



Identification and Labeling of Pharmaceutical Products with barcode

1. Introduction

The safe use of pharmaceutical products depends on access to accurate information and the ability of users to read the Identification and labeling. This depends on the information presented on label and databases. The EFDA seeks to uniquely identify products in the supply chains through uniform identification, automated data capture, and sharing of information. The fact sheet provides guidance for implementation and compliance with requirements of the identification and labeling of pharmaceutical products as outlined in global standards and provisions in national laws

2. Purpose

This fact sheet is a guidance to trading partners on identification and labeling of medicines considering the GS1 global standards. It is designed to support the implementation of existing regulations on medicines packaging and labeling.

3. Required data elements and format

The GS1 two dimensional (2D) symbol and the GS1-128 symbol(s) shall include all mandatory element strings, and may include additional element strings if the manufacturer believes it is important. The data elements to be encoded in barcode must be structured according to the rules of the GS1 System of standards and the national regulations. The element strings must begin with an Application Identifier (AI) followed by the data that the AI denotes.

Table 1: mandatory 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

3. Identification and labeling requirements for Pharmaceutical Products

Knowing and implementing product identification and labeling requirements on pharmaceutical products is crucial. The labeling and identification of pharmaceutical products in accordance with Ethiopian laws are explained below, and this depends on each level of the packaging hierarchy.

3.1. Tertiary pack trade item

The tertiary pack trade item packages must include a GS1-128 Linear Barcode or a GS1 two dimensional (2D) DataMatrix barcode encoded with **GTIN, Batch or Lot number, Expiry Date, and Serial Number** and printed adjacent to the data carrier in Human Readable Interpretation. An example of the 2D DataMatrix and GS1-128 Linear Barcode, and placement of the human readable interpretation:

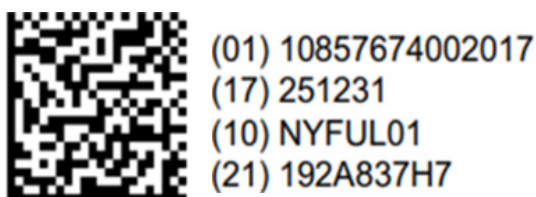


Fig 1: 2D DataMatrix



Fig 2: GS1-128 Linear Barcode

3.2. Tertiary pack logistic unit

All tertiary pack logistic units must include a GS1-128 Linear Barcode encoded with SSCC and printed adjacent to the data carrier in Human Readable Interpretation.

AI	Description	Number of digits
00	Serial Shipping Container Code	18

An example of this in practice:



Fig 3: GS1-128 Linear Barcode with SSCC

3.3. Secondary pack trade item

The secondary trade item packaging, including inner and intermediate secondary packaging levels, must include a GS1 2D DataMatrix barcode encoded with **GTIN, Expiry Date, Batch or Lot Number, and Serial Number** and printed adjacent to the data carrier in Human Readable Interpretation.

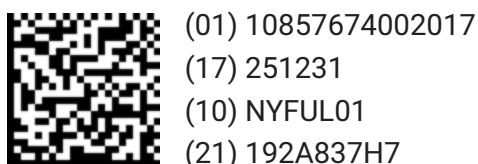


Fig 4: Human Readable Interpretation