Recommendations on a harmonised implementation of the EU Falsified Medicines Directive using GS1 standards

Executive Summary

The EU Falsified Medicines Directive 2011/62/EU (FMD) and the supplementing Commission Delegated Regulation 2016/161 require the interoperability of product verification repositories across Europe. A harmonised coding structure across countries is the key to achieve this goal. For the identification of pharmaceutical products, the large majority of EU member states currently encodes the GS1 Global Trade Item Number (GTIN) in a linear barcode. GS1 recommends that these member states transition to the GS1 DataMatrix containing four lines of coding (GTIN for the product code, Serial Number, Batch Number, and Expiry Date) and – even though permitted by the FMD – refrain from adding a national number to the code since their usage unnecessarily increases complexity and costs to the supply of products.

For those countries 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 that member states allow the use of Option 1 or 2 to implement the FMD. 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, Option 3 can be used. The following options are in descending order of preference, with Option 1 being the most preferred.

1. Replace national number with a GTIN for both supply chain and reimbursement purposes (Option 1). This is the most efficient and effective way for all stakeholders to identify products and therefore the recommended option.
2. If a national number is to be kept, 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 (Option 2).
3. If necessary, GTIN and national number – i.e. National Health Reimbursement Number (NHRN) - can both be encoded in the GS1 DataMatrix (Option 3), however this is sub-optimal as it requires larger barcodes. Therefore, GS1 Healthcare only recommends this as a migration path to Option 1 or 2.

GS1 Healthcare – representing all their members – calls on the respective national authorities to collaborate with local stakeholders in order to establish clear and explicit guidance for the usage of the GTIN plus the additional data elements for expiry date, lot and serial number as the ideal solution to ensure interoperability across the EU.

The Global Language of Business

Recommendations on a harmonised implementation of the EU Falsified Medicines Directive using GS1 standards

Purpose

This paper provides recommendations on the implementation of the FMD requirements for harmonised identification of pharmaceutical products in Europe using GS1 standards. The following aspects are explored: different coding structures of the unique identifiers, the use of national numbers in certain EU member states, standards used and implication on multi-market packs.

The EU Falsified Medicines Directive

The ultimate goal of the EU Falsified Medicines Directive (FMD) is to prevent falsified medicines entering the legal supply chain and reaching patients. The FMD requires medicinal products subject to prescription to bear safety features, consisting of a Unique Identifier (i.e. Product Code, Lot, Expiry, Serial Number, and National Number, if required) and an Anti-Tampering Device (ATD). As this paper will illustrate, the product code can be presented in several varying forms. Due to legacy legislation and practices, there is currently a need for "national" identification numbers for specific purposes in a few EU member states. The EU FMD explicitly calls for a harmonised approach to be developed across Europe in order to ensure the interoperability of the national identification systems. The FMD and the relevant EU Commission Delegated Regulation allow use of a national reimbursement number or national identification number in the unique identifier but clearly mentions it as an optional component.
The EU FMD also states that only one single two-dimensional barcode carrying the unique identifier should be applied on the packaging[1] of pharmaceutical products for the purpose of authentication and verification. This is strongly supported by many of the stakeholders who see issues in quick and easy usage if multiple barcodes are printed on a package.

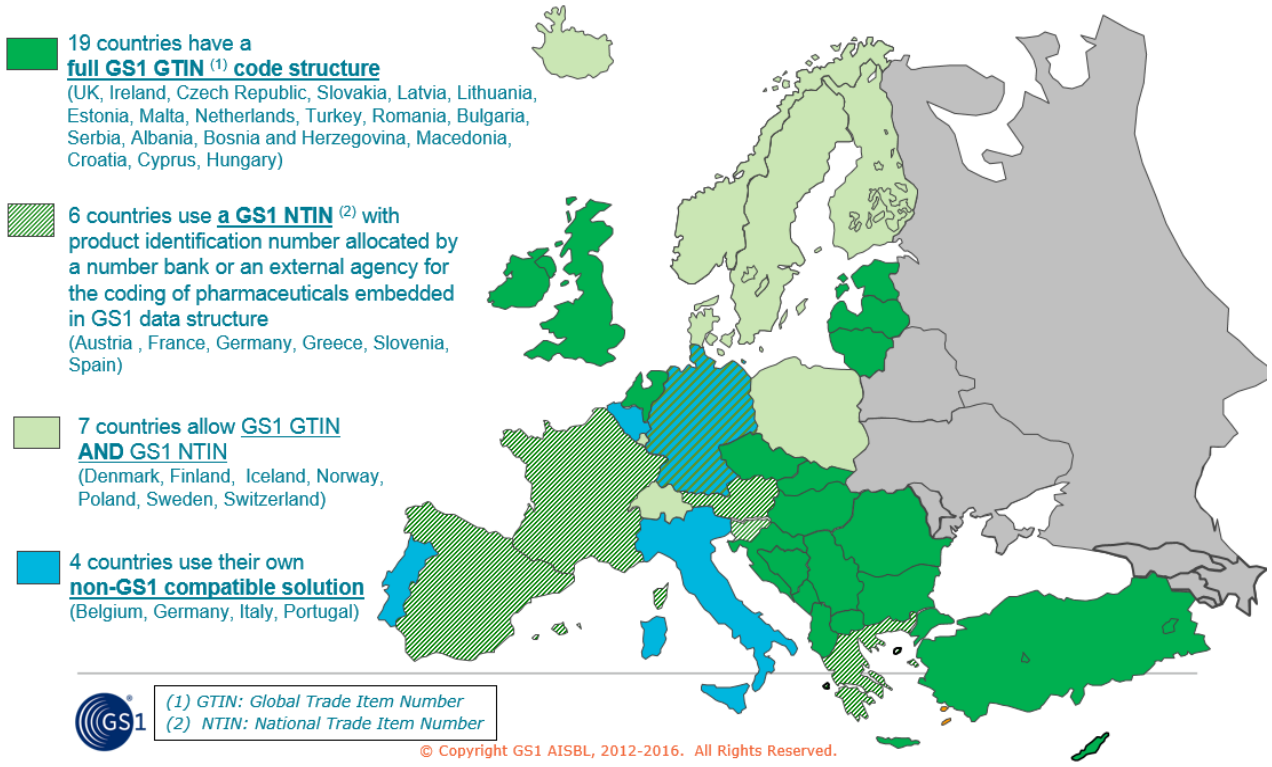
Problem Statement

For those countries that are using a GTIN today, the path forward to implement the FMD is clear as these countries should keep the GTIN as product code and utilise four lines of printing. However, for those using or contemplating the use of national numbers the path forward is less straight forward and needs to be defined.

The Current Status of Coding in Europe

The figure below illustrates the existing landscape across Europe for product identification. As noted there are two main methods in use based on GS1 compatible solutions today, GTIN and NTIN. In some countries, both are used while in others, a non-GS1 compatible solution is being used.

[1] Article 9 of the EU Commission Delegated Regulation 2016/161



Harmonizing Using A Global Approach

Countries having a global approach use a GTIN for both product identification and reimbursement purposes which assures harmonisation of the unique identifier across the EU as required by the EU FMD (Option 1). This also facilitates the sharing of joint packages in multiple EU countries, which is common practice today and should be maintained also after the implementation of the FMD.

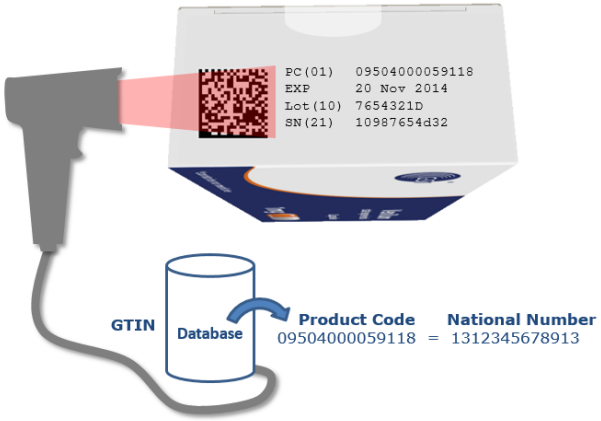
If a national number needs to be available at the point of dispensing, it can be an attribute to the GTIN within an associated database record (Option 2). This option avoids adding data overhead to the label and the GS1 DataMatrix, while – although adding complexity compared to Option 1 – still enabling multi-market packaging.

Alternatively the national number can be associated with the GTIN within the GS1 DataMatrix by use of a GS1 Application Identifier (AI) specific to the country requesting a national number i.e. the NHRN (Option 3). This option is not recommended by GS1 as it adds complexity and data content to the GS1 DataMatrix. But this option can be used in member states where the national number must be applied on the packaging. It will still enable multi-market packaging in markets where this approach is accepted.

The least globally compatible solution is to embed the national number into a so-called NTIN instead of using a GTIN . The use of an NTIN is not recommended by GS1 and should only be considered where all other alternatives, e.g. the use of a GTIN alone or a GTIN with NHRN, have been excluded. This option may only be accepted in single or specific markets and will considerably limit the use of multi-market packaging.
Clarification is often sought regarding the combined use of an NTIN and NHRN. This configuration is not allowed within GS1 standards.

Option 1 - Recommended

Option 2 - Recommended



Option 3 – required in some cases

The product code line is part of the artwork rather than printed on line.
Printing 5 lines of text at a readable point size adds technical constraints on the production lines.

These illustrations are examples of how Human Readable Interpretation (HRI) and other regulatory required text on a pack ("Non-HRI Text") can be combined to make efficient use of space. Refer to GS1 General Specifications Sections 4.14 *Human readable interpretation (HRI) rules* and 4.14.1 *Healthcare human readable interpretation rules* for details.

Since their introduction in retail, GTINs have saved industry billions of Euros in supply chain efficiencies through harmonised interoperable processes. GS1 standards are increasingly used to achieve similar savings within the Healthcare sector[2]. At the same time they are also helping to support healthcare providers in providing safer care and even to gain benefits in terms of clinical management. Use of the 'pure' GTIN as the product code to meet the requirements of the FMD can be leveraged to realise these benefits.
It is important to understand that the possibility to add a national number in the unique identifier has only been included to facilitate a quick implementation of the EU FMD requirements in countries, where this national number is today deeply embedded in their systems. The Nordic countries are in the process of transitioning to the use of a GTIN (instead of an NTIN). The Slovenia government has also stated they will move to the GTIN with the implementation of the FMD in 2019.

Recommendations

In order to comply with the interoperability requirements of the EU Falsified Medicines Directive, GS1 Healthcare strongly recommends use of a GTIN as the product code for both supply chain and reimbursement purposes (Option 1), and where this is not possible that Option 2 is implemented as an alternative. These two options are recommended by GS1 as they provide the most efficient ways for all stakeholders to identify products and enables flexibility when working with multi-market packs. Therefore, national competent authorities should not require the inclusion of a national number in the unique identifier nor its encoding in the GS1 DataMatrix.

GS1 Healthcare and its global members invite the respective national authorities to liaise with local stakeholders to establish clear and explicit guidance on the identifier to be used to implement the EU FMD in their country and to take into account the current use of GTINs in most of the EU member states in their decision making.

Terminology

AI	Abbreviation for "Application Identifier"
Application Identifier	The field of two or more digits at the beginning of an Element String that uniquely defines its format and meaning
Global Trade Item Number (GTIN)	The GS1 Identification Key used to identify trade items. The key comprises a GS1 Company Prefix, an Item Reference and Check Digit. Irrespective of where a product is made or sold, the GS1 Company Prefix can be allocated by any GS1 local office.
GTIN	Abbreviation for "Global Trade Item Number"

[2] McKinsey report "Strength in unity: the promise of global standards in healthcare", October 2012

Multi-Market pack	A product which is designed to be supplied and used in more than one country
National Healthcare Reimbursement Number (NHRN)	National and/or regional identification number used on pharmaceutical and/or medical devices where required by national or regional regulatory organisations for product registration purposes and/or for the management of Healthcare provider reimbursement
National Trade Item Number (NTIN)	A coding scheme, administered in the Healthcare sector by a national organisation for which a GS1 Prefix has been issued to permit its uniqueness within the GTIN pool but without assurance of full compatibility with GTIN functionality. The result is a product identification number assigned by a third party (not the brand owner or manufacturer).
NHRN	Abbreviation for "National Healthcare Reimbursement Number"
NTIN	Abbreviation for "National Trade Item Number"

References

Current status of coding across European countries:
GS1 Healthcare discussion paper on facilitating the implementation of the EU Falsified Medicines Directive with GS1 standards
http://www.gs1.org/docs/healthcare/GS1_Global_FM_%20Readines_%20Paper.pdf

Product identification options for medicinal products:
GS1 Healthcare discussion paper – Product Identification in Healthcare
http://www.gs1.org/sites/default/files/docs/healthcare/position-papers/20100819_gtin-ntin-nhrn_option_evaluation.pdf

Identification and marking of multi-market packs:
GS1 Healthcare - Discussion paper on multi-market packs for pharmaceutical products
http://www.gs1.org/docs/healthcare/20140319_Discussion_Pape_%20Multi-Market_Pack_Guideline.pdf