White Paper

REQUIREMENTS AND CHALLENGES OF AGGREGATION IN EUROPE

Finding a Smart Way to Fight Counterfeiting

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The global pharmaceutical industry is an ever-evolving and fast-paced environment that must always adapt to the needs of the patients while following the requirements of various national health organisations and governments.

But the question is: Why does our industry need to regulate such a well-oiled machine? The answer is simple. Counterfeit and fraudulent products are a lucrative business that is consistently on the rise, especially in the case of medicines, powered by the booming economy of online shopping, the flattening of the world and the opening of international borders.

For more than a decade, counterfeiters have built strong networks and continue to take advantage of an industry in dire need of regulations and protection. The black market for prescription medication has become a global threat that floods hospitals and pharmacies around the world, putting many patients' lives at risks.

CURRENT STATUS

To fight against the rise of counterfeit medicine, many governments across the globe are taking the necessary steps to implement stringent regulations and new legislation that will protect their countries, the various actors along the pharmaceutical supply chain and, above all, the patients.

Throughout the European Union, today's serialisation requirements are limited to marking the serialised item with a unique identification number. Serialisation should be applied by February 2019, when it becomes mandatory under the EU Falsified Medicines Directive (FMD). The fast-approaching deadline has created uncertainty about the impact of not having all supply chains ready.

Item serialisation applies only to the individual item sold to the consumer and, in accordance with universal GS1 standards, must include the following data: GTIN, expiry date, batch/lot number, and serial number, which are all included in a 2D Data Matrix code. In addition to GS1 standards, some countries require additional information to be included in the Data Matrix code or printed as human-readable codes, such as government product-registration codes or 1D barcodes.

This is only the first step to protect and improve the supply chain. In many countries, shipping containers must be serialised, and aggregation must be implemented, with the goal of informing and protecting the end users by making all pharmaceutical products completely traceable throughout their journey along the supply chain.

Thanks to the impending implementation of the new legislation, more and more companies are starting to see the value and potential return on investment of serialisation and regulatory compliance.

AGGREGATION: A DEFINITION

Unit-level serialisation, as complex as it can be to implement, is a fairly simple concept, unlike aggregation, which associates uniquely serialised items to higher packaging levels also having a unique serial number. The serialised items inside the larger containers are referred to as the children, while the serialised packaging containing these items is called the parent. In a bundle of bottles or cartons, each unit has its own serial number, but the bundle itself has a top label including a unique serial number. In this case, the bottle or cartons are the children, and the bundle is the parent.

In short, aggregation is the process of creating a hierarchical relationship between unique identifiers assigned to packaging containers.

Aggregation is the next logical step in serialisation requirements, and many companies that are looking at implementing serialisation are foreseeing this next critical step.

WHAT IS AGGREGATION?

- Aggregation is the association of uniquely serialised packs to a higher packaging level also having its unique serial number.

- Example: 12 bottles are packed in the same bundle. In serialisation terms, it means that 12 children were aggregated to a parent.

EXPECTATIONS

Although aggregation will not be mandatory in all countries, many manufacturers, along with the top pharmaceutical companies, will get ready to serialise and have already implemented an interoperable Track&Trace system with their serialisation.

Along with the FMD, the European Medicines Verification System (EMVS) implementation is key to finding an optimal way to seamlessly track and trace products throughout the entire supply chain.

Acting as a hub between the national systems (NMVS) and the manufacturing and distribution sectors, it allows traceability up to the dispensing point. To fully accompany the end users, however, further steps such as unit-dose unique ID for aggregation might be required, adding many benefits.

This global transparency will prevent counterfeit and fraudulent products from entering the improved healthcare supply chain, thereby ensuring the safety of patients across the world and creating trust in the pharmaceutical industry.

CHALLENGES

While this next step is key for the survival of a secure pharma industry and patient safety, it comes with new challenges that can be complicated to overcome in the current workflows, with the current skill sets of employees, and ultimately with the attendant cost. Any kind of major change or improvement to follow national and international guidelines and requirements can leave a big hole in a company's pockets, but these changes are mandatory.

Adding aggregation in a second phase after serialisation will limit the scope and complexity of the first serialisation phase; however, it will have a greater overall financial impact, since the lines will have to be stopped once again for a new installation and validation. Operators and anyone working on the lines will require two new phases of training and standard operating procedures, and new resources will be needed to complete the second phase of project management.

Aggregation obviously adds supplementary steps to the packaging process, and it may therefore reduce the current productivity rate. It is therefore essential to integrate a solution that is adapted and, as much as possible, tailored to your needs and production processes to minimize these impacts.

With new serialisation and aggregation requirements, product reinsertions onto the packaging line require companies to have more control than ever before; and reinsertion points and operator training must be adapted to comply with strict guidelines.

BENEFITS

The aggregation process is meant to facilitate and benefit everyone involved in the supply chain, from the manufacturers of medications all the way to the end users. Firstly, it greatly increases ease of use concerning the rework, meaning that all necessary and important information about the medications will be accessible when scanning the parent, which will save a great deal of time since we will no longer need to open each container to scan each individual child. Secondly, aggregation provides all the necessary information and makes it easier to track any medication throughout the supply chain, leading to a more efficient, secure and trustworthy system.

STATUS QUO

A lot of companies are lost as to what steps they should be taking to meet international guidelines. But there are risks involved should the issue not be taken seriously, and maintaining the status quo, implementing the wrong solution or even choosing the wrong vendor could result in a colossal price to pay, such as losing your competitive edge or even losing clients. Considering legislation in many countries, and the challenges and impact of serialisation on the supply chain, companies in the pharma industry are left with two choices:

1. **The Easy Way Out**: Choosing this first and easiest option will only require manufacturers and actors in the healthcare supply chain to implement, at a lesser cost, the serialisation requirements due in February 2019. This will respond to the statutory serialisation requirements in Europe enforced by the Council and Parliament of the European Union. As with any short-term fix, there are a few drawbacks to consider. Firstly, investments will drastically increase if serialisation and aggregation are implemented in two phases rather than one, since lines will be stopped during the time of integration and validation that will need to be done twice, and while new technologies, knowledge and procedures are mastered. And secondly, this decision could lead to the loss of contracts since many healthcare manufacturers and distributors require aggregation from their suppliers today.

2. **The Smart Way**: Should you choose to implement aggregation right away, there are a few key challenges you should consider. Firstly, you need to be aware that implementing an aggregation system will benefit your whole company, since serialisation has already affected every department, including their processes and workflows. While aggregation creates additional steps in the production process and your company's productivity may be inadvertently impacted at first, it will save crucial time down the line thanks to improved management of inventory, rework and even recalls. In time, new processes will be learned and adjusted to fit the needs of each company, and the employees' knowledge and level of training will be sufficiently high to have fully functional lines implemented seamlessly into the workflow, while answering the pressing needs of the pharma industry, clients and suppliers alike.

CONCLUSION

With the various mandatory serialisation regulations put in place by most countries involved in the healthcare supply chain, the world is working to provide a safer and better industry. But with so many countries involved, all with different standards and rules, it will take a while before a true international, homogeneous system takes form. It's time to start thinking about the future and the upcoming changes in the industry, and to take the next necessary steps to stay ahead of the competition, build stronger and lasting relationships with your clients and play your part in creating a secure supply chain.

As a global traceability leader, OPTEL offers low-cost solutions that help manufacturers and CMOs seamlessly integrate serialisation and aggregation systems that will follow the legislation while providing efficient solutions tailored to your business.

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