

LZVO Newsletter No. 3.  
October 2022



## Hello!

Each participant in the medicines verification system, which has been established in Europe to protect people's health and life from falsified medicines, has a specific role and tasks.

I represent manufacturers of medicines on the board of the Latvian Medicines Verification Organization (LZVO). Manufacturers were those who raised the alarm about falsified medicines and their risk to the life and health of people more than ten years ago. As a result, the EU Falsified Medicines Directive (2011) was created, and the Delegated Regulation entered into force in the EU on February 9, 2019. The fact that the verification system covers 29 European countries is very positive. On the part of the manufacturers, a huge amount of work was invested to implement the necessary safety requirements for the packages of medicine. The basic costs of both the creation and maintenance of the system are borne by the manufacturers, because we believe that the greatest value is human life and health, therefore these costs should be perceived by us and other system participants with understanding and support. Confidence in the safety and effectiveness of medicines is very important for manufacturers, healthcare professionals and users of medicines themselves.

The medicines verification system is in constant development – this applies both to IT system provision and operational procedures, as well as cooperation between all participants of the system. In September, LZVO organized a face-to-face seminar series for manufacturers and end-users of the system on new developments in the verification system, as well as best-practice stories. Thanks to the more than 130 participants who participated in the seminars and grew their knowledge and skill base about medicines verification system!

Only if we all fulfil our responsibilities in good faith will the system work effectively and achieve its goal.

*Wishing you a productive last act of the year,  
Evita Jaunzeme, Member of the Board of LZVO*



## LZVO invite to update the information about represented MAHs

In November, the budget of year 2023, as well as the annual fee for marketing authorization holders (MAHs), will be reviewed and approved at the General Assembly meeting of LZVO members. For LZVO to be able to correctly calculate the amount of the annual fee for the next year, we invite all manufacturers' representatives immediately, but no later than by October 30, to update the information about the represented MAH on LZVO Client portal. If you represent more than one MAH in the Latvian market, please update the information on all MAHs represented.

As previously informed, LZVO has created a client portal to store legitimate information about its cooperation partners – MAHs and end-users. In the client portal an individual profile has been created for each LZVO client. Every company can be represented by two contact persons who are granted access to the portal. Please inform LZVO promptly if relevant contact persons have changed.

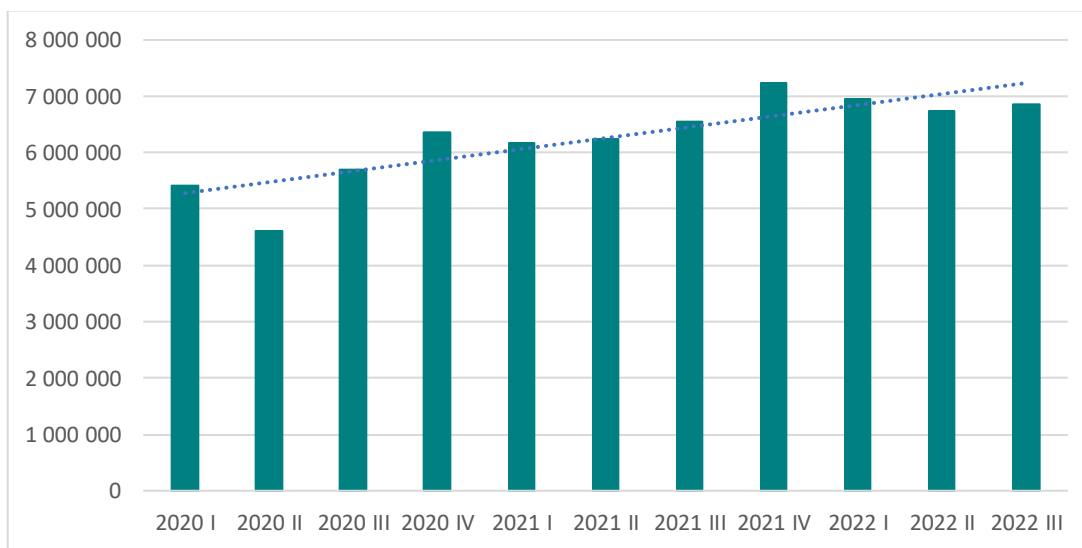
The client portal allows you to update data about the represented company and MAH, submit and receive current documents, conclude contracts, receive invoices, and contact LZVO at any time convenient for you. It also contains detailed, up-to-date, and professional information on the operation of the verification system, system updates, operational guidelines of the European Union and Latvia and various other documents.

We invite you to make sure that the client portal has updated information about your company, the represented MAH, the information necessary for invoicing, the current telephone and e-mail contacts for communication about contracts, invoice payment and investigation of alerts.

## Performance indicators of verification in Latvia

In the nine months of 2022, 77.4 million transactions have been performed in LZVS, of which 20.5 million packages were decommissioned and supplied to the patients. This is 8% more than in the same period of 2021. The number of verified and decommissioned packages in Latvia is gradually increasing every year since the verification system was launched.

Number of dispensed packs in LZVS per quarters



## A cycle of seminars was held in September

In September of this year, LZVO held a series of free seminars about the current events of the verification system for manufacturers and end-users.



Information to end-users was provided in two seminars, applying the content to the needs of end-users as much as possible – one seminar was intended for pharmacies and wholesalers, the other for healthcare institutions. Thanks to the long-term cooperation with the Pharmacists' Society of Latvia, pharmacists and pharmacist assistants had the opportunity to receive LFB TIP points. Attendees of the seminars were introduced to system news and regulatory changes, alert investigation and the future *Alert Management System*, as well as had the opportunity to familiarize themselves with practical experience stories about system use and alert investigation, which were shared by both end-user IT representatives and IT system developers.

On the other hand, in the seminar for the representatives of manufacturers or marketing authorization holders (MAHs), the main focus of the seminar was on the operation of the verification system in Latvia for more than three years, LZVO's international experience in working with other national verification systems and in Arvato working groups, investigation of alerts, quality management system and procedures for data for ensuring quality and operational efficiency, as well as IT security aspects.

## The new LZVS Core release 1.11 installed

LZVS developer Arvato prepared the next Core release 1.11, which replaced the current version 1.10. With the new version of the Core release, several functional changes and improvements are introduced, including SSO (*single sign out*) functionality improvements, as well as system security enhancements. The tests of the new version of the system in the LZVS test (IQE) environment were successfully completed, therefore, release 1.11 was installed in the production environment on October 11th.

No new version of the end user interface will be introduced after the Core release 1.11 installation, so the current v4 and v5 versions will be supported.

You can read more about the Core release 1.11 here: <https://lzvo.lv/en/aktualitates/october-11th-new-lzvs-core-release-111-will-be-installed>

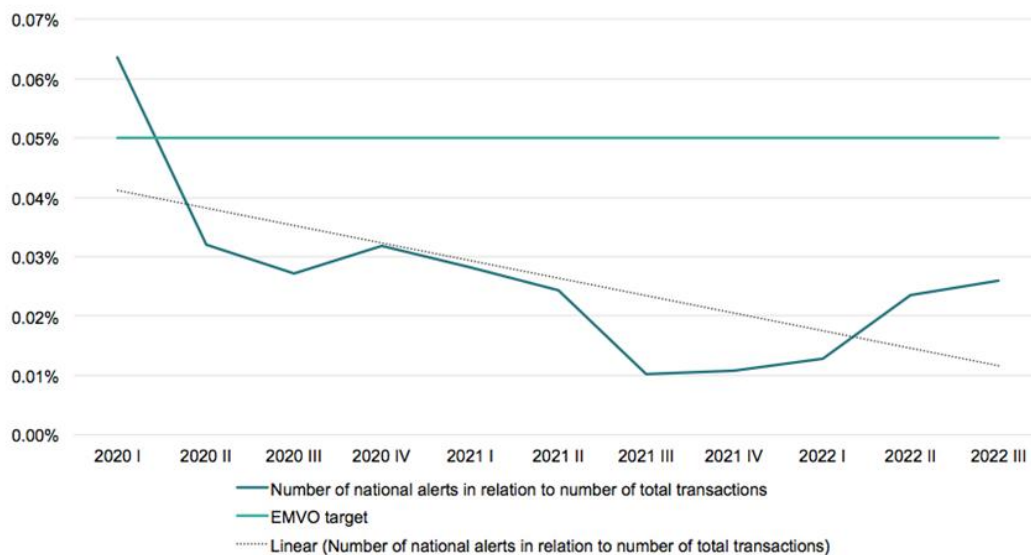


## Number of alerts

As one of the target indicators of the system’s operation, determined by EMVO, is the proportion of alerts from the total number of transactions – during optimal daily system operation, this indicator should not exceed the 0.05% mark. Thanks to the efforts of all participants in the Latvian system, the number of alerts has significantly decreased over time in Latvia, and in the 3rd quarter of 2022, the proportion of alerts from the number of transactions was only 0.03%. This indicator shows a stable operation of the LZVS, and it is significantly lower than the average indicator of the member states of the system – 0.19%.

Latvian end-users on average receive alerts once in a three days, thus end-users, manufacturers, state institutions and LZVO are able to track and analyze these notifications.

**Number of national alerts in relation to number of total transactions**

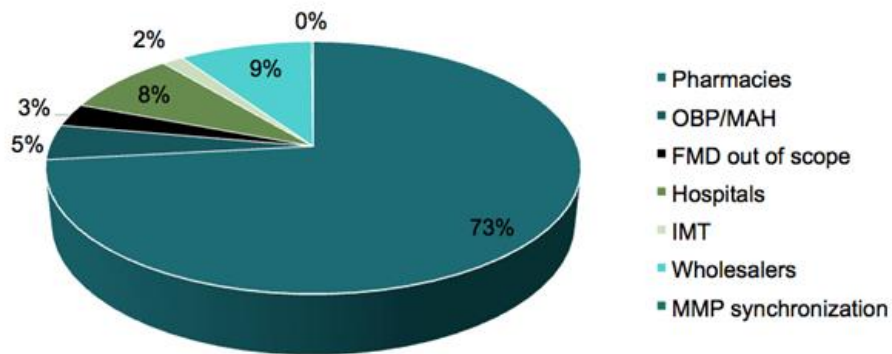


## Alerts by origin and cause

In the 3rd quarter of this year, the total number of alerts returned to normal. In this quarter, alerts were most often associated with return codes: 43% were “property is already set on pack”, 25% “unknown serial number”, and 19% “batch does not match serial number”.

Analysing the origin and causes of alert notifications, in the 3rd quarter of 2022, in 81% of cases, the reason for alert notifications was technical or procedural errors in pharmacies, hospitals and other healthcare institutions, where medicines are most often dispensed to patients. Some of the alerts were related to a change in repackaging status. About a fifth of these alerts were generated by one particular IT supplier's solution for pharmacies, where due to technical reasons the integration of the medicine's verification solution did not take place and the server sent out false notifications to LZVO. LZVO works closely with IT system developers and suppliers to help identify the causes of false alert notifications and eliminate them as soon as possible.

Alerts by origin and cause



## Where can you follow LZVO news?

We invite you to follow the news of LZVO and be informed about current events in the world of medicines verification:

- LZVO website <https://lzvo.lv/en>
- LZVO LinkedIn account <https://www.linkedin.com/company/latvian-medicines-verification-organisation-lzvo>
- LZVO end-user portal <https://lzvo.lv/lv/login>
- LZVO portal for MAHs <https://lzvo.lv/lv/login>

If you are not a recipient of the LZVO newsletter, but would like to receive it in your e-mail, please write to e-mail [info@lzvo.lv](mailto:info@lzvo.lv) or apply using our website <https://lzvo.lv/en/aktualitates>.

Send feedback or suggestions about the LZVO newsletter to [info@lzvo.lv](mailto:info@lzvo.lv).

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