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THE IMPACT OF THE MEDICINAL PRODUCTS IDENTIFIER ON WHOLESALE DISTRIBUTION

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INTRODUCTION

The European Union issued the Falsified Medicines Directive (FMD), to protect the legal supply chain of medicinal products. The Falsified Medicines Directive enables stakeholders to verify the authenticity of a medicinal product through the use of a Unique Identifier for each unit pack.

AIMS

To assess the impact the Unique Identifer will have on the wholesale distribution of medicinal products.

To identify and review requirements set out by the Falsified Medicines Directive.

To identify 3 scenarios faced by wholesale distributors.

To write SOPs for each scenario chosen to show how the directive can be implemented in a practical setting.

METHOD

Directive 2011/62/EU—the Falsified Medicines Directive—was analysed and reviewed and the requirements set out identified.

Meetings with different stakeholders were carried out and the Malta Medicines Authority consulted to verify the requirements published in the new legislation.

Three scenarios in the distribution of pharmaceutical products were identified for the study.

Standard Operating Procedures were written for each scenario chosen. The procedures address the requirements of the unique identifier introduced in the FMD.

Validation of the procedures was carried out using the services offered by a wholesale distributor and an importer of pharmaceutical products.

RESULTS

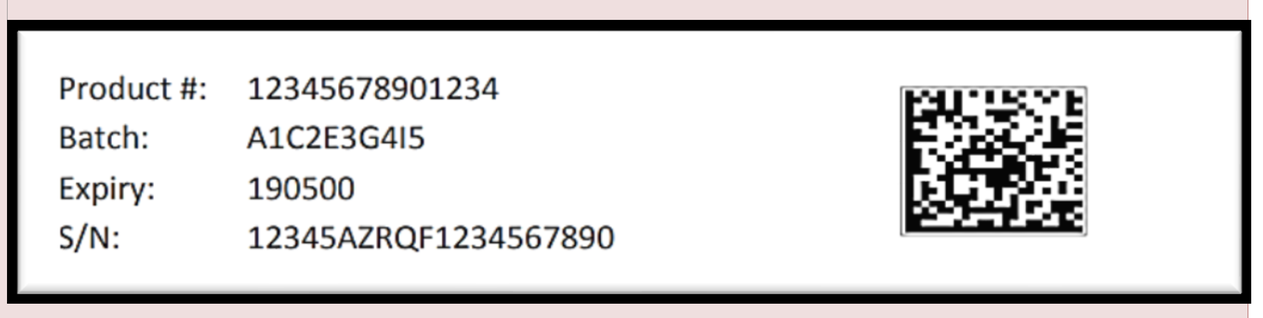
The three scenarios chosen were 1) Importation of products; 2) local wholesale distribution and 3) repackaging of products. The procedures developed show the process flow for each scenario and the area most impacted. The process includes 5 additional steps for entities that manufacture, import, repackage or sell pharmaceutical products.

The results show that wholesale distributors are impacted when not representing the marketing authorization holder. Each pack must be commissioned into the repository upon manufacture/importation, verified along the supply chain and then decommissioned once exiting the market. There may be problems with the new supply chain, increasing timelines which may delay delivery of orders to clients.

The identifier must include both a data matrix code developed to ISO and human-readable formats.

With 30 alphanumeric characters available for the building of the serial number, there are 30^{20} possible serial numbers per product code ensuring a high degree of security and the chance of duplication or falsification is eliminated within reasonable limits.

Figure 3.1: Example of a Unique Identifier [1]



CONCLUSION

The Falsified Medicines Directive requires increased investment in time and costs. Wholesale dealing is impacted by the FMD. Verification of the packs along the supply chain requires a considerable investment in new technologies, equipment and soft-ware by the warehouses where products are received. Importation of products is impacted when the certification of the batch is done in the EU for a product coming from a third, non-Mutually Recognised country, when all the packs must be scanned for verification. Local wholesale dealing will be impacted when repackaging is done, all packs will need to be re-serialised.

REFERENCES

1. Krähenbühl C. EU-Falsified Medicines Directive EMVO And NMVO - Stakeholder Awareness Meeting. Presentation; 2017; Malta.