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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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 DataMatrix) 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. The Austrian Medical Chamber has also been a member of the AMVO since August 2017. 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.

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.

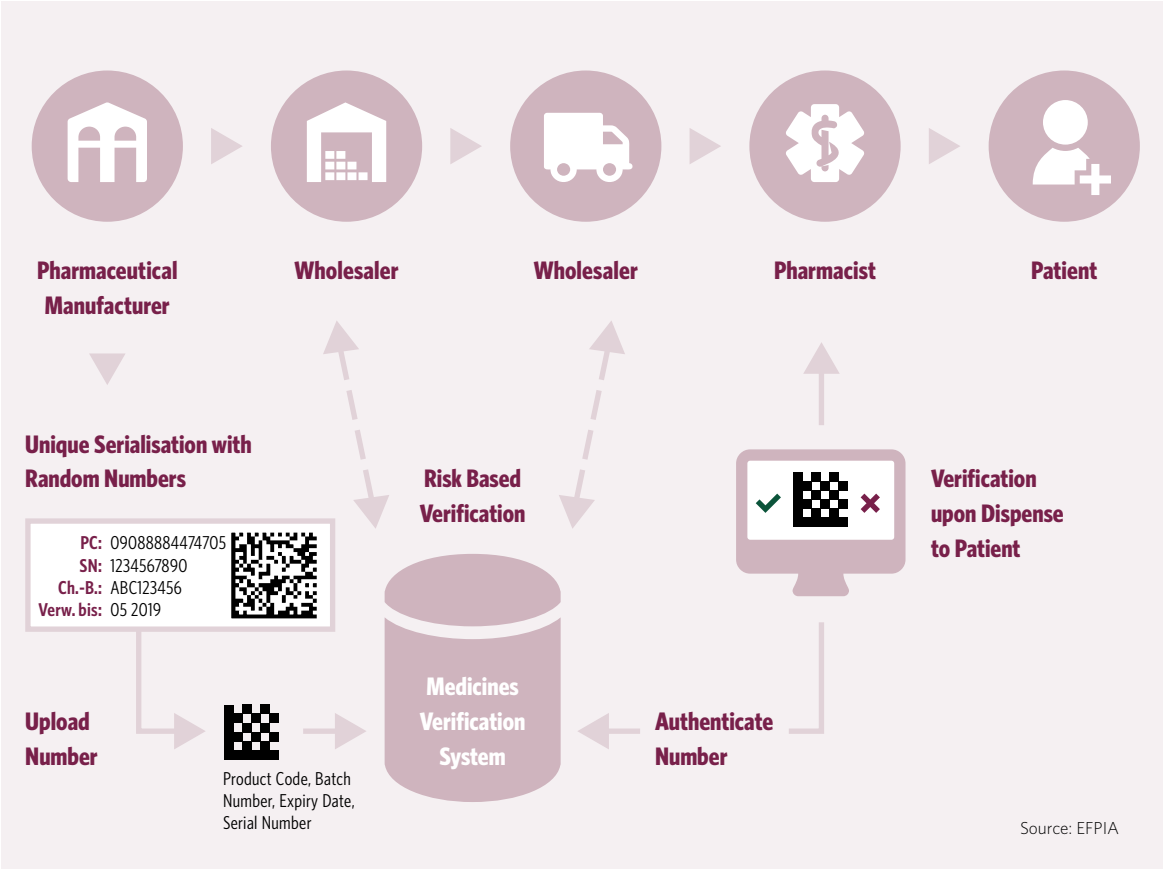

Image 1: System of drug verification in the supply chain

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 Delegated Regulation 2016/161 (EU), annex 1) as well as non-prescription medicines for human use listed in Delegated Regulation 2016/161 (EU), 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 DataMatrix (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 Singlemarket-Packages 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). For Multimarket-packages, a GTIN may be used (see 3.2.)

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 Singlemarket-Packages as well as Multimarket-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, AMG). 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 medicinal products requiring verification

Since February 09th 2019, the GS1 DataMatrix must be applied on all medicinal products requiring verification. The EAN-13 barcode is no longer required. It is therefore recommended not to apply it any more or to remove it in the course of planned packaging material changes.

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

	EAN-13 Barcode	**GS1 DataMatrix**			
	NTIN (13 digits)	"0" + NTIN (13 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) is responsible for issuing the pharmaceutical central number (PZN) and therefore the NTIN.

Six digits of the PZN are for identifying specific items whereas the seventh digit serves as check digit.

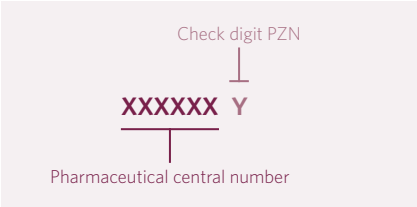

Image 3: Structure of the pharmaceutical central number

The NTIN (encoded in an EAN-13 barcode) used up to now for identification purposes consists of a total of exactly 13 digits. The first 6 digits represent the GS1 base number of ARGE Pharma (908888), the following 6 digits represent the first 6 digits of the pharmaceutical central number. The last digit represents the check digit.

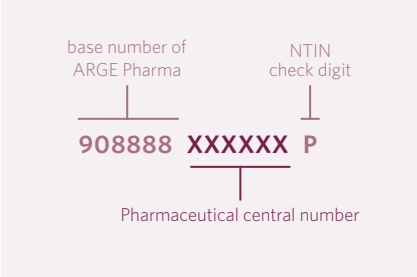

Image 4: NTIN-structure based on the pharmaceutical central number

By prefixing a leading "0", the 13-digit NTIN is converted to the 14-digit format required for the GS1 DataMatrix. The check digit does not change.

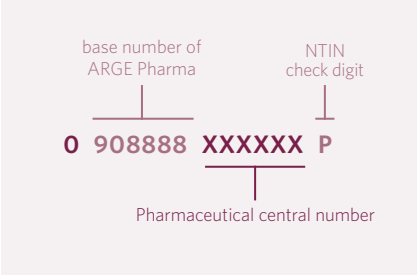

Image 5: NTIN-structure with leading "0" specifically for the GS1 DataMatrix

Image 6: Example of a GS1 DataMatrix

Note: The leading "0" in this context is a fill digit for the 14-digit data field in the GS1 DataMatrix. The use of the digits 1 to 9 (indicator – see General GS1 Specifications chapter 2.1.7.) at this point is not permitted, as the formation of package hierarchies with NTINs is not possible.

3 Data Content of the GS1 DataMatrix

3.1 Data identifier and contents for Singlemarket-Packages

The data identifiers used[1] 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 DataMatrix, 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 shall be unique for each medicinal product package for a period of at least one year from the expiry date of the package or at least five years from placing the medicinal product on the market (whichever is longer) according to Article 4 lit. (d) of the Delegated Regulation 2016/161 (EU).
  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 DataMatrix.
- **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 DataMatrix.
  The expiry date has 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 (AMVSystem) remains as encoded in the GS1 DataMatrix.

[1] according to the Delegated Regulation Article 5 paragraph 4: Standard ISO/IEC 15418 and "General GS1 Specifications"

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.

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	Datum	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 7: Overview of the data elements in the GS1 DataMatrix

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

- The character string should contain only uppercase letters of the Latin alphabet.
- The use of the letters "Y" and "Z" should be avoided as these are interchanged in German and English keyboards. In general, the use of special characters (e.g. "/", ".", "_", "-") should be avoided. 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 I and O.
- The special characters with the decimal ASCII code values excluded from the technical processing are 32 (Space), 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 full stop ".". The use of the full stop 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.

It is strongly advised to follow the recommendations described above. Failure to do so may lead to misinterpretation, which in the worst case will prevent the affected package from being dispensed and this package may then be treated as a potential counterfeit.

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 Multimarket-Packages

Multimarket-Packages are commercial packages 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 Multimarket-Packages 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 Multimarket-Packages 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 DataMatrix 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 DataMatrix 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 Multimarket-Packages 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.).**

The most important part of a GS1 identification number is the GS1 base number. The GS1 base number is assigned by a national GS1 member organisation (e.g. GS1 Austria), at GS1 Austria these numbers consist of 7 and 9 digits.

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 TradeItem Number (GTIN) or alternative product code in compliance with GS1 specifications		
21	Serial number		
10	Batch number		
17	Expiry date		
		7xx	NHRN

Image 8: Data elements in the GS1 DataMatrix of Multimarket-Packages

Option 1:
Productcode GTIN
Elements in the
GS1 DataMatrix: 5

PC: 09099999000970
SN: A1B2C3D4E5
Lot.: ABC123
EXP: 12 2022
NHRN: 12345678

Option 2:
Productcode NTIN-DE
Elements in the
GS1 DataMatrix: 4

PC: 04150123456782
SN: A1B2C3D4E5
Lot.: ABC123
EXP: 12 2022

Image 9: Variants of coding a Multimarket-Package for the Austrian and German market. PZN-AT = 4474700, PZN-DE = 12345678

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 AI is included in the human readable text, the information and data format must match the encrypted data in the GS1 DataMatrix.

PC: 09088884474705
SN: 1234567890
Ch.-B.: ABC123456
Verw. bis: 05 2019

Abbildung 11: GS1 DataMatrix with human readable text elements

4 Additional recommendations based on practical experience

QR-Codes on the package

The use of QR-Codes on the packages should be avoided where possible to avoid problems during dispensing. However, if a QR-Code is required, it should not be applied in proximity of the GS1 DataMatrix. Please refer to the Q&A document of the European Commission, chapter 2.12.

Improving the barcode quality

To avoid errors during scanning due to poor quality of the GS1 DataMatrix which may result in problems with dispensing the package, we recommend "Broschüre Strichcodequalität – Lesbarkeit von Strichcodes" ("Brochure Barcode Quality – Readability of Barcodes") by GS1 Austria.

5 Literature (in the currently valid version)

5.1 Legal texts, national

Medicinal Products Act (Arzneimittelgesetz, AMG)

Medicinal Products Site Regulation (Arzneimittelbetriebsordnung, AMBO)

Labelling Ordinance (Verordnung über die Kennzeichnung von Arzneimittelspezialitäten/Kennzeichnungs-VO)

5.2 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 forhuman use.

5.3 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 – bar code symbology specification

5.4 GS1

General GS1 specifications

Broschüre Strichcodequalität – Lesbarkeit von Strichcodes

5.5 Other Sources

EMVO – European Medicines Verification Organisation
https://emvo-medicines.eu

Webseite der EU-Kommission betreffend Umsetzung d. Fälschungsrichtlinie
https://ec.europa.eu/health/human-use/falsified_medicines_en

6 Contact details

6.1 Members of AMVO

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6.3 Further contacts

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7 Change Index

Document AMVO-001- **Version** 1.0 **Valid from** October 12th 2017
Change reason

New creation

Document AMVO-001- **Version** 2.0 **Valid from** March 8th 2018
Change reason

Whole document
- "GS1" added to "Data Matrix code"
- "barcode" added to "EAN-13" where required

Chapter 2.1.
- Definition of "medicinal products requiring verification" described in more detail

Chapter 2.2.
- "ECC 200" added to "Data Matrix code"
- 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

Chapter 2.3.
- new creation (free samples)

Chapter 2.5.
- Title changed
- Text regarding "NTIN" changed
- Description of images changed
- Examples added for EAN-13 barcode and GS1 Data Matrix code

Chapter 3.1.
- Definition of character length for serial number changed in table
- Footnote of table amended
- Space character (ASCII 32) excluded from the technical processing
- Text changed regarding the order of the data elements

Chapter 3.2.
- National Healthcare Reimbursement Number added for Portugal
- Paragraph regarding PZN and "national code" removed

Chapter 3.3.
- Text changed regarding AI and human readable text

Chapter 4.1.
- complete name of the labelling ordinance added

Chapter 4.5.
- new creation (other sources)

Chapter 5.3.
- Phone number of "DATACARE Datenpflege des Pharmagroßhandels GesmbH" corrected

Document AMVO-001- **Version** 3.0 **Valid from** March 7th 2019
Change reason

Document code "AMVO-001" assigned

Chapter 1.
- Introduction adapted as Delegated Regulation 2016/161 EU became effective on February 09th 2019
- Term "AMVSystem" introduced

Chapter 2.2.
- Reference to Appendix 4 of EMVS Master Data Guide added

Chapter 2.4.
- Requirements regarding the EAN-13 (bar-)code adapted
- Text adapted as Delegated Regulation 2016/161 EU became effective on February 09th 2019

Chapter 3.1.
- Requirements regarding the expiry date adapted with respect to EMVO requirements
- Recommendation regarding the usage of special characters added

Chapter 3.2.
- Requirements regarding the usage of NTINs of another country added

Chapter 3.3.
- Requirements regarding the human readable information adapted based on the revision of the Austrian Labelling Ordinance

Chapter 5.1.
- contact detail updated

Imprint updated

Document AMVO-001- **Version** 4.0 **Valid from** November 12th 2020
Change reason

Entire Document:
- minor revision of the text

Chapter 2.2:
- Clarification concerning Singlemarket- and Multimarket-Packages

Chapter 2.4:
- Recommendation in line with Q&A of the European Commission (v.17), 2.3. to no longer affix or to remove the EAN-13 (bar) code

Chapter 2.5:
- Clarification with regard to the NTIN
- initial image 5 (example of an EAN-13 barcode) removed

Chapter 3.1:
- Adjustment: only Singlemarket-Packages mentioned. All specifications for Multimarket-Packages can be seen in chapter 3.2.
- Recommendations for the character set based on Q&A of the European Commission (v.17), 2.23 adapted
- character "/" (ASCII 47) removed according to GS1 specifications
- urgent advice to comply with the recommendations modified

Chapter 3.2:
- Explanation of the GS1 base number added
- new image (9) added: example for a Multimarket-Package for the Austrian and German market

Chapter 3.3:
- Clarification regarding the Application Identifier (AI) in the human readable text

Chapter 4 (NEW):
- additional recommendations based on practical experiences

Chapter 5.4:
- Chapter renamed "GS1"
- „Broschüre Strichcodequalität – Lesbarkeit von Strichcodes" added

Chapter 6.1:
- phone number of the Austrian Medical Chamber updated

Chapter 6.2:
- postal address of AMVS GmbH updated

Chapter 6.3:
- postal address and phone number of DATACARE GmbH updated
- new logo of Österreichische Apotheker-Verlagsgesellschaft m.b.H added

Disclaimer: AMVO assumes no liability for the correctness and completeness of the contents. In case of doubt, the German version shall prevail

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