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INNOVATION IN SMART AND DIGITAL LABELLING AGAINST COUNTERFEIT DRUGS

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ABSTRACT

Counterfeit drugs, otherwise known as substandard and falsified drugs according to WHO, present a significant challenge to global health. There exist various limitations in packaging and labelling techniques, which include inefficiency, a lack of innovation, and poor security against counterfeiting. The latter is associated with medication errors and decreased patient compliance. Another limitation that adds to the problems of pharmaceuticals is related to the complexity and fragmented nature of the supply chain and lack of product traceability, thereby facilitating the entry of counterfeit drugs into the market. In this regard, there are several promising solutions in the form of smart and digital labelling techniques that can overcome the above-mentioned problems. For example, QR codes, RFID, NFC, IoT technology, blockchain technology, and ePL have proven to be efficient and effective tools that provide real-time tracking, authentication, and access to updated information on medicines. In general, they contribute to greater transparency within the supply chain and regulatory compliance. However, certain obstacles, namely, high costs, technical issues, data management, and digital access barriers, can be seen in this area. Therefore, digital labelling is a promising aspect way to move forward.

Keywords: Counterfeit Drugs, Supply Chain Traceability, Digital Labelling Technologies, Drug Authentication, Smart Packaging Systems

1. INTRODUCTION

The World Health Organization says that fake drugs are those that are intentionally and fraudulently misrepresented in terms of their identity and/or source. The organization has recently adopted the classification of "substandard and falsified (SF) medical products." Substandard products are authorized medicines that do not meet established quality standards or pharmacopeial specifications **[1]**.

The limitations of traditional drug/packaging, through their inability to support many aspects of patient safety, have generated significant interest in the development of more modern technology-enhanced alternatives to meet the perceived needs of patients. The foremost of these limitations is the difficulty that patients have in accessing medication due to child-resistant packaging. While such packaging serves a valid purpose to protect young children from access to medications, it may at the same time increase the chances of improper handling or dosing or the failure to adhere to medications, particularly for elderly patients. Despite the changing patient population and the corresponding evolution in the needs of patients, packaging design has experienced very little significant change over the past several decades; therefore, innovations in this area have been virtually non-existent.

These characteristics present patients with avoidable medication safety risk, and indicate a need for more intuitive user-centric approaches to labelling. Through the incorporation of digital technologies into labelling systems, there exists the opportunity to improve patient's ability to comprehend the label, reduce the potential for medication errors, and enhance adherence to prescribed therapeutic regimes **[2]**.

The limitations of traditional drug/packaging, through their inability to support many aspects of patient safety, have generated significant interest in the development of more modern technology-enhanced alternatives to meet the perceived needs of patients. The foremost of these limitations is the difficulty that patients have in accessing medication due to child-resistant packaging. While such packaging serves a valid purpose to protect young children from access to medications, it may at the same time increase the chances of improper handling or dosing, or the failure to adhere to medications, particularly for elderly patients. Despite the changing patient population and the corresponding evolution in the needs of patients, packaging design has experienced very little significant change over the past several decades; therefore, innovations in this area have been virtually non-existent. These characteristics

present patients with avoidable medication safety risk, and indicate a need for more intuitive user-centric approaches to labelling. Through the incorporation of digital technologies into labelling systems, there exists the opportunity to improve patient's ability to comprehend the label, reduce the potential for medication errors, and enhance adherence to prescribed therapeutic regimes **[3]**.

Despite ongoing improvements in labelling practices, evidence shows that over 50% of medication errors result from misunderstandings of key instructions, such as dosage, route of administration, and dosing frequency. This issue is especially serious for people with limited health literacy and those taking multiple medications **[4]**.

E-labelling systems are electronic labelling solutions that expand access to updated medical information for patients and their health care providers. Many types of digital devices exist in society today that can provide patients and their health care providers with quick, easy access to the latest medical information via an electronic label system (e.g., QR codes, bar codes, the internet). Moving away from static, paper-based labels to dynamic, digital labels has numerous benefits, including improved access to medical information, the ability to update label information in real-time, improved patient understanding of medication, increased efficiency in supply chain management, as well as contributing to sustainability by reducing dependence on paper-based documentation **[5]**.

This review paper aims to examine emerging smart and digital labelling technologies and evaluate their potential to enhance safety, mitigate counterfeiting risks, and support the delivery of patient-centric pharmaceutical care.

2. EVOLUTION OF PHARMACEUTICAL LABELLING AND TRACEABILITY SYSTEMS

The pharmaceutical labelling system has changed from simply providing product identification to a more complex purpose that focuses on four broad objectives; patient safety, compliance, authenticity and supply chain integrity. In order to meet these objectives, the use of barcodes and track-and-trace technologies has enabled verification and provide improved visibility to the supply chain. Additionally, regulatory requirements such as the European Union’s Falsified Medicines Directive (EU FMD) and India’s IVEDA coupled with the U.S. Food and Drug Administration’s (FDA) oversight is driving the implementation of new labelling requirements to help diminish counterfeit medications and ensure quality in pharmaceuticals **[6]**. Serialization is a major innovation in drug package labelling where each package will receive its own unique identifier in order to facilitate

effective identification, authentication, and traceability of the package throughout the supply chain. Serialization will allow for enhanced package-level visibility and monitoring during distribution. There are many countries like Turkey, China, and South Korea that have implemented serialization technique, and the U.S. Drug Supply Chain Security Act (DSCSA) advocates for electronic tracing that can be interoperable between systems **[7]**. But with that, challenges such as incompatible barcodes, complex data management, and high implementation costs still remain. Two-dimensional (2D) barcodes improve inventory management but it requires label redesigning and system integration. The primary and secondary packaging helps to connect the products to the regulatory information while ensuring to protect and support logistics tracking through the GS1 standards **[8]**.

3. COUNTERFEITING DRUGS

Counterfeit drugs are defined as products that have been intentionally produced and passed off as medication or produced but not as they were classed to be. Counterfeit drugs are an ongoing and persistent challenge faced by the pharmaceutical industry for decades. To combat the increasing threat of counterfeit drugs, numerous digital and smart labelling technologies have come into the pharmaceutical industry as an important way to increase drug security, drug traceability, and drug authentication. These technologies can help identify legitimate products while preventing the distribution of illegally produced counterfeit product. The global COVID pandemic greatly increased the number of counterfeit products due to the disruption of the global supply and business models, increases in cyber threat activity such as ransomware attacks, and the additional vulnerabilities created for counterfeiters as a result of these disruptions. The severe impact of these counterfeit drugs on public health and on the pharmaceutical industry has been immense and cannot be ignored **[9]**. Counterfeit drugs are typically missing active ingredients or have low-quality or wrong active ingredients in the drug. A large drug enforcement operation took place in Europe in March 2020, where 34,000 counterfeit face masks and almost 4 million units of counterfeit drugs were taken. According to the World Health Organization, 10% of drugs are sold in low to middle-income countries are either counterfeit or substandard and this demonstrates that this problem is global affecting many people **[10]**.

3.1 IMPACT OF COUNTERFEIT DRUGS ON THE PHARMACEUTIC SECTOR

The issue of counterfeit drug has a severe impact on the pharmaceutical sector, including various problems like legal,

financial, and operational. If a counterfeit item uses a company's trademarks or logos or if a company incorrectly represents itself, they could incur huge legal costs if their customers take legal action against them **[11]**. Finances, lost sales, and increased legal costs resulting from counterfeit drug cases would amount to billions of dollars in lost revenues **[12]**. Counterfeit drugs increase the need for manufacturers to comply with additional regulations by requiring them to comply with stricter rules and regulations to maintain product safety **[13]**. You also lose brand reputation when counterfeit products are sold, which reduces public confidence in that particular brand and in the pharmaceutical sector overall **[14]**. To fight this, manufacturers must invest millions of dollars in anti-counterfeit technology like tamper-evident packaging and serialization systems **[15]**. Counterfeit drugs can also make it more difficult for manufacturers to enter into the global drug marketplace by forcing countries to have stricter import requirements in order to assure the safety of the drugs being imported into their countries **[16]** and these adverse financial and reputational consequences can limit funds that are available for manufacturers to conduct research and develop products, which slows the ability to innovate **[17]**.

Counterfeiting medication isn't something that's solely occurred in this era alone – there have been instances going back all the way to the seventeenth century. Though finding out just how major this problem has proven very difficult due to there being limited amounts of reporting and detection. Because counterfeit drugs are typically made by way of multi-level, global distribution channels as well as via/intermediaries using on-line distribution, they can be quite difficult to trace back to their sources. Unfortunately, the developing world (and specifically Africa) has significantly higher levels of counterfeit drug use than any other area of the globe – particularly with regards to antibiotics and anti-malarial drugs. In developed countries, however, it's still common for counterfeit versions of "lifestyle" drugs to be an issue there too and those numbers are also increasing around the world **[18]**.

4. EMERGENCE OF SMART AND DIGITAL LABELLING

Smart and digital technologies make labelling more effective to tackle the counterfeiting and improving authentication and traceability in the pharmaceutical supply chain. Devices like the TruScan Raman spectrometer and FDA CD3+ helps in verification of medicines. Digital methods such as serialization a unique code to each package so it can be tracked well. Anti-counterfeit labels using micro- or nano-structured materials also help in authentication of the products and technologies like RFID, NFC, QR codes,

sensor-based labels support real-time monitoring, better transparency, and patient safety as well.

Earlier, GTIN barcodes were used as a low-cost way in identification of the products, but they required line-of-sight scanning. The 2D barcodes or QR codes were introduced in 1994 that allowed more data storage and could be scanned using smartphones. However, they still have limits such as short scanning range. RFID improves this by enabling wireless identification and dynamic data storage. With Industry 4.0, smart labels now include sensors to track the temperature, humidity, tampering of the product and its condition **[19], [20], [21], [22], [23], [24]**.

5. VARIOUS SMART AND DIGITAL LABELLING TECHNOLOGIES

Digitization was fast-tracked by the coronavirus pandemic, as well as further developed. Electronic product information, especially in the hospitals, improves safety by providing updated and reliable data through trusted sources to the patients **[25]**. Smart and digital labels integrate various technologies such as RFID, NFC, QR codes, sensors, IoT, and blockchain to enable product identification, data storage, communication, and real-time monitoring. Unlike the conventional labels, these combine physical and digital features to enhance the traceability, user engagement and most importantly authentication of the product.

5.1 Barcodes / QR Codes based labelling

QR codes are commonly employed in pharmaceutical labelling because of their extensive data storage capabilities, fast scan time, and ability to be scanned by smartphones and other digital devices. As part of the most advanced two-dimensional barcodes that allow vast quantities of data to be encoded into one symbol using sophisticated algorithms, they are capable of storing a lot of information, which makes them highly useful for mass pharmaceuticals usage since 2D barcodes are more efficient in storing larger amounts of information than 1D barcodes .QR codes provide a connection between the actual package of a drug and its information on the internet, allowing users to obtain information about drugs, including dosing information, warnings, storage conditions, manufacturer details, etc., which is needed to establish e-labelling while not changing the printing on packages. Also, QR codes are important tools in the process of serialization and traceability of products, which allows regulators to monitor the products during manufacturing and distribution, as well as providing authentication, including product identifiers, serial numbers, expiration date, etc. **[26], [27], [28], [29], [30]**.

5.2 Electronic Package Leaflet (ePL) Labelling System

Electronic Package Leaflets (ePLs) are one important feature of intelligent drug labelling and are being increasingly used to offer electronic access to approved medicine data like package leaflets, label information, and Summary of Product Characteristics (SmPC). Such information can be accessed via various means of digital communication, including the Internet, smart phone applications, databases, and many more. The access is facilitated using special markers on drug packaging, like QR codes. As opposed to printed package leaflets, the use of ePL systems offers the possibility of making amendments and changes to the data related to dosage, precautions, and contraindications in real time without having to reprint new packages. This guarantees that both medical personnel and the patients have accurate information at hand at any moment in time. Moreover, the ePL systems have made the system accessible through the support of multiple languages, searching capability, customization of display options, and auditory guidance. Moreover, the integration of technology into ePL makes it possible to have reminders, educational material, and alerts for patients. This ensures improved compliance and engagement of patients. Nonetheless, issues such as limited digital literacy, disparities in the availability of internet-capable gadgets, and dependence on robust digital infrastructure have been identified as some of the limitations associated with ePL systems. Therefore, the use of ePL is common in combination with printed pamphlets **[31], [32], [33]**.

5.3 Internet of Things (IoT) in Smart and Digital Labelling system

The emergence of the Internet of Things (IoT) has proven to be one of the significant factors in driving smart and digital labels through which connections between products and digital systems are made. In contrast to conventional labels that solely provide static information, IoT-based labels merge sensors and communications to enable the creation of systems capable of monitoring changes within the supply chain cycle. IoT labels have brought about improvements in terms of transparency and minimized the need for human intervention. In practice, IoT labels can be used to monitor aspects such as humidity, temperature, and movement of products. This is particularly important for drugs and other products that require constant supervision of their quality and conditions. The concept of smart packaging refers to either active or intelligent packaging in which products can communicate and provide feedback. Traceability has been greatly enhanced by IoT labelling in conjunction with RFID technology and sensor-based packaging. On the other hand, the challenges are created by the differences between the existing technology and the new IoT technology; this

creates problems in data exchange and compatibility. The challenges can be resolved by means of standardization, and the application of middleware and cloud computing will assist in solving this problem **[34], [35], [36], [37]**

5.4 RFID-Based Labelling System

RFID based label technology is a significant improvement in the packaging and distribution systems of pharmaceuticals. Through the use of radio frequency identification technology, tagging allows the automatic collection of data, increased visibility and better control throughout the product life cycle, from manufacturing through to consumption by the patient. While traditional barcode technology involves scanning, RFID works through electromagnetic radiation of radio waves which do not need line of sight and are capable of identifying several items at once. Traceability is an essential feature associated with the implementation of RFID technology. The use of the unique identity of the RFID tag ensures that tracking is available at all times during the production, storage, transport and distribution process. This increases inventory management, recall procedures, minimizes the number of lost items and human errors. In addition, it helps in diverting products from getting into unauthorized hands and meets any regulatory requirement on serialization and traceability. Moreover, RFID assists in authentication of products in order to counteract counterfeits. RFID can be used in cold chain management when products are sensitive to temperature changes. For instance, in health care organizations, RFID ensures efficient inventory management, medication tracking and minimizes errors in dispensation for better patient safety. With the incorporation of Internet of Things, there will be efficient tracking and supply chain management of pharmaceutical products. Despite some issues that RFID may face, including high cost and security, RFID continues to improve pharmaceutical operations **[38], [39], [40], [41], [42], [43]**.

5.5 NFC-Based Labels

NFC (Near Field Communication) labels represent another level of sophistication that is based on the application of RFID technologies to pharma product's labelling. NFC labels combine functions such as identification, tracing, and interactivity for patients. Contrary to RFID devices that need special scanners, NFC tags can be scanned using any smartphone. Each label has its own identity code that links it to databases for verification of its authenticity to avoid fraud, particularly regarding expensive medicines.

NFC tags provide opportunities for patients-centred approach as they offer patients easy access to vital information about medicines, their dosages, storage requirements, expiry dates, etc. Moreover, they contain electronic

leaflets to help understand how to use a medicine and improve patient compliance. Besides, NFC tags can also serve the purpose of preventing tampering or counterfeiting during the transportation process. Using NFC in conjunction with connected systems or blockchain technologies provides transparent data that reflects the history of the product **[44], [45], [46]**.

5.6 Blockchain-Based Labelling

Blockchain technology offers solutions in pharmaceutical product labelling to ensure product traceability, authentication, and transparency in the supply chain. The technology uses blockchain technology together with QR codes, RFID tags, or serialized barcodes as unique identifiers to create immutable records of all products. The use of an immutable record system at each stage of the pharmaceutical production process helps ensure that information in the pharmaceutical industry can be relied on while not subject to tampering.

The technology is capable of real-time verification of the authenticity of pharmaceutical products with label-linked digital records, which can help in tracking defective batches and managing recalls. High costs and lack of interoperability with existing databases can pose serious barriers to adoption of this approach, but overall, it has proven itself to be a useful solution in the pharmaceutical industry **[47] [48]**.

6. ADVANTAGES AND APPLICATIONS OF DIGITAL AND SMART PACKAGING

Various advanced technologies have been integrated into smart and digital packaging systems to improve the safety, traceability, and efficiency of pharmaceutical products. The intelligent sensors applied in smart packaging facilitate the identification of any contaminant and pathogen, hence enhancing the quality control processes. The system offers an enhanced capability for monitoring and tracing pharmaceutical products through all stages of the supply chain, while the track and trace technologies provide unique identification to each individual item. Anti-counterfeiting technologies and tampering proof packaging help to combat the threat of counterfeit drugs in the market by securing the products against manipulation. Automatic identification, data collection, and inventory management is achieved using technologies such as RFID and barcodes, which make logistics more efficient. The application of the QR code in packaging increases the effectiveness of communication. These technologies can also provide labels and dispensers at the level of individual units, which can eliminate medication errors. Moreover, the system allows for providing up-to-date information related to the safety issues regarding the medicine because they provide digital connections with the databases.

Additionally, smart packaging enables monitoring of drug usage as well as its patients, which improves treatment outcomes. These technologies can help older people or patients with visual impairment by facilitating their access to medicine. Additionally, the technologies mentioned above may be used for customization of medicine packages by means of, for example, 3D screen printing **[49], [50]**.

7. CHALLENGES MAY FACED WITH DIGITAL AND SMART LABELLING SYSTEM

Several technical and practical problems hinder the use of digital and smart packaging in pharmaceuticals. First, there is an accessibility challenge since not all patients will be able to scan and use the QR codes and other digital platforms. This reduces the utility of digital technology and necessitates the provision of printed leaflets. It is crucial to ensure adequate patient education on how to read the digital information safely. Secondly, digital content management is a problem since QR-coded information may be outdated, unregulated, and underdeveloped **[51]**. This poses risks to patients' well-being and requires strict regulation. Thirdly, there are other factors that may impede successful adoption such as disruptions and technical glitches in the system and cybercrime risks **[52]**. Lastly, there are technical problems such as failure to maintain adequate connectivity and device functionality. Therefore, it is essential to have alternative methods for accessing digital information **[53]**. The expensive nature and complexity are other factors that hinder their use, more so in RFID technology. This needs a sophisticated infrastructure which not all places can afford. Technical problems may arise such as the inability to scan biologic or liquid items accurately. Companies could be resistant to use this technology because of its expense, uncertainty in its success and prior losses. Though 2D barcodes are relatively inexpensive, they cannot be used effectively because of other weaknesses, such as line-of-sight scanning and ease of replication **[54]**. Other obstacles include inadequate visibility in the supply chain process, cooperation and trust between the different players, and controlling the temperature **[55]**.

8. TEMPORAL EVOLUTION OF QR CODE-BASED DRUG LABELING SYSTEMS (2016–2026)

The last decade witnessed the development of QR code-based drug labelling technology from simple security systems for products to digital platforms that provide real-time tracking and monitoring. One of the first studies carried out by Fei & Liu (2016) offered a completely innovative biodegradable label on QR codes embedded in drug dosages. Labels were created by means of micromolding and laser engraving

technologies with the use of biocompatible polymers, including polyvinyl alcohol, hyaluronic acid, and pharmaceutical gelatin. Such QR code structures were extremely thin and provided the possibility to contain necessary information about drugs. The main aim of such labelling technology was increasing security against fraud by providing protection of the product itself through secure embedding of the label. In turn, new developments (2026) indicate the transition to the implementation of digitalized systems, where QR codes work as individual codes for centralized databases. Each unit of the product comes with a traceable identifier during the process of manufacture, facilitating authentication at different stages such as distribution and retail. The technology offers real-time identification of the product through use of mobile apps by making available information about the product including the producer and its expiration status.

This comparison highlights an obvious shift from a passive approach to labelling individual products to a more active approach that integrates the entire system. Despite their similarity in goals, the QR system offers greater functionality compared to the barcode system by offering real-time communication and increased traceability of the drug throughout its lifetime **[56], [57]**.

9. FUTURE PERSPECTIVE

Digital and smart pharmaceutical packaging is set to incorporate more integration, patient orientation, and data analytics features. The use of IoT technology can ensure the monitoring of environmental factors, consumption rate, and logistics operations, thus contributing to increased quality and improved pharmacovigilance. It seems reasonable to assume that there will be an increase in the number of ePL systems that will offer updated and translated information regarding drugs. QR codes will remain popular because they provide immediate access to various data about products, their origin and composition, as well as suggestions for appropriate treatment for patients. Blockchain technology may enhance the security and transparency of the process because all transactions can be tracked without any possibility of alteration. Artificial intelligence technologies can help to improve personalized drug management and health services. In terms of material development, future innovations will concentrate on environmentally friendly materials. Data security and privacy, international cooperation concerning regulations, and user-friendliness should be considered in this context. All in all, smart packaging will be used extensively in pharmaceutical practice **[58]**.

10. CONCLUSION

The concept of smart and digital labelling in pharmaceuticals is an extremely innovative solution that contributes to increased drug safety, traceability, and supply chain management in general. The combination of various technologies (QR codes, RFID, NFC, serialization, blockchain, IoT, and ePL) converts the traditional system of labelling into a highly advanced and connected structure. Such system makes it possible to control drug transportation and storage continuously, contributing to effective management even further. Drug authentication and counterfeiting prevention is the main area where the use of the above-mentioned techniques brings great benefits to pharmaceutical supply chains. This reduces the risks of counterfeit drugs entering the market significantly and increases the accessibility of drug data for patients and medical practitioners alike, meeting the needs of regulators and ensuring more efficient coordination of all stakeholders involved.

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