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

# Content

# 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 packages ("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 shall apply these rules since February 09th 2019. As from this date forward, no products affected by the Falsified Medicines Directive shall be placed on the market without bearing 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 package shall bear a randomised, unique serial number which is encrypted in a two-dimensional barcode (GS1 Data Matrix code) along with the product code, batch number, and expiry date. This shall be applied to the package 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 self-dispensing doctors).

The delegated regulation provides that a repository system must be set up 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 Austrian drug verification system and ensuring that all relevant stakeholders may participate in the system. 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 repository 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 (AMVSystem) operated by AMVS GmbH.
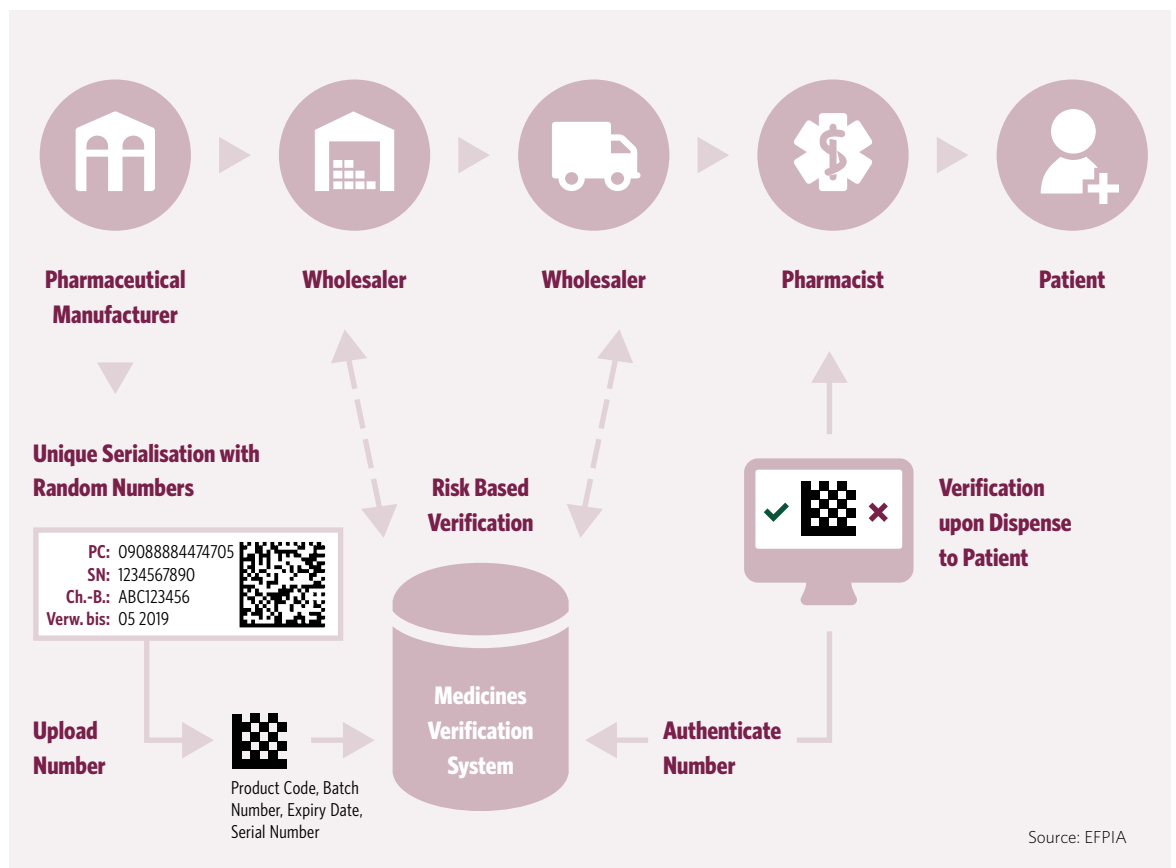


**Image 1:** System of drug verification in the supply chain

# 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. Medicinal products requiring verification are medicinal products for human use (apart from those listed in 2016/161, annex 1) as well as non-prescription medicines for human use listed in 2016/161, annex 2. These rules also apply to free samples.

The document 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 GS1 Data Matrix code (DMC) ECC 200 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 2.5, from the pharmaceutical central number (Pharmazentralnummer, PZN).

**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 repository system. This applies to single market- as well as multi market packages (see also appendix 4 of the EMVS Master Data Guide issued by EMVO).**

## 2.3 Free samples

The rules for medicinal products requiring verification (see chapter 2.1.) also apply to free samples (refer to article 96 of directive 2001/83 and article 58 of the Austrian Arzneimittelgesetz). Thus, free samples also require a pharmaceutical central number (PZN). In addition, free samples must bear the permanent and clearly readable advice "Unverkäufliches Ärztemuster" (free sample – not to be sold) according to article 58 of the Austrian Arzneimittelgesetz. These rules apply also to medicinal products which are solely intended to be dispensed as free samples. It is not envisaged to provide 2 different PZNs for the same package size of a medicinal product only for the purpose of distinguishing between a free sample and a package intended to be sold.

## 2.4 Codes and data on pharmaceutical packages

The coding of the pharmaceutical central number in the EAN-13 barcode may be retained on all commercial packages until further notice.
In addition, in the case of medicinal products requiring verification, the GS1 Data Matrix code shall be applied since February 09th 2019.

For all other products the application is optional. In addition to the NTIN, further data may be included in the GS1 Data Matrix code. However, serial numbers are not permitted for medicinal products not requiring verification.

| | EAN-13 | GS1 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 packages

## 2.5 Generating the National Trade Item Number (NTIN) from the pharmaceutical central number 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 barcode. Six digits of the PZN are for identifying specific items whereas the seventh digit serves as check digit.
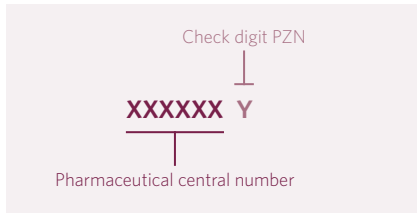
**Image 3:** Structure of the pharmaceutical central number

The NTIN (coded in an EAN-13 barcode) is used for identification purposes and 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.
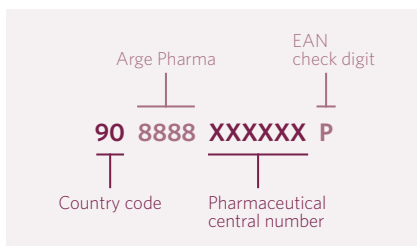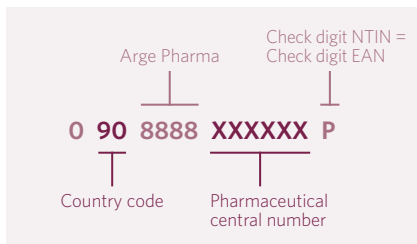


**Image 4:** NTIN-structure for the EAN-13 barcode based on the pharmaceutical central number



**Image 5:** Example of an EAN-13 barcode

By prefixing a "leading 0", the EAN-13 code is converted to the 14-digit format of the NTIN required for use in the GS1 Data Matrix code. The check digit does not change compared to EAN-13.



**Image 6:** NTIN-structure with "leading 0" for the GS1 Data Matrix code, based on the EAN-13 code



**Image 7:** Example of a GS1 Data Matrix code

**Note:** The "leading 0" in this context and for further processing in the Austrian repository system should not be equated with the indicator of the GS1 specifications which characterises package hierarchies.

# 3 Data Content of the GS1 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 GS1 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 package 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 GS1 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 GS1 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)
  – To comply with EMVO requirements (see letter of announcement 0062 of February 28th 2019), there shall be no interpretation of the expiry date format by software systems. It shall be ensured by technical means, that the expiry date information sent to the NMVS remains as encoded in the Data Matrix Code. If no proof can be provided, that the above mentioned requirements are met (also in the course of data transfer between software systems), it's recommended not to use "00" for indicating the last day of the month.

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

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 | – | max. 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, unless the data element is not located at the end of the code.

**Image 8:** Overview of the data elements in the GS1 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.
- Its recommended not to use any special characters as the risk of misinterpretation is very high. An incorrectly interpreted code means that a package cannot be verified and thus cannot be sold. The special characters with the decimal ASCII code values excluded from the technical processing are 32 (Space), 35 (#), 36 ($), 47 (/), 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.

The order of the data elements is arbitrary.

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 repository systems together with the corresponding serial number and the other information. When the medicinal product is sold, the status of the relevant packages is again synchronised in all national repository 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 repository system. These supplements are also to be included in the GS1 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 GS1 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, 714 ... Portugal).

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. Provided that no other country specific numbers are coded into the 2D Data Matrix, NTINs of other countries (e.g. Germany) may be used as product code, if they comply with GS1-specifications.

**However, using a GTIN or NTIN of another country does not discharge from the liability to upload the Austrian pharmaceutical central number (PZN) to the EMVS (see chapter 2.2.).**

**Note:** When using a product code which differs from the Austrian NTIN, it is the responsibility of the company to promptly report this number together with the PZN to the Apothekerverlag in order to ensure a linking of these numbers in the Warenverzeichnis. It should also be noted that product code and PZN are to be reported independently to those trading partners as well as logistics service providers who do not have access to the national repository system and thus cannot guarantee an automated link between product code and the PZN.

**The absence of the link between the product code and the pharmaceutical central number (PZN) can lead to the fact that the product code and the PZN 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) or alternative product code in compliance with GS1-specifications | | |
| 21 | Serial number | | |
| 10 | Batch number | | |
| 17 | Expiry date | | |
| | | 7xx | NHRN |

**Image 9:** Data elements in the GS1 Data Matrix code of multi-market packs

## 3.3   Data elements in human readable text

Since February 09th 2019, pharmaceutical manufacturers, in addition to the batch name and the expiry date, must display the product code and the serial number on the package 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.", "Lot." |
| Expiry date * | "Verw. bis", "EXP" |

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

**Image 10:** 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 is not identical with the information contained in the GS1 Data Matrix code, the specification of the AI in the human readable text shall be omitted.
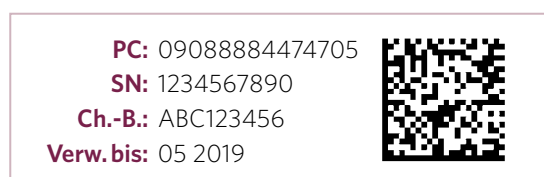
**PC:** 09088884474705
**SN:** 1234567890
**Ch.-B.:** ABC123456
**Verw. bis:** 05 2019

**Image 11:** GS1 Data Matrix code with human readable text elements

# 4 Literature <span style="font-size:small">(in the currently valid version)</span>

## 4.1 Legal texts, national

Medicinal Products Act (Arzneimittelgesetz, AMG)
Medicinal Products Site Regulation (Arzneimittelbetriebsordnung, AMBO)
Labelling Ordinance (Verordnung über die Kennzeichnung von
Arzneimittelspezialitäten/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 General GS1 specifications

## 4.5 Other Sources

EMVO – European Medicines Verification Organisation
emvo-medicines.eu

EC website related to the Falsified Medicines Directive
ec.europa.eu/health/human-use/falsified_medicines_en

# 5 Contact details

## 5.1 Members of AMVO

**Pharmig – Association of the Austrian Pharmaceutical Industry**
Garnisongasse 4/2/8, 1090 Wien
Tel. +43 1 40 60 290 0
office@pharmig.at
www.pharmig.at

**Austrian Generics Association**
**C/O Gaisberg Consulting GmbH**
Lugeck 4, 1010 Wien
Tel. +43 650 544 92 92
office@generikaverband.at
www.generikaverband.at

**PHAGO – Austrian Association of Full-Line Pharmaceutical Wholesalers**
Am Belvedere 8, 1100 Wien
Tel. +43 1 71 72 8 794
office@phago.at
www.phago.at

**Austrian Chamber of Pharmacists**
Spitalgasse 31, Postfach 87, 1091 Wien
Tel. +43 1 404 14 100
info@apothekerkammer.at
www.apotheker.or.at

**Austrian Medical Chamber**
Weihburggasse 10-12, 1010 Wien
Tel. +43 1 51406 0
post@aerztekammer.at
www.aerztekammer.at

## 5.2    AMVO and AMVS

**AMVO – Austrian Medicines Verification Organisation**
(Austrian Medicines Verification Organisation)
Garnisongasse 4/1/5, 1090 Wien
Tel. +43 1 9969499 0
office@amvo-medicines.at
www.amvo-medicines.at

**AMVS – Austrian Medicines Verification System GmbH**
Garnisongasse 4/1/5, 1090 Wien
Tel. +43 1 9969499 0
office@amvs-medicines.at
www.amvs-medicines.at

## 5.3    Further contacts

**ARGE Pharma**
Fachverband der Chemischen Industrie Österreichs – FCIO
Wiedner Hauptstraße 63, 1045 Wien
Tel. +43 5 90 900 3340
office@fcio.at
argepharma.fcio.at

**DATACARE Datenpflege des Pharmagroßhandels GesmbH**
Haidestraße 4 – Tür 1016, 1110 Wien
Tel. +43 1- 40104 1955
info@datacare.at
www.datacare.at

**GS1 Austria GmbH**
Brahmsplatz 3, 1040 Wien
Tel. +43 1 505 86 01
office@gs1.at
www.gs1.at

**Österreichische Apotheker-Verlagsgesellschaft m.b.H.**
Spitalgasse 31A, 1090 Wien
Tel. +43 1 402 35 88
direktion@apoverlag.at
www.apoverlag.at

**Change Index**

| Document | Version | Valid from | Change reason |
|---|---|---|---|
| AMVO-001- | 1.0 | October 12th 2017 | New creation |
| | 2.0 | March 8th 2018 | **Whole document**<br>• "GS1" added to "Data Matrix code"<br>• "barcode" added to "EAN-13" where required<br><br>**Chapter 2.1.**<br>• Definition of "medicinal products requiring verification" described in more detail<br><br>**Chapter 2.2.**<br>• "ECC 200" added to "Data Matrix code"<br>• mandatory requirement added for single market packages to upload pharmaceutical central number (PZN) as "national code" via EMVS Master Data Elements to the EU-hub<br><br>**Chapter 2.3.**<br>new creation (free samples)<br><br>**Chapter 2.5.**<br>• Title changed<br>• Text regarding "NTIN" changed<br>• Description of images changed<br>• Examples added for EAN-13 barcode and GS1 Data Matrix code<br><br>**Chapter 3.1.**<br>• Definition of character length for serial number changed in table<br>• Footnote of table amended<br>• Space character (ASCII 32) excluded from the technical processing<br>• Text changed regarding the order of the data elements<br><br>**Chapter 3.2.**<br>• National Healthcare Reimbursement Number added for Portugal<br>• Paragraph regarding PZN and "national code" removed<br><br>**Chapter 3.3.**<br>• Text changed regarding AI and human readable text<br><br>**Chapter 4.1.**<br>• complete name of the labelling ordinance added<br><br>**Chapter 4.5.**<br>new creation (other sources)<br><br>**Chapter 5.3.**<br>• Phone number of "DATACARE Datenpflege des Pharmagroßhandels GesmbH" corrected |
| | 3.0 | March 7th 2019 | Document code "AMVO-001" assigned<br><br>**Chapter 1.**<br>• Introduction adapted as Delegated Regulation 2016/161 EU became effective on February 09th 2019<br>• Term "AMVSystem" introduced<br><br>**Chapter 2.2.**<br>• Reference to Appendix 4 of EMVS Master Data Guide added<br><br>**Chapter 2.4.**<br>• Requirements regarding the EAN-13 (bar-)code adapted<br>• Text adapted as Delegated Regulation 2016/161 EU became effective on February 09th 2019<br><br>**Chapter 3.1.**<br>• Requirements regarding the expiry date adapted with respect to EMVO requirements<br>• Recommendation regarding the usage of special characters added<br><br>**Chapter 3.2.**<br>• Requirements regarding the usage of NTINs of another country added<br><br>**Chapter 3.3.**<br>• Requirements regarding the human readable information adapted based on the revision of the Austrian Labelling Ordinance<br><br>**Chapter 5.1.**<br>• contact detail updated<br><br>**Imprint updated** |