Národní organizace
pro ověřování
pravosti léčiv

# SPRÁVA ALERTŮ NOOL (CZMVO)

7 února 2019

# ÚVOD

**V sobotu 9. února 2019 vejde v účinnost prováděcí nařízení Evropské unie, které přináší jednotná pravidla pro ověřování pravosti léčiv.**

**Dle článku 37** stanovujícího povinnosti právních subjektů, zřizujících a spravujících úložiště, má NOOL (CZMVO) **zajistit okamžité vyšetření všech potenciálních případů padělání označených v systému v souladu s čl. 36 písm. b) a v případě, že se padělání potvrdí, upozornit příslušné vnitrostátní orgány, Evropskou agenturu pro léčivé přípravky a Komisi.**

Za účelem řízení vyšetřování alertů NOOL (CZMVO) vytvořil **CENTRUM SPRÁVY ALERTŮ**, které bude ve spolupráci s MAHy řešit vyšetřování alertů a zajišťovat další s tím související činnosti.

**CENTRUM SPRÁVY ALERTŮ** využívá systém správy alertů a podpůrný tým InnOne a NOOL.

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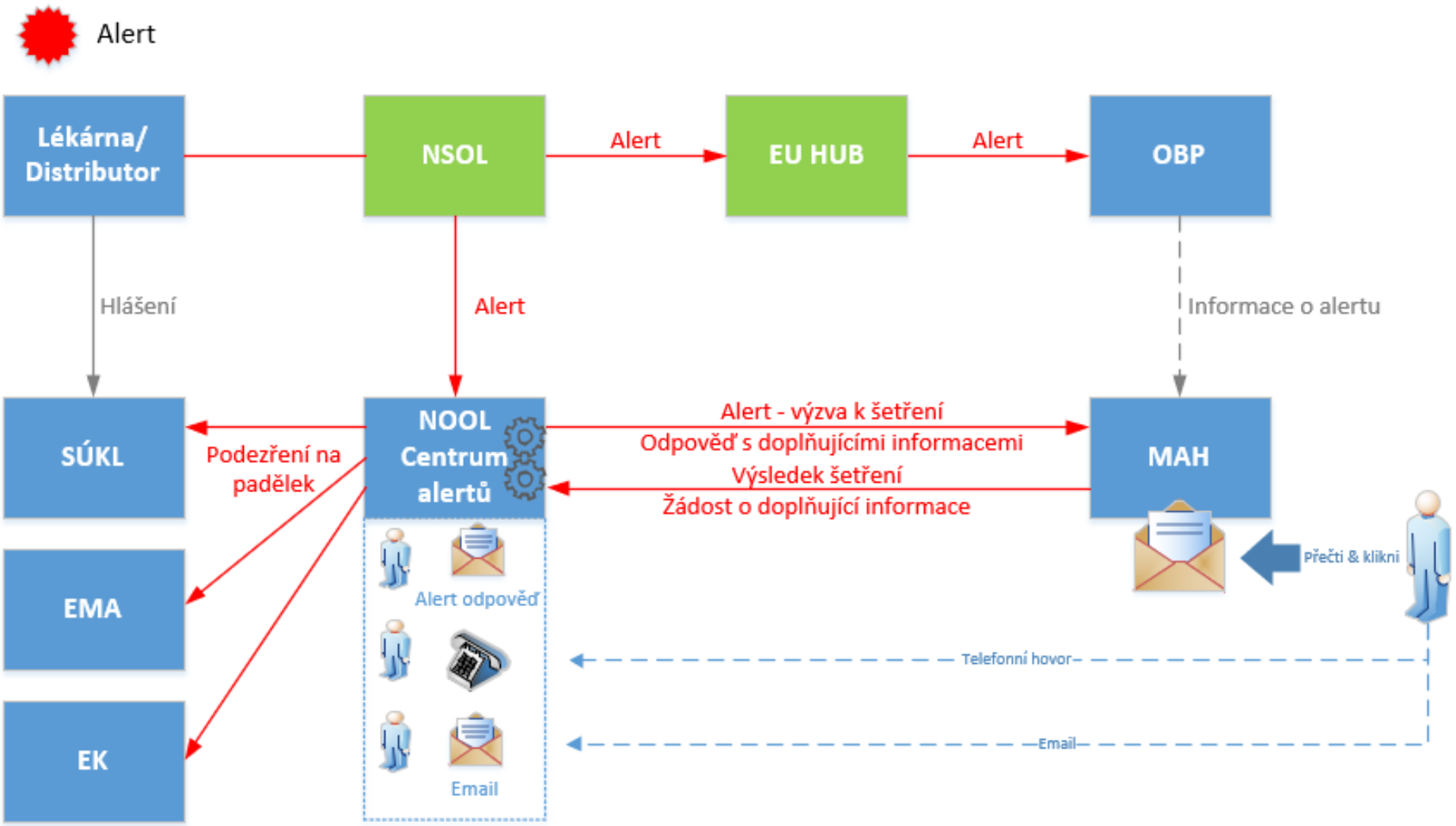
# SCHÉMA - CENTRUM SPRÁVY ALERTŮ NOOL

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# SPRÁVA ALERTŮ NOOL (CZMVO)

- ✓ Přijaté alerty ze systému NSOL jsou dále zpracovány v systémech „Centra správy alertů NOOL (CZMVO)“
- ✓ Po zpracování jsou alerty s výzvou k zahájení vyšetřování zaslány prostřednictvím emailové adresy: alert@czmvo-alert.cz
- ✓ Takto zaslané emailové zprávy obsahují ke každému alertu tzv. „feedback buttons“, na které MAH klikne dle příslušného řešení alertu.
- ✓ Nebude-li MAH reagovat do 10 dnů, bude mu automaticky zaslána eskalace k vyjádření (obdobný mechanismus - viz výše)
- ✓ Bude-li MAH vyžadovat dodatečné informace, zvolí příslušnou volbu a po dokončení vyšetřování použije opět stejný postup – viz výše.
- ✓ Je-li výsledkem vyšetřování MAHa podezření na padělek, systém centra správy alertů NOOL vygeneruje kompletní auditní záznam a zašle informaci na SUKL, EMA a EK

# POŽADOVANÉ INFORMACE OD DRŽITELŮ REGISTRACE PRO NASTAVENÍ KOMUNIKACE

Pro správné nastavení komunikace alertů k MAHům a zpracování jejich výsledků šetření potřebujeme doplnit a zaslat následující informace na adresu: **info@czmvo.cz**

- ✓ **MAH ID** – u každého MAHa, který nahrává data pro český trh, tedy prostřednictvím EU HUBu pro CZMVO (NSOL)
- ✓ **Kontaktní osobu pověřenou pro řešení alertů – jméno a e-mail**
- ✓ Pokud MAH není ještě registrován k NOOL, měl by neprodleně zahájit registraci - viz: https://www.czmvo.cz/cs/uzivatele-systemu/registracni-proces/

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# KOMUNIKACE MAH NA VÝZVU CENTRA SPRÁVY ALERTŮ

**MAH může zvolit 3 různé formy komunikace s centrem správy alertů**

1. **Použít „tlačítko“ v zaslaném e-mailu (klikne na příslušný link)**


- ✓ „Alert solved, Issue closed (Investigation completed)“
- ✓ „Alert solved on MAH side, Issue caused by another stakeholder (Investigation completed)“
- ✓ „Additional information about alert needed “
- ✓ „Verified potential falsification (Investigation completed)“

**Nepreferované formy komunikace**

2. Napsat e-mail s identifikací alertu, který chce řešit na adresu alert@czmvo-alert.cz
3. Zavolat do centra výstrah Nool na tel. číslo +420 224 834 153, +420 224 834 154, +420 224 834 155

*Pozn. Detail zaslaných zpráv na konci prezentace*

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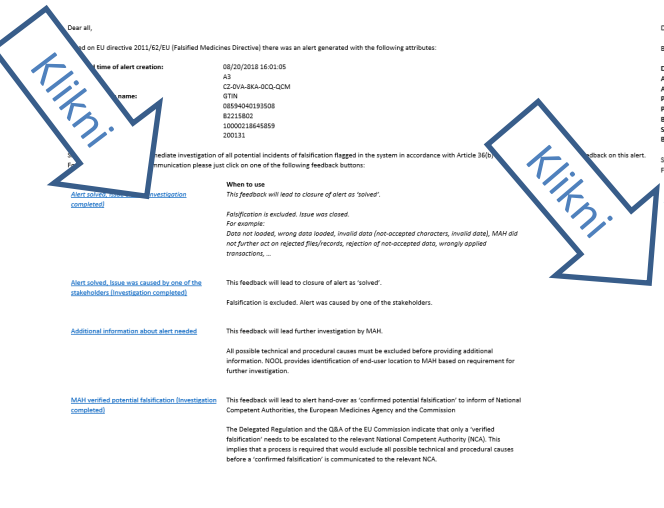
# PŘÍKLADY EMAILOVÝCH ZPRÁV


Dear all,

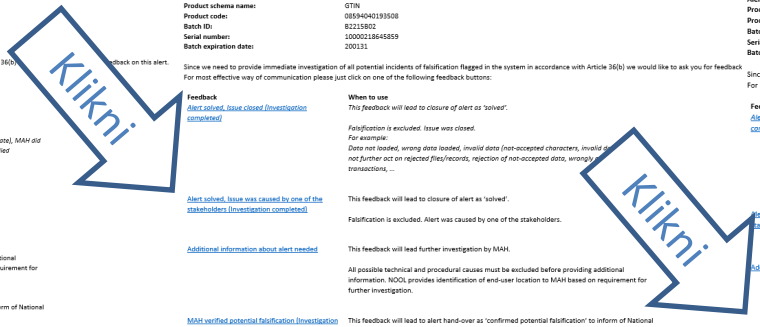
Based on EU directive 2011/62/EU (Falsified Medicines Directive) there was an alert generated with the following attributes:

| | |
|---|---|
| **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 |

...mediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) ...edback on this alert.
...mmunication 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'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*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'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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<br><br>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. |

Klikni


Dear all,

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| **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'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*Data not loaded, wrong data loaded, invalid data (not-accepted characters, invalid da...*<br>*not further act on rejected files/records, rejection of not-accepted data, wrongly ...*<br>*transactions, ...* |
| Alert solved, Issue was caused by one of the stakeholders (Investigation completed) | This feedback will lead to closure of alert as 'solved'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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. |
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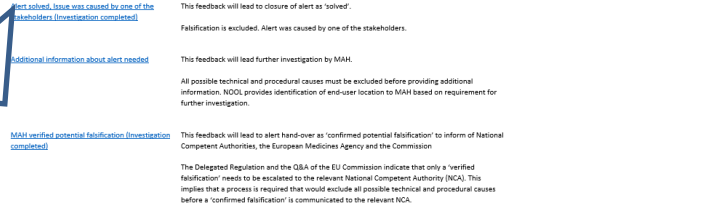
Klikni


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 |
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| Feedback | When to use |
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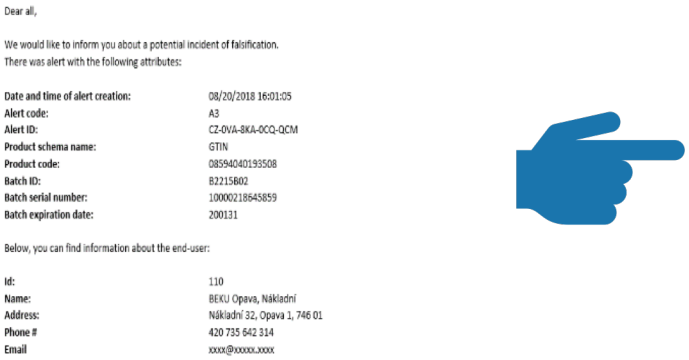
| Alert solved, Issue was caused by one of the stakeholders (Investigation completed) | This feedback will lead to closure of alert as 'solved'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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<br><br>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. |


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 |
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| **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 zpráv najdete na konci prezentace!

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# Doplňující informace

## Vzory emailových zpráv ver. 1.0

## NOOL

# PODNĚT K ZAHÁJENÍ VYŠETŘOVÁNÍ

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-0VA-8KA-0CQ-QCM |
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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.
For most effective way of communication please just click on one of the following feedback buttons:

| Feedback | When to use |
|---|---|
| Klikni *Alert solved, Issue closed (Investigation completed)* | *This feedback will lead to closure of alert as 'solved'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*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, ...* |
| Klikni Alert solved, Issue was caused by one of the stakeholders (Investigation completed) | This feedback will lead to closure of alert as 'solved'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Klikni Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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. |
| Klikni 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<br><br>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. |

Přečti

Přečti

Přečti

Přečti

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# PODNĚT PRO ZAHÁJENÍ VYŠETŘOVÁNÍ

## DETAIL 1

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-0VA-8KA-0CQ-QCM |
| **Product schema name:** | GTIN |
| **Product code:** | 08594040193508 |
| **Batch ID:** | B2215B02 |
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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.
For most effective way of communication please just click on one of the following feedback buttons:

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# PODNĚT PRO ZAHÁJENÍ VYŠETŘOVÁNÍ

## DETAIL 2

Klikni

| Feedback | When to use |
|---|---|
| Alert solved, Issue closed (Investigation completed) | *This feedback will lead to closure of alert as 'solved'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*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'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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<br><br>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. |

# OPAKOVANÝ PODNĚT K ZAHÁJENÍ VYŠETŘOVÁNÍ

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 |

Klikni

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'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*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'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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<br><br>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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# ZASLÁNÍ VYŽÁDANÝCH DODATEČNÝCH INFORMACÍ NA ŽÁDOST MAH

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.xxx |

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'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*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'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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<br><br>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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# ZASLÁNÍ VYŽÁDANÝCH DODATEČNÝCH INFORMACÍ 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 |

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# ZASLÁNÍ VYŽÁDANÝCH DODATEČNÝCH INFORMACÍ DETAIL2

Klikni

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'.*<br><br>*Falsification is excluded. Issue was closed.*<br>*For example:*<br>*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'.<br><br>Falsification is excluded. Alert was caused by one of the stakeholders. |
| Additional information about alert needed | This feedback will lead further investigation by MAH.<br><br>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<br><br>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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# PODEZŘENÍ NA PADĚLEK

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-0VA-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:

Národní organizace pro ověřování pravosti léčiv

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# Doplňující informace

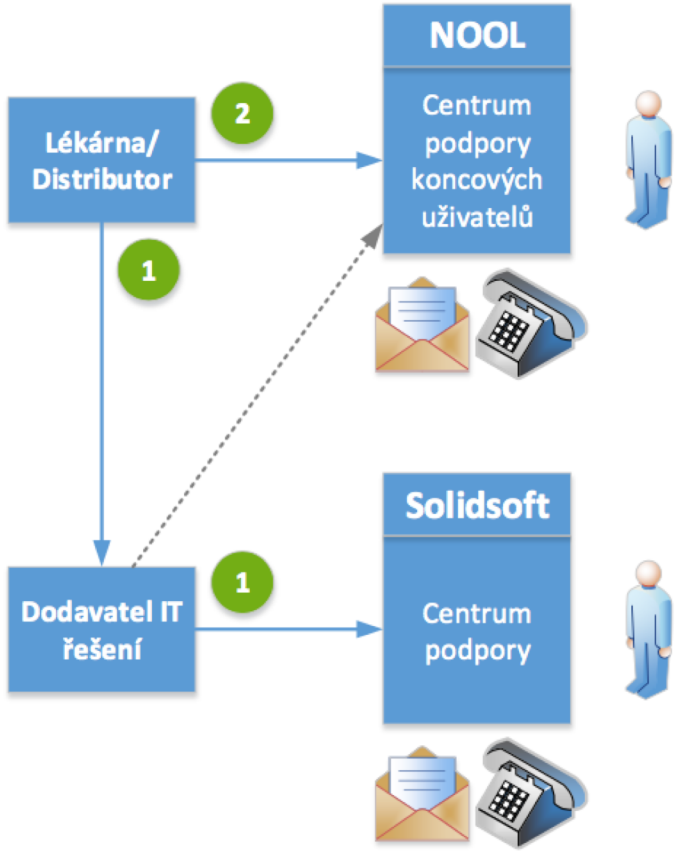
## Podpora koncovým uživatelům

## NOOL

# PODPORA KONCOVÝM UŽIVATELŮM

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

Telefonický kontakt:
+420 224 834 153
+420 224 834 154
+420 224 834 155

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# PODPORA KONCOVÝCH UŽIVATELŮ

**NOOL zřídil centrum podpory pro koncové uživatele NSOL. Centrum slouží k poskytování informací a podpory spojené s protipadělkovou směrnicí, ale není schopné řešit technické problémy spojené s provozem IT systému lékárny či distributora.**

**Dodržujte prosím proto níže zmíněné pokyny:**

- ✓ Problémy primárně řešte se svým dodavatelem IT služeb
- ✓ Pokud Váš IT dodavatel potřebuje technickou podporu, měl by se obrátit na podporu dodavatele národního řešení (Solidsoft), která k tomuto účelu byla zřízena czmvo.support@reply.com
- ✓ Koncový uživatel by měl kontaktovat podporu NOOLu až v případě, že jsou předchozí možnosti vyčerpány, nebo pokud se jedná o administrativní záležitost, případně dotaz na stav alertu

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