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Seven steps to avoid falling foul of FMD

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The Falsified Medicines Directive (FMD) imposes strict serialisation requirements on pharmaceuticalmanufacturers, distributors and dispensers. Mark Davison, Head of Operations in the EU for rfxcel, outlines everything you need to know and what you need to do for a seamless serialisation process – before regulators remove your right to trade.

Pharma manufacturers are currently the main actors in a serial drama where getting their lines right is paramount. Well, four lines of data, to be precise; in (and next to) DataMatrix barcodes applied to every pack of prescription medicines. The introduction of serialisation, designed to ensure the authenticity and traceability of individual medicines, promises to improve patient safety and create exciting opportunities for digital health. But there's a twist in the plot. Failure to comply with the EU regulation that mandates it means you cannot legally ship your product. No barcode, no trade. That's when a serial drama turns into a tragedy. And time is running out to be ready.

The unfolding story of the Falsified Medicines Directive (FMD), which was first introduced in 2011, is into its final episodes. The denouement arrives on February 9, 2019, when the Directive is fully enforced and the penalties for non-compliance officially come into play. FMD is an attempt to prevent inauthentic, substandard or harmful medicines entering the supply chain. It imposes strict serialisation, traceability and verification requirements on pharmaceutical manufacturers and their associated wholesalers, distributors and contract manufacturers. In particular, it mandates companies to print a unique identifier on the packaging of prescription medicines. Furthermore, companies aren't just responsible for the data that goes on the packaging, they're responsible for submitting it to the central data hub that will enable pharmacists to authenticate products before they dispense them. It's a complex undertaking that could be easily underestimated - but not if you understand some key steps.

The implementation of serialisation is not an overnight task – it encompasses processes that have multiple touch-points across global organisations, partner networks and the wider supply chain. Yet despite this – and despite the enormous implications of getting it wrong – many companies are still some distance from being fit for purpose. Indeed, in some organisations, the Directive has not yet hit their radar. It needs to – because the clock is ticking. But all is not lost. Here are seven steps to successful serialisation.

1: Get executive buy-in

The significance of serialisation is often underestimated. It's typically considered a production issue and punted to manufacturing as an operational challenge. Yet serialisation is a board level issue, with ramifications that could directly affect business performance. Indeed, it's not a manufacturing cost – it's a business continuity risk that touches every aspect of an organisation. So the first step towards serialisation – one that's often overlooked – is to appoint an executive sponsor, ideally with board level oversight, to lead a holistic strategy. Implementation will naturally be delegated to project teams, but executive leadership will be crucial to making things happen quickly.

2: Assemble a multi-disciplinary team

Multi-disciplinary engagement is essential. Many organisations don't understand all their business processes in sufficient detail to overlay serialisation. It's therefore vital that a multi-disciplinary team (MDT) is convened at the earliest opportunity to map the process flow of the business and establish a roadmap of how serialisation can be applied across multiple organisational boundaries. An MDT should actively engage representatives from manufacturing, supply chain, IT, legal/regulatory and partner/contract management.

3: Establish long-term user requirements to ensure you're 'future ready'

The next step is to define your user requirements and establish a template for the solution that will help ensure you're compliant. You must consider immediate and long-term factors. For example, which markets do you currently ship product to and which do you plan to target in the future? Which products in both your portfolio and your pipeline will need to be coded? Is there a potential future requirement to be able to track and trace products as they journey through the supply chain? Regulations, from FMD to the US Drug Supply Chain Security Act (DSCSA), differ from country to country and are constantly evolving. Take the opportunity to become 'future ready' by creating a design template that doesn't just focus on FMD but is flexible enough to be interoperable and implementable between national systems *and* provides the flexibility to adapt to change as it happens.

4: Understand the data implications of FMD

The barcodes required for FMD must include 4 lines of data; Global Trade Item Number (GTIN), serial number, batch number and expiry date. Some countries require a fifth element, usually for national reimbursement purposes. These datasets often live in disparate systems within organisations. The master data – including GTINs – is fixed information that's commonly stored in an enterprise resource planning (ERP) system. Although that data doesn't change, it still requires attention to ensure it's clean and accurate when uploaded to the repositories. In terms of variable data, the processes required to generate serial numbers, transfer them to production and ensure they're used appropriately are complex. Managing that immensity of numbers throughout the supply chain lifecycle is hugely important; mistakes can lead to expensive delays, medicines shortages and loss of revenue. Serialisation software is therefore an essential requirement to help you maintain control of all aspects of fixed and variable data.

5: Choose the right software

There are numerous factors to consider when selecting software:

Quality

Serialisation should not be divorced from the founding principle of Good Manufacturing Practice (GMP) – quality. GMP guidelines, as well as data integrity advice from regulators such as the UK MHRA, state that users of computer systems must always be in control. However, multi-tenant serialisation solutions (where multiple independent entities share the same instance of a software solution) can sometimes impose software updates without prior dialogue, leaving users out of control. The potential impact on quality is significant. Passive acceptance of change is not an option. Multi-tenant solutions require license-holding companies to ensure that risk assessment processes are in place to monitor and adapt to change. By contrast, the most effective solutions allow users to maintain control of their specific software instance and to dictate the timing, relevance and nature of upgrades.

Data Validation

An effective solution will focus on both connectivity and data integrity. Some systems concentrate on enabling a connection and flow of data across and between organisations but are blind to data quality. Companies should never assume that the

data entering, or generated within, their systems is clean, tidy and accurate. Internal data checks are essential. The best solutions routinely monitor data to detect human error, inaccuracy and duplication. Smart solution providers validate data flowing through a system – in some cases up to 70 data validation checks on incoming records to ensure its integrity - essentially preventing bad data entering the EU hub.

Network connectivity

It's not enough to ensure your own business is ready: your partners must be ready too. With outsourcing now common across the industry, it's important that the software you use connects all parties to a single version of the truth. The most effective solution providers connect your entire partner network as standard. This means more than just having a potential connection – it means working with you and your partners to make sure that data really flows.

6: Choose the right partner

It's important to find a vendor that can partner with you to design responsive solutions that go beyond technology. Certification of your vendor by the European Medicines Verification Organisation (EMVO) is a pre-requisite if you want to be compliant. In addition, a partner should be a recognised provider with experience, credibility and evidence that shows it can implement effectively within tight timeframes. A good partner will be committed to your success, keeping you abreast of fluctuating global regulations, and collaborating with you to customise solutions that adapt to changes in your business and the wider marketplace.

7: Act now

The complexities of serialisation mean that a failure to act now could make it extremely difficult to complete implementation in time for the FMD deadline. Moreover, with the fees for registering with EMVO and other affiliate repositories set to increase in June, the internal costs of your project will inevitably rise if you wait. However, the biggest price of non-compliance will be your inability to ship product. So why risk it?

Act now and you can prevent your serial drama becoming a tragedy.