Národní organizace
pro ověřování
pravosti léčiv

ALERTS MANAGEMENT CZMVO

7th February 2019

INTRODUCTION

Commission delegated regulation will enter into force on Saturday, February 9, 2019 which sets out the rules for verification of medicinal products.

Pursuant to Article 37, defining duties of legal entities setting up and managing a repository that is part of a repository system, NOOL (CZMVO) has to **ensure investigation of all potential counterfeits identified in the system in accordance with Article 36 (b) and**

if the counterfeiting is confirmed, notify the competent national authorities, the European Medicines Agency and the Commission.

In order to alert investigation NOOL (CZMVO) has created **ALERT CENTER** which solves alerts in cooperation with MAH's and coordinates all related activities.

ALERT CENTER consists from alert management system and support team InnOne a NOOL.

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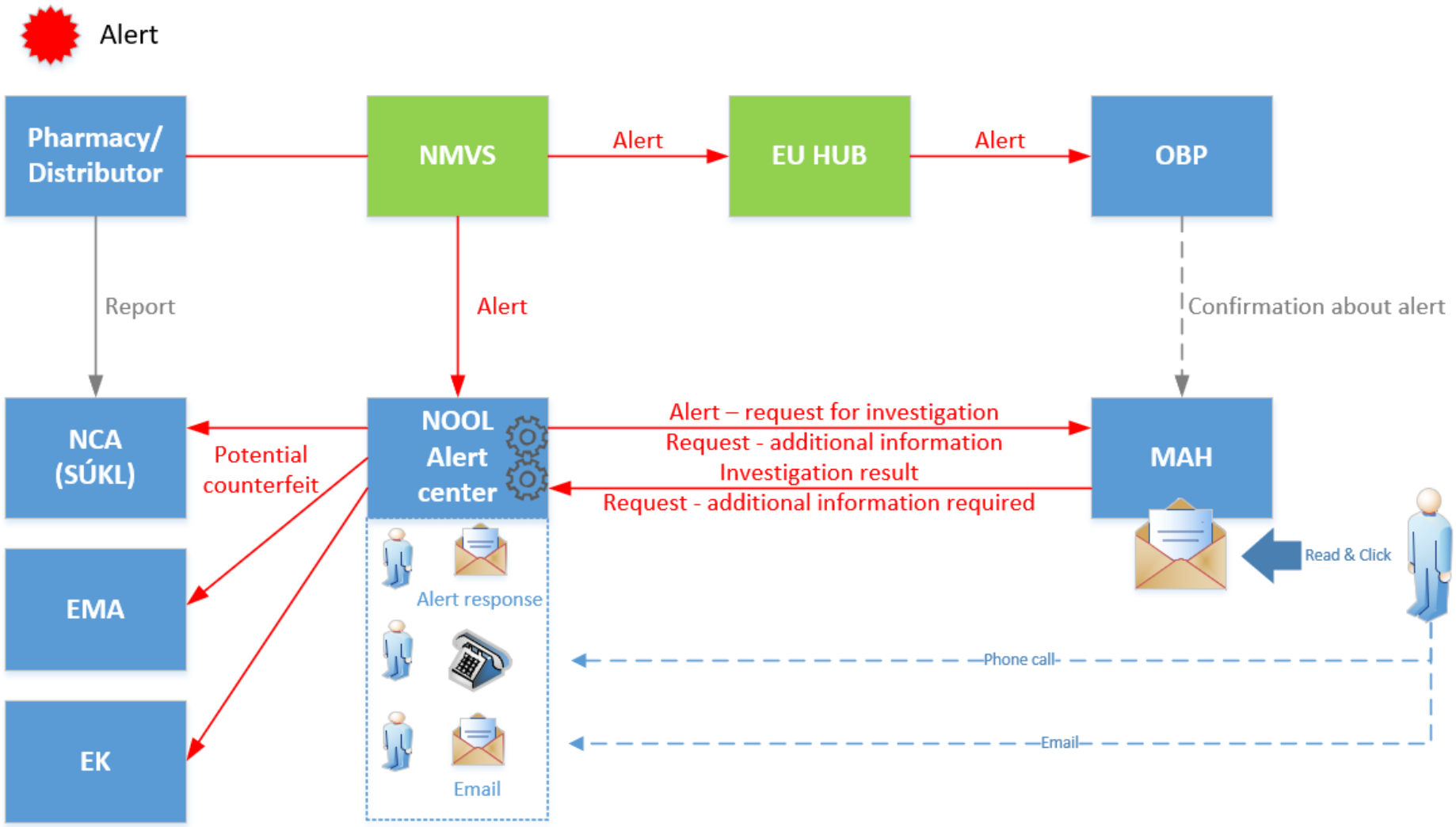
SCHEMA – CZMVO ALERT CENTER MANAGEMENT



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CZMVO ALERTS MANAGEMENT

- ✓ Alerts received from CZMVS are processed by the system of „CZMVO Alert center“
- ✓ Request to start investigation by MAH with necessary details is automatically send from email: alert@czmvo-alert.cz to the contact provided by MAH
- ✓ Such messages includes „feedback buttons“ for each alert. Clicking on one of the options MAH provides information to CZMVO about the alert investigation status(resolution)
- ✓ No reaction received within 10 days starts escalation process, automatic reminder to MAH (similar mechanism – as described above)
- ✓ Additional information requested by MAH can be provided (click on the link). To close the investigation same process should be followed as described above.
- ✓ If MAH’s investigation leads to “verified potential counterfeit”, system generates complete audit trai and information to NCA, EMA a EC

INFORMATION REQUIRED FROM MAH TO SET UP COMMUNICATION CHANNELS

For a proper setup of communication related to alerts, please complete information bellow and send it to email address: **info@czmvo.cz**

- ✓ **MAH ID** – for the each MAH operating on the Czech market, e.g. loading data via EU HUB to the CZMVS.
- ✓ **Contact person responsible for resolving alerts** –

  name and e-mail
- ✓ In case MAH is not registered yet immediately start registration process described here: https://www.czmvo.cz/cs/uzivatele-systemu/registracni-proces/

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MAH'S COMMUNICATION TO ALERT CENTER

MAH can choose 3 different types of communication with alert center

1. **Use „button" in the received message (click to one of the links)**

- ✓ „Alert solved on MAH side, Issue closed (Investigation completed)"
- ✓ „Alert solved on MAH side, Issue not closed (Investigation completed)"
- ✓ „Additional information about alert needed "
- ✓ „Alert wasn't on MAH side, verified falsification (Investigation completed)"

Not prefered ways of communication

2. Write an e-mail with alert ID, that is to be solved to address: alert@czmvo-alert.cz
3. Make a call to alert center of CZMVO. Phone numbers: +420 224 834 153, +420 224 834 154, +420 224 834 155

Note: Detail of each message can be found at the end of this material!

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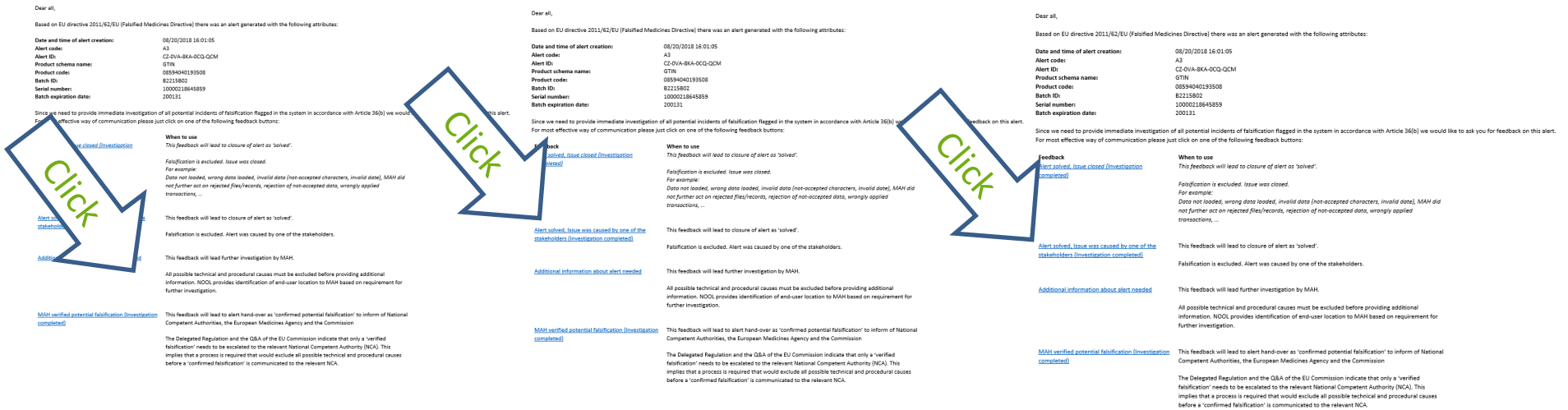
SAMPLE E-MAIL MESSAGES



Dear all,

Based on EU directive 2011/62/EU (Falsified Medicines Directive) there was an alert generated with the following attributes:

Date and time of alert creation:	08/20/2018 16:01:05
Alert code:	A3
Alert ID:	CZ-OVA-8KA-0CQ-QCM
Product schema name:	GTIN
Product code:	08594040193508
Batch ID:	B2215B02
Serial number:	10000218645859
Batch expiration date:	200131

Since we need to provide immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) we would like to ask you for feedback on this alert.
For most effective way of communication please just click on one of the following feedback buttons:

Feedback	When to use
Alert solved, Issue closed (Investigation completed)	*This feedback will lead to closure of alert as 'solved'.* *Falsification is excluded. Issue was closed.* *For example:* *Data not loaded, wrong data loaded, invalid data (not-accepted characters, invalid date), MAH did not further act on rejected files/records, rejection of not-accepted data, wrongly applied transactions, ...*
Alert solved, Issue was caused by one of the stakeholders (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders.
Additional information about alert needed	This feedback will lead further investigation by MAH. All possible technical and procedural causes must be excluded before providing additional information. NOOL provides identification of end-user location to MAH based on requirement for further investigation.
MAH verified potential falsification (Investigation completed)	This feedback will lead to alert hand-over as 'confirmed potential falsification' to inform of National Competent Authorities, the European Medicines Agency and the Commission The Delegated Regulation and the Q&A of the EU Commission indicate that only a 'verified falsification' needs to be escalated to the relevant National Competent Authority (NCA). This implies that a process is required that would exclude all possible technical and procedural causes before a 'confirmed falsification' is communicated to the relevant NCA.

Click

Click

Click

Dear all,

We would like to inform you about a potential incident of falsification.
There was alert with the following attributes:

Date and time of alert creation:	08/20/2018 16:01:05
Alert code:	A3
Alert ID:	CZ-OVA-8KA-0CQ-QCM
Product schema name:	GTIN
Product code:	08594040193508
Batch ID:	B2215B02
Batch serial number:	10000218645859
Batch expiration date:	200131

Below, you can find information about the end-user:

Id:	110
Name:	BEKU Opava, Nákladní
Address:	Nákladní 32, Opava 1, 746 01
Phone #	420 735 642 314
Email	xxxx@xxxxx.xxxx

The MAH in question was asked to investigate. They completed their investigation and excluded all possible technical and procedural causes and therefore proved that the alert was not on their side.

The following table shows email communication associated with the alert:

Detail of each message can be found at the end of this material!

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Additional information

Examples of email messages ver. 1.0

NOOL

REQUEST TO START INVESTIGATION

Dear all,

Based on EU directive 2011/62/EU (Falsified Medicines Directive) there was an alert generated with the following attributes:

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Alert code:	A3
Alert ID:	CZ-0VA-8KA-0CQ-QCM
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For most effective way of communication please just click on one of the following feedback buttons:

Feedback	When to use
Click → Alert solved on MAH side, Issue closed (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders. Issue was closed. For example: *Data not loaded, wrong data loaded, invalid data (not-accepted characters, invalid date), MAH did not further act on rejected files/records, rejection of not-accepted data, wrongly applied transactions, ...*
Click → Alert solved on MAH side, Issue not closed (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders. Issue cannot be closed.
Click → Additional information about alert needed	This feedback will lead to reporting alert as ‚potential falsification' to National Competent Authority (NCA). All possible technical and procedural causes must be excluded before providing additional information. NOOL provides identification of end-user location to MAH based on requirement for further investigation.
Click → Alert wasn't on MAH side, verified falsification (Investigation completed)	This feedback will lead to alert hand-over as 'confirmed falsification' to inform of national competent authorities, the European Medicines Agency and the Commission The Delegated Regulation and the Q&A of the EU Commission indicate that only a 'verified falsification' needs to be escalated to the relevant National Competent Authority (NCA). This implies that a process is required that would exclude all possible technical and procedural causes before a 'confirmed falsification' is communicated to the relevant NCA.

Read

Read

Read

Read

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REQUEST TO START INVESTIGATION

DETAIL 1

Dear all,

Based on EU directive 2011/62/EU (Falsified Medicines Directive) there was an alert generated with the following attributes:

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Since we need to provide immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) we would like to ask you for feedback on this alert.
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REQUEST TO START INVESTIGATION

DETAIL 2

Click

Alert solved on MAH side, Issue closed (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders. Issue was closed. For example: *Data not loaded, wrong data loaded, invalid data (not-accepted characters, invalid date), MAH did not further act on rejected files/records, rejection of not-accepted data, wrongly applied transactions, ...*
Alert solved on MAH side, Issue not closed (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders. Issue cannot be closed.
Additional information about alert needed	This feedback will lead to reporting alert as ‚potential falsification' to National Competent Authority (NCA). All possible technical and procedural causes must be excluded before providing additional information. NOOL provides identification of end-user location to MAH based on requirement for further investigation.
Alert wasn't on MAH side, verified falsification (Investigation completed)	This feedback will lead to alert hand-over as 'confirmed falsification' to inform of national competent authorities, the European Medicines Agency and the Commission The Delegated Regulation and the Q&A of the EU Commission indicate that only a 'verified falsification' needs to be escalated to the relevant National Competent Authority (NCA). This

REMINDER TO START INVESTIGATION

Dear all,

We would like to kindly remind you to provide us with results of alert investigation e-mailed to you before with the following attributes:

Date and time of alert creation:	08/20/2018 16:01:05
Alert code:	A3
Alert ID:	CZ-0VA-8KA-0CQ-QCM
Product schema name:	GTIN
Product code:	08594040193508
Batch ID:	B2215B02
Batch serial number:	10000218645859
Batch expiration date:	200131

Since we need to provide immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) we would like to ask you for feedback on this alert.
For most effective way of communication please just click on one of the following feedback buttons:

Feedback	When to use
Alert solved on MAH side, Issue closed (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders. Issue was closed. For example: *Data not loaded, wrong data loaded, invalid data (not-accepted characters, invalid date), MAH did not further act on rejected files/records, rejection of not-accepted data, wrongly applied transactions, ...*
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Alert wasn't on MAH side, verified falsification (Investigation completed)	This feedback will lead to alert hand-over as 'confirmed falsification' to inform of national competent authorities, the European Medicines Agency and the Commission The Delegated Regulation and the Q&A of the EU Commission indicate that only a 'verified falsification' needs to be escalated to the relevant National Competent Authority (NCA). This implies that a process is required that would exclude all possible technical and procedural causes before a 'confirmed falsification' is communicated to the relevant NCA.

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ADDITIONAL REQUESTED INFORMATION BASED ON MAH REQUEST

Dear all,

You have asked for additional information about the following alert:

Date and time of alert creation:	08/20/2018 16:01:05
Alert code:	A3
Alert ID:	CZ-0VA-8KA-0CQ-QCM
Product schema name:	GTIN
Product code:	08594040193508
Batch ID:	B2215B02
Batch serial number:	10000218645859
Batch expiration date:	200131

You can find the required information about the end-user below:

Id:	110
Name:	BEKU Opava, Nákladní
Address:	Nákladní 32, Opava 1, 746 01
Phone #	420 735 642 314
Email	xxxx@xxxxx.xxxx

Since we need to provide immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) we would like to ask you for feedback on this alert.
For most effective way of communication please just click on one of the following feedback buttons:

Feedback	When to use
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ADDITIONAL REQUESTED INFORMATION

DETAIL1

Dear all,

You have asked for additional information about the following alert:

Date and time of alert creation:	08/20/2018 16:01:05
Alert code:	A3
Alert ID:	CZ-0VA-8KA-0CQ-QCM
Product schema name:	GTIN
Product code:	08594040193508
Batch ID:	B2215B02
Batch serial number:	10000218645859
Batch expiration date:	200131

You can find the required information about the end-user below:

Id:	110
Name:	BEKU Opava, Nákladní
Address:	Nákladní 32, Opava 1, 746 01
Phone #	420 735 642 314
Email	xxxx@xxxxx.xxxx

Since we need to provide immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) we would like to ask you for feedback on this alert. For most effective way of communication please just click on one of the following feedback buttons:

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ADDITIONAL REQUESTED INFORMATION

DETAIL 2

Click

Since we need to provide immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) we would like to ask you for feedback on this alert. For most effective way of communication please just click on one of the following feedback buttons:

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Alert solved on MAH side, Issue closed (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by one of the stakeholders. Issue was closed. For example: *Data not loaded, wrong data loaded, invalid data (not-accepted characters, invalid date), MAH did not further act on rejected files/records, rejection of not-accepted data, wrongly applied transactions, ...*
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VERIFIED POTENTIAL FALSIFICATION

Dear all,

We would like to inform you about a potential incident of falsification.
There was alert with the following attributes:

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Alert code:	A3
Alert ID:	CZ-0VA-8KA-0CQ-QCM
Product schema name:	GTIN
Product code:	08594040193508
Batch ID:	B2215B02
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Id:	110
Name:	BEKU Opava, Nákladní
Address:	Nákladní 32, Opava 1, 746 01
Phone #	420 735 642 314
Email	xxxx@xxxxx.xxxx

The MAH in question was asked to investigate. They completed their investigation and excluded all possible technical and procedural causes and therefore proved that the alert was not on their side.

The following table shows email communication associated with the alert:

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Additional information

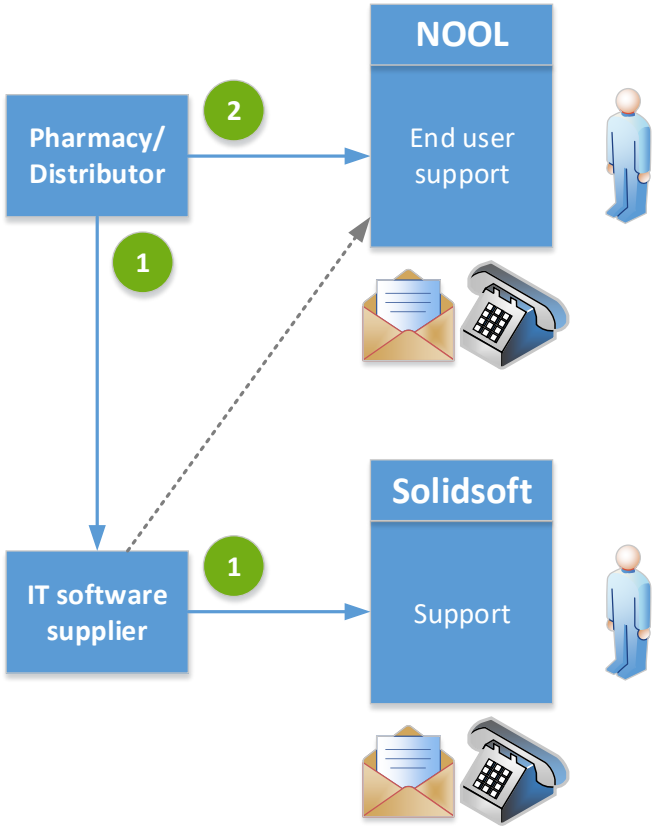
End user support

NOOL

END USER SUPPORT

E-mail contact:
support@czmvo-alert.cz

Phone contact:
+420 224 834 153
+420 224 834 154
+420 224 834 155



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END USER SUPPORT

NOOL has created end user support center. Center provides information and support for activities related to the FMD but it is not able to solve technical problems related to operation of pharmacy or distributor IT system.

Please follow the instructions below:

- ✓ In case of problem contact your IT service supplier first.
- ✓ In case your IT service supplier needs assistance, Solidsoft support should be contacted (Solidsoft is a supplier of national medicine verification system) czmvo.support@reply.com
- ✓ The end user should contact NOOL support only after the previous possibilities have been exhausted, or if it is an administrative matter or alert status question

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