



GS1 Healthcare Discussion paper on Mobile Applications and Services in Healthcare

Mobile Applications and Services

In the last 20 years there has been a significant growth of mobile communication devices, such as mobile/cell phones, tablet computers and personal digital assistants (PDAs); for 'smart' mobile/cell phones in particular there has been exponential and continually expanding development and availability of usually free and downloadable applications or 'Apps'.

An emerging healthcare application involves the use of **Mobile Authentication Services (MAS)** to verify information found on pharmaceutical product packaging with data held in a database. Specifically, a manufacturer may apply a number onto a product's package (e.g. a blister card, a tube, etc.) which the patient/consumer can send to a designated mobile short message services (SMS) number (also printed on the primary package) (Figure 1) and an SMS message is returned confirming if the number associated with that product is verified, or not.



Figure 1

Use of SMS solutions in healthcare and their potential benefits to increase patient safety can be viewed as promising. A number of solution providers have developed proprietary SMS solutions that have been adopted by a few pharmaceutical manufacturers and wholesalers, almost exclusively for those products destined for Low-medium income countries (LMIC)¹. The LMICs have been widely reported to be a major source or recipient of falsified pharmaceuticals. Reducing and/or detecting falsified medicines are therefore a key driver for deployment and use of MAS solutions. But while these solutions may be suitable for specific drugs in specific countries, they are not scalable on the broader, regional or even global level as they are often proprietary and not standards-based.

In general, for pharmaceutical manufacturers, SMS solutions represent one of several possible technologies that can strengthen the likelihood that only genuine products will reach patients. And, given the technological framework in LMICs is often less mature, the use of MAS

¹ [World Health Organisation \(WHO\) terminology](#)





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solutions has been seen in some of these countries as a good first step in providing patients/consumers with the means to verify the medicinal products they have received.

However, based on limited adoption to date of SMS applications in healthcare, the strength and robustness of these solutions has not been demonstrated. Consequently, it may be ill-advised for any regulator or government to mandate the use of SMS technology for product verification purposes without a strict regulatory framework, which would ensure that in determined cases such a solution could be implemented to prevent product falsification.

In addition, on a practical level, manufacturers and others remain technically challenged with applying these codes to the various types of primary or secondary packaging and an appropriate and sufficient print quality of the number applied to the packaging is critical to ensure the consumer can accurately read and send the correct number to the SMS service.

Also, with SMS solutions, as opposed to using a smart phone app to scan a bar code, the opportunity for human data entry error is high, even with legible numbers. The image in Figure 1 shows how difficult it can be to read the number on a blister pack due to creasing or wear, increasing the likelihood that an incorrect number is entered, e.g. a 3 instead of an 8 or a 5 instead of a 6; resulting in an invalid number being sent and not receiving an SMS response, receiving a response for a valid number on a different product or a response indicating that the number cannot be verified, which may indicate the product is counterfeit when it isn't.

Concerns with defeating SMS Solutions

A regulation or mandate that requires adoption of a single, proprietary solution could be significantly compromised when the technology is defeated, successfully copied or mimicked by a falsifier. When this occurs, as is common with brand protection technologies, the regulation or mandate intended to secure the supply chain becomes the means by which falsifiers can proliferate their fraud and endanger patients' lives; manufacturers utilize a range of technological solutions as it is unlikely that a single technological solution would be successful in fighting counterfeiting.

Importantly, the responsibility for confirming a product is genuine or not, should not be solely with the patient and not based entirely on verification of a number. Responsibility for ensuring the integrity of the product and supply chain rests with all supply chain stakeholders. Solutions, in which the first patient to verify a valid number receives a message, e.g. 'this is a genuine product', particularly in the situation where the number has been copied and the product is falsified, give the patient a false sense of security. In reality, in some cases of suspected falsification, the only practical solution is to return the suspect product to the manufacturer to determine its authenticity based on forensic testing.





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Regulations – Falsified Medicinal Product

The issue of falsified pharmaceuticals is one important driver of regulations in force or emerging from around the world, predominantly led by developed countries. These regulators are introducing various tools in order to prevent falsified pharmaceuticals from entering the supply chain and reaching patients/consumers.

The European Union (EU) 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."

To this end, in 2010 the US FDA released a 'Guidance for Industry' intended to provide a common and comprehensive framework on the development of package-level standardized numerical identifiers (SNIs) for prescription drugs². In this Guidance, the FDA is explicitly referring to GS1 standards; the use of Global Trade Item Numbers (GTINs) for the product identification, as a measure to secure the drug supply chain and to guarantee international interoperability. Due to the wide variety of packaging, the FDA is leaving options open for encoding the SNIs into machine-readable forms of data carriers but is proposing the use of 2D bar codes and radio-frequency identification (RFID).

More recently, the European Union's Directive on falsified medicines has been adopted³. In order to fight against falsified medicines, the European regulator is requiring safety features, which are defined further as a unique identifier and anti-tampering solutions on the medicines packaging. The European Commission is currently working on drafting the detailed rules for the implementation of this Directive and is considering the use of linear bar codes, 2D bar codes and RFID tags as possible data carriers.

² <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm>

³ http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm





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The need for a comprehensive/holistic approach

Requirements for a protection system are only effective if they are part of a larger system that assists in identifying falsified products. Brand Owners, World Customs, GS1 etc. have international experience in different protection technologies and are willing to support the development of new requirements to improve their effectiveness. However, single proprietary solutions, defined by solution providers, may lead to uncompetitive markets, strong dependencies, reduced supply chain efficiency and hinder the cross border movement of product and information.

Global Standards

There is some variability in the emerging regulations regarding serialisation, in terms of serialised identification, unique identifiers, linear and 2D data-carriers and data registries, but ultimately the aim is, to ensure patient safety, increase efficiency across healthcare supply chains, protect manufacturer's brands, and eventually to establish full end-to-end traceability⁴ of these products from finished goods to the patient.

A common and recurring theme in these regulations is for compliant systems and processes to be based on global standards, increasingly the GS1 System of Standards. This approach is supported by a recent white paper by McKinsey & Company: "Strength in Unity: The promise of global standards in Healthcare"⁵.

The McKinsey report concludes "...Our research also suggests that these benefits would be put at risk if the industry continues to try to manage the complexity of multiple standards rather than aligning around one. Global healthcare leaders have a window of opportunity now to work together to align around a single set of global standards and to collaborate to drive adoption of the practices enabled by these standards..." However, today there continues to be divergence from this; in this context, the emerging MAS solutions are proprietary to the solution provider; as the number of proprietary solutions grow so does the complexity and cost for the pharmaceutical manufacturers if they are required to adopt different solutions for different markets.

Due to regulations, like those in Turkey, Korea, France, Japan, US and Europe, manufacturers globally are adopting and implementing GS1 standards, in particular the Global Trade Item Number (GTIN) as the product identifier. And, increasingly the need to capture related data attributes (e.g. expiry date, lot/batch number, serial number) is driving the adoption of a 2D bar code: GS1 DataMatrix; which also has the advantage of requiring less space on a label compared to the usual linear bar code. While there can be significant costs associated with implementations these would be even higher if these companies had to implement regulations

⁴ Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration (taken from GS1 Global Traceability Standard for Healthcare (GTSH) - http://www.gs1.org/docs/gsm/traceability/Global_Traceability_Standard_Healthcare.pdf)

⁵ http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf





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advocating local and/or proprietary solutions for the numerous markets that they trade with across the globe.

Conclusion / Recommendations - Regulators

GS1 Healthcare recommends that a holistic 'proof of concept' should be developed and published, in regards to the use of SMS technology, which addresses the issues surrounding falsified medicines. This work should involve industry stakeholders from all healthcare sectors and take into consideration the technical capabilities and infrastructure in a given market. For example, there may be widespread use of mobile/cell phones in a particular region but not 'smart phones' and there may be a high prevalence of medicines falsification. Implementing a 'point of dispense' authentication model or a track-and-trace system, including consumer verification, may not be an achievable solution in these markets; effective and practical alternatives are needed to enhance patient safety.

GS1 Healthcare also recommends regulators refrain from specifically mandating the proprietary solutions within their domains and that further study on the effectiveness and relevant strengths and weaknesses of these solutions be conducted. In addition, GS1 Healthcare encourages regulators to support global standards as a tool to fight product falsification, and look at future-proofed concepts.

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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.

