



## Discussion paper on recent developments of the Russian system of goods labelling with identification means

### **Purpose**

*The purpose of this paper is to facilitate the discussions about the establishment of a globally harmonised system for traceability of pharmaceuticals within Russia, but also between Russia and other international trading partners, using GS1 global standards.*

*This will enable timely, less complex and more cost effective implementation for manufacturers who have already invested in implementing international traceability requirements based on global standards in around 70 countries around the globe. It will also enhance the competitiveness of Russian producers by reducing the complexity of production and cost of traceability and removing barriers to export of products to the great majority of countries already using GS1 standards for pharmaceutical traceability. It will reinforce Russia's commitment to patient safety based on globally traceable medicines.*

### **About GS1 Healthcare<sup>1</sup>**

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. GS1 Healthcare members include over 110 leading Healthcare organisations worldwide.

### **State of play: Russia's recent modifications of its system**

The Government of the Russian Federation is developing a system of goods labelling with identification for its market that could strongly impact pharmaceutical traceability in Russia. Indeed, the Government of the Russian Federation recently amended the Federal Law N°61-FL of April 12<sup>th</sup>, 2010 on drugs circulation, and approved a model for a unique product and package identification and labelling in Russia by the Resolution n°791 of April 28<sup>th</sup>, 2018.

### **Issue statement: foreseen impact on pharmaceutical traceability and infringement to the EEU Treaty**

Members of GS1 Healthcare are particularly concerned about the currently discussed propositions for revising the existing monitoring system by introducing cryptographic protection of package serial numbers and switching from the commonly used product identification based on UNISCAN GS1/RUS (i.e. GS1 Global Trade Item Number - GTIN) to a local isolated solution.

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<sup>1</sup> [www.gs1.org/healthcare](http://www.gs1.org/healthcare)



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This action could lead to a decrease in the ease of exporting pharmaceuticals and potential isolation of the domestic pharmaceutical industry within the Russia market.

This would also substantially increase the cost of creation and maintenance of the monitoring system, possibly resulting in a significant increase in prices for medicines and a reduction in their availability for the Russian population.

Moreover, this would not be compliant with article 30 of the Treaty on the Eurasian Economic Union, dated 29 May 2014, according to which the common market of medicines shall be based among others on “ensuring the uniformity of mandatory requirements for the quality, effectiveness and safety of circulation of medicines on the territory of the Union” and on the “adoption of common rules in the sphere of circulation of medicines”.

### **GS1 traceability standards in Healthcare**

GS1 Standards are a complete set of standards for implementing traceability to enable fully actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale, point of dispense or point-of-care. Implementation of these standards ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.

GS1 standards are ISO-compliant<sup>2</sup> 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 (in Russia UNISCAN GS1/RUS). Within the GS1 System, GTINs uniquely identify items that are traded across the supply chain, such as pharmaceuticals. In addition GS1 Application Identifiers (AIs) are used to communicate item-specific/production information in a barcode (e.g., batch/lot number, serial number, expiration date).

GS1 standards enable manufacturers, distributors and providers to share accurate, standardised and synchronised traceability data electronically.

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<sup>2</sup> <https://www.gs1.org/docs/GS1-and-ISO-06BD.pdf> see further CEN ISO TS 16791, which addresses Requirements for international machine-readable coding of medicinal product package identifiers



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In most countries today, the regulatory requirements for pharmaceuticals traceability are implemented using GS1 standards. In practice, the GS1 GTIN is encoded in a GS1 DataMatrix with an expiration date, a batch/lot number and a serial number (as additional AI's within the same barcode). This provides the basis for globally unambiguous identification of pharmaceuticals and builds a global and secure framework for a full traceability system across all packaging levels.

The examples below show the difference in size of a GS1 DataMatrix aligned with the global framework - *Example 1* - (ie. encoding the GTIN, Expiration date, batch/lot number and a serial number) compared to a GS1 DataMatrix based on the Russian requirements - *Example 2*. The increase in size is approximately 45%.



(01)09506000117843  
(17)201231  
(10)1234AB  
(21)5678634802537

*Example 1*



(01)09506000117843  
(21)5678634802537  
(91)A1B2  
(92)1234AB325448295672948  
5037820503859375057204004  
TR0385730505729830503036  
040264552834940572

*Example 2*

### Globally harmonised pharmaceutical traceability systems

To fight against counterfeiting, the traceability of pharmaceuticals is a key objective of regulators around the world. More and more regulators require the use of unique identifiers to be encoded into data carriers on the secondary packaging and linked to relevant information in a database. Increasingly, regulators are recommending or requiring the use of GS1 standards to implement these traceability requirements.

For example, GS1 standards are followed for drug coding referenced for use to comply with regulations from the U.S.A., Argentina, Turkey, Saudi Arabia, the United Kingdom, Europe, South Korea, Japan and India. Adopting requirements for a harmonised approach across countries, using global standards, enable these regulators to efficiently address the issues surrounding falsified medicines and to allow cross-border traceability.

If the Government of the Federation of Russia does not amend the Resolution n°791 accordingly, it will be one of the only countries across the world using a national coding system for pharmaceuticals. China has already experienced a similar situation with the implementation of requirements that were only valid for their local market. The challenges faced for implementation resulted in the current transition from a national Chinese system to the development of a traceability system based on global standards.





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As the pharmaceutical industry becomes more global, managing the labelling and packaging used in so many countries globally and having to adapt their processes to meet individual country requirements, becomes more and more challenging and will significantly impact the competitiveness of Russian manufacturers.

In addition, the limits of having a purely national system for drug traceability in turn limits the benefits relating to patient safety and supply chain security in an increasingly globalised context.

### **APEC moving towards alignment on Global Data Standards (GDS) for drugs integrity and supply chain security**

The APEC (Asia-Pacific Economic Cooperation) work group on track and trace systems for drugs (TTWG) is one of ten work groups working on the APEC Roadmap for Global Medical Product Integrity and Supply Chain Security.

Common themes and practices have emerged through the APEC dialogue and the TTWG have developed three key overarching recommendations. The third of these recommendations is the use of global data standards (GDS), such as GS1 standards, for implementation of the traceability system for drugs.

The APEC Committee on Trade and Investment (CTI) summary of the Third Senior Officials Meeting identifies the lack of common data standards for product verification and serialisation as the first barrier to trade in healthcare products and recommends addressing these barriers as a priority.

APEC Ministerial Meeting (AMM) statement in November 2017 “commend(ed) the progress achieved by APEC members in establishing the Supply Chain Security Toolkit for Medical Products.”

### **Conclusion**

It is widely recognised that global traceability is necessary to combat counterfeiting across borders. The use of global data standards, namely the GS1 standards, is recommended by inter-governmental organisations (e.g. WHO) as well as by key trade associations across the world. The GS1 standards are used and implemented by the healthcare sector in at least 70 countries worldwide.



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- GS1 Healthcare recommends the Government of the Russian Federation to remain using GS1 standards in order to ensure harmonisation and alignment with healthcare regulators across the world.
- GS1 Healthcare recommends the Government of the Russian Federation does to not change the cryptographic protection for package serial numbers and to continue using product identification based on UNISCAN GS1/RUS (i.e. GTIN).
- GS1 recommends the Government of the Russian Federation meets the requirement of Article 30 of the EEU Treaty.

To ensure Russia's **global competitiveness, growth and future prosperity**, alignment on a suite of global standards as outlined, will have a significant and positive outcome in reducing supply chain complexity, cost and risk for all stakeholders while enhancing the potential for much desired supply chain optimisation and interoperability and ultimately, improving patient safety outcomes.