Serialization remains a major topic in pharmaceutical packaging. In this article, we discuss the industry’s readiness for the new and upcoming serialization regulations in the US and Europe.

The US Drug Supply Chain Security Act (DSCSA) officially went into effect last November, and the European Union’s Falsified Medicines Directive (FMD) goes into effect in February 2019. While these regulations will help to ensure the integrity of drug products sold in their respective markets, preparing to comply with the laws has been a challenge for pharmaceutical companies and contract manufacturers and packagers.

To minimize potential disruptions to the US prescription drug supply, the FDA announced last summer that it would delay DSCSA enforcement until November 2018 [1]. On March 12, the European Medicines Verification Organization (EMVO), which operates the European hub, where pharmaceutical companies must report serialization data under the FMD, announced that 500 of the approximately 2,500 pharmaceutical companies in the EU had begun the onboarding process [2]. While encouraged by the milestone, the EMVO noted in the announcement that the onboarding figures were “still far behind schedule.”

Recently, Tablets & Capsules spoke with several industry professionals about how well-prepared pharmaceutical companies and CMOs are to comply with DSCSA and FMD serialization requirements.

With less than a year remaining before companies must comply with DSCSA and FMD serialization requirements, how are pharmaceutical companies and CMOs progressing?

Staffan Widengren, director corporate projects, Recipharm: I would say the industry is prepared but not to the extent that it should be. A lot of brand owners are not ready. Some companies may be underestimating the
workload, and some may not have the financial means to invest in serialization. I think they know that if they’re going to do this they need to invest and if they don’t do it now, it will be too late, because the lead time for equipment is greater than 9 months. Also, some CMOs may not continue to package and will contract packaging and serialization out to an external company.

Dexter Tjoa, director of corporate strategy, Tjoapack: I think the general consensus is that the industry is progressing very slowly. There are still quite a few companies struggling to figure out what exactly they have to do to comply with the US or European regulations or both. Most companies have made some sort of move and have set up a serialization program, but I think the general state of readiness is behind schedule.

John Duffin, president, Clarke Solutions: Most of the industry is progressing well and is ready for the initial requirements of unique identification at the unit of sale, but for the 2022 and 2023 aggregation requirements in the US, there is still much work to be done. Larger CMOs and CPOs are either ready or nearly ready, but there are some smaller manufacturers that are still identifying and implementing systems with very little room for error to meet the deadlines.

**Are there aspects of serialization that companies tend to overlook or underestimate?**

Duffin: We see many companies underestimating the overall impact of the changes on their manufacturing operations. The new systems require extensive training and revisions to current processes. A new mindset is required now that every product on the line is unique.

Tjoa: I think when the legislation was announced, companies said, “Okay, we just need to print something on the box.” A lot of companies focused on the machinery on the shop floor and how to install a printer on the line, etc. The biggest challenge of serialization is actually the data-management aspect, which many companies have overlooked or put off until further down the line. Software service providers have brought out solutions, so companies can buy the software, but they also need to design their processes around the fact that sharing data is now going to be part of how things have to run. I think companies are struggling with that aspect and may have underestimated the additional process design work that goes along with serialization.

Jean-Marie Aulnette, vice president for Europe, Middle East, and Africa sales, TraceLink: There is a lack of understanding of the complexity and resource intensiveness of serialization. The implementation process is almost entirely new, and a lot of uncertainty remains when it comes to understanding what is really needed to comply with different markets.

One of the biggest problems is that many companies think that serialization vendors have sufficient delivery capacity and that waiting to implement will lead to lower costs. However, a serialization program typically takes 6 to 9 months to implement, so companies looking to make the February 2019 EU deadline should have started this phase of their projects by now, and many have not. Given that vendor availability is becoming increasingly scarce, there is a real possibility that companies that haven’t already installed the required hardware and line systems will not meet the deadlines.

Widengren: Some companies may not fully understand the purpose of serialization. For example, a company may request that we send the serial numbers to them in an email or an Excel file, which would make it quite easy for an unauthorized person to access the numbers and use them on the black market.

**How have serialization requirements affected pharma outsourcing? Are a greater percentage of pharma companies choosing outsourcing versus in-house production?**

Aulnette: I think so. In France, for example, a relatively large number of pharmaceutical companies have historically manufactured their own products. In the last five years or so, many of these companies have sold their production facilities to outsourcing organizations. While this is part of a larger trend toward more virtual pharma companies and isn’t entirely due to serialization, the added complexity and costs of packaging are likely a contributing factor. The costs of complying with these regulations may also lead to consolidation in the CMO/CPO market, where smaller contractors may merge with or be bought by larger CMOs.

Duffin: It has definitely created opportunity for companies that are able to effectively serialize products. The increased complexity and the level of investment required have many companies evaluating outsourcing and more easily justifying the investment.

**In what ways can brand owners and/or patients benefit from serialization requirements beyond compliance and improved product safety?**

Duffin: The technology available and required to meet the standards opens up a myriad of benefits to both brand owners and patients, allowing for a more direct connection between them. Traditionally, brand owners are separated from the consumer by a complex supply chain that makes it difficult to truly understand the patient and consumer market. With serialization, we’ll start to see connected apps that allow the consumer to scan a package and review the product’s entire life cycle, including where ingredients were sourced, where the product was manufactured, current product warnings and indications, rebate offers, and many other options that are just starting to be developed.

Aulnette: In a serialized environment, drug manufacturers will be able to establish how much of their product is in the market. More importantly, they will be able to develop a deeper understanding of their supply chain, product use, and uptake and use this information to get a more accurate picture of demand. Ultimately, inferences can be made from serialization data to create better forecasting models and predict manufacturing lead times, which should help to prevent drug shortages.

There’s also an opportunity to support disease awareness campaigns by creating digital assets that are made available to dispensers and patients when a serialized product is scanned. Dispensers can receive and communicate product information letters, lifestyle advice, guidance on reporting adverse events, or even the option to enroll in patient registries or focus groups.
Tjoa: In Europe, the legislation is really based on a point-of-dispense verification system that's all about reducing counterfeit medicine in the supply chain. It's not so much aimed at tracing a drug product as it flows from the manufacturer downstream to the patient. I do think that the infrastructure in Europe is being built for such tracking, so once products start going to market with serial numbers, aggregating those serial numbers to shipment levels either on a shipping container or pallet or both will likely follow shortly after simply because of the potential logistical benefits.

In the US, companies will realize logistical benefits that could benefit patients in terms of costs of supply. There is still quite a lot of room for improvement in the pharma world on the supply-chain-management side of things to bring down the cost of delivering products to patients.

Widengren: If the system works according to plan, the patient can be assured that the product is real. For the supply chain, there will also be other benefits. For example, in the case of a recall, the company can actually identify the unit or units with the defect, so the recall will be easier, and the company won't necessarily have to recall the...
whole batch. Determining these benefits beyond compliance is something that’s on our agenda now. How can we utilize the data? How will it benefit our customers? How will it benefit us? Analyzing the data is not free, however, and may require us to invest in additional systems, so we need to prepare a business justification showing what added value the investment will provide.

**What challenges do brand owners and CMOs face with respect to the varying serialization requirements in different countries and regions?**

Tjoa: In Europe, we may be a little more used to meeting various packaging requirements because each country in the EU has slightly different rules already. With regard to serialization, it’s mostly on the side of the manufacturer where it gets challenging with reporting obligations. In Europe, you need to send the serialization data to the European hub; in the US, you need to send the data to the next partner in the chain. There are variations on reporting throughout the world, so I think for manufacturers that is the major challenge.

The main challenge for CMOs is connecting with all of their market authorization holders. For example, we work with about 50 market authorization holders that use a number of different types of software. We need to configure our software so that we can seamlessly send and receive data with all of them.

Duffin: This is a significant challenge for both brand owners and CMOs. To meet and keep up with changing requirements, companies have had to create entire departments that monitor and manage the requirements including how each requirement is met with current software. They also need to quickly assess whether changes in requirements can be met with their existing systems, because revisions take time and could take a manufacturer out of a market completely.

Aunnette: One of the biggest challenges in the EU market will be the proliferation of package designs resulting from new requirements introduced by each member state. Currently, packaging is often used in numerous markets where there is a shared language. For example, the same German-language packaging is supplied to both Germany and Austria. Once FMD is in place, these markets may specify different requirements, creating the need for additional package designs. This will increase inventory, logistical challenges, and costs and, if not managed properly, will have a detrimental effect on supply-chain efficiency.

**What are the industry’s biggest remaining challenges with respect to serialization?**

Duffin: The biggest challenge is integration and communication throughout the entire supply chain. A drug product generally goes through three parties—manufacturer, wholesaler, and pharmacy—before reaching the consumer, and not necessarily at the unit-of-sale level. Wholesalers, repackers, and pharmacies break down the unit of sale depending on dosage and overall consumer needs. Tracing back to the unit of sale may still be a challenge, especially before 2023 when aggregation is required.

Aunnette: In the EU, one of the biggest challenges remaining is the onboarding of smaller and midsized market authorization holders and brand owners, who have greater resource and budget constraints than their larger counterparts. Smaller companies are also struggling to get the attention of their CMO and CPO partners, who must prioritize higher-volume customers.

The level of risk for these companies is now significant, and their decisions over the coming months could determine whether they’re able to continue operations or not. A validated, network tenant approach to partner connection is the lowest-risk option for these businesses, just as it is for CMOs and CPOs that are struggling with vendor availability—the time constraint means that individual point-to-point connections simply aren’t viable at this stage.

Tjoa: The challenge for contractors is twofold. At the site level, there are line implementations and validations and software implementations and validations. At the company level, there is the external part of communicating and making an IT connection with customers, validating that connection, and doing any trial serialization runs where applicable.

Pharmaceutical companies often have multiple contract service providers to manage, so they face similar communication challenges but the other way around. That can be very complex. In other industries, such as the semiconductor or automotive industries, it’s much more common to talk regularly with your closest suppliers. In pharma manufacturing that’s still not as common, so this type of across-the-supply-chain collaboration is still quite a new experience. It’s shaken some things loose within the pharmaceutical world, where companies are asking, “How do we engage with our suppliers? How can we leverage their expertise instead of just buying a service from them?” I think this improved communication between supply chain partners can only lead to better collaboration and a more efficient supply chain that, at the end of the day, will benefit patients.

**References**


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