Summary
09.02.2019 13:15:00

Differences exist between documents.

New Document:
securPharm_Regeln_Codierung_EN_V2_04a(3)_aus_Ps
41 pages (700 KB)
09.02.2019 13:14:50
Used to display results.

Old Document:
securPharm_Regeln_Codierung_EN_V2_03_aus_Ps
36 pages (573 KB)
09.02.2019 13:14:50

Get started: first change is on page 1.

No pages were deleted

How to read this report

Highlight indicates a change.
~~**Deleted**~~ indicates deleted content.
 indicates pages were changed.
 indicates pages were moved.

securPharm

CODING RULES FOR MEDICINES REQUIRING VERIFICATION FOR THE GERMAN MARKET

Pursuant to the EU Falsified Medicines Directive 2011/62/EU and the Delegated Regulation (EU) 2016/161

Coding of packaging using Data Matrix Code with the product codes PPN or NTIN and additional data elements

Automatic identification of retail packs in the pharmaceutical supply chain

ASC-Format

GS1-Format

IFA CODINGSYSTEM

Version: 2.04a **Date of issue: 12/12 2018**

The editor points out that these "Coding Rules" were generated to the best of his knowledge based on the current findings at the time of printing.

Due to open legal and technical questions and the possibly required adjustment of social law requirements and others, future modifications and adjustments cannot be excluded, which means that this right must be expressly reserved.

For additional information on securPharm, please visit www.securPharm.de.

Summary of Comments on securPharm_Regeln_Codierung_EN_V2_04a(3).pdf

Page: 2

Number: 1 Author: Compare: Replace Subject: text Date: 09.02.2019 13:18:49

[New text]: "The editor points out that these “Coding Rules” were generated to the best of his knowledge based on the current findings at the time of printing. Due to open legal and technical questions and the possibly required adjustment of social law requirements and others, future modifications and adjustments cannot be excluded, which means that this right must be expressly reserved. For additional information on securPharm, please visit www.securPharm.de."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:05:51

content

Contents

Page: 3

Number: 1 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:48:38
New table of contents (depending on document version)

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"Contents"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:05:51
content

1 Introduction

In accordance with Article 54a para. 1 of Directive 2001/83/EC, which was amended by the so-called EU Falsified Medicines Directive 2011/62/EU (FMD), all medicinal products generally subject to prescription must bear safety features that facilitate specifically the identification of individual packs and the verification of their authenticity. Pursuant to Article 2, para. 2 (b) of the FMD, the member states must implement these provisions for affixing safety features three years after publication of the Delegated Regulation with additional details.

These details with regard to the properties and technical specifications of the unique identifier for the safety features are stipulated in the COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015 (DR) and were published in the Official Journal of the European Union on 9 February 2016. The stakeholders of the legal pharmaceutical supply chain in Germany must implement these requirements by 9 February 2019 at the latest. From this date onward, no products covered by the Falsified Medicines Directive and its Delegated Regulation can be released for sale or distribution without bearing the required safety features.

The DR requires a system that ensures the identification and authentication of pharmaceuticals based on end-to-end verification of all medicinal products that bear the safety features.

In light of this situation, the stakeholders listed below established the organisation "securPharm e.V." in order to develop the verification rules early on, to set up and test the system, and to continuously improve it:

- **ABDA – Bundesvereinigung Deutscher Apothekerverbände e.V.** (Federal Union of German Associations of Pharmacists)
- **Avoxa – Mediengruppe Deutscher Apotheker GmbH**
- **Bundesverband der Arzneimittel-Hersteller e.V. (BAH)** (German Medicines Manufacturers' Association)
- **Bundesverband der Pharmazeutischen Industrie e.V. (BPI)** (German Pharmaceutical Industry Association)
- **IFA Informationsstelle für Arzneispezialitäten GmbH** (German Issuing Agency for Pharmacy Products)
- **PHAGRO | Bundesverband des Pharmazeutischen Großhandels e.V.** (Association of Pharmaceutical Wholesalers)
- **Verband Forschender Arzneimittelhersteller e.V. (vfa)** (Association of Research-Based Pharmaceutical Companies)

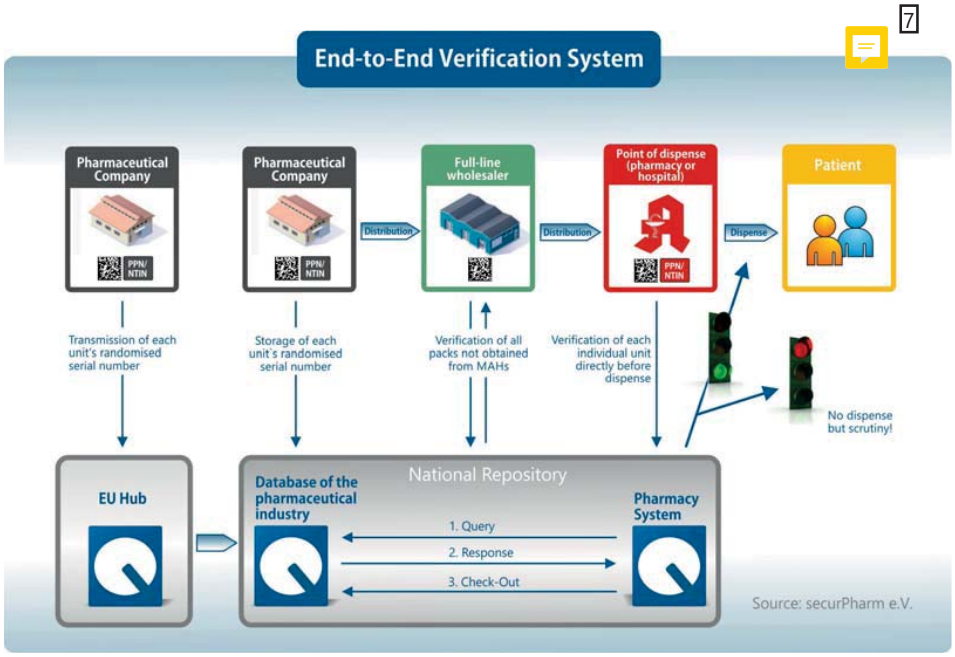

Figure 1: End-to-End Verification System

Page: 5

Number: 1 Author: Compare: Delete Subject: text Date: Indeterminate
"a concept for the operational implementation of"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:07:16
content

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Act."

[New text]: "Regulation with additional details."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:07:16
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:48:38
Replace:
(Old text): "The details with regard to the properties and technical specifications of the safety feature "unique identifier" are stipulated in the Delegated Regulation (EU) 2016/161 of the Commission of 2 October 2015, and published it in the Official Journal of the European Union on 9 February 2016.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:06:56
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
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[New text]: "Manufacturers'"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:06:56
editorial

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Now the"

[New text]: "The"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:06:44
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "This Regulation"

[New text]: "The DR"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:06:44
editorial

Number: 7 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:49:18
Replace:
(New Figure 1)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:06:44
content

securPharm is based on a concept in which the technical approach of the system ensures that the stakeholders remain in charge of their data (see Figure 1). The marketing authorisation holders (MAHs) upload their pack-related data to the database system of the pharmaceutical industry (ACS MAH system), which is operated by ACS PharmaProtect GmbH. The managing partners of this operating company are the trade associations BAH, BPI, Pro Generika and vfa. Verification inquiries from the pharmacies and other entities authorised to dispense pharmaceuticals are bundled via a centralised pharmacy system and sent to the ACS MAH system in anonymised form. The pharmacy system is operated by Netzgesellschaft Deutscher Apotheker mbH (NGDA). Wholesalers also conduct their verifications via the centralised pharmacy system. This system separation and anonymization of the verification inquiries from the pharmacy system ensures mutual data confidentiality and leaves the responsibility with the process operators.

With securPharm, the National Medicines Verification System (NMVS) has been created for Germany. As such, it serves as a partner within the safety network in Europe provided by the European Medicines Verification Organisation (EMVO).

As a core element for verification, the FMD requires that each package shall bear a so-called unique identifier. To ensure identification of the unique identifier on the pharmaceutical packages, this specification includes the requirements of the legislature and supplements it with the necessary technical details.

2 Scope

Since verification takes place in a networked system between various stakeholders in a so-called open system, mutual technical coordination is a mandatory prerequisite for smooth operations.

It is for this purpose that these coding rules describe the technical specifications of the unique identifier (UI) for pharmaceuticals that are subject to verification and that are to be placed on the German market. They must be used by the marketing authorisation holders (MAHs), manufacturers or commissioned service providers who label the UI as well as the stakeholders who have to perform the verification of the UI. The latter are primarily pharmacies and wholesalers. Their system providers must also observe and implement these specifications.

The document at hand contains the special features of the product code defined for the German market. Coding, code content, code size and print quality as well as the associated labelling of the pharmaceutical packages are described in detail.

Note: The rules set out in this document may deviate in individual parts from the current GS1 specifications. However, in such cases the rules set out in this document take precedence.

Transport logistics and the associated external packaging are outside the scope of this specification. The underlying ISO coding standards for the securPharm project allow the operator to integrate data and the system of the Pharmacy Product Number (PPN, see ***Chapter 4.2***) or the National Trade Item Number (NTIN, see ***Chapter 4.3***) into higher-level standard logistics and aggregation systems (ISO 15394).

Furthermore, these coding rules do not describe the following:

- the necessary information technology (IT) processes as part of verification; and
- the anti-tampering device required in the FMD.

Page: 6

Number: 1 Author: Compare: Insert Subject: text Date: Indeterminate
"also"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:57
editorial

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Replace:
(Old text): "The marketing authorisation holders (MAH) upload their package-related data to the database system of the pharmaceutical industry (ACS-MAH-System). To run the ACS-MAH-System, the associations of BAH, BPI and vfa have established ACS PharmaProtect GmbH as the operating
company."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:57
content

Number: 3 Author: Compare: Insert Subject: text Date: Indeterminate
"at hand"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:08:21
editorial

Number: 4 Author: Compare: Insert Subject: text Date: Indeterminate
"and other entities authorised to dispensepharmaceuticals"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:08:21
content

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "some"

[New text]: "individual"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:08:21
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Avoxa – Mediengruppe"

[New text]: "Netzgesellschaft"
The following text attributes were changed:
font

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:08:21
content

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "GmbH."

[New text]: "mbH (NGDA)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:08:21
editorial

Number: 8 Author: Compare: Insert Subject: text Date: Indeterminate
"system separation and"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:08:21
content

Number: 9 Author: Compare: Delete Subject: text Date: Indeterminate
"It has also created the most favourable conditions interms of efficiency of organisational costs, investments and operating costs.Since 2013, pharmaceutical companies have been able to use securPharm and practice their own processes."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
content

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate

Comments from page 6 continued on next page

securPharm is based on a concept in which the technical approach of the system ensures that the stakeholders remain in charge of their data (see Figure 1). The marketing authorisation holders (MAHs) upload their pack-related data to the database system of the pharmaceutical industry (ACS MAH system), which is operated by ACS PharmaProtect GmbH. The managing partners of this operating company are the trade associations BAH, BPI, Pro Generika and vfa. Verification inquiries from the pharmacies and other entities authorised to dispense pharmaceuticals are bundled via a centralised pharmacy system and sent to the ACS MAH system in anonymised form. The pharmacy system is operated by Netzgesellschaft Deutscher Apotheker mbH (NGDA). Wholesalers also conduct their verifications via the centralised pharmacy system. This system separation and anonymization of the verification inquiries from the pharmacy system ensures mutual data confidentiality and leaves the responsibility with the process operators.

With securPharm, the National Medicines Verification System (NMVS) has been created for Germany. As such, it serves as a partner within the safety network in Europe provided by the European Medicines Verification Organisation (EMVO).

As a core element for verification, the FMD requires that each package shall bear a so-called unique identifier. To ensure identification of the unique identifier on the pharmaceutical packages, this specification includes the requirements of the legislature and supplements it with the necessary technical details. 12

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Furthermore, these coding rules do not describe the following:

- the necessary information technology (IT) processes as part of verification; and
- the anti-tampering device required in the FMD.

[Old text]: "(PPN)"

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Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
content

Number: 11 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "(NTIN)"

[New text]: "(NTIN, see Chapter 4.3)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
content

Number: 12 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:49:18
Delete:
(Deleted text): ""The editor points out that these “Coding Rules” were generated to the best of his knowledge based on the current findings at the time of printing. Due to open legal and technical questions and the possibly required adjustment of social law requirements and others, future modifications and adjustments cannot be excluded, which means that this right must be expressly reserved. For additional information on securPharm, please visitwww.securPharm.de."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
content

Number: 13 Author: Compare: Insert Subject: text Date: Indeterminate
"(UI)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
editorial

Number: 14 Author: Compare: Replace Subject: text Date: Indeterminate
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[New text]: "verification"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
content

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Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:09:41
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Number: 16 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "pharmaceuticals"

[New text]: "the UI"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:57
content

Number: 17 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "unique identifier."

[New text]: "UI."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:57
editorial

3 Notes on verification

The following subchapters contain notes on additional elements and processes that are closely linked to coding.

3.1 Verification labels

In the IFA database (product master data), the verification indicators (Verifizierungskennzeichen) are assigned to the article/PZN in question and are as follows:

- *Verifizierung im Pflichtbetrieb ab Hochladedatum (VKZ-H - Verification in mandatory operations from upload date) and*
- *Verifizierung im Pflichtbetrieb ab Verfalldatum (VKZ-V - Verification in mandatory operations from expiry date)*

With these verification labels, pharmaceuticals subject to mandatory verification should be recognizable as such and ensure that pharmaceutical packs released and entering the market prior to 9 February 2019 (existing merchandise) can be dispensed without verification.

Details on these labels and regarding notification to IFA can be viewed at this link[1].

3.2 Serial number rules

Pursuant to Article 4 of the Delegated Regulation (EU) 2016/161 (DR), the serial number required for verification is a numeric or alphanumeric sequence of a maximum of 20 characters generated by the marketing authorisation holder (MAH). To make matters as difficult as possible for forgers, these serial numbers assigned by the MAH must be generated by a deterministic or non-deterministic randomisation algorithm. In any case, the probability of deriving a serial number must be lower than 1:10,000. In addition, the randomised serial number in combination with the product code based on the PZN must be unique for each pharmaceutical pack for a period of at least one year after the pack's expiry date or at least five years after the pharmaceutical has been released for sale or distribution (the longer time period shall apply).

Reusing serial numbers represents a potential error source and is therefore not recommended.

3.3 Data transfer to the database system of the pharmaceutical industry

For pharmaceuticals destined for the German market, verification will be conducted on principle via the German database system of the pharmaceutical industry (also known as the ACS MAH system), which is operated by ACS PharmaProtect GmbH. The basic prerequisite for the verification process is the successful transmission of the pack data to the system. The pack data contain the following key data elements:

- Product code (either in PPN or NTIN format)
- Serial number
- Batch number
- Expiry date

Apart from the above-mentioned key elements, the marketing authorisation holder (MAH) must transmit additional information (so-called product master data) pursuant to Art. 33 of the DR, among others the marketing authorisation holder pursuant to Art. 33 para 2 g) of the DR.

From a point in time (yet to be determined) shortly after the effective date (9 February 2019) of the DR, the MAH can upload the pack data for products exclusively destined for the German market directly into the German database system of the pharmaceutical industry (ACS MAH system). To avoid data inconsistencies, the direct upload to the national system, which has been in effect since the start of pilot operations in 2013, must be terminated for technical reasons at the end of 2018. It will become available again in the first half of 2019 after an effective date that is yet to be announced. The ACS MAH system will inform its users regarding this effective date directly and via the website.

Furthermore, the marketing authorisation holder can upload pack data indirectly via the interface of the so-called EU Hub at the European Medicines Verification Organisation (EMVO). For multi-market packs, this is the path defined by the EMVO. During the above-mentioned transition phase, uploads are only possible via the EU Hub.

1 www.ifaffm.de/en/ifa-fuer-anbieter.html

Page: 7

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Technical information concerning"

[New text]: "Notes on"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:57
editorial

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " securPharm System"

[New text]: " database system of the pharmaceutical industry"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:29
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Number: 3 Author: Compare: Insert Subject: text Date: Indeterminate
"3.3"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:29
added chapter was chapter 3.2 in previous version 3.3

Number: 4 Author: Compare: Replace Subject: text Date: 09.02.2019 14:39:34
[Old text]: "– overview"
[New text]: "The following subchapters contain notes on additionalelements and processes that are closely linked to coding."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:29
content

Number: 5 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:12:11
(New chapter 3.1)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:11:29
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
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data to the ACS-MAH-System of securPharm. These contain the following key data elements:
• product code (either as PPN or NTIN)
• serial number
• batch number
• expiry date

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 7 Author: Compare: Insert Subject: text Date: Indeterminate
"Verification labels In the IFA database (product master data), the verifica- tion indicators (Verifizierungskennzeichen) are assigned to the article/ PZN in question and are as follows:• Verifizierung im Pflichtbetrieb ab Hochladedatum(VKZ-H - Verification in mandatory operations from upload date) and• Verifizierung im Pflichtbetrieb ab Verfalldatum (VKZ-V - Verification in mandatory operations from expiry date)With these verification labels, pharmaceuticals subject to mandatory verification should be recognizable as such and ensure that pharmaceutical packs released and entering the market prior to 9 February 2019 (existing merchandise) can be dispensed without verification.Details on these labels and regarding notification to IFA can be viewed at this link1 ."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
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Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Replace:
(Old text): "Apart from the above-mentioned key data elements, the MAH must also transfer additional information, e.g. pursuant
to Art. 33 para. 2 lit. (f) of the Delegated Regulation, the manufacturer who affixed the safety features."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 9 Author: Compare: Move Subject: text Date: Indeterminate

Comments from page 7 continued on next page

3 Notes on verification

The following subchapters contain notes on additional elements and processes that are closely linked to coding.

3.1 Verification labels

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With these verification labels, pharmaceuticals subject to mandatory verification should be recognizable as such and ensure that pharmaceutical packs released and entering the market prior to 9 February 2019 (existing merchandise) can be dispensed without verification.

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Pursuant to Article 4 of the Delegated Regulation (EU) 2016/161 (DR), the serial number required for verification is a numeric or alphanumeric sequence of a maximum of 20 characters generated by the marketing authorisation holder (MAH). To make matters as difficult as possible for forgers, these serial numbers assigned by the MAH must be generated by a deterministic or non-deterministic randomisation algorithm. In any case, the probability of deriving a serial number must be lower than 1:10,000. In addition, the randomised serial number in combination with the product code based on the PZN must be unique for each pharmaceutical pack for a period of at least one year after the pack's expiry date or at least five years after the pharmaceutical has been released for sale or distribution (the longer time period shall apply).

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11 www.ifaffm.de/en/ifa-fuer-anbieter.html

3.3 Data transfer to the database system of the pharmaceutical industry

For pharmaceuticals destined for the German market, verification will be conducted on principle via the German database system of the pharmaceutical industry (also known as the ACS MAH system), which is operated by ACS PharmaProtect GmbH. The basic prerequisite for the verification process is the successful transmission of the pack data to the system. The pack data contain the following key data elements:

- Product code (either in PPN or NTIN format)
- Serial number
- Batch number
- Expiry date

Apart from the above-mentioned key elements, the marketing authorisation holder (MAH) must transmit additional information (so-called product master data) pursuant to Art. 33 of the DR, among others the marketing authorisation holder pursuant to Art. 33 para 2 g) of the DR.

From a point in time (yet to be determined) shortly after the effective date (9 February 2019) of the DR, the MAH can upload the pack data for products exclusively destined for the German market directly into the German database system of the pharmaceutical industry (ACS MAH system). To avoid data inconsistencies, the direct upload to the national system, which has been in effect since the start of pilot operations in 2013, must be terminated for technical reasons at the end of 2018. It will become available again in the first half of 2019 after an effective date that is yet to be announced. The ACS MAH system will inform its users regarding this effective date directly and via the website.

Furthermore, the marketing authorisation holder can upload pack data indirectly via the interface of the so-called EU Hub at the European Medicines Verification Organisation (EMVO). For multi-market packs, this is the path defined by the EMVO. During the above-mentioned transition phase, uploads are only possible via the EU Hub.

This text was moved from page 6 of old document

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
Was Chapter 3.1 in previous version

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "The"

[New text]: "Pursuant to Article 4 of the Delegated Regulation (EU)2016/161 (DR), the"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 11 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Insert:
New footnote;
2 previous footnotes deleted

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

The product master data stipulated by the EMVO must always be uploaded via the EU Hub. Additional information on uploading product master data via the EU Hub are available in the "EMVS Master Data Guide" at this link[2].

In any case, the MAH needs the contract with the EMVO and with ACS PharmaProtect GmbH as a prerequisite for Europe-wide verification. The contracts allow the MAH to use the systems.

In reference to the corresponding PZN, the required product master data are directly transmitted to the ACS MAH system by IFA GmbH. Based on these master data, the MAH's authorisation to upload pack data is derived via the assignment of the PZN to the IFA supplier number. Therefore, when uploading via the EU Hub, correct entry of the five-digit[3] IFA supplier number in the field "MAH ID" is obligatory.

With EMVO master data, the PZN must always be entered in the field "National Code" for pharmaceuticals placed on the market in Germany. This applies equally to multi-market packs (MMP) and single-market packs (SMP).

Since the verification process is based on the PZN as a key element, only those pharmaceutical packs can participate in verification to which a PZN was assigned and for which the above-mentioned verification labels have been reported for issue in the IFA information services.

A timely connection to the ACS MAH system is key for testing the processes and for ensuring a smooth procedure. The time allowances required for administrative processes must also be taken into account.[4]

For more detailed information on the organisational and technical connection to the database system of the pharmaceutical industry by ACS PharmaProtect GmbH, please visit www.pharmaprotect.de/de/.

---

6 www.emvo-medicines.eu/knowledge-database

3 With leading zeros, if necessary.

4 Due to the higher number of inquiries to connect to the ACS MAH system, marketing authorisation holders should plan sufficient lead time for concluding the contract with ACS PharmaProtect GmbH in order not to jeopardise the marketability of their products subject to mandatory verification after 9 February 2019.

To avoid conflict situations, we recommend that MAHs act in a very timely manner when it comes to notifying IFA GmbH, accessing the ACS MAH system and uploading product master data to the EU Hub.

3.4 Anti-tampering device

On 11 April 2017, the BfArM and the PEI stated in a joint announcement that the anti-tampering device may also be voluntarily affixed to pharmaceuticals that are not affected by the Falsified Medicines Directive:

"[...] For pharmaceuticals for which affixing of the anti-tampering device is not mandatory pursuant to Article 54a para. 1 of Directive 2001/83/EC, marketing authorisation holders can already affix the anti-tampering device for patient protection and to recognise potential manipulation on a voluntary basis at this point or after the above-mentioned effective date. [...]"

For the complete and certified text of the announcement, please visit the PEI website. The announcement can also be read in the "Bundesanzeiger".

3.5 Assignment of pharmaceuticals subject to mandatory verification

The higher federal authorities PEI and BfArM have classified pharmaceuticals that must bear the safety features pursuant to the DR accordingly in the public part of the AMIS Database. Pharmaceutical companies can check the classifications and contact Department 1 at the BfArM via email, if there are discrepancies.

Page: 8

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Insert:

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Insert:
(new text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Insert:
(New chapter 3.4)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 16:49:18
Replace:
(Old text): "In reference to the corresponding PZN, the required product master data are currently directly transmitted to the ACS-MAH-System[1] via the information services of the IFA.
The verification process is available for those products the MAH has reported to IFA via the change service. The upload of product master data from the IFA system to the ACS-MAH-System also depends on this report.
The prerequisite for participation in the national verification system is a concluded user agreement with ACS.
An early connection is important in order to practice the corporate processes and to identify and exclude possible internal error sources.[2]
For more detail information on the organisational and technical connection to the ACS-MAH-System, please visit http://www.pharmaprotect.de/en/."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(new chapter 3.5)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New footnotes 2-4)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
content

4 Coding agreements

4.1 General

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

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

An additional element mentioned in Article 4 is the national reimbursement number. For pharmaceuticals destined for the German market, it is included in the product code (PC) in the form of the PZN (see ***Chapter 4.2***) and therefore does not need to be listed as a separate fifth element pursuant to Article 4 (e) of the Delegated Regulation.

Coding is done in the Data Matrix Code (DMC) in accordance with ISO/IEC 16022 (see ***Chapter 6.1***) and the data structure and syntax pursuant to ISO/IEC 15418 and ISO/IEC 15434 (see ***Chapter 5***).

This ensures machine readability of these data elements and creates the technical prerequisite for the implementation of the EU Falsified Medicines Directive and additionally expected legal requirements for the verification of pharmaceutical packages.

At the same time, the requirements from Article 5 “Carrier of the unique identifier” of the DR are met.

In order to comply with the requirements of Article 4 (d) of the DR, an unambiguous product code on a Europe-wide scale is needed. For pharmaceuticals eligible for marketing in Germany, the product code can be represented in the Data Matrix Code either in the format of a Pharmacy Product Number (PPN) or of a National Trade Item Number (NTIN). Both formats can be generated from the eight-digit (German) PZN. The marketing authorisation holder (MAH) can freely choose between the two above-mentioned formats of the product code and also use both side by side.

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

For the retail segment, the PZN will remain the relevant article number and it will continue to be used for reimbursement and legal pharmaceutical concerns. As a result, existing processes will be preserved without change.

Interoperability with other numeric systems, e.g. GTIN (with GS1 as the issuing agency in charge) or HIBC (with EHIBCC as the issuing agency in charge) is reliably ensured by the joint basis of international standards. The following chapters describe the properties and methods for generating the PPN and the NTIN.

Page: 9

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Regulation,"

[New text]: "Regulation (EU) 2016/161 (DR),"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
editorial

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"(UI)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
editorial

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "product"

[New text]: "Product"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
editorial

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "serial"

[New text]: "Serial"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
editorial

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "batch"

[New text]: "Batch"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
editorial

Number: 6 Author: Compare: Delete Subject: text Date: Indeterminate
"briefly"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:14:04
editorial

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "expiry"

[New text]: "Expiry"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 8 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "next two"

[New text]: "following"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 9 Author: Compare: Insert Subject: text Date: Indeterminate
"(PC)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 10 Author: Compare: Insert Subject: text Date: Indeterminate
"the"

Comments from page 9 continued on next page

4 Coding agreements

4.1 General

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

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

An additional element mentioned in Article 4 is the national reimbursement number. For pharmaceuticals destined for the German market, it is included in the product code (PC) in the form of the PZN (see ***Chapter 4.2***) and therefore does not need to be listed as a separate fifth element pursuant to Article 4 (e) of the Delegated Regulation.

Coding is done in the Data Matrix Code (DMC) in accordance with ISO/IEC 16022 (see ***Chapter 6.1***) and the data structure and syntax pursuant to ISO/IEC 15418 and ISO/IEC 15434 (see ***Chapter 5***).

This ensures machine readability of these data elements and creates the technical prerequisite for the implementation of the EU Falsified Medicines Directive and additionally expected legal requirements for the verification of pharmaceutical packages.

At the same time, the requirements from Article 5 “Carrier of the unique identifier” of the [11] are met.

In order to comply [12] the requirements of Article 4 (d) of the DR, an unambiguous product code on a Europe-wide scale is needed. For pharmaceuticals eligible for marketing in Germany, the product code can be represented in the Data Matrix Code either in the format of a Pharmacy Product Number (PPN) or of a National Trade Item Number (NTIN). Both formats can be generated from the eight-digit (German) PZN. The marketing authorisation holder (MAH) can freely choose between the two above-mentioned formats of the product code and also use both side by side.

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

For the retail segment, the PZN will remain the relevant article number and it will continue to be used for reimbursement and legal pharmaceutical concerns. As a result, existing processes will be preserved without change.

Interoperability with other numeric systems, e.g. GTIN (with GS1 as the issuing agency in charge) or HIBC (with EHIBCC as the issuing agency in charge) is reliably ensured by the joint basis of international standards. The following chapters describe the properties and methods for generating the PPN and the NTIN.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 11 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Delegated Regulation"

[New text]: "DR"

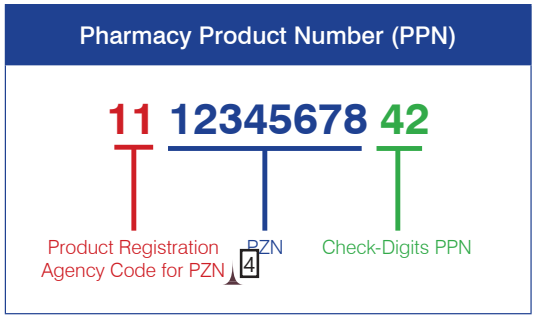
Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 12 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Replace:
(Old text): "In order to comply with Article 4 lit. (d) of the Delegated
Regulation, an unambiguous product code on a Europe- eide scale is needed. In order to meet this requirement in Germany the Pharmacy Product Number (PPN)
is used as product code for verification. In the Data Matrix Code, the product code can be represented either in
the format of a PPN or of a National Trade Item Number (NTIN). Both formats can be generated from the eight-digit (German) PZN. The marketing authorisation holder can choose between the two above-mentioned formats of the product code."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
content

4.2 Pharmacy Product Number (PPN)

As shown below, the PZN is embedded into the globally unambiguous format of a PPN.



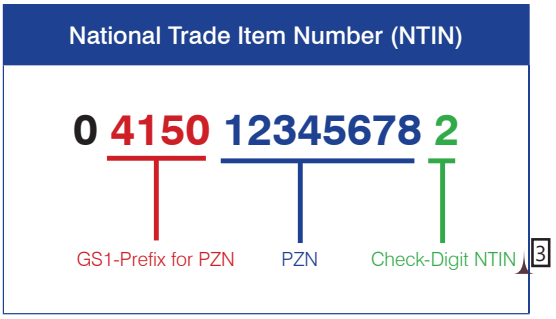
The PPN consists of three parts that are highlighted in red, blue and green. The "11" stands for a Product Registration Agency Code (PRA Code). This code is managed and assigned by IFA. The "11" is assigned for the German PZN. The national article number follows after the "11" and is represented in blue. This is the unmodified PZN (8 digits). The subsequent digits (shown in the figure in green) form the two-digit, calculated check number of the PPN across the entire data field (including the "11"). This together with the PZN represented in this example results in a value of "42".

The use of the PPN is available to all users without a licence.

The links to additional information regarding the PPN[5] and the PPN Generator[6] can be found in the footnotes.

4.3 National Trade Item Number (NTIN)

As shown below, the PZN is embedded into the globally unambiguous format of a TIN[7].



The NTIN consists of three parts that are highlighted in red, blue and green. The "4150" is the prefix assigned for the PZN by GS1 Germany. The unmodified PZN (8 digits), represented in blue, follows. The last digit (shown in the figure in green) represents the check digit across the entire data field. Detailed information on the NTIN and the generation of the check digit can be found in the NTIN Guideline[8] of GS1.

In addition, the NTIN must be prefixed by a "0" to generate a 14-digit format for this application.

In both its technical form and logistic application, the NTIN formed in this manner is a full Global Trade Item Number (GTIN). The different term "NTIN" merely points out the difference in the assignment of the GTIN: While the part of the GTIN that follows the prefix assigned by GS1 (country and manufacturer ID) is typically assigned by the "manufacturer" (supplier) himself for an individual item ID, this part is instead assigned centrally by a national entity for an NTIN. For an NTIN used in Germany, this will be the PZN assigned by IFA.

---

5 https://www.ifaffm.de/en/ifa-codingsystem/von-pzn-zu-ppn.html

6 https://www.ifaffm.de/en/ifa-codingsystem/weltweite-nutzung-ppn.html

7 Unless stated otherwise, this specification understands the term NTIN or NTIN-DE to be a GTIN that bears the prefix assigned to the German PZN.

8 https://www.gs1-germany.de/fileadmin/gs1/basis_informationen/kennzeichnung_von_pharmazeutika_in_deutschland.pdf

Page: 10

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "– Use in Germany"

[New text]: "4.3 National Trade Item Number (NTIN)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
content

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "NTIN:"

[New text]: "NTIN7 ."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
New number for footnote

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 3 Author: Compare: Delete Subject: text Date: Indeterminate
"Figure 3: Generation of the NTIN"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
Figure legend deleted

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:16:25
editorial

Number: 4 Author: Compare: Delete Subject: text Date: Indeterminate
"Figure 2: Generation of the PPN"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
Figure legend deleted

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
editorial

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Replace:
(Old text): "The PPN consists of three parts that are highlighted in
red, blue and green. The "11" stands for a Product Registration
Agency Code (PRA Code or PRAC). This code is
managed and assigned by the IFA. The "11" is reserved for the PZN. The national article number follows after the
"11" and is represented in blue. This is the unmodified PZN (PZN8). The subsequent digits (shown in the figure in green) form the two-digit, calculated check number
across the entire data field (including the "11"). Together with the PZN represented in this example a value of "42" is resulting.
For more detailed information on the PPN and the PPN-generator, please see http://www.ifaffm.de/en/
ifa-codingsystem/pzn-to-ppn.html and the document "Data Matrix Code for retail packs" at http://www.ifaffm. de/en/ifa-codingsystem/data-matrix-code-retailpacks.
html."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Replace:
(Old text): "The unmodified PZN,
represented in blue, follows (PZN8). The last digit (shown in the figure in green) represents the check digit across the entire data field. In addition, the NTIN must be prefixed
by a "0" to make it to a 14-digit format for this application. Detailed information on the NTIN and the generation of the check digit can be found in the NTIN Guideline of GS1 (https://www.gs1-germany.de/fileadmin/gs1/basis_
informationen/kennzeichnung_von_pharmazeutika_in_deutschland.pdf).

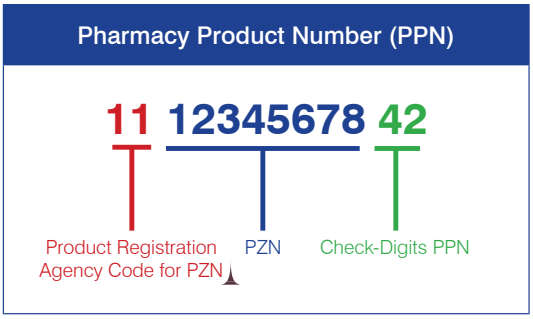
Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 7 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New text)

Comments from page 10 continued on next page

4.2 Pharmacy Product Number (PPN)

As shown below, the PZN is embedded into the globally unambiguous format of a PPN.



The PPN consists of three parts that 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 IFA. The "11" is assigned for the German PZN. The national article number follows after the "11" and is represented in blue. This is the unmodified PZN (8 digits). The subsequent digits (shown in the figure in green) form the two-digit, calculated check number of the PPN across the entire data field (including the "11"). This together with the PZN represented in this example results in a value of "42".

The use of the PPN is available to all users without a licence.

The links to additional information regarding the PPN[5] and the PPN Generator[6] can be found in the footnotes.

4.3 National Trade Item Number (NTIN)

As shown below, the PZN is embedded into the globally unambiguous format of a NTIN[7].

The NTIN consists of three parts that are highlighted in red, blue and green. The "4150" is the prefix assigned for the PZN by GS1 Germany. The unmodified PZN (8 digits), represented in blue, follows. The last digit (shown in the figure in green) represents the check digit across the entire data field. Detailed information on the NTIN and the generation of the check digit can be found in the NTIN Guideline[8] of GS1.

In addition, the NTIN must be prefixed by a "0" to generate a 14-digit format for this application.

In both its technical form and logistic application, the NTIN formed in this manner is a full Global Trade Item Number (GTIN). The different term "NTIN" merely points out the difference in the assignment of the GTIN: While the part of the GTIN that follows the prefix assigned by GS1 (country and manufacturer ID) is typically assigned by the "manufacturer" (supplier) himself for an individual item ID, this part is instead assigned centrally by a national entity for an NTIN. For an NTIN used in Germany, this will be the PZN assigned by IFA.

5 https://www.ifaffm.de/en/ifa-codingsystem/von-pzn-zu-ppn.html

6 https://www.ifaffm.de/en/ifa-codingsystem/weltweite-nutzung-ppn.html

7 Unless stated otherwise, this specification understands the term NTIN or NTIN-DE to be a GTIN that bears the prefix assigned to the German PZN.

8 https://www.gs1-germany.de/fileadmin/gs1/basis_informationen/kennzeichnung_von_pharmazeutika_in_deutschland.pdf

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New footnotes)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 9 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New footnotes)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

This is because in Germany the partners of the master agreement pursuant to Section 131 of the German Social Code Book V have concluded a binding agreement that pharmaceuticals, among others, must be exclusively labelled with the PZN, both in clear text and in machine-readable format. According to this agreement, a GTIN assigned by the manufacturer (supplier, marketing authorisation holder) is not permitted in this respect.

When using the NTIN, the manufacturer (supplier, marketing authorisation holder) must adhere to the licencing terms of GS1 Germany.

4.4 Codes and data content on pharmaceutical packages

Figure 2 shows the different contents of the Data Matrix Code (DMC) for pharmaceuticals that are subject to mandatory verification and those that are not. For pharmaceuticals not subject to mandatory verification, affixing of the DMC is voluntary.

	Data Matrix Code			
	PC	**SN**	**LOT**	**EXP**
Medicinal product subject to mandatory verification	PPN or NTIN	Obligatory	Obligatory	Obligatory
Pharmaceutical not subject to mandatory verification	PPN or NTIN	Not allowed	Allowed	Allowed

Figure 4: Variations of application in coding

The additional coding of the PZN in Code 39 can be omitted for packs, if they include the DMC in accordance with this specification and are placed on the market after 9 February 2019. However, the PZN must always be affixed in clear text (see ***Chapter 6.6***). It is recommended to maintain Code 39 at least for the time being to make the transition easier for the parties involved.

The Data Matrix Code must be affixed to all pharmaceuticals subject to mandatory verification with the above-mentioned data contents. For pharmaceuticals that are not subject to mandatory verification, affixing of the Data Matrix Code as such and the additional data content regarding the PPN/NTIN is optional. However, serial numbers are not allowed for pharmaceuticals that are not subject to mandatory verification.

The FMD allows that additional one- or two-dimensional codes be affixed to the pack, as long as they do not contain the unique identifier that serves to verify the authenticity or identity. As a result, it may be possible as part of the individual marketing authorisation to affix codes that contain additional information or reference other sources, e.g. a uniform resource locator (URL). Additional visible codes may misdirect users during pack identification, thereby making the scanning process more difficult. They should be restricted to the bare minimum required. Additional data content makes the Data Matrix Code larger. It must be ensured that the minimum print quality required in the DR (see ***Chapter 7***) remain preserved.

Page: 11

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 17:15:52
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:57
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Replace:
(Old text): "The coding of the PZN within Code 39 and other codes such as the EAN-13 will be kept on retail packages until further notice.[1] This ensures retention of established processes. By products subject to mandatory verification the Data Matrix Code must be affixed additionally.
For all other products the affixement of a Data Matrix Code is optional. In addition to the PPN/NTIN other elements can be included in the Data Matrix Code. Exception: a serial number is not allowed for products not being subject to mandatory verification.
The basic versions are described below:

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 3 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:50:10
Figure/Table has been replaced

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "4:"

[New text]: "2:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
editorial

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "package,"

[New text]: "pack,"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Delegated Regulation"

[New text]: "DR"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
editorial

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Replace:
(Old text): "However other codes may affect process security and should be limited to an absolut necessary minimum."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

4.5 Multi-market packs

Multi-market packs (MMPs) are packs that can be dispensed in multiple countries with a certain layout. They bear several national product codes for reimbursement and merchandise management purposes as well as various country-specific pieces of information.

Apart from the requirements for the German market, the respective national requirements in terms of coding and text information must also be taken into account for MMPs. This results in various versions in the labelling of MMPs. The following table provides a basic overview of the various forms of MMPs:

	Data Matrix Code							
	PC	**SN**	**LOT**	**EXP**	**GTIN**	**NTIN-non DE**	**PZN-DE**	**Other NHRN**
GS1-Version1	GTIN	1)	1)	1)	n.a.	n.a.	obligatory	additionally allowed
GS1-Version2	NTIN-DE	1)	1)	1)	n.a.	n.a.	not allowed 2)	not allowed 2)
ASC-Version	PPN	1)	1)	1)	additionally allowed	additionally allowed	n.a.	n.a.

1) Use of the data elements SN, LOT and EXP analogously to the single-market packs
2) In accordance with the GS1 code specification

Figure 3: MMP versions

For MMPs that are subject to mandatory verification, it is imperative that a product code be defined that can be used for all countries in which the pharmaceutical in question must be verified. Together with the associated serial number and all other pieces of information, this product code is uploaded via the EU Hub to all national verification systems. When the pharmaceutical is dispensed, the status of the pack in question is synchronised via the EU Hub in all national verification systems concerned.

Each country determines which national number apart from the product code (PC) must be incorporated in the Data Matrix Code. For MMPs destined for the German market, it is mandatory to include the PZN in the Data Matrix code, either directly in the product code or as an additional element, if the product code is assigned to another country.

Page: 12

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Multi Market Packs Multi market"

[New text]: "Multi-market packs Multi-market"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
editorial

Number: 2 Author: Compare: Delete Subject: text Date: Indeterminate
"retail"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:15:52
content

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Within the “blue box”, they"

[New text]: "They"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 5 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:50:10
Insert:
New table: "Figure 3"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "HUB"

[New text]: "EU Hub"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "HUB"

[New text]: "EU Hub"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 8 Author: Compare: Insert Subject: text Date: Indeterminate
"(PC)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Code. This can be done"

[New text]: "Code, either"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "pharmaceuticals"

Comments from page 12 continued on next page

4.5 Multi-market packs

Multi-market packs (MMPs) are packs that can be dispensed in multiple countries with a certain layout. They bear several national product codes for reimbursement and merchandise management purposes as well as various country-specific pieces of information.

Apart from the requirements for the German market, the respective national requirements in terms of coding and text information must also be taken into account for MMPs. This results in various versions in the labelling of MMPs. The following table provides a basic overview of the various forms of MMPs:

	Data Matrix Code							
	PC	**SN**	**LOT**	**EXP**	**GTIN**	**NTIN-non DE**	**PZN-DE**	**Other NHRN**
GS1-Version1	GTIN	1)	1)	1)	n.a.	n.a.	obligatory	additionally allowed
GS1-Version2	NTIN-DE	1)	1)	1)	n.a.	n.a.	not allowed 2)	not allowed 2)
ASC-Version	PPN	1)	1)	1)	additionally allowed	additionally allowed	n.a.	n.a.

1) Use of the data elements SN, LOT and EXP analogously to the single-market packs
2) In accordance with the GS1 code specification

Figure 3: MMP versions

For MMPs that are subject to mandatory verification, it is imperative that a product code be defined that can be used for all countries in which the pharmaceutical in question must be verified. Together with the associated serial number and all other pieces of information, this product code is uploaded via the EU Hub to all national verification systems. When the pharmaceutical is dispensed, the status of the pack in question is synchronised via the EU Hub in all national verification systems concerned.

Each country determines which national number apart from the product code (PC) must be incorporated in the Data Matrix Code. For MMPs destined for the German market, it is mandatory to include the PZN in the Data Matrix Code, either directly 12 he product code 11 s an additional element, if the product code is assigned to another country.

[New text]: "MMPs"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 11 Author: Compare: Delete Subject: text Date: Indeterminate
"as described in Chapter 4"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 12 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "within"

[New text]: "in"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

The GS1 versions listed in Figure 3 are shown in Figure 4 as an example of an MMP for the Austrian and German market. A GTIN or NTIN-DE is used as product code. As a result, there is a difference in the content of the PC and the number of elements of the DMC. Other than that, the layout (e.g. of the blue box) remains identical:

GS1-Version	PC: <Example>	Elements of DMC	PZN-DE encoded (DMC) <Example>	PZN-AT
1	a) GTIN (MAH) <04012312345676>	5	a) NHRN (710) 12345678	Look Up
2	b) NTIN-DE <04150123456782>	4	b) part of PC (01) <04150123456782>	Look Up

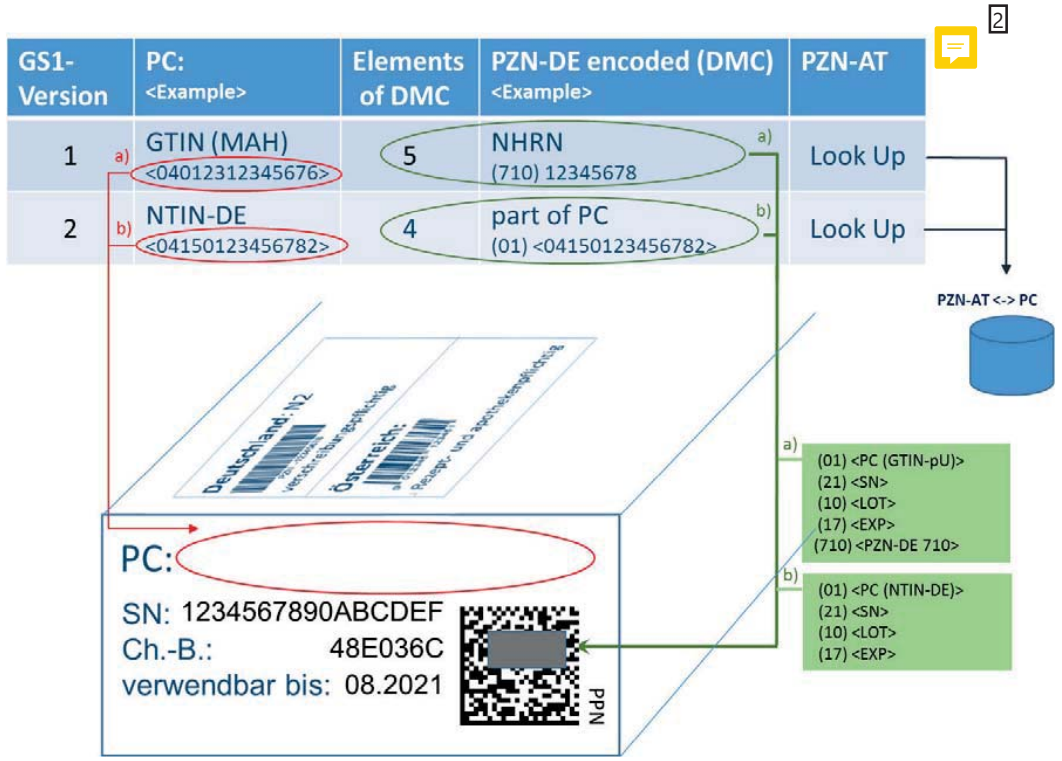


Figure 4: Example of an MMP for Germany and Austria

Page: 13

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 18:05:11
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 2 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:50:10
Insert:
"New Figure 4)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:50:10
Insert:
(New Figure 4)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

The GS1 version 2 (NTIN-DE) lends itself to MMPs that are sold in Germany and other countries where the national ID is deposited in a so-called look-up table. For example, this applies to Austria. Then the Data Matrix Code only contains four elements. As a product code, the NTIN with the German PZN (NTIN-DE) will be used.

For MMPs in accordance with the example from Figure 4, the marketing authorisation holder must issue the following notifications:

	Österreichischer Apotheken-verlag	EMVO	IFA / ACS
Notification	Link of the PC (GTIN or NTIN) in the format of a GTIN - in a 1:1 relation to the PZN-AT.	Link of the PC (GTIN or NTIN) in the format of a GTIN - in a 1:1 relation to the PZN-AT and the PZN-DE.	none
Application	The link is routed to the data recipients via the data services (in Austria) and creates the reference of the PC to the PZN-AT for the merchandise management systems.	The EMVO derives from this relationship the features and processes required for MMPs.	The national data do not represent MMPs. With regard to the PZN, the MMP acts like an SMP.

Figure 5: Notifications regarding MMPs for Germany and Austria

For additional details on the notifications, see "AMVO - Coding Rules for Austria"[9] and "EMVS Master Data Guide"[10].

The same rules as for single-market packs apply to the coding of the PZN.

Coding details are described in ***Chapter 5.3***.

For details on clear text, please see ***Chapter 6.6***.

---

6 www.amvo-medicines.at/en

10 www.emvo-medicines.eu/knowledge-database

Page: 14

Number: 1 Author: Compare: Insert Subject: text Date: Indeterminate
"The GS1 version 2 (NTIN-DE) lends itself to MMPs that are sold in Germany and other countries where the national ID is deposited in a so-called look-up table. For example, this applies to Austria. Then the Data Matrix Code only contains four elements. As a product code, the NTIN with the German PZN (NTIN-DE) will be used.For MMPs in accordance with the example from Figure 4, the marketing authorisation holder must issue the following notifications:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 2 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:51:04
Replace:
New Figure 5

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 4 Author: Compare: Move Subject: text Date: Indeterminate
This text was moved from page 9 of old document

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
editorial

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Insert:
(New footnotes)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:19:12
content

4.6 Clinic packs

Clinic packs that are subject to mandatory verification must be coded like all other packs that are subject to mandatory verification. Clinic packs consisting of clinic components represent a special scenario. In this case, the clinic pack, not the clinic component, represents the customary retail pack. As a result, the unique identifier must be affixed to the clinic pack, not the clinic component. For e.g. logistical reasons, the clinic components can bear a Data Matrix Code (DMC), but this DMC must not contain a serial number. Consequently, the data elements of clinic components cannot and must not be transmitted to the database system of the pharmaceutical industry and used for verification. See Figure 6 below.

	Typical pharmacy pack	Clinic pack	Clinic pack with so-called clinic components[11]	
				
Pack contents	Individual objects (blister, coated tablets, vials, ...)	Individual objects (blister, coated tablets, vials, ...)	Individual packs, so-called clinic components, that are combined in a bundle or different outer packaging to form a clinic pack	
IFA article type	Standard Merchandise	Clinic pack	Clinic pack	Clinic component
PZN in clear text[12]	√	√	√	√
Data Matrix Code - Data content	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Batch number - Expiry date
ACS MAH system	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	–
Object for verification	√	√	√	–

Figure 6: Overview of clinic packs

11 The term clinic component describes a pack that, while representing a separate unit, is also a part (component) of a clinic pack as such. An individual clinic component cannot be sold as a retail pack. Several identical clinic components form a clinic pack. The clinic component and the clinic pack have different PZNs. The PZN of the clinic component references the PZN of the clinic pack. For retail purposes, only the PZN of the clinic pack is relevant.

12 Code 39 can be omitted after 9 February 2019 (but not the PZN in clear text), if the pack bears a DMC that includes the PZN. See also *Chapter 4.4*.

Page: 15

Number: 1 Author: securPharmSubject: Hervorheben Date: 18.02.2019 09:53:39
Replace:
(Old text): "In principle clinic packs are coded identically to pharmacy retail packs. Clinic packs consisting of clinic components[1] represent a special scenario. In this case, the clinic pack, not the clinic component, represents the retail pack. As a result the unique identifier must be affixed to the clinic pack, not the clinic component.

Clinic components may bear a DMC, e.g. for logistical reasons, but the data elements must not be transmitted to the ACS-MAH-System or used for verification (see table below)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:23:09

Author: securPharmSubject: Sticky Note Date: 18.02.2019 10:02:05
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(Old text); "Pharmacy retail packs"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:23:09
editorial

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(Old text): " Clinic packs"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:23:09
editorial

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(New footnote number)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:23:09
editorial

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Single"

[New text]: "Individual"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
content

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Single"

[New text]: "Individual"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Retail pack"

[New text]: "Standard"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
content

Number: 8 Author: Compare: Insert Subject: text Date: Indeterminate
"merchandise"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
content

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "the Code 39 (bar code)"

Comments from page 15 continued on next page

4.6 Clinic packs

Clinic packs that are subject to mandatory verification must be coded like all other packs that are subject to mandatory verification. Clinic packs consisting of clinic components represent a special scenario. In this case, the clinic pack, not the clinic component, represents the customary retail pack. As a result, the unique identifier must be affixed to the clinic pack, not the clinic component. For e.g. logistical reasons, the clinic components can bear a Data Matrix Code (DMC), but this DMC must not contain a serial number. Consequently, the data elements of clinic components cannot and must not be transmitted to the database system of the pharmaceutical industry and used for verification. See Figure 6 below.

	Typical pharmacy pack	Clinic pack	Clinic pack with so-called clinic components[11]	
				
Pack contents	Individual objects (blister, coated tablets, vials, ...)	Individual objects (blister, coated tablets, vials, ...)	Individual packs, so-called clinic components, that are combined in a bundle or different outer packaging to form a clinic pack	
IFA article type	Standard merchandise	Clinic pack	Clinic pack	Clinic component
PZN in clear text[12]	√	√	√	√
Data Matrix Code - Data content	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Batch number - Expiry date
ACS MAH system	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	–
Object verification	√	√	√	–

Figure 6: Overview of clinic packs

11 The term clinic component describes a pack that, while representing a separate unit, is also a part (component) of a clinic pack as such. An individual clinic component cannot be sold as a retail pack. Several identical clinic components form a clinic pack. The clinic component and the clinic pack have different PZNs. The PZN of the clinic component references the PZN of the clinic pack. For retail purposes, only the PZN of the clinic pack is relevant.

12 Code 39 can be omitted after 9 February 2019 (but not the PZN in clear text), if the pack bears a DMC that includes the PZN. See also *Chapter 4.4*.

[New text]: "clear text12"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
content

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "optional"

[New text]: "obligatory"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
content

Number: 11 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(Old text):
"product code
- batch number
- expiry date"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
editorial

Number: 12 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(Old text):
"- product code
- serial number
- batch number
- expiry date"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:25:56
editorial

Number: 13 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(Old text):
"- product code
- serial number
- batch number
- expiry date"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:26:32
editorial

Number: 14 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
(Old text):
"- product code
- serial number
- batch number
- expiry date"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
editorial

Number: 15 Author: Compare: Insert Subject: text Date: Indeterminate
"Data"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
editorial

Number: 16 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "of"

[New text]: "for"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
editorial

Number: 17 Author: Compare: Replace Subject: text Date: Indeterminate

Comments from page 15 continued on next page

4.6 Clinic packs

Clinic packs that are subject to mandatory verification must be coded like all other packs that are subject to mandatory verification. Clinic packs consisting of clinic components represent a special scenario. In this case, the clinic pack, not the clinic component, represents the customary retail pack. As a result, the unique identifier must be affixed to the clinic pack, not the clinic component. For e.g. logistical reasons, the clinic components can bear a Data Matrix Code (DMC), but this DMC must not contain a serial number. Consequently, the data elements of clinic components cannot and must not be transmitted to the database system of the pharmaceutical industry and used for verification. See Figure 6 below.

	Typical pharmacy pack	Clinic pack	Clinic pack with so-called clinic components[11]	
				
Pack contents	Individual objects (blister, coated tablets, vials, ...)	Individual objects (blister, coated tablets, vials, ...)	Individual packs, so-called clinic components, that are combined in a bundle or different outer packaging to form a clinic pack	
IFA article type	Standard merchandise	Clinic pack	Clinic pack	Clinic component
PZN in clear text[12]	√	√	√	√
Data Matrix Code - Data content	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Serial number - Batch number - Expiry date	obligatory - Product code - Batch number - Expiry date
ACS MAH system	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	NTIN/PPN SN LOT EXP	–
Object for verification	√	√	√	–

Figure 6: Overview of clinic packs

19 The term clinic component describes a pack[18]t, while representing a separate unit, is also a part (component) of a clinic pack as such. An individual clinic component cannot be sold as a retail pack. Several identical clinic components form a clinic pack. The clinic component and the clinic pack have different PZNs. The PZN of the clinic component references the PZN of the clinic pack. For retail purposes, only the PZN of the clinic pack is relevant.

20 Code 39 can be omitted after 9 February 2019 (but not the PZN in clear text), if the pack bears a DMC that includes the PZN. See also *Chapter 4.4*.

[Old text]: "clinical"

[New text]: "clinic"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
editorial

Number: 18 Author: securPharmSubject: Highlight Date: 14.02.2019 16:51:04
Replace:
Old text): "The term clinic component describes a pack whose layout is identical to the retail pack but which cannot be sold independently. A PZN has been assigned to the clinic component for identification. The PZN of the clinic component refers to the PZN of the clinic pack. Clinic components combined in a bundle or a different outer packaging form a clinic pack to which a PZN is assigned, that is relevant for wholesale and retail purposes."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
content

Number: 19 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "1"

[New text]: "11"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
editorial

Number: 20 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New footnote)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:27:24
content

2.7 Free samples

The DR explicitly includes free samples in the mandatory verification. This requires that free samples be subject to item identification. In Germany, free samples (Ärztemuster) are governed by Section 47 para. 3 and 4 of the German Medicinal Products Act (AMG). The following table shows what options and layout versions are available to marketing authorisation holders.

Layout version	Package size	PZN	IFA master data
Use of the customary retail pack with the subsequently affixed information “Ärztemuster”.	Smallest retail pack (typically N1)	No separate PZN for dispensation as physicians‘ sample	- No differentiation between article type “Standard” and “Ärztemuster” according to AMG - No separate notification to IFA regarding the free sample
Specific “free sample” layout (separate packaging)	Smallest retail pack (typically N1)	Specific PZN	- Assignment of the specific PZN with the article type “Ärztemuster” according to AMG”
Specific “free‘ sample” layout (separate packaging)	Separate pack size that is smaller than the smallest retail pack (smaller than N1)	Specific PZN	- Assignment of the specific PZN with the article type “Ärztemuster” according to AMG”

Figure 7: Layout versions for physicians’ samples

Page: 16

Number: 1 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:52:07
Insert:
New chapter 4.7

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"4.7 Free samples The DR explicitly includes free samples in the mandatory verification. This requires that free samples be subject to item identification. In Germany, free samples (Ärztemuster) are governed by Section 47 para. 3 and 4 of the German Medicinal Products Act (AMG). The following table shows what options and layout versions are available to marketing authorisation holders."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 3 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:51:04
Insert:
(New table): " Figure 7: Layout..."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

5 Data content and requirements for the Data Matrix Code

5.1 Data identifiers and structures

This chapter defines the data identifier/application identifier to be used in the Data Matrix Code (DMC) and the characteristics of the data elements. The data identifier/application identifier in accordance with international standard ISO/IEC 15418 is used (references the ANSI MH10.8.2 standard; Data Identifier and Application Identifier Standard). IFA uses the ASC MH10 data identifiers (DI) and GS1 works with the application identifiers (AI).

Typically, the standards leave the characteristics of the data elements open. Therefore, this specification defines the data type, length and character set in question in a manner that is binding for all market participants (see ***Chapter 7.2*** and ***Appendix A***). The use of one of the following two versions is allowed for structures and identifiers:

9 **Structure in format 06 according to ISO/IEC 15434 and Data Identifier (DI) according to ISO/IEC 15418 (ANSI MH10.8.2, Section I).** For details, please consult the IFA Specification.[13]

B **System Identifier "FNC1" and Application Identifier (AI) according to ISO/IEC 15418.** For details, please consult the GS1 Specification.[14]

A summary of the usable data identifier/application identifier as well as the permissible data types, character sets and data lengths for the data to be coded is presented in *Appendix A.*

The sequence of the data elements is discretionary.

Data identifiers/application identifiers that are not used in this specification but follow the syntax of MH10.8.2. should be correctly issued in the applications and result in defined conditions. Furthermore, this should not jeopardise the reading process and the associated data capture, and the specified data structures must not be violated by such extensions.

13 https://www.ifaffm.de/en/ifa-codingsystem/data-matrix-handelspackungen.html

14 https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/

If the market participants request additional data designators for joint use, these will be included in addition to those described in ***Chapter 5.2*** and their application will be clearly described.

5.2 Single Market Packs – Data elements and corresponding data identifiers/ application 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 9N (8 digits), which can be extracted from it (see ***Chapter 4.2*** Pharmacy Product Number (PPN) and ***Chapter 4.3***).

Example:

Format	DI AI	Data
ASC	9N	110375286414
GS1	01	04150037528643

Page: 17

Number: 1 Author: Compare: Insert Subject: text Date: Indeterminate
" for the Data Matrix Code"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "If any additional data designators are employed for joint usage by the market participants, securPharm will add these to the data designators described in *Chapter 5.2*
of the Coding Rules and provide a clear description of their application."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Identifiers"

[New text]: "Data identifiers"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
editorial

Number: 4 Author: Compare: Insert Subject: text Date: Indeterminate
"in the Data Matrix Code (DMC)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "Single market packs – Data elements and corresponding data identifiers / application identifier

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "document"

[New text]: "specification"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "5.2)."

[New text]: "5.2 and Appendix A)."
The following text attributes were changed:
font

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 8 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "PZN,"

[New text]: "PZN (8 digits),"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 9 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "A **Structure in format 06 according to ISO/IEC 15434 and ASC MH10 Data Identifier (DI) according to ISO/IEC 15418 (ANSI MH10.8.2)** For
details, see IFA's specification: http://www.ifaffm.de/

Comments from page 17 continued on next page

5 Data content and requirements for the Data Matrix Code

5.1 Data identifiers and structures

This chapter defines the data identifier/application identifier to be used in the Data Matrix Code (DMC) and the characteristics of the data elements. The data identifier/application identifier in accordance with international standard ISO/IEC 15418 is used (references the ANSI MH10.8.2 standard; Data Identifier and Application Identifier Standard). IFA uses the ASC MH10 data identifiers (DI) and GS1 works with the application identifiers (AI).

Typically, the standards leave the characteristics of the data elements open. Therefore, this specification defines the data type, length and character set in question in a manner that is binding for all market participants (see ***Chapter 5.2*** and ***Appendix A***). The use of one of the following two versions is allowed for structures and identifiers:

A **Structure in format 06 according to ISO/IEC 15434 and Data Identifier (DI) according to ISO/IEC 15418 (ANSI MH10.8.2, Section I).** For details, please consult the IFA Specification.[13]

B **System Identifier "FNC1" and Application Identifier (AI) according to ISO/IEC 15418.** For details, please consult the GS1 Specification.[14]

A summary of the usable data identifier/application identifier as well as the permissible data types, character sets and data lengths for the data to be coded is presented in *Appendix A.*

12 e sequence of the data elements is discretionary.

Data identifiers/application identifiers that are not used in this specification but follow the syntax of MH10.8.2. should be correctly issued in the applications and result in defined conditions. 13 thermore, this should not jeopardise the reading process and the associated data capture, and the specified data structures must not be violated by such extensions.

14 https://www.ifaffm.de/en/ifa-codingsystem/data-matrix-handelspackungen.html

14 https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/

If the market participants request additional data designators for joint use, these will be included in addition to those described in ***Chapter 5.2*** and their application will be clearly described.

5.2 Single Market Packs – Data elements and corresponding data identifiers/ application 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), which can be extracted from it (see ***Chapter 4.2*** 11 armacy Product Number (PPN) and ***Chapter 4.3***). 10

Example:

Format	DI AI	Data
ASC	9N	110375286414
GS1	01	04150037528643

en/ifa-codingsystem/data-matrix-code-retailpacks.html (document "Data Matrix Code on retail packs")
B **System Identifier "FNC1" and Application Identifier (AI) according to ISO/IEC 15418** For details, see GS1's specification: https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 10 Author: Compare: Delete Subject: text Date: Indeterminate
"The expanded eight-digit PZN must be used."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 11 Author: Compare: Insert Subject: text Date: Indeterminate
" Pharmacy Product Number (PPN)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
editorial

Number: 12 Author: Compare: Insert Subject: text Date: Indeterminate
"The sequence of the data elements is discretionary."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 13 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "**This must not jeopardize the scan process and the associated data capture. The specified data structures must not be violated by such extensions.**"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 14 Author: Compare: Insert Subject: text Date: Indeterminate
"13 https://www.ifaffm.de/en/ifa-codingsystem/data-matrix-handelspackungen.html 14 https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content; new footnotes

5.2.2 Serial number

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

The serial number is generated by the marketing authorisation holder (MAH) and assigned to an individual pack. It is mandatory for the verification process. For pharmaceuticals that are not subject to mandatory verification, the DMC must not contain a serial number.

Example:

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

The usable characters are described in ***Appendix A***.

5.2.3 Batch number

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

The batch number is assigned by the MAH. Predefined special characters can be used to distinguish partial/sub-batches (see ***Appendix A***).

Example:

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

5.2.4 Expiry date

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

The expiry date is set by the MAH.

The expiry date has the format “YYMMDD”.

YY = two-digit year number
Since the expiry date can only be in the future, the dates are for the 21st century (2000–2099).

MM = Numerical representation of the month (01–12)
DD = Day

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

Example:
Expiry date in June 2021

Format	DI AI	Data
ASC	D	210600
GS1	17	210600

This example implements the requirement of the German Medicinal Products Act (AMG) for clear text listing the month and year also in coding.

Example:
Expiry date on 30 June 2021

Format	DI AI	Data
ASC	D	210630
GS1	17	210630

This example presents the possibility of indicating an expiry date that is exact to the day.

Note: : In ANSI H10.8.2 standard, “D” is defined as the date in general. In the context of the PPN, the date “D” is necessarily the expiry date. For other date listings, such as the date of manufacturing, other identifiers must be used. For date of manufacturing, this would be the DI “16D” or the AI “11” respectively.

5.2.5 Additional data elements Example of a URL

The above-mentioned data elements are obligatory for meeting the requirements of the Delegated Regulation (EU) 2016/161 (DR). Article 8 of the DR allows the integration of additional data elements, if this is permitted by the authority in charge pursuant to Title V of Directive 2001/83/EC or Section 10 para. 1, clause 5 of the German Medicinal Products Act (AMG).

Page: 18

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text):" The serial number is generated by the marketing authorisation holder and represents the corresponding data element of the unique identifier. It is mandatory for the verification process. The serial number must not be affixed to pharmaceuticals for which verification is not mandatory."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"This example implements the requirement of the German Medicinal Products Act (AMG) for clear text listing themonth and year also in coding."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "generated"

[New text]: "assigned"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "marketing authorisation holder, thereby representing the correspondingdata element for the DMC."

[New text]: "MAH."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "MH10.8.2,"

[New text]: "MH10.8.2 standard,"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "production,"

[New text]: "manufacturing,"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "the production date,"

[New text]: "date of manufacturing,"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 8 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " – Sample"

[New text]: " - Example of a"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "marketing authorisation holder, thereby representing the corresponding data element for the DMC."

[New text]: "MAH."

Comments from page 18 continued on next page

5.2.2 Serial number

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

The serial number is generated by the marketing authorisation holder (MAH) and assigned to an individual pack. It is mandatory for the verification process. For pharmaceuticals that are not subject to mandatory verification, the DMC must not contain a serial number.

Example:

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

The usable characters are described in ***Appendix A***.

5.2.3 Batch number

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

The batch number is assigned by the MAH. Predefined special characters can be used to distinguish partial/sub-batches (see ***Appendix A***).

Example:

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

5.2.4 Expiry date

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

The expiry date is 10 by the MAH.

The expiry date has the format “YYMMDD”.

YY = two-digit year number
Since the expiry date can only be in the future, the dates are for the 21st century (2000–2099).

MM = Numerical representation of the month (01–12)
DD = Day

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

Example:
Expiry date in June 2021

Format	DI AI	Data
ASC	D	210600
GS1	17	210600

This example implements the requirement of the German Medicinal Products Act (AMG) for clear text listing the month and year also in coding.

Example:
Expiry date on 30 June 2021

Format	DI AI	Data
ASC	D	210630
GS1	17	210630

This example presents the possibility of indicating an expiry date that is exact to the day.

Note: : In ANSI MH10.8.2 standard, “D” is defined as the date in general. In the context of the PPN, the date “D” is necessarily the expiry date. For other date listings, such as the date of manufacturing, other identifiers must be used. For date of manufacturing, this would be the DI “16D” or the AI “11” respectively.

5.2.5 Additional data elements - Example of a URL

The above-mentioned data elements are obligatory for meeting the requirements of the Delegated 11 gulation (EU) 2016/161 (DR). Article 8 of the 12 allows the integration of additional data elements, if this is permitted by the authority in charge pursuant to Title V of Directive 2001/83/EC or Section 10 para. 1, clause 5 of the German Medicinal Products Act (AMG).

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "generated"

[New text]: "set"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 11 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Regulation."

[New text]: "Regulation (EU) 2016/161 (DR)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 12 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Delegated Regulation"

[New text]: "DR"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
editorial

Analogously, this stipulation also applies for the other product categories.

For example, a URL can be integrated into the code:

Example: URL:

Format	DI AI	Data
ASC	33L	http://Example.com
GS1	8200	http://Example.com

It must be noted that long URLs considerably enlarge the code and the scan rate could deteriorate accordingly.

5.3 Multi-market packs – Data elements and associated data identifiers

5.3.1 General

For pharmaceuticals subject to mandatory verification, a pack authorised for several countries (multi-market pack - MMP) only contains one DMC just as for single-market packs, and the product code included in it is used for verification.

One special characteristic is the fact that the product code does not necessarily represent the country-specific identification of a pharmaceutical completely and that multiple national item or reimbursement numbers can therefore be included in the DMC. According to the country-specific provisions and trade requirements, these supplementary pieces of information in addition to the other data for the unique identifier must also be included in the DMC. This makes it possible to capture the data relevant for verification as well as the additional numbers for country-specific identification of the pharmaceutical with a single scan.

The user software extracts from the DMC the item or reimbursement numbers known to the merchandise management system, which are required for identification and further handling. This process is analogous to the present approach during the sequential scanning of linear barcodes.

In the GS1 format, the unique identifier of the product code is provided by the AI (01) and the DI (9N) in the ASC format.

If necessary, the higher data volume can be managed via the additionally defined Data Matrix rectangular codes (see ***Chapter 6.2***).

The details for coding country-specific identification numbers is described below. All other specifications from ***Chapter 5.1*** and ***Chapter 5.2*** also apply to the MMPs.

5.3.2 Country-specific identifier in GS1 format

The product code is marked by the AI (01). The additional country-specific numbers for identification of the pharmaceutical are marked by the AI (71x) assigned to the so-called NHRN (e.g. AI (710) PZN Germany, (711) CIP France, (712) CN Spain, (714) AIM Portugal.

For multi-market packs, the GS1 format allows two coding options:

- As product code (AI = 01), a GTIN assigned by the MAH is used and the country-specific numbers (AI=71x) are represented as additional elements in the DMC.
- For existing look-up tables, an NTIN can be selected as the product code (AI = 01), if it is possible to do without the additional country-specific numbers in the DMC.

One of the countries that does without the representation of the NHRN in the DMC and creates a technical data reference of their NHRN to the product code via the look-up tables is e.g. Austria. This opens up the possibility that even multi-market packs can do with four elements in the DMC. See also Example 2 below.

Page: 19

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
content

Number: 2 Author: securPharmSubject: Hervorheben Date: 14.02.2019 17:33:36

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:34:32
Insert: (New text); editorial

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "http://Example.de"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:33:22
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 17:33:22
Replace:
(Old text): "http://Example.de"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:33:22
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 17:28:22
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:33:22
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "For MMPs that are marketable in Germany, the German PZN with the AI (710) as NHRN and the GTIN of one of the other markets as the product code must be represented in the Data Matrix Code.
Additional markets must be labeled in the Data Matrix Code with the NHRN in question. The country-specific requirements must be taken into account.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:33:22
content

Number: 7 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "As for single market packs, the Data Matrix Code for multi market packs also includes the unique identifier and the product code included in it is used for verification."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 8 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "additional"

[New text]: "multiple"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 9 Author: Compare: Delete Subject: text Date: Indeterminate
"also"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "code in additionto the unique identifier."

Comments from page 19 continued on next page

Analogously, this stipulation also applies for the other product categories.

For example, a URL can be integrated into the code:

Example: URL:

Format	DI AI	Data
ASC	33L	http://Example.com
GS1	8200	http://Example.com

It must be noted that long URLs considerably enlarge the code and the scan rate could deteriorate accordingly.

5.3 Multi-market packs – Data elements and associated data identifiers

5.3.1 General

For pharmaceuticals subject to mandatory verification, a pack authorised for several countries (multi-market pack - MMP) only contains one DMC just as for single-market packs, and the product code included in it is used for verification.

One special characteristic is the fact that the product code does not necessarily represent the country-specific identification of a pharmaceutical completely and that multiple national item or reimbursement numbers can therefore be included in the DMC. According to the country-specific provisions and trade requirements, these supplementary pieces of information [11] addition to the other data for the unique identifier must also be included in the [12] IC. This makes it possible to capture the data relevant for verification as well as the additional numbers for country-specific identification of the pharmaceutical with a single scan.

The user software extracts from the [13] IC the item or reimbursement numbers known to the merchandise management system, which are required for identification and further handling. This process is analogous to the present approach during the sequential scanning of linear barcodes.

In the GS1 format, the unique identifier of the product code is provided by the AI (01) and the DI (9N) in the ASC format. [14]

If necessary, the higher data volume can be managed via the additionally defined Data Matrix rectangular codes (see ***Chapter 6.2***).

The details for coding country-specific identification numbers is described below. All other specifications from ***Chapter 5.1*** and ***Chapter 5.2*** also apply to the MMPs.

5.3.2 Country-specific identifier in GS1 format

The product code is marked by the AI (01). The additional country-specific numbers for identification of the pharmaceutical are marked by the AI (71x) assigned to the so-called NHRN, e.g. AI (710) PZN Germany, (711) CIP France, (712) CN Spain, (714) AIM Portugal.

For multi-market packs, the GS1 format allows two coding options:

- As product code (AI = 01), a GTIN assigned by the MAH is used and the country-specific numbers (AI=71x) are represented as additional elements in the DMC.
- For existing look-up tables, an NTIN can be selected as the product code (AI = 01), if it is possible to do without the additional country-specific numbers in the DMC.

One of the countries that does without the representation of the NHRN in the DMC and creates a technical data reference of their NHRN to the product code via the look-up tables is e.g. Austria. This opens up the possibility that even multi-market packs can do with four elements in the DMC. See also Example 2 below.

[New text]: "DMC."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 11 Author: Compare: Insert Subject: text Date: Indeterminate
"in addition to theother data for the unique identifier"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 12 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Data Matrix Code."

[New text]: "DMC."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 13 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "code"

[New text]: "DMC"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 14 Author: Compare: Delete Subject: text Date: Indeterminate
" It is recommended to code the productcode as the first data element."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Example 1:

MMP in GS1 format, GTIN as PC

Format	AI	Data
GS1	01[2]	08701234567896
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	210600
GS1	7106	12345678
GS1	7117	91234567

Example 2:

MMP Germany/Austria, NTIN-DE as PC

Format	AI	Data
GS1	01[18]	04150123456782
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	210600

5.3.3 Country-specific identifier in ASC format

The product code is marked with the DI (9N). If the additional country-specific number for identification of a pharmaceutical is available in the format of a GTIN or NTIN, it is labelled with the DI (8P).

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

If the additional country-specific characteristic for product identification is available in a format that deviates from the GTIN or NTIN, the corresponding MH10 – DI assigned to the format in question pursuant to the ANSI standard must be used, e.g. (25P) for HIBC.

The implementation of this version must be coordinated with the European Medicines Verification Organisation (EMVO). Until then, the technical implementation within the EU Hub is pending. securPharm will send out special information as soon as the implementation has been completed.

Example:

MMP in ASC format

Format	DI	Data
ASC	9N[19]	111234567842
ASC	S	1234567890ABCD
ASC	1T	1234AB
ASC	D	210600
ASC	8P[20]	08701234567896
ASC	8P[21]	03400912345676

15 Product code (PC) GTIN.

16 Additional country-specific product identification via NHRN, example with a German PZN.

17 Additional country-specific product identification via NHRN, example with a French CIP.

18 Product code (PC) NTIN-DE, 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 4.5).

19 Product code (PC) PPN, example with the German PZN "12345678".

20 Additional country-specific product identification via GTIN.

21 Additional country-specific product identification via NTIN.

Page: 20

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "**Example of an MMP in the GS1 format (AIs)"**

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " 1"

[New text]: " 15"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
Footnote number changed

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "EMVO."

[New text]: "European Medicines Verification Organisation(EMVO)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "separatelyinform"

[New text]: "send out special information"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "HUB"

[New text]: "EU Hub"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " 2"

[New text]: " 16"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
Footnote number changed

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " 3"

[New text]: " 17"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
Footnote number changed

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New): "Example 2"

Comments from page 20 continued on next page

Example 1:
MMP in GS1 format, GTIN as PC

Format	AI	Data
GS1	01[15]	08701234567896
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	210600
GS1	710[16]	12345678
GS1	711[17]	91234567

Example 2:
MMP Germany/Austria, NTIN-DE as PC

Format	AI	Data
GS1	01[18]	04150123456782
GS1	21	1234567890ABCD
GS1	10	1234AB
GS1	17	210600

5.3.3 Country-specific identifier in ASC format

The product code is marked with the DI (9N). If the additional country-specific number for identification of a pharmaceutical is available in the format of a GTIN or NTIN, it is labelled with the DI (8P).

If there are several country-specific numbers in the format of a GTIN or NTIN, the additional data identifiers (8P) are included in the 14[IC] multiple times.

If the additional country-specific characteristic for product identification is available in a format that deviates from the GTIN or NTIN, the corresponding MH10 – DI assigned to the format in question pursuant to the ANSI standard must be used, e.g. (25P) for HIBC.

The implementation of this version must be coordinated with the European Medicines Verification Organisation (EMVO). Until then, the technical implementation within the EU Hub is pending. securPharm will send out special information as soon as the implementation has been completed.

9 **xample:**
MMP in ASC format

Format	DI	Data
ASC	11[19]	111234567842
ASC	S	1234567890ABCD
ASC	1T	1234AB
ASC	D	210600
ASC	12[20]	08701234567896
ASC	13[21]	03400912345676

15 Product code (PC) GTIN.

16 Additional country-specific product identification via NHRN, example with a German PZN.

17 Additional country-specific product identification via NHRN, example with a French CIP.

18 Product code (PC) NTIN-DE, 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 4.5).

16 Product code (PC) PPN, example with the German PZN "12345678".

20 Additional country-specific product identification via GTIN.

21 Additional country-specific product identification via NTIN.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 9 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New): "Example"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 10 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:52:07
Insert:
(New table added)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 11 Author: Compare: Insert Subject: text Date: 10.02.2019 12:04:07
"9N 19"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
Footnote number changed

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 12 Author: Compare: Insert Subject: text Date: 10.02.2019 12:04:23
"8P 20"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
Foodnote number changed

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 13 Author: Compare: Insert Subject: text Date: 10.02.2019 12:04:38
"8P 21"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
Footnote number changed

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 14 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "code"

[New text]: "DMC"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
editorial

Number: 15 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New footnotes added)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 16 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New footnotes added)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

6 Marking with code and clear text

6.1 Symbology

This chapter describes the code requirements for clear text (human-readable form) and the emblem for the Data Matrix Code (DMC). The data carrier used or the symbology is the DMC pursuant to ISO/IEC 16022. Error correction follows the Reed Solomon method, which is named 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 26x36 modules. Smaller matrix sizes are allowed, provided their capacity for the data to be coded is sufficient. If a consistent matrix size is to be printed at all times, this will be stipulated in the print layout. The potentially resulting excess capacity is automatically filled with padding characters by the code generation software.

Depending on the package layout and the technical printing conditions, the square or rectangular DMCs can be used in accordance with ISO/IEC 16022 or the expanded rectangular DMCs (DMRE) in accordance with ISO/IEC 21471 DMRE[22]. See the tables below for typical matrix sizes and their characteristics:

Square symbols pursuant to ISO/IEC 16022

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	Numeric	Alphanumeric
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 x 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

Rectangular symbols pursuant to ISO/IEC 16022

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	Numeric	Alphanumeric
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

22 At the time this specification was generated, this was still the Committee Draft (CD) of ISO/IEC 21471.

Page: 21

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "human readable"

[New text]: "clear"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "This chapter describes the code requirements for human
readable form (clear text) and elements such as the code emblem. The data carrier used or the symbology is the data matrix pursuant to ISO/IEC 16022. Error correction
is done according to ECC200. The other error correction methods (ECC000 to ECC140) must not be used. If a consistent matrix size is to be printed at all times, padding characters may have to be inserted."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "40"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:52:07
Replace:
(Old text): "For rectangular codes, the additionally specified versions in accordance with DIN 16587:2015-11 can also be used."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 7 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text): " Dimension (mm)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text): "Rows"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Number: 9 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text): "Columns"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:37:01
content

Comments from page 21 continued on next page

6 Marking with code and clear text

6.1 Symbology

This chapter describes the code requirements for clear text (human-readable form) and the emblem for the Data Matrix Code (DMC). The data carrier used or the symbology is the DMC pursuant to ISO/IEC 16022. Error correction follows the Reed Solomon method, which is named 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 allowed, provided their capacity for the data to be coded is sufficient. If a consistent matrix size is to be printed at all times, this will be stipulated in the print layout. The potentially resulting excess capacity is automatically filled with padding characters by the code generation software.

Depending on the package layout and the technical printing conditions, the square or rectangular DMCs can be used in accordance with ISO/IEC 16022 or the expanded rectangular DMCs (DMRE) in accordance with ISO/IEC 21471 DMRE[22]. See the tables below for typical matrix sizes and their characteristics:

Square symbols pursuant to ISO/IEC 16022

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	Numeric	Alphanumeric
22	22	11 x 7,7	12 x 5,5	13 8 x 21,8	60	43
24	24	14 x 8,4	16 6	15 8 x 23,8	72	52
26	26	17 x 9,1	18 x 6,5	19 8 x 25,8	88	64
32	32	20 5 x 11,5	8,2 x 8,2	32,7 x 32,7	124	91

Rectangular symbols pursuant to ISO/IEC 16022

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	Numeric	Alphanumeric
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

22 At the time this specification was generated, this was still the Committee Draft (CD) of ISO/IEC 21471.

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "0.615"

[New text]: "0.99"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:19
content

Number: 11 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "7.7 5.5 13.5"

[New text]: "7,7 x 7,7"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:19
content

Number: 12 Author: Compare: Insert Subject: text Date: Indeterminate
"5,5 x 5,5"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:19
content

Number: 13 Author: Compare: Insert Subject: text Date: Indeterminate
"21,8 x 21,8"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:19
content

Number: 14 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "8.4 6.0 14.8"

[New text]: "8,4 x 8,4"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:19
content

Number: 15 Author: Compare: Insert Subject: text Date: Indeterminate
"23,8 x 23,8"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 16 Author: Compare: Insert Subject: text Date: Indeterminate
"6 x 6"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 17 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "9.1 6.5 16.0"

[New text]: "9,1 x 9,1"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 18 Author: Compare: Insert Subject: text Date: Indeterminate
"6,5 x 6,5"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 19 Author: Compare: Insert Subject: text Date: Indeterminate
"25,8 x 25,8"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 20 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "11.5 8.2 20.3"

[New text]: "11,5 x 11,5"

Comments from page 21 continued on next page

6 Marking with code and clear text

6.1 Symbology

This chapter describes the code requirements for clear text (human-readable form) and the emblem for the Data Matrix Code (DMC). The data carrier used or the symbology is the DMC pursuant to ISO/IEC 16022. Error correction follows the Reed Solomon method, which is named 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 allowed, provided their capacity for the data to be coded is sufficient. If a consistent matrix size is to be printed at all times, this will be stipulated in the print layout. The potentially resulting excess capacity is automatically filled with padding characters by the code generation software.

Depending on the package layout and the technical printing conditions, the square or rectangular DMCs can be used in accordance with ISO/IEC 16022 or the expanded rectangular DMCs (DMRE) in accordance with ISO/IEC 21471 DMRE[22]. See the tables below for typical matrix sizes and their characteristics:

Square symbols pursuant to ISO/IEC 16022

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	Numeric	Alphanumeric
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 x 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	21 x 8,2	22 7 x 32,7	124	91

23

Rectangular symbols 25 rsuant to ISO/IEC 16022

24

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	Numeric	Alphanumeric
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

26 At the time this specification was generated, this was still the Committee Draft (CD) of ISO/IEC 21471.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 21 Author: Compare: Insert Subject: text Date: Indeterminate
"8,2 x 8,2"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 22 Author: Compare: Insert Subject: text Date: Indeterminate
"32,7 x 32,7"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 23 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:53:23
Deleted:
(Old table "Rectangular symbols" deleted

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 24 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:53:23
Insert:
(New table added)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 25 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Number: 26 Author: Compare: Insert Subject: text Date: Indeterminate
"22 At the time this specification was generated, this was still the Committee Draft (CD) of ISO/IEC 21471."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
New footnote added

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:40:55
content

Rectangular symbols pursuant to ISO/IEC 21471

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	Numeric	Alphanumeric
22	48	7,7 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	133

It should be noted that the rectangular variants of the DMC specified in ISO/IEC 21471 cannot be read at the points of verification as of the date this specification was issued. These points of verification have to adapt their scanners gradually and must be able to read these codes no later than the date of publication of ISO/IEC 21471.

6.3 Code size and quiet zone

The MC module size may vary between 0.25 and 99 mm. The technical properties of the scanners used must be adjusted to this area of module sizes. Within this area, the module sizes can be scaled as needed in consideration of the print quality (see ***Chapter 7***) and the printing systems to be used. In this respect, it should be noted that the print quality tends to get worse with a smaller module size and that the resolution of the printing system is aligned with the chosen module size.

The dimension of the DMC (see tables in ***Chapter 6.2***) results from the module size and the matrix size.

The areas immediately surrounding the code must be kept free of printing. To ensure an acceptable initial reading rate, this specification stipulates a distance of at least three modules.

6.4 Positioning of the Data Matrix Code

There are no specific rules concerning code positioning. The manufacturer determines the position based on the package layout and the printing conditions.

This also applies to centralised marketing authorisations in Europe. In this case, the DMC must be placed outside the “blue box”.

Page: 22

Number: 1 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:07
Insert:
(New table added)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:38
content

Number: 2 Author: Compare: Delete Subject: text Date: Indeterminate
"X = Module size in mmThe codes in the last two rows of the table rectangular symbols originate from DIN 16587:2015-11 Information technology – Automatic identification and data capture techniques – Data Matrix Rectangular Extension. It is applied to assimilate these and more rectangularmatrix dimensions to ISO standards."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:38
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text): "It should be noted that currently (date of issue of these coding rules) these new variants of the Data Matrix Code can not be read at all points of verification. Those have to adapt gradually and must be able to read these codes until the application of the Delegated Regulation."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:38
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "code"

[New text]: "DMC"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:38
editorial

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "0.615"

[New text]: "0.99"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:38
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:41:38
content

Number: 7 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text): "The module size describes the size of one matrix cell (see *Chapter 6.2*). Typical module sizes range from 0.33 to 0.45 mm."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 17:39:09
Replace:
(Old text): "This area, the so-called quiet zone,
should be at least three modules wide to ensure an acceptable initial reading rate of this application."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "for centrally authorised medicines, whereby"

[New text]: "to centralised marketing authorisations in Europe. In this case,"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Comments from page 22 continued on next page

6.5 Data Matrix Code emblem

The “PPN” emblem of the MC indicates to the points of verification the code, which is used for automatic identification of the product code and other data, regardless of which format is used to embed the PZN in the MC (PPN or NTIN). The emblem “PPN” is used until another uniform emblem is specified and agreed upon at the international level.

Figure 9: Emblem of the code

During a transition period the emblem may be omitted. As a result, the marketing authorisation holder has more freedom during the conversion processes.

Affixing the emblem is mandatory for packages that bear a second 2D code.

There are various possible versions and details for the graphical representation of the emblem (see ***Appendix B***).

The emblem can be affixed through both primary and inline printing. The minimum spacing to the code (quiet zones) must be observed.

6.6 Clear text information

6.6.1 General

After 9 February 2019, apart from the elements of PZN, batch number and expiry date, marketing authorisation holders will additionally have to place the product code and serial number on the pack in human-readable format. To ensure readability, the explanations of the so-called EU Readability Guideline[23] must be observed.

6.6.2 PZN

The PZN is the key element of the typical retail pack. According to effective legal requirements, the PZN must be affixed in clear text. This can be done in two variants:

In the previously customary form with Code 39:

or

With the short identifier “PZN” without Code 39:

PZN: 12345678

From 9 February 2019 onward, the PZN can be represented without Code 39. However, it is recommended to maintain the variant involving Code 39 at least for the time being to make the transition easier for the parties involved. It is even allowed to maintain it for the foreseeable future.

For coding requirements of the PZN in Code 39, please consult the IFA document “Technische Hinweise zur PZN-Codierung der PZN im Code 39” (Technical Information regarding PZN Coding in Code 39).

For pharmaceuticals with centralised marketing authorisation in Europe, the PZN must be represented in the “blue box”. Otherwise, it can be placed arbitrarily.

23 Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use.

Page: 23

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Human readable"

[New text]: "Clear text"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 2 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:53:23
(New chapter): "6.6.1

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Data Matrix Code"

[New text]: "DMC"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
editorial

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "DMC."

[New text]: "DMC (PPN or NTIN)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "as long as"

[New text]: "until"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
editorial

Number: 7 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
(New chapter number)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
editorial

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text): "The PZN is the key element of the retail pack. According to the currently effective regulations, the PZN must be placed in clear text with the Code 39 (see the specification
for the PZN at http://www.ifaffm.de/en/ifa-codingsystem/
encoding-pzn-code39.html).

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "7:"

[New text]: "8:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
editorial

Comments from page 23 continued on next page

6.5 Data Matrix Code emblem

The “PPN” emblem of the DMC indicates to the points of verification the code, which is used for automatic identification of the product code and other data, regardless of which format is used to embed the PZN in the DMC (PPN or NTIN). The emblem “PPN” is used until another uniform emblem is specified and agreed upon at the international level.

Figure 8: Emblem of the code

During a transition period the emblem may be omitted. As a result, the marketing authorisation holder has more freedom during the conversion processes.

Affixing the emblem is mandatory for packages that bear a second 2D code.

There are various possible versions and details for the graphical representation of the emblem (see ***Appendix B***).

The emblem can be affixed through both primary and inline printing. The minimum spacing to the code (quiet zones) must be observed.

6.6 Clear text information

6.6.1 General

After 9 February 2019, apart from the elements of PZN, batch number and expiry date, marketing authorisation holders will additionally have to place the product code and serial number on the pack in human-readable format. To ensure readability, the explanations of the so-called EU Readability Guideline[23] must be observed.

6.6.2 PZN

The PZN is the key element of the typical retail pack. According to effective legal requirements, the PZN must be affixed in clear text. This can be done in two variants:

10

In the previously customary form with Code 39:

or

11

With the short identifier “PZN” without Code 39:

PZN: 12345678

12 From 9 February 2019 onward, the PZN can be represented without Code 39. However, it is recommended to maintain the variant involving Code 39 at least for the time being to make the transition easier for the parties involved. It is even allowed to maintain it for the foreseeable future.

For coding requirements of the PZN in Code 39, please consult the IFA document “Technische Hinweise zur PZN-Codierung der PZN im Code 39” (Technical Information regarding PZN Coding in Code 39).

For pharmaceuticals with centralised marketing authorisation in Europe, the PZN must be represented in the “blue box”. Otherwise, it can be placed arbitrarily.

13 Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use.

Number: 10 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:53:23
New box added.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 11 Author: securPharmSubject: Sticky Note Date: 14.02.2019 16:53:23
New box added

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 12 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old text); "In the furture, apart from the elements of PZN, batch number and expiry date, marketing authorisation holders will have to place the product code and serial number in a human-readable format to the pack. To ensure readability, the explanations of the *„Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use"* (the so-called EU Readability Guideline) must be observed.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 13 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New footnote text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

2.6.3 Product code and serial number

If followed by the packaging dimensions, the clear text information of the product code and the serial number shall be located next to the two-dimensional code that contains the unique identifier.

If the product code and the serial number are represented in two lines below each other, the product code should be presented in the first line and the serial number in the second line.

The PPN or NTIN contained in the GMC must be used as **product code**. For labelling, the abbreviation "**PC:** " is used as a prefix.[24] Since the product code is fixed for the product layout in question, this can also be affixed in primary printing.

The **serial number** must be preceded by the abbreviation **SN:** ".[25]

Exceptions according to the Delegated Regulation:

If the sum of the two longest dimensions of the packaging equals or is less than 10 cm, the clear text representation of the product code and the serial number can be omitted.

6.6.4 Batch number and expiry date

The pharmaceutical law requirements for labelling shall apply to the clear text information of the batch number and the expiry date. The abbreviation "**Ch.-B.** " must be selected for the batch number.

The expiry date must be supplemented with the German phrase "**verwendbar bis** " ("use before "). For containers with a nominal fill quantity of up to 10 millilitres and for single-dose ampoules, the phrase can be appropriately abbreviated (e.g. "**verw. bis** ") pursuant to the German Medicinal Products Act (AMG).

24 Mind the blank space after the colon.

25 Mind the blank space after the colon.

Following the requirements of the QRD template[26] of placing a colon after the abbreviations for product code (PC) and serial number (SN), this specification recommends adopting this practice also for the batch number and expiry date. Furthermore, a blank space must be inserted after the colon.

6.6.5 Examples

Example 1:
PZN with Code 39:

Example 2:
PZN without Code 39:

Beispiel 3:
Multi-market pack Germany/Austria.
For pharmaceuticals with centralised marketing authorisation in Europe, the PZN must be represented in the "blue box".

26 CMDh ANNOTATED QRD TEMPLATE FOR MR/DC PROCEDURES; CMDh/201/2005/Rev.9 - February 2016.

Page: 24

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:38:58
content

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"6.6.3"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial; new chapter number

Number: 3 Author: Compare: Insert Subject: text Date: Indeterminate
"allowed by"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "barcode"

[New text]: "code"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
New chapter 6.6.5 and new examples added

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

Number: 6 Author: Compare: Insert Subject: text Date: Indeterminate
"product code should be presented in the"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "product code and"

[New text]: "serial number in"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial

Number: 8 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "code"

[New text]: "DMC"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "prefix.1"

[New text]: "prefix.24"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial; new footnote number

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "„SN: ".1 1 Mind the blank after the colon.Page 16All contents copyright © securPharm e.V. | English V 2.03"

[New text]: ""SN: ".25"

Comments from page 24 continued on next page

6.6.3 Product code and serial number

If allowed by the packaging dimensions, the clear text information of the product code and the serial number shall be located next to the two-dimensional code that contains the unique identifier.

If the product code and the serial number are represented in two lines below each other, the product code should be presented in the first line and the serial number in the second line.

The PPN or NTIN contained in the DMC must be used as **product code**. For labelling, the abbreviation "**PC:** " is used as a prefix.[24] Since the product code is fixed for the product layout in question, this can also be affixed in primary printing.

The **serial number** must be preceded by the abbreviation "**SN:** ".[25]

Exceptions according to the Delegated Regulation:

If the sum of the two longest dimensions of the packaging equals or is less than 10 cm, the clear text representation of the product code and the serial number can be omitted.

6.6.4 Batch number and expiry date

The pharmaceutical law requirements for labelling shall apply to the clear text information of the batch number and the expiry date. The abbreviation "**Ch.-B.** " must be selected for the batch number.[12]

The expiry date must be supplemented with the German phrase "**verwendbar bis** " ("use before "). For containers with a nominal fill quantity of up to 10 millilitres and for single-dose ampoules, the phrase can be appropriately abbreviated (e.g. "**verw. bis** ") pursuant to the German Medicinal Products Act (AMG).[13]

Following the requirements of the QRD template[26] of placing a colon after the abbreviations for product code (PC) and serial number (SN), this specification recommends adopting this practice also for the batch number and expiry date. Furthermore, a blank space must be inserted after the colon.

6.6.5 Examples

Example 1:
PZN with Code 39:

Example 2:
PZN without Code 39:

Beispiel 3:
Multi-market pack Germany/Austria.
For pharmaceuticals with centralised marketing authorisation in Europe, the PZN must be represented in the "blue box".

---

14 Mind the blank space after the colon.

25 Mind the blank space after the colon.

15 CMDh ANNOTATED QRD TEMPLATE FOR MR/DC PROCEDURES; CMDh/201/2005/Rev.9 - February 2016.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial; new footnote number

Number: 11 Author: Compare: Insert Subject: text Date: Indeterminate
"6.6.4"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial; New chapter number

Number: 12 Author: Compare: Delete Subject: text Date: Indeterminate
"1"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
Footnote number deleted

Number: 13 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

Number: 14 Author: securPharmSubject: Highlight Date: 14.02.2019 16:53:23
Replace:
(Old footnote text):
"1 Mind the blank after the colon"
"2 Mind the blank after “bis”."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial

Number: 15 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Insert:
(New footnote)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

7 Quality check of the Data Matrix Code

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

When checking the quality of a code, one must basically distinguish between code scanning and the metrological control of print quality. Code scanning verifies the code content in order to be able to ascertain the correctness of data. In this respect, the stipulations of the previous chapters and the following information must be considered:

In digital printing, each print must be considered individually. Therefore, the code content of each pack must be verified via code scanning.

Determination of print quality:
Print quality is the physical quality of printing. The determination of and compliance with a predefined minimum print quality safeguards a high initial reading rate. This purpose is served by the explanations in this chapter. Further details are presented in ***Appendix D***.

Pursuant to the Delegated Regulation (EU) 2016/161 (DR), print quality must be judged according to certain parameters (see ***Appendix D.5***).

The marketing authorisation holder (MAH) must determine the minimum print quality for code readability along the entire supply chain and during the usage cycle[27] and establish the threshold values for the parameters mentioned in ***Appendix D.5***.

More practicable is the possibility provided in Article 6 para. 4 of the DR that the requirements are considered met for a print quality of at least 1.5 pursuant to ISO/IEC 15415 (see side table), if the MAH also took into account the effects of aging and wear and tear on the printing.

27 Minimum time period according to the Delegated Regulation: One year beyond the expiry date or five years after a pharmaceutical is first placed on the market. In each case, the longer time period shall apply.

Quality levels pursuant to ISO/IEC 15415

ISO/IEC grade	ANSI grade	Ø for multiple measurements*	Meaning
4	A	3,5 – 4,0	Very good
3	B	2,5 – <3,5	Good
2	C	1,5 – <2,5	Satisfactory
1	D	0,5 – <1,5	Adequate
0	F	0,5	Failed

Figure 9: Quality levels pursuant to ISO/IEC 15415

*) Multiple measurements are no longer required in the current version of ISO/IEC 15415 (Dec. 2011). As a result, the minimum requirement of 1.5 always implicitly corresponds to ISO/IEC grade 2.

Conventional scanners can read codes even below grade 2 pursuant to ISO/IEC 15415 (a value of less than 1.5). However, technical variations among conventional scanners are very large.

Users must select or parameterise scanners in such a manner that codes of ISO/IEC grade 1 pursuant to ISO/IEC 15415 are still readable (a value of ≥ 0.5). The scanners must be selected in such a manner that their optical properties match the dimensions of the DMC (see ***Chapter 6.2***).

Based on this determination, printing with a quality lower than 1.5 meets the requirement of the DR. During this determination, the MAH must also take into account the effects of aging and wear and tear of printing.

However, to achieve a very high initial reading rate, the MAH must not permanently go below the 1.5 requirement (according to ISO/IEC 15415).

In practice, a control by 100% scanning check (with or without inline pseudo grading) is frequently performed with inline systems in combination with a metrological sample inspection, for quality assurance.

Page: 25

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): "control"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
editorial

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "can"

[New text]: "must"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:01
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): "2.5 – 3.49"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): "1.5 – 2.49"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:49:11
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): "0.5 – 1.49"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "check"

[New text]: "the metrological control of"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 7 Author: Compare: Delete Subject: text Date: Indeterminate
"content, thereby ascertaining the interpretation of the data"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): "Less than 0.5"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 9 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): " Fail"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 10 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "and"

[New text]: "in order to be able to ascertain"

Comments from page 25 continued on next page

7 Quality check of the Data Matrix Code

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

When checking the quality of a code, one must basically distinguish between code scanning and the metrological control of print quality. Code scanning verifies the code content in order to be able to ascertain the correctness of data. In this respect, the stipulations of the previous chapters and the following information must be considered:

In digital printing, each print must be considered individually. Therefore, the code content of each 12ck must be verified via code scanning.

Determination of print quality:
Print quality is the physical quality of printing. The determination of and compliance with a predefined minimum print quality safeguards a high initial reading rate. This purpose is served by the explanations in this chapter. Further details are presented in ***Appendix D***.

Pursuant to the Delegated 17gulation (EU) 2016/161 (DR), print quality must be judged according to certain parameters (see ***Appendix D.5***).

The 18rketing authorisation holder (MAH) must determine the minimum print quality for code readability along the entire supply chain and during the usage 19cle[27] and establish the threshold values for the parameters mentioned in ***Appendix D.5***.

More practicable is the possibility provided in Article 6 para. 4 of the DR that the requirements are considered met for a print quality of at least 1.5 pursuant to ISO/IEC 15415 (see side table), if the MAH also took into account the effects of aging and wear and tear on the printing.

27 Minimum time period according to the Delegated Regulation: One year beyond the expiry date or five years after a pharmaceutical is first placed on the market. In each case, the longer time period shall apply.

Quality levels pursuant to ISO/IEC 15415

ISO/IEC grade	ANSI grade	Ø for multiple measurements*	Meaning
4	A	3,5 – 4,0	Very good
3	B	2,5 – <3,5	Good
2	C	1,5 – <2,5	Satisfactory
1	D	0,5 – <1,5	Adequate
0	F	< 0,5	Failed

11gure 9: Quality levels pursuant to ISO/IEC 15415

*) Multiple measurements are no longer required in the current version of ISO/IEC 15415 (Dec. 2011). As a result, the minimum requirement of 1.5 always 13plicitly corresponds to ISO/IEC 14ade 2.

Conventional scanners can read codes even below 15ade 2 pursuant to ISO/IEC 15415 (a value of less than 1.5). However, technical variations among conventional scanners are very large.

Users must select or parameterise scanners in such a manner that codes of ISO/IEC grade 16pursuant to ISO/IEC 15415 are still readable (a value of ≥ 0.5). The scanners must be selected in such a manner that their optical properties match the dimensions of the DMC (see ***Chapter 6.2***).

Based on this determination, printing with a quality lower than 1.5 meets the requirement of the DR. During this determination, the MAH must also take into account the effects of aging and wear and tear of printing.

However, to achieve a very high initial reading rate, the MAH must not permanently go below the 1.5 requirement (according to ISO/IEC 15415).

In practice, a control by 100% scanning check (with or without inline pseudo grading) is frequently performed with inline systems in combination with a metrological sample inspection, for quality assurance.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 11 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Insert:
(Figure 9 legend added)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 12 Author: Compare: Replace Subject: text Date: 14.02.2019 17:44:40
[Old text]: "package"
[New text]: "pack"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 13 Author: Compare: Insert Subject: text Date: Indeterminate
"implicitly"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 14 Author: Compare: Replace Subject: text Date: 11.02.2019 11:00:33
[Old text]: "category"
[New text]: "grade"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 15 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "ISO/IEC category 1.5 (ISO/IEC 15415)."

[New text]: "grade 2 pursuant to ISO/IEC 15415 (a value of less than 1.5)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 16 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "0.5 (ISO/IEC 15415) are still readable."

[New text]: "1 pursuant to ISO/,(&•• ˇ□□ˇ□DUH•VWLOO•UHDGDEOH•D•YDOXH•RI••••• ˇ□□7KH•VFDQners must be selected in such a manner that their optical properties match the dimensions of the DMC (seeChapter 6.2)."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 17 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Regulation,"

[New text]: "Regulation (EU) 2016/161(DR),"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 18 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "MAH"

[New text]: "marketing authorisation holder (MAH)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 19 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "cycle1"

[New text]: "cycle27"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
New footnote number

Comments from page 25 continued on next page

7 Quality check of the Data Matrix Code

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In digital printing, each print must be considered individually. Therefore, the code content of each pack must be verified via code scanning.

Determination of print quality:
Print quality is the physical quality of printing. The determination of and compliance with a predefined minimum print quality safeguards a high initial reading rate. This purpose is served by the explanations in this chapter. Further details are presented in ***Appendix D***.

Pursuant to the Delegated Regulation (EU) 2016/161 (DR), print quality must be judged according to certain parameters (see ***Appendix D.5***).

The marketing authorisation holder (MAH) must determine the minimum print quality for code readability along the entire supply chain and during the usage cycle[27] and establish the threshold values for the parameters mentioned in ***Appendix D.5***.

More practicable is the possibility provided in Article 6 para. 4 of the 23 that the requirements are considered met for a print quality of at least 1.5 pursuant to ISO/IEC 15415 (see side 25 le), if the MAH also took into account the 26 ects of aging and wear and tear 27 the printing.

28 Minimum time period according to the Delegated Regulation: One year beyond the expiry date or five years after a pharmaceutical is first placed on the market. In each case, the longer time period shall apply.

Quality levels pursuant to ISO/IEC 15415

ISO/IEC grade	ANSI grade	Ø for multiple measurements*	Meaning
4	A	3,5 – 4,0	Very good
3	B	2,5 – <3,5	Good
2	C	1,5 – <2,5	Satisfactory
1	D	0,5 – <1,5	Adequate
0	F	< 0,5	Failed

Figure 9: Quality levels pursuant to ISO/IEC 15415

*) Multiple measurements are no longer required in the current version of ISO/IEC 15415 (Dec. 2011). As a result, the minimum requirement of 1.5 always implicitly corresponds to ISO/IEC grade 2.

Conventional scanners can read codes even below grade 2 pursuant to ISO/IEC 15415 (a value of less than 1.5). However, technical variations among conventional scanners are very large.

Users must select or parameterise scanners in such a manner that codes of ISO/IEC grade 1 pursuant to ISO/IEC 15415 are still readable (a value of ≥ 0.5). The scanners must be selected in such a manner that their optical properties match the dimensions of the DMC (see ***Chapter 6.2***).

Based on this determination, printing with a quality lower than 1.5 meets the requirement of the 20 . During this determination, the 21 AH must also take into account the 22 ects of aging and wear and tear of printing.

However, to achieve a very high initial reading rate, the 24 AH must not permanently go below the 1.5 requirement (according to ISO/IEC 15415).

In practice, a control by 100% scanning check (with or without inline pseudo grading) is frequently performed with inline systems in combination with a metrological sample inspection, for quality assurance.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 20 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Delegated Regulation."

[New text]: "DR."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 21 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "manufacturer"

[New text]: "MAH"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 22 Author: Compare: Insert Subject: text Date: Indeterminate
"effects of aging and"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 23 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Delegated Regulation"

[New text]: "DR"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 24 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "marketing authorisation holder"

[New text]: "MAH"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 25 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "table). The MAH, has to take"

[New text]: "table), if the MAH also took"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 26 Author: Compare: Insert Subject: text Date: Indeterminate
"effects of aging and"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Number: 27 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "of"

[New text]: "on the"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 28 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old footnote text): "1 Minimum time period pursuant to the Delegated Regulation:
One year past the expiry date or five years after releasing the pharmaceuticals for sale or distribution. The longer time period is relevant.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
content

Comments from page 25 continued on next page

Information on sample inspection[28]:
Quality assurance at pharmaceutical companies typically works with sampling plans. These determine how many inspections must pass the test and usually also allow a certain quantity of samples that fall below the minimum quality.[29] The QAH is responsible for defining the sampling plans.

Information on the measuring devices:
Measuring devices (see ***Appendix D.3***) that work in accordance with ISO/IEC 15415 must be configured by the user for the application in question. The number of parameters varies depending on the measuring device manufacturer.

The present coding rules are the user specification according to ISO/IEC 15415[30] and therefore the requirement for the correct configuration of a measuring device for print quality inspection of the Data Matrix Code is applied in accordance with this specification.

Information on measurements:
The minimum print quality must be determined under red light (660 nm), a synthetic aperture of 80% of the code's module size and four-sided lighting under 45°. Additional details are presented in ***Appendix D.4***.

Inverse representation of the Data Matrix Code:
Negative data matrix symbols, in which the substrate colour and the module or code colour are swapped, are permitted.

28 The ISO/IEC 15415 standard, which is listed in the Delegated Regulation in Article 6 (4), includes the sampling system in 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". As a result, the system for sample inspections implicitly becomes part of Article 6 (4) of the Delegated Regulation, since Chapter 5.1 is the normative and therefore binding part of ISO/IEC 15415.

29 However, in extreme cases, a lower-quality code could result in non-reading.

30 ISO/IEC 15415 stipulates the rules for quality determination. The standard requires that the user specification define the type of light, lighting arrangement and synthetic aperture for measurements.

8 Interoperability based on XML standards

Appendix B and ***Appendix C*** describe a standard to be preferentially used that is based on general XML standards and includes a neutral description of the data/application identifiers. This facilitates an open data exchange as described in Figure 10, independent of symbols and data structures.

The XML nodes defined in *Appendix A* are for the standardized XML data exchange.

Figure 10: XML-based data exchange between scanner and system

Page: 26

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(New footnote number)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:46:12
editorial

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "manufacturers"

[New text]: "companies"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 3 Author: Compare: Insert Subject: text Date: Indeterminate
"A and Appendix"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "presents"

[New text]: " describe"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 5 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "quality.3"

[New text]: "quality.29"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
New footnote number

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "marketing authorisation holder"

[New text]: "MAH"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "8,"

[New text]: "10,"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 8 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "154154"

[New text]: "1541530"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
New footnote number

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 9 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Insert:
(New text added)

Comments from page 26 continued on next page

Information on sample inspection[28]:
Quality assurance at pharmaceutical companies typically works with sampling plans. These determine how many inspections must pass the test and usually also allow a certain quantity of samples that fall below the minimum quality.[29] The MAH is responsible for defining the sampling plans.

Information on the measuring devices:
Measuring devices (see ***Appendix D.3***) that work in accordance with ISO/IEC 15415 must be configured by the user for the application in question. The number of parameters varies depending on the measuring device manufacturer.

The present coding rules are the user specification according to ISO/IEC 15415[30] and therefore the requirement for the correct configuration of a measuring device for print quality inspection of the Data Matrix Code as applied in accordance with this specification.

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The minimum 11ht quality must be determined under red light (660 nm), a synthetic aperture of 80% of the code's module size and four-sided lighting under 45°. Additional details are presented in ***Appendix D.4***.

13erse representation of the Data Matrix Code:
Negative data matrix symbols, in which the substrate colour and the module or code colour are swapped, are permitted.

14 The ISO/IEC 15415 standard, which is listed in the Delegated Regulation in Article 6 (4), includes the sampling system in 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 15[illegible]9-1". As a result, the system for sample inspections implicitly becomes part of Article 6 (4) of the Delegated Regulation, since Chapter 5.1 is th16ormative and therefore binding part of ISO/IEC 15415.

17 However, in extreme cases, a lower-quality code could result in non-reading.

18 ISO/IEC 15415 stipulates the rules for quality determination. The standard requires that the user specification d19e the type of light, lighting arrangement and synthetic aperture for measurements.

8 Interoperability based on XML standards

Appendix A and ***Appendix C*** describe a standard to be preferentially used that is based on general XML standards and includes a neutral description of the data/application identifiers. This facilitates an open data exchange as described in Figure 10, independent of symbols and data structures.

The XML nodes defined in *Appendix A* are for the standardized XML data exchange.

Figure 12 XML-based data exchange between scanner and system

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 10 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(Old text): "**To obtain comparable, valid measuring results, the following applies:"**

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 11 Author: Compare: Insert Subject: text Date: Indeterminate
"print"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 12 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "8:"

[New text]: "10:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 13 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 14 Author: securPharmSubject: Highlight Date: 14.02.2019 16:54:13
Replace:
(New footnote number)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 15 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "2859-10”."

[New text]: "2859-1”."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 16 Author: Compare: Delete Subject: text Date: Indeterminate
"located in"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 17 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "3 In an extreme scenario, a code in lesser quality could result in a non-scan."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
content

Number: 18 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(New footnote number)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Number: 19 Author: Compare: Delete Subject: text Date: Indeterminate
"has to"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
editorial

Appendix A
Overview and reference of identifiers

The table below specifies the characteristics of the individual data/application identifiers:

Data elements	XML node	DI	AI	Data type	Data format	Character length	Character set
Pharmacy Product Number (PPN)	<PPN>	9N		AN	—	4–22	0–9; A–Z no special characters, no use of lowercase letters, no national characters
National Trade Item Number (NTIN)	<GTIN>	8P	01	N	—	14	0–9
Serial number	<SN>	S	21	AN	—	1–20	Numeric or alphanumeric characters), no national characters
Batch number	<LOT>	1T	10	AN	—	1–20	Numeric or alphanumeric characters), no national characters
Expiry date	<EXP>	D	17	Date	YYMMDD	6	0–9

Note:
Details for the data elements are located in ***Chapter 4*** and ***Chapter 5*** of this document, for example the specifica of the expiry date.

Recommendations to the marketing authorisation holders regarding the character set for serial number and batch number:

a) The character string should only include either uppercase or lowercase letters of the Latin alphabet.

b) To avoid human reading errors and depending on the font used and print quality, the marketing authorisation holder should exclude characters that are prone to be mistaken for each other. These include e.g.: i, j, l, o, q, u and I, J, L, O, Q, U.

c) While some special characters are technically processed,[31] they should not be used because the risk of misinterpretation is very high. A misinterpreted code results in a package being unable to be verified, thereby making it ineligible to be dispensed.

If separating characters are necessary within a batch number, the use of a hyphen "-", underscore "_" or full stop (".") is recommended.[32]

---

[3] The special characters with the decimal ASCII code values of 35 (#), 36 ($), 64 (@), 91 ([), 92 (\), 93 (]), 94 (^), 96 (`), 123 ({), 124(|), 125 (}), 126 (~) and 127 (¦) and all control characters (ASCII code value 00-31) are excluded from technical processing. In principle, all ASCII characters with a decimal value of more than 127 are excluded. The technically processed characters are in accordance with „GS1 AI encodable character set 82" (GS1 General Specifications, section 7.11 (figure 7/11-1)).

[4] The use of the full stop character is particularly recommended, since its location is identical in German and English keyboards. If the wrong language is selected for the keyboard scanners used, the risk of misinterpretation does not exist per se.

Page: 27

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "processed,1"

[New text]: "processed,31"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
New footnote number

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"recommended.32"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
New footnote number

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "1"

[New text]: "31"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
New footnote number

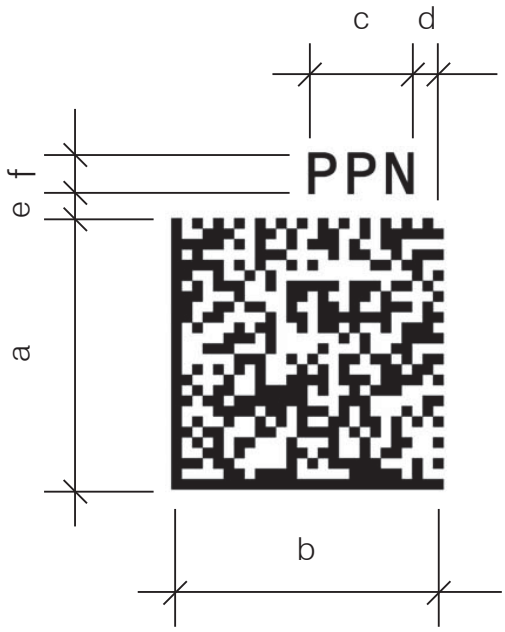
Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "2"

[New text]: "32"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:53:10
New footnote number

Appendix B
Code emblem

The string “PPN” in the font “OCR-B” has been defined as the PPN-Code Emblem. The graphical representation is to be found in the following sketch:



Nominal dimensions:

a: results from the chosen module and matrix sizes

b: for a square code a = b; for rectangular – depends on chosen module and matrix sizes

c: 0,4 * a

d: *)

e: results from the required quiet zone *) (Quiet zone refer to ***Chapter 6.3***)

f: results from the font type and dimension c

*) The dimensions d and e should be chosen so that the code is associated with the emblem.

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

The following orientations are in principle possible:

In exceptional cases, the emblem can be applied to an adjacent surface.

Appendix C
Interoperability based on XML descriptors (informative)

C.1 General

For manufacturers, wholesalers, pharmacies and clinics, the interoperability of coding is a prerequisite for reading and unequivocal identification of data elements. Integrated interoperability helps to ensure cost-effective processes for the involved parties. The interoperability is based on the joint use of the standards IEC 15434 Syntax for High Capacity Media, ISO/ IEC 15459 Unique identifier, as well as system and data identifier/application identifier according to ISO/IEC 15418.

In order to provide manufacturers and users in the pharmaceutical field an even greater interoperability, in this Appendix, an XML-based standard is described for interpreting the data. This applies both for data transmission to the printer, as well as for data transmission from the code reader to the connected systems.

The Standard set out in this appendix applies only to the data contents, i.e. it does not refer to the layout properties of the code, which include the provisions of the clear text printing and symbology (eg, Data Matrix Code).

During data transmission and in accordance with this standard, the data will be uniformly named using XML nodes independent of the Data Identifiers used in the code. Following layers are formed in the representation of the data:

Application: XML nodes
Data envelope: ISO/IEC 15434 e.g. Format 05, Format 06 etc.
Data structure: Data Identifier (DI) or Application Identifier (AI)
Symbology: e.g. Data Matrix Code

C.2 Data Format Identifier (DFI)

By the transmission of XML-Standard data elements, the properties for the display of the data in the Data Matrix Code are assigned to the Data-Format-Identifier (DFI) and only this is transferred.

The DFI tells us which data envelope according to ISO/ IEC 15434, which Application Identifier (AI or DI) and whether a macro according to ISO/IEC 16022 is used. The DFI instructions can be found in Table 1.

XML Data Format Identifier (DFI)	Format-ID According ISO/IEC 48767	Data-Type Identifier According ISO/IEC 16022	Data Identifier / Application Identifier According ISO/IEC 15418
IFA	06	Macro 06	DI-ASC
GS1		FNC1	AI-GS1

Table 1: Data Format Identifier

The DFI can have the values “IFA” or “GS1” and is transferred in the attribute of the higher level XML node “<Content>“.

C.3 XML-Node for Data

The table below shows the XML-Nodes for data and their mapping to the Data Identifier (DI) und Application Identifier (AI):

Data Identifier			
XML-Node	DI dfi="IFA"	AI dfi="GS1"	Description
<PPN>	9N		product code
<GTIN>	8P	01	product code
<LOT>	1T	10	batch number
<EXP>	D	17	expiry date
<SN>	S	21	serial number

Table 2: XML-Nodes for Data

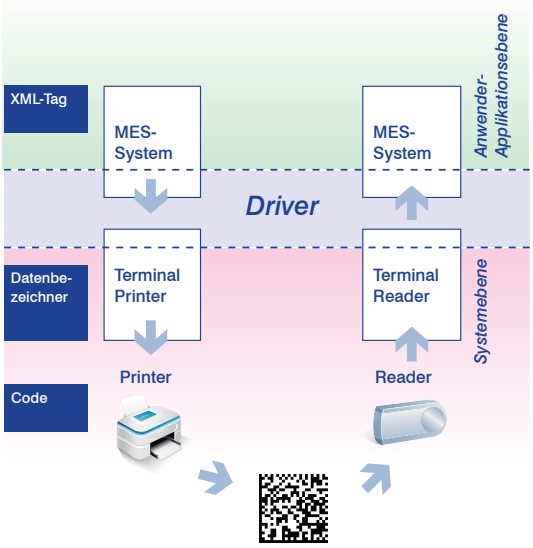


Figure 11: Data transfer based on XML description

The complete list of currently defined nodes is shown in ***Appendix A***. On this technical level of the description there is no difference between NTIN and GTIN. On this basis the comprehensive term GTIN is used.

<Content> envelops the XML nodes <Data> (refer to ***C.4*** and ***C.5***).

From the XML-Data and the "DFI" value contained therein, the printer derives all necessary information to create the Data Matrix Code. This includes the data elements, the DI or AI, the delimiters and the header.

C.4 Implementation

The XML description can be used both in the data transfer to the printer driver, as well as for the data output from the code readers (refer to schematic representation):

The drivers for interpreting the XML description can be part of the higher-levels systems (MES) or the printer and reader. The use of the unified description enhances interoperability and helps to reduce errors. Further, the uncertainty regarding non-printable control character in transmission and interpretation is eliminated in the XML description.

When reading the code, the scanner puts the data content in the XML structure, by using the corresponding XML nodes. By default, data transmission from the code reader to the higher systems only the data is transferred without the "DFI". Output of "DFI" is optional for cases when e.g. the correct use of structures within the code is to be checked.

Generic XML description of data transmission to the printer and from the code reader:

```
<Content dfi="value_dfi">
    <data_1>value_data_1</data_1>
    <data_2>value_data_2</data_2>.
    <data_n>value_data_n</data_n>
</Content>
```

When transferring from the code reader the value of "dfi" is optional.

Page: 30

Number: 1 Author: Compare: Replace Subject: text Date: Indeterminate

[Old text]: "9:"

[New text]: "11:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06

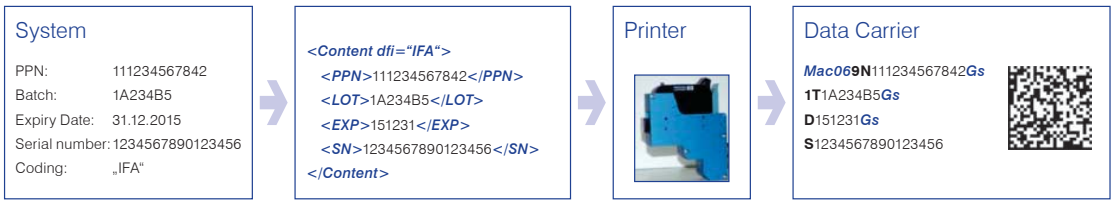
content

C.5 Examples

In the following examples the use of the four data elements product number, batch number, expiry date and serial number is illustrated:

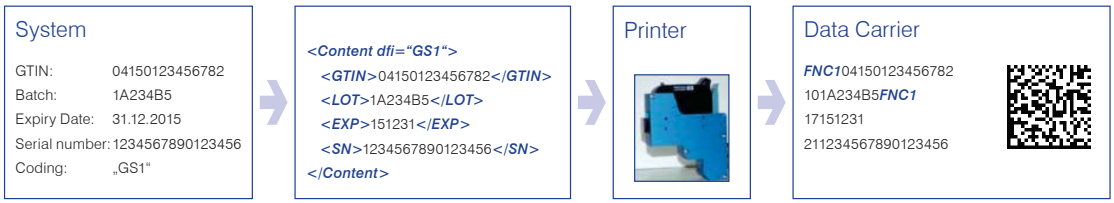
Example 1: Data transfer to printer – ASC-Format

Product Code: PPN | Data Identifier: DI | Data Format Identifier: IFA



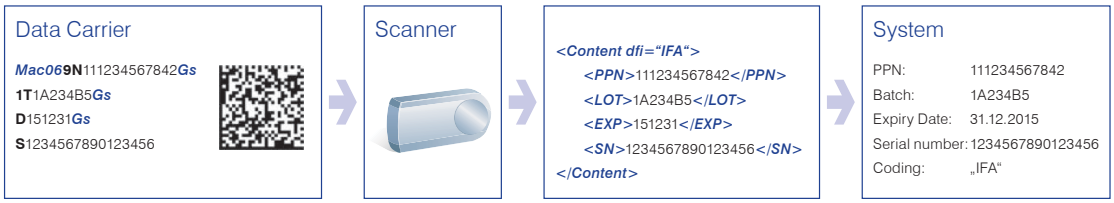
Example 2: Data transfer to printer – GS1-Format

Product Code: 1TIN[33] | Data Identifier: AI | Data Format Identifier: GS1



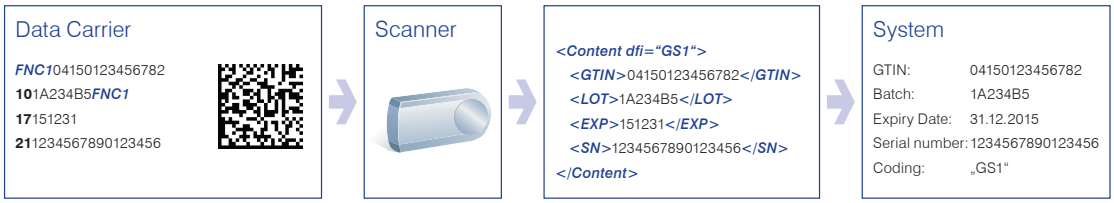
Example 3: Data transfer from scanner – ASC-Format

Product Code: PPN | Data Identifier: DI | Data Format Identifier: IFA



Example 4: Data transfer from scanner – GS1-Format

Product Code: 2TIN[33] | Data Identifier: AI | Data Format Identifier: GS1



If you have any questions or suggestions about this appendix, please do not hesitate to contact securPharm.

---

[33] At this technical level there is no difference between a NTIN and a GTIN. Hence the comprehensive term GTIN is used.

Page: 31

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 17:51:47
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Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:04:56
editorial; New footnote number

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 18:05:11
Replace:
(Old text): "GTIN1

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
editorial; new footnote number

Number: 3 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "1"

[New text]: "33"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
New footnote number

Appendix D
Details for quality inspection of the Data Matrix Code

D.1 General

The quality inspection is composed of the components of code scanning (***D.2***) and measurement of print quality (***D.3***). The marketing authorisation holder determines depending on his processes whether the code scanning check is performed according to ***D.2.1*** or ***D.2.2***.

Based on the code scanning check, it must be ensured that each package bears a code with the correct content. Packages without a code or with incorrect content will be removed. Based on this check, the serial number is valid and can be entered into the ACS-MAH-System together with the other necessary data.

Scanning systems vary strongly in their performance. Manual scanners are typically very error-tolerant while in-line high-speed scanners are more demanding in terms of print quality. Therefore, identical print qualities can result in different initial scan rates with different scanning systems.

D.2 Code scanning check

The Code scanning check tests if

- the code is present;
- the correct symbology was used; and
- the content complies with the specifications.

A check of the human readable text print with the code content is also part of a code scanning check, since this clear text information counts among the required components of the unique identifier. In digital printing, every single package must be checked (100 % scanning).

During the packaging process, it must be ensured that any packages without unreadable codes or carrying codes with contents deviating from the requirements are rejected.

The code scanning check does not include a measurement of print quality: To assess print quality, a measurement as demanded in Article 6 of the Delegated Regulation is obligatory.

Typically, print quality is determined with a sample spot check measuring device (see ***D.3***).

D.2.1 Manual code scanning check

For pharmaceuticals that are produced in small quantities the scan code scanning check can be performed with a manually operated scanner and the data can be transmitted to the database. In this case, the clear text data can be checked either purely manually or with the help of a manual scanner.

D.2.2 Inline code scanning inspection

Inline code scanning inspections are built-in, fully automated camera based inspection systems which perform the code scanning scan check described previously in Annex ***D.2***. The inline scanners have been optimized for logistic processes to a high reading rate and error tolerance based on the corresponding software algorithms and optoelectronic and mechanical properties.

The inline inspection can be a pure code scanning check or, in addition, pseudo grading can be performed. Pseudo grading is the expanded capability of scanning systems to analyse and determine print quality in the style of the ISO/IEC 15415 measuring method.

However, it must be noted that the assessment of contrast and dimensional measurement values in the style of ISO/IEC 15415 measuring method does not constitute a measurement. Nonetheless, these results can be used to assess qualitative parameters for the purpose of recognizing fluctuations in print quality. This offers the advantage that the code scanning check of all packs is associated with a stability check of print quality.

A metrological assessment pursuant to ISO/IEC 15415 (***D.3***) based on inline inspection currently fails due to the conditions of the available systems. The settings for efficient code scanning in terms of exposure, sharpness, geometry as well as available different ambient light and the later adjustment of camera and light positions lead to print quality assessment results that deviate more or less strongly from a genuine measurement (***D.3***). These partly unsystematic deviations cannot be adjusted and may lead to seemingly random different results.

To take this fact into account, additional random sample measurements are typically conducted in parallel to the

inline inspection (see ***D.3***). Sampling volume and frequency depend on the stability of the printing process and the pseudo grading.

If a device for inline inspection cannot meet the metrological requirements in terms of calibration and adjustment as well as traceability of the results to national standards, sample taking measurements will be indispensable. Only then will the requirements of the Delegated Regulation be met.

D.3 Measurement in accordance with ISO/IEC 15415

In Article 6 the Delegated Regulation demands an assessment of print quality.

Usually, this process employs measuring devices whose construction is stipulated by ISO/IEC 15415. These are optical measuring devices with a predefined measuring precision (ISO/IEC 15426-2) and whose results can be traced back to national standards (e.g. PTB, NIST).

Apart from the information mentioned in ***Chapter 7*** regarding the parameters of the measuring devices, their alignment and calibration (DIN 1319-1) must absolutely be observed.

D.4 Measuring conditions according to ISO/IEC 15415

The code to be measured is described in ***Chapter 6.1*** and the print quality inspection is described in ***Chapter 7***.

The testing parameters (***D.5***) are meaningful and comparable only if they are determined under predefined conditions. The international Standard ISO/IEC 15415 shows various possibilities and demands that the user specification stipulate these measurement conditions.

The corresponding requirements for measurement conditions are as follows:

Property	Stipulation
Type of light	Red light, wavelength of 660 nm (+/-10 nm)
Filtering (synthetic aperture)	80 % of the matrix cell size (module size) of the code to be measured
Illumination angle	4 lights that illuminate the field of view from four sides below 45°
Camera angle *)	90° above the code (perpendicular to the plane of packaging)
Distance *)	Must cover illumination angles, image must be in focus and resolution must be sufficient.
Resolution *)	At least 10 x 10 camera pixels per matrix cell or less, if it can be proven that the required measuring precision of ISO/IEC 15426-2 is met. Based on past experience, less than 5 x 5 camera pixels lead to unusable results.

*) typically specified by the construction of the measuring device

D.5 Parameters for print quality

The Delegated Regulation stipulates the minimum required parameters for assessing print quality. For a better overview, the following table presents the terms from the Delegated Regulation and the corresponding standards in German and English and the terminology from the standards is listed completely.

Table 3: Testing parameters for the assessment of print quality:

Article 6 para. 1 of the Delegated Regulation		Standard ISO/IEC 15415		Technical meaning
English version	German version	English	German[3][4]	
(a) the contrast between the light and dark parts	(a) Kontrast zwischen hellen und dunklen Elementen	SC = Symbol contrast	Symbol-kontrast	Contrast is determined between the brightest and the darkest spot in the overall symbol. To achieve this, the brightest and darkest matrix cells are determined respectively (including fixed patterns). The difference between these reflection values is the symbol contrast. Decreasing values result in the devaluation of this parameter.
(b) the uniformity of the reflectance of the light and dark parts	(b) Homogenität der Reflexion heller und dunkler Elemente	Modulation, reflectance margin and contrast uniformity	Modulation, Reflexions-bereich und Kontrast-gleichmäßig-keit	Ideally, all white areas should have the same reflection values, as should the black ones. Based on material transparency, print gains, grid distortions and uneven print blackness as well as uneven brightness of the substrate, the unevenness of the reflection value will increase. This results in the devaluation of this parameter.
(c) the axial non-uniformity	(c) axiale Inhomogenität	AN = Axial nonuniformity	Axiale Ungleich-mäßigkeit	The axial distortion assesses whether a symbol was printed stunted or stretched in its entirety. The larger the distortion, the worse the assessment of this parameter.
(d) the grid non-uniformity	(d) Inhomogenität des Rasters	GN = Grid nonuniformity	Gitterungleich-mäßigkeit	The grid non-uniformity looks at the code matrix in detail. Deviations of individual matrix cells from ideal checkerboard geometry result in devaluation of this parameter.
(e) the unused error correction	(e) nicht genutzte Fehlerkorrektur	UEC = Unused error correction	Ungenutzte Fehlerkorrektur	Individual white or black matrix cells that have the wrong colour based on flawed spots or stains are recognised by the error correction and the data are reconstructed from the redundant matrix cells. UEC is devaluated in accordance with the unused error correction.
(f) the fixed pattern damage	(f) Beschädi-gung des festen Musters	FPD = Fixed pattern damage	Beschädigung der festen Muster	The Data Matrix Code contains areas that serve the purpose of orientation and grid reconstruction. These areas do not contain any data. Damage of these patterns results in devaluation of this parameter.
(g) the capacity of the reference decode algorithm to decode the Data Matrix.	(g) Kapazität des Referenzdekodie-rungsalgorithmus zur Dekodierung der Datenmatrix	Decode	Dekodierung	Decoding and grid reconstruction in a code measurement is done with the standardised reference decode algorithm. If decoding fails, this results in devaluation of this parameter.
—	—	Contrast uniformity	Kontrast-gleichmäßig-keit	MOD[5] values are determined for all code words. The MOD values are used for determination of the modulation and the reflectance margin. Contrast uniformity is the worst individual MOD value (informative, relevant for calibration according to ISO/IEC 15426-2).
—	—	Print gain	Druckzuwachs	Informative parameter that indicates whether a symbol is overprinted (too bold) or underprinted (too thin).
—	—	Module size	Modulgröße	The size of a matrix cell of the overall code is known as module size. The scanner properties in terms of scanner depth of field, scanner resolution and minimum scanning distance depend on the module size.
—	—	Matrix size	Matrixgröße	The entire code consists of individual matrix cells (= modules) of a certain, identical module size. Standard ISO/IEC 16022 defines 10x10 modules as the smallest matrix size and 144x144 as the maximum matrix size. In practical applications, the area of permitted matrix sizes is limited in order to restrict the proportion of camera resolution to the matrix size and in order to have a sufficiently large number of camera pixels per module available. This is required for scanning reliability.

The final assessment is determined by the testing parameter with the worst measuring result. The quality levels are represented in a table in *Chapter 7*.

[3] The German terms were created by the authors, since no German version of this standard exists.

[4] MOD is the assessment of the modulation for a single code word of the Data Matrix Code. A code word is a small part of the code, which always consists of 8 matrix cells.

Page: 34

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "German1"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
editorial; new footnote number

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
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(Old text): "MOD_2

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
editorial; new footnote number

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[New text]: "34"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
editorial; New footnote number

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "35"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
editorial; new footnote number

Appendix E

Glossary/Abbreviations

The following are the terms and abbreviations used in this document:

ACS describes ACS PharmaProtect GmbH, Berlin. It is in equal shares a company of the pharmaceutical associations BAH, BPI, Pro Generika and vfa. ACS has developed the database system of the German pharmaceutical industry (MAH system) as a partial system for operating within the securPharm system in which data for the verification of pharmaceuticals will be deposited by the marketing authorisation holder prior to marketing.

AMG see German Medicinal Product Act.

Application Identifiers (AI) are identifiers developed by the users of GS1 which exactly define the encoded data content. These are valid worldwide and applicable in multiple sectors in accordance with ISO/IEC 15418. Published by GS1 in the German-speaking region under the term “Datenbezeichner”.

Article number - The number that clearly 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 article identification in the retail sector. In contrast to the product code, which represents part of the unique identifier (UI) in terms of the Delegated Regulation (EU) 2016/161, both an article number and a product code can be assigned to one article.

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

Barcode - An optical data carrier consisting of lines. Two-dimensional matrix codes are sometimes also referred to as 2D barcodes. This also includes the Data Matrix Code.

Blue Box - Found in pharmaceuticals with centralised European marketing authorisation. For these pharmaceuticals, the leaflet has to be compliant with Article 57 of EU Directive 2011/83/EC. Country specific requirements have to be printed inside the so-called “blue box” (visually distinguished by a blue-coloured frame). These are specified by the European Medicines Agency (EMA) or the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) in the “blue-box requirements”.

Code 39 is a barcode specified in ISO/IEC 16388. The printed space requirement of this code is high for a relatively low data volume. The Code 39 is used as a data carrier for representation of the PZN in the barcode.

Data Matrix Code (DMC) - A two-dimensional matrix code consisting of square elements. In the ECC200 version pursuant to ISO/IEC 16022, the code includes error correction in accordance with the Reed Solomon code for missing dots or damaged spots.

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

Data Identifiers are standardized identifiers that label the data element and precede the data content. The most frequently 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 reciprocally. **For linguistic simplification, this document uses the term “data identifier” when DI and AI are mentioned.**

Data Matrix - A general term for the Data Matrix Code in the German version of the DR.

Data Format Identifier (DFI) - The identifier in XML descriptions that stands for the code characteristics in accordance with ISO standards. It sets out the guidelines for the use and form of the following parts: the envelope data according to ISO/IEC 15434, the specific application identifier (AI or DI) and what header information should

Page: 35

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[New text]: "Glossary/Abbreviations"

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(Old text): "**Blue Box:** For centrally registered medicines in Europe, the leaflet has to be compliant to article 57 of the EU Directive 2011/83/EC. Country specific requirements have
to be printed inside the so called "blue box" (visually distinguished by a blue colored frame). These are specified by the EMA respectively the CMDh in the "blue-box-requirements".

EMA:
• Notice to Applicants
•http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm
• Volume 2C Regulatory, „Guideline on the packaging information of medicinal products for human use authorised by the Union"; ANNEX: ‚Blue box'.

CMDh:
• http://www.hma.eu
• Procedural Guidance
• Application for Marketing Authorisation (MA), „Bluebox requirements".

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "**ACS PharmaProtect GmbH (ACS):** The operating company of the database system of the pharmaceutical industry (www.pharmaprotect.de) at securPharm.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
content

Number: 4 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:04:56
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(Old text): "**CMDh:** The Co-ordinated Group for Mutual Recognition and Decentralised Procedures – Human is set -up in accordance with Directive 2001/83/EC for the examination
of any question relating to marketing authorisation of a medicinal product in two or more Member States, in accordance with the Mutual Recognition Procedure (MRP)
or the Decentralised Procedure (DCP).

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
content; description deleted

Number: 5 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:04:56
Delete:
(Old text): "**Clinic Component:** A clinic component is a package that resembles the retail pack but cannot be sold individually.
A PZN is assigned to the clinic component for
package identification that refers to the contents and the characteristic of "clinic component". Bundled clinic components make up clinic packs to which a retail-relevant
PZN is assigned.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
content; description deleted

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
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(Old text): "**AMG:** In the interest of proper pharmaceutical care for humans and animals, it is the purpose of the German Medicinal Products Act (AMG) to guarantee safety during
the circulation of medicinal products, specifically ensuring the quality, efficacy and safety of medicinal products in accordance with the provisions contained in the AMG
(see section 1 AMG).

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:55:06
content

Comments from page 35 continued on next page

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Number: 7 Author: securPharmSubject: Highlight Date: 14.02.2019 18:05:11
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[New text]: "Identifiers (AI) are identifiers developed"

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editorial

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creates a constant stream of ink droplets, which is deflected electrostatically. Due to the high solvent content, the ink dries and adheres very well to all non-porous surfaces. The resolution is low.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
content; description deleted

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editorial

Number: 11 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:04:56
Delete:
(Old text): "The same-coloured,
neighbouring elements of the code should directly transition to each other without interruption. (In the German version of Delegated Regulation 2016/161, the Data Matrix
Code is translated as “data matrix” (“Datenmatrix”).)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
content; deleted from keyword "Data Matrix Code"

Number: 12 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Identifier (DI):"

[New text]: "Identifiers (DI) -"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
editorial

Number: 13 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "This terms stands in"

[New text]: "In"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
editorial

Number: 14 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "UI"

[New text]: "unique identifier (UI)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
editorial

Number: 15 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Regulation. As a result,"

[New text]: "Regulation (EU) 2016/161,"

Comments from page 35 continued on next page

Appendix E
Glossary/Abbreviations

The following are the terms and abbreviations used in this document:

ACS describes ACS PharmaProtect GmbH, Berlin. It is in equal shares a company of the pharmaceutical associations BAH, BPI, Pro Generika and vfa. ACS has developed the database system of the German pharmaceutical industry (MAH system) as a partial system for operating within the securPharm system in which data for the verification of pharmaceuticals will be deposited by the marketing authorisation holder prior to marketing.

AMG see German Medicinal Product Act.

Application Identifiers (AI) are identifiers developed by the users of GS1 which exactly define the encoded data content. These are valid worldwide and applicable in multiple sectors in accordance with ISO/IEC 15418. Published by GS1 in the German-speaking region under the term “Datenbezeichner”.

Article number - The number that clearly 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 article identification in the retail sector. In contrast to the product code, which represents part of the unique identifier (UI) in terms of the Delegated Regulation (EU) 2016/161, both an article number and a product code can be assigned to the article.

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

Barcode - An optical data carrier consisting of lines. Two-dimensional matrix codes are sometimes also referred to as 2D barcodes. This also includes the Data Matrix Code.

Blue Box - Found in pharmaceuticals with centralised European marketing authorisation. For these pharmaceuticals, the leaflet has to be compliant with Article 57 of EU Directive 2011/83/EC. Country specific requirements have to be printed inside the so-called “blue box” (visually distinguished by a blue-coloured frame). These are specified by the European Medicines Agency (EMA) or the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) in the “blue-box requirements”.

Code 39 is a barcode specified in ISO/IEC 16388. The printed space requirement of this code is high for a relatively low data volume. The Code 39 is used as a data carrier for representation of the PZN in the barcode.

Data Matrix Code (DMC) - A two-dimensional matrix code consisting of square elements. In the ECC200 version pursuant to ISO/IEC 16022, the code includes error correction in accordance with the Reed Solomon code for missing dots or damaged spots.

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

Data Identifiers are standardized identifiers that label the data element and precede the data content. The most frequently 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 reciprocally. **For linguistic simplification, this document uses the term “data identifier” when DI and AI are mentioned.**

Data Matrix - A general term for the Data Matrix Code in the German version of the DR.

Data Format Identifier (DFI) - The identifier in XML descriptions that stands for the code characteristics in accordance with ISO standards. It sets out the guidelines for the use and form of the following parts: the envelope data according to ISO/IEC 15434, the specific application identifier (AI or DI) and what header information should

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
editorial

Number: 16 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "a product."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
content

Number: 17 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:01
content

Number: 18 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "**ASC-Format:** Is structure that uses format 6 of ISO/IEC 15434 and the ASC MH10 Data Identifiers (DI) of ISO/IEC 15418 (reference to ANSI MH10.8.2). The specifications
of IFA Coding Systems are based on that format (see also data identifier)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 19 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Replace:
(Old text): "**Data Matrix:** In the German version of the Delegated
Regulation, the Data Matrix Code is translated as “Datenmatrix”. See Data Matrix Code.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 20 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "Colloquially, two-dimensional"

[New text]: "Two-dimensional"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
editorial

Number: 21 Author: securPharmSubject: Highlight Date: 14.02.2019 17:04:56
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

be used. Currently, “IFA” and “GS1” are defined as the value for the DFI.

Delegated Regulation (EU) 2016/161 (DR) stands for “Delegated Regulation (EU 2016/161 of the European Commission of 2 October 2015 supplementing Directive 2001/83/EU of the European Parliament and the Council by stipulating exact provisions regarding the safety features on the packaging of medicinal products for human use.”

DFI - see Data Format Identifier.

DMC - see Data Matrix Code.

DR - see Delegated Regulation (EU) 2016/161.

European Medicines Verification Organisation (EMVO) describes the EMVO asbl. Based in Brussels, this is the non-profit organisation established by the European stakeholder associations that operates the EU Hub and connects the national medicines verification systems (NMVS) to the EMVS.

EMVS stands for “European Medicines Verification System” and describes the data repository and access system established and operated pursuant to Chapter VII of the DR. It consists of the EU hub, the securPharm system and additional national and supranational verification systems and facilitates the authentication of a pharmaceutical according to the Falsified Medicines Directive and the Delegated Regulation, also across multiple countries.

EU Hub is the “centralised information and data router (Hub)” operated by the EMVO pursuant to Art. 32 para 1 a) of the DR, also referred to as “European Hub” by the EMVO.

European Medicines Verification System (EMVS) is the system landscape consisting of the EU hub and the connected national medicines verification systems (NMVS).

Falsified Medicines Directive (FMD) - describes the European Directive 2011/62/EU of the European Parliament and the Council of 8 June 2011 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. It was transposed into German law on 19 October 2012 with the “Second Amendment Act for Pharmaceutical Law and other Regulations”.

German Medicinal Product Act (AMG) - Its purpose in the interest of proper pharmaceutical care for humans and animals is to guarantee safety during the circulation of medicinal products, specifically ensuring the quality, efficacy and safety of medicinal products in accordance with the provisions contained in the AMG (see section 1 AMG).

Global Trade Item Number (GTIN) - A globally unambiguous article number used in many sectors (FMCG, chemistry, healthcare, fashion, DIY, military, banking, etc.). The GTIN (formerly EAN) can be encoded in various data carriers, e.g. in a barcode of the EAN-13 type. Other coding versions of the GTIN in GS1-128, the Data Matrix Code and GS1-DataBar are possible. The IA in charge is GS1.

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

GTIN - see Global Trade Item Number.

HIBC – Health Industry Barcode – A compressed structure that is primarily used for labelling medicinal products. The HIBC is prefixed by the system identifier “+”, followed by the alphanumeric 2- to 18-digit product code and the variable product data (see www.hibc.de). HIBC is another issuing agency (IA) registered in accordance with ISO/IEC 1549-2 that (like other IAs) also provides for the use of the data identifier (DI).

IA - see Issuing Agency.

IFA - stands for Informationsstelle für Arzneispezialitäten – IFA GmbH, Frankfurt am Main (www.ifaffm.de). IFA is in equal parts an organisation of ABDA, BPI and PHAGRO. The IFA is an information service provider for the German pharmaceutical market and a joint clearing house of the pharmaceutical industry, the pharmaceutical wholesale sector and pharmacists in the Federal Republic of Germany. It is the organisation in charge of assigning the PZN and the PRA code for use of the PPN. The IFA is also registered as an issuing agency (IA) in accordance with ISO/IEC 15459-2.

Page: 36

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "The Delegated Regulation (EU)
2016/161 of the Commission of 2 October 2015, supplements..."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
editorial

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**DFI – Data Format Identifier:** Defines the parameters according to the ISO standard. Additionally, it sets out the
guidelines for the use and form of the following parts: the envelope data according to ISO/IEC 15434, the specific application identifier (AI or DI), whether a macro should be used (ISO/IEC 16022) and the appropriate syntax.
Currently, "IFA" and "GS1" are defined as the value for the DFI.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 6 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:02:45
Delete:
(Old text): "**Dot Data Matrix Code:** This is a data matrix code consisting individual, round dots. The data matrix standard does not specify a dot code variant. In practice, there are many dot code data matrix applications. They require
scanners capable of reading such applications. This application is an open system that does without the data matrix dot code variant.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 7 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:04:56
Delete:
(Old text): "**Dotcode:** This is a separate code type consisting of individual, detached dots. This code type is mentioned here in order to ensure a clear distinction between the dot
code and a data matrix code in the dot variant.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:02:45
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 9 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:02:45
Delete:
(Old text): "**European Medicines Agency (EMA):** European regulatory
agency for certain pharmaceuticals. Grants approval for medicinal products with centralised marketing authorisation

Comments from page 36 continued on next page

be used. Currently, "IFA" and "GS1" are defined as the value for the DFI.

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

DFI - see Data Format Identifier.

DMC - see Data Matrix Code.

DR - see Delegated Regulation (EU) 2016/161.

10 **ropean Medicines Verification Organisation (EMVO)** describes the EMVO asbl. Based in Brussels, this is the non-profit organisation established by the European stakeholder associations that operates the EU Hub and connects the national medicines verification systems (NMVS) to the EMVS. 11

12 **IVS** stands for "European Medicines Verification System" and describes the data repository and access system established and operated pursuant to Chapter VII of the DR. It consists of the EU hub, the securPharm system and additional national and supranational verification systems and facilitates the authentication of a pharmaceutical according to the Falsified Medicines Directive and the Delegated Regulation, also across multiple countries.

EU Hub is the "centralised information and data router (Hub)" operated by the EMVO pursuant to Art. 32 para 1 a) of the DR, also referred to as "European Hub" by the EMVO.

European Medicines Verification System (EMVS) is the system landscape consisting of the EU hub and the connected national medicines verification systems (NMVS).

Falsified Medicines Directive (FMD) - describes the European Directive 2011/62/EU of the European Parliament and the Council of 8 June 2011 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. It was transposed into German law on 19 October 2012 with the "Second Amendment Act for Pharmaceutical Law and other Regulations".

German Medicinal Product Act (AMG) - Its purpose in the interest of proper pharmaceutical care for humans and animals is to guarantee safety during the circulation of medicinal products, specifically ensuring the quality, efficacy and safety of medicinal products in accordance with the provisions contained in the AMG (see section 1 AMG).

Global Trade Item Number (GTIN) - A globally unambiguous article number used in many sectors (FMCG, chemistry, healthcare, fashion, DIY, military, banking, etc.). The GTIN (formerly EAN) can be encoded in various data carriers, e.g. in a barcode of the EAN-13 type. Other coding versions of the GTIN in GS1-128, the Data Matrix Code and GS1-DataBar are possible. The IA in charge is GS1.

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

13 **IN** - see Global Trade Item Number.

HIBC – Health Industry Barcode – A compressed structure that is primarily used for labelling medicinal products. The HIBC is prefixed by the system identifier "+", followed by the alphanumeric 2- to 18-digit product code and the variable product data (see www.hibc.de). HIBC is another issuing agency (IA) registered in accordance with ISO/IEC 1549-2 that 14 e other IAs) also provides for the use of the data identifier (DI).

15 - see Issuing Agency.

16

17 **A -** stands for Informationsstelle für Arzneispezialitäten – IFA GmbH, Frankfurt am Main (www.ifaffm.de). IFA is in equal parts an organisation of ABDA, BPI and PHAGRO. The IFA is an information service provider for the German pharmaceutical market and a joint clearing house of the pharmaceutical industry, the pharmaceutical wholesale sector and pharmacists in the Federal Republic of Germany. It is the organisation in charge of assigning the PZN and the PRA code for use of the PPN. The IFA is also registered as an issuing agency (IA) in accordance with ISO/IEC 15459-2.

in Europe.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 10 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**European Medicines Verification Organisation (EMVO):** This non-profit organisation established by the European stakeholder associations operates the European
hub (HUB) and connects the national medicines
verification systems (NMVS) to the EMVS.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 11 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:02:45
Delete:
(Old text): "**European Medicines Verification System (EMVS):**
The system landscape consisting of the European hub (HUB) and the connected national medicines verification systems (NMVS).

Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:57:38
content

Number: 12 Author: Compare: Insert Subject: text Date: 13.02.2019 11:36:54
"**EMVS** stands for "European Medicines Verification System" and describes the data repository and access system established and operated pursuant to Chapter VII of the DR. It consists of the EU hub, the securPharm system and additional national and supranational verification systems and facilitates the authentication of a pharmaceutical according to the Falsified Medicines Directive and the Delegated Regulation, also across multiple countries.

EU Hub is the "centralised information and data router (Hub)" operated by the EMVO pursuant to Art. 32 para 1 a) of the DR, also referred to as "European Hub" by the EMVO."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:03:25
content

Number: 13 Author: Compare: Insert Subject: text Date: Indeterminate
"GTIN - see Global Trade Item Number."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:03:25
content

Number: 14 Author: Compare: Insert Subject: text Date: Indeterminate
"(like other IAs)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:03:25
editorial

Number: 15 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:03:25
content

Number: 16 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:02:45
Delete:
(Old text): "**Identifier:** To indicate the content of a data element these are headed by standardised identifiers. The most common
identifiers are the ASC MH10 Data Identifiers (DI) and the GS1 Application Identifiers (AI). In ANSI MH10.8.2 both kinds are included separately as well as being mapped
to each other. Whenever Data Identifiers and Application Identifiers are meant, this document uses the short term identifier.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:03:25
content

Number: 17 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**IFA:** *IFA Informationsstelle für Arzneispezialitäten GmbH* (www.ifaffm.de). The organisation assigning the PZN and the PRA code for use of the PPN. The IFA is also registered as an issuing agency (IA) in accordance with ISO/IEC 15459-2.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:03:25
content

Comments from page 36 continued on next page

be used. Currently, “IFA” and “GS1” are defined as the value for the DFI.

Delegated Regulation (EU) 2016/161 (DR) stands for “Delegated Regulation (EU 2016/161 of the European Commission of 2 October 2015 supplementing Directive 2001/83/EU of the European Parliament and the Council by stipulating exact provisions regarding the safety features on the packaging of medicinal products for human use.”

DFI - see Data Format Identifier.

DMC - see Data Matrix Code.

DR - see Delegated Regulation (EU) 2016/161.

European Medicines Verification Organisation (EMVO) describes the EMVO asbl. Based in Brussels, this is the non-profit organisation established by the European stakeholder associations that operates the EU Hub and connects the national medicines verification systems (NMVS) to the EMVS.

EMVS stands for “European Medicines Verification System” and describes the data repository and access system established and operated pursuant to Chapter VII of the DR. It consists of the EU hub, the securPharm system and additional national and supranational verification systems and facilitates the authentication of a pharmaceutical according to the Falsified Medicines Directive and the Delegated Regulation, also across multiple countries.

EU Hub is the “centralised information and data router (Hub)” operated by the EMVO pursuant to Art. 32 para 1 a) of the DR, also referred to as “European Hub” by the EMVO.

European Medicines Verification System (EMVS) is the system landscape consisting of the EU hub and the connected national medicines verification systems (NMVS).

Falsified Medicines Directive (FMD) - describes the European Directive 2011/62/EU 18 the European Parliament and the Council of 8 June 2011 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. It was transposed into German law on 19 October 2012 with the “Second Amendment Act for Pharmaceutical Law and other Regulations”.

German Medicinal Product Act (AMG) - Its purpose in the interest of proper pharmaceutical care for humans and animals is to guarantee safety during the circulation of medicinal products, specifically ensuring the quality, efficacy and safety of medicinal products in accordance with the provisions contained in the AMG (see section 1 AMG).

Global Trade Item Number (GTIN) - A globally unambiguous article number used in many sectors (FMCG, chemistry, healthcare, fashion, DIY, military, banking, etc.). The GTIN (formerly EAN) can be encoded in various data carriers, e.g. in a barcode of the EAN-13 type. Other coding versions of the GTIN in GS1-128, the Data Matrix Code and GS1-DataBar are possible. The IA in charge is GS1.

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

GTIN - see Global Trade Item Number.

HIBC – Health Industry Barcode – A compressed structure that is primarily used for labelling medicinal products. The HIBC is prefixed by the system identifier “+”, followed by the alphanumeric 2- to 18-digit product code and the variable product data (see www.hibc.de). HIBC is another issuing agency (IA) registered in accordance with ISO/IEC 1549-2 that (like other IAs) also provides for the use of the data identifier (DI).

IA - see Issuing Agency.

IFA - stands for Informationsstelle für Arzneispezialitäten – IFA GmbH, Frankfurt am Main (www.ifaffm.de). IFA is in equal parts an organisation of ABDA, BPI and PHAGRO. The IFA is an information service provider for the German pharmaceutical market and a joint clearing house of the pharmaceutical industry, the pharmaceutical wholesale sector and pharmacists in the Federal Republic of Germany. It is the organisation in charge of assigning the PZN and the PRA code for use of the PPN. The IFA is also registered as an issuing agency (IA) in accordance with ISO/IEC 15459-2.

Number: 18 Author: Compare: Insert Subject: text Date: Indeterminate
"of the European Parliament and the Council of 8 June 2011"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Issuing Agency (IA) - An organisation in charge of assigning number systems that is accredited in accordance with ISO/IEC 15459-2. An issuing agency is able to provide its system participants with a system for the unambiguous identification of objects on a worldwide scale. The ISO has commissioned industry association AIM to serve as registration authority.

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

MAH - see Marketing Authorisation Holder

MAH System (MAHS) - The database system of the pharmaceutical industry, which is operated by ACS.

Marketing Authorisation Holder (MAH) - Pursuant to Section 4 para. 18 of the German Medicinal Products Act (AMG), the marketing authorisation holder - so-called "pharmazeutischer Unternehmner" - owns the marketing authorisation or registration for pharmaceuticals subject to approval and registration and is the party placing a medicinal product on the market under his own name. Both the marketing authorisation holder and the co-distributor are pharmaceutical entrepreneurs, but the latter does not hold the marketing authorisation. As the so-called suppliers, both the marketing authorisation holder and the co-distributor can apply for a PZN for their medicinal products with IFA GmbH. This supplier will also be the contractual partner of ACS and responsible for uploading the data of his PZN.

Module size - Describes the intended edge length of one matrix cell.

National Trade Item Number (NTIN) - A GTIN into which the national item numbers are embedded and which is assigned and managed by other issuing agencies and not, as is usually the case with a GTIN, by the manufacturer. For each of the number ranges managed by issuing agencies, GS1 assigns a specific prefix. Prefix "4150" was assigned for the German PZN. As for GTIN, "01" must be used as application identifier (AI). Analogously, the data identifier "8P" must be applied when using the ASC format.

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

National Medicines Verification System (NMVS) - The national medicines verification system for a member state. corresponds to the national data repository and access system in the Delegated Regulation (EU) 2016/161.

TC pharmaceuticals (OTC = over the counter) - Non-prescription pharmaceuticals that must be sold in pharmacies in Germany. Pursuant to Section 48 of the German Medicinal Products Act (AMG), medicines are classified as non-prescription, if they do not endanger the user's health when used as intended, even if they are used without medical supervision. sually, freely sold pharmaceuticals are also considered OTC drugs.

harmacy Product Number (PPN) - A globally unambiguous article number in the healthcare sector, which is assigned by IFA GmbH as the (internationally recognised) issuing agency in accordance with ISO/IEC standards. The PPN can be embedded without change into any national article number. IFA GmbH automatically generates the PPN for the PZN when the article is entered. The data identifier (DI) "9N", which was exclusively standardized by the ANSI MH10 Maintenance Committee, identifies the PPN in any data carrier such as the Data Matrix Code.

Product Registration Agency Code (PRA Code) - Two-digit prefix to the unique identifier of a PPN. It is assigned and managed by IFA GmbH.

oduct Code (PC) - Pursuant to the Delegated Regulation (EU) 2016/161, this is part of the unique identifier on which the verification is based in connection with the serial number. The combination of product code and serial number is globally unique for each pharmaceutical pack. In the Data Matrix Code of a pack for the German market, the product code is included in the format of a PPN or NTIN, which both contain the PZN.

Pharmazentralnummer (PZN) - An unambiguous, 8-digit (including check digit) numeric identification key in the German market for pharmaceuticals, certain medical products and other health products (overall, this corresponds to typical pharmacy merchandise). As such, it identifies a certain article (a trading form) with a certain name, package size (quantity and unit), dosage form, pharmaceutical information, and a certain article type of a certain supplier. At the same time, the PZN is

Page: 37

Number: 1 Author: Compare: Insert Subject: text Date: Indeterminate
"It corresponds to the national data repository and access system in the Delegated Regulation (EU)2016/161."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**OTC Medicines:** OTC (= over the counter) is a term used for non-prescription drugs."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 4 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 5 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "Non-prescription drugs are further categorised into pharmacy-only and freely sold medicines."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 6 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**Pharmacy Product Number (PPN):** A globally unique article number for health care products into which national article numbers are embedded. For embedding the German PZN the product registration agency code “11” is used as a prefix, followed by the national article number (in Germany the PZN), followed by a two number check digit. The data identifier for a PPN is “9N”."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 7 Author: Compare: Insert Subject: text Date: Indeterminate
"- so-called “pharmazeutischer Unternehmner” -"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "registration as well as the party circulating a medicinal product."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 9 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "the IFA. Typically, however, only one of the two applies for the PZN and becomes the registered supplier with the IFA."

[New text]: "IFA GmbH."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:04:19
content

Number: 10 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**Product Code:** Pursuant to the Delegated Regulation, this is the safety feature on which the verification is based

Comments from page 37 continued on next page

Issuing Agency (IA) - An organisation in charge of assigning number systems that is accredited in accordance with ISO/IEC 15459-2. An issuing agency is able to provide its system participants with a system for the unambiguous identification of objects on a worldwide scale. The ISO has commissioned industry association AIM to serve as registration authority.

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

MAH - see Marketing Authorisation Holder

MAH System (MAHS) - The database system of the pharmaceutical industry, which is operated by ACS.

Marketing Authorisation Holder (MAH) - Pursuant to Section 4 para. 18 of the German Medicinal Products Act (AMG), the marketing authorisation holder - so-called "pharmazeutischer Unternehmner" - owns the marketing authorisation or registration for pharmaceuticals subject to approval and registration and is the party placing a medicinal product on the market under his own name. Both the marketing authorisation holder and the co-distributor are pharmaceutical entrepreneurs, but the latter does not hold the marketing authorisation. As the so-called suppliers, both the marketing authorisation holder and the co-distributor can apply for a PZN for their medicinal products with IFA GmbH. This supplier will also be the contractual partner of ACS and responsible for uploading the data of his PZN.

11 **odule size** - Describes the intended edge length of one matrix cell.

12 **tional Trade Item Number (NTIN)** - A GTIN into which the national item numbers are embedded and which is assigned and managed by other issuing agencies and not, as is usually the case with a GTIN, by the manufacturer. For each of the number ranges managed by issuing agencies, GS1 assigns a specific prefix. Prefix "4150" was assigned for the German PZN. As for GTIN, "01" must be used as application identifier (AI). Analogously, the data identifier "8P" must be applied when using the ASC format.

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

National Medicines Verification System (NMVS) - The national medicines verification system for a member state. It corresponds to the national data repository and access system in the Delegated Regulation (EU) 2016/161.

OTC pharmaceuticals (OTC = over the counter) - Non-prescription pharmaceuticals that must be sold in pharmacies in Germany. Pursuant to Section 48 of the German Medicinal Products Act (AMG), medicines are classified as non-prescription, if they do not endanger the user's health when used as intended, even if they are used without medical supervision. Usually, freely sold pharmaceuticals are also considered OTC drugs.

Pharmacy Product Number (PPN) - A globally unambiguous article number in the healthcare sector, which is assigned by IFA GmbH as the (internationally recognised) issuing agency in accordance with ISO/IEC standards. The PPN can be embedded without change into any national article number. IFA GmbH automatically generates the PPN for the PZN when the article is entered. The data identifier (DI) "9N", which was exclusively standardized by the ANSI MH10 Maintenance Committee, identifies the PPN in any data carrier such as the Data Matrix Code.

Product Registration Agency Code (PRA Code) - Two-digit prefix to the unique identifier of a PPN. It is assigned and managed by IFA GmbH.

Product Code (PC) - Pursuant to the Delegated Regulation (EU) 2016/161, this is part of the unique identifier on which the verification is based in connection with the serial number. The combination of product code and serial number is globally unique for each pharmaceutical pack. In the Data Matrix Code of a pack for the German market, the product code is included in the format of a PPN or NTIN, which both contain the PZN.

13 **armazentralnummer (PZN)** - An unambiguous, 8-digit (including check digit) numeric identification key in the German market for pharmaceuticals, certain medical products and other health products (overall, this corresponds to typical pharmacy merchandise). As such, it identifies a certain article (a trading form) with a certain name, package size (quantity and unit), dosage form, pharmaceutical information, and a certain article type of a certain supplier. At the same time, the PZN is

in connection with the serial number. The combination of product code and serial number is globally unique for each pharmaceutical package. In Germany, the product code used for a verification pursuant to the FMD is the PPN. In the data matrix code the product code can be included in the format of a PPN or NTIN, which both contain the PZN.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:32
content

Number: 11 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**Module Size:** Specifies the ideal size of a matrix cell in the Data Matrix Code."

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:32
content

Number: 12 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**National Trade Item Number (NTIN):** A globally unique item number in which national article numbers are embedded
and a GS1 prefix is used. For the PZN, the prefix
"4150" has been assigned. As for GTIN, "01" must be used as application identifier (AI). Analogously, the data identifier "8P" must be applied when using the ASC format.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:32
content

Number: 13 Author: securPharmSubject: Highlight Date: 18.02.2019 10:02:18
Replace:
(Old text): "**Pharmazentralnummer (PZN):** National article number of German pharmaceutical products or merchandise
typically sold in pharmacies. Since 2013, the PZN has had eight digits. Assignment of the PZN is governed by law and is the responsibility of the IFA. The retail sector uses the PZN for unambiguous item identification while
the health care sector uses it for billing purposes. See also http://www.ifaffm.de/service/index.html. The corresponding number in Austria is also known as PZN. However, it originates from a different circle of numbers and is managed by the corresponding Austrian issuing agency.

Author: securPharmSubject: Sticky Note Date: 18.02.2019 10:02:30
content

The uniform German label pursuant to Section 300 of the German Social Code Book V (SGB V), which marketing authorisation holders must affix to the outer packaging of pharmaceutical packs. The corresponding article number in Austria is also known as PZN and managed by the corresponding Austrian issuing agency. To make the relevant distinctions, this document labels the article numbers with PZN-DE and PZN-AT.

PPN - see Pharmacy Product Number.

Product Registration Agency (PRA) - Issuing agency of (national) article numbers that are transferred into the PPN together with the PRA Code.

Pseudo-Grading - The term describes an assessment of print quality modelled after the ISO/IEC 15415 standard. This method is used by camera systems that are firmly integrated into a production line, perform scan checks and assess print quality criteria. Since these camera systems are not standardised measuring devices, the term is prefixed by the word “pseudo”.

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

Randomised Serial Number - A serial number generated at random based on a deterministic or non-deterministic randomisation algorithm.

Rx Drugs - Prescription drugs are often colloquially referred to as Rx drugs.

securPharm - The non-profit organisation in Frankfurt/Main operating the national medicines verification system in Germany (National Medicines Verification Organisation (NMVO)). It arose from an initiative to protect patients from falsified medicines in the legal supply chain in Germany and is sponsored by a consortium of pharmaceutical, wholesale and pharmacists’ associations.

Unique Identifier - Pursuant to Article 3 of Delegated Regulation (EU) 2016/161, the unique identifier describes the safety feature that facilitates the authentication and identification of an individual pharmaceutical pack.

Verification - The process of identifying falsified medicines or duplicates, specifically with a serial number on pharmaceutical packs. In the field of optical codes, the term verification is also used for the quality inspection of printed codes (barcode verification). For the sake of unambiguous terminology, this specification only uses the term “verification” within the context of detecting falsifications.

XML - This abbreviation was derived from the term “Extensible Markup Language”. XML is a markup language to represent hierarchically structured data in the form of text data.

Page: 38

Number: 1 Author: securPharmSubject: Highlight Date: 18.02.2019 10:02:40
Replace:
(see comment on "Pharmazentralnummer (PZN)" above)

Author: securPharmSubject: Sticky Note Date: 18.02.2019 10:02:49
content

Number: 2 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Replace:
(Old text): "**securPharm:** An initiative to protect patients from falsified medicines in the legal supply chain in Germany. It is sponsored by a consortium of pharmaceutical, wholesalers' and pharmacists' associations. securPharm e.V. is the non-profit organisation operating the national medicines verification system in Germany.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:32
content

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 17:02:45
Insert:
(New text)

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:32
content

Number: 4 Author: securPharmSubject: Sticky Note Date: 14.02.2019 17:02:45
Delete:
(Old text): "**PPN Code:** Describes a Data Matrix Code ECC200 in accordance with ISO/IEC 16022 and the data structure and syntax of ISO/IEC 15418/ANSI MH10.8.2 and ISO/IEC 15434. As the leading data element, the PPN Code
includes the Pharmacy Product Number (PPN) and other data elements depending on the application in question. For pharmaceuticals subject to mandatory verification, these are always the serial number, batch number and
expiry date.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:32
content

Number: 5 Author: Compare: Insert Subject: text Date: Indeterminate
"(EU)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "this term"

[New text]: "the unique identifier"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
editorial

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "verification"

[New text]: "authentication"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 8 Author: securPharmSubject: Highlight Date: 14.02.2019 17:03:32
Replace:
(Old text): "package"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
editorial

Number: 9 Author: Compare: Delete Subject: text Date: Indeterminate
"pseudo grading"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
editorial

Comments from page 38 continued on next page

the uniform German label pursuant to Section 300 of the German Social Code Book V (SGB V), which marketing authorisation holders must affix to the outer packaging of pharmaceutical packs. The corresponding article number in Austria is also known as PZN and managed by the corresponding Austrian issuing agency. To make the relevant distinctions, this document labels the article numbers with PZN-DE and PZN-AT.

PPN - see Pharmacy Product Number.

Product Registration Agency (PRA) - Issuing agency of (national) article numbers that are transferred into the PPN together with the PRA Code.

Pseudo-Grading - The term describes an assessment of print quality modelled after the ISO/IEC 15415 standard. This method is used by camera systems that are firmly integrated into a production line, perform scan checks and assess print quality criteria. Since these camera systems are not standardised measuring devices, the term is prefixed by the word “pseudo”.

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

Randomised Serial Number - A serial number generated at random based on a deterministic or non-deterministic randomisation algorithm.

Rx Drugs - Prescription drugs are often colloquially referred to as Rx drugs.

securPharm - The non-profit organisation in Frankfurt/Main operating the national medicines verification system in Germany (National Medicines Verification Organisation (NMVO)). It arose from an initiative to protect patients from falsified medicines in the legal supply chain in Germany and is sponsored by a consortium of pharmaceutical, wholesale and pharmacists’ associations.

Unique Identifier - Pursuant to Article 3 of Delegated Regulation (EU) 2016/161, the unique identifier describes the safety feature that facilitates the authentication and identification of an individual pharmaceutical pack.

Verification - The process of identifying falsified medicines or duplicates, specifically with a serial number on pharmaceutical packs. In the field of optical codes, the term verification is also used for the quality inspection of printed codes (barcode verification). For the sake of unambiguous terminology, this specification only uses the term “verification” within the context of detecting falsifications.

XML - This abbreviation was derived from the term “Extensible Markup Language”. XML is a markup language to represent hierarchically structured data in the form of text data.

Number: 10 Author: securPharmSubject: Highlight Date: 14.02.2019 17:03:32

Replace:

(Old text): "**Verification:** Describes the process of detecting falsifications or duplicates with the help of a serial number printed on pharmaceutical packages. In the field of optical
codes, the term verification is also used for the quality inspection of printed codes. For the sake of unambiguous terminology, this specification only uses the term “verification” within the context of detecting falsifications.
Print quality inspection is always described as barcode or matrix code verification.

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14

content

Number: 11 Author: Compare: Insert Subject: text Date: Indeterminate

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

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14

content

Appendix F
Bibliography

F.1 Standards

ISO 22742: Packaging – Linear barcode and two-dimensional symbols for product packaging

ANSI MH10.8.2: Data Identifier and Application Identifier Standard

DIN 16587:2015-11: Information technology – Automatic identification and data capture techniques – Data Matrix Rectangular Extension DIN 16587

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 – Barcode 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 15459-2: Information technology – Unique identifiers – Part 2: Registration procedures

ISO/IEC 15459-3: Information technology – Unique identifiers – Part 3: Common rules for unique identifiers

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

ISO/IEC 19762: Information technology – Automatic identification and data capture (AIDC) techniques – Harmonised vocabulary

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

DIN ISO 2859-1: Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

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

F.2 Reference to specifications

The specifications listed below contain the necessary details of coding, specifically for the two possible structures in the Data Matrix Code:

Specifications of the IFA:

See “IFA Coding System: PPN Code Specification for Retail Packaging”: http://www.ifaffm.de/en/ifa-codingsystem/data-matrix-handelspackungen.html

Part of the IFA coding system, see http://www.ifa-coding-system.org

Specifications of GS1:

1.) Identification of Medicines in Germany – NTIN Guideline for use in the securPharm pilot project (https://www.gs1-germany.de/fileadmin/gs1/basis_informationen/kennzeichnung_von_pharmazeutika_in_deutschland.pdf).

2.) Labelling of pharmaceuticals in Germany – NTIN guide for use in the securPharm pilot project (https://www.gs1-germany.de/loesung-fuer-faelschungssichere-arzneien/).

3.) General GS1 Specification (www.gs1.org).

Page: 39

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 17:03:32
Replace:
(Old text): "Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 2 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "bar code"

[New text]: "barcode"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
editorial

Number: 3 Author: securPharmSubject: Highlight Date: 14.02.2019 17:03:32
Replace:
(Old text): "**ISO 3951:** Sampling procedures and charts for inspection by variables for per cent nonconforming"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "16587:"

[New text]: "16587:2015-11:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 5 Author: Compare: Delete Subject: text Date: Indeterminate
"Informationstechnik – Automatische Identifikation und Datenerfassungsverfahren Rechteckige Erweiterung des Data Matrix-Codes"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "http://www.ifaffm.de/en/ifa-codingsystem/data-matrix-code-retailpacks.html"

[New text]: "http://www.ifaffm.de/en/ifacodingsystem/data-matrix-handelspackungen.html"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 7 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: "see: http://www.ifaffm.de/en/ifa-codingsystem.html B"

[New text]: "see http://www.ifacoding-system.org"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Number: 8 Author: Compare: Insert Subject: text Date: Indeterminate
"ISO/IEC CD 21471: Information technology – Automatic identification and data capture techniques — Barcodesymbology specifications — Extended Rectangular Data Matrix (DMRE)DIN"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14
content

Appendix G
Document Maintenance Summary

Version	Date	Type of change	Change
V 1.0	2012-06-13	First release	
V 1.01	2012-08-20	Layout/content correction	Chapters: 4; 5.1; Appendices: A; C; H; I (update)
V 1.02	2012-11-05	Layout/content correction	Editorial changes
V 1.03	2013-12-03	Layout/content correction	Chapters 4.2; 6; Appendix H
V 2.00	2016-03-15	Layout/content correction	Incorporated requirements from the Delegated Regulation (EU) 2016/161 into the corresponding chapters
V 2.01	2016-05-10	Content added/removed	Chapters 4.5, 5.2.5, 6.4, 6.6 and Appendix E
V 2.02	2016-07-01	Layout/wording correction	Title, chapters 2, 6.2, Appendix F
V 2.03	2017-05-05	Content added/removed	Chapters 4.5, 4.6 and 5.3
V 2.04a	2018-12-12	2 ew: 4 ontent added or removed: 5 ditorial changes:	1 hapters 3.1, 3.4, 3.5, 4.7, 6.6.1, 6.6.2 3 hapters 3.3, 4.5, 5.3, 6.2, 6.6.4, Appendix E Chapters 1, 2, 4, 5, 6, 7, Appendix F

Page: 40

Number: 1 Author: Compare: Insert Subject: text Date: Indeterminate
"Chapters 3.1, 3.4, 3.5, 4.7, 6.6.1, 6.6.2"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:02:14

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"New:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
editorial

Number: 3 Author: Compare: Insert Subject: text Date: Indeterminate
"Chapters 3.3, 4.5, 5.3, 6.2, 6.6.4, Appendix E"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
editorial

Number: 4 Author: Compare: Insert Subject: text Date: Indeterminate
"Content added or removed:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
editorial

Number: 5 Author: Compare: Insert Subject: text Date: Indeterminate
"Editorial changes:"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
editorial

Imprint

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Hamburger Allee 26–28
60486 Frankfurt am Main
Germany

Internet: http://www.securPharm.de

The content was created with the greatest care. If you discover errors or omissions, please contact us. This document is a translation of the German version 2.04a of the securPharm coding rules and for your convenience. If there are any deviations to the German version – the German version applies.

Note regarding the preparation of this specification:

The "Coding" working group of securPharm e.V. has developed this specification. It consists of the following members (in alphabetical name order):

- **Dr. Ehrhard Anhalt,** Bundesverband der Arzneimittel-Hersteller e.V. (BAH), Bonn
- **Martin Bergen,** securPharm e.V., Frankfurt/Main
- **Lutz Boden,** Informationsstelle für Arzneispezialitäten - IFA GmbH, Frankfurt/Main
- **Michael Borchert,** Avoxa – Mediengruppe Deutscher Apotheker GmbH, Eschborn
- **Thomas Brückner,** Bundesverband der Pharmazeutischen Industrie e.V. (BPI), Berlin
- **Michael Dammann,** PHAGRO | Bundesverband des Pharmazeutischen Großhandels e.V., Berlin
- **Maria Mehnert,** ACS PharmaProtect GmbH, Berlin
- **Paul Rupp,** (Head of the Working Group) Informationsstelle für Arzneispezialitäten (IFA) GmbH, Frankfurt/Main
- **Dr. Wolfgang Stock,** ACS PharmaProtect GmbH, Berlin
- **Wilfried Weigelt,** (Member of the Standards Committee DIN NA 043-01-31 AA

Page: 41

Number: 1 Author: securPharmSubject: Highlight Date: 14.02.2019 17:03:32
Replace:
(Old text): "The Working Group (AG) "Coding" of the securPharm project created this specification. It consists of the following members (in alphabetical name order):"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
content

Number: 2 Author: Compare: Insert Subject: text Date: Indeterminate
"• Lutz Boden, Informationsstelle für Arzneispezialitäten - IFA GmbH, Frankfurt/Main"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
content

Number: 3 Author: Compare: Insert Subject: text Date: Indeterminate
"Maria Mehnert, ACS PharmaProtect GmbH, Berlin•"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
content

Number: 4 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " (Leiter der AG) IFA"

[New text]: " (Head of the Working Group)"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
content

Number: 5 Author: Compare: Insert Subject: text Date: Indeterminate
"– IFA"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
editorial

Number: 6 Author: Compare: Replace Subject: text Date: Indeterminate
[Old text]: " Mitglied im Normenausschuss"

[New text]: " Member of the Standards Committee"

Author: securPharmSubject: Sticky Note Date: 14.02.2019 18:01:40
editorial