIS	GS1	http://www.gs1.org/docs/healthcare/EPCIS_Healthcare.pdf
Support Guide for Codification of Medicines	GS1	https://www.gs1br.org/educacao-e-pratica/MateriaisTecnicos/Support%20Guide%20for%20Codification%20of%20Medicines.pdf
Instrução Normativa Nº6/2014	ANVISA	http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=19/08/2014&jornal=1&pagina=42&totalArquivos=84
RDC 54/2013	ANVISA	http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=11/12/2013&jornal=1&pagina=76&totalArquivos=168