Regulatory Update:

The EU Falsified Medicines Directive, with the Final Delegated Regulation

December 2017

Regulatory Agency	European Medicines Agency (EMA)
Regulation Name or System Name	Falsified Medicines Directive (FMD) and final Delegated Regulation (DR)
Compliance Dates	**February 9, 2019**: The "mass serialization of drugs" as described in the DR must occur in EU Member States that did not already have a drug tracing regulation in 2011. Italy, Belgium and Greece are given until February 9, 2025 to meet these requirements, although all have said they will either meet the requirements by February 9, 2019, or soon after. **February 9, 2025**: The "mass serialization of drugs" as described in the DR must occur In EU Member States that already had a drug tracing regulation in 2011. This includes Italy, Belgium and Greece (see note above)
Applies to	Drug manufacturers, "marketing authorization holders", wholesalers, and persons authorized or entitled to supply medicinal products to the public

Unit-level Packaging ("units of sale"):

Barcode Symbology	Data Matrix ECC200
Barcode Contents	The "unique identifier" consisting of: ○ Product code, identifying the name, form, strength, pack size and type; ○ Serial number, up to 20 alphanumeric characters ○ A national reimbursement number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market; ○ Batch number; ○ Expiry date.
Serial Number Randomization	Must be generated by a deterministic or a non-deterministic randomization algorithm resulting in the probability that the serial number can be guessed being negligible and in any case lower than one in ten thousand
Serial Number Reuse	"The character sequence resulting from the combination of the product code and the serial number shall be unique to a given pack…until at least one year after the expiry date …or five years after…sale or distribution…"
Human Readable Expiry Date Format	Covered by existing regulation

Barcode Data Encoding	Any encoding scheme that conforms with ISO/IEC 15418:2009 (this includes GS1 Application Identifiers and ASC MH 10 Data Identifiers and Maintenance) and perhaps others (see the DR)
Product Code notes	"The product code shall follow a coding scheme and begin with characters specific to the coding scheme used. It shall also contain characters or character sequences identifying the product as a medicinal product. The resulting code shall be less than 50 characters and be globally unique." GS1 GTINs fulfill this requirement but some member states will expect the use of a National Trade Item Number (NTIN), or a National Health Reimbursement Number (NHRN). Check with each member state for their specific requirements. GS1 has compiled a table of which are required or allowed in each member state.
Free Samples must be marked?	Yes, but these units must be decommissioned when shipped as samples
Stickering after manufacturing allowed?	No

Homogeneous Cases

Barcode Symbology	N/A
Barcode Contents	N/A

Logistics Units

Logistics Units Must be Serialized?	No

Data Capture

Unit-to-Case Aggregation Capture?	No

Data Exchange

Send Unit Data to Government Repository?	In some cases (National Repositories)
Send Unit Data to Third-Party Repository?	Yes (European Medicines Verification Organization, EMVO, "European Hub")
Send Unit Data to Trading Partner?	No
Send Aggregation Data to Government Repository?	No
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	No

Authentication

Who Offers Data Repository for Authentication?	Third-Parties (EMVO) and National Repositories
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	Only dispensers, others optional except for products with a high likelihood of illegitimacy. Decommissioning is required by anyone who exports EU drugs outside of the EU.
Downstream Trading Partners Must Authenticate on Shipment?	Dispensers must authenticate prior to dispense

Government Reporting

Manufacturer Activity Reported?	No
Downstream Trading Partner Activity Reported?	No

Challenges

- Data exchange with the EMVO (Third-Party) European Hub and/or National Repositories
- Some E.U. Member States will require their National Reimbursement Number in the barcode and others will not
- The product code may be a GTIN in some Member States, in others it must be a National Trade Item Number (NTIN) and it others it can be either a GTIN or an NTIN;
- Confusion over timing of application of the barcode to packages
- Requires all parties to Decommission serial numbers in repositories when product is removed from the market
- Free samples must be serialized and commissioned in the EU Hub but then decommissioned in the EU Hub
- Countries outside the EU but located in Europe are likely to participate in the requirements to secure trade with the EU member states
- Belgium and Greece have announced that they intend to meet the FMD/DR on the same schedule as the rest of the Union, despite being allowed extra years to comply
- The departure of the United Kingdom from the EU during the same period of time that the FMD is taking effect. The UK has said that they intend to meet the FMD on time, despite their departure from the EU.

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