About Serialisation and OSMR

There is an alarming growth in the number of medicinal products found to be falsified within the European Union in terms of their identity, history or source. Prior experience shows that such falsified medicinal products reach patients not only through illegal means, but also through the legal supply chain. This poses a special threat to human health and can lead to patient's mistrust of the legal supply chain, too.

Consequently, the European Union stipulated, through **Directive 2011/62/EU**, the establishment of a Community code on medicinal products for human use to prevent the entry of falsified medicinal products into the legal supply chain. The Directive requires the introduction of safety features consisting of a unique identifier and an anti-tempering device placed on the packaging of certain medicinal products for human use in order to allow their identification and authentication. Within the **Delegated Regulation (UE) 2016/161,** the European Commission established a set of detailed rules for the safety features appearing on the packaging of medicines for human use. Starting 9 February **2019**, only prescription medicinal products which bear the new safety features may be put into circulation.

The Romanian Organisation for Serialisation of Medicines (OSMR) is the non-governmental, autonomous, independent, apolitical and non-profit organisation established for the implementation of European Directive no. 2011/62/EU of 8 June 2011 on falsified medicinal products and Delegated Regulation 2016/161. OSMR is also responsible for implementing and managing the **National Medicines Verification System (NMVS),** a verification platform through which pharmacies or other stakeholders, such as wholesalers in Romania, can verify the authenticity of a product.

MAH & PIAH in the Serialisation Context

Manufacturers of medicinal products apply the safety features on the medicinal products' packaging.
Marketing Authorisation Holders (MAHs) and Parallel Import Authorisation Holders (PIAHs) connect to the European Hub via the OBP (On-Boarding Partner) and make sure that the information related to medicinal products with unique identifiers is uploaded on the European Hub.
Obtaining the OSMR affiliated member status ensures fulfillment of the legal obligations entailed from being a MAH or PIAH on the Romanian market.

More details about the OSMR affiliation process can be found here: https://osmr.ro/en/dapp/

End users in the Serialisation Context

Within the legal distribution chain, pharmacies and hospitals verify the safety features – the unique identifier and the anti-tempering device – and decommission the unique identifier when supplying the medicinal product to the patient.
Wholesalers and PIAH (Parallel Import Authorisation Holders) verify the authenticity of the unique identifiers of medicines packs.

Connecting the company/organisation to the NMVS will be done through the End User's software provider, through validation and registration procedures which fall under the responsibility of the OSMR.

Information about the onboarding steps to NMVS can be found here: https://osmr.ro/en/2020/02/24/pasi-inscriere-in-osmr-snvm/

FAQ – OSMR & NAMMDR

This document includes a set of Frequently Asked Questions and Answers related to the implementation of the safety elements requirements on the packaging of the medicinal products for human use.

https://osmr.ro/2020/03/24/faq-osmr-anmdmr/