PUBLIC CONSULTATION
IN PREPARATION OF A LEGAL PROPOSAL
TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE
KEY IDEAS FOR BETTER PROTECTION OF PATIENTS
AGAINST THE RISK OF COUNTERFEIT MEDICINES

Introduction

The Commission has published on 11 March 2008 the current consultation, and invites all interested parties to express their point of view regarding a set of propositions, which focus on combating counterfeited medicinal products being marketed in the European Union.

GS1, as a not for profit organisation, is grouping a large number of actors of the pharmaceutical supply chain, who wish to implement a set of standards which respond to the increased complexity of modern Healthcare and especially with the mission to enhance patient safety.

The propositions in the consultation are in summary welcomed by GS1 Healthcare's members. They see in many of the propositions the development of a framework, which addresses the fight against counterfeiting with technical, standard tools which respect market activities and competition, together with the scope to make the placement of counterfeited medicinal products (increasingly) more difficult.

Detailed comments to the proposals

As a standards organisation, GS1's mission is to represent its member's interest in the disposition of a unique standard responding to many market requirements, regardless of the region and regardless of the product segment. The following comments on the consultation are of two categories:

- GS1's users' comments
- GS1's standard tools as the recommended way to address the "key ideas for changes to EC legislation".

We will concentrate our comments to the § 4.1 (Medicinal products placed on the market), whilst the two other chapters will only have brief comments.

Chapter 4.1.1 *Subject all actors of the distribution chain to pharmaceutical legislation*

GS1's users' comments:

The pharmaceutical supply chain is very diverse across Europe. In some countries, transport companies have developed services which include pre-wholesale activities and very thin distribution, sometimes even direct to patients. In other countries, actors in the supply chain – as retail pharmacies (chains and free groupings) and other groupings of care givers (hospitals, laboratories, radiology institutes) have developed common purchasing activities with central warehousing.

We expect the definition of the exception to the proposed extension of obligations of wholesalers, to be precise enough to include all actors as illustrated above and to truly limit the exception to those on the market who have the direct contact with the patient and do not simultaneously trade medicinal products.

GS1's standard tools recommended by its users

As the consultation states in § 4.1.6, authorised wholesalers (and those parties underlying the same obligations) have to be found in a publicly accessible database. This requires a party identification key, whilst the authorisation(s) is/are attribute to this key and has its own rules.

The GS1 *Global Location Number [GLN]* is the appropriate key for this purpose; it provides global uniqueness and is already widely implemented for many purposes. This identification key is further used by the UN INCB (United Nations *International Narcotics Control Board*) for the control of the narcotic trade.

Chapter 4.1.2 *Tightening rules on inspections*

GS1's users' comments:

These propositions are the logical consequence of the previous paragraph.

Chapter 4.1.3 *Improving product integrity through a unique seal from the manufacturer to the retailer or wholesaler, using a risk-based approach, supported by a ban on repackaging*

GS1's users' comments:

GS1 Healthcare's user community has developed guidelines for the identification of medicinal and medical products; *Healthcare GTIN*[1] *Allocation Rules*. These guidelines include several considerations about the allocation of a new product identification key when trade items are modified in certain ways. This approach of the management of identification will be strengthening by the proposed rules, especially with the ban of repackaging by third parties other than the market authorisation holder and end-user (hospital, healthcare professionals, patient). In the case a hospital or a healthcare professional is re-conditioning the medication for a patient, the Healthcare GTIN Allocation Rules state that a new GTIN has to be allocated, as mentioned above; this implies/allows the full traceability management by this organisation

Chapter 4.1.4. *Centrally accessible record to facilitate traceability of batches throughout the distribution chain*

GS1's users' comments:

We understand the traceability by batch (§ 4.1.4) and the mass-serialisation (§ 4.1.5) as completing each other.

Traceability by batch (and the possibility to access batch records) is a request to secure the supply chain where the granularity at item level is technically not achievable at all levels of the healthcare supply chain with current technologies.

[1] Global Trade Item Number (www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf)

GS1's standard tools recommended by its users

Traceability at batch level is a process which GS1's user community has deployed in numerous markets. It is highly cost efficient. A distributor or wholesaler can capture automatically traceability information at the goods receipt and keep record of its deliveries from individual batches, as the scanning at the picking / delivery process is technically / due to volumes handled and time constraint not achievable.

Chapter 4.1.5. *Mass serialisation for pack-tracing and authenticity checks on a case-by-case basis*

GS1's users' comments:

Authenticity check at the delivery point as the ultimate step in the supply chain, allows enhancing safety in the medicinal product delivery. This requires mass serialisation of the medicinal products and should work in a similar way as the validity check for payments with credit cards. As this is a protection for the patient/consumer, it should also be possible to verify authenticity of their purchased medicinal product, by questioning a data pool with the product identity.

Securing the supply chain is conceived on new rules for manufacturers, distributors and wholesalers. It should also include a certification programme for the hospital and healthcare professionals (the exceptions listed in § 4.1.1) – possibly privately managed, but encouraged in the regulatory framework.

GS1's standard tools recommended by its users:

The GS1 standard provides the architecture for mass serialisation, for the documenting of data repositories and the retrieval of "events" (e.g. incoming / outgoing items) etc. This is built on the use of GS1 Identification Keys (see above: GTIN, GLN), standardised symbologies for automatic identification (GS1 DataMatrix) and communication standards (standardised EDI or XML messages).

Chapter 4.1.6. *Increasing transparency concerning authorised wholesalers through a Community database*

GS1's users' comments:

A Community database where market actors are identified and their valid or passed authorisations are to be found, contributes not only to market transparency, but to securing the supply chain.

GS1's standard tools recommended by its users:

See recommendations from chapter 4.1.1 regarding the need to identify the actors with a global identification key guarantying uniqueness of the identification regardless of the region and the market.

Chapter 4.2. *Tightening requirements for the import/export/transit (transhipment) of medicinal products*

GS1's users' comments:

GS1 users consider this set of propositions as contributing to better security, although the propositions are not in GS1's field of activities.

Chapter 4.3. *Tightening requirements for manufacture, placing on the market of active substances and inspections*

GS1's users' comments:

GS1 users consider this set of propositions as contributing to better security. They impact the "upstream traceability", which GS1's users in other market segments are addressing under the project "GUSI" (Global Upstream Supply Initiative).

Conclusions

Automatic identification and traceability system will enable verification and authentication of pharmaceuticals throughout the Healthcare supply chain. By harmonising around global standards, solutions can be implemented faster than if each market would individually mandate their own.

GS1 Standards are well suited to meet the specific needs of Healthcare. The GS1 global Healthcare user group welcomes most of the propositions made by the Commission in this consultation, as they prepare the framework for the deployment, Europe wide, of global standards which contribute to fight counterfeiting of medicinal products and reducing the risk of a wrong or unsafe medication for patients.

About GS1 and GS1 Healthcare

The GS1 global Healthcare User Group is a voluntary and open group formed by leading global pharmaceutical and medical devices companies, wholesalers, hospitals and trade associations from around the world. Its primary objective is to enhance patient safety worldwide through accurate and standardised product identification. The group is striving for global standards for automatic product identification and is currently working with a number of regulatory bodies. More information can be found at www.gs1.org/healthcare

The GS1 System of Standards is the most widely used identification numbering and data carrier system throughout the world. Over 1 million users across 145 countries and across more than 24 industry sectors have adopted what is today known as the GS1 System of Standards. It is recognised by organisations such as the International Standards Organisation (ISO), the American National Standards Institute (ANSI) and the European Committee for Standardisation (CEN).

The GS1 global Healthcare user group is working on developing global standards for the healthcare industry and their members have agreed on a roadmap for AIDC (Automatic Identification & Data Capture) Application Standards for Healthcare. They have further built a Traceability in Healthcare Work Team for the development of standard tools to meet traceability requirements on a global perspective, which includes the US Pedigree regulations and others, such as the future EU requirements.

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.

Pierre Georget

CEO GS1 France
President GS1 in Europe
2 rue Maurice Hartmann
92137 Issy les Moulineaux Cedex, France
T +33 140 955 423

E pierre.georget@gs1fr.org

Nicolas Florin

CEO GS1 Switzerland
Head Healthcare, GS1 in Europe
Laenggassstrasse 21
3012 Bern
T +41 32 621 31 14

E nicolas.florin@gs1.ch

Contact

Ulrike Kreysa

GS1 Global Office
Director Healthcare
Blue Tower, Avenue Louise 326, bte 10
1050 Brussels, Belgium
T +32 2 788 78 00
F+32 2 788 78 99
E ulrike.kreysa@gs1.org