Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Drug Sector
Licensing Executive Directorate

Guidance for Industry

Saudi Drug Code (SDC), and Drug Barcoding Specifications

This document outlines the SDC and the new drug barcode requirements for pharmaceuticals.

Version 3.0

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Table of Contents

I.   Introduction

Unified standards for automatic identification in the healthcare field provide an opportunity to make the drug supply chain in Saudi Arabia, safer and yet more efficient and accurate. The Drug Sector in Saudi Food and Drug Authority (SFDA) believes that a standardized identification system from the manufacture to the patient is imperative to comply with the increasing need for product integrity and traceability.

Therefore, and since the Global Standards (GS1) system, globally endorsed by the healthcare community, is one of the most widely used trade item identification systems worldwide (GS1, 2011), the Drug Sector is urging all drug manufacturers in Saudi Arabia and international manufacturers exporting to Saudi Arabia, to adopt GS1 supply-chain standards. This document outlines the new requirements, benefits, and the current and future objectives of this project.

II.   Objectives

- Increase patient safety.
- Reduce medication errors.
- Counterfeit detection.
- Traceability and fast product recalls or withdrawals.
- Real-time and accurate information flow between stakeholders.

III.   Requirements

The following are the new requirements that must be applied by drug manufacturers on all type of drug products (Human and Veterinary drugs). Please refer to related circulars announced by SFDA in regard to dates of implementation:

1. New Carrier

All drugs' marking must be upgraded from linear barcodes (Figure A) to GS1 Data Matrix Barcode (Figure B).

(Figure A) Linear Barcode   (Figure B) GS1 Data Matrix

Coded Data: The Data Matrix barcode must, at minimal, carry the following data:

- **GTIN**: GS1 Global Trade Identification Number.
- **Expiry Date** in YYMMDD format (Attribute).
- **Batch/Lot Number** (Attribute).

2. Printed Information

The following are the minimal data attributes that must be printed on every drug unit of sale (*if EXPIRY, Batch number, and package size is printed somewhere else on the box, then no need to repeat them. However GTIN, EXPIRY, Bach number, and package size are included in the data matrix barcode itself.*). All must be on the same pack side where the barcode is printed:

GTIN:	**62800000000000**
EXPIRY:	**YYMMDD**
BATCH/LOT:	**ABCD1234**

3. Drug Serialization

Marking each drug package with a unique serial number will be required in the near future in order to support the drug track and trace project in Saudi Arabia. The date and the guidelines of implementation will be published by SFDA in the near future to clarify the requirements and the processes of notifying the drug tracking DBs.

4. GLN:

All pharmaceutical manufactures licensed by SFDA, must acquire a Global Location Number (GLN) from GS1 in order to uniquely identify every physical location. **It will be gradually introduced** into SFDA systems such as Establishments' Licensing System and Inspection systems.

5. Products need to be barcoded:
All pharmaceutical products that are finally packaged and ready to be marketing are required to have 2 D barcode. However, primary packaged products that enter to Saudi Arabia to be repackaged are not required to be barcoded, after the final packaging then the barcoded is a must.

Free samples are not required to be barcoded.
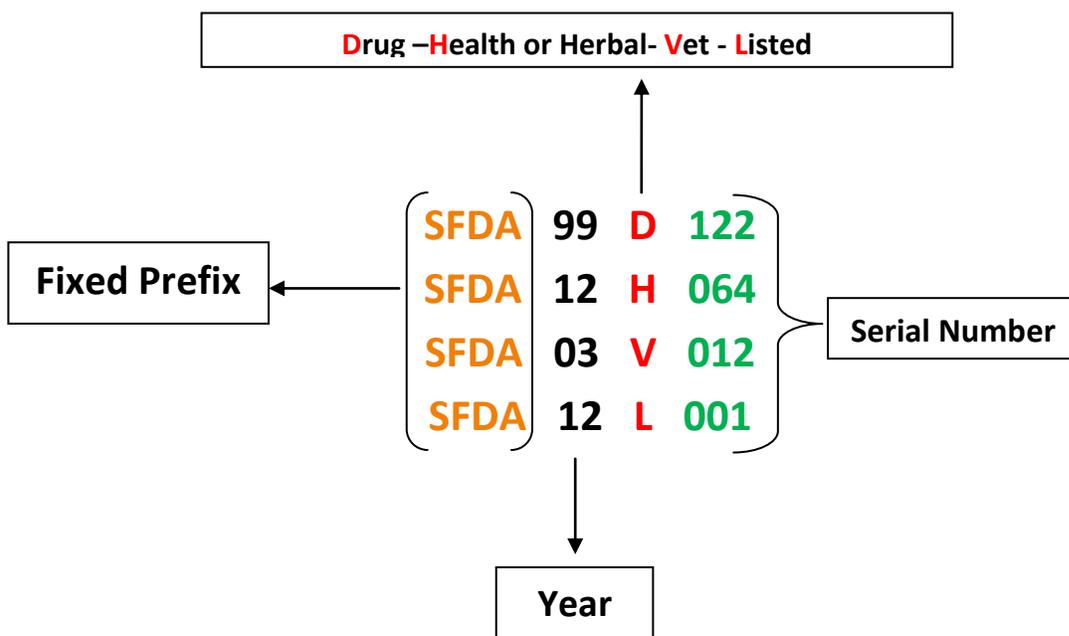
IV. Saudi Drug Code

Saudi Drug Code (SDC) is a new registration code that is going to be given by the Drug Sector to each registered drug in the Saudi market. This new code shall eventually replace the current drug registration number (example: A) which is normally granted with the approval of the drug registration.

Example: a

12-111-07

The SDC will contain fewer variables than its predecessor. Therefore, it will be more stable and reflects the application type in addition to the year of registration. Guidelines of printing SDC will be published on a later stage.

The following illustrate the structure of SDC:

Drug –Health or Herbal- Vet - Listed

SFDA	**99**	**D**	**122**
SFDA	**12**	**H**	**064**
SFDA	**03**	**V**	**012**
SFDA	**12**	**L**	**001**

Fixed Prefix

Serial Number

Year

Here are some examples of the final SDC format:

<div align="center">

SFDA12D001

SFDA13H011

SFDA14V111

</div>

V. Databases:

The Drug Sector will start gradually to collect all registered drug's GTIN numbers in order to add them to the periodically published drug database on the SFDA's website. Each registered product in the database is going to carry a GTIN and a SDC number as in the following example:

	A	B	C	D
1	الرمز السعودي للدواء	رمز الباركود من GS1	رقم التسجيل	الاسم العلمي
2	**SDC**	**GTIN**	**Regsiteration Number**	**Generic Name**
3	SFDA12D001	8124569854123	48-803-12	Drug Example A
4	SFDA13H011	1236548245369	57-803-12	Drug Example B
5	SFDA14V111	2547896321458	46-803-12	Drug Example C
6	SFDA12L006	2156987411222	47-803-12	Drug Example D

VI. What Industry has to do?

For Barcodes:

1. Contact the GS1 Saudi Arabia office for more information about acquiring GTIN, GLN, and Data Matrix barcodes.
2. Prepare your production lines for printing and verifying the new barcodes.
3. Plan to be logistically ready for drug serialization.

VII. Benefits

a) To Manufacturers

- Reduce inventory assets: Improve demand forecasting and inventory planning.
- Reduce inventory financing and holding cost:
  - Reduce financing due to lower inventory assets.
  - Reduce inventory management cost with more efficient and accurate processes.
- Reduce produce waste due to obsolescence: Improve inventory management to shrink inventory levels and unused product.
- Reduce cost of recalls:
  - More efficient execution (increased supply chain visibility).
  - Reduce scope of recalls (better targeting).
- Reduction in counterfits and recovery lost profit: Reduction in counterfit supply raises sales volume.
- Brand Protection.
- To support track and trace of products.
- Errors reduction.
- To support patient and product safety.
- To obtain hospitals accreditation.

b) To distributors and wholesalers

- Reduce inventory assets: Improve demand forecasting and inventory planning.
- Reduce inventory financing and holding cost:
  - Reduce working capital requirements by lowering inventory assets.
  - Reduce inventory management cost with more efficient and accurate processes.
- Recall effectiveness: distributors capture shipment lot numbers for potential recall processing
- Counterfeits: The distributor would comply with track-and-trace regulations, and mitigate the risk of inadvertently accepting counterfeit or diverted products into its supply chain.

- Transaction challenges: serialization could create efficiencies in the chargeback process for distributors subject to this practice and make returns processing more effective and accurate.

c) To retail pharmacies

- Reduce recall processing cost: Minimize manual recall processing such as visually inspecting products and contacting all patients potentially impacted.
- Reduce data cleansing cost: Reduce staff to cleanse supply chain data, such as matching product data with master catalogue, validating accounts receivable and payable data.
- Reduction in counterfeit risk: When pharmacy validates product authenticity upon receipt by the barcode.
- Obsolescence reduction: Excellent management of nearly expired product.

d) To hospitals

- Reduce adverse drug events: Reduce preventable medication errors and ADEs through bedside scanning.
- Reduce inventory levels: Improve demand forecasting and inventory control.
- Reduce cost of inventory (financing and management): Automate processing for inbound receiving, SKU management, stock audits, product returns.
- Reduce obsolescence: Improve inventory control and visibility on product expiry).
- Reduce recall processing costs: Minimize time spent searching for information.
- Reduce data cleansing cost: Automate data management, order processing, financial transactions.

VIII.   Appendix A: GS1 Data Matrix (2D) Barcode

a) Definition

It is a graphic representation of any digital data in a 2-dimensional format, with high decoding information capacity that can be read by optical equipment. It provides:

- High storage capacity: Encoding and marking of a greater amount of data within a smaller space.
- Direct marking: On items where labels may not be practical.
- Image Readable.
- Auto-correction: Error detection and correction capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label.

b) Printing Location

The Data Matrix barcode must be printed on one of the sides of the secondary packaging. It must be placed preferably on a flat surface. To facilitate the reading process, it must be placed on the same side where possible.

c) Printing Instructions

- › Ensure that the surface to be marked is suitable for printing.
- › Verify through testing that rubbing does not damage the marking,
- › Testing the legibility of barcode marking in certain moist conditions.
- › Using the same printing quality for information redundancy.

d) Readers

To read the Data Matrix barcode, camera-based bar code scanners are required. Laser bar code scanners cannot read data matrix bar codes. However, camera-based bar code scanners can read both linear and all 2-D bar codes such as Data Matrix. Generally, camera-based scanners have a higher price point than laser scanners, but they offer distinct advantages, such as:

- › Flexibility: they can read both 2D and linear bar codes versus laser scanners which can only read linear bar codes.

> Reliability: It has less moving parts than laser based scanners. Therefore, lower total cost of ownership.
> It support image capture: allowing imaging of a product or an identification card, or even a document up to 21.6 x 28 cm (8"x11").
> Compact: allow easier integration with other systems (e.g. packaging line verification) or in a handheld computer.

IX. Appendix B: Global Trade Item Number (GTIN)

a) Definition

The GS1 Global Trade Item Number (GTIN) is an identification key that uniquely identifies products worldwide. It can be encoded into various types of data carriers such as Data Matrix.

b) GTIN-14

GTIN's are available in several lengths. GTIN-14 is the required form and it is composed of 14 digits:

> First digit represents the Indicator digit to indicate packaging level.
> Next twelve digits are the GS1 Company Prefix and the Item Reference assigned by your company.
> Last digit representing the Check Digit.

c) Why GTIN

- It facilitates the global flow of trade products and associated information used in electronic commerce.
- Uniquely identifies trade products at all levels of packaging (item, case, and pallet).
- Allows accurate machine reading of trade products when placed in bar codes.
- Delivers trade products data in a consistent format and structure.
- Simplifies supply chain management.

X. Appendix C: Global Location Number (GLN)

a) Definition

The Global Location Number (GLN) is a globally unique GS1 Identification Number that is used to identify any location in the supply chain that needs to be uniquely identified.

b) Why GLN?

GLN is very important to help in the location identification process. It links to the organization's name, address, and type in the databases, reducing effort to maintain and communicate this information between all parties. This increases the efficiency, accuracy and precision of sharing location information, crucial to logistical operations. It is also substantial to achieve traceability in healthcare and improve supply chain efficiency and visibility.

XI. References

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