

# GROUP OF ALERTS



FMD Alerts - Group ID: 10001, version 14.08.2019 17:17

Pokud se vyskytly potíže se zobrazením této zprávy, kliknutím sem ji zobrazíte ve webovém prohlížeči.

Dear all,

Based on EU directive 2011/62/EU (Falsified Medicines Directive) alerts have been generated. 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 these alerts.

For most effective way the alerts showing similar signs have been grouped as they may have been created by the same cause. Please open the link below for displaying all the alerts in the group. Select all or only some of them in case not all alerts in the group have the same resolution and click on one of the feedback buttons.

You may have processed some of the alerts already which is indicated by their status. If you do not want to change it, check the **Hide processed** checkbox and only new alerts in the group will be shown.

Open the alerts [here](#).

With Best regards!

CZMVO SUPPORT TEAM

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**Národní organizace  
pro ověřování  
pravosti léčiv**


**Disclaimer:**

*The content of this email is confidential and intended for the recipient specified in message only. It is strictly forbidden to share any part of this message with any third party, without a written consent of the sender. If you received this message by mistake, please inform the sender and immediately delete this email.*

- **Email with notification about new group of alerts is sent to MAH address with Group ID and its version mentioned in the Email Subject**
- **List of alerts in group is accessible through the link in the email**
- **The list only contains new alerts sharing identical characteristics, not all alerts of the MAH**

# GROUP CLOSURE

Filter Search Group 25556 

Status:  Alert code:  Product code:  Batch id:  Expiration:  

Hide processed

<input type="checkbox"/>	Alert id	Alert code	Product code	Batch id	Expiration	Status
<input type="checkbox"/>	02-DAT-2024-198-02V	A2	020000007040	27007		03: Sent to MAH
<input type="checkbox"/>	02-DAT-2024-198-03V	A2	020000007040	27007		03: Sent to MAH
<input type="checkbox"/>	02-DAT-2024-198-04V	A2	020000007040	27007		03: Sent to MAH
<input type="checkbox"/>	02-DAT-2024-198-05V	A2	020000007040	27007		03: Sent to MAH
<input type="checkbox"/>	02-DAT-2024-198-06V	A2	020000007040	27007		03: Sent to MAH
<input type="checkbox"/>	02-DAT-2024-198-07V	A2	020000007040	27007		03: Sent to MAH


Page size:


Select action:

Selected only

- Please note that the list only contains alerts sharing identical characteristics. It is not a full overview of all alerts for concerned MAH
- Alerts sharing identical characteristic are added to the group continuously, email with notification about new alerts added in the group is sent to MAH address, marked as a new version
- Full updated list of alerts in individual groups is accessible through links in all emails regarding the group

# SEARCH PAGE



Filter Search **Type the alert ID** Group 25556 


Type search text 

<input type="checkbox"/>	Alert id	Alert code	Product code	Batch id	Expiration	Status
<input type="checkbox"/>	CE2V74B5798J2V	A2	CE2V74B5798J2V	77607		03: Sent to MAH
<input type="checkbox"/>	CE2V74B5798J2V	A2	CE2V74B5798J2V	77607		03: Sent to MAH
<input type="checkbox"/>	CE2V74B5798J2V	A2	CE2V74B5798J2V	77607		03: Sent to MAH
<input type="checkbox"/>	CE2V74B5798J2V	A2	CE2V74B5798J2V	77607		03: Sent to MAH
<input type="checkbox"/>	CE2V74B5798J2V	A2	CE2V74B5798J2V	77607		03: Sent to MAH
<input type="checkbox"/>	CE2V74B5798J2V	A2	CE2V74B5798J2V	77607		03: Sent to MAH

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Select action:

 Approve all (6)  Approve selected (0)

 Export to Excel  Selected only

- Search specific alert through ID on the Search page

# FILTER PAGE

The screenshot shows a web interface for filtering alerts. At the top, there is a 'Group Name' field containing 'Group 25556'. Below this, there are several filter options: a 'Status' dropdown menu with the value '03: Sent to MAH, 04a: MAH asked for additiona', an 'Alert code' dropdown menu with the value 'A1, A10, A11, A12, A13, A16', and three empty text input fields for 'Product code', 'Batch id', and 'Expiration'. A checkbox labeled 'Hide processed' is located on the left. On the right side, there is a 'Filter button' with a funnel icon and a 'Refresh button' with a circular arrow icon. Blue arrows point from callout boxes to the 'Status', 'Alert code', 'Product code', 'Batch id', and 'Expiration' fields. A green arrow points to the 'Filter button', and another green arrow points to the 'Hide processed' checkbox.

- Filter alerts by status, Alert code, Product code, Batch Id and Expiration date – to display the filtered alerts, use the *“Filter button”*
- Checkbox *“Hide processed”* filters out alerts with closed investigation and leaves in the list only alerts still requiring feedback
- Please use the *“Refresh button”* after any change of status of alerts in order to display the updated information

Actual status

<input type="checkbox"/>	Alert id	Alert code	Product code	Batch id	Expiration	Status
<input type="checkbox"/>	CE2VT405798Z9V	A2	CE2000007345	7345		03: Sent to MAH
<input type="checkbox"/>	CE2VT407104V39H	A2	CE2000007345	7345		03: Sent to MAH
<input type="checkbox"/>	CE2VT4034768Z9H	A2	CE2000007345	7345		03: Sent to MAH
<input type="checkbox"/>	CE2VT403442Z9V	A2	CE2000007345	7345		03: Sent to MAH
<input type="checkbox"/>	CE2VT404140Z49V	A2	CE2000007345	7345		03: Sent to MAH
<input type="checkbox"/>	CE2VT404105Z9FE	A2	CE2000007345	7345		03: Sent to MAH

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- Select concerned alerts through the appropriate checkbox
- After Approval of a change, while the request is being processed the affected checkboxes are inactive

Select action:

Selected only

- Requested additional information are available through clicking on the alert in the list or in Excel exported data
- Choose closure of only selected alerts or all displayed alerts – the total number shown in the text on the buttons
- Export data to excel format to access full filterable
- Closing an alert with feedback choice different from the previously closed alerts leads to exclusion of the alert from the group and the alert is removed from the list

Select action:

Alert solved, Issue closed (Investigation completed)  
Alert solved, Issue was caused by one of the stakeholders (Investigation completed)  
Additional information about alert needed  
MAH verified potential falsification (Investigation completed)

Approve all (2)

Approve selected (2)

Export to Excel

Selected only

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➤ Choose from the feedback options as you would in an alert email

**Feedback**

[Alert solved, Issue closed \(Investigation completed\)](#)

**When to use**

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 to 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 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.