

LZVO Newsletter No. 4. January 2023



Hello!

On this Newsletter, we will look back at the year 2022 and highlight the current events of 2023. Really soon we will be able to say that the medicines verification system has been operating for 4 years, and this is a respectable period to evaluate the results achieved.

Throughout this period the Latvian Medicines Verification System (LZVS) has been working stably and without interruptions. The year 2022 was no exception either. Like other years, system improvements were constantly made at LZVS last year as well. Together with IT Supplier Arvato and the Arvato Customer Group, the System is being further improved and refined. During the year, the operational target indicators specified in the SLA (*Service Level Agreement*) contract have been met.

The basis of any system's successful operation is its people and their interest in the development of the system's operation. The LZVO team is actively participating in the overall activities of the EMVS, particularly within the change control board (CAB) representing Quality Assurance, the Tech Council of IT managers, as well as representing the Arvato Customer Group in the CCB. The LZVO team work closely with and take care of our clients and partners in Latvia – they support daily activities, consult in case of questions, and provide various types of informative and educational activities for MAHs and end-users (seminars, newsletters, reminders). The LZVO keeps regular contact also with local public through media and provides information via social networks. For the successful operation of the verification system in Latvia, we say the biggest thanks to our stakeholders, partners, end-users and the Latvian NCA.

The main challenge of the year 2023 will be the implementation of the AMS – a centralized tool for investigating alerts. Currently, the level of alerts in Latvia is significantly lower than the target indicator set by the EMVO. The proportion of alerts affecting end-users is constantly decreasing. We expect that the AMS will improve the speed of communication, facilitating a faster investigation of alerts, offering a more secure exchange of information in one platform among all involved parties, as well as keeping all investigation records in one place. However, it is the investigation of alerts that still causes the biggest complications for end users in the verification system, so we are sure that AMS will make this task significantly easier.

May we all have new, interesting challenges and opportunities this year and the ability to cope with them!

Inese Erdmane, Chairwoman of the Board at the Latvian Medicines Verification Organisation (LZVO)



LZVO invites end users to upgrade to version v5 of the LZVS Interface (API)

On October 11, 2022, the Core release 1.11 was installed for the Latvian Medicines Verification System (LZVS), which supports the current versions – v4 and v5 – of the interface (API).

The latest version of the interface, v5, provides several improvements that can make it easier for end users to use the verification system. Therefore, LZVO invites end users to contact their IT suppliers to switch to version v5 of the LZVS interface as soon as possible.

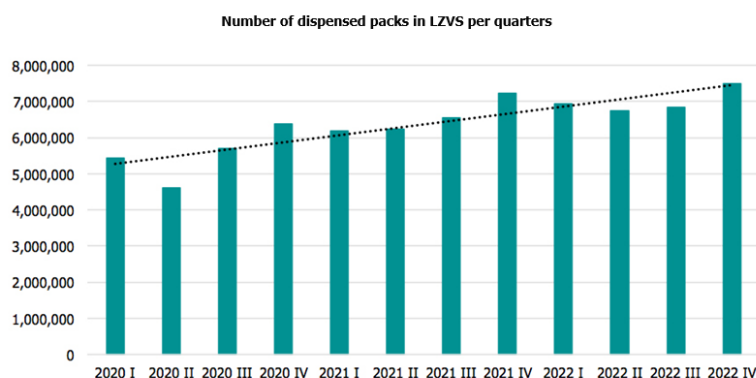
For example, the new interface allows the end user to receive a final warning by double decommissioning the package before an alert is generated.

On the other hand, along with the new version, several other functional changes and improvements were also introduced, for example, the response to the request for national verification transactions will include additional information about the product packaging and whether it is possible to return its status.

Information for IT suppliers is available on the Arvato SWS portal.

Performance indicators of verification in Latvia

In the 4th quarter of 2022, 28.2 million transactions have been performed in LZVS, of which 7.5 million packages were decommissioned and supplied to the patients. In 2022, a total of 105.7 million transactions have been performed in LZVS, of which 28 million were decommissioned and supplied to patients. This is 7% more than in 2021. The number of verified and decommissioned packages in Latvia is gradually increasing every year since the verification system was launched.



The General Assembly of LZVO approved the annual flat fee for MAHs

On November 30, 2022, a General Assembly meeting of stakeholders of the Latvian Medicines Verification Organisation (LZVO) was held, where the strategy and budget for 2023 were approved.

At the General Assembly meeting, in accordance with the financing policy for the maintenance and development of the Latvian Medicines Verification System (LZVS), the fixed annual flat fee for the year 2023 for the marketing authorisation holders (MAHs), including parallel importers and parallel distributors of medicines in the territory of Latvia, was approved – for each MAH it will be EUR 3,000.

MAHs representatives are kindly invited to contact LZVO about the annual fee or other questions by writing to info@lzvo.lv.

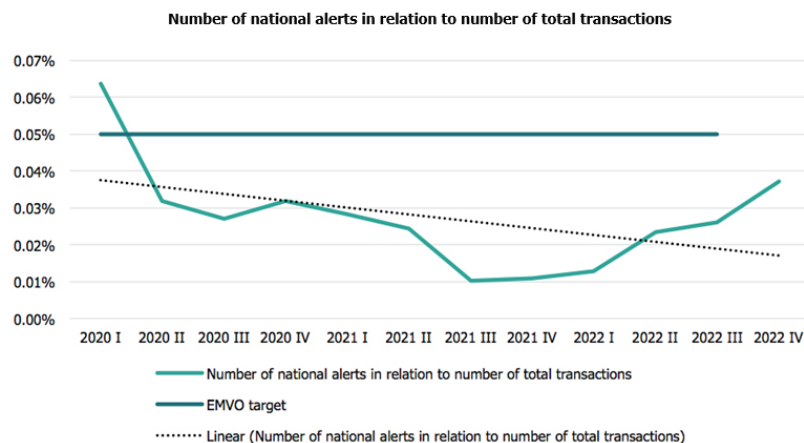


Number of alerts

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. Although in the 4th quarter of 2022, the share of alerts in the number of transactions increased slightly, it was still only 0.04%. 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%.

In the 4th quarter of 2022, the proportion of national alerts in the total number of transactions was relatively the highest in the last two years – 99%. This is explained by the fact that the end-users (wholesalers) repeatedly performed large-scale procedurally incorrect actions, and one of the IT service providers had initiated a software change, which caused additional technical errors in software operations.

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.

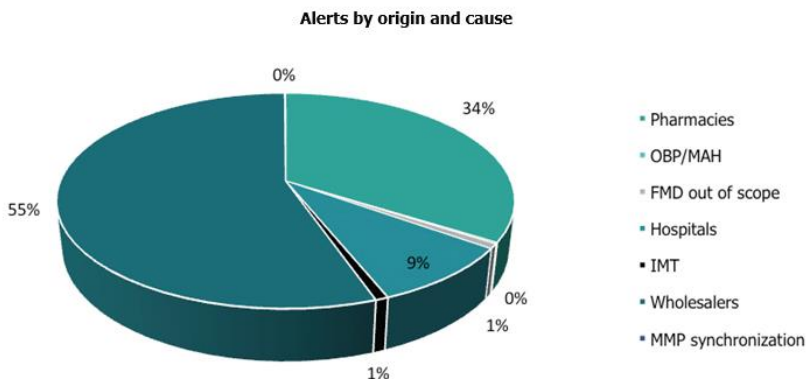


Alerts by origin and cause

In the 4th quarter of 2022, alert notifications were most often associated with technical or human errors: 59% were “property is already set on pack”, 18% were “the batch ID does not match the serial number in the NMVS”, and 15% – “unknown serial number”. These three types of alerts were the most common throughout 2022 as well. The fourth most frequently received alert notification was “pack is already inactive”.

Analysing the origin and causes of alert notifications, in the 4th quarter of 2022, in 55% of cases, the reason for alert notifications was technical or procedural errors by wholesalers. The reason for the increase in the number

of alerts in wholesale can be explained by the fact that wholesalers repeatedly carried out large-scale procedurally incorrect errors.



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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