

Press Release

Statement by CZMVO on Problems with Verification System

Prague, 28 May 2019. The Czech Medicines Verification Organisation would like to make a statement about the situation concerning the slowdown or unavailability of the system in the last few days. **On Monday, 27 May, an area generating problems was identified in the main database and an alteration to the configuration was made, so medicines could be verified. In addition, however, there is an ongoing review and simulations in a testing environment to uncover the precise cause, so that it is possible to correct the error or make a change to eliminate it. The system is being very intensively checked to see whether it contains other problematic places, so that CZMVO can guarantee problem-free operation for all end users of the system. The availability of medicines was not limited by this defect.**

The verification of products in the national system was, in recent days, significantly limited or completely interrupted. The first incident of this kind appeared on 10 April 2019. The problem then occurred several times, the situation got worse from Wednesday, 22 May 2019, when most end users were affected by the unavailability of the system. With the exception of a three-hour outage on Wednesday, 22 May 2019, the operation of the system was not interrupted, or rather its components were available as a part of monitoring. However, for end users the response time was extended to tens of seconds and this was followed by unavailability due to timing out. This inability to verify a medicinal product concerned approximately one in two or three packages. Problems were experienced by various end users with different IT systems.

From the escalation of the problems with verification there was intensive work on ascertaining the possible causes of the system's problems. At first, it was not clear where the problem was coming from, so a whole number of hypotheses were examined: from an application error, to infrastructure problems, to a targeted attack.

We still do not know the precise cause, but on Monday, 27 May, we managed to locate the area that is generating the problems. The error is evidently in the module distributing the load to individual nodes, or in combination with the node code. **After this finding, alterations were made to the configuration of the solution, so the service is now available, and it is possible to perform verification in the standard manner (from the early afternoon on 27 May).**

The examination of the cause did not confirm whether it was an attack or misuse of the system. After re-deployment, performance tests were also performed and proved that the national system is able to handle a much higher load than is currently generated by the Czech Republic. There is also an ongoing code review and simulations in a testing environment to uncover the precise cause, so that it is possible to correct the error or make a change to eliminate it.



The European Medicines Verification System is a very complex and the most complicated project that was launched in the environment of the pharmaceutical market. Problems with implementation were anticipated, so in the Czech Republic an act was passed providing a temporary/trial period until the end of 2019 for the fine-tuning of the National Medicines Verification System, in order not to interfere with the availability of medicines.

Although other countries use an identical version of the system, the problem appeared only in the Czech Republic, which has the largest volume of transactions among Solidsoft customers. However, stress tests were performed and proved a significant reserve in the whole system's capacity.

The Czech Medicines Verification Organisation is also working with representatives of IT software companies and end users and is asking them to provide specific (anonymised) transaction records.

Looking for the cause of the problem in co-operation with Solidsoft included:

- Intensive communication with the team dealing with the incident;
- Repeated communication with Solidsoft's management;
- The provision of detailed information from end users for a possible analysis— anonymised information from an end user with its consent;
- Own monitoring (CZMVO) of the NMVS system;
- Escalation of the problem to the European level (EMVO) and other interested entities.

This incident was certainly unpleasant, but its solution also tested the reactivity and co-operation between the participants, which led to the effective identification of the defect. CZMVO would like to thank all those who are working on solving the problem and who provide information. At the same time, it apologises for the complications that the system failure caused to pharmacists.

We will keep you informed of further developments in the situation. More at www.czmvo.cz

For CZMVO: Mgr. Jakub Dvořáček, MHA

For additional information please contact:
MUDr. Marta Šimůnková, CZMVO consultant
marta.simunkova@czmvo.cz
+420 602 226 726