White Paper

The Fast Track to Serialisation Compliance (EU version)

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Falsified medicines have always been a major concern for the European Union (EU) as they represent a serious threat to public health and safety. To address this concern, the European Commission (EC) has released the Falsified Medicines Directive (FMD), which details the safety features designed to protect European patients and ensure that medicines are safe and of good quality. The Delegated Regulation will apply as of February 9, 2019.

Manufacturers, wholesalers, and contract manufacturing organizations (CMOs) will soon have the obligation to guarantee the authenticity of any prescription drugs by identifying individual packs and checking whether the outer packaging of medicines has been tampered with.

This white paper will explain why safety features must be applied and why CMOs should start their serialisation project soon. It will also address how to become serialisation-compliant, despite the short timeline and complex implementation steps. And finally, it will explain what to do to maximize remaining time, including the sums to invest and the steps to prioritize.

In addition, the white paper will present faster ways and solutions to implement rules on safety features and serialised items. Such preconfigured products were specifically designed for those who haven't started their serialisation project or are finding themselves behind schedule.

Furthermore, 95% of the amount invested in these preconfigured units which include the hardware, cameras, touchscreens, and computers can be transferred to an automated packaging line and integrated within a full-fledged custom solution later on. The unequivocal benefit of these new off-the-shelf solutions is that they enable CMOs to quickly become serialisation-compliant, while allowing customization steps to resume once supply activities have returned to their normal pace.

PART I: Reasons behind the Falsified Medicines Directive (FMD)

In 2011, the European Parliament adopted the Falsified Medicines Directive (FMD). This delegated regulation details the characteristics of the safety features designed to improve the protection of public health and outlines the critical steps used to build a system that will identify and trace prescription drugs as they are distributed across Europe.

EU members had to transpose the Directive into national law by January 2, 2013, and this process is now complete in all countries. The obligatory safety features introduced in the Directive are a unique product identifier and an anti-tampering device. These characteristics will facilitate the exchange of information and enable the verification of drug product identifiers down to the package level, thus ensuring their legitimacy. It will also improve the detection of illegitimate products and falsified medicines (and subsequent notification) in the drug supply chain and facilitate recalls of drug products to make them more efficient.

Manufacturers, wholesalers, and contract manufacturing organizations (CMOs) are expected to implement these safety features. The Delegated Act and the new medicine verification system it requires will apply as of February 9, 2019.

Note that countries that already have a serialisation law (Italy, Greece, Belgium) have six more years to become serialisation-compliant with the rest of Europe, as these countries have already demonstrated that they protect the public against falsified medicines. Therefore, they can continue to use their current standard or their own local system for another 72 months.

OBLIGATORY SAFETY FEATURES INTRODUCED IN THE DIRECTIVE

1- Unique Product Identification Code

Serialisation is the assignment and application of a unique product identification code to all prescription drug packages. This means that manufacturers and packagers must put a unique product identification code on prescription drug packages. Concretely, all sellable units such as bottles and cartons, must be supplied with serial numbers that use, for example, a barcode that can be easily read electronically.

2- Anti-Tampering Device

This is a device allowing the verification of whether the packaging of the medicinal product has been tampered with.

Both these obligatory safety features enable pharmacists and drug distributors to verify the authenticity of medicinal products subject to prescription and protect patients from the risks of falsified medicines.

3- Other Features

Other additional features may also be applicable. These vary from country to country, as some were implanted prior to the legislation and will now remain.

EUROPEAN HUB

Manufacturers, wholesalers, and CMOs are responsible for supplying unique identifiers for each product lot to their regulatory government institution/ministry of health. Each country's database is connected to a European hub.

For example, a prescription drug is manufactured in France, but sold in Germany. When the pharmacist's system in Germany makes a request to the German database and realizes that this unique identifier is not listed, it will automatically connect to the European hub. Thus, hospitals do not have to be connected to all European countries, but only to their own country's database and to the hub.

UNPREDICTABLE IDENTIFIERS: 1 IN 10,000

With the new Directive, serial numbers cannot be predictable. One identifier out of 10,000 will be valid. Thus, a probability factor is added to the allocation process of serial numbers.

For example, between serial number 00001 and 10000, only 1 identifier will be valid, while 9999 identifiers will not be printed. So, if someone tries to falsify serial numbers, this person will only have one chance in 10,000 to assign a valid serial number. In other words, the person will need to be very lucky to find a series of valid identifiers.

Why should CMOs start the process soon? A few good reasons:

1. The long duration of such an implementation project.
2. The cost of addition in the packaging process.
3. The involvement of all teams are required in an organization.
4. The various collateral modifications required (artwork changes, new SOPs, etc.).

VALIDATION AND DECOMMISSIONING

As previously explained, manufacturers, wholesalers, and CMOs are responsible for supplying unique identifiers for each product lot they produce. This is the beginning of the chain. The serial number is validated by the regulatory government institution.

The other end of the chain, hospitals and pharmacists (those who will supply the prescription drug to patients) must decommission the serial number in order to inform the government database that the drugs have been sold.

The database could then confirm that the medicine does exist and that it was not sold twice (i.e., falsified).

Serialisation will enhance the ability to protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The process will also improve the detection and removal of potentially dangerous drugs from the drug supply chain to protect European consumers. Failure to comply with the requirements of the law can result in penalties.

POSSIBLE IMPACTS

The FMD does not require that the entire warehouse become serialized overnight. The law states that any new sellable units must be serialized. Therefore, some CMOs may opt for a strategy to increase their inventory, but the same expiration dates for these new products will be applicable.

Legally, any prescription drugs could no longer be produced. The law's enforcement could lead to a temporary shutdown of the plant or a ban on producing until the company is serialisation-compliant. These possible sanctions will inevitably lead to a decrease in the number of customers, lower revenues, and in some cases, permanent shutdowns.

PART II: How to comply

The ideal way to become serialisation-compliant and to maintain the normal flow of activities on the packaging line is by getting a custom solution that will be integrated into the line, facilitating handling and optimizing the packaging steps. Such custom solutions, however, require preliminary actions, such as an engineering visit, the design of the solution, and the customization of software, hardware, and interfaces with existing machines, before their implementation. Moreover, extra time is required to implement the IT infrastructure and to connect it with the government database. All these steps leading to the installation and implementation of a custom solution can take 12 to 15 months.

The process doesn't end when the system is installed. There are a series of important steps that must also be planned and performed, including:

1. Validation to make sure the packaging lines remain safe and secure. Validation is used to demonstrate that when a problem is detected, the faulty product is ejected.

2. Training to ensure that all personnel shifts (day, evening, night) are adequately instructed on the implications of serialisation. For instance, an ejected product could, before the law's enforcement, be put back on the conveyor. That will no longer be possible. The serial number of an ejected product can no longer be sold; therefore, it cannot be replaced on the conveyor. Operators must know that they will have to rescan it.

3. Processes to explain and document each step required to produce a batch and each step to follow in case of problems. For instance, the law prescribes a new stage of reconciliation that will be necessary at the end of each lot. This new process ensures that destroyed serial numbers of ejected products will not be sold.

In addition to the design, manufacturing, delivery and installation period, which typically lasts 12 to 15 months for custom serialisation modules, another two to three months are required for validation, training, and processes. And before the whole process even gets started, time must also be allocated to selecting the most suitable solution, which will depend on specific needs and available budget. Therefore, based on our experience, it takes approximately 15 to 18 months to get everything ready and everybody trained (and to keep the experience pleasant).

Although the directive requires serialisation for February 2019, several manufacturers will ask their customers (CMOs) to comply 6 to 12 months in advance. Indeed, CMOs are generally subcontractors of manufacturers who, in order to better manage risk, can demand that their different line packagers become compliant up to one year before the actual February 2019 deadline.

Companies that produce their own brands will have the leeway to wait until February 2019, but those who work with subcontractors are more likely to be cautious. As it is happening elsewhere, CMOs could be asked to meet a tighter deadline, and manufacturers may be tempted to judge CMOs' effectiveness based on their level of reactivity in terms of becoming compliant. If they realize that the CMO does not seem to go forward with its serialisation project, their packaging contract could simply be given to someone else. Thus, CMOs will greatly benefit from showing their customers that they are ready, that they meet the requirements, and that they are compliant in order to not lose any contracts.

Considering that it takes about 15 to 18 months to complete the process and that CMOs might be required to become compliant up to one year before the actual deadline, what should you do if you have not yet started the process? Where should you start?

PART III: What to do

To help ensure that CMOs are able to comply with FMD requirements in time for their customers, OPTEL has developed ready-to-use, preconfigured serialisation modules.

Although full-fledged custom solutions are preferable and somewhat inevitable in the long-term, off-the-shelf serialisation modules are now available to ensure the first step to compliance by the required dates, either for those who find themselves behind schedule or have a limited budget.

These entry-level ready-to-go serialisation modules allow CMOs to meet the directives now while being scalable later. CMOs will therefore be able to print and inspect a unique serial number on all sellable products as well as perform aggregation. In addition to being available quickly, these units are less expensive and easier to operate than custom solutions.

Because off-the-shelf products are not customized to packaging lines, they can be delivered quickly. However, manual interventions are required to compensate for missing automated operations. For example, it may be necessary to move a box manually from one station to another on the packaging line. This operation would be automated with a custom solution. Thus, additional manual steps are likely to be needed with off-the-shelf solutions.

However, these manually completed activities can all be effectively rectified later on. Indeed, 95% of the amount invested in preconfigured units can be transferred to an automated packaging line within a full-fledged custom solution. Off-the-shelf solutions can be seen as a simple first step to ensure serialisation compliance before the deadline. Then, personalised support can be offered in order to optimize performance and maximize efficiency for all operations.

With its preconfigured solutions, OPTEL wants to provide CMOs that have not yet implemented serialisation processes with a quick compliance program. Moreover, it is an efficient solution that guarantees the best return on investment. Thus, if additional manual operations affect the production cost, it will be easy for OPTEL to customize an off-the-shelf product and integrate it into an automated packaging line at a later date. Preconfigured units have been specially designed so they can be used in custom solutions.

So if you find yourself in this time-sensitive situation, what steps should you take immediately to get the process going and ensure that the proposed system is the most appropriate for your needs?

- Make an inventory of your product formats
- List the countries where your products are distributed
- Anticipate whether you will need to perform aggregation

Once you have completed these three things, examine all five of OPTEL's off-the-shelf solutions to see which best meets these requirements:

Fast Series Description	
MANUAL PRINT STATION	Solution for carton serialisation, manual labeling and aggregation for up to four packaging levels. For all markets.
OFFLINE LABEL TRACKER	Solution for label serialisation for bottles. Mainly for the US market.
PACKSTATION SAP	Semi-automatic aggregation station for cartons. Mainly for the US market, other countries that require aggregation and companies that produce products to be sold in the US.
LINEMASTER TABLE	Fully manual label serialisation aggregation station for cartons and bottles. For all markets.
CLTRACKER TE	Automated serialisation solution for cartons, including tamper evidence. Only for the European market and companies that sell products to Europe.

Conclusion

These ready-to-use solutions are truly the fast track to serialisation compliance. They are inexpensive and most are available in six weeks from the start of the project. Contact OPTEL to speak to an advisor who will recommend the best solution for your needs.

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