RESOURCES:

The European Commission

European Medicines Verification Organisation

GS1 Healthcare

EU FMD GUIDE

Finding information about the EU Falsified Medicines Directive (FMD) and its companion, the Delegated Regulation (DR), and how to meet them has proven difficult for many. The information is partly concentrated on the European Medicines Verification Organisation's website, but also dispersed in a few other places. It's difficult to assess which documents are valuable and which are marginally useful.

To solve this problem, we asked industry veteran and Founder of RxTrace, Dirk Rodgers, to compile a complete list of internet resources that comprise the most authoritative information you need to understand and meet the FMD requirements.

The European Commision

Including the full text of the FMD and DR.

- EU Falsified Medicines Directive document is the indispensable, authoritative document of the FMD.
- EU Delegated Regulation related to the FMD is another indispensable document containing the specific regulations that describe the two safety features that must now be on all drug covered by the FMD before they enter the supply chain.
- Medicinal Products for Human Use, Falsified Medicines is a collection of vital, official information about the FMD and EUDR.

European Medicines Verification Organisation

The EMVO is the third-party non-profit responsible for setting up and operating most of the infrastructure mandated by the FMD and DR. They have designed not only the European Hub that is the centerpiece of the system of repositories, but they also designed the National Blueprint System that is the basis for the majority of the National Medicines Verification Systems.

- Safety Features for Medicinal Products for Human Use Questions and Answers Version 13 is an excellent document providing answers to many important questions related to the two safety features that must be placed onto drug packages in the EU.
- European Medicines Verification Organisation (EMVO) is collection of crucial information about the primary data repository and its operation
- EMVO Downloads provides a collection of downloadable documents related to everything related to the EMVO, from setting up a National Medicines Verification Organisation (NMVO), to onboarding partners to the European Hub.
- EMVO Glossary has abbreviations and terminology related to FMD, DR and EMVO.
- EMVO: Requirements for the European Medicines Verification System – URS Lite gives a very detailed explanation of the operation of the EU Hub and the National Blueprint systems. This is one of the foundational documents of the EMVO.
- White Paper on EMVS Data Upload is a white paper that discusses some of the design goals of the data upload to the EU Hub.
- EMVS Master Data Guide explains the initial master data requirements for drugs handled by the EU Hub.
- EMVO: On-boarding Guideline/Manual for MAH (without parallel distribution activity) and Parallel Distributors (MAH with parallel distribution activity). This delivers detailed description of the onboarding process for drug manufacturers and other market authorization holders (MAH).

GS1 Healthcare

Including essential and hard to find foundational documents for GS1 standards that the industry has chosen to use to meet the FMD/DR. These are not presented in a FMD context but they provide an understanding of the technology behind the interoperable exchange of data within a supply chain like ours that uses GS1 standards.

- The FMD Pack Coding, Sharing and Transition gives an excellent description of the different ways EU Member States might require packages to be identified. Included topics that are explained: GTIN, GTIN+NHRN, NTIN, and more. Published in 2017 so it is a little dated.
- EMVO/EMVS – The European State of Play is a brilliant presentation on the latest status of the EMVO.
- Recommendations on a harmonised implementation of the EU Falsified Medicines Directive using GS1 standards. GS1 Healthcare's position on identifying drug packages under the FMD. Takes aim at the use of NTIN and NHRN in some EU Member States.
- GS1 Healthcare GTIN Allocation Rules is an excellent, easy to understand explanation of GS1 GTIN allocation rules for healthcare products.
- Global Trade Item Number (GTIN) contains a great collection of information about the GTIN.
- An introduction to the global trade item number (GTIN) provides basic background on the GS1 Global Trade Item Number used to meet many pharmaceutical regulations around the world.
- An Introduction to the Serial Shipping Container Code (SSCCC) provides exceptional background on the SSCC for anyone using it.
- Serial Shipping Container Code (SSCC) contains links to documents related to the SSCC standard.
- GS1 Check digit calculator is a very useful tool to confirm your calculation of check digits for GTINs and SSCCs.
- GEPIR: Global Electronic Party Information Registry is useful for doing research into existing usage of GS1 identifiers (GTIN, SSCC, GRAI, GLN, etc.).
- Two-dimensional (2D) barcodes links to documents related to various 2D barcode standards including GS1 Datamatrix, which is the type required by the FMD/DR.
- GS1 General Specifications gives a download the latest GS1 General Specification which outlines the GS1 element string standard used in GS1 Datamatrix and other barcodes.

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