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GDSN Healthcare Use Cases Guideline

This document contains healthcare business process and regulatory Use Cases which enable the efficient exchange of accurate and complete product information across the healthcare value chain via the GDSN to fulfil specific needs.

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5 ## Log of Changes

Release	Date of Change	Changed By	Summary of Change
Release 1	7 May 2012	Community Review	Edits from the April Community Review
Release 2	20 January 2014	Pete Alvarez	Added Medicine Dispensing and Safety Use Case
Issue 3	31 August 2015	Pete Alvarez	GS1 branding applied
Release 3.0	Dec 2015	Pete Alvarez & D.Buckley	Added links to medical device and pharmaceutical data attributes Updated contributor lists & editorial update prior to publication
Release 3.1	May 2017	Pete Alvarez & D.Buckley	WR 17-000052: Attributes updated to GDSN version 3.1.2

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1 Introduction

This document contains healthcare business process and regulatory Use Cases which can bring significant value for both the supplier and the provider while improving patient safety. The objective is to enable the efficient exchange of accurate and complete product information across the healthcare value chain to fulfil specific needs. The exchange of information is facilitated by the use of the Global Data Synchronisation Network (GDSN), Certified Data Pools and the GS1 Global Registry to ensure that the customer's database is aligned and current with the manufacturer, as the source of the information.

The Use Cases contained in this document have been tested by existing implementations or validation with GS1 Healthcare User Group. GS1 Member Organisations and/or GDSN Data Pools.

2 Use Cases

The use cases contained in this document are designed to encourage consistent data synchronisation practices. Trading partners must have already allocated GTINs to the products for which they want to synchronise data and GLNs to identify each other. Some use cases may require the physical marking of the product. Therefore, the steps required to assign GTINs and GLNs are found in the appropriate implementation guides and not in this document.

The link below provides the GDSN data requirements needed to achieve the objective of each use case. This listing includes the ability to filter the information by country, use case, and product type (medical device or pharmaceutical drug):
_http://www.gs1.org/docs/gdsn/GDSN_Healthcare_Use_Cases_and_Attributes.xlsx_

67 ## 2.1   Tendering/Sourcing

Use Case ID	UC-1
Use Case Name	Tendering / Sourcing
Objective	Ensure the supplier provides the buyer accurate and standardised data as part of the tender submission, and that the buyer can subsequently source the correct product at the correct level of packaging.
Use Case Description	Generally, tender data is collected by different buyers / jurisdictions using different mechanisms. This may be proprietary spreadsheets or in hard copy format. The lack of clear direction and inconsistency in instruction leads to poor quality tender submissions and inability for buyers to source the appropriate products at the appropriate pack size.
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*
Preconditions	▪ 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 ▪ An agreement has been made that GDSN data will provide the foundation for tender submission and sourcing decisions.
Post conditions	Accurate tender and sourcing information is provided to the customer and available in the recipient's internal system for tendering
Scenario	**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

Ends when... the customer (data recipient) utilises the tendering and sourcing data into their internal system to

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70 ## 2.2 Contracting

Use Case ID	UC-2
Use Case Name	Contracting
Objective	Ensure the customer has accurate and complete product data to enable a fair and appropriate contracting decision to be made.
Use Case Description	Very often customers lack consistent information required to make appropriate and detailed contracting decisions, for example it is difficult to make an informed contracting decision if data from different suppliers has been provided in different formats / structures (refer Use Case 2.1 above).
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*
Preconditions	■ 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 ■ An agreement is in place that allows for contracting decisions to be made based on GDSN data.
Post conditions	Accurate and complete product and price information is provided to the customer and available in their internal system for contracting decisions.
Scenario	**Begins when**… the manufacturer records the appropriate product data needed by this specific Use Case in their internal Master Data Management system. **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

Ends when… the customer (data recipient) utilises the product and price data into their internal system to enable informed contracting decisions.

Related Rules	1. Ensure a mechanism is in place so that the contract information is updated in an amendment to the contract (inclusive of contract price as applicable) between trading partners

71 ## 2.3   Procurement

Use Case ID	UC-3
Use Case Name	Procurement
Objective	Ensure the customer has accurate and complete product data to enable an efficient procurement process.
Use Case Description	Very often customers do not have complete or the latest information available to place product orders. The GDSN is often used to provide information about products and their levels of packaging to ensure the correct products in the correct quantity are procured.
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*
Preconditions	■ 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 ■ Tendering, Sourcing and Contracting steps have been completed
Post conditions	Accurate and complete procurement information is provided to the customer and available in their internal system for procurement
Scenario	**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

Ends when… the customer (data recipient) integrates the procurement data into their internal system to enable procurement

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74 **2.4** **Order and Invoice Reconciliation**

Use Case ID	UC-4
Use Case Name	Order and Invoice Reconciliation
Objective	Ensure the customer has accurate product pricing information to address order and invoice discrepancies
Use Case Description	Often invoice payment is delayed due to lack of accuracy in the order price quoted versus the invoice price returned. Alternatively, there is often inaccuracy between the price quoted in the buyer purchase order and the price in the supplier system. GDSN can be used to provide accurate pricing information and allow faster invoice reconciliation and therefore payment.
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*
Preconditions	▪ 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 ▪ An agreement is in place that the GDSN data will be the primary source of data for order placement and invoice reconciliation. ▪ Tendering, Sourcing, Contracting and Procurement steps have been completed
Post conditions	Accurate and complete product and price information is provided to the customer and available in their internal system for placing purchase orders and reconciling invoices against these to minimise pricing discrepancies and therefore invoice queries.
Scenario	**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
9	Data Recipient	Generates purchase order using GDSN data
10	Supplier	Order is processed and invoice generated using GDSN data

Ends when... the customer (data recipient) makes a comparison between the purchase order and invoice applicable to the transaction.

75 ## 2.5 Reimbursement Codes and GTINs

Use Case ID	UC-5
Use Case Name	Reimbursement Codes and GTINs
Objective	Ensure the customer has the proper regulatory reimbursement code mapped to the appropriate GTIN for their Target Market.
Use Case Description	Reimbursement codes vary between markets. There is a need to identify the correct reimbursement code for particular product at specific level of packaging. There are often multiple reimbursement codes for a particular product at a particular level of packaging within a given market. The GDSN provides an effective mechanism to ensure the product is mapped to the proper reimbursement code for a particular market.
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*
Preconditions	■ Supplier keeps accurate records of the reimbursement numbers that apply to their products. ■ 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, including reimbursement numbers ■ Basic information such as the Trading Partner GLNs and GTINs have been provided to each other as needed to enable data synchronisation
Post conditions	Accurate product identification information and all associated reimbursement code information is provided to the customer and available in their internal system as the first point of reference to be used when reimbursement claims are made.
Scenario	**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

Ends when... the customer (data recipient) uses the GTINs and reimbursement codes specified in GDSN for their reimbursement claims.

76 ## 2.6   Regulated Product Formulations and Target Markets

Use Case ID	UC-6
Use Case Name	Regulated Product Formulations and Target Markets
Objective	Ensure the correct relationship between the GTIN (actual products on market) and the product formulations registered with a specific regulator.
Use Case Description	Often a supplier will gain regulatory authority to sell a range of pack size combinations and formations of a particular product within a given market. Generally not all of these regulated / authorised pack sizes and formations are released in that market. It is important for that regulatory authority to have a record of the pack sizes and formations actually being sold in a market for recall and traceability purposes.
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*
Preconditions	▪ Seller assigns GTINs to their products, and a GLN as required for data synchronisation via their GDSN Data Pool ▪ Regulator is a registered GDSN data recipient (and takes on the role of 'buyer' in this use case) ▪ 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. This information includes reference to regulatory numbers applicable to the market in which the regulator functions. ▪ An agreement is in place that GDSN is the mechanism by which suppliers will communicate to the regulator the authorised product configurations for sale in a given market.
Post conditions	The buyer / regulator uses the GDSN data to match the product configurations regulated for sale in a particular market with the actual products being sold.
Scenario	**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

Ends when… the regulator (data recipient) uses the GTINs and regulatory codes specified in GDSN for match the product configurations regulated for sale in a particular market with the actual products being sold

77 **2.7   Logistics**

Use Case ID	UC-7
Use Case Name	Logistics
Objective	Provide accurate dimensions and weights for warehousing and hospital storage optimisation.
Use Case Description	Hospitals and other health facilities are finding that storage areas in pharmacy and general stores, as well as operating theatres among other areas are being reduced as more space is claimed for patient facilities. As such, optimisation of available storage space is critical. GDSN is being used to provide accurate weights and dimensions for storage, handling and warehousing purposes.
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.*
Preconditions	▪ 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, including reimbursement numbers ▪ Basic information such as the Trading Partner GLNs and GTINs have been provided to each other as needed to enable data synchronisation
Post conditions	Accurate product identification information and product weights / dimensions are provided to the customer and available in their internal system as the reference to be used by their warehouse management system.
Scenario	**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	Reviews dimensions and weights provided by supplier to ensure these align with current records and identifies any discrepancies.
9	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

Ends when... the customer (data recipient) uses the identification, weights and measures provided in GDSN as their primary source of logistics and warehousing information.

78 **2.8   Logistics for Distribution Channel**

Use Case ID	UC-8
Use Case Name	Logistics for Distribution Channel
Objective	Provide accurate product hierarchy information, pack size information, dimensions and weights to allow effective distribution function.
Use Case Description	Distributors and suppliers need to understand the pack configurations, relationships and weights / dimensions of the products they handle to ensure that their warehouse operations are seamless. Having incorrect information about a product pack size may mean that an order for 10 items may in fact contain 12. Alternatively, the entity packing a logistics unit may have an incorrect weight for a product meaning that the logistics unit packed is too heavy for the transport provider to handle.
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.*
Preconditions	▪ 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, pack size, hierarchy and dimensions / weight information. ▪ Basic information such as the Trading Partner GLNs and GTINs have been provided to each other as needed to enable data synchronisation
Post conditions	Accurate product identification information and product weights / dimensions as well as pack size / pack hierarchy are provided to the customer and available in their internal system as the reference to be used by their warehouse management system.
Scenario	**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	Authorizes 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	Reviews dimensions and weights provided by supplier to ensure these align with current records and identifies any discrepancies.
9	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

Ends when… the customer (data recipient) uses the identification, weights and measures provided in GDSN as their primary source of logistics and warehousing information.

79 **2.9 Unique Device Identifier (UDI)**

Use Case ID	UC-9
Use Case Name	Unique Device Identifier (UDI)
Objective	To leverage the GDSN and the use of a Data Pool to register data as an efficient mechanism and trusted source of data for multiple UDI databases, worldwide.
Use Case Description	Unique Device Identification will improve patient safety and business processes and requires an investment by manufacturers, providers and other organisations. A single, global system of standards and a reliable mechanism to provide product data is fundamental to enable an efficient and effective implementation of UDI by all stakeholders worldwide. Different regulators will operate individual databases. These databases will be operated independently of each other and may not contain the same "data elements" (may vary in number and /or definition). By using their GDSN connection, product data will flow from the manufacturer's internal database to their GDSN data pool and then to the UDI database. This same approach is already used to provide product data to Providers and health authorities in many jurisdictions. The GDSN can serve both needs. This Use Case includes two possible scenarios for the use of the GDSN as a data feed for UDI databases plus an additional scenario for a Provider to subscribe to UDI data published by a manufacturer in the GDSN. ▪ **Regulator Scenario 1:** This scenario includes how to use the GDSN as a data feed for a UDI database when a Regulator chooses not to subscribe to a GDSN data pool, such as the U.S FDA and the GUDID. This scenario makes use of the GDSN Third Party Data policy to push data to a UDI database with the authorisation and instructions from the manufacturer who is the owner of the product and source of the data. The data will only be provided to the UDI database indicated by the Data Source (manufacturer). The GDSN Trading Partner Service Agreement (TPSA) will need to be signed by the data source and provided to their data pool. Without this agreement in place the data cannot be provided to a third party (e.g. a UDI database) ▪ **Regulator Scenario 2:** This scenario includes how a Regulator can subscribe to a GDSN data pool and pull data into their UDI data base. In this scenario they will synchronise data as a traditional data recipient within the GDSN. ▪ **Provider Scenario 1**: This scenario illustrates how a Provider can use the GDSN to subscribe to a Manufacturer's UDI data via a GDSN data pool. It functions the same way as the normal GDSN Publication and Subscription choreography. All scenarios ensure that the Manufacturer, as the Data Source, maintains control of how, and to whom, their data is provided by their data pool. One of the main benefits of using the GDSN as a UDI data feed is that it provides a single connection through which data is shared and updated, regardless of the data recipient.
Actors (Goal)	Manufacturer, Source Data Pool, UDI Data Recipient (Regulator responsible for the UDID), GS1 Global Registry Provider Scenario 1, additional Actors: Buyer (Provider), Recipient Data Pool
Performance Goals	*To be defined...*

Use Case ID	UC-9

Preconditions Regulator Scenario 1	▪ Manufacturers will have assigned and identified their products with the Global Trade Item Number (GTIN) and have all UDI database required information stored in an internal database.
	▪ A business relationship between a manufacturer and a GDSN Data Pool.
	▪ A contractual agreement between must be established by the manufacturer and the GDSN data pool including expressed written consent authorising the data pool to provide the manufacturer's device product data to a UDI database.
	
	    Note: Refer to the GDSN Inc. bulletin titled "GDSN Policy for 3rd Party Recipients" released August 2011 and the updated Trading Partner Service Agreement (TPSA). For more information contact GDSN Inc. at _gdsninc@gs1gdsn.org_.
	
	▪ It is strongly recommended that each manufacturer and their Source Data Pool use the GDSN guide for UDI databases – available here _http://www.gs1.org/healthcare/share-data_. This guide illustrates how to map GDSN attributes to the UDI database elements.
	
	    Note: The U.S. FDA requires the use of the HL7 Structured Product Labelling (SPL) standard to register data in their Global UDI databases (GUDID. For more information click here for the _U.S. FDA's GUDID_ and here _SPL_ for more information.

Regulator Scenario 2	Other preconditions in addition to those listed above for Scenario 1. ▪ The UDI Data Recipient (Regulator responsible for the UDID) has agreed to synchronise data via a GDSN data pool and has subscribed to a GDSN data pool. ▪ The UDI Data Recipient assigns GLNs as required for data synchronisation, via their GDSN Data Pool.
Provider Scenario 1	▪ The Provider and the Manufacturer have agreed to synchronise data via the GDSN. ▪ The Buyer assigns GLNs as required for data synchronisation, via their GDSN Data Pool ▪ The Buyer subscribes to a GDSN data pool. ▪ The Manufacturer and the Provider have an established business relationship and have agreed to synchronise data via the GDSN.
Post conditions for both Regulator Scenarios	▪ The manufacturer's device product data is stored in the appropriate UDI database for use as indicated by UDI regulation.
Post Conditions for Provider Scenario 1	▪ The manufacturer's device product data is stored in the Provider's internal system for use as required by the Provider.
Regulator Scenario 1	**Begins when**… the manufacturer establishes the proper contractual agreement including the GDSN Trading Partner Service Agreement (TPSA) with a GDSN data pool which authorises the data pool to provide data to a third party and the required technical connection to the Source Data Pool. **Continues with**… <table><tr><th>Step #</th><th>Actor</th><th>Activity Step</th></tr><tr><td>1</td><td>Manufacturer</td><td>Provides the appropriate device product data to their GDSN data pool</td></tr><tr><td>2</td><td>Source Data Pool</td><td>A subset of this data is registered in the GS1 Global Registry</td></tr><tr><td>3</td><td>Source Data Pool</td><td>Converts the GDSN data format and message to the UDI database SPL data format (see links to the appropriate guides above)</td></tr><tr><td>4</td><td>UDI Data Recipient</td><td>The UDI database acknowledges receipt of UDI data Note: Check with the appropriate regulator for specific information.</td></tr><tr><td>5</td><td>Source Data Pool</td><td>Sends confirmation to the Manufacturer that the medical device data has been registered in the subject UDI database</td></tr></table> **Ends when**… the data is available in the UDI database in compliance with UDI regulation

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Regulator Scenario 2	This scenario covers the UDID Regulator subscribing to a GDSN Data Pool

Step #	Actor	Activity Step
1	Manufacturer (Seller)	Provides the appropriate device product data to their GDSN data pool
2	Source Data Pool	A subset of this data is registered in the GS1 Global Registry
3	UDI Data Recipient	The UDI Data Recipient 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	Manufacturer	Authorises the publication of the requested information
6	Source Data Pool	The manufacturer's data pool publishes the requested information to the UDI Data Recipient's Data Pool
7	Recipient Data Pool	The UIDD Data Recipient's data pool publishes the data to the Data Recipient
8	UDI Data Recipient	The UDI Data Recipient sends a confirmation message to the seller via each other's data pool Note: Check with the appropriate regulator for specific information.

Provider UDI Scenario 1	This scenario outlines a Provider receiving a manufacturer's UDI data via a GDSN Data Pool. This scenario is designed to function through the regular GDSN publication and subscription choreography.

Step #	Actor	Activity Step
1	Manufacturer (seller)	Provides the appropriate device product data to their GDSN data pool
2	Source Data Pool	A 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	Manufacturer	Authorises the publication of the requested information
6	Source Data Pool	The manufacturer'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

Related Requirements	
Related Rules	

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81

82   2.10   Medicine Dispensing and Safety

83   **Note:** The use case of Medicine Dispensing is included as an example to demonstrate the
84   importance of GDSN data in patient safety initiatives. It is understood that there are a range of
85   other use cases related to patient safety in which GDSN data is critical, these include:

86   ■   Scanning for product validation at point of use (e.g. in the operating theatre, patient bedside)

87   ■   Referencing of product information in the patient's electronic health record

Use Case ID	UC-10
Use Case Name	Medicine Dispensing and Safety
Objective	Ensure accurate, complete and up to date product information for validation of medicines (medications) at point of dispensing (which may be in the pharmacy or by any regulated healthcare provider). **Note**: Identification of the caregiver and patient is out of scope for this particular Use Case.
Use Case Description	The use case involves capturing the unique product identification (.e.g. scanning a bar code) and validation at the point of medicine (medication) dispensing. This process requires accurate data to be in the associated product database.
Actors (Goal)	Seller, Buyer, Healthcare Practitioner / Provider (.e.g. pharmacist, nurse, physician, or other regulated healthcare provider) GDSN Data Pool, GS1 Global Registry
Performance Goals	To measure the effectiveness of: (1) Quantity - number of products dispensed to the number of times it was scanned; (2) Item Identification - accurately identifying and capturing the right medication was dispensed against the record in the pharmacy information system/ electronic medical record.
Preconditions	■ Seller assigns GTINs to their products' primary and secondary package, 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 ■ An agreement has been made that GDSN data will provide the foundation for data capture for product validation at the time of medicines dispensing. Where the GDSN data does not meet all requirements for a regional or local area, then the regional requirements will need to be accommodated.
Post conditions	Accurate and complete product information has been integrated in the Provider's internal systems in order to enable scanning for dispensing of medicine and electronic prescription systems. The Provider's pharmacy dispensing system has capability to hold the information provided by GDSN.

Use Case ID	UC-10
Scenario	**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

Ends when… the Provider (data recipient) utilises the synchronised product data to scan to validate the product when dispensing medicines.

88 # 3   Additional Requirements

89 ■ Trading Partners must have a pre-established commercial relationship and have exchanged
90   necessary information about each other as needed in the process of conducting normal
91   business.

92 ■ Changes to internal processes and systems may be required. Consult with your appropriate
93   business unit owner and IT staff.

94 ■ The minimum set of GDSN mandatory attributes are required in order to facilitate data
95   synchronisation. For further information refer to the GDSN Trade Item Implementation Guide
96   *http://www.gs1.org/gdsn*

97 ■ For further information regarding this document or further information regarding GDSN in
98   healthcare please contact your local *GS1 Member Organisation*.