

INTRODUCTION

The Power of GS1 Standards in Healthcare



Industry aligns around one single set of global standards

To comply with all the latest regulations, healthcare organisations and governments are turning more and more to GS1. To cite only one of the most advanced systems, in Turkey, the Turkish Drug and Medical Device National project, launched in 2006, required that every single medical device be registered in the main national database (TITUBB). **Today approximately 2.5 million medical devices have been registered in the database and 91.84% of the devices registered are marked with GS1 Standards.** In 2007, the Turkish Ministry of Health launched the Turkish Pharmaceuticals Track & Trace System (ITS) which defines the infrastructure to track and trace all units belonging to each pharmaceutical product in Turkey. GS1 Standards are here also required: all pharmaceuticals need to include a Global Trade Item Number (GTIN) encoded in a GS1 DataMatrix bar code to ensure the uniqueness of each single unit.

Equally, in Australia, healthcare companies are increasingly using GS1 BarCodes despite the absence of binding healthcare legislation in their market. **Today 97.05% of medicines carry GS1**

BarCodes, and 75,49% of medical devices are marked using GS1 Standards.

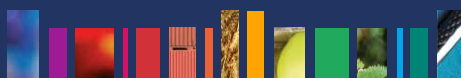
Many other governments are recommending the use of GS1 Standards. The UK Department of Health endorses GS1 Standards in its latest NHS eProcurement Strategy published in April 2014. The Saudi Arabia Food and Drug Administration requires the use of GS1 DataMatrix on pharmaceutical products by 2015. Last April, the Philippines Food and Drug Administration published a circular mandating the use of Global Trade Item Numbers on all FDA-regulated products.

Change has finally come, get ready for UDI!



The U.S. is the first country to have released a specific regulation on Unique Device Identification.

On September 24, 2013, the United States Food and Drug Administration (FDA) published a final Unique Device Identification rule establishing an identification system for all medical devices sold in the U.S. The rule provides a standardised way to identify medical devices across all information





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sources and systems, including electronic health records and devices registries as well as a Global Unique Device Identification Database (GUDID), which will serve as a reference catalogue for every device with an identifier.

Global GS1 Standards meet the government’s criteria for UDIs and will help manufacturers to address requirements of the new U.S. FDA UDI regulation. **In that context, GS1 was the first organisation to have received accreditation, in December 2013, by the U.S. Food and Drug Administration (FDA) as issuing agency for unique device identifiers (UDIs).**

By unambiguously identifying medical devices, GS1 Standards benefit patients and the healthcare system. GS1 Standards assist healthcare organisations around the world to quickly and efficiently identify devices when recalled, improve the accuracy and specificity of adverse event reports and provide a foundation for a global, secure distribution chain.

Paving the way for healthcare providers

In order to achieve **full visibility** down to the patient, healthcare providers need to implement

traceability systems too. That is why, GS1 created the Healthcare Provider Advisory Council (HPAC) which consists of thought leaders and early adopters of GS1 Healthcare Standards that support the adoption of global standards in healthcare institutions and retail pharmacies. In 2013, HPAC introduced two awards, the Provider Recognition Award and the Provider Implementation Best Case Study Award which were given this year to:

- Feargal McGroarty, St. James’s Hospital, Dublin, Ireland and Kevin Capatch, Geisinger Health System, US (winners of the HPAC Provider Recognition Award).
- Michael Innes, Kaiser Permanente, Oakland, US and The Hong Kong Hospital Authority (winners of the HPAC Provider Implementation Best Case Study Award).

According to the 2012 McKinsey & company report - Strength in unity: The promise of global standards in healthcare – “implementing global standards **across the entire healthcare supply chain** could save 22-43,000 lives and avert 0.7 to 1.4 million patient disabilities.” Let’s work towards that promise.

