Authentix



If your pharmaceutical products haven't been counterfeited yet, someone will probably try to soon. That's why you need the right authentication partner.

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2012: The makers of the cancer-fighting medication Avastin notify physicians that a counterfeit version of the medication has been discovered that does not contain the active ingredient of the drug.¹

2008: A counterfeit version of the blood thinner heparin appears. The active ingredient was replaced with a cheaper substance that was suspected to be the cause of up to 81 deaths and resulted in a nationwide recall of the medication. The U.S.-based firm that sold heparin was subjected to 740 lawsuits, and eventually was compelled to sell off the division that marketed the drug.²

Those are the big cases that you are undoubtedly familiar with, and they demonstrate without a doubt that counterfeit medications are a big problem. They cost pharmaceutical companies billions and make people sick, prevent them from getting better, or even kill them. Counterfeits are a pervasive problem. The World Health Organization estimates that up to 30% of the pharmaceuticals sold in parts of Asia, Africa, and Latin America are counterfeit. In 2011, 64% of antimalarial drugs in Nigeria were discovered to be counterfeit. In fact, an estimated 10% of all medicines worldwide are counterfeit.



¹ NCBI/American Health & Drug Benefits, The Health and Economic Effects of Counterfeit Drugs, 2014 Jun

² Ibid



In most counterfeiting cases, the pharmaceutical companies involved have reacted timely and decisively. But, as with any crime, prevention is infinitely preferable to even the swiftest reaction. That's not to say that prevention is easy. Keeping counterfeits out of the market is hard. For example, in the U.S., almost 40% of our pharmaceuticals are manufactured elsewhere, and about 80% of their active ingredients are imported. The rise of internet pharmacies, where many consumers turn for lower prices, makes regulation of drug safety more difficult. Many pharmaceutical products pass through a complex, globally-dispersed distribution network, making it easier for counterfeits to enter the legitimate supply chain. What makes counterfeit prevention more difficult than anything else is the fact that drug counterfeiting, due to its high profitability, attracts some very smart people. The "bad guys" can match your product packaging in a blink of an eye, and they're always looking for new ways to stay one step ahead of you.

As your company's brand protector, you're the one standing between the counterfeiters, patient safety and your brand's reputation. Don't go it alone. You need a reputable authentication partner to help get you out of "reaction mode" and develop a proactive process that includes instant authentication. Here are six tips for finding the right authentication partner:

1. Pharmaceutical expertise, knowledge and experience are essential

Choose an authentication partner that offers consultative services—it's critical that your partner has experience with pharmaceutical products and understands your industry inside and out. Your partner should fully understand your challenges, articulate your exact problems, and work with you to set goals for your program. In this way, a trusted relationship can be established that will provide:

- Common vision for the goals, resources and time management of your authentication plan
- Knowledge transfer on key topics such as global regulations and advanced technologies
- Development of a realistic risk assessment matrix
- Proactive approach to managing your supply chain and preventing problems



2. "Off-the-shelf" won't work

Select an authentication partner who can fully customize a solution to fit not only the unique challenges of the pharmaceutical industry, but also the needs of your specific organization. Your partner should have the necessary expertise on what types of security features are needed for different types of medical packaging, such as tamper-evidence seals, blister foils, vials, etc. This will allow you to take a proactive approach to combating counterfeit medicines. Look for a partner who offers:

- √ State-of-the-art color marking systems
- ✓ Multi-layered security features
- ✓ Monitoring and enforcement plan
- ✓ Ability to function properly in a multi-channel distribution environment

3. Expect outstanding business intelligence

Your ideal authentication partner should provide, in addition to the physical layer, a data analytics platform that can adapt as needed and employs the highest data quality standards. Actionable insights will allow you to make proactive decisions that will protect patients and your brand reputation—and give you the ability to reinvest dollars into other areas. The platform should be able to:

- ✓ Aggregate and analyze data
- ✓ Deliver insights directly to interested parties via their smartphones, tablets, and computers
- ✓ Utilize the M3 (Mark, Monitor and Measure) process

4. Look for an enabler

More than likely, your current supply chain is complicated and has lots of moving parts. A good authentication partner should be able to instantly integrate within that chain. In addition, the partner should be a "third-party agnostic" solution integrator without any prejudice towards other links in your supply chain. This partner will be able to objectively analyze your supply chain, identify where potential problems lay, and make recommendations on correcting them. Look for the following attributes:

- ✓ Third-party printer, logistic partner certification and support
- ✓ Integration with existing systems and manufacturers
- ✓ Trial runs that provide actual samples for testing purposes/quality assurance

5. Remember that implementation is everything

A smart authentication plan is great, but some potential partners are great at planning and not-so-great at implementing their plan. It's important to link up with a partner with extensive, and documented, experience in implementing a strategy. They should have a resume consisting of several multi-year relationships with their customers. In addition, your partner must



understand your business inside out, become an integrated part of your team, and extend that support to your third-party vendors. You need a partner who is flexible enough to adapt to your culture, your challenges, and processes. A good implementation strategy should encompass:

- ✓ Execution across your entire global supply chain
- ✓ Training and enablement for all involved parties
- ✓ Flexibility to expand and grow with your changing needs

6. Build an ongoing relationship

If you think you can find a partner, develop an effective authentication strategy, implement it, and then abandon that partner, think again. The counterfeiters will always be devising new ways of beating you. You need an ongoing relationship with your partner to stay one step ahead of the bad guys. It's absolutely critical to work with a partner who offers ongoing customer support after the initial deal is done. An established, trusted customer support strategy is the only way for your program to succeed long-term. It should include:

- ✓ Dedicated project manager to handle programs
- ✓ Security features testing
- ✓ Ability to retain sample programs to ensure consistency
- ✓ Ongoing reports and result interpretation that provide actionable insights
- ✓ Regular auditing of third-party vendors for proper use of security materials

Regardless of who you select as your authentication partner, remember to discuss everything of importance up front and in detail. To help you do that, we have developed a **downloadable checklist** (link) that will help you select the most compatible authentication partner for your pharmaceutical company.

Reducing the availability of counterfeit medicines is not easy—but it is necessary. The only way to get a grip on the pharmaceutical counterfeiting problem is for all the stakeholders involved—those within your company, third-party supply chain vendors, and of course your authentication partner—to cooperate fully in designing and implementing effective authentication methods. As always, timing is everything. Instant authentication can save you precious time when a possible counterfeiting incident occurs. And the time to find your best authentication partner is now.



Cheryl Smith-Johnson is Brand Marketing Manager at Authentix, a leading global authentication and information services company. Authentix assists its customers in many industries, including pharmaceuticals, by combating illicit trade and managing the integrity of their global supply chains. Using comprehensive end-to-end authentication solutions, Authentix safeguards industry leaders worldwide from counterfeiting, product theft, product diversion, and adulteration.

Stay tuned for our next article: Discover the Right Authentication Solution to Save Time, Millions and Lives.

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