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Pharmaceutical Serialisation and Traceability Use Case

Enable the sharing of pharmaceutical product information via the GDSN

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1 Introduction

This use case was developed with input and guidance from GS1 Healthcare members. The objective of this use case is to outline the pharmaceutical master data required by serialisation and traceability regulations and enable manufacturers to register that data in the Global Data Synchronisation Network (GDSN) and for their trading partners (i.e. distributors, hospitals, retailers, etc.) to subscribe and use it internally.

Additionally, under certain serialisation and traceability legislation, failure to have synchronised product and location attributes can result in process failure, potentially leading to product quarantine, unneeded destruction, and supply issues.

As such, this document includes the basic master data requirements needed to facilitate operations in support of these regulations across several countries. In addition, three "date" attributes are included to indicate when the item becomes available in the Target Market, the publication date and the date when the master data becomes available.

This document contains a small set of generic attributes intended for all Target Markets plus specific set of attributes required by regulations in the European Union for the Falsified Medicine Directive (FMD) and the U.S. FDA's Drug Supply Chain Security Act (DSCSA).

Further, it is acknowledged that certain markets have been synchronising Pharmaceutical product data via GDSN for some time to support various supply chain and patient care use cases. As such, the users in these markets may require additional information beyond this basic set of attributes to satisfy local use cases. Therefore, it is not the intention of this use case to stall or negatively affect the users in these Target Markets.

The intention is to accelerate the synchronisation of trusted pharmaceutical master data at a global level via the GDSN and enable distributors / wholesalers, hospitals, retailers and other data recipients to consume the data and integrate into their internal processes and further drive patient safety.

2 Use Case Description

Use Case ID	UC-11
Use Case Name	Regulatory-Driven Serialisation and Traceability Pharmaceutical Master Data
Objective	Ensure the "Data Recipient" (i.e. customer, distributor, regulator, hospital) has accurate pharmaceutical product information to support the exchange of master data associated with regulator-driven serialisation and traceability
Use Case Description	Leverage the master data required by serialisation and traceability regulation to enable manufacturers to register the same product master data in the GDSN and their trading partners (i.e. distributors, hospitals, retailers, etc.) to subscribe and use it internally. Additionally, under the certain serialisation and traceability legislation, failure to have synchronised product and location attributes can result in process failure and in product quarantine, unneeded destruction, and supply issues.
Actors (Goal)	Seller, Buyer, GDSN Data Pool, GS1 Global Registry
Performance Goals	*To be defined by each organisation according to their internal, or industry agreed, metrics*

Use Case ID	UC-11		
Preconditions	- Trading partners must have an existing relationship to do business with each other		
	- Seller assigns GTINs to their products, and a GLN as required for data synchronisation via their GDSN Data Pool		
	- Buyer assigns GLNs as required for data synchronisation via their GDSN Data Pool		
	- Trading Partners subscribe to a GDSN data pool		
	- The supplier and the customer have an established business relationship and have agreed to synchronise data via the GDSN		
	- Basic information such as the Trading Partner GLNs and GTINs have been provided to each other as needed to enable data synchronisation		
Post conditions	- An agreement is in place that the GDSN data will be the primary source of data to facilitate the exchange of serialised product attributes.		
Scenario	Accurate and complete product information is provided to the Data Recipient to ensure unimpeded exchange of master data via GDSN.		
	Begins when... the manufacturer records in their internal Master Data Management system the appropriate product data needed by this specific Use Case.		
	Continues with... the seller is ready to load their product and company data in their GDSN data pool		
	Step#	Actor	Activity Step
	1	Seller	Provides the appropriate data to their GDSN data pool
	2	Source Data Pool	A small subset of this data is registered in the GS1 Global Registry
	3	Buyer	The buyer, through its own data pool, sends a subscription request to the GS1 Global Registry
	4	GS1 Global Registry	Sends a subscription request to the source GDSN data pool
	5	Seller	Authorises the publication of the requested information
	6	Source Data Pool	The seller’s data pool publishes the requested information to the buyer’s data pool
	7	Recipient Data Pool	The buyer’s data pool publishes the data to the Data Recipient
	8	Data Recipient	The buyer sends a confirmation to the seller via each company's data pool, which informs the supplier of the action taken by the buyer using the information

Use Case ID	UC-11		
	9	Supplier	Order is processed and the serialised product information is communicated. This occurs outside the GDSN via other mechanisms such a EPCIS.
	10	Data Recipient	Recipient receives product and corresponding information
	Ends when... the Data Recipient has the necessary information as required. This may include the regulator and any data recipient who wishes to use it (i.e. distributors, hospitals, retailers, etc.), globally		

3 Recommended Attributes

The table below includes master data elements which support regulation for serialisation and traceability of pharmaceutical drugs across the various countries which have existing regulation as of February 2018. The data elements have been cross-referenced to GDSN attributes to enable the synchronisation of master data via the GS1 Global Synchronisation Network (GDSN). The common definitions have been drawn from example provided by some of the regulatory language, or created to explain the intent of the data element. References to specific countries are included purely as examples, and without intention to exclude any particular country or region.

The table consists of two sections, the top portion which lists generic data elements applicable to any region and specifically for the purpose of data synchronisation. The lower portion of the table includes data element which are specific to the countries listed.

GS1 welcomes further input and clarification as needed to clarify the intended use of the data and to enable data synchronisation via the GDSN.

Data Requirement	Common Definition	GDSN Attribute	Global Data Dictionary Definition	Generic / Country Specific
Manufacturer Name	Name that identifies the party who is responsible for the manufacture of the product.	**nameOfManufacturer**	Descriptive name of the manufacturer of the trade item.	Generic
Manufacturer GLN	The identifier assigned to the manufacturer as listed above. 1:1 relationship with manufacturer's name.	**manufacturerOfTradeItem/PartyInRole:GLN**	Manufacturer of the Trade Item	Generic
Product ID (GTIN)	The primary trade item (product) identifier. This is the 14-digit Global Trade Item Number. GTINs must be properly formed in accordance with GS1 standards Pharmaceutical products.	**GTIN**	The GS1 Identification Key used to identify trade items. The key comprises a GS1 Company Prefix, an Item Reference and Check Digit.	Generic
Additional Product Identifier	The ability to communicate an additional product identifier besides the GTIN, such as a manufacturer's internal part number, or the National Product Code (i.e. NTIN), or any other identifier. NOTE: The GTIN remains as the primary identifier of the product in the data record.	**AdditionalTradeItemIdentification** AND **AdditionalTradeItemIdentificationList**	This optional code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship.	Generic

Proprietary Name	This is the brand name of the drug, if this is a branded product.	**brandName**	The recognisable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.	Generic
Functional Name	Describes use of the trade item by the consumer.	**functionalName**	Describes use of the product or service by the consumer. Should help clarify the product classification associated with the GTIN.	Generic
Product Description	This is the description of the product commonly used in trade. This generally contains information about the product name, strength, form, and package size, such as "atorvastatin 10 mg tab 500".	**tradeItemDescription**	An understandable and useable description of a trade item using brand and other descriptors. This attribute is filled with as little abbreviation as possible while keeping to a reasonable length. Free form text field, this data element is repeatable for each language used and must be associated with a valid ISO language code. Field length is 178 characters. This should be a meaningful description of the trade item with full spelling to facilitate message processing. Retailers can use this description as the base to fully understand the brand, flavour, scent etc. of the specific GTIN in order to accurately create a product description as needed for their internal systems. Examples: GS1 Brand Base Invisible Solid Deodorant AP Stick Spring Breeze GS1 Brand Laundry Detergent Liquid Compact Regular Instant Stain 1 GS1 Brand Hair Colour Liquid Light to Medium Blonde	Generic
Target Market	The country in which the product is intended to be sold / distributed.	**targetMarketCountryCode**	The code that identifies the target market. The target market is at country level or higher geographical definition and is where a trade item is intended to be sold. Note: GDSN uses the three digit numeric ISO 3166 1	Generic
End Availability Date Time	Enter the date that the product is no longer available from the supplier or their representative.	**endAvailabilityDateTime**	Date from which onwards the trade item will no longer be available.	Generic
Quantity	The total dosage units contained in one unit of the product. That is to say, total dosage units in an each, not the total dosage units included in the package level described by the GTIN.	**numberOfSmallestUnitsPerPackage**	The total number of smallest units contained in the package. The smallest unit cannot be further divided without breaking or slicing the product. Example: 10 pancakes.	Generic

Dosage Form	The dosage form of the product. This field contains the local code value appropriate for describing the product's dosage form.	**dosageFormTypeCodeReference**	A dosage form is the physical form of a medication that identifies the form of the pharmaceutical item for example oral. This attribute is populated by Local Code Lists and code lists for target market can be found on the GDSN Standards web site.	Generic
Strength	The strength of the product included in each dosage unit.	**ingredientStrength**	Used to define the strength of each ingredient in a trade item or unit volume of non-food and beverage the trade items.	Generic
Packaging Level	The packaging level described by the GTIN. Suggested values include Each and Case, but additional packing levels may be appropriate depending on the product.	**tradeItemUnitDescriptor**	Describes the hierarchical level of the trade item. TradeItemUnitIndicator is mandatory. Examples: "CASE" , ”PALLET”	Generic
Data Carrier Type Code	Identifies the barcode marked on the product or package; For example linear versus DataMatrix	**dataCarrierTypeCode**	A code indicating the type of data carrier physically present on the trade item.	Gerenic
Serial Number	Identifies if the label or the barcode includes a Serial Number	**SerialNumberLocationCode**	Serial number is on the trade item’s packaging	Generic
Batch/Lot	Identifies if the label or the barcode includes Batch / Lot number	**hasBatchNumber**	Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or not batch or lot number allocated. A batch or lot number is a manufacturer assigned code used to identify a trade item's trade item on batch or lot. Differs from Serial Number which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item.	Generic
Expiry	Identifies if the label or the barcode includes Expiry date	**tradeItemDateOnPackagingTypeCode**	Indicates the type of date marked on the packaging for example Best Before Date.	Generic
Effective Date	Date as of which the information of the master data is valid.	**effectiveDateTime**	Date as of which the information of the master data is valid.	Generic
Start Availability Date Time	The date (CCYY-MM-DDTHH:MM:SS) from which the trade item becomes available from the supplier, including	**startAvailabilityDateTime**	The date (CCYY-MM-DDTHH:MM:SS) from which the trade item becomes available from the supplier, including seasonal or temporary trade item and services.	Generic

	seasonal or temporary trade item and services..			
Publication Date	Timestamped with the Publication Date. It will be current date in the GDSN.	**publicationDate**	A date on which all static data associated with the trade item becomes available for viewing and synchronisation.	Generic
Country / Region Specific				
Common Name	The common name in Europe is the international non-proprietary name or the usual common name of the active substance(s)	**regulatedProductName**	The prescribed, regulated or generic product name or denomination that describes the true nature of the item and is sufficiently precise to distinguish it from other products according to country specific regulation.	EU
Pharmacy Duty	In Europe, the "pharmacy duty" is a sales distinction for pharmaceuticals. Such designated drugs may only be dispensed through pharmacies. It allows the data source to indicate if a Product is under prescription or not. For example, product type, prescription drug, OTC drug, medical device, nutritional product, etc.)	**PrescriptionTypeCode**	GDD Link: http://apps.gs1.org/GDD/bms/GDSN_31/Pages/bieDetails.aspx?semanticURN=urn:gs1:gdd:bie:HealthcareItemInformation.prescriptionTypeCode **Codes:** 1. HOSPITAL_PRESCRIPTION: Available only through a hospital when prescribed by a doctor. 2. HOSPITAL_PRESCRIPTION_REQUIRED_FOR_FIRST_PRESCRIPTION: This pharmaceutical or medical device must be prescribed for the first time at a hospital. 3. NO_PRESCRIPTION_REQUIRED: No prescription is needed for this trade item 4. PRESCRIPTION_REQUIRED_ANY_LICENSED_PRESCRIBER: A prescription is required and may be prescribed by any licensed prescriber. 5. PRESCRIPTION_UNDER_MONITORING: Prescription Under Monitoring. The healthcare product can be prescribed only after specific exams. The result of the exam (such as radiography, blood count, scanner, etc.) will determine if the product can be prescribed or not. 6. SPECIALIST_PRESCRIPTION_REQUIRED: Specialist Prescription Required. Medical Device	EU

			of pharmaceutical must be prescribed under the direction of a specialist authorised to prescribe the trade item.	
MAH Name	Registered name of the Market Authorisation Holder (MAH) in the market (stated in row 1). i.e. World Class Medicines Limited	Use the GDSN Party class **Note:** This class includes a series of attributes which can be used to communicate a variety of information about a "contact". Meaning, one would select the	GDD Link: http://apps.gs1.org/GDD/bms/GDSN_31/Pages/bieDetails.aspx?semanticURN=urn:gs1:gdd:bie:Party	EU
List of Designated Wholesalers	This will be a list organised as <ID> (if available) <Name> i.e. ID=N/A			EU

with ID, name and address **See EMVO Appendix 5 for guidance**	<Address>. The list should contain the details of each wholesaler (eqv.) who is contracted by, or on behalf of, the MAH detailed above (thus only pertinent to the stated local market) to handle the product represented by the product code in table 1 row 1. The ID is optional and reserved for future inclusion when Wholesalers are identified as meticulously as MFR's and MAH's. i.e. Name = 'Better Wholesaling GmbH' Address = 'Neue Strasse 12, 10119 Berlin, Germany'	attribute(s) needed for the intended purpose.		EU
Established Name	In the U.S. this is the designated FDA Official name, the Compendial name, the USAN Council name or the common or usual name (section 502(e)(3) of the Act and 21 CFR 299.4). Ordinarily, the established name of a drug will be the compendial name. However, FDA may designate an established name in cases where a monograph does not exist.	**regulatedProductName**	The prescribed, regulated or generic product name or denomination that describes the true nature of the item and is sufficiently precise to distinguish it from other products according to country specific regulation	US
NDC	The 10 character National Drug Code issued by the Food and Drug Administration.	**AdditionalTradeItemIdentificationTypeCode = FDA_NDC_10**	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship, plus value	US
NDC11	This field contains the 11-digit version of the NDC	**additionalTradeItemIdentification TypeCode = FDA_NDC_11**	This code will be used to cross-reference the Vendors internal trade item number to the GTIN in a one to one relationship, plus value	US

Contained GTIN	This field indicates which GTIN is directly contained within the package described in the GTIN column. For packaging levels which do not contain another GTIN, this field should be left NULL. For higher packaging levels, this should contain only the GTIN directly included within the package, in accordance with the examples provided in the "Calculating Eaches" section of this document.	**Class = ChildTradeItem Attribute = GTIN**	A trade item in the item hierarchy level immediately below the parent trade item.	US
Contained QTY	This field indicates how many of the Contained GTINs are included within the package described in the GTIN column. See the "Calculating Eaches" section of this document for further examples.	**totalQuantityOfNextLowerLevelTradeItem**	This represents the Total quantity of next lower level trade items that this trade item contains.	US
Less Than Each	This is a flag which indicates that the GTIN represents a package smaller than the smallest saleable unit ("each") for the product. This may include, for example, individual vials of an injectable product which are only traded in trays containing several vials. In order to keep the entry of product data as simple as possible for contributors, this flag only needs to be set to 1 to indicate that a GTIN represents a packaging level smaller than the each. For most products, there will likely be no GTINs where this flag is set because they are not serialized at a "less-than-each" level. This field may be left NULL or set to zero to indicate that a GTIN is not a "less-than-each".	**componentDescription**	A description of the component.	US

Note: Your GDSN Data Pool may require additional attributes in order to establish data synchronisation, or due to trading partner or national requirements beyond the intention of this use case. Please consult with your individual GDSN Data Pool. Click here for a *list of GDSN certified data pools*.