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Anti-Counterfeiting Program Strategies for Small to Mid-sized Pharmaceutical Brands

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Implementing risk-based anti-counterfeiting strategies is a critical component of a product launch.

Counterfeit, adulterated, and diverted medicines present a critical risk to patient safety and account for hundreds of billions of dollars in global illicit trade. The proliferation of fake medicines, the severe risk to patient safety, and lack of a unilateral approach by governments to combat this crisis leaves the pharmaceutical industry in a posture of self-defense to remediate this ever-growing menace. With so many points of attack and opportunity for illegitimate supply to comingle with genuine product, a company's ability to detect, measure, and mitigate the adverse events caused by illicit products is the key to your own defense.

While larger pharmaceutical companies generally have anti-counterfeiting programs, or ACPs, in place to combat this crisis, small and mid-sized pharmaceutical companies often overlook the critical need to accurately assess potential risks and implement strategies and product security measures early in the launch and commercialization process. Delaying or waiting to implement an

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assessment and implementing a product protection solution can put patients at significant risk as well as severely and adversely impacting the company's financial success, brand reputation, and capacity to manage crisis events in the supply chain.

Program and Risk Evaluation for all Newly Launched Products is Critical

Launching a new product is the lifeblood of any pharmaceutical company. For small to mid-size companies, it can be the very essence of surviving or failing. For these companies, enacting a solid ACP can make a significant impact on reducing issues as products commercialize and begin contributing to the company's value creation. Brand owners spend millions of dollars in product development and bringing a product to market including base research, clinical studies, regulatory filings, scaling manufacturing, supply chain operations, and other activities deemed critical to the success of the launch.

Items that may be considered peripheral to the task at hand, including anti-counterfeiting technologies and their benefits, are often overlooked while launching a new product.

Even one unauthorized sale of a launched product (counterfeit or otherwise) into the marketplace can have a devasting impact on any brand owner, especially a smaller, less capitalized company and could result in far-reaching market implications creating a lack of confidence in the brand and potential loss of future market share. During the launch phase of a new product, any event that erodes confidence in the brand can

be the difference between success and failure. The reputation of your new product and your brand must be the highest priority and a well-designed ACP will significantly impact the ability to mitigate such potential outcomes.

Small and mid-sized companies can leverage lessons learned by peers that have witnessed the devastating impact of illicit products found in the supply chain. In comparison to the overall product development costs incurred to launch a product, the amount of incremental resources needed for a good ACP implementation is, in fact, one of the best investments you can make.

The Five Key Steps to Implementing an Effective ACP Program

The diagram below illustrates the suggested roadmap for companies to create a cost effective, efficient, and manageable ACP to mitigate the expected risks associated with the discovery of unauthorized product suspected and/or determined to exist in the supply chain.

The first step for this critical program is the engagement of an industry professional and partnering with an experienced technology supplier capable of offering a series of robust solutions. Once on board, their expertise will be leveraged to understand the risk of the product, design program strategies, select the correct technology and features, and support enablement activities designed to provide the least impact and greatest value to your organization.

Executive Summary
Counterfeit medicines present a critical risk

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to patient safety and can have a devasting impact on a new company, creating a lack of confidence in the product and potential loss of revenue. With lack of a consistent global strategy to combat counterfeiters, the pharmaceutical industry must assume an active role in the monitoring, authentication, and enforcement of pharmaceutical crimes. Implementing risk-based anti-counterfeiting strategies is a critical component of a product launch and can be accomplished efficiently and effectively by engaging industry experts and technology partners capable of integrating ACP into your existing product launch process.

Failure to take early steps to assess risk to your products and design defensive strategies to combat counterfeiting risks is a critical mistake experienced by new companies that often find themselves reacting to an adverse event after the product has come to market. To avoid this unnecessary risk, companies must take action to defend their products.

Interested in learning more? Get the full white paper, "Pharmaceutical Anti-Counterfeiting Programs: How Small and Mid-Sized Drug Companies Can Implement an Effective Strategy" at www.authentix. com/pharmaACP. You'll get insight on:

- The current state of global pharmaceutical counterfeiting
- How small to mid-sized companies can implement an ACP early in drug development despite limited resources
- Key considerations to design ACP policies and criteria
- Risk assessment and security technology
- Efficient ACP implementation and support
- Questions to ask potential security solution providers

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