

EU Falsified Medicines Directive (FMD) – A Technical & Implementation Success

From 19th February 2019, pharmaceutical manufacturers were legally bound to implement processes for the creation and management of an audit trail covering every single packet of prescription medicine produced for import or trade into the European Union (EU).

The EU legislator's serialisation challenge had implications across the physical aspects of pharmaceutical production lines and the data management processes that drove them. This article explores what the implications for pharmaceutical producers were, the benefits that have resulted from an increased focus on production line efficiency, and what might be next for EU FMD.

The EU's Falsified Medicines Directive was a strategic move by European legislators to safeguard the public against potentially substandard prescription medicines and eliminate counterfeit goods from the legitimate supply chain. The directive requires that authentic producers of prescription medicines include specific, machine-readable data on their product packaging for verification throughout the entire supply chain – down to the point of sale at an individual pharmacy level.

Industry Response

Six months before the Food and Drug Administration's stringent Drug Supply Chain Security Act (DSCSA) came into force, GS1 collaboratively investigated US production lines and found just one in 16 pharmaceutical packages was displaying a readable barcode complete with all four DSCSA data elements¹. Anecdotal evidence would suggest a very similar picture presented itself across the EU in the six months prior to the launch of the EU FMD.

Indeed, while the majority of pharmaceutical companies and contract manufacturing centres were compliant at the point of go-live, for as long as six months after February 2019 Domino had requests to aid with the FMD compliance requirements. The reality today – nearly two years on –

EU Falsified Medicines Directive: A Recap of the Requirements

Since early 2019, manufacturers of pharmaceutical goods have been required to add additional security labelling to certain products sold in the European Union.

Under the terms of the EU Falsified Medicines Directive (EU FMD), prescription pharmaceutical products are now required to have a verifiable 2D data matrix code and tamper-evident labelling included as part of their product packaging. In addition, a human-readable unique serial number is required to meet the directive's requirements, as well as a product code, batch number, and expiry date for the contents.

Data matrix scanners are a much less forgiving verifier of data than the human eye and operate on strict binary principles, which means that even the slightest cell corruption will result in the rejection of the code.

Upon scanning, the 2D data matrix code provides access to data that has been transmitted to the European Medicines Verification System (EMVS) portal and will reside in corresponding national databases.

The medicine's name, common name, pharmaceutical form, strength, pack size and pack type, as well as a serial number and a national reimbursement number for certain markets, is instantly accessible via the 2D code. Additionally, a record is created each time a product is scanned, allowing the product in question to be tracked through the National Medicines Verification System (NMVS) at every stage of the supply chain.

Any issues or inconsistencies with products that arise will be flagged in the systems, and the medicine in question instantly rejected by the respective party. This information is then passed on to the Medicines and Healthcare Products Regulatory Agency, which may wish to investigate the product in question, as well as the company that manufactured it.

Two years on from the introduction of the EU FMD and the legislation has not only increased the security of legitimate medicines, but it has also helped manufacturers to improve production line efficiency and is providing access to data on supply chains and the point of sale of medicines that could be used to enhance operational and commercial performance.

is that EU FMD is no longer a big issue for pharmaceutical manufacturers in Europe.

Given the choice of market displacement by competitive products that were compliant or equipping production lines with new serialisation technology, the industry as a whole conformed and is now fully aligned with the legislation. And from a technical perspective, particularly given the huge volume of pharmacies across Europe connected to the system, the directive has been a resounding success. Indeed, other geographies are now actively exploring regulatory change similar to EU FMD, such as south-east Asia and Brazil, for example.

So, what next for EU FMD?

Monitor Print Quality and Longevity

While the legislation is only two years old, one challenge we have yet to see play out is in the longevity of code print quality. With most medicines having a shelf-life of four to five years, the EU FMD's stringent specifications for code quality, contrast to substrate, and lightfastness capability may yet see medicines being rejected at the point of sale if the print grades used on a production line have not been suitably verified.

Under the ISO 15415 standard, there are eight parameters that measure overall code quality. Only codes that meet the specifications of grades A to C will be acceptable to DG Sanco – the European Commission Directorate-general for Health



and Consumer Protection. All else will be rejected.

For those manufacturers who find themselves facing product rejection due to poor print quality, printing pin-sharp data at high speed can be achieved in multiple ways. The thermal inkjet (TIJ) method, known for high-quality alphanumeric text, barcodes, and 2D data matrix codes, produces extremely durable print that is favoured within the pharmaceutical sector. Its superfast drying capacity and excellent adhesion to a variety of porous and non-porous packaging surfaces will prove vital to post-coding tamper-evident labels on pharmaceutical packaging.

Laser printers are also capable of delivering high-quality codes, at high speeds, onto multiple substrates. The technology produces durable, indelible serial numbers and matrix graphics onto different packaging types, ensuring a final code that will stand the test of time, remaining readable for the entire shelf-life of a pharmaceutical product.

Consider the OTC Market

With the success of EU FMD with regard to prescription medicine, it is likely that the

over-the-counter (OTC) market could be next. Russia's serialisation requirements², which came into effect in July 2020, cover all prescription and over-the-counter medicines manufactured within or imported into Russia and set a clear precedent.

While unlikely to be implemented in the immediate future, it is highly conceivable

that the EU legislation will be extended to OTC medicines within the next five years.

As pharmaceutical manufacturers have experienced, equipping production lines with new control systems, high-speed printers, and cameras requires significant project management and – depending on company size – can take six to nine months.





Once installed, it will then take time for overall equipment effectiveness (OEE) to return to pre-installation rates. This is because of the serialisation equipment's interaction with other departments, such as IT, logistics, order processing, and quality control. Testing will need to be performed to make sure that all sections of the business are working in tandem and the new or upgraded serialisation equipment is fully integrated.

However, despite the significant initial disruption, a positive by-product of serialisation has been that OEE has increased. Reports from some pharmaceutical manufacturers have suggested that new technologies which were initially installed to provide serialisation, including control systems and verification solutions, have increased overall productivity by 10–15%.

Explore Data Opportunities

The benefits of pharmaceutical serialisation in terms of boosting patient safety, and the security of legitimate medicines, have been well documented. What should also be considered is the wealth of data that serialisation presents for manufacturers and how this can be used to build efficiencies in the wider pharmaceutical supply chain.

The EU FMD has presented pharmaceutical manufacturers with a raft of data on their downstream supply chains that, hitherto, they have not had access to – from general market access data on where specific drugs are performing well to sales data down to an individual pharmacy level.

Such data presents an opportunity for sales teams to engage with pharmacy chains to improve sales performance and could – direct-to-consumer legislation permitting – enable forward-thinking manufacturers to consider a whole new level of consumer-focused marketing or engagement. This capacity to springboard a company into the big data revolution is the kind of insight that excites the C-suite and marketing department of any business.

Conclusion

Aside from the benefits of retaining European customers, implementing serialisation with the right focus on long-term data quality will have reduced waste, provided better control of products, and is now set to give manufacturers' supply chains an efficiency boost – which ultimately serves to optimise pharmaceutical production processes in the long term. What the market must now consider is where EU FMD will go next, and in particular, manufacturers of OTC products would do well to start exploring

opportunities for serialisation in the future.

And of course, let's not forget the impact that Brexit may yet have. With the UK SecurMed system now effectively disconnected from the EU FMD hub, the next few months may see new UK-specific serialisation requirements emerge that manufacturers are well-advised to keep a watchful eye on.

Domino Printing Sciences (Domino) has provided coding and marking solutions to the pharmaceutical industry for over 20 years. Our sales and support teams assist pharmaceutical companies from the consultation and purchase phase through to setup and ongoing servicing. With the help of its partners, Domino has the experience and technology to ensure small to medium-sized manufacturers meet compliance within six months and ensure products can be sold legally and safely within Europe, the UK, and beyond. Domino's print quality grades are independently verified.

REFERENCES

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