EFDA
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ETHIOPIAN FOOD & DRUG AUTHORITY

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DIGITAL HEALTH ACTIVITY (DHA)
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Overview of barcode use for pharmaceutical products in Ethiopia

1. Introduction

The pharmaceutical supply chain system faces many challenges including presence of substandard and falsified products, recall ineffectiveness, medication errors, supply chain inefficiencies and end-to-end data visibility. The use of global standards in product identification, data capture and sharing is crucial to alleviate the aforementioned challenges. Recalling this, the Ethiopian Food and Drug Authority (EFDA) requires the use of unique identifiers and required data elements encoded in machine-readable forms. This helps to minimize the supply chain security challenges, improve supply chain efficiency and integrity, and easy and accurate data exchange. In addition, the use of barcodes helps to reduce medication errors in health care settings by enabling health care professionals to verify that the right medication, in the right dose and right route of administration, is being given to the right patient at the right time.

2. Purpose

The fact sheet provides information on and clarifies the legal requirements for the barcoding of pharmaceutical products and is intended to serve as advice for manufacturers and other supply chain players.

3. Legal provisions about barcode

The Ethiopian government published a proclamation in 2019 that requires the placement of barcodes on the labels of pharmaceuticals. Article 53 (5) of the Food and Medicine Administration Proclamation No. 1112/2019 reads, “No person may import or place into use any medicine or medical device unless its labeling contains a barcode.” The pharmaceutical products traceability directive No. 43/2019 was issued in 2019 by the EFDA to supplement and translate the legal provision provided in the proclamation. In the directive, the GS1 data matrix that encodes GTIN, expiry date, batch number, and serial number is mandatory and needs to be placed on the pack as a label.

4. Key roles of barcode

Barcodes play a key role in supply chains. Barcodes are used to identify and track products as they move through the supply chain and exchange information. It also helps to track data of business operations such as inventory, status of transactions, shipments, and verify product authenticity.

The GS1 DataMatrix barcode is the recommended barcode type used for pharmaceutical products across the globe. The main reasons for choosing the GS1 DataMatrix barcode:

- Captures the largest amount of identification data in the smallest amount of space on packaging
- Can be printed directly on the products
- Has sophisticated error detection and correction algorithms, allowing the GS1 DataMatrix barcode to be scanned even if damaged, torn or printed poorly.

5. Types of barcodes

Barcodes are symbols that can be scanned electronically using laser or image-based technology. Barcodes are used to encode information such as key identifiers and key attributes. There are two types of barcodes namely linear and 2D barcodes.

The 2D barcodes use patterns of squares, hexagons, dots and other shapes to encode data and it can hold more data than 1D barcodes.

6. Barcoding technical requirements

One of the key components of pharmaceutical regulation is uniquely identifying products from the point of manufacture to the point of dispensing and use. The EFDA requires the use of unique identifiers to be encoded into machine-readable forms. Ethiopia is requiring the GS1 DataMatrix on pharmaceutical products and all supply chain stakeholders must make sure that the products they purchase have GS1 DataMatrix barcodes in the labels of pharmaceutical products. Some of the technical characteristics of the GS1 DataMatrix barcode are stated below.

6.1. Shape and size of the barcode

GS1 DataMatrix is a two-dimensional barcode which may be printed as a square or rectangular form. The choice of the symbol must be made based upon ***configuration support, available space on the product type, amount of data to encode, printing process***, and etc. The size of the GS1 DataMatrix symbol varies depending on the amount of data and format of encoded data. The square form is the most commonly used and enables encoding of large amounts of data. The EFDA recommends the square shape of the GS1 DataMatrix barcode.

6.2. Number of symbols

Barcodes representing different Global Trade Item Numbers (GTINs) must never be placed on one trade item. Multiple barcodes on a single item can result in symbol quality problems and potentially dangerous user confusion. This can also lead to scanning and reading performance challenges as the user might find it difficult to identify which barcode should be or has been scanned for the purpose of identification and verification of authenticity of pharmaceuticals.

6.3. Placement of the barcodes

The exact location of a GS1 DataMatrix barcode on a product is determined by the manufacturer where it considers the available space on the product package, the type of product and printing substrate (packaging material), and other packaging constraints such as folds or seams, curvature, perforations, die-cuts, ridges, edges, tight curves, folds, flaps, overlaps, and rough textures. The GS1 DataMatrix barcode must be printed on one side of the packaging either on the front or end side, preferably on a flat surface. To facilitate the reading process, it should be placed on the same side where possible.

6.4. Colours and Contrast

Different colours of barcodes can be used. Selecting a good colour combination will help to achieve good symbol contrast. Contrast is heavily impacted by the colour and reflectance of the substrate used. The optimum colour combination for a barcode symbol is black bars with a white background. Some common contrast problems are caused by:

- A bad choice of colours for the dark and/or light areas.
- The use of a transparent background (known as 'Opacity')
- A 'blurring' of the dark colours into the light area.
- Excessive reflectance from very shiny or glossy surfaces.

7. Encoding data elements

It is possible to encode any type of data in Data Matrix symbols. But, the data must be structured according to the rules of the GS1 System when using GS1 DataMatrix. Element strings begin with an Application Identifier (AI) followed by the data that the AI denotes. GS1 Application Identifiers (AIs) are 2, 3 or 4 digit numbers which define the meaning and the format of the data that follows. Application Identifiers should be clearly recognisable by putting parentheses around AI in the Human Readable Interpretation under the symbol. According to the Ethiopian regulations, the GS1 DataMatrix barcode must encode the following data elements:

Table 1: Required element strings to be encoded in a barcode

AI	Data definition	Number of digits
1	Global Trade Item Number (GTIN)	14
10	Batch or lot number	Up to 20
17	Expiration date (YYMMDD)	6
21	Serial number (SN)	Up to 20

This does not replace the label requirements stated in other regulations of the country.

8. Human readable interpretation (HRI)

According to the Ethiopian traceability legislation, the Human Readable Interpretation of the Application Identifiers and their associated data must be positioned near the GS1 DataMatrix symbol in which they are encoded, preferably underneath the barcode. The characters should be clearly legible and must be obviously associated with the symbol. Watch out for the following examples:

(01)03453120000011
(17)191125
(10)ABCD1234

(01)09501101020917(17)190508(10)ABCD1234(21)10

9. Reading of barcodes (Scanner environment)

Once the symbol is printed, a reading or scanning device is required to capture the encoded data. GS1 DataMatrix symbols require scanners that can be read in 2-dimensions. GS1DataMatrix barcode requires camera or image technology for reading. Almost any scanner capable of reading GS1 DataMatrix can also read linear barcodes as well.

Anything that will obscure or damage a barcode will reduce scanning performance and SHALL be avoided. This includes but not limited to for example:

- Never position the barcode on the item in an area with inadequate space. Do not let the other graphics encroach on the space for the barcode.
- Never place barcodes on perforations, die-cuts, seams, ridges, edges, tight curves, folds, flaps, overlaps, and rough textures.
- Never put staples through a barcode
- Never fold a symbol around a corner.
- Never place a symbol under a package flap
- Barcodes used for production control purposes should be obstructed wherever possible before entering general distribution.