The Fight Against Counterfeit Pharmaceuticals: Innovative Technologies to the Rescue?

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Today's pharmaceutical market and supply chains are becoming increasingly complex, which makes the discovery, tracking and policing of counterfeit medicines difficult. Given that counterfeit products divert nearly one trillion dollars from the global economy annually, a focused effort is now required not only by law enforcement, policy makers and pharmaceutical companies, but technology developers, who have the increasingly difficult task of developing innovative solutions to track and identify real or counterfeit medicines, and more importantly ensure that consumers are not being exposed to ineffective or potentially life-threatening fake medications.

In this article we explore existing solutions and the next wave of promising innovative technologies which are at the forefront of the pharmaceutical industry's global fight on counterfeits. First we begin with a brief discussion about where the fake medicines are originating and how they are produced.

Where do counterfeit medicines originate?

Although the true scope and size of the pharmaceutical counterfeit market is hard to ascertain with accuracy, at least local governments and international organizations now have a better idea of how traffickers are saturating regional and global markets with fake medicines. For the MENA region, and also other major international markets, fake medicines are usually originating somewhere in Asia. According to a recent report by the U.N. Office on Drugs and Crime ("UNODC"), China and India are the largest sources of fake medicines, with China being the originating point for an estimated 60 percent of medical counterfeits seized globally. According to the report, recent efforts by China and India to curb counterfeit production may prove difficult to enforce, as production is likely to be moved elsewhere, including Myanmar and Vietnam.

The rise in e-commerce has also increased the ease with which counterfeiters can now enter the market, which has in turn increased the inherent difficulties in tracking and policing fake medicines. Online retailers have made it easy for counterfeits to be delivered to the hands of unsuspecting consumers in a quick and efficient way. A counterfeit operation could occur at any step in the supply chain in any country in which a pharmaceutical company may be located, from manufacturing, to distribution, labelling and packaging.

Counterfeit production and consumer risks

So how are counterfeits produced, and how risky are they for consumers? With the advancement in printing technologies available to the public, counterfeiters can fake or mimic any product labelling or packaging, including bar codes. Firstly, to make the medicines, a simple tablet pressing tool is used to produce fake pills. Most solid oral dosage drugs can be easily manufactured in this way. Oftentimes the counterfeiters provide what are called substandard drugs, which do not incorporate a sufficient amount of the active ingredient required. In more severe cases, they use unhygienic or dangerous materials. Enforcers have reported finding highly hazardous materials including brick dust, sheet rock, and printer ink

for fake colouring, in counterfeit pills.

Some extreme cases have shown that the dangers lie not only in the risk posed by a substandard active ingredient, but also in the incorporation of contaminated ingredients. In one case, vials of a cancer fighting drug were found to contain no active ingredient at all. In another notable instance in the U.S. in 2007, 149 Americans died from a contaminated blood thinner that was legally imported into the U.S.

Currently the most common types of medicines that are counterfeited and are entering the market in the GCC, and particularly here in the UAE, include lifestyle drugs, such as those addressing erectile dysfunction or weight loss. In international markets, highly counterfeited medicines also include specialty drugs (e.g. cancer treating), and drugs with a high "street value", such as potent pain medications. Although recently, pharmaceutical companies have seen an even broader spectrum of counterfeits, including for example diabetes test strips and injectable drugs such as Botox.

It is evident that for technology developers, the potential market opportunities for providing anti-counterfeiting solutions to pharmaceutical companies and regulators are large, and these solutions have become increasingly necessary for safeguarding the consumer. This field of technology has been rapidly developing and there are already sophisticated technologies deployed by pharmaceutical companies and by governmental enforcers, and with new promising technologies in the pipeline, there are hopes that combating pharmaceutical counterfeiting will become more successful and efficient.

Is there a solution?

In the past few years several tech companies have come forward with solutions to this problem. Innovations in this field utilise a wide spectrum of technologies, including radiofrequency identification ("RFID"), microtagging and nano-encryption. Let's take a closer look at each of these solutions and how they are or could be implemented by the industry and enforcement agencies.

Radio frequency identification ("RFID") allows manufacturers and distributors to more precisely track drug products through the supply chain. RFID makes it easier to ensure that drugs are authentic, and it also creates an electronic record of the chain of custody from the point of manufacture to the point of dispensing. An individual drug package is equipped with an RFID tag containing information about the drug's origin, and this information is hard to manipulate. In practice, authorized drug ingredient manufacturers tag all their ingredients with RFID tags before distribution to the pharmaceutical companies. As the drugs are manufactured, the tags of the ingredients are scanned and reported. Information about medicinal ingredients as well as a serial number and other essential product information are added to an RFID tag that is attached on the package of the drug. Now the drug package tag contains information not only about its own origin, but also about the ingredients and the amount of each ingredient in the drug. The information on the tag can be converted into an electronic record, which can be added to with more and more information about the events on the drug's supply chain journey, from the manufacturer all the way to its end destination (i.e. pharmacy, hospital).

Microtagging is another innovative technology, which has been developed with the purpose of identifying characteristics of individual pills or tablets. In essence, microtags serve as non-visible edible bar codes and can be utilized by pharmaceutical companies to track their drug product on a batch basis. The microtag is made up of porous silicon dioxide particles, which have been electrochemically etched and thereafter contain a unique porous structure, thus creating a unique ID. The particles are mixed with the outer coating of a pill or tablet prior to the tablet being coated, and thus the edible microtags are integrated and become part of the pill coating. The microtags enable companies to determine the identification and supply chain history of an individual pill, including information such as product type, dosage type, the manufacturing facility, lot/batch number and so on. The unique microtag signature and related information can be then read with a simple spectrometer-based device so that the pills can be identified and authenticated throughout the supply chain and ultimately once they have reached their destination.

Nanoscale encryption is another technology that has in recent years caught the eye of the

pharmaceutical industry. The encryption details are proprietary, but in essence an individual pill can be embossed with specific encrypted information or codes at the nanoscale. This can include a variety of encrypted information, for example the point of manufacturing, the delivery destination, the dosage and expiration data and other such information which would be utilised to identify and authenticate the medicines. The embossed encrypted codes are in the range of about 200 nanometers in size. The codes and information contained therein can then be decrypted through the use of a customized scanning electron microscope and proprietary decryption software.

Enforcement in the GCC

So what do these technologies mean for the fight against counterfeits in the GCC region? Authorities in the GCC region, particularly in Saudi Arabia and the United Arab Emirates have taken a strong stance to secure the safety of medicines being provided to local consumers. With nearly 60% of the regional share, Saudi Arabia is the largest pharmaceutical market in the GCC, and forecasted to reach nearly 4.7 billion USD this year. The Saudi Food & Drug Authority (SFDA) has put in place several measures to ensure counterfeit medicines are not infiltrating the supply chain. These measures include the use of spectroscopy devices, which are used as scanners to analyse the chemical composition of the medicines and thereby identify counterfeits.

The UAE has also recently increased efforts to eliminate fake medicines from reaching consumers. As a result, Dubai Customs authority recently seized a large shipment of 556,000 drugs, which were counterfeits of a blood clot prevention medicine. The Health Authority in Abu Dhabi (HAAD) has also announced that it will commence using a new device which can detect counterfeit medicines in about seven seconds. Additionally from a legislative perspective, the UAE Federal Law N°4 of 1983 on the pharmaceutical profession and industry will be updated to introduce new seizure measures and procedures for suspected counterfeit shipments, and will strengthen penalties against those dealing with counterfeit drugs. These updates are expected by the end of this year.

Considering that regulatory agencies, enforcement authorities and pharmaceutical companies in the GCC are beginning to turn to innovative technologies and evolve their means of combating counterfeits, the tech companies providing such solutions should consider expanding their market presence in the region and accomplishing this includes putting in place the appropriate intellectual property protection strategies for their new technologies. As with any new innovative devices or processes, it is always advised that companies protect their intellectual property and know how, through appropriate patenting strategies in this region. Having a strong proprietary patent portfolio in place will help these companies to be competitive solution providers and ensure their interests in the region are adequately protected.

It remains to be seen how new technologies will fare in terms of ease of implementation, cost, effectiveness in deterring counterfeits, and scope of applicability, but nevertheless, the available tools for enforcement agencies and regulatory bodies in the GCC region are rapidly evolving and will hopefully in the near future aid in eradicating dangerous medicines from reaching unsuspecting consumers.

Al Tamimi & Company's Patents, R&D and Innovations team regularly advises technology companies particularly in the life sciences and pharmaceutical industries on patent protection and commercial/regulatory issues associated with these industries in the GCC region. For further information, please contact Ahmad Saleh (A.Saleh@tamimi.com) and Ina Agaj (i.agaj@tamimi.com).