Whitepaper - Medicine Verification in France

THE CIP VIP 2400 CODE DEBATE

France has interim arrangements in place to manage the unique identification of medicinal products subject to verification for the purposes of the Falsified Medicines Directive (FMD). It currently uses GS1-compliant national numbers. A long-term approach is needed, and the current arrangements are under review. The **Club Inter Pharmaceutique**[1] (CIP) has published a proposal that, if adopted, will move France away from using GS1 standards.

This document provides an independent assessment of the CIP guidelines. **Solidsoft Reply**[2] recommends that France adopts GS1 standards for medicine verification. This document explains our thinking and reasons. We recommend that France should remain aligned to GS1 standards. If, however, France decides to move away from GS1 alignment, the current CIP proposal will require some amendments to bring them into line with global standards and EU law. They also exhibit some additional shortcomings.

The decisions made in France will only affect Solidsoft Reply indirectly. Solidsoft Reply does not possess the contract to provide the French National System[3] and has no association with the French MoH, ANSM, CIP or GS1 France. We did not consult GS1 in the creation of this document.

[1] See https://www.cipmedicament.org/
[2] See https://www.reply.com/solidsoft-reply/en/
[3] See https://www.france-mvo.fr/

BACKGROUND

CIP is a not-for-profit stakeholder association in France that promotes interoperability across the French pharmaceutical supply chain. It plays a key role in enabling national traceability of medicinal products in collaboration with regulatory authorities. In May 2023, **AIM**[4] (Association for Automatic Identification and Mobility) certified CIP as an Issuing Agency. AIM is the International Registration Authority (RA) for Issuing Agencies under the terms of the ISO/IEC 15459 standard. CIP intends to provide a **VIP Code**[5] which will incorporate the CIP number used in France.

Under the terms of a national decree, the **National Agency for the Safety of Medicines and Health Products**[6] (ANSM) assigns national numbers to medicines authorised on the French market. Medicine packs in France currently use a GS1[7] **National Trade Item Number** (NTIN) that incorporates a CIP number. France generates NTINs under a current three-year 'tripartite' agreement between ANSM, CIP and GS1 France[8], signed in 2022 and renewable once. Meanwhile, under the auspices of the French MoH[9], discussions are underway to decide on a long-term solution for France which may move away from the current use of NTINs.

In June 2024, CIP published a document entitled "Club Inter Pharmaceutique Guidelines for the Coding of Medicinal Products"[10]. This document describes how manufacturers can adopt the **VIP 2400 Code** for unique identifiers provided on medicinal products, including medicinal packs subject to verification using the **European Medicines Verification System**[11] (EMVS). CIP envisages the gradual adoption of these guidelines, which they also describe as a standard. They expect that, over time, the new VIP Code will replace the use of NTINs on medicine packs. CIP does not specify the status of their guidelines, but probably envisages that France will adopt these once the tripartite agreement has ended, with the agreement of the regulatory authority.

In 2023, GS1 responded to initial proposals from CIP in a paper entitled "Discussion paper on the use of global vs. national standards for the codification of medicinal products to implement the EU Falsified Medicine Directive in France"[12]. GS1 is keen to promote the continued use of GS1 standards on serialised medicinal products in France and raises concerns and objections to the approach advocated by CIP.

[4] See https://www.aimglobal.org/
[5] CIP proposes to use the VIP 2400 Code for unique identifiers. "VIP" is the Issuing Agency Code assigned to CIP by AIM (Association for Automatic Identification and Mobility) which acts as the International Registration Authority (RA) for Issuing Agencies under the terms of the ISO/IEC 15459 standard.
[6] See https://ansm.sante.fr/
[7] GS1 Global Office is a certified Issuing Agency under the terms of the ISO/IEC 15459 standard.
[8] See https://www.gs1.fr/
[9] See https://sante.gouv.fr/
[10] CIP has published the document in English and French. You can download the document from the CIP web site. See https://www.cipmedicament.org/documentation/.
[11] See https://emvo-medicines.eu/mission/emvs/
[12] The document is not available on-line but is partly reproduced in a SoftGroup article. See https://www.softgroup.eu/2023/09/12/changes-codification-of-medicinal-products-france/

SUMMARY OF FINDINGS

The following points are discussed in detail later in this paper:

1. All other European markets have adopted the GS1 standard[13] for unique identification of medicines. Globally, other markets have adopted the same standard. If France adopts the CIP guidelines it will be at a disadvantage in terms of global initiatives and the evolution of European and global supply chains. See **Global adoption and interoperability** for an explanation of these disadvantages.

2. The GS1 standard provides a more robust foundation than the ANSI ASC MH10.8.2 standard, advocated by the CIP guidelines, for uniquely identifying medicinal products. See **Encoding** for technical examples and **Parsimony** for a more general explanation.

3. The GS1 standard provides greater flexibility for manufacturers and wholesalers when managing traceability across the supply chain. See **Supply Chain Democratisation** for an explanation of how the GS1 standard 'democratises' the assignment of product codes, allowing manufacturers to better support their supply chain needs.

4. Adoption of the CIP guidelines will lead to increased costs for manufacturers, wholesalers, and pharmacists in terms of new equipment, code re-engineering and changes to operating procedures to handle multiple standards. See **Interoperability** and **Global adoption and interoperability**.

5. Alignment to the GS1 standard includes good practices that reduce risk, including risks to patients, while also reducing costs and complexity. See **Supply Chain Democratisation** for further details.

6. Thanks to the way GS1 manages and encodes corporate identity in product codes, the GS1 standard provides a better foundation for managing merger, acquisition, and divestiture, reducing the burden on national organisations and agencies. See **Supply Chain Democratisation** for further details.

7. If manufacturers use the proposed VIP Code, this may cause disruption, both in France and other markets when verifying multimarket packs. Any disruption could be perceived as a barrier to free trade within the EU. See **Transition Period** and **Interoperability** for further explanation.

8. The CIP guidelines result in larger barcodes. Together with the need for manufacturers to include an emblem, this increases the problems manufacturers encounter in applying the unique identifier to small packs. See **Barcode Size and Emblem** for worked examples.

9. The current CIP guidelines compromise the global uniqueness of each VIP-based unique identifier by adopting a coding scheme which does not follow the semantics of the ANSI ASC MH10.8.2 standard. Any manufacturer that follows the current CIP guidelines will violate Article 5 (4) of the DR. See **Invalid use of 'P' Data Identifier**. See **Appendix B: Article 5 of EU Delegated Regulation 2016/161** for the legal text.

10. CIP's current inclusion of an additional data element in the barcode is redundant. A better approach would be to agree a definition of a specific DI. As well as ensuring global uniqueness, adoption of a specific DI will reduce the size of barcodes, making it easier to fit them on small packaging. See **Our Recommended Approach**.

[13] On entering the European Medicines Verification System (EMVS), Germany adopted GS1 standards alongside existing IFA standards.

11. CIP envisages a gradual adoption of their guidelines during a transition period. All verification applications must be adapted to support both GS1 barcodes and VIP Codes before manufacturers are allowed to place any VIP-encoded packs on the market. This is necessary to ensure that pharmacists and wholesalers can continue to meet their legal obligations. See **Transition Period**.

12. The current CIP proposal imposes a character length restriction on Unique Identifiers which is unnecessarily restrictive, and which could potentially conflict with existing processes implemented by some manufacturers. See **50 Character Limit**.

13. If France adopts CIP's guidelines, Francophone low- and middle-income countries will find it harder to adopt medicine verification and traceability in the fight against falsified medicines. See **Interoperability** for further explanation.

CURRENT AND PROPOSED USE OF CIP NUMBERS

Currently, the tripartite agreement ensures that ANSM incorporates CIP numbers (national numbers) into GS1 National Trade Item Numbers (NTINs). GS1 supports NTINs primarily to help transition from national numbers to globally unique numbers. Product codes must be globally unique under Article 5 of EU **Delegated Regulation 2016/161**[14] (the DR) which governs the modalities of the **Falsified Medicines Directive**[15] (FMD) across the European Union. Working with a national issuing agency, GS1 ensures that NTINs remain globally unique within the GS1 ecosphere, even though they apply to a specific market. In France, ANSM generates NTINs under the current 'tripartite' arrangement together with CIP and GS1 France. This agreement is temporary. France must make a permanent decision concerning national product identifiers in the coming months or extend the current agreement for a period.

In 2023, CIP achieved certification as an authorised ISO/IEC 15459-compliant issuing agency. AIM assigned 'VIP' to CIP as its unique Issuing Agency Code (IAC)16. CIP can now create product codes that fulfil the requirements for Article 5 (4, 5) of the DR. The 'VIP 2400' Code will be globally unique according to a scheme entirely separate to that operated by GS1. A comparable situation exists in Germany for PPNs (Pharmacy Product Numbers). These are globally unique 12-digit product codes that GS1 does not control or maintain. An organisation called IFA17 (Informationsstelle für Arznei) serves as the Issuing Agency for PPNs. The European Medicines Verification System (EMVS) supports PPN-based unique identifiers. CIP describes its proposed approach in a document entitled 'CIP Guidelines for the Coding of Medicinal Products' published in June 2024.

[14] See https://eur-lex.europa.eu/eli/reg_del/2016/161/oj
[15] See https://health.ec.europa.eu/document/download/7bd5d800-08de-47a3-be9f-d5832682c262_en?filename=dir_2011_62_en.pdf
[16] See the Register of Issuing Agency Codes for ISO/IEC 15459 – ISO, CEN, AIM. https://d7t5d7.p3cdn1.secureserver.net/wp-content/uploads/2024/02/Register-IAC-15459-2-20230505.pdf
[17] See https://www.ifaffm.de/de/home.html

STANDARDISED SUPPORT FOR DIFFERENT ENCODINGS

The DR specifies that manufacturers must encode unique identifiers in two-dimensional Data Matrix barcodes that support the highest current level of error correction (ECC 200). This accords with GS1 recommendations to use Data Matrix barcodes in healthcare-related scenarios. The Data Matrix standard provides barcodes that are more compact and reliable compared to alternative barcode standards.

Manufacturers of medicines for the German market encode PPNs into Data Matrix barcodes in a way that is clearly distinguishable from GS1 GTINs. This involves the use of different syntactical rules and semantic identifiers to represent data in different encoding schemes. The GS1 standard designates each data element by a semantic '**Application Identifier**' (AI). GS1 defines AIs in their **General Specifications**[18] standard, together with the syntactic rules that govern data representation. In a comparable way, the **ANSI ASC MH10.8.2**[19] standard designates each data element in a German PPN barcode by a semantic '**Data Identifier**' (DI). PPN barcodes conform to the high-level syntactic rules specified by the ANSI ASC MH10.8.2 standard together with additional applicable rules specified by industry bodies. In the case of German PPNs, IFA specifies aspects of the data syntax. IFA serves as the globally recognised issuing agency[20] for PPNs, in accordance with **ISO/IEC 15459**.

A single global standard (**ISO/IEC 15418**) incorporates both the GS1 and ANSI ASC MH10.8.2 approaches. The DR lists this standard in Article 5 (4). ISO/IEC 15418 gives these two standards broadly equivalent status for the representation of structured supply chain data in Data Matrix barcodes. This is emphasised by the inclusion of data encoding mechanisms in the Data Matrix standard (**ISO/IEC 16022**) that support both approaches. There is a 'hidden' code in the first position in the barcode. Barcode scanners never report this code to the computer. For GS1 barcodes, the code is 232 which designates a GS1 'FNC1' barcode. Technically, manufacturers could also use 236 (a GS1 'Format 05' barcode). However, the use of Format 05 barcodes would be problematic across Europe. PPN barcodes use the 237 code to indicate an ANSI ASC MH10.8.2 'Format 06' barcode. Other codes exist but are not relevant here.

To comply with the Data Matrix standard, barcode scanners must recognise these codes and process the data correctly according to the standard. For GS1 FNC1 barcodes, processing involves the simple conversion of any subsequent 232 codes to ASCII 29 characters. These non-printing characters function as data element delimiters. For 236 (Format 05 GS1) or 237 (Format 06, including PPN) codes, the barcode scanner must embed the barcode data in a standards-compliant (**ISO/IEC 15434**) data envelope structure and report the entire envelope and its contents to the computer. The DR lists this standard in Article 5 (6).

The following diagram illustrates the current association between the four ISO/IEC standards listed in Article 5 of the DR and their relationship to GS1 and ANSI ASC MH10.8.2 standards and the use of FNC1, Format 05 and Format 06 barcodes. The author is not aware of any actual use of Format 05 barcodes within the European market, although this is a legally acceptable approach which complies with the DR. Apart from German PPN barcodes, manufacturers uniformly use GS1 FNC1 barcodes across Europe.

[18] See https://ref.gs1.org/standards/genspecs/
[19] See https://webstore.ansi.org/standards/mhia/ansimh102016. You can download the latest version for free from MHI. See https://my.mhi.org/s/store#/store/browse/tiles
[20] The Issuing Agency Code for IFA is 'PP'.

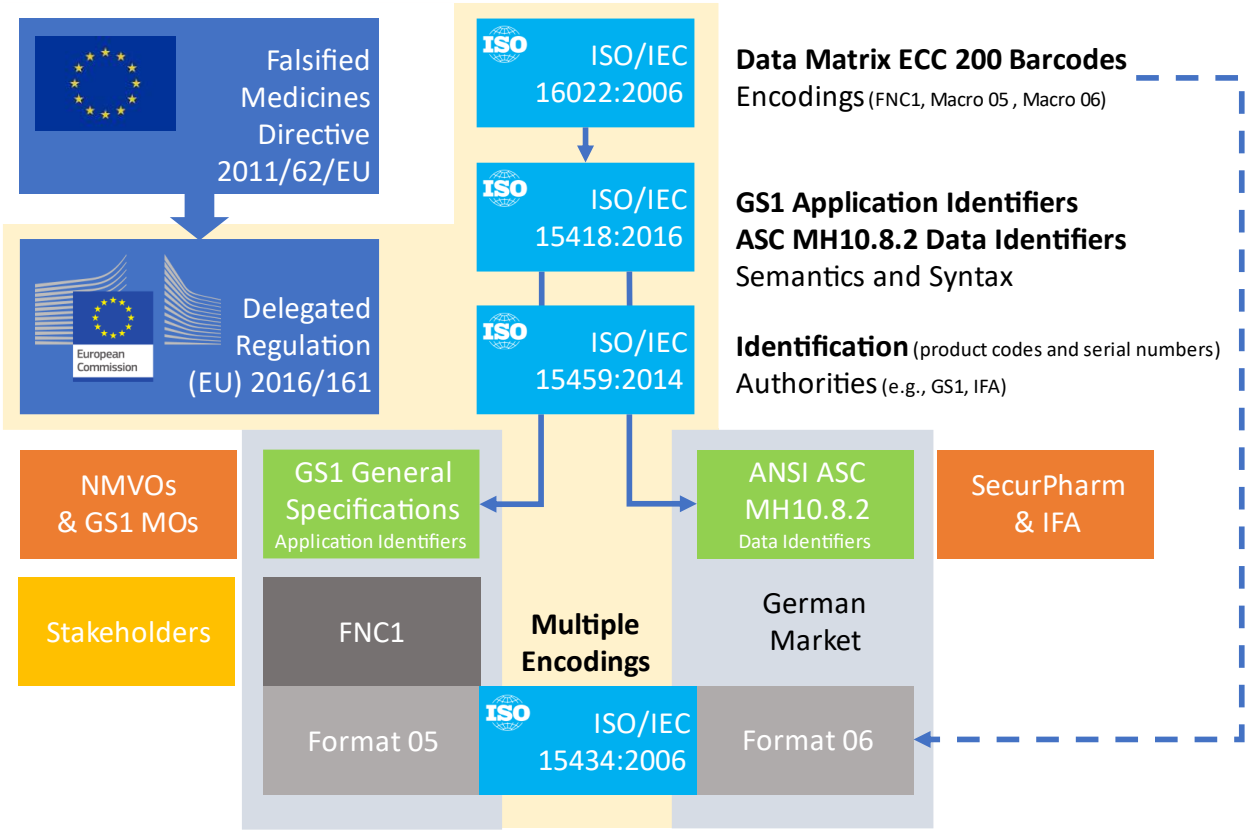

Figure 1: The EU Delegated Regulation 2016/161 and Standards

There is no possibility of confusion when reading GS1 and PPN barcodes. The use of semantic identifiers, syntactic rules and data envelopes ensure that systems can make a clean distinction between GS1 barcodes and PPN barcodes. This is important because GS1 and PPN barcodes must be globally unique. However, issuing agencies can only guarantee global uniqueness within their own ecosystem. If there was any possibility of mistaking a GS1 barcode as a PPN barcode, there would be no guarantee of global uniqueness for identifiers provided by each barcode type.

The ISO/IEC 15434 standard specifies the data envelope used for PPN barcodes. The DR identifies this standard as a means of representing different coding schemes in a single barcode where manufacturers wish to incorporate additional data into a barcode alongside a unique identifier. However, limitations within the Data Matrix standard mean that barcode scanners must always generate the envelope for German PPN (ANSI ASC MH10.8.2) barcodes, even for barcodes that only contain the unique identifier data. Barcode scanners can also incorporate GS1 data into the same envelope structure, although manufacturers avoid this in the context of the EMVS. However, even in this case, GS1 and PPN barcodes are readily distinguishable by a code in the envelope (‘05’ for GS1 and ‘06’ for ANSI ASC MH10.8.2) and the use of different syntactic rules.

THE CIP PROPOSAL

CIP intends to use the ANSI ASC MH10.8.2 standard to govern the syntax and semantics of unique identifiers for medicinal products subject to verification using the EMVS. This is the same standard used for German PPN barcodes. However, CIP will use a different Data Identifier[21] (DI) for the product code. PPNs use an industry-specific DI ('9N') which provides a semantic prefix indicating that the following twelve digits represent a PPN, whereas CIP will use a generic DI ('1P') which simply designates the following data as an 'Item Identification Code' with no indication of any specific format.

CIP proposes to use the new '29D' DI for expiry dates, whereas PPN barcodes continue to use the much older and generic 'D' DI. However, the CIP document illustrates the use of the generic '9D' DI (date with mutually agreed structure and significance) for expiry dates, rather than '29D'. The ANSI ASC MH10.8.2 committee added '29D' to the standard very recently, and this discrepancy may indicate that CIP has only partially updated its documented guidelines to reflect this change. The date format for '29D' corresponds to the same date format used in GS1 barcodes to represent the expiry date. There is, however, no predefined format for '9D'.

Encoding

Given the use of the ANSI ASC MH10.8.2 standard, our assumption is that CIP expects manufacturers to encode barcodes using Format 06 (the 237 code) in line with the ISO/IEC 16022 standard. However, CIP does not state this explicitly. GS1 has stated that "The proposed CIP code will be encoded into a ***generic*** ISO/IEC Data Matrix, meaning a new, specific data management system." We have provided the emphasis here but cannot explain with certainty what GS1 means by a 'generic ISO/IEC Data Matrix'. The CIP document does not contain any similar statements or terms.

CIP provides an illustration of the data that the barcode scanner will report. However, CIP does not embed the illustrated data in an ISO/IEC 15434 data envelope. This may simply be an oversight. However, given the use of the term 'generic ISO/IEC Data Matrix' by GS1, and the fact that GS1 provides a graphical illustration of a Data Matrix barcode containing ANSI ASC MH10.8.2 data encoded as plain ASCII data rather than structured data in a 'Format 06' data envelope, GS1 may believe that CIP barcodes will be encoded as plain ASCII and will not use 'Format 06' encoding. Encoding ANSI ASC MH10.8.2 structured data as plain ASCII text is technically valid but is poor practice[22]. It could lead to errors within equipment that expects barcodes to follow the ISO/IEC 15434 standard listed in Article 5 (6) of the DR, based on support for Format 06 in ISO/IEC 16022 listed in Article 5 (2) of the DR.

Using the example provided in the CIP document, we have embedded the data in an ISO/IEC 15434 data envelope and have represented non-printing characters as ␝, ␞ and ␄. This illustrates how barcode scanners will report the data if manufacturers use Format 06 to represent these barcodes, rather than plain ASCII data:

[)>␞06␝PVIP␝1P024009324129519␝9D251231␝1T12345ABCD␝S6789EFGH␞␄

If encoded as plain ASCII data, barcode scanners will report this data as:

PVIP␝1P024009324129519␝9D251231␝1T12345ABCD␝S6789EFGH

[21] A Data Identifier is a semantic code which is included in the barcode data and used to designate the meaning of an individual data element.

[22] Specifically, it fails to provide a 'system identifier', as defined in DIN V 66403, incorporated into ANSI ASC MH10.8.2 Category 0 DIs and indirectly supported by ISO/IEC 16022 codewords. This can be rectified by including the ISO/IEC 15434 data envelope in the barcode, but this significantly increases the barcode size.

The barcode scanner generates the additional envelope characters included in the first example (Format 06).

These characters do not exist in the barcode itself.

The table below illustrates the content of the VIP barcode.

Table 1: CIP Barcode Content Example

DI	Explanation	CIP content
P	Item Identification Code assigned by Customer	VIP
1P	Item Identification Code assigned by Supplier	02400932412951
S	Serial Number or Code Assigned by the Supplier to an Entity for its Lifetime	6789EFGH
9D	Date (structure and significance mutually defined)	251231
1T	Traceability Number assigned by the Supplier to identify/trace a unique group of entities	12345ABCD

Here is a representation of a GS1 FNC1 barcode, as reported by a barcode scanner. GS1 provides this example in their discussion paper.

`0103400935974419171411221 0NY2006␝2119283748`

The table below illustrates the content of the GS1 barcode.

Table 2: GS1 FNC1 Barcode Content Example

AI	Explanation	GS1 content
01	Global Trade Item Number (GTIN). NB., the example is an NTIN.	03400935974419
21	Serial Number	2119283748
17	Expiry Date	141122
10	Batch (Lot)	NY2006

Barcode Size and Emblem

Two issues are immediately obvious. The first is that the CIP guidelines require the inclusion of five data elements. Equivalent GS1 FNC1 barcodes contain just four data elements. The other is that the GS1 specification minimises the use of non-printing characters. The ANSI ASC MH10.8.2 standard does not. Taken together, VIP Codes will contain more data than equivalent GS1 barcodes. Consequently, these barcodes will be larger.

Size is an important consideration when printing unique identifier barcodes on the outer packaging of medicinal products. Manufacturers must carefully consider the location of unique identifiers (e.g., avoiding areas of the pack to which pharmacists or wholesalers may affix sticky labels) and may have to print the barcode in a size-constrained area. One reason the law requires the use of Data Matrix barcodes is that they are more compact than alternatives. GS1 standards build on this by promoting a compact representation of data in a Data Matrix barcode. Regulatory authorities should prefer any approach that minimises the size of the barcode.

France should follow the normal convention of printing an emblem indicating that the barcode contains a VIP Code. This is useful in cases where users or automated machinery must determine what type of code the manufacturer placed in the barcode. However, this may make it harder for manufacturers to fit barcodes to the available space. Because packs that appear in France or other countries may be encoded with either a GS1 FNC1 barcode or a Format 06 barcode containing a VIP Code, it will be necessary to distinguish between the two barcode types. Pharmacists and wholesalers may need the emblem to help them select the correct mode in their software to read distinct types of unique identifier. Automated machinery may use optical character recognition to determine the barcode type. By convention, GS1 barcodes do not carry an emblem. Non-GS1 barcodes display an emblem which states the code type. The CIP guidelines could be improved by specifying the emblem and rules for its size and position. We will use 'VIP' to illustrate the emblem below.

Here are examples of VIP (Format 06) and GS1 FNC1 barcodes showing the size difference:

Figure 2: VIP (Format 06) and GS1 FNC1 barcodes.

Here is the same VIP Code, this time encoded using plain ASCII data, rather than Format 06. We do not recommend the use of this encoding as it could cause issues for scanning equipment.

Figure 3: VIP (plain ASCII data) barcode.

Invalid use of 'P' Data Identifier

In comparison to GS1 barcodes, the CIP approach uses an additional data element that could increase the risk of incorrect data processing by verification software. We assume that the reason that CIP includes this additional 'VIP' specifier is related to the proposal to use the generic '1P' DI for the CIP number. '1P' semantically represents an item identification code assigned by the supplier. The ANSI ASC MH10.8.2 standard does not define any format or issuing agency for this identifier. The 'P' data element provides a mechanism to allow software to distinguish between VIP Codes and other numbers that could appear as '1P' data elements in other barcodes. The CIP approach, however, is not robust.

The core issue here is that an issuing agency cannot unilaterally guarantee the uniqueness of unique identifiers printed on the secondary packaging of medicine products simply by generating a unique sequence of digits. Other issuing agencies could generate the same sequence of digits. An issuing agency must indicate that the digits they provide represent a specific type of code for which they are responsible (e.g., a VIP Code), rather than a different code type generated by another issuing agency. CIP intends to do this by including a 'P' data element containing the characters 'VIP'. However, this is a poor approach that does not guarantee uniqueness.

The reason for this is that CIP's use of the 'P' DI does not align with the semantics provided by the ANSI MH10.8.2 standard. The standard defines 'P' semantically as an 'item identification code assigned by the customer'. The CIP

proposal, however, uses this DI to ***qualify***[23] the identifier by indicating that the identifier provided in the '1P' element is a VIP Code. This is an incorrect use of the 'P' DI. Confused semantics often cause issues within supply chains. For example, software may simply ignore this data element or may misinterpret its meaning.

The incorrect use of the 'P' DI represents a legal impediment to the adoption of the current guidelines. Any manufacturer who generates barcodes according to the CIP proposal will violate Article 5 (4)[24] of the DR which states that the structure of the unique identifier must follow an internationally recognised, standardised data syntax and semantics. The CIP proposal does not follow an internationally recognised, standardised semantics.

Our Recommended Approach

A better (and unambiguously legal) approach would be to follow the lead taken by IFA for PPN barcodes. The IFA has registered a PPN-specific DI ('9N') as part of the ANSI ASC MH10.8.2 standard. The standard specifies that the IFA is the issuing agency responsible for assigning PPN values. Hence, by using the '9N' DI, PPN barcodes ensure that the semantics and data format of PPN product codes is clear and unambiguous. There is no need for any additional code or mechanism to specify the code type.

If France decides to move away from GS1 alignment, CIP should request a new 'N'-category Data Identifier specifically for VIP numbers, identifying the organisation as the issuing agency. This would make the use of the 'P' DI redundant and adopt a clear semantics for French barcodes. It would simplify the representation of unique identifiers in France, aligning them more closely with the approach taken in all other European countries. Annex C, attached to the ANSI ASC MH10.8.2 standard, contains a Data Identifier Request Form that CIP can complete and return to the email address provided to request a new DI.

If we assume that ANSI ASC MH10.8.2 assigns '13N' for VIP Codes (the next available 'N' category code at the time of writing), and if we also assume the adoption of the new '29D' DI for expiry dates, the contents of a VIP barcode, under our suggested amendments, would be:

Table 3: Suggested content for VIP barcodes

DI	Explanation	CIP content
13N	VIP 2400 Code maintained by CIP	02400932412951
S	Serial Number or Code Assigned by the Supplier to an Entity for its Lifetime	6789EFGH
29D	Expiration date with the format YYMMDD	251231
1T	Traceability Number assigned by the Supplier to identify/trace a unique group of entities	12345ABCD

As well as complying with the DR, this has the advantage of reducing the size of the resulting barcode (the exact size depends on a range of factors), although the barcode will often be larger than an equivalent GS1 FNC1 barcode. We illustrate this below.

[23] ISO/IEC 15459-4 discusses qualification (see Clauses 4 and 5) and provides some examples of how identifiers can be qualified. These examples are not exhaustive. Clause 4.1.2 provides an example using the '25P' DI in which 'VIP' would be prefixed to the 2400 code. We recommend the definition of a specific 'N'-category code, but CIP could consider the use of '25P', rather than combining 'P' and '1P'.

[24] See **Appendix B: Article 5 of EU Delegated Regulation 2016/161** for the legal text.

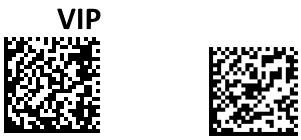

Figure 4: VIP (Format 06) barcode with suggested content, with GS1 FNC1 barcode.

Comparison of Coding Schemes

The ANSI ASC MH10.8.2 standard defines a large number of DIs, many of which are industry-specific. Others are generic. One consequence of this is that there are often multiple ways in which suppliers can represent the same data. Although Germany uses the same standard for PPN barcodes, CIP proposes to use a distinct set of data elements. It is not yet entirely clear if CIP proposes to represent expiry dates using '29D' or '9D'. However, Germany uses the generic 'D' DI.

The following table summarises the use of GS1 AIs and the current (PPN) and proposed (CIP) use of ANSI ASC MH10.8.2 DIs in the EMVS, illustrating the equivalence between different standards. 'Yes?' indicates uncertainty in the current CIP proposal.

Table 4: Comparison of GS1, CIP and PPN approaches

GS1 AI	Application	DI	Explanation	PPN	CIP
01	Global Trade Item Number (GTIN)	**P**	Item Identification Code assigned by Customer		Yes
		1P	Item Identification Code assigned by Supplier		Yes[25]
		9N	Pharmacy Product Number maintained by IFA	Yes	
21	Serial Number	**S**	Serial Number or Code Assigned by the Supplier to an Entity for its Lifetime	Yes	Yes
17	Expiry Date	**D**	Format YYMMDD	Yes	
		9D	Date (structure and significance mutually defined)		Yes?
		29D	Expiration date with the format YYMMDD		Yes?[26]
10	Batch (Lot)	**1T**	Traceability Number assigned by the Supplier to identify/trace a unique group of entities	Yes	Yes

[25] As discussed in the body of the document, the use 'P' and '1P', as envisaged in the current CIP guidelines, does not comply with the DR. Solidsoft Reply recommends that CIP instead requests the assignment of a new 'N'-category DI for its specific use.

[26] In Solidsoft Reply's view, the use of '29D' is preferable to '9D'. It has a specific semantics that designates an expiry date, and it adopts the same date format used by GS1. The use of 'D' for expiry dates in PPNs predates the definition of '29D'. However, France may deem 'D' to be preferable, especially if it shares a significant volume of multimarket packs with Germany.

Transition Period

CIP advocates a gradual introduction and adoption of its guidelines as a standard. They state clearly that this will be necessary “because of the time needed to adapt information systems to read this new coding throughout the distribution chain”. They also state that “coding users are encouraged to plan to use the functionalities described in [the CIP] guideline and to implement them gradually”. See “Club Inter Pharmaceutique Guidelines for the Coding of Medicinal Products”, section 2.

France will need to exercise considerable care when planning an effective transition. Medicine verification is already mandatory in the French market and GS1-encoded packs may remain in the pharmaceutical supply chain for several years after VIP Codes are introduced. Most packs are dispensed within a few months, but packs may remain in the supply chain until their batch expires.

Any application that pharmacists or wholesalers use to verify VIP-encoded medicines must be upgraded to scan both GS1 and ANSI ASC MH 10.8.2 barcodes ***before*** manufacturers place any VIP-encoded packs on the market. This applies within France and may apply in other countries where VIP-encoded multimarket packs will appear in any significant quantity. Pharmacists and wholesalers must be able to continue to meet their legal obligations as soon as manufacturers start to commission VIP-encoded packs. France must therefore complete any transition period before manufacturers commission any packs that use the VIP Code.

It is vital that all verification applications continue to support a dual verification mode so that they can continue to verify GS1-encoded packs for several years after the VIP Code is introduced. **FranceMVO** must liaise carefully with IT suppliers to ensure this is the case.

After several years, France could allow verification applications to drop dual-mode verification in favour of supporting VIP Codes, only. However, as there will always be a possibility of GS1-encoded packs appearing in the French market, it may be preferable for IT suppliers to maintain support for both standards indefinitely.

50 Character Limit

The CIP guidelines state that ISO/IEC 15459-4 specifies that the entire Unique Identifier (product code, serial number, batch (lot) and expiry date) must not exceed 50 characters. However, the ISO/IEC 15459-4 standard does not recognise the notion of the ‘Unique Identifier’ defined in the DR. The examples given in the standard apply the 50-character restriction only to a serial component or the combination of the qualified product code and serial number. The DR recognises, in several places, that the unique identity of the pack depends only on the product code and serial number.

Article 5 (5) of the DR restricts the qualified *product code*, only, to less than 50 characters. NB. the GS1 standard uses 16 characters and PPN barcodes use 14 characters. The DR then states that conformance to ISO/IEC 15459-4 is presumed to fulfil the requirements of Article 5 (5). This is strictly correct, but ISO/IEC 15459-4, taken together with various requirements in the DR, implies that the qualified product code must certainly be less than 47 characters. The DR allows the product code to be up to 49 characters in length.

This discrepancy within the DR does not cause any issues or disruption. Similarly, the qualified VIP Code, in the current proposal, is only 20 characters, which complies with the DR. However, the CIP guidelines introduce an additional restriction, not supported by the ISO/IEC 15459-4 standard or the DR, that affects the number of characters that manufacturers can use for batch numbers and/or serial numbers. For some manufacturers, this restriction could potentially conflict with their existing processes.

MULTIMARKET PACKS

GS1 suggests that there may be issues with multimarket packs if France adopts the CIP proposals. There is nothing in the CIP document that prevents the creation of VIP-encoded multimarket packs in the EMVS. The EMVS designates multimarket packs by the provision of multiple target markets in the master data uploaded to the European Hub by the pharmaceutical manufacturer for a given product code. The form of the product code (GTIN or PPN) and the barcode encoding are irrelevant, assuming, of course, that national systems can store and use different types of unique identifier. SecurPharm (the German NMVO) provides documented guidance[27] on creating multimarket packs using either GS1 or ANSI ASC MH10.8.2 standards. France could mandate a similar approach to the use of PPNs for multimarket packs. It is worth noting, however, that the GS1 standard provides a stronger framework than the ANSI ASC MH10.8.2 standard for modelling multiple National Healthcare Reimbursement Numbers (NHRNs) used in different markets.

Although the CIP proposals support multimarket packs, there is an underlying issue that French regulatory authorities should consider carefully. Today, suppliers use GS1 standards for all EMVS unique identifiers with the single exception of German PPN barcodes. Given that the industry stakeholders do not specify, control, or validate the functionality of client systems that interoperate with national systems, it is reasonable to assume that many pharmacists and wholesalers across Europe do not have access to software that can process ANSI ASC MH10.8.2 barcodes.

Although it is possible, and valid, to use VIP Codes on multimarket packs, it is likely that this will prove disruptive in markets other than France. There may be significant re-tooling costs to manage VIP-encoded packs, and existing operating procedures may need to change to accommodate the VIP. Even in Germany, the adoption of the VIP Code on multimarket packs is likely to cause problems due to the proposed use of the ‘P’, ‘1P’ and ‘29D’ (or ’9D’) DIs which Germany does not support for PPN barcodes. French multimarket packs may not, therefore, be readily verifiable in other markets, and may unintentionally function as a barrier to trade across the EU.

The argument works in the opposite direction. All other markets across Europe support GS1 standards and, except for some German packs, manufacturers serialise medicinal packs using GS1 FNC1 barcodes. It is likely, therefore, that GS1-encoded multimarket packs will continue to appear on the French market. Today, these can be verified using the same software currently used for French packs because, in both cases, the barcodes adhere to the same GS1 standards. If the CIP proposal is adopted, issues may arise in future where some packs cannot be verified on the French market due to a lack of support in verification software for GS1 standards.

INTEROPERABILITY

The EMVS depends on interoperability between a central European Hub and each national system. GS1 has suggested that there could be interoperability issues between the French national system and other systems implemented in the EU because those other systems are based on global standards.

The CIP proposal is based on global standards which the EMVS supports today for German PPN barcodes. The CIP proposal should not cause any interoperability issues between the French system and the European Hub. However, the EMVS will require extensions to manage the new VIP scheme correctly. For example, it will need to introduce additional validation rules for VIP Codes uploaded to the hub by manufacturers and it may require other

[27] See section 5.3 of SecurPharm’s “Coding Rules for Medicines Requiring Verification for the German Market” document, v2.04a (https://www.securpharm.de/wp-content/uploads/2019/01/securPharm_Codierung_Regeln_EN_V2_04a.pdf) which provides examples of unique identifiers for multimarket packs in both formats.

changes to correctly support inter-market transactions and produce correct reports. These changes may affect each national system as well as the European Hub. However, introducing these changes should not disrupt other markets.

There could be interoperability issues between the French national system and other unspecified (non-EMVS) European systems, which could include, for example, alert management systems.

The French system will continue to interoperate with the rest of the EMVS in the same way the German system does today. France must comply with Article 5 of the DR which specifies how markets must apply global standards across Europe to ensure successful interoperability. The CIP proposals will ensure that the French system uses global standards (but not GS1 standards) in accordance with EU law. Nothing in the CIP guidelines contradicts the requirements of the DR in this respect.

The significant interoperability issues lie at the periphery of the EMVS, rather than within it. They concern interchange between manufacturers, wholesalers, hospital pharmacies and community pharmacists with the EMVS. We have already discussed the potential impact on pharmacists and wholesalers, both in France and in other countries, for multimarket packs. This applies to any other scenarios where VIP-encoded packs may appear in other markets (e.g., on compassionate grounds) or GS1-encoded packs appear in the French market. Today, pharmacists and wholesalers use software systems that read GS1 barcodes. Under the CIP proposal, these must be changed to support ANSI ASC MH10.8.2 barcodes and may drop support for GS1 barcodes or may introduce greater complexity to handle both barcode types.

There will be a significant cost to manufacturers and parallel distributors who must support a separate approach to encoding packs specifically for France. This may require investment in separate serialisation machinery and barcode validation equipment. Wholesalers may need to adopt new systems and processes to manage French packs. Gateway providers such as SAP, TraceLink and the EMVO will need to extend their services.

GS1 suggests that a lack of interoperability may function as a barrier to trade across EU countries and the world. Any impediment to the effective verification of packs of medicinal product will have a detrimental effect on trade with Europe. However, manufacturers, wholesalers and pharmacists can address these issues, albeit at a greater expense and inconvenience.

GS1 calls out the impact on global trade and medicine safety. Europeans often overlook these issues but should give them greater consideration. International agencies are making a significant effort to drive medicine verification and traceability into national supply chains in low- and middle-income countries (LMICs) where the problems of substandard and falsified medicines are most acute. However, today, most LMICs do not have any significant manufacturing base for essential and high-risk medicines and depend largely on imported products.

Serialisation issues are a major practical barrier to the introduction of medicine verification and traceability in LMICs. What these countries need is a single global standard adopted by default by global and national manufacturers to serialise their packs, together with trustworthy and cost-effective channels that allow manufacturers to share unique identifiers with LMICs. The CIP proposals will introduce a greater degree of fragmentation in the standards used for unique identification and verification, especially in Francophone countries, making it harder for LMICs to achieve real progress in the fight against falsified medicines.

WHY ADOPT GS1 STANDARDS?

In this section, we summarise the reasons to promote the use of GS1 standards in France, rather than ANSI ASC MH10.8.2 and the VIP Code.

Supply chain democratisation

GS1 promotes the 'democratisation' of the assignment of numbers. GS1 Member Organisations (e.g., GS1 France) act as issuing agencies and carefully control subsets of the GTIN digits in accordance with a global scheme to ensure global uniqueness. This approach allows manufacturers to assign the remaining digits in accordance with their needs, as well as a preliminary 'indicator' digit (for GTIN-14) to indicate packaging levels. The GS1 standard specifies that manufacturers should always assign these digits, rather than regulatory authorities or other organisations[28].

Regulatory authorities often overlook the power and benefit of this democratisation, but they should never underestimate it. This is especially true in healthcare where GS1 articulates recognised good practice (GxP) in their healthcare standards which markets enforce through market authorisation and national law. Good practice ensures that manufacturer-assigned product codes always reflect any difference in finished product that could be a source of risk to patients. This includes pharmaceutical characteristics such as the non-proprietary name (e.g., INN), common (brand or generic) name, form, strength, and dosage unit of the product. However, it also considers any notable change to pack branding and presentation, the target market of the product and the language of the included patient information leaflet.

Of course, numbers assigned by a national body can also reflect these differences. However, allowing the manufacturer to assign unique product codes as GTINs has benefits. National regulatory bodies can still assess the assignment of numbers through the market authorisation process to ensure GxP compliance. However, manufacturers can generate product codes to better fit their own internal and supply chain needs. For example, manufacturers often label consignments of goods with a barcode that contains a GTIN. In this case, there can be significant benefits if the GTIN on a shipped container directly represents the product contained in that container. Manufacturers often use GTINs which are identical to those used at the product pack level, except for the first digit and the final check digit. This can be important when tracking aggregated shipments across the pharmaceutical supply chain.

One advantage of the approach adopted by GS1 is that GTINs (and other GS1 key values) naturally support merger, acquisition, and divestiture over time without the need to involve national authorities directly in the process of managing these changes to commercial relationships. It is vital, in a medicine verification or traceability system, to ensure that national systems track these changes so that ownership of data uploaded to these systems always remains clear and unambiguous, even for commissioned product in the supply chain.

In summary, the GS1 approach meets all the needs of national regulatory authorities in compliance with recognised GxP approaches which maximise the ability of manufacturers to use a single representation of each product effectively across the entire supply chain. This reduces complexity, risk (including risk to patients) and cost. It supports both current and potential future requirements through a single proven mechanism designed for use at both global and national levels.

[28] This, of course, does not apply to NTINs, such as the current 3400 code used in France. GS1 recognises the need for NTINs in healthcare, but explicitly advocates the use of GTINs, noting that NTINS are less interoperable with other GS1 standards and can lead to problems across the global supply chain. See section 2.1.6 of GS1 General Specifications.

Parsimony

GS1 provides a comprehensive set of standards and specifications to enable real-world supply chain and regulatory management of trade items, shipments, locations, and other entities in an independent, vendor-neutral fashion. GS1 is a network of non-profit member organisations focused on the needs of the entire industry, rather than promoting specific vested interests.

GS1's specifications reflect this mission by adopting a degree of parsimony which may be absent in other global standards. This document provides a good example when comparing the GS1 standard with the ANSI ASC MH10.8.2 standard. At one level, the ANSI ASC MH10.8.2 standard is like the GS1 standard. Both standards contain a list of semantic identifiers for data elements that may be included in electronic messages and barcodes. However, ANSI[29] acts as a top-level standards organisation which creates a space for incorporation of different industry standards. This is why the four AIs defined by GS1 which comprise the basic EMVS unique identifier (the GTIN, serial number, batch identifier and expiry date) correspond to multiple combinations of different DIs in the ANSI ASC MH10.8.2 standard. CIP specifies (ambiguously) that manufacturers should use '29D' to represent expiry dates. Germany continues to use 'D' for the expiry date element.

With GS1, there is just one way to represent unique identifier data. Unique identification plays a key role in healthcare and other industry sectors, and the semantics provided by GS1 are clear and fit well with real-world needs. This is not the case with ANSI ASC MH10.8.2 Data Identifiers which comprise a mix of national, industry-specific, and even company/organisation-specific identifiers managed by bodies external to ANSI ASC MH10.8.2, together with 'generic' Data Identifiers whose semantics may not always provide the best fit with real-world needs. GS1 provides a significantly stronger foundation than ANSI ASC MH10.8.2 for the unique identification of trade items. Adoption of the ANSI ASC MH10.8.2 standard can lead to significant differences in the representation of common data in different markets, and even cause potential confusion within a single market.

Global adoption and interoperability

GS1's strongest claim is to be a truly global organisation which offers a comprehensively global scheme. The pharmaceutical supply chain is global in nature, extending back to Active Pharmaceutical Ingredients as well as incorporating the uniquely identified finished products sold on European markets. The EMVS, itself, is a single logical 'repositories system' that supports the principles of the single market without compromising the sovereign interests of individual states. All markets across Europe, with the partial exception of Germany, have opted to select the GS1 standard rather than the ANSI ASC MH10.8.2 standard, for uniquely identifying and verifying medicinal products. Germany's use of ANSI ASC MH10.8.2 is historic. It has adopted the GS1 standard as an alternative to the old approach.

As explained in this document, there is no technical or legal impediment to the adoption of the ANSI ASC MH10.8.2 standard in France. However, that does not imply that adoption of this standard will avoid unnecessary friction. It will single out France as unique amongst all other European countries in its approach to medicine verification, and an outlier at the global level. We have seen that this is likely to cause disruption both in France and in countries that consume multimarket medicines or any other French medicines (e.g., medicines distributed on compassionate grounds). It will force additional expense on software providers that will have to re-engineer existing systems to manage VIP-encoded packs. It will lead to additional expense by manufacturers who will need to implement new tooling and automated validation to manage VIP Codes. It may impact existing traceability within the supply chain. These factors will certainly place France at a disadvantage if the European Union moves, in future, to end-to-end traceability of medicines across the European supply chain. Moreover, this 'exceptional' national approach could

[29] See https://www.ansi.org/

adversely impact medicine costs in France.

It is worth noting that the approach adopted in all other European markets reflects a much wider consensus at the global level. Although this global consensus does not have any significant impact on the current point-of-dispense approach adopted across the European Union, it will potentially impact future global evolution of supply chain management and medicine safety. It certainly conflicts with the growing interest in monitoring the global supply chain to provide better detection of emerging product shortages and other issues. It may be an impediment to future provision of electronic Patient Information (ePI) or collection of real-world evidence from the field to support pharmacovigilance.

Mapping Product Codes to National Numbers

Nothing stated in this document conflicts with the legitimate need for individual countries to adopt national numbers to represent medicinal products authorised for sale within their markets. This is a common approach in European markets. Advocacy of the GS1 standard for medicine identification implies a need to map from GTINs to national numbers. From one perspective, this introduces additional complication and cost. Regulatory authorities must weigh this against the benefits of adopting the GS1 standard outlined above.

ANSM can map from GTINs to CIP VIPs in a reliable and cost-effective manner using different approaches. These range from placing the VIP as a 'fifth element' in the barcode (a good solution, except in terms of barcode size which inevitably increases), capturing the CIP VIP Code as part of the product master code in the EMVS national system so that it can be reported each time a pack is verified or decommissioned or even providing a centralised mapping service that resolves GTINs to CIP VIPs. Other European markets use these approaches today[30], including the largest countries in the European Union. Alternatively, of course, France could simply decide to make the use of NTINS permanent.

[30] See https://emvo-medicines.eu/new/wp-content/uploads/Annex2_MS-Coding-Requirements.pdf

SUMMARY

France plans to continue to fully conform with the EU FMD and Delegated Regulation though the adoption of a standards-based approach. CIP proposes, however, that France does not use the GS1 standard in future. Understandably, GS1 is keen to advocate the use of its standard which has been widely adopted in markets across Europe and the rest of the world.

We have given reasons in this document why Solidsoft Reply recommends the adoption of GS1 standards in France, rather than ANSI ASC MH10.8.2 standards. However, we recognise that France has the right to select the use of ANSI ASC MH10.8.2 standards if it wishes, and that this complies with the requirements of the FMD and Delegated Regulation. If the final decision is to adopt ANSI ASC MH10.8.2 standards, we recommend that CIP amends its current guidelines to avoid the use of the ‘P’ and ‘1P’ Data Identifiers, and to adopt the use of ‘29D’ rather than ‘9D’ to represent expiry codes. It is important to provide clarity and accuracy regarding the representation of unique identifiers in France.

It remains only for us, once again, to emphasise our recommendation that France adopts the GS1 standard on a permanent basis. This will serve its needs better, both now and in the future, and the advantages significantly outweigh the disadvantages. Adoption of the GS1 standard will not compromise the sovereign interests and needs of France but will allow it to play a more effective role in the wider EMVS landscape, avoiding potential risks and elevated costs while protecting its interests in the evolving global supply chain landscape.

APPENDIX A: GLOSSARY

This document contains the following terms.

ANSI ASC MH10.8.2	A standard developed by MHI and the MH10 committee under the auspices of the American National Standards Institute (ANSI) Accredited Standards Committee (ASC) for labelling and identification of products for logistics applications.
Application Identifier (AI)	A prefix used in GS1 barcodes to define the meaning and format of the data following it, such as batch number or expiry date.
ANSI	The American National Standards Institute, a private non-profit organization that oversees the development of voluntary consensus standards for products, services, processes, and systems in the United States of America.
ASC	Accredited Standards Committee, a committee accredited by ANSI to develop standards.
ASCII	American Standard Code for Information Interchange, a character encoding standard for electronic communication, representing text in computers and other devices.
Association for Automatic Identification and Mobility (AIM)	An industry association that supports the advancement of technologies and standards for automatic identification and data capture (AIDC).
Batch (Lot)	A specific quantity of material or product processed in a single run or produced in a particular period, identified by a unique batch number.
CEN	The European Committee for Standardisation (Comité Européen de Normalisation), responsible for developing and defining voluntary standards at the European level.
CIP Number	A unique identifier for medicinal products in France, part of the CIP code system.
Club Inter Pharmaceutique (CIP)	An organization that manages the unique identification system for pharmaceutical products in France.
Data Identifier (DI)	A prefix used in automatic identification systems to specify the type and format of the data that follows.
Data Matrix	A type of 2D barcode consisting of black and white cells arranged in a square or rectangular pattern, used for encoding data in a small space.
Delegated Regulation 2016/161 (DR)	A regulation by the European Commission that sets out detailed rules for the safety features appearing on the packaging of medicinal products for human use.
DIN V 66403 pre-standard	A German pre-standard that provides guidance and serves as the basis for Category 0 DIs in ANSI ASC MH10.8.2. It contains a list of all currently assigned system identifiers.
Dosage Unit	The specific quantity of a drug product that a patient takes at one time.
ECC 200	The most common version of Data Matrix codes, offering error correction and higher data capacity.
Emblem	A symbol or image used to represent an organization, standard, or regulation, often found on packaging to signify compliance.
European Hub	The central database managed by the European Medicines Verification Organisation (EMVO) that connects national medicines verification systems for the authentication of medicines across Europe.
European Medicines Verification Organisation (EMVO)	An organization that manages the European Medicines Verification System (EMVS) to prevent the entry of falsified medicines into the supply chain.
European Medicines Verification System (EMVS)	A system designed to ensure the authenticity of medicinal products by enabling the verification of unique identifiers at the point of dispensing.
European Union (EU)	A political and economic union of member states located primarily in Europe, working together on shared policies and regulations.

Expiry Date	The date until which the manufacturer expects a medicinal product to remain effective and safe to use, usually indicated on the packaging.
Falsified Medicines Directive (FMD)	A directive by the European Union aimed at preventing falsified medicinal products from entering the legal supply chain by requiring unique identifiers and tamper-evident packaging.
Form	The physical state or format of a medicinal product, such as tablet, liquid, or injection.
Format 05	A specific data format standard used in Data Matrix barcodes, including a combination of GS1 data elements, and allowing the inclusion of data encoded using other schemes.
Format 06	A specific data format standard used in Data Matrix barcodes, including a combination of ANSI ASC MH10.8.2 data elements and allowing the inclusion of data encoded using other schemes.
FNC1	A Function Code 1, a non-printable character used in GS1 barcodes to indicate the boundary between data fields.
FranceMVO	The National Medicines Verification Organisation (NMVO) in France.
Francophone	Relating to French-speaking populations or regions.
Gateway	A system that connects manufacturers to the European Hub, allowing for communication and data exchange, particularly in the context of serialised medicinal products.
Global Trade Item Number (GTIN)	A unique identifier for trade items, developed by GS1, used globally to identify products and services.
GS1	An international organization that develops and maintains standards for barcodes and other identifiers used in supply chains.
GS1 General Specifications	The comprehensive document that outlines the standards and guidelines for implementing GS1 barcodes and identifiers.
GxP	A collection of quality guidelines and regulations for manufacturing practices and processes in the pharmaceutical and life sciences industries, including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).
Information Leaflet	A document included with medicinal products providing information about the drug, its uses, dosage, side effects, and precautions.
Informationsstelle für Arznei (IFA)	A German organization responsible for the unique identification of medicinal products in Germany.
INN	International Non-proprietary Name, a unique and globally recognised name that identifies pharmaceutical substances or active ingredients.
ISO/IEC	International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC), organizations that develop and publish international standards.
ISO/IEC 15418 standard	A standard that specifies the data identifier and application identifier structures used in automatic identification and data capture.
ISO/IEC 15434 standard	A standard that defines the syntax for high-capacity ADC media.
ISO/IEC 15459 standard	A standard that specifies the unique identification of items.
ISO/IEC 16022 standard	A standard that specifies the requirements for Data Matrix barcodes.
Issuing Agency	An organization authorised to issue and manage unique identifiers for products, such as GS1 for GTINs.
Issuing Agency Code	A code, provided by a Registration Authority (see AIM) that identifies the issuing agency responsible for assigning unique identifiers to products.
Item Identification Code	A unique code assigned to identify a specific item, often used in supply chain management and logistics.
Low- and Middle-Income Country (LMIC)	Countries classified by the World Bank as having lower or middle levels of income per capita.
Manufacturer	The company or entity that produces medicinal products.
MH10.8.2	A standard for labelling and identifying logistics units. The standard is maintained by the 'Coding & Labelling of Unit-Loads' sub-committee of the MHI Material Handling 10 committee.

MHI	The Material Handling Institute. MHI is a trade association for the Material Handling industry in the United States of America.
Multimarket Pack	A medicinal product package designed to be distributed and sold in multiple markets or countries, often with multi-language labelling.
National Agency for the Safety of Medicines and Health Products (ANSM)	The French regulatory authority responsible for the safety of medicinal products and health products in France.
National Healthcare Reimbursement Number (NHRN)	A unique identifier assigned to medicinal products for reimbursement purposes within a national healthcare system.
National Medicines Verification Organisation (NMVO)	A country-specific organization responsible for implementing and managing the national medicines verification system in line with the European Medicines Verification System.
National Regulatory Authority	A governmental agency responsible for regulating and supervising the safety, efficacy, and quality of medicinal products within a country.
National System	The national infrastructure and processes used for the verification and traceability of medicinal products.
National Trade Item Number (NTIN)	A unique identifier for trade items within a specific country, used alongside or in place of the GTIN.
Parallel Distributor	A company that imports and sells medicinal products in a market where the original manufacturer may already sell that product, without the consent of the original manufacturer.
Pharmacist	A healthcare professional licensed to prepare, dispense, and advise on the use of medicinal products.
Pharmacovigilance	The practice of monitoring and evaluating the safety of medicinal products after their release on the market, to identify and assess adverse effects.
Pharmacy Product Number (PPN)	A unique identifier for medicinal products used in pharmacy settings, ensuring accurate dispensing and inventory management.
Real-world evidence	Data on the usage and potential benefits or risks of medicinal products derived from real-world settings, outside of clinical trials.
Register of Issuing Agency Codes	A database maintained by AIM that lists the codes assigned to issuing agencies responsible for unique product identifiers.
Registration Authority (RA)	An entity (see AIM) responsible for the registration and maintenance of unique identifiers for products, such as the GS1 Global Office.
SecurPharm	The organization responsible for implementing the medicines verification system in Germany, ensuring the authenticity of medicinal products.
Serial Number	A unique identifier assigned to each individual pack of a medicinal product, ensuring traceability and authenticity.
Serialisation	The process of assigning and affixing unique serial numbers to individual packs of medicinal products for traceability and anti-counterfeiting purposes.
Strength	The concentration or amount of active ingredient(s) in a medicinal product, usually expressed in milligrams, grams, or percentage.
Supply Chain	The entire process of producing, distributing, and delivering medicinal products from manufacturers to end-users, including all intermediaries.
Traceability	The ability to track and trace medicinal products throughout the supply chain, from production to dispensing to patients.
Traceability Number	A unique number assigned to a medicinal batch to enable its traceability throughout the supply chain.
Verification	The process of checking and confirming the authenticity and validity of a medicinal product's unique identifier before dispensing it to patients.
VIP 2400 Code	A proposed identifier for use in the French healthcare industry, related to unique product identification standards.
Wholesaler	A company that buys medicinal products in bulk from manufacturers and distributes them to pharmacies, hospitals, and other healthcare providers.

APPENDIX B: ARTICLE 5 OF EU DELEGATED REGULATION 2016/161

Carrier of the unique identifier

1. Manufacturers shall encode the unique identifier in a two-dimensional barcode.

2. The barcode shall be a machine-readable Data Matrix and have error detection and correction equivalent to or higher than those of the Data Matrix ECC200. Barcodes conforming to the International Organization for Standardisation/International Electrotechnical Commission standard ('ISO/IEC') 16022:2006 shall be presumed to fulfil the requirements set out in this paragraph.

3. Manufacturers shall print the barcode on the packaging on a smooth, uniform, low reflecting surface.

4. When encoded in a Data Matrix, the structure of the unique identifier shall follow an internationally-recognised, standardised data syntax and semantics ('coding scheme') which allows the identification and accurate decoding of each data element of which the unique identifier is composed, using common scanning equipment. The coding scheme shall include data identifiers or application identifiers or other character sequences identifying the beginning and the end of the sequence of each individual data element of the unique identifier and defining the information contained in those data elements. Unique identifiers having a coding scheme conforming to ISO/IEC 15418:2009 shall be presumed to fulfil the requirements set out in this paragraph.

5. When encoded in a Data Matrix as data element of a unique identifier, the product code shall follow a coding scheme and begin with characters specific to the coding scheme used. It shall also contain characters or character sequences identifying the product as a medicinal product. The resulting code shall be less than 50 characters and be globally unique. Product codes which conform to the ISO/IEC 15459-3:2014 and ISO/IEC 15459-4:2014 shall be presumed to fulfil the requirements set out in this paragraph.

6. Where necessary, different coding schemes may be used within the same unique identifier provided that the decoding of the unique identifier is not hindered. In that case, the unique identifier shall contain standardised characters permitting the identification of the beginning and the end of the unique identifier as well as the beginning and the end of each coding scheme. Where containing multiple coding schemes, unique identifiers which conform to ISO/IEC 15434:2006 shall be presumed to fulfil the requirements set out in this paragraph.

Solidsoft Reply

Solidsoft Reply is a leading technology company creating award-winning solutions utilising the Microsoft Azure cloud platform. As a globally acclaimed Microsoft AI Cloud Solutions Partner, we specialise in GS1 traceability systems worldwide, crucially ensuring the authenticity, legality, and safety of our customers' products and services. Serving non-profits, NGOs, healthcare, and the pharmaceutical industries, we deliver technology for positive social impact. Your products, safe in our hands.

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