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LETTER TO STAKEHOLDERS REGARDING THE IMPLEMENTATION OF SAFETY FEATURES UNDER THE FALSIFIED MEDICINES DIRECTIVE 2011/62/EU¹

A key measure to address falsification in the EU and protect the legal supply chain of medicines is an end-to-end verification system introduced by the Falsified Medicines Directive (FMD). The end-to-end verification is a medicines authentication system including mandatory safety features and a repository that stores information on each individual pack.

The new rules will become applicable in the EU and EEA on 9 February 2019². From this date, prescription medicines³ placed on the EU market will need to carry a unique identifier (UI) and anti-tampering device (ATD), in accordance with the FMD and Commission Delegated Regulation (EU) 2016/161.⁴ The repository system, currently being set up by stakeholders and consisting of a European hub and national databases, will also need to be operational by 9 February 2019.

Marketing authorisation holders, manufacturers, wholesalers and those supplying medicines to the public will need to scan medicines at different points in the supply chain to introduce them into the repository, verify their authenticity and decommission them from the database at the time of dispense. Further information regarding the obligations of each actor in the supply chain is outlined below.

Marketing authorisation holders

Marketing authorisation holders (MAHs) are responsible for ensuring that medicines marketed in the EU carry the safety features (UI and ATD) from 9 February 2019. Information on the safety features must also be included in the marketing authorisation application. For already authorised products, the addition of safety features to packaging

¹ Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74).

² Article 50 of Commission Delegated Regulation (EU) 2016/161. Please note Greece and Italy benefit from an additional six-year transitional period and will need to introduce the new rules by 9 February 2025.

³ Unless explicitly exempted ("whitelisted")

⁴ Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1)

requires an update of the marketing authorisation dossier. This variation can be introduced at the same time as another variation in order to reduce costs.

MAHs must also sign contracts with the National Medicines Verification Organisations or NMVOs⁵ (who are responsible for setting up the national repositories) in the Member States where they market their products. This will enable them, or their manufacturers, to store the required data on the unique identifier in the repository system. It is essential that all concerned MAHs register with the NMVOs to avoid bottlenecks and secure market access. As part of their contract, MAHs are required to pay fees to the NMVOs⁶.

Marketing authorisation holders must also connect (onboard) to the European Medicines Verification Organisation (EMVO)⁷. Onboarding to the EMVO allows the central upload of unique identifier data through the European hub and is subject to a one-off fee.

Half of the marketing authorisation holders are already in the process of connecting to the EMVO. It is essential that all MAHs submit their applications to the NMVOs and EMVO on time to ensure compliance by 9 February 2019.

Manufacturing and importation authorisation holders

Manufacturers, including parallel importers, must update their production lines to ensure that the UI and ATD are placed on products released for sale or distribution from 9 February 2019. From this date, manufacturers must keep records of the operations they perform with the UIs and, together with the MAH, ensure the upload of the UI data via the European hub.

Manufacturers must be ready to place safety features on their products and upload UIs at the latest by 9 February 2019.

Wholesale distributors (distribution authorisation holders)

Wholesale distributors, including parallel distributors, must update their computer systems to allow them to connect to the national repositories to verify and decommission unique identifiers from 9 February 2019.

Verification of the authenticity of the unique identifiers is required for all products received from wholesalers who are not the MAH, manufacturer or designated by the MAH. Any products returned by pharmacies or another wholesaler must also be verified. Wholesalers must be ready to decommission the unique identifier of the products they intend to export outside the European Economic Area or, in certain circumstances, on behalf of persons supplying medicines to the public⁸.

Persons authorised or entitled to supply medicines to the public

Community pharmacies, hospital pharmacies and healthcare institutions have a critical role in ensuring the authenticity of medicines delivered to patients. At the time of dispense (community pharmacies) or after receipt of medicines (hospital pharmacies or

⁵ <https://emvo-medicines.eu/mission/emvs/#countries>

⁶ Article 54a(2)(e) of Directive 2001/83/EC and Article 31 of Commission Delegated Regulation (EU) 2016/161

⁷ <https://emvo-medicines.eu/>

⁸ See Chapter V of Commission Delegated Regulation (EU) 2016/161

healthcare institutions), they must verify the safety features and decommission the unique identifier⁹.

Verifying the safety features and decommissioning of unique identifiers will require the purchase of scanners to read the unique identifier and the upgrade of software to connect to the repository system. Due to the large volumes of medicines they handle, hospital pharmacies will also need to ensure that they are able to quickly and efficiently check individual packs from 9 February 2019.

Pharmacies will not be allowed to dispense medicines with safety features if they cannot verify and decommission unique identifiers and must allow enough time to prepare for 9 February 2019.

Software providers

Software providers play an important role in the update of the computer systems used by community pharmacies, hospital pharmacies, healthcare institutions and other actors in the supply chain. The systems must be operational by 9 February 2019 and sufficient time should be allocated to testing and piloting.

Legal obligations and sanctions

With the aim of protecting patients, the Falsified Medicines Directive and the Commission Delegated Regulation envisage legal obligations that will apply from 9 February 2019. Non-compliance with the above-mentioned requirements constitutes a violation of EU law. Such a violation is sanctioned by penalties according to Member State legislation.

It is important that all stakeholders act now to ensure compliance with the new rules whilst there is still sufficient time to prepare.

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On behalf of the Heads of
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⁹ See Chapter VI of Commission Delegated Regulation (EU) 2016/161