FMD Implementation Status Report

Country: *Czech Republic*

Responsible personnel: *[Pavlína Štisová, Project Manager]*

Date: *[February 20th, 2018]*

Overall country readiness: [On the same level as Mainstream]

This report covers project status and provides all necessary information regarding current status of FMD implementation in Czech Republic monitoring progress of both Governance Work Stream in form of Czech Medicines Verification Organization (CZMVO-NOOL) and Technical Work Stream in form of National Medicines Verification System (NMVS). Additionally, the report provides current status of Legal environment.

The implementation phase of CZMVS is closed. Open issues will be solved during production period.

Contents

Project plan and timeline

Overall initial project setup status:

| A steering group set up and working | A project manager assigned and working | A project plan created and approved | A project team set up and working |

Step	Status
A steering group to take overall accountability, provide support, resources and budgets set up and working	[**Done**]
A project manager who is in overall charge of the implementation process assigned and working	[**Done**]
A project plan with clear milestones and work-packages created and approved	[**Done** - detail project plan and other documents updated together with the IT supplier and approved by NOOL board]
A project team to carry out the activities organized in work streams set up and working	[**Done**]

Governance Work Stream (CZMVO-NOOL)

Overall work stream status:

| Alignment between all Stakeholders | MoU signed | NMVO Statutes agreed | NMVO established |

Step	Status
Alignment between all Stakeholders	[**Done**]
Memorandum of Understanding (MoU) signed	[**Done**]
CZMVO-NOOL Statutes agreed	[**Done**]
CZMVO-NOOL established	[**Done** – 6.3.2017 registered]

Additional remarks:

[Web pages http://czmvo.cz/ were established. Update of the project status is provided regularly]

Contract with IT supplier signed	→	Contract with EMVO signed	→	Cooperation with NCAs set up	→	Contracts with end users, MAHs signed

A-1) Implement national stakeholder organization

Step status:

Relevant topics	Status
CZMVO-NOOL entered into contracts with IT service providers	[**Done** – Solidsoft Reply has been chosen, contract signed by June 2017]
CZMVO-NOOL entered into contract with EMVO	[**Done** – EMVO contract was approved by NOOL board and signed by both countries]
CZMVO-NOOL set up a relationship with national competent authorities (NCA)	[**Done** – NOOL continues in cooperation with NCAs – intensive cooperation with SÚKL during WS, seminars, answers to the questions from the market; activities will continue]
CZMVO-NOOL created contract with end-users	[**Done** – contract was approved by NOOL board]
CZMVO-NOOL entered into contracts with end-users in pilot	[**Done** – contract send to pilot participants, start of signing the contract NOOL from 16.4.2018, 100% of pilot participants signed the contract]
CZMVO-NOOL entered into contracts with end-users	[**Done** – from 24th October registration and connecting of end-users including signing the Agreement om the use of the NOOL National is published for information on web pages www.czmvo.cz , 1829 companies till now were invited to begin registration, 1442 signed the contract with NOOL, 1435 companies with their localities =pharmacies and warehouses are created and connected to NSOL=CZMVS. Companies, which did not sign the contract with NOOL till 9th Feb 2019 (official start of FMD) are able to register with NOOL in the future]
CZMVO-NOOL created contract for MAHs and NOOL	[**Done** – comments to contract proposal for MAH adopted and approved by board; MAHs to be informed during May 2018; information regarding registration process published on web www.czmvo.cz]
CZMVO-NOOL entered into contracts with MAHs	[**Done** – Contract proposal for MAH presented on the web pages as a part of registration process with NOOL from end of May 2018; 312 MAHs signed

Relevant topics	Status
	cooperation agreement with NOOL already, 349 MAHs registered. Those who did not register with NOOL yet, should do it and sign the cooperation agreement at least 1 months before they start to upload the data into EU HUB]
CZMVO-NOOL defined the fees for MAHs related to NSOL for 2019	[Done – fees approved by NOOL board, model "flat fee"- according to the EMVO's recommendation registration fee + annual user fee; MAHs informed and information regarding registration process published on web www.czmvo.cz in May; fee reduction for small MAHs was approved for user fee 2019 -communication published by 30th August 2018 on web pages NOOL]
CZMVO-NOOL received requests for reduced user fee for 2019, signed contract amendment	[Done – requests for reduced user fee received and being processed, applications can be sent till 30th January 2019, contract Amendment approved by NOOL board, communication directly to applicants followed]

Additional remarks: [N/A]

Technical Work Stream (NMVS)

Overall work stream status:

B-1) System implementation support

Step	Status
IT service provider selected, cooperation started	[Done - regular weekly calls between Solidsoft Reply and NOOL and together with access to Confluence database to share documentation; a control visit to Solidsoft Reply took place from 16th-17th October 2017]
Quality Assurance (QA) over technical and project part of implementation performed on the ongoing basis	[Done – cooperation with EY continues; continuous process revision related to FMD a quality system preparation for NOOL]
Technical workshops were done between Solidsoft and IT providers to pharmacies and distributors; all	[Done – WS with IT providers were prepared by NOOL & Solidsoft; WS took place on 30.8. and 20.9

Step	Status
requirements to modify systems are known to IT providers of end user systems	and 30.11.2017, communication regarding IT WS and registration of IT SW companies described on web www.czmvo.cz, including agenda and NDAs proposals]
Fully functional registration portal for end-users of NMVS is in place	[**Done** – registration process and contract signature with end-user was set by NOOL; registration portal being tested and modified with pilot participants, registration of all end-users started by 24th October 2018]
Fully functional registration portal for MAHs, which sell/markets medicinal products on the Czech market	[**Done** – registration process and contract signature with MAHS was published by NOOL on web pages - ; www.czmvo.cz/cs/uzivatele-systemu/registracni-proces/ ; today 348MAHs are registered, registration continues; all necessary information available on the web page]

Additional remarks:

[N/A]

B-2) System testing and qualification

Step status:

Relevant topics	Status
ITE (Integrated testing environment) available and accessible	[**Done** – testing environment accessible by all IT suppliers providing distribution and pharmacy SW registered with Solidsoft after they attended IT WS; testing started]
Communication for pilot participants in place	[**Done** – NOOL presented the communication regarding participation in pilot on www.czmvo.cz ; memorandum of cooperation is signed with registered pilot participants - 52 pilot participants applied; registration closed; introductory meeting with pilot participants was realised, individual meetings with pilot producers and IT SW companies continues, further communication with all pilot participants via teleconf. + via freedcamp aps.]
Pilot phase planned in detail	[**Done** – NOOL in cooperation with Solidsoft, EY and Expert group prepares detail plan of the pilot phase, check-list of readiness for pilot, contact list of participants, test scenarios etc.]

Relevant topics	Status
Kick-off meeting with pilot participants realised	[**Done** – NOOL prepares the meeting of pilot participants; kick-off meeting 9.1.2018]
Testing prepared and planned	[**Done** – NOOL together with IT group of Solidsoft customers defined automated testing – 2000 tests; testing strategy and ITAT and UAT test plan for verification approved]
ITAT (integration acceptance testing) of NSOL done	[**Done** – ITAT of NSOL successfully done 8.-12.1.2018, mainly automated testing (2000 tests) for all Solidsoft Reply customers, additional ITAT for R 1.1 was realised 1st week in March 2018]
1. Part of validation QMS NOOL by EMVO successfully completed	[**Done** – required QMS documentation was provided to EMVO, revised documents and additional requirements for updates from EMVO provided back; statement of successful validation was provided]
2. Part of validation QMS NOOL by EMVO successfully completed	[**Done** – required QMS documentation was provided to EMVO, validation closed and passed on 23rd April 2018 by positive report from EMVO]
Process of validation and contract acceptance between NOOL and end-users in place and tested	[**Done** – NOOL portal for verification and contract approval with end-users was tested as well as Solidsoft Reply portal for companies' registration and creating of access credentials to CZMVS; the manual was updated and published on NOOL web pages, also presented on webinar by ČLnK regarding the process of end-users connecting to CZMVS]
IQE (Integrated quality environment) available and accessible	[**Done** – IQE available for IT SW companies – pilot participants for self-certification]
UAT (user acceptance testing) done and approved validation criteria achieved	[**Done** – user acceptance testing of Solidsoft Reply blueprint system took place in Ljubljana in Slovenia 19.-25. 2018 January managed by NMVO Slovenia - ZAPAS. Full end-to-end testing of the system took place using pack data uploaded by 2 producers to the EU Hub and with the 2D data matrix codes scanned using Slovenian pharmacy and wholesaler IT systems. The testing took place in the EU Hub and Solidsoft Reply national blueprint system quality environments which are identical to the relevant live production environments.
UAT 1.3 (user acceptance testing) for Release 1.1 was done and validation criteria approved	[**Done** – according to EMVO new requirements for additional functionalities „Master data update" for EU HUBu & NMVS before pilot starts extra UAT 1.3 for Release 1.1 done 20.3.2018; same approach lead

Relevant topics	Status
	by ZAPAZ Slovenia]
NMVS tested (including security, individual interfaces including interface to European Hub, UAT – user acceptance testing, OAT etc.)	[**Done** – UAT took place during 4th week in January 2018 in Slovenia – ZAPAS together with other Solidsoft Reply customers, additional UAT 1.3. for R 1.1 successfully realised on 20.3., OAT provided during following weeks]
NMVS test results review	[**Done** – ITAT test report available, UAT test report 1.3. for R 1.1 reviewed and approved by NOOL and EMVO]
Self-certification of "end-users' IT systems" started	[**Done** – started in IQE; self-certification of end-user IT systems readiness is a mandatory condition together with end-user contract/conditions acceptance to be connected to the NMVS; Guide material available in Confluence, 36 IT SW companies passed validation with their SW till now for connecting to CZMVS. Those, who did not pass self-certification yet can still continue it@czmvo.cz]
Information to public about pilot testing preparation	[**Done** – 13.3.2018 press conference organized by NOOL took place; few pilot participants as well as SÚKL and MZ ČR representatives attended press conference about pilot of FMD project, 10.4.2018 stakeholder meeting on british embassy with Solidsoft Reply, stakeholders representatives and pilot participants with MZ ČR, SÚKL and NOOL]
Technical „go-live"	[**Done** – connection between NMVS PRD and EU HUB PRD after successful UAT 1.3. for R 1.1. and passing documentation validation part 2 by EMVO from 25th April 2018]
Pilot test with selected producers, hospital, distributor and pharmacies was done	[**Done** – start of pilot phase May 3rd 2018, duration until last planned release of new functionalities in Autumn 2018, run in the production environment; producers/MAHs willing to up-load the data for serialized products during pilot should contact NOOL via info@czmvo.cz , pilot finished by the end of 2018]
Data for medicinal products uploaded successfully to NMVS	[**Done** - today product data to medicinal products uploaded by 253 MAHs – currently in CZMVS 36 108 555 packs of medicinal products, uploaded batches numbers available in NOOL upon request]
All end-users participating in the pilot connected to	[**Done** – based on signature of end-user contracts

Relevant topics	Status
CZMVS	and IT systems certification pilot participants were connected]
First product successfully verified in pharmacy/hospital	[Done – during pilot – on 28th June 2018 – hospital pharmacy FN Sv. Anny Brno successfully verified and supplied first medicinal product (uploaded by Roche company in EU HUB for CZMVS. Verification with support of SW Farmis]
Products verified in pharmacies/hospitals in the pilot	[Done – hospital pharmacies, 2 pharmacy chains, group of 4 pharmacies, distributors during the pilot]
Feedback from pilot and findings corrections/change proposals	[Done – continuous communication with all pilot participants regarding system functionalities, registration portal and other related items; relevant findings and recommendations from the pilot to be shared outside the pilot as well; correction of bugs and findings related to CZMVS corrected during R 4.1.; any remaining complex issues managed in cooperation of EMVO-Arvato-Solidsoft]
ITAT – integrated testing – NSOL R 2.0 as well as documentation review for release R 2.0 completed	[Done – ITAT successfully done 7.-13.6.2018, automated tests, all Solidsoft Reply customers, Documentation review complete]
UAT 2.0 (user acceptance testing) for Release 2.0 **was done**	[Done – successfully passed on 21st June, all Solidsoft Reply customers; data provided by Johnson and Johnson (J&J); 12 end-to-end test cases; Production environment Release 3.7.2018]
ITAT – integrated testing – NSOL R 3.0 as well as documentation review for release R 3.0 completed	[Done – ITAT successfully done 23.-30.8.2018, automated tests, all Solidsoft Reply customers, Documentation review complete, **100% of planned test done, 99% successfully passed, no failures priority 1 or 2**]
UAT 3.0 (user acceptance testing) for Release 3.0 **was done**	[Done – successfully passed on 20th September, all Solidsoft Reply customers; data provided by Johnson and Johnson (J&J); 26 end-to-end test cases; Production environment Release 2.10.2018.]
ITAT – integrated testing – NSOL R 4.0 as well as documentation review for release R 4.0 completed	[Done – ITAT successfully done 8.-13.11.2018, automated tests, all Solidsoft Reply customers, documentation under revision now]
UAT 4.0 (user acceptance testing) for Release 4.0 **was done**	[Done – successfully passed on 26th November 2018, all Solidsoft Reply customers; data provided by J&J; 27 end-to-end test cases in Zapas and Danish

Relevant topics	Status
	systems; Production environment Release 6.12.2018]
ITAT – integrated testing – NSOL R 4.1 as well as documentation review for release R 4.1 completed	[Done – ITAT of minor release successfully passed by 30th January 2019]
End-to-end testing of komplex EMVS system completed	[Done – 4 countries are part of testing – 2 with Solidsoft Reply systems (Czech Republic and Denmark) 2 with Arvato systems (Norway and France), preparation of test scenarios, tests realized by 5th Feb. 2019; minor issues in IMT occurred; CAPA created and under control by EMVO-Arvato-Solidsoft]
All requirements on the IT solution met	[Done – validation of the system is compared to User Requirement Specifications = URS; minor deviations from URS mapped, revised with EMVO and Solidsoft, CAPA created; solution to be in place during R5 or within URS revisions in 2019]

Additional remarks:

[UAT = User Acceptance testing; IQE = Integrated Quality Environment; OAT = Operation Acceptance testing]

B-3) Go-live and Ramp up to full operation with all users connected

Step status:

Relevant topics	Status
Go-Live date set up	[Done –connection between NMVS PRD and EU HUB PRD date "technical go-live" from 25th April 2018; ramp-up start during Q4]
Go-live and post-go-live support prepared	[Done – monitoring started, EVI portal created and managed by EMVO to provided up to date info about systems downtimes and serious issues; monitoring put in place by Solidsoft Reply; Alert management centre set up by NOOL for alerts handling and end-users support centre]
Go-Live QA performed	[Done –continuously from beginning of the pilot phase in production environment; QMS documentation reviewed and completed]
NMVS up and running	[Done – functionalities added in releases of the system; system running in full scope from 9.2.2019; additional releases 5 and 6 planned for 2019 mainly

Relevant topics	Status
	for NCA reporting, API and CZMVS portal improvements]
QMS audit of Solidsoft Reply	[Done – scope agreed and approved, external auditor selected, audit took place on 8-10th January 2019; no critical or high findings were identified; closer report should be provided to SSR and its customers by 25th January, CAPA plan presented, CAPAs under revision by EMVO should follow]
ISMS audit NSOL	[Done – scope definition and RFP, external auditor selected, audit took place from 3rd-22nd January 2019; no critical or high findings were identified]

Additional remarks:

[N/A]

B-4) Pharmacies and hospitals Readiness

Step status:

Relevant topics	Status
Pharmacy SW providers fully informed	[Done – NOOL provides information to with end users during seminars and also by publishing information on web www.czmvo.cz and other web pages, workshops with hospital representatives on 29.9., 31.10. a 23.11.2018; presentations and video from WS is available on the web pages; instructions how to register into Confluence and NOOL published on web NOOL; informative IT WS took place on 9th October 2018 with presence of IT SW companies representatives, SÚKL, NOOL]
Pharmacy SW providers fully trained and educated	[Done – 3 WS with IT providers were prepared by NOOL & Solidsoft; info regarding IT WS is available in - WS agenda, NDA, presentation and video (access based on requirement for companies with signed NDA); pilot finding regarding IT systems + connection of end-users from system point of view was presented to IT SW companies during informative IT WS on 9th October 2018 with presence of IT SW companies representatives, SÚKL, NOOL; all IT companies were provided by access to freedcamp]
IT SW adjustment and connection to NMVS implemented and tested by pharmacy SW providers	[Done – ITE used, IQE started to be used for self-certification by IT companies; 36 IT SWs for

Relevant topics	Status
	pharmacies and distributors validated till now]
Pharmacies fully informed	[Done – NOOL organized workshops with hospitals and pharmacies on 26.9.,31.10. and 23.11., information provided to webs and portals www.nemlek.cz a www.apatykar.cz ; manuals how to connect, is on NOOL web side https://www.czmvo.cz/cs/uzivatele-systemu/lekarnici/ (English version to be provided soon) and for use by ČLnK for trainings and webinars on 8.11 and 15.11.2018 – can be seen on ČLnK web pages]
Pharmacies fully trained and educated	[Done – during pilot, recommendations to other subjects to be provided on web pages or via seminars' **stakeholders' responsibility to train their members**]
Pharmacies connected to NMVS and tested by pharmacies	[Done – 1239 companies with their localities (pharmacies) are connected to CZMVS now]
Pharmacies ready for go-live	[Done – outside NOOL's control and responsibility. Support and information regularly provided by NOOL; continuously news and findings presented on NOOL web pages; call centre for end-users set up by NOOL: **Support Centre:** +420 224 834 153, +420 224 834 155, +420 224 834 155]

Additional remarks:

[N/A]

B-5) Manufacturers and Parallel Distributors Readiness (in common „MAH")

Step status:

Relevant topics	Status
MAH SW providers fully informed	[Done – NOOL started information process with manufactures during seminar on 2nd July 2017 and via AIFP and CAFF associations; also by publishing information on web CZMVO; regular information provided by associations AIFP, ČAFF; information materials for MAHs under preparation as well as WebEx meetings and workshops in Q1/2018]; information meeting for pharmaceutical companies regarding EMVO on-boarding requirements and FMD with EMVO, SÚKL and NOOL representatives

Relevant topics	Status
	realised on 10th April 2018 in SÚKL premises – video with presentation published on NOOL web; info for MAHs available on EMVO web: https://emvo-medicines.eu]
MAH SW providers fully trained and educated	[Done - info regarding IT related to MAH is available https://emvo-medicines.eu/]
MAHs fully informed	[Done – NOOL provides information via AIFP and ČAFF associations; also by publishing information materials on web CZMVO; under preparation materials regarding contracts and fee system published on web www.czmvo.cz https://www.czmvo.cz/en/system-users/registration-process/]
MAH s fully trained and educated	[Done – all info regarding MAHs on-boarding on EMVO www.emvo-medicines.eu in „Knowlegde Database", news also on www.czmvo.cz]
EMVS implemented and tested by MAHs	[Done – MAHs or OBPs connect to EU HUB and upload data for serialized product, data used for testing by end users connected]
MAHs ready for go-live	[Done - outside NOOL's control and responsibility. Support and information regularly provided by NOOL; continuously news and findings presented on NOOL web pages; **Alert management centre** set up by NOOL: support@czmvo-alert.cz , +420 224 834 153, +420 224 834 155, +420 224 834 155]

Additional remarks: [On – boarding to EU HUB should be done as soon as possible as this seems to be critical risk in terms of time planning and readiness]; OBP = onboarding partner]

B-6) Wholesalers Readiness

Step status:

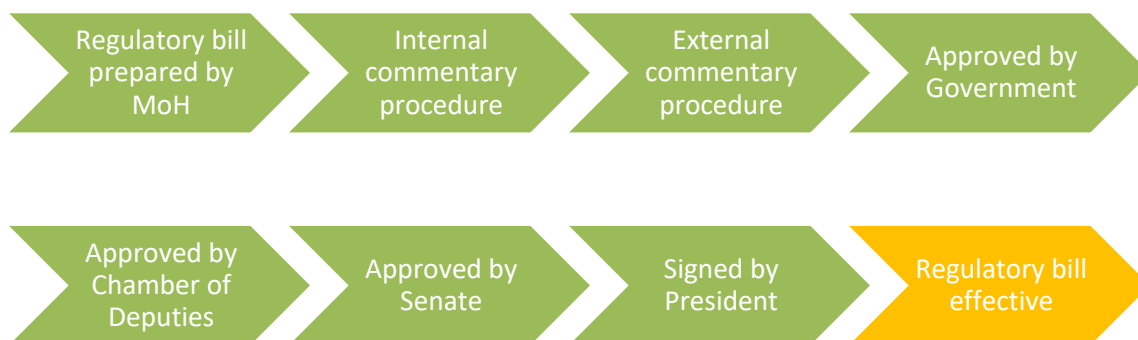| Relevant topics	Status
Wholesaler SW providers fully informed	[Done – NOOL providing information to wholesalers during seminars and also by publishing information on web www.czmvo.cz]
Wholesaler SW providers fully trained and educated	[Done - WS with IT providers were prepared by NOOL & Solidsoft; info regarding IT WS is available – WS agenda, NDA, presentation and video (access based

Relevant topics	Status
	on requirement for companies with signed NDA)]
NMVS implemented and tested by wholesaler SW providers	[Done – in pilot]
Wholesalers fully informed	[Done – NOOL providing information to wholesalers by publishing information on web www.czmvo.cz]
Wholesalers fully trained and educated	[Done – in pilot]
Wholesalers connected to NMVS and tested by wholesalers	[Done – 236 distribution companies with their warehouses are connected now]
Wholesalers ready for go-live	[Done – outside NOOL's control and responsibility. Support and information regularly provided by NOOL; continuously news and findings presented on NOOL web pages; Alert management and support centre set up by NOOL: support@czmvo-alert.cz , +420 224 834 153, +420 224 834 155, +420 224 834 155]

Additional remarks: [N/A].

Legal Work Stream

Overall work stream status:

Regulatory bill prepared by MoH	→	Internal commentary procedure	→	External commentary procedure	→	Approved by Government

Approved by Chamber of Deputies	→	Approved by Senate	→	Signed by President	→	Regulatory bill effective

Step	Status
Regulatory bill prepared by MoH	[**Done** – The amendment to the Pharmaceuticals Act prepared by Ministry of Health and send for comments – till 1st March 2018]
Internal commentary procedure	[**Done** – comments sent by relevant subjects; processed by Ministry of Health]
External commentary procedure	[**Done** – subjects provided their comments during May]
Approved by Government	[**Done** – approved by Government and pass to the Chamber of Deputies of the Parliament of the Czech Republic]
Approved by Chamber of Deputies	[**Done** -The amendment to the Pharmaceuticals Act passed / was approved in the Chamber of Deputies of the Parliament]
Approved by Senate	[**Done** – The amendment to the Pharmaceuticals Act passed / was approved by Senate]
Signed by President	[**Done** – The amendment No. **378/2007 Sb** to the Pharmaceuticals Act was signed by President]
Regulatory bill effective	[In progress – should be effecteve by 2nd March 2019, 15 days after publishing in the Collection of Laws]

Additional remarks: [N/A]