Published By: Origin Pharma Packaging
Creator: Jon Lant – NPD Director
Document: Whitepaper: **The Future of Tamper-proof Pharmaceutical Packaging**

ORIGIN

The Future of Tamper-proof Pharmaceutical Packaging

How the Commission Delegated Regulation (EU) 2016/161 will protect the population health.

Introduction

The pharmaceutical industry is an ever-changing environment that is constantly threatened by illegal activity, especially in the form of falsified products and vandalism to packaging.

Serialisation and tamper-resistance are essential in the inhibiting of bogus and unsafe medicines reaching the public. Unifying both measures, a new EU Regulation taking effect in 2019 will help to make the universal distribution and sales process become safer than ever before.

What is falsified medicine?

Falsified medicine is the production of counterfeit pharmaceutical products that do not adhere to the strict regulatory standards imposed by government agencies to ensure consumer safety. This can take various forms, with the key factor being that they usually contain low quality or incorrect ingredients, or an incorrect dose of them.

Falsification can also be in the form of the information surrounding the product's provenance trail, such as the manufacturer, country of manufacture, and commercialisation owner. Similarly, the distribution channels logged in its records and documents can be falsified to cover up the original source.

Why is it a problem?

The falsification of medicine is a serious threat due to its potential dangers to the consumer. Examples range from close replicas that do not meet regulatory standards, which are inconsistent and unreliable, to entirely dangerous imitations that result in adverse effects and possibly even prove life threatening.

The main problem is not so much the falsification of products, but rather the increasing difficulty in detecting them before they reach the consumer. If a product is noticeably fake, it can be removed from the distribution process and possibly tracked to its source, whereas a highly convincing reproduction can spread across the globe.

Over recent years, the manufacturing process behind falsified medicines has become so sophisticated and adaptive that large quantities have passed through quality control and legislative tests. This poses a very real problem to the health and wellbeing of consumers worldwide.

What are the different types?

Falsified medicines can vary greatly. It has been found that in some developing countries there are falsified versions of medicines that are crucial to basic health and survival. These include antibiotics, medicines for malaria and tuberculosis, analgesics, anti-inflammatory medicines, and anti-retroviral preparations for combating HIV.

In wealthy countries, falsified medicines have seen a steep increase in distribution, with online sales being a major cause. Prime examples are lifestyle medicines, such as products that allegedly promote weight loss, increase levels of energy and concentration, and alleviate sexual dysfunction.

The combined effect is the spreading of falsified medicines in countries that are poor, war-torn and in need of aid due to necessity, and households across the world due to desire, curiosity and availability.

What are the existing laws and regulations?

Due to falsified medicines posing a significant risk to global health, the European Parliament and Health Council published the Falsified Medicines Directive 2011/62/EU on 1 July 2011, taking effect from 2 January 2013. This Directive imposed more stringent measures throughout Europe, ensuring protection and control across the board.

These measures include obligatory safety features, an EU-wide logo to identify legal online pharmacies, tougher rules surrounding producers of ingredients, and enhanced record-keeping requirements for wholesale distributors.

What else is being introduced?

The Commission Delegated Regulation (EU) 2016/161 was laid out on 9 February 2016. This stipulates a new medicine verification system that will take effect from 9 February 2019.

The new safety features that are to become essential are a unique identifier sequence carried by a two-dimensional barcode, and a device allowing the verification of whether the packaging of the medicine has been tampered with.

Serialisation and anti-tampering measures have long been in place across the pharmaceutical sector, but this Regulation will ensure greater consistency and regulated control.

How will it work?

The only way to effectively identify a pack is to give it a unique identifier. This must contain an ISO-compliant product code of up to 50 characters, a randomised serial number of up to 20 characters, a batch number and an expiry date. There is also the option to include a national reimbursement or identification number.

All of this information is carried by a 2D barcode meeting a minimum print quality and in a human-readable format. It is then checked against its entry in an official repositories system during the distribution process.

With regard to tamper-proofing measures, the choice of the technical specification is left to the manufacturer. Whatever the chosen solution, it must be suitable for an end-to-end verification system and effective against all forms of tampering.

Where will this apply?

Due to this being an EU Directive, it will apply to all Member States: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

What happens if a product is suspected of being falsified?

In the event of a pharmaceutical product failing authentication processes or showing signs of tampering, it shall not be released for sale or distribution. The person suspecting the falsification or tampering must immediately inform the relevant competent authorities. Through this rigorous system, the consumption of ineffective and unsafe medicines will be prevented.

Conclusion

The pharmaceutical industry has a long history of working to combat the counterfeiting, falsification and tampering of products. With the risks ranging from low quality replicas to entirely unsafe ingredients, it is crucial that consistency, quality control and containment measures are universally applied to protect global health.

Whilst unique identifiers through serialisation play a key role in verifying the origin and legitimacy of a product, anti-tampering technology ensures that authentic products that have been rendered void do not reach the public.

About Origin

With a dedicated Pharmaceutical Packaging, Logistics and Innovation Centre in East Yorkshire and offices in London and New York, Origin has over fifty years of experience in keeping consumers safe.

Our expert teams create world-class and innovative packaging solutions, specialising in serialisation and childproofing technologies. This plays a major role in preventing everything from counterfeiting to accidental consumption.

We are dedicated to revolutionising the pharmaceutical primary packaging supply chain through our Hybrid Pharma Packaging Partner (HP3). This programme is designed to enable rapid improvement in the effectiveness of the industry’s supply chain.

To find out more about how Origin is Bringing Healing Home, please visit www.originltd.com or call (+44) 1482 638380.