
Position paper on the identification of the primary package level of drugs

This position paper provides good practice recommendations that enable enhanced medication administration processes in care settings such as in hospitals, nursing homes, or at patient's home for chronic diseases. It is adopted by stakeholder organisations that recognise how important it is to support efforts for enhanced safety in the medication process by sharing a joint vision to make this a reality.

Positioning the problem

Medication errors are recognised as an important failure point in care processes. Studies have been conducted to measure such errors and their impact on patients, as well as to measure the benefits of processes that are supported by electronic means (e.g. prescription, dispensation, administration). It is recognised that medication administration at the point of care is significantly more accurate if it is supported by scanning a medicinal product's barcode, matching this with the patient's identification, the physician's computerised order entry and other process factors such as time and route of administration. Identification of primary packages such as vials, pre-filled syringes or solid forms in blister cavity is an important prerequisite for successful point of care verification and registration in electronic health records.

Several stakeholders¹ or regulators² already require manufacturers to identify primary packages with barcodes. Hospital implementation can be observed in various places³, but their number is limited since a critical mass of source barcoded primary packages has not been reached in many regions.

As healthcare providers see this critical importance, many hospitals today are re-labelling all medications to enable scanning at the point of care. This is a time and cost intensive process that ideally should not take place at the hospital, but at the source of manufacturing, where the right equipment, control and expertise exist.

Purpose of this position paper

By supporting this position paper, the supporting organisations noted wish to stress the importance of enabling safer processes at the point of care. This can be done with appropriate identification of primary packages, thus avoiding errors due to "sound-alike" or "look-alike" medicinal product packages.

¹ E.g. Amgros, in Denmark

² E.g. US FDA

³ E.g. Belgium, Netherlands, Portugal, Brazil, USA, Spain, Switzerland, Argentina, Singapore

The organisations associated with this position paper recognise the importance of focusing on the same vision, identification and labelling of primary packages in such a way that scanning at the point of care is enabled. This labelling effort should be undertaken without delay when existing packages provide sufficient space; if packaging modifications would be necessary, labelling with barcodes should be considered each time packaging redesign is required.

Each organisation additionally recognises that healthcare providers should strongly consider investment in IT system development that supports prescription-dispensation-administration processes. This investment will enable efficient process deployment progressively when labelled primary packaging becomes increasingly available.

Primary packaging: some examples

The following illustrations provide examples of common primary packaging forms for medicinal products. Each is identified with its own GTIN, and optionally with variable information such as lot/batch and expiry date.



Single vials, or combinations of vials and their diluent, identified each with its own GTIN



Ampoules, identified with their GTIN, if provided label size and mandatory texts allows.



Pouches, with medicinal product



Medicinal product in solid form, each blister cavity having the same GTIN, identifying the solid form included in that cavity



Prefilled syringe: combined product – medical device including medicinal product.

What does product identification look like?

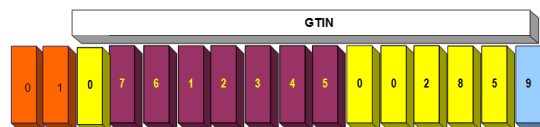
The most appropriate barcode symbology to carry information on primary packages where available space is generally limited, is a “two dimensional” or “matrix” data carrier. In the implementation examples below, the GS1 DataMatrix is shown as this barcode is the only permitted GS1 2D matrix data carrier for the healthcare sector. The symbol example and human readable interpretation have been enlarged to facilitate readability in this document; the GS1 General Specifications provide guidance on the recommended sizes for the symbols. The colours used reflect the following characteristics:

- The **orange** digits (e.g. 01, 17...) correspond to “application identifiers”, which define the semantics or format of the data element that follows. They are shown with parenthesis in the human readable interpretation; these parentheses are not encoded within the barcode.
- The **prune** coloured digits correspond to a “Global Company Prefix” (GCP) allocated by one GS1 Member Organisation to a specific user. Note: GCP might have different lengths, whilst the GTIN has a fix length of 14 numerical characters.
- The **yellow** data field are to be used by the responsible organisation (e.g. manufacturer), according GS1 General Specifications.
- The **blue** last character is a check digit, which is calculated according GS1 General Specifications.

- a) Product identification only, when technical or space constraints do not allow the inclusion of additional information in the barcode (GTIN only encoded in the barcode).



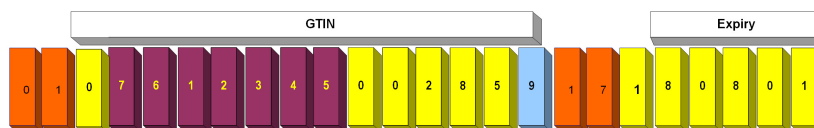
(01)07612345002859



- b) Product information with additional information in the barcode (expiry date only)



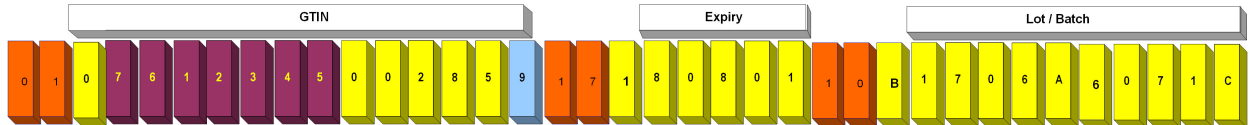
(01)07612345002859
(17)180801



- c) Product information with additional information in the barcode (expiry date and lot/batch)



(01)07612345002859
 (17)180801
 (10)B1706A6071C



- d) Human readable information
 The human readable interpretation shown follows the GS1 General Specifications and regulatory requirements; it serves as an example, since other formats are as well recommended:

GTIN(01) 07612345002859
 Expiry Aug. 2018
 Batch/Lot B1706A6071C



Characteristics of the data carrier

A "GTIN Only" GS1 DataMatrix... using the following sample data:

GTIN - 09506000117829

...would require a 16 x 16 matrix (18 x 18 including the minimum Quiet Zone). Based upon the present "Minimum X-dimension" noted in the GS1 General Specifications of 0.255mm (0.0100 inch) this would provide a symbol size (with minimum Quiet Zone) of:

4.59mm (0.180 inch) x 4.59mm (0.180 inch)



(01)07612345002859

A "GTIN + Expiry + Batch/Lot" GS1 DataMatrix with an 11 alphanumeric character (maximum) Batch/Lot with at least one alpha character, using the following sample data:

GTIN - 09506000117829

Expiry - 180801

Batch/Lot - B1706A6071C

would require a 20 x 20 matrix (22 x 22 including the minimum Quiet Zone).



Based upon the present “Minimum X-dimension” noted in the GS1 General Specifications of 0.255mm (0.0100 inch) this would provide a symbol size (with minimum Quiet Zone) of:

5.61mm (0.220 inch) x 5.61mm (0.220 inch)



(01)07612345002859
(17)180801
(10)B1706A6071C

Though this represents the smallest sizes based upon the sample data noted and the GS1 General Specifications’ “Minimum X-dimension” for this use case, for improved scanning performance it is always best to print the largest X-dimension and symbol size that can be accommodated within the space available, and also the print quality of the symbol has to meet the minimum quality grade required by the General Specifications.

Priorities and timelines

The organisations supporting this position paper do currently not envisage any formal timelines for implementation of the concepts within this position paper. The priorities that should guide implementation by manufacturers are as follows:

First priority is to support care processes with appropriate human readable information on the packaging, considering in particular readability and solutions to avoid product confusion (e.g. tall man letters).

Second priority is to extend primary package⁴ label information by adding item identification with a GS1 GTIN, as appropriate in a GS1 DataMatrix data carrier (barcode). This stable, static information is the simplest to implement quickly and efficiently through existing artwork change process, and already supports care processes (e.g. avoiding dosage confusion).

Third priority is to provide product identification (GS1 GTIN) *and* variable information (batch/lot, expiry date) on every primary package. This has priority for high-alert medicinal products⁵ (or regulated products such as blood derivative).

Healthcare providers will consider their priorities by taking the above into consideration, and engage similar identification and labelling processes for their internal productions (e.g. compounding).

Call to action

Stakeholders in the Healthcare market are invited to consider this position paper when planning their forward looking strategies and investments. In the future,

⁴ See glossary

⁵ See List of High-Alert Medications of the Institute for Safe Medication Practices (ISMP):
<http://www.ismp.org/Tools/highalertmedications.pdf>

market (e.g. hospital) requirements will become even stronger, so high expectations exist that demands and offers will come together on this topic, as patient safety in the medication administration process is recognised a high priority.

Definitions

Term	Definition	Source
Application Identifier (AI)	GS1 AIs identify generic and simple data fields for use in cross-sectorial and international supply chain applications. The GS1 General Specifications provide rules for the definition, format and structure of the data fields.	ISO 15418, § 4.1
GTIN	A Global Trade Item Number (GTIN) is used to identify any item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in any supply chain.	GS1 General Specification, v16 § 4.3.1.1
Medicinal Product	Any substance or combination of substances that may be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions	EN ISO 11615, § 3.1.49
Multiple dose blister	Package which fully encloses the drug. Each dosage form is individually packaged. The individually blistered identical dosage forms are attached to each other to one strip. The labelling is imprinted on the complete strip but not on the individual blistered dosage forms	EAHP (in scope)
Primary package	See "single unit package"	
Secondary package	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.	GS1 General Specification, v16 (out of scope)
Single unit package / blister	A healthcare primary package that contains one discrete pharmaceutical dosage form, i.e. a tablet, a certain volume of a liquid or that is the immediate package for a medical device like a syringe. A number of single units may be attached to each other, but are easy to separate through a perforation. Synonyms: immediate container ; immediate packaging : immediate packaging in which a manufactured item or pharmaceutical product is contained and with which it is in direct contact (EN ISO 11615, § 3.1.23)	GS1 General Specification, v16 (in scope)

References

GS1 Healthcare GTIN Allocation Rules:

http://www.gs1.org/sites/default/files/docs/gsmc/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Endorsed by:

