Improving Adherence: Packaging's Synergistic Role in Delivery, Communication and Education

On February 9th 2016, the European Parliament and Council published the amended version of the Falsified Medicines Directive (FMD), detailing the characteristics of the security features that will be required on packaging for medicinal products for human use. It stated that both a unique identifier and an anti-tampering device will be mandatory, helping to address the current ever-growing threat of counterfeit medicines.

Data released by the United States Food and Drug Administration (USFDA) states that approximately 10% of all pharmaceuticals sold globally are counterfeit. While counterfeiters are active around the world, not all markets suffer equally. Developed nations have the lowest amount of counterfeit pharmaceutical goods, with an estimated 1% penetration rate in Europe and the USA, whilst developing nations show particularly severe penetration rates. For example, it is estimated that up to 30% of all medicines in Africa and the Far East are fake. In 2011, the World Health Organization reported that 64% of all antimalarial drugs in Nigeria were counterfeit.

These figures continue to grow due to increasingly complex supply chains, the increased sophistication of counterfeiters, a lack of enforcement capacity, and the expansion of ecommerce. It is widely believed that up to 50% of drugs available online are fake – with estimates reaching up to 70% in some African and Eastern European countries.

In light of this, various anti-counterfeiting efforts have been developed by pharmaceutical companies, and multiple legislations such as the FMD are being implemented by governments around the world. The biggest challenge present is the fact that there is no set global standard, which in turn makes implementation complicated and inconsistent. As such, both governments and companies must continue to work together in order to continuously improve.

The effectiveness of these localised legalisations should not be underestimated, however; the EU FMD has not only raised the issue of counterfeiting publicly in the pharmaceutical industry, but has also prescribed some specific solutions, such as serialisation and tamper-verification, that will require changes from data management throughout the supply chain to packaging.

The solutions proposed for combatting counterfeiting generally fall into one or more of the following categories:

- Track & trace
- Tamper verification
- Authentication systems

As a leading global provider of packaging and authentication solutions, Essentra advocates implementing multiple measures to provide enhanced security, particularly before the new medicine verification system commences in early 2019.

Track & Trace: Serialisation

Serialisation is the system of tracking, tracing and verifying products via unique identification codes. These unique identifiers reveal a complete history of the drug; from the supplier to consumer, for the whole duration of the drug's stay on the market and additional time necessary for returning and disposing of the pack after it has expired. The codes are commonly presented as a linear barcode, 2D barcode or a combination of numbers, and technologies for more advanced solutions are currently being developed. However, irrespective of the format, the code will convey key data elements about the drug contained in the box, such as the drug's product code, national reimbursement and identification number, batch number and expiry date of the unique identifier. These data elements should in addition be printed on the packaging in human-readable format in case the barcode is unreadable. Codes and unique identifiers will be encoded by a standardised data structure and syntax to ensure that it can be correctly recognised and decoded throughout the Union by commonly-used scanning equipment. In addition to confirming the integrity of the medicine and helping to ensure that patients are taking the correct reliable medicine, these data elements also facilitate withdrawal and return procedures should a recall be necessary.

There still remain a number of challenges that the pharmaceutical industry must overcome when implementing an efficient serialisation system. Firstly, a uniform system must be put in place that meets the requirements at each level of the supply chain. This may require existing suppliers and companies within the supply chain to integrate new IT systems, databases and business structures, which could prove difficult both financially and administratively. Plus the creation of the required serial codes themselves will call for significant expenditure, particularly if additional elements are included. The more complex the structure of the serial codes, the more challenging standardisation will be across all companies in the supply chain. According to some estimates, the majority of the coding solutions currently used in the pharmaceutical and healthcare industries could be rendered obsolete due to the FMD.

The key to the implementation of a successful serialisation system is the ability to run a functioning repositories system that supports end-to-end verification and allows for precise data management and the control of data integrity. The process of track and trace will mean that every point within the manufacturing chain will have to carry out a stop-check, resulting in the collection of a large amount of data. Each individual unit will have a unique identifying code and, once printed and supplied to the public, must be decommissioned in the repositories system so any other pack that has the same code cannot be verified. If, under certain circumstances, a box is accidentally damaged and made unusable, the code must be recorded as inactive in the system. The organisation of this vast network of data will prove challenging, so companies and governments must work together to create a successful way of managing it effectively.

One country that is currently running a comprehensive track and trace infrastructure is Turkey. The system

was initially implemented as a means of combatting insurance fraud, but is now capable of tracking and tracing all products within, and entering, the country. Goods are constantly documented as they advance through the supply chain, and when the goods finally reach the consumer, these unique identifiers are cross-referenced with the master database to confirm the product's authenticity and original manufacturer. Without this confirmation, there is no way for reimbursement through Turkey's health system. Their system also utilises unique GS1 GTIN serial numbers through both human- and machine-readable formats. This provides both track and trace and an economic disincentive for people to use 'out-of-system' medication.

Tamper-verification

Indeed, while serialisation verifies the authenticity of the pack of medicine, counterfeiters can easily collect used genuine packs and refill them with fake product, reclosing the original packaging and passing the product off as genuine. This is already occurring in countries such as China, where counterfeiters obtain genuine boxes from patients leaving pharmacies. This demonstrates the need for a multi-layered security approach, to provide protection for both the packaging and the contents inside.

Tamper-verification shows whether the packaging has been opened or altered since it left the manufacturer, ensuring that the content of the packaging is authentic. It provides the end user with confidence, allowing them to personally judge that the product they are opening is genuine and originates from the legitimate manufacturer.

As stated in the Directive 2011/62/EU, tamper-verification features must be applied to packaging of certain medicinal products as required. There are now nine categories of tamper-verification features included in the European Standard:

- Flaps of folding boxes closed with glue or closed with labels or tapes
- Specially constructed folding boxes
- Sealing labels and tapes
- Film wrappers
- Sleeves
- Breakaway or tear-away closure
- Display blister pack
- Blow-fill-and-seal-container (BFS)
- New and emerging technologies

Beginning with folding boxes, tamper-evidence can be built into the design of cartons via the use of glued locks, such as the reverse tuck end with glued flaps, or dagger locks. The side-walled glued skillet with scored top opening and the standard side-wall glue skillet with zip-tear opening provide additional solutions. All of these 'built-in' features entail the destruction of the original carton. In these cases, it should be noted that providing consumers with features that allow for easy opening of the pack, such as those with scored opening, help to eliminate frustrating experiences that could put the consumer off a particular brand or product.

In the case of sealing labels, tamper-verification can be provided with varying levels of sophistication. At entry level, simple labels with high-adhesive provide a clear visual indicator that the pack has been opened as the removal of the label will also remove part of the packaging. One example of this is a fibre-tear label, which irreversibly damages both print and carton board on to which it is affixed, including even varnished coatings.

For brands that require a more consumer-friendly experience, labels which leave behind a visual cue on the original packaging upon removal can be utilised. One such example is a void release label that leaves a void message or pattern behind when the label is removed. Another option is a frangible label that uses a specially engineered substrate that disintegrates the label when attempting to remove from the carton board. Both of these labels leave a clean visual cue that alert the consumer that the original box has been opened.

Authentication Systems

Lastly, authentication systems help consumers to verify if packaging is genuine. Authentication solutions can come in different forms – overt, covert and forensic. Overt solutions are obvious to the naked eye and enable instant authentication through visual inspection, such as holographic devices and colour-shift inks. Covert solutions are more sophisticated as they often require specialist equipment to identify their presence, such as UV fluorescent inks and microtext. For an extra advanced layer of authentication there are also forensic solutions, which include molecular markers and biological tracers, which can only be identified using laboratory equipment.

Taggant systems are another popular solution, which in fact bridge covert and forensic layers of authentication. Taggant systems use transparent taggant inks which can be chemically engineered to provide customers with a unique signature, which are only readable through taggant readers throughout the products' journey.

Summary

The optimal approach to protect against counterfeiting will include several layers of security to combine both overt and covert technologies, track and trace systems and tamper-verification, thus making it as difficult as possible for counterfeiters and the illicit trade to succeed. Such layers should, wherever possible, be intrinsic to the item or packaging to ensure that the item is authenticated rather than the security feature alone being authenticated.

It is clear that the pharmaceutical industry must react to the threat posed by counterfeiters, not only to protect the integrity of brand-owners, but also more importantly, to ensure that patients are consuming the genuine medicine they require, particularly as there is now a three-year deadline. Implementing various levels of solutions, from serialisation to tamper-evidence, helps to ensure that pharmaceutical products are not falsified or have been altered by counterfeiters.

Ian Lemon. As Essentra's Global Product Director - Health & Personal Care Packaging, Ian Lemon is responsible for leading the company's product offering in this category, as well as its new product development in line with customer and category needs and demands. He has over fifteen years of experience delivering value-added packaging solutions and has worked with several of the world's leading FMCG businesses.
Email: ianlemon@essentra.com