

1. Data Content of the Data Matrix Code

1.1 Data identifier and contents



GTIN: (01) 07046261398572
Expiry: (17) 130331
Batch / lot: (10) TEST5632
S/N: (21) 19067811811

Product code

Application Identifier (AI): „01“

For product identification, the product code is used in the form of the Global Trade Item Number (GTIN). The product code is the leading data element in the data matrix code, all other data elements refer to it. The pharmaceutical central number is contained in the product code and can be extracted from it.

Serial number

Application Identifier (AI): „21“

The serial number is generated by the pharmaceutical company and forms the corresponding data element of the individual identifier. It is mandatory for the verification process. In the case of non-medicinal products requiring verification, the serial number may not be applied.

The serial number required for verification is a numeric or alphanumeric sequence of a maximum of 20 characters generated by the pharmaceutical company. In order to make it as difficult as possible for a falsifier to guess or reproduce allocated serial numbers, serial numbers are to be generated by a deterministic or non-deterministic randomisation algorithm. The probability that the serial number can be derived must in any case be less than 1: 10,000. In addition, the randomised serial number in combination with the product code according to Article 4 lit. (d) shall be unique for each medicinal product packaging for a period of at least one year from the expiry date of the pack or at least five years from placing the medicinal product on the market (whichever is longer). The re-use of serial numbers is a potential source of error and is therefore not recommended.

Batch number

Application Identifier (AI): „10“

The batch designation is generated by the pharmaceutical company and thus forms the corresponding data element for the data matrix code.

Expiry date

Application Identifier (AI): „17“

The expiry date is generated by the pharmaceutical company and thus forms the corresponding data element for the data matrix code.

The expiry date has here the format „YYMMDD“

YY = two-digit year number

As the expiry date is exclusively in the future, these are dates for the 21st century (2000-2099).

MM = Numerical month (01–12)

DD = Day

- Expiry date with day, month and year (DD = 01–31)
- Expiry date with month and year (DD = 00)

The data format specified here is independent of the format used in the plain text to indicate the expiry date.

The applicable data identifiers as well as the permissible data types, character sets, and data lengths of the data to be encoded are summarised in the following table.

Data element	XML nodes	AI	Data type	Data format	Character length	Character set
National Trade Item Number (NTIN)	<GTIN>	01	N	-	14	0-9
Serial number	<SN>	21	AN	-	1-20*	numerical or alphanumeric characters, no umlauts
Batch number	<LOT>	10	AN	-	1-20*	numerical or alphanumeric characters, no umlauts
Expiry date	<EXP>	17	Date	YYMMDD	6	0-9

* Length-variable data elements must be limited by an FNCI separator.

Recommendations for the character set for serial number and batch designation:

- The character string should either contain only uppercase letters or only lowercase letters of the Latin alphabet.
- The use of the letters „Y“ and „Z“ or „y“ and „z“ should be avoided as these are interchanged in German and English keyboards. If the language of the keyboard scanners is incorrect, there is a risk of misinterpretation.
- In order to avoid human reading errors, depending on the font used and the quality of the printed image, the use of similar characters harbouring a risk of being misread should be avoided. These include, e.g.: i, j, l, o, q, u as well as I, J, L, O, Q, U.
- Even though some special characters are technically processed, but they should not be used, as the risk of misinterpretation is very high. An incorrectly interpreted code means that a packaging cannot be verified and thus cannot be sold. The special characters with the decimal ASCII code values excluded from the technical processing are 35 (#), 36 (\$), 64 (@), 91 ([), 92 (\), 93 (]), 94 (^), 96 (`), 123 ({), 124 (|), 125 (}), 126 (~) and 127 (|) as well as all control characters (ASCII code value 00-31). In principle, all ASCII characters with a decimal value of > 127 are excluded.
- If separators are required within a batch number, it is recommended to use the hyphen „-“ or the underscore „_“ or the fullstop „.“. The use of the fullstop is particularly

recommended since it is identical for German and English keyboards. In the case of incorrect language selection of the keyboard scanners used, there is thus no risk of misinterpretation per se.

As a rule, data elements with a predefined length should be in front of variable length data elements. The order of the data elements is the responsibility of the person who compiles the data elements.

1.2 Multi-market Packs

Multi-market packs (MMPs) are commercial packs which in a specific presentation are marketable in several countries. They can have several national item numbers for reimbursement and merchandise management purposes in the „blue box“, as well as a variety of other country-specific information.

For multi-market packs requiring verification, it is necessary to define a product code generally covering all the countries in which the medicinal product in question is subject to verification. This product code is uploaded via the European hub into all repositories systems together with the corresponding serial number and the other information. When the medicinal product is sold, the status of the relevant packaging is again synchronised in all national repositories systems concerned via the European hub.

The product code for multi-market packs might therefore not be a full guarantee for the country-specific identification of a medicinal product. Thus, in addition to the individual identifier, further national item or reimbursement numbers can be included in the code and/or stored in the national repositories system. These supplements are also to be included in the data matrix code according to the country-specific specifications. This makes it possible to record both the data relevant for verification as well as the additional numbers for the country-specific identification of the medicinal product with the help of a scan.

The product code is identified by the AI (01). The other country-specific numbers for the identification of the medicinal product - provided that these must be included in the data matrix code pursuant to national guidelines - are identified by the AI assigned to the National Healthcare Reimbursement Number (NHRN) (7xx, e.g., 710...Germany, 711...France, 712...Spain).

A Global Trade Item Number (GTIN), which is valid in Slovak republic, is to be shown as the product code for multi-market packs marketable in Slovakia. The Slovak pharmaceutical central number must be uploaded via the European hub using the EMVS Master Data Elements (field „National Code“ of the Market Specific Master Data Elements for Slovak republic) and stored in the national repositories system.

Note: When using a GTIN which is allocated directly by the pharmaceutical company (in accordance with GS1 specifications), it is the responsibility of the company to report this number promptly to the Pharmacy together with the pharmaceutical central number in order to ensure a linking of the numbers in the product number.

It should also be noted that GTIN and pharmaceutical central number are to be reported independently to those trading partners as well as logistics service providers who do not have access to the national repositories system and thus cannot guarantee an automated link between GTIN and the pharmaceutical central number.

The absence of the link between the GTIN and the pharmaceutical central number can lead to the fact that the GTIN and the pharmaceutical central number assigned to the product are not correctly matched.

Obligatory		Optional (in accordance with national requirements)	
AI	Data element	AI	Data element
01	Global Trade Item Number (GTIN)		
21	Serial number		
10	Batch number		
17	Expiry date		
		7xx	NHRN