The Impact of Falsified Medicines

Now that the Falsified Medicines Directive has come into play, understanding what this means for pharmaceutical manufacturers, pharmacists in acute and community settings, and, ultimately, the impact on patient safety is important

Neil Piper at GS1 UK

In recent years, the number of falsified and counterfeit medications infiltrating the supply chain has become a growing problem for global health organisations and pharmaceutical manufacturers. Not only have there been cost implications, but there are also huge risks to patient safety.

The WHO references illegitimate medications as substandard and falsified medical products, with falsified medicines defined as "medical products that deliberately/ fraudulently misrepresent their identity, composition, or source" (1).

According to the WHO, about one in 10 pharmaceutical products in low and middle income countries are either substandard or falsified (2). The WHO also reported that, as of November 2017, "20 global medical product alerts and numerous regional warnings" had been issued, with "technical support provided in more than 100 cases" (2).

Taking into account compounding factors such as the impact of loss of income to pharma companies and governments, as well as remedial expenses, it has been estimated that the cost to the European Commission equates to €950 million per year (3).

It has been predicted that, by 2020, the falsified market in Europe could be worth €3.3 billion, which sheds some light on the sheer scale of the problem (4). The financial consequences are real; however, the most compelling and worrying implications arise when considering the severe level of risk to human health.

> Pharma manufacturers need to consider and invest in technology that can cope with significantly different requirements from global organisations

The Human Cost

Annually, hundreds of thousands of children in lower income countries die as a direct result of having consumed drugs for treating malaria, pneumonia, and other diseases that are either substandard or falsified (5).

That being said, high-income countries are not immune from the challenges of falsified medicines. Perhaps the most prominent news story in recent months has been the identification of a counterfeit form of the drug 'Xanax', which is said to have claimed more than 200 lives in the UK and 126 in Scotland alone (6).

How Could Standards Help?

Maintaining and enhancing the integrity of the end-to-end pharma supply chain is vital to help prevent the infiltration of falsified medicines.

Where appropriate, the introduction of a standardised, unique identification for drugs or medical devices will enable the authentication and traceability of products. In turn, this would greatly frustrate the ability of counterfeiters to integrate their products into the healthcare supply chain.

Adopting a single, global standard in healthcare would provide key supply chain stakeholders with end-to-end visibility and traceability of products from the manufacturer to the patient. In doing so, this will result in huge cost savings and critical patient safety benefits.

A recent McKinsey study highlighted just how important standards are (7):

- Implementing global standards across the entire healthcare supply chain could save 22,000-43,000 lives and avert 700,000 to 1.4 million patient disabilities
- Rolling out standards-based systems globally could prevent tens of billions of dollars' worth of counterfeit drugs from entering the legitimate supply chain
- Healthcare costs could be reduced globally by US $40-100 billion from the implementation of global standards

International organisations are working collaboratively in an effort to prevent counterfeit products from reaching the patients. For example, Interpol Foundation, the WHO, and the World Customs Organisation are working alongside regulators such as the FDA and the EU Commission. Collectively, they work to raise global awareness, introducing sanctions and presenting measures to secure the supply chain.

The Falsified Medicines Directive

To ensure the integrity of the pharma supply chain, the EU have introduced the Falsified Medicines Directive (FMD), which came into force on 9 February 2019. The rules have become mandatory for the majority of countries in the EU.

Furthermore, beyond Europe, the battle against falsified medicines is a worldwide struggle. Legislation is being rolled out in the US and Canada, and many countries, such as Argentina, India, and China already have serialisation systems in place. This integration is a must for any company selling or buying drugs and failure to comply will mean that pharma companies cannot sell their products.

The FMD requires the serialisation of every pack of prescribed drugs. The measures mean every pack can be verified and decommissioned. If anything needs recalling, it can be identified down to the individual packet – a big change for pharmacies and manufacturers.

All medicinal products for human use need to have, and adhere to, two key safety feature requirements. The first supports the use of a single global standard, validating the comments in the McKinsey report. Each product's packaging is required to carry a unique identifier: "a unique sequence carried by a two-dimensional barcode allowing the identification and authentication of the individual pack on which it is printed" (8).

The second requirement is "a device allowing the verification of whether the packaging of the medicinal product has been tampered with (anti-tampering device)" (8). The anti-tampering device ensures an end-to-end verification system of authenticity and integrity of the safety features placed on the packaging of a medicinal product at the time the medicinal product is supplied to the public.

Future Opportunities

Pharma manufacturers need to consider and invest in technology that can cope with significantly different requirements from global organisations. They need to be able to feed into different regulatory databases, which may have varying requirements of data to be updated at variable points in the supply chain.

With every medicine receiving a different serial number, systems are needed

> Identifying every product empowers healthcare professionals by allowing them to easily access accurate and transparent product information

to manage these numbers and track information related to the product and its movement.

System infrastructure will need to be able to bring together information from vast networks and upload all information to a national or European database. Each manufacturer should also ensure that they have aggregation solutions in place to allow for a full track and trace model as this could potentially become a requirement in Europe.

Despite the considerations and investment that need to be made by pharma manufacturers, serialisation and the use of standards provide huge value and opportunities for the future. These have already been validated and are in use in the retail sector, with very tangible benefits.

Serialisation in the NHS

When it comes to serialisation in the NHS, the benefits would be unprecedented, particularly in acute trust settings to create a safer and more efficient NHS.

With the unique product identifier, serial number, expiry date, and batch/lot number on every product, medications can be easily tracked and traced throughout the patient pathway, directly to administration to patient.

Identifying every product empowers healthcare professionals by allowing them to easily access accurate and transparent product information, facilitating precise ordering, improving product availability, and lowering transaction costs.

However, the real power comes from the ability to painlessly identify and remove all recalled products across trusts and down to the patient level once they have been discharged.

University Hospitals of Derby and Burton NHS Foundation Trust is one such example of how standards implementation has rewarding results on the time taken to process product recalls. As with many trusts, Derby are faced with the problem of managing product safety recalls quickly and efficiently, minimising the risk to patients.

Traditionally, traceability was a manual paper-based process which was labour-intensive for clinicians. Using unique identifiers and barcodes, Derby used product scanning to quickly identify all products held in the trust and even identify patients that had been discharged and may have been affected.

Advancing the Chain

As the development of falsified medicines becomes increasingly sophisticated, the healthcare supply chain needs to constantly evolve with robust processes to ensure it is being reinforced. Global efforts are being taken to transform the supply chain and increase visibility and traceability throughout.

Ultimately, it is about patient safety and reducing the risk of harm to patients. This is why standards and serialisation are critical to ensure seamless, lean, and secure end-to-end distribution practice.

References

1. Visit: www.who.int/medicines/regulation/ssffc/definitions
2. Visit: www.who.int/en/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
3. Visit: ec.europa.eu/health/sites/health/files/files/pharmacos/pharmpack_12_2008/counterfeit-ia_en.pdf
4. ASOP EU, ASOP EU strategic review of costs to the public purse due to the production and sale of falsified medicines, Falsified Medicines Costing the Earth: 2013
5. Visit: www.bbc.co.uk/news/health-47055499
6. Visit: edition.cnn.com/2019/03/11/health/fake-drugs-killing-children-study/index.html
7. Visit: www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf
8. Visit: ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf

About the author

Neil Piper is an Auto ID expert and business consultant with over 25 years' experience working predominantly in the retail and healthcare sectors. He is skilled in GS1 International Society of Blood Transfusion standards, barcode technologies (printing and scanning), radio frequency identification, electronic product code information services, and regulatory compliance (FMD, unique device identification, both FDA and EU medical devices regulation/*in vitro* diagnostic medical devices, UK Medicines and Healthcare products Regulatory Agency GS1 compliance, and more). Neil is currently redrafting Information Standards Board (ISB) 1077 and ISB 0108 standards to comply with NHS digital requirements. He has provided consultancy to numerous NHS trusts and pharmaceutical and medical device suppliers.

Email: neil.piper@gs1uk.org