

LZVO Newsletter No. 2. July 2022



Hello!

The price of the risk of falsified medicines is human health and even life, therefore, concern for the safety of medicines is a very important issue in the pharmaceutical and medical industry. Latvian customs data show that in 2021, 80% of confiscated counterfeit products were medicinal products, mainly lifestyle medicines, but they do not enter the legal supply chain. Therefore, the operation of the medicines verification system is even more important to guarantee the safety of those medicinal products supplied to the public in pharmacies and healthcare institutions.

Latvian medicines verification system (LZVS) fully operates since 9 February 2019, when EU Falsified Medicines Directive entered into force. The system is constantly being developed and improved to optimize its operation and reduce the risks of counterfeit medicine for all citizens.

Since June 1 of this year, LZVS has been fully operational with the new system release or version 1.10, developed by Arvato. With this version of the system, the interoperability between Arvato national systems and the EU HUB has been improved, the operation of the system has been stabilized and optimized through technical and functional improvements.

LZVO always actively communicates with its cooperation partners – read more about the planned autumn events in the newsletter. Also, this time we talk about LZVS performance indicators in the first half of 2022 and analyze received alerts in the system.

Have a great summer!

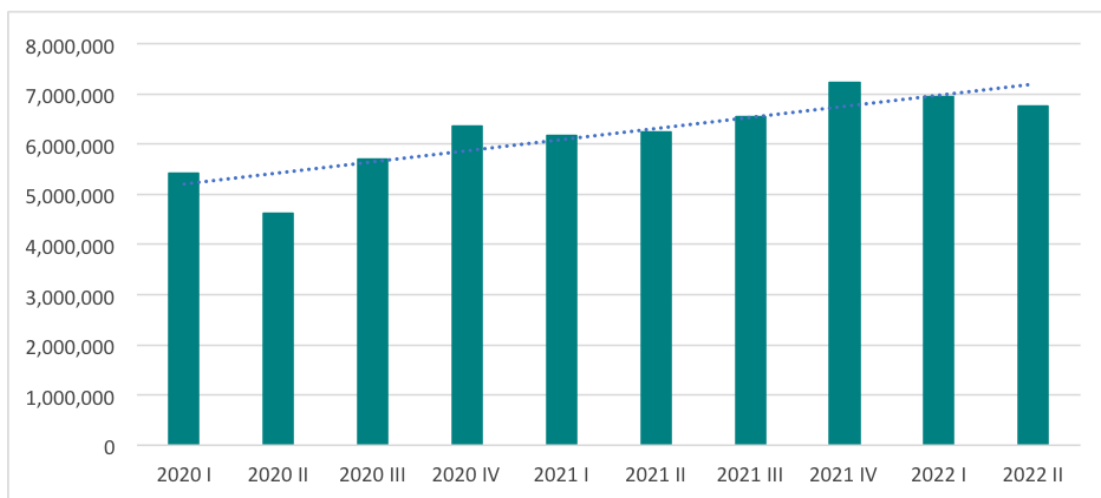
Mārcis Rutulis, Member of the Board of LZVO



Performance indicators of verification in Latvia

In the first six months of 2022, 52,2 million transactions have been performed in LZVS, of which 13,7 million packages were decommissioned and supplies to the patients, which is 10% 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



Cycle of seminars in autumn

LZVO is planning a cycle of seminars in the fall of this year for various groups of cooperation partners to inform about the new features of the system.

Information will be provided to end-users in two seminars, applying the content to the needs of end-users as much as possible – one seminar is intended for pharmacies and wholesalers, the other is planned for healthcare institutions. We will talk about new features of the system and regulatory changes, about the investigation of alerts and the upcoming *Alert Management System*, and we will share the best practice experiences.

In the seminar for representatives of manufacturers or marketing authorization holders (MAH), the main focus of information will be on system performance improvements, investigation of alerts and system data quality.

But you don't have to wait until the fall to hear about verification news – the actual information is always available on the LZVO website and LinkedIn account <https://www.linkedin.com/company/latvian-medicines-verification-organisation-lzvo>. Follow us and you will always be up to date on current developments!



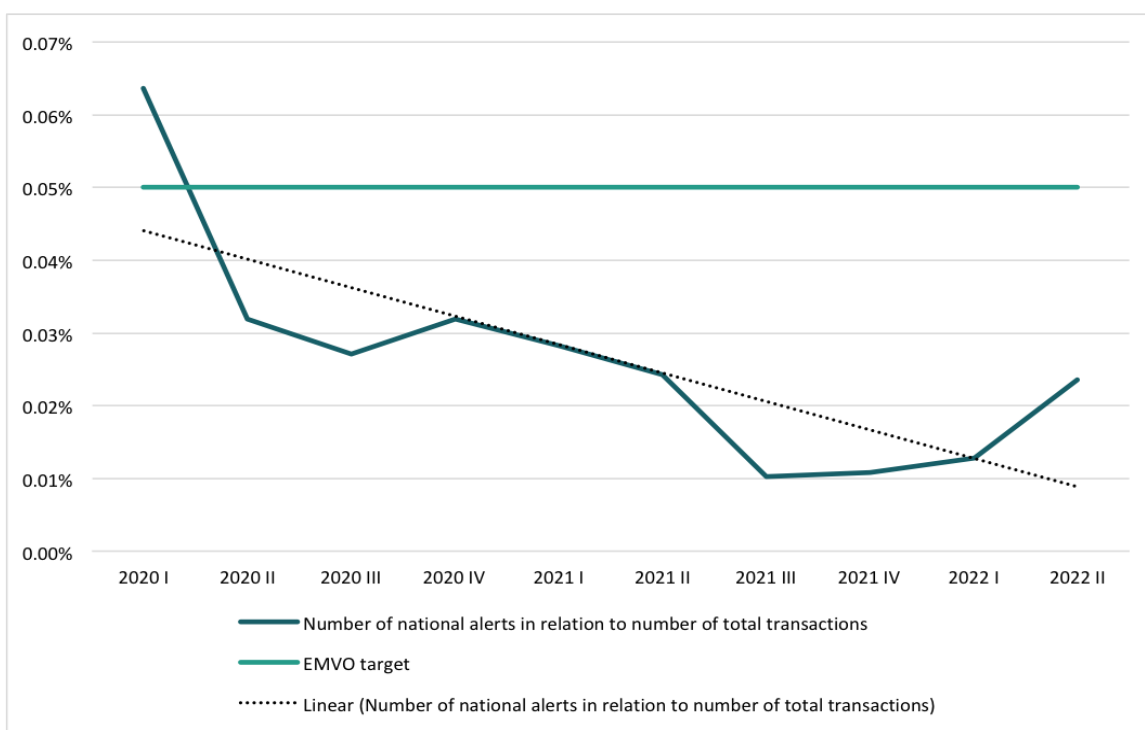
Number of alerts

EMVO has determined the share of alerts from the total number of transactions as one of the target indicators of the system's operation – during the optimal daily system operation, it should not exceed 0,05%. Already at the beginning of the second year of operation – in the 2nd quarter of 2020 – Latvia was able to fit in this level. Now, thanks to the efforts of all Latvian system participants, the number of alerts has significantly decreased, and in the 2nd quarter of 2022, the share of alerts from the total number of transactions was only 0,02%. This is significantly less than the average indicator of the member states of the system – 0,19%, and it proves a stable operation of LZVS.

In the 2nd quarter of 2022, the share of national alerts increased by 76% in June, due to an error detected in the servers of one information system developer, thus affecting the end-users of that developer and generating more than 3.500 alerts in the system.

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 warnings.

Number of national alerts in relation to number of total transactions



The number of repeatedly decommissioned packages has increased

One of the reasons for alerts is repeated scanning of the medicines package or the same code. In the second quarter of 2022, LZVO has detected an increase in repeated scanning or decommissioning of the unique identifier on the end-user side, which also increased the number of alerts. In the new LZVS core system release 1.10 it is implemented, that in case of repeated decommissioning of the unique identifier, not only the number of repeated actions is limited, but also the time limit in which the actions are performed.

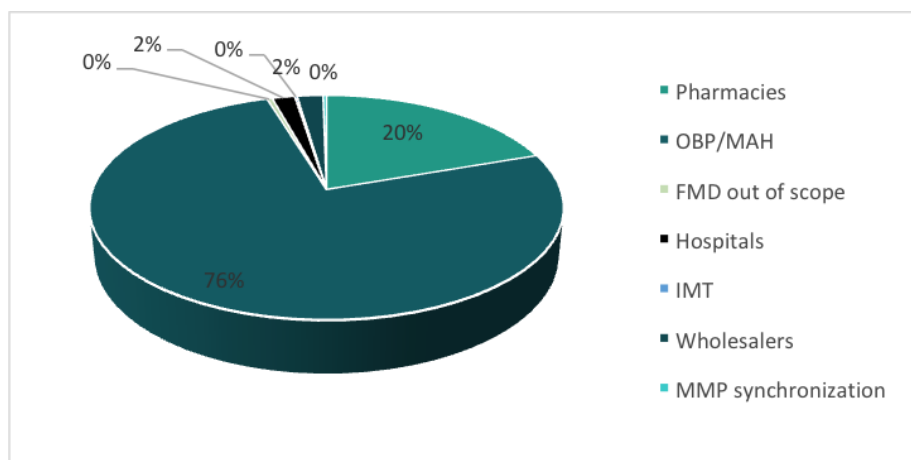
LZVO reminds all LZVS end-users that packages against LZVS must be decommissioned only once, i.e., when opening the package for the first time. End-users must follow their own procedures to remove only part of a pack from the internal accounting system.

In case the package has been decommissioned by mistake, the return (undo) operation must be done within 10 days.

Alerts by origin and cause

In the 2nd quarter of this year, the total number of alerts and the share of them, the reason of which can be found on the side of manufacturers or MAHs, have increased significantly. In June, one of the manufacturers, after uploading a batch of medicines in the system, without receiving a response from the system that it was successful, uploaded the same batch of medicines in the system again, resulting in generating of more than 14.500 alerts. Consequently, errors in uploading data of all manufacturers' products and batches of medicines have resulted in alerts in 76% of cases. Latvian end-users – pharmacies, hospitals, and wholesalers – generated alerts in 24% of cases, making technical or procedural errors.

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>

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