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IMPLEMENTATION OF A MEDICINES VERIFICATION SYSTEM TO FIGHT FALSIFIED PRODUCTS IN UKRAINE

About SAFEMed

One of the Government of Ukraine's (GOU) top priorities is improving access to safe and affordable medicines for the Ukrainian population, as evidenced by ambitious health reforms. The USAID SAFEMed project (2017-2025) supports this effort by applying health system-strengthening best practices and evidence-based interventions such as institutionalizing rational medicine selection and regulation of medicines verification; systematizing public procurement of pharmaceuticals and commodities; supporting sustainable public-sector pharmaceutical financing; and strengthening the pharmaceutical supply chain in collaboration with the GOU, civil society, and the private sector.

BACKGROUND

Medications formulated with incorrect or ineffective ingredients, produced at unlicensed sites, or distributed without necessary market approvals can negatively affect patient health. These medications, referred to as falsified medications, may worsen medical conditions, prolong illnesses, foster medicines resistance, and in severe cases, endanger lives. Patients often require more medical attention, which increases health care costs and resource use. Substandard or falsified medicines can also erode trust in the health care system, causing some to avoid seeking medical help at all. Falsified medications present a serious risk to public health, health care systems, and the economy[1].

Globally, many fake medicines go undetected due to under-resourced regulatory agencies and infrastructure and weak regulatory systems[2]. The Ukrainian pharmaceutical market has seen an increase in falsified medicines due to a myriad of factors, such as rising medicine prices, weak regulation, and porous borders. The growth of online pharmaceutical sales, while legal, also increases the risk of falsified medicines. The complex procedure to prove falsification and the lack of severe penalties create a sense of impunity among counterfeiters[3]. The GOU has prioritized the reform of medicines verification, which is a system that ensures the authenticity of medicines from manufacturer to end user, and aims to create a system that integrates with the European Union (EU)

[1] WHO Global Surveillance and Monitoring System for substandard and falsified medical products Reports and Executive summary
[2] Pathak R, Gaur V, Sankrityayan H, Gogtay J. Tackling Counterfeit Drugs: The Challenges and Possibilities. Pharmaceut Med. 2023 Jul;37(4):281-290. doi: 10.1007/s40290-023-00468-w. Epub 2023 May 15. PMID: 37188891; PMCID: PMC10184969.
[3] https://www.legalalliance.com.ua/publikacii/falsifikovani-liki-v-ukraini-ak-princip-bezkarnosti-abo-comu-sudi-ne-mozut-pritagnuti-do-kriminalnoi-vidpovidalnosti/

verification systems for increased access to safe, affordable medications. Although this tool may be a financial burden for the pharmaceutical supply chain, the health, economic, ecological, and societal losses from falsified medicines may far exceed that cost. In just one example, an estimated 72,000 to 169,000 children die from pneumonia globally due to fake medications annually[4], and in the EU, falsified medicines result in an estimated EUR 1.7B in lost revenue for EU governments, not including the cost of treating those who use falsified medicines. Moreover, the unregulated production of these substances contributes to environmental pollution and other social issues[5].

UKRAINE'S JOURNEY TO FIGHT FALSIFIED MEDICINES

Ukraine has made multiple attempts to implement a verification program since 2011, with the last attempt failing in 2019. The problem has been a lack of resources to support the required infrastructure, draft normative legal acts, and scale up pilot programs. Implementing a medicines verification system in Ukraine is a multifaceted challenge requiring substantial resources and collaboration among all relevant parties. In 2019, the Ministry of Health (MOH) turned to SAFEMed for assistance in starting over from scratch to implement a system in Ukraine that would meet EU requirements and allow wholesalers, pharmacies, and other dispensers to check a product's authenticity.

SAFEMED SUPPORT FOR INITIATING A VERIFICATION SYSTEM

To accelerate the process, SAFEMed provided support to the MOH to research verification best practices; develop recommendations, legislative frameworks, and technical requirements; and engage stakeholders in Ukraine.

LANDSCAPE ANALYSIS OF VERIFICATION AND SERIALIZATION SYSTEM IN UKRAINE

In February-March 2019, SAFEMed conducted a comprehensive landscape analysis of Ukraine's medicines verification system to deepen understanding of the existing ecosystem and review EU legislation. The initial findings were validated through stakeholder interviews. During a stakeholder roundtable, SAFEMed presented key recommendations: (1) Establish a cross-sectoral working group; (2) adopt best practices to implement the Ukrainian verification system and allow for ready interconnectivity to the current EU verification platform; and (3) take a holistic and transparent approach to developing and implementing a verification system that addresses all components of the pharmaceutical supply chain.

WORKING GROUP ESTABLISHMENT

An official MOH working group (WG) was established in August 2020 following the initial roundtable. It included representatives of various branches of the pharmaceutical market and state authorities as well as SAFEMed experts. All WG members acknowledged that implementing a medicines verification system in Ukraine was complex, requiring significant resources and collaboration. The WG recognized that both new and amended policy would improve the tracking of medicines from production to sale, reduce corruption, and increase transparency, and that the policy would need to be acceptable to all stakeholders to maximize collaboration during implementation. The WG functioned until the start of Russia's full-scale invasion of Ukraine in February 2022 at which time the format shifted to regular meetings and discussions with a wider circle of industry representatives, government agencies, and other stakeholders.

[4] https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/Trade_in_Counterfeit_Pharmaceutical_Products/Trade_in_Counterfeit_Pharmaceutical_Products_en.pdf
[5] Ibid

ANALYTICAL REPORT ON 2D CODING OF MEDICINES IN UKRAINE

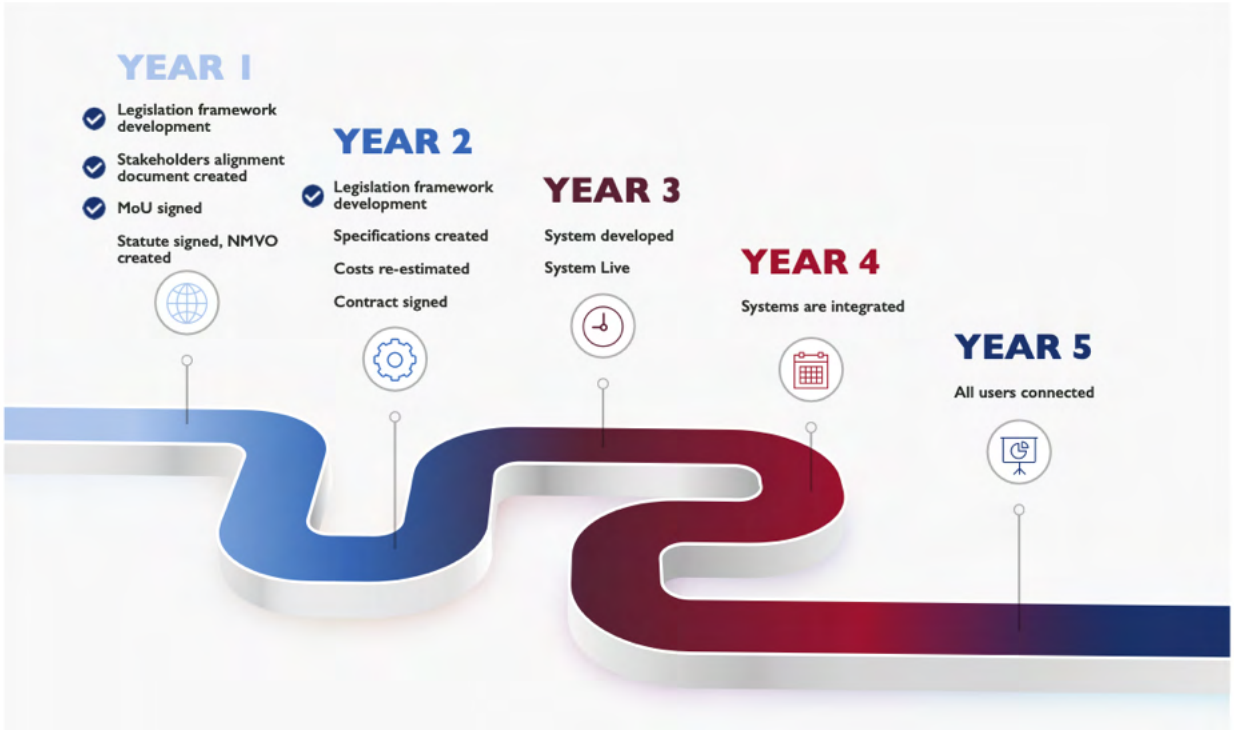
In 2021, SAFEMed presented a report on two-dimensional (2D) coding of medicines to the WG, which contained a comprehensive analysis and review of state-of-the-art verification models. (Using 2D coding to track individual products is an integral component of medicines verification.) The report focused on three national systems and compared implementation models, general system descriptions, systems structure, responsibilities and functions of participants, and procedures for launching the systems. After several rounds of review and discussion, the MOH officially selected the EU's European Medicines Verification System (EMVS) model for Ukraine, which is described in further detail below.

LEGAL FRAMEWORK

The GOU established the foundation for the verification system with the adoption of the Law of Ukraine on July 28, 2022, No. 2469-IX "On Medicinal Products." The law mandated the establishment of the national medicines verification system (NMVS) by 2028 and that medicines subject to verification must include unique identifiers (UIs) and anti-tampering devices on their packaging. It also required that the national system interact with the EU EMVS to ensure interoperability and seamless cross-border verification.

ROADMAP DEVELOPMENT

In mid-2022, both MOH and industry stakeholders confirmed their readiness to continue rolling out the system in Ukraine after a brief pause due to the war and asked for further SAFEMed support. Political will was reinforced when on June 23, 2022, the European Council granted Ukraine candidate status for accession into the EU. To help with the initiative, SAFEMed developed a detailed roadmap to establish a NMVS in Ukraine (See figure).



Note: checked items are completed as of November 2024.
Figure1. Roadmap to establish a medicines verification system in Ukraine

EUROPEAN UNION MEDICINES VERIFICATION SYSTEM

To counter the threat of falsified medicines entering the legal supply chain across Europe, the European Parliament and Council required marketing authorization holders (those approved to distribute or sell medications) and manufacturers to establish the EMVS. Verification is done through information exchange technologies and continuous cooperation among stakeholders across the supply chain[6]. The use of a verification system throughout a drug's entire lifecycle — from production to dispensing to the patient — is recognized as an effective way to address falsified medicines through the World Health Organization's three-level approach (prevention, detection, and response).

The EMVS is composed of a central European hub (EU-Hub) and various national verification systems (see figure). The EU-Hub is a vast database that stores information on all medicine packs introduced to the market since February 9, 2019. The hub is the gateway for transmitting data from manufacturers to national and subnational systems and ensures smooth cross-border data exchange and verification.

The European Medicines Verification Organisation (EMVO), who manages the EU-Hub, designed a 'National Blueprint System' that countries can adapt to set up their own verification systems to ensure alignment with the EMVS and to minimize overall system costs, the risk of failure, and implementation time — in other words — a national verification system template for consistency. Countries that do not adhere to the EMVO blueprint approach for their national systems can be connected to the EU-Hub as autonomous systems, but without EMVO support. Each EU member state must have a functioning national medicines verification organization (NMVO) to effectively manage the process at the national level.

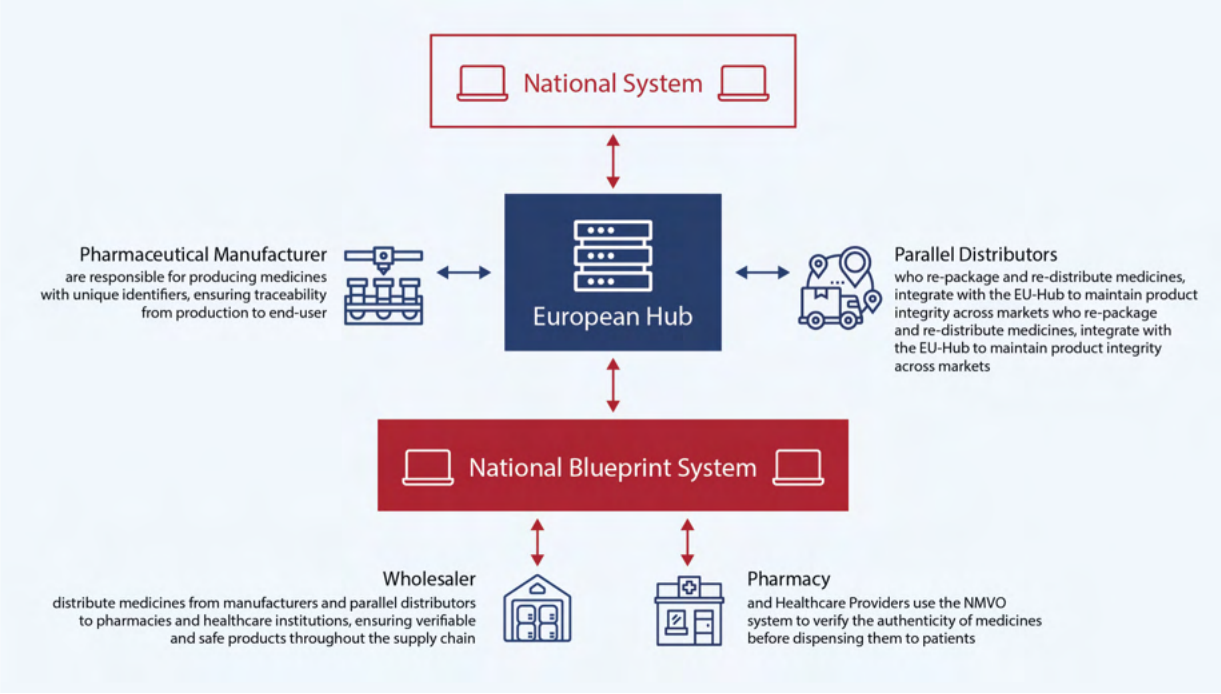


Figure 2. EU-Hub interface with national systems and pharmaceutical sector stakeholders

EMVO also supports pharmaceutical companies to comply with the EU's requirements to join the system. Once connected, pharmaceutical companies can upload their products' unique identifiers to the EU-Hub for national systems to use in verification[7]. Unique identifiers should be in a form of a 2D GS1[8] DataMatrix code containing a global trade identification number, serial number, batch (lot) identifier, expiry date, and in certain countries, a national health care reimbursement number. Manufacturers affix the 2D code with UI information and an anti-tampering device on the outside of each medicine pack, which contains the actual product. At the point of dispensing, the packs will be scanned, checked, and verified for

[6] https://emvo-medicines.eu/mission/emvs/
[7] https://emvo-medicines.eu/new/wp-content/uploads/European-Medicines-Verification-System-An-introduction.pdf
[8] GS1 is a nonprofit, international organization that develops standards related to barcoding followed by 2M+ companies around the world.

authenticity against the information within the national system. If the UI on the pack matches the system information, it will be released for dispensing to the patient. However, if the UI cannot be matched with information in the national system, the system will flag the pack for authorities to investigate for potential falsification. This interconnected network of stakeholders guarantees that every step in the pharmaceutical supply chain is monitored and verified, protecting consumers and reinforcing the health care system's integrity.

The EU-Hub is a key component of the EMVS and serves as the central repository of core data and a gateway for transmitting data from manufacturers to national and state systems. The system facilitates communication and compatibility between national systems and manufacturers' systems. These interfaces allow for operations such as data transmission and verification of product and packaging information across borders.

ESTABLISHING THE NMVS: THREE BUILDING BLOCKS AND PROGRESS AS OF NOVEMBER 2024

After SAFEMed's recommendations and the WG's discussions and go-ahead, Ukraine embarked on building and formalizing its NMVS based on EMVS requirements in time for its mandated completion on January 1, 2028. With SAFEMed's support, the country has already made progress in forming the system's foundation using the following three building blocks with critical advances still to be made.

ESTABLISHING THE AGENCY: NATIONAL MEDICINES VERIFICATION ORGANIZATION

According to EU and Ukrainian legislation, the NMVO must be a nonprofit legal entity founded by one or more associations of pharmaceutical manufacturers with voluntary participation by members. Additional NMVO members may include distributors, importers, of other non-founder professional associations. The NMVO's main function will be to create and manage the NMVS for its market and provide the opportunity for political and legal representatives to take part. Specifically, the NMVO will be responsible for connecting local supply chain actors (pharmacies, hospital pharmacies, and wholesalers) to the verification system. It will also invoice users of the verification services such as marketing authorization holders.

Progress in Ukraine as of November 2024: SAFEMed supported the development of the NMVO charter, which was thoroughly discussed with the associations that will establish it. This important and comprehensive document lays the foundation for the organization's mission, governance, operational protocols, and financing principles. Following the passage of the Cabinet of Ministers Decree in September 2024 authorizing establishment of the NMVS, stakeholders are ready to move forward with the official establishment of the organization.

ESTABLISHING THE STRUCTURE: IT DEVELOPMENT

At its core, the IT infrastructure serves as the NMVS backbone by facilitating the seamless exchange of data between regulatory authorities, pharmaceutical manufacturers, wholesalers, and pharmacies. This interconnected network enables the verification of medicines by scanning UIs on packaging, which are then cross-referenced with a centralized database to check each medicine's authenticity and verification status. The IT system also sets serialization requirements for pharmaceutical products, where each pack of medicine is assigned a UI during the manufacturing process. These UIs provide a digital fingerprint for each medicine that can be easily accessed and verified by authorized parties.

Considering Ukraine's progression toward EU accession and future reporting to the EMVO, the country needs to build an NMVS that meets its requirements. The IT infrastructure's integration with the EU EMVS will enhance its functionality and interoperability, allowing for medicines verification across borders. This integration will not only strengthen overall supply chain security but also align Ukraine's pharmaceutical sector with international standards and best practices.

Progress in Ukraine as of November 2024: SAFEMed supported Ukrainian stakeholders to develop technical requirements for the NMVS IT system and compared two IT vendors to provide recommendations on vendor selection. This comparison, critical for evaluating potential providers on various technical and operational criteria, ensures that the chosen solution will best fit the national system's needs.

ESTABLISHING QUALITY ASSURANCE: QUALITY MANAGEMENT SYSTEM

Before the development of the IT system begins, a dedicated quality management system for the NMVO must be designed to give IT service providers clear guidance on the NMVO's quality control requirements. Additionally, the EMVO must verify the quality management system when the national system is connected to the EU-Hub to ensure that it meets the required standards. The quality management system should coordinate and support all key processes of the system's operation.

Progress in Ukraine as of November 2024: After a market assessment, SAFEMed launched the process of engaging a vendor to write the business plan and processes for the NMVO's quality management system.

MAJOR MILESTONES AND NEXT STEPS

Below is a figure that summarizes Ukraine's important future milestones in creating an NMVS and SAFEMed's continued support in 2025.

Implementation of Cabinet of Ministers decree

A key milestone in enhancing the safety and verification of medicines in Ukraine was the approval of the resolution, **"Some issues of safety and verification of medicinal products"**, by the **CMU**, on September 26, 2024. The decree formalizes the application of UIs and anti-tampering devices on pharmaceutical packaging, ensuring they adhere to technical standards. Additionally, it establishes a framework for the NMVS by outlining system architecture, stakeholder responsibilities, verification and decommissioning processes, and compliance requirements.

NMVO official establishment

Creation of a strong, transparent, and **EU-focused NMVO** is a compulsory step in the creation of the NMVS. Now that the CMU decree is approved, the **NMVO** may be officially established and begin managing implementation processes. **SAFEMed** will develop a business plan for the organization that will include all necessary guidance on each stage of establishing, managing, and sustaining an **NMVO** in Ukraine.

Further legislation framework development

To ensure integrity and alignment, **SAFEMed** will continue to support further legislation framework development. This will include Orders on the list of medicines obliged for the coding and verification and changes to the licensing of the entities participating in the verification process.

Strategy and collaboration for stakeholder engagement

The complexity of stakeholders involved in pharmaceutical safety requires ongoing collaboration across regulatory bodies, pharmaceutical companies, and health care providers. Continuous engagement with these stakeholders is crucial to ensuring alignment, compliance, and the successful implementation of the verification systems and safety measures. **SAFEMed** will continue to support the **MOH** and industry to create the **NMVO** and **NMVS** through holding stakeholder engagement events and continuing to facilitate discussions.

Strategic IT plan for system implementation

A clearly defined strategic IT plan will guide the technological advancements needed to support the **NMVO's** verification processes, ensuring efficiency and reliability. **SAFEMed** has presented a comparison of potential providers to the **MOH**, but the ultimate decision will lie with the newly established **NMVO**. **SAFEMed** is ready to assist the organization in directing technical standards once a provider is selected.

Continued communication with the European Commission and EMVO

Efforts to join the **EMVO** and the **EU-Hub** are gaining momentum. Constant communication with the European Commission and **EMVO** at the central **GOU** level is key to Ukraine's integration into the international network, strengthening cross-border cooperation in medicines verification. **SAFEMed** will continue to support legal translation and drafting key documents for integration into the **EU** systems.