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Using New digital anti-counterfeiting Technologies to Protect the Egyptian Pharmaceuticals Packages against counterfeiting

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Abstract:

Medicine counterfeiting is an urgent problem, it is a growing issue that cannot be tolerated and one that cannot be ignored. The World Health Organization (WHO) estimates that counterfeit medicine accounts for 10% of the market worldwide, and more than 30% in some countries. As these counterfeit medicine increasing, patients will be the ones to pay the price. According to a 2017 report by PricewaterhouseCoopers, the counterfeit medicine market earns between \$163 billion to \$217 billion per year, making it one of the most profitable types of counterfeited goods. Counterfeiters increasingly use advanced means to produce fake medicines. So, the pharmaceutical industry must continuously update innovative technological solutions to ensure the protection and traceability of products, to identify fake products, and to secure the supply and distribution chain. The packaging is a necessary component that helps in making the medicine safe until it is used. Counterfeit medicine is an important issue for Sanofi, which is doing best efforts to fight counterfeit of its medicines and has developed several programs to promote access to safe medicines. Nevertheless, PLAVIX® Clopidogrel, one of its important and effective drugs that used in Egypt to reduce the chances of blood clots forming, which packed in a package secured with many overt and covert features to increase its protection from counterfeiting, like Serial Number, Sanofi Security Label (SASL), Data Matrix Code, Linear Barcode and Scratched Code, it can still be counterfeited. So the research hypothesis is that finding an effective, comprehensive solution like using new digital technologies, such as using RFID tags, NFC tags, ATT–Titanium Security, Fiber Tags, and others, will greatly increase the level of the medicine security and consequently achieve the research aim which is protecting The Egyptian pharmaceuticals packages against counterfeiting.

Keywords:

Medicine counterfeiting, RFID, NFC, Drug Packages, ATT–Titanium Security, Fiber Tags

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Introduction

Taking medicine is important for helping us addressing health problems and improve the quality of lives, wherefore, patients are placing their safety in the hands of the medicine supply chain every day just to stay alive. So medicine must be authentic because, with counterfeit medicine, it will be the patients who will pay the price. The World Health Organization (WHO) estimates that counterfeit medicine accounts for 10% of the market worldwide, and more than 30% in some countries (Fighting Counterfeit Medicines, 2017). Medicine counterfeiting takes place because of diverse and sophisticated reasons like poor regulation, lack of awareness, financial interests, and many more. According to a 2017 report by PricewaterhouseCoopers, the counterfeit medicine market earns between \$163 billion to \$217 billion per year, making it one of the most lucrative types of illegally-copied goods. (Pharmaceutical Counterfeiting: A Global Threat, 2020). The growth of pharmaceutical trafficking

and its illegal activities all over the world make it urgent to guarantee the highest levels of safety for medicines during their life cycle. Unit traceability has enabled big advances in resolving certain distribution issues but does not meet all needs, especially those presenting the greatest risks to public health. So Finding effective, comprehensive solutions to save human lives is a very urgent issue. These effective security solutions can be divided into three categories:

1. A label may clearly indicate first-opening and tampering.
2. Integrated technologies of various security and detection levels provide effective protection against counterfeiting.
3. Track & trace system solutions serve to identify and trace products, and thus indicate gray market activities.

All functional components can be customized and combined. (Nadine Lampka and Arne Rehm, 2018). This will help in making effective security features that strongly hamper the counterfeiter's

action, and will offer a wide range of added values to the pharmaceutical companies.

Originality/ value:

This paper serves for securing The Egyptian Pharmaceuticals Packages against counterfeiting, to guarantee the highest levels of safety for medicines during their life cycle. Because of counterfeit medicines are a threat to public health and the national economy in Egypt

Literature Review:

The security of the pharmaceutical supply chain can be reinforced by innovative packaging technologies. The packaging is a necessary component that helps in making the medicine safe until it is used. With advanced digital scanners and color printers, packaging can often be easily and cheaply imitated, to the degree of which it is not possible to distinguish between fake packaging from the genuine one. Counterfeiters are focusing most of their energies on replicating the features that can be easily seen and checked visually. So we have to make packaging harder to reproduce by making it visually more complex. The simplest way for a pharmaceutical manufacturer to add security features to the packaging is by incorporating them during packaging manufacturing. These security features provide some protection against naive counterfeiting attempts.

On the other hand, a combination of overt, semi-covert, covert, and forensic security features, may provide optimal security because they help prevent counterfeiting and reassure patients. For example, using medicine product serialization in combination with electronic identification like RFID tags or Data matrix code, extremely helpful in the verification of both the product and the transaction safety. However, using a combination of security features will result in additional costs as the technologies become more complex and should be carried out according to the risk analysis of the medicine to be counterfeited.

Many industry executives are hesitant to spend the money to keep up with anti-counterfeiting securities and regulations, especially when many of these expensive anti-counterfeiting systems and measures prove to have short lifespans (Pharmaceutical Counterfeiting: A Global Threat, 2020). Regardless of the huge cost in human lives as well as the billions of pounds that result from the harm in the name of pharmaceutical brands, the cost to keep up with and hopefully beat counterfeiter's activities is just as great.

Authentication Technologies:

Authentication is an expression used in

determining if the product or packaging is real or not. There are a lot of various security technologies that can be used for medicine authentication at different levels of packaging and in different conditions. You have to keep into consideration some factors like price, security level, feasibility, etc. when choosing authentication technology. Also, it should have characterized by a high level of security, higher authentication speed, difficulty to remove and reapply, easy to check automatically, be useable by end-users, etc. It has to be kept in mind that counterfeit medicines are those that are mislabeled from the viewpoint of their identity, their history, or their source (Fighting Counterfeit Medicines, 2017). Identity means its packaging and labeling and its name. Source, means the manufacturer, country of origin, marketing authorization holder. History means the records and documents relating to the distribution channels used. So new authentication technologies, like cloud-based databases of supply chain information that allows for tracking through every point of distribution, have to be impossible to collapse, as they are used in monitoring and improving both security and supply chain efficiency.

Digital Authentication:

Track and Trace and Serialization Technologies:

It is one of the important digital authentication methods that rely on identifying each product or its packaging during the manufacture with a nonesuch set of information, that personalized, stored on data carriers like linear bar codes, two-dimensional bar codes or/and radio frequency identification (RFID) tags, etc., and updated without making any tangible changes to the product or its packaging by computers, only by authorized persons, and may also be printed on the product like serial numbers. This system of authentication ensures that prescription medicine cannot easily be replaced with counterfeit ones.

(National Council for Prescription Drug Programs Drug pedigree in healthcare background) says that the pharmaceutical industry has interested latterly toward serialization. Serialization includes the processes of generating, encoding, and verifying the unique identity of individual physical items. The main challenges of implementing serialization are the complexity of data that is to be tracked, and the need for potentially huge, multi-access databases. (Pharmaceutical Technology Europe Improving packaging security, 2011). It is using as a main part of the track and trace system to facilitate the medicine tracking through the

pharmaceutical supply chain and allows for specific identification of medicines for recall.

Study Problem:

Counterfeit medicine is an important issue for SANOFI pharmaceutical company, which is doing best efforts to fight to counterfeit of its medicines and has developed many programs to promote access to safe medicines. **PLAVIX® Clopidogrel**, one of its important and effective medicines that are using in **Egypt** to reduce the chances of blood clots forming, which packed in a package secured with several overt and covert features to increase its protection from counterfeiting, like Serial Number, Data Matrix Code, Linear Barcode,

Scratched Code and Sanofi has developed a specific label known as the Sanofi Security Label (SASL), as shown in (*figure 1*). It contains overt security features for distributors and patients, as well as covert ones known by SANOFI only, nevertheless, the package and subsequently the medicine can still be counterfeited. So SANOFI should be aware that these features alone will not guarantee a medicine's authenticity. Only the combination with additional anti-counterfeiting authenticity features can produce an impossible-cracked package, Expert and consumer must be informed with these multi-level security concepts to achieve the goal for which it was created.



Figure 1: illustrate security features on SANOFI Plavix® package

The author supposes that finding an effective, comprehensive solution like using new digital anti-counterfeiting technologies, such as using (NFC tags technology) and (ATT–Titanium Security and Fiber Tags technologies, invented by HP Development Company), will greatly increase the level of the medicine security and subsequently achieve the research aim which is protecting The Egyptian pharmaceuticals packages against counterfeiting.

Objectives

This study aims to protect The Egyptian pharmaceuticals packages against counterfeiting with an effective, comprehensive solution like using new digital anti-counterfeiting technologies, such as using NFC tags, ATT–Titanium Security and Fiber Tags

Methodology

To achieve the research objective, a descriptive,

analytical, and experimental study is conducted:

Materials and procedures:

The author suggested to apply the next new digital anti-counterfeiting technologies on **PLAVIX® package** to make its counterfeiting impossible as following:

NFC Technology:

NFC stands for near-field communication and it allows phones, tablets, laptops, and other devices to easily share data, stored directly on the NFC chip as shown in (*figure 2*), or retrieved via the internet, with other NFC-equipped devices. NFC is very much like RFID, but NFC is limited to communication within about four inches (Simon Hill, 2019), NFC communication happens over the air, and a thief would have to be within centimeters of your deceive to skim your data via NFC. For example, if you are using Google Pay, you can rest assured that your credit card number is never transmitted. Instead, an individual digital account number is used to identify your payment details. (Nicholas Montegriffo, 2020)

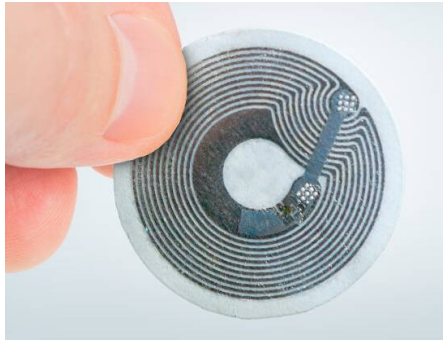


Figure 2: illustrate The NFC Chip

The NFC Advantages:

- The NFC-interface is already integrated into virtually all cellphones
- The NFC technology is standardized worldwide offering a broad range of applications – industry, logistics, marketing, automotive, etc.
- You don't need any special app
- According to the International Transmission standard, the frequency is 13.56 MHz and is based upon the ISO14443 standard or ISO15693
- Maximum distance up to 5 cm and fast transmission establishment
- Every NFC-chip has a worldwide unique identification number. Thus, every product becomes unique, retractable, and original as well.
- Invisible integration into an already existing design, as no visual contact with the smartphone is needed.
- A virtual 100 % first-pass read rate
- The data on the chip can be supplemented, readout and changed at any time

<https://www.smart-tec.com/en/auto-id-world/nfc-technology>

1- Advanced Track & Trace (ATT–Titanium) Technology:

ATT-Titanium is a 3-in-1 security solution for packaging and labeling. The solution includes high-security elements that can be mixed and matched per need for authentication, tracking and tracing, and building consumer trust with his products. The first of these anti-counterfeit label features, the copy-sensitive Seal-Vector code, it is a verification mark printed at the highest resolution possible, and damaged when copied,

making it possible for brand agents to detect fake products with a smartphone and optical adapter as shown in (figure 3). All components of a product, whatever the material and the processing and production processes, can receive the Seal Vector® marking solution. (Pharmaceutical Industry). The next two security labeling features are a unique serial number and QR code. Together, these features allow you to track and trace products with great accuracy and detect and deter parallel markets. Each customer will be issued an individualized QR code that can be read via an optical adaptor or smartphone. (LabelValue Team, 2018)

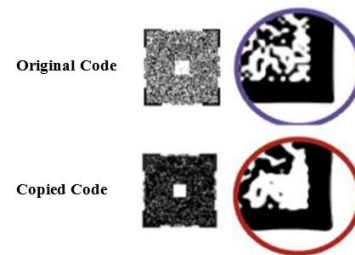


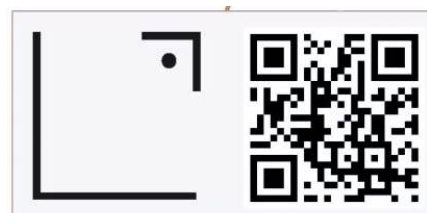
Figure 3: illustrate the copy-sensitive Seal-Vector code

2- Online FiberTag Technology:

Fiber Tracker Labels takes a special authentication technology that provides for the random distribution of fibers and unique security on each label. <https://www.nuceriagroup.com/en/fiber-tracker-etichette-industria-farmaceutica/> FiberTag is a security solution for producing security labels with a unique and visible fingerprint that is impossible to duplicate even by its original manufacturer. The FiberTag labels are printed on the Fibertracker material with any **HP Indigo digital press**, using its serialization capability. After printing, each FiberTag is scanned and recorded offline and uploaded to **ProofTag's** online platform. FiberTag seals are serialized with a 2D code as shown in (figure 4), to enable item-level track and trace, offering online visual authentication through any internet-connected device. Each FiberTag label is linked to a dynamic presentation page to provide information on the secured item. The FiberTag label is also designed to function as a seal tampering prevention mechanism. (Security & Brand Protection Solutions, HP Indigo, 2018)



Figure 4: illustrate the FiberTag



Results:

By Applying the new digital anti-counterfeiting technologies, NFC tag, ATT–Titanium Security and Fiber Tag to the PLAVIX® Clopidogrel package, as shown in (figure 5), this would result in the following:

- NFC is one of the neglected new innovative digital authentication technologies that can help in monitoring the pharmaceutical supply chain and consolidating patient safety. Due to their thin and flexible structure, the NFC tags can be easily applied to the medicine package during production to be used in counterfeiting protection, interaction with patients and pharmaceutical manufacturer authentication, by providing the manufacturer with important information that used in to monitor the supply chain and to clarify possible gray market activities. The patient also can obtain further information and assistance when using these NFC tags, which can gain easy and interactive access to important information about his medicine, such as clear identification of the medication, its expiration date as well as product or warning messages. Thus, the administration of counterfeit or wrong medicines can be prevented and dosage errors avoided. Also, the programming of the NFC chip in the label prevents reuse and thus misuse of the original container.
- Advanced Track & Trace ® solutions allow secure traceability of production and packaging

operations and authentication of products and their components, at all times, throughout the supply chain. They allow in particular to provide reliable information to the patient. All components of a product, whatever the material and the processing and production processes, can receive the Seal Vector® marking solution. Requiring no additional consumables, with the best cost-performance ratio, Seal Vector® is the ideal solution for the pharmaceutical industries.

- For Fiber Tracker Labels, the element of innovation is the application of a QR code on the label, which enables the patient with his smartphone to verify the authenticity of the medicine and access to accurate information about the manufacturer, the medicine and the curative indications. A not replicable pattern of fibers can identify and track every single label and a Qr code easy to read with a common smartphone. A reliable, effective, and sustainable tool to check immediately for the authenticity of the medicine. Anyone with a smartphone can then, utilizing a scanning the QR code, verify that the medicine is not counterfeited and can also display a variety of in-depth information on the product, created by the manufacturer. Protection levels are extremely high because the data behind the QR code in the database reside ProofTag online platform.



Figure 5: illustrate the suggested new digital anti-counterfeiting technologies

Conclusion

The growth of pharmaceutical trafficking and its illegal activities all over the world make it urgent to guarantee the highest levels of safety for medicines during their life cycle. It is a threat to public health and the national economy in Egypt. So, to save human lives, finding effective,

comprehensive solutions like using new digital technologies, such as making a combination of anti-counterfeiting authenticity features like NFC tags, ATT–Titanium Security, and FiberTags, is a very urgent issue for producing impossible-cracked pharmaceutical packages.

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