

Combating counterfeiting through product authentication and traceability

'Global standards enable anti-counterfeiting technologies'

The situation

The World Health Organisation (WHO) defines counterfeit medical products as deliberately and fraudulently mislabelled with respect to identity or source: their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. Counterfeit pharmaceuticals and medical devices are a risk to public health. It is almost impossible for patients and dispensing healthcare professionals to spot the fakes. The consequences of counterfeiting include; treatment failure, drug resistance, device failure and sometimes death.

The prevalence of counterfeit pharmaceuticals and medical devices is difficult or even impossible to quantify. The World Health Organisation estimates that :

- Many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on the market can be counterfeit
- In many of the countries of the former Soviet Union the proportion of counterfeit medicines is above 20% of market value
- Most industrialised countries with effective regulatory systems and market control (e.g. USA, most of EU, Australia, Canada, Japan and New Zealand) have an extremely low proportion, i.e. significantly less than 1% of the market value

Counterfeiting is an increasing global threat and has grown in recent years due to counterfeiting methods becoming more sophisticated and to the increasing amount of products crossing borders.

Medical products are supplied through complex, multi-echelon global supply chains that currently lack transparency. The complexities of the increasingly global Healthcare supply chain are vast. Supply chains that deliver Healthcare products cross in and out of geographic and political borders, with products changing ownership a

number of times. Significant inconsistencies in the amount of legislation, regulation and resources exist from country to country and these inconsistencies further complicate an already complex distribution system.

What is the solution?

To increase awareness and action in the fight against counterfeiting, WHO created the first global initiative, known as the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), working on five key areas:

- Legislative and regulatory framework (civil and penal aspects)
- Regulatory implementation (importation, distribution etc.)
- Enforcement (INTERPOL, World Customs Organisation etc.)
- Communication (create awareness and foster cooperation)
- Technologies aiming to prevent, deter or detect counterfeit pharmaceuticals and medical devices

Such technologies may include micro-text, colour shifting ink, holograms and carton inserts.

Traceability and authentication systems are another important tool, which will make it much more difficult for counterfeiters to intrude into the Healthcare supply chain, or at least, make it uneconomic. The introduction of a unique identification for each and every pack of drugs and medical device, where appropriate (risk-based), will enable traceability and authentication systems, such as Chain of Custody, Chain of Ownership, Identifier Authentication and/or Recall, with readily available technology.

This unique identification allows the dispensing Healthcare professional to cross-check each pack (or product), online in a database or through its electronic pedigree (chain of custody documentation) to enable authentication. When

the GS1 Identification Keys⁽ⁱ⁾ are cross-checked, and there is no confirmed dispensing record, the Healthcare professional can dispense this pack of drugs or use the medical device. Counterfeiters would need a legitimate identification that is registered in the database or an electronic pedigree to enable authentication. In the worst case, two packs with the same serial number would be present in the supply chain, in which case stakeholders would be alerted about this intrusion when the second pack is being cross-checked.

How to implement traceability

Increased international collaboration is essential to enable the effective and efficient implementation of traceability and authentication systems.

Global, open standards ensure full interoperability and compatibility between all involved parties and across borders. The GS1 System of Standards⁽ⁱⁱ⁾ provides a suitable framework to achieve this:

- Unique identification
 - » Product information carried in GS1 Identification Keys⁽ⁱ⁾, providing identification numbers that are globally unique
 - » Production information, considering the risk related to the product, lot/batch number or serial number (unique number at the unit level) carried in GS1 Application Identifiers⁽ⁱⁱⁱ⁾
- Automatic data capture
 - » GS1 Data Carriers^(iv) include bar codes (linear or two-dimensional) and EPC^(v)/RFID (Radio Frequency Identification)
 - » There is consensus in IMPACT and GS1 Healthcare that, in the short term, GS1 DataMatrix^(vi) (two-dimensional bar code) is the most realistic alternative to enable traceability, allowing, in an efficient way (high production rates and reliability), coding of more static and dynamic information, within a significantly smaller area than linear bar codes

- Global Traceability Standards^(vii): business process and technical standards
 - » The Global Traceability Standard for Healthcare provides a process standard describing the traceability process independent from the choice of enabling technologies defining minimum requirements for all stakeholders, organisations and countries and corresponding GS1 Standards to be used in combination with information management tools
 - » Technical standards include EPCIS^(v) (EPC Information Services Standard), Object Naming Service Standard (ONS) and Discovery Services Standard

What can governments and regulators do?

To enable traceability and authentication systems, GS1 Healthcare recommends:

1. Endorse *global automatic identification and traceability standards* to ensure interoperability and compatibility throughout the Healthcare supply chain worldwide (links to many of these standards and documents are listed below).
2. Issue policy guidance on how traceability systems can be used to fight counterfeiting.
3. Fund investment projects to ensure infrastructure is in place to enable authentication and traceability.

- (i) www.gs1.org/barcodes/technical/id_keys
- (ii) www.gs1.org/healthcare/standards
- (iii) www.gs1.org/barcodes/technical/application_identifiers
- (iv) www.gs1.org/barcodes/technical/genspecs
- (v) www.gs1.org/epcglobal
- (vi) www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf
- (vii) www.gs1.org/gsm/kc/healthcare



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