RESOURCES

Home

EU FMD: The Risks of Product Stockpiling

For the past 3 years, the pharmaceutical industry has been focused on the February 9, 2019 deadline for the Falsified Medicines Directive. Yet a surprising number of pharmaceutical manufacturers remain unprepared to make the transition to packaging and shipping serialized product. Some companies are buying time beyond the enforcement deadline by “stockpiling” non-serialized product batch-released prior to February 9. By doing so, they may avoid—temporarily—the legal and business consequences of not being in compliance, but this approach offers no long-term value—and carries significant risks.

The risk of unpredictable demand

If you think, “We have time—we have enough stock to last 6 to 9 months,” you are at risk of running short of product and missing sales opportunities—and opening the door for a competitor—if you underestimate demand. Or, if you *overestimate* demand, you could be

carrying the cost of excess inventory on your books.

The risk of lost revenue and increased costs

Leaving product in a warehouse over an extended period of time increases the risk of damage or loss and having expired medicines that need to be destroyed—resulting in write-offs and lost revenue due to lack of salable product. And, by waiting to implement a serialization solution, you could end up paying higher fees to EU and national systems. In 2018 alone, EMVO more than doubled its registration fees as the 2019 deadline got closer.

The risk to your business reputation

As your customers begin to understand that you are operating with a limited supply, they will begin to assess their own business dependencies and your reliability as a trusted trading partner. In fact, they may ask for assurance that you will be able to deliver serialized product when—not if—you run out of stockpiled inventory.

The risk of waiting any longer

No company selling in-scope medicines in the EU can afford to wait any longer to plan and implement a serialization solution. You will need to execute an OBP agreement with the EMVO and establish the technical connection to the EU Hub; integrate your line packaging systems; establish connections with your CMOs; and test and launch your solution. Because EMVO onboarding can take as long as 6 months, the sooner you

begin the process, the better your chances of being able to ship serialized—and compliant—product before your stockpile runs out.

Get up and running quickly—with lower cost of ownership

Manufacturers with relatively simple supply chain needs must still comply with the EU Falsified Medicines Directive (EU FMD)—but often with fewer resources and tighter budgets. To help small- and mid-size companies control costs and minimize business impact, TraceLink offers **EU FMD Express**: a cost-effective, simplified compliance solution based on the same proven technology that has made TraceLink the world's largest track-and-trace network.

EU FMD Express is a complete, turnkey solution that lets smaller manufacturers comply with EU FMD and integrate with their partners through a single, secure connection to the TraceLink Life Sciences Cloud. From project start to go-live, EU FMD Express lets you stay focused on your business while TraceLink manages your implementation. And EU FMD Express removes the burden of software maintenance and upgrades—lowering your total cost of ownership and keeping you up to date with regulatory changes.

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