# Status report of Czech national medicines verification system (CZMVS)

*Country:*                  *Czech Republic*

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*Date:*                     *[July 25th, 2019]*

This report provides all necessary information regarding current status of Czech National Medicines Verification System (CZMVS) and rate of its use by other subjects in relation to FMD legislative requirements in Czech Republic. Additionally, the report is to inform about key upcoming FMD activities and other related information.

**The implementation phase of CZMVS is closed. Open issues are continuously solved during production period.**

## Contents

## MAHs and their activity in CZMVS

| Relevant areas | Status |
|---|---|
| **Registration of MAHs to NOOL** | [354] |
| • **Of which MAHs with signed cooperation agreement with NOOL** | [337] |
| • **Of which MAHs with small revenue** | [41] |
| **A number of MAHs uploading data to CZMVS** | [331] |

**Additional remarks:** [CZMVS - Czech National Medicines Verification System]

## End-users activity in CZMVS

| Relevant areas | Status |
|---|---|
| **Registration of legal entities of end users in the role of "pharmacy" with a signed contract for using CZMVS** | [1486] |
| **Number of connected pharmacies (locations) to CZMVS** | [99% - 2709] |
| • **Of which number of connected hospital pharmacies** | [100% - 116] |
| **Registration of legal entities of end users in the role of "wholesaler" with a signed contract for using CZMVS*** | [268] |
| **Number of connected warehouses (locations) to CZMVS**** | [380] |
| **Number of End Users Certified IT SW for connection to CZMVS** | [44] |

**Additional remarks:** [* Number of distribution licenses in the Czech Republic 747; ** the reference number of the total number of warehouses is not available]

# Products and activity in CZMVS

| Relevant topics | Status |
|---|---|
| **Number of products/product codes up-loaded in CZMVS – master data*** | [6834] |
| **Number of packs with uploaded data in CZMVS*** | [117 720 950] |
| **Transactions in CZMVS*** | [slightly increasing trend – see chart] |
| **End-users activities in CZMVS (legal entities)* *** | [69%] |

**Additional remarks:** [*up to 21st July 2019, ** share of legal entities verifying in CZMVS at least once a day from total number or registered end-users; visible drop due to the summer holidays]



Počty transakcí a alertů v NSOL - trend počtu transakcí
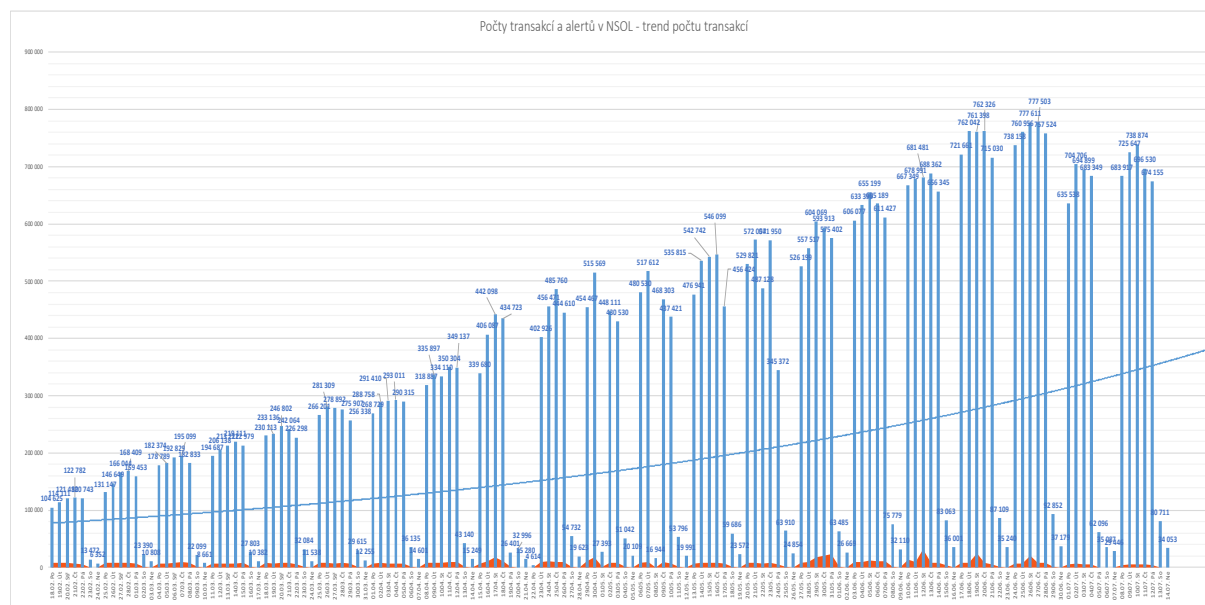
# Status and development of CZMVS and Alert Management System

| Relevant areas | Status |
|---|---|
| **SLA – time of the transaction (end-to-end) < 300 ms \*** | [99,4 %] |
| **SLA – achieving of the critical Service Level Agreements (SLAs) defined to Solidsoft Reply – total 16 SLAs** | [May – 12 from 16 SLAs achieved<br>June – 16 from 16 SLAs achieved] |
| **Identified speed or system response problems \*\*** | [Repeatedly – May 22, there was a several-hour outage of the MS database, in the following days in 23.-27.5 repeated problems occurred with the general availability of NSOL and so-called "time outs" in the system response. Even during June (5th, 6th, 13th, 14th, 18th, 20th, 21st June 2019), problems persisted for a short time. Thanks to intensive monitoring on both the NOOL and Solidsoft side and identification of probable causes, these were quickly found and eliminated within a few minutes. Subsequently, the stress testing was modified to better reflect the situation in the Czech Republic, a corrective release was implemented according to the test results (25.6.2019)] |
| **Number of tickets solved for CZMVS\*\*** | [15] |
| **Number of open probémů** | [2] |

**Additional remarks:** [\*completed transactions, \*\*since the last FMD report, from 21st May]

| Relevant areas | Status |
|---|---|
| Release 4.1.2 | [Done – implemented and tested] |
| CZMVS development | [In progress – adding functionality in system releases, CZMVS in full operation from 9th Feb. 2019, Release 5 planned for 8/2019 and Release 6 for 11/2019; scope primarly NCA reports, API and portal improvmentes] |

| Relevant areas | Status |
|---|---|
| Monitoring of CZMVS availability | [Done – own monitoring of NSOL availability from NOOL launched - available online at https://www.czmvo.cz/en/czmvs-status/ ; simultaneously SSR monitoring is available for all Solidsoft Reply customers; preparing to use EMVO GTIN for monitoring the interconnection of EU HUB, Arvato systems and Solidsoft Reply systems - will be fully available within R5] |
| Alert management centre and end-user support centre | [Done – ongoing adjustments and system setting according to experience from operation, training of alert centre employees] |
| Workshop on possible development of Alert management system with IT SW companies | [Done – ongoing adjustments and system setting according to experience from operation, training of alert centre employees] |
| Alert management system development | [In progress – modification of the existing solution, allowing "grouping" of alerts according to defined common features by 15.8., based on the selection procedure, the supplier selected for the preparation of the API and the portal for the verification of the status of alerts by the end users and the management of alerts by the MAHs; delivery and testing schedule approved, pilot operation planned from 09/09/2019, completion of implementation by 30 September 2019] |
| Release 4.1.3 | [Done - additional standardised alert data to alert e-mails and Azure performance improvements. Both changes passed tests successfully. May 21st, 2019 implemented into CZMVS] |
| Release 4.1.4 | [Done – successfully tested and implemented bug correction of IMT – UTC time] |
| Release 4.1.5 | [Done – successfully tested and implemented bug fix in JSON schema – identified as a reason of issue in Czech verification system – specific release for CZMVS 25th June 2019] |
| Release 5.0 | [In progress – test ITAT and UAT successfully completed; expected date of R5 – 13th August 2019] |
| Release 6.0 | [In progress – scope definition; mainly NCA reports; expected date of R6 – 2nd half of Nov. 2019] |

| Relevant areas | Status |
|---|---|
| Release of NCA reports | [**In progress** – defined groups of NCA reports according to priorities 1-4, implementation in all countries according to the joint plan of Solidsoft Reply, Arvato and EMVO – reports priority No. 1 - October 2019, priority No. 2-3 - December 2019, priority No. 4 - April 2020] |

**Additional remarks:** [N/A]

## Alerts and exceptions classification in CZMVS

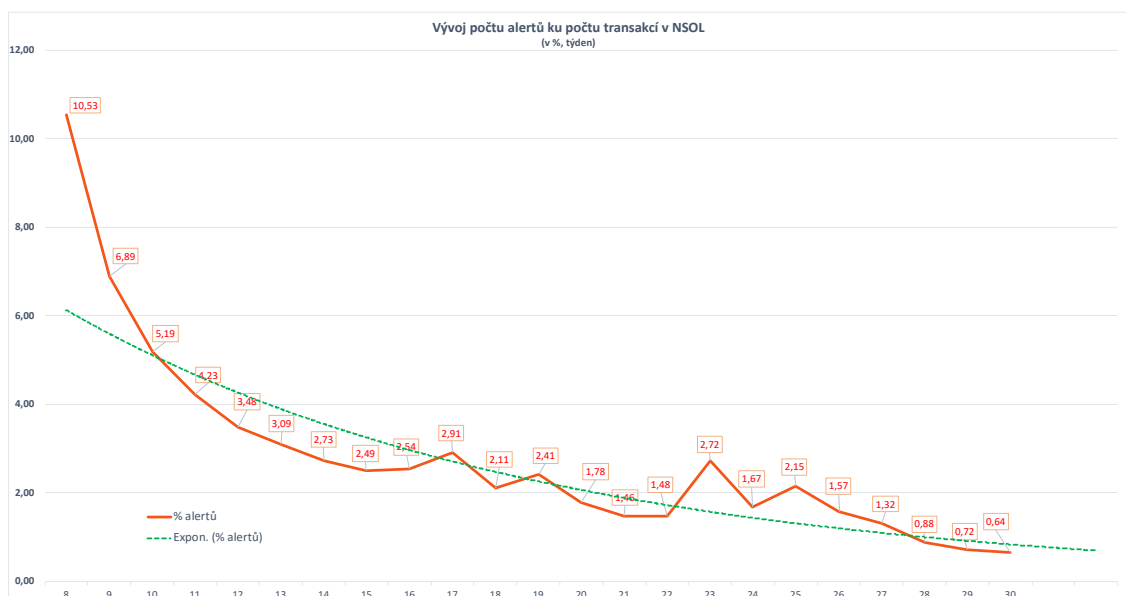| Alert or exception definition | Status |
|---|---|
| A2 – level 5 alert | Batch ID unknown/Batch not found |
| A3 – level 5 alert | Unknown serial number /Pack not found |
| A5 – level 5 alert | Attempted Undo by Different Party/Undo can only be executed by the same user who previously set the attribute |
| A7 – level 5 alert | Pack already in requested state/Attempt to decommission an already decommissioned pack |
| A24 – level 5 alert | Pack status Change Not Allowed |
| A52 – level 5 alert | Expiry data mismatch |
| A68 – level 5 alert | Batch ID mismatch |
| A1 – exception, not reported as L5 alert | Product code unknown |

**Additional remarks:** [N/A]

# Alerts, root causes, improvement actions

| Relevant topics | Status |
|---|---|
| **% of alerts in CZMVS compare to total number of transactions** | [2,01% - long term average - slightly decreasing trend – see chart] |
| **Actual % of alerts in CZMVS compare to total number of transactions during last week** | [0,64% - short term weekly average] |
| **Alerts evaluation** | [Continuously done – analysis, search for causes - communication with MAHs and representatives of end users or IT SW companies] |

**Additional remarks:** [N/A]

- [Monitoring the share of alerts in the total amount of transactions in NSOL displayed by weeks for clarity.
- The fluctuations and increase in alerts in weeks 23-26 are also related to problems with the availability of the NSOL system.
- A slight decrease in the number of transactions in holiday operations has the effect of reducing the occurrence of alerts, but at the same time there is a clear downward trend in the number of alerts in the last few weeks. This reduces the ratio of alerts to transactions.]

**Vývoj počtu alertů ku počtu transakcí v NSOL**
(v %, týden)

10,53 | 6,89 | 5,19 | 4,23 | 3,48 | 3,09 | 2,73 | 2,49 | 2,54 | 2,91 | 2,11 | 2,41 | 1,78 | 1,46 | 1,48 | 2,72 | 1,67 | 2,15 | 1,57 | 1,32 | 0,88 | 0,72 | 0,64

— % alertů
- - - Expon. (% alertů)

| Alert types | Types of alerts share on total alerts |
|---|---|
| A2 - Batch not found | [36%/51% - increasing share on total number of alerts] |
| A52 - Expiry data mismatch | [35%/23% - decreasing share on total number of alerts] |
| A3 – Pack not Found | [16%/11%  - stable trend (except 2 fluctuations)] |
| A7 – Pack already in requested state | [5%/7%  - 1 fluctuation] |
| A24 – Status change could not be performed | [5%/8%  - 1 fluctuation] |
| A68 – Batch ID Mismatch | [3%/0%  - strongly decreasing share on total number of alerts] |

**Additional remarks:** [Data from 9th February/ last month = weeks 26 -30]

**A68 - Batch ID Mismatch A7 - Pack Already Available, A24 - Status Change Could Not be Performed**

Report and Trend (weekly)
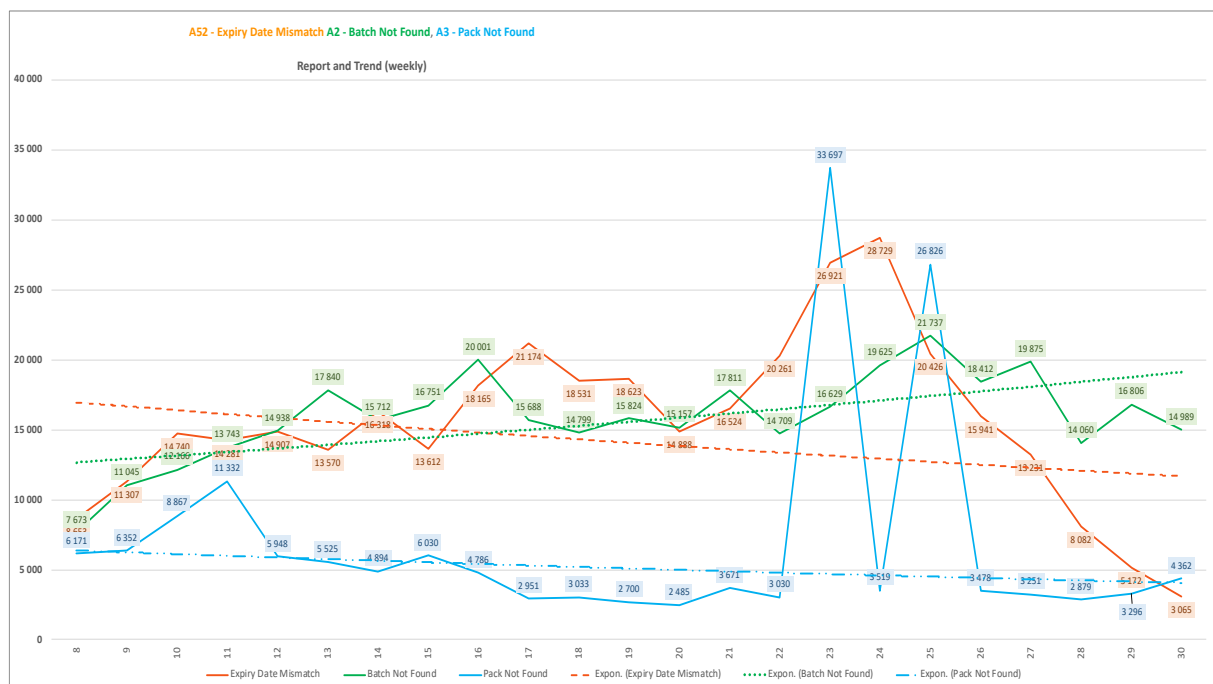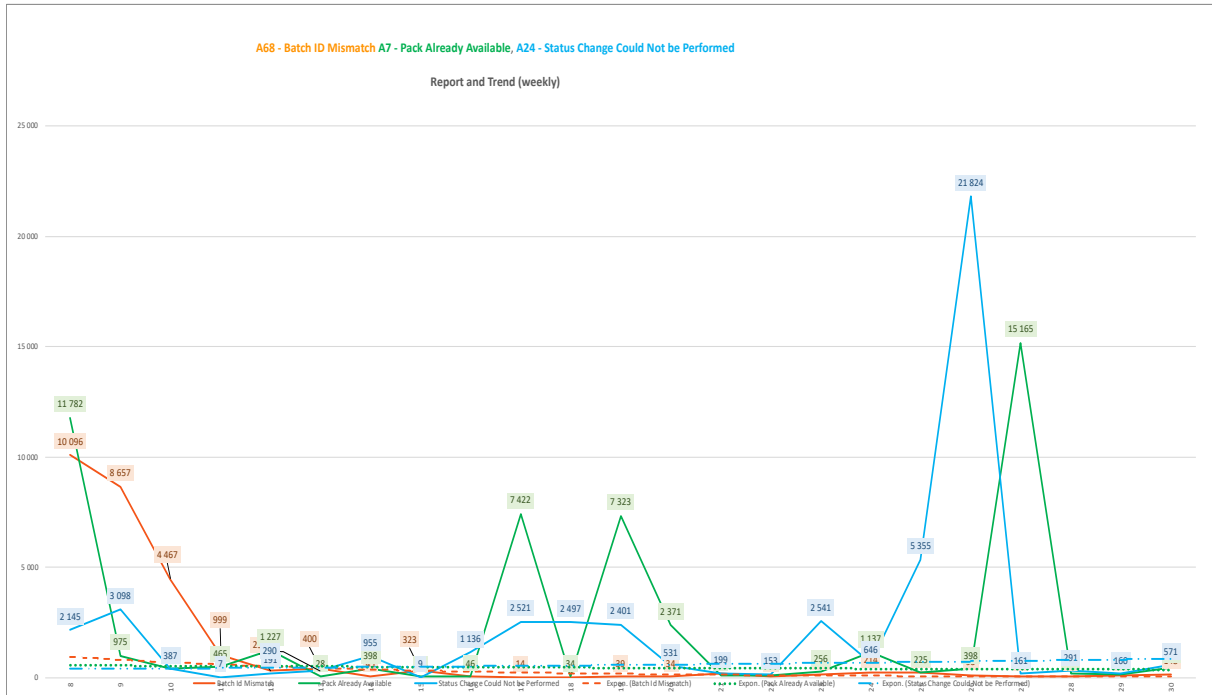
**Additional remarks:**

» **A68 (Batch ID Mismatch)** share on alerts, however there are also problems with recording incomplete batch or packet numbers between alerts **A2 and A3 (batch or package not found)**, therefore communication between NOOL with end users and their IT providers of SW solutions continues regarding individual alerts.

» Fluctuations of **A7 and A24** caused by activity of 1 MAH in most cases last weeks; there is also impact of CZMVS system issues from previous weeks.

» Share of **A2 + A52** in last weeks on total alerts around 742%; direct communication to MAHs to solve the cause of the alerts is in place – primarily individual meetings and consultations. Information regarding par 11r of Medicinal Act that can be used by MAHs, which is not able to retrospectively upload or correct data to serialized products.

| Alert types, exceptions | Identified root causes of alerts |
|---|---|
| A2 - **Batch not found** | • Data not uploaded– batch missing or not correctly uploaded.<br><br>• Y/Z or small and big letters mismatch – due to wrong set up of scanners of 2D codes.<br><br>• OBP with „indian packs" uses a GTIN, which later is used for FMD, so alert is generated.<br><br>• One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly. |

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| Alert types, exceptions | Identified root causes of alerts |
|---|---|
| | • Products scanning with not properly set-up scanners, send wrong Batch ID, with a mismatch to the data which is encoded in the Data Matrix Code.<br>• Manual entry error by the End-User. |
| A52 - **Expiry data mismatch** | • Wrong expiry date uploaded, meaning that the data uploaded into the Hub is different from that encoded in the Data Matrix Code (e.g. the date '00' printed in the DMC and then '31' uploaded in the in the EMVS).<br><br>• One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly.<br><br>• End-User software sends wrong expiry date. For instance, some software and scanners being used by End-Users convert the expiry date 210600 wrongly into other dates e.g. 210531 or 210631 etc. instead of sending the data as encoded in the Data Matrix Code (210600) without adulteration or change).<br><br>• Incorrect manual entry of the expiry date or interpretation of MM/YYYY. |
| A3 – **Pack not Found** | • Incomplete upload – Serial numbers not uploaded or not correctly uploaded.<br><br>• One element of the Data Matrix Code appears in the Serial Number field, because group separators have not been set properly.<br><br>• Y/Z or small and big letters mismatch – due to wrong set up of scanners of 2D codes.<br><br>• Manual entry error by the End-User.<br><br>• Failed scanning procedure: batch number incomplete (missing characters) or linear barcode (EAN code) attached to batch number. |
| A68 – **Batch ID Mismatch** | • Batch data not uploaded correctly.<br><br>• One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly. |
| A7 – **Pack already in requested state** | • OBP performs batch update on already distributed packs. |

| Alert types, exceptions | Identified root causes of alerts |
|---|---|
|  | • OBP attempts to decommission an already decommissioned pack (e.g. 'sample to sample' or 'checked out to checked out').<br><br>• Errors leading to the re-sending of request. |
| A24 – **Status change could not be performed** | • OBP attempts to decommission an already decommissioned pack (e.g. 'sample to checked out').<br><br>• End-User (software) attempts to decommission an already decommissioned pack (double dispense).<br><br>• End-User performs a destroy operation for a pack already dispensed and inactive in the EMVS or expired pack. |
| A1 – **Product code unknown** | • Product Code not uploaded into the EMVS.<br><br>• Product Master Data not uploaded into the EMVS (or failure to transmit to CZMVS.<br><br>• Product codes not compliant with national coding requirements (NTIN instead of GTIN).<br><br>• Scan products which are out of scope of the FMD (OTC, 'Indian Product Codes', medical device, etc.).<br><br>• Manual entry error by the End-User. |

**Additional remarks:** [Alerts root causes identified in cooperation with other countries, not only NOOL input. * in Solidsoft Reply systems, A1 is not reported as L5 alert - identified and required in the future to be included in L5 alerts, which will be notified to national verification organizations, including NOOL].

| Alert types, exceptions | Preventive actions to minimise alerts root causes |
|---|---|
| A2 - **Batch not found** | • Reaching out to OBPs or MAHs from NOOL to advise them on the missing data.<br><br>• OBPs or MAHs asked to upload data to serialized products retrospectively (even packs release before 9th Feb. 2019).<br><br>• Communication with IT SW companies regarding proper scanners and end-users' SW set-up.<br><br>• Implementation of ad hoc solutions for End-Users' scanners testing and validation (caps lock etc.). |
| A52 - **Expiry data mismatch** | • Reaching out to OBPs or MAHs to advise them on the incorrect data. |

| Alert types, exceptions | Preventive actions to minimise alerts root causes |
|---|---|
|  | • Educating End-Users regarding scanning best practices. |
| A3 – **Pack not Found** | • Reaching out to OBPs or MAHs to advise them on the missing data.<br>• Communication with IT SW companies regarding proper scanners and end-users' SW set-up.<br>• Scanning „Best practice", Implementation of ad hoc solutions for End-Users' scanners testing and validation (caps lock etc.). |
| A68 – **Batch ID Mismatch** | • Communication with IT SW companies regarding proper scanners and end-users' SW set-up.<br>• Implementation of ad hoc solutions for End-Users' scanners testing and validation (caps lock etc.). |
| A7 – **Pack already in requested state** | • Re-upload of data by OBP - Relaying educational material and guidance. |
| A24 – **Status change could not be performed** | • Communication to MAHs and/or end-users regarding wrong process. |
| A1 – **Product code unknown** | • Reaching out to OBPs or MAHs from NOOL to advise them on the missing data – if available information. |

**Additional remarks:** [Alerts corrective actions identified in cooperation with other countries, not only NOOL input]

# Communication and other activities

| Relevant areas | Status |
|---|---|
| NOOL created 3rd version of End-user contract | [Done – incorporation of modifications according to binding requirements from the contract between EMVO - NOOL for the production phase, the wording of the contract was approved by the Board of Directors NOOL] |

| | |
|---|---|
| NOOL concluded a contract amendment with NSOL users - pharmacies, distributors | [In progress – preparation of electronic acceptance of the amendment and communication on the web |
| Communication with IT software providers of end-users systems | [Continuously done – communication via Freedcamp] |
| Presentation of the current state of NSOL, alerts and topics related to FMD in the Czech Republic at conferences (Pharmaprofit, Good Distribution Practice LP, others) | [Continuously done – information regarding number of connected end-users, MAHs, alerts and their root causes] |
| Every 2nd month, a "press release" about the FMD status in the press | [Continuously done – information regarding number of connected end-users, MAHs, alerts and FMD status] |
| Articles in professional media and professional websites about the status of FMD at distributors and pharmacies, alerts and their solutions | [Continuously done – according to the planned scenario (Pharma Profit, Sortiment, Medical Tribune, Apatykář etc.)] |
| Information regarding exception for MAHs – medicinal packs according to par. 11 r of Act on Pharmaceuticals | [Done – a suggestion for MAHs to use the option to apply for an exemption to Ministry of Health for a particular batch in the event that the data in EMVS (CZMVS) cannot be corrected was published on NOOL web pages] |
| Case studies on the basis of findings from the ongoing operation of CZMVS and FMD best practise | [In progress – to be published on an ongoing basis; report regarding issues with CZMVS and solutions put in place was published] |
| Establishing procedures for practicing crisis communication in case of problems with CZMVS | [In progress – direct communication to key subjects; fine tuning by the end of August] |
| Preparation of a press conference: appeal to end users - it is necessary to learn to verify and solve alerts | [In progress - fine tuning by the end of August] |
| NOOL defined the amount of user fees for using CZMVS by MAHs in 2020 | [In progress – fees defined and approved, to be published during September] |
| Expert group consultations | [Continuously done - sharing information on FMD developments from the point of view of pharmacies, distributors, IT SW companies and manufacturers; preparation of materials and info] |
| Wel pages update | [Continuously done] |

**Additional remarks:** [N/A]