RESOURCES

50 Must-Know Terms to Achieve EU FMD Compliance

On the 9th of February 2019, new regulations come into force whereby prescription medicines sold in the EU must bear safety features.

With the regulations come an abundance of new technical and legal terms, especially if your company has to connect and upload data to the European Hub. For example, do you know if you're an RR or an OBP-CP? Should you connect to your NMVS or the EMVS?

To help you figure it out, we've compiled new terms specific to EU FMD as a supplement to our popular glossary, "144 Must-Know Terms to Decipher Serialization".

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A

Anti-tampering Device—A safety feature that shows if a product or its packaging has been tampered with. Reduces the ease of replacing authentic product with Falsified Medicine.

AR—Authorised Representative. In the context of the EMVS, this refers to a person

or body in the European Economic Area who has been designated by a non-European manufacturer to act on their behalf.

B

Batch Number—A unique combination of letters and numbers that identifies a set of products in a single unique production or packaging run. Also known as a lot number.

Black List—A common shorthand name for the list of non-prescription (OTC) medicines documented in Annex II of the Delegated Regulation to which the EU FMD requirement applies, as they are deemed to be at risk of falsification. The criteria for a medicine being included on the Black List are that it has one or more documented incidents of falsification in the legal supply chain in the EU or collaborating third countries.

Blueprint System—The name given by EMVO to their specification for a National System, available for Member States to use when setting up their NMVS. Blueprint Systems are currently available from multiple providers. Member States are not obligated to use a Blueprint System, but there are several benefits of doing so: 1) it will be faster to build; 2) it is guaranteed to be compliant; 3) it is a tested, validated solution; and 4) it is expected to be more cost-effective.

Bollino—The name of Italy's existing tracking regulation for medicines, whereby serial numbers must be applied to all packaging and tracked via a central database. Italy is one of the countries to which the Transitional Period applies.

Bulk Verification—The processing of multiple verification requests in one go. Users will be able to scan/enter multiple serial numbers before requesting verification, rather than processing them one at a time.

C

Central Repository—A central database and system where information about products and product identity are stored. For the EU FMD, the EMVS forms the overall system acting as the repository for medicines in the European market, with each specific National System being the specific central repository for product pack information in a given country. For more information see European Hub.

CNK—The name of Belgium's existing serialisation code, requiring a one dimensional barcode to be applied to all medicine packaging. Belgium is one of the countries to which the Transitional Period applies.

Counterfeit Medicine (EU)—Generally refers to medicines which has been adulterated, relabelled or otherwise modified without consent of the Marketing Authorization Holder, thus creating a potential patient safety threat. In the EU, this term is used to describe IP violations of medicines, where they have been copied without the consent of the Marketing Authorisation Holder.

CSR—Certificate Signing Request. An electronic message sent from an applicant to the process owner to apply for an electronic certificate. This will be used by EMVO to verify the identity of those requesting access to the European Hub.

D

Data Matrix—A two-dimensional (2D) matrix barcode with black and white cells in a square or rectangular matrix. For EU FMD, the barcode shall conform to ISO/IEC standards and the industry has aligned on the GS1 2D DataMatrix barcode as the standard.

Delegated Act—Regulation detailing the mechanism by which the requirements of the Falsified Medicines Directive will be implemented in each Member State. Various delegated acts have been implemented, with the delegated act related to the implementation of safety features and the implementation of a system of repositories and verification to be completed by February 2019.

Directive 2011/62/EU—An EU law relating to medicinal products for human use, specifically regarding ways to prevent falsified medicines entering the supply chain.

DR—Delegated Regulation. The EU FMD Delegated Regulation was introduced on 2nd October 2015, and contains detailed rules on safety features on packaging of medicines intended for human use.

E

EAEPC—European Association of Euro-Pharmaceutical Companies. Professional body for those engaged in the parallel trade and distribution of pharmaceuticals in Europe. It represents around 100 companies across 23 countries. The EAEPC is a full member of EMVO.

EFPIA—European Federation of Pharmaceutical Industries and Associations. Trade association representing the research-based pharmaceutical industry in Europe. It represents 33 national pharmaceutical industry associations and 42 leading pharmaceutical companies. EFPIA is a full member of EMVO.

EMVL—European Medicines Verification Landscape. Describes the systems that will make up the verification network: the EMVS, National Systems, and the connecting systems of manufacturers, parallel distributors, pharmacies, and wholesalers.

EMVO—European Medicines Verification Organisation. A not-for-profit organisation that was set up to oversee the EMVS and manage the European Hub.

EMVS—European Medicines Verification System. The overall system designed to enable point of dispensation and risk-based verification of medicines. It consists of the European Hub connecting manufacturers/ MAHs and parallel importers/distributors, National System repositories connecting pharmacy dispensers and wholesale distributors, and the infrastructure to link the European

Hub to each National System.

End-to-end Verification—A process that checks the authenticity of a product from manufacture through to point of dispense, so as to reduce the risk of the product being tampered with whilst moving through the supply chain. EU FMD specifically focuses on point of dispense verification coupled with risk-based verification and decommissioning at certain other points in the supply chain depending on the specific business scenario.

EOF—The name of Greece's existing serialisation code. It requires the use of a linear GS1 128 serialised barcode, plus an EAN 13 product barcode. Greece is one of the countries to which the Transitional Period applies.

European Hub—Also known as EU Hub. A system that acts as a central router or switchbox for transferring data between pharmaceutical manufacturers and parallel distributors who place products into the supply chain and the national systems which serve as repositories for verification by pharmacy dispensers, wholesale distributors, etc.

F

Falsified Medicine—Fake medicine whose ingredients may be different, of poor quality or incorrect dosage compared to the authorised medicine.

G

GIRP—European Healthcare Distribution Association. Umbrella organisation representing the national associations of pharmaceutical wholesalers in Europe. GIRP members distribute around 15 billion packs of medicines per year. GIRP is a full member of EMVO.

I

IQE—Integrated Quality Environment of the European Hub. This is where QA

(quality assurance) checks will be carried out on the system after it has passed testing in the ITE before being set live.

ITE—Integrated Test Environment of the European Hub. This is where the system's functionality and performance will be checked after development, to ensure it works properly before being set live. After ITE, the Hub will pass to IQE.

L

Lot Number—See Batch Number.

M

Medicinal Product (EU)—In the EU, a medicinal product is a substance used in humans to 1) to prevent or treat disease; 2) restore, correct or modify physiological functions: or 3) make a medical diagnosis.

Multimarket Pack—A medicine pack which can be supplied to more than one country in Europe in an unaltered form (using a common packaging form, label, etc.). This is common within the EU and introduces challenges for pharmaceutical companies and packaging processes given the diversity of product coding, national reimbursement numbers and other unique country-specific requirements. Under EU FMD, the Marketing Authorisation Holder will upload the product master data to the European Hub, specifying the target countries for which the product is destined to be dispensed within. The European Hub will then route that information to the relevant National Systems.

N

National Code—A country-specific product code that an EU Member State may require medical products to bear, depending on their national requirements as distinct in form and content from a common GS1 Global Trade Identifier (GTIN) that may be shared across countries. A National Code may be required to be used as-is

in the encoding of the product code field in the 2D DataMatrix or the country and GS1 may collaborate on the creation of GS1 National Trade Identification Number (NTIN) which encapsulates this code in a common GS1 coding structure. There are currently three countries that have requested the functionality to look up products by National Code in the EMVS: Belgium, Luxembourg and the UK.

National System—The verification platform for one (or more than one) country, which is used at point of dispense by pharmacy dispensers or by other members of the supply chain to verify the product identifier encoded on medicinal packs. Each National System forms part of the EMVS, and exchanges data with the European Hub.

NCA—National Competent Authority. The organization responsible for medicine regulation in an EU Member State; e.g. the UK's NCA is the MHRA (Medicines & Healthcare Products Regulatory Agency).

NHRN—National Healthcare Reimbursement Number. A national and/or regional identification number which may be required by regulatory organizations for the purposes of product registration or for the management of healthcare-provider reimbursement.

NMVO—National Medicines Verification Organisation. A not-for-profit organization that is responsible for managing the NMVS in an EU Member State; e.g. Belgium's NMVO is BeMVO.

NMVS—National Medicines Verification System. Managed by the relevant NMVO. Also referred to as National System.

O

OBP—Onboarding Partner. A person or organization that registers with the European Hub. The OBP for a product must be the MAH (Marketing Authorisation Holder) or legally authorized to operate on behalf of the MAH. Thus, an OBP may

represent multiple MAHs across an organization and its affiliate companies or operating brands. The OBP is the owner of the serialization data for the products of its represented MAHs and is ultimately responsible for uploading it to the European Hub.

OBP-CP—Onboarding Partner Connection Provider. An OBP can choose to develop their own system to connect directly to the European Hub, or use a certified solutions provider, known as an OBP-CP, who has developed a Gateway Connection and undergone specific certification testing with EMVO. Use of an OBP-CP can help to significantly reduce the testing and certification activities required by an OBP/MAH to connect to the European Hub.

P

PD—Parallel Distributor. Also known as Parallel Importer or Repackager. In EU law, a PD is not the Marketing Authorisation Holder of medicines originally introduced into the supply chain, but holds specific product authorizations for repackaged or relabelled products. For that reason, Parallel Distributors must connect to the European Hub to upload data related the product master data and product pack data (identity information) for the medicine packs which it places in the supply chain.

PGEU—Pharmaceutical Group of the European Union. European association representing over 400,000 community pharmacists. The PGEU is a full member of EMVO.

PRD—Productive Environment of the European Hub. This is the validated, operational system where commercial product information is received and exchanged with other systems as part of the live EMVS. Product Catalogue The name of the module in the European Hub where product master data is maintained. This will ultimately be a complete list of all prescription medicines for human use available in the EU. The master data will contain the product name,

pack details, dosage, authorized wholesalers and market data.

Product Code—A unique code applied to product packaging to identify a specific trade item and packaging level. This is one of four core data elements that forms part of the Unique Identifier that must be applied to packaging under EU FMD, along with serial number, lot or Batch Number, and an expiry date. EU FMD provides that each country following the regulation may decide upon the specific product coding structure to be used on packs to be dispensed to patients in that country. Thus a country may choose to use a GS1 GTIN, a GS1 NTIN, or a unique national code.

Product Pack Data—This is the term used to describe the unique product identity (serialization data) and other product attributes for a specific pack of medical products. The OBP/Marketing Authorisation Holder is responsible for uploading the Product Pack Data to the European Hub for all product packs intended to be introduced into the supply chain.

R

Repositories System—The collection of systems and databases involved in the verification of medicines across the EU. For more information see EMVL.

Response Time—The time taken from receipt of a transaction to the response being sent from either the European Hub or a National System. (Note that this excludes general internet response time.)

RR—Registration Requester. A person who has requested access to EMVO's OBP Portal. See OBP for more information on who can be an RR.

T

Transitional Period—The period of time allowed to Belgium, Greece and Italy for transitioning from their existing verification systems to the harmonized EU system.

This is a maximum of 6 additional years after the February 2019 deadline.

U

Unique Identifier (EU)—In the EU, this safety feature must appear on every individual pack of medicine, and include a Product Code, serial code, national number (if required by the Member State), Batch Number and expiry date.

W

White List—A common shorthand name for the list of prescription medicines documented in Annex I of the Delegated Regulation that are exempt from the EU FMD requirements. The criteria for inclusion on the White List are dependent on a medicine’s risk and history of falsification, price, and the severity of the condition it treats.

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