



**Národní organizace
pro ověřování
pravosti léčiv**

Press Release

Prague, April 10th, 2019

The authenticity of drugs has been verified for two months without serious problems

The first two months have shown that a comprehensive and complex drug verification system is fully operational. After an initial temporary higher number of alerts, their level has now stabilized at two percent of the verified drugs. The majority of alerts is caused by the disagreement of the data loaded by the marketing authorization holder (MAH) into the central hub with data in 2D code printed on packing and missing data in the system. These sub-problems were predictable and the shortcomings were eliminated. The communication between drug dispensers and the MAH in the Czech Republic is coordinated by the Alert Management Center operated by the National Drug Validation Organization (NOOL). So far, the patient has not been given a medicine as a result of verification process.

The proportion of alerts to transaction counts was tens of percent in the first week, mostly due to incorrect reader settings at the end user, or lack of data or error in data in the central storage (European hub and regional storage where manufacturers upload data). Repeated unsuccessful verifications of the concrete package caused a higher number of alerts. During the second half of February and in March 2019 alerts accounted for 2-3%.

The most common reasons were differences of printed data on packing and data in Unique Identifier (UI, 2D code), which had usually a formal nature, such as different expiration date format (33% of all alerts), lot number (33%) or product (17%), and their mismatch.

Current information to the FMD at the beginning of April 2019

The number of products in the National Drug Authentication System (NSOL) with recorded data is 6,043 (83%) from about 7,300 active medicinal products in the Czech Republic. The National Drug Authentication System on April the 1st 2019 contained a total of 54,424,638 packs and 286 manufacturers have uploaded their product data to NSOL.

1,450 subjects had a contract with NSOL: 1,203 pharmacy service providers, 155 distributors and 92 pharmacies with distribution permit.

The NSOL is connected to 3,013 facilities (2,742 pharmacies and 271 distributors - warehouses). About 66% of all connected end users verify the medicine at least once a day.

A total of 5,137,505 transactions took place in NSOL and 246,072 alerts were created. The current daily average of transactions is 240,000, while the daily average of alerts is 7,000 (about 3%).

NOOL Alert Management Center

According to the European Directive, the National Drug Authorization Organization (NOOL, CZMVO) is obliged to ensure immediate investigation of all potential case of false medicines and to notify them to the relevant national authorities (SÚKL), the European Medicines Agency (EMA) and the European Commission.

To investigate alerts, NOOL (CZMVO) has created the Alert Management Centre, which coordinates solution of alerts in cooperation with the MAH and provides other related activities. In doing so, it uses the alert management system and the InnOne and NOOL support team.

About the Authentication System

The European Drug Authentication System is a comprehensive and complex project coordinated by the European Drug Validation Organization (EMVO). The process of validation of drugs before delivering to the end user was launched on February 9th 2019 due to the European Union Falsified Medicine Directive (FMD 2011/62 / EU) and other legal regulations (2016/161 / EU). Pharmaceutical Validation Authority (NSOL), under the responsibility of the National Drug Validation Organization (NOOL). FMD is part of the adopted amendment to Act No. 378/2007 Coll., about drugs.

Protective elements

End users verify security features:

- unique identifier (2D code)
- protection against manipulation of the contents of the medicinal product package (eg. stickers).

The security features on the manufacturer's packaging is placed by MAH, who uploads unique identifiers to the system (via the European hub) to the national storage before it is released to the market.

Current information at www.czmvo.cz