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GS1 Standards

Guidelines for the Serialisation of Medicinal Products

With a Focus on Labelling and Identification

Application recommendation

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GS1 Germany GmbH

GS1 Germany assists companies in all sectors of industry to implement modern communication and process standards in practice and in doing so, improve the efficiency of their business processes. Amongst other things, the company is responsible in Germany for the globally unique GS1 item numbering system - the basis of the barcode. In addition, GS1 Germany promotes the use of new technologies for automatically identifying items (EPC/RFID) and standardised electronic communication (EDI). The company also focuses on solutions that increase customer orientation (ECR - Efficient Consumer Response) and on ensuring that development work takes into account current trends, such as mobile commerce, multi-channelling and sustainability.

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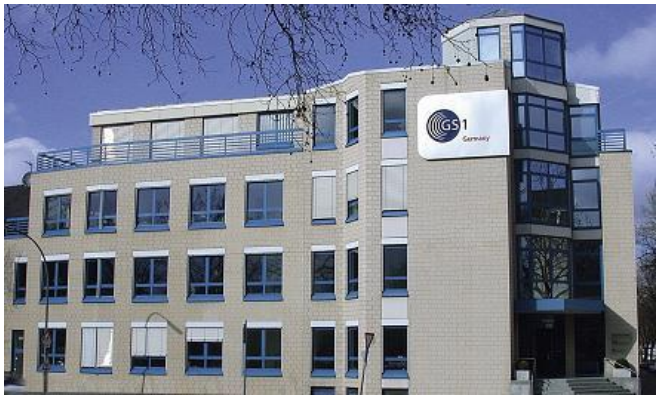

About this paper

EU Directive 2011/62/EU (FMD - Falsified Medicine Directive) calls for standardised measures for effectively preventing fake medicines entering the legal supply chain. Under Regulation (EU) 2016/161, after 09/02/2019, prescription medicines may only be offered for sale if they bear certain security features. Specifically, it means that every single pack of all affected medicinal products must be labelled with a unique serial number and marked with a 2D code. Before the medicine is dispensed to the patient, it is first subject to a verification procedure in order to eliminate any suspicion of falsification.

But along with the benefits come challenges in relation to how this can be sustainably implemented by the pharmaceutical industry. The legally required serialisation of products creates a solid basis for protecting against falsification. Pharmaceutical manufacturers must now begin to restructure their production, IT and logistics processes to comply with the FMD.

GS1 Germany developed these guidelines to assist companies in doing so. The main focus of these guidelines is on identifying and labelling medicinal products. On the one hand, GS1 standards can be used in Germany to encode the PZN (pharmaceutical identification number) in the GS1 DataMatrix Code. On the other, the international GS1 standards are being implemented worldwide in order to meet other regulatory requirements outside of the European Union. The guidelines indicate what advantages arise from following a harmonised and internationally proven approach, and point out the disadvantages of a purely national solution in an era of increasing globalisation.

Since the guidelines relate to the identification and labelling of medicinal products, it should be noted that details of the end-to-end verification system* can be obtained through the European Medicines Verification Organisation (EMVO).

Cologne, February 2018

* The regulation stipulates a system that ensures the identifying and authenticity of medicinal products by means of the end-to-end verification of all medicinal products equipped with the security features. The pharmaceutical manufacturer generates the individual identifier in the end-to-end system during manufacture of the medicinal products. Its authenticity is verified at the end of the supply chain by the pharmacist when dispensing the product to the patient and booking it out of the IT system.

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1 The role of the PZN (pharmaceutical identification number) in Germany

Under the Healthcare Reform Act from 20/12/1988, pharmaceutical companies are obligated "to declare the pharmaceutical registration number on the outer packaging of the medicinal product in a format that is standard nationwide and machine-readable for pharmacies. The details are to be elaborated in agreements by the national associations of health insurance companies and the main national organisations established to look after the economic interests of the pharmaceutical companies at the federal level." The national associations of the health insurance companies and the deutsche Apothekerverband (German Pharmacy Association) subsequently agreed on 04/11/1994 to use the Pharmazentralnummer (PZN) as the standard identifier within the meaning of the aforementioned legislative base.

As the range of products carried by pharmacies not only includes pharmacy-only medicines, like pharmaceuticals, but is being increasingly supplemented by articles commonly found in pharmacies that are also sold via other distribution channels (e.g. chemists, supermarkets, health food shops), it is permissible to use the GTIN to unambiguously identify both pharmacy-only products and those commonly found in pharmacies. This requires that the manufacturer informs the IFA of the GTIN that corresponds to a PZN. The two numbering systems are then linked with one another in the IFA database so that the legally required ability to identify the product can be achieved using the national identifier. When the GTIN is scanned at a pharmacy or hospital, the user is automatically given access to the associated data, such as the PZN, supplementary payment level, price, etc.

In short: It is already possible to identify a pharmaceutical product with a GTIN and label it with a GS1 code (e.g. EAN code). This possibility plays a specific and important role when it comes to so-called multi-country packs, i.e. packs that are sold on more than one market.

2 Global Trade Item Number (GTIN)

The principle, and legally compliant option for identifying medical products of all kinds, i.e. both medicinal products and medical devices, is for the manufacturer or brand owner to assign a Global Trade Item Number (GTIN).

The GTIN is assigned autonomously by and is the sole responsibility of the manufacturer (brand owner)[1]. Every GTIN is based on the so-called GS1 Global Company Prefix, which in Germany is assigned by GS1 Germany in combination with a GLN (Global Location Number). The GLN is part of the GS1 Complete package and allows the unambiguous and mutually exclusive identification of all manufacturers worldwide.

The GTIN is normally 13 digits long and has the following structure:

Global Trade Item Number GTIN		
Global Company Prefix	Individual number segment	Check digit
4 0 1 2 3 4 5	0 0 0 2 5	2
4 2 1 2 3 4 5 6	0 0 2 5	8
4 3 1 2 3 4 5 6 7	0 2 5	8

Fig. 2-1: Global Trade Item Number

- Global Company Prefix:

  The 7 to 9-digit Global Company Prefix is derived from the Global Location Number (GLN) of the brand owner. It ensures that the GTIN is globally unique and non-overlapping. The range of numbers available to the user is determined by the length of the Global Company Prefix.

- Individual item number:

  Up to five additional, freely selectable digits are appended to the Global Company Prefix. With a 7-digit Global Company Prefix, any five-figure combination of digits between "00000" and "99999" can be created. Thus a maximum of 100,000 different GTINs can be generated using such a Global Company Prefix.[2]

- Check digit:

  The 13th digit of the GTIN is a check digit. It is computed from the previous 12 digits modulo 10. Under no circumstances may the GLN check digit be used; a new check digit must be calculated for every GTIN.

[1] For reasons of simplicity, the following only makes reference to the manufacturer who is generally the brand owner of a product.

[2] Should even the 7-digit Global Company Prefix, i.e. the quota of 100,000 items, be insufficient, an additional GLN can be requested from GS1 Germany for a one-off fee.

3 National Trade Item Number (NTIN)

The National Trade Item Number (NTIN) corresponds to the product code stipulated in the delegated regulation 2016/161. The NTIN is formed from the current 8-digit PZN incorporated into the GTIN structure. GS1 Germany makes the 4-digit prefix 4150 available for this purpose.

Thus the NTIN for Germany has the following structure:

NTIN for pharmaceuticals in Germany		
GS1 Germany country prefix	8-digit PZN	Check digit*
4150	12345678	2

* The check digit is calculated modulo 10, as with the GTIN check digit.

Fig. 3-1: Structure of NTIN in Germany[3]

The empty segment of the number is populated by the IFA with the 8-digit PZN and is used solely for the purpose of identifying individual packs

If a 7-digit PZN is used, the first place after the prefix 4150 is padded with a 0, e.g. 4150 01234567 8.

Important:
The 13-digit NTIN (or GTIN) is padded with a leading 0 for encoding in the GS1 DataMatrix e. g. 04150012345678.

The NTIN offers pharmaceutical manufacturers the possibility of indirectly identifying their products via the PZN and using one of the recognised GS1 data carriers, namely the GS1 DataMatrix, at the same time.

	Code 39	Data Matrix Code			
	PZN	PPN/NTIN	SN	LOT	EXP
Medicinal product requiring verification	✓	✓	✓	✓	✓
Medicinal product not requiring verification	✓	✓	Not permitted	optional	optional

Fig. 3-2: Identification and labelling variants in Germany[4]

[3]The check digit is calculated modulo 10 as with the GTIN check digit.

[4]According to the fifth volume of the Social Security Code (SGB V), it continues to be obligatory to provide the PZN in the PZN code for the time being.

4 Structure of the individual identifier

The delegated regulation of the FMD from the 9th of February 2016 not only stipulates that medicinal products are uniquely identifiable using the product code, but that every single pharmaceutical pack is labelled with a serial number in addition. Moreover, the variable information batch number and expiry date must be encoded on every pack too. These four elements make up the individual identifier.

4.1 The GS1 application identifier concept

In order that the four stipulated data elements can be distinguished between and separated from each other, GS1 uses the GS1 application identifier concept. This allows several pieces of information to be encoded in a code and unambiguously read and interpreted by every business partner. It is based on an exact definition of the information to be encoded (e.g. product code, serial number, expiry date, batch number), the specification of their formats and the assignment of qualifying application identifiers (AI).

These identifiers indicate what type of information the following code contains and in what format it was encoded. They enable recipients of encoded data to select which information should be processed by the downstream applications and which should be ignored according to their requirements.

00	SSCC (Serial Shipping Container Code)
01	GTIN (Global Trade Item Number)
10	Lot / Batch
17	Expiry Date
21	Serial Number
7003	Expiry Date + Time
7004	Active Potency
8003	GRAI (Global Returnable Assets Identifier)
8004	GIAI (Global Individual Assets Identifier)

Fig. 4-1: Excerpt from the application identifier list (AI)

Important:
The 13-digit GTIN (or NTIN) is padded with a leading "0" in order to make it up to the stipulated 14 digits, e. g. 04150012345678.

The application identifier concept known from the GS1-128 barcode standard is used in the protected GS1 symbology GS1 DataMatrix. The combination of application identifier and protected symbology ensures that data encoded in the GS1 DataMatrix can not only be read, but unambiguously interpreted by every partner in the supply chain. This excludes the possibility of data conflicts caused by incorrectly scanned and processed data. The resultant data integrity plays an important role, especially when it comes to sensitive product segments such as in the healthcare industry.

4.2 Encoding of the GTIN/NTIN

Both the GTIN and NTIN are encoded in the GS1 DataMatrix with the application identifier "01". The 13-digit GTIN and NTIN are prefixed with a zero to pad them to the required length of 14 digits.

4.3 Encoding of the serial number

In addition to the product code, e.g. the NTIN, the delegated regulation stipulates that a serial number be generated for every single product pack. The serial number can be numeric or alphanumeric and up to 20 characters in length. It should be noted that the serial number must be generated by a deterministic or non-deterministic randomisation algorithm. The serial numbers generated in this way are encoded in the GS1 DataMatrix with the application identifier 21.
As the serial number is variable in length with a maximum of 20 places, followed by additional information such as the expiry date or batch number, a separator must be included in order to separate the data. The separator that is used by GS1 is the so-called FNC1 character. The next piece of information can only come after it. The FNC1 character ensures that the encoded data is processed reliably and without misinterpretation.

4.4 Encoding of the expiry date

It is also stipulated that the expiry date be encoded on the medicinal product packaging. It is signalled by the application identifier "17" and represented in the format YYMMDD (e.g. 200405 for the 5th of April 2020). Where no day is specified, the places reserved for the day must be padded with zeros. The expiry date is a data element of fixed length, so it is not necessary for the FNC1 character to be used as a separator.

4.5 Encoding of the batch number

The batch number is a number generated by the manufacturer and is generally assigned on a production-related basis. It is encoded in the GS1 DataMatrix using the application identifier "10". It should be noted that the batch number is a field with a variable length of up to 20 alphanumeric places. In order to indicate clearly when this information comes to an end and the next data element begins, the FNC1 character must be used as a separator following the information if more data is to come after.

Thus the data contained in the individual identifier is assembled as follows:

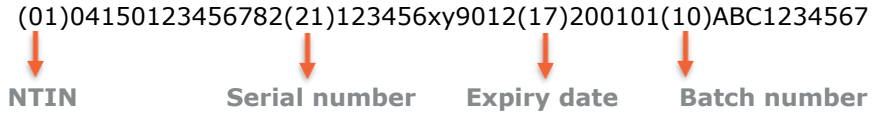


Fig. 4-2 Structure of the individual identifier

It should be noted that the separator FNC1 is inserted after the serial number as described above.

5 Data carrier of the individual identifier: Data Matrix and GS1 DataMatrix

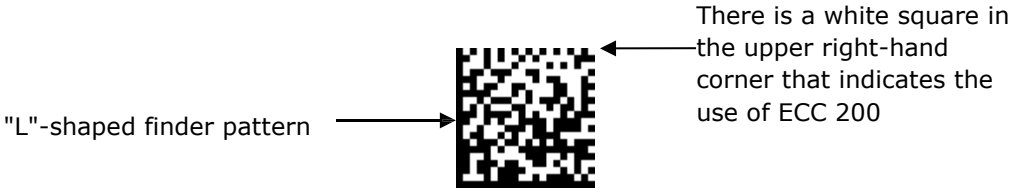
The delegated regulation stipulates that the individual identifier is to be applied to the medicinal product pack using the data matrix symbology. The data matrix is a two-dimensional matrix symbology that was developed back in the mid-1990s. Since the adoption of the ISO standard 16022, the protected subset GS1 DataMatrix, which also meets the legal requirements, has been available for GS1 applications.

The advantage of the GS1 DataMatrix compared to the conventional data matrix is that it is the only one that offers GS1's customary symbology protection. This is achieved in a similar way to the GS1-128 barcode in that function code one (FNC1) is encoded as the first character of the GS1 DataMatrix. This means that the user enjoys the same interpretation and processing reliability that all other GS1 symbologies offer.

As mentioned at the outset, the GS1 DataMatrix is a 2D symbology that allows a large amount of information to be encoded in a very small space. As a general rule, however, it should be used to encode as much information as absolutely necessary and as little as possible. The GS1 DataMatrix is read using 2D scanning devices. These make use of modern image processing technologies, which is why they are also referred to as image scanners. The advantage of 2D scanners is that they can read both linear and 2D codes making them all-purpose devices. The data contained in the GS1 DataMatrix is encrypted as described above in accordance with the GS1 application identifier concept. As a result of the legal requirement for individual identifiers, pharmacies are now obliged to invest in compatible 2D scanning equipment and upgrade their POS systems.

5.1 Technical attributes of the (GS1) data matrix

A (GS1) data matrix code has the following characteristic structure:



- The "L"-shaped finder pattern of the (GS1) data matrix helps the scanner locate the code. On the opposite side of the finder pattern is the timing pattern, which is composed of alternating light and dark cells. The area bordered by the finder pattern and timing cells is the data matrix in which the information is stored in the form of computed code words.

- The (GS1) data matrix must be surrounded on all sides by a quiet zone that is at least one module[5] wide. As with all barcode quiet zones, this zone must not be printed on.

[5]A cell of a certain height and width is referred to as a module.

- In the case of square (GS1) data matrix symbols, there are the same number of rows and columns. The smallest symbol size is 10 rows by 10 columns (10 x 10) and the largest 144 rows by 144 columns (144 x 144) depending on the information being encoded. A code up to 26 rows by 26 columns (26 x 26) in size is composed of a single square. If more characters need to be encoded, the amount of space required quadruples. For this reason, sizes exceeding 26 x 26 should be avoided (see also chapter 4.1.5). The smallest unit of a (GS1) data matrix code is a module (a cell within the code). A module is 1X by 1X in size, where X is the height and width of a cell.

- The (GS1) data matrix uses an error correction algorithm called Reed-Solomon. This makes it possible to reconstruct a certain amount of information that is unreadable during scanning (e.g. due to dirt).

- The FNC1 character in position one of the GS1 DataMatrix signals data that is encoded according to the GS1 application identifier standard, thereby ensuring compatibility with the GS1 system. It corresponds to the code word value[6] 232. The FNC1 character with this code word value is also used as a separator.

- The following character sets can always be used for encoding data:

    - Values 0 -127 as per ISO/IEC 646, i.e. all 128 ASCII characters.

    - Values 128 - 255 as per ISO/IEC 8859-1 (extended ASCII character set).

    The GS1 system only requires one subset from ISO/IEC 646 to encode the data elements of the application identifier standard (the special characters with the decimal ASCII values 35 (#), 36 ($), 64 (@), 91 ([), 92 (\), 93 (]), 94 (^), 96 (`), 123 ({), 124 (|), 125 (}), 126 (~) and 127 (¦) and all control characters (ASCII values 00-31 are excluded)).

- The maximum possible amount of data, i.e. the maximum encodable number of characters, corresponds to:

    - alphanumeric data: up to 2335 characters

    - numeric data: 3116 digits

- The data matrix symbol can be represented in inverted form, i.e. using dark modules on a light background or light modules on a dark background.

- Rectangular symbol: Six symbol formats are defined for rectangular versions (see also chapter 5.3). In contrast to the SecurPharm Coding Guidelines, the GS1 DataMatrix only allows the use of these six rectangular formats, as none of the other formats are standardised internationally and can only be used on the German market.

[6] Data is encoded in the (GS1) data matrix in the form of so-called code words.

5.2 Symbol structure

A (GS1) data matrix symbol consists of at least one matrix with cells that are fixed (finder and timing pattern) and cells that are variable (data content).

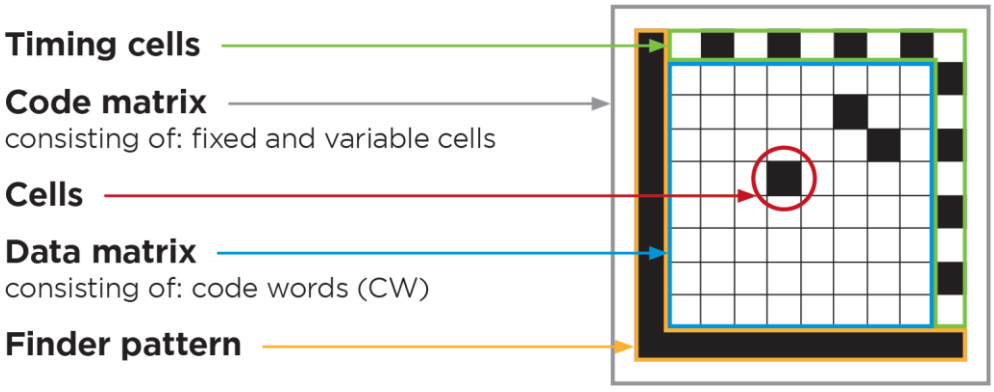


Fig. 5-1: Basic concepts of the (GS1) data matrix

5.3 Square and rectangular formats

There are both square and rectangular formats of the (GS1) data matrix that can be used. The square format is typically used as it offers a greater number of sizes and can encode a larger amount of data. The largest rectangular symbol can encode 98 digits, whereas the largest square format can encode 3116 digits.

Fig. 5-2: Rectangular and square (GS1) data matrix symbol. Both symbols contain the same data.

5.4 Symbol sizes

The (GS1) data matrix symbology must be represented in different sizes depending on the amount of data to be encoded. There are 24 different square (GS1) data matrix symbol formats, from 10 x 10 modules to 144 x 144 modules in size (excluding the 1X quiet zone). There are six different rectangular formats, from 8 x 18 modules to 16 x 48 modules in size (excluding the 1X quiet zone).

Square geometry:
- 24 matrix sizes
- from 10 x 10 to 144 x 144 cells*


1 quadrant: up to 26 x 26
4 quadrants: up to 52 x 52
16 quadrants: up to 104 x 104
36 quadrants: up to 144 x 144

Rectangular geometry:
- 6 matrix sizes
- from 8 x 18 to 16 x 48 cells*

1 rectangle: up to 16 x 48

* Excluding quiet zone

Fig. 5-3: ECC 200 data matrix – code sizes

The two tables below show a selection of possible matrix sizes and their respective data capacities.

a) Attributes of square symbols (excerpt)

Symbol size[7]		Data region		Represent	Total		Reed-Solomon		Linked blocks	Data capacity			Error	Max. correctio
					Code words		Block							Code word
Row	Column	Size	No.	Matrix size	Data	Error	Data	Error		Num. cap.	Alphan. cap.	Byte cap.	Corr. overhead %	Error/ deletion
10	10	8x8	1	8x8	3	5	3	5	1	6	3	1	62.5	2/0
12	12	10x10	1	10x10	5	7	5	7	1	10	6	3	58.3	3/0
14	14	12x12	1	12x12	8	10	8	10	1	16	10	6	55.6	5/7
16	16	14x14	1	14x14	12	12	12	12	1	24	16	10	50	6/9
18	18	16x16	1	16x16	18	14	18	14	1	36	25	16	43.8	7/11
20	20	18x18	1	18x18	22	18	22	18	1	44	31	20	45	9/15
22	22	20x20	1	20x20	30	20	30	20	1	60	43	28	40	10/17
24	24	22x22	1	22x22	36	24	36	24	1	72	52	34	40	12/21
26	26	24x24	1	24x24	44	28	44	28	1	88	64	42	38.9	14/25

[7] The size of the symbols is specified without counting the quiet zone.

Attributes of rectangular symbols (excerpt)

Symbol size[8]		Data region		Repr esent	Total		Reed-Solomon		Linked blocks	Data capacity			Error	Max. correction
					Code word		Block						Corr.	Code word
Row	Column	Size	No.	Matrix size	Data	Error	Data	Error		Num. cap.	Alphan. cap.	Byte cap.	overhead %	Error/ deletion
8	18	6x16	1	6x16	5	7	5	7	1	10	6	3	58.3	3/+
8	32	6x14	2	6x28	10	11	10	11	1	20	13	8	52.4	5/+
12	26	10x24	1	10x24	16	14	16	14	1	32	22	14	46.7	7/11
12	36	10x16	2	10x32	22	18	22	18	1	44	31	20	45.0	9/15
16	36	14x16	2	14x32	32	24	32	24	1	64	46	30	42.9	12/21
16	48	14x22	2	14x44	49	28	49	28	1	98	72	47	36.4	14/25

5.5 Dimensions/module width and height (X)

The value X specifies both the height and width of a module. This value must remain constant for the entire symbol. The module width and height (X) is defined in the application guidelines of GS1. For applications in the medical retail and pharmacy sector, the nominal size of the X module is 0.495 mm with a minimum size of 0.396 mm and a maximum size of 0.990 mm.

5.6 Human-readable format

The delegated regulation stipulates that the individual identifier, i.e. product code, expiry date, batch and serial number, must be printed on the pack in a human-readable format. This ensures that even in the event a code is unreadable, there is a back-up of all of the information it contains that can be entered manually.

The plain-text information should be located next to the code containing the individual identifier as per the delegated regulation.

If the space available on the packaging is insufficient to contain the human-readable information, it may be omitted. This applies where the sum of the two longest dimensions of the packaging is 10 cm or less.

[8] The size of the symbols is specified excluding the quiet zone.

6 Print quality and quality control

The quality of the symbol and/or printing is very important and it is imperative that it is included in the quality control routines associated with the production process because the delegated regulation makes stipulations in this regard too. These correspond to the international standard ISO/IEC 15415 on the print quality of 2D symbols.

The standard defines the following quality parameters as test criteria:

- Contrast between light and dark elements
- Difference in reflectance between light and dark elements (modulation)
- Axial non-uniformity
- Grid non-uniformity
- Unused error correction
- Fixed pattern damage
- Ability of the reference decoding algorithm to decode the (GS1) data matrix code.

According to the delegated regulation and according to the GS1 specifications also, the printed code must score at least 1.5 according to ISO/IEC 15415.

7 The EU Falsified Medicines Directive: Implementation in Europe

Falsified medicinal products are still a sad fact of life and the figures remain alarmingly high: according to the Pharmaceutical Security Institute, 123 countries are affected. The World Health Organisation (WHO) estimates that 15 percent of all medicines in circulation may be falsified. Around a third of all malaria deaths throughout the world may be attributable to falsified medicines. These are just a few snapshots of a shocking overall picture. The legislature is being mobilised, regulations being enacted and the market is being prompted to take action. The Falsified Medicines Directive EU 2016/161 is one of them. It stipulates a variety of measures intended to protect patients from falsified medicinal products.

7.1 Necessity for a uniform global approach with national numbering systems

Bearing in mind the European goal, namely creating a compatible system to protect against falsified pharmaceuticals within the EU Member States, the following becomes apparent: It would be desirable to have a single code on the product packaging that all those involved in the supply chain could work with - irrespective of the country in which the pack is being sold and through which distribution channel.

GS1's global standards mean it is in a position to provide the functionality needed to devise packaging for more than one country, i.e. which uses the same code across international borders. This has been possible in the global retail sector for decades thanks to GS1.

7.2 Identification using GTIN

In order to make the complexity of medicinal product identification in Europe comprehensible, it is first assumed that all of the processes in a given country (logistics, reimbursements etc.) are executed based on the GTIN and the packet is only sold in this country. Consequently, encoding the GTIN (plus other supplementary information) in a GS1 DataMatrix is a perfectly adequate approach. The situation is different if the pack is not just offered for sale in one country, but in several different ones (so-called multi-country or multi-market packs). If the GTIN is used in these countries as well, this does not present a problem (provided that all regulatory and legal requirements are fulfilled). I.e. in these countries the same pack with the same GTIN is scanned and processed (scenario 1a, see fig. 7-1). Some countries, however, have (due to the legal situation and for historical reasons) their own national numbering systems that are used for the purpose of reimbursing costs (National Healthcare Reimbursement Number, NHRN). It is in principle possible to grant access/link to these numbers via the GTIN so that the GTIN can (continue) to be used (scenario 1b, see fig. 7-1).

Fig. 7-1: Pack identification solely using GTIN

7.3 Identification using GTIN and NHRN (National Healthcare Reimbursement Number)

If, however, it is necessary to have both the national number (NHRN, which is the PZN in Germany) included in the code on the pack in addition to the GTIN, this can be achieved using the appropriate GS1 application identifiers. This could be done for the German market using the application identifier 710 for the PZN (scenario 2, see fig. 7-2).

Fig. 7-2: Pack identification using GTIN and NHRN

The important thing is that the NHRN is always encoded in conjunction with the GTIN. Only then it is possible for the packs to be supplied to countries that use the GTIN. These countries scan the GS1 DataMatrix, process the GTIN and ignore the NHRN.

It is in principle possible to encode several NHRN numbers for a single GTIN in a GS1 DataMatrix symbol (scenario 3, see fig. 7-3).

Fig. 7-3: Pack identification using GTIN and several NHRNs

There are currently four application identifiers for encoding national pharmaceutical registration numbers. Besides the German PZN, these include the respective numbers for France, Spain and Brazil.

Application Identifier	National Healthcare Reimbursement Number			Organisation
710	X_1	variable Länge	X_{20}	Deutschland IFA
711	X_1	variable Länge	X_{20}	Frankreich CIP
712	X_1	variable Länge	X_{20}	Spanien National Code
713	X_1	variable Länge	X_{20}	Brasilien ANVISA
nnn (*)	X_1	variable Länge	X_{20}	Land "A" NHRN Behörde
(*) Dies ist ein Beispiel zur Illustration von zukünftigen weiteren NHRNs. Falls ein weiterer NHRN AI erforderlich wird, MUSS ein entsprechender Antrag im GS1 GSMP gestellt werden				

Fig. 7-4: Application identifiers for national pharmaceutical registration numbers (NHRN)

Although the possibility of encoding several national NHRNs for a single GTIN exists, technical limitations due to the resultant increase in data volume and the impact on process efficiency should be considered.

In Germany, it will be possible in future to encode the GTIN together with the German NHRN, i.e. the PZN, for so-called multi-market packs. This will allow companies to realise at least to some extent the rationalisation potential offered by a standardised identification system.

7.4 Identification using NTIN

In some countries, such as Germany, the national systems are embedded in the structure of the GTIN. Because this number is no longer a globally valid GTIN but rather a number that only has national applicability, this numbering system is referred to as a National Trade Item Number (NTIN).

Because it comes from the GS1 number pool and is non-overlapping, the NTIN can be used in every market, however. It only fulfils its intended purpose in the country whose national number it integrates, though (scenario 4, see fig. 7-5).

Fig. 7-5: Identification using NTIN

Because the national numbers and all of the rules pertaining to them, such as the assignment rules, originate from a GS1-external organisation, GS1 is unable to guarantee full global interoperability with all supply chain systems. An NTIN-based solution should only be considered when all other alternatives (GTIN or GTIN with NHRN) have been assessed and concluded to be unfeasible.

Important:
An NTIN may not be combined with an NTIN of another country!
A NTIN may not be combined with an NHRN!

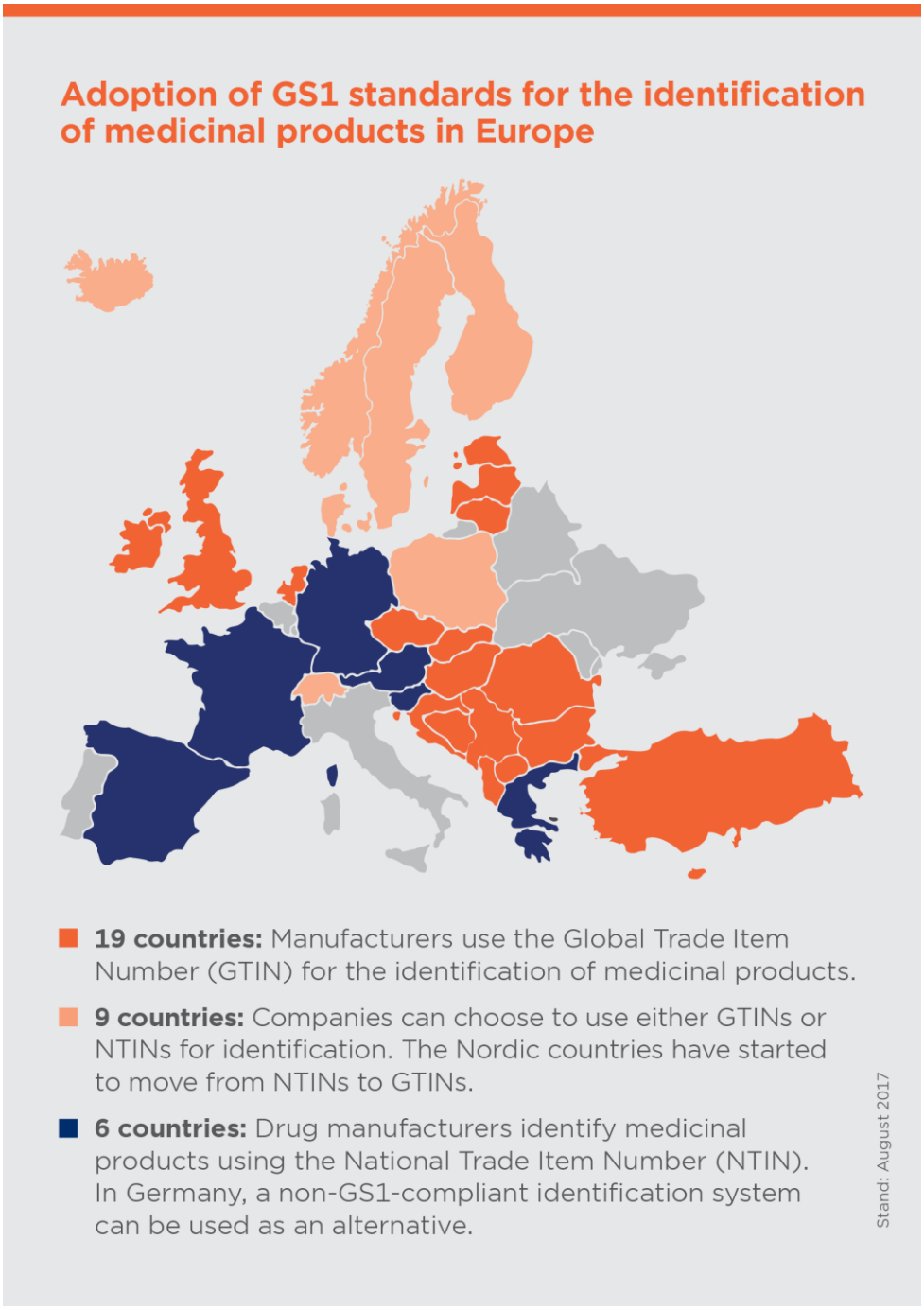
The following overview provides a summary of the described encoding rules:

Fields in GS1 DataMatrix			Market types which can take this pack		
Primary key	Other fields				
(01) Containing a GTIN			GTIN countries		
(01) Containing a GTIN	NHRN 1		GTIN countries	NHRN 1 country	
(01) Containing a GTIN	NHRN 1	NHRN n	GTIN countries	NHRN 1 country	NHRN n country
(01) Containing an NTIN			NTIN country		
(01) Containing an NTIN			GTIN countries	NTIN country	

Fig. 7-6: Possible combinations for multi-country packs

7.5 Current status of encoding in the European Union

The following diagram shows the current situation regarding the encoding of pharmaceutical packaging in Europe:



Germany, France, Slovenia, Greece, Austria and Spain currently use their own national numbering systems. The Nordic countries, on the other hand, are switching from the NTIN to the GTIN. The legislator in Slovenia, Bulgaria and Croatia has similarly decided to switch over to using the GTIN by 2019 in the course of implementing the FMD.

7.6 Recommendations

In the absence of a common approach, dealing with the identification and labelling of medicinal products that are offered for sale worldwide can prove costly and time-consuming.

It is for this reason that many pharmaceutical manufacturers use GS1 standards in order to establish a common foundation for product identification and traceability. Pharmaceutical manufacturers can operate more efficiently, lower costs, reduce errors and ultimately save time when it comes to meeting prescribed deadlines.

Even the service providers involved in retooling the various production lines at the manufacturing facilities and implementing the extensive data management systems appreciate the benefits of an international standard. Standardised operating procedures, common platforms and the GS1 standards play their part in simplifying process workflows and successfully completing retooling projects.

The biggest advantage comes from having a common language that forms the basis for a common system and facilitates interoperability between companies, industries and even countries.

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