



# WHITE PAPER

**COUNTERFEITERS IN THE PHARMACEUTICAL SUPPLY CHAIN**  
HOW TO MINIMIZE THE RISK AND AVOID A CRISIS

## A suspicious product has been reported in the field...

You receive news of a physician preparing to administer one of your critical care drugs, only to stop the treatment as they notice some anomalies with the packaging and color of the medicine.

You must move quickly to preserve patient safety. But how quickly can you move? How long does it take to gather pertinent details and decide on next steps? Do you send an in-field investigator to validate whether the medicine is indeed counterfeit? If so, does he have the right tools to quickly identify the situation? The big question is....

### Now what?

At the point of authentication, many in-field investigators fail to use real-time technology and instead opt for time-consuming manual processes. These in-field investigators may choose to:

- Meet with the person who alerted them about the suspicious product
- Purchase suspicious package and manually review the product label for such elements as color, price, misspelling, label placement, product ID number, bottle cap size, etc.
- Send suspicious product or photos of it back to a lab to be sampled and tested
- Create a chain of custody
- Review databases for import and export records in certain jurisdictions of the world.

Depending on the severity of the counterfeit product and the threat to the public, the in-field investigations can take anywhere from two to six weeks to locate the origin of the threat before an alert notice is issued. This time-consuming, inefficient process can have several devastating effects, not limited to,

- Large risks to patient safety
- Negative impacts on brand reputation
- Lost revenue
- Delayed production

### Key indicators that a counterfeiter has breached your legitimate supply chain:

- Identification of erroneous packaging at various stages of the supply chain (distributor, hospital/pharmacy, patient, return center)
- Unexplained variances in the volumes of drug(s) supplied
- Adverse and unexplained health concerns following administration of a drug
- Increased calls or submission of product into the quality department
- Decrease in reliable sales areas

### Risks

The inefficiencies attached to manual authentication heighten the risks to both patients and affected companies.

Counterfeit pharmaceuticals harm or kill millions globally. The backing of such activity by organized crime syndicates, provides the access to technology and equipment that allows illicit drug trafficking to operate like a legitimate business. This illegal activity also increases spending on policing and decreases taxation.

With the rise of e-commerce pharmaceutical counterfeiters are using digital channels to enter the marketplace to avoid the traditional brick and mortar distribution channels that are better regulated.

**“With annual sales ranging from \$163 billion to \$217 billion, counterfeit pharmaceuticals are estimated as the most lucrative sector of the global trade in illegally copied goods.” - PWC<sup>1</sup>**

**50 percent of drugs sold online by illegal sites are counterfeit<sup>2</sup>**

## So what does this mean for pharmaceutical companies?

There are so many points of attack for legitimate medicine to intertwine with counterfeit products. Brand owners are stretched with managing the brand, in addition to trying to prevent legitimate product from being stolen, adulterated / diluted, diverted or infiltrated at the point of product being repackaged for parallel distribution.

Counterfeit drugs cause serious damage to major pharmaceutical manufacturers, resulting in tarnished brand reputation, lost market share, increased lawsuits, and ultimately, loss in revenue. As a result, manufacturers are spending money to combat counterfeit products, money that could be invested in R&D and often requires expense reductions in other areas.

**A large pharmaceutical company spent more than \$110 million on serialization to thwart reproductions of big name remedies.<sup>3</sup>**

Another concern is reputational cost. There is no denying that counterfeiting damages a company's brand. When a pill disguised as one of your products hurts or fails to help a patient, you take the blame. Not the unknown counterfeiter. Customers rarely realize they've taken a fake drug, but they remember the name on the bottle - **yours**.

## It's not a matter of if, but when and where

When defending a pharmaceutical supply chain from counterfeiters, brand protection teams must equip themselves with the right mitigation and damage control strategies. The threat of a breach is never too far away.





The urgency of the counterfeit medicine issue has many in pharmaceuticals focused on strengthening anti-counterfeiting measures – as it should. However, it is even more important to execute the right plan of action when a counterfeit product is reported. While it may come in different forms, the most effective ways to identify counterfeit goods are:

- Overt security features and inks on packaging
- Covert machine-readable inks and taggants preferably with read-through packaging detection
- Tamper evidence indicators
- Serialization Track and Trace.

These security measures make it easier to validate products in the field, in real-time and send back important data for analyzing the entire lifecycle of product. Having the right plan in place saves time, money and most importantly lives.

## The right plan of action

Introducing real-time technology into this process can significantly improve outcomes. Real-time cloud technology can validate, communicate, investigate and activate within seconds of identifying a suspicious package.

An in-field investigator can utilize a hand-held reader to get instant package authentication and send

insights directly to selected smartphones, tablets or computers. This one-step process enables brand investigators to act quickly and take swift action against counterfeiting activities.

## Four steps to real-time authentication

When a counterfeit product is reported, you must be prepared to validate, communicate, investigate, and activate in real-time on a global scale.

### #1 Validate

Counterfeiting has advanced to the level that it is often difficult to distinguish an authentic package or product from a counterfeit one.

Serialization is often cited as a panacea for combating counterfeits in the supply chain. It is indeed a useful traceability tool; however, how can you be certain that the code hasn't been copied? As with anything you are trying to protect, having multiple layers of security is the optimal approach.

You must rely on advanced detection technology to confirm whether the product is legitimate or counterfeit.

One option is to return the product to the lab.



However, consider the implications of sending the product to a facility to be tested. How many more patients are at risk during the time it will take to confirm the drug is a counterfeit? In order to put patient safety first, the best practice is to quickly validate the product in the field.

With the appropriate authentication marks on packaging or in products, today's technology can easily read security markers and validate if you are dealing with a counterfeit drug. Remember, a lot of repackaging by local agents, under different names, leads to the potential of counterfeits entering the market.

## #2 Communicate

If you are able to validate in the field, you can immediately notify key stakeholders with the findings and rapidly enact your risk analysis and mitigation strategies. This is especially true of the local regulatory authority, which has the legal powers to take action.

Your internal team must be fully aware of the situation and of the potential impact the breach may have on patients and the organization. Throughout the entire process, communication needs to be a consistent thread at all levels. Keeping all the stakeholders connected is advantageous to minimizing risks.

Case in point: One of the largest global pharmaceutical companies was able to quickly alert their local healthcare network, after discovering a counterfeit product in market. This product had advanced security markers in place that allowed for real-time detection, enabling them to quickly remove all counterfeit products from inventory.

## #3 Investigate

The more intelligence you gather, the better chance you have of identifying problem areas, decreasing response time and stopping any further damage.

- Spot check regional distribution around "hot spot area" by checking anti-counterfeiting features on packaging

- Immediately and accurately quarantine suspicious product
- Reference any previous cases in region or facility
- Send samples to lab for further analysis
- Track all shipping and touch points associated with counterfeit drug to determine where it entered the system.

## #4 Activate

Confidence is key for this stage. When you have confirmed a counterfeit, you must synchronize the appropriate resources to take immediate action.

- Inform regulators; start with your legal team
- Alert the general public of the counterfeit and how to identify it
- Update existing anti-counterfeiting features, if they have been compromised
- Freeze or recall the legitimate supply chain, if there is a known breach (this is a costly option).

In one recent case, the FDA alerted a manufacturer that one of their critical care drugs was found to lack its required active ingredient. This would have rendered the product completely useless or potentially unsafe for consumption. After receiving the notification and following internal protocols, the company



swiftly upgraded the product's tamper evidence seals and made policy changes with wholesalers to help prevent counterfeiters from breaching their supply chain in the future.

## How product authentication impacts your business

Regardless of whether you have an established brand protection system in place or are just starting out with limited resources, it is important to understand and acknowledge your organization's level of competence in brand protection. This can range from undeveloped - no team in place, to advanced - a fully functioning knowledgeable brand protection team with a comprehensive system implemented.

Where does your company fit on the spectrum? To discover your status, here are some critical questions to answer:

- Do we have a brand protection team in place?
- How do we efficiently verify the validity of a potential counterfeit report?
- How do we respond to a counterfeit report? What are the roles and responsibilities?
- What is the process to authenticate products in the field?
- How long does it take to identify a fake product? Root cause assessment?
- What methods do we use?
- Do we have to shut down the entire production line until an assumed fake product is authenticated or not?

- How much revenue are we losing due to the time it takes to identify a counterfeit product?
- Who should be informed of the breach? How do we contain communications?

The efficiency levels, as well as confidence in internal systems and structure, is critical to managing the crisis.

Responding to a counterfeit report really tests the stability of the internal infrastructure. When the brand protection culture is not efficient, confident and ready to respond to criminal attacks like counterfeits, problems start to compound.

## No move is not a strategy

In this "not if, but when" environment, there is no need to gamble with patient safety. You must feel confident that the plan you have in place can detect authenticity, in real-time, outside of the laboratory where it matters most.

Counterfeiters continue to elevate their game. You should too.

Contact Authentix® today at [info@authentix.com](mailto:info@authentix.com) for a quick assessment of your brand protection program and innovative ways to beat counterfeiters. Your move.

### Sources

1. PWC "Fighting counterfeit pharmaceuticals" report. 2017
2. <http://www.who.int/bulletin/volumes/88/4/10-020410/en/>
3. <https://www.reuters.com/article>

## About Authentix

As the authority in authentication solutions, Authentix helps customers thrive in supply and distribution chain complexity. We provide advanced authentication solutions for governments, central banks and commercial products, ensuring local economies grow, banknote security remains intact and commercial products have robust market opportunities. Our partnership approach and proven sector expertise inspires proactive innovation, helping customers mitigate risks to promote revenue growth and gain competitive advantage.



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