



NEWSLETTER No.12

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Greetings in 2025!

We will soon be celebrating the sixth anniversary of the Medicines Verification System in Europe and Latvia. Being part of the European medicines verification community inspires the Latvian Medicines Verification Organisation (LZVO) to continuously improve to guarantee the safeguarding of patients against counterfeit medicines. This year we have started ISO certification, which will help us ensure that our processes meet the highest quality and safety standards.

We continue to draw inspiration from the work of other organisations contributing to patient safety. In this newsletter, we will look at the Romanian medicines verification system, the experience of pharmacists from the Apotheka pharmacy chain in authenticating medicines, the work of the Patent Office with pharmaceutical patents, and their insights into the counterfeit market. We will also provide useful guidance to medicines manufacturers, for example on the latest EMVO requirements for inputting product data.

A sincere thank you to LZVO members, staff, and partners in Latvia and around the world for working together to strengthen the healthcare system. Let us continue joining forces for safety and reliability!

Inese Erdmane, Chairwoman of the Board at the LZVO

EMVO reminds OBPs about mandatory fields in PMD and PPD

In line with the deployment of EU Hub Release 1.16, which takes effect on 25 January 2025, the European Medicines Verification Organisation (EMVO) is introducing critical changes to the structure of Product Master Data (PMD) and Product Pack Data (PPD). Additional existing fields will now become mandatory and require action to ensure compliance.

More: <https://lzvo.lv/en/aktualitates/emvo-reminds-obps-about-mandatory-fields-in-pmd-and-ppd>

Insights from Romania's medicines verification system experience

Laurențiu Mihai, OSMR General Manager



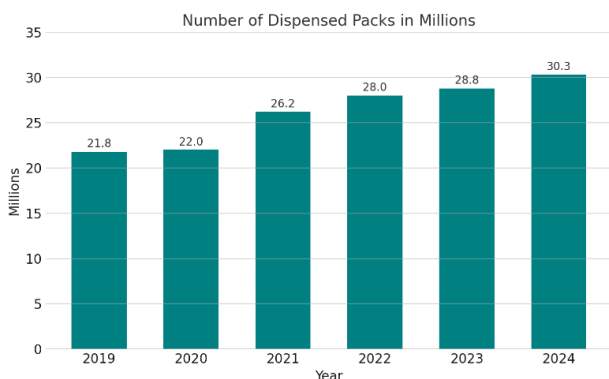
The main mission of the Romanian Medicines Serialisation Organisation (Organizația de Serializare a Medicamentelor din România – OSMR) is to manage the National Medicines Verification System (NMVS), through which we ensure that every medicine put into circulation on the national market is authentic. The system processes millions of scans each day and its robust architecture ensures high availability, with minimal to zero downtime, allowing stakeholders to rely on its functionality seamlessly.

More: <https://lzvo.lv/en/aktualitates/insights-from-romanias-medicines-verification-system-experience>

Performance indicators of the medicines verification system in Latvia

In Latvia, the verification system continues to strengthen, and the number of verified and decommissioned medicine packages is increasing each year. In 2024, a total of 116.4 million transactions were carried out in the Latvian medicines verification system, of which 30.3 million were the decommissioning of medicine packages in Latvia when they were dispensed to the public. This represents a 5% increase compared to 2023.

In 2024, the proportion of alerts affecting end users in Latvia remained unchanged compared to the previous year and was only 0.01% on average. This is significantly lower than in the early days of the system when alerts accounted for around 0.2% of the total number of transactions.



At the end of 2024, the total number of LZVS end users was 1180, comprising 817 pharmacies, 58 wholesalers, and 305 medical institutions.

More: <https://lzvo.lv/en/aktualitates/performance-indicators-of-the-latvian-medicines-verification-system-in-2024>

Patent Office on pharmaceutical patents and educating the public about the dangers of counterfeits

The patent system provides incentives for enterprising inventors to invest in costly but socially important research. However, alongside the development of innovative goods, medicines included, the ambitions of counterfeiters are growing. The Patent Office has a public education function in the fight against counterfeiting.

Unfortunately, a 2024 study published by the European Union Intellectual Property Office (EUIPO) on the ecosystem of intellectual property crime reveals that the proliferation of counterfeiting in Europe is underpinned by the involvement of pharmaceutical professionals in the manufacture, supply, and dispensing of medicines. For example, counterfeiters may obtain fake prescriptions through pharmaceutical manufacturers, doctors, and pharmacists, giving them access to medicines.

More: <https://lzvo.lv/en/aktualitates/patent-office-on-pharmaceutical-patents-and-educating-the-public-about-the-dangers-of-counterfeits>

Pharmacy chain "Apotheka" on medicines verification

The Medicines Verification System is used countless times daily in our pharmacies, and pharmacists report that it is convenient and fast. An important aspect is that the system is technically robust, and functions as intended. If the system works and the medicines are authentic, the system is almost invisible to customers.

More: <https://lzvo.lv/en/aktualitates/pharmacy-chain-apotheka-on-medicines-verification>

Changes in the medicines verification system

On 31 December 2024, Northern Ireland was disconnected from the EU medicines verification system, resulting in the permanent deletion of all related data on medicine packages and verification transactions. From 1 January 2025, prescription medicines in the UK, including Northern Ireland, must be labelled "UK Only" and are not allowed on the EU market. Meanwhile, the transition period for Greece and Italy to fully join the EU medicines verification system will end on 9 February 2025.

More: <https://lzvo.lv/en/aktualitates/2024-in-the-medicines-verification-system-achievements-and-upcoming-developments>

LZVO starts ISO certification process

The Latvian Medicines Verification Organisation has begun the ISO certification process for Quality management system (ISO 9001) and Information security management system (ISO 27001) certificates. The assessment of the medicines verification system and its supporting processes against international quality and security standards will contribute to the development, stability, and reliability of the system.

More: <https://lzvo.lv/en/aktualitates/lzvo-to-start-iso-certification-process-next-year>

The General Assembly of LZVO approves the budget for 2025

On 28 November 2024, a General Assembly meeting of stakeholders of the Latvian Medicines Verification Organisation was held. At this meeting, the strategy for the coming years and the budget for 2025 were approved. The General Assembly also approved the fixed annual fee for 2025 for the marketing authorisation holders (MAHs), including parallel importers and parallel distributors of medicines in the territory of Latvia.

More: <https://lzvo.lv/en/aktualitates/the-general-assembly-of-lzvo-approves-the-budget-for-2025>

Where can you follow LZVO news?

We invite you to keep up with LZVO news and stay informed about current events in the world of medicines verification through:

- LZVO website <https://lzvo.lv/en>
- LZVO LinkedIn account <https://www.linkedin.com/company/latvian-medicines-verification-organisation-lzvo>

If you are not yet a recipient of the LZVO Newsletter but would like to receive it in your e-mail, please sign up on our website <https://lzvo.lv/en/aktualitates>.

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