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# 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

## Purpose

This paper aims to provide technical clarifications on the use of global vs national standards for the codification of medicinal products to implement the EU Falsified Medicine Directive (EU FMD<sup>1</sup>) in France.

It is important to note that GS1 remains committed to continue supporting harmonised implementation of medicinal product identification worldwide, including that of the EU FMD in France.

## Background

In 2019, the General Assembly of GS1 adopted a policy setting certain rules to ensure unique identification and the integrity of the GS1 codification system including when codes are assigned by a third party (these rules included requirements for third parties to communicate to their local GS1 Member Organisations the codes assigned and associated data). Following this policy being confirmed, GS1 France sought to align its contract, signed in 2006, with the Club Inter Pharmaceutique (CIP).

As a result, in December 2021, the ANSM (French National Agency for the Safety of Medicines and Health Products), the Club Inter Pharmaceutique and GS1 France have formalised the framework – “tripartite agreement”- to guarantee the continuation of the current codification system of medicinal products in France, for a transition period of three years, with an option for one renewal.

Since then, the **codification in France is framed by a Decree, an and a tripartite Agreement<sup>2</sup>**, aiming at ensuring the continuity of the supply chain, traceability and reimbursement of medicinal products in France and securing the supply of medicinal products to patients.

The decree and the order of the French Ministry of Health (MoH) dates 30 December 2021 relates to the allocation and technical specifications of the codification of medicinal products (i.e., Article R. 5121-4 of the Public Health Code) bringing the CIP and UCD (see below details) codes into French legislation. Article 1 states that the codes used to identify medicinal products authorised on the French market are:

- the national number identifying each packaging called " code identifiant de présentation " (CIP code)
- and, where applicable, the number identifying the common dispensing unit (usually, the primary package level), called the " code identifiant l'unité commune de dispensation " (UCD code).

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<sup>1</sup> [EU FMD](#): "Safety features for medicinal products should be harmonised within the Union in order to take account of new risk profiles, while ensuring the functioning of the internal market for medicinal products" (cons.11).

[Delegated Regulation on safety features](#): "Art.5 (4) (5) (6)"

<sup>2</sup> <https://sante.gouv.fr/soins-et-maladies/medicaments/le-circuit-du-medicament/article/la-codification-des-medicaments>

These are the current 13-character codes, with the first 4 digits being the prefix 3400 assigned by GS1 France to the CIP since 2006. This code complies with ISO/IEC 15459-3 2014 and ISO/IEC 15459-4 2014, i.e., GS1 standards recognised by ISO. ISO/IEC 15459 is a series of standards dealing with unique identification. It recognises Issuing Agencies. The standard specifies that identifiers starting with a number are GS1 ID keys. All other codifications are alphanumerical.

The tripartite agreement specifies the implementation details of the above-mentioned legislation in accordance with the GS1 standards, illustrated in Figure 3 below.

In parallel, the French MoH set up a Steering Committee in June 2021, bringing together the stakeholders involved in codification of medicinal products in order to, among other things, define the permanent solution to be implemented in the next 3 to 6 years.

In this context, interviews are currently being undertaken to support the assessment - of packaging management, software integration, costs, risks and timing for the healthcare supply chain actors, and healthcare providers - of different proposals for the future permanent solution for the codification of medicinal products in France.

### **Technical considerations on a global vs national system for codification of medicinal products.**

The proposals for the long-term solution to be implemented in France for the codification of medicinal products include:

- the continuation of the use of global standards based on GS1 standards as the code used for supply chain/logistic purposes (i.e. with the national number used for market authorisation and for reimbursement), either with the current National Trade Item Number (NTIN starting with 3400) or by mapping the national number to a Global Trade Item Number (GTIN) as is implemented in other EU countries.

Or

- the transition to the use of a national standard based on the CIP code. Since May 2023, the CIP is an authorised ISO/IEC 15459 issuing agency<sup>3</sup> and can generate unique identifiers starting with the prefix VIP.

#### **The proposal to continue using global standards based on GS1 standards.**

For those countries, such as France, where legacy national numbers are in use today, the GS1 standards provide various approaches to transition from national numbering to a globally harmonised numbering scheme. GS1 recommends<sup>4</sup> that member states allow the use of the GTIN (Figure 1) to implement the EU FMD. **The most preferred option if a national number is to be kept, is to solely encode the GTIN in the GS1 DataMatrix. The national number can be looked-up by a cross-reference in a database, without encoding it in the GS1 DataMatrix.**

However, GS1 also acknowledges that in some member states, due to specific requirements for the management of healthcare national systems or due to the need to have a transition toward the use of globally harmonised standards, the national number must appear on the packaging. In those cases, **the national number can be printed in human readable format in the packaging and does not have to be encoded in the barcode.**

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<sup>3</sup> [https://www.aimglobal.org/uploads/1/2/4/5/124501539/register\\_iac\\_15459-2\\_20230505.pdf](https://www.aimglobal.org/uploads/1/2/4/5/124501539/register_iac_15459-2_20230505.pdf)

<sup>4</sup> [https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/final\\_recommendations\\_harmonised\\_implementation\\_fmd\\_using\\_gs1\\_dec2016.pdf](https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/final_recommendations_harmonised_implementation_fmd_using_gs1_dec2016.pdf)



The proposal is to map the CIP code to a GTIN using a conversion table, as implemented in Belgium for example, and enable its use within the GS1 System. If needed on the packaging in human readable format, the CIP code can be printed but not encoded in the barcode, like done in Spain today for example.

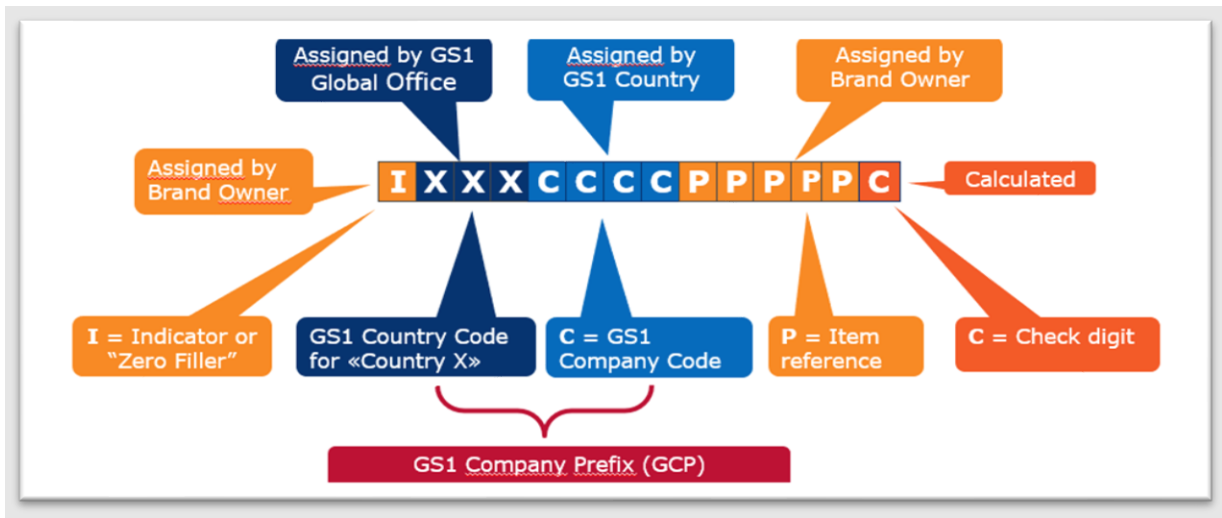


Figure 1: Global Trade Item Number (GTIN).

Another option, **still compatible within the GS1 system even if not the most globally interoperable, is to embed the national number into a NTIN, instead of using a GTIN**. The use of an NTIN is accepted in single or specific markets and will considerably limit the use of multimarket packaging.

This is the solution currently implemented under the contract between GS1 France, the CIP and the ANSM. The GS1 prefix 3400 is licensed by GS1 France to the CIP in order to allow embedding the number issued by CIP and ANSM into the GTIN structure as an NTIN (see Figure 2); it then enables its use within the GS1 System.

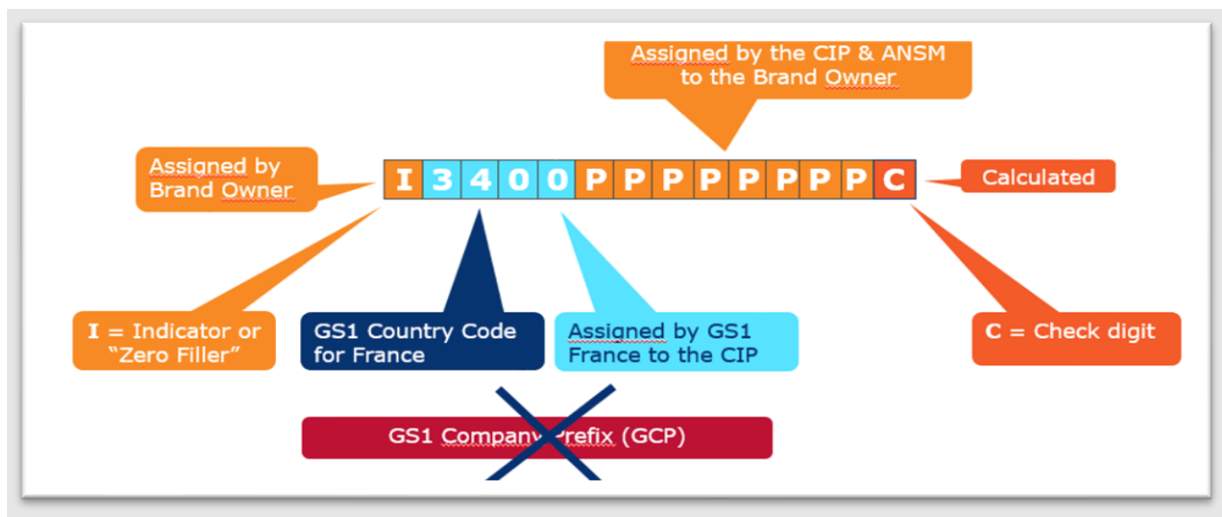
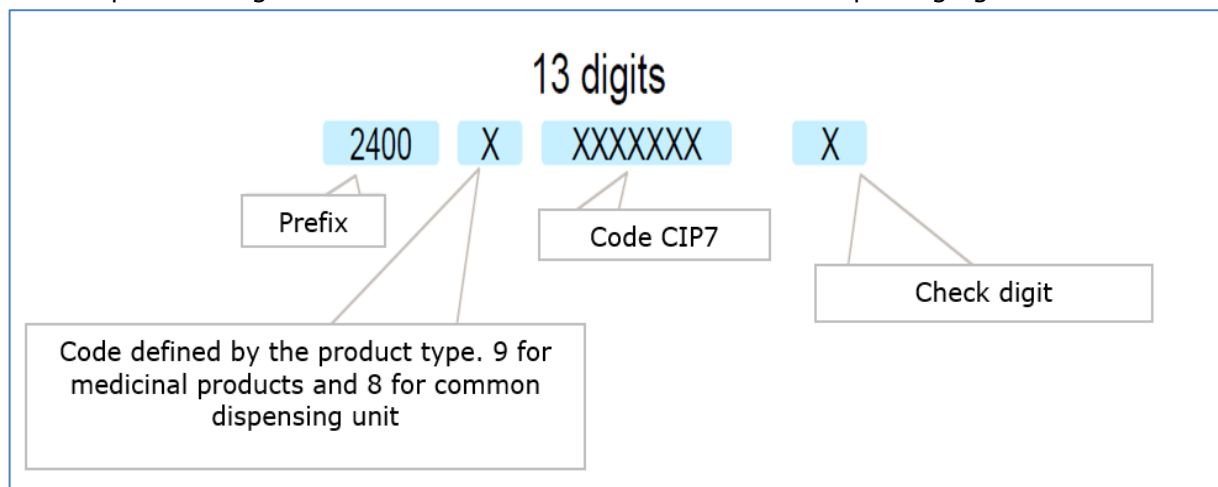


Figure 2: National Trade Item Number (NTIN): CIP code into the structure of a GTIN, creating an NTIN.

## The proposal to transition to national standards based on the CIP code.

The CIP code (see Figure 3) proposed is different from the current NTIN used for the French Market as the proposed "CIP code" would not be embedded into a GS1 key. This national code will only be accepted in France for specific usage and will not allow the use of multimarket packaging.



**Figure 3:** CIP code according to the description given in the pre-read for the assessment of the long-term solution.

As described above, the proposed new CIP code looks like but is not exactly the same as the current NTIN. The main differences can be summarised as follows:

Encoding of GS1 identifiers	Encoding of the proposed CIP code
A leading Function One character - which by GS1 definition and ISO/IEC standardisation - tells the scanning system when it is a GS1 DataMatrix and that GS1 decoding rules must be used for the data elements that follow	The proposed CIP code will be encoded into a generic ISO/IEC Data Matrix, meaning a new, specific data management system. The proposed CIP code does not contain certain characters that are standardised for use in a GS1 formatted data string. Non GS1-standardised data elements cannot be encoded with GS1 AIs in a DataMatrix. New online printing, verification, scanning, decoding, processing systems, etc will be needed.
AI (01) (AI : Application Identifier) at the beginning of the NTIN: which by GS1 definition and ISO/IEC standardisation tells the scanning / decoding system the following characters represent a GTIN or NTIN (i.e., product code).	1P as a data delimiter ("AI" is only used in the GS1 syntax) at the beginning of the CIP code (the new CIP code will be encoded with a leading zero): which should* tell the scanning / decoding system the following characters represent a CIP code (i.e., product code).
AI (17) at the beginning of the Expiration date: which by GS1 definition and ISO/IEC standardisation tells the scanning / decoding system the following characters represent an expiration date.	9D as the data delimiter at the beginning of the expiration date: which should* tell the scanning / decoding system the following characters represent an expiration date.
AI (10) at the beginning of the batch/lot number: which by GS1 definition and ISO/IEC standardisation tells the scanning / decoding system the following characters represent a batch/lot number.	1T as the data delimiter at the beginning of the batch/lot number: which should* tell the scanning / decoding system the following characters represent a batch/lot number.
AI (21) at the beginning of the Serial number: which by GS1 definition and ISO/IEC standardisation tells the scanning / decoding	S as the data delimiter at the beginning of the serial number: which should* tell the scanning /

system the following characters represent a serial number	decoding system the following characters represent a serial number.
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\* the CIP syntax is not (yet) registered/standardised by ISO/IEC standardisation and can not be decoded.

## Potential impact of the implementation of a global vs. national system for codification of medicinal products.

The **labels and packaging of medicinal products supplied to France will need to be revised** in order to carry the generic ISO Data Matrix (Figure 4) encoding the CIP code and other data attributes. The GS1 DataMatrix will continue to be used in other EU countries (Figure 5).



1PVIP0240000000013S1234ABCD1TABCD12349D20231225

General symbol / data errors found - Contact your GS1 Me...

Mandatory elements in the current scanning environment  
The following AIs are required in the current scanning environment: (01)

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ISO/IEC Data Matrix DOES NOT MEET GS1 STANDARD >

Decode:  
jd11PVIP0240000000013S1234ABCD1TABCD12349D20231225

Errors found within the barcode symbol - Contact your GS1 Member Organization for assistance

Barcode symbol not compatible with selected scanning environment - Contact your GS1 Member Organization for assistance

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1PVIP0240000000013S1234ABCD1TABCD12349D20231225

Encoded data is not compatible with the scanning environment  
Encoded data is not compatible with the barcode symbol type

Figure 4



(01)03400935974419  
(17)141122  
(10)NY2006  
(21)19283748

GS1 DataMatrix MEETS GS1 STANDARD >

Decode:  
jd201034009359744191714112210NY20062119283748

GTIN  
(01) 03400935974419

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USE BY OR EXPIRY  
(17) 141122

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BATCH/LOT  
(10) NY2006

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SERIAL  
(21) 19283748

Figure 5

As a result, **any existing scanning / decoding / processing system will not be able to identify and automatically interpret the data elements within the Data Matrix.** Without custom upgrades, systems used by hospitals, pharmacies, and all other supply chain actors will not be able to process and use these non-standard barcode symbols. Such a change will **not only affect the manufacturers but the entire supply chain, and more importantly, the pharmacies and hospitals**, which are already delayed in implementing the EU FMD. This can ultimately lead to an increased risk for medication errors and for patient safety.





Beyond the packaging and data management systems changes, the implementation of a national coding system for medicinal products in France, as currently proposed, will **not allow multi-market packs** as the encoded data will only be relevant in the French national system. The French national system will **not be interoperable with other systems implemented in the EU**, which are based on global standards. On this point, it is important to note that the proposed national coding system in France is different from the hybrid system implemented in Germany, in particular because the GS1 standards are allowed and implemented for multi-market packs in Germany. This lack of interoperability can be considered a **barrier to trade across EU countries and the world**.

In light of the current discussions about **medicinal products shortages, pandemic preparedness, and IDMP** in the EU and worldwide, adding complexity and costs for the implementation of a non-interoperable national coding system will **potentially undermine the access to medicinal products in France**.

This will also **impact the competitiveness of the local industry**, as France would be the one of only few countries<sup>5</sup> in the world with a national coding system for medicinal products (Figure 6).

It should be further noted that distributors/wholesalers, **retail pharmacies and hospitals will nonetheless have to implement GS1 identification standards** as they will trade other products, such as para-pharmaceuticals, cosmetics, medical devices and more.

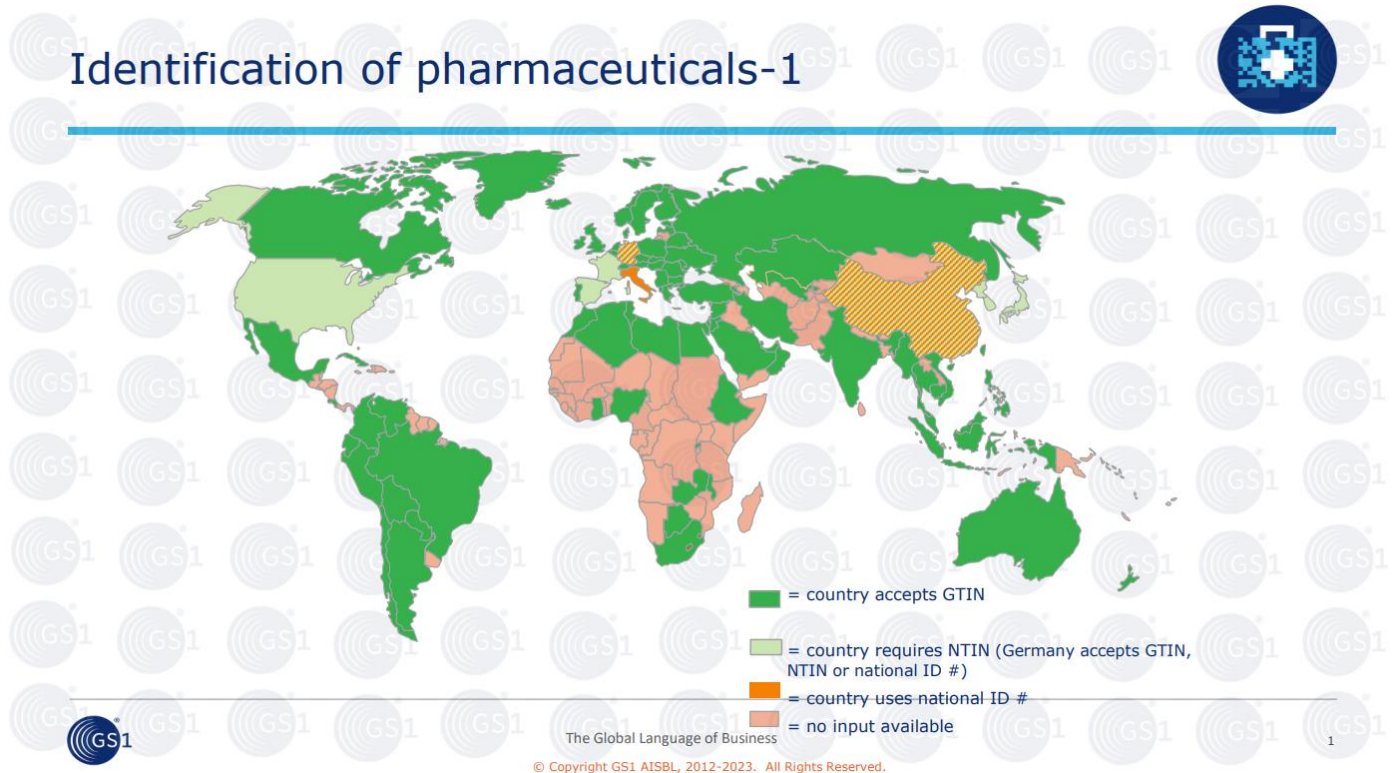


Figure 6

## Conclusion

Implementing the proposed national approach, would result in change in the packaging artwork, in the data management systems and in the software used to read and process encoded data. This would increase complexity and costs, and will impact all supply chain stakeholders – suppliers, distributors,

<sup>5</sup> NB: Italy has until 2025 to implement the EU FMD

hospitals and pharmacies. This would undermine the interoperability within the French system and between the French system and the other EU systems, as well as endanger access to medicinal products in France and competitiveness of the local industry.

