Implementation Guidelines for Coding & Labelling Pharmaceuticals and Drugs Using Global Supply Chain Standards to Meet Directorate General of Foreign Trade's (DGFT) Authentication, Track and Trace Requirements

For Manufacturers, Brand Owners, Responsible Entities, Exporters and Merchant Exporters

Version 1.3 – August 2015

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Introduction

Introduction

On 10 January 2011, Directorate General of Foreign Trade (DGFT), issued a public notice announcing the implementation of a track and trace system incorporating barcode technology as per GS1 standards for all drugs and pharmaceutical products exported from India. Under this notice, all export pharmaceutical consignments should be marked and coded at various packaging levels using GS1 barcode standards.

DGFT issued this mandate as a step towards implementing a traceability system to address counterfeit and ineffective product recall challenges, which effects the entire healthcare supply chain, from manufacturers all the way to patients, wholesalers, distributors, exporters and healthcare providers. Adopting globally harmonised standards for product identification and data exchange, is a critical step in addressing these issues.

The traceability solution implemented by the DGFT requires the use of product serialisation at the secondary level packaging. Serialisation enables to build a comprehensive system to track and trace the movement of drugs through the entire supply chain. By identifying every product with a globally unique product number (Global Trade Item Number [GTIN]), and by capturing information on its expiry date, batch/lot number, and unique serial number (where applicable) allows the product's lifecycle to be tracked from production to distribution across borders, all the way to its dispensation to patients at the drugstore or hospital.

In addition to the coding and marking guidelines of products outlined in the specifications, Manufacturers/Brand Owners/Responsible Entities/Exporters/Merchant Exporters will submit additional information to a central track and trace portal. Manufactures need to maintain records of serial numbers assigned to drugs and pharmaceuticals exported for a minimum period of six months after their expiry date.

NOTE: For those drugs and pharmaceuticals manufactured for export purposes, where the government of the importing country has mandated a specific requirement and the exporter intends to avail the option of printing barcodes in their format, will need to seek permission from the appointed authority.

However, the tertiary level of packaging will have printed barcodes as per DGFT requirements in addition to the importing country's requirement, if any.

IMPLEMENTATION GUIDELINES USING GLOBAL SUPPLY CHAIN STANDARDS FOR BARCODING TO MEET DGFT REQUIREMENTS FOR AUTHENTICATION, TRACK AND TRACE REQUIREMENTS

DOCUMENT INFORMATION

This implementation guideline has been prepared to assist Manufactures/Brand Owners/Responsible Entities/Exporters/Merchant Exporters in India to implement against the requirements specified by the DGFT, using GS1 standards. These guidelines are only for the coding and marking requirements, is developed based on information provided by the concerned regulatory authorities.

PURPOSE

The purpose of this document is to provide recommendations to the industry on how to use GS1 standards in order to implement the requirements specified. Industry must always refer to the final DGFT notice first for all details on the requirements.

AUDIENCE

These guidelines are primarily for Manufacturers/Brand Owners/Responsible Entities/Exporters/Merchant Exporters but is relevant to solution providers, label printers and others who play a role in the drug or pharmaceutical supply chain.

ENTITY DESCRIPTIONS

Manufacturer: An entity that makes or produces drugs or pharmaceuticals through a process involving raw materials, components, or assemblies, usually on a large scale.

Brand Owner: An entity that owns the 'brand' and marketing rights of a product but not necessarily the actual production of the product. The brand owner outsources the actual production of their product to a third party or manufacturer.

Exporter: An entity that sells the drugs or pharmaceuticals produced in India to a buyer from another country.

Merchant Exporter: An entity, which holds the license and gets the drugs manufactured from a third party manufacturing location or who sources drugs from wholesalers/distributors and exports it.

Responsible Entity: An entity, which act as an intermediary between two or more parties such as the manufacturer, brand owner or exporter. The Responsible Entity is involved or plays a role in either the buying, selling or production of the drug or pharmaceutical.

Solution Provider: A solution provider is a vendor that provides technical or service support to a company. They offer hardware, software, guidance, resources and tools in a variety of areas to companies. Examples include; barcode services – labels, printing, designing, verifying, barcode hardware – printers, readers, scanners, barcode software, etc.

GS1: GS1® is a neutral, not-for-profit, global organisation that develops and maintains the widely used supply chain standards in the world. Through GS1 Healthcare, a global, voluntary user group, GS1 develops standards to advance global harmonisation. GS1 Healthcare consists of manufacturers, wholesalers, distributors, hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organisations worldwide. GS1 Healthcare drives the development of GS1 standards and solutions to meet the needs of the global healthcare industry and promotes the effective utilisation and implementation of global standards for the industry.

PART 1
CODING AND MARKING GUIDELINE FOR VARIOUS PACKAGING LEVELS

1.0 Overview of DGFT Requirements

The requirements specify the following use of GS1 standards for coding and marking products at various packaging levels:

PACKAGING LEVEL	PACKAGING TYPE	BARCODING REQUIREMENT	HUMAN READABLE FORMAT	TIMELINE
Tertiary level Comprises of the last level of packaging containing secondary and other intermediate packages meant for transport (cartons, pallets, shipments)	Homogenous	GS1-128 barcode symbology encoded with: • GTIN 14 • Expiry date • Batch number **PLUS** A GS1-128 encoding a Serial Shipping Container Code (SSCC). *[Tertiary level homogenous packs will have one label with 2 barcodes printed on it]*	Information printed in human readable format: • GTIN 14 • Expiry date • Batch number • SSCC *Illustration:* Expiry: November 2015 Batch No: TC022U SSCC: 189010720012345676	In effect as of OCT 2011
	Heterogeneous	GS1-128 symbology barcode encoded with a Serial Shipping Container Code (SSCC)	Information printed in human readable format: • SSCC *Illustration:* SSCC: 189010720012345676	
Secondary Level Packaging level containing primary level packages. (**Mono-cartons** will be considered as secondary level packaging). Affixing a barcode on mono-cartons, which contain only one primary pack is optional at this time.		GS1 DataMatrix or a GS1-128 barcode symbology encoded with: • GTIN 14 • Expiry date • Batch number • Unique serial number	Information printed in human readable format: • GTIN 14 • Expiry date • Batch number • Unique serial number *Illustration:* GTIN (01): 1890172002536 Exp (17): Aug 15, 2018 Batch No: RNBXY0514 S. No (21): 15892152002	In effect as of JAN 2013
Primary Level Is the first level of packaging in direct contact with the product e.g. medicine strip, vial, single therapy kit etc. for is meant for sale to consumers.		GS1 DataMatrix encoded with: • GTIN 14 • Expiry date • Batch number • Unique serial number	Information printed in human readable format: • GTIN 14 • Expiry date • Batch number • Unique serial number Illustration: GTIN (01): 0891072002539 Exp (17): Aug 15, 2018 Batch No: RNBXY0514 S. No (21): 1256897542	Printing of the barcode and the information in human readable format at the primary level is optional at this time.

1.1 Overview of GS1 Standards Used

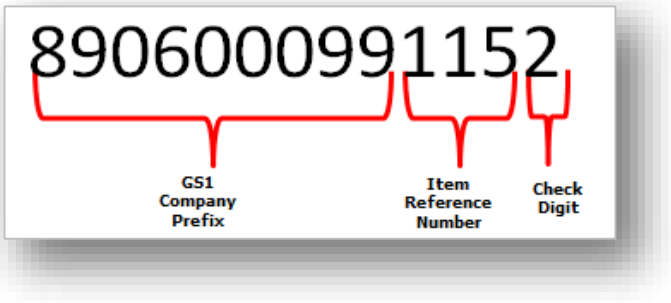
This section provides a brief definition of some of the key GS1 standards used in this guideline.

1.1.1 Global Trade Item Number (GTIN)

The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number used to identify "trade items" (i.e. products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. GTINs are used to uniquely identify trade items (i.e. each product type/variant etc.).

A GTIN is created using:

- GS1 Company Prefix
- Item Reference Number
- Check Digit



A GTIN is a globally unique number:

- A GTIN (which is the number that identifies the product or trade item), is encoded in a barcode symbology, (which is called the data carrier)
- GTIN can be an 8, 12, 13 or 14-digit number

To meet DGFT requirements, GTINs used to identify primary level items should be in a 14-digit format when encoded in the GS1 DataMatrix barcode

1.1.2 Indicator Digit

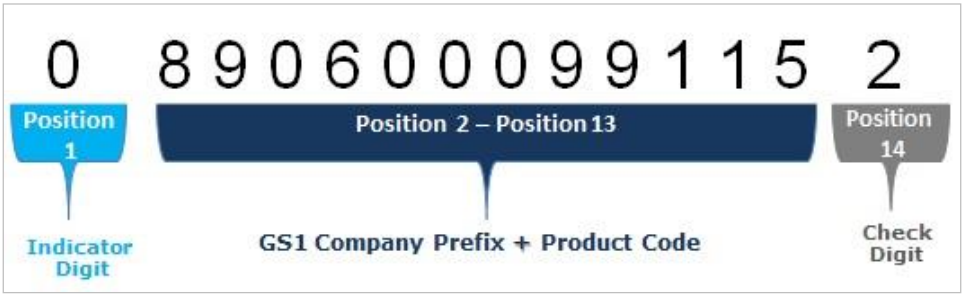
In addition to the three segments (i.e. GS1 Company Prefix, Item Reference and Check Digit) the GTIN-14 consists of a fourth segment called the Indicator Digit.

The **Indicator Digit** is the first digit of a GTIN-14 and is used to identify the packaging level. The field consists of a numeric value. The track and trace portal requires the following indicator digits to be used to identify the various product packaging levels.

Indicator Digit	Packaging Level
Indicator Number 0	Denotes the primary packaging level (strip/vial/bottle, single therapy kits etc.)
Indicator Number 1	Denotes the innermost level of the secondary package
Indicator Number 2	Denotes the second level of the secondary package
Indicator Number 3	Denotes the outermost level of the secondary package
Indicator Number 5	Denotes the tertiary packaging level (*i.e. carton/shipper/pallet)*

1.1.3 Generating GTIN-14

Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-14. The Indicator Digit and the Check Digit comprise the remaining two digits of the GTIN-14.



Segments of a GTIN-14 (based on the hypothetical GTIN "08906000991152")

For additional guidance on how to generate a GTIN-14, please refer:
http://www.gs1.org/barcodes/technical/idkeys/gtin

1.1.4 Application Identifiers

In addition to the static unique product identification code (i.e. GTIN), certain *item-specific dynamic information* needs to be marked on products to enable communication of that information *wherever the barcode is scanned.* The GS1 System provides "Application Identifiers" to support this need. GS1 Application Identifiers (AIs) are a finite set of specialised identifiers encoded within barcodes to indicate the type of data represented in the various barcode data segments. There are approximately 100 AIs, including an AI for each GS1 Identification Number as well as AIs for various types of secondary dynamic information (e.g., expiration date; lot number; batch number). Each data element in a barcode is preceded by its AI. For example, the AI for lot/batch number is 10. Thus, when "10" appears in the encoded numerical string of a barcode, it means a lot/batch number follows in the next segment.

Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in brackets (or parentheses). However, the brackets are not part of the barcode's encoded data). More than one AI can be carried in one barcode.

The five AI's mentioned in these guidelines are:

AI (00)	SSCC
AI (01)	GTIN (the requirement specifies using GTIN-14 or other GTINs in a 14-digit format)
AI (10)	Batch/lot number
AI (17)	Expiration date
AI (21)	Serial number

When encoding data in the GS1 DataMatrix barcode, each data element in the data string is preceded by its AI. The AI defines data type and field size. For example, the AI for GTIN is (01).

Thus, when "01" appears in the encoded numerical string, it means a GTIN follows in the next segment. The AI for expiration date is (17). When "17" appears in the encoded numerical string of a barcode, it means an expiration date follows in the next segment.

When rendered in human-readable form, AIs are usually shown in brackets. However, neither the brackets (nor the spaces) are part of the encoded data.

This example illustrates a GS1 DataMatrix barcode with AI (01) for GTIN and AI (21) for Serial Number

Interpreting the data string in this example

(01)	This indicates that the data following (01) is a GTIN. The brackets are not encoded in the barcode and are only shown as part of the HRI (Human Readable Interpretation)
08901072002539	This number is the GTIN of the drug or pharmaceutical trade item
(21)	This indicates that the data following (21) is the serial number of the drug or pharmaceutical trade item. The brackets are not encoded in the barcode and are only shown as part of the HRI
1256897542	This number denotes the unique serial number of the drug or pharmaceutical trade item. The serial number can be alphanumeric and is variable length and can be a maximum of 20 characters long. The serial number should not be repeated and remain unique for all the packs (i.e. SKU/stock keeping unit)

1.1.5 Serial Shipping Container Code (SSCC)

SSCC or Serial Shipping Container Code is a GS1 standard for creating a number string, which is used to uniquely identify a logistic unit.

The SSCC is 18 digits long and consists of:

- **An Extension Digit**. The Extension digit is used to increase the capacity of the Serial Reference within the SSCC. It is assigned by the company that constructs the SSCC. The Extension digit ranges from 0-9.
- **GS1 Company Prefix** number
- **Serial Reference Number** of the tertiary level (shipper/carton/pallet) packaging. This number is created by the company. The recommended way to allocate the serial number is sequentially, for example ….00000, …00001, …00002.
- **Check Digit**

The format of the SSCC is as follows:

Extension Digit	GS1 Company Prefix	Serial 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}

The SSCC can be encoded in a barcode, ensuring the logistic unit can be accurately and easily identified and tracked as it travels between trading partners anywhere in the world. When SSCC data is exchanged electronically, it enables companies to share information about the status of logistic units in transit.

As the SSCC provides a unique number for the logistic unit, companies can electronically provide detailed information about the unit's contents in advance of the shipment reaching its destination. This helps to significantly speed up the receipt of goods as well as the subsequent invoicing process.

What is a Logistic Unit?

When any combination of trade items are packaged together for transport and/or storage and needs to be managed through the supply chain, is called a Logistical Unit. Logistical Units can either be homogeneous (i.e. several quantities of the same product) or heterogeneous (i.e. a mix or assortment of different products). Logistical Units are identified with Serial Shipping Container Codes (SSCC).

For generation of SSCC, refer:

- http://www.gs1.org/barcodes/technical/idkeys/sscc
- http://www.gs1.org/sites/default/files/docs/transportlogistics/GS1_Logistic_Label_Guideline.pdf

1.2 Primary Level Packaging (optional)

Primary level packaging is defined as the first level of packaging that is in direct contact with the product. This packaging level is marked with an Automatic Identification and Data Capture (AIDC) data carrier (e.g. GS1 DataMatrix) either on the packaging itself or on a label affixed to the packaging. Marking products at this level is optional.

Some examples of primary level packaging. These are not intended to be all-inclusive.

Primary level packages when identified, should be marked with:

- GS1 DataMatrix (a 2D barcode), along with the following encoded information:
  - Unique product identification code (GTIN)
  - Expiry date
  - Batch number
  - Unique serial number

When printing the human readable format along with the barcode, the recommended format is:

GTIN (01): 0891072002539
Exp (17): Aug 15, 2018
Batch No: RNBXY0514
S. No (21): 1256897542

Printing the barcode and the information in human readable format at the primary level is optional at this time.

ADDITIONAL REMARKS

If marking products at the primary level please ensure:

- The indicator digit used to identify the primary product packaging level is "0"
- The serial number should be unique for each pack (stock keeping unit) and can never be repeated. Manufacturers need to assign these unique serial numbers using an algorithm
- The GTIN shall never be reallocated or reused even if the product becomes obsolete
- Fixed length data fields should always precede variable length fields when encoded in the barcode. E.g., the expiry date (a fixed length data field should be encoded before the batch/lot number and serial number data field, as both these data fields are variable length).
- The GS1 Datamatrix is printed with Function 1 Symbol Character (FNC1) in the first position of the data encoded and between batch no and serial number.

For printing GS1 Datamatrix barcodes please refer:
http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf

1.3 Secondary Level Packaging (Effective from Jan 1, 2013)

Secondary level packaging is defined as a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item, marked with an AIDC (Automatic Identification and Data Capture) data carrier (e.g., GS1-128, GS1 DataMatrix) either on the packaging or on a label affixed to the packaging.

NOTE: Mono-Cartons: As per the requirements, mono-cartons should be treated as secondary level packages. However, affixing a barcode on mono-cartons containing a single item such as a strip, blister pack, bottle or vial is optional at this time.

Some examples of primary level packaging. These are not intended to be all inclusive

The requirements outlined for secondary level packaging are:

- Incorporation of either the GS1-128 (which is a 1D linear barcode) or the GS1 DataMatrix which is the 2D matrix barcode on all secondary level packages
- These barcodes need to be encoded with a unique product identification code (i.e. the GTIN), expiry date, batch number and serial number

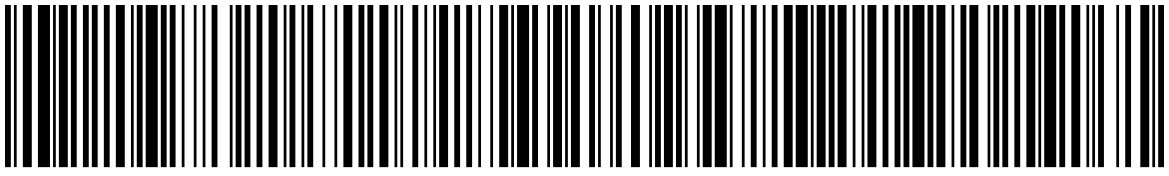
At the secondary level packaging, the barcode should encode the following information using the respective application identifiers:

AI (01)	GTIN of the secondary package using the 14-digit format
AI (17)	Expiration date in YYMMDD format
AI (10)	Batch/lot number
AI (21)	Serial number of the secondary package

GTIN (01): 1890172002536
Exp (17): Aug 15, 2018
Batch No.: (10): RNBXY0514
S.No (21): 15892152002

Illustration of GS1 DataMatrix barcode for a Secondary Pack, with AI (01) for GTIN, AI (17) for Expiration Date, AI (10) for Batch number and AI (21) for Serial Number

Fig 1



(01) 1 8901072 00253 6 (17) 180815 (10) RNBXY0514 (21) 15892152002

Illustration of a GS1-128 barcode for a secondary pack, with AI (01) for GTIN, AI (17) for Expiration Date, AI (10) for Batch number and AI (21) for Serial Number

Fig 2

Interpreting the barcode data strings of Fig 1 & Fig 2

(01)	Indicates that the data following AI (01) is the GTIN. The brackets are not encoded in the barcode and are only mentioned as part of the human readable format
18901072002536	Denotes the GTIN of the Secondary Pack
(17)	Indicates that the data following AI (17) is the expiry date. The brackets are not encoded in the barcode and are only mentioned as part of the human readable format
180815	Denotes the expiry date in YYMMDD format
(10)	Indicates that the data following AI (10) is the batch/lot number of the secondary package. The brackets are not encoded in the barcode and are only mentioned as part of the human readable format
RNBXY0514	Denotes the batch/lot number of the product. The batch number can be alphanumeric and is variable length with a maximum of 20 characters
(21)	This indicates that the data following the AI (21) is the serial number of the secondary package. The brackets are not encoded in the barcode and are only mentioned as part of the human readable format
15892152002	This number denotes the serial number of the secondary pack. The serial number can be alphanumeric and is variable length with a maximum of 20 characters. The serial number should not be repeated and remain unique for all secondary packs.

For printing GS1 Datamatrix, refer:
http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf

ADDITIONAL REMARKS

- The indicator digit to be used to identify the innermost secondary product packaging level is "1". The indicator digit to identify the second level of the secondary package is "2" and the indicator digit to identify the outermost level of the secondary package is "3".
- The GTIN of the secondary level packaging will be different from the GTIN of the primary level packaging
- The GTIN shall never be reallocated or reused even if the product becomes obsolete
- The serial number should be unique for each pack and never be repeated
- It is mandatory to print data encoded in barcodes as human readable information as well
- These coding requirements shall be in addition to any existing statutory labelling & marking requirements
- To improve encoding efficiency fixed length data fields should precede variable length fields when encoded in the AIDC data carrier (i.e. barcode). E.g., the expiry date, which is a fixed length data field should be encoded before the batch/lot number and serial number data field as both these data fields are of variable length.
- The GS1 Datamatrix is printed with Function 1 Symbol Character (FNC1) in the first position of the data encoded. (GS) is used as a field separator when variable length information (e.g., batch number, serial number) is encoded together within the AIDC data carrier (barcode).

GTIN (01): 1890172002536
Exp (17): Aug 15, 2018
Batch No.: (10): RNBXY0514
S.No (21): 15892152002

GS1 DataMatrix

(01) 1 8901072 00253 6 (17) 180815 (10) RNBXY0514 (21) 15892152002

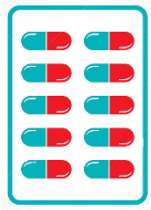
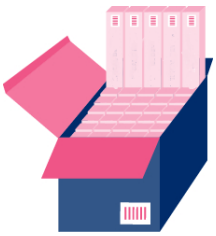
GS1 -128

Start Character	AI	GTIN	AI	Expiry Date	AI	Batch No.	Separator Character	AI	Serial Number
FNC1	01	18901072002536	17	180815	10	RNBXY0514	GS	21	15892152002

When the GS1 DataMatrix and GS1-128 are printed, they should be encoded with the FNC1 in the first position. The (GS) is encoded as a field separator to differentiate between the fixed length data fields and the variable length data fields when these data segments are encoded together within the AIDC data carrier (barcode).

NOTE: If there is more than one level of secondary packaging for a drug or pharmaceutical product, such as an inner pack (bundles) and intermediate packs (inner case), these intermediate packaging levels maybe identified using indicator digits 2 and 3. (Coding and marking secondary level inner packs is optional).

Summary of Indicator Digits to be utilised for all packaging hierarchy levels

Primary level	Secondary Level	Tertiary Level
	**Secondary Level 1** 	
Primary level package should be identified with 0 as the indicator digit	The innermost level of the secondary package should be identified with 1 as the indicator digit	Tertiary level package should be identified with 5 as the indicator digit
	Optional **Secondary Level 2** 	
	The second level of the secondary package (if it exists and if identified) should be marked with 2 as the indicator digit. Marking at this level is optional.	
	Optional **Secondary Level 3** 	
	The outermost level of the secondary package, if identified, should be marked with 3 as the indicator digit. Marking at this level is optional.	

1.4 Tertiary Level Packaging (Effective from Oct 1, 2011)

Tertiary level packaging, for the purpose of this document, is defined as the shipper, carton, or pallet that contains one or more primary/secondary levels of packaging. The tertiary level is also considered as the logistical unit that is shipped in this context.

The requirements for the tertiary level packaging are:

- Use of an SSCC to uniquely identify each tertiary pack (logistical unit) of the drug or pharmaceutical being transported.

- If the tertiary pack is **homogenous** [i.e. it contains only one type of item with the same batch/lot number and expiry date (e.g. only Drug A with batch number RNX0514 and expiry date of Aug 18, 2015) then:
  - Two GS1-128 barcode images should be printed on the label
  - The first GS1-128 barcode should be encoded with the GTIN identifying the product, expiry date, and batch number contained inside the tertiary pack
  - The 2nd GS1-128 barcode should have the SSCC encoded in it

- If the tertiary pack is **heterogeneous** [i.e. it contains one type of item with different batch/lot number or expiry date (e.g. Drug A with batch number RNX0514, and RNY0903, and expiry date of Aug 18, 2015 and Sept 30, 2015) OR the pack contains more than one type of item (e.g. Drug A and Drug B)] then:
  - Only one GS1-128 barcode should be used and encoded with the SSCC to uniquely identify the logistical unit.

1.4.1 Homogeneous Packaging

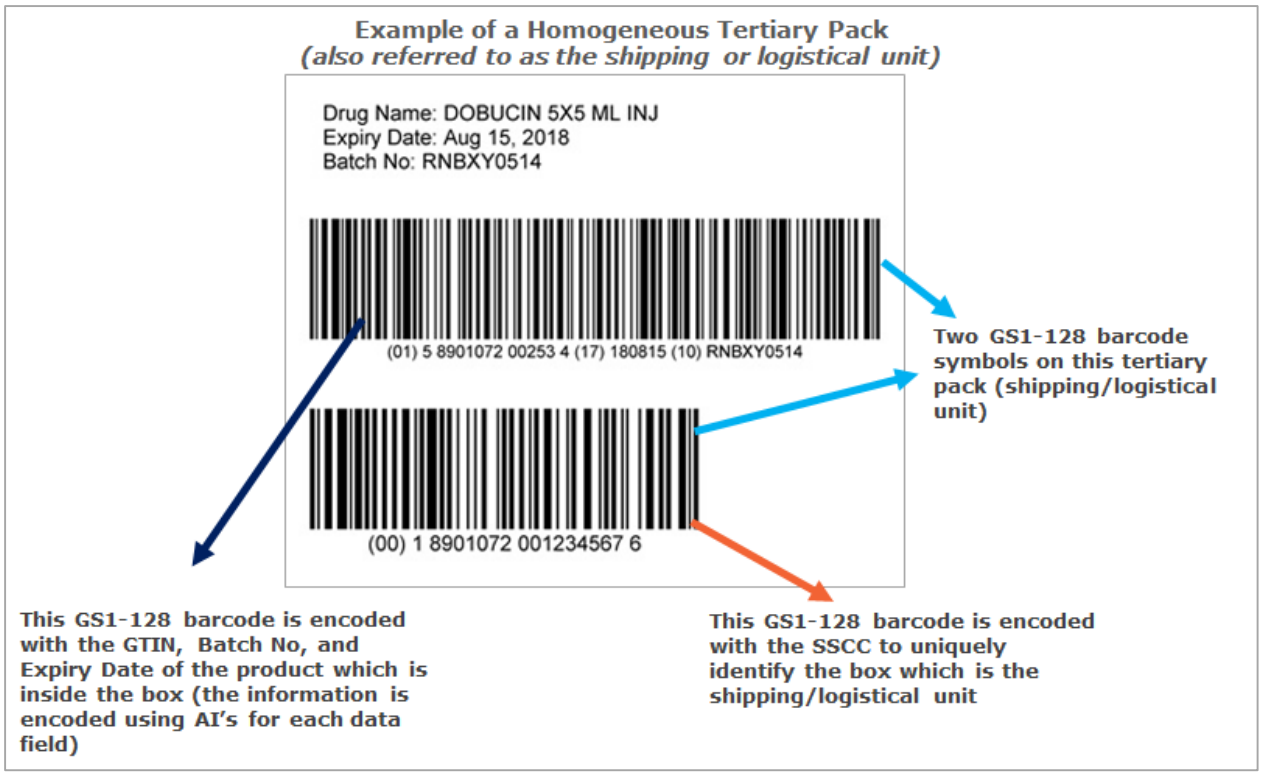
As mentioned previously a homogeneous package consists of only **one type of item**, with the **same batch/lot number and expiry date**. For such homogenous tertiary level items, the package should have **two** GS1-128 barcodes.

The first GS1-128 barcode will encode the following information using the respective application identifiers:

AI (01)	GTIN for identification of the trade item
AI (17)	Expiry date in YYMMDD format
AI (10)	Batch/lot number

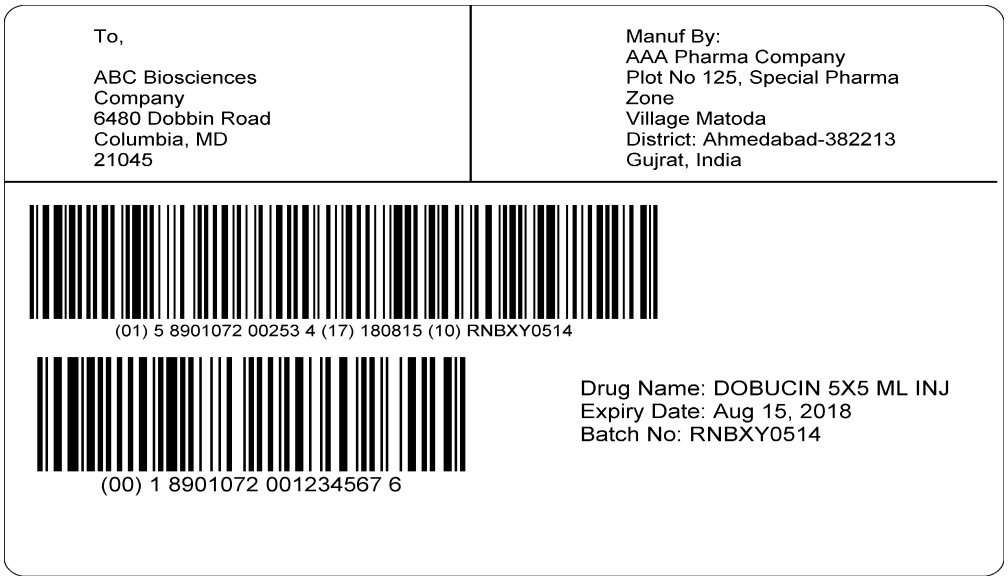
The second GS1-128 barcode will encode:

AI (00)	SSCC (Serial Shipping Container Code) to uniquely identify the individual tertiary level (shipper/carton/pallet) packaging as a logistic unit



Recommended label size is 6x4 inches

Interpreting the barcode data string of the homogenous label below:



The first GS1-128 barcode contains:

(01)	This indicates that the data following AI (01) is the GTIN. The brackets are not encoded in the barcode and only mentioned as part of the human readable format.
58901072002534	Denotes the GTIN for the tertiary pack
(17)	This indicates that the data following AI (17) is the expiry date. The brackets are not encoded in the barcode and only mentioned as part of the human readable format.
180815	The expiry date in YYMMDD format
(10)	This indicates that the data following AI (10) is the batch/lot number of the secondary package. The brackets are not encoded in the barcode and only mentioned as part of the human readable format.
RNBXY0514	Denotes the batch/lot number of the product. The batch number can be alphanumeric and is variable length with maximum of 20 characters.

The second GS1-128 barcode contains:

(00)	Is the application identifier indicating that the data following it is the SSCC of the tertiary level (shipper/carton/pallet) packaging.
189010720012345676	Denotes the 18-digit unique identification number (SSCC) for the tertiary level package.

1.4.2 Heterogeneous Packaging

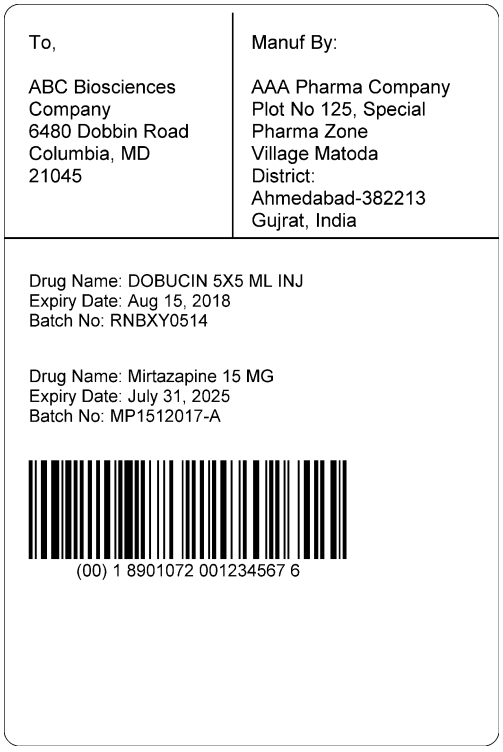
A heterogeneous package, which consists of:

- One type of item but with **different batch/lot number or expiry date**
  - E.g. Drug A with batch number RNX0514 and RNY0903, and expiry date of Aug 18, 2015 and Sept 30, 2015
- **More than one** type of product (e.g., Drug A and Drug B) within the same tertiary/logistical unit.
  - E.g., Drug A and Drug B are packed in the same carton

The requirements specify that for such heterogeneous tertiary level items, the package should have only **one** GS1-128 barcode with the SSCC encoded.

The GS1-128 barcode will encode the following information:

AI (00)	SSCC (Serial Shipping Container Code) to uniquely identify the individual tertiary level (shipper/carton/pallet) packaging as a logistic unit



Interpreting the barcode number string of the heterogeneous label above:

AI (00)	This indicates that the data following AI (00) is the numeric serial number of the tertiary level (shipper/carton/pallet) packaging
189010720012345676	Denotes the 18-digit unique identification number (SSCC) for the tertiary level package.

For additional information on GS1 Logistics Label please refer:
http://www.gs1.org/sites/default/files/docs/transportlogistics/GS1_Logistic_Label_Guideline.pdf

ADDITIONAL REMARKS

- As specified in the requirements the indicator digit to be used to identify the tertiary level product packaging is "5"

Product Packaging Indicator Number	Packaging Level	Example of a Tertiary Level GTIN
Indicator Number 5	Denotes the tertiary (shipper/carton/pallet) packaging level	**5**8901072002534

- GTIN of the tertiary level packaging should be different from the GTIN of primary and secondary package
- The GTIN shall never be reallocated or reused even if the product becomes obsolete
- It is mandatory to print data encoded in barcodes as human readable information
- SSCC number should be unique for each shipper/carton/pallet and never be repeated
- These requirements shall be in addition to existing statutory labelling & marking requirements
- To improve encoding efficiency fixed length data fields should precede variable length fields when encoded in the AIDC data carrier
- Any final labelling or wrapping should also be examined to ensure that the barcodes remain visible and can be easily scanned

PART 2

IMPLEMENTATION PROCEDURES

2.1 Steps to Implementation

The following steps are informative in nature and are intended to help companies with their implementations. You can always contact GS1 India for further assistance.

Manufacturers, Brand Owners, Responsible Entities, Exporters and Merchant Exporters should ensure that their internal process and/or software application used for the allocation of GTINs (e.g., Enterprise Resource Planning or ERP) is configured in accordance with the **Indicator Digits** specifications.

The track and trace portal would use the following Indicator Digits (which is the first digit of a GTIN-14) to identify specific packaging levels. *Using incorrect indicator digits may cause the packaging level to fail authentication when verified.*

Product Packaging Indicator Number	Packaging Level
Indicator Number 0	Denotes the primary packaging level [strip/vial/bottle, single therapy kits etc.]
Indicator Number 1	Denotes the innermost level of the secondary package
Indicator Number 2	Denotes the second level of the secondary package
Indicator Number 3	Denotes the outermost level of the secondary package
Indicator Number 5	Denotes the tertiary packaging level [i.e. shipper/carton/pallet]

2.1.1 Step 1: Engage with a GS1 Member Organisation (MO)

Manufacturer, Brand Owner, Responsible Entities, Exporters, or Merchant Exporters should have a valid GS1 Company Prefix either issued by GS1 India or any other GS1 Member Organisation.

To check whether the company has a valid GS1 Company Prefix, you can contact GS1 India from http://www.gs1india.org/aboutgs1india/contactus or email GS1 India at implementation@gs1india.org.

2.1.2 Step 2: Training and Education

GS1 India conducts regular online webinars and face-to-face educational workshops to assist companies with the implementation and compliance of the DGFT requirement. Companies should nominate their staff members to attend the training before the implementation is initiated. The training schedule is available at http://gs1india.org./service/education-training

2.1.3 Step 3: Allocation of GTINs

Allocate a unique Global Trade Item Number (GTIN) for each trade item (drug or pharmaceutical product), across the three packaging levels (i.e., Primary, Secondary, Tertiary). Refer to the *Coding and Marking Guidelines for Various Packaging* section of this document.

GS1 MOs allocate GS1 Company Prefixes (GCPs) to manufacturers/brand owners etc. and these GS1 Company Prefixes are used by the manufacturers/brand owners to create the GTIN's allocated to their products. These GTINs can be in various formats - GTIN-8's, GTIN-12's, GTIN-13's or GTIN-14's.

To comply with these guidelines, GTIN-8's, GTIN-12's and GTIN-13's need to be converted to a 14-digit format before encoding them into a GS1-128 or GS1 DataMatrix. This can be done by right justifying and using the indicator digits (as filler digits) as specified in the requirements to identify the various packaging levels.

- Indicator digit 0 for primary level
- Indicator digit 1 for innermost level secondary package
- Indicator digit 2 for the second level of the secondary package
- Indicator digit 3 for the outermost level of the secondary package
- Indicator digit 5 for tertiary level

Conversion of GTIN-13 and GTIN-12 into GTIN-14 format at **Primary level**

	1 Indicator Digit	2	3	4	5	6	7	8	9	10	11	12	13	14 Check Digit
GTIN-14	**0**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-13	**0**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-12	**0**	**0**	N	N	N	N	N	N	N	N	N	N	N	CD

The check digit needs to be calculated http://www.gs1india.org.in/calculator.aspx

Conversion of GTIN-13 and GTIN-12 into GTIN-14 format at the **Innermost level of the** Secondary package

	1 Indicator Digit	2	3	4	5	6	7	8	9	10	11	12	13	14 Check Digit
GTIN-14	**1**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-13	**1**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-12	**1**	**0**	N	N	N	N	N	N	N	N	N	N	N	CD

The check digit needs to be calculated http://www.gs1india.org.in/calculator.aspx

Conversion of GTIN-13 and GTIN-12 into GTIN-14 format at the **second level** of the Secondary package

	1 Indicator Digit	2	3	4	5	6	7	8	9	10	11	12	13	14 Check Digit
GTIN-14	**2**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-13	**2**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-12	**2**	**0**	N	N	N	N	N	N	N	N	N	N	N	CD

The check digit needs to be calculated http://www.gs1india.org.in/calculator.aspx

Conversion of GTIN-13 and GTIN-12 into GTIN-14 format at the **outermost level** of the Secondary package

	1 Indicator Digit	2	3	4	5	6	7	8	9	10	11	12	13	14 Check Digit
GTIN-14	**3**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-13	**3**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-12	**3**	**0**	N	N	N	N	N	N	N	N	N	N	N	CD

The check digit needs to be calculated http://www.gs1india.org.in/calculator.aspx

Conversion of GTIN-13, and GTIN-12 into GTIN-14 format for **Tertiary level**

	1 Indicator Digit	2	3	4	5	6	7	8	9	10	11	12	13	14 Check Digit
GTIN-14	**5**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-13	**5**	N	N	N	N	N	N	N	N	N	N	N	N	CD
GTIN-12	**5**	**0**	N	N	N	N	N	N	N	N	N	N	N	CD

The check digit needs to be calculated http://www.gs1india.org.in/calculator.aspx

The table below illustrates how to use Indicator Digits in a packaging hierarchy when encoding the GTIN into a GS1-128 or GS1 DataMatrix. See the GS1 General Specifications for more details.

 If the product / trade item at a Primary Package level has a GTIN-13 of **8901072002539**	…to encode the GTIN-13 into a new GS1-128 or GS1 DataMatrix barcode data carrier on that Primary Package…	 …add the Filler Digit 0 (zero) to the left of the GTIN-13 to form a 14-digit encoded number: **0**8901072002539
 If the product / trade item at a Primary Package level has a GTIN-13 of: **8901072002539**	…to use the GTIN-13 to create a GTIN-14 and encode it into a GS1-128 or GS1 DataMatrix bar code data carrier on the innermost Secondary Package…	…add Indicator Digit 1 (one), to  the left of the GTIN-13 to form a GTIN-14 for encoding: **1**8901072002536
 If the product / trade item at a Primary Package level has a GTIN-13 of: **8901072002539**	…to use the GTIN-13 to create a GTIN-14 and encode it into a GS1-128 or GS1 DataMatrix bar code data carrier on the second level of the Secondary Package…	 …add Indicator Digit 2 (two), to the left of the GTIN-13 to form a GTIN-14 for encoding: **2**8901072002533
 If the product / trade item at a Primary Package level has a GTIN-13 of: **8901072002539**	…to use the GTIN-13 to create a GTIN-14 and encode it into a GS1-128 or GS1 DataMatrix bar code data carrier on the outermost level of the Secondary Package…	 …add Indicator Digit 3 (three), to the left of the GTIN-13 to form a GTIN-14 for encoding: **3**8901072002530
 If the product / trade item at a Primary Package level has a GTIN-13 of: **8901072002539**	…to use the GTIN-13 to create a GTIN-14 and encode into a GS1-128 or GS1 DataMatrix barcode data carrier on a Tertiary Package…	 …add Indicator Digit 5 (five), to the left of the GTIN-13 to form a GTIN-14 for encoding: **5**8901072002534

2.1.4 Step 4: Linking GTIN's in Internal Software Applications

In order to meet the requirements Suppliers/Brand Owners/Responsible Entities/Exporters/Merchant Exportes will have to capture the GTINs and other related attributes like name, description, content etc. in ERP applications or other internal software applications.

- Build a GTIN allocation process for new products to ensure duplication does not occur and that GTINs are never reallocated or reused even if the product becomes obsolete.
- Build an automatic check digit calculator into your system.
  Refer: http://www.gs1india.org.in/calculator.aspx
- Companies should maintain the aggregation of production data from the primary pack to the tertiary pack. Parent-child relationships for the products should be maintained in the database that links the Primary, Secondary, Tertiary GTINs of each product and its variants.
- Merchant exporters, who source from wholesalers/distributors and export, should upload the the SSCC details as per the portal requirements.
- The SSCC number on the tertiary pack should be linked with the Secondary GTIN(s), Serial Numbers and Primary GTINs and Serial Numbers as illustrated below. The data should be uploaded in the specified format to the track & trace portal being setup by the Government.

Illustration of Homogeneous Pack: Parent-Child GTIN Relationship when there is only one secondary level

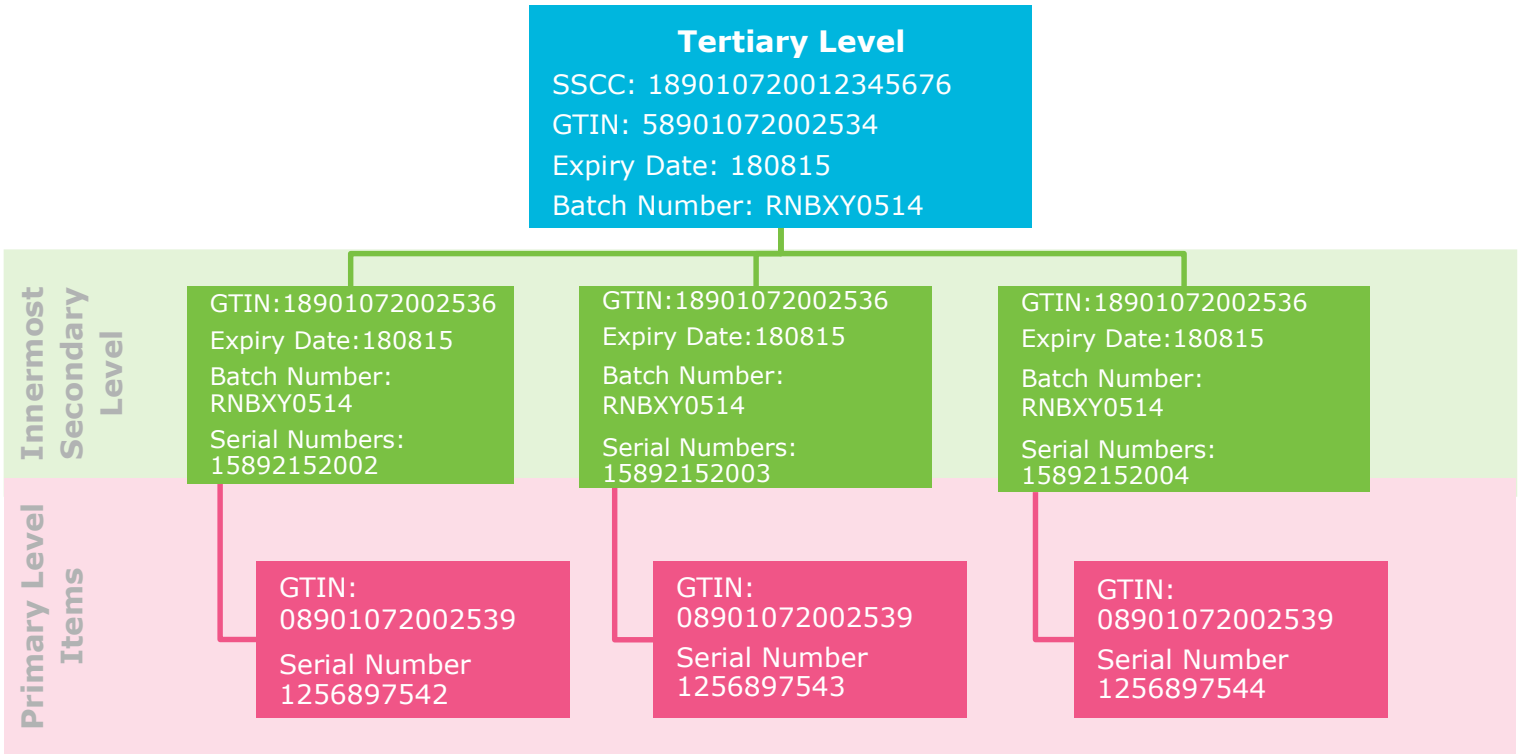


Illustration of Heterogeneous Pack: Parent-Child GTIN Relationship when there is only one Secondary Level

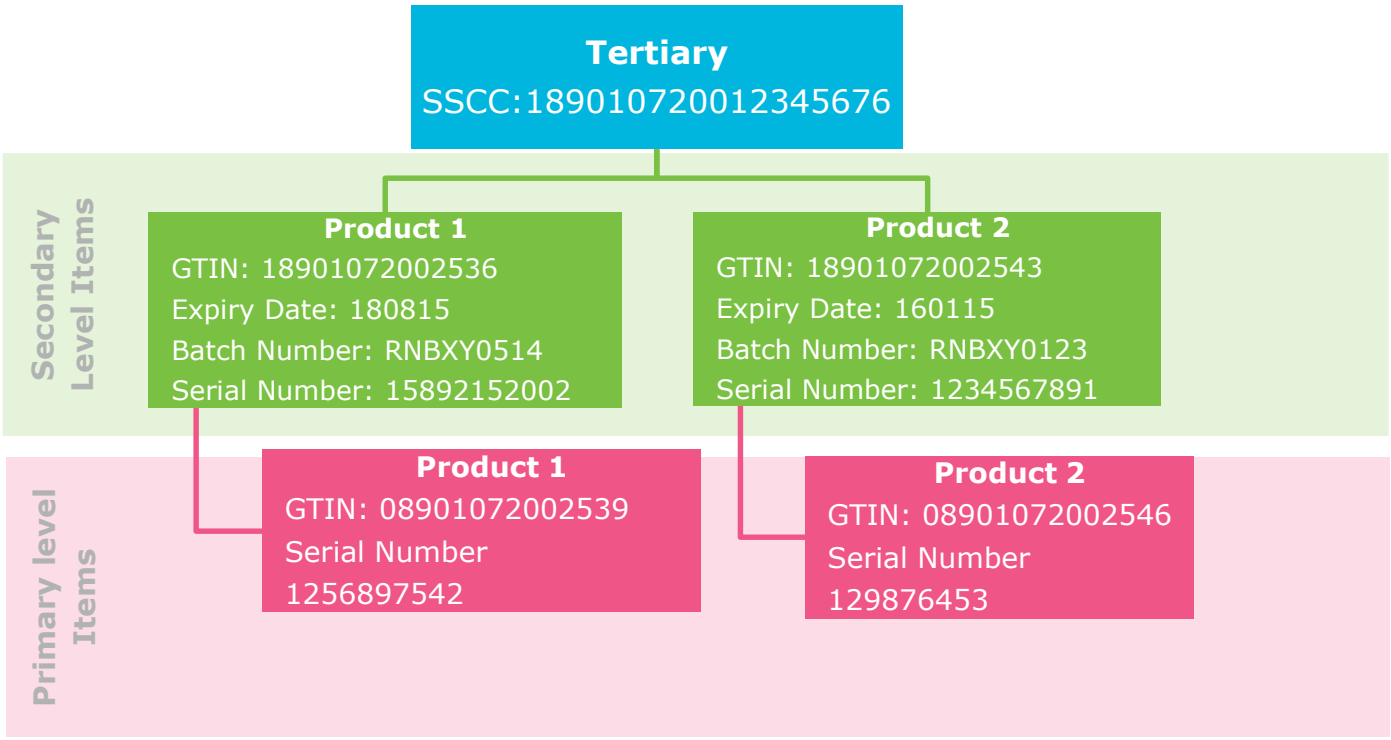


Illustration of Homogeneous Pack: Parent-Child GTIN Relationship when there are multiple secondary levels

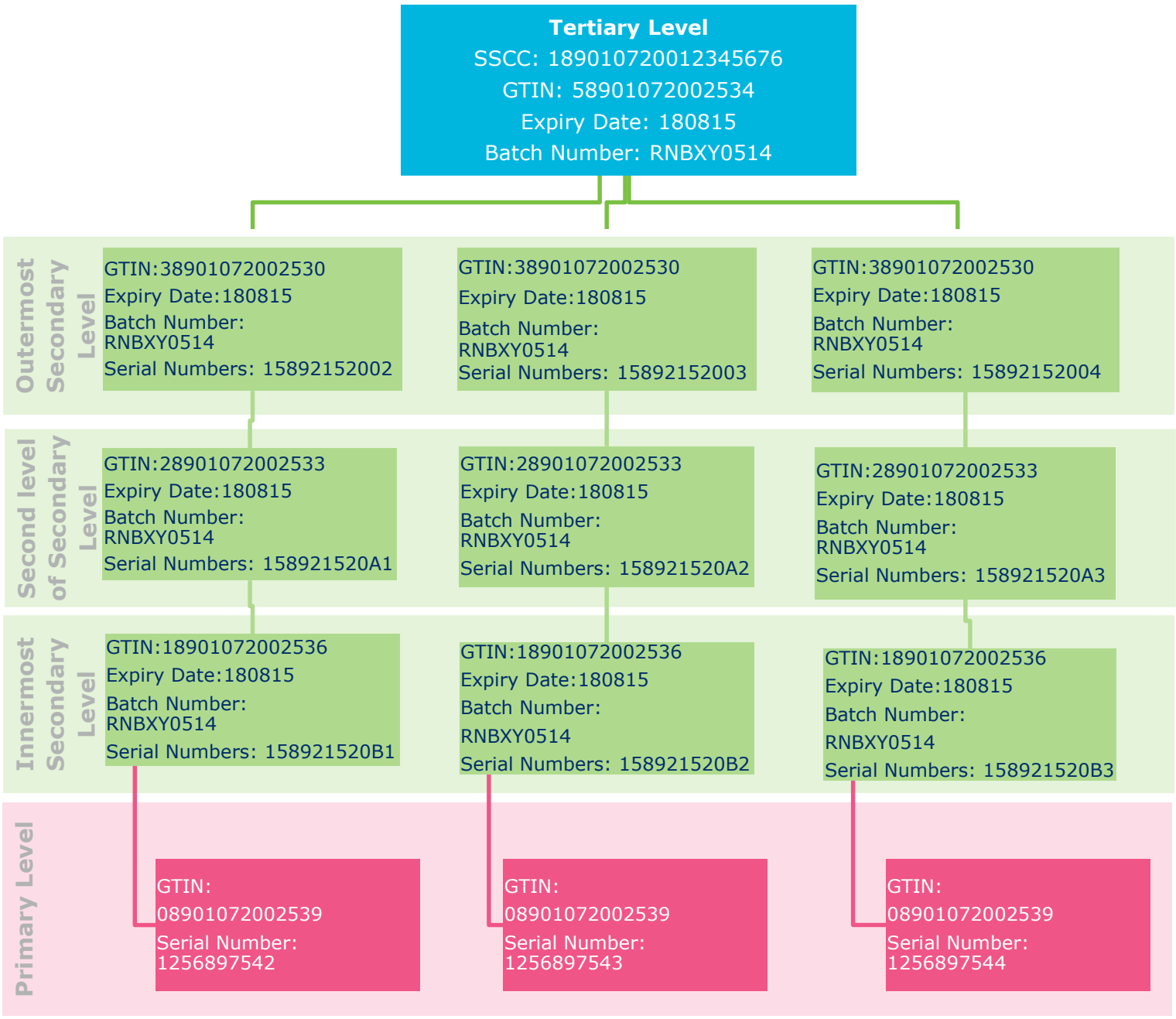
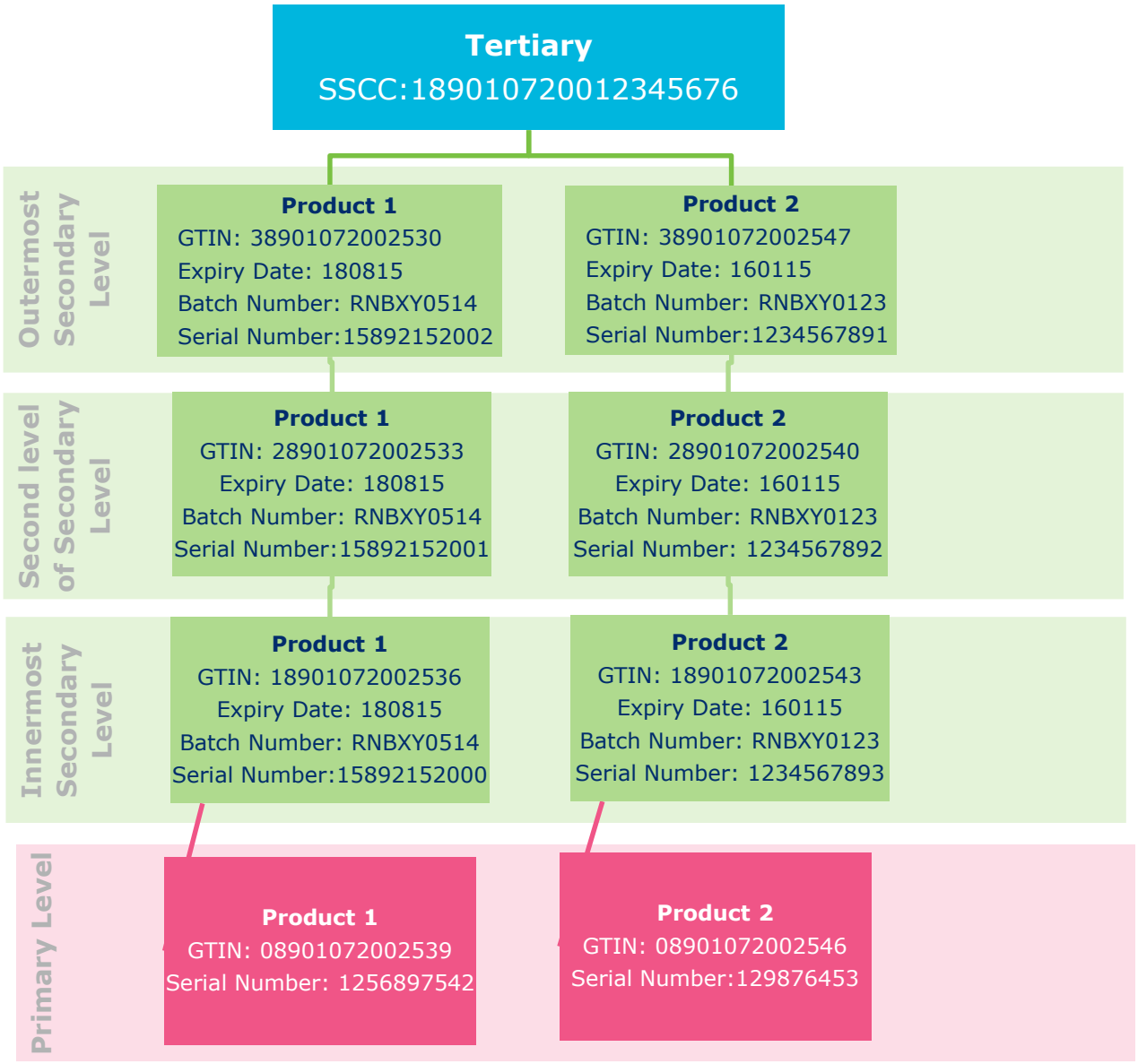


Illustration of Heterogeneous Pack: Parent-Child GTIN Relationship when there are multiple Secondary Level



2.1.5 Step 5: Implementation

Evaluate printing software and hardware: When choosing or using existing printer software, check the capability to properly format/encode, and print GS1 symbol(s) in accordance with the coding and marking guidelines provided in this document and the GS1 General Specifications.

The position of the barcode on the packaging will need to be checked to ensure that it meets the use case and any requirements within the GS1 General Specifications: http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf

Any final labelling or wrapping should also be examined to ensure that the barcodes remain visible and easy to scan.

Identifying Solution Providers: For barcoding and printing solutions, companies can approach solution providers registered with GS1 India for various barcoding, hardware/software, consumables, and other services. Details on solution providers are available at http://www.gs1india.org/Support/SolutionProvider

PART 3
BARCODE PRINTING INFRASTRUCTURE REQUIREMENTS

3.1 Barcode Printing Methods

For printing barcodes on various packaging levels two common printing methods can be adopted:

- Online or Inline Printing
- Offline Printing

Online or Inline Printing refers to the printing method where the print and apply system is deployed on the production and packaging line itself and could be directly connected with an application/ERP that generates and print barcodes in the production process for Primary, Secondary, and Tertiary packaging.

Offline Printing refers to the printing method where the printing and labelling process is done post production for all levels of packaging.

3.2 Barcode Printing Technologies

There are several barcode printing technologies that are available today. Some of the most common printing technologies used within the AIDC industry globally are:

- Thermal Transfer
- Laser Printing
- Inkjet Printing

Thermal Transfer: Thermal transfer printing is one of the most widely used technologies for printing on-demand barcode labels. The technology works through heat being transmitted onto a ribbon (a tape coated with specially designed ink) that then transfers the image to the label. Very good quality barcodes can be achieved when the labelling material and print ribbon are fully compatible.

Though historically direct thermal materials have been known for their 'image fade issues', there are some direct thermal materials that are very durable and sustainable, however due to the general nature of direct thermal materials they may be an expensive option. Thus care should be taken when looking into direct thermal printing options.

Examples of Thermal Transfer Printers

Laser Printing: Laser printing is an electrostatic digital printing process. Density and resolution are relatively high, allowing the production of scannable barcodes at any wavelength when read with an infrared scanner. Multiple barcodes can be designed to fit on a single sheet of paper and can be printed directly from the laser printer. For barcode designing and printing, barcode generation software would be required.

Examples of Laser Printers

Inkjet Printing: Inkjet is a printing process that does not require contact between the printer and the substrate. The technology works by propelling tiny drops of ink onto the substrate to create the symbol. There are two main categories of InkJet printer:

a. **Continuous Inkjet:** A high-pressure pump creating a continuous stream of ink droplets that are then subjected to an electrostatic field. This results in a controlled, variable electrostatic charge that determines if the ink drop should be printed on the substrate or recycled (leaving a light area).
b. **Drops on Demand:** Printers in this family only use drops of ink that are required to print. It is particularly suited for high resolution printing. The print head needs to be close to the substrate (some products can print from a distant as far as 20 mm) and it is suitable for printing on a variety of media and substrates.

Examples of Inkjet Printers

For further details on printer or appropriate technology contact solution providers at: http://www.gs1india.org/Support/SolutionProvider

3.3 Barcode Generation Software

Any barcode generation software selected must be capable of generating GS1 Datamatrix and GS1-128 barcode symbols in full conformance to the GS1 General Specifications. Ensure the software has features to check and automate the encoding of data according to the GS1 standards (e.g., Application Identifiers, Data Formats, Check-digit and FNC1 as start and separator characters).

Many barcode generation software packages provide user-friendly wizards that facilitate GS1 compatible data carrier barcode generation.

For barcode generation, licensed and open source software's are available. Open source software's are available free of cost. Licensed software presently costs anywhere from INR 20,000 to INR 50,000 depending on the features and functionalities in the marketplace today. Apart from that, most of the printers come with inbuilt drivers for printing GS1 compliant barcodes.

3.4 Barcode Label Specification for Corrugated Boxes (shipper/carton/pallet)

Material Description: It is recommended that barcode labeling materials that are specifically designed for corrugated boxes that have a rough surface, dust and high moisture content should be selected. The material should be highly effective for manual application of the labels or where no applicator is being used. Moreover, the material selected should be such that the labels don't peel off if the boxes are not stored properly or are damaged. The label should be receptive to Thermal Transfer, Inkjet printing.

Adhesive: The best solution for the label adhesive would be highly aggressive permanent rubber based adhesive and excellent ultimate bond strength to a wide range of substrates. The Adhesion is equally effective for Manual as well as Auto Application of the Labels. The adhesive layer must possess high permanence characteristics such that labels, once applied, remain attached permanently and can be removed only with difficulty.

Service Temperature Range: -20° C to +70° C (The temperature range to which the label can be exposed after the adhesion bond to the substrate has been formed)

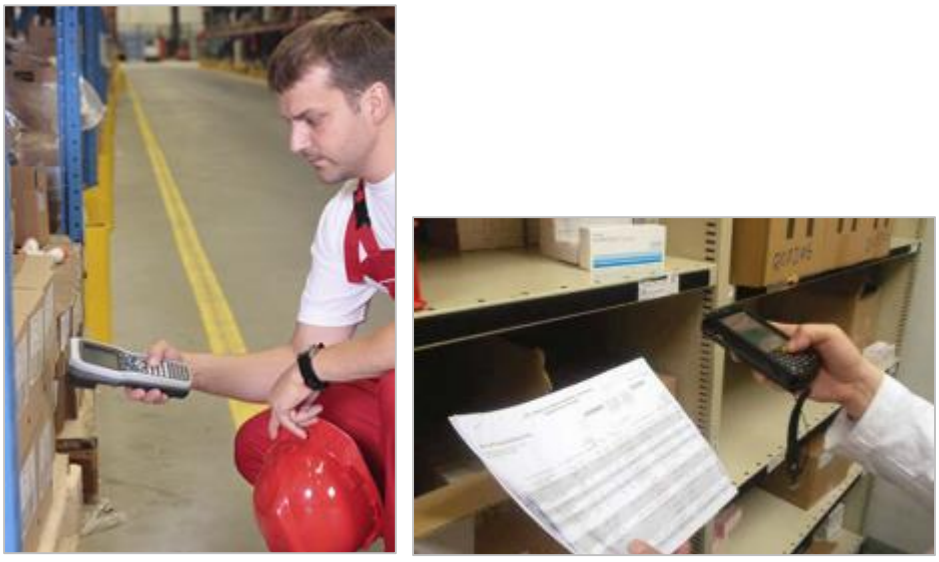
Application: Typical applications include product identification labels on various types of corrugated boxes, Mono Cartons, Shrink Wraps etc.

Conversion: This product can be printed in the usual printing technologies; for variable information printing thermal transfer and inkjet printing can be used. It's recommended to use Resin Ribbons for Thermal Transfer Printing for better outcome. Material should be handled with great care; rough handling may leave permanent impressions in the relatively soft face stock.

3.5 Automatic Data Capture

To facilitate automatic data capture, barcode scanners and/or portable data terminals (PDT) are used within warehouses, point of shipping, etc. to capture the data by scanning the barcode labels. As a product/drug moves through the supply chain there will be various touch points where information needs to be automatically captured and shared with the DGFT. Ensure scanners selected are capable of scanning and decoding GS1 DataMatrix (a 2D Matrix barcode symbology) and GS1-128 (a 1D/Linear barcode symbology) as per the gudelines. Refer http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

Image Based Scanners



Portable Data Terminals

PART 4
SUPPORT PROVIDED BY GS1 INDIA

4.1 Training and Education

To help companies prepare and be compliant with the requirements, GS1 India conducts regular training programs. The training is provided in two formats:

- Pharma Workshops: These classroom-style workshops are held at GS1 India offices in New Delhi, Mumbai and Bangalore. You can view the schedule here: http://gs1india.org/service/education-training/workshop
- Pharma Online Webinars: These are online training sessions provided over the internet. The schedule for the internet based webinar training sessions can be viewed here: http://gs1india.org/service/education-training/webinar

The agenda for these training sessions include:

- Overview and details of the barcoding requirements that have been specified
- How to implement barcodes on your pharmaceutical products based on the requirements
- How to assign product packaging level indicators to enable authentication of your products in the track and trace portal.
- How to maintain the parent-child hierarchy information of the various product packaging levels

Registration for these training sessions can be done online (www.gs1india.org) or by emailing GS1 India at workshop@gs1india.org

4.2 Barcode Verification Services

The GS1 General Specification outlines verification steps for all GS1 Data Carriers, including for barcodes printed on various packaging levels. This ensures barcodes consistently meet the quality requirements and are standards-compliant.

GS1 India provides a comprehensive Barcode Verification service to ensure companies are accurately implementing GS1 barcodes.

Companies **must** send packaging samples for both tertiary and secondary levels for at least two different products with barcodes printed on them to GS1 India. Labels can be sent directly at the address below:

GS1 India
330, 2nd Floor, C-Wing, August Kranti Bhawan
Bhikaji Cama Place, New Delhi – 110066

The verification conducted by GS1 India is to ensure that not only is the information encoded in the barcode meets the requirements but also that the barcodes scan efficiently by any type of barcode scanner in a variety of scanning environments.

The verification would also check for correctness of the product codes generated and the additional information related to the batch number, expiry date, and serial number, etc., are encoded properly in the barcodes.

A nominal fee is payable for generating the barcode verification report for each barcode sample as per details available at http://www.gs1india.org/service/barcodeverification.
The reports would also provide guidance on any changes that may need to be made prior to going for bulk printing of the barcode labels.

Example of the Verification Reports provided by GS1 India

4.3 Helpdesk Support

To assist with the implementation of requirements specified, companies can contact GS1 India at any of the following locations:

	South Region	Western Region	North & Eastern Region
Contact	Hemanth Kumar Chandramouli Balasubramanian	Abhijit Puradkar Shweta Vichare	Kalpana Sharma Amrit Garg Anirudh Sharma
Phone	080 – 23305550 080 - 23305554	022 - 28576516 022 – 28576517	011 - 26168720 011 - 26168 725
Email	info.bangalore@gs1india.org	info.mumbai@gs1india.org	implementation@gs1india.org

PART 5
ANNEXURES

I. Frequently Asked Questions

Question 1	**Is a 2D/Matrix bar code symbology the only type to be used in the secondary level of packaging?**
Answer	Barcoding at secondary level of packaging can be done using either a 2D/Matrix barcode symbology (i.e. GS1 DataMatrix) or 1D/linear barcode symbology (i.e. GS1-128) barcode.
Question 2	**Which guidelines need to be adhered to in case the buyer from the importing country has specific requirements?**
Answer	As per the DGFT notification, if the importing country regulator has mandated their own specific requirements for barcoding, the exporter need not comply with the DGFT stipulations for identification and marking of various levels of packaging. However this first needs to be confirmed with all the concerned authorities.
Question 3	**In the event of changing the brand name of an existing medicine, do I need to change the GTIN also?**
Answer	Yes. As per the GS1 GTIN Allocation Rules a change or modification to any of the basic elements that characterise a trade item will usually lead to a change and Product Name, Product Brand, and Product Description are basic pre-defined characteristics of a trade item.
Question 4	**What information should be printed on the primary level packaging in human readable format?**
Answer	For primary packaging, the GTIN, expiry date, batch number, and unique serial number maybe printed in human readable form if desired as marking products at the primary level is optional.
Question 7	**6 bottles are shrink wrapped together and packed in a box. Many such boxes are then packed in the shipper carton. Where should the Secondary barcode be applied? Should it be on the label of each bottle or the box which contains the 6 shrink wrapped bottles.**
Answer	The box containing the 6 shrink wrapped bottles will be considered as the secondary pack & the shipper carton will be treated as the tertiary/logistic pack. The packages should be identified accordingly with barcodes for each of the packaging levels.
Question 8	**Must the serial number for each carton in the same batch be allocated a unique serial number?**

Answer	Yes, whether primary, secondary or tertiary each serial number shall be unique. In the case of the tertiary this will be accomplished via the SSCC as the tertiary is considered as the Logistic Unit as per the specifications.
Question 9	**If there are 10x10's blisters (i.e. 10 blisters with 10 tablets in each blister) packed in a carton and 10 such cartons are shrink-wrapped together, what should be the primary pack and what should be the secondary pack?**
Answer	Each blister should be treated as the primary pack and one carton consisting of the 10X10 blisters (i.e. 10 blisters with 10 tablets in each blister) should be treated as the secondary pack.
Question 10	**Barcoding for secondary packages is applicable for which products?**
Answer	The mandate is applicable to all drugs and pharmaceutical products. For details refer to the public notice.
Question 11	**When printing information in human readable format, does the manufacturer need to use AI's or can texts like "Exp. Date", "Serial No." etc. be used?**
Answer	Refer section 4.14. "Human Readable Interpretation (HRI) Rules" of the GS1 General Specifications for specific recommendations and examples of HRI form, format and placement.
Question 12	**If an exporter gets an order from either a foreign or an Indian brand owner and outsources the manufacturing to a 3rd party manufacturer in India, then whose GS1 Company Prefix should be used to identify the secondary and tertiary level products?**
Answer	Ideally the GS1 Company Prefix registered to the Brand Owner of the product should be used. If the brand owner does not provide their company prefix then either the actual Manufacturer or Exporter has to identify the drugs using a GS1 Company Prefix registered to them in order to comply with the requirements.
Question 13	**A company has 1 blister in a carton, 2 blisters in a carton and 3 blisters in a carton of the same medicine as saleable units to the end customer. The company already has different GTIN's for each of the above packaging configurations. Should all these types of cartons be considered as primary OR only the cartons with 1 blister should be considered as a primary pack and cartons with 2 and 3 blisters packs be considered as secondary packs?**
Answer	Per GS1 definitions, all three packaging configurations would be considered as secondary packages.

II. Glossary of Terms

Term	Definition
2-Dimensional Symbology	Optically readable symbols that must be examined both vertically and horizontally to read the entire message. Two-dimensional symbols may be one of two types: matrix symbols and multi-row symbols. Two dimensional symbols have error detection and may include error correction features.
Bar Code Verification	The assessment of the printed quality of a bar code based on ISO/IEC standards using ISO/IEC compliant bar code verifiers.
Batch / Lot	The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it.
Brand owner	The party that is responsible for manufacture of the drug / product. The administrator of a GS1 Company Prefix that is allocated by GS1 India.
Check Digit	A final digit calculated from the other digits of Global Trade Item Number (GTIN). This digit is used to check that the data has been correctly composed.
Data Matrix	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix ISO version ECC 200 is the only version that supports GS1 System identification numbers, including Function 1 Symbol Character. Data Matrix Symbols are read by two-dimensional imaging scanners or vision systems.
EAN-13 Bar Code	A bar code of the EAN/UPC Symbology that encodes GTIN-13
Extension digit	The first digit within the SSCC (Serial Shipping Container Code) which is allocated by the user and is designed to increase the capacity of the SSCC.
Function 1 Symbol Character (FNC1)	A symbology character used in GS1 Datamatrix / GS1-128 data carriers as symbol identification and separation characters for segregating the concatenated variable length information
Global Trade Item Number (GTIN)	The GS1 Identification Key used to identify trade items. The key comprises a GS1 Company Prefix, an Item Reference and Check Digit.

GS1-128	GS1-128 is a 1D barcode, which can carry all GS1 ID keys (e.g. GTIN) and attributes like serial numbers, expiration dates and more. GS1-128 is only applied in general distribution and logistics environments, and not applied at the retail point-of-sale (POS). Some key characteristics of a GS1-128 barcode are: • Symbol ID:]C1 • Capacity: 48 Alphanumeric capacity (per symbol, multiple symbols may be used) • Supports all GS1 keys & attributes
GS1 Application Identifier	The field of two or more digits at the beginning of an element string (For e.g. GTIN-14) that uniquely defines its format and meaning.
GS1 Company Prefix	Part of the GS1 System identification number consisting of a GS1 Prefix and a Company Number, both of which are allocated by GS1 Member Organisations.
GS1 Identification Key	A numeric or alphanumeric data field defined by GS1 to ensure the global, unambiguous uniqueness of the identifier in the open demand or supply chain.
GTIN-13	The 13-digit GS1 Identification Key composed of a GS1 Company Prefix, Item Reference, and Check Digit used to identify trade items.
GTIN-14	The 14-digit GS1 Identification Key composed of an Indicator digit (1-9), GS1 Company Prefix, Item Reference, and Check Digit used to identify trade items.
Primary Packaging	The first level of packaging in direct contact with the product and marked with a data carrier either on the packaging or on a label affixed to the packaging. May consist of a single item or group of items for a single therapy such as a Kit.
Responsible Entity	The party responsible for the safety and effectiveness of the medical product at a moment in time in its lifecycle, according to the approved regulatory file (including labelling) and regulatory/legal/professional obligations associated with the medical product. (E.g. Brand Owner, Repackager, Hospital Pharmacy, etc.)
Secondary Packaging	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.
Serial Shipping Container Code (SSCC)	The GS1 Identification Key used to identify logistics units. The key comprises an Extension digit, GS1 Company Prefix, Serial Reference, and Check Digit and is 18-digits long. For more details refer: http://www.gs1.org/barcodes/technical/idkeys/sscc

Unique Serial Number	The serialised identification of trade items, which enables total connectivity of information and communication systems, is achieved through the use of a GTIN and a Serial Number. When combined with a GTIN, a serial number uniquely identifies an individual item. • The overall creation and structure of the Serial Number (e.g., random versus sequential, numeric versus alphanumeric; etc.) is determined by the manufacturer. • Serial Number is represented by Application Identifier (21). • The data is alphanumeric • The length is variable with a maximum of 20 alphanumeric characters. • Databases should treat the serial number as a text field so that leading zeros are not inadvertently stripped off.
Traceability	Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration. http://www.gs1.org/sites/default/files/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf