

GS1 Standards

Guidelines for the Serialisation of Medicinal Products

With a Focus on Labelling and Identification



Table of Contents

Table of figures	6
1 The role of the PZN (pharmaceutical identification number) in Germany	7
2 Global Trade Item Number (GTIN)	8
3 National Trade Item Number (NTIN)	9
4 Structure of the individual identifier.....	10
4.1 The GS1 application identifier concept	10
4.2 Encoding of the GTIN/NTIN	11
4.3 Encoding of the serial number	11
4.4 Encoding of the expiry date	11
4.5 Encoding of the batch number	11
5 Data carrier of the individual identifier: Data Matrix and GS1 DataMatrix....	12
5.1 Technical attributes of the (GS1) Data Matrix	12
5.2 Symbol architecture	14
5.3 Square and rectangular formats.....	14
5.4 Symbol sizes	15
5.5 Dimensions/module width and height (X)	16
5.6 Human-readable format	16
6 Print quality and quality control	17
7 The EU Falsified Medicines Directive: Implementation in Europe.....	18
7.1 Necessity of a globally uniform approach with national numbering systems	18
7.2 Identification using GTIN.....	18
7.3 Identification using GTIN and NHRN (National Healthcare Reimbursement Number)	19
7.4 Identification using NTIN.....	20
7.5 Current status of encoding in the European Union	22
7.6 Recommendations.....	23
Imprint	24

Table of figures

Fig. 2-1: Global Trade Item Number	8
Fig. 3-1: Structure of NTIN in Germany	9
Fig. 3-2: Identification and labelling variants in Germany	9
Fig. 4-1: Excerpt from the application identifier list (DB)	10
Fig. 5-1: Basic (GS1) data matrix concepts	14
Fig. 5-2: Rectangular and square (GS1) data matrix symbol. Both symbols contain the same data.....	14
Fig. 5-3: ECC 200 data matrix – code sizes	15
Fig. 7-1: Pack identification solely using GTIN.....	18
Fig. 7-2: Pack identification using GTIN and NHRN	19
Fig. 7-3: Pack identification using GTIN and several NHRNs.....	19
Fig. 7-4: Application identifier for national pharmaceutical registration numbers (NHRNs)	20
Fig. 7-5: Identification using NTIN.....	20
Fig. 7-6: Possible combinations for multi-country packs	21

1 The role of the PZN (pharmaceutical identification number) in Germany

Under the Healthcare Reform Act from 20/12/1988, pharmaceutical companies are obligated "to declare the pharmaceutical registration number on the outer packaging of the medicinal product in a format that is standard nationwide and machine-readable for pharmacies. The details are to be elaborated in agreements by the national associations of health insurance companies and the main national organisations established to look after the economic interests of the pharmaceutical companies at the federal level." The national associations of the health insurance companies and the deutsche Apothekerverband (German Pharmacy Association) subsequently agreed on 04/11/1994 to use the Pharmazentralnummer (PZN) as the standard identifier within the meaning of the aforementioned legislative base.

As the range of products carried by pharmacies not only includes pharmacy-only medicines, like pharmaceuticals, but is being increasingly supplemented by articles commonly found in pharmacies that are also sold via other distribution channels (e.g. chemists, supermarkets, health food shops), it is permissible to use the GTIN to unambiguously identify both pharmacy-only products and those commonly found in pharmacies. This requires that the manufacturer informs the IFA of the GTIN that corresponds to a PZN. The two numbering systems are then linked with one another in the IFA database so that the legally required ability to identify the product can be achieved using the national identifier. When the GTIN is scanned at a pharmacy or hospital, the user is automatically given access to the associated data, such as the PZN, supplementary payment level, price, etc.

In short: It is already possible to identify a pharmaceutical product with a GTIN and label it with a GS1 code (e.g. EAN code). This possibility plays a specific and important role when it comes to so-called multi-country packs, i.e. packs that are sold on more than one market.

2 Global Trade Item Number (GTIN)

The principle, and legally compliant option for identifying medical products of all kinds, i.e. both medicinal products and medical devices, is for the manufacturer or brand owner to assign a Global Trade Item Number (GTIN).

The GTIN is assigned autonomously by and is the sole responsibility of the manufacturer (brand owner)¹. Every GTIN is based on the so-called GS1 Global Company Prefix, which in Germany is assigned by GS1 Germany in combination with a GLN (Global Location Number). The GLN is part of the GS1 Complete package and allows the unambiguous and mutually exclusive identification of all manufacturers worldwide.

The GTIN is normally 13 digits long and has the following structure:

Global Trade Item Number GTIN			
Global Company Prefix		Individual number segment	Check digit
4 0	1 2 3 4 5	0 0 0 2 5	2
4 2	1 2 3 4 5 6	0 0 2 5	8
4 3	1 2 3 4 5 6 7	0 2 5	8

Fig. 2-1: Global Trade Item Number

- Global Company Prefix:

The 7 to 9-digit Global Company Prefix is derived from the Global Location Number (GLN) of the brand owner. It ensures that the GTIN is globally unique and non-overlapping. The range of numbers available to the user is determined by the length of the Global Company Prefix.

- Individual item number:

Up to five additional, freely selectable digits are appended to the Global Company Prefix. With a 7-digit Global Company Prefix, any five-figure combination of digits between "00000" and "99999" can be created. Thus a maximum of 100,000 different GTINs can be generated using such a Global Company Prefix.²

- Check digit:

The 13th digit of the GTIN is a check digit. It is computed from the previous 12 digits modulo 10. Under no circumstances may the GLN check digit be used; a new check digit must be calculated for every GTIN.

¹ For reasons of simplicity, the following only makes reference to the manufacturer who is generally the brand owner of a product.

² Should even the 7-digit Global Company Prefix, i.e. the quota of 100,000 items, be insufficient, an additional GLN can be requested from GS1 Germany for a one-off fee.