

**Informative Note 020/CD/100.20.200**

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**The original document, published in Portuguese, can be found [here](#).**

The obligation to apply safety features to medicine packs was established by the Directive 2011/62/UE of the European Parliament and of the Council, which introduced amendments to Directive 2001/83/EC that established an European code concerning medicinal products for human use (Article 54A of such Directive).

The verification system to be implemented, by placing safety features on the packaging of medicinal products will enable the detection of counterfeit medicines by the individual identification of the packaging of medicinal products and by the adoption of mechanisms to prove the inviolability of the same packaging, namely an unique identifier and an anti-tampering device.

On October 2<sup>nd</sup> 2015 the Delegated Regulation 2016/161, was published, supplementing the abovementioned Directive by indicating the characteristics and technical specifications of the safety features, the medicinal products to bear the safety features, the technical mechanisms for the verification of safety features and the decommissioning of the unique identifier and provisions on the establishment, management and accessibility of the system of repositories.

The Marketing Authorization Holders are responsible for the data upload in the system via European hub, and the wholesalers, pharmacies and public and private hospitals (mentioned in the list issued by INFARMED, I.P.) must verify and decommission the safety features in accordance with the Delegated Regulation and the Decree-Law 176/2016 (article 105-A).

In order to be able to comply with the obligations, the wholesalers, pharmacies and public and private hospitals (mentioned in the list issued by INFARMED, I.P.) must be connected to the national verification system, managed by MVO Portugal, using their information systems.

From February 9th 2019 the entities that are part of the medicines legal supply chain must apply the new regulation. The non-connection to the national verification system by reasons imputable to the entity would mean non-compliance with the Delegated Regulation. The entity may be sanctioned by such non-compliance.

After February 9th 2019, the verifications and decommissioning of the unique identifiers may generate alerts of potential falsification incidents. In spite of that and considering that the data upload is mandatory only from February 9<sup>th</sup> 2019, during an initial period alerts may be related to technical, procedural or handling problems and not because of falsification incidents.

As such, and considering the European scope of the system and the existence of operations at both national and super national levels, in the go-live, transition and stabilization period after the Delegated Regulation entered into force is necessary to ensure the normal activity of the market and the regular supply of medicines by all entities, without any interruptions, having into consideration the legal and deontological of all supply chain participants.

As a precautionary measure and to support the need to ensure the continuity of supply with the known and usual quality, security and effectiveness, until further notice by INFARMED, I.P., the alerts of possible falsifications generated by the national verification system will not be visible to the user, so the supply of medicines can continue with no disturbance. A generic message is showed to the user, confirming the transaction was recorded in the national system.

The alerts generated by the national verification system will be monitored by MVO Portugal and INFARMED, I.P. The Marketing Authorization Holders will be notified of the alerts, via European hub, so investigation of the problems occurred, concerning the products under their responsibility, can be carried out.

The detection of potentially falsified medicines in the legal supply chain is communicated to INFARMED, I.P. by MVO Portugal, after having verified that the alert is not explained by technical, procedural or pack handling problems. The entities will be informed by MVO Portugal about the alerts concerning medicines that were in their possession. In case of need, and considering the already existing procedures, INFARMED, I.P. will immediately trigger the necessary investigations and actions to inform the entities and recall the products from the national market, so the public health of the Portuguese is not endangered.

The medicine packs already in the market on the February 9th 2019 and that do not carry one or neither of the safety features, can continue to be supplied to all entities in the legal supply chain until expiry date<sup>2</sup>. To preserve the normal supply of the market, all packs that do not carry one or neither of the safety features but with valid expiry date are to be considered to be released before February 9th 2019.

It is important to highlight the fact that the legal supply chain in Portugal, in which no falsification incidents have ever occurred, is based on a robust and proven effective system of Good Practices, operating under the supervision of INFARMED, I.P. As the National Competent Authority, INFARMED, I.P. periodically performs inspections to the entities, thus ensuring the quality, safety and effectiveness of the medicines supplied to the patients in Portugal. The European Verification System is an additional safety mechanism for entities and citizens to ensure that those products were produced in a legitimate fashion in facilities approved by INFARMED, I.P. or by another authority within the European Union.

MVO Portugal and INFARMED, I.P. will accompany the entities that are still in the implementation phase of their systems to be able to verify and decommission the medicine packs on their possession.

For additional information it is recommended the reading of the frequently asked questions concerning safety features, available in INFARMED's website.

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