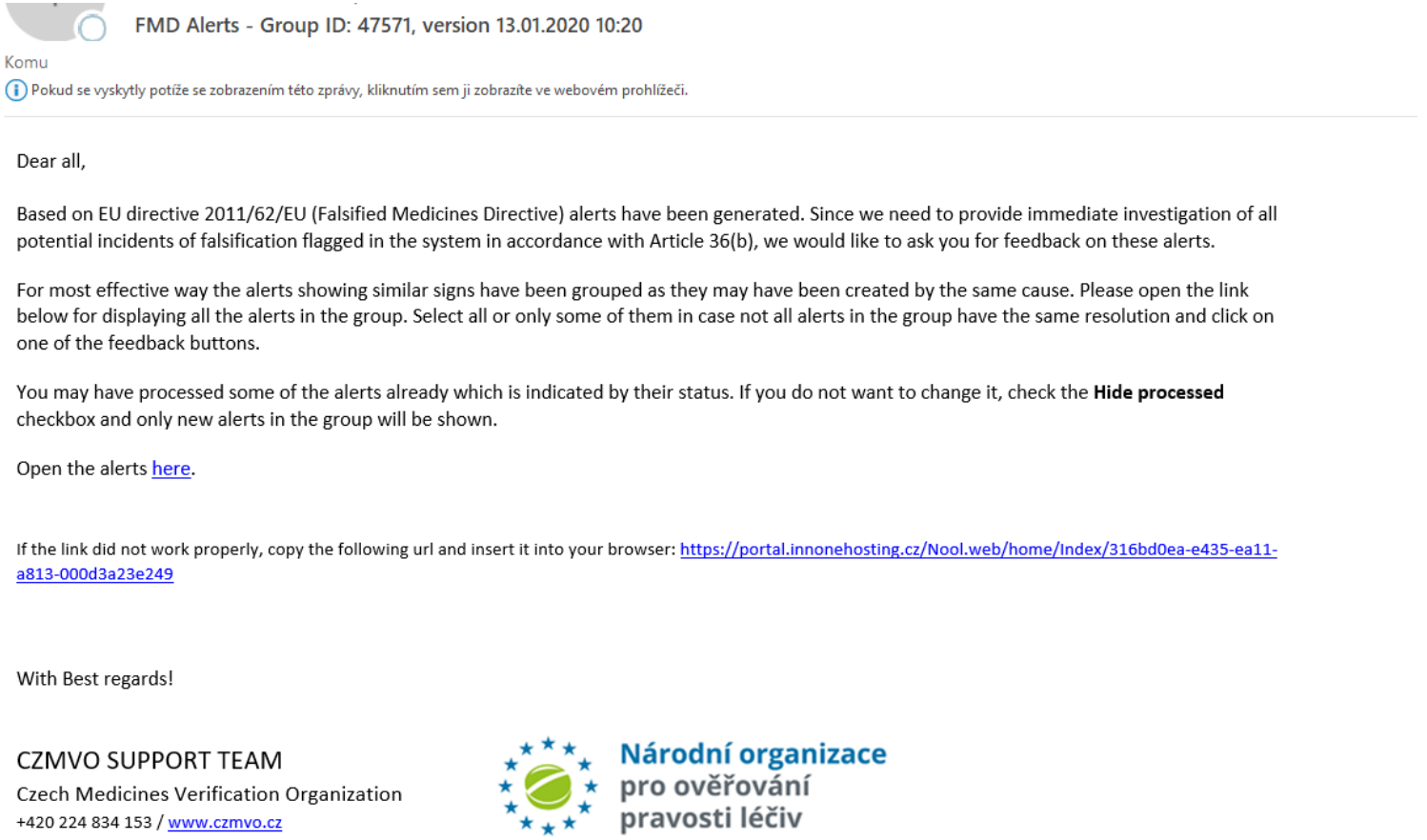
GROUP OF ALERTS



FMD Alerts - Group ID: 47571, version 13.01.2020 10:20

Komu

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.

If the link did not work properly, copy the following url and insert it into your browser: https://portal.innonehosting.cz/Nool.web/home/Index/316bd0ea-e435-ea11-a813-000d3a23e249

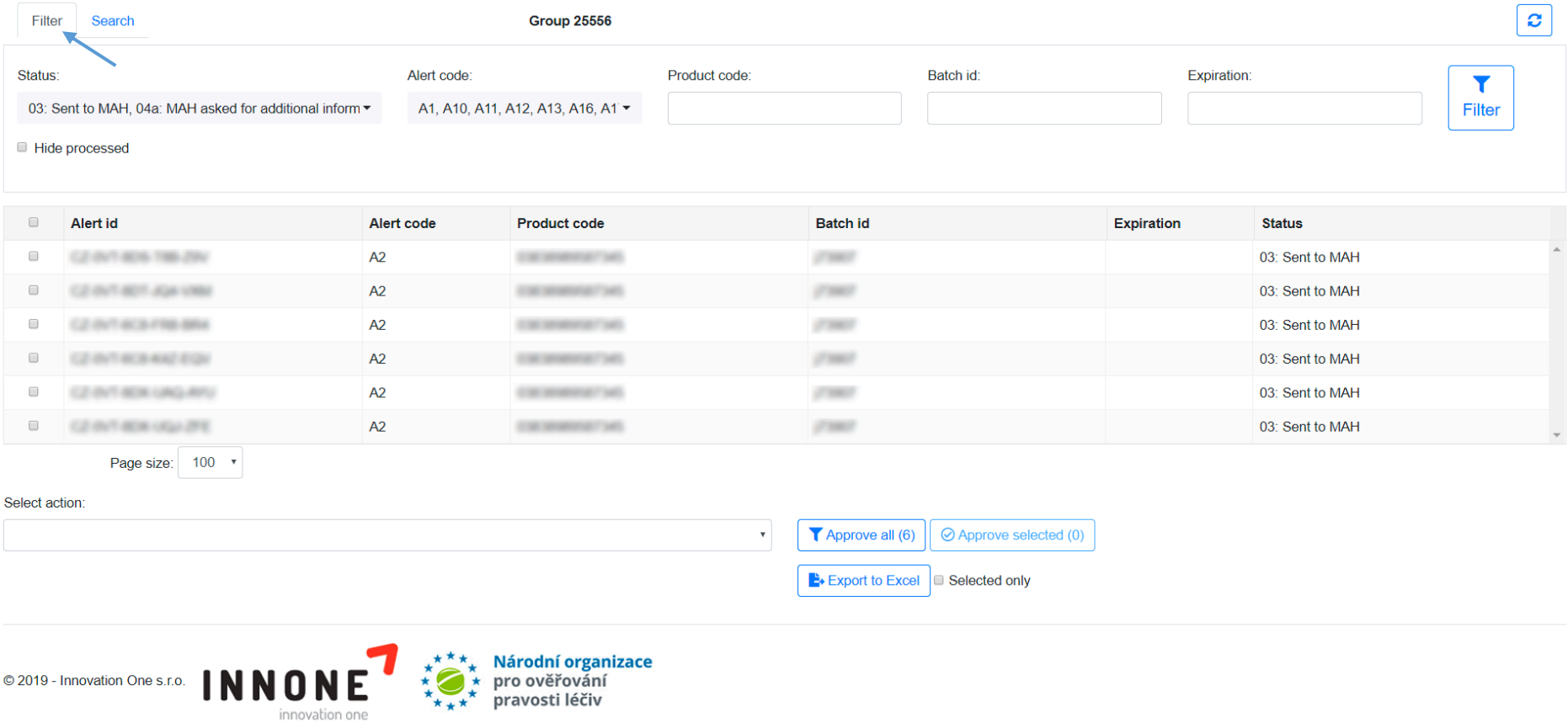
With Best regards!

CZMVO SUPPORT TEAM
Czech Medicines Verification Organization
+420 224 834 153 / www.czmvo.cz

Národní organizace pro ověřování pravosti léčiv

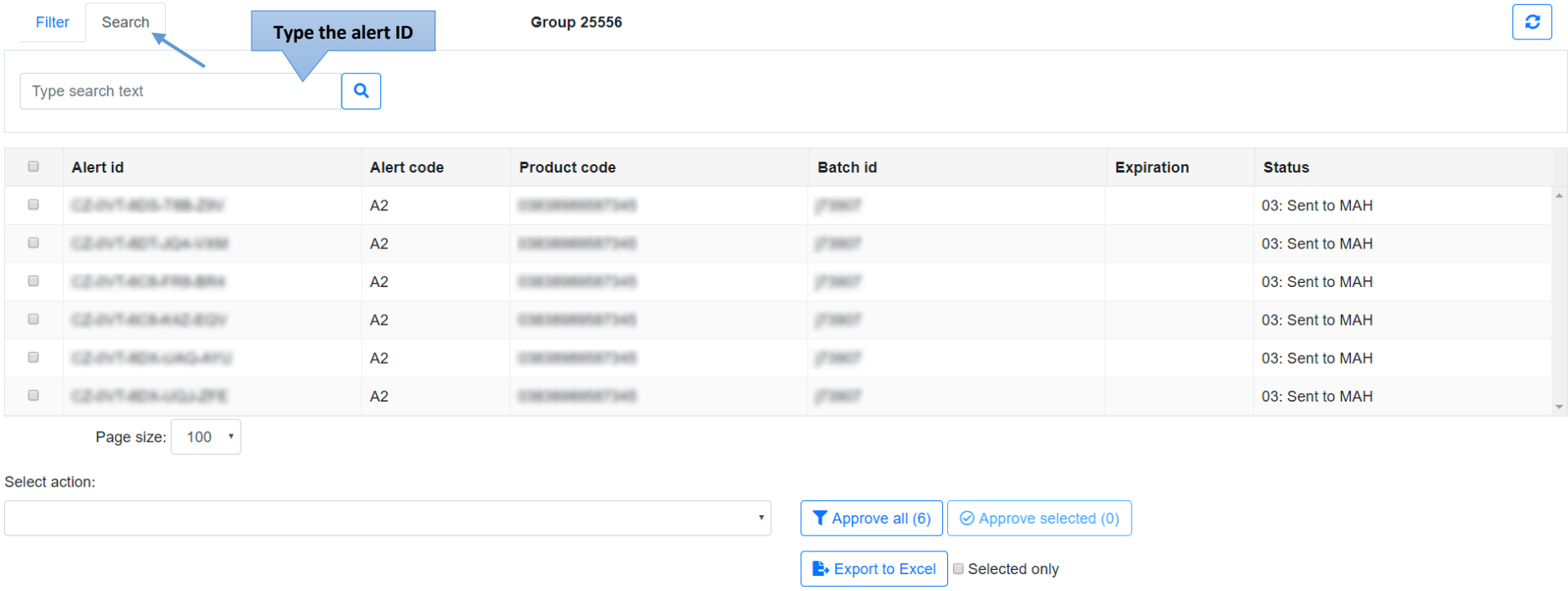
- **Email with notification about new group of alerts is sent to MAH address with Group ID and its version mentioned in the Email Subject.**
- **List of alerts in group is accessible through the link or you can copy the following url and insert it into the browser.**
- **The list only contains new alerts sharing identical characteristics, not all alerts of the MAH.**

GROUP CLOSURE



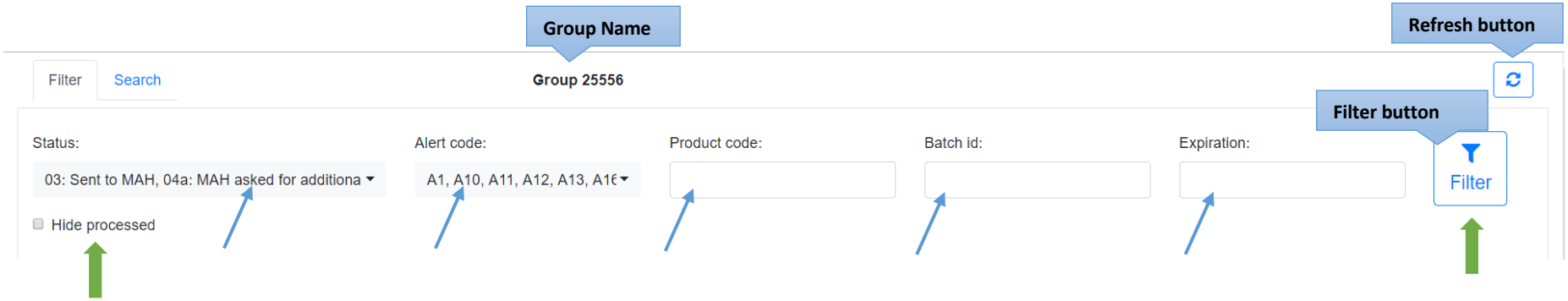
- **Please note that the list only contains alerts sharing identical characteristics. It is not a full overview of all alerts for concerned MAH**
- **Alerts sharing identical characteristic are added to the group continuously, email with notification about new alerts added in the group is sent to MAH 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

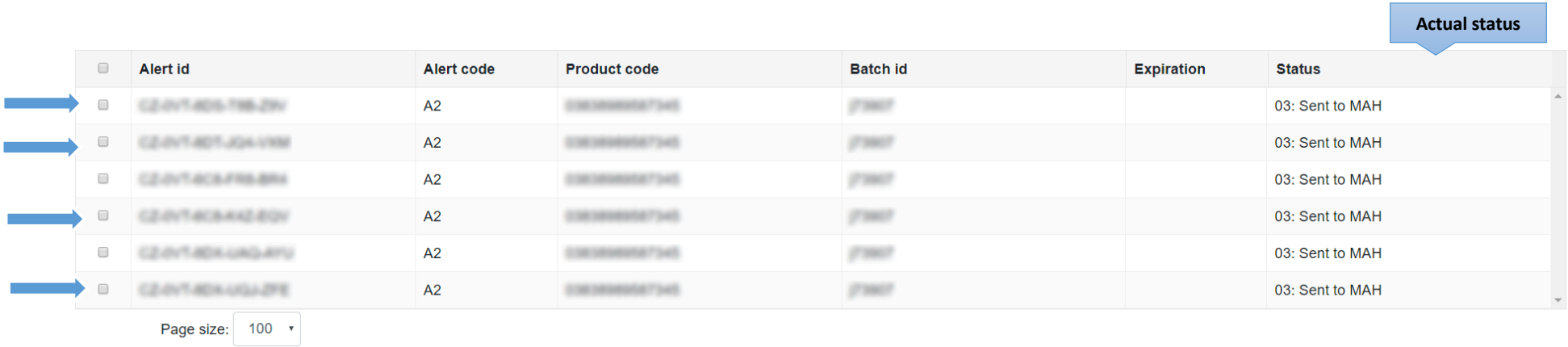


- **Search specific alert through ID on the Search page**

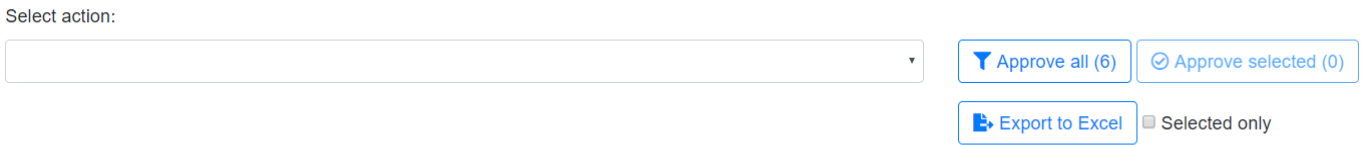
FILTER PAGE



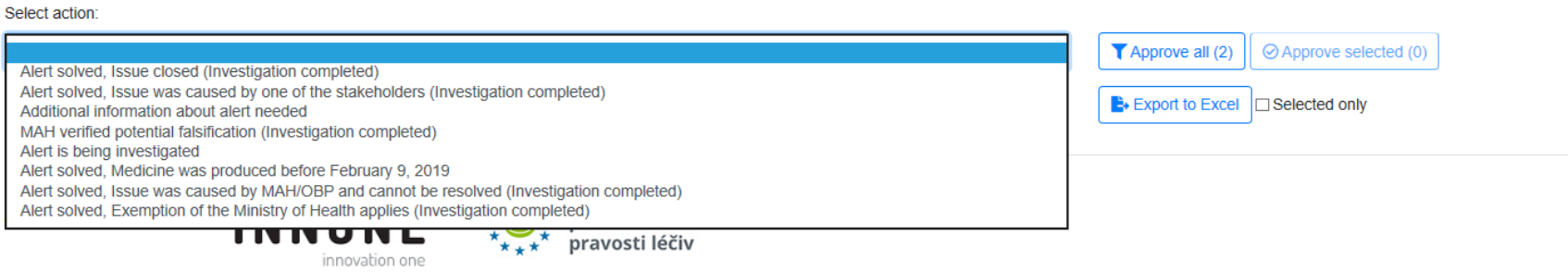
- **Filter alerts by status, Alert code, Product code, Batch Id and Expiration date – to display the filtered alerts, use the "*Filter button*"**
- **Checkbox "*Hide processed*" filters out alerts with closed investigation and leaves in the list only alerts still requiring feedback**
- **Please use the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



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



- **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**

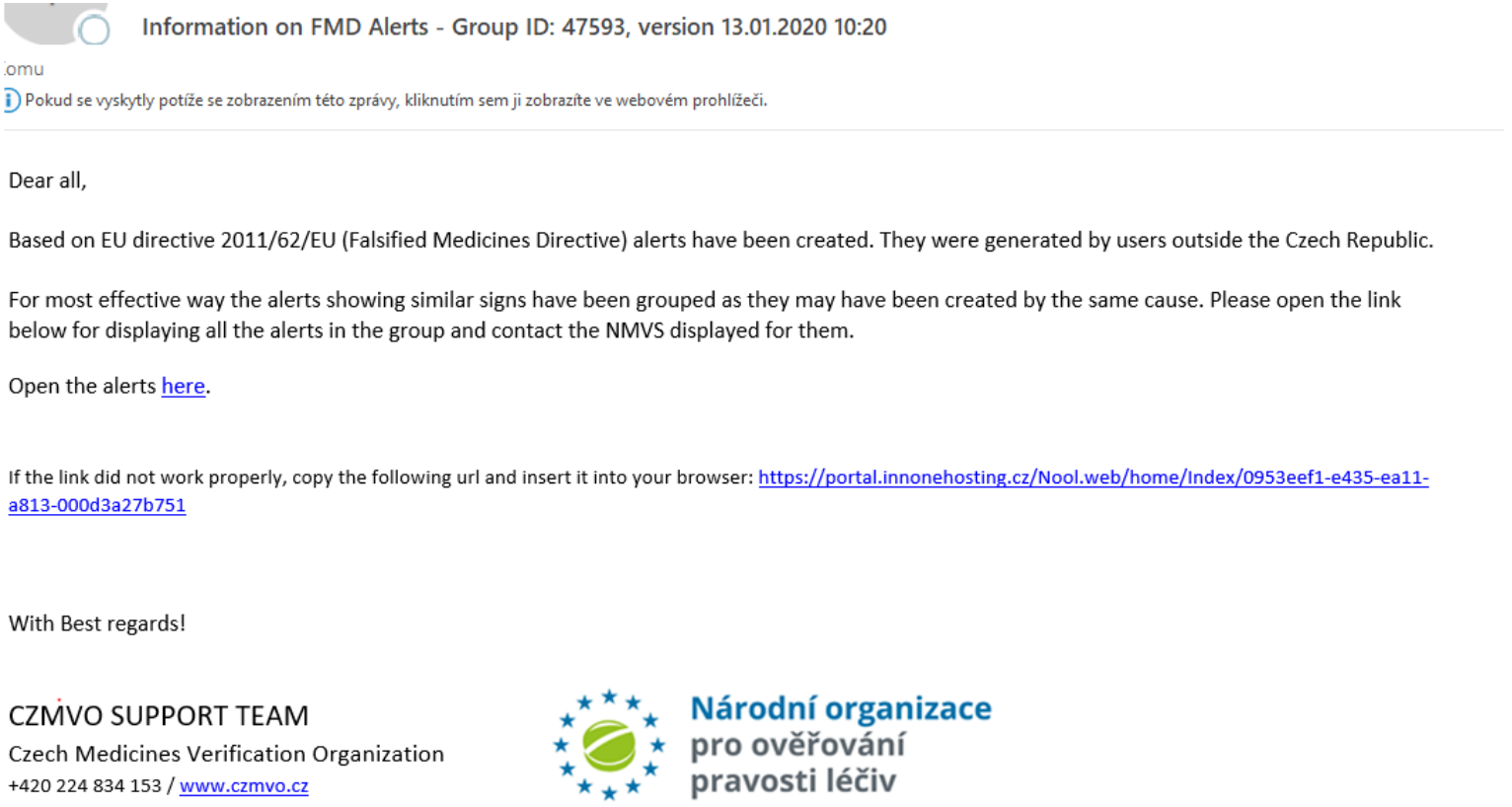


- **Choose from the feedback options as you would in an alert email**

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.
Alert solved, Issue was caused by MAH/OBP and cannot be resolved (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by MAH/OBP and cannot be resolved.
Alert solved, Medicine was produced before February 9, 2019 (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Alert was caused by the fact that the medicine was produced before February 9, 2019.
Alert solved, Exemption of the Ministry of Health applies (Investigation completed)	This feedback will lead to closure of alert as 'solved'. Falsification is excluded. Exemption of the Ministry of Health of the Czech Republic applies.

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.
Alert is being investigated	This feedback will report that MAH has started investigation. Please use this option only if you anticipate that the investigation will take more than 9 days from the alert creation.

INTERMARKET LOCAL ALERTS



Information on FMD Alerts - Group ID: 47593, version 13.01.2020 10:20

omu

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 created. They were generated by users outside the Czech Republic.

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 and contact the NMVS displayed for them.

Open the alerts here.

If the link did not work properly, copy the following url and insert it into your browser: https://portal.innonehosting.cz/Nool.web/home/Index/0953eef1-e435-ea11-a813-000d3a27b751

With Best regards!

CZMVO SUPPORT TEAM
Czech Medicines Verification Organization
+420 224 834 153 / www.czmvo.cz

Národní organizace pro ověřování pravosti léčiv

- **Informative email with notification about new group of alerts which were generated by users outside the Czech Republic is sent to MAH address with Group ID and its version mentioned in the Email Subject.**
- **Fot the alert investigation please contact the relevant NMVS, Location ID of alert creation is displayed for each alert.**
- **Contact information are available through clicking on the alert in the list or in Excel exported data.**
- **In Czech system we are consider these alerts as closed.**