PHARMSOL NEWS

EU REGULATORY REQUIREMENT ON FALSIFIED MEDICINE DIRECTIVE (FMD)

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European Union Legislative Law "Directive on Falsified Medicines (2011/62/EU) (amending Directive 2001/83/EC)" demands for serialization and tamper proof packaging system to eliminate counterfeit products from supply chain.

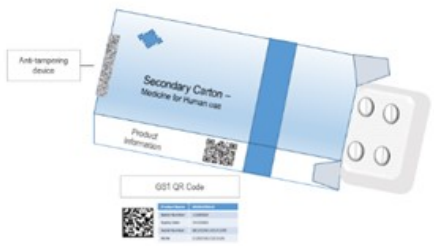
EU REGULATORY REQUIREMENT

The responsibility for the safety, quality and efficacy of a medicinal product over its lifetime lies with the marketing authorisation holder (MAH). However, "Annex 16" of EudraLex guideline for Medicinal products, legally requires a QP of the importer Site to certify the finished medicinal product before the batch is released for sale in EU. The medicinal products intended for EU market shall fulfill the requirements of Falsified Medicine Directive (EU) 2011/62/EU regarding safety features for the packaging of medicinal products for human use.

AUTOMATED PACKAGING SYSTEM

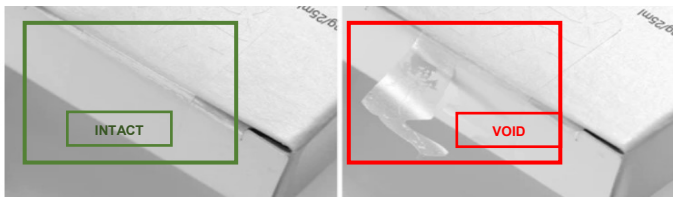
Role of automation in pharmaceutical manufacturing and packaging process has extensively minimized the human intervention, errors and effectively counteracted distribution of counterfeit medicinal products. Regulatory agencies expect the manufacturer to have automation for secondary packaging process. Auto cartooning followed by Anti- tampering labelling system, serialization for track and trace (Unique Identifier in Human and Machine-readable format) and Aggregation (Linking of packages) prior to shipment are part of such automated system.

Primary Cartons are scanned (for identification), unfolded (shaped) in auto cartooning machine along with scanning and folding of leaflets. The primary packed blisters/ bottles/ sachets are inserted into primary carton along with folded leaflet and closed at folding end. Barcode scanning of cartons and leaflet needs to be performed to avoid any mix-up of leaflet and carton.



TAMPER EVIDENT LABELLING SYSTEM

Filled individual cartons are passed on to Tamper evident Labelling Machine (TAVM), where the individual cartons are labelled for tamper evident seal. The automated system also counts the number of cartons sealed with tamper evident label. Tamper proof labelling system provides the assurance to the end user, that the contents of the pack have not been interfered with, since the pack was released by the manufacturer.



SERIALIZATION

Primary packed cartons are connected to the conveyor of serialization machine for printing of batch information along with a unique serial number and GS1 complying bar code/ 2D Matrix code/ 2D QR code for each carton. The serialization data has to be registered with the EU member state through EU Hub (Master Data), where a maximum of 20 digit numeric or alpha-numeric randomly generated serial number will be verified and further notified to all member states intended for product distribution via European Medicine Verification System (EMVS). At the point of use, the Product will be scanned, checked and verified for authenticity. If the UI (Unique identification code) on the pack matches the information in the repository, the pack is decommissioned and supplied to the patient (at hospital) or released for sale by Pharmacist (at Pharmacy).

CONCLUSION

Secondary packaging requirements for EU market have been made stringent to improve patient safety by mandating the Market Authorization holders and manufacturers to put a system in place that is preventing falsified medicines from entering the legal supply chain, which guarantees medicines authenticity by an end-to-end verification.

PharmSol being a trusted and independent organization, helps out Pharmaceutical manufacturers to set up packaging requirements compliant to FMD.

Contact PharmSol for a great learning experience, continued business and compliance.

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