GS1 healthcare Discussion paper on facilitating the implementation of the EU Falsified Medicines Directive with GS1 Standards

Purpose

The purpose of this paper is to facilitate the discussions for a harmonised implementation of the EU Falsified Medicines Directive using global standards and moving away from national coding systems.

EU legal framework on pharmaceutical traceability

The EU has a strong legal framework for the licensing, manufacturing and distribution of medicines. At the end of the distribution chain, only licensed pharmacies and approved retailers are allowed to offer medicines for sale, including the legitimate sale via the internet.
In July 2011, the EU strengthened the protection of patients by adopting a new Directive on falsified medicines (FMD)[1].

The European Commission defines 'Falsified medicinal product' as

"Any medicinal product with a false representation of:

(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(c) its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights."

The ultimate goal of this Directive is to prevent falsified medicines entering the legal supply chain and reaching patients. It introduces harmonised safety features and strengthened control measures across Europe.
In particular, the FMD is including requirements that medicinal products subject to prescription shall bear safety features. A mandatory authenticity feature will be printed on or attached to the outer packaging of the medicines.

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:en:pdf

While the modalities are still to be defined, the assumption is that this feature will be entered or checked into a database by the manufacturer, and checked out when dispensed by a pharmacy. The Delegated Acts will provide more detailed requirements on this capability when they are published during 2014. The requirements will have to be implemented by healthcare supply chain actors in the EU Member States by 2017[2].

GS1 traceability standards in Healthcare

GS1 Traceability Standards provide a complete set of standards for implementing traceability to enable full actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale, point of dispense or point-of-care and to ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.
GS1 standards are ISO-compliant[3] and likewise ISO standards are a mainstay of the references within GS1 documents.

As background, the GS1 Global Trade Item Number (GTIN) is the foundation of the GS1 System (formerly EAN/UCC System). The GS1 GTIN encoded in a GS1 DataMatrix together with an expiry date, a lot/batch number and a serial number, provides the basis for unambiguous identification of pharmaceutical products globally and enables traceability at pack level.

In some countries due to history, national numbers (such as national reimbursement numbers) have been embedded into the structure of a GS1 GTIN which then became a GS1 National Trade Identification Number (NTIN). As NTIN's are allocated from the GTIN number pool they can be used by any market which uses GTINs but only one will be able to utilise the embedded national number. The GS1 NTIN can also be encoded in a GS1 DataMatrix with an expiry date, a lot/batch number and a serial number..

[2] Apart from MS with existing measures (BE, GR, IT), for which the deadline will be 2023
[3] http://www.gs1.org/docs/gs1_iso_brochure.pdf

Implementation of GS1 standards for pharmaceutical traceability in the EU

EU Member State	GS1 standards		National	Note
	GTIN	NTIN		
Austria		√		
Belgium			√	Could move to using GS1 standards through one of the methods described later in this paper
Bulgaria	√			
Croatia	√			
Cyprus	√			
Czech Republic	√			
Denmark	√	√		GTIN is the preferred option but NTIN are accepted
Estonia	√			
Finland	√	√		GTIN is the preferred option but NTIN are accepted
France		√		
Greece		√		
Germany		√	√	GS1 NTIN is in place for Germany and would allow the PZN to be captured in a GS1 DataMatrix
Hungary	√			
Ireland	√			
Italy			√	Could move to using GS1 standards through one of the methods described later in this paper
Latvia	√			
Lithuania	√			
Luxembourg	√	√	√	Belgium national number is also used in Luxembourg
Malta	√			
Netherlands	√			
Poland	√	√		
Portugal			√	Could move to using GS1 standards through one of the methods described later in this paper
Romania	√			
Slovakia	√			
Slovenia		√		
Spain		√		
Sweden	√	√		GTIN is the preferred option but NTIN are accepted
United Kingdom	√			

Conclusion

There is currently a need for national numbers for specific purposes in some countries. However, there is also a need for a harmonised approach to be developed across Europe, using global standards to efficiently address the issues surrounding falsified medicines and to enable cross-border traceability. To place both these on the pack would require two separate bar codes, one for the national number and the other for the GTIN; this is confusing and, error prone, it requires large amount of space on packs.

As the pharmaceutical industry becomes more global, managing the labelling and packaging in as many as 28 countries in Europe becomes more and more challenging for manufacturers. Utilising a GS1 GTIN in the different EU countries would make it possible to supply multi-country packages.

In addition, the overview of the implementation of GS1 standards provided in this Discussion Paper emphasises that the large majority of EU Member States are using GS1 GTIN or GS1 NTIN today, and are therefore able to implement the requirements of the FMD within a short time frame when the database to hold the information on the safety feature is prepared.

In order to facilitate the development of a harmonized system for pharmaceuticals identification, GS1 has created a standard allowing national numbers to be utilised within the GS1 standards. Including the national number in an Application Identifier allows holding a GTIN and national number in the same bar code so that both can be captured with a single scan.

The following list of options has been developed with the Healthcare sector in order to move from the use of national number in a particular country toward the use of global identification numbers[4] :

- GTINs (Global Trade Item Number) for supply chain and reimbursement purposes *(Option 1)*. This is the most effective way to ensure traceability beyond the countries.
- In case of an existing system of NHRNs (National Health Reimbursement Numbers), GTINs can be cross-referenced to the NHRN in a database *(Option 2)*.
- GTIN and NHRN can also both be encoded in one bar code *(Option 3)*, but that is less optimal than the first and second option as it requires larger bar codes and adds complexity for cross-border trade and interoperability. This is recommended

[4] For more information : http://www.gs1.org/docs/healthcare/20100819_GTIN-NTIN-NHRN_Option_Evaluation.pdf

as a migration path to Options 1 or 2 and would require the creation of an NHRN application identifier for the specific national number (following a GS1 established process).

- The NHRN can also be embedded in the GTIN, creating a NTIN (National Trade Item Number) *(Option 4)*, but this is sub-optimal as by definition, it prohibits reciprocity of packaging because the country using them typically does not permit GTINs or NTINs from other countries, so traceability across borders is more difficult and multi-country packaging more restricted.

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About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.