Public consultation on the European Commission's concept paper in preparation for the delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification

GS1 in Europe/GS1 Healthcare Submission to the public consultation

April 2012

Introduction:

GS1 Healthcare welcomes the opportunity to provide input to the European Commission's concept paper dated 18 November 2011 submitted for public consultation in preparation for the delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification as required by Directive 2011/62/EU.

We applaud the European Commission and the European Parliament for its ongoing commitment to increase the security of the pharmaceutical supply chain and prevent the entry into the legal supply chain of falsified medicinal products. The GS1 Healthcare user group fully supports this endeavor.

Executive summary:

As the European Commission moves forward, GS1 Healthcare recommends a harmonised approach across the European Union, and even worldwide. EU Member States may have existing, diverging requirements for machine-readable information for product registration and reimbursement purposes, but product identification for authentication/verification purposes should be unique and aligned across Europe.

In particular, we recommend that the European Commission adopts GS1 Standards (as other countries have), providing a framework to fulfil the needs of various applications, including authentication/verification as required by Directive 2011/62/EU.

The vast majority of countries in the European Union already use GS1 Standards, across many business sectors, and we firmly believe that there are significant benefits to the use of a single global standard across Europe. However, GS1 Healthcare recognises there are a few Member States currently using national product identification numbers but GS1 Standards can

accommodate these national numbers to allow the time necessary for the harmonisation process to occur.

We therefore favour setting a framework for the industry which will allow it to move towards the use of GS1 Standards across the European Union. This could be achieved by mandating that all systems must be able to use GS1 Standards. We believe that the majority of Member States would then adopt the GS1 Standards immediately. For the few that cannot achieve this immediately, they would have the ability to adopt a system which uses both GS1 and national numbers, and facilitates a migration to GS1 Standards when appropriate. A deadline for full adoption to GS1 Standards should be set, and we suggest 2022 in alignment with the requirement for the final market compliance deadline.

GS1 Healthcare also recommends not over-specifying technology and tools. Instead, we encourage the European Commission to adopt a comprehensive, global system of standards that provides the necessary framework.

Background: About GS1, GS1 in Europe and GS1 Healthcare

GS1 is a neutral, not-for-profit organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains.

GS1 in Europe is a collaboration of 45 GS1 member organisations and leads the creation and implementation of harmonised, user-driven solutions for improving the supply and demand chain of European companies.

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.
Sixty six leading organisations actively participate and support the global Healthcare user group and over 700 organisations are engaged in local Healthcare user groups worldwide.

Serialisation

Even though it seems that there will not be one solution against counterfeiting, industries and academia see mass-serialisation among the most promising single countermeasure.

The definition of serialisation used in GS1 is “the unique identification of each one in a large set of entities”. In other words it refers to identification of an instance rather than a ‘class’. The two

should also not be mixed into one identification number, but rather combine the (static) identification key for the ‘class’ with a (dynamic) attribute including the serial number for the specific unit.

The Global Trade Item Number (GTIN) is the foundation of the GS1 System for uniquely identifying trade items, which includes “products and services upon which there is a need to retrieve pre-defined information about that item; this product or service may be priced, ordered, or invoiced at any point in the supply chain”. The identification key is comprised of a GS1 Company Prefix followed by an Item Reference Number assigned by the brand owner, and Check Digit.

GTINs provide unique product identification worldwide.

The serial number of a specific unit/instance of that product/trade item is then linked to the GTIN in a different field as an ‘attribute’. The GS1 General Specifications detail how GS1 Application Identifiers (AIs) are encoded into one data carrier.

It is not the serial number by itself that provides unique identification of a specific unit/instance, but a serialised GTIN, that is the combination of the GTIN and the serial number.

Example of a serialised GTIN:

GTIN: (01)09876543210982
Batch: (10)A1C2E3G4I5
Expiry: (17)140531
S/N: (21)12345AZRQF1234567890

Data carrier: GS1 DataMatrix
Product Identification Number: GTIN (Global Trade Item Number)
Attribute for Lot Number AI(10) and Expiry Date AI(17)
Application Identifier AI(21): Attribute for Serial Number

In the case where the party assigning the GTIN is providing the serialisation, management of the serial number to ensure the uniqueness required by the GS1 System is their responsibility. But the party assigning the GTIN is not necessarily the same as the party assigning the serial number to some instances of the item. Industry standards on how to assign the serial number need to ensure uniqueness, regardless of who assigns them.

Need for harmonisation and standards

To ensure the effective verification of serial numbers in the European Union, serial numbers have to be unique across manufacturers and across countries.

It is therefore critical that serialised GTINs are different from one Member State to another, and even for countries outside of the European Union. Global pharmaceutical manufacturers operating in a multitude of countries work in a global environment where products move across borders.

Stakeholders looking into serialising trade items for specific applications may consider using proprietary solutions for the coding conventions and/or the data carrier representation of the serial numbers. Although this approach may seem adequate in the short term, it will usually lead to problems in the longer term. As a matter of fact, closed loop applications often become open loop applications after some time. It is therefore strongly advised to use a standard data content and data carrier approach for serialisation right from the start.

Global standards are essential in today's complex markets where supply chain lines are blurring and channels of distribution for various sectors are overlapping.

The Consumer Goods sector has adopted the GS1 System of Standards for over 30 years. Today, over 1 million companies are members of one of the 111 GS1 Member Organisations worldwide and GS1 Standards enable over 6 billion business transactions per day.

Since 2005, GS1 has worked with the Healthcare community to create such a neutral forum for all Healthcare supply chain stakeholders and to develop and enhance the GS1 System of Standards to meet Healthcare specific needs. Today, the GS1 Standard for product identification - GTIN or Global Trade Item Number - has already been chosen to uniquely identify pharmaceutical products in 65 countries worldwide. Efforts by Healthcare providers and regulators to achieve even broader global adoption are on-going. Most pharmaceutical manufacturers are also leveraging the standards to efficiently manage their supply chains and meet their customer needs and requests. Many hospital groups across the world now require or will in the very near future (end of 2012) the GTIN as part of their tender processes (Canada, England, Hong Kong, Netherlands, Spain, USA). Any restriction on being able to use GS1 would mean substantial additional costs and change of processes and systems already in place today across Europe.

One has also to consider that identification of products also plays a major role in other processes to improve patient safety, for example patient bedside wristband scanning. GS1 Healthcare is in the process of developing a global standard for unit-dose marking. It will be important for

manufacturers when implementing that level of identification that they can keep the logical relationship between the product identifiers on all packaging levels.

Also, for other important processes like robotic dispensing, electronic healthcare records, product recalls, adverse event reporting, clinical management, inventory management and supply chain efficiency, a standardised product identifier will play an important role. In Europe patients are traveling today from one country to another and cross border treatment is permitted (notably under the EU Directive on patients' rights in cross-border healthcare) – it will be necessary as a consequence to have standards implemented which accommodate this and are in use across Europe and, in the future, the world.

A. CONSULTATION TOPIC N° 1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Consultation item n°1: Leaving the choice of the technical specification to the individual manufacturer or Harmonisation through regulation
Where do you see the benefits and disadvantages of each policy option?

GS1 Healthcare recommends establishing harmonisation through regulation based on global standards. GS1 Standards provide a flexible, global framework allowing the pharmaceutical manufacturer to create the serial numbers within the boundaries of that global standard.

This will avoid lengthy debates in the industry on the way forward and avoid delays in the implementation.

Consultation item n°2: Manufacturer product code and pack number
Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.

GS1 Healthcare recommends not regulating the composition and allocation of serial numbers, but allowing the manufacturer to manage serialisation based on global standards. Manufacturers should be allowed to compose their serial numbers in different ways depending on the needs and circumstances, but all within a framework of global standards to ensure compatibility. The GS1 General Specifications detail how to encode the product identification number (GTIN) and the serial number into the data carrier.

Relevant needs and circumstances include:

- Serial numbers will not be used in a vacuum. Product identification through bar codes is already used for other applications today, including supply chain management and reimbursement processes.
- Most pharmaceutical manufacturers have already implemented GS1 Standards in their production processes and packaging lines, and can efficiently now add serial numbers to their GTIN range.
- Manufacturers have different product portfolios, with differences in risk profiles.

<u>Consultation item n°3:</u> Additional product information: batch number & expiry date.
Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2? Please comment.

GS1 Healthcare recommends not regulating the encoding of the batch number and expiry date in the data carrier, but allowing the manufacturer to manage encoding of batch number and expiry date based on GS1 global standards.

For the purpose of verification and traceability, only the product identification number and serial number are necessary.

Correctly identifying product and managing out-of-date stock is another significant challenge for the Healthcare sector in Europe. Batch number and expiry date should always be on the package as human-readable information for patient safety and supply chain management purposes. Machine-readable information on batch number and expiry date also helps to address this challenge and makes the processes automatic, accurate and easier to handle.

There is a great deal of demand to have machine-readable information on batch number and expiry date. Adding a second bar code with this information should be avoided. GS1 Standards show a way to carry that information in the same bar code in standardised way that will be much easier for manufacturers to implement, and the end users to scan.

Bar codes can include a lot of information, and the batch number and expiry date can also be included as another 'attribute' (data element). Standards allow manufacturers to consistently and efficiently encode the proper information and allow IT systems across the supply chain to read and understand all the information.

However, packaging constraints need to be considered. Requiring the batch number and expiry date to be encoded in the data carrier will increase the size of the bar code and make it more difficult for certain product packaging (pack size limitation). Always requiring encoding of the batch number and expiry date in the data carrier will also result in sub-optimal production and packaging processes. Manufacturers lose the flexibility on how to implement serialisation in the most efficient and effective manner. For example, it may be optimal for packaging to be pre-print, i.e. before the product is actually manufactured and assigned a batch number. Batch numbers are often only known shortly before the batch is produced, while a range of serial numbers can more easily be allocated to a certain packaging line.

Also the human-readable information needed on the package should be considered. If packaging size allows, human-readable information as well as the bar code with related information should be printed. If space is restricted it must be considered which information really needs to be

included to avoid misunderstandings/errors. Manufacturers should have the flexibility to choose the information which is most important for patient safety purposes. GS1 General Specifications detail recommendations on how to handle existing requirements for human-readable information. If new requirements emerge, the GS1 Standard development process can assess those.

Consultation item n°4: National reimbursement numbers.
Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.

Most EU Member States accept manufacturer's use of GTINs as product identification for reimbursement purposes. In 23 EU Member States, it is possible to use the product identification number (GTIN) and serial number for verification and reimbursement purposes.

Today only a few EU Member States require another number outside of the GTIN range for product identification in their reimbursement systems and shouldn't have to change their numbering systems for reimbursement purposes as a consequence of the Directive. GS1 Standards provide a framework to allow both the global GTIN and the national reimbursement number to be carried in one data carrier so that with a single scan multiple functions can be fulfilled. With both the GTIN and the national reimbursement number in the same bar code, the dispensing pharmacist only has to scan one bar code for verification, reimbursement and stock management.

GS1 Healthcare has outlined the advantages and disadvantages of both options in a position paper:http://www.gs1.org/docs/healthcare/20100819_GTIN-NTIN-HRN_Option_Evaluation.pdf
This position paper also describes the option to link the GTIN to the reimbursement number in a repository, whereby the supplier manages the linkage and ensures accuracy. Details on the standard for this can be found at http://www.gs1.org/docs/healthcare/GS1_NHRN.pdf

However, using national numbers for verification purposes, under the Directive adds risk, i.e., if the product identification numbers are not based on a global standard, they may not be globally unique even if nationally unique.

Consultation item n°5: Linear bar code, 2D bar code, RFID
Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts. What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example: costs for reading devices for the different carriers; costs for adapting packaging lines of medicines packaged for the EU market.

GS1 Healthcare recommends not to regulate which data carrier to used, but to allow the manufacturer to choose the optimal data carrier based on global standards. The GS1 General Specifications include all relevant data carriers and detail how and when to use them.

2D-bar codes (GS1 DataMatrix) allow for the encoding of a large amount of information to be stored in a small area, which makes them particularly relevant for the serialisation of pharmaceutical products considering the packaging constraints. Furthermore, they allow variable information (such as the serial number) to be marked at high production rates. GS1 position paper can be found at: http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf

However, camera-based scanners are needed to read 2-D bar codes, and most pharmacies do not have them yet. To facilitate the future adoption of GS1 DataMatrix, GS1 Healthcare in 2009 issued an investment recommendation investment in such scanners when replacing existing laser bar code scanners. Generally, camera-based scanners may have a slightly higher price point than laser scanners, but with less moving parts, they are more reliable than laser scanners, decreasing their total cost of ownership. They provide resolutions able to support image capture, allowing imaging of a product or an identification card, or even a document up to 21.6 x 28 cm (8"x11"). They are also compatible with scanning linear bar codes.

Radio Frequency Identification (RFID) also has distinct advantages, in particular as the technology doesn't require line of sight (reading/scanning). However, this is not an issue for the purpose of verifying the serial number at the dispensing point as the dispenser has line of sight when holding the package. Furthermore, because of its current cost of implementation, GS1 Healthcare considers RFID as an optional data carrier in addition to a bar code, rather than replacing the bar code at this point of time.

B. CONSULTATION TOPIC N° 2: MODALITIES FOR VERIFYING THE SAFETY FEATURES

Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered? How can these be addressed in this policy option?

Retail and hospital pharmacies are the prevalent points for dispensing medicinal products. However, other points of dispensing should be considered, including clinics and doctor's offices, nursing care facilities, online pharmacies and the home. As the need for verification of serial numbers will be less frequent at these points, widely available information communication technologies should be considered. Mobile devices such as a smart phone with a built-in camera can have an application to read the bar code and verify/check the serial number from the repository systems.

The GS1 System of Standards provides a framework to ensure interoperability and compatibility of such applications, in particular with regards to a consistent data structure of the serial number (serialised GTIN) and how to exchange data between the application and the repository systems. GS1 Electronic Product Code Information Services (EPCIS) is a set of standardised network interfaces and protocols for sharing supply chain data, creating a single way to capture and share information automatically.

Consultation Item n°.7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages?
Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point
Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors
Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors

Regarding the policy options, GS1 Healthcare recommends a standards-based approach to ensure interoperability and compatibility of processes and technologies across organisations and across borders. A foundational framework is needed that can be used by any organisation, large or small, and by any country in order to develop specific implementation guidelines or additional requirements.

The GS1 System of Standards was recently successfully used in the European Federation of Pharmaceutical Industry Associations (EFPIA) point of dispense pilot in Sweden. This pilot demonstrated the advantages of checking out the serialised GTIN prior to the product being dispensed to the patient; the final critical point to stop falsified medicines reaching the patient. Go to http://www.gs1.org/docs/healthcare/EFPIA_Product_Verification_Project_Report.pdf to obtain the pilot report.

We also recommend considering the implementation of GS1 Standards in other applications of traceability in the Healthcare supply chain. Healthcare organisations require consistent traceability solutions spanning the extended supply chain regardless of country, including:

- Product recall and withdrawal (notably to achieve a greater degree of precision, to demonstrate control, increase efficiency and reduce the cost of product recall or withdrawal)
- To comply with a trading or traceability partner's specifications
- Efficient logistics management
- Effective quality management

- To update patients Electronic Health Records with agreed traceability information, including caregiver identification which would assist hospitals improve the speed, efficiency and effectiveness of products recall.

There are numerous and an ever increasing number of case studies from around the world showing how the GS1 standard-based traceability systems can realise such benefits over and above point of dispense authentication. Go to: http://www.gs1.org/healthcare/library for case study examples.

A notable example is the successful implementation of GS1 Standards in the haemophilia medication traceability system in Ireland. The National Centre for Hereditary Coagulation Disorders (NCHCD) located at St James's Hospital, Dublin, manages patients with inherited and acquired bleeding disorders, of which many require intensive care/treatment, including expensive medication requiring specific cold chain handling. To ensure immediate product recalls, optimise stock management and save on wastage, a traceability system was implemented allocating GS1 identification numbers to each patient and location, and serialised GTINs to the medicinal products. This system facilitates the automatic linking and capture of data during the supply process, validating each step of the cold chain storage and delivery process in real-time, ensuring that the correct drug is prescribed to the right patient as well as automatically updating the stock management system so that patient consumption trends can be analysed. Product wastage due to failure of cold chain conditions or documentation issues has been eliminated. Interestingly, possibly because patients have confidence in the delivery method, €5 million worth of medication has been removed from the supply chain.

GS1 Healthcare work groups have already developed traceability standards and implementation guidelines, and the global and local Healthcare user groups are committed to continue to develop and enable the implementation of industry standards.

The GS1 Global Traceability Standard for Healthcare (GTSH[1]) is a process standard defining minimum requirements for all stakeholders, organisations and countries and corresponding GS1 Standards to be used in combination with information management tools. Physical flow of product should happen in parallel with the transmission of data about that product; and establishes the foundational traceability model as "One up, one down". In this model the buyer of the product, and recipient of the corresponding information, must know the supplier of the product (one up). The supplier of the product must also know the buyer and dispatch the physical product and information to them (one down).

In the long term the GS1 members Vision for Traceability in Healthcare is "full, end-to-end, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production to Point of Use". GS1 continues development of the system of standards to

enable achievement of this Vision, and thus enable traceability related processes in addition to authentication of a serialised identifier, such as:

- Tracking items (forward / downstream; production to use) and Tracing items (backward / upstream; from current location back to the producer) in real time to ensure Chain of Custody/Chain of Ownership has not been broken, for example as required by California ePedigree regulation and to assist in detection of counterfeit products entering the legitimate supply chain
- Use of the items' identification at the patient bedside to ensure the Patient Rights are achievable and avoid potential medical errors

1. http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf