



CODING RULES FOR MEDICINES REQUIRING VERIFICATION FOR THE GERMAN MARKET

Changelog between Version 2.02 and 2.03

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The content was created with the greatest care. This document is based on the German version 2.03 of the Coding Rules for medicines requiring verification for the German market and is for your convenience. If there are any deviations to the German version – the German version applies. Errors and omissions excepted.

Type of change	Source	Version 2.02	Version 2.03
Editorial change	Chap. 1, p.4, right column	Bundesverband des Pharmazeutischen Großhandels – PHAGRO – e.V.	PHAGRO Bundesverband des pharmazeutischen Großhandels e. V.
Change of content	Chap. 1, p.4, right column	Werbe- und Vertriebsgesellschaft Deutscher Apotheker mbH	Avoxa – Mediengruppe Deutscher Apotheker GmbH
Change of content	Chap. 1, p.5, left column, 1. para.	The pharmacy system is operated by Werbe- und Vertriebsgesellschaft Deutscher Apotheker mbH.	The pharmacy system is operated by Avoxa – Mediengruppe Deutscher Apotheker GmbH.
Change of content	Chap. 1, p.5, left column, 4. para.	Due to open legal and technical questions, e.g. on the coding of so-called “multi-country packs” 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.	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.
Editorial change	Chap. 3.2, p.6, right column, 2. para.	Apart from the above-mentioned key data elements, the MAH must also transfer additional information, e.g. pursuant to Article 33.2 (f) of the Delegated Regulation, [...].	Apart from the above-mentioned key data elements, the MAH must also transfer additional information, e.g. pursuant to Article 33 para. 2 lit. (f) of the Delegated Regulation, [...].
Editorial change	Chap. 3.2, p.6, right column, footnote 1	The concept will be revised as soon as details concerning the connection to the EU hub are available.	The concept will be revised as soon as details concerning the connection to the HUB are available.

Type of change	Source	Version 2.02	Version 2.03
Editorial change	Chap. 4.1, p.7, right column, 2. para.	[...] The next two paragraphs briefly describe the properties and methods for generating the PPN and the NTIN.	[...] The next two chapters briefly describe the properties and methods for generating the PPN and the NTIN.
Editorial Change	Chap. 4.2, p.8, left column, 2. para	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).	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").
Editorial change	Chap. 4.5, p.9, left column	4.5 Multi Country Packs	4.5 Multi Market Packs
Editorial change	Chap. 4.5, p.9, left column, 1. para.	Multi-country packs (MCPs) are retail packs that can be dispensed in multiple countries with a certain layout. [...]	Multi-market packs (MMPs) are retail packs that can be dispensed in multiple countries with a certain layout. [...]

Type of change	Source	Version 2.02	Version 2.03
Change of content	Chap. 4.5, p.9, left column, 2. para.	The definition of the data elements for MCP is not finished yet. In the end it is subject to the verification process of MCP. As soon as this process is specified by EMVO, this chapter is extended. This also applies for the human readable format.	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 HUB to all national verification systems. When the pharmaceutical is dispensed, the status of the pack in question is synchronised via the HUB in all national verification systems concerned.
Change of content	from --- to chap. 4.5, p.9, left column, 3. para.	---	Each country determines which national number apart from the product code must be incorporated in the Data Matrix Code. For pharmaceuticals destined for the German market, it is mandatory to include the PZN in the Data Matrix Code. This can be done directly within the product code as described in Chapter 4 or as an additional element, if the product code is assigned to another country.
Change of content	from --- to chap. 4.5, p.9, right column, 2. para.	---	Coding details are described in Chapter 5.3.

Type of change	Source	Version 2.02	Version 2.03
New figure	from --- to chap. 4.5, p.9, right column, 2. para.	---	Figure 5: Multi-market pack
New figure Clarifying of article types, their content and their verifying objects	Chap. 4.6, p.10	Figure 5: Overview of clinical packs	Figure 6: Overview of clinical packs
Editorial change	Chap. 4.6, p.10, footnote 1	A clinic component is a pack that resembles a pharmacy retail pack but cannot be sold individually. A PZN is assigned to the clinic component for pack identification that refers to the contents and the characteristic of the “clinic component”. Bundled clinic components make up clinic packs to which a retail-relevant PZN is assigned.	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 clinic packs to which a PZN that is relevant for wholesale and retail purposes is assigned.
Editorial change	Chap. 5.2, p.11, right column	5.2 Data elements and corresponding data identifiers / application identifier	5.2 Single market packs – Data elements and corresponding data identifiers / application identifier
New chapter	from --- to chap. 5.3, p.13	---	5.3 Multi market packs – Data elements and associated data identifiers
New figure Modification of matrix size and their data capacity	from chap. 6.2, p. 13 to chap. 6.2, p. 15	Rectangular symbols	Rectangular symbols

Type of change	Source	Version 2.02	Version 2.03
Change of content	from chap. 6.2, p. 13 to chap. 6.2, p. 15	The codes in the last four 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 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. The later ones will adapt gradually and will be able to read these codes until the application of the Delegated Regulation.	The 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 rectangular matrix dimensions to ISO standards. 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.
New figure	from chap. 6.6, p.15, left column to chap. 6.6, p.17, left column	Example NTIN:	Example NTIN:
Editorial change	from chap. 7, p.16, right column, footnote 2 to chap. 7, p.19, left column, footnote 2	The ISO/IEC 15415 standard, which is listed in the Delegated Regulation in Article 6 (4), [...]. As a result, the system for sample inspections implicitly becomes part of Article 6 (4) of the Delegated Regulation, [...].	The ISO/IEC 15415 standard, which is listed in the Delegated Regulation in Article 6 para. 4, [...]. As a result, the system for sample inspections implicitly becomes part of Article 6 para. 4 of the Delegated Regulation, [...].

Type of change	Source	Version 2.02	Version 2.03
Change of content	from annex A, p.18, footnote 1 to annex A, p.20, footnote 1	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 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)).
Editorial change	from annex B, p.19, right column to annex B, p.21, right column	Nominale Maße:	Nominal dimensions:
Editorial change	from annex C.1, p.20, left column, 1. para to annex C.1, p.22, left column, 1. para.	The interoperability is based on the joint use of the IEC standards 15434 Syntax for High Capacity Media, ISO/ IEC 15459 Unique identifier, as well as system and data identifier/application identifier according to ISO/IEC ISO/IEC 15418.	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.
Editorial change	from annex C.5, p.22, 2. para to annex C.5, p.24, 2. para.	If you have any questions or suggestions about this appendix, please drop us a mail.	If you have any questions or suggestions about this appendix, please do not hesitate to contact securPharm.

Type of change	Source	Version 2.02	Version 2.03
Editorial change	from annex D.1, p. 23, left column, 2. para to annex D.1, p. 25, left column, 2. para.	Based on this check, the serial number is valid and can be entered into the ACS MAH database system together with the other necessary data.	Based on this check, the serial number is valid and can be entered into the ACS-MAH-System together with the other necessary data.
Editorial change	from annex D.3, p. 24, left column, 2.para to annex D.3, p. 26, left column, 2.para.	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, N.I.S.T.).	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).
Editorial change	from annex E, p. 27, left column to annex E, p. 29, left column	Data Matrix Code: [...] In the ECC 200 version pursuant to ISO/IEC 16022, [...].	Data Matrix Code: [...] In the ECC200 version pursuant to ISO/IEC 16022, [...].
Editorial change	from annex E, p. 27, right column to annex E, p. 29, right column	European Medicines Verification Organisation (EMVO): This non-profit organisation established by the European stakeholder associations operates the European hub and connects the national medicines verification systems (NMVS) to the EMVS.	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.
Editorial change	from annex E, p. 27, right column to annex E, p. 29, right column	European Medicines Verification System (EMVS): The system landscape consisting of the European hub and the connected national medicines verification systems (NMVS).	European Medicines Verification System (EMVS): The system landscape consisting of the European hub (HUB) and the connected national medicines verification systems (NMVS).
Editorial change	from annex E, p. 28, left column to annex E, p. 30, left column	IFA: Informationsstelle für Arzneispezialitäten IFA GmbH (www.ifaffm.de).	IFA: IFA Informationsstelle für Arzneispezialitäten GmbH (www.ifaffm.de).

Type of change	Source	Version 2.02	Version 2.03
Editorial change	from annex E, p.28, left column to annex E, p.30, left column	National Trade Item Number (NTIN): [...] For the PZN, the prefix 4150 has been assigned.	National Trade Item Number (NTIN): [...] For the PZN, the prefix "4150" has been assigned.
Change of content	from Annex E, p. 28, right column to ---	Optical readable media (ORM): Oberbegriff für Codierungen, die mit optischen Geräten erfasst werden. Dazu gehören OCR-Schriften, Barcodes und 2D-Codes etc.	---
Editorial change	from Annex E, p. 28, right column to annex E, p. 30, right column	PPN Code: Describes a Data Matrix Code ECC 200 in accordance with ISO/IEC 16022 and the data structure and syntax of ISO/IEC 15418/ANSI MH10.8.2 and ISO/IEC 15434.	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.
Change of content	from annex G, p. 30 to annex G, p. 33	Document Maintenance Summary	Document Maintenance Summary
Editorial change	Imprint	This document is a translation of the German version 2.02 of the securPharm coding rules and for your convenience.	This document is a translation of the German version 2.03 of the securPharm coding rules and for your convenience.
Editorial change	Imprint	Dr. Ehrhard Anhalt, Bundesverband der Arzneimittel-Hersteller (BAH), Bonn	Dr. Ehrhard Anhalt, Bundesverband der Arzneimittel-Hersteller e.V. (BAH), Bonn
Editorial change	Imprint	Martin Bergen, securPharm e.V., Frankfurt	Martin Bergen, securPharm e.V., Frankfurt/Main
Change of content	Imprint	Michael Borchert, Werbe- und Vertriebsgesellschaft Deutscher Apotheker mbH, Eschborn	Michael Borchert, Avoxa – Mediengruppe Deutscher Apotheker GmbH, Eschborn

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Editorial change	Imprint	Thomas Brückner, Bundesverband der Pharmazeutischen Industrie (BPI), Berlin	Thomas Brückner, Bundesverband der Pharmazeutischen Industrie e.V. (BPI), Berlin
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Change of content	Imprint	Tobias Beer, ACS PharmaProtect GmbH, Berlin	Dr. Wolfgang Stock, ACS PharmaProtect GmbH, Berlin