amvo

Austrian Medicines
Verification Organisation

Coding Rules for Austria

for medicinal products subject to mandatory verification
on the Austrian market according to EU Directive 2011/62/EU
and delegated regulation (EU) 2016/161

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1 Introduction

According to Directive 2011/62/EU „for the prevention of entry of falsified medicinal products into the legal supply chain" (Article 54a paragraph 1), briefly referred to as „Falsified Medicines Directive" (FMD), all medicinal products subject to prescription shall bear safety features which, in particular, permit verification of their authenticity and the identification of individual packagings („unique identifier"). The details with regard to the characteristics and technical specifications of the individual identification feature for the safety features are laid down in the Commission's delegated Regulation (EU) 2016/161, which was published in the Official Journal of the European Union in February 2016. Member States must apply these rules three years after the publication of the delegated regulation, i.e. as from 9 February 2019. As from this date forward, no products affected by the Falsified Medicines Directive may be placed on the market without the safety features.

In principle, all medicinal products for humans which are subject to prescription are affected, exceptions can be found on the „Black & White List" of the delegated Regulation (Annexes 1 and 2). Each drug packaging will in the future bear a randomised, unique serial number which is encrypted in a two-dimensional barcode (data matrix code) along with the product code, batch number, and expiry date. This will be applied to the packaging by the pharmaceutical industry and stored in a database accessible by pharmaceutical wholesalers and persons authorised or entitled to supply medicinal products to the public (public pharmacies, hospital pharmacies, and dispensing doctors).

A repositories system must be set up for this operation. The delegated regulation provides that the system is established by the pharmaceutical manufacturers and marketing authorisation holders with the involvement of the other stakeholders (e.g., wholesalers and pharmacists). The EMVO (European Medicines Verification Organisation), an organisation founded by the European associations, operates the so-called „European Hub", in which all drug data must be recorded by the industry. There they are allocated to the respective national systems.

In Austria, Pharmig (Association of the Austrian Pharmaceutical Industry), Österreichischer Generikaverband (Austrian Generics Association), PHAGO (Austrian Association of Full-Line Pharmaceutical Wholesalers), and Österreichische Apothekerkammer (Austrian Chamber of Pharmacists) have jointly founded AMVO, the Austrian Medicines Verification Organisation. It is responsible for the governance of the drug verification system and ensuring that all relevant stakeholders participate in the system in time before its launch in 2019. At the same time, the members of the AMVO undertake to jointly cooperate in the investigation and elucidation of suspected cases of falsifying in the future. The Austrian Medical Chamber has also been a member of the AMVO since August 2017.

For the technical operation of the Austrian repositories system AMVO has founded its own operating company, AMVS GmbH (Austrian Medicines Verification System). In order to fulfil their legal obligations all stakeholders have to get linked up to the system operated by AMVS GmbH.

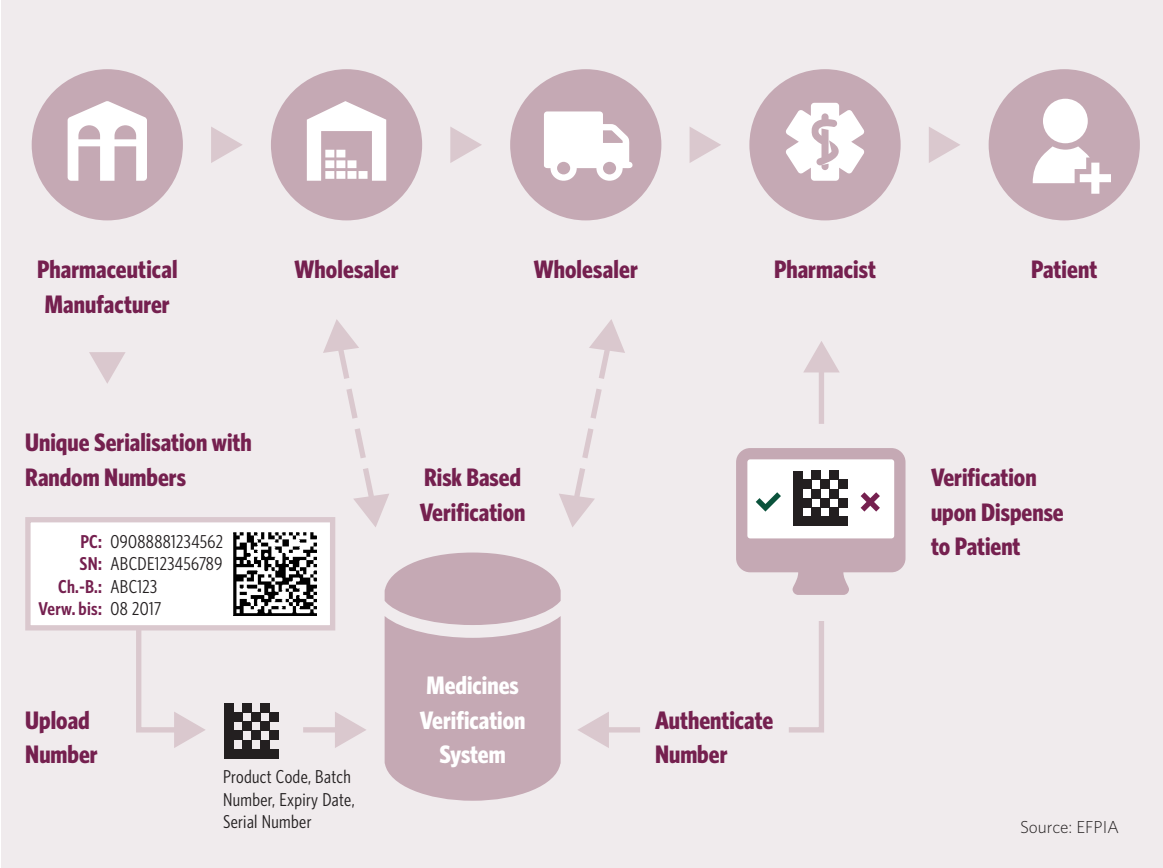

Image 1: System of drug verification in the supply chain

2 Coding of Medicinal Products Requiring Verification

2.1 Preliminary remarks

This document specifies the requirements for the coding of medicinal products requiring verification on the Austrian market.

It has been coordinated and approved by members of AMVO.

Should changes or enhancements to the content of this document become necessary in the course of the implementation of the verification of medicinal products in Austria, these will be implemented by the members of AMVO.

2.2 General information on coding

According to Article 4 lit. (b) of the delegated regulation the unique identifier shall include the following data elements:

- Product code
- Serial number
- Batch number
- Expiry date

The national cost reimbursement number, also referred to in Article 4, for medicinal products intended for the Austrian market is already included in the product code in the form of the pharmaceutical central number and therefore, according to Article 4 lit. (e) of the delegated regulation no longer needs to be repeated in the individual identification feature.

Coding is implemented in the data matrix code (DMC) according to ISO / IEC 16022 and the data structure and syntax according to ISO / IEC 15418 as well as ISO / IEC 15434.

This fulfils the requirements of Article 5 of the delegated regulation „carrier of the unique identifier“ and the data elements can be read by machines.

A unique product code applicable throughout all of Europe is needed to meet the requirements of Article 4.d). For medicinal products marketable in Austria, the product code is to be displayed in the format of the National Trade Item Number (NTIN). This is generated, as described under point 2.3, from the pharmaceutical central number (Pharmazentralnummer, PZN).

2.3 Codes and data on pharmaceutical packagings

The coding of the pharmaceutical central number in the EAN-13 code shall be retained on all commercial packagings until further notice.

In addition, in the case of medicinal products requiring verification, the data matrix code must be applied no later than by February 2019. Relevant here is the date by which the product is placed on the market.

As from February 2019 the EAN-13 code for medicinal products requiring verification can be omitted.

For all other products the application is optional. In addition to the NTIN, further data may be included in the data matrix code. However, serial numbers are not permitted for medicinal products not requiring verification.

	EAN-13	Data Matrix Code			
	NTIN (13 digits)	NTIN (14 digits)	Serial number	Batch number	Expiry date
Medicinal products requiring verification	x	x	x	x	x
Medicinal products not requiring verification	x	x	Not permitted	Optional	Optional

Image 2: Variants of the coding of medicinal product packagings

2.4 Generating of the National Trade Item Number (NTIN) from pharmaceutical central number and EAN-13 in Austria

ARGE Pharma who holds a seat in the Fachverband der chemischen Industrie Österreichs (FCIO) (Association of the Austrian Chemical Industry) will continue to be responsible for issuing the pharmaceutical central number (PZN) and therefore the EAN-13.
Six digits of the PZN are for identifying specific items whereas the seventh digit serves as check digit.

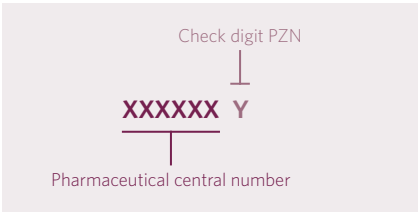

Image 3: Structure of the pharmaceutical central number

The EAN-13 code (basis for the 1D barcode) used to date for identification purposes consists of a total of exactly 13 digits, with two digits for the country code of Austria (90), the next 4 digits for the Arge Pharma identifier (8888) and the following 6 digits representing the first 6 digits of the pharmaceutical central number. The last digit is the check digit specific to the EAN-13 code.

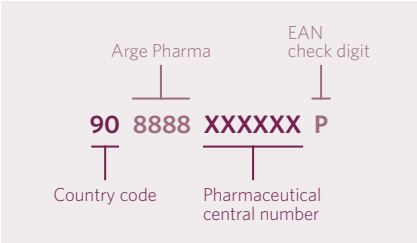

Image 4: Generating of the EAN-13 Codes from the pharmaceutical central number

By prefixing a leading „0“, the EAN-13 code is converted to the 14-digit format of the NTIN required for use in the data matrix code. The check digit does not change compared to EAN-13.

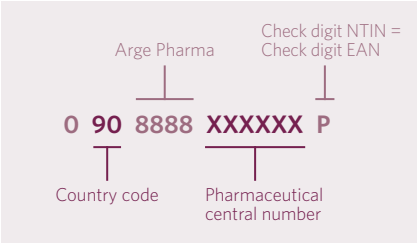

Image 5: Generating the NTIN from the EAN-13 code

Note: The leading „0“ in this context and for further processing in the Austrian repositories system should not be equated with the indicator of the GS1 specifications which characterises packaging hierarchies.

3 Data Content of the Data Matrix Code

3.1 Data identifier and contents

The data identifiers used* are described below.

- **Product code**
  Application Identifier (AI): „01“
  For product identification, the product code is used in the form of the National Trade Item Number (NTIN). 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.

* according to the delegated Regulation Article5 paragraph 4: Standard ISO / IEC 15418 and „General GS1 Specifications“

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 FNC1 separator.

Image 6: Overview of the data elements in the data matrix code

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.

Should further data identifiers be used for joint use for the market participants, AMVO will also include these in the coding rules and clearly describe their use.

3.2 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 Austria, is to be shown as the product code for multi-market packs marketable in Austria. The Austrian 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 Austria) 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 Apothekerverlag together with the pharmaceutical central number in order to ensure a linking of the numbers in the Warenverzeichnis.

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

Image 7: Data elements in the data matrix code of multi-market packs

3.3 Data elements in human readable text

In future, pharmaceutical manufacturers, in addition to the batch name and the expiry date, must display the product code and the serial number on the packaging in a format readable by humans (plain text).

For readability, the Austrian Labelling Ordinance (Kennzeichnungs VO) as well as the „Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use“ (EU Readability Guideline) must be observed.

Data content	Abbreviation human readable text
Product code	“PC: “
Serial number	”SN: ”
Batch number*	“Ch.-B.: “
Expiry date	“Verwendbar bis “ oder “Verw. bis “

* as well as other possible designations according to the Austrian Labelling Ordinance

Image 8: Overview of plain text elements

Exceptions according to the delegated Regulation Article 7 paragraph 2:
If the sum of the two longest dimensions of the package is 10 centimetres or less, the plain text display of the product code and of the serial number can be omitted.

The AI can be included in the human readable text. If the human readable text information is not identical with the information contained in the data matrix code, the specification of the AI in the human readable text should be omitted.

E.g.: Expiry date in plain text: 11 2023
Expiry date coded: 231130 or 231100

PC: 09088881234562
SN: ABCDE123456789
Ch.-B.: ABC123
Verw. bis: 08 2017

Image 9: Data matrix code with human readable text elements

4 Literature (in the currently valid version)

4.1 Legal texts, national

Medicinal Products Act (Arzneimittelgesetz, AMG)
Medicinal Products Site Regulation (Arzneimittelbetriebsordnung, AMBO)
Labelling Ordinance (Kennzeichnungs-VO)

4.2 Legal texts EU

Directive 2001/83/EC of the European Parliament and of the Council relating to medicinal products for human use.

Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.

Guideline on the readability of the labelling and package leaflet of medicinal products for human use.

4.3 Standards quoted in the delegated regulation

ISO/IEC 15415: Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15418: Information technology -- Automatic identification and data capture techniques -- GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance

ISO/IEC 15434 Information technology -- Automatic identification and data capture techniques -- Syntax for high-capacity ADC media

ISO/IEC 15459-3: Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 3: Common rules

ISO/IEC 15459-4: Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 4: Individual products and product packages

ISO/IEC 16022: Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

4.4 Specifications

General GS1 specifications

5 Contact details

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