Status report of Czech national medicines verification system (CZMVS)

Country:	*Czech Republic*
Responsible personnel:	*[Pavlína Štisová, Project Manager NOOL]*
Date:	*[May 20th, 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 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**	[332]
• **Of which MAHs with small revenue**	[41]
A Number of MAHs uploading data to CZMVS	[313]

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	[1424]
Number of connected pharmacies (locations) to CZMVS	[97% - 2663]
• **Of which number of connected hospital pharmacies**	[100% - 114]
Registration of legal entities of end users in the role of "wholesaler" with a signed contract for using CZMVS*	[260]
Number of connected warehouses (locations) to CZMVS**	[371]
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]
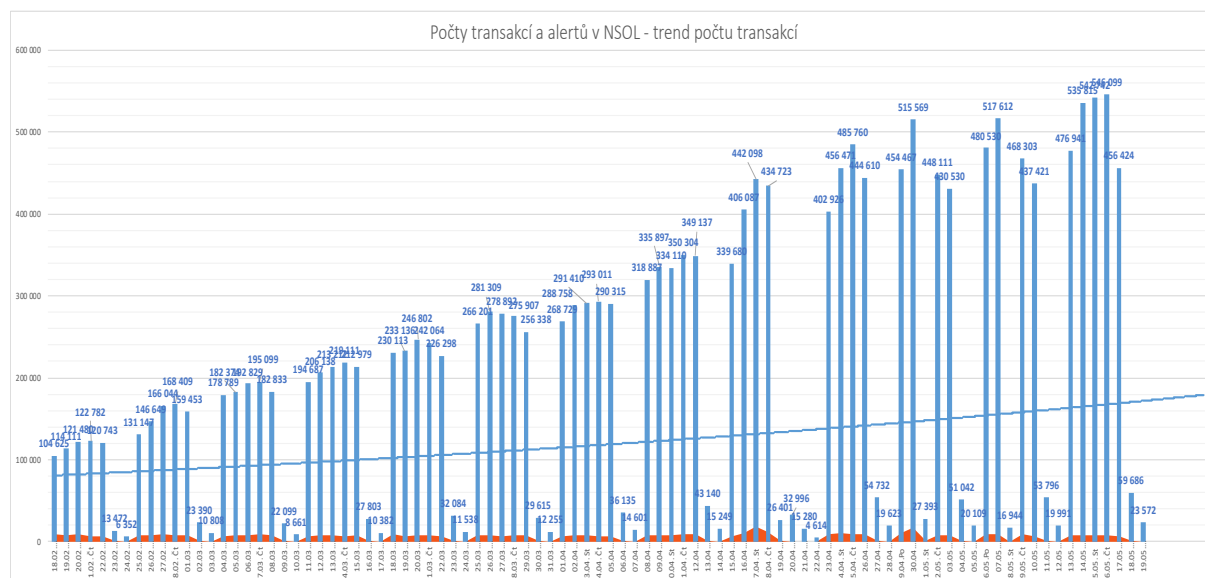
Products and activity in CZMVS

Relevant topics	Status
Number of products/product codes up-loaded in CZMVS – master data	[6513]
Number of packs with uploaded data in CZMVS	[81 014 688]
Transactions in CZMVS	[slightly increasing trend – see chart]
End-users activities in CZMVS (legal entities)*	[67%]

Additional remarks: [* share of legal entities verifying in CZMVS at least once a day from total number or registered end-users]

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 *	[99,15 %]
Identified speed or connection problems (slow or temporarily no transaction response for several end users with different IT SWs)	[3x – 10.4., 15.4. and 17.5.; investigation with Soilidsoft Reply support still on-going, immediate action taken + additional capacity of infrastructure to increase performance in R4.1.3]
Number of tickets solved for CZMVS	[396]
Number of open tickets	[3]

Additional remarks: [*completed transactions]

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 7-8/2019 and Release 6 for 11/2019; scope primarly NCA reports, API and portal improvmentes]
Monitoring of CZMVS availability	[In progress – the use of the EMVO GTIN will be completely available under 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]

Relevant areas	Status
Alert management system development	[**In progress** – ongoing supplier selection addressed to 3 pre-selected suppliers; Expected delivery date and completion of delivered services by Sept. 2019]
Release 4.1.3	[**In progress** – new functionalities - additional standardised alert data to alert e-mails and Azure performance improvements. Both changes passed tests successfully. Date: May 21st, 2019 till Wednesday, May 22nd, 2019, between 10pm and 2am CET, Czech NSOL will not be available in either IQE or PRD environment]
Release 5.0	[**In progress** – planning, initial testing; expected date of R5 – 28.7.2019]
Release 6.0	[**In progress** – scope definition; mainly NCA reports; expected date of R6 – 2nd half of Nov. 2019]

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

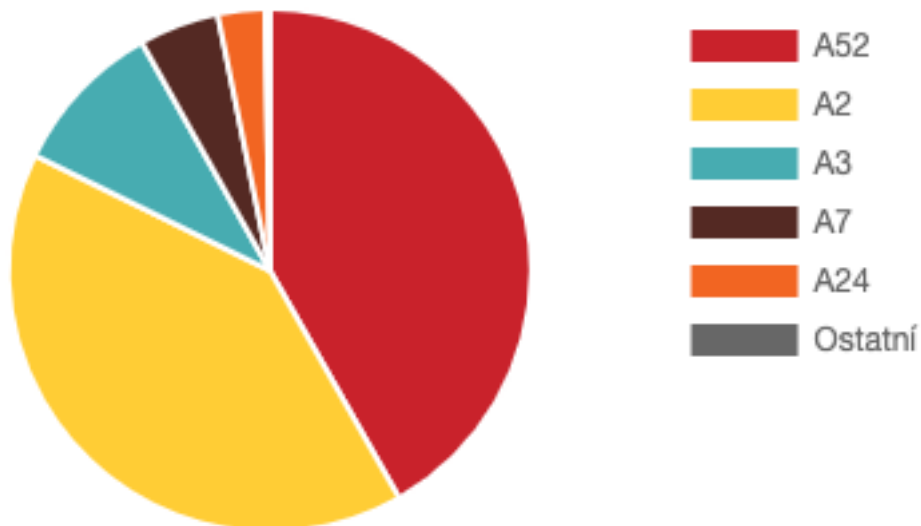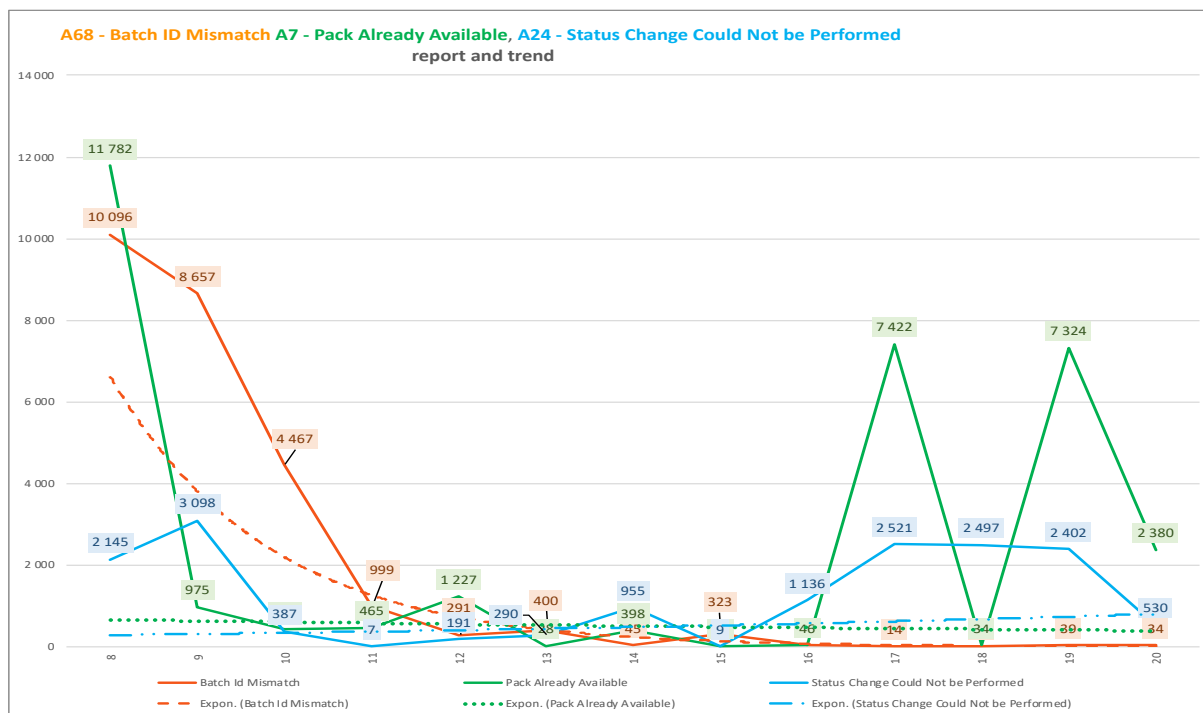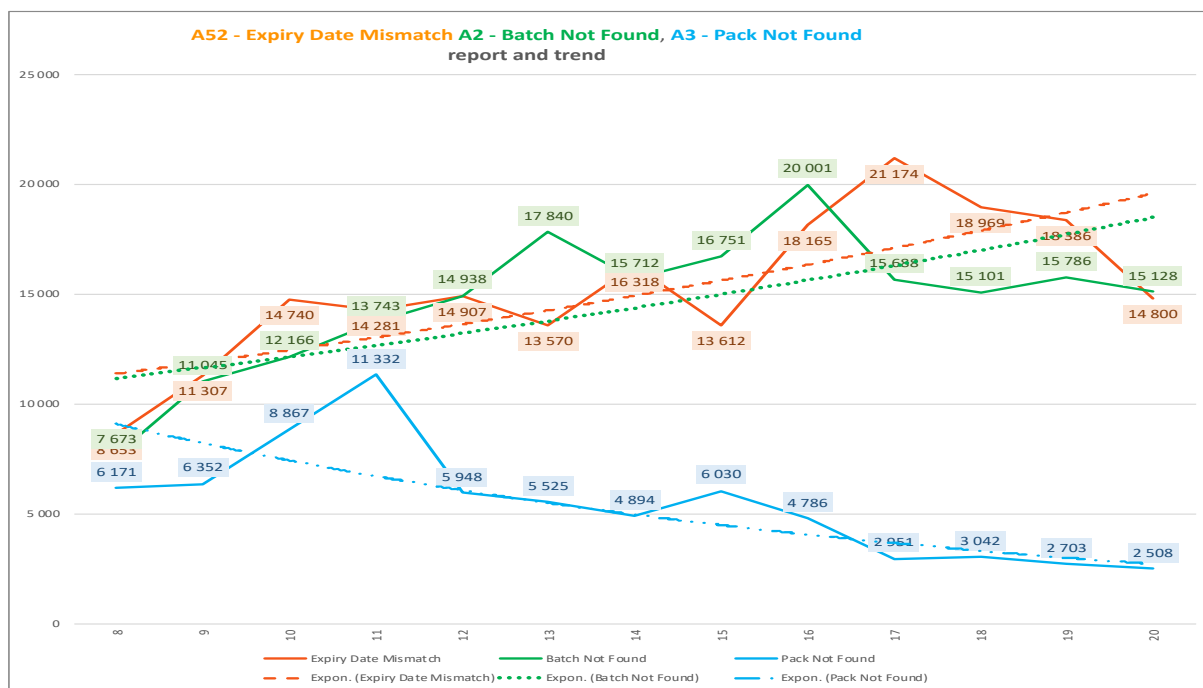| Relevant topics	Status
% of alerts in CZMVS compare to total number of transactions	[2% - slightly decreasing trend – see chart]
Alerts evaluation	[Continuously done – analysis, search for causes - communication with MAHs and representatives of end users or IT SW companies]

Additional remarks: [N/A]

Vývoj počtu alertů ku počtu transakcí v NSOL - trend
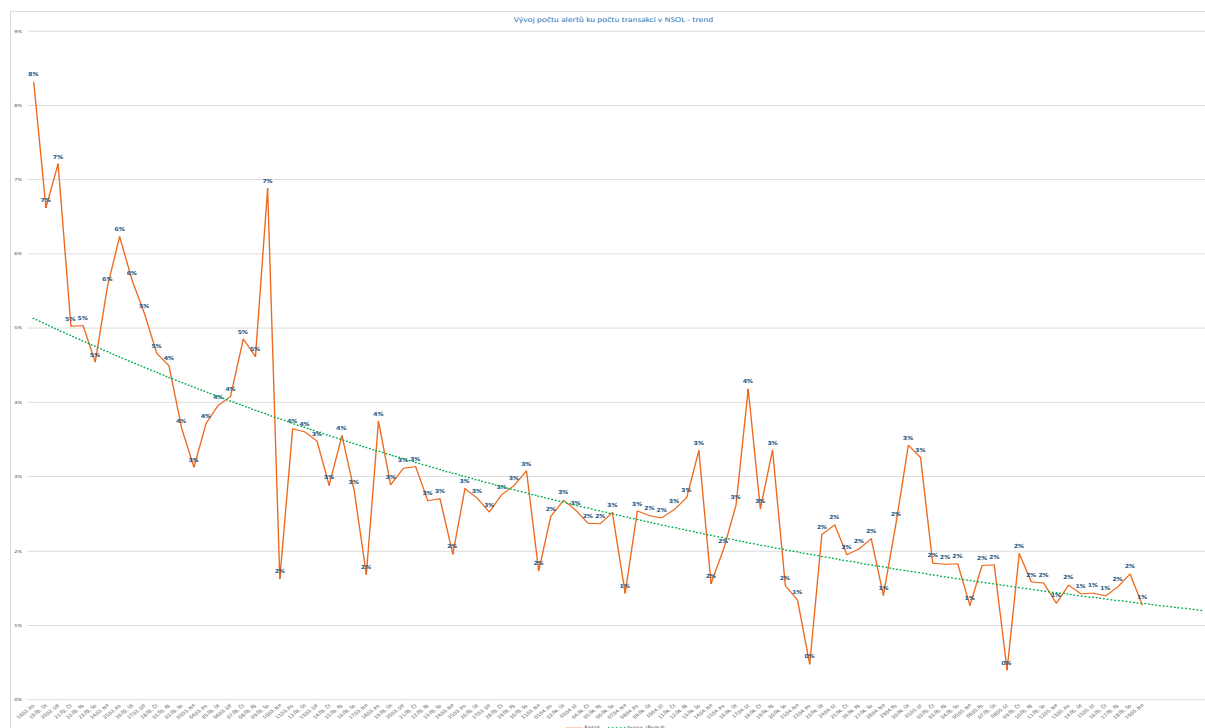
Alert types	Types of alerts share on total alerts
A2 - Batch not found	[42% - increasing trend]
A52 - Expiry data mismatch	[40% - increasing trend]
A3 – Pack not Found	[10% - decreasing trend]
A7 – Pack already in requested state	[3% - decreasing trend]
A24 – Status change could not be performed	[3% - decreasing trend]
Ostatní alerty (L5)	[2,7% - decreasing trend]
A68 – Batch ID Mismatch	[0,3% - strongly decreasing trend]

Additional remarks: [Data for last 2 months]

Podle kódů

A52
A2
A3
A7
A24
Ostatní

A52 – Expiry Date Mismatch A2 – Batch Not Found, A3 – Pack Not Found
report and trend

A68 – Batch ID Mismatch A7 – Pack Already Available, A24 – Status Change Could Not be Performed
report and trend

Additional remarks:

» Significant decrease of **A68** in last 5 weeks to minimum after communication with end-users and their IT SW providers, SW and scanners set-up revised;

» Fluctuations of **A7** caused by activity of 1 MAH in most cases last weeks

» Share of **A2** + **A52** in last 9 weeks on total alerts around 82%; direct communication to MAHs to solve the cause of the alerts – primarily to upload missing data into EMVS and correct expiration data to remove mismatch.

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

Alert types, exceptions	Identified root causes of alerts
	• 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 • 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 • OBP attempts to decommission an already decommissioned pack (e.g. 'sample to sample' or 'checked out to checked out') • 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') • End-User (software) attempts to decommission an already decommissioned pack (double dispense) • 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 • Product Master Data not uploaded into the EMVS (or failure to transmit to CZMVS) • Product codes not compliant with national coding requirements (NTIN instead of GTIN) • Scan products which are out of scope of the FMD (OTC, 'Indian Product Codes', medical device, etc.) • Manual entry error by the End-User

Additional remarks: [Alerts root causes identified in cooperation with other countries, not only NOOL input].

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 • OBPs or MAHs asked to upload data to serialized

Alert types, exceptions	Preventive actions to minimise alerts root causes
	products retrospectively (even packs release before 9th Feb. 2019) • Communication with IT SW companies regarding proper scanners and end-users' SW set-up • 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 • Educating End-Users regarding scanning best practices
A3 – Pack not Found	• Reaching out to OBPs or MAHs to advise them on the missing data • Communication with IT SW companies regarding proper scanners and end-users' SW set-up • 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 • 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	[**In progress** – 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; to be published by the end of the week]
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]
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 May]
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** – to be published during September]

Additional remarks: [N/A]