European Medicines Verification System (EMVS)

- **What is the European Medicines Verification System (EMVS)?**

The EMVS is a new system of end-to-end verification of prescription medicines, designed to uphold patient safety through preventing falsified medicines from entering the legal supply chain. It is a multi-stakeholder enterprise, devised, funded and run by the stakeholders of the pharmaceutical sector.

The EMVS is a system foreseen in the Falsified Medicines Directive (Directive 2011/62/EU) (FMD), and the associated Delegated Regulation (EU/2016/161) on safety features. The regulation provides for prescription medicines packages to present two new safety features; a Unique Identifier (UI), which is encoded in a 2D data matrix holding information related to the pack so that it can be verified to be safe, and an anti-tampering device; such as a seal to ensure the pack cannot physically be tampered with.

- **When does the EMVS launch?**

After several years of thorough preparations, the EMVS will officially enter the operational phase on February 9th, 2019. Preparations for this have been ongoing for several years. This means that all prescription medicines released on the market by a manufacturer from this date will have to comply with the legal requirements for new safety features. Patients will still encounter medicines released before February 9th for up to 5 years in pharmacies or hospitals.

- **How is the EMVS structured? Who is involved?**

The EMVS exists out of a European Hub and national repositories. The European Hub serves as a large databank containing information on all medicinal packs put on the market after February 9th, 2019. It acts as a link between supply chain stakeholders and national repositories; and facilitates the interoperability between national systems. The **European Medicines Verification Organisation** (EMVO) is the structure responsible for running the European Hub. As such, EMVO helps pharmaceutical companies to connect to the system. Once they have connected, pharmaceutical companies can upload the Unique Identifiers of their medicines to the Hub. Every EU Member State and EEA country has their own **National Medicines Verification Organisation** (NMVO). The NMVO is responsible for helping the local pharmaceutical supply chain, i.e. pharmacies, hospital pharmacies and wholesalers connect with the new system. NMVOs also connect their national systems to the European Hub. The responsibility for introducing the new safety features and complying with the European legislation rests with the individual pharmaceutical companies.

- **How does the EMVS affect patients?**

Patients across Europe will benefit from this system; and can rest assured that the EMVS ensures that the risk of falsified or counterfeit medicines is minimized. Once the EMVS is fully operational, patients should notice no difference, as the new barcode is scanned by the pharmacist at point of sale; after they have already checked the anti-tampering device. Information is sent to the European Hub in a matter of seconds, confirming the medicine is safe to be dispensed to the patient.

- **Who pays for the EMVS?**

The EMVS is entirely funded by the stakeholders of the pharmaceutical sector. The EU and national governments, and therefore the public, will make no financial contributions.

European Medicines Verification Organisation: www.emvo-medicines.eu

EMVO: The European Medicines Verification Organisation (EMVO) represents stakeholders united in securing the legal supply chain from falsified medicines. Its founding members are EFPIA (The European Federation of Pharmaceutical Industries and Associations), Medicines for Europe (The European Generic and Biosimilar Medicines Association), PGEU (The Pharmaceutical Group of the European Union), GIRP (The European Healthcare Distribution Association) and EAEPC (The European Association of Euro-Pharmaceutical Companies).

Annex:

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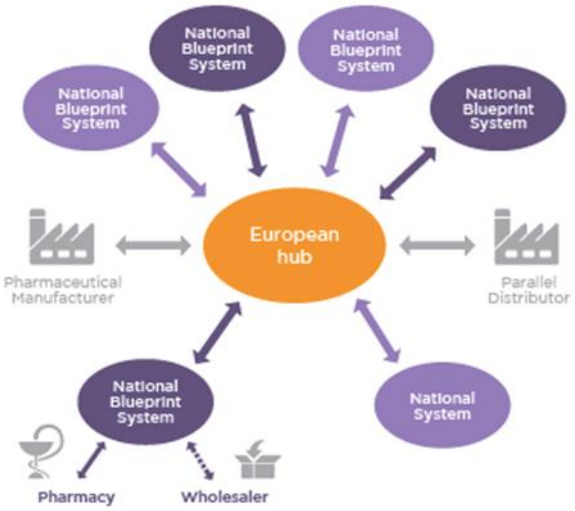

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