



The GS1 System

Supply Chain Management in the Swiss Healthcare Sector

Guideline for the implementation of the GS1 System

Version 1.3

Joining forces to create values



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1. Management Summary

1.1. Initial position

Many market participants within the Swiss healthcare sector suffer from the lack of standardisation of processes with their partners. They have realised that cooperation is necessary – in areas such as product identification and barcoding, master data alignment, ordering, delivery and invoicing processes as well as logistics processes.

With its experience of the GS1 System in the retail sector, GS1 has proven that it is able to address the aforementioned issues efficiently - for the benefit of all market participants. With rising costs in the healthcare sector, all market participants are feeling growing political pressure, making the need for optimisation even more urgent.

This guideline has been written to show all market participants within the healthcare sector how the GS1 System can be successfully rolled out between trading partners and helps all stakeholders achieve greater efficiency.

1.2. Key statements

Section 2 presents the different target groups and explains the role of GS1 Member Organisations within the healthcare sector. The main GS1 Identification Keys are presented: Global Trade Item Number GTIN, Global Location Number GLN and Serial Shipping Container Code SSCC. The use of these GS1 Identification Keys makes it possible to significantly optimise the efficiency of the flow of goods and any associated information flows. Furthermore, thanks to the correct use of the GS1 Identification Keys, of the GS1 BarCodes and a proper understanding of the product packaging hierarchies, many other processes within a hospital are also optimised (e.g. improved patient safety through bedside scanning, care activity recording in electronic patient records, etc.).

As far as the electronic exchange of information is concerned, these guidelines define the circumstances under which the GS1 XML is to be used and when it is possible to fall back on the HL7 reports. The GS1 standards are designed for the flow of information between trading partners. To that effect, the GS1 XML is used from the manufacturer to the hospital. The GS1 XML messages accompany the flow of goods to the hospital. On the other hand, the HL7 messages are better suited for internal consumption reports or care activity recording. However, it is extremely important that the product information of the GS1 System is also used in the HL7 messages to avoid media discontinuities and interface issues.

Section 3 describes the electronic processes that take place between two trading partners. It shows which processes can be supported with which GS1 XML messages.

- Master Data Alignment
- Production (labelling, decollating)
- Order
- External Delivery (Dispatch)
- Internal goods transfer (Despatch Advice) and Production (Order & Receiving Advice)
- Invoice

The summary tables also illustrate which GS1 Identification Keys must be used where.

Section 4 presents the services of GS1 Switzerland.

1.3. Conclusion

These guidelines is addressed to at all those who are looking for ways to optimise the supply chain within the healthcare sector. These guidelines set out to show how the GS1 System can be successfully applied. All market participants must understand and apply the GS1 System in the same way to benefit from the increased efficiency.

These guidelines cover a very broad spectrum. They do not claim to present all the themes down to the last technical details. These guidelines refer to existing documents. All the technical details can be taken from those documents. Only Section 5 Appendix sets out to present the main aspects of the GS1 General Specifications. Those requiring a more detailed explanation of the subject are invited to read the technical documents.

2. Introduction

2.1. Vision

Our vision is that of a sustainable world in which optimal flows of goods and information increase the efficiency of the economy and improve people’s quality of life.

We bring together the players, provide expertise and actively promote cooperation between all stakeholders. Together, we come up with solutions to make value-added networks effective, efficient, sustainable, safe and transparent.

Thanks to our neutrality and global network, we create value by joining forces.

The GS1 members have been working together world-wide according to these principles for more than 40 years. Years of development and open cooperation with global and local representatives of trade and industry have led to the present state of development: an effective and efficient supply chain management, which is enabled by the GS1 identification system.

The Swiss healthcare sector performs well compared with global peers. The diagnosis and treatment methods, pharmaceutical products and medical technology is state of the art. The investments have always aimed for better, faster and more effective means of treating patients. A look at the supply chain management of the healthcare sector shows, however, that there is potential for optimisation, compared to other countries and industries.

The GS1 members from the healthcare sector world-wide have the vision to be able to provide patients with even more efficient and effective care. That is why the supply chain management in the healthcare sector needs to be improved to support the current needs. With the GS1 System, GS1 has come up with a tool box that can significantly improve the business processes between players in the healthcare sector – from the manufacturer to the patient. GS1 Healthcare is made up of well-known international companies, active at all stages of the supply chain. They work towards standardising and optimising the business processes in the healthcare sector - in favour of improved patient safety.

2.2. Objective of the guidelines/area of conflict

These guidelines set out to show which processes can be supported in the Swiss healthcare sector with the GS1 System to significantly increase their efficiency through standardisation. The focus is on the logistics processes (the flow of goods, information and money) between suppliers and care providers with the involvement of all partners (e.g. logistics service providers).

For the first time, the processes internal to the hospital are laid out in the GS1 perspective, from goods entry to care activity recording in an electronic patient record.

All partners involved in the healthcare sector learn in these guidelines how and why GS1 Identification Keys (e.g. GTIN, GLN and SSCC) are used to support the required processes (e.g. ordering and delivery processes).

The GS1 System covers the following areas:

Efficiency between trading partners	Efficiency within the care provider
<ul style="list-style-type: none"> ■ Master data alignment of product and partner master data ■ Automated ordering and delivery processes ■ Electronic payments ■ Product traceability/Recall management ■ Measures against product counterfeiting 	<ul style="list-style-type: none"> ■ Patient safety ■ Ensuring efficient care activity recording in the hospital (-> DRG) ■ Internal flow of goods ■ Inventory management (central warehouse/ward stockroom) ■ Procurement process/supplier management

2.3. Target groups of the guidelines

This document is aimed at decision-makers and project managers in organisations that want to implement the GS1 System with their partners.

2.3.1. Hospitals, Manufacturers and Suppliers

In the hospital, the document is targeted at the heads of the following departments:

- Hospital management
- Quality control
- Logistics, procurement, master data, pharmacy
- IT and project managers
- Sterilisation, laboratory, care and internal services

In the case of manufacturers, suppliers, wholesalers and fulfilment service providers, this document is targeted at:

- Management
- Supply Chain Managers
- IT and Project Managers
- Sales, logistics, master data
- Packaging and labelling

2.3.2. Supply Chain and IT Consultants, Software manufacturers and Master data pool operators

Service providers are expected to address the GS1 standards and methods in the concept phase of a project and evaluate them with the customer for sustainable process improvements.¹

- Management and process consultants
- ERP sales representatives
- Software companies
- IT support departments
- Master data pools

2.3.3. Logistics service providers

Logistics service providers are an important part of the entire supply chain. They must be able to support its customers' processes. In these guidelines, the business managers and project managers can find information about the use of the GS1 System in the healthcare sector, in particular on the processes of the upstream and downstream business partners.

¹ GS1 Switzerland offers specific training on the GS1 System to ensure the correct implementation of the GS1 System and to support the correction of incorrect product labelling or badly implemented process applications.

2.3.4. Pharmacies and drug stores

Pharmacists will find information in these guidelines on the application of the GS1 System in the healthcare sector. The product range of drug stores includes not only pharmaceutical products, but a wider range of products, e.g. cosmetics. These are already identified today with GS1 Identification Keys and labeled with GS1 BarCodes.

2.3.5. Self-dispensing doctors

Self-dispensing doctors can check in these guidelines, how the GS1 System is applied in the healthcare sector. The product range of self-dispensing doctors mainly covers pharmaceutical products. Self-dispensing doctors benefit from the use of the GS1 System in the following areas: automated orders, optimised delivery processes, warehouse management and simplified care activity recording in electronic patient records.

2.4. Role of the GS1 Member Organisations in the healthcare sector

2.4.1. At international level

At international level, GS1 Healthcare² provides an networking platform for market participants operating at all stages of the supply chain from around the world. Within the framework of working groups, the needs of the industry are evaluated, the use of the GS1 standards are defined and - where necessary - existing standards are adjusted in line with the particularities of the healthcare sector. Regular conferences³ promote the open exchange of experience and serve to disseminate jointly defined standards so that all market participants can benefit from them.

GS1 Healthcare is controlled by its members and works closely with various government agencies⁴ and other stakeholders and industry associations⁵ around the world. This ensures that their needs can be taken into account when developing the GS1 standards and that legislation and recommendations are suitable for global use. GS1 seeks to cooperate with other organisations to ensure the interoperability of the GS1 System with other standards and recommendations.

2.4.2. Switzerland

GS1 Switzerland has been active in the Swiss healthcare sector since 1984. Accordingly, all drugs subject to compulsory registration in Switzerland are identified with a GS1 Identification Number (GTIN)⁶. Since 1993, all care providers (e.g. doctors or hospitals) receive a GS1 Identification Number (GLN) from Refdata that is used for the service invoicing with the funding agencies (insurance companies) or for the control of narcotics.⁷ Medical devices are also usually identified with a GS1 identification key (GTIN). Many Swiss companies are already members of GS1 Switzerland and apply the GS1 System.

GS1 Switzerland has the following core tasks:

- First Level Support: GS1 Switzerland is the point of contact for questions regarding the GS1 System in Switzerland and Liechtenstein. GS1 Switzerland provides first-level support to the GS1 System. Here, for

² GS1 Healthcare; <http://www.gs1.org/healthcare> (6.9.2011)

³ Overview of the scheduled GS1 Healthcare Conferences: http://www.gs1.org/healthcare/news_events/events (6.9.2011)

⁴ For example: the U.S. Food and Drug Administration (FDA) or the European Commission; <http://www.gs1.org/healthcare/about/endorsements> (6.9.2011)

⁵ For example: the European Federation of the Pharmaceutical Industries and Associations (EFPIA), Eucomed, HL7 and many more; <http://www.gs1.org/healthcare/about/collaboration> (6.9.2011)

⁶ The Swissmedic number can be integrated into a GTIN structure.

⁷ The GLN is assigned on behalf of Refdata by e-mediat: <http://www.medwin.ch/> (6.9.2011)

example, issues such as the correct use of the GS1 Identification Keys or the right choice of barcode data carriers are answered.

- Barcode verification: GS1 Switzerland analyses the barcode quality of the products on the basis of the recognised ISO standards to ensure the quality.
- Application recommendations: The members of GS1 Switzerland develop national application recommendations (e.g. barcoding or electronic messages) in national working groups, based on existing standards. The open and mutual exchange of information between market participants is actively promoted and results in industry-specific recommendations, useful to all market participants.
- National needs: If the existing standards do not support national needs, these can be introduced internationally by GS1 Switzerland. GS1 Switzerland represents the interests of national members in the Global Standards Management Process (GSMP⁸).
- Training: GS1 Switzerland offers its members training in the GS1 System. These courses cover various aspects of the GS1 System: barcodes and identification, electronic communication, master data alignment and RFID technology. The objective is to qualify members to implement the GS1 System in their company. The seminars are aimed at operatives, as well as management.
- Consulting services: GS1 Switzerland does not only offer training courses but also project support in the implementation of the GS1 System. Within the framework of short consulting assignments, companies are shown how the GS1 System helps optimise processes.

2.5. Role of the GS1 System in the healthcare sector

As already mentioned in section 2.4 Role of the GS1 Member Organisations *in the healthcare sector*, the GS1 System is already used in many areas of the Swiss healthcare sector today. The areas of application are diverse. Their common denominator, however, is that the GS1 System serves as the basis for effective and efficient process management.

The GS1 System is very extensive and supports a wide variety of processes. You will now be shown how the GS1 System can support the logistical processes between the manufacturer and the hospital or at internal hospital level. If the logistics processes are optimised, this allows a variety of other processes in the hospital, such as traceability, stock management at departmental level or efficient care activity recording at patient level.

Several other guidelines, recommendations and implementation guides are available to supplement this guideline. Where necessary, reference is made in this document to other sources.

Section 5.1 GS1 System – Excerpt from the GS1 General Specifications summarises the most important foundations of the GS1 System. All GS1 brochures, guidelines, recommendations, and implementation guides are based on the GS1 General Specifications⁹, which provide a comprehensive (and very technical) description of the GS1 System.

Figure 1: The GS1 System in the supply chain of the healthcare sector.¹⁰



⁸ Global Standards Management Process (GSMP): <http://www.gs1.org/gsmg> (12.10.2011).

⁹ GS1 General Specifications (GS1 Global Office, 2013)

¹⁰ GS1 Standards in the Healthcare Supply Chain – improving patient safety (GS1 Global Office, 2007)

The GS1 System provides investment protection. Once implemented, it can be used with several trading partners. With the GS1 System, the processes of the partners can be mutually supported and the continuity of flows of goods, money and information is ensured. The GS1 System is replacing proprietary customer and industry solutions, enabling a standardised process for handling multiple customers. Implementation costs and times are reduced and the customer base broadened.

2.5.1. GS1 product labelling directives

Three core elements for the optimal management of flows of goods:

- unambiguous product identification
- defined product/packaging hierarchies
- standardised data carriers

The unambiguous identification of products reduces communication errors between trading partners and allows the data capture of each product in the system. But it is not enough to identify the delivery unit. The entire packaging hierarchy, from the individual product to the trading units to the transport units must be identified with unique numbers. This allows an efficient control of inventory management processes. Standardised data carriers must be used to allow machine-readable identifications. Standardised data carriers increase system security. This makes it possible to ensure that the right information is captured at the right point in the supply chain.

At internal hospital level, the unambiguous identification of products and patients with appropriate barcodes is important to manage internal flows of goods and to ensure efficient care activity recording. The same product identifications can also be used in communication, e.g. with the insurance agencies.

2.5.2. GS1 Company Prefix (GCP)

A GS1 Company Prefix (GCP) is the prerequisite to create all GS1 Identification Keys. The GS1 Company Prefix is allocated by the relevant GS1 country organisation to its members.

The GS1 Company Prefixes all have the same structure:

- GS1 Country Prefix: The first digits identify the GS1 Member Organisation, which has issued the number.
- Company Reference: The next digits identify the company that has been assigned the GS1 Company Prefix.
- The GS1 country prefix and the company reference are variable in length. Therefore, all GS1 Identification Keys must always be considered as a whole and should not be interpreted as a significant number. For more information, please contact your local GS1 Member Organisation.¹¹ A description of the GS1 Company Prefix for Switzerland can be found on the Swiss GS1 website.¹²

2.5.3. Unambiguous identification of products (GTIN)

With the Global Trade Item Number (GTIN), GS1 offers a globally unique identification key for products. Thanks to the GTIN, the manufacturer has the possibility of defining globally unique article numbers that can be used with all customers. The recipient of the goods can be certain that there are no duplicates in its system. The administrative burden is significantly reduced for all partners involved.

So that the partners involved also know which GTIN identifies which product, the master data must be exchanged beforehand. The Refdata foundation provides via its Medwin database¹³ a publicly accessible

¹¹ Addresses of all GS1 Member Organisations: <http://www.gs1.org/contact> (12.1.2012).

¹² The GS1 Company Prefixes: <http://www.gs1.ch/gs1-system/das-gs1-system/barcodes-identification#Section2> (13.7.2013)

¹³ Medwin database: http://www.refdata.ch/content/page_1.aspx?Nid=77&Aid=910&ID=470 (18.9.2011).

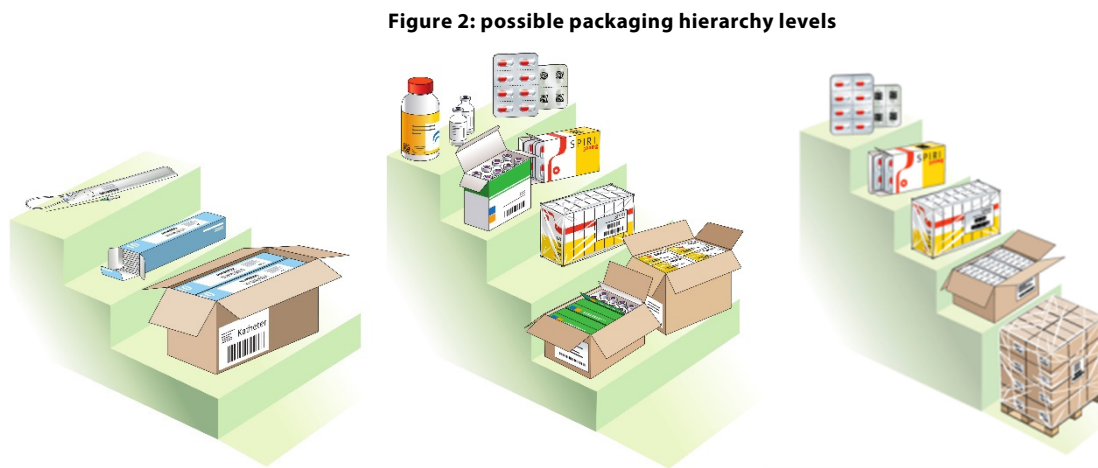
master data pool. This allows queries on the product master data of drugs that are subject to compulsory registration.

The GS1 members from the health sector world-wide have together defined the rules for the allocation of GTINs to products. The result is the GTIN Allocation Rules for Healthcare¹⁴. These are available in various languages and consider the different product groups in the healthcare sector.

2.5.3.1. Defined packaging hierarchies

When goods are traded between two partners, various packaging levels are involved, depending on the type of product:

- Primary packaging (e.g. blisters with tablets/syringes in sterile packaging)
- Secondary packaging (e.g. box of two blisters/with 10 packed syringes)
- Multipacks (e.g. 7 boxes)
- Box (e.g. 3 multipacks)
- Pallet (e.g. 24 boxes)



Implants, for example, often have only one packaging level. A detailed description of packaging hierarchies follows in section 3.3 *Production (labelling, decollating)*.

To ensure efficient process management, it is important that all levels of the packaging hierarchy are identified (-> GTIN). It is necessary to unambiguously define the ordering units and the delivery units and which units are to be invoiced.

For inventory management, it is essential that the different levels of the packaging hierarchy are known in the system and that conversion factors or minimum stock levels can be defined.

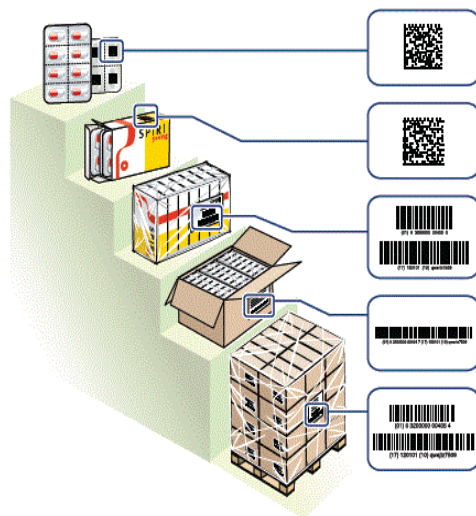
2.5.3.2. Standardised data carriers

Depending on its application and corresponding requirements, the GS1 System features various types of barcodes with which the GTIN can be made machine-readable. This means that it makes no sense, for example, to implement a (small) GS1 DataMatrix in a warehouse environment or to affix a (large) GS1-128 on a blister.

Depending on the process, in addition to the GTIN, other data are added to the barcode: e.g. expiry date, batch number and/or a serial number. The members of the healthcare sector have together developed a recommendation as to which products should be provided with which information at what level of the packaging hierarchy – the *AIDC Healthcare Implementation Guide*¹⁵.

¹⁴ GTIN Allocation Rules for Healthcare: <http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare> (8.9.2011).

¹⁵ AIDC Healthcare Implementation Guide (GS1 Global Office, 2010)

Figure 3: packaging hierarchy levels with possible GS1 barcoding

The illustration of information in the GS1 BarCode symbologies (e.g. GS1-128 or GS1 DataMatrix) is done using the Application Identifier Standard¹⁶.

2.5.4. Unambiguous identification of business partners (GLN)

With the Global Location Number (GLN), the GS1 System offers a world-wide unique number for the identification of geographical locations and organisational units. The GLN is therefore used for two different purposes. For both needs, the master data of each GLN must be communicated in advance. The Refdata foundation offers via the SwissINDEX database¹⁷ a publicly available master data pool. The GLNs can be queried via this database.

2.5.4.1. Identification of geographical locations

When communicating with a trading partner, the geographic locations must be defined, which are relevant for the trading relationship (flow of goods). This can be, for example locations such as goods entry, operating room or a ward dispensary in the hospital. For each of these locations, a GLN is defined, which must be used in communication with the partner. For example, it is defined in an order and delivery message, which GLN (e.g. goods receipt ramp 2 of the central warehouse) will receive the products.

For supply chain management within a hospital, it is important that all stock (central warehouse, ward stockroom, pharmacies, etc.) can be identified with a GLN. Thus, it is possible to capture internal goods flow properly. It is even feasible for goods to be picked and delivered by the supplier to each individual department (-> Cross-Docking).

2.5.4.2. Identification of organisational units

To allow electronic communication, organisational units (e.g., supplier A, hospital B, insurance agency C) must be identified. In the electronic messages (e.g., ordering, delivery, Clinical Data Architecture CDA) these GLNs are used for addressing messages. In this scenario, the GLN identifies a legal or organisational unit or even an electronic mailbox that does not exist physically.

The members of the healthcare sector have together developed a recommendation on how to allocate the GLN: *GLN in Healthcare Implementation Guide*¹⁸.

¹⁶ Application Identifier Standard: <http://www.gs1.ch/gs1-system/das-gs1-system/barcodes-identification#Section7> (31.7.2013)

¹⁷ SwissINDEX: http://www.refdata.ch/content/page_1.aspx?Nid=6&Aid=628&ID=291 (18.9.2011).

¹⁸ GLN in Healthcare Implementation Guide (GS1 Global Office, 2010)

2.5.5. Identification of transport units (SSCC)

With the Serial Shipping Container Code (SSCC), the GS1 System offers a globally unique identification number for transport units. Each transport unit that leaves a company can be identified with this unique number.

The SSCC is illustrated on the GS1 logistics label^{19, 20}. It is an unambiguous reference to a despatch advice, which may include one or more line items. Each line item references the same article number and if the expiry date is relevant, each line item references the same batch/lot number.

Each trading partner must capture, which SSCC was sent or received by which customer. This ensures product traceability.

The combination of SSCC with electronic data exchange significantly reduces the cost of goods entry at the recipient. The SSCC is transmitted electronically to the trading partner as a reference number with all relevant information about the transport unit. Upon receipt of the goods, the SSCC is scanned on the transport unit. The information obtained can subsequently be consulted in the ERP system. The goods received can be entered into the system after a visual check. Manual recording of goods upon goods entry is no longer necessary.

2.5.6. Identification of care giver and subject of care (GSRN)

Thanks to the Global Service Relationship Number (GSRN) the GS1 System offers a globally unique identification number used to identify the relationship between a care giver and a subject of care, such as between nurses and patients. In principle, the GS1 System does not identify a person but a medical case (a person in a particular role, e.g. doctor/nurse or patient, with a particular relationship (illness) to an organisation (such as a hospital)).

Upon the admission to a hospital, the patient is assigned a GSRN as the identification of its subject of care role, which they keep for the stay in the hospital. The GSRN is used, for example, to log care activities in their (electronic) file.

All health professionals can be identified in their care giver role with a GSRN so that automated data capture can take place in the care processes.

2.5.7. Electronic master data alignment (GDSN)

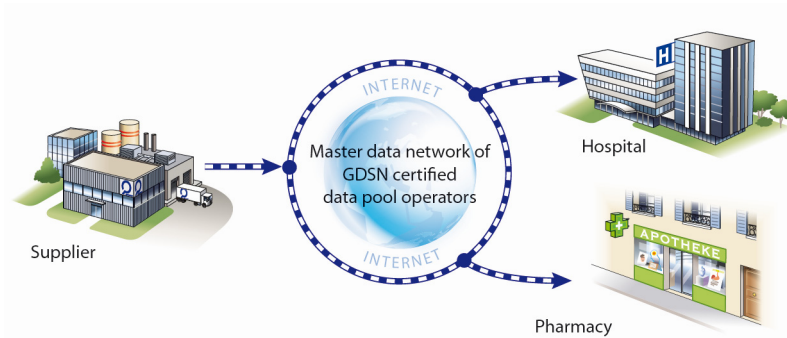
Another important pillar of the GS1 System is the Global Data Synchronization Network (GDSN)²¹. The GDSN is a network of interconnected and certified data pools that enable the electronic master data alignment. A manufacturer can therefore upload its master data to its preferred master data pool. The customer then has the opportunity to draw the data from its preferred master data pool.

The advantage is obvious: master data are available from one single source and potential adjustments to the master data are immediately available to all customers. Since both manufacturers and customers have the same master data in their systems, errors in the subsequent processes are minimised.

¹⁹ GS1 logistics label: <http://www.gs1.ch/gs1-system/broschüren-und-downloads/gs1-system-broschüren#Section6> (31.7.2013)

²⁰ Training tool on the creation of a logistic label: <https://ssl27.inode.at/gs1-labelview.at/front.php?lang=4&new> (16.9.2011).

²¹ Global Data Synchronisation Network (GDSN): <http://www.gs1.ch/gs1-system/das-gs1-system/gdsn> (31.7.2013)

Figure 4: alignment of master data via interconnected databases

2.5.8. Definition of electronic messages (GS1 XML)

The GS1 System is composed of four main pillars: barcodes, eCom, GDSN and EPCglobal. In the previous sections, an excerpt of the GS1 Identification Keys (GTIN, GLN, SSCC and GSRN), and of the GS1 BarCodes (GS1-128 and GS1 DataMatrix) have been mentioned. Other important parts of the GS1 System are the definitions of various types of electronic messages. These messages are used in the communication between two partners (e.g. between supplier and hospital or between two systems within a hospital group).

The electronic messages are defined in working groups by the members of the GS1. There are following messages:

- Master data messages
- Commercial messages (order, invoice)
- Messages ahead of the flow of goods (delivery)
- Sales and stock-related messages (reports, statistics)

In each electronic message, the GS1 Identification Keys are used as references in order to avoid communication errors.

GS1 has two different standards for the electronic exchange of messages: EANCOM²² and GS1 XML²³. In Switzerland, XML is mainly used in the healthcare sector. Therefore, this guide focuses on the GS1 XML. Each member can introduce change requests (Work Request WR) to electronic messages if desired processes are not supported. The WRs are examined by GS1 Switzerland and presented in international bodies. Once the international community agrees to the WR, the standard²⁴ is changed accordingly.

Both standards require that all parties involved familiarise themselves with the structure and the content of a message. Those responsible for electronic data exchange need to know the exchanged business information. And the technicians must know the structure of a message to program interfaces accordingly.

2.5.9. Definition of electronic messages of other organisations

GS1 works very closely with other healthcare organisations. The intention is that the data from the procurement process can also be used for the clinic's internal processes.

We will refer in Section 3 Process descriptions to these HL7 messages, when it comes to ensuring the traceability of products from the supplier to the patient.

²² EANCOM: <http://www.gs1.org/ecom/eancom/overview> (13.9.2011)

²³ GS1 XML: <http://www.gs1.org/ecom/xml/overview> (13.9.2011)

²⁴ EANCOM is based on the UN/EDIFACT and is mainly used in retail in Switzerland. EANCOM is probably the most widely used standard for electronic data exchange world-wide. In the global healthcare sector, the GS1 XML is more frequent. GS1 XML has the advantage of offering more free tools. The forwarder and the recipient can also personally check an XML message to see whether the XML contains any structural errors. The communication during implementation can thus be reduced, as only structurally correct data are sent to the partners.

Further information on cooperation between GS1 and HL7 can be found in the Memorandum of Understanding²⁵.

2.6. Role of the Intermediaries/Service Providers

The trade relationship between the supplier and the hospital is often supported by organisations that sit between the two partners and provide services for the benefit of both parties. We refer to these service providers as intermediaries. All intermediaries require unique identification of the affiliated partner. GS1 offers the GLN for this purpose. This ensures that there will be no confusion and goods or electronic messages are delivered to the correct recipient. In addition to the partners, the goods (e.g. transport units (-> SSCC)) must be clearly identified so that the processes of the business partners involved can be handled efficiently.

2.6.1. Master data pools

2.6.1.1. Commercial organisations

The master data pools services include the efficient exchange of product master data. The suppliers can transmit the master data to a master data pool. This consolidates the data with master data from other manufacturers.

In the GS1 world there are certified master data pools. They form a network of master data pools that are interconnected. This network is called the Global Data Synchronization Network (GDSN)²⁶.

GS1 provides the global definitions of the different GS1 GDSN XML messages²⁷. These messages contain definitions of which data should be transmitted and in which structure/format is to be used.

2.6.1.2. The Refdata foundation/Department of Health (BAG)

Certain products and care providers must be registered with the state authorities (Swissmedic and BAG). The products and care providers subject to compulsory registration are recorded in databases. The information is publicly available.

Refdata²⁸ is a foundation, in which various associations of the Swiss healthcare sector are represented. Developing and delivering "an affordable, socially acceptable and economically relevant referencing of products, services, people and institutions for the Swiss healthcare sector"²⁹ is the mission entrusted to it.³⁰ Refdata has delegated the operational implementation (allocation and management of the GTINs and GLNs in the appropriate databases (Swiss Index³¹ and Medwin³²) to e-mediat AG³³.

The Medwin database contains the drugs subject to registration. The Swiss INDEX database includes the list of all registered care providers and health professionals.

2.6.2. Ordering platforms/EDI service providers/Invoice settlement service providers

In addition to master data pools, there are also other service providers who perform data transmission tasks. Some offer ordering platforms, via which the procurement processes can be performed. Other offer traditional EDI services: they receive the transaction data, validate them if necessary and convert them into another format and pass them on to the recipients. The third category are service providers that offer

²⁵ GS1 and HL7 Join Forces to Develop Global Standards to Improve Patient Care (GS1 Global Office and HL7, 2007)

²⁶ You can find out more about GDSN from GS1 Switzerland (<http://www.gs1.ch/gs1-system/das-gs1-system/gdsn>, 31.7.2013) or from the GS1 Global Office (www.gs1.org/gdsn, 9.9.2011)

²⁷ GS1 XM messages: http://www.gs1.org/gsmpr/kc/ecom/xml/gdsn_grid (9.9.2011).

²⁸ Refdata: <http://www.refdata.ch/> (13.9.2011).

²⁹ The Refdata mission: http://www.refdata.ch/content/page_1.aspx?Nid=9&Aid=618&ID=284 (13.9.2011).

³⁰ To do so, the Refdata has obtained company prefixes from GS1 Switzerland with which the corresponding GS1 Identification Keys (GTINs and GLNs) can be assigned.

³¹ SwissINDEX database: see also Section 2.5.4 *Unambiguous identification of business partners (GLN)*.

³² Medwin database: see also section 2.5.2 *GS1 Company Prefix (GCP)*

³³ e-mediat: <http://www.e-mediat.ch/> (13.9.2011)

electronic invoicing with encryption and archiving compliant to legal requirements. Of course, some service providers offer several of these services. All service providers have in common that they use the GS1 System in order to support the processes of trading partners as intermediaries. Only if all partners use unique references (GTIN and GLN), can an efficient and effective supply chain management be achieved.

2.6.3. Logistics service providers/Wholesalers/3PL/Fulfillers

Logistics service providers, wholesalers and other companies have in common:

- they collect the products to be checked according to the specifications by the supplier,
- they store the products,
- they pick/repack the products and
- they distribute them within the specified deadline.

In addition, the logistics service providers are obliged to ensure traceability of the product up to the consumer of the goods. The Serial Shipping Container Code (SSCC) is used for this purpose.

If products are correctly barcoded by the manufacturer, the logistics provider can also use the barcode of the GS1 System for the control of internal processes (receipt, storage, picking and delivery of goods). This means that it must not map the flow of goods with a proprietary system.

2.6.4. Service providers internal to the hospital

Internal hospital departments (service providers) are also involved in the transfer of goods and exchange of information. The GS1 System is used in areas where goods are exchanged between two companies or channelled through a company. In the hospital, for example, goods are delivered from goods entry to the patient and used there. However, since goods do not only make their way to the patient via central goods entry but also through various other channels (e.g. directly to the ward), it makes sense to use the GS1 System also at internal hospital level. Unique identifiers and data carriers help to standardise and automate processes. With the help of electronic communication between different systems within a hospital, processes can be implemented more efficiently. They are less prone to error because media discontinuities in communications can be avoided.

If the GS1 System is used from the manufacturer to the patient, logistics processes are supported, but also planning and follow-up processes such as the care activity recording and subsequent communication with service providers. At the end of the day, the optimisation of the logistics processes also increases patient safety.

2.7. Main focus of the document

This document examines several aspects of how the GS1 System is used in the healthcare sector. The focus lies on the logistical processes: pharmaceutical and medical devices are supplied by the manufacturer (possibly via service providers) to hospitals. The important thing is the product identification (GTIN, SSCC), the data carriers (barcodes: GS1-128, GS1 Datamatrix), and the electronic communication (GLN, GS1 XML). Section 2 describes these processes in detail.

In addition to the logistical processes, other processes, such as care activity recording, for example, are introduced. The following aspects, which can be supported with the GS1 System, are not covered:

- Hospital facility management: the identification and management of assets, such as wheelchairs, beds or transport containers
- Asset management: the identification and management of consumables within a hospital, such as surgical instruments or loan sets
- Settlement procedures (e.g. DRG, Tarmed)
- Exchange of medical documents, such as laboratory reports or radiographs

2.7.1. Overview of the areas of application of the GS1 System in the SCM of the healthcare sector

2.7.1.1. Table of the scope

The table summarises the topics that can be supported by the GS1 System and colour codes the topics that are covered by this document.

Figure 5: table of the scope³⁴

	Supply Chain Element	Possible message types, supply strategies, SCM models, tools, value flows and support services					
Order-Process Management	External	Order	Consignment Stock Consumption Report	Replenishment proposal used for VMI	Order Response	Surgical trays for rent	
	hospital internal	Order	Consignment Stock Consumption Report	Replenishment proposal used for VMI			
	Hospital internal production	Order/ Receiving Advice	Order Response				
Flow of goods	External	Despatch Advice (DESADV)	Cross-Docking	Direct delivery	Consignment replenishment process	Kanban delivery	
	Internal	Transfer of goods	Medication	Disposal	Kanban replenishment process		
	Invoicing procedure	INVOIC	Debit Advice	Credit Advice	Self-Billing	Remittance advice	
	Collection of bills	Supplier	Invoice settlement service	Collection of bills			
Supply-Chain-Models, Tools, Load Carriers, Means of Transport	Material planning management	Vendor Managed Inventory	Buyer Managed Inventory	Co-Managed Inventory	Consumption based Inventory		
	Reverse logistics	Returns	Repairs	Recycling	Disposal	Traceability	Goods recalls
	Load carriers-(EUL)	EPAL pallet	Chep pallet	Displays and Dollies	Single use pallet	Industry standard	Proprietary transport items
	Means of transport	Lorry	Sprinter	Car			
Enabling Technologies (tools)	Master data	GDSN	Item Data Notification	Catalogue	Excel-data sheet	Article master data sheet	
	Information flow	EANCOM	GS1 XML	Proprietary Flatfile	Extranet/ Internet-platform	E-Mail	Fax, Letter, telephone
	Identification numbers	GTIN	SSCC	GLN	Log Nr., Los Nr.	GRAI/GIAI/ GDTI/GSRN	Proprietary article number
	Data carrier	UPC/EAN	GS1-128	GS1 DataMatrix	GS1 DataBar	EPC RFID	
Implementation, support	Training	Master data course for practitioners	SCM course for logistics managers				
	Engagement	Implementation initiative	Working group procurement in the healthcare sector	Lectures, appearances	Studies		

³⁴ Section 2 has described the topics marked in blue. Section 3 will describe the topics marked in green in detail. Many of the topics not covered can also be supported with the GS1 System. GS1 Switzerland will be happy to answer any questions you may have.

2.7.2. HL7-relevant messages for the SCM in the health sector

Figure 6: table of the relevant HL7 messages³⁵

	Supply Chain Elements	Drugs and Dispensation					
Flow of goods	Prescription Management	Medication Preparation Order "RGV"	Prescription Dispense Order "RDE"				
	Stock Management	Stock update "MNF^16"	Stock Refill Order "OMS"				
	Dispense Management (roles tbd)	Dispense Report "RDS"					
	Identification /data carriers						

³⁵ The messages above refer to a version of the IHE Draft White Paper dating from 18.7.2011. The detailed process, in particular the role description is currently being drawn up. The Medication Preparation Order "RGV" is known in the current, official IHE-HMW-Profile as "PHARM-H3".

3. Process descriptions

3.1. Introduction

Standards serve as the foundation for a clear, understandable communication between companies in an increasingly globalised economy. In this sense, we want to take up the challenge and transfer the GS1 System to the global Healthcare supply chain and demonstrate which business cases can be handled consistently and uniformly with the GS1 System.

For a better general understanding, we will illustrate the relevant processes in the following sections and categorise the individual GS1 messages³⁶.

3.1.1. Alignment of master data

The first group of GS1 messages covers the structured synchronisation of product and partner master data based on the GDSN Standards³⁶. Certified pool operators are responsible for ensuring that the master data transmitted to them are validated and can be passed on to various authorised clients.

Electronic messages also exist for bilateral master data alignment³⁷, for example, for a contract with special conditions (Purchase Conditions).

3.1.2. Alignment of commercial data

These are messages that, in general, have a binding character through a framework agreement between the seller and the buyer and are connected to a flow of value. Specifically, we speak of an Order³⁶ and Order Response³⁶, Invoice³⁶, Credits and Debit Advice³⁶, and of Advanced Remittance Notification³⁶. All cash messages with VAT details must be electronically signed, encrypted and archived in line with the statutory provisions.³⁸

3.1.3. Exchange of messages preceding the flow of goods

Messages preceding the flow of goods are primarily GS1 messages that are used for the physical handling of goods trading. Specifically, we speak of the Despatch Advice³⁶ and the Receiving Advice³⁶.

These messages are used primarily to plan logistics processes and to be able to reproduce electronically what, when and where a product will be physically delivered, transferred or changed. These messages are used in combination with the detailed delivery note (including article and batch numbers). They are analysed in the event of product recalls for example. It is therefore all about ensuring product traceability.

3.1.4. Alignment of sales and inventory related data

The fourth group of GS1 messages covers sales, consumption and inventory-relevant information for goods scheduling, billing and statistical information. The most commonly used message are Consumption Reports³⁶ and Inventory Reports³⁶.

³⁶ Technical descriptions of all GS1 XML messages: http://www.gs1.org/gsm/ke/ecom/xml/xml_bms (18.9.2011).

³⁷ Excel or EANCOM PRICAT: <http://www.gs1.ch/gs1-system/brosch%C3%BCren-und-downloads/downloadbereich-gdsn> (31.7.2013).

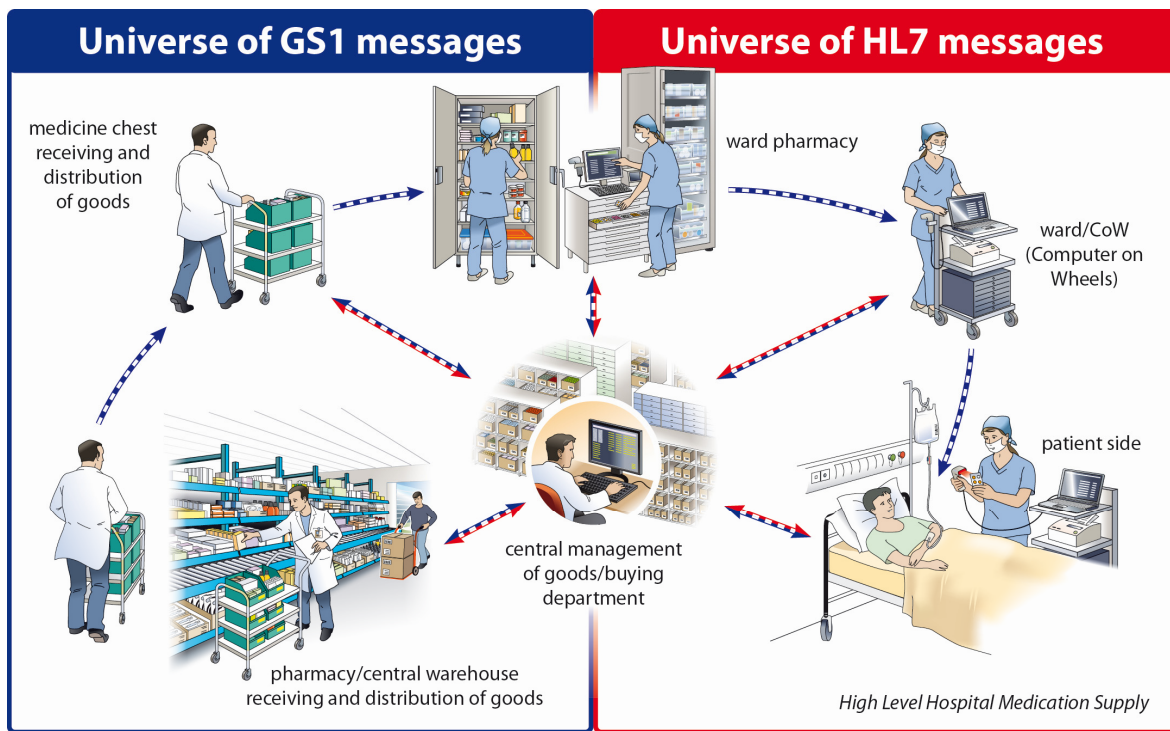
³⁸ e-Invoicing: <http://www.gs1.ch/gs1-system/das-gs1-system/gs1-lösungen/einvoicing> (31.7.2013).

3.1.5. Exchange of hospital internal data

Safe medication and accurate drug administration to the patients are two of the major concerns in the healthcare sector. To ensure this, HL7 has defined various types of electronic messages³⁹ that are primarily used for hospital internal processing.

We will mention these messages⁴⁰ in each description of the individual processes and refer to the appropriate HL7 documents. Interested readers will quickly note that there is data interoperability between GS1 and HL7 message types.

Figure 7: delimitation of the use of GS1 and HL7 messages



GS1 and its members from the healthcare sector world-wide are convinced that the use of the messages described in detail below supports a variety of business transactions in the healthcare supply chain. Thanks to the multiplier effect, in the long term all players in the supply chain stand to gain from efficient processes. This leads to lower costs and higher quality.

³⁹ www.hl7.org (1.11.2011).

⁴⁰ RDE for Prescription Dispense Order, OMS for Stock Refill Order, RDS for Dispense or for Delivery Report and MFN^M16 for Stock update.

3.2. Master Data Alignment

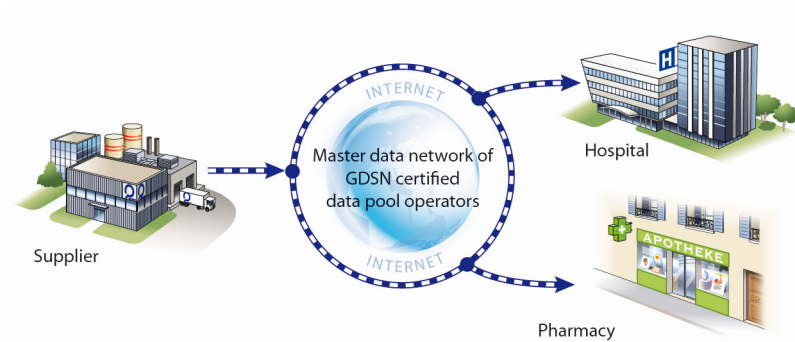
3.2.1. Introduction/Importance of master data

The electronic alignment of master data has gained enormous importance because hospitals (just like the retail pharmacists) increasingly want to map their processes using an IT system. Basically GS1 supports two variants:

3.2.1.1. Alignment of master data via (globally) networked databases

Countless manufacturers store their product master data in a standardised and certified master data network. There, the master data are available to customers (for example, hospitals and retail pharmacies). In doing so, a 1: N relationship arises for each business relationship: the manufacturer provides its data once and all its clients can retrieve the data from the network. This considerably simplifies the master data alignment between manufacturers and care providers.

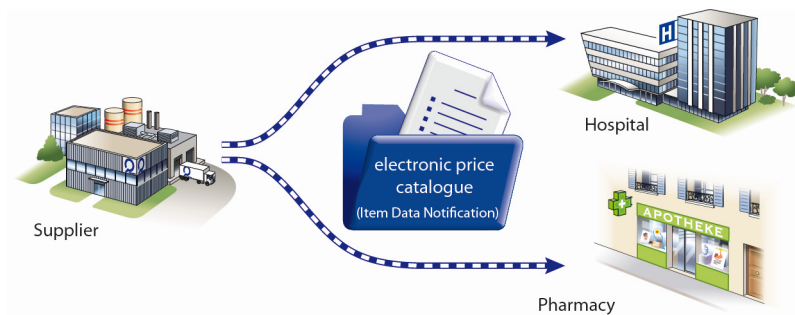
Figure 8: alignment of master data via interconnected databases



3.2.1.2. Alignment of master data via defined (bilateral) communication channels

Other suppliers choose a direct path for the alignment of master data. In addition to the physical delivery of price lists and catalogues, master data can also be transmitted via standardised electronic messages (e.g. Item Data Notification). This message is suitable for bulk migrations, e.g. price changes by government decisions to reduce prices or for the inclusion of seasonal assortments. The alignment of master data takes place 1:1, which means that each client must be informed individually about the changes to master data.

Figure 9: alignment of master data via bilateral interfaces



3.2.1.3. Master data and their sub-categories

To meet the demands of the various process participants, the master data have been classified into different subcategories. Under **General Master Data**, logistic data is transmitted primarily on the orderable unit, such as the number of products per unit or the weight and dimensions of a product. This information is used by the logistics providers/wholesalers, as well as in materials management in the hospital for order processing.

Specific master data, e.g. the exact description of the product, such as properties or images, are also important master data elements that need to be made quickly available electronically to employees of pharmacies and hospitals.

Comprehensive information about the **packaging hierarchy** is a prerequisite for efficient business processing. The identification of the administered single unit with a GTIN is one of the urgent initiatives GS1 sets out to implement, so that proprietary numbering systems for the single unit administered in hospitals can be successively replaced by GTINs.

Prices, quantity discounts, product classification, etc. belong to the subcategory **Purchase Conditions**. These must, at all cost, be maintained properly by the seller as well as the buyer, so that the invoice is drawn up error-free in the course of the procurement process and thus allow reliable analyses to be created per group of goods for strategic purchasing.

3.2.2. Global Data Synchronisation Network (GDSN)

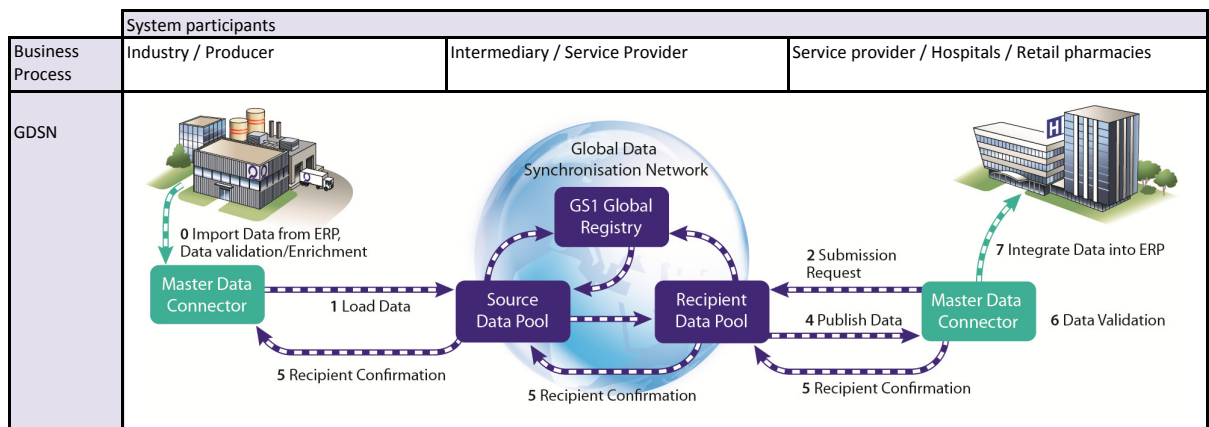
Below, you will find an outline of the variants of the electronic alignment of master data, for which GS1 technical message implementation guidelines exist. Following this overview, we will show which range of services and which points of contact these two variants have to other databases and process systems.

3.2.2.1. Function description

The GDSN⁴¹ is a global network of certified data pools where data can be exchanged between sellers and buyers. The GS1 GDSN XML messages include all product master data categories. The manufacturer is obliged to keep the master data up to date as part of the Data Quality Framework⁴², and to report updates by using the GDSN messages. To do so, the Catalogue Item Notification CIN⁴³ is used.

Data alignment via data pools means reduced costs for interface and format maintenance. Cross-industry rules and standards improve data quality and accuracy. When many customers (hospitals and pharmacies) formulate their needs in relation to suppliers together, all parties stand to benefit. Individual prices, basic master data, product descriptions and images can also be handled by pool operators.

Figure 10: electronic master data alignment with the GDSN



The integration capability, the interaction with the upstream or downstream master data connectors⁴⁴ of buyers and sellers, is a major advantage of the data pool provider. Therefore, in the healthcare sector, the alignment of the master data of product data/ingredients, prices/terms and hierarchy data and pure logistics data is primarily performed with the help of the data pool operator.

⁴¹ <http://www.gs1.org/gdsn> (14.11.2011).

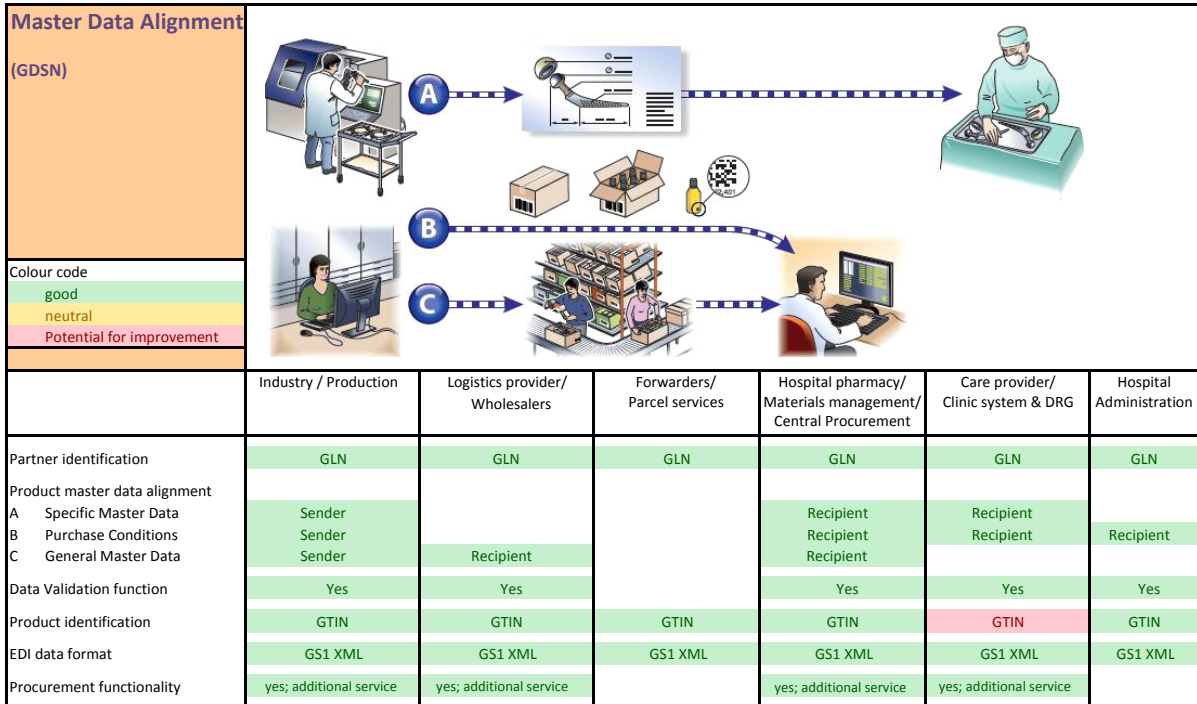
⁴² Data Quality Framework http://www.gs1.org/gdsn/dqf/data_quality_framework (10.4.2012).

⁴³ Catalogue Item Notification CIN: http://www.gs1.org/gsmc/kc/ecom/xml/gdsn_grid (10.4.2012).

⁴⁴ In general, both buyers and sellers use a Product Information Management System (PIM) for the management and validation of master data before electronically aligned master data are transferred to the ERP or hospital information system, via a master data connector. This practice applies primarily to the alignment of master data via GDSN, PRICAT and data pool connections. For the sake of clarity, it should be mentioned here that many sellers transfer their master data via Excel or product master sheets to the hospitals and retail pharmacies.

The following diagram shows which types of master data (A, B and C) are transmitted and to whom, or are provided through the GDSN data pool. Product information and ingredients are made available to care providers, specialists and doctors. The hospital procurement department and inventory management needs prices, terms and conditions and hierarchical data. Master data for the logistics process are needed by all process participants, from production through to care.

Figure 11: overview of the Global Data Synchronisation Network GDSN: GS1 System, processes and EDI



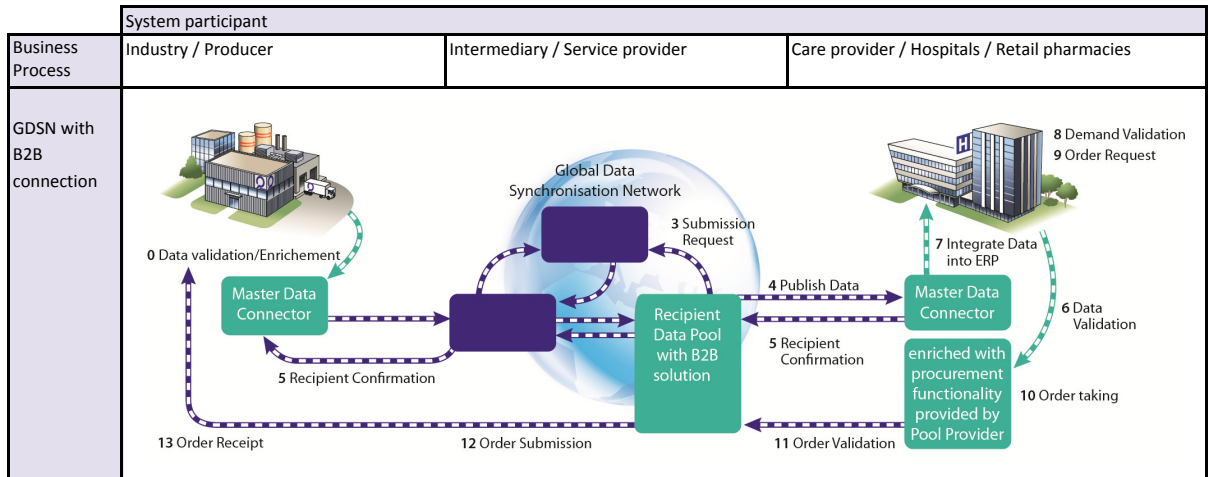
To ensure that services (-> drugs and medical devices) are correctly captured in the clinical, logistical and/or financial system (-> DRG), the packaging hierarchy must be defined accordingly. This also includes the lowest packaging level (single unit), which is charged to the patient. The relevant GTINs must be defined and barcoded on each level.

It should be mentioned here that many hospitals and retail pharmacies in addition to the alignment of master data also make use of the procurement functionality (cf. the process steps 10 through 13 in the following diagram) of the data pool provider and use them daily as an integrated part of their ordering process⁴⁵.

Meanwhile, several thousand master data records can be retrieved via this data pool operator from several branches and many of these products can be ordered directly online. We address the problem of partially missing "back documents" in section 3.4.5.

⁴⁵ Orders are generally transferred from the proprietary Data Pool Procurement System to the in-house ERP system so that at the time of the physical delivery, a corresponding order is available for the processing of the incoming goods.

Figure 12: electronic master data alignment according to GDSN, incl. procurement functionality

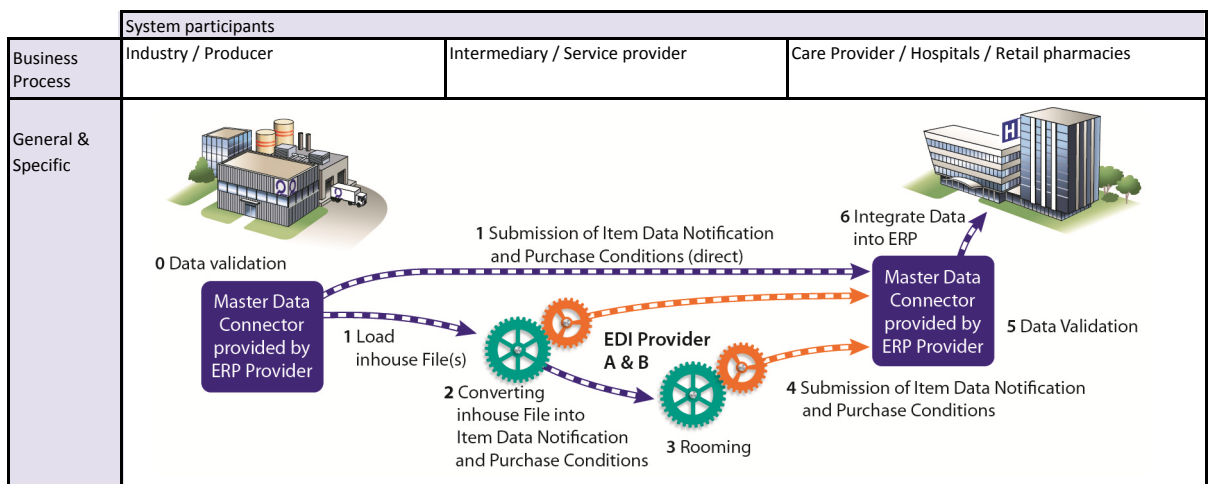


3.2.3. Alignment of master data via defined (bilateral) communication channels

3.2.3.1. Functional description catalogue/price list (Item Data Notification and Purchase Conditions⁴⁶)

The Item Data Notification and Purchase Conditions are GS1 XML messages that specify the details for the delivery of goods and services between the seller and the buyer. For example, logistic master data or different vendor-specific prices and delivery conditions are exchanged electronically. The recipient of the message is defined by the GLN. The unambiguous assignment of the line information is ensured by the GTIN.

Figure 13: electronic master data alignment General and Specific (1:1 Business relationship)

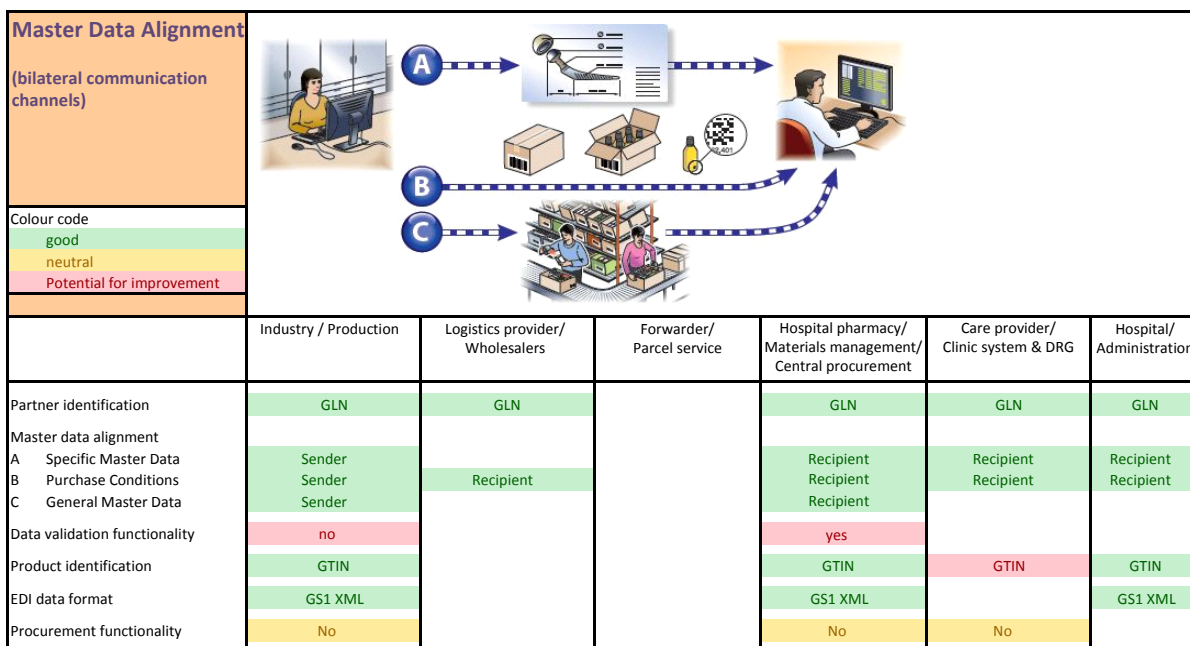


The diagram below shows which master data (A, B or C) will be transmitted to whom and which downstream processes can be controlled with it. Master data A (specific master data) are generally required for HIS (Hospital Information Systems). Master Data B (Purchase Conditions) are required by Procurement and the master data department of the hospital. And master data C (General Master Data) are needed in all internal and external IT systems to ensure a smooth process.

It should be mentioned again here, that this is a point-to-point communication. This means that each client must be informed in good time separately about range or product changes.

⁴⁶ Technical descriptions of all GS1 XML messages: http://www.gs1.org/qsmp/kc/ecom/xml/xml_bms (6.12.2011).

Figure 14: overview of bilateral communication channels: GS1 System, processes and EDI



3.3. Production (labelling, decollating)

In this section, we describe the correct specifications for labelling and decollating of drugs and medical devices using barcodes. The descriptions in this section are taken from the AIDC Healthcare Implementation Guide⁴⁷, which provides more detailed information.

We mean by "products to be marked" a drug or a medical device in its primary and secondary packaging as well as in its higher packaging levels. The table below illustrates the issue with reference to two examples.

During production, information is generated, which applies to all packaging levels such as the batch number and expiry date for example. The information that applies to all packaging levels should also be barcoded at all packaging levels to ensure that product traceability can be guaranteed by all parties involved.

3.3.1. GS1 Identification Keys and GS1 BarCodes at different packaging levels

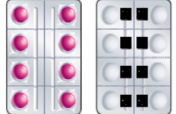


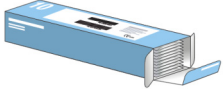



We use the following illustrations as a guiding example. It is important that:

- Each product and each packaging level corresponds to its own GTIN.
- The primary and secondary packaging are identified with the GTIN-13⁴⁸.
- The higher packaging levels can be identified with the GTIN-13 or GTIN-14⁴⁸.
- In the example, the GS1 Company Prefix: 76154335xxxxP is used.

⁴⁷ AIDC Healthcare Implementation Guide (GS1 Global Office, 2010)

⁴⁸ See also Section 5.1.1 Global Trade Item Number GTIN.

Figure 15: overview of the GS1 Identification keys, GS1 BarCodes and the packaging hierarchy

	Drug	Medical device	GS1 Identification key
Primary packaging	 1x tablet per blister; Unit for the dispensation process	 1x catheter packed	GTIN A Example: 76154335 12346 (GTIN-13)
Secondary packaging	 2x blisters in a box; unit for the ward pharmacy	 10x catheters in the box	GTIN B Example Drug: 7680 12345678 1 (Swissmedic-Nr. in GTIN-13) Example medical device: 76154335 12575 (GTIN-13)
Multi-Pack (Hospital packaging)	 7x boxes; Unit for central pharmacy		GTIN F Example.: 76154335 26718 (GTIN-13) or Example.: 176154335 12343 (GTIN-14 ⁴⁹)
Carton	 8x Multi-Pack; Unit for wholesalers	 1x carton with 6 boxes	GTIN D Example: 76154335 26732 (GTIN-13) or Example: 276154335 12340 (GTIN-14 ⁴⁹)

The GTINs are allocated once and do not have to respect any particular order. As an example, here the hospital packaging (GTIN F) was subsequently introduced (and identified). The structure of the GTIN is not significant.

GTINs may only be allocated to one product (drug or medical device) and may never be used again - even if the product is no longer sold.

3.3.2. Generating GTIN according to the Swissmedic rules (only drugs)

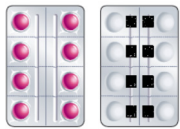
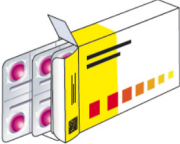
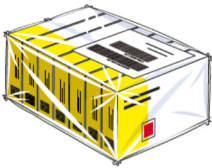

According to the current rules⁵⁰, drugs registered with Swissmedic are identified with a GTIN, which contains the authorisation number. This number is usually printed on the secondary packaging or on the hospital packaging.

The following table shows this situation for a theoretical supplier who has obtained the GS1 Company Prefix 76154335xxxxP:

⁴⁹ Indicator Digit Method: http://en.wikipedia.org/wiki/Global_Trade_Item_Number (8.3.2012).

⁵⁰ These rules date back to the year 1984 and meet two requirements: on the one hand, Swissmedic requires that the registration number is applied in plain text. And on the other hand the market partners demand that the drugs are provided with a GS1 barcode. Therefore, the Swissmedic number is represented in a GS1 barcode.

Figure 16: example of GTIN allocation in a packaging hierarchy⁵¹

	Drug	Identification
Primary packaging One tablet per blister		GTIN A (7615433512346)
Secondary packaging (Swissmedic number 12345678) 2x blisters in the packaging		GTIN B (7680123456781)
Multi-Pack (hospital packaging) 7x boxes		GTIN F (7615433526718) or (17615433512343)
Carton 8x Multi-Pack		GTIN D (7615433526732) or (27615433512340)

GTINs are not allocated sequentially, so they do not need to be consecutive. GTINs with the Swissmedic number may only be used on the packaging, which is registered with Swissmedic. All other packaging levels receive a GTIN from the GS1 Company Prefix of the user.

3.3.2.1. When is a GTIN modified?

When the authorisation number is modified by Swissmedic, the GTINs of all the higher packaging levels are also changed. The manufacturer has the responsibility for deciding, if the GTIN of the Single Unit must also be changed. (Changes, such as the composition of the drug, require new GTINs. On the other hand, no GTIN change is necessary, for example if it only relates to the packaging design.)

For medical devices, similar rules apply even if no registration is required with Swissmedic.

Detailed information can be found in the GTIN Allocation Rules for Healthcare⁵².

3.3.3. **Barcoding of the GTIN, batch number and expiry date**

The aim is to ensure that the drugs are provided with relevant information, subject to the technical possibilities. Here it is emphasised that, as from 1.1.2011 (end of the transitional period), the ANSM in France requires that all drugs sold must be provided with a GS1 DataMatrix that includes the GTIN, the batch number and the expiry date⁵³.

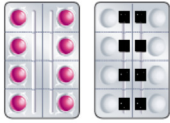


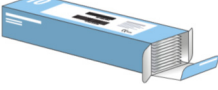



The table here is designed to serve as an example. In any case, the aim is not to come up with the smallest symbol but with the best use of the available space:

⁵¹ AIDC Healthcare Implementation Guide (GS1 Global Office, 2010)

⁵² GTIN Allocation Rules for Healthcare: <http://www.gs1.org/1/gtinrules/index.php?p=static/t=healthcare> (26.3.2012)

⁵³ Journal officiel de la République Française, 16.3.2007, Text 107.

Figure 17: encoded information on different packaging hierarchies

	Drug	Medical device	Data in the GS1 BarCode in packaging hierarchies
Primary packaging	 <p>1x tablet in the blister; unit for the dispensation process</p>	 <p>1x catheter packed</p>	<p>Identification: GTIN A Attribute: Batch number.: abc123 Expiry date: 31.12.2010</p> <p>Information encoded in the GS1 DataMatrix: (01)07615433512346(17)101231(10)abc123 or (01)07615433512346</p>
Secondary packaging	 <p>2x blisters in a box unit for ward pharmacies</p>	 <p>10x catheters in the box</p>	<p>Identification: GTIN B Attribute: Batch number.: abc123 Expiry date: 31.12.2010 and/or poss. Serial number: 3a46</p> <p>Information encoded in the GS1 DataMatrix⁵⁴: Drug (Swissmedic-No.): (01)07680123456781(17)101231(10)abc123(21)3a46 Medical device: (01)07615433512575(17)101231(10)abc123(21)3a46</p>
Multi-Pack (Hospital packaging)	 <p>7 boxes; unit for the central pharmacy</p>		<p>Identification: GTIN F Attributes: Batch number: abc123 Expiry date: 31.12.2010</p> <p>Information encoded in the GS1 DataMatrix or GS1-128: (01)07615433526718(17)101231(10)abc123 or (01)17615433512343(17)101231(10)abc123</p>
Carton	 <p>8x Multi-Pack; unit for wholesalers</p>	 <p>1x carton with 6 boxes</p>	<p>Identification: GTIN D Attributes: Batch no.: abc123 Expiry date: 31.12.2010</p> <p>Information encoded in the GS1-128: (01)07615433526732(17)101231(10)abc123 or (01)27615433512340(17)101231(10)abc123</p>

The sequence in which the attributes are placed in the barcode hardly plays a role. Fields with fixed lengths (e.g. expiry date) should precede fields of variable lengths (e.g. serial number), as this will reduce the size of the barcode.

There is no general answer to the question on which packaging level what attributes should be encoded in the barcode. Often a serialisation of products is indeed desired. But in technical terms, this is only economically feasible as from the secondary packaging level. It is important to find an economic balance between costs and benefits. Note: In some countries there are legal requirements⁵³ that must be adhered to.

⁵⁴ EAN-13 has to be used for products sold via retail point of sale.

3.3.4. Choice of symbology/of the data carrier

There are two solutions available for the affixing of information on the various packaging levels:

The linear GS1-128⁵⁵ is chosen for objects that have enough space on the printing surface. This is especially interesting for cartons whose barcode needs to be scanned at a distance (boxes stored in high bay warehouses). In any case, symbols wider than 16.5 cm should be avoided. It is possible to display the information in two symbols, although this is not recommended.⁵⁶

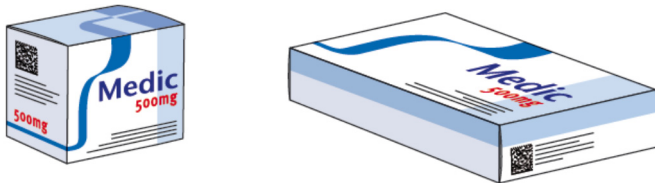
The two-dimensional GS1 DataMatrix⁵⁵ is chosen for smaller objects, if only little space is available for a marking on the packaging.

The smallest symbol is not always the best. Symbols may be as small as possible, but as large as necessary to be scannable.

3.3.5. Recommendation on the placing of the symbol

If more than one barcode symbol must be used, only one GTIN must be used. Ideally, the symbols are printed on different sides of the packaging, so that either the GS1 DataMatrix or EAN-13⁵⁵ can be individually scanned during the scanning process.

Figure 18: drug box with GS1 DataMatrix



We would like to stress once again that the mapping of information in two complementary symbols is undesirable. The information in the data carrier, such as item number or expiry date must be affixed also in human readable form. For each GS1 BarCode, the information must be applied in plain text to the symbol.

⁵⁵ Section 5.1.1.2. GS1 Barcodes for the GTIN.

⁵⁶ The effective width of a GS1-128 Barcode depends on the number of user data characters and the selected X module width. Do not hesitate to contact GS1 Switzerland should you have any questions.

3.4. Order

3.4.1. Order process

Online ordering platforms and electronic networking between seller and buyer have led to different ordering processes existing in parallel within an organisation (e.g., in a hospital or a retail pharmacy).

The care provider is usually the buyer of the product or service. The buyer will determine in its supply chain management, which product group is ordered through which wholesalers or direct suppliers and which ordering process should be applied.

There are various reasons⁵⁷ and incentives⁵⁸ why this is so. In any case, all variants of the order messages are based on the same structure of a basic order message.

Figure 19: possible order variants



Below, the individual ordering process variants are identified and the individual application examples described. The world-wide members of GS1 have developed in close cooperation different business process models that are rolled out in a range of different industries, supported by the GS1 Identification Keys, GS1 BarCodes and electronic messages.

The order is a legal action between the seller and the buyer. To avoid having to renegotiate the reference prices and the purchasing conditions with each order process, a framework agreement is concluded between the seller and buyer and its details filed in the condition system of the business partner.⁵⁹ This practice applies to all subsequent ordering process variants and will not be described in greater detail.

3.4.2. The traditional order

3.4.2.1. Process description

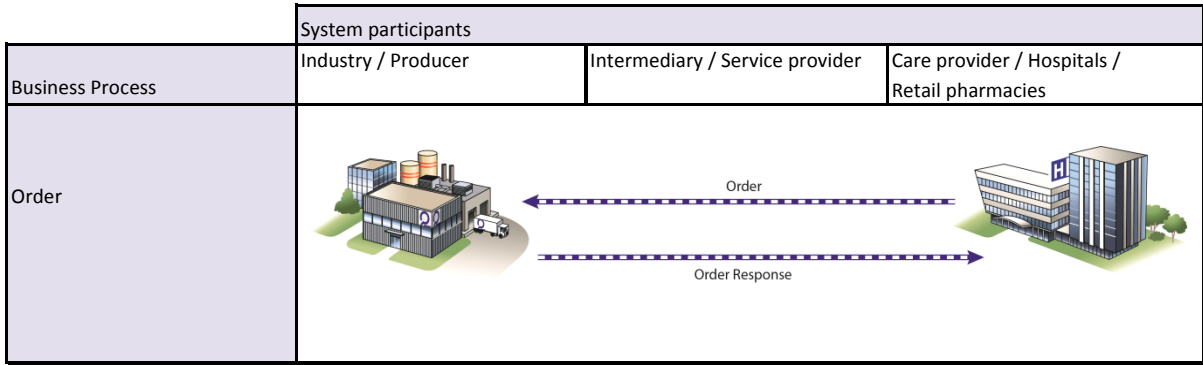
The order (by letter, fax, phone or electronic message) is transferred from the buyer to the seller, to order products or services. The buyer determines the amount, the desired delivery date, the place of delivery or the place where the ordered service is to be provided.

⁵⁷ For example requirements relating to the availability of the products or legal requirements relating to an order.

⁵⁸ For example, requirements relating to the ordering process of a procurement pool, so that the care provider (e.g. hospital x) can obtain better procurement conditions.

⁵⁹ See also Section 3.2 Master data alignment.

Figure 20: the traditional order with GS1 XML



The electronic order refers to an offer previously received from the seller (products or services). In the electronic ordering process, trading partners and products or services are identified with the GS1 identification keys (GLN and GTIN) that were previously aligned with the master data.

An order is generally generated per delivery and place of delivery. The order is triggered due to consumption or a specific requirement by the buyer.

3.4.2.2. Information elements for process participants

Figure 21: overview of the traditional order: GS1 System, processes and EDI

Order processing (ORDER)						
	Colour code good neutral Potential for improvement					
	Industry / Production	Wholesalers	Logistics provider	Hospital pharmacy / Materials management Central procurement	Care provider OR / Care department	Hospital Administration
Partner master data	GDSN bilateral	GDSN bilateral		GDSN bilateral	yes yes	Yes yes
Partner identification	GLN	GLN		GLN		
Stock related transaction	yes	yes		yes		
Procurement functionality	ms	yes		yes		
Product identification	GTIN	GTIN		GTIN	GTIN	GTIN
EDI data format	GS1 XML Proprietary solution Fax, Mail, Tel	GS1 XML Proprietary solution Fax, Mail, Tel		GS1 XML Proprietary solution Fax, Mail, Tel		
A Order	Recipient	Recipient		Sender		
B Order Response	Sender	Sender		Recipient		
C Order Change	Sender	Sender		Recipient		
Delivery note reference	Yes	Yes		Yes		

The counterparties agree bilaterally which additional electronic message types are to be used for message A (order) in the daily ordering process, so that the procurement process works smoothly. In addition to the traditional order, an order response message B or order change message C may be used. The order confirmation is to be used if the delivery differs from the order in terms of quantity or date. In the event of order changes by the seller, it is usually agreed that the purchaser is informed so that he can take appropriate measures to ensure the product's availability.

All the above messages are based on the message type order.

3.4.3. Vendor Managed Inventory VMI

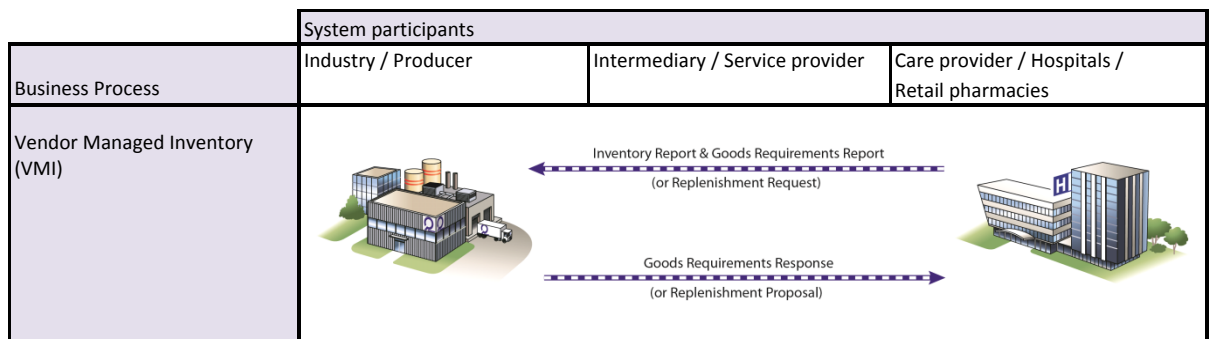
3.4.3.1. Process description

The Goods Requirements⁶⁰ message is usually used in combination with the inventory Report⁶⁰. The business partners involved agree that these messages are transmitted from the buyer to the seller on a daily basis or at least once a week. If the information is to be sent at the same time, alternatively the Replenishment Request⁶⁰ can be used.

If the responsibility for stocks rests with the seller, the process is called a vendor-managed inventory business relationship or a supplier-driven inventory management. This means that the stock (e.g. in the hospital pharmacy or on the ward) is managed independently by the seller. Often, the buyer is granted a full right of return.

The objective of this procurement philosophy is to improve the performance (logistics costs and general availability of products) of the supply chain.

Figure 22: Vendor Managed Inventory (VMI)



3.4.3.2. Information elements for process participants

The Vendor Managed Inventory is based on statistical figures, which the seller has built up using data from the Goods Requirements Report⁶⁰ and the Inventory Report⁶⁰ (or Replenishment Request). The Goods Requirements Report includes the consumption amount for the defined time period. The recipient of this message (seller) can process this information electronically, consolidate it and use it for its own production, planning and/or statistical purposes.

In addition to the current inventory, if available, the planned stock issues and receipts can be transmitted to the seller by electronic messages. If these messages are sent daily and/or weekly in this combination to the seller, automatic order proposals can be generated from its scheduling tool and transferred to its business partner/buyer. The rights and obligations shall be transferred to the hospital at the time of delivery.

⁶⁰ Technical descriptions of all GS1 XML messages: http://www.gs1.org/qsmp/kc/ecom/xml/xml_bms (6.12.2011).

Figure 23: overview of Vendor Managed Inventory: GS1 System, processes and EDI

VMI process (replenishment proposal based on the Inventory/Consumption Report)						
	Colour code good neutral Potential for improvement					
	Industry / Production	Logistics provider	Forwarder	Hospital pharmacy Materials management Central procurement	Care provider OR / Ward	Hospital
Partner master data	GDSN bilateral		GDSN bilateral	GDSN yes	GDSN yes	
Partner identification	GLN		GLN	GLN	GLN	
Stock-related transaction	yes		yes	yes		
Procurement functionality	yes		yes	yes		
Product identification	GTIN		GTIN	GTIN		
EDI data format	GS1 XML proprietary solution		GS1 XML Proprietary solution			
A Replenishment Request	Recipient		Trigger			
B Replenishment Proposal	Sender		Recipient			
Delivery note reference	Yes		Yes			

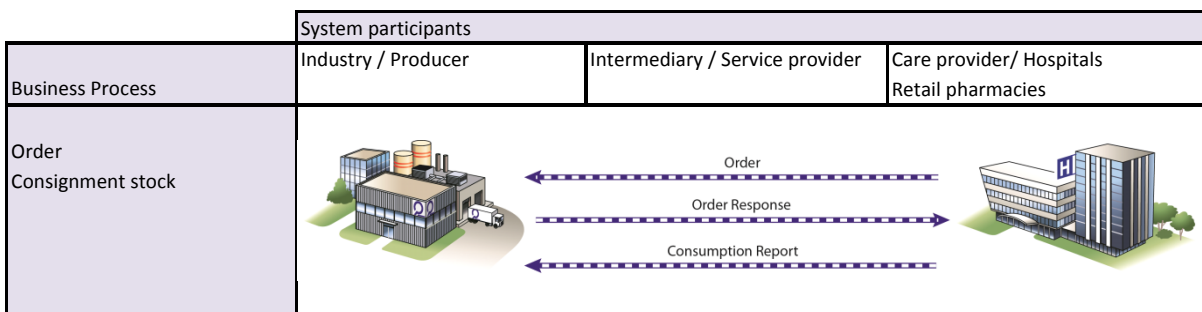
3.4.4. Order with consignment stock

3.4.4.1. Process description

In contrast to the ordering processes previously described, here the seller retains ownership of the products until they are used by the service recipient. This means that ordering and delivery triggers no financial transaction, neither by the seller nor the buyer.

The characteristics of the consignment stock is that usually only a few people at care provider level work with the products from the consignment stock (e.g. special suture material for surgery). It therefore makes no economic sense to buy all the products from this range for stock purposes.

Figure 24: ordering with consignment stock



3.4.4.2. Information elements for process participants

The initial order (building up of a consignment stock) is usually performed manually and subsequent reorders are triggered automatically (report B). Thus, the reorder process for consignment products of a department is done identically to the traditional order process. In the case of consignment stocks without a VMI process, the buyer triggers the electronic order (consumption report or replenishment) in line with the planning or the specific needs of (report A).

In case of vendor managed inventory management (VMI) the seller sends the consumption and inventory reports (Goods Requirements and Inventory Report) to the buyer who confirms via message C (Goods

Requirements Response) (alternatively, it is possible to work with the Replenishment Request and the Replenishment Proposal). This allows the supplier to plan on the basis of the data obtained.

Figure 25: overview of the consignment stock order: GS1 System, processes and EDI

Ordering consignment stock						
	Industry / Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider OR / Ward	Hospital Administration
Colour code	<div style="display: flex; justify-content: space-between;"> <div style="width: 20%;"> <p>good</p> <p>neutral</p> <p>Potential for improvement</p> </div> <div style="width: 60%; text-align: center;"> <p>B</p> <p>A</p> <p>C</p> </div> <div style="width: 20%; text-align: right;"> </div> </div>					
Partner master data	GDSN bilateral			GDSN bilateral	yes yes	yes yes
Partner identification	GLN			GLN	GLN	
Inventory-related transaction	yes			yes	yes	
Procurement functionality	yes			yes	yes	
Product identification	GTIN			GTIN	GTIN	
EDI data format	GS1 XML Proprietary solution			GS1 XML Proprietary solution	GS1 XML Proprietary solution	
A Order	Recipient			Trigger		
B Order	Recipient			yes (in copy)	Trigger	
C Replenishment Proposal	Trigger			Recipient	Recipient	
Inventory management	yes			yes	yes	
Delivery note reference	yes			yes	yes	
Invoicing and payment process	Consumption Report			Consumption Report	Consumption Report	

The business partners generally agree in a contract that, after physically receiving the goods, the receipt of the goods is confirmed with a Receiving Advice. Only the removal from the consignment stock (-> Consumption Report), so the effective consumption by the care provider is relevant to the invoicing. This triggers corresponding financial transactions. Periodic inventory of consignment stock differences are offset manually.

3.4.5. B2B order via electronic ordering platforms

3.4.5.1. Process description

In section 3.2 *Master Data Alignment* we have already mentioned the electronic ordering platforms, in context with the alignment of master data. The providers of these platforms usually offer a total package, beginning with the data clearing⁶¹, data transfer, definition of the transfer protocols, selection of "in house" data formats and item maintenance up to data updating.⁶² These electronic ordering systems use different numbering systems and carry, if available, the GTIN unfortunately only as attributes. These ordering platforms are subject to a charge. Generally, the seller pays a percentage of the volume of orders, depending on the selected services.

The advantages of order processing via an electronic platform are primarily the multilingualism, automation of existing order settlement processes, statistic modules and "Business Intelligence" for the seller.

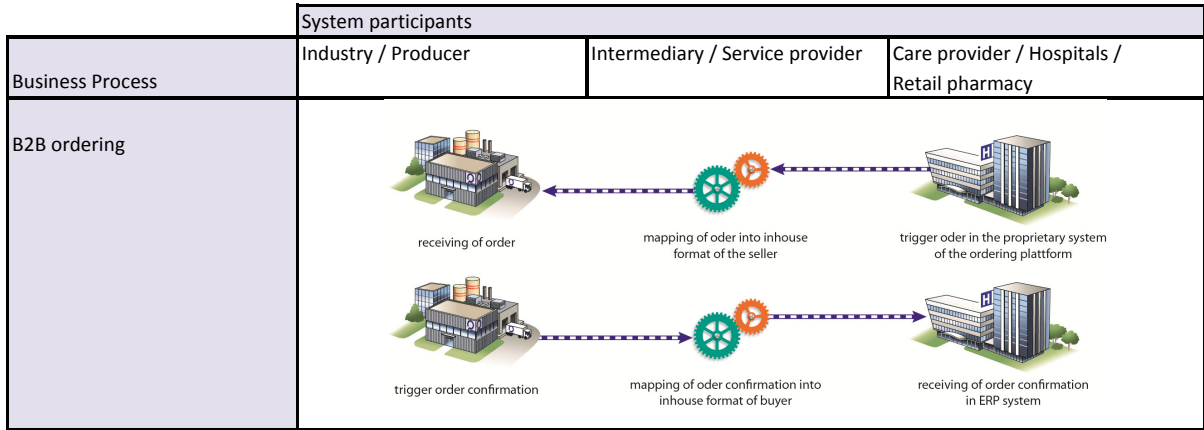
From the perspective of care providers (buyers), the advanced services, such as Contract management, back documents⁶³ from the proprietary ordering system, data validation and classifications of all products for efficient processing in the ERP system are advantageous.

⁶¹ For example automatic fax data capturing system with electronic transfer to the ERP system

⁶² Permanent validation and plausibility checks on the transactions as well as the clarification of possible sources of error

⁶³ For example order confirmation, delivery slip, invoice.

Figure 26: B2B ordering via electronic ordering platforms



3.4.5.2. Information elements for process participants

The B2B order messages A and B differ from the GS1 XML order in that respect, as the data exchange is carried out through a closed system of the platform operator. Order message A is triggered patient-related as opposed to the order message B (e.g. for an individually produced hip). If, during order capture the GTIN for the patient-specific product is missing, an internal identification number for the corresponding purchase order item is used. Thus, the document flow from order to payment is ensured.

Orders to non-participating companies (sellers) are also processed, but not implemented in the electronic "in-house" format of the seller. The ordering platform forwards the order to them, for example as a fax. Therefore, the back documents for the ERP systems of the provider are missing. This media discontinuity is of course a disadvantage⁶⁴ for the care provider. The operators of order platforms are encouraged to take appropriate standardisation measures to avoid the media discontinuity.

The B2B Order message via electronic ordering platforms usually includes all the information contained in the GS1 XML order, such as GTIN, quantity, delivery date or the GLN of the place of delivery. Depending on the provider, this information is not always available.

⁶⁴ If back documents are missing, this forces the service provider to manually capture the order data in their own ERP or materials management system.

Figure 27: B2B ordering via electronic ordering platforms GS1 System, processes and EDI

B2B ordering						
(Orders)						
Colour code						
Good						
Neutral						
Potential for improvement						
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR / Ward	Hospital administration
Partner master data	GDSN bilateral			GDSN bilateral	GDSN bilateral	Yes bilateral
Partner identification	GLN			GLN	GLN	
Inventory related transaction	yes			Yes	Yes	
Procurement functionality	yes			Yes	Yes	
Product identification	GTIN Proprietary No.			GTIN Proprietary No.	GTIN Proprietary No.	GTIN Proprietary No.
EDI data format	GS1 XML inhouse			GS1 XML inhouse	GS1 XML inhouse	GS1 XML inhouse
A Order for direct delivery	Recipient			yes (in copy)	Trigger	yes (in copy)
B Order	Recipient			Trigger		
Back documents	Recipient			Recipient	Recipient	Recipient

In addition to the partial absence of back documents, the use of proprietary identification numbers for products is a problem. These proprietary identifications are not barcoded on the products. Therefore, they cannot be used for follow-up processes in the hospital such as the medication.

3.4.6. Internal consumption report/HL7 RDS Pharmacy Dispense Message

3.4.6.1. Process description

For the optimisation of internal and external hospital order processing, GS1 proposes to consolidate internal hospital consumption reports with HL7 RDS Pharmacy Dispense Messages (instead of the HL7 Stock Refill Order) promptly in the materials management of the hospital.⁶⁵ This consolidation process is mandatory from the perspective of supply chain management, so that the physical replenishment process can take place on time and in a consumer-friendly manner and in the correct package size.⁶⁶ The advantage of this practice is that the central replenishment is informed of the currently available stock of the local storage facility⁶⁷ and can respond quickly to supply shortages.

In addition, the supply from the central warehouse, respectively the supply from external sources, can be automated⁶⁸, if stock has fallen below a safety level and an order is triggered (reorder point procedure).

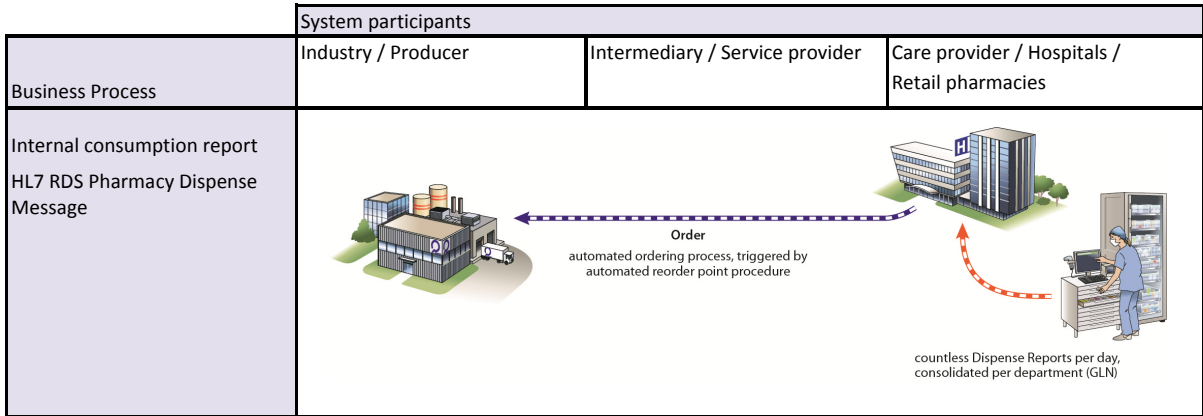
⁶⁵ Without a consolidation process, according to the current state of knowledge, for each consumption a so-called "Stock Refill Order" process would be joined by the "Prescription and Dispense Process", that triggers the physical individual deliveries in the materials management of the hospital. This would be very inefficient and would lead to a huge logistical extra cost.

⁶⁶ HL7 provides in the corresponding messages of the RXG segment field 4 that the code used, e.g. by GS1 (GLN sender) and the drugs administered (GTIN) can be used.

⁶⁷ This can also be pharmacy automation systems or drug cabinets that are inventory managed.

⁶⁸ Similar to the Kanban principle or the just-in-time philosophy used by industry.

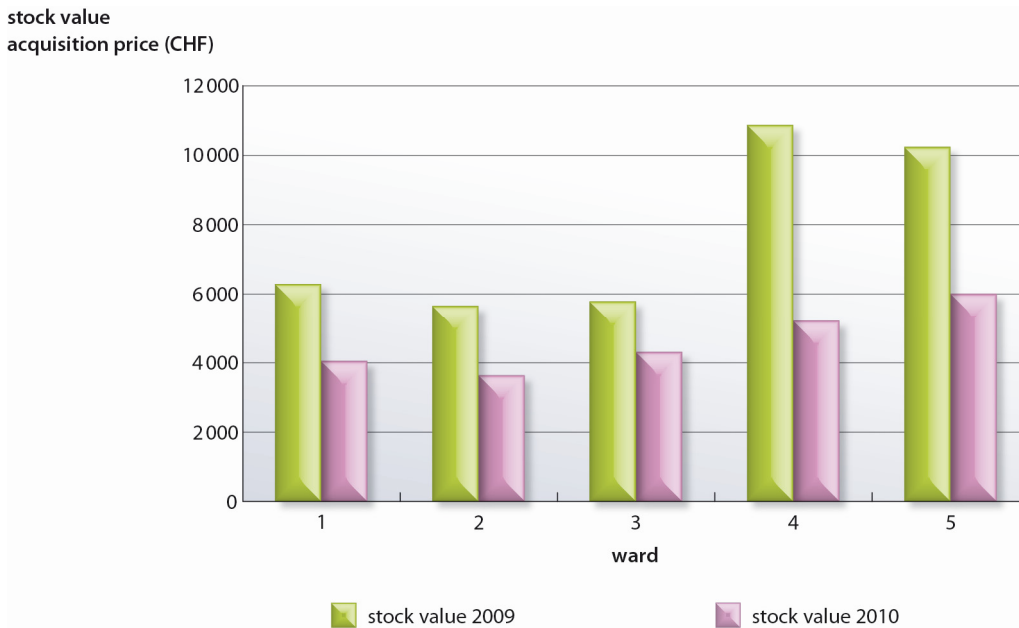
Figure 28: internal consumption report/HL7 RDS Pharmacy Dispense Message



The experience of the Limmattal hospital show that the stocks of the locally-controlled warehouse (ward stockroom with drugs) are reduced drastically after a short time. After the process change in the Limmattal Hospital, fewer products must be returned or destroyed.

The evaluation of the Limmattal Hospital shows a striking reduction in stock between January and March 2009 and January to March 2010. During this period the average number of order lines increased from 4.57 to 6.87 lines per order.⁶⁹

Figure 29: reduction in stock value



3.4.6.2. Information elements for the process participants

The internal consumption report differs from the external consumption report insofar as the structure is given by the current ERP and inventory control systems. The care providers that map the business process models with HL7 messages can use the benefits arising from the data interoperability with GS1, provided that they also consistently use the GTIN for internal product identification. This is very important so that the

⁶⁹ Ricarda Luzio, Deputy Director of Limmattal Hospital Pharmacy, GSASA advanced training, 9.6.2010.

scanning⁷⁰ along the supply chain can be done efficiently and desired consumption reports (report C and D) can be automatically transferred to the following systems and are processed without media discontinuity.⁷¹

These are namely:

- Hospital Information Management System / update doctors, therapists, nurses,
- Hospital accounting system for billing,
- Hospital inventory management system for replenishment and purchasing.

Figure 30: overview of the internal consumption report/HL7 RDS Pharmacy Dispense Message: GS1 System, processes and EDI

consolidated HL7 Consumption report						
	Industry / Production	Hospital pharmacy/ Materials management	Care provider 1/ Doctor	Care provider 2/ Hospital pharmacist	Care provider 3/ Nursing staff	Hospital administration
Colour code	<div style="display: flex; justify-content: space-between;"> <div style="width: 15%;"> <p>good</p> <p>neutral</p> <p>Potential for improvement</p> </div> <div style="width: 85%;"> </div> </div>					
Partner identification		GLN	GLN	GLN	GLN	GLN
Clinic information system			yes	yes	yes	yes
Service capture			yes	yes	yes	yes
Materials management		yes	yes	yes	yes	yes
Procurement functionality		yes	yes	yes	yes	yes
Product identification		GTIN	GTIN	GTIN	GTIN	GTIN
		Proprietary no.	Proprietary no.	Proprietary no.	Proprietary no.	Proprietary no.
EDI data format		inhouse / OMS	inhouse / OMS	inhouse / OMS	inhouse / OMS	inhouse / OMS
A HL7 Prescription dispense Order			Trigger	Recipient		
B HL7 Prescription approval			Recipient	Trigger	Recipient	
C HL7 RDS Pharmacy Dispense			Recipient	Recipient	Trigger	Recipient
D HL7 consolidated used/ consumption report instead of HL7 Stock Refill Order		Recipient	tbd	tbd	Trigger	

The experts believe today that it is still unclear how the interaction between the HL7 Stock Refill Orders should work with the proposed Consolidated Used or Consumption Report in practice. We at GS1 recommend consolidating the use per department several times per day⁷² and organising the replenishment in a way that is decoupled from the individual HL7 Stock Refill Orders. Hospital-procurement is a time-critical process and should be controlled primarily through stock and availability data.

For internal hospital stock transfers (from one department to another department), we recommend an internal hospital “shipment” analogue to the Despatch Advice. Responsibility for triggering the necessary shipments lies with Replenishment/Logistics, which at the same time monitors the corresponding stock adjustments.

⁷⁰ For example, to check the stock entry, for a stock transfer, for dispensation or for the care activity recording.

⁷¹ If the GTIN is used, no translation tables between GTINs and internal hospital identification numbers need to be managed.

⁷² According to supply intervals.

3.5. External Delivery (Dispatch)

3.5.1. Description/significance of external deliveries

An exact mapping of the external flow of goods is essential for efficient supply chain management. This implies guaranteeing the accuracy of the master data of all market participants (sellers, logistics service providers, parcel services) as well as clearly defined transaction descriptions (traditional delivery, cross-docking delivery, consignment stock-replenishment process, etc.) for the different business process models.

The key business processes mentioned above are in widespread use in industry and are deployed in different sectors. That is why we do not make a distinction between the procurement of medical devices and drugs, but reflect the differences between a multi-tier and single-tier trading model.

3.5.1.1. [Multi-tier business model \(stock held by the wholesaler\)](#)

The two-tier business model with wholesalers has evolved over many years. The actual stockholding of the products and the bundling of the product ranges of the various sellers are entrusted to the wholesalers, who then supply their customers daily⁷³ with the products they need. Industry, in turn, supplies the wholesalers, either directly or through their logistics service providers. This means that the number of business relations can be mapped for each participant. This allows efficiency gains through the pooling of distribution. The processes are usually supported with electronic messages.

3.5.1.2. [Single-tier business model \(stock held by the supplier or logistics provider\)](#)

The market for individualised drugs and medical devices is evolving rapidly. In parallel, electronic ordering platforms have become more and more accepted in the healthcare sector and allow efficient, single-tier business models. The B2B procurement process is carried out by the care providers themselves, without order-taking by the suppliers.

Some logistics providers seized this opportunity to perform the physical replenishment processes on behalf of different suppliers. In the meantime, these service providers have grown into efficient logisticians. They can effortlessly map various direct delivery processes, such as cross-docking or consignment delivery.

The legal requirements for the logistics service providers⁷⁴ may be different, but the technical implementation as such should be uniform/identical. As already described in section 2.5.5 *Identification of transport units (SSCC)*, GS1 recommends using the SSCC (Serial Shipping Container Code) to roll out the delivery processes. Each participant in a trading relation must capture which transport unit has been allocated which SSCC and to which partner it has been sent or which partner has received it. In combination with the Despatch Advice, the SSCC enables product traceability. The traceability process is described in detail in the document *GS1 Global Traceability Standard for Healthcare (GTSH)*⁷⁵.

The most important delivery or replenishment processes of a hospital are outlined below, along with the corresponding GS1 XML message types.

3.5.2. Traditional delivery (with Despatch Advice)

3.5.2.1. [Process description](#)

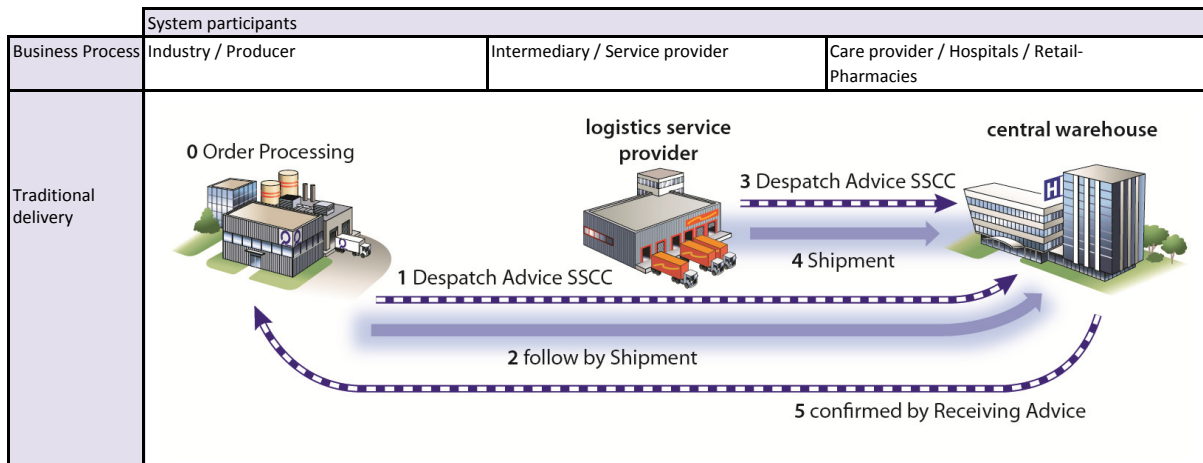
The delivery notification (Despatch Advice for traditional delivery between industry, logistics provider, freight forwarder and hospital) describes the details of the goods to be supplied under agreed conditions or that are ready for delivery. The Despatch Advice may be used both as "notification of delivery" and as a "Notification for returning goods" (Collection).

⁷³ Customer proximity and product availability are significant service KPIs for this supply chain.

⁷⁴ Swissmedic authorisation for warehousing as well as distribution and/or authorisation for the packaging/repackaging of drugs.

⁷⁵ GS1 Global Traceability Standard for Healthcare (GTSH) Implementation Guide (GS1 Global Office, 2009)

Figure 31: traditional delivery



The message includes a seller (GLN⁷⁶) and a buyer (GLN⁷⁶) or their agents (intermediaries). The Despatch Advice refers to a consignor (GLN⁷⁷) and one or more delivery locations or destinations (1 to N GLNs⁷⁷). The message can include several different delivery positions and includes, among others, detailed information (e.g. product name, quantity, expiry date, batch or serial numbers) about the respective GTINs. Each transport unit is identified by a SSCC. At the time the recipient takes delivery of the goods, the SSCC allows access to the electronic preliminary information that was previously received with the Despatch Advice. The SSCC serves as a key to access data and detailed data about the delivery (GTIN plus batch or serial number) can be automatically transferred to subsequent systems and process steps.

Depending on the sector in question, the receipt of the goods is confirmed by means of a Receiving Advice sent by the buyer to the seller. The seller then creates the electronic invoice on the basis of the Receiving Advice. Any delivery deviations or defective products supplied are taken into account in the Receiving Advice and there is no need for extensive invoice reversals.

Experts agree that the Despatch Advice is the starting point for many automated process steps and is best used to feed the following external storage location or internal department.

⁷⁶ GLN is used here for the unambiguous identification of the “Legal Entity”. The correct use of the GLN (Global Location Number) is a prerequisite for electronic data exchange with GS1 eCom standards.

⁷⁷ GLN is used here for an unambiguous identification of a physical location of a company (e.g. warehouse ramp 2).

3.5.2.2. Information elements for process participants

Figure 32: overview of a traditional delivery: GS1 System, processes and EDI

External delivery (Despatch Advice)						
Colour code						
Good Neutral Potential for improvement						
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR/Ward	Spital administration
Partner identification	GLN	GLN	GLN	GLN		
Identification of the transport unit	SSCC	SSCC	SSCC	SSCC		
Inventory related transaction	yes	yes	yes	yes		
Product traceability	yes	yes	yes	yes		
Product identification	GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)		
EDI data format	GS1 XML			GS1 XML		
	proprietary solution	proprietary solution	proprietary solution	proprietary solution		
A Despatch Advice	Trigger			Recipient		
Order and delivery note reference	yes			yes		

The arrows marked in blue show the preceding information flow (Despatch Advice). Details about the Despatch Advice (e.g. which product has what production batch number) are usually captured in the picking process and linked to the appropriate customer order. The Despatch Advice is then the technical aggregation of all the picking lines of the corresponding customer order, linked to the individual transport units.

The vertical arrows illustrate the possibility of unambiguously tracing the physical transport at any time (or later in the case of a product recall) via the SSCC to see, which customer received which production batch.

3.5.3. Cross-docking delivery (with Despatch Advice)

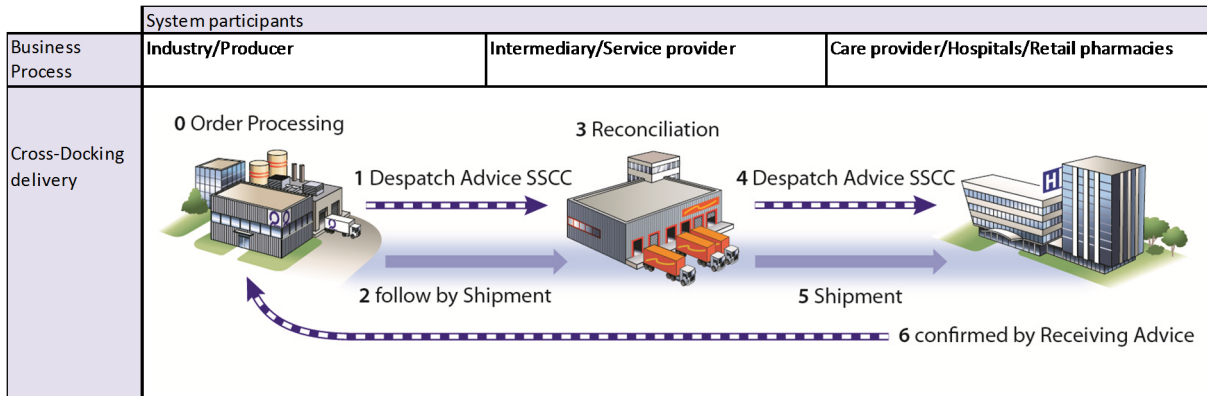
3.5.3.1. Cross-docking process description

Cross-docking delivery differs from traditional delivery in the sense that, at the time of delivery, it is already clear, for which care providers (e.g. hospital or hospital ward) the desired product is to be picked. The physical execution of the delivery takes place according to the rules of the Despatch Advice⁷⁸: the logistics providers or freight forwarder must transmit the cross-docking shipment as quickly as possible to the recipient without "storing the goods"⁷⁹.

⁷⁸ Unlike the traditional Despatch Advice, in cross-docking each end recipients must be identified.

⁷⁹ No actual goods entry takes place at the logistics service provider, but the incoming goods are immediately further distributed without an inventory-relevant booking.

Figure 33: cross-docking delivery



3.5.3.2. Information elements for process participants

The blue arrows show, as already described, the information flow of the Despatch Advice. The forwarder is added, because he performs the delivery to the hospital or directly to the department on behalf of various suppliers. The freight forwarder generally obtains the information about the individual transport units from the suppliers and notifies the subsequent storage location as set out in section 3.5.2.2 Information elements for process participants.

Figure 34: overview of a cross-docking delivery: GS1 System, processes and EDI

Cross-Docking (Despatch Advice)						
	Colour code Good Neutral Potential for improvement					
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR/Ward	Spital administration
Partner identification	GLN	GLN	GLN	GLN	GLN	
Identification of the transport unit	SSCC	SSCC	SSCC	SSCC	SSCC	
Inventory related transaction	yes	yes	no	yes	yes	
Product traceability	yes	yes	yes	yes	yes	
Product identification	GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)	
EDI data format	GS1 XML	GS1 XML	GS1 XML	GS1 XML	GS1 XML	
	proprietary solution	proprietary solution	proprietary solution	proprietary solution	proprietary solution	
A Despatch Advice	Trigger		Recipient			
B Despatch Advice			Trigger	Recipient 1	Recipient 2	
Order and delivery note reference	yes			yes	yes	

If the cross-dock shipment is delivered directly to the ward, we recommend to follow the technical implementation below.

3.5.4. **Delivery directly to the department (with Despatch Advice)**

3.5.4.1. Process description

Direct delivery to the department differs from a traditional delivery in the sense that, at the time of delivery, it is already known, for which care provider/department (GLN) the product in question must be picked. The

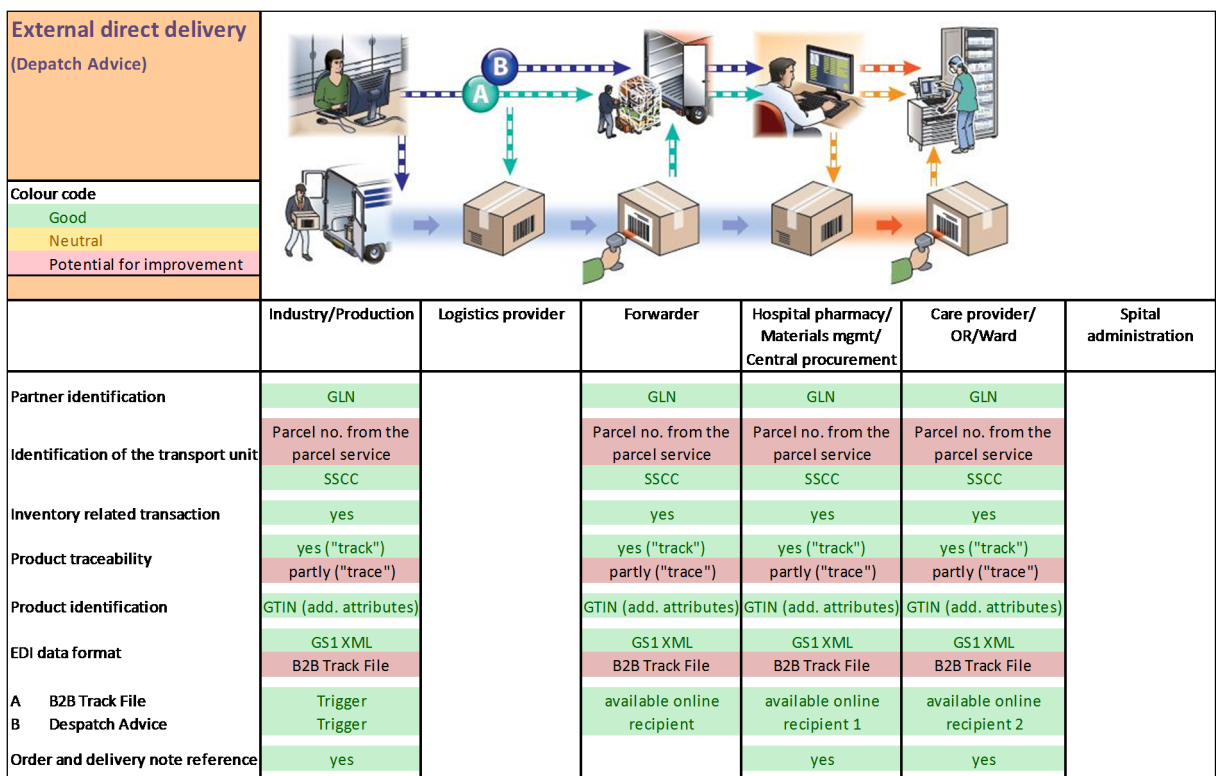
physical delivery of the goods is usually performed by a forwarder or a parcel service directly to the ward. For this process it is compulsory to have a clean back office processing of the incoming goods to the department.

This process incurs higher logistics costs for the seller/manufacturer. On the other hand, the latter can ensure quality assurance and quality control of the distribution channel using "track and trace" functionality and, if necessary, speed up the delivery process with an express delivery. These are critical success factors for individual suppliers to hospitals and retail pharmacies.

3.5.4.2. Information elements for process participants

Instead of the Despatch Advice B, usually the B2B applications/Event-Management-Systems of the parcel service (orange marked flow of information) are used for this. "Track and trace" functionality is an integral part of these applications and make it possible to track the dispatch process from A in real time on the PC. Everyone involved in the process must confirm that they have completed their part of the task via a scan (proprietary parcel number) in the B2B application of the parcel service.

Figure 35: overview of delivery directly to the department: GS1 System, processes and EDI



Given that several parcel service providers make deliveries, the recipient needs to know which products are delivered via which service providers. This process is cumbersome for the recipient of the goods. It forces the hospitals to make an extra effort to ensure traceability.

3.5.5. **Consignment-Replenishment process**

3.5.5.1. Process description

Consignment is a process in which an adequate range of the assortment is stored with the care provider, without the buyer/care provider having to invest their own capital.

The consignment-replenishment process differs from traditional delivery in the sense that the goods remain in the possession of the seller, even after physical delivery to the buyer. The goods remain the property of the seller until removal from the consignment stock. To do so, the buyer transmits a corresponding report

(Consumption Report) to the seller and then receives a daily or weekly invoice corresponding to the goods removed from the consignment stock.

3.5.5.2. Information elements for process participants

The traceability of the shipments is ensured either by information contained in the Despatch Advice B or through the "track and trace" system of parcel service A. The "track and trace" system of the parcel service requires that all process participants confirm their respective processing step in the B2B application and enter information on the product, e.g. batch or serial number, either manually or by scanning.

Figure 36: overview of the consignment-replenishment process: GS1 System, processes and EDI

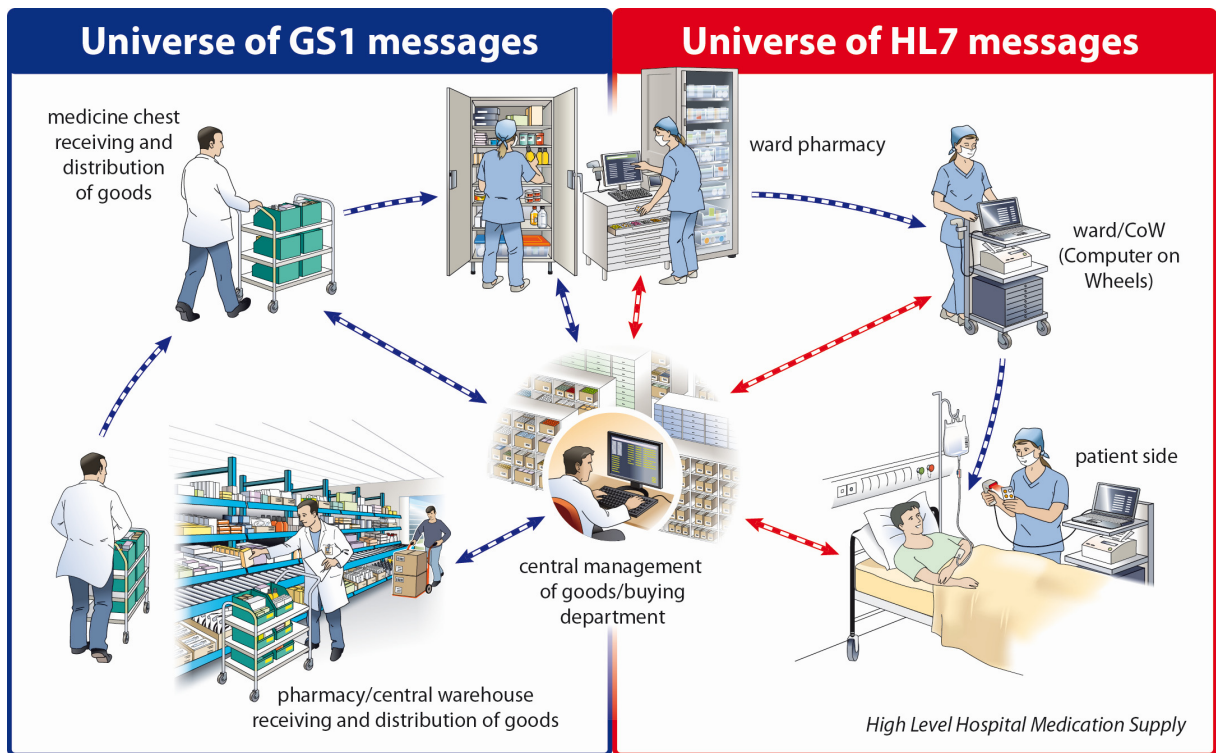
External delivery (Consignment replenishment process)						
	Colour code Good Neutral Potential for improvement					
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR/Ward	Spital administration
Partner identification	GLN		GLN	GLN	GLN	
Identification of the transport unit	Parcel no. from the parcel service		Parcel no. from the parcel service	Parcel no. from the parcel service	Parcel no. from the parcel service	
	SSCC		SSCC	SSCC	SSCC	
Inventory related transaction	yes		yes	yes	yes	
Product traceability	yes ("track")		yes ("track")	yes ("track")	yes ("track")	
	partly ("trace")		partly ("trace")	partly ("trace")	partly ("trace")	
Product identification	GTIN (add. attributes)		GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)	
EDI data format	GS1 XML		GS1 XML	GS1 XML	GS1 XML	
	B2B Track File		B2B Track File	B2B Track File	B2B Track File	
A B2B Track File	Trigger		available online recipient	available online recipient 1	available online recipient 2	
B Despatch Advice	Trigger					
Order and delivery note reference	yes			yes	yes	

3.6. Internal goods transfer (Despatch Advice) and Production (Order & Receiving Advice)

3.6.1. Introduction/significance of internal deliveries

Only a few hospitals still provide all services in-house. Through hospital mergers or through the specialisation of individual clinics, certain support functions (e.g. pharmacies) have been centralised or outsourced to a third party (e.g. the laundry service, sterilisation or catering). As a result, the demands on internal hospital logistics have grown. Hospitals and suppliers alike express their wish for uniform standards for the handling of internal deliveries. To allow the transport process (blue arrows) to be individually tracked, a link between the physical transfer, the transport unit and the associated flow of information must be guaranteed.

Figure 37: delimitation of the GS1 and HL7- messages universe



For internal deliveries of drugs or medical devices (goods transfer) to the ward or drugs cabinet (in blue), GS1 recommends using the Despatch Advice in combination with the SSCC. This guarantees traceability (e.g. in the case of a product recall) across all wards.

By scanning the SSCC with each goods issue (sender) and goods entry (recipient), the movements of goods to local storage facilities (e.g., a ward drugs cabinet) can be mapped in the inventory management (blue arrows). Each transfer order refers to a unique recipient (-> GLN). For the corresponding shipment (box/caddy) a SSCC is generated and put into a barcode.

The effective consumption (red arrows, e.g. medication and administration process) will ideally be recorded in real time in a HL7 RDS Pharmacy Dispense Message⁸⁰. Since GS1 signed a Memorandum of Understanding with HL7 International⁸¹ in 2007, the HL7 universe is mentioned in this document.

To ensure that the consolidated consumption per department (GLN) can be identified, it is essential that, in addition to the Dispense Report, messages for general consumption, for returns, for goods for destruction, etc. are implemented in the ERP system.

⁸⁰ HL7 message type with patient identification and consumed HL7 drugs (including production batch or serial number).

⁸¹ GS1 and HL7 Join Forces to Develop Global Standards to Improve Patient Care (GS1 Global Office and HL7, 2007)

The different types of internal deliveries are outlined below. Generally, internal delivery/transfer of goods should be handled in the same way as the external deliveries. The advantage of this is that information can be used in the same way throughout all the various systems of a hospital.

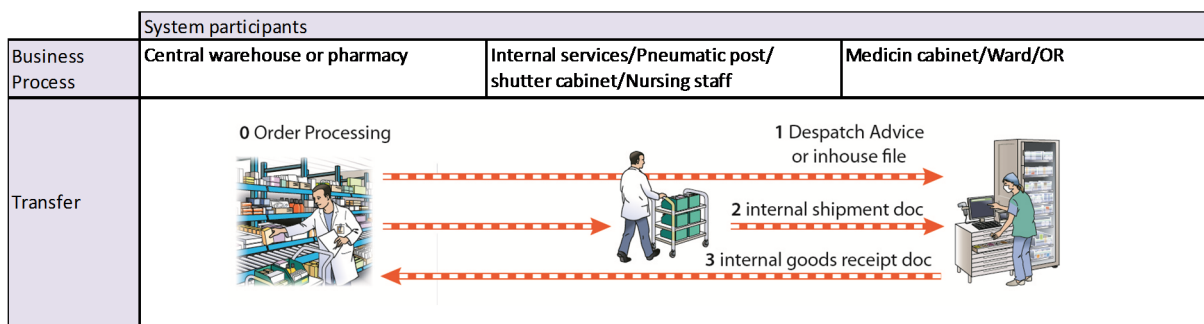
3.6.2. Transfer (Despatch Advice)

3.6.2.1. Process description

Ideally, the information in the electronic messages for the internal hospital transfer structurally match the external Despatch Advice, so that the details of the transfer can be applied automatically (without media discontinuity) without manual data capture. The SSCC on the logistics label is an "enabler" for this.

In many places, representatives of hospitals and of the supply industry demand generally applicable standards for internal goods transfer. But there are also guidelines for the proper use between hospitals or care homes of the same entity/organisational unit, for example.

Figure 38: transfer



3.6.2.2. Information elements for process participants

It makes sense to standardise internal hospital goods transfer in line with the external deliveries. The hospital departments can be delivered in the same way via a harmonised replenishment process and via internal goods transfers and via external deliveries (e.g. direct and cross-docking deliveries). This increases the sovereignty of the individual departments in accordance with the defined procurement strategy.

The goods reference, i.e. identification, takes place in the same way as in the central warehouse via the SSCC scanning process. The delivery note is approved and forwarded to the accounting department for cost center clearing. Ideally, this workflow runs electronically without paper.

Figure 39: overview of goods transfer: GS1 System, processes and EDI

Internal transfer (Despatch Advice)						
Colour code						
Good						
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR/Ward	Disposal/ Production
Partner identification				GLN	GLN	GLN
Identification of the transport unit				SSCC	SSCC	SSCC
Inventory related transaction				yes	yes	yes
Product traceability				yes	yes	yes
Product identification				GTIN (add. attributes)	GTIN (add. attributes)	GTIN (add. attributes)
EDI data format				GS1 XML	GS1 XML	GS1 XML
				ERP inhouse File	ERP inhouse File	ERP inhouse File
A Despatch Advice or ERP transaction				Trigger	Recipient 1	
B Despatch Advice or ERP transaction				Trigger		Recipient 2
Order and delivery note reference				yes	yes	yes

3.6.3. Dispensation and administration

The following process description (highlighted in red in the diagram below) is based on a working paper, which is under development as part of IHE (Pharmacy Working Group). IHE (Integrating the Healthcare Enterprise)⁸² is an international initiative to improve electronic data exchange between information systems in the healthcare sector. IHE defines Integration Profiles in which already defined standards such as HL7, DICOM or, in future, GS1 are applied.

One of the concerns of the IHE Pharmacy Technical Committee is to clarify the roles and the necessary process steps in hospital supply chain management. The work will be incorporated into a corresponding specific integration profile or, at the very least, lead to an extension of the existing "Hospital Medication Workflow (HMW)" profile.

The messages planned to date

- Prescription Dispense Order
- Dispense Reports
- Supply Refill orders

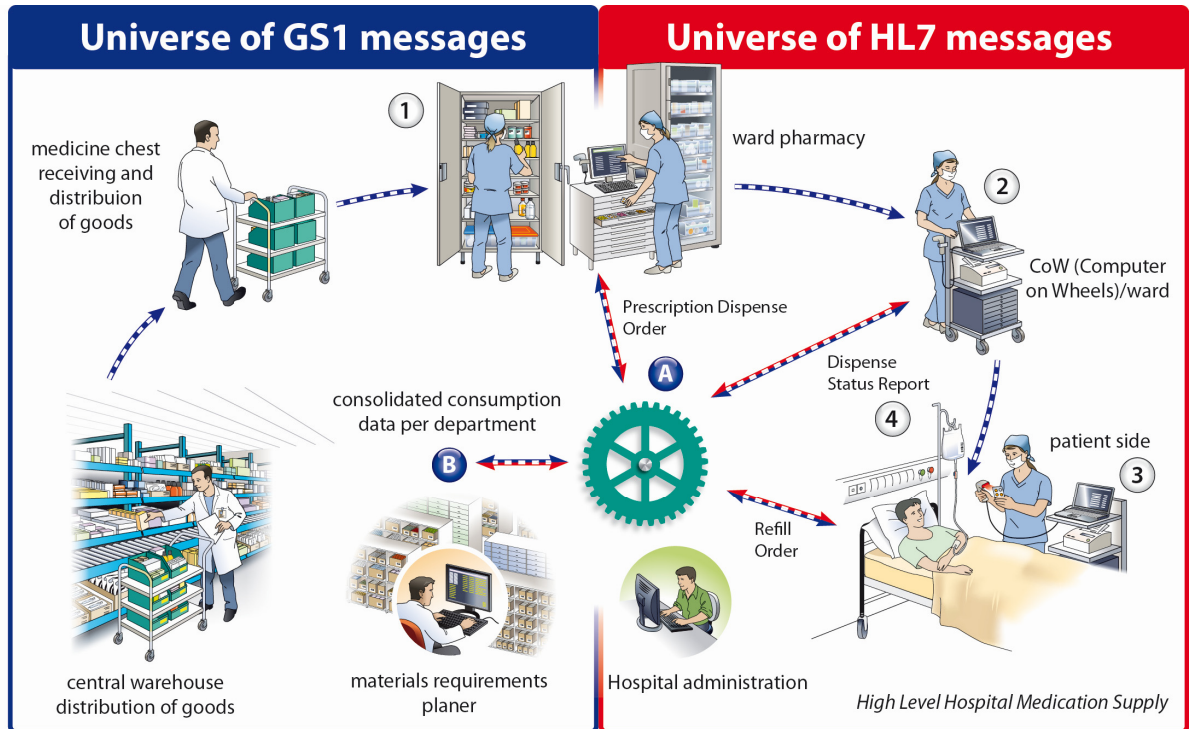
should be formulated with the help of the HL7 standard.

GS1 focuses on the external and internal hospital replenishment processes, which must run efficiently and independently from the clinical processes (e.g. drug administration). This requires consolidated consumption data B (per GTIN (product) and GLN (department/ward)), and the process steps already described previously with the corresponding messages.

The following diagram shows the rough delimitation between the GS1 and HL7 universes and illustrates the need for a compatible data hub A.

⁸² www.ihe-suisse.ch (12.1.2012)

Figure 40: data hub for the connection of the HL7 and GS1 universe



3.6.3.1. Process description

In hospitals, the dispensation is often carried out according to the “second set of eyes” principle. Hospital pharmacy associations⁸³ and GS1 recommend to change processes so that after provision of drugs (point ①), the product is booked to another party of a ward (point ②; e.g. Computer on Wheels (CoW)). The second verification of the dispensation then takes place at the point of administration⁸⁴ by nursing staff (point ③). This should minimise administration errors and it is recorded accurately into the dispense report status message, which drug was administered at what time and in which dose to which patient (point ④).

In the same process sequence, the patient-specific care activity recording takes place, which is the basis for the case calculation. This requires an electronic prescription and a unique patient identification. Ideally, the patient is given a bracelet with a barcode (GSRN⁸⁵), which creates a link between the hospital information system and to the care activity recording.

For expensive products or certain drugs, it is useful to have GTINs in the hospital information system⁸⁶, even if only for the lowest packaging level – the single unit/unit of dose. This allows the amount administered to the patient to be documented and invoiced⁸⁷.

⁸³ Sources: E. Poon, Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy, *Ann Intern Med.* 2006 Sep 19;145(6):426-434 as well as E. Poon, Effect of bar-code technology on the safety of medication administration, *N Engl J Med.* 2010 May 6;362(18):1698-1707.

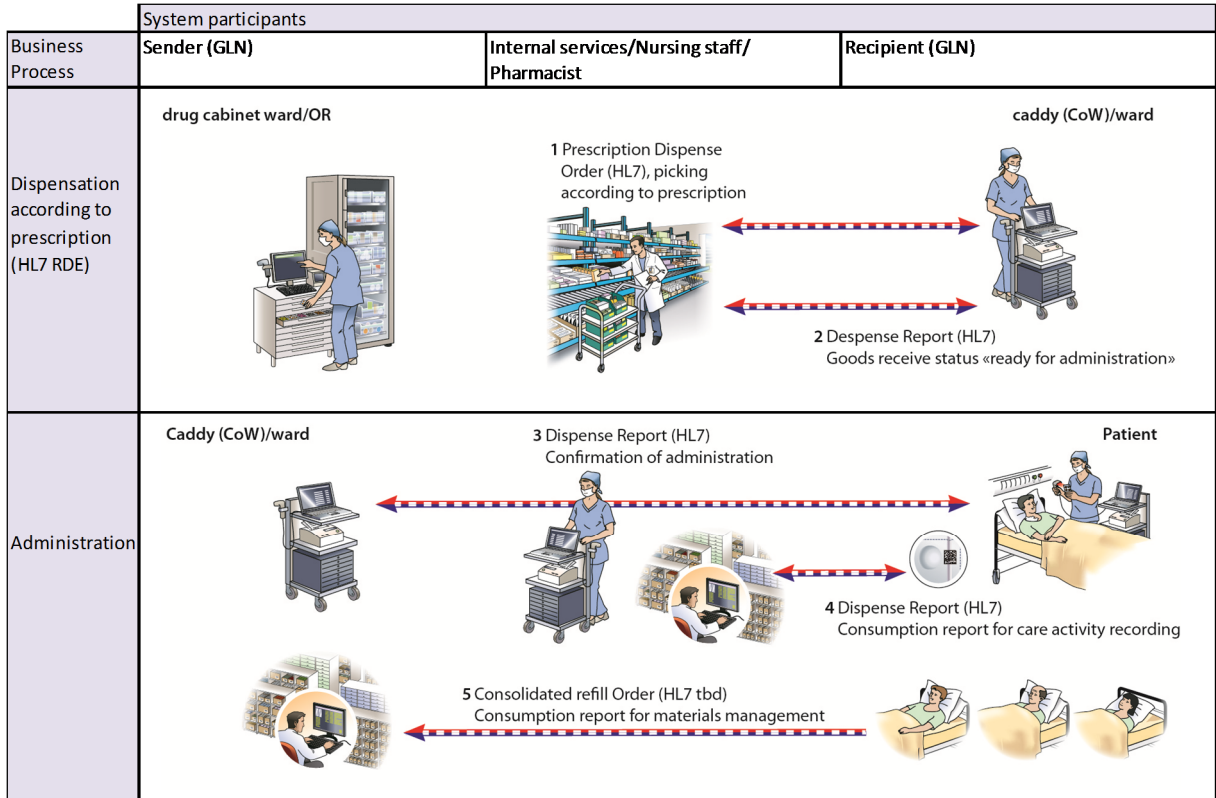
⁸⁴ For the purpose of reducing administration errors.

⁸⁵ See also Section 2.5.6 Identification of care providers and recipients (GSRN).

⁸⁶ The HIS defines which products and nursing activities are to be captured with a barcode. This decision depends on the following factors: costs of the treatment, risks for the patients and optimisation of the scanning procedures.

⁸⁷ Through the blister cut, many products lose their effective expiry date and are consequently no longer dispensed by the nursing staff. This leads to considerable residual stock that needs to be liquidated.

Figure 41: dispensation and administration



The effective consumption per department (GLN; see point ⑤) can then be consolidated, so that this product is reordered when it falls below a minimum stock level. Depending on the defined purchasing process, the replenishment (order) is drawn from the central warehouse or from external suppliers.

3.6.3.2. [Information elements for the process participants](#)

Figure 42: overview of dispensation and administration: GS1 System, processes and EDI

Consolidated HL7 consumption report Colour code Good Neutral Potential for improvement						
	Industry/Production	Pharmacy/Materials management	Care provider 1/ Doctor	Care provider 2/ Pharmacy	Care provider 3/ Nursing staff	Hospital administration
	Partner identification	GLN	GLN	GLN	GLN	GLN
Clinic Information System			yes	yes	yes	yes
Care activity recording			yes	yes	yes	yes
Material management	yes	yes	yes	yes	yes	yes
Procurement functionality	yes	yes	yes	yes	yes	yes
Product identification	GTIN	GTIN	GTIN	GTIN	GTIN	GTIN
EDI data format	proprietary No.	proprietary No.	proprietary No.	proprietary No.	proprietary No.	proprietary No.
A HL7 Prescription dispense Order			Trigger	Recipient		
B HL7 Prescription approval			Recipient	Trigger	Recipient	
C HL7 Dispense Report			Recipient	Recipient	Trigger	Recipient
D HL7 consolidated used/ consumption report instead of HL7 Stock Refill Order		Recipient	tbd	tbd	Trigger	

The HL7 messages have been developed to support internal hospital processes (e.g. drug administration). Players that create or process the messages are doctors, pharmacists or nursing staff who capture the data in the hospital information system.

For example, the HL7 Prescription Dispense Order (Report A) requires an electronic prescription (of drugs or medical devices). The sender of the HL7 Prescription Dispense Order is the attending physician. Subsequently the pharmacist or the qualified staff on the ward checks (Report B) the HL7 Prescription Dispense Order and picks the products in question.

The actual dispensing process (Report C) starts with the sending of the order to the appropriate ward and ends after proper drug administration by the caregiver. The HL7 RDS Pharmacy Dispense Message message for example, can in an "emergency case" come directly from an e-medicine cabinet, triggered by a dispensation process by the caregiver.

The processes described are generally related to finished products, which are identified with a GTIN. Medication processes that relate to variable measure products are not described here. These administration cases are based on the master data of the finished products, but must be recorded separately with manual input (e.g. mixture of 10 ml from a vial with a bag of 50 ml NaCl x %).

3.6.4. Hospital internal production (Order and Receiving Advice) without goods invoicing

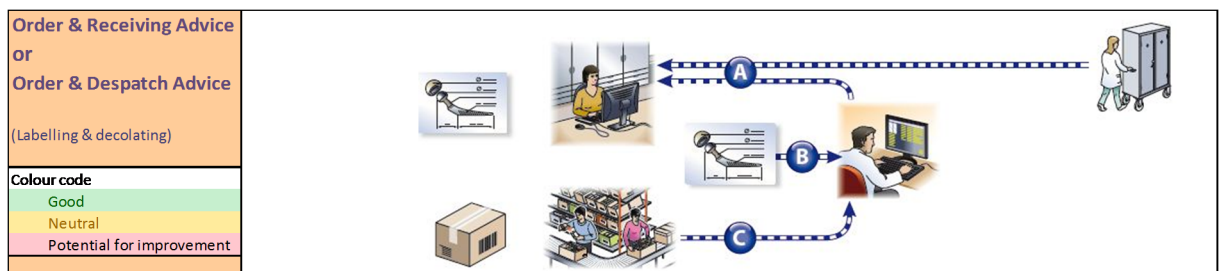
To allow processes to be designed as efficiently as possible, it is recommended to implement internal productions in the same way as external goods deliveries. The GS1 messages support both the external delivery of goods, as well as internal production/delivery.

For example: A hospital has out sourced the preparation of the surgical boxes to a third party. The individual preparation order is sent with the order (report A), which is triggered by materials management. For this process, it is crucial that the order contains the GTIN of the product to be delivered and the components (part of the Bill of Material).

The third party prepares the surgical boxes, transfers them to the central warehouse or the delivery destination, and confirms the amount supplied to materials management, using the Receiving Advices (Report B).

The process can take place identically with an internal department, e.g. sterilisation. But this process will only be successful if the barcoding guidelines of GS1 are met and the necessary messages are correctly implemented by the participating business partners.

Figure 43: overview of hospital internal production: GS1 System, processes and EDI



	Industry/Production	External contract manufacturer	Hospital internal production	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/OR/ward	Disposal
Order & Receiving Advice or Order & Despatch Advice (Labelling & decolating)						
Colour code						
Good						
Neutral						
Potential for improvement						
Partner identification		GLN	GLN	GLN	GLN	GLN
Product identification		GTIN	GTIN	GTIN	GTIN	GTIN
Inventory related transaction		yes	yes	yes	yes	yes
Product traceability		yes	yes	yes	yes	yes
EDI data format		GS1 XML	GS1 XML	GS1 XML		GS1 XML
		inhouse file	inhouse file	inhouse file		inhouse file
A Order		Recipient 2	Recipient 1	Trigger 1		Trigger 2
B Receiving Advice			Trigger	Recipient		
C Despatch Advice		Trigger		Recipient		

It should be added that third party contract manufacturers or internal hospital departments that cannot directly deliver the produced goods to the required stock, must generate a Despatch Advice (message C) for transport.⁸⁸ This secures product traceability. The receiving of the products supplied is identical with the deliveries of third party suppliers.

⁸⁸ See also section 3.5 *External Delivery (Dispatch)* or Section 3.6 *Internal Goods transfer (Despatch Advice) and Production (Order & Receiving Advice)*.

3.7. Invoice

3.7.1. Introduction

The term "invoice" includes following messages: invoice, credit advice and debit advice. In this document, the invoice is always to be understood in connection with procurement and not with patient-related billing. All cash-related electronic messages with VAT details must be electronically signed, encrypted and archived in accordance with the legal requirements. In the light of these increased requirements for electronic invoicing, many EDI service providers offer VAT-compliant processing and archiving systems. This allows even smaller companies to participate in the electronic invoicing and payment process.

There are service providers active in various sectors, who take care of the invoices of the various sellers on behalf of the buyer and settle them according to the different due dates of payments. The function of these invoice recipients responsible for settlement is useful, as they deal with the different invoice due dates. On the other hand, they transform the different invoice formats of the sellers into the uniform format of the buyer for electronic invoice control.

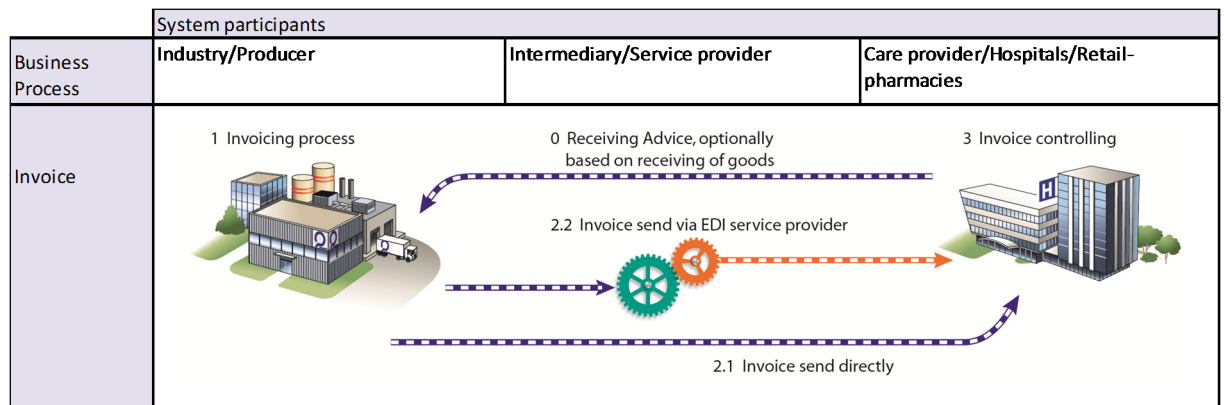
3.7.2. Invoice message

3.7.2.1. Process description

A seller sends an invoice for one or more transactions. An invoice may refer to goods or services on the basis of an order, delivery, delivery schedule, consignment stock removal, etc.

An invoice can contain references to payment conditions (e.g. payment terms, discounts, etc.). For cross-border transactions, an invoice may contain additional information for customs and/or statistical purposes. It can also include costs for the transport carried out.

Figure 44: invoicing



The invoice is used for the invoicing process. It is the message that requests payment. The invoice usually responds to the commercial conditions, which were agreed between the seller and buyer in a framework agreement.

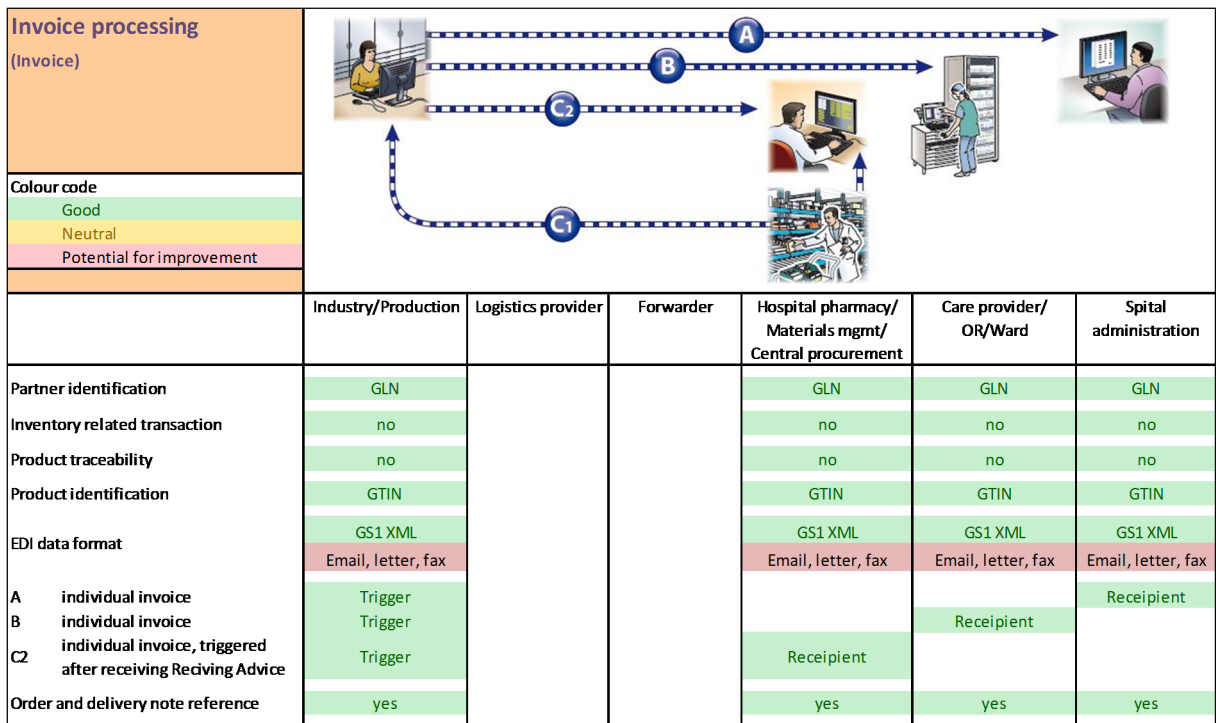
If differences are noted during invoice control, the parties have to clarify why there has been a difference.

Leading trading partners meticulously measure the "Invoice Accuracy"⁸⁹ and regularly exchange indicators (KPIs) for this purpose.

⁸⁹ The reason for the meticulous control of invoicing is that only complete and correct invoices can be electronically and automatically further processed by the recipient of the invoice.

3.7.2.2. Information elements for process participants

Figure 45: overview of invoicing: GS1 System, processes and EDI



In general, the invoice recipient determines which department (A, B and C) receives which invoice from which supplier. Internal transfers by the recipient ensure that the invoices are checked and approved for payment on time.

GS1 recommends that trading partners with a high turnover (e.g. wholesalers) only trigger the invoicing process C2 after receipt of the Receiving Advice C1. This allows them to minimise invoice differences⁹⁰ that are triggered by minimum delivery differences. The invoice can thus be transmitted within the hospital for immediate payment. This recommendation is also very important for business relations with very short payment terms (e.g. 0 or 5 days), so that the payments can be effectively guaranteed by the agreed deadline.

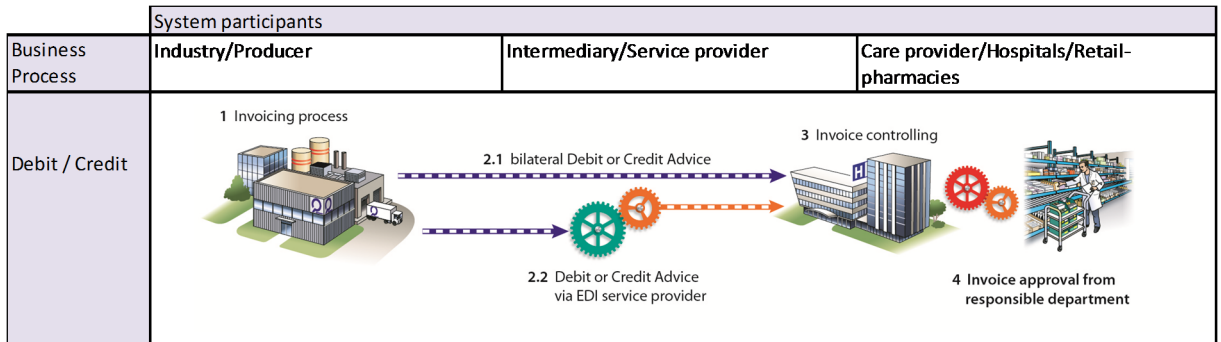
3.7.3. Debit Advice and Credit Advice message

3.7.3.1. Process description

The Debit Advice and Credit Advice are electronic messages used for the settlement of services without order reference (e.g. the fee of a consultant or telephone bills) or used in the event of corrections to a previous invoice.

⁹⁰ The clarification time and effort can usually be drastically reduced.

Figure 46: debit advice and credit advice



There are usually no specific master data (no GTIN) for Debit Advices without an order reference, that were exchanged between the business partners. That is why these documents cannot be automated in the electronic invoice control. This means that they must be approved by the cost center manager.

For these types of transactions, many companies have switched to so-called "internal orders" so that, at the time of receipt of the invoice, the outstanding invoice can be referenced to an internal document/budget in relation to a cost center. In large companies, these documents are then transmitted (physically or in a separate workflow system) to the cost center manager, who is responsible for the release of payment.

For a Debit Advice and Credit Advice with order reference, the same rules apply as for the invoice so that the internal control and approval processes B and C can be triggered automatically via an authorisation workflow.

3.7.3.2. Information elements for process participants:

Figure 47: overview of the Debit Advice and Credit Advice: GS1 System, processes and EDI

Invoice processing (Debit & Credit Advice)						
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR/Ward	Spital administration
Colour code	<ul style="list-style-type: none"> Good Neutral Potential for improvement 					
Partner identification	GLN			GLN	GLN	GLN
Inventory related transaction	no			no	no	no
Product traceability	no			no	no	no
Product identification	poss. yes; GTIN			poss. yes; GTIN	poss. yes; GTIN	poss. yes; GTIN
EDI data format	GS1 XML			GS1 XML	GS1 XML	GS1 XML
	Email, letter, fax			Email, letter, fax	Email, letter, fax	Email, letter, fax
A Debit & Credit Advice	Trigger			Recipient	Authorisier	poss. Recipient
B Payment authorisation				Recipient	Trigger	poss. Recipient
C Approval for payment				Trigger		Recipient
Order and delivery note reference	yes			yes	yes	yes
Reference to internal order	yes			yes	yes	yes

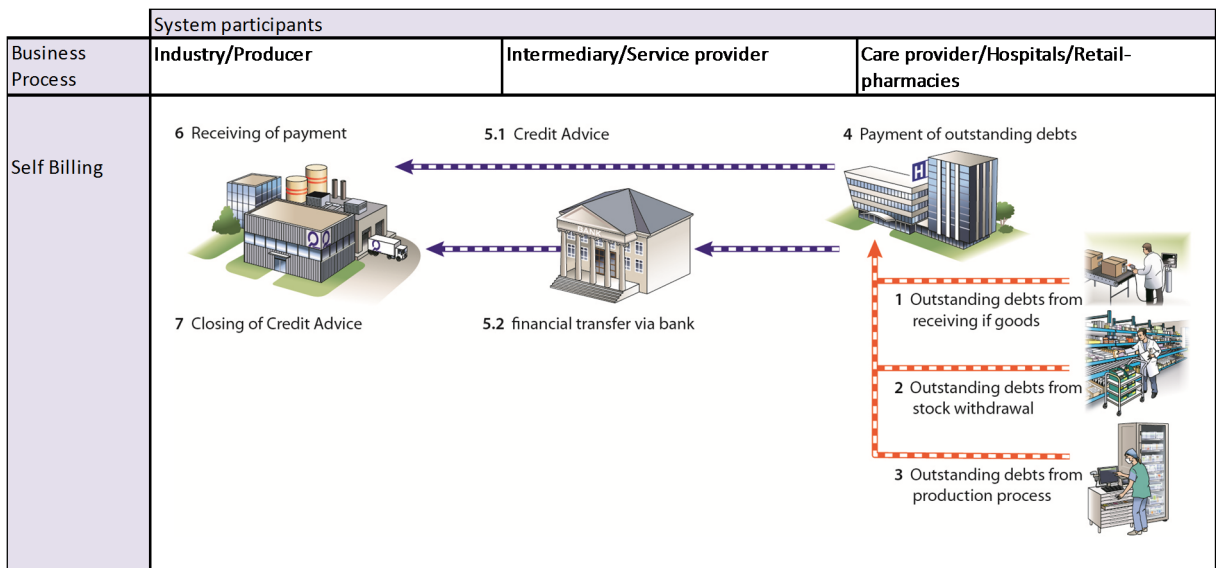
3.7.4. Self-Billing

3.7.4.1. Process description

Self-billing is part of the payment processing. In contrast to the traditional process, in which the seller issues the invoice based on the order or the delivery process, the buyer executes the payment independently on a daily, weekly or monthly basis. The seller is informed by the buyer by means of a credit note about the details of payment. That is why it is very important for the success of the system that both partners can rely on each other's systems.⁹¹

A great advantage of self-billing is the elimination of redundant communication flows between buyers and sellers, such as invoice submission from the seller and payment notice by the buyer. These advantages are significant for a business relationship when hundreds of transactions are carried out every day.

Figure 48: self-billing



3.7.4.2. Information elements for process participants

The Credit Advice A or A1 can be triggered in three ways:

- based on the goods receipt booking B,
- based on the stock withdrawal or the booking of the goods issue C from the material or consignment stock for the production or the sale,
- based on internal hospital production or manufacturing processes D (Receiving Advice message).

The common denominator of these bookings is that they were all generated by the customer/buyer itself.

⁹¹ In particular, the credit advice method and the basis for payment, as well as the prices and discounts must be clearly defined and always be transparent. They should be available in form of current partner and product master data as well as in the framework agreement.

Figure 49: overview of self-billing: GS1 System, processes and EDI

Self Billing process (Credit Advice)						
	Colour code Good Neutral Potential for improvement					
	Industry/Production	Logistics provider	Forwarder	Hospital pharmacy/ Materials mgmt/ Central procurement	Care provider/ OR/Ward	Hospital internal production
Partner identification	GLN			GLN	GLN	GLN
Product identification	GTIN			GTIN	GTIN	GTIN
EDI data format	GS1 XML			GS1 XML	GS1 XML	GS1 XML
	Email, letter, fax			Email, letter, fax	Email, letter, fax	Email, letter, fax
A + A1 Credit Advice	recipient			trigger		poss. recipient
B booking of received goods				trigger & recipient		
C Consumption Report				recipient	trigger	
D Receiving Advice				recipient		trigger
Order and delivery note reference	yes			yes	yes	yes

3.7.5. Pro-Forma invoice

A bill that does not ask the recipient to pay is a pro forma invoice. This form is used for example for free deliveries in the event of goodwill claims or when records in written form are required in the case of intra-community services.

Pro forma invoices are common in relations between wholesalers and retail pharmacies as shipping documents, as many pharmacies thus not only carry out an incoming goods control but also a sales price calculation.

3.7.6. Advanced Remittance Notification

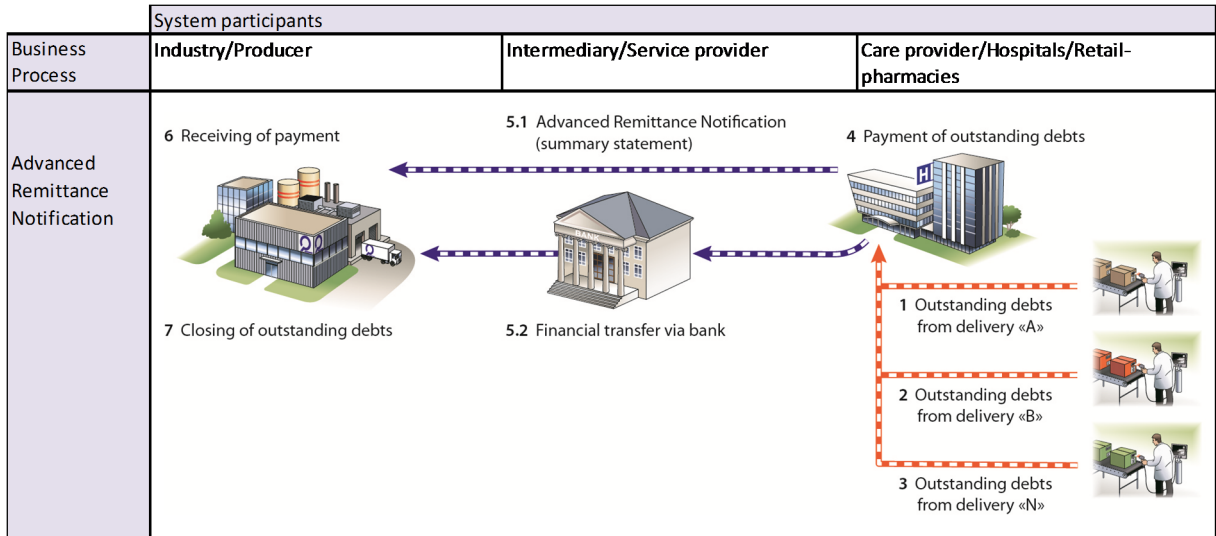
3.7.6.1. Process description

The Advanced Remittance Notification is a communication between trading partners (e.g. sellers, buyers, banks) to show a payment or other form of financial regulation.

The information relates to payments of goods and services as they are detailed in the payment. An advanced remittance notification may be based on several business cases and related transactions, such as Invoice, Debit or Credit Advice. An advanced remittance notification can be used in the event of both national and international payment processing. But every notification should only refer to one currency, one payment date and one trading partner.

Depending on the agreement, the advanced remittance notification can be triggered by any business partner.

Figure 50: Advanced Remittance Notification

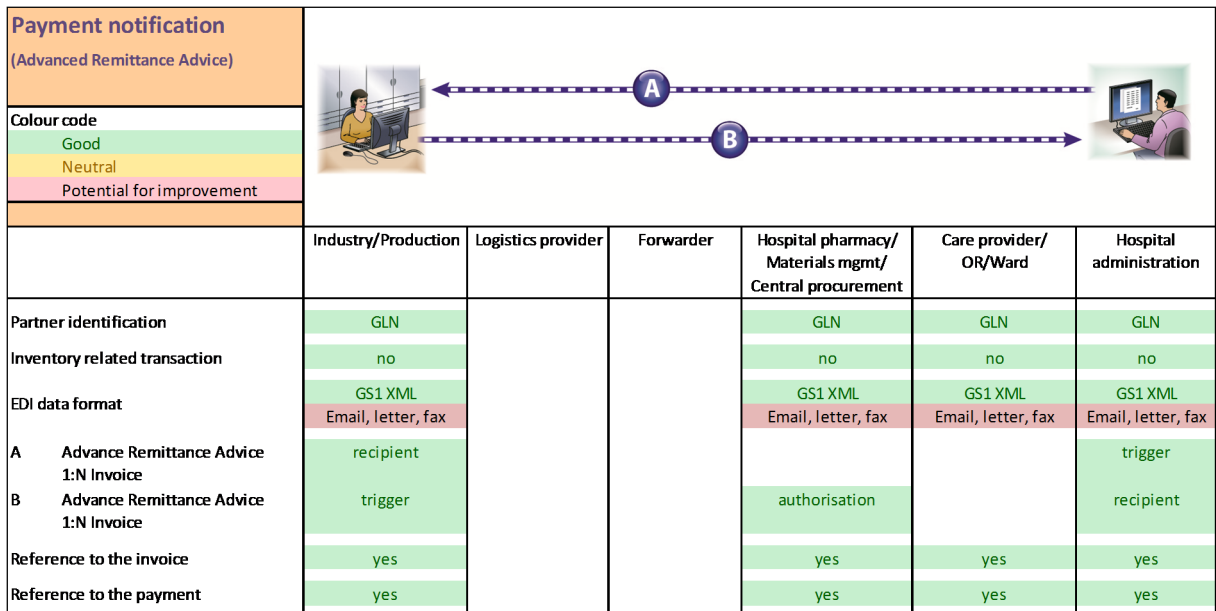


The cash-related Advanced Remittance Notification is very common in trade and industry. The Advanced Remittance Notification contains a reference to a payment order that has been executed in parallel or in a timely manner.

3.7.6.2. Information elements for process participants

In general, the release of the payment is decoupled from the payment capture. This ensures that no person alone can "capture and release payments". The authorisation person does not necessarily belong to the hospital administration.

Figure 51: overview of the advance remittance notification: GS1 System, processes and EDI



4. The services of GS1 Switzerland

4.1. Membership with GS1

GS1 is a network of more than 110 national GS1 organisations, which are spread all over the world. Each GS1 organisation provides its members with various services related to the GS1 System. All companies that want to actively use the GS1 System have to become a member of one of the national GS1 organisations.

GS1 Switzerland offers its members the following services:

- You will receive a GS1 Company Prefix and can use the GS1 System.
- Barcode tests and first level support (telephone & email) are free for members of GS1 Switzerland.
- GS1 Switzerland offers its members cost efficient consulting services on the use of the GS1 System.
- You can find out more at conferences, during study tours or site visits.
- You benefit from basic and advanced training offered by GS1 Switzerland.
- The basic and advanced training is offered at a reduced price for members.
- GS1 organises events to enable sharing of experiences with market participants and to support the network.
- You can not only address your own challenges but also actively participate in standard development on the GS1 working groups.
- You obtain access to the extensive expertise of the national and international GS1 community.
- You have direct access to established best-practice process models.

4.2. Basic and advanced training on the GS1 System

GS1 Switzerland offers several industry-neutral seminars on the GS1 System⁹². These seminars are held several times a year and help members roll out the GS1 System in their company. The following courses are offered.

4.2.1. Compact seminar "GS1 System-Expert" with certificate

This compact seminar provides a comprehensive overview of the GS1 standards. All aspects such as GS1 identification keys, GS1 data carriers (barcodes and RFID tags), electronic data interchange (EDI using EANCOM and GS1 XML), GS1 EPCglobal (RFID) and master data alignment (GDSN) are covered in four days.

This seminar is designed for those who need an overview of the GS1 System and want to implement the GS1 System across their company.

4.2.2. GS1 System basics

With the help of the GS1 System, each company, regardless of its size, can offer its partners and customers article numbers and other identification keys that are worldwide unique.

This course explains the basics of the GS1 System. It is designed for new members who want to label their products for the first time with GS1 BarCodes.

⁹² An overview of all the GS1 System seminars: <http://www.gs1.ch/weiterbildung/seminare/gs1-system-seminare> (31.7.2013).

4.2.3. GS1 System in the supply chain

The logistical applications within the GS1 System require a holistic approach to the supply chain and cannot usually be limited to one company. This seminar shows, how trade and transport units must be labelled to ensure efficient receiving of goods processes.

This course is designed for all companies that want to optimise the logistics processes with their partners in the supply chain.

4.2.4. GS1 eCom

A basic requirement for electronic data exchange with several business partners is the existence of a unified messaging standard. This seminar explains the "order to cash" EDI process and shows which EDI standards exist.

GS1 eCom is suitable for all companies that need to roll out an EDI project and want to learn about the processes and EDI standards.

4.2.5. GS1 EPCglobal

RFID stands for Radio Frequency Identification. By using RFID, contactless identification, control and tracking of any number of goods and objects across the entire value chain can be carried out - from production to "after sales".

This seminar is designed for companies that want to implement projects using radio frequency technology.

4.2.6. GS1 GDSN

Master data quality is crucial for a company's success. It not only has a significant influence on the efficiency of an organisation, but also has a decisive influence on product and service quality.

This seminar is aimed at all companies that want to increase their master data quality and exchange their master data electronically.

4.2.7. In-house training courses

GS1 Switzerland also offers in-house seminars that are specifically tailored to businesses and their needs. We are happy to discuss your processes and explain, how the GS1 System can support and optimise these processes.

4.3. Barcode verification

The readability of a barcode symbol depends on various factors, such as size, print quality, colour selection, or the material on which the barcode is printed. For your customers, it is extremely important that barcodes are easily readable. This applies to both bar code symbols on sale units, and to single-unit, commercial and transport units.

To ensure that the barcodes have a high first read rate, GS1 Switzerland offers its members a free barcode verification service. GS1 Switzerland possesses professional verification equipment, allowing the quality of a barcode to be verified against the GS1 and ISO standards.

Send a final draft version of your packaging or your logistics label by mail to

- GS1 Switzerland
"Bar code test"
Länggassstrasse 21
3012 Bern

and you will receive an e-mail with information on the quality of your bar codes within a few working days.

4.4. Professional Services

GS1 Switzerland has professional consultants, who support complex projects in the design phase. Our expert consultants can help those interested with any issues arising from the use of the GS1 System.

4.5. GS1 working groups

4.5.1. Healthcare advisory body

- The role of the advisory body is to advise the business units of GS1 Switzerland on strategic issues and – in line with the needs of the healthcare sector – to provide a guidance on the strategic development of GS1 Switzerland services.
- All existing and future measures are primarily designed to promote patient safety.
- Paving the way for solid product, location and partner identification in the healthcare sector.
- Anticipating and accompanying members with mass serialisation to combat piracy.
- Introducing the principles of traceability with the international GS1 standards.
- Influencing the proposed e-health projects, so that the already partially introduced GS1 System is used optimally.
- In the development of the above listed topics, all market partners and authorities concerned should be granted equal consideration.

4.5.2. Working group “procurement in the healthcare sector”

Experts come together in the GS1 Switzerland work groups to solve challenges in a given area and to exchange experiences. The results are made available to GS1 members in the form of publications, market analyses and studies and best practice cases.

The work group deals with all technical requirements in order to implement standardised procurement processes in the healthcare sector. Thus, project and investment safety is increased for all partners in the supply chain. Through leverage effects, process costs are permanently reduced in the medium to long term.

The work group has in particular the task of creating publicly available recommendations (guidelines) and of updating them constantly in line with market changes.

In particular, the expert group focuses on the following work packages:

- Labelling guidelines to secure efficient goods receipt, storage and distribution,
- Description of the procurement processes (partners, data, communication),
- Promotion of efficient master data alignment,

- Implementation of recommendations for electronic data exchange.

The work of the work group is based on the existing GS1 standards according to the GS1 General Specifications, EDI guidelines and recommendations of GS1 Healthcare.

4.5.3. National and international committees

Within the GS1 world there are various committees and working groups that deal with various topics. GS1 Switzerland is the contact point for participation in international working groups.

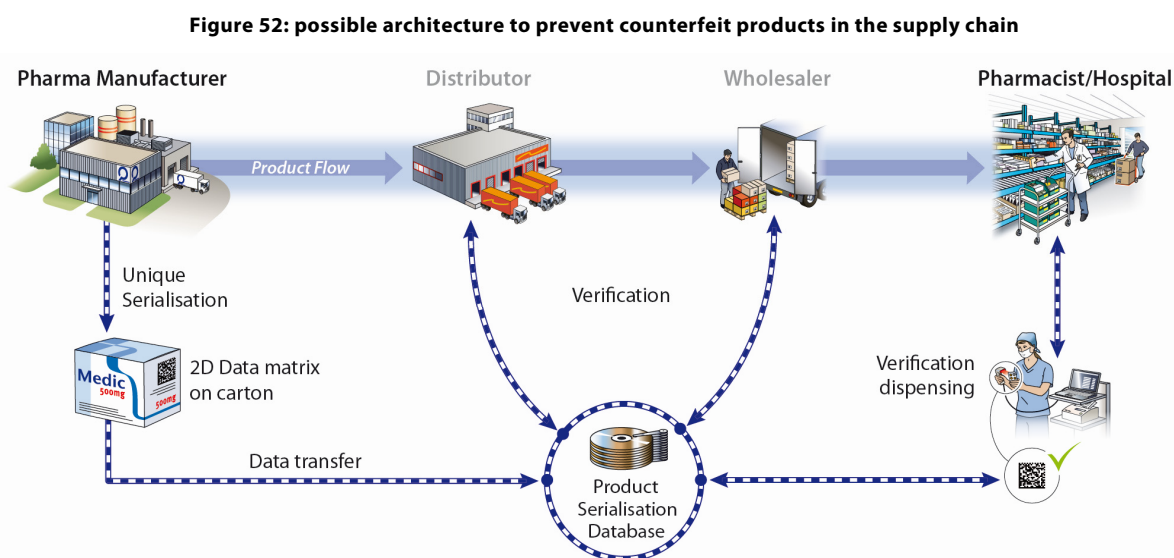
4.6. Measures against product counterfeiting

4.6.1. EU decisions

The EU has published a first binding Directive⁹³, one of the aims of which is to implement traceability at the level of individual drug packaging to allow the early detection of counterfeit products in the supply chain. In the future, in accordance with suggestions from the industry, each box of drugs will carry a product identification number (GTIN) and a serial number.

In December 2011, the European Commission launched a public consultation on detailed implementation measures. Over the next 12 months, these concrete measures are to be published and come into force.

The architecture of the new solution could take the form of the European Stakeholder Model (ESM⁹⁴) as shown in the figure below, so that the serial number of the product can be verified before dispensation/ before sale. Thus, the authenticity can be verified.



⁹³ Directive 2011/62/EU.

⁹⁴ European Stakeholder Model (ESM): <http://www.esm-system.eu/> (30.7.2013).

5. Annex

5.1. GS1 System – excerpt from the GS1 General Specifications

It is vital that all partners involved use the same relevant terms and interpret them in the same way. Therefore this chapter is an excerpt from the GS1 General Specifications⁹⁵ and points out some technical intricacies of the GS1 System.

5.1.1. Global Trade Item Number GTIN

5.1.1.1. Structure of a GTIN

A GTIN can have four different sizes: GTIN-8⁹⁶, GTIN-12⁹⁶, GTIN-13 and GTIN-14.

GTIN-13

Figure 53: structure of a GTIN-13

GS1 Company Prefix (GCP) ->						<- Article reference						Check digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃

Since the GS1 Company Prefix can vary in length depending on country and type of membership with the respective GS1 Member Organisation. The article reference then naturally has a different length. A GTIN must never be broken down by the scanner, but has to be read as a whole.

GTIN-14

Figure 54: structure of a GTIN-14

Indicator	GS1 Company Prefix (GCP) ->						<- Article reference						Check digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄

The structure of a GTIN-14 is basically the same as the structure of a GTIN-13. The first digit of the GTIN-14 is an "indicator" digit. This indicator can be a number from 1 to 9.

The indicators 1 through 8 are used to identify packaging hierarchy levels. However, here again, only the manufacturer knows the meaning of the indicator. The recipient must use the number as a whole and must not read any logic into it.

The indicator 9 is reserved for variable units. This is used above all for fruits, vegetables and meat and is rarely seen in the healthcare sector.

Note: the indicator 0 means that it is a GTIN-13 and not a GTIN-14.

5.1.1.2. GS1 BarCodes for GTIN

A GTIN is used to identify a product. The barcode to be used depends on the context in which the barcode is to be scanned. Primary and secondary packaging are usually labeled with a GS1 DataMatrix. The same is true




⁹⁵ GS1 General Specifications (GS1 Global Office, 2013)

⁹⁶ 8-digit and 12-digit GTINs are practically never seen in the European healthcare sector. That is why no detailed description is given.

for products where the coding is applied with Direct Part Marking. Higher packaging levels that are usually scanned in a logistics environment should be labeled with a GS1-128 barcode.

Packaging levels at which no additional information needs to be encoded can be provided with an EAN-13 symbol.

Figure 55: barcoding of a GTIN

GS1 BarCode	Area of application
GS1 DataMatrix  (01)07680123456781 (17)101231 (10)abc123 (21)3a46	<ul style="list-style-type: none"> Direct Part Marking on medical devices Primary and secondary packaging in the healthcare sector
GS1-128  (01)07680123456781(17)101231(10)abc123(21)3a46	<ul style="list-style-type: none"> Multi-Pack Carton (Higher packaging levels)
EAN-13  7 680123 456781	<ul style="list-style-type: none"> Compulsory for all products that are scanned at the retail point of sale Primary and secondary packaging that are scanned at the point of sale

Both GS1 DataMatrix and GS1-128 use the Application Identifier Standard⁹⁷ for the encoding of data.

5.1.1.3. [GTIN Allocation Rules](#)

The allocation of the GTIN for products and the rules governing, when a product is allocated a new GTIN, is described in section 2.5.3 Unambiguous identification of products (GTIN). With the GTIN Allocation Rules for Healthcare⁹⁸, GS1 provides a guide which covers this subject in detail.

5.1.2. **Global Location Number GLN**

A GLN can refer to a physical location (warehouse ramp, ward cabinet), a legal entity (hospital) or to an electronic mailbox (EDI server). In addition, there are other applications: identification of a consignee, invoice recipient or final recipient of goods. In all cases, the structure remains the same.

5.1.2.1. [The structure of a GLN](#)

Figure 56: Structure of a GLN

GS1 Company Prefix (GCP) ->						<- Location reference						Check digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃

Here again, the 13-digit number should not be interpreted and must be processed as a whole.

⁹⁷ Application Identifier Standard: <http://www.gs1.ch/gs1-system/das-gs1-system/barcodes-identification#Section7> (21.8.2013)

⁹⁸ GTIN Allocation Rules for Healthcare: <http://www.gs1.org/1/gtinrules/index.php?p=static/t=healthcare> (23.3.2012).

5.1.2.2. [GS1 BarCode for the GLN](#)

For the barcoding of a GLN, the GS1-128 has to be used. Depending on the type of identification, another Application Identifier⁹⁹ is used. AI (414) is used to identify a physical location.

Figure 57: barcoding of a GLN

GS1 BarCode	Area of application
<p>GS1-128</p>  <p>(414)7612345679914</p>	<ul style="list-style-type: none"> Global Location Number for the identification of a physical location AI(414)

5.1.2.3. [GLN Allocation Rules](#)

The rules governing the allocation of the GLN are described in section 2.5.4 *Unambiguous identification of trading partners (GLN)*. With the GLN in Healthcare Implementation Guide¹⁰⁰, GS1 provides a guide that covers this topic in detail.

5.1.3. **Serial Shipping Container Code SSCC**

A SSCC¹⁰¹ unambiguously identifies a transport unit. It is therefore a serial number.

5.1.3.1. [Structure of a SSCC](#)

Figure 58: Structure of a SSCC

extension digit	GS1 company prefix (GCP) ->									<- serial reference number							Check digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈

Originally, the extension digit had a meaning similar to the indicator in the GTIN. The number "3" was therefore commonly used. Today the extension digit can be any number from 0 to 9. The extension digit is used to increase the number capacity, if the serial reference number is not sufficient.

The extension digit is sometimes used to identify the production location where the transport unit was put together. However, here also applies: the recipient must use the 18-digit number as a whole and must not interpret parts of it.

5.1.3.2. [GS1 BarCode for the SSCC](#)

Only the GS1-128 is allowed for barcoding the SSCC.

Figure 59: barcoding of a SSCC

GS1 BarCode	Area of application
<p>GS1-128</p>  <p>(00)376123456700000011</p>	<ul style="list-style-type: none"> Transport units AI(00)

⁹⁹ Application Identifier Standard: <http://www.gs1.ch/gs1-system/das-gs1-system/barcodes-identification#Section7> (21.8.2013)

¹⁰⁰ GLN in Healthcare Implementation Guide (GS1 Global Office, 2010)

¹⁰¹ In German-speaking countries, the old concept of NVE or Number of the Shipping Unit is still in widespread use.

5.1.4. Global Service Relation Number GSRN

The GSRN is used to identify either the subject of care (e.g. patient) or care provider (e.g. doctor) in the context of a service relation. Two GSRNs are available in order to provide an identification for both roles in a service relation (subject of care and the care provider).




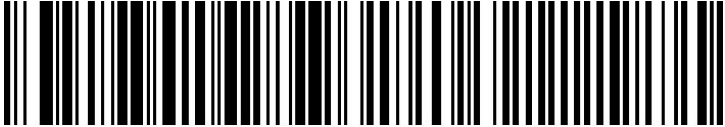
5.1.4.1. Structure of a GSRN

Figure 60: structure of a GSRN

GS1 Company Prefix (GCP) ->														<- Service reference				Check digit
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈	

5.1.4.2. GS1 BarCode for the GSRN

Figure 61: barcoding of a GSRN

GS1 BarCode	Area of application
<p>GS1 DataMatrix</p>  <p>(8017)761234567000000010</p>  <p>(8018)761234567000000027</p>	<ul style="list-style-type: none"> Global Service Relation Number (Provider: AI(8017)) Global Service Relation Number (Recipient: AI(8018))
<p>GS1-128</p>  <p>(8017)761234567000000010</p>  <p>(8018)761234567000000027</p>	<ul style="list-style-type: none"> Global Service Relation Number (Provider: AI(8017)) Global Service Relation Number (Recipient: AI(8018))

Both the GS1 DataMatrix, and the GS1-128 use the Application Identifier Standard¹⁰² for data coding.

5.1.5. Encoding GTIN and additional information in a GS1 BarCode

How is the information (GTIN and any additional information) encoded in the corresponding GS1 BarCodes? For this, the GS1 Application Identifier Standard¹⁰² must be used.

5.1.5.1. EAN-13

The EAN-13 can only contain a 13-digit GTIN. By scanning an EAN-13 the system knows that a product ("1" unit) was scanned. A GLN cannot be encoded in the EAN-13.

¹⁰² Application Identifier Standard: <http://www.gs1.ch/gs1-system/das-gs1-system/barcodes-identification#Section7> (21.8.2013)

5.1.5.2. [GS1 DataMatrix and GS1-128](#)

GS1 DataMatrix and the GS1-128 can also include much additional information alongside the GTIN. All information must be encoded using the GS1 Application Identifier Standard. The GS1 Application Identifier Standard contains a series of codes (Application Identifiers AI), which tells the scanner or middleware the meaning and structure of the following information. In the healthcare sector, the following AIs occur:

(01) = Contains the identification of a trade item. The field is exactly 14 digits. This means that a GTIN-13 with an extension digit "0" or a GTIN-14 has to be used.

(17) = Contains the expiry date in the format YYMMDD. The field is exactly 6 digits.

(10) = Contains the batch number, which may be alpha-numeric, and 1 to 20 characters long.

(21) = Contains a serial number, which may be alpha-numeric, and 1 to 20 characters long.

A complete list of GS1 Application Identifiers (- > figures in brackets) can be found in the GS1 General Specifications.

Please note: While the brackets are displayed in the human readable text line below the bar code, they are not encoded in the barcode.

5.1.6. **Please note: clarification of technical terms**

In communications with the trading partner, every possible effort must be made to use the right terms. For example, the "EAN-Code" is often mentioned but in fact, this is not a reference to the barcode type EAN-13 but to the GTIN represented in the EAN-13.

Figure 62: overview of the technical terms – barcode types vs. identification Keys

GS1 BarCode type	GS1 Identification Keys
EAN-13	GTIN-13
GS1 DataMatrix	GTIN-12, GTIN-13, GTIN-14, GSRN and any additional information
GS1-128	GTIN-12, GTIN-13, GTIN-14, GLN, SSCC, GSRN, GLN and any additional information

The barcode types are therefore only the data carriers in which the GS1 identification keys can be represented.

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6.3. Glossary

Abbreviation	Description
Advanced Remittance Notification ¹⁰⁴	GS1 XML message used for the payment notification.
AIDC	Automatic Identification and Data Capture
Application Identifier Standard	GS1 Standard with which information among others must be encoded in these barcode types: GS1-128, GS1 DataMatrix, GS1 DataBar
Consumption Report ¹⁰⁴	GS1 XML message with which the consumption is reported.
Cross-Docking	Goods are picked and delivered in line with the end recipient. There are several levels of cross-docking.
Debit Credit Advice ¹⁰⁴	GS1 XML message with which the debit and credit advices are transmitted.
Despatch Advice ¹⁰⁴	GS1 XML message that is used for the Despatch Advice.
DRG	Diagnosis Related Groups
EAN-13	Barcode type that is mainly scanned at the point of sale in retail stores.
EDI	Electronic Data Interchange
GCP	GS1 Company Prefix A number with which all other GS1 identification keys can be created.
GDSN	Global Data Synchronisation Network A global, certified network of master data pools with defined GS1 GDSN XML messages.
GLN	Global Location Number Identification number for locations or legal entities.
GS1 DataMatrix	A barcode type that is mainly used on small items.
GS1 XML	A set of defined EDI messages in XML format. These messages are suitable both for bilateral master data exchange and for the exchange of transaction data.
GS1-128	Barcode type that is used mainly in logistical environment.
GSMP	Global Standards Management Process
GSRN	Global Service Relationship Number Identifies for example a medical expert or a patient.
GTIN	Global Trade Item Number Identification number for "trade Items".
Inventory Report ¹⁰⁴	GS1 XML message that is used to communicate the warehouse inventory.
Invoice ¹⁰⁴	GS1 XML message that is used to communicate the invoice.
Item Data Notification ¹⁰⁴	GS1 XML message that is used for bilateral master data alignment.
Kanban	A system to manage the distribution of parts with the aim of lower local stocks according to the pull principle. The consumption point reports a need to the delivery points in which it prepares an empty container at a defined transfer location. A parcel dispatch card (Japanese: Kanban) gives the type and amount of the required article.
Consignment	A logistics process: goods are stored with the recipient but are still considered to be the property of the supplier. The payment takes place once the goods are removed from stock.
Order Response ¹⁰⁴	GS1 XML message used for the order response.
Order ¹⁰⁴	GS1 XML message used for the ordering process.
Receiving Advice ¹⁰⁴	GS1 XML message with which the goods reception is confirmed.
SCM	Supply Chain Management
SSCC	Serial Shipping Container Code Serial identification number for transport units.
VMI	Vendor Managed Inventory The seller manages the warehouse with the customer.

¹⁰⁴ A complete process description of all GS1 XML messages, as well as the technical GS1 XML schemas and further helpful information on the introduction of the individual GS1 XML messages are available in the *GS1 XML Implementation-Packages*: GS1 XML Version 3: http://www.gs1.org/gsm/kc/ecom/xml/xml_v_3 (23.3.2012).

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Competence platform: building networks – sharing experiences



Transfer of competence: transferring knowledge – heightening competence



Collaboration: promoting cooperation – improving value creation



Standards: applying standards – increasing efficiency



Sustainability: thinking holistically – preserving resources