LZVO Newsletter No.1. April 2022

LZVO

LATVIJAS ZĀĻU VERIFIKĀCIJAS ORGANIZĀCIJA

Hello!

For just over three years now, a medicines verification system has been in place across Europe, including Latvia, to ensure patient safety by preventing counterfeit medicines from reaching people through legal supply chain. In Latvia, the Latvian Medicines Verification Organisation (LZVO) ensures the safety of medicines.

We are now reaching out to our customers and partners with a new informative material – the LZVO Newsletter. From now on, we will offer the most important information on the activities of LZVO and the Latvian Medicines Verification System (LZVS) in a short and summarised form on a quarterly basis.

In current newsletter we cover the development of LZVS and European Medicines Verification System (EMVS), provide insights into the development of the Alert Management System (AMS), as well as inform about the launch of the new release LZVS Core 1.10 and further support for LZVS interface versions v4 and v5. We also report on the key performance indicators for LZVS in Q1 2022.

We hope that the information in the new Newsletter will be useful to our customers and partners and that you will become our regular readers!

Sincerely,
Inese Erdmane, Chairwoman of the Board of LZVO

On the development of LZVS

The medicines verification system became operational across Europe on 9 February 2019. Latvia was one of the few countries that was able to fully launch the system by this date, with no transition or stabilisation period. This was achieved through the successful work of LZVO over the previous three years, during which both the medicine verification system itself and the Latvian regulatory framework were developed. However, the main effort was to reach, inform, and connect end-users to the LZVS, so that all Latvian community and hospital pharmacies,

pharmaceutical wholesalers, healthcare, and dental institutions, holding a permit for the acquisition of medicinal products, can verify the authenticity of medicines with safety features and decommission them at the point of dispensing.

After the system had gone live, the main tasks remained end-user support and monitoring of LZVS. However, for a couple of years now, regular work has been carried out to maintain and improve LZVS, improve customer service, and reduce the number of alerts. The day-to-day work involves constant cooperation with the system developer Arvato as well as with the end-users of LZVS and their IT suppliers, marketing authorisation holders (MAHs), national competent authorities, founders and full-fledged members, and international partners.

In 2021, a total of 26.2 million verified and safe packages of medicines were delivered to the population through the Latvian legal medicines supply chain. This was 18% more than in 2020, when 22 million packages of medicines were verified and decommissioned through the system.

On the development of the EMVS

However, we cannot just consider LZVS as an isolated system. It is part of a unique, large, and international ecosystem – the European Medicines Verification System (EMVS) – which connects more than 2 500 marketing authorisation holders, 5 000 wholesalers, 110 000 pharmacies, and 6 000 healthcare institutions in 29 European countries. Across this network, millions of prescription medicines are dispensed to patients every day. From the EMVS perspective, pharmacies, hospitals, and wholesalers carry out more than 30 million transactions in real time every day. Many terabytes of data are stored in our databases. EMVS provides an extra level of security for over 460 million people across the European Economic Area and Northern Ireland. Managing such a system is a complex process with continuous improvement. This is a unique project of a scale that has never been seen before.

In most countries, so-called stabilisation periods have been introduced to allow everyone to complete their medicines verification implementation tasks and stabilise the EMVS environment. Spring 2020 brought COVID-19, which completely disrupted our lives and created additional concerns for medicine suppliers, pharmacies, and especially hospitals. The turn of 2020 was marked by Brexit, affecting all Member States traditionally linked to the UK market. In 2020, the EMVS Change Control Board (CCB) was approved to make sure that changes to the overall ecosystem are implemented in a controlled manner and that the interoperability, security, and uninterrupted operation of the entire EMVS is ensured.

LZVO, together with other national medicines verification organisations and the EMVO, continues to work towards further stabilisation and development of the EMVS.

New LZVS release Core 1.10

The LZVS developer Arvato has prepared the next release Core 1.10, which will replace the current version 1.09. The new release will introduce several functional changes and improvements, including support for interface versions v4 and v5. Testing of the new version is currently underway. In Latvia, it is scheduled to be installed in the test environment on 18 May and in the production environment on 31 May. For more information on the scope of release, please, follow the information published on www.lzvo.lv "News" section.

After deployment of the release Core 1.10, the interface version v3 of the LZVS will no longer be available, as LZVS provides simultaneous support and availability for the two latest versions of the interface. LZVO is independently monitoring the situation with end-user connections and encourages a timely migration to the latest interface versions so that the medicine verification process is not affected. LZVO has repeatedly sent letters to the managers of the specific companies.

Towards a unified alert management system

The European Medicines Verification System (EMVS) is developing a common, new, and important project – the Alert Management System (AMS), which aims to improve and simplify the investigation of alerts by supporting system users at all levels of the investigation. The AMS will connect marketing authorization holders, wholesalers, pharmacies, and hospitals on a single platform. This will allow more efficient management and faster investigation of alerts. The system will consist of several components: a HUB AMS (central repository, like the EU HUB), an OBP AMS (connecting manufacturers), and a national AMS to be used by the end-users of the verification system (wholesalers, pharmacies, healthcare institutions) as well as by the supervising authorities.

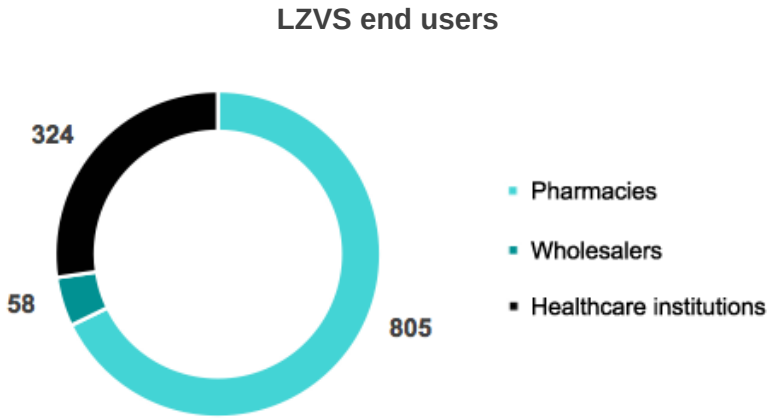
The first test version of the HUB AMS was already launched in October 2021. A pilot project of the system is currently underway, with the aim of launching the full system in May 2022.

LZVO aims to implement a national AMS system in 2022-2023, which would be connected to the common ecosystem and would allow LZVS end-users to manage alert investigations securely and efficiently while preserving user anonymity and data ownership. The use of the national AMS will be possible through a dedicated application or through integration into existing corporate systems.

End-users of the system

When LZVS was launched in February 2019, 1 043 users – pharmacies, hospitals, wholesalers, and healthcare institutions – joined the verification system in Latvia. During 2019 and 2020, the number of end-users increased until all potential users joined the system. However, from the beginning of 2021, the number of users has been decreasing as access is closed for users who do not use and do not intend to use the system. These include pharmacy branches, instead of which a central pharmacy performs the verification of medicines. Several small healthcare institutions have found that the volume of medicines purchased is low, so they are renouncing their authorization to purchase medicines and continuing to buy medicines from pharmacies. LZVO ensures that only

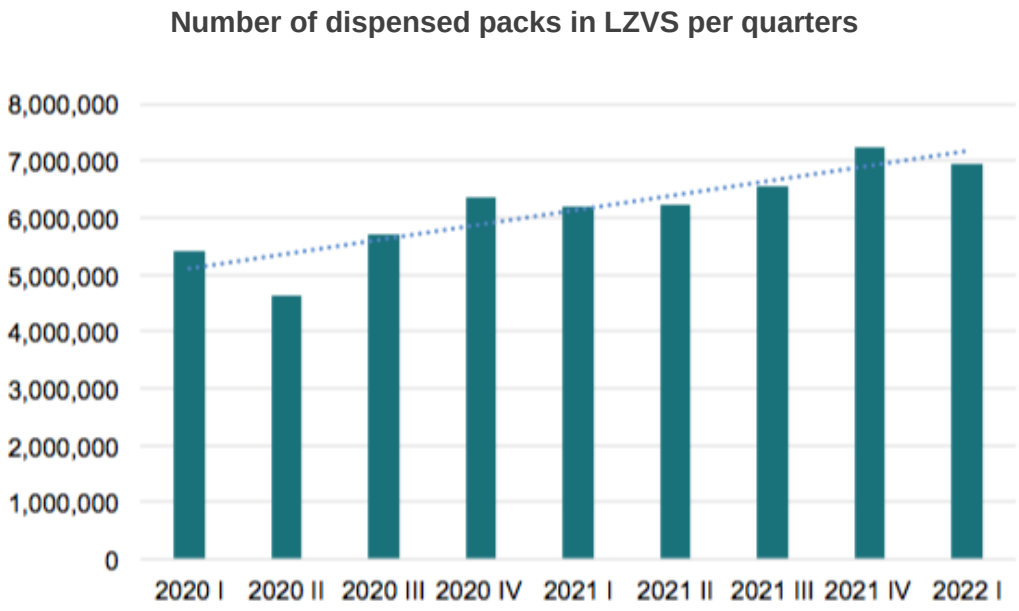
legitimate end-users are connected to the system. LZVO grants access to national competent authorities – the State Agency of Medicines (ZVA) and the Health Inspectorate (VI) for supervising the functioning of the repositories and investigating potential incidents of falsification. As of 1 April 2022, 1 187 active end-users had joined LZVS.



LZVS performance indicators for verification

Since the launch of the verification system in Latvia, the number of packages verified and decommissioned has been gradually increasing each year. This is mainly due to two reasons: firstly, the number of end-users gradually increased during the first years of the system's operation, as well as the experience and quality of using the system improved. The second reason is the growth of the market and the increase in the consumption of medicines. According to the State Agency of Medicines of Latvia, the turnover of medicines in community pharmacies increased by 2.1% in 2021 compared to 2020.

In Q1 2022, 26.6 million transactions were made in LZVS, of which 6.2 million were package decommissioning and dispensing. This is 12% more than in the same period last year. Successful decommissioning of unique identifiers account for approximately 58% of the total number of transactions in Q1 2022.

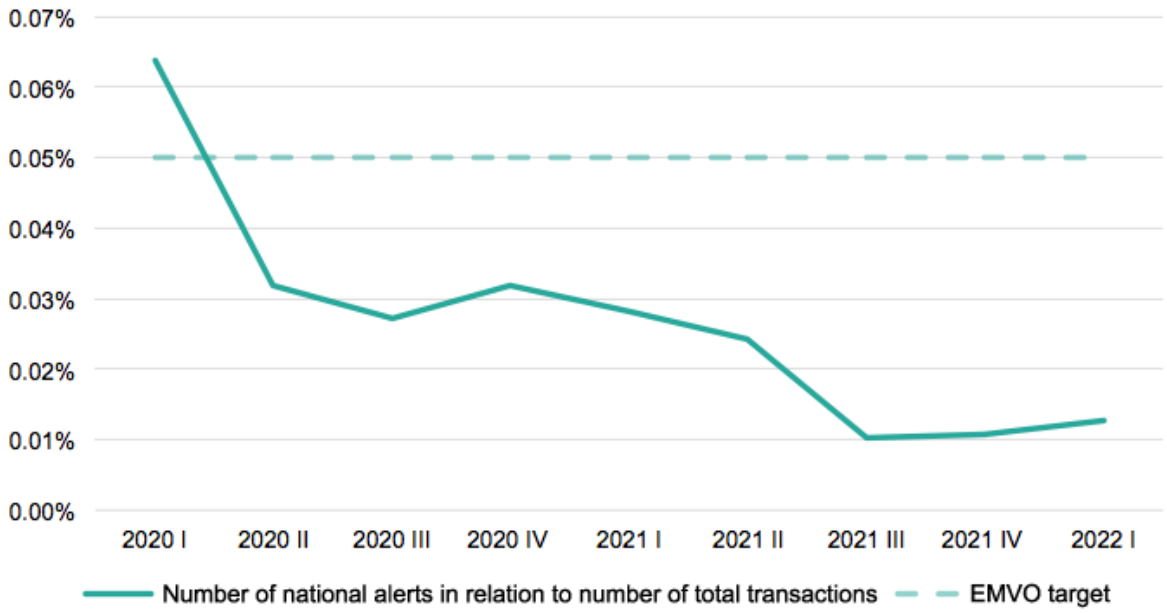


End-users face low number of alerts

The alerts that caused the most concern and questions for end-users in the early days of the system have diminished significantly over time. While in 2019 the share of alerts in the total number of transactions in Latvia was 0.1%, by March 2022 the share of alerts affecting end-users of LZVS was on average only 0.01%, which is in line with the EMVO target of 0.05% (see figure below).

In the first quarter of 2022, 67% of the total alerts were of a local nature affecting LZVS end-users. On average, Latvian end-users receive only 1 alert in 3 days. Comparing the share of national alerts in Latvia with the total number of alerts in all EU countries (0.19%), it is significantly lower. This number of alerts indicates a robust functioning of the system. National competent authorities, end-users, manufacturers, and LZVO can track and analyse these alerts.

Number of national alerts in relation to number of total transactions

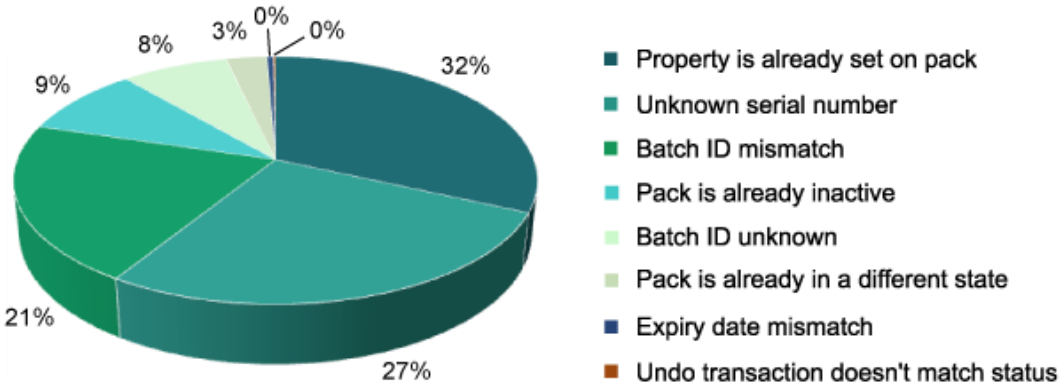


LZVO, together with all the participants of the verification system, has made great efforts to reduce the number of alerts. LZVO has conducted many seminars and provides ongoing advice to end-users and manufacturers on the prevention and investigation of alerts.

Alert codes

The alert codes ‘Property is already set on pack’, ‘Unknown serial number’, and ‘Batch ID mismatch’ accounted for 80% of all L5 alert codes in Q1 2022. According to information collected from end-users and MAHs, technical or procedural errors were the cause of about 82% of the alerts. LZVO is involved and actively monitors the resolution of the alert causes and assists the end-user in resolving them as quickly as possible.

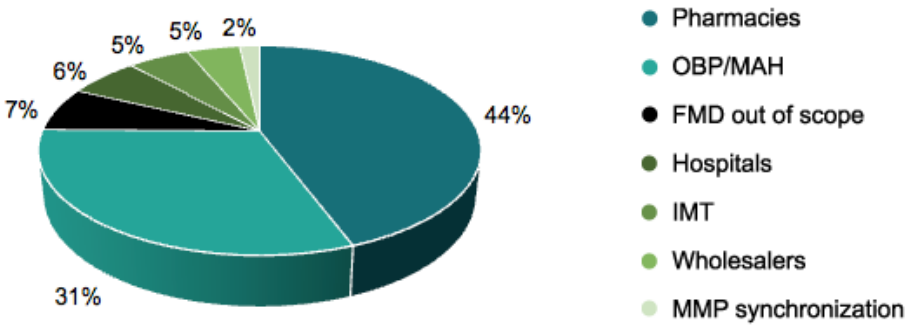
Alert codes in the 1st quarter of 2022



Reasons for alerts

Looking at the origins and causes of alerts, 50% of alerts in Q1 2022 were due to technical or procedural errors in pharmacies, hospitals, and other healthcare institutions where medicines are most frequently dispensed to patients. In 31% of cases, product master data and batch upload errors were found which had to be corrected by the manufacturers (OBP/MAH). There are still products on the Latvian market that are not covered by the Falsified Medicines Directive (FMD) and do not need to be verified, but this was still being done by end-users, thus generating false alerts (7%). In 5% of the cases, the cause of the alerts lied in the process of synchronisation of intermarket transactions between the involved markets.

Alerts by origin and reason



Where to read LZVO news?

We invite you to follow the LZVO news and keep up to date with the latest developments in the world of medicines verification:

- LZVO homepage https://lzvo.lv/en
- LZVO LinkedIn account https://www.linkedin.com/company/latvian-medicines-verification-organisation-lzvo
- LZVO end-users' portal https://lzvo.lv/en/login
- LZVO MAHs portal https://lzvo.lv/en/login

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Please direct your feedback or suggestions about the LZVO Newsletter to info@lzvo.lv

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