

Tackling Pharma's Shadow Market: Getting 'Smarter' in the Fight Against Fake Pharmaceuticals

If you were to ask a member of the public "what is the world's most counterfeited product?", it's highly likely they'll say designer handbags or watches. But, in fact, the world's largest fraud market is pharmaceuticals – and by a large margin.

The larger the industry supplying a consumer product, the more likely it is that criminals will try and exploit it. And with counterfeit and falsified medicine, the profits can be huge. But so too can the risks to public health and the industry's reputation.

And this risk is growing, accelerated by the disruption of the COVID-19 pandemic, complex global supply chains, widening access to healthcare in emerging economies and the rise of pharmaceutical e-commerce.

An Important Distinction Between 'Counterfeit' and 'Falsified'

Within the pharmaceutical shadow market there are two threats – 'counterfeit' and 'falsified'. It's important to distinguish between these different types as how criminals create and distribute them can differ, as well as the danger to consumers and a brand's reputation.

According to the European Medicines Agency, "a counterfeit medicine is made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or rights and infringe trademark law".

This means counterfeit medicines try to pass themselves off as legitimate products, causing the impersonated pharma brands reputational damage if the drugs are less effective or dangerous to unsuspecting customers.

Whereas falsified medicines are "fake medicines that pass themselves off as real, authorised medicines." This could mean they contain ingredients of low quality or in the wrong doses, are deliberately and fraudulently mislabelled with respect to their identity or source, have fake packaging,

the wrong ingredients, or low levels of the active ingredients.

Falsified medicines pass themselves off as the real deal by mimicking (not copying) legitimate pharmaceutical products. It can be difficult, if not possible, to tell whether a falsified medicine is made by an authorised manufacturer or not.

Both types of fake medicines can be equally dangerous to public health and have far-reaching consequences for healthcare systems and the global pharmaceutical industry.

Pharma's Growing Shadow Market is a \$200bn-a-year Industry

The pharmaceutical market has experienced significant growth during the past two decades, and pharma revenues worldwide totalled 1.27 trillion U.S. dollars in 2020.¹

And as the legitimate pharmaceutical industry grows, so too does its shadow market run by criminal networks.

The most recent trusted estimate of the size of the global annual market for counterfeit and falsified medicines stands at approximately US\$200 billion² according to data from the World Customs Organisation.

And in March 2020, Interpol's Operation Pangea XIII³ seized counterfeit pharmaceuticals worth more than \$14 million worldwide, just months after the COVID-19 virus was first discovered. Since then, the situation hasn't let off.

The true cost goes beyond financial, though.

It's an issue that is both fuelled by and is fuelling widening health inequalities. While counterfeit and falsified medicines exist in every region of the world, they are most likely to be circulating at their highest in low-and middle-income countries, such as in Africa and Asia where demand for healthcare is growing.

Technology is also opening new opportunities for fake pharmaceuticals to be marketed, bought, and consumed.

Criminal networks are leveraging the same digital channels, including e-commerce sites and social media platforms, to penetrate developed countries where barriers and regulatory frameworks are more advanced.

In fact, WHO estimated in 2015 that 50 percent of drugs for sale over the internet were fake and this is only increasing as buying medicines and lifestyle products online becomes more common practice.

Today, no country or company can afford to overlook their vulnerability, nor the opportunities available to reduce the threat of fake medicines and improve existing supply chain safeguards.

Serialisation on Packaging – The New Global Standard

Packaging technologies play an important role in hampering criminals' ability to produce, transport and sell counterfeit and falsified medicine. To stay one step ahead of criminal networks whose approaches get smarter every year, packaging must become smarter too.

A major leap forward came when a new worldwide standard for mass serialisation on packaging, often combined with 'trace-and-trace' requirements, was introduced. In 2019, two important pieces of serialisation regulation came into force – the EU's False Medicines Directive and the U.S's anti-counterfeiting protocol The Drug Quality and Security Act.

The EU's FMD ensures complete product traceability from manufacturing to decommissioning, instead of placing the burden of authentication on any single stage of the process. The Drug Quality and Security Act requires authentication at every supply chain juncture, including wholesalers. Both don't require product-level coding but rely on barcodes printed on secondary packaging which sophisticated criminal networks can quite easily replicate.

Digital watermarking techniques are also becoming more widely used, providing an extra layer of protection by printing invisible, encoded data on packaging that can only be verified by

specialist software. Invisible to the human eye, the watermarks can be captured using webcam, mobile phones and other specialist scanning equipment.

We're also seeing developments in holograms, designed so that they're only visible behind each pill/capsule cavity on the back of each blister pack, thereby allowing the printing of dosage and marketing information on the area surrounding the recess.

Supply Chain 4.0 and the Role of Big Data

The comprehensive nature of end-to-end drug traceability in a market which is increasingly global means FMD compliance shouldn't be the final step.

There's a real opportunity for manufacturers, working in collaboration with packaging companies, to create the next generation of tamper-proof technology and become pioneers in digital packaging that can make tracking products across the supply chain much simpler.

Perennial encryption technology is a largely untapped innovation, preventing duplication and replication of 2D and 3D unique identifiers. By issuing a single-use URL, perennial encryption technology renders any cloning attempt useless. Only the secure cloud host knows the sequence of coding and any attempt to re-use the previous URL is detected by the cloud host and an invalid message is issued warning the product has been copied. The same process can be used to identify tamper evidence too.

Intelligent tracking systems, built into medicine packaging, is also a developing science which will prove valuable in the fight against falsified and counterfeit medicine. As a live programme, the location of a product at any given time can be seen in real-time remotely together with its end-to-end journey, revealing any unauthorised routes or interventions.

Not only can technology aid the pharma industry in removing falsified products from its supply chain, but the data insights gained can also be used to increase efficiencies. Despite companies innovating in the field of science to discover, develop and market medicines more efficiently, many companies have failed to upgrade their supply chains. Collected data can highlight inefficiencies and bottlenecks which can be addressed to streamline processes and drive cost-savings.

With biologic and personalised medicine already re-shaping the industry, there needs to be a two-way street where information is being used to inform the downstream flow of products. Data holds the key to creating efficient, safe and demand-driven supply chains which benefit manufacturers, health systems and above all else, patients.

Drug companies won't necessarily have to build their own anti-counterfeiting ecosystems, either. Manufacturers can avoid the high up-front costs of developing an anti-counterfeiting system by handing off all or part of the work to external providers.

A Leaner Supply Chain Will Help to Eliminate the Shadow Market

As part of Pharma 4.0, there's also a real opportunity for pharma manufacturers to work with packaging and supply chain management companies to develop innovative new digital-first solutions that help to eliminate 'fake' products from circulating. And to make the supply chain smarter and leaner.

At the heart of transforming the supply chain is the application of lean principles. This essentially means using less human effort, less inventory, less space, and less time to produce high-quality products. It also means working as efficiently and economically as possible while being highly responsive to customer demand.

However, becoming 'leaner' requires more than merely using the terminology or plugging in a new technical tool. Rather, it requires a fundamental rewiring of operation and management systems.

Historically, pharma companies globally have relied on a network of hundreds of suppliers to manufacture, package, and deliver different products to market. It's still not uncommon for multiple teams to be managing multiple international supplier sites. As a strategy, this is overly complex, largely inefficient, and very expensive. It also makes the industry easy picking for criminal networks looking to exploit it.

A pragmatic solution is to simplify the supply chain, bringing it under one roof, merging the best of manufacturing, design and innovation, supply chain networking and infrastructure. When doing so, it's important there are internationally dispersed sales offices, manufacturing cells and storage facilities in strategic locations.



Beyond helping to eliminate the shadow pharma market, consolidating the supply chain brings a host of benefits including reduced risks and overheads, greater innovation, increased speed to market, assurance of supply and compliance, tighter quality control and local availability via regional distribution sites on a global scale.

Anti-counterfeiting solutions are becoming smarter every year. But so too are criminal networks. There is a real opportunity here for pharma companies with the foresight to invest in Supply Chain 4.0 to set the stage for new business models that can create value in many ways – and limit counterfeit activity in the process, too.

REFERENCES

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Rich Quelch is an experienced global marketer within the healthcare and pharmaceutical sector. He has led the development of the Origin brand, positioning it as a world-leading supplier of innovative and ground-breaking pharmaceutical packaging devices, as well as offering a unique supply chain model which is disrupting the pharma industry.