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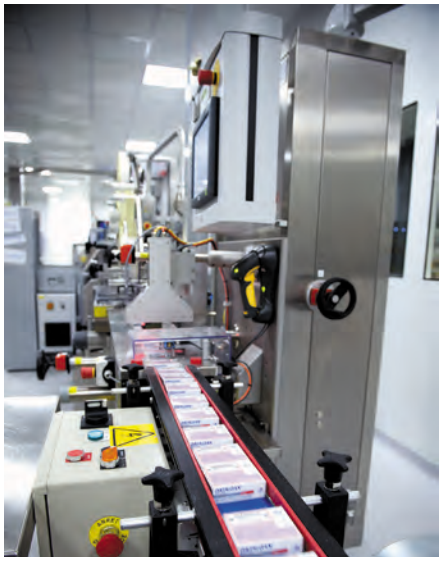
# What Does the Falsified Medicines Directive (FMD) Mean for SMEs and CMOs; and More Importantly, Are These Organisations Ready?

The Falsified Medicines Directive (FMD) 2011/62/EU will come into full force on 9th February 2019. The legislation, which was passed by the European Union Parliament, aims to increase the security of the manufacturing process and delivery of medicines throughout Europe, providing greater protection for patients.

Larger pharmaceutical companies have long been implementing changes to their processes, but some smaller SMEs have been slow on the uptake, many holding back from making any changes, awaiting clarification around confusion which stemmed from other countries receiving extensions, as well as waiting to see what effect Brexit may or may not have on the legislation. However, it has now become clear that the UK will not be granted an extension and Brexit will have little to no effect on the implications of FMD. With less than 200 working days before it comes into effect, CMOs and small to medium-sized pharmaceutical manufacturers can no longer delay when it comes to becoming compliant with the regulation.

The implications of the directive are far-reaching and affect all pharmaceutical manufacturers, regardless of size. As time runs out and the deadline grows ever closer, how can CMOs and SME pharmaceutical manufacturers ensure they are compliant, in time?

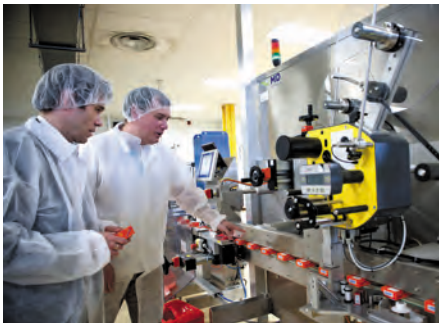


**What Are the Requirements of FMD?**
Firstly, it is important that manufacturers know and understand what the requirements of the Directive (FMD 2011/62/EU) are. If we look at the directive in a broader sense, the requirements fall into five separate categories, broken down below:

1. An obligatory feature on the outer packaging of prescription medicines that demonstrate identification and enable product verification.
2. An obligatory feature on the outer packaging of prescription medicines to demonstrate that they haven't been tampered with – an anti-tamper device (ATD).
3. Strengthened requirements for the inspection of the manufacturers of active pharmaceutical ingredients.
4. Manufacturers are obligated to report any suspicions of falsified medicines.
5. An obligatory logo must be applied to websites of legally operating online pharmacies, with a link to official national registers.

From February 2019 onwards, if a manufacturer fails to comply with any aspect of the directive it will have to withdraw its products from circulation within the European market. With the consequences of non-compliance so high, pharmaceutical manufacturers and distributors alike must now take steps to ensure their supply chains are ready for the regulation.

**How Will the FMD Regulations Work in Practice?**
Counterfeit medication costs the pharmaceutical industry billions of pounds every year and, more importantly, it puts patients at risk. As such, serialisation is the key to ensuring that businesses become and remain compliant, keeping patient safety at the fore.



The directive requires that at the point of manufacture, all packaging must carry a GS1 compliant, 2D barcode that contains specific information, including a serial number so that the location of production can be ascertained and uploaded to the European Medicines Verification Organisation. The introduction of the barcode will also allow the product to be checked at any point in the supply chain. Wherever the product is, the barcode can be scanned and the product can be checked to ensure it is where it's supposed to be, and that it hasn't been sold before – ensuring its validity.

At the point of distribution to patients, the product will then be verified and de-serialised, so that serial number cannot be used again. If a unique serial number does come up somewhere else in the future, the product can easily be identified as counterfeit.

There's no denying that for those without robust serialisation processes currently in place, these implementations will be complex, but the benefits of being compliant far outweigh any initial concerns.

**The Key Challenges Faced by CMOs and SMEs**
With a high level of outsourced pharmaceutical production, CMOs

and smaller pharmaceutical manufacturers are a key part of the global supply process. Yet, many are still delaying the initiation of their serialisation projects. One of the main reasons is a perceived high cost and the sheer magnitude and complexity of the projects can also be seen as a deterrent.

However, businesses can no longer stall; time is of the essence and organisations will have to comply. The equipment will have to be serialised, that serial number will have to be electronically checked for content, and it will have to be sent to the European Medicines Verification Organisation.

It is increasingly important for CMOs and SMEs to have the capability to meet international requirements, but it's also crucial that they remain flexible enough to meet the differing requirements of their customers. Ultimately the implications are significantly more complex than just making modifications to their physical labelling machines and infrastructure.

There is a preconceived idea that in order to introduce compliance and a higher level of serialisation into the supply chain, a costly 'rip and replace' approach has to be taken. This doesn't always have to be the case. If smaller organisations take the time to review their entire supply chain and all of its processes, there are ways that serialisation can be retrofitted and integrated with the solutions already in place. This high level of integration is something that will prove to be invaluable to organisations now and in the future.

**What Are the Key Considerations CMOs and SMEs Should Take When Choosing a Vendor?**

One of the key challenges that comes with serialisation is the complex mix of data including master data and transactional data – tracking a

serialised item through the packaging execution process and the physical product. Compliance requires all of these elements to be continuously and dynamically associated.

As such, when smaller organisations are looking at a vendor to implement their serialisation processes, they should look for one that is capable of delivering overall equipment efficiency as well as compliance. They should be able to demonstrate the capability to integrate the serialisation solution within a business's existing IT and packaging infrastructure, maintaining speed on the packaging line and adding true business value.

For example, small batch repackaging organisations could implement a handheld device that not only scans a product, but also takes a low-res image of the seal over the packet at the time of scanning. The image wouldn't need to be sent to the legislation hub, but the manufacturer could store the image so that if they were to be audited they could prove that the boxes were securely sealed. Innovative and scalable solutions like these will keep smaller businesses compliant, but don't require a complete overhaul of existing systems.

A major challenge faced by many serialisation projects is between the software and the hardware already in place. More often than not, the two will work in silo and businesses can no longer allow this to continue. Quite often, for example, you will see machine vendors providing equipment and devices with very little expertise or consideration for the software and vice versa. So, it is important for smaller organisations to ensure they look for vendors that can bring together both of the necessary skills and capabilities to reduce project complexity, risk and delivery timeframes.

It is important for manufacturers to evaluate any potential providers on their ability to help the business stay agile. If an organisation chooses a serialisation system that is heavily

reliant on specific hardware or software, for example, it will not be able to take advantage of any new processes or technology without having to re-implement a whole new project further down the line.

It is vital that businesses have scalable, agile solutions that are not embedded so that they don't encounter issues in four or five years' time because technology has progressed and left them behind. This should also be seen as an opportunity for organisations to automate the process that manages the packaging line and work order process, which in turn reduces the risk of human error at input, further decreasing the risk of non-compliance and process failure.

There's no hiding from the complexity of serialisation. In the majority of cases for larger pharmaceutical companies, they can afford a multi-vendor approach, but this isn't something that smaller manufacturers necessarily have the means to implement on a large scale. Instead, they need to look for innovative vendors that can assess the entire business and bring all the software, data and hardware together harmoniously in a cost-efficient way.

CMOs and SMEs should start with a broader perspective of how they can extend the value of compliance and then refine their plans with a phased, modular approach that puts steps together in accordance with regulatory timescales. Once they have mapped out their approach to meet minimum standards, they can then also look at taking advantage of enhanced efficiencies that they were previously unable to achieve.

Serialisation is only the beginning; the next business driver that will come into play is track-and-trace, so taking steps now to have a serial number in place is one thing, but there are much broader business benefits. Implementing a serialisation process that is completely scalable also ensures that further capability can be unlocked throughout the supply chain as and when it is required.

**Beyond Compliance; Future-proofing Supply Chains**

Ultimately, serialisation can be seen as the entry level, enabling manufacturers to capture all of their supply chain events from manufacture right the way through to wholesale and distribution. The ability to capture and store data this way – creating complete real-time visibility and greater traceability – will unlock efficiencies throughout the entire supply chain. Allowing CMOs and SMEs to be poised to react to future regulation changes and making it easier for them to keep up with the larger pharmaceutical organisations.

It is very likely that legislation will progress in the coming years. It can already be seen in other industries that have undergone serialisation and have now moved on to track-and-trace. Behind this legislation, there are distinct efficiency and quality advantages to be found. For example, through defining each serialised item, recalls can subsequently be simplified.

The complexity of the pharmaceutical supply chain cannot be disputed, but if smaller organisations embrace these regulatory changes – using them as an opportunity to optimise their supply chains, update data flows and break down silos – they can create true business value, making it pay to be compliant.

Despite the deadline looming, there is still time for CMOs and SMEs to build comprehensive and agile serialisation infrastructures in time for 9th February 2019.

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Christian is a GS1 accredited Business Consultant specialising in serialisation and the FMD and UDI legislations. With over 10 years' experience delivering infrastructure and software solutions within industries including; pharmaceutical, military and government, Christian is one of the leading authorities in the ZetesAtlas solution in the UK and Europe.