



Instant authentication of your pharmaceutical products. Go from Zero to Hero in Weeks.

With the right partner, you can design and implement an end-to-end, customized authentication program and put it to work quickly.

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If you were part of the pharmaceutical industry in 2002, you will remember the Procrit[®] counterfeiting case. If you weren't, here's a brief recap: Procrit, a clear liquid that at the time cost about \$500 an injection, was used to treat severe anemia (often in very sick patients with cancer or AIDS). Its manufacturer was alerted to a suspicious product in the marketplace/field. While the suspicious product could not be instantly identified in the field, investigation confirmed fairly quickly that it was counterfeit—and much more was to be found in the supply chain. In one instance, counterfeiters had copied Procrit labels and packaging and had filled vials with water. Some of the vials comprised genuine Procrit containers scavenged from bags of medical waste. In another case, the counterfeiters had relabeled bottles to substitute a weak dosage for a much more expensive, concentrated one. A prosecutor estimated that the switch might have made the counterfeiters a tidy \$46 million in profit. And unfortunately, only about 10 percent of the counterfeit medication was ever recovered.¹

The Procrit manufacturer responded to the crisis as quickly and efficiently as they could. In 23 days, they were able to authenticate the suspicious product in their lab, repackage it with security features, and ship. Here's the timeline for their response:

Day 1: Suspicious package reported

Day 2: Package confirmed as counterfeit

Day 3: All Procrit shipments halted, sent back, and new security feature authorized

Day 9: New labels received

Day 11: Equipment procured and set up in warehouse

Day 23: Procrit with new packaging shipped out

¹ *Dangerous Doses: How Counterfeiters are Contaminating America's Drug Supply*, Katherine Eban, 2005



This reaction was considered “world class” at the time—but it still caused massive disruption to the Procrit supply chain and effected over 200 employees. Why? Because the company's response was reactive, not proactive. The critical factor was this: when the suspicious product was initially discovered, it could not be instantly authenticated in the field.

In the years since the Procrit case, the problem of counterfeit pharmaceuticals has grown exponentially as the “bad guys” devise increasingly sophisticated and hard-to-detect counterfeiting schemes. A 23-day response to a counterfeiting incident might have been considered “world class” in 2002—today it would be clearly inadequate. A proactive solution and instant authentication have to be the goals for any pharmaceutical company that doesn't want to be at the complete mercy of the counterfeiters in 2018.

How close is your company to taking a proactive approach to identifying suspicious medicines in the field? To answer that question, you must ask yourself other questions first, like: What do we have in place to authenticate a suspicious package when it's reported in the field? How quick and supply-chain-wide is our response? How much time does it take to authenticate? What security features do we currently lack that would help us authenticate instantly? How complex would such a system need to be? Have the stakeholders in our company bought into the concept of instant authentication? What is the ROI outlook? It might seem it would take you forever just to answer these questions, much less develop an authentication strategy and implement it. Your options are to find a partner to help you develop the right authentication strategy and implement it or depend on luck— in the hope that the counterfeiters don't get around to counterfeiting your products. The only problem is, they will. And when they do, it won't be pretty.

The importance of proactive authentication

When Procrit was counterfeited in 2002, its manufacturer's reaction was deemed a fast response. But still, the counterfeit products caused massive disruption to the company and their supply chain—because they were in a reactive, not proactive, mode. In 2018, authenticating a suspicious product instantly in the field is a must. And instant authentication can be achieved. Let's compare the results of a reactive vs. proactive authentication approach:

Reactive

- Authentication not in place
- Company resources impacted to an unpredictable degree
- Budgeted cost impact
- Processes unknown
- Supply chain weakened
- Distribution chains unclear
- Departments fragmented
- No checks and balances in place

Proactive

- Authentication in place
- Resources already allocated
- Budgeted cost control
- Processes understood
- Stronger supply chain
- Distribution chain transparent
- Departments cooperate to address problem quickly
- Process checks and balances in place



The reality is, answering all those questions and developing an instant authentication solution isn't as difficult as it may seem—if you're working with the right partner. The right partner will devise an effective strategy and guide you along the way to implementation and beyond. The key point is: finding the partner that will work with you and your third-party vendors to establish a customized program that will make instant authentication a standard operating procedure. To accomplish this, the program must include design, seamless implementation, and operational and ongoing support.

Your ideal partner will have a complete understanding of the pharmaceutical industry in general and your business in particular. They will become an integrated part of your team and extend that support to your third-party vendors. They'll be agile enough to adapt to your culture, your unique challenges, and your particular processes. Here's what the authentication planning/implementation process should look like:

Your partner will work with you to create an **end-to-end, customized plan and budget**. They will demonstrate the ability to **print security feature samples** for internal demonstration and buy-in.

They will be completely independent so **they can work with all of your third-party vendors without interruption**.

They will help you **seamlessly implement your authentication plan**, including the following components:

- Execution across your entire global supply chain
- Training and enablement for everyone involved
- The flexibility to expand and grow with your changing needs

With the right authentication partner by your side, and with the right authentication solution in place, you can make instant authentication a reality. Instead of reacting to incidents, you'll be in proactive mode. You can go from zero to authentication hero, staying one step ahead of the counterfeiters and thwarting their most villainous schemes.

Here's a timeline² for a typical counterfeiting incident that might hit a pharmaceutical company without an authentication solution in place:

Week 1: Suspicious package reported.

Weeks 2-3: Visual inspection and visual documentation of suspicious package.

Weeks 4-8: Suspicious package shipped to lab for in-depth analysis (depending on where the package was found, it may well have to be shipped to a lab in a different country).

Weeks 9-10: Lab inspection and analysis of suspected counterfeit product.

² *Authentication Empowerment, June 2018 webinar, David Howard, Retired Global Brand Protection Manager, J&J*



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Stay tuned for our next article: *Life is better with the Right Authentication Strategy.*
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