European Medicines Verification System (EMVS)

European Pack Coding Guidelines

Version 4.0
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efpia
European Federation of Pharmaceutical Industries and Associations

E A E P C
European Association of Euro-Pharmaceutical Companies

medicines for europe
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Revision History

V1.0 June 2008	Initial Release
V1.1 June 2008	Amended some typographical errors, added extra detail to the serial number constraints and added information regarding the randomisation requirements.
V1.2 Aug 2008	Removed the background and abstract sections. Removed the SSCC section (potentially applicable later in the project) and amended the serial number constraints. Added section to define the human readable text requirements.
V1.3 Sept 2008	Removed a small amount of duplication. Cross referenced the code size section to the GS1 specifications. Clarified the human readable text size requirements. Corrected a small number of typos. Awaiting incorporation of further clarification on the randomisation.
V1.4 Dec 2008	Provided information regarding the serial number randomisation criteria.
V1.5 Dec 2008	Amended the serial number criteria. Amended the human readable text specification and scope. Amended the pack code size criteria.
V1.6 Jan 2009	Removed obsolete text from section 1. Removed paragraph from Product code section referencing the use of the package level indicator initial setting. Included some suggested clarifications from GS1. Added definition for alphanumeric character range, comments about permissible code quality standards. Amended randomisation section. Removed the requirement for the batch/lot code to be placed at the end of the data set (due to the use of ASCII encoding)
V1.7 Jan 2009	Amended text in section 1 regarding the minimum human readable content, randomisation section definition of data retention period. Added clarification regarding the human readable text requirements. Replaced the AI references for Expiry and Lot mistakenly deleted from V1.6. Defined the use of, and value of, the package level indicator digit in the GTIN/pseudo GTIN. Added the reference to the GS character within the lot code definition. Amended both GS character usage statements to ensure that GS is not appended to the end of the code after the final field. Removed picture from the front page.
V2.0 Feb 2009	First official general release.
V2.1 May 2009	Added footnote to define a Pseudo GTIN to aide clarity.
V3.0 April 2011	Added section to define the additional element for national reimbursement number inclusion
V3.1 Jan 2013	Added a) new GS1 NTIN rules; b) reference to other schemas such as PPN; c) suggestions regarding placement of codes
V3.2 Jan 2013	Internal review
V3.3 Feb 2013	Added example of SN, minor changes throughout
V3.4 March 2013	Minor changes
V3.5 April 2013	Minor changes, WS-3 Approved
V3.6 June 2013	Wording on randomisation requirements in sec. 2.2 updated to provide additional clarity
V3.7 August 2015	Wording revised to remove all but the technical detail. Randomisation wording clarified. Serial number character set recommendation revised the text. Revised the code quality level to be in-line with expected Delegated Regulation requirements.
V3.8 April 2016	Amended serial/batch number character set slightly, added multi-market section.
V3.9 March 2017	Added amends from Medicines for Europe, corrected and update the NHRN content, de-branded from EFPIA to become a joint industry publication.
V3.91 June 2017	Added amends from EFPIA (Bayer)
V4.0 July 2017	Added further amends to section 2.3 and 2.9 from MfE and released.

Table of Contents

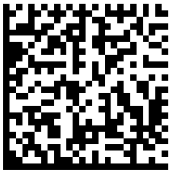
1. The European Medicinal Pack Coding Specification

1.1 Recommendation of GS1 Standard / 2D Data Matrix

In February 2006, the EFPIA board recommended the adoption of a unique standard for the coding of pharmaceutical product across Europe based on the Data Matrix ECC-200 to be introduced on all secondary packaging of prescription products sold in Europe.

The pack/item code will be accompanied by human readable text. The human readable text will be in a font and size that are in accordance with country specific requirements or GS1 recommendations depending on local requirement.

As new members joined the EMVO alliance, EAEPC and Medicines for Europe have helped to make this document a common industry guideline.



Data Matrix ECC-200

1.2 Accommodation of National Numbers

National numbers may be required within the code in specific situations. The GS1 General Specifications have been extended to accommodate the inclusion of national product identifiers[1]. This capability is provided by the use of NHRN (National Health Reimbursement Numbers) which can be added to the data content of the code using the appropriate Application Identifiers (AI's). This is described below in section *2.5.*

Alternatively, in some countries, GS1 has allocated a range of GTIN's (Global Trade Item Numbers) specifically for use with that country. These are collectively referred to as NTIN's (National Trade Item Numbers).

[1] See "EFPIA & GS1: a shared vision for product identification in the context of the EU Directive on Falsified Medicines", issued January 2012

2. Content of the 2D Code

The recommendation for coding of pharmaceutical products is to encode in a Data Matrix code a minimum of four items of data. The preferred code structure would utilise the GS1 standards and in particular would make use of the AI's already in use throughout the supply chain today. The preferred structure uses only four of the many AIs available to define

1. the product code,
2. the serial number,
3. the expiry date and
4. the lot number (batch code).

Some markets may require the addition of a national number to the code. This is described in section 2.5.

2.1 The Product Code

The preferred (by manufacturers) implementation for the product Code is to use the GS1 GTIN (Global Trade Item Number) however the European Hub and thus EMVS supports both GTIN/NTIN and PPN coding schemes.

The four critical aspects for the GTIN element are:

1) It must be preceded by the application identifier 01.
2) It must have a code length of 14 digits
3) It must use a GS1 standard checksum in the 14th digit
4) It must adhere to the GS1 use for the first digit:
    a. For a sales unit a 0 is required.
    b. For identification of higher package levels the range is 1-8. (the value 9 has a special defined meaning – ref GS1 specifications.)

Where the GTIN is held by the organisation as a GTIN-13, to use this value in the 2D code it must first be converted to a GTIN-14. This can be achieved by simply prefixing the GTIN-13 value with a zero '0'. This addition does not affect the value of the check-digit, any other value of prefix would require the re-calculation of the check digit.

Note: Special Consideration NTIN (National Trade Item Number):

The GTIN number pool allows for the inclusion of national coding schemes (for example the CIP-13 code in France, the post 2009 PZN in Austria, the Nordic Vnr or the extended German PZN.) These codes are generally referred to as NTINs (National Trade Item Numbers). Under special agreements with GS1, NTINs do not start with the company prefix but with a GS1-approved country-specific prefix followed by the national license or registration code, i.e. NTIN codes are not determined by the MAH but instead assigned by a Number Issuer, Industry body etc.

The NTIN differs to the national identifier NHRN described below in section *2.5,* The National Healthcare Reimbursement Number (NHRN), in that NTINs are taken from the GTIN number pool and their global uniqueness is therefore guaranteed. They formally present as a GTIN and can generally be used as a GTIN[2].

[2] There are only some areas where the use of an NTIN instead of a pure GS1-GTIN requires special consideration: Similarly, deriving GTINs for higher pack levels using the indicator digit is problematic: In the case of a GTIN, this can be derived by the pharma company who owns the company prefix but in the case of NTINs, companies do NOT own the prefix and would therefore be modifying a GTIN/NTIN that is not theirs to modify.

Examples of NTINs in use in Europe and formation rules:

Market	NTIN formation rules
Austria	908888 + PZN + check digit
France	3400 + CIP/ACL Code + check digit
Germany	4150 + 8-digit PZN + check digit
Spain	847000 + Codigo Nacional
Sweden, Finland, Denmark, Iceland, Norway	704626 + Nordic Drug Code issued by Nordic Number office + check digit
Switzerland	7680 + Code assigned by Swissmedic (consists of 5 digits Product License number + 3 digits Pack Size indicator) + check digit

2.2 The Serial Number

The serial number is preceded by the AI 21 and adheres to the GS1 specification where this field is a variable length (up to 20) alphanumeric field followed by a Group Separator (GS) character (to delimit it from the next field unless it is the last field).

It is recommended that three further modifications should be considered to aide consumer readability:

- The alphanumeric range shall include the digits 0-9 and the letters of the western alphabet but exclusion of the following letters: i, j, l, o, q and u. (I J L O Q U) might help avoid confusion with similarly shaped characters/numerics.
- The serial number character string should only contain either lower case or upper case letters, not a mixture.
- Use of the extended symbols, as defined by the complete GS1 specification and documented below, should ideally be avoided.

The serial number will be unique per product code (i.e. not per batch or per product code-batch code pair).

If these recommendations are fully adopted, this gives a range of 30 different alphanumeric character options, 50 combinations if only the letter confusion aspects is adopted. 62 combinations if the case limitation is ignored and 82 combinations if the full GS1 specification is utilised. All of these options provide an essentially limitless provision of serial numbers per product SKU

Using the GS1 specification (which is the industry norm and also represents the most mature standard available in the supply chain today), the permissible characters include the digit value 0 to 9 inclusive. Letters A to Z inclusive in both upper and lower case and the non-numeric, non-letter based extended characters:
/.,-+*)(‘&%”!:;<?=>_

Thus the GS1 scheme permits 82 character combinations. The full GS1 supported character set is documented in the GS1 Standard Specifications section 7.11 figure 7/11-1.
http://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf

2.2.1 Randomisation

In order to provide a reasonable level of complexity within the serial number, the probability that a valid serial number can be guessed should be less than 1 in 10,000 (i.e. < 0.0001). The rationale being that a potential counterfeiter would have to make and distribute 10,000 uniquely coded packs and only have one of those packs get through the system as valid.

Also, in order to minimise the opportunity for a counterfeiter to estimate the randomisation pattern from two or more samples, the following randomisation rules or equivalent apply:

Given a sufficiently large set of (randomised) serial numbers for a product, the randomisation substrings of the serial numbers[3] have to fulfil the following randomisation criteria:

1. The randomisation substrings must be equally distributed. e.g. the serial number substring should not contain fixed blocks of fixed digits.
2. Any randomisation substring must be independent of other substrings.
3. The randomisation substrings must not be built using an algorithm that is easy to find out when knowing the given set of serials or a subset thereof.

Serial IDs shall not be reused within the longer of a) Exp Date +1 year or b) five years.

Examples that do not fulfil the randomisation rules:

Sequence	Sorted ascending	Comment
1,090,580 2,076,648 351,029 2,323,165 1,337,097 597,546 3,062,716 3,309,233 2,816,199 1,583,614 844,063 104,512 2,569,682 1,830,131	104,512 351,029 597,546 844,063 1,090,580 1,337,097 1,583,614 1,830,131 2,076,648 2,323,165 2,569,682 2,816,199 3,062,716 3,309,233	Not random: generated using incremental value of 246,517
023010724 423000710 723020723 623030711 723000779 823030764 523090785 023050702 623050782	023010724 023050702 423000710 523090785 623030711 623050782 723000779 723020723 823030764	Poor randomness: fixed substrings „230“ and „07“

[3] Manufacturers might want to compose the serial numbers e.g. of a header substring with fixed contents (e.g. determining the production site) followed by a substring with variable contents containing the randomisation part of the serial id.

2.3 The Expiry Date

This field will conform to GS1 standards and is preceded with the AI 17. It is a fixed 6-digit field with the digits representing YYMMDD. Organisations more used to a four-digit year code will be required to truncate the code to the two least significant digits. This field being of fixed length does not require to be followed by a GS character and in the interests of minimum printed code size should not be followed by a GS. It is required to enter '00' for the day when the day code is not specified/used and only a year and month identifier is used – e.g. YYMM00 (ref GS1 specifications section 3.6.11) and setting the day code to 00 implies the last day of the specified month.

Examples:

"171215" = 15 Dec 2017
"171200" = Dec 2017.

2.4 The Lot Number (Batch Code)

The lot number (batch code) conforms to GS1 standards and is preceded with the AI of 10 and is a variable length field of up to 20 alphanumeric digits followed by a Group Separator (GS) character (to delimit it from the next field unless it is the last field). It is recommended that the range of characters defined for the GS1 specification (see section 2.2) is permitted within the batch code as is already common industry practice, however where possible we recommend to reduce the characters used according to the same guidelines described above in section 2.2 for the serial numbers.

2.5 The National Healthcare Reimbursement Number (NHRN)

The updated GS1 General Specifications now makes provision for national numbers to be accommodated within the GS1 standards. When a national number is held in this format in accordance with GS1 standards, it will be called an NHRN (National Healthcare Reimbursement Number).

It is not the intention for the NHRN to replace the GTIN, rather to allow national numbers to be held and stored within systems and data carriers in a GS1 compliant way. This will allow, for example, a GTIN and national number to be held in the same Data Matrix code so that both can be captured with a single scan. In this way any stakeholder wishing to obtain the national number for a product will be able to derive it based on the NHRN field.

The following Application Identifiers have so far been defined[4] (note that the NHRN part is defined and controlled by the associated regulatory body or assigning organisation indicated below):

Application Identifier	National Healthcare Reimbursement Number	Organisation
710	X_1 variable length X_{20}	Germany (IFA)
711		
712		
713	X_1 variable length X_{20}	Brazil (Anvisa)

Additional NHRN AI's can be requested through the GS1 GSMP.

The NHRN is usually assigned by a national authority to healthcare brand owners for specific trade items and shall only be used for compliance to regulatory requirements where the GTIN alone in a bar code symbol will not meet the requirements. Use of NHRN on the item is controlled by and subject to the rules and regulations of national/regional agencies.

[4] ref GS1 General Specifications Release 17.0.1 Jan 2017 Figure 3.8.17-2

When a regionally specific NHRN AI is approved (as above), the overall variable length (i.e. allowable number of characters) is specified by the national authority, with a twenty (20) alpha-numeric characters maximum as noted in the general format above.

Where the NHRN is required, the data set will need to include more than four elements;

1. The GTIN (which will be provided by the manufacturing organisation)
2. The Expiry Date
3. The Lot Number
4. The Serial ID and
5. The NHRN.

In fact, it is possible to associate more than one NHRN with a given GTIN, dependent upon regional and market needs, though in practical terms (size of code and associated issues around printing and placement of larger Data Matrix codes) manufacturers will probably try to avoid this.

3. Pack Code Attributes

3.1 Multi-Market Packs

Multi-market packs are those that can be supplied by the original manufacturer (or re-packer) in an unaltered form to more than a single market. The simplest way to achieve a common pack is where each market of intended sale is able to use the product code as the identifier for the product. This is where a globally accepted coding scheme such as the GS1 GTIN provides great benefit. In this ideal scenario, each pack will be provided with a Data Matrix code containing the four basic data elements only. In addition, the EMVS system allows the product code (GTIN) and local reimbursement number to be linked at database level further enhancing the advantages of a four element, GTIN only based code.

GS1 have published a very detailed guidance document covering multi-market packs entitled “Recommendations on a harmonised implementation of the EU Falsified Medicines Directive using GS1 standards”

There will be circumstances where local market conditions require that the local reimbursement number is included within the code.

As an example, a two market pack is supplied where one market is able to utilise the GTIN directly and the other requires that a local reimbursement number is provided within the code. If we take the market requiring the local reimbursement number in this example as Germany, the Data Matrix code might contain (using the GS1 scheme):

Data Element Description	Application Identifier	Example Data
Product Code	01	05060141900015
Expiry Date	17	190200
Batch Number/Lot Code	10	ABC123992
Serial Number	21	28574abczz3456
NHRN	710	45678912

The data encoded into the Data Matrix code for this example would be:

0105060141900015171902001 0ABC123992<GS>2128574abczz3456<GS>71045678912

The local reimbursement number, PZN in this example, is shown as the last element in the code following the AI (Application Identifier) 710.

The <GS> is a symbolic representation for the ASCII Group Separator character (ASCII value 29).

3.2 Pack Code Size

The use of either rectangular codes or square codes is left to manufacturer preference and the limitations of the printing technology available

The GS1 numbering specification for very small healthcare items specifies the dimensions shown in the table adjacent. It is recommended that these targets are also employed on larger healthcare items such as folding boxes and bottles.

Symbol(s) Specified	X-Dimension mm (inches)		
	Minimum	Target	Maximum
Data Matrix	0.255 (0.01005 in.)	0.3 (0.012 in.)	0.615 (0.024 in.)

Note: Small module sizes should be avoided where possible to increase the readability of the code and avoid the need to use specialised code marking equipment.

The pack code may be printed in either normal orientation or inverse to allow for coding techniques such as laser ablation.

3.3 Pack Code Quality

The quality of the Data Matrix code printing applied to the pack should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011, and printed using ECC200 error correction and will utilise ASCII encoding according to ISO 16022. The use of ASCII encoding is to ensure maximal interoperability with code reading devices likely to be used in the field.

3.4 Human Readable Representation

The requirement is that the fields of product code, expiry date, lot number (batch code) and serial number shall be shown on the pack in human readable format.

If a national Code (national reimbursement number/NHRN) is also included, the human readable representation of that value shall also appear on the pack.

Where the dimensions of the pack allow, the human readable elements shall be adjacent to the Data Matrix code.

In the event that the sum of the two longest dimensions of the pack are equal to, or less than 10 centimetres, the human readable fields do not have to be applied.

In most cases, country specific requirements will prevail both in terms of character size and format e.g. DD/MM/YYYY for expiry date etc.

Each field printed on the pack should be preferably prefixed according to the following guideline:

Field Name	Preferred Prefix
Product Code	PC:
Expiry Date	EXP
Batch Number/Lot Code	Lot
Serial Number	SN:
NHRN	NN:

3.5 Code Placement

Learning from the EFPIA Sweden Pilot and from manufacturers who are already serialising packs is that where to place the code on the pack is an important consideration:

Experience has shown that printing high-quality codes is one of the decisive elements between successful implementation and failure. In addition to selecting the most appropriate printing technology this requires manufacturers to ensure that the pack carton is suitable, i.e. that the appropriate substrate is selected, that varnish-free areas are available, and that there is enough free space on the artwork (including possible interaction with the chosen tamper-evident technology).

Establishing good control over the packs as they are presented to the printer is a key measure in achieving high and consistent print quality and enables successful operation of the vision systems.

Also consider the implications of placing the Data Matrix in relation to other barcodes, as the Sweden Pilot has shown that carrying codes in close proximity will lead to read errors.