50 years ago...

- standardized machine readable product identifier
- connecting physical products to digital product data

GS1 is a global organization

Offices in **116 countries**, over **two million user companies**, and **10 billion barcodes scanned every day** – helps securing a common digital business language across the world

Not-for-profit

Not-for-profit organization with industry neutral standards

User driven

GS1 standards are developed in collaboration with our users

Open

GS1 standards can be used by all companies

Globally standardized business language

Identify

Create unique numbers for products, packages, places, and much more to enable unique identification and increased visibility, security, and traceability in the value chain

Capture

Standards of how to capture unique identities to increase efficiency in handling of data exchange

Share

Receive and share information about products, packages, and places in a standardized, seamless, and secure fashion throughout the value chain

One of these medicines is fake.

Can *you* tell which?

SAFEMEDICINES.org

European Directive - Falsified Medicines Directive

- Aims to prevent falsified medicines from entering the legal supply chain and ultimately ending up with the patient
- Since 2019 every package of a prescription medicine must have a unique serial number
- Manufacturers of prescription drugs use the 2D barcode for the serial numbers
  - Places the numbers in Central database of the Member state where the boxes go to
  - When administered, the serial number is verified

EU Falsified Medicines Directive – Technical Specification

Article 4 – Composition of the unique identifier

(b) The unique identifier shall consist of the following data elements:

- (i) a code allowing the identification of at least the name, the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product bearing the unique identifier ('product code');
- (ii) a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm ('serial number');
- (iii) a national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market;
- (iv) the batch number;
- (v) the expiry date.

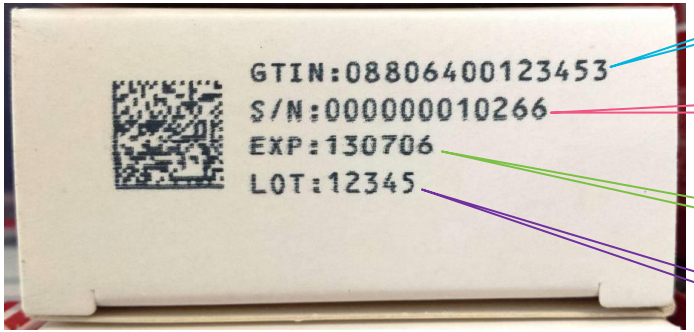
Article 5 – Carrier of the unique identifier

2. The barcode shall be a machine-readable Data Matrix…

5. When encoded in a Data Matrix as data element of a unique identifier, the product code shall follow a coding scheme and begin with characters specific to the coding scheme used. It shall also contain characters or character sequences identifying the product as a medicinal product. The resulting code shall be less than 50 characters and be globally unique. Product codes which conform to the ISO/IEC 15459-3:2014 and ISO/IEC 15459-4:2014 shall be presumed to fulfil the requirements set out in this paragraph.

Note: This is an exerpt. Full text is available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0161#d1e40-1-1

GS1 DataMatrix
4 identifications data elements



Product Identifier (GTIN)

Serial Number

Expiry date

Lot/Batch number