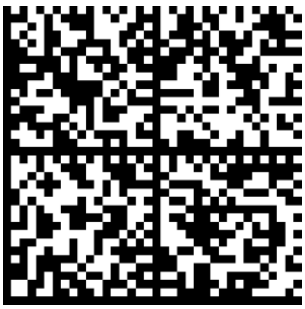
securPharm Coding Rules

(as of 10th September 2025, MB)

Applicable to medicinal products subject to verification on the German market in accordance with EU Directive 2011/62/EU and Delegated Regulation (EU) 2016/161.



- Coding using Data Matrix Code with the product codes PPN or NTIN and the additional data elements.
- Automatic identification of medicinal product packaging in the pharmaceutical supply chain.

Imprint

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The contents have been compiled with the utmost care. Should you discover any errors or find that any content is missing, please notify us at info@securpharm.de

Note: The publisher points out that the present coding rules (hereinafter referred to as coding rules) have been compiled to the best of our knowledge based on the current state of knowledge at the time of publication.

However, due to legal and technical issues and any necessary adjustments to social security or other regulations, changes and adjustments cannot be ruled out in the future and must therefore be expressly reserved.

Further information about securPharm can be found at https://www.securpharm.de

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1 Introduction

In accordance with Article 54a(1) of Directive 2001/83/EC, as amended by the EU Falsified Medicines Directive 2011/62/EU (**FMD**), prescription-only medicinal products must be labelled with safety features that enable, in particular, the authenticity of the product to be verified and individual packs to be identified. To this end, each pack subject to verification must be provided with a unique identifier (UI).

The characteristics and technical specifications of the safety features were laid down in Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 (**DVO**) and published in the Official Journal of the European Union on 9 February 2016. Since 9 February 2019, operators in the legal pharmaceutical supply chain have been required to comply with the provisions of the Delegated Regulation.

The identification and authenticity of medicinal products is ensured by end-to-end verification of all medicinal products subject to verification within the European Medicines Verification System (**EMVS**). The German component of the anti-counterfeiting system is the **securPharm system.** This is set up and managed by securPharm e.V. in accordance with Article 31(1) of the DVO.[1]

1.1 Structure of the German verification system

For data protection reasons, the securPharm system is operated in two separate subsystems:

- the database system for the pharmaceutical industry, also known as **the MAH System**, and
- the pharmacy system, also known as **the Concentrator**.

The MAH System is operated by ACS PharmaProtect GmbH (**ACS**)[2] and serves as a data repository for the unique identifiers (**UI**). The pharmacy system is the access point for verifying entities (including public pharmacies, pharmaceutical wholesalers and hospital pharmacies) to the securPharm system. As a concentrator, it checks and anonymises the verification requests and forwards them to the PU system. The concentrator is operated by Netzgesellschaft Deutscher Apotheker mbH (**NGDA**)[3] . This separation of systems and the anonymisation of requests in the concentrator ensure complete mutual confidentiality of data.

[1] https://www.securpharm.de
[2] https://www.pharmaprotect.de
[3] https://www.ngda.de

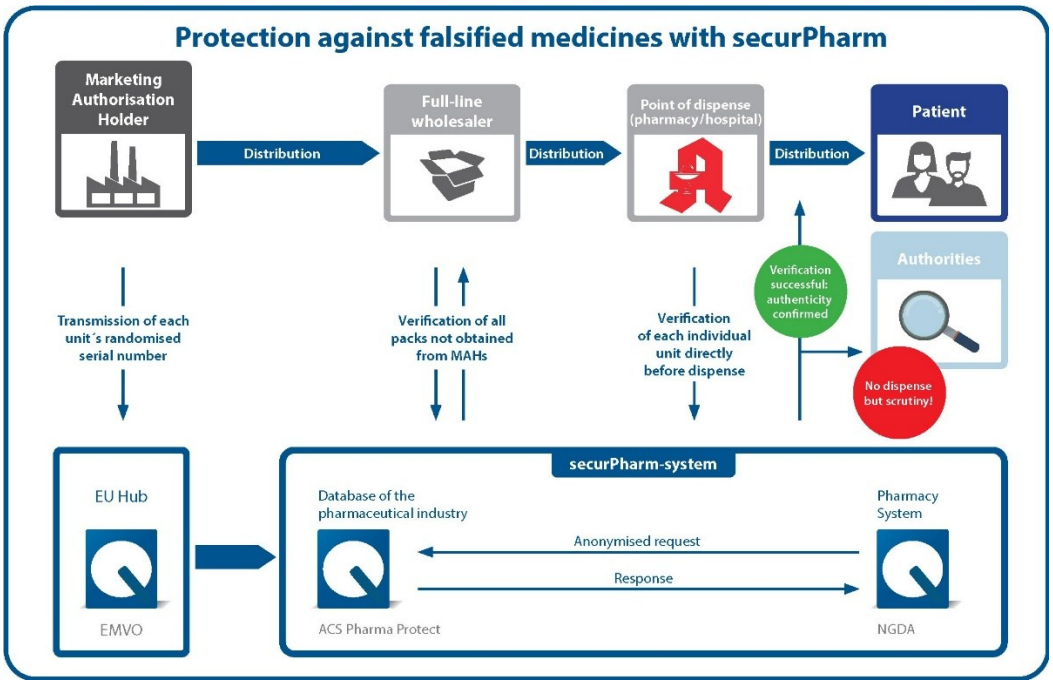


Figure 1: Illustration of the end-to-end verification system

In addition, the securPharm system is embedded as a national verification system (**NMVS**) in the European EMVS network to ensure cross-border patient protection. The EU hub, operated by the European Medicines Verification Organisation (**EMVO**),[4] , ensures data exchange between the member states of the EU, the EEA and Switzerland.

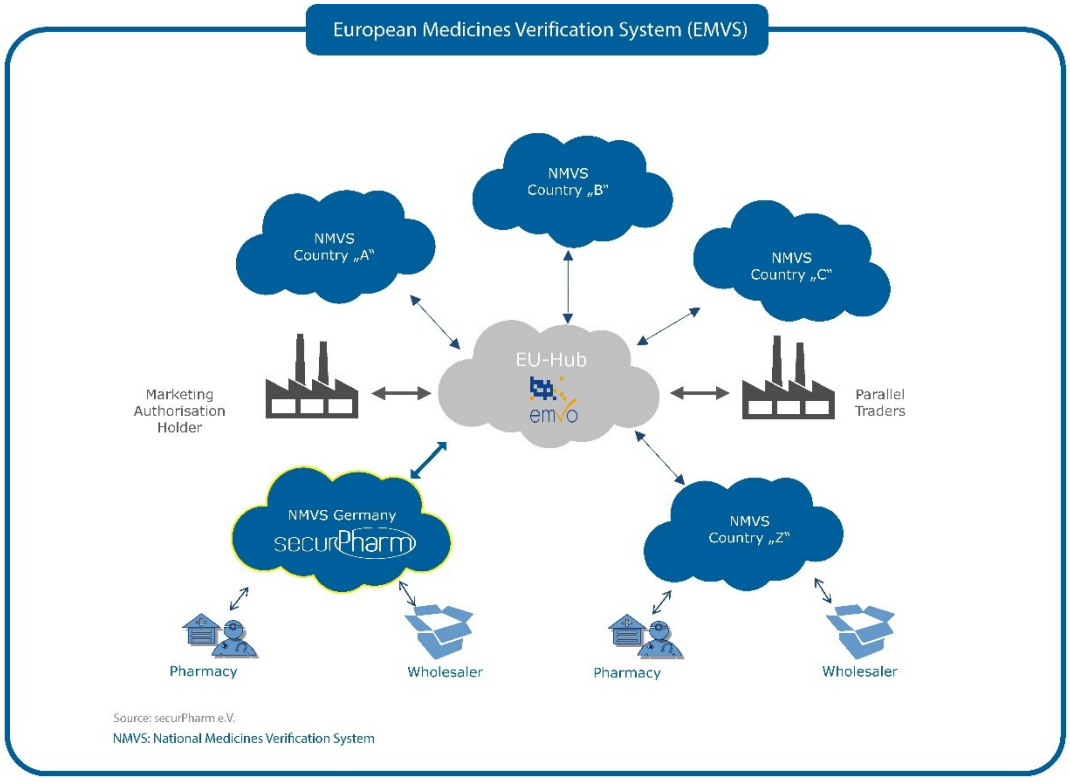


Figure 2 : Overview of the European anti-counterfeiting system aka European Medicines Verification System

[4] https://emvo-medicines.com

1.2 How the German verification system works

Marketing authorisation holders and parallel distributors ensure that their product and packaging-related data is uploaded to the ACS MAH System via the European data router, known as the EU Hub. The EU Hub is operated by the EMVO. It is not possible to upload data directly to the MAH System. Marketing authorisation holders and parallel distributors must ensure that the data is uploaded before the medicinal product is placed on the market and subsequently kept up to date.

Product master data and product data for medicinal products subject to verification for the German market uploaded via the EU Hub are automatically transferred to the MAH System by the EU Hub.

Note: When uploading data via the EU Hub, the requirements of the EMVO Product Master Data Guide in its currently valid version must be observed. The latest information on uploading product master data and product data via the EU Hub can be found on the EMVO website.

Important for medicinal products intended for the German market: In the EMVO master data**,** the PZN must always be entered in the "National Code" field for medicinal products marketed in Germany. This applies equally to Single Market Packs (SMP) and Multi Market Packs (MMP).

The transferred data is stored in the ACS MAH System. The MAH System maintains the interfaces to the EU Hub and the Concentrator. For this reason, marketing authorisation holders and parallel distributors who place medicinal products subject to verification on the German market require a separate cooperation agreement with ACS in addition to a contract with the EMVO.

Note: Further information on the organisational and technical connection to the ACS MAH System can be found at: https://www.pharmaprotect.de

Before a medicine subject to verification is dispensed to the public, the medicine packaging is "verified" by the authorised dispensing body. In order to enable this data comparison with the data uploaded by the medicinal product manufacturer when a medicinal product subject to verification is dispensed, the FMD stipulates that each medicinal product pack must be provided with a **unique identifier**, which must be affixed to the outer packaging in the form of a data matrix code. The data stored in the unique identifier is compared with the data stored in the European Medicines Verification System (EMVS). Verification requests from pharmacies and other entities authorised to dispense medicines are bundled via the concentrator and sent anonymously to the MAH System.

In order to ensure the identification of the unique identifier on the medicinal product packaging, this specification reproduces the requirements of the legislator and supplements them with the necessary technical details (**coding rules**).

2 Scope

The coding rules are to be applied by marketing authorisation holders and parallel distributors or their contracted service providers who affix the Unique Identifier (UI) to the medicinal products in the form of a Data Matrix Code, as well as by the parties responsible for verifying the UI. The latter are primarily pharmacies and wholesalers. Their system suppliers must also observe and implement this specification.

The coding rules describe in detail the coding systems, code contents, code size and print quality, as well as the associated labelling of medicinal product packaging.

The ISO standards applied in the context of coding for counterfeit protection allow users to integrate the data and the Pharmacy Product Number (PPN) or National Trade Item Number (NTIN) system into higher-level standardised systems for transport logistics and aggregation (ISO 15394). See also chapter 4.2 .

Note: The rules set out here may differ in individual points from the current GS1 specifications, but shall take precedence in all cases.

These coding rules **do not** describe the information technology (IT) processes required for verification, nor do they describe the transport logistics and aggregation of trade items.

3 Notes on additional elements and processes

The following subchapters refer to additional elements and processes that are closely related to coding.

3.1 Rules for serial numbers

According to Article 4 of the DVO, the serial number required for verification is a numerical or alphanumeric sequence of no more than 20 characters generated by the manufacturer. To make it as difficult as possible for counterfeiters to guess or reproduce the serial numbers assigned by the manufacturer, these must be generated using a deterministic or non-deterministic randomisation algorithm. The probability of the serial number being derived must be less than 1:10,000 in all cases. In addition, the randomised serial number, in combination with the PZN-based product code, must be unique for each medicinal product pack for a period of at least one year from the expiry date of the pack or at least five years from the date of placing the medicinal product on the market (whichever is longer).

Recommendation: The reuse of serial numbers is a potential source of error and is therefore not recommended.

3.2 Anti-tampering device

3.2.1 ISO 21976:2020 as best practice for tamper-evident packaging

The anti-tampering device is intended to ensure that medicinal product packaging cannot be opened unnoticed before dispensing. Although there are no binding specifications, manufacturers can refer to ISO 21976:2020 "Packaging – Characteristics for verification of tampering with medicinal product packaging". This document specifies the requirements and guidelines for the application, use and control of tamper-evident features on the packaging of medicinal products.

Recommendation: The ISO 21976 standard has proven to be best practice for implementing anti-tampering devices and is recommended for consideration.

3.2.2 Applicability also for non-FMD products

On 11 April 2017, the BfArM and the PEI published a joint announcement stating that the anti-tampering device may also be applied voluntarily to medicinal products that are not affected by the Falsified Medicines Directive:

"[...] For medicinal products for which the anti-tampering device is not mandatory under Article 54a(1) of Directive 2001/83/EC, devices for detecting possible tampering may, however, be applied voluntarily by marketing authorisation holders to protect patients, either now or after the above-mentioned deadline. [...]"

The full text of the announcement can be found on the PEI website, among other places. The announcement can also be found in the Federal Gazette.

3.3 Classification of medicinal products subject to verification

The higher federal authorities PEI and BfArM have classified medicinal products that must bear the safety features in accordance with the DVO in the public section of the AMIce database. Pharmaceutical companies can check the classifications and, if necessary, contact Department 1 at the BfArM by email in the event of discrepancies.

4 Agreements on coding

4.1 General

In accordance with Article 4 of Delegated Regulation (EU) 2016/161 (DVO), the unique identifier (UI) comprises the following data elements:

- Product code
- Serial number
- Batch number,
- Expiry date,
- National number (only for certain multi-market packages).

The coding is carried out in Data Matrix Code (**DMC**) in accordance with ISO/IEC 16022 (see chapter 6.1) and the data structure and syntax in accordance with ISO/IEC 15418 and ISO/IEC 15434 (see chapter 5).

This ensures that these data elements are machine-readable and fulfils the technical requirements for implementing the EU Directive on the protection against falsification of medicinal products and other legal requirements for the verification of medicinal product packaging.

At the same time, the requirements of Article 5 "Carrier of the unique identifier" of the DVO are fulfilled.

4.2 Permitted formats for the product code (PPN and NTIN)

A unique product code is required throughout Europe to meet the requirements of Article 4(d) of the DVO. For medicinal products marketable in Germany, the product code is displayed in the DMC either in the format of the Pharmacy Product Number (**PPN**) or the National Trade Item Number (**NTIN**). PPN and NTIN are each generated from the 8-digit PZN. The manufacturer is free to choose between the two product code formats mentioned above and may also use both formats simultaneously.

Note: Unless otherwise stated, the term NTIN or NTIN-DE in this specification refers to a GTIN that has the prefix assigned to the German PZN.

Existing databases and software systems can algorithmically generate a PZN from the PPN or NTIN and, conversely, generate a PPN or NTIN from the PZN.

For trade, the PZN remains the relevant article number and will continue to be used for reimbursement and pharmaceutical regulatory purposes. This means that existing processes will remain unchanged.

Interoperability with other numbering systems, e.g. GTIN (GS1 as the responsible issuing agency) or HIBC (EHIBCC as the responsible issuing agency), is reliably ensured by the common basis of international standards.

Pharmacy Product Number (PPN)	National Trade Item Number (NTIN)
Identical basis: ISO/IEC 15418, ISO/IEC 15434 and ISO/IEC 16022	
Identical core: The Pharmaceutical Central Number (PZN)	

The PZN is embedded in the globally unique PPN format as shown below.

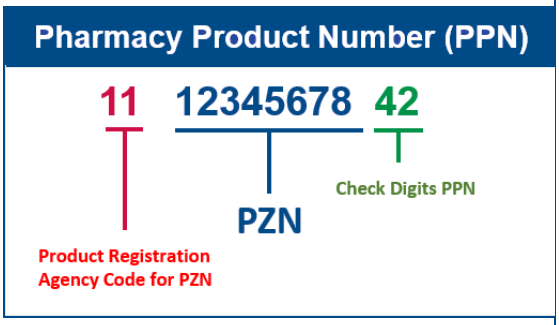


Figure 3: General structure of the PPN

The PPN consists of three parts, which are highlighted in red, blue and green. The "11" stands for a Product Registration Agency Code (PRA code). This code is managed and assigned by the IFA. The "11" is assigned to the German PZN. The "11" is followed by the national article number, shown in blue. This is the unchanged PZN (8 digits). The following digits (shown in green in the image) form the two-digit, calculated check digit of the PPN across the entire data field (including the "11"). Using the PZN shown in the example, the value "42" is obtained.

The PPN can be used by all users free of licence.

Further details can be found on the IFA website.[5]

The PZN is embedded in the globally unique NTIN format as shown below.

Figure 4: General structure of the NTIN

The NTIN consists of three parts, highlighted in red, blue and green. "4150" is the prefix assigned to the PZN by GS1 Germany. This is followed by the unchanged PZN (8 digits) in blue. The last digit (shown in green in the image) forms the check digit for the entire data field.

In addition, the NTIN must be converted to a 14-digit format for this use by prefixing it with a "0", as shown above.

The NTIN formed in this way is a fully-fledged Global Trade Item Number (GTIN) in terms of both its technical characteristics and its logistical application.

Further details can be found on the GS1 Germany website.[6]

Figure 5: Representation of the product code as PPN or NTIN in Germany

Note: In Germany, the partners to the framework agreement pursuant to section 131 of the German Social Code (SGB V) have agreed that, among other things, medicinal products must be labelled exclusively with the PZN in plain text and in a machine-readable format. Accordingly, a GTIN assigned by the manufacturer itself is not permitted for this purpose.

When using the NTIN, the manufacturer must observe the licence conditions of GS1 Germany. The use of the IFA's PPN is licence-free.

[5] https://www.ifaffm.de
[6] https://www.gs1-germany.de

4.3 Codes and data content on medicine packaging

shows the different contents of the Data Matrix Code (DMC) for medicines subject to verification and those not subject to verification, whereby the application of the DMC is voluntary for medicines not subject to verification.

	Data Matrix Code			
	PC	**SN**	**LOT**	**EXP**
Medicinal product subject to verification	PPN or NTIN	Mandatory	Mandatory	Mandatory
Medicinal products not subject to verification	PPN or NTIN	Not permitted	permitted	permitted

Figure 6: Contents of the Data Matrix Code for Single Market Packs

The additional coding of the PZN in Code 39 can be omitted for packages if they contain the DMC in accordance with this specification and are placed on the market after 9 February 2019. However, the PZN must always be printed in plain text (see chapter 6.6).

Note: The Data Matrix Code must be applied to medicinal products subject to verification with the above data content. For medicinal products not subject to verification, the application of the Data Matrix Code as such and the additional data content for the PPN / NTIN is optional. However, a serial number is not permitted for medicinal products not subject to verification.

The DVO allows additional one- or two-dimensional codes to be applied to the packaging, provided that these do not contain the individual identification feature used to verify authenticity or identity. Thus, within the scope of individual authorisation, codes containing additional information or referring to other sources, such as a Uniform Resource Locator (URL), may be applied. Additional visible codes may mislead the user when identifying the package and thus complicate the scanning process. They should be kept to a minimum. Additional data content increases the size of the Data Matrix Code. It should be noted that the minimum print quality required by the DVO (see chapter 7) must be maintained.

4.4 Multi Market Packs

Multi Market Packs (**MMP**) are packs that can be sold in several countries in a specific design. They carry several national item numbers for reimbursement and merchandise management purposes, as well as other country-specific information.

In addition to the requirements for the German market, the respective national requirements regarding coding and text information must be taken into account for MMPs. This leads to different variants of MMP labelling. The following table provides a basic overview of the different types of MMPs:

Data Matrix Code								
	PC	**SN**	**LOT**	**EXP**	**GTIN**	**NTIN non-DE**	**PZN-DE**	**Other NHRN**
GS1 variant 1	GTIN	Use of data elements SN, LOT and EXP analogous to Single Market Packs			n/a	n/a	Mandatory	additionally permitted
GS1 variant 2	NTIN-DE				n/a	n/a	Not permitted[1]	Not permitted [1]
ASC variant	PPN				additionally permitted	additionally permitted	n/a	n/a
1: according to GS1 code specification								

Figure 7: Contents of the Data Matrix code for multi-market packs

For MMPs subject to verification, it is mandatory to define a product code that is used across all countries in which the medicinal product in question is subject to verification. This product code is uploaded to all relevant national verification systems via the EU Hub, together with the associated serial number and other information. When the medicinal product is dispensed, the status of the relevant package is synchronised via the EU Hub in all relevant national verification systems.

Note: Each country determines which national number is to be included in the Data Matrix Code alongside the product code (PC). For MMPs, the PZN must be included in the Data Matrix Code for medicinal products intended for the German market, either directly in the product code (in NTIN or PPN format) or as an additional element if the product code is assigned to another country.

The GS1 variants listed in are shown in Figure 8 as examples of an MMP for the Austrian and German markets, where either a GTIN or an NTIN-DE is used as the PC. Consequently, the packaging differs in the content of the PC and in the number of elements of the DMC. Otherwise, the presentation, such as that of the Blue Box, remains identical:

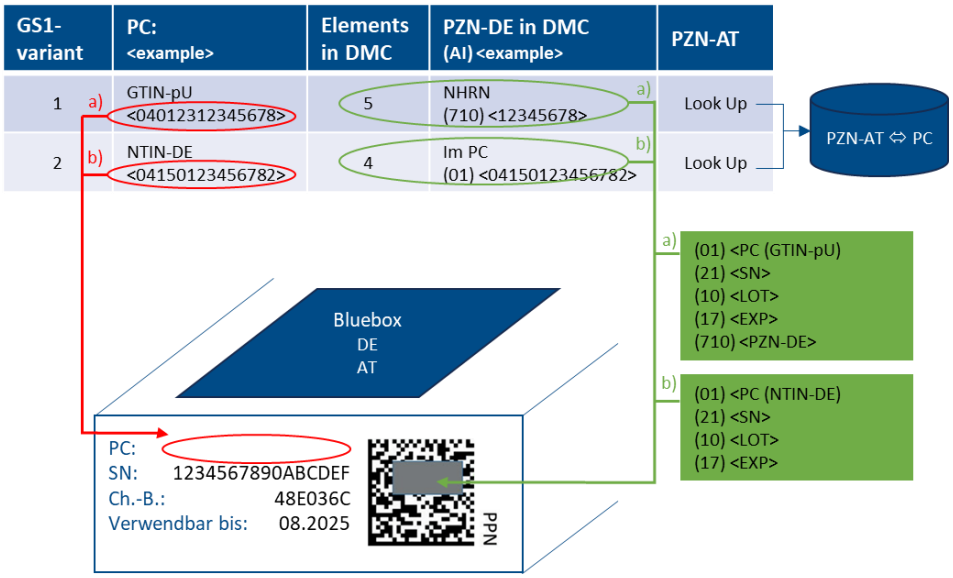


Figure 8: Example of an MMP for DE and AT

GS1 variant 2 (NTIN-DE) is suitable for MMPs that are distributed in Germany and other countries where the national identifier is stored in a look-up table. This is the case in Austria, for example. The Data Matrix Code then contains only four elements. The NTIN with the German PZN (NTIN-DE) is used as the product code.

For MMPs in accordance with the example from Figure 8 , the pharmaceutical company must submit the following reports:

	Austrian Pharmacy Publishing House	EMVO	IFA / ACS
Report	Link the PC (GTIN or NTIN) in GTIN format – in a 1:1 relationship to the PZN-AT	Link the PC (GTIN or NTIN) in GTIN format in a 1:n ratio to PZN-AT and PZN-DE.	None
Application	The link is forwarded to the data recipients via the existing data services (in Austria) and establishes the reference of the PC to the PZN-AT for the merchandise management systems.	The EMVO derives the characteristics and processes required for MMP from this relationship.	The national data does not map the MMP. With regard to the PZN, the MMP behaves like an SMP. the MMP behaves like an SMP.

Figure 8: Reports for MMPS for DE and AT

For further details on the reports, see "AMVO - Coding rules for Austria" from the AMVO[7] and "EMVS Master Data Guide" from the EMVO [8]

The same rules apply to the coding of PZNs as to Single Market Packs. Details on the coding of MMPs are described in chapter 5.3 . For details on plain language, see chapter 6.6 .

[7] https://www.amvs-medicines.at
[8] https://www.emvo-medicines.eu

4.5 Hospital packs

Hospital packs subject to verification must be coded in the same way as other packs subject to verification. Hospital packs consisting of hospital modules are a special case. In this variant, the hospital pack and not the hospital module represents the commercially available pack. Therefore, the individual identification feature must be applied to the hospital pack and not to the hospital module.

A clinic module is a package that is a separate package but is part (module) of a clinic package. A single hospital module is not sold to retailers. Several identical hospital modules form a hospital pack. Hospital modules and hospital packs have different PZNs. The PZN of the hospital module refers to the PZN of the hospital pack. Only the PZN of the hospital pack is relevant for retailers.

For logistical reasons, for example, hospital modules may carry a Data Matrix Code (DMC), but this must not contain a serial number. Consequently, in such cases, the data elements of the hospital modules cannot and must not be transmitted to the pharmaceutical industry's database system and thus used for verification purposes. See the illustration below Figure 9 .

	Standard pharmacy packaging	**Hospital pack**	**Hospital pack with so-called hospital modules**	
				
Pack contents	Individual items (blister packs, coated tablets, vials, etc.)	Individual items (blister packs, coated tablets, vials, etc.)	Individual packs, known as hospital modules, which are combined in a bundle or other outer packaging to form a hospital pack.	
IFA article type	Standard goods	Hospital pack	Hospital pack	Hospital module
PZN in plain text	Mandatory	Mandatory	Mandatory	Mandatory
Data Matrix Code (data content)	PC SN LOT EXP	PC SN LOT EXP	PC SN LOT EXP	PC LOT EXP
ACS MAH System	NTIN/PPN SN LOT EXP			n/a
Object for verification	Yes	Yes	Yes	No

Figure 9 : Overview of hospital packs

Code 39 can be omitted from 9 February 2019 (but not the PZN in plain text) if the pack has a DMC that includes the PZN. See also chapter 4.3

4.6 Doctor's samples

The DVO explicitly includes doctor's samples in the verification requirement. This requires the identification of doctor's samples. Doctor's samples are regulated in Germany in section 47 (3) and (4) of the AMG. The following table shows the options and presentation variants available to the manufacturer.

Presentation variant	Pack size	PZN	IFA master data
Use of the standard packaging with the note "Ärztemuster" (doctor's sample) added subsequently.	Smallest pack available in stores (usually N1)	No separate PZN for dispensing as a doctor's sample	• No differentiation between article type "Standard" and "Doctor's sample in accordance with AMG" • No separate notification of the doctor's sample to IFA
Specific presentation as "doctor's sample" (separate packaging)	Smallest pack available on the market (usually N1)	Specific PZN	• Assignment of specific PZN with the article type "doctor's sample in accordance with AMG"
Specific presentation "doctor's sample" (separate packaging)	Separate pack size that is smaller than the smallest package available on the market (smaller than N1)	Specific PZN	• Assignment of specific PZN with the article type "Doctor's sample in accordance with AMG"

Figure 10: Presentation variants for doctor samples

5 Data contents and requirements for the Data Matrix Code

5.1 Data identifiers and structures

This chapter defines the data identifiers to be used and the characteristics of the data elements for use in the Data Matrix Code (DMC). The data identifiers used are in accordance with the international standard ISO/IEC 15418 (which refers to the standard ANSI MH10.8.2, Data Identifier and Application Identifier Standard). The ASC MH10 Data Identifier (DI) is used in the IFA standard and the Application Identifier (AI) is used in the GS1 standard.

The standards generally leave the characteristics of the data elements open. For this reason, this specification defines the respective data type, data length and character set in a manner that is binding for all market participants (see chapter 5.2 and Appendix A: Overview and references of data identifiers). One of the following two variants is permitted for structures and data identifiers:

A. Structure in format 06 in accordance with ISO/IEC 15434 and Data Identifier (DI) in accordance with ISO/IEC 15418 (ANSI MH10.8.2, section I). For details, see the IFA specification. [9]
B. Structure identifier "FNC1" and Application Identifier (AI) in accordance with ISO/IEC 15418. For details, see the GS1 specification.[10]

Note: The data identifiers that can be used and the permissible data types, character sets and data lengths of the data to be encoded are summarised in Appendix A: Overview and references of data identifiers .

The order of the data fields is arbitrary.

Data identifiers not used in this specification, but which follow the syntax of ANSI MH10.8.2. should be output correctly in the applications and lead to defined states.

This must not compromise the reading process and the associated data acquisition, and the specified data structures must not be violated by such extensions.

If market participants require additional data identifiers for shared use, these shall be added to the data identifiers described in chapter "5.2 " and their use shall be clearly described.

[9] https://www.ifaffm.de/de/ifa-codingsystem/data-matrix-handelspackungen.html
[10] https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/

5.2 Single Market Packs – Data elements and associated data identifiers

5.2.1 Product code

- **Data Identifier (DI): "9N"**
- **Application Identifier (AI): "01"**

The product code is used for product identification, either in the form of the Pharmacy Product Number (PPN) or the National Trade Item Number (NTIN). The product code is the leading data element in the DMC; all other data elements refer to it. The product code contains the PZN (8 digits) and can be extracted from it (see chapter 4.2).

Format	DI AI	Data
ASC	9N	111234567842
GS1	01	0415123456782

Figure 11: Example of a product code in the DMC (for PZN 12345678)

The characters that can be used are described in the Appendix A: Overview and references of data identifiers .

5.2.2 Serial number

- **Data Identifier (DI): "S"**
- **Application Identifier (AI): "21"**

The serial number is generated by the manufacturer and assigned to the individual package. It is mandatory for the verification process. For medicinal products that are not subject to verification, no serial number may be included in the DMC.

Format	DI AI	Data
ASC	S	12345ABCDEF98765
GS1	21	12345ABCDEF98765

Figure 12: Example serial number in the DMC (for SN 12345ABCDEF98765)

The characters that can be used are described in the Appendix A: Overview and references of data identifiers .

5.2.3 Batch number

- **Data Identifier (DI): "1T"**
- **Application Identifier (AI): "10"**

The batch number is assigned by the manufacturer. Defined special characters can be used to distinguish between partial/sub-batches.

Format	DI AI	Data
ASC	1T	12345ABCD
GS1	10	12345ABCD

Figure 13: Example of a batch designation in the DMC (for LOT 12345ABCD)

The characters that can be used are described in the Appendix A: Overview and references of data identifiers .

5.2.4 Expiry date

- **Data Identifier (DI): "D"**
- **Application Identifier (AI): "17"**

The expiry date is specified by the manufacturer.

The expiry date is in the format "YYMMDD".

YY = two-digit year

MM = Numerical month (01–12)

DD = day

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

The following example also implements the requirement of the German Medicines Act (AMG) for plain text with the indication of month and year in the coding:

Format	DI AI	Data
ASC	D	290800
GS1	17	290800

Figure 14: Example of a monthly expiry date in the DMC (expiry date August 2029)

Note: Since January 2025, GS1 requires the exact day to be specified. The use of "00" is no longer permitted. With ASC, "00" is still permitted.

The following example shows the option of specifying a date down to the day.

Format	DI AI	Data
ASC	D	290800
GS1	17	290831

Figure 15: Example of a day-specific expiry date in the DMC (for EXP 31 August 2029)

Note: In the ANSI MH10.8.2 standard, "D" is generally defined as the date. In the context of the PPN, the date "D" is always the expiry date. For other dates, such as the production date, other date identifiers must be used. For the production date, this would be the DI "16D" or the AI "11".

5.2.5 Additional data elements – example URL

The data elements described above are mandatory in order to comply with the requirements of Delegated Regulation (EU) 2016/161 (DVO). In accordance with Article 8 of the DVO, it is permitted to include additional data elements if the competent authority permits this in accordance with Title V of Directive 2001/83/EC or section 10, paragraph 1, sentence 5 AMG.

This provision also applies mutatis mutandis to other product categories. For example, a URL can be included in the code:

Format	DI AI	Data
ASC	33L	https://www.securpharm.de
GS1	8200	https://www.securpharm.de

Figure 16: Example URL in the DMC

Please note that long URLs significantly increase the size of the code and can therefore reduce the reading rate.

5.3 Multi Market Pack – Data elements and associated data identifiers

5.3.1 General

For medicinal products subject to verification, packaging approved for several countries (Multi Market Pack – MMP) contains only one DMC, as is the case with Single Market Packs, and the product code contained therein is used for verification.

A special feature is that the product code does not necessarily fully reflect the country-specific identification of a medicinal product, which means that several national article or reimbursement numbers may be contained in the DMC. These additions to the other data for the unique identifier must also be included in the DMC in accordance with country-specific requirements and trade necessities. This allows both the data relevant for verification and the additional numbers for country-specific identification of the medicinal product to be captured with a single scan.

Note: The user software extracts the item or reimbursement numbers known to the merchandise management system and required for identification and further processing from the DMC. This process is analogous to the current procedure for sequential scanning of linear barcodes. The unique identifier of the product code is provided in GS1 format by the AI (01) and in ASC format by the DI (9N).

If necessary, the higher data volume can be handled using the additionally defined Data Matrix rectangular codes (see chapter 6.2).

The details for encoding the country-specific identification numbers are described below. All other specifications from the chapter 5.1 and the chapter 5.2 also apply to the MMPs.

5.3.2 Country-specific identifier in GS1 format

The product code is identified by the AI (01). The other country-specific numbers for identifying the medicinal product are identified by the AI (71x) assigned to the NHRN, e.g. AI (710) PZN Germany, (711) CIP France, (712) CN Spain, (714) AIM Portugal.

Note: The GS1 format allows two coding options for multi-market packs:

- A GTIN assigned by the manufacturer is used as the product code (AI=01) and the country-specific numbers (AI=71x) are displayed as additional elements in the DMC.
- If look-up tables are available, an NTIN can be selected as the product code (AI=01), provided that the additional country-specific numbers in the DMC can be omitted.

If a GTIN is selected as the product code, the NHRN must be included as a so-called 5th element. The following example shows German PZN (AI=710) and French CIP (AI=711).

Format	AI	Data
GS1	0	08701234567896
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	290800
GS1	710	123456
GS1	711	91234567

Figure 17: Example 1 – MMP in GS1 format (GTIN as PC)

Austria is one of the countries that does not display the NHRN in the DMC and instead links its NHRN to the product code using look-up tables. This makes it possible to use the DMC even for multi-market packs with four elements. See example 2 below.

Format	AI	Data
GS1	01	04150123456782
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	290800

Figure 18: Example 2 – MMP in GS1 format (NTIN-DE as PC)

Product code (PC) NTIN-DE, for example with German PZN "12345678"; the PZN-AT is linked via the look-up table and therefore does not appear in the code (see also chapter 4.4).

5.3.3 Country-specific identifier in ASC format

The product code is identified with the DI (9N). If the additional country-specific number for identifying a medicinal product is available in GTIN or NTIN format, it is identified with the DI (8P).

If there are several country-specific numbers in GTIN or NTIN format, the additional data identifiers (8P) are included multiple times in the DMC.

If the additional country-specific feature for identifying a product is in a format that differs from the GTIN or NTIN, the MH10 - DI assigned to the respective format in accordance with the ANSI standard must be used, e.g. (25P) for HIBC.

Format	AI	Data
ASC	9N	111234567842
ASC	S	1234567890ABCD
ASC	1T	1234AB
ASC	D	290800
ASC	8P	08701234567896
ASC	8P	03400912345676

Figure 19: Example 3 – MMP in ASC format

In this example, the PC is represented as a PPN with a German PZN. The last two lines contain additional country-specific product identifications using GTIN and NTIN.

6 Markings in code and plain text

6.1 Symbology

This chapter describes the coding with the specifications for plain text and the optional emblem for the Data Matrix Code (DMC). The data carrier or symbology used is the DMC in accordance with ISO/IEC 16022. The error correction method follows the Reed Solomon procedure, referred to as ECC200 in the standard. The other error correction methods (ECC000 to ECC140) must not be used.

6.2 Matrix size

Typically, the matrix size should not exceed 26x26 or 26x48 modules. Smaller matrix sizes are permitted provided that their capacity is sufficient for the data to be encoded. If a consistent matrix size is always to be printed, this is specified in the print layout. Any excess capacity that may arise is automatically filled with fill characters by the code generation software.

Depending on the packaging layout and the printing requirements, square or rectangular DMCs in accordance with ISO/IEC 16022 or extended rectangular DMCs (DMRE) in accordance with ISO/IEC 21471 DMRE can be used. Typical matrix sizes and their characteristics can be found in the following tables:

Matrix size		Dimension of the DMC (mm) X = module size (mm)			Data capacity	
Modules per line	Modules per column	Typical X=0.35	Min X=0.25	Max X=0.99	Numerical	Alpha numeric
22	22	7.7 x 7.7	5.5 x 5.5	21.8 x 21.8	60	43
24	24	8.4 x 8.4	6	23.8 x 23.8	72	52
26	26	9.1 x 9.1	6.5 x 6.5	25.8 x 25.8	88	64
32	32	11.5 x 11.5	8.2 x 8.2	32.7 x 32.7	124	91

Figure 20: Typical square symbols according to ISO/IEC 16022

Matrix size		Dimension of the DMC (mm) X = Module size (mm)			Data capacity	
Modules per row	Modules per column	Typical X=0.35	Min X=0.25	Max X=0.99	Numerical	Alpha numeric
16	36	5.6 x 12.9	4.0 x 9.2	15.9 x 36.6	64	46
16	48	5.6 x 17.2	4.0 x 12.3	15.9 x 48.5	98	72

Figure 21: Typical rectangular symbols according to ISO/IEC 16022

Matrix size		Dimension of the DMC (mm) X = Module size (mm)			Data capacity	
Modules per row	Modules per column	Typical X=0.35	Min X=0.25	Max X=0.99	Numerical	Alpha numeric
22	48	7x7 x 17.2	5.5 x 12.3	21.8 x 48.5	144	106
24	48	8.4 x 17.2	6.0 x 12.3	23.8 x 48.5	160	118
26	40	9.1 x 14.5	6.5 x 10.3	25.8 x 40.6	140	103
26	48	9.1 x 17.2	6.5 x 12.3	25.8 x 48.5	180	13

Figure 22: Typical rectangular symbols according to ISO/IEC 21471

6.3 Code size and quiet zones

The module size of the DMC may vary between 0.25 and 0.99 mm. The technical characteristics of the scanners used must be adapted to this range of module sizes. Within this range, the module sizes may be scaled as desired, taking into account the print quality (see chapter 7) and the printing systems to be used. It should be noted that the print quality tends to deteriorate with smaller module sizes and that the resolution of the printing system must be consistent with the selected module size.

The module size and matrix size determine the dimensions of the DMC (see tables in chapter 6.2).

Note: The areas adjacent to the code must be kept free of any other printing. To ensure an acceptable first-read rate, this specification specifies a minimum distance of three modules.

6.4 Positioning of the Data Matrix code

No specific requirements are specified for positioning. The position is determined by the manufacturer based on the packaging layout and printing conditions, as well as other legal requirements.

6.5 Emblem for the Data Matrix code " " (optional)

The optional "PPN" emblem on the DMC indicates to verification bodies the code used for machine reading of the product code and other data, regardless of the format of the PZN in the DMC (PPN or NTIN). "PPN" will be retained as the emblem until another uniform identifier is established at international level.

Note: The emblem must be affixed to packs that carry a second 2D code.

Figure 23: "PPN" emblem for the code

Various variants and details are possible for the graphic design of the emblem (see Appendix B: Emblem for the code).

The emblem can be applied in both primary and inline printing. The minimum distances to the code (clearance zones) must be observed.

6.6 Plain text information

6.6.1 General

From 9 February 2019, pharmaceutical companies must affix the product code and serial number in a human-readable format to the packaging of medicines subject to verification, in addition to the PZN, batch number and expiry date. To ensure legibility, the provisions of the EU Readability Guideline (Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use) must be observed.

In principle, the following regulations in their currently valid version apply to plain language labelling:

- Section 10 AMG (German Medicinal Products Act)[11]
- QRD template (CMDh ANNOTATED QRD TEMPLATE FOR MR/DC PROCEDURES, CMDh/201/2005/Rev. 12.1 of March 2024 – or newer)[12]
- Appendix IV of the QRD template (terms/abbreviations for "batch number" and "expiry date" to be used on the labelling of human medicinal products)[13]

Note: The labels and abbreviations specified in this document comply with the requirements of the QRD template in version CMDh/201/2005/Rev.12.1 – April 2024 and its Appendix IV in version EMA/286379/2019 rev. 14 of December 2021. In the event of any discrepancies between these specifications, the following order of precedence applies: AMG, QRD template including Appendix IV, these coding rules

6.6.2 PZN

The PZN is the key element of the commercially available pack. According to the applicable legal requirements, the PZN must be printed in plain text. This can be done in two ways:

PZN with Code 39	PZN without Code 39
	PZN: 12345678

Figure 24: Indication of the PZN in plain text with and without Code 39

[11] https://www.gesetze-im-internet.de/amg_1976/__10.html
[12] https://www.hma.eu/human-medicines/cmdh/templates/qrd.html

The representation of the PZN without Code 39 has been permitted since 9 February 2019. However, it is recommended that the variant with Code 39 be retained, at least temporarily, in order to facilitate the transition for stakeholders. It may even be retained until further notice.

For requirements regarding the coding of the PZN in Code 39, please refer to the IFA document "Technical information on PZN coding of the PZN in Code 39".

Note: For medicinal products authorised centrally in Europe, the PZN must be displayed in the blue box. For all other authorisations, it can be placed anywhere.

6.6.3 Product code and serial number

If the dimensions of the packaging allow, the plain text information of the product code and the serial number shall be located next to the two-dimensional code containing the unique identifier.

If the product code and serial number are written in two lines one below the other, the product code should be placed in the first line and the serial number in the second line.

The PPN or NTIN contained in the DMC must be used as **the product code**. The abbreviation "**PC:**" must be prefixed for identification purposes, whereby the colon is optional and the space is mandatory. As the product code is fixed for the respective packaging design, it can also be applied in the primary printing.

The **serial number** must be preceded by the abbreviation **"SN:** ", whereby the colon is optional and the space is mandatory.

Exceptions in accordance with the delegated regulation:

Note: If the sum of the two longest dimensions of the packaging is 10 centimetres or less, the plain text representation of the product code and the serial number may be omitted.

6.6.4 Batch number and expiry date

The clear text information for the **batch number** and expiry date must comply with the labelling requirements specified in the legislation on medicinal products. The abbreviation "**Ch.-B.**" must be used for the batch number.

The **expiry date** must be accompanied by the words "**usable until**" or the abbreviation **"use by**".

6.6.5 Examples

Figure 25: Example of plain text with PZN and Code 39

Figure 26: Example of plain text with PZN without Code 39

For medicinal products centrally authorised in Europe, the PZN must be displayed in the blue box.

Figure27: Example of plain text multi-market pack

7 Quality check of the Data Matrix code

The basic prerequisite for a usable code is the correct encoding of the data and compliance with a defined print quality. Both must be ensured through quality assurance measures.

When checking the quality of a code, a distinction must always be made between reading control and metrological control of the print quality. Reading control checks the code content in order to determine the accuracy of the data. The specifications in the previous chapter and the following must be observed for this purpose:

Note: In digital printing, each print must be considered individually. Therefore, the code content of each pack must be checked by means of a read check.

7.1 Determining print quality:

Print quality is the physical quality of the print. Defining and maintaining a minimum print quality ensures a high first-read rate. The information in this chapter serves this purpose.

According to Delegated Regulation (EU) 2016/161 (DVO), print quality must be assessed according to certain parameters.

The manufacturer must determine the minimum print quality for the legibility of the code throughout the entire supply chain and during the usage cycle, and set the limit values for the parameters.

Note: Minimum period of the life cycle according to the Delegated Regulation: one year beyond the expiry date or five years from the date of placing the medicinal product on the market. The longer period applies in each case.

A more practical option is provided in Article 6(4) of the DVO, which states that if the print quality is at least 1.5 in accordance with ISO/IEC 15415 (see table below), the requirements are deemed to be met, provided that the manufacturer has also taken into account the ageing and wear effects of the printing.

7.2 Quality levels according to ISO/IEC 15415

ISO/IEC class	ANSI grade	Average of multiple measurements*	Meaning
4	A	3.5 – 4	Very good
3	B	2.5 - < 3.5	Good
2	C	1.5 - < 2.5	Satisfactory
1	D	0.5 - < 1.5	Sufficient
0	F	< 0.5	Failed
*) Multiple measurements have been omitted from the current version of ISO/IEC 15415 (Dec. 2011). Implicitly, the minimum requirement of 1.5 therefore always corresponds to ISO/IEC Class 2.			

Figure 28: Quality levels according to ISO/IEC 15415

Commercially available scanners are capable of reading codes even if they fall below Class 2 according to ISO/IEC 15415 (value < 1.5). However, there are considerable technical variations between commercially available scanners.

Note: Users are required to select or configure scanners so that Class 1 codes according to ISO/IEC 15415 are still readable (value ≥ 0.5). Scanners must be selected so that their optical properties match the dimensions of the DMC (see chapter 6.2).

Based on this specification, printing in a quality lower than 1.5 meets the requirements of the DVO. When making this specification, the manufacturer must also take into account the effects of ageing and wear on the printing.

However, in order to achieve a very high first-read rate, the manufacturer must not permanently fall below the requirement of 1.5 (according to ISO/IEC 15415).

In practice, a 100% read check (with or without inline pseudo grading) is often carried out using inline systems in combination with a metrological random sample check for quality control purposes.

7.3 Note on random sampling

Quality assurance at pharmaceutical manufacturers usually works with sampling plans. The sampling plans specify how many samples must pass the test and usually also allow a certain number of samples that fall below the minimum quality (however, in extreme cases, a code of

lower quality could lead to non-reading). The manufacturer is responsible for defining the sampling plans.

Note: The ISO/IEC 15415 standard, which is referred to in the delegated regulation Art. 6, para. 4, includes the sampling system in its chapter 5.1 "General": "Information on sampling plans may be found in the following: ISO 3951-1, ISO 3951-2, ISO 3951-3, ISO 3951-5 or DIN ISO 2859-1". The sampling system is therefore implicitly part of the delegated regulation Art. 6, para. 4, as chapter 5.1 is the normative and therefore binding part of the ISO/IEC 15415 standard.

7.4 Note on measuring devices

Measuring devices that operate in accordance with ISO/IEC 15415 must be configured by the user for the specific application. The number of parameters varies depending on the manufacturer of the measuring device.

Note: ISO/IEC 15415 specifies the rules for determining quality. The standard requires that the light type, lighting arrangement and measuring aperture be specified in the user specification.

These coding rules are the user specifications in accordance with ISO/IEC 1541530 and therefore the requirements for the correct configuration of a measuring device for print quality control of the Data Matrix code as used in accordance with this specification.

Appendix A: Overview and references of data identifiers

The following table specifies the characteristics of the individual data identifiers:

Data elements	Content	DI	AI	Data type	Data format	Character length	Character set
Pharmacy Product Number (PPN)	PPN	9n	-	AN	-	11-28	0-9;A-Z No special characters, no lower case letters, no umlauts
National Trade Item Number (NTIN)	GTIN	8P	0	N	-	14	0-9
Serial number	SN	S	21	AN	-	1-20	Numeric or alphanumeric characters, no umlauts
Batch number	LOT	1T	1	AN	-	1-20	Numeric or alphanumeric characters, no umlauts
Expiration date	EXP	D	17	Date	YYMMDD	6	0

Figure 29: Overview of the characteristics of the individual data identifiers

Details on the data elements can be found in chapter 4 and chapter 5 . These describe, among other things, the character lengths to be used and the special features of the format for the expiry date.

Recommendation for the character set for serial numbers and batch descriptions:

To minimise reading errors, manufacturers are advised to do the following:

a) The character string should contain either only upper-case letters or only lower-case letters of the Latin alphabet.

b) To avoid human reading errors, the manufacturer should exclude similar characters that could be confused, depending on the font used and the quality of the print image. These include, for example: i, j, l, o, q, u and I, J, L, O, Q, U.

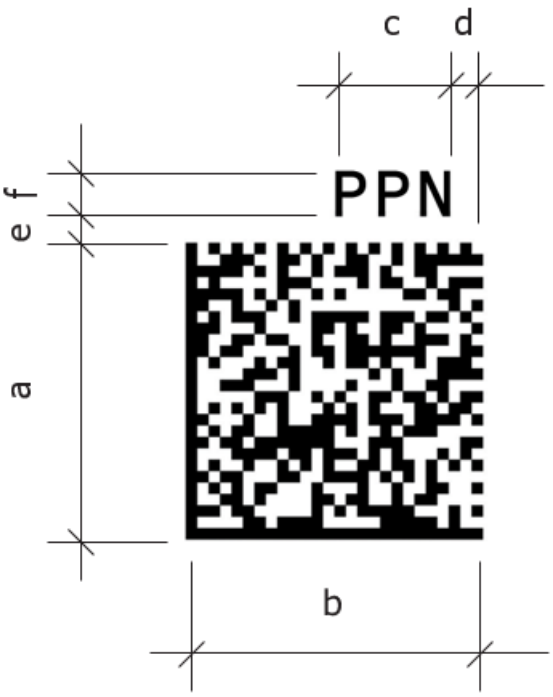
c) Some special characters are technically processed but should not be used as there is a very high risk of misinterpretation. A misinterpreted code means that a pack cannot be verified and is therefore not suitable for distribution.

d) If separators are necessary within a batch number, we recommend using the hyphen "-", the underscore "_" or the full stop "." The use of the full stop is particularly recommended as it has the same function on German and English keyboards. This means that there is no risk of misinterpretation if the wrong language is selected on the keyboard scanner.

Note: Special characters with the decimal ASCII code values 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) are excluded from technical processing. In principle, all ASCII characters with a decimal value > 127 are excluded. The technically permissible character set corresponds to the "GS1 AI encodable character set 82" (GS1 General Specifications, section 7.11 (Figure 7/11-1)).

Appendix B: Emblem for the code

An emblem for the code helps verification bodies to identify the correct code. This is particularly helpful for packs that contain more than one machine-readable code. Here, the character string "PPN" is specified in the "OCR-B" font. The graphic design is shown in the sketch below:



Nominal dimensions:

a: results from the selected module and matrix size

b: is equal to a for square codes and corresponds to the module and matrix size for rectangular codes

c: 0.4 * a

d:

e: results from the required quiet zone *) (See chapter "6.3 " for quiet zone)

f: results from the font type and dimension c

*) Dimensions d and e must be selected so that the emblem is assigned to the code.

Figure 30: Nominal dimensions of the emblem

Tolerances: The tolerances can be freely defined according to the selected printing process.

The following alignments are possible:

Figure 31: Possible alignments of the emblem

In exceptional cases, the emblem may also be affixed to another adjacent surface.

Appendix C: Interoperability based on XML descriptions (informative) [omitted]

n/a

Appendix D: Details on quality checking of the Data Matrix code [omitted]

n/a

Appendix E: Glossary/abbreviations

The terms and abbreviations used in this document are listed below:

ACS refers to ACS PharmaProtect GmbH, Berlin. It is a company owned in equal shares by the manufacturers' associations. ACS developed the database system of the German pharmaceutical industry (MAH System) as a subsystem for operation in the securPharm system, in which data for the verification of medicinal products is stored by the pharmaceutical company prior to marketing. ACS is the contractual partner for MAHs.

AMG see Medicines Act.

Application Identifiers (AI) are data identifiers developed by GS1 users that define exactly which data content is encrypted and how. These are valid worldwide and can be used across multiple sectors in accordance with ISO/IEC 15418. Published in the German-speaking GS1 region under the term "Datenbezeichner" (data identifier).

The article number is the number that uniquely identifies an article or product. A synonym for article number is product number. In this document, the term article number is used when referring to the identification of the article in retail. In contrast to the product code, which is part of the Unique Identifier (UI) within the meaning of Delegated Regulation (EU) 2016/161, an article can be assigned both an article number and a product code.

German Medicines Act (AMG) – its purpose is to ensure the safety of medicinal products in trade, in particular their quality, efficacy and safety, in accordance with the provisions of the AMG, in the interests of the proper supply of medicinal products for human and veterinary use (see section 1 AMG).

ASC format describes a structure that uses format 6 in accordance with ISO/IEC 15434 and the ASC MH10 Data Identifier (DI) in accordance with ISO/IEC 15418 (reference to ANSI MH10.8.2). The specifications of the IFA Coding System are based on this format. See also "Data Identifier".

Bar code (also known as a barcode) is an optical data carrier consisting of lines (also called barcodes). Two-dimensional matrix codes are also referred to as 2D barcodes. This includes the Data Matrix Code.

Blue Box is used for medicinal products with central European authorisation. For these medicinal products, the pack information must be prepared in accordance with the European requirements of Article 57 of Directive 2001/83/EC. The country-specific requirements must be included in the Blue Box (visually recognisable by a blue frame). These are specified by the European Medicines Agency (EMA) or the Coordination Group for Medicinal Products for Human Use (CMDh) in the "blue box requirements".

Code 39 is a barcode or barcode type specified in ISO/IEC 16388. This code requires a large amount of space for comparatively small amounts of data. Code 39 is used as a data carrier for displaying the Pharmazentralnummer (PZN) in the barcode.

Concentrator refers to the access point for verifying bodies to the securPharm system. The concentrator is operated by the NGDA and is connected to the ACS MAH System. It checks and anonymises the requests from the verifying bodies, forwards them to the MAH System and coordinates the feedback for the corresponding requests.

Data Matrix Code (DMC) is a two-dimensional matrix code consisting of square elements. In the ECC200 version according to ISO/IEC 16022, the code includes error correction according to the Reed Solomon method for missing or damaged areas.

Data identifiers (DI) are data identifiers assigned by the ASC MH10 Data Identifier Maintenance Committee and listed in the international standard ANSI MH10.8.2. The data identifier always ends with an alphabetic character. To distinguish between variants, this can be preceded by a one-, two- or three-digit number.

Data identifiers are standardised identifiers that are placed in front of the data content to identify the data element. The most commonly used identifiers are the ASC MH10 Data Identifier (DI) and the GS1 Application Identifier (AI). In ANSI MH10.8.2, both types are listed separately and mapped to each other. For the sake of simplicity, the term "data identifier" is used in this document when referring to DI and AI.

Delegated Regulation (EU) 2016/161 (DVO) stands for "Delegated Regulation (EU) 2016/161 of the European Commission of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed provisions on safety features for the packaging of medicinal products for human use".

DMC see Data Matrix Code.

DVO see Delegated Regulation (EU) 2016/161.

EMVO see European Medicines Verification Organisation

EMVS refers to the European Medicines Verification System.

European Medicines Verification Organisation (EMVO) refers to EMVO asbl, a non-profit organisation founded by European stakeholder associations and based in Brussels to operate the EU Hub and connect the national verification systems (NMVS) to the EMVS.

The EU Hub is the "central information and data router" operated by the EMVO in accordance with Article 32(1)(a) of the DVO, also referred to by the EMVO as the "European Hub".

The European Medicines Verification System (EMVS) is the system landscape consisting of the EU Hub and the connected national verification systems (NMVS). It allows the authenticity of a medicinal product to be verified across borders in accordance with the Falsified Medicines Directive and the FMD Regulation.

The Falsified Medicines Directive (FMD) stands for the "European Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC to establish a 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", which was transposed into German law by the "Second Act Amending the Medicinal Products Act and Other Regulations" of 19 October 2012. The abbreviation FMD is derived from the English term "Falsified Medicines Directive".

Global Trade Item Number (GTIN) is a globally unique item number used in many industries (FMCG, chemicals, healthcare, fashion, DIY, defence, banking, etc.). The GTIN (formerly EAN) can be encoded in various data carriers, such as in an EAN-13 barcode. Other encodings of the GTIN are possible in GS1-128, Data Matrix Code and GS1-DataBar. The responsible issuing agency is GS1.

GS1 – a registered trademark – is the abbreviation for Global Standards One, which is registered as an issuing organisation (IA) in accordance with ISO/IEC 15459-2 and manages the GS1 numbering systems worldwide.

GTIN see Global Trade Item Number.

Manufacturer is a company that manufactures medicinal products. According to Art. 4 (13) AMG, manufacturing includes extraction, production, preparation, processing, repackaging, including filling, packaging, labelling and release.

HIBC – Health Industry Bar Code – is a compressed structure and is primarily used for the labelling of medical devices.

IA see Issuing Agency

IFA refers to the Information Centre for Medicinal Products – IFA GmbH, Frankfurt am Main, (www.ifaffm.de). The IFA is a joint clearing house for the pharmaceutical industry, pharmaceutical wholesalers and pharmacists in the Federal Republic of Germany. It is the competent issuing agency for the PZN and the PRA code for the use of the PPN. The IFA is also registered as an issuing agency in accordance with ISO/IEC 15459-2.

Unique identifier refers to the security feature that enables the authenticity and identification of a single pack of a medicinal product to be verified, as defined in Article 3 of Delegated Regulation (EU) 2016/161. In the English version, the term Unique Identifier (UI) is used for this.

Issuing Agency (IA) is an issuing organisation for numbering systems accredited in accordance with ISO/IEC 15459-2. An Issuing Agency is able to provide its system participants with a system for the globally unique identification of objects. ISO has commissioned the industry association AIM to act as the Registration Authority.

Issuing Agency Code (IAC) is the registration code assigned to an Issuing Agency (IA) by the Registration Authority for ISO/IEC 15459.

Marketing Authorisation Holder (MAH) refers to the holder of a marketing authorisation as notified to the competent authority.

Module size refers to the nominal edge length of a matrix cell in the Data Matrix Code.

National Trade Item Number (NTIN) is a GTIN in which national item numbers are embedded, which are assigned and managed by other issuing agencies and not, as is usually the case with a GTIN, by the manufacturer. GS1 assigns a specific prefix for each of these number ranges managed by the issuing agencies. The prefix "4150" has been assigned to the German PZN. As with the GTIN, the AI "01" must be used as the application identifier. Similarly, when using the ASC format, the data identifier (DI) "8P" must be used.

The National Medicines Verification Organisation (NMVO) is the non-profit legal entity responsible for operating the national verification system (NMVS). In Germany, this is securPharm e. V.

National Medicines Verification System (NMVS) is the national verification system for a member state. It corresponds to the national data storage and retrieval system of Delegated Regulation (EU) 2016/161. For Germany, this is the securPharm system.

NGDA refers to Netzgesellschaft deutscher Apotheker mbH, Eschborn. With the Concentrator, it provides the access point to the securPharm system for the verification bodies. The NGDA is the contractual partner of the verification bodies.

Pharmacy Product Number (PPN) is a globally unique item number in the healthcare sector, which is assigned by IFA GmbH as the issuing agency (internationally recognised issuing body) in accordance with ISO/IEC standards. The PPN has the property that any national item number can be embedded in it without being changed. IFA GmbH automatically generates the PPN for the PZN when the item is added. The data identifier (DI) "9N", which is standardised exclusively for the PPN and assigned by the

ANSI MH10 Maintenance Committee, identifies the PPN in any data carrier, such as the Data Matrix Code.

The Product Registration Agency Code (PRA Code) is the two-digit prefix used to uniquely identify a PPN. It is assigned and managed by IFA GmbH.

The product code (PC) is, in accordance with Delegated Regulation (EU) 2016/161, a component of the unique identifier (UI) on which verification is based in conjunction with the serial number. The combination of product code and serial number is unique worldwide for each medicinal product pack. In the Data Matrix Code of a pack for the German market, the product code is issued in the format of the PPN or the NTIN, both of which contain the PZN.

The Pharmazentralnummer (PZN) is a unique, 8-digit numerical identification key used in the German market for medicinal products, certain medical devices and other health products (corresponding to all products commonly found in pharmacies). As such, it identifies a specific article (a commercial form) with a specific name, pack size (quantity and unit), dosage form, information about the medicinal product and a specific article type from a specific supplier. The PZN is also the standardised federal identification number pursuant to section 300 of the German Social Code, Book V (SGB V), which pharmaceutical companies are required to affix to the outer packaging of medicinal product packs pursuant to section 131 SGB V. The corresponding article number in Austria is also referred to as PZN and is managed by the relevant Austrian issuing agency. For the sake of clarity, the article numbers in this document are designated with PZN-DE and PZN-AT.

PPN see Pharmacy Product Number.

Product Registration Agency (PRA) is the issuing authority for (national) article numbers, which are transferred to the PPN in conjunction with the PRA code.

Pseudo grading is a term used to describe an assessment of print quality based on the ISO/IEC 15415 standard. This method is used by camera systems that are permanently installed in a production line and determine print quality criteria in addition to reading control. As these camera systems are not standardised measuring devices, the term "pseudo" is prefixed.

MAH System refers to the database system used in the pharmaceutical industry, which is operated by ACS. Also known as the ACS MAH System. The MAH System is connected to the EU Hub and the concentrator.

PZN, PZN-DE and **PZN-AT** see Pharmazentralnummer

securPharm refers to securPharm e.V., Frankfurt am Main, and is the non-profit legal entity (National Medicines Verification Organisation – NMVO) responsible for operating the national verification system in Germany.

The securPharm system is the national verification system (NMVS) for Germany and is operated by securPharm e.V. Essential components of the securPharm system are the ACS MAH System and the Concentrator.

Unique Identifier (UI) see Individual identification feature

Verifying entity refers to users of the Concentrator who use the securPharm system to verify the authenticity of medicine packaging. These may include public pharmacies, pharmaceutical wholesalers, hospital pharmacies, blister centres, compounding manufacturers and central procurement agencies of the federal government. The NGDA is the contractual partner of the verifying entities.

Verification refers to the process of checking medicine packaging using the unique identifiers applied to it. In the field of optical coding, the term verification is also used for print quality control (barcode verification) of codes. To ensure that the terms are used unambiguously, "verification" is only used in the context of counterfeit detection in this specification.

XML is derived from the English term "Extensible Markup Language". XML is a markup language for representing hierarchically structured data in the form of text data.

Marketing authorisation holder refers to the holder of a marketing authorisation as notified to the competent authority, also known as the Marketing Authorisation Holder (MAH). This term also includes parallel traders and importers. The contractual partner of the marketing authorisation holder is ACS.

Appendix F: Bibliography

ANSI MH10.8.2: Data Identifier and Application Identifier Standard

ISO/IEC 15418: Information technology – Automatic identification and data capture techniques – GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance
This standard references ANSI MH10.8.2

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

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

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

ISO/IEC CD 21471: Information technology – Automatic identification and data capture techniques — Bar code symbology specifications — Extended Rectangular Data Matrix (DMRE)

DIN ISO 2859-1: Acceptance sampling inspection based on the number of defective units or defects (attribute inspection) – Part 1: Sampling plans based on the acceptable quality limit (AQL) for the inspection of a series of lots.

ISO 3951 Part 1-5: Sampling procedures and charts for inspection by variables.

Appendix H: Note on changes from the previous version (dated 12 December 2018)

The previous version is version 2.04a, dated 12 December 2018.

In particular, chapters 1 to 3 have been revised for this previous version. These have no impact on the implementation of the Data Matrix Code.

The chapters relevant to the implementation of the Data Matrix Code (chapters 4 to 7) have only been marginally adapted. Minor changes concern the printing in plain text, which includes an adaptation to the currently valid QRD template and makes the colon after the short identifier optional. Furthermore, the text has been clarified and refined.

The former chapter 8 ("Interoperability based on XML standards") has been omitted. The former Annexes C ("Interoperability based on XML descriptions (informative)") and D ("Details on quality checking of the Data Matrix code") have also been omitted, as these specifications can already be found in the GS1, IFA and ISO standards.

Appendix I: List of figures