The Global Language of Business

Traceability of medicines and the Falsified Medicines Directive (FMD): is your organisation ready?

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Did you know that between June 9-16th 2015, in just one week, a record 20.7 million fake and illicit medicines, with an estimated value of $81m were seized, including blood pressure medication, erectile dysfunction pills, cancer medication and nutritional supplements? This was part of Operation Pangea, an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the dangers of buying medicines online. Coordinated by INTERPOL, the annual operation brings together customs, health regulators, national police and the private sector from countries around the world.

Healthcare systems around the globe are facing challenges that affect the entire supply chain. The sector is concerned primarily with two main issues: patient safety and greater supply chain efficiency and accuracy. The facility to identify things uniquely and accurately is essential - be it a medication, an item of clinical equipment or even a patient. The regulatory landscape continues to evolve globally. New regulations in the EU, the US and elsewhere will have a major direct impact on the healthcare supply chain.

Ensuring regulatory compliance

Product serialisation, compliance with EU, FDA and other international drug pedigree requirements and establishing anti-counterfeiting solutions are key priorities for the pharmaceutical industry. The EU Falsified Medicines Directive (FMD) which seeks to establish a more secure supply chain for the distribution of prescribed medicines will require the serialisation of patient packs, as well as tamper evident labelling to enable the authentication of medicines prior to being dispensed to patients.

The European Federation of Pharmaceutical Industry Associations (EFPIA) has developed and successfully piloted an authentication solution based on GS1 automatic identification and data capture standards together with the use of a standards-based federated database, which ensures that a retail pharmacy can check the authenticity of a medicine before dispensing to a patient. In January 2012, GS1 and EFPIA issued a joint vision statement for achieving the EU regulatory requirements.

The introduction of the European Falsified Medicines Directive means all manufacturers of prescription medicines will be expected to print a 2D datamatrix barcode with serialisation data on medicine packs and these packs then need to be verified at the point of dispense. This requires significant changes for pharmaceutical manufacturers and will require IT development changes in hospitals and community pharmacies.

The final Delegated Acts for the European Falsified Medicines Directive were published in February 2016. The new legislation is expected to take effect three years after publication of the delegated acts for countries without pre-existing measures, and six years for countries with pre-existing measures. In the Irish context, this means that all prescription medicines sold in Ireland will need to be fully EU-FMD compliant by 9th Feb 2019. The compliance deadline for Belgium, Italy and Greece is 9th Feb 2025.

A framework for validating pharmaceuticals

The EU medicine authentication system will consist of:

- A Unique identifier (UI) – a 2D barcode (ISO compliant) containing 4 mandatory elements: product code, serialisation number, batch number and expiry date, the national reimbursement number can be included (optional), if requested by the Member State

- Verification of the safety features - systematic verification of the safety features at the dispensing point, supplemented by risk-based verification by wholesale distributors. Note the choice of the most appropriate anti-tampering device will be left to the manufacturer.

- Establishment, management and accessibility of the repository system for the Unique Identifier (UI) by stakeholders. A repository has been established by the European Stakeholder Model (ESM) and is managed by the European Medicines Verification Organisation (EMVO). Manufacturers will upload information relating to the medicines packs being shipped to Europe. Each member country is expected to establish an NMVO (National Medicines Verification Organisation) to oversee the implementation of the national repository which should be interoperable and interconnected with the other repositories.

"There is less time than you think – act now"

Implementation of the Falsified Medicines Directive requires many different disciplines. Developing solutions will be a team effort with manufacturers assembling consortia of specialists in coding, imaging, data management and handling. Be warned - this will take time and manufacturers are finding there is less time than they think. Based on experience it can take six months to select vendor partners, anything up to a year to set up and test the pilot packaging line, and a further year to then upgrade other lines, each of which will differ slightly from the pilot. So team selection needs to start now!

In addition to the FMD legislation, the proposed European and existing US FDA Unique Device Identification (UDI) regulations are to the fore in the medical device arena and companies need to transform disparate medical identification methods into a standardised UDI system.

Both pharmaceutical and medical device manufacturers are leveraging GS1 standards and the support of GS1 experts, to prepare for these new requirements and ensure regulatory compliance. Get involved! Go to *www.GS1ie.org/Healthcare*

Why GS1 standards?

Use of GS1 standards enables traceability and promotes a safe and secure supply chain by providing greater visibility, accuracy and efficiency for the benefit of all parties. Preventing medical errors, enabling traceability & recall and combating counterfeiting are key concerns facing the sector, and GS1 standards are helping to solve these issues.

Benefits of adopting GS1 standards in Healthcare

- Improving patient safety
- Lowering costs through increased efficiency
- Reducing medication errors
- Enabling supply chain visibility
- Facilitating effective product recalls
- Tracking pharmaceutical products/medical devices
- Reducing introduction of counterfeit products
- Enhancing inventory management
- Linking critical product data to the patient record
- Supporting regulatory compliance
- Optimising order, invoice, sales reporting, and chargeback/rebate processes

Background

GS1 is an international, neutral, not-for-profit organisation with operations in 112 countries around the world, including Ireland. The GS1 system of standards is the most widely-used system of supply chain standards, serving more than 2 million organisations (both public and private sector) worldwide.

In addition to the traditional sectors of Grocery, Food Service and DIY, membership in Ireland also includes the Health Service Executive (HSE) with over 40 hospitals and many suppliers of healthcare products. GS1 is recognised by organisations such as the International Organisation for Standardisation (ISO), and the European Committee for Standardisation (CEN).

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