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Offline coding a solution to FMD compliance

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As of January 2016, pharmaceutical manufacturers who sell their products on the European market will have to comply with the Falsified Medicines Directive (FMD). This legislation aims to decrease the number of counterfeit medicines infiltrating the legal pharmaceutical supply chain in Europe.

Under the FMD, all pharmaceutical packs sold in Europe are required to carry machine readable 2D datamatrix codes that contain unique serial numbers (per individual pack) as well as a manufacturer product code, expiry date and batch number.

These 2D codes will be verified via a camera-based system and there is a risk that blurry or slightly out-of-position codes will be unreadable, leading to those packs being rejected. This puts tremendous pressure on manufacturers who do not have inline coding systems that are capable of producing reliable, readable codes at high speeds - as well as mechanisms for inspecting the codes and rejecting problem packs.

However, this does not mean that manufacturers will have to upgrade their production lines at great expense. One solution is for manufacturers to opt for an **offline** coding and inspection system that enables them to comply with the new legislation without impacting their existing production lines.

Rotech Machines points out that the cost of complying with FMD through an offline system is less costly and far less disruptive than the cost of re-engineering an online system.

"Based on experience, it can take several months to decide on your equipment supplier, then up to a year to set up and test a new line. An offline system is independent of the production line and can be up-and-running in a matter of weeks.

"By taking this process offline, the cartons are brought to the line ready printed and inspected, eliminating any delays due to coding issues. The potential for rejects is massively reduced because the carton can be presented to the printer in the most favourable orientation. For example, an offline system will print cartons flat, so there are no problems with mis-codes on bulging end flaps," reports a spokesperson for Rotech Machines.

At Pyrotec PackMark, we have a range of offline coding systems from Rotech Machines and Markem-Imaje that incorporate printing, labelling, inspection and automatic stack-to-stack feeding technology. Contact us today to find the ideal solution for your production line.

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