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EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 1 of 74


EAMS Portal User Manual

Revision History

Version Date	Version	Author	Reason For Changes
29-SEP-2021	V1.0	Athanasios Kantarelis	Initial Document
16-NOV-2021	V2.0	Matisse Jubb	Adding first time log-in instructions
09-DEC-2021	V3.0	Matisse Jubb	Adapting log-in instructions and screenshots. Updated with new alert schema.
01-AUG-2022	V4.0	Marius Malinauskas	Updated to align with the AMS Lilith release (Portal 2.0): user management, filters, investigation status, sending messages and files, custom columns, group alerts, bulk actions, notifications and import & export alerts. Additional update to user roles and alert rules
31-AUG-2023	V5.0	Tiago Barrosa Anjos	Updated Section 5 "Secret Management (Cybersecurity 1)" Updates based on comments received by OBPs. Minor updates on sections: <ul style="list-style-type: none"> - "OBP User roles" - "Access to alerts" - "Notifications" - "Exporting alerts"
06-OCT-2023	V6.0	Tiago Barrosa Anjos	Document title updated to "EAMS Portal User Manual" Update to align with the AMS Clementine:

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 2 of 74

Version Date	Version	Author	Reason For Changes
			<ul style="list-style-type: none"> - Sections updated: "Password policy"; "Manage OBP rules"; "Change columns"; - "Performing external actions" was split into five sections: "Change investigation status", "Send external message/file", "Change alert status" and "Import .csv files for mass-alerts updates", and "Activity" - Sections added: "Remove users", "Alerts workflow"
25-MAR-2024	V7.0	Floyd Cutinha	Update the section "Manage OBP rules" to include the "Serial Number" and "Batch Number" sections. Removed section in 7.5 regarding Email Notification for Client Secret ID expiry as this was not implemented.
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12-FEB-2026	V9.0	Floyd Cutinha	Update section 10.9 to reflect the current list of connected countries.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 3 of 74

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Translations

The English version of the EMVO documentation is the only official and binding version.

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EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 4 of 74

Table of Contents

1.	List of figures	6
2.	Background.....	10
3.	Definitions	10
4.	Introduction	12
4.1.	Browser support.....	13
4.2.	Environments.....	13
5.	The EAMS Portal setup	13
5.1.	Request Access to the EAMS Portal.....	13
5.2.	First connection - Log-in	14
5.3.	Terms and conditions of acceptance	17
5.4.	Password policy.....	18
6.	EAMS Portal overview	19
7.	Organisation Management	21
7.1.	Generic view and actions	21
7.2.	Managing organization.....	21
7.3.	Managing Teams.....	23
7.4.	Remove users and teams.....	25
7.5.	Client ID and Secret	26
7.6.	OBP User Roles	30
8.	Manage OBP rules	32
8.1.	Serial number	32
8.2.	Batch number	33
8.3.	Client ID	33
9.	Alerts workflow	34
9.1.	Messages received in the last 8 days	34
9.2.	Suggested actions	34
9.2.1.	Accept actions per alerts code.....	35
9.2.2.	Accept actions per alert code and market	36
9.2.3.	Automate per alert code and market (limited to Administrators).....	37

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 5 of 74

- 10. Alerts List37
 - 10.1. Access to alerts37
 - 10.2. Change columns.....42
 - 10.3. Select alerts and Page navigation43
 - 10.4. Select all.....44
 - 10.5. Notifications.....45
 - 10.6. Filtering and sorting47
 - 10.7. By default view – Unresolved alerts49
 - 10.8. See connected countries50
 - 10.9. Show mismatches only51
 - 10.10. Alerts with multiple Serial numbers.....52
 - 10.11. Tag alerts – organise alerts by tags52
 - 10.12. Exporting alerts.....54
 - 10.13. Performing external actions57
 - 10.14. Change investigation status57
 - 10.15. Send external message/file58
 - 10.16. Change alert status60
 - 10.17. Import CSV files for mass-alerts updates62
 - 10.18. Grouping alerts by tags.....64
- 11. Alert detailed view.....66
 - 11.1.1. Change investigation status67
 - 11.1.2. Change alert status68
 - 11.1.3. Send external message or file68
 - 11.1.4. Related alerts section69
 - 11.2. Activity view.....72
- 12. Archived alerts74

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 6 of 74

1. List of figures

Figure 5.1. Log in window	14
Figure 5.2. Enter email address.....	15
Figure 5.3. Complete verification.....	16
Figure 5.4. Select to acknowledge terms and conditions	17
Figure 5.5. Accept terms and conditions	17
Figure 6.1. Organisation management section	19
Figure 6.2. Top menu.....	19
Figure 6.3. Alerts List window	20
Figure 7.1. OBP User management	21
Figure 7.2. Add users	21
Figure 7.3. Enter user details	22
Figure 7.4. Add administrator	22
Figure 7.5. Choose an administrator for an entity.....	22
Figure 7.6. Add team	23
Figure 7.7. Creating a new team.....	23
Figure 7.8. Enter team name and save	24
Figure 7.9. Assign user to the team.....	24
Figure 7.10. Countries list.....	24
Figure 7.11. Select users to the team	25
Figure 7.12. Remove administrator	25
Figure 7.13 - Remove users.....	26
Figure 7.14. AMS' Dashboard "Alerts" menu	26
Figure 7.15 Secret Management option	27
Figure 7.16 Secret Management before clicking on "Add Secret"	28
Figure 7.17 Secret Management, after clicking on "Add Secret"	28
Figure 7.18 One time Secret visibility and option to copy	29
Figure 7.19 Deletion of old secret	29
Figure 7.20 Notification of new secret creation	30
Figure 7.21 OBP user role matrix	31


			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 7 of 74

Figure 8.1. Manage OBP rules section32

Figure 8.2. Add a rule for serial number 32

Figure 8.3. Save new rule of serial number length validation33

Figure 8.4 Save new rule of client ID.....33

Figure 9.1 Alerts workflow34

Figure 9.2 Alerts with external messages.....34

Figure 9.3 Select affected countries.....35

Figure 9.4 Information about the suggested actions.....35

Figure 9.5 Execute suggested actions per alert code.36

Figure 9.6 Execute suggested actions per alert code and market/country36

Figure 9.7 Automate suggested actions37

Figure 10.1. Displayed default columns38

Figure 10.2. Change displayed columns.....42

Figure 10.3. Save, remove, add or change columns43

Figure 10.4. Navigation pane44

Figure 10.5. Navigation pane details44

Figure 10.6 - Selecting 200 alerts.....45

Figure 10.7. Notification icon45

Figure 10.8. Notifications screen45

Figure 10.9. Notification of failed action46

Figure 10.10. Download .CSV of failed actions47

Figure 10.11. Filtering from the header48

Figure 10.12. Filter menu with options48

Figure 10.13. Typing in the filters48

Figure 10.14. Remove filtering49

Figure 10.15. Show unresolved alerts.....50

Figure 10.16. Filter National status.....51

Figure 10.17. Show mismatches only for Serial Number.....51

Figure 10.18. Multiple serial numbers icon52

Figure 10.19. Tags filtering.....52


			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 8 of 74

Figure 10.20. Filtering tags with "OR" example53

Figure 10.21. Filtering tags with "AND" example53

Figure 10.22. Sorting.....53

Figure 10.23. Export options in the Alert Management window54

Figure 10.24. Date interval for exporting all alerts action54

Figure 10.25. Confirm export all alerts action.....54

Figure 10.26. Downloading report55

Figure 10.27. CSV export by countries example55

Figure 10.28. Export selected example56

Figure 10.29. Selecting columns for exported alerts report56

Figure 10.30 See External actions57

Figure 10.31 - Change investigation status58

Figure 10.32. Add external message59

Figure 10.33. Add file to the external message60

Figure 10.34. Choose Alert status and Reason61

Figure 10.35. Import CSV file for Investigation status.....62

Figure 10.36. Example of CSV file for Investigation status upload62

Figure 10.37. Import CSV file for Alert status (when scrolling down the user will see the same reasons as below in "Reason codes and default text").....63

Figure 10.38. Example of CSV file for Alert status upload.....63

Figure 10.39. Tag alerts64

Figure 10.40. Create new tag.....65

Figure 10.41. Applied tag view.....65

Figure 10.42. Update tags65

Figure 10.43. Manage tags66

Figure 11.1. Go to detailed information of an alert66

Figure 11.2. Detailed view of an alert67

Figure 11.3. Changing alert status through the detailed alert view67

Figure 11.4. Change investigation status through the detailed alert view68

Figure 11.5. Sending external message through detailed alert view.....69

Figure 11.6. Related alerts section70


			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 9 of 74

Figure 11.7. "Show more" button in the related alerts section.....70

Figure 11.8. Related alerts list view71

Figure 11.9. Pop up window with information of processing bulk action.....71

Figure 11.10. Highlighted columns for related alerts as filters71

Figure 11.11. Bulk action for related alerts72


Figure 11.12. Activities history73

Figure 11.13. Conversation section.....73

Figure 11.15. Save image as.....73

Figure 11.14. Download .pdf, .xlsx files73

Figure 12.1 - Search for Alert ID74

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 10 of 74

2. Background

The European Alert Management System (EAMS) is a European Medicines Verification System (EMVS) project which involves representatives from all EMVS stakeholders. The EMVS is designed to facilitate medicines verification across multiple European markets and prevent counterfeit medicines from being introduced into the supply chain. The EAMS is a living system that is part of the EMVS as a complementary component to it.

The objective of the EAMS is to facilitate communication between EMVS users to increase the efficiency of alert management and handling, as well as support the EMVS users when following up on alert investigations and ensuring that the actions taken are correctly audited.

An alert occurs when a medicinal pack cannot be authenticated. The EAMS is provided solely to manage these so-called Level 5 alerts indicating a potential falsification. However, alerts are not automatically related to falsified medicines; they can be raised by a suspicion of falsification or can indicate products or packs with technical or procedural issues related to the applied serialised code.

The aim of an investigation, as defined by the EU Commission Q&A on Safety Features , is to "rule out that alerts triggered in the system have been caused for technical reasons." Ultimately, the goal of the EAMS is to maximise the efficiency of alert investigations. An alert investigation comprises a series of tests designed to identify the root cause of the alert by assessing and ruling out (by way of decision trees) possible causes.

3. Definitions

Table 1: Definitions

Term/Acronym	Definition
Alert	An alert is an exception which is deemed as critical and therefore should be notified. Alerts, therefore, produce notifications.
Alert ID	An Alert ID is an identifier for a single instance of an alert. One pack can be associated with one or many Alert IDs. This term is commonly called by "Unique Alert Return Code" (UPRC), which is physically related to a pack as part of a returns process.
EAMS	The European Alert Management System that consists of the AMS Hub, a set of National AMSs, and one or multiple AMS MAH systems.
AMS MAH	A system that an MAH uses to process the alerts relevant to him. The MAH uses this system to interact with the AMS Hub.
AMS Hub	Alert Management System that is hosted in the EU Hub and accessible via National systems for end-users and EU Hub for MAHs.



EAMS Portal User Manual

Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 11 of 74

Term/Acronym	Definition
API	Application Programming Interface. An agreed protocol that allows client and server software to communicate through requests and responses.
Delegated Regulation	Commission Delegated Regulation (EU) 2016/161 as amended.
EMVO	European Medicines Verification Organisation.
EMVS	European Medicines Verification System.
End-Users	Pharmacy, Hospital, Wholesaler or any other person authorised or entitled to supply medicinal products to the public in accordance with the Delegated Regulation.
GTIN	A GTIN is the acronym for Global Trade Item Number. It's a number that uniquely identifies a product. GTINs are used as a global standard to identify products.
HTML5 CSS3 compliant web browser	CSS3 is simply the newer "version" of CSS which has more advanced features than earlier "releases." Likewise, HTML5 simply is HTML and CSS3 is simply CSS. Those are both standards supported by all the major browsers, including Chrome, Firefox, Safari, Opera, as well as iOS for Chrome and Safari and Android browsers.
ITE	Integration Testing Environment used by the users connected to the EAMS Hub APIs directly and not using the EAMS Portal.
IQE	Integration Quality Environment, also known as UAT – User Acceptance Testing – Environment. This environment is identical to Production and it is used to the last validation phase before the system moves onto Production (PRD).
ISO Country Code	The ISO country codes are internationally recognised means of identifying countries (and their subdivisions) using a two-letter or three-letter combination.
MAH	Marketing Authorisation Holder. See entry for "OBP"
National AMS (NAMS)	A national system that is tasked to connect the different national users to the AMS Hub and to support the alert investigation of these users.




EAMS Portal User Manual

Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 12 of 74

Term/Acronym	Definition
NCA	National Competent Authority is an entity which supervises the functioning of any repository physically located in their territory. NCAs are ultimately responsible for the decisions made if an alert is confirmed and if it has an impact on public health.
NHRN	National Health Reimbursement Number
NMVO	National Medicines Verification Organisation.
NMVS	National Medicines Verification System.
OBP	On-Boarding Partner. A company or Organisation that represents the affiliated entities that hold marketing authorisation for products for which the MAH uploads product and pack data to the EU Hub. For practical reasons, the document mentions the OBP instead of the MAH. It is understood that in some member states the legally responsible entity is the MAH (Marketing Authorisation Holder).
PPN	The PPN (Pharmacy Product Number), containing the national product code PZN, is the primary data element of the IFA Coding System, designed to meet the requirements for uniqueness in the global market.
PRD	The dedicated environment for the upload of OBP operational data that has been qualified to be released on the market.
UAT	UAT – User Acceptance Testing – Environment.
User	User is an entity which can interact with the EAMS.
UTC	UTC stands for Coordinated Universal Time, a standard used to set all time zones around the world.

4. Introduction

The EAMS allows efficient and direct communication between end-users, MAHs/OBPs, NMVOs and EMVO during an alert investigation and provides each party with visibility over investigations being carried out simultaneously. The EAMS also preserves end-user anonymity vis-à-vis the MAH/OBP and provides the opportunity for NCAs to be alerted about suspected falsified packs in a timely manner. In addition, the EAMS, provided thorough and consistent documentation of alert investigations and resolutions.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 13 of 74

This document aims at providing instructions to "EAMS Portal" users to efficiently utilize the system.

4.1. Browser support

We recommend using a fully updated HTML5 CSS3 compliant web browser to get the best experience from the EAMS, older non-HTML5 browsers or versions will not work correctly. We recommend only the latest versions of:

- Microsoft Edge
- Google Chrome
- Firefox
- Safari

Experiences with the mobile versions will vary. No support can/will be provided for unlisted versions and file transfer requires a browser capable of using file transfer protocols.

All web browsers are subject to the same technical restrictions:

- The web browser must support JavaScript; it must be enabled and must have permission to run it.
- The web browser must support Cookies; they must be enabled, and the site must have permission to read/write them.
- File uploads are restricted to web browsers that support XMLHttpRequest Level 2. This is an unofficial part of the HTML5 spec.


4.2. Environments

- **Production Environment (PRD):** The dedicated environment for the upload of OBP operational data that has been qualified to be released on the market. <https://ams.emvo-medicines.eu>
- **Integrated Quality Environment (IQE):** The dedicated environment for validating OBP solutions and qualifying users, it has the same functions and behaves as a PRD, but without affecting the PRD environment of the OBP. <https://ams-uat.emvo-medicines.eu>

5. The EAMS Portal setup

This section provides an overview of the EAMS Portal. It will also provide the user with the necessary steps to set up the application. **Request Access to the EAMS Portal**

Please contact EMVO using the contact information helpdesk@emvo-medicines.eu. [This link](#) will also take you to the slides that explain what the necessary steps are to be taken.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 14 of 74

5.2. First connection - Log-in

After accessing the EAMS Portal, the OBP will log in for the first time. To do so, the OBP will have to reset the password to the Portal. This will have to be done for each environment.

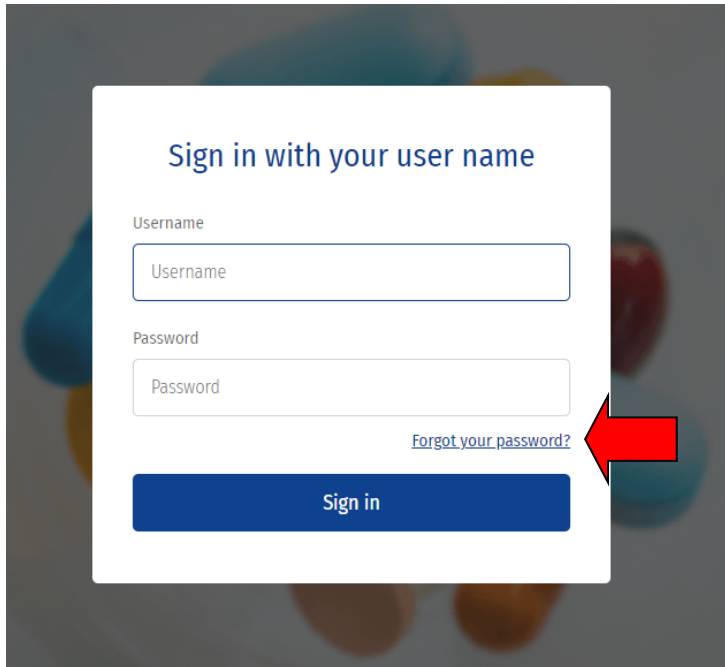



Figure 5.1. Log in window

After clicking on "Forgot your password?", the OBP will be redirected to the **verification page**. Please note that this action will allow you to create your own password. The button "Forgot your password?" also logically means "Create a new password".

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 15 of 74

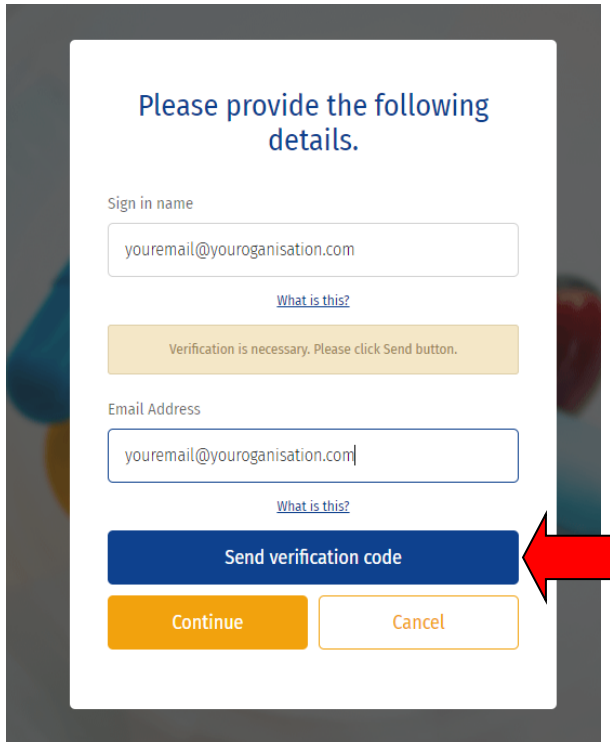

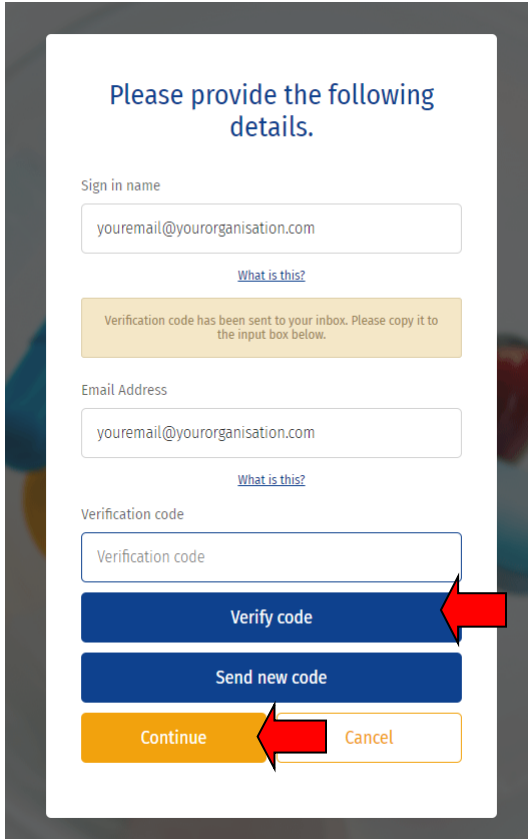


Figure 5.2. Enter email address

The OBP will enter its **Email address** in the fields: "Sign in name" and "Email address" and click on "Send verification code".

The OBP will receive a **verification code** by email, type the code received by email in the dedicated section, and **verify the code**. The OBP will be able to reset the password and proceed to logging in.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 16 of 74



Please provide the following details.

Sign in name
youremail@yourorganisation.com
[What is this?](#)

Verification code has been sent to your inbox. Please copy it to the input box below.

Email Address
youremail@yourorganisation.com
[What is this?](#)


Verification code
Verification code

Verify code

Send new code

Continue Cancel

Figure 5.3. Complete verification

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 17 of 74

5.3. Terms and conditions of acceptance

After the initial successful login to the EAMS Portal, a dialogue with the **Terms and Conditions** will be displayed.

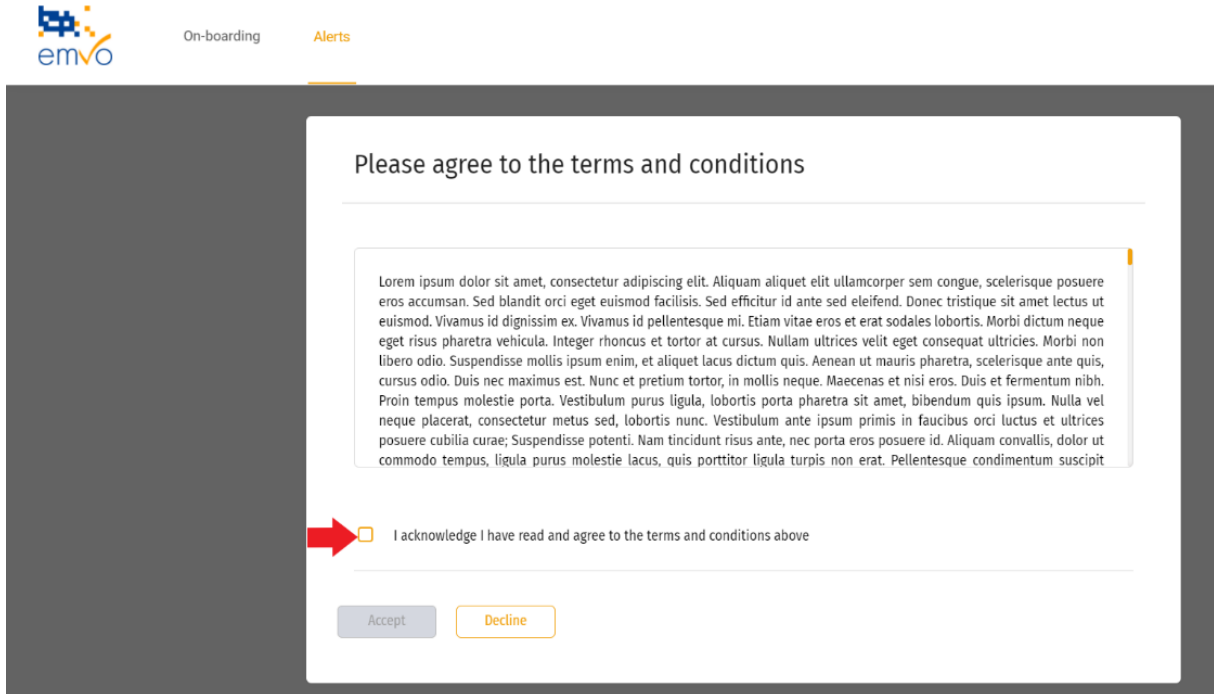


Figure 5.4. Select to acknowledge terms and conditions

The first OBP User logging in must check **the acknowledge box** for the accept button to become active. Please note that for each OBP, the Terms and Conditions must only be accepted once in the course of the first log-in to become active and access the EAMS. Please ensure that the person who does this is entitled to do so.

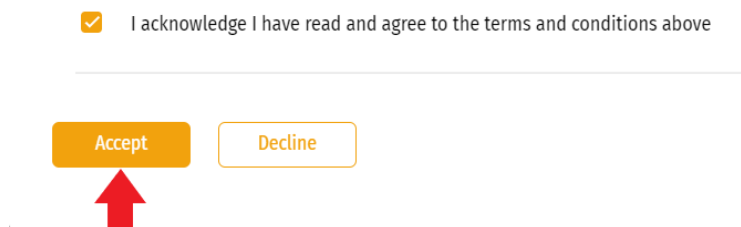



Figure 5.5. Accept terms and conditions

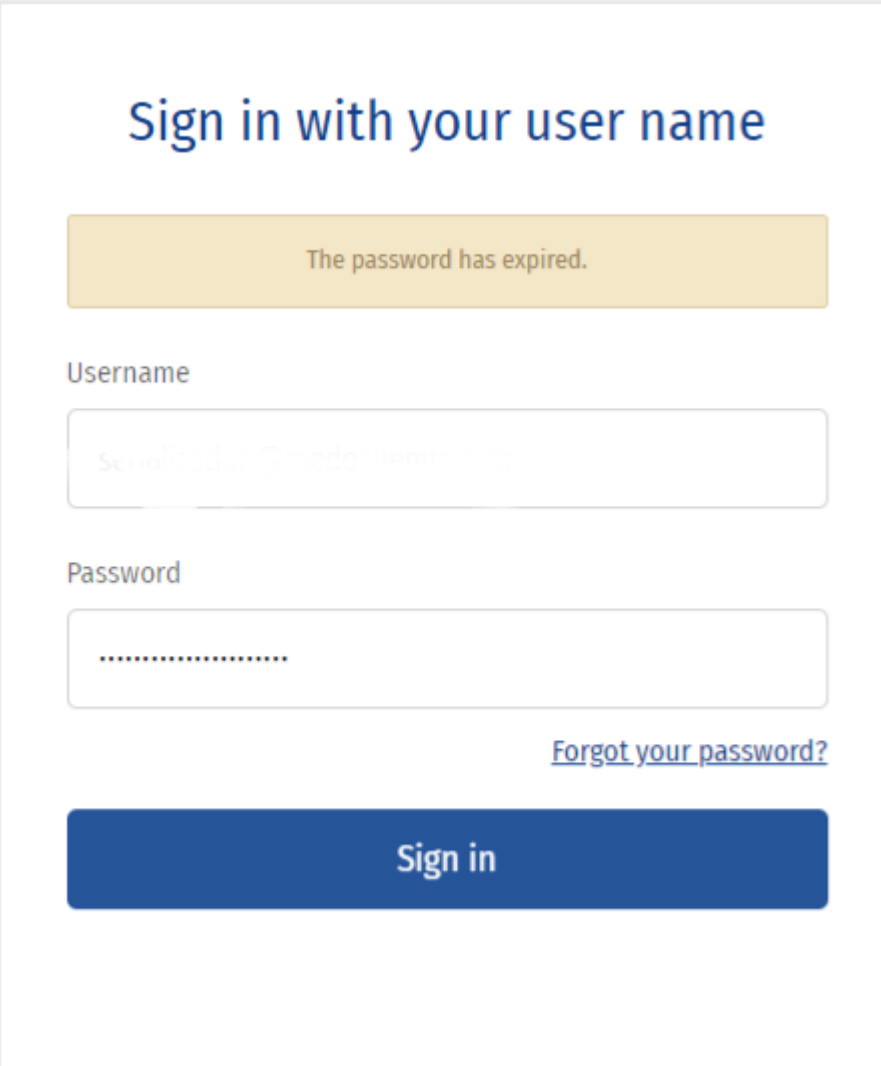
- If the OBP User accept the **Terms and Conditions**, the application will save it and close the dialogue.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 18 of 74

The OBP must accept the Terms and Conditions to have access to the AMS Portal.

5.4. Password policy

EAMS Portal passwords are set to expire after 90 days. Currently, no email notification is planned to warn of password expiration. The Portal shall display the following error to the user and invite the user to reset their password via the button "Forgot your password" as explained for the initial log-in in paragraph 2.




The screenshot shows a login page with the following elements:

- Header: "Sign in with your user name" in blue text.
- Error message: A yellow box containing the text "The password has expired."
- Username field: A text input field with the placeholder text "serial@ag.com".
- Password field: A text input field with masked characters (dots).
- Link: A blue underlined link labeled "Forgot your password?".
- Sign in button: A large blue button with the text "Sign in" in white.

All passwords must follow the following requirements:

8-16 characters, containing 3 out of 4 of the following:

- Lowercase characters,
- uppercase characters,

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 19 of 74

- digits (0-9),
- and one or more of the following symbols: @ # \$ % ^ & * - _ + = [] { } | \ : ' , ? / ` ~ " () ; .

The user will automatically be logged out of their account when closing the browser window or tab.

6. EAMS Portal overview

When logging in to the AMS Portal for the first time, the OBP will be directed to the **Organisation management section**. This section currently displays the users, entities and teams.

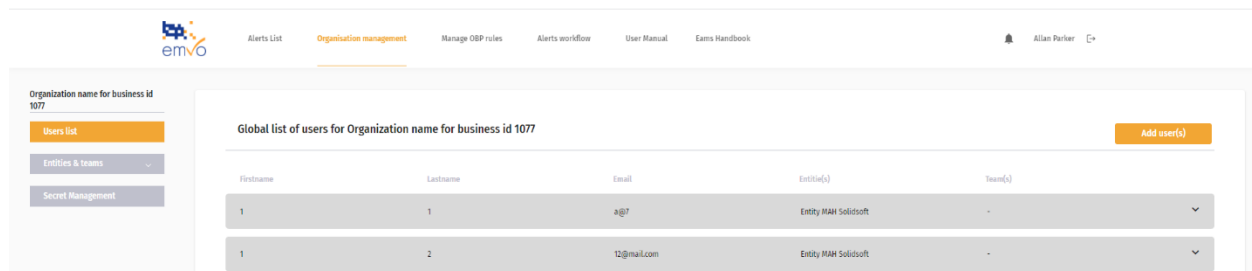


Figure 6.1. Organisation management section

After this, the OBP will be able to access the alert list in the section alert dashboard by accessing the menu at the top of the page.

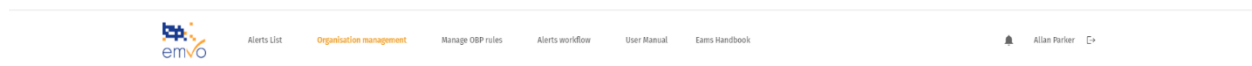



Figure 6.2. Top menu

That will lead the OBP to the **Alerts List** page, where all alerts are listed.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 20 of 74

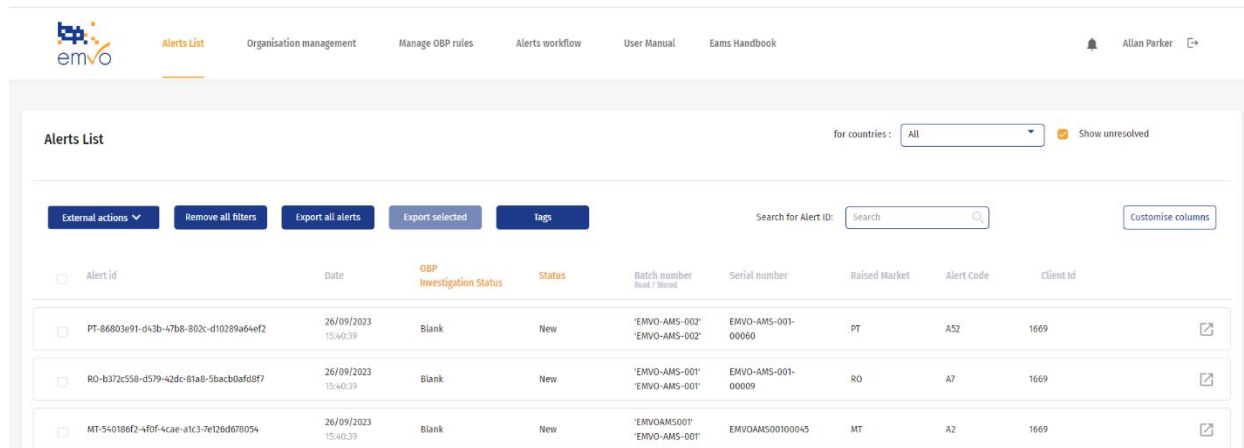



Figure 6.3. Alerts List window

There are also other sections, the table below provides an overview of each section and what they can be used for:

Title	Description	Reference in this document
Alerts List	This section allows users to manage alerts.	Alerts
Organisation management	This section allows users to manage users and teams.	Organisation Management
Manage OBP rules	This section allows users to indicate what rules are applied to the structure of their batch and serial number. This will be relevant to maximise the usage of the AMS Portal. Please check the relevant section for more information.	Manage OBP rules
Alerts workflow	This section offers a concise summary of key considerations that users should keep in mind to accelerate the alert handling process, such as: <ul style="list-style-type: none"> - Suggested actions - Messages received in the last 8 days 	Alerts workflow
User manual	This is a link in the application to the document in hand (EMVO-01376 the EAMS Portal User Manual)	N/A
EAMS Handbook	This is a link in the application to this EAMS Handbook document (EMVO-01392 EAMS Handbook)	N/A

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 21 of 74

7. Organisation Management

7.1. Generic view and actions

The OBP Administrator Users can access the **User Management** screen, where they can see their "**OBP Name**", "**User list**" and their "**Entities & Teams**" through the drop-down menu at the top of the EAMS Portal page.

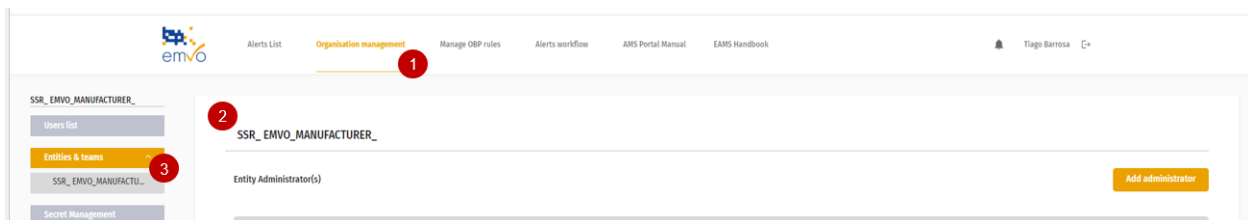


Figure 7.1. OBP User management

NOTE: By default, the Administrators are the SPOC and/or SPOC assistant for each OBP accordingly.

7.2. Managing organization

In order to use the EAMS Portal, global users must be created first. This is available when (1) the "User List" is selected on the left menu and (2) "Add User(s)" is clicked.

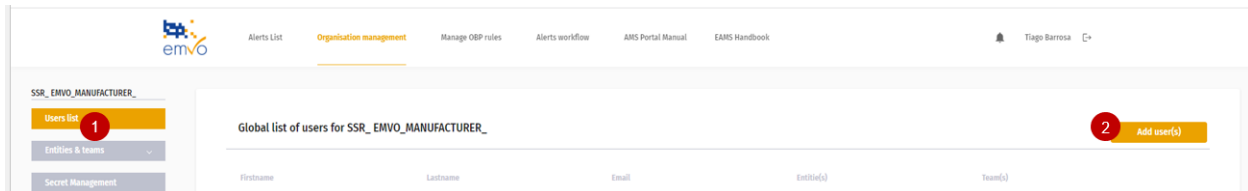



Figure 7.2. Add users

There are only 3 mandatory details needed to be filled in: First name, Last name and Email. All users

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 22 of 74

created by the administrator will receive a confirmation email.

Add users
×




Figure 7.3. Enter user details

Under the "Entities & teams" section on the left menu, where all created teams of an OBP entity can be seen, choose "Add administrator" and choose from the list of users that were created, as shown below.

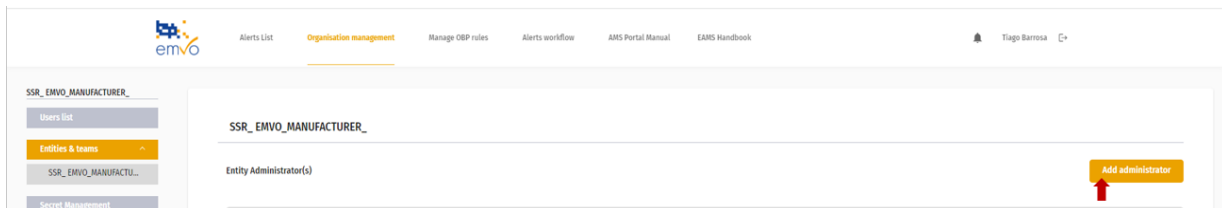



Figure 7.4. Add administrator

Add administrator(s)
×

User for tst TST

test@test.com

Figure 7.5. Choose an administrator for an entity

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 23 of 74

7.3. Managing Teams

If there are no teams or a new one is needed, the OBP administrator should click on “Entity & teams” and (2) on the “Add team” button.

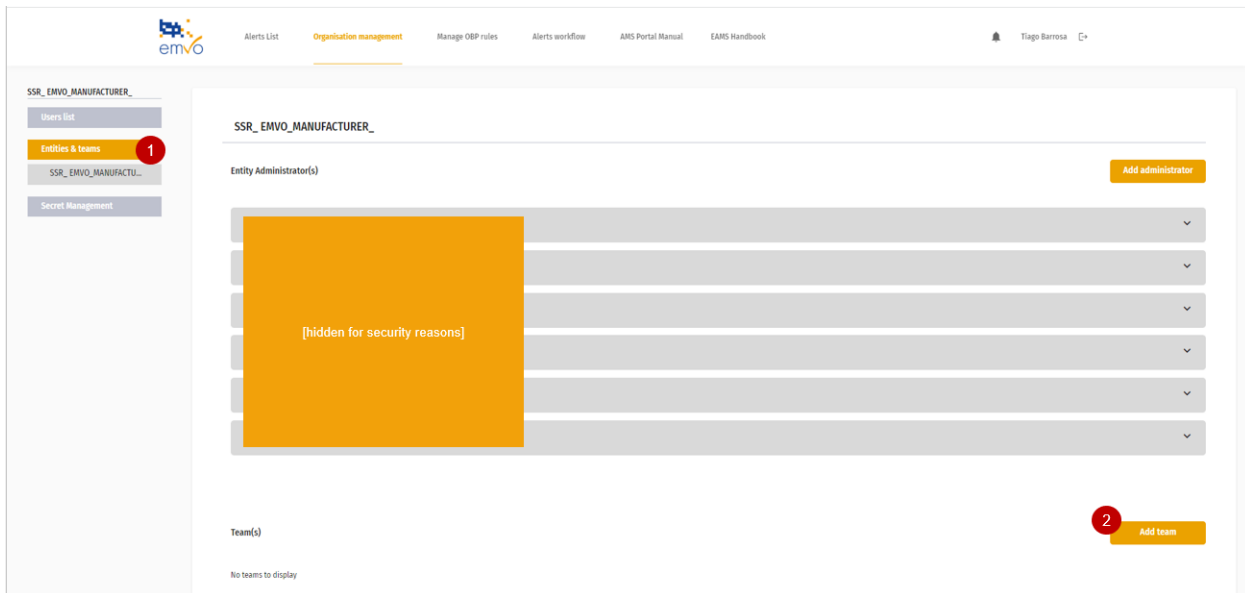


Figure 7.6. Add team

First, the team name must be created (1) and saved (2) so that markets and members can later be assigned to the team.

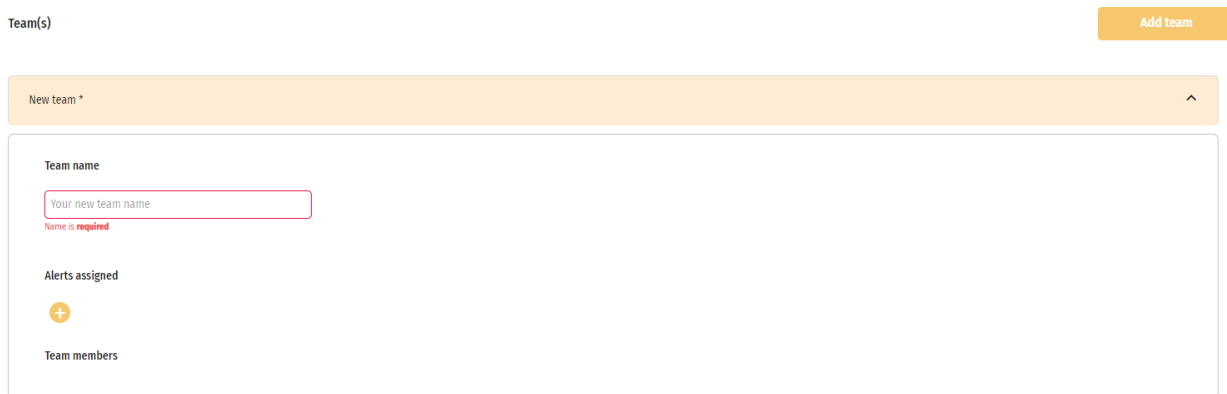


Figure 7.7. Creating a new team





			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 24 of 74

Figure 7.8. Enter team name and save

By clicking on the edit icon  near **"Alerts raised in:..."** under the section **"Alerts assigned"**, the Administrator user can select the countries where alerts are raised in the figure above. The country list is present in the figure below. To assign a member to the team, click on **"Add team member"** and choose from an existing user in the list.

NOTE: If the user is not assigned to any team or if their team has no associated market, then the user will not see alerts in the Alert Management view. The same user can be assigned to several teams with different markets, and that user would see all alerts from the countries specified in these teams' configuration.

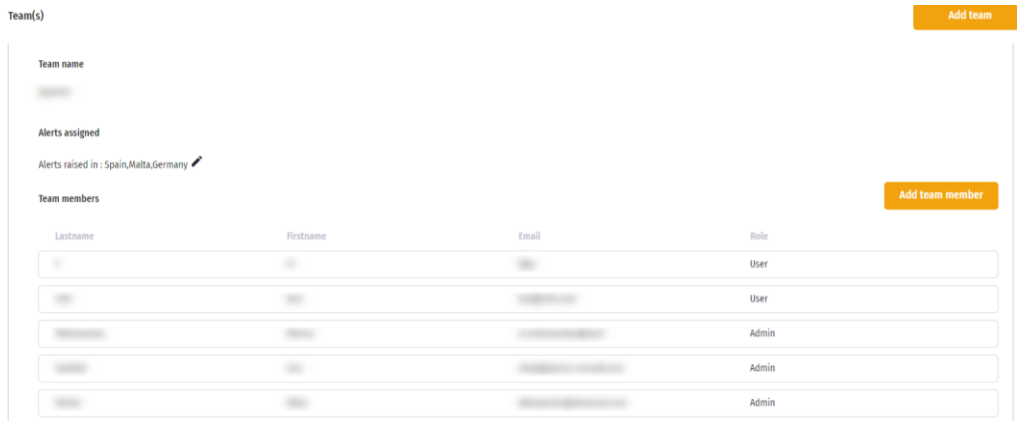


Figure 7.9. Assign user to the team

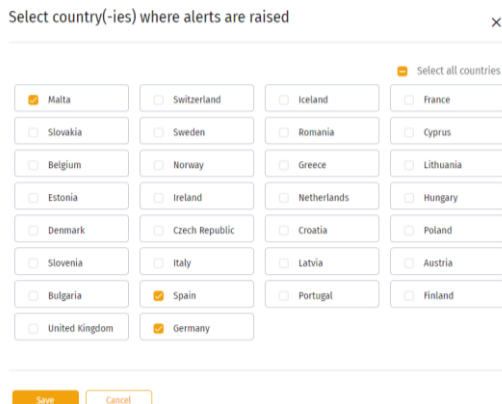



Figure 7.10. Countries list

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 25 of 74


Add member to [blurred] ×

🔍 Search

<input type="checkbox"/>	User for tst TST	test@test.com
<input checked="" type="checkbox"/>	[blurred]	[blurred]
<input type="checkbox"/>	new OBP OBP	obp@email.com
<input checked="" type="checkbox"/>	[blurred]	[blurred]
<input type="checkbox"/>	[blurred]	[blurred]
<input type="checkbox"/>	[blurred]	[blurred]

Add to team
Cancel

Figure 7.11. Select users to the team

To remove the administrator from the list, click on the  icon under the "Entity Administrator(s)" section.

Organization name for business id 1077

Users list

Entities & teams

Entity MAH Solidsoft

Entity MAH Solidsoft (entity)

Entity Administrator(s) Add administrator

new OBP OBP




Firstname	new OBP	Email address	obp@email.com	
Lastname	OBP			

Figure 7.12. Remove administrator

7.4. Remove users and teams

To remove users, the administrator shall go to the "Users list" section. In this section, after expanding the user who needs to be deleted, the administrator shall click on the  icon as per the image below:

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 26 of 74

Firstname	Lastname	Email	Entitie(s)	Team(s)
1	2	12@mail.com	Entity MAH Solidsoft	-

Firstname: Email address: 🗑️

Lastname:

Entity: [Entity MAH Solidsoft](#)

Team: -

Figure 7.13 - Remove users

The same principle applies when removing a team.

Team(s) Add team

Simple does it 🗑️

Figure 7.14 – Remove team

7.5. Client ID and Secret

Each EAMS Organisation is responsible for managing its secrets. We recommend that AMS users take note of when their Client ID Secret expires in order to renew it in a timely manner.

Once the OBP is made aware that a secret renewal is required, they need to login to their AMS’ Dashboard and click on “Alerts” on the top left.

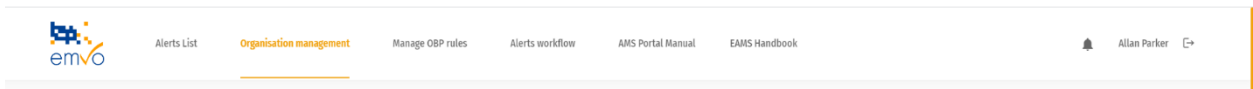

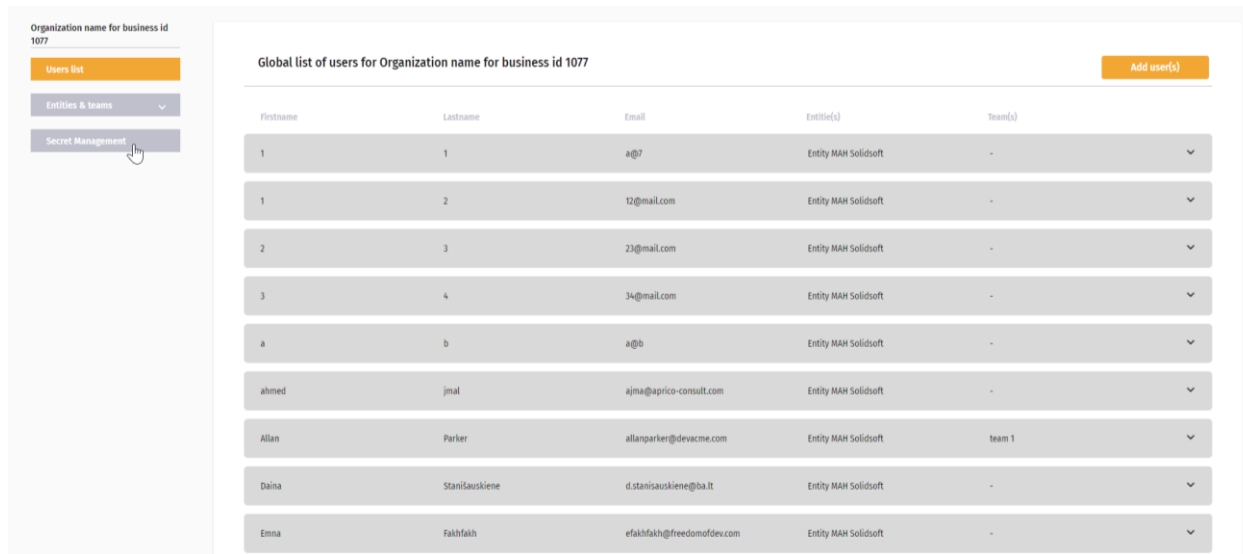


Figure 7.14. AMS’ Dashboard “Alerts” menu

Upon clicking on “Alerts”, the OBP should click on “Users management”. From there, the OBP should click on “Secret Management” on the left of the screen. It can take some time for the page to load.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 27 of 74



Organization name for business id 1077

Users list

Entities & teams

Secret Management

Global list of users for Organization name for business id 1077

Firstname	Lastname	Email	Entite(s)	Team(s)
1	1	a@7	Entity MAH Solidsoft	-
1	2	12@mail.com	Entity MAH Solidsoft	-
2	3	23@mail.com	Entity MAH Solidsoft	-
3	4	34@mail.com	Entity MAH Solidsoft	-
a	b	a@b	Entity MAH Solidsoft	-
ahmed	jmal	ajma@aprico-consult.com	Entity MAH Solidsoft	-
Allan	Parker	allanparker@devacme.com	Entity MAH Solidsoft	team 1
Daina	Stanisauskiene	d.stanisauskiene@ba.lt	Entity MAH Solidsoft	-
Emna	Fakhfakh	efakhfakh@freedomofdev.com	Entity MAH Solidsoft	-

Add user(s)


Figure 7.15 Secret Management option

The OBP user will arrive on the Secret Management page, where they are able:

- To see your secret ID
- To see when your secret will expire
- To see the value of the secret (only at the creation)
- To create a new secret
- To delete your existing secret

Scenario 1: There is already one secret created.

In this case, the OBP can click on "Add Secret", and a new secret will be created.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 28 of 74

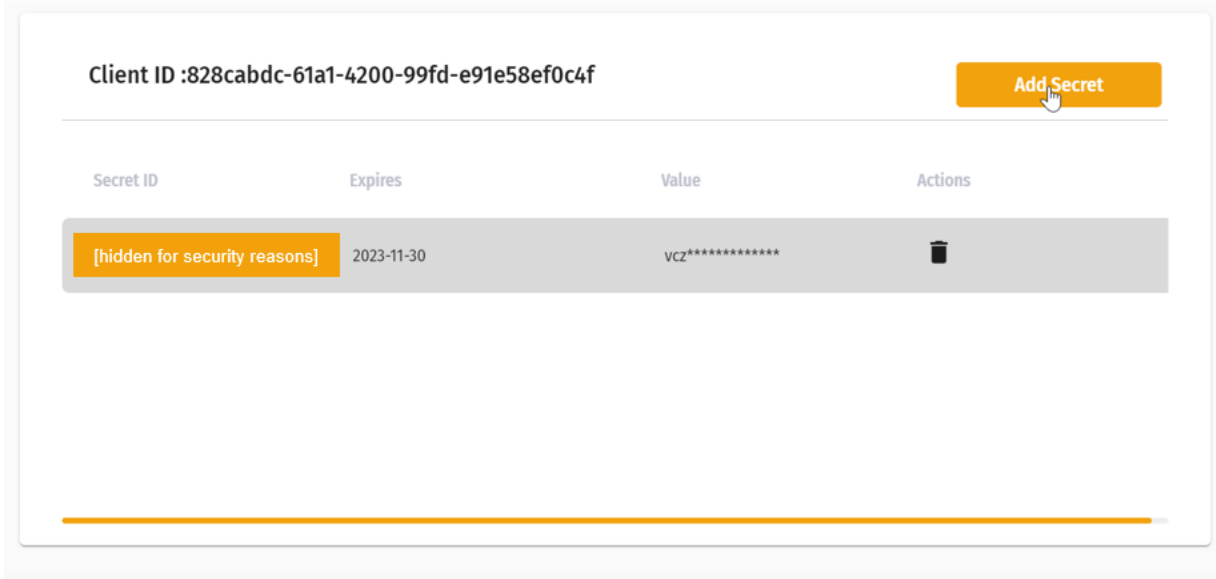


Figure 7.16 Secret Management before clicking on "Add Secret"

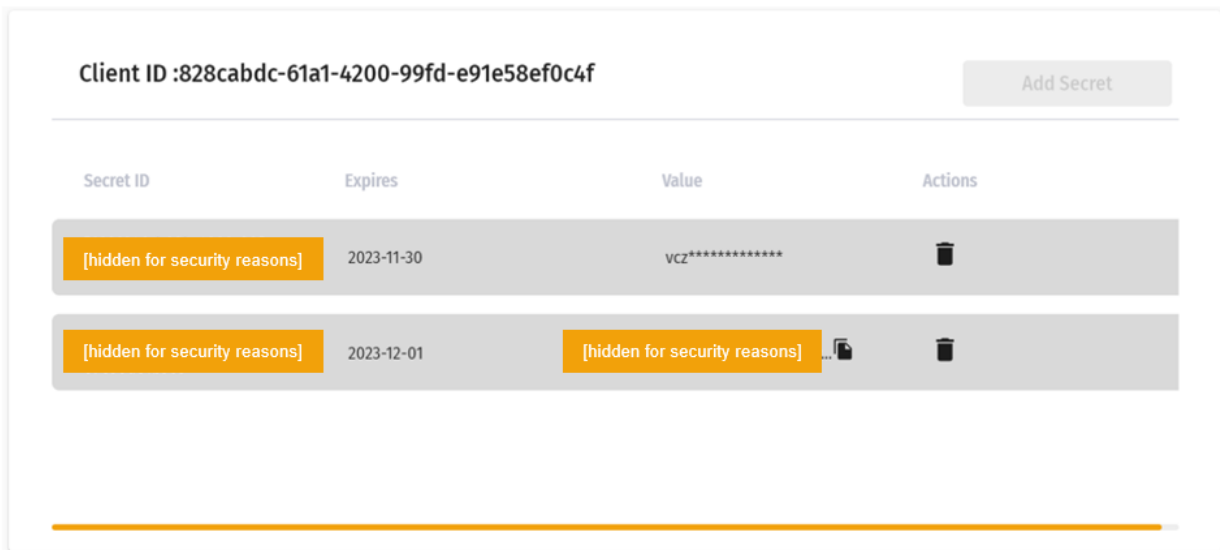



Figure 7.17 Secret Management, after clicking on "Add Secret"

With the creation of this new secret, it will be the only time that an OBP is able to see its value and is able to copy it. **The OBP must click on the "copy" icon to store the secret for later use.**

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 29 of 74

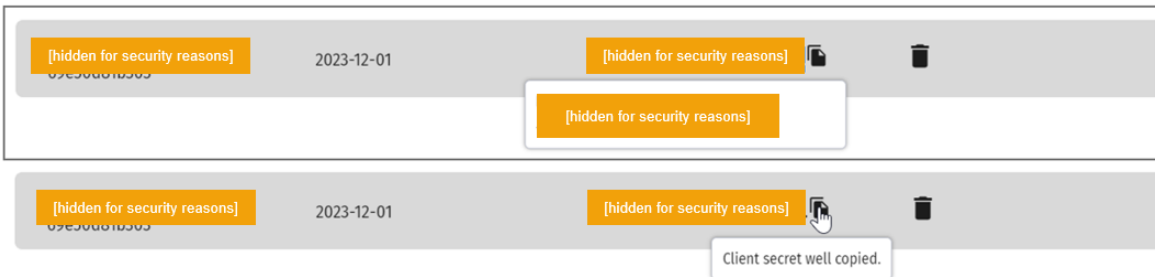


Figure 7.18 One time Secret visibility and option to copy

Since a second secret has been created on the account, the limit of secrets allowed is reached and the "Add Secret" button is disabled.

An OBP can delete the old secret by clicking the "delete" icon and click "Confirm" in the following pop-up window. Once the deletion has been completed, a green notification will confirm the deletion, and the old secret will disappear from the list.

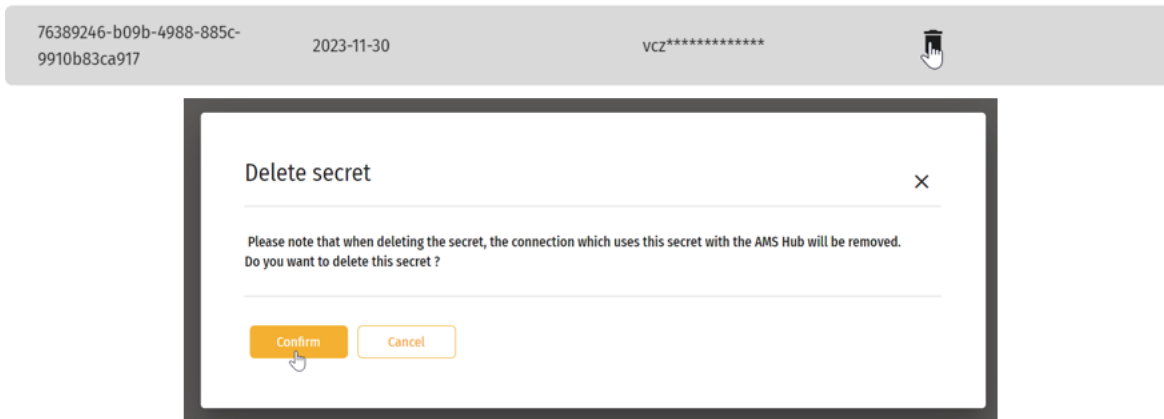



Figure 7.19 Deletion of old secret

Scenario 2: There is no secret created yet.

As in Scenario 1, the OBP has to click on "Add Secret" if they do not have a secret created yet or begin by deleting their secret.

A green window will pop up to confirm the creation of the secret and appear on the OBP's secret management dashboard.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 30 of 74

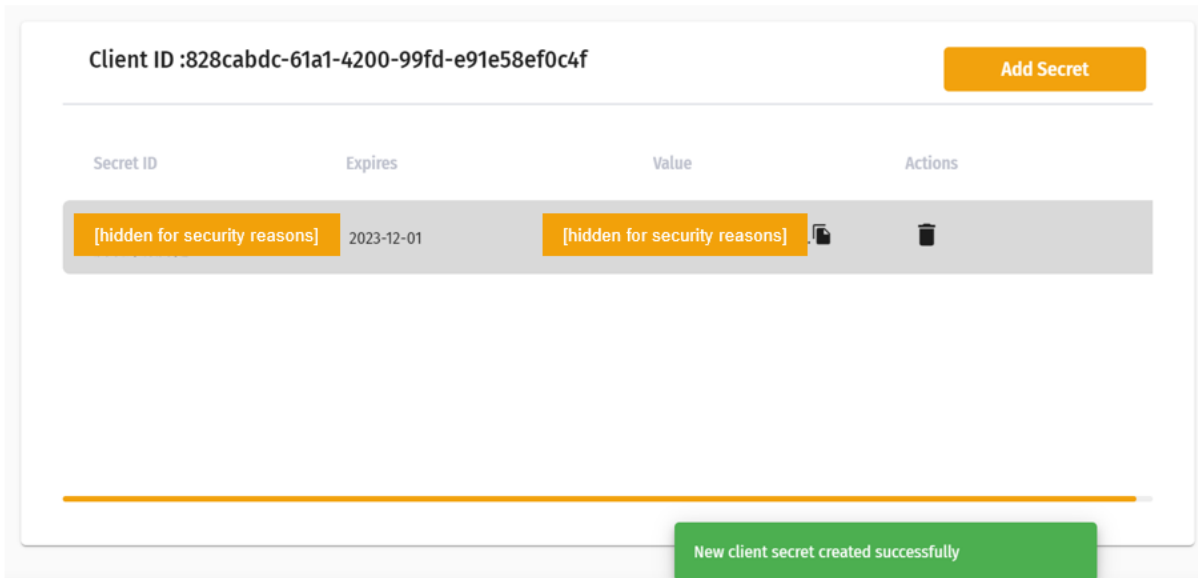


Figure 7.20 Notification of new secret creation


As in Scenario 1, the creation of a new secret will be the only time an OBP can see its value and can copy it.

7.6. OBP User Roles

OBP users must have one of the following roles:


- OBP user
- OBP administrator

The following matrix describes the screens and functions each role can access.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 31 of 74

	Description	Administrator (OBP)	User (OBP)
Screen	User management screen	Yes	No
	Alert Dashborad screen	Yes	Yes
	Alert details management	Yes	Yes
	Messages Section	No	No
	Rules Section (Batch Number / Serial number Paterns)	Yes	No
	Feature	Get credentials	Yes
Add new user to organisation		Yes	No
Manage its own entity		Yes	No
Manage entity administrators		Yes	No
Manage users		Yes	No
Manage teams		Yes	No
Assign alerts to teams		Yes	No
Manage team member		Yes	No
Manage assigning rules		Yes	No
Manage groups		Yes	No
Assign alerts to groups		Yes	No
Consult all alerts		No	No
Consult OBP alerts		Yes	No
Consult and investigate alerts assigned to the teams		Yes	Yes
Consult alerts assigned to this groups		Yes	Yes

Figure 7.21 OBP user role matrix

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 32 of 74

8. Manage OBP rules

This functionality is only accessed by Administrators. To access the "Manage OBP Rules" section in the AMS Portal, the user must go to the menu and then click on "Manage OBP rules". This item is only visible for the OBP administrator(s).

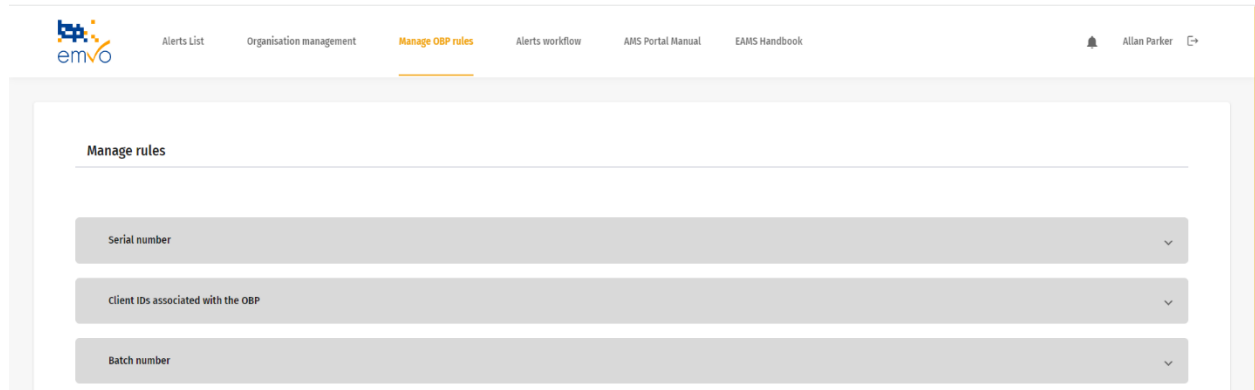


Figure 8.1. Manage OBP rules section


8.1. Serial number

To see mismatches of the serial number, the rules must be set first by that OBP organisation in the Manage OBP rules section. The set rule would highlight when filtering whether the length of the scanned serial number in the alert corresponds to the structure of OBP's stored serial number length. To define the serial number structure, the user goes to the "Manage OBP rules" section, clicks on "Serial number" (1) and on the "+" sign to add a rule (2).



Figure 8.2. Add a rule for serial number

And then the user can enter:

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 33 of 74

- The serial number length is from 1 to 20
- The serial number structure per position, being those:
 - o Digits – numbers, including zero.
 - o Letters – Any upper- and lower-case alphabetical characters
 - o Special characters – Any character from the list below:
 - ? ~ à é è) (* ` ^ ç = \$ £ ¨ ; ; | ° μ - _ ù § ! ` / " [] , %
 - o Specific character - any specific allowed character from the ones above
- Then click on "Save changes" (see figure below)



Figure 8.3. Save new rule of serial number length validation

NOTE: Organisation can have a maximum of 20 rules and each rule can be unique by length.

To remove the rule, the user can simply press the bin icon.

8.2. Batch number


The process for Batch number is identical to the Serial number one.

8.3. Client ID

There is also the opportunity to add the client IDs of wholesalers associated with the OBP. This might be relevant in the context of investigating the alert from those users. For instance, as per the [EAMS Handbook](#), the OBP/MAH should check for those alerts generated by them. However, these might include wholesalers. In this section, the administrators can include those partners.



Figure 8.4 Save new rule of client ID

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 34 of 74

NOTE: Organisation can have a maximum of 20 client IDs.

9. Alerts workflow

This section provides key features to the EAMS Portal users. Users can either check external messages from NMVOs and end-users, or automate actions. To access the "Alerts workflow" section in the EAMS Portal, the user must go to the menu and then click on (1) "Alerts workflow".

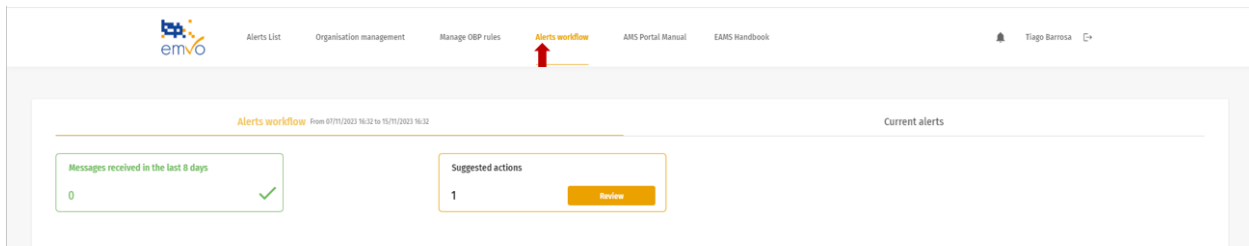


Figure 9.1 Alerts workflow

There are two main sections that allow users to start different workflows. They are described in the following sections.

9.1. Messages received in the last 8 days

This section allows users to check messages received from external parties. This functionality helps to find what incoming messages occurred in any alert for a fast reaction and to find it.

To access this section, the user should click on "View list", which will display all alerts that received a message, ordered by alert creation date.

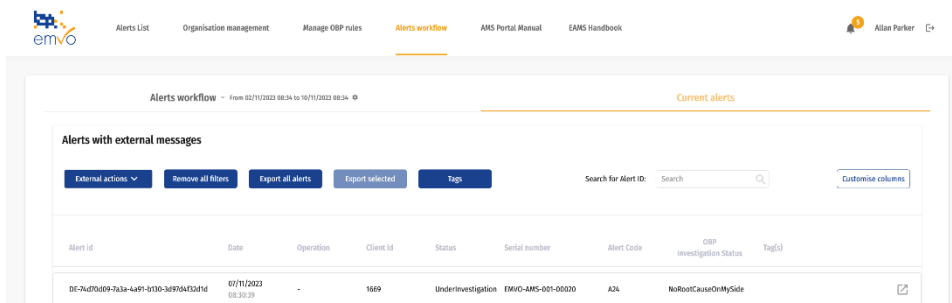



Figure 9.2 Alerts with external messages

9.2. Suggested actions

This section allows users to accept suggested actions based on the alert details. OBPs can perform three actions:

- Accept actions per alerts code

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 35 of 74

- Accept actions per alert code and market
- Automate per alert code and market (limited to Administrators)

The users can also select the countries where the different actions can be performed.

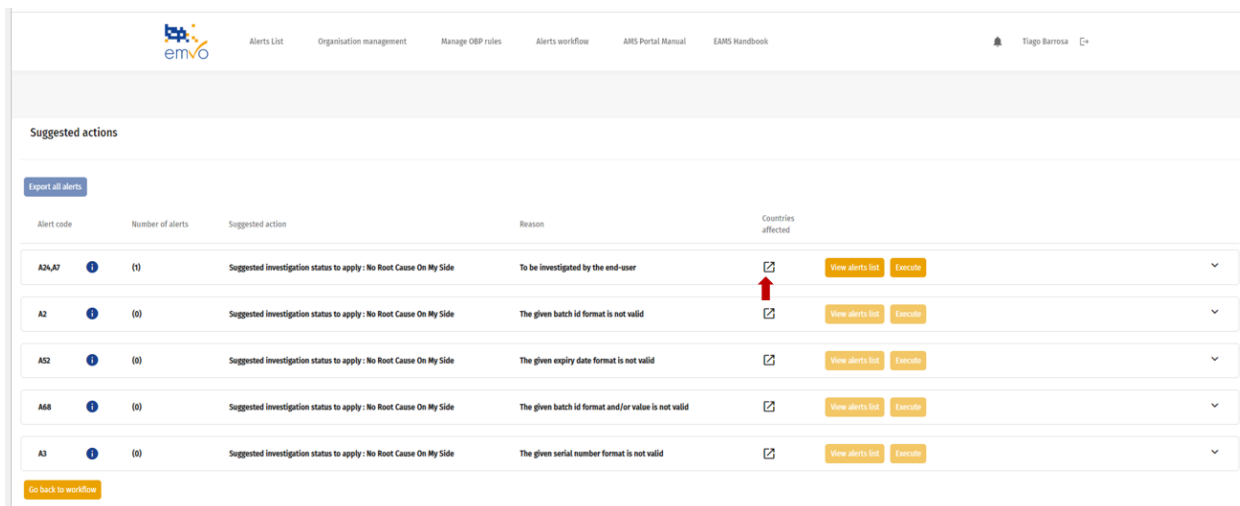


Figure 9.3 Select affected countries

To wrap up this introductory overview of the proposed action, for further details on these actions, the EAMS Portal features an information icon. This icon provides insights into the meaning of the suggested actions and identifies the alerts they impact.

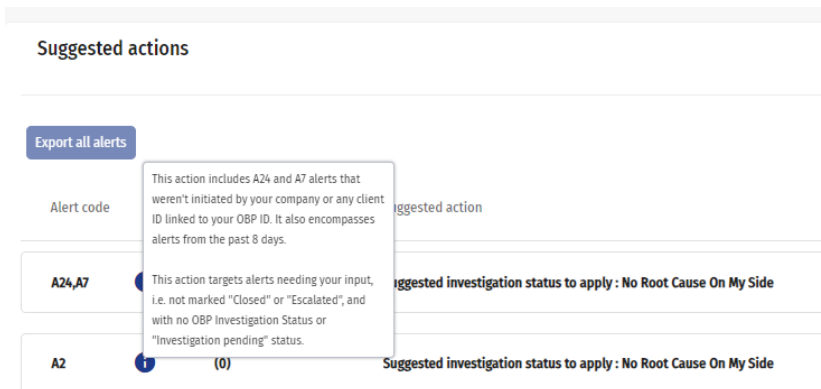



Figure 9.4 Information about the suggested actions

9.2.1. Accept actions per alerts code

This action is accessible to any OBP user, limited to alerts within their access. Alert accessibility is contingent upon the user's assigned country within their respective team. It's important to note that

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 36 of 74

administrators have access to all alerts. Hence, if you centrally manage alerts, the concept of 'teams' may not be pertinent for you.

To accept the suggested actions per alert code, the user only needs to (1) set up the affected countries (a one-time task, saved after selection), (2) press the "Execute" button, and (3) await the notification that will appear to display the result.

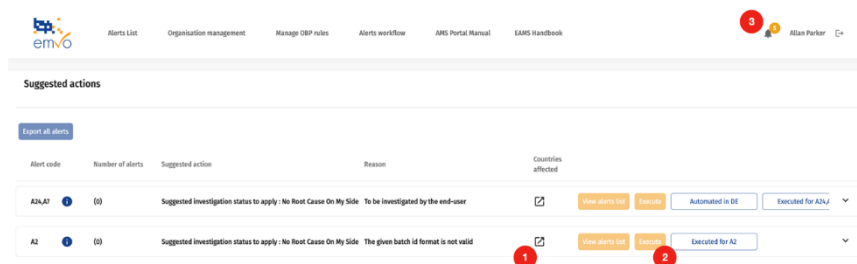


Figure 9.5 Execute suggested actions per alert code.

9.2.2. Accept actions per alert code and market

If the user prefers to execute the suggested action per country or pay special attention to a particular country instead of running it per alert code, they can do so.

To accomplish this, they should (1) expand the view by clicking the arrow on the right, then (2) navigate to the specific country and click on "Execute."

Please note that if the "Execute" button appears greyed out, it may be due to the following reasons:

- The affected country has not been selected
- The number of alerts is 0 (zero)

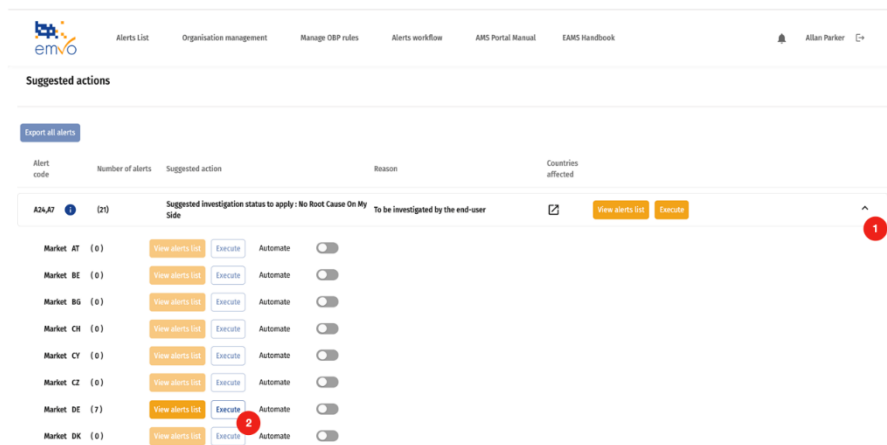



Figure 9.6 Execute suggested actions per alert code and market/country

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 37 of 74

9.2.3. Automate per alert code and market (limited to Administrators)

However, this feature is exclusive to administrator users. Automations serve to streamline repetitive tasks, benefiting all users within a company. The EAMS Portal provides the option to automate all the previously described actions, eliminating the necessity for manual triggering by users. Activating the automation is done on a per-alert code and per-country basis. While configuring it might take some time, the process is straightforward and remains active until the administrator chooses to deactivate it. The procedure mirrors the activation steps.

To set this up, the user must (1) expand the suggested actions and (2) activate the automation for that specific country. To reverse the action, the user follows the same process, but instead of toggling it to turn blue, they must switch it back to grey.

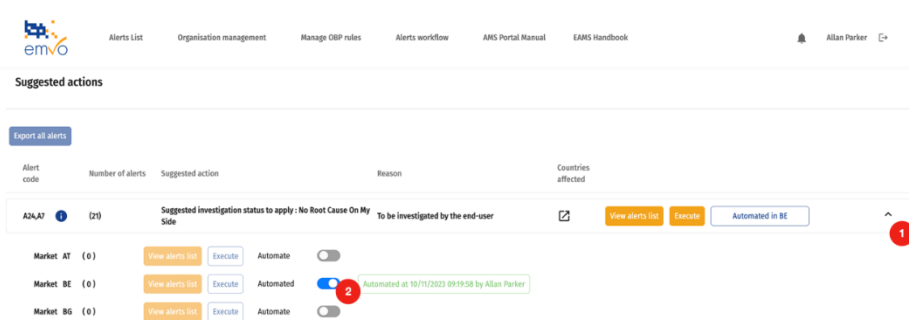


Figure 9.7 Automate suggested actions

10. Alerts List


The following sections will provide you with more information regarding this page.

10.1. Access to alerts

After the successful login, the OBP Users will be able to access the alerts of their organisation based on the teams they have been assigned to and to which markets these teams have been assigned. The alert screen will provide the OBP Users with the following attributes, for each alert displayed, to help them with their investigation.

Those attributes are (displayed by default):

- Alert ID
- Date
- Product
- Batch Number

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 38 of 74

- Expiry Date
- Serial Number
- Alert code
- Alert Status
- National Status

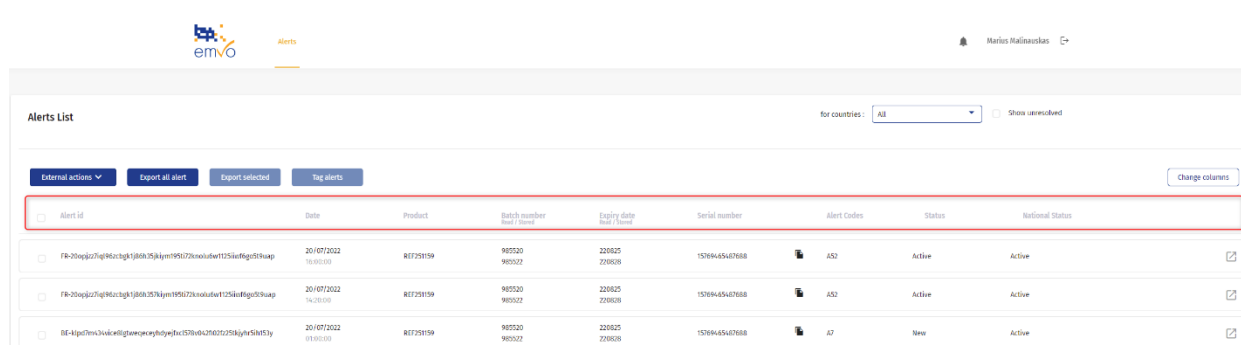



Figure 10.1. Displayed default columns

The EAMS attributes are:

Element	Description	In the EAMS Portal
Remaining hours	Shows the number of hours to solve alerts from the time of its arrival, based per country configuration set by EMVO.	Remaining Hours
Alert status	This reflects the status of the alert. It can be: <ul style="list-style-type: none"> - New - Under investigation - Closed - Escalated - 	Status
OBP ID	The OBP ID which is the responsible to investigate the alert shall be added to the Alert Message to be sent to the EAMS. Any other party will receive the message as it currently is, i.e., no modifications to the alerts API is needed. The element name is "obpid" which shall be passed onto the EAMS. The	OBP ID

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 39 of 74

Element	Description	In the EAMS Portal
	OBP ID shall be represented in the alert message as belonging to the Market ID "EU" and the Client ID the 4-digit which represents the OBP Organisation ID.	
OBP Status	This is the status of the OBP. It can be either "Active", "Inactive" or "Deactivated"	OBP Status
National Status	This is the status of the National AMS. It can be either "Active", "Inactive" or "Deactivated"	National Status
Tag	This is a free value that can be chosen by the OBP to add to alerts. This can be used to find alerts with specific tags.	Tag
[User] investigation status	<p>It allows each user to inform other parties about the status of their activity on the investigation. It can be:</p> <ul style="list-style-type: none"> • Blank; This is the default value and means that the alerts have not been worked on by the corresponding user. • Investigation pending; This is to be used by the user when the investigation has started to let other parties know that they are still investigating. • No root cause on my side; This is to be used by the user when the investigation has been completed and no root cause was identified on their side. • Root cause is on my side; This is to be used by the user when the investigation has been completed and root cause was identified on their side. 	<p>[User] Investigation status</p> <p>User can be:</p> <ul style="list-style-type: none"> - MAH - NMVO - End User - OBP
Last Modification Date	This is the date and time of the last modification done on a specific alert.	Last Modification Date


EMVS fields in the EAMS Portal:




EAMS Portal User Manual

Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 40 of 74

Element	Description	In EAMS Portal
Error Code	EMVS error raised represented by an #AXX (e.g. #A2)	Alert Code
Error Message	Error message described the details of the message that have been provided by the error code	Error Message
Date	Date is the date of the process that causes the alert	Date
Time	Time is the time of the process that causes the alert in UTC	Date
Alert ID	The Alert ID is the unique product return code for the alert	Alert id
Product Code	Product Code is the product code from the pack scanned	Product
Product Code Scheme	Product Code Scheme is either GTIN or PPN reflecting the type of product code above	Product Code Scheme
Serial Number	Serial Number is the serial number from the pack scanned	Serial number
Batch ID	Batch ID is the batch code from the pack scanned	Batch number
Batch Expiry Date	Batch Expiry Date is the expiry date from the pack scanned	Expiry date
Fulfilling Market ID	This field is populate by the European Hub. Upon Verification: Market ID is the ISO country code from the market where authentication of the pack was attempted (where the physical pack resides and was scanned) Upon Product Pack Data Uploads: Market ID where packs are being uploaded to (Fulfilling market)	Raised Market
Source Market	Market ID is the ISO country code from the market where the pack is located. The market ID shall be "EU" if the request comes via the EU-Hub. (Initiating market)	Located Market

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 41 of 74

Element	Description	In EAMS Portal
Client ID	Client ID is the market unique id of the location of the client which initiated the operation and resulted in the alert being raised. It can be either a user connected with the NMVO or and OBP. This identifier does not consider the equipment identifier of the user. In some countries this value might not be consistent and dynamically changes.	Client Id
Manual Entry Flag	Manual Entry Flag is a true/false indication that the data has been manually entered by the end-user connected to the NMVS	Manual Entry
NHRN	NHRN is the national reimbursement number or other national number identifying the medicinal product from the pack scanned	NHRN
Product Name	Product Name is the name of the product held in the NMVS database taken from the master data	Product Name
Client ID of last pack status change	Client ID is the market unique id of the location of the client which last successfully changed the state of the pack that raised the alert. It can be either a user connected with the NMVO or and OBP. This identifier does not consider the equipment identifier of the user. In some countries this value might not be consistent and dynamically changes, this is the case for countries with concentrators (Germany, Spain and Portugal)	Pack Last Update Location
Date and Time of last pack status change	Date and time of the last successful pack state change. The time shall be provided in UTC.	Pack Last Update Date
Market of last pack status change	The market ID is the ISO country code of the market where the last successful pack state change occurred.	Pack Last Update Market
Pack Status in the	Pack Status in the request is the pack state to which the user attempted to do the	Requested Target State

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 42 of 74

Element	Description	In EAMS Portal
request	modification.	
Pack Status Stored	Pack Status Stored is the pack state which is stored in the national system in case of an invalid pack status change.	Actual State
Attempted Operation	The name of the operation conducted by the user or system that caused an alert.	Operation
Stored Batch ID	Stored Batch ID is the batch code stored in the database for the pack just scanned	Batch number
Stored Expiry Date	Stored Expiry Date is the expiry date stored in the database for the pack just scanned	Expiry date
Stored NHRN	Stored NHRN is the NHRN stored in the database for the pack just scanned	NHRN Type
Source Business Process	Source Business Process is the process which was used when the alert was raised.	Business Process

10.2. Change columns

Also, for a more informative look at the alerts, there is a possibility to replace columns by clicking on the "Change columns" button. This allows users to choose other columns into the displayed alert list view, including the option to remove or add a column altogether.

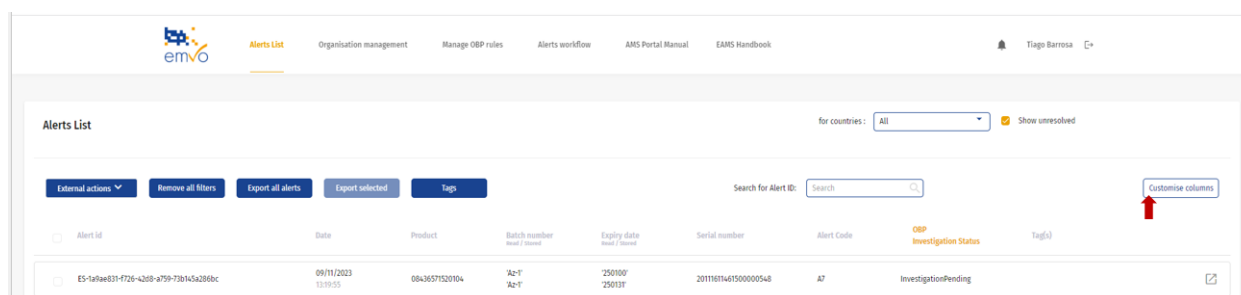



Figure 10.2. Change displayed columns

Any column can be changed with every other column, except for the "Alert ID" column, which is not changeable. After columns are selected, the user should click on "Save changes".

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 43 of 74

Columns can be removed from the displayed list by clicking the “minus” icon next to the column name. Once again, when the change has been performed the user will click on “Save changes” to apply the modifications selected.

Note: the maximum column amount is 10.

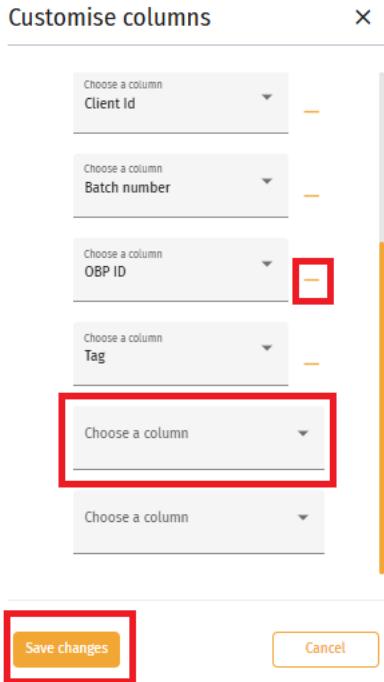



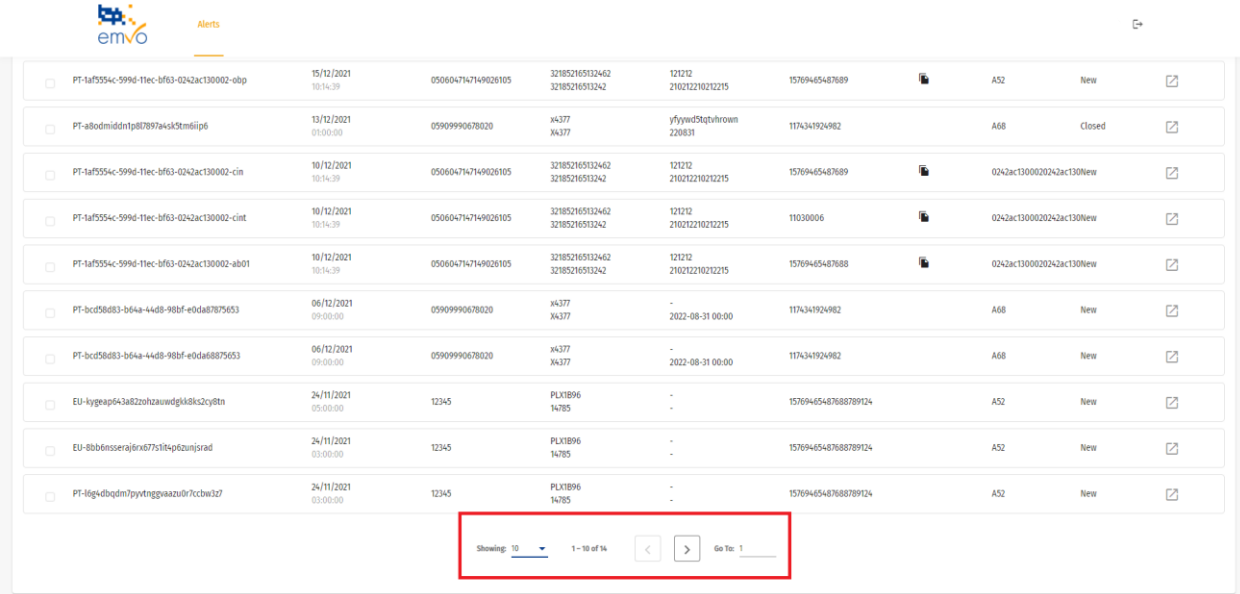
Figure 10.3. Save, remove, add or change columns

10.3. Select alerts and Page navigation

The OBP users can navigate to see every alert for their organisation, but also navigate through pages or even change the number of alerts that will be displayed on every page. To do so, the OBP user will have to scroll down the alert list.

There is a limit for this selection of 200 number of alerts.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 44 of 74



Alert ID	Date	Status	Other Info
PT-1af5554c-599d-11ec-bf63-0242ac130002-ebp	15/12/2021 10:14:39	0506047147149026105	321852165132462 32185216513242
PT-ab0dmidn1p8l7897a5k5tmilip6	13/12/2021 05:00:00	05909990678020	x4377 x4377
PT-1af5554c-599d-11ec-bf63-0242ac130002-cin	10/12/2021 10:14:39	0506047147149026105	321852165132462 32185216513242
PT-1af5554c-599d-11ec-bf63-0242ac130002-clint	10/12/2021 10:14:39	0506047147149026105	321852165132462 32185216513242
PT-1af5554c-599d-11ec-bf63-0242ac130002-ab01	10/12/2021 10:14:39	0506047147149026105	321852165132462 32185216513242
PT-bcd58683-b64a-44d8-98bf-e0da68875653	06/12/2021 09:00:00	05909990678020	x4377 x4377
PT-bcd58683-b64a-44d8-98bf-e0da68875653	06/12/2021 09:00:00	05909990678020	x4377 x4377
EU-kygeap643a8220zauwdjgk8ks2cy8tn	24/11/2021 05:00:00	12345	PLX1896 14785
EU-8bb6esseraj6m675104p62unjsrad	24/11/2021 03:00:00	12345	PLX1896 14785
PT-l8g4dbqdm7pyrtnngvaazu0r7ccbw3z7	24/11/2021 03:00:00	12345	PLX1896 14785

Showing: 10 1 - 10 of 14 < > Go To: 1

Figure 10.4. Navigation pane

The "Showing: X-X of X" shows the number of alerts available in the AMS Portal Alerts List whereas the "Go To:" refers to the page number.

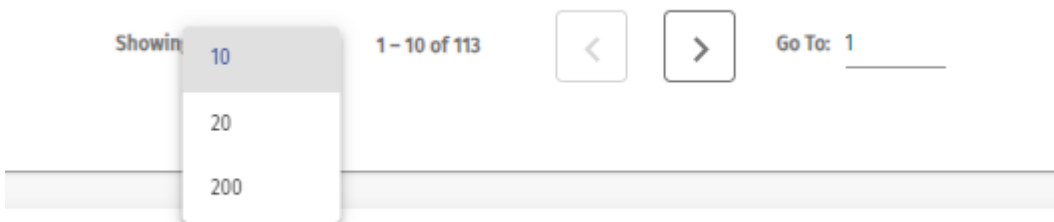



Figure 10.5. Navigation pane details

10.4. Select all

The EAMS Portal imposes a restriction, allowing users to select and display only up to 200 alerts at once. When this limit is reached, triggering a click action prompts the EAMS Portal to refresh and exhibit the initial set of 200 alerts, sorted according to the specified columns. The default ordering of alerts is based on the date and time of their origination.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 45 of 74

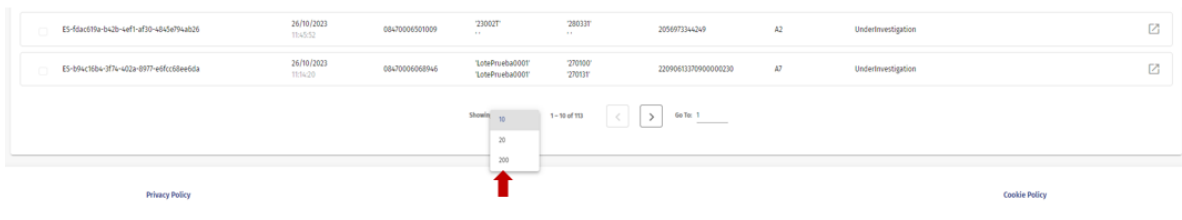


Figure 10.6 - Selecting 200 alerts

10.5. Notifications

The user will see a notification icon with a yellow numbered bubble under their name in the upper right corner.

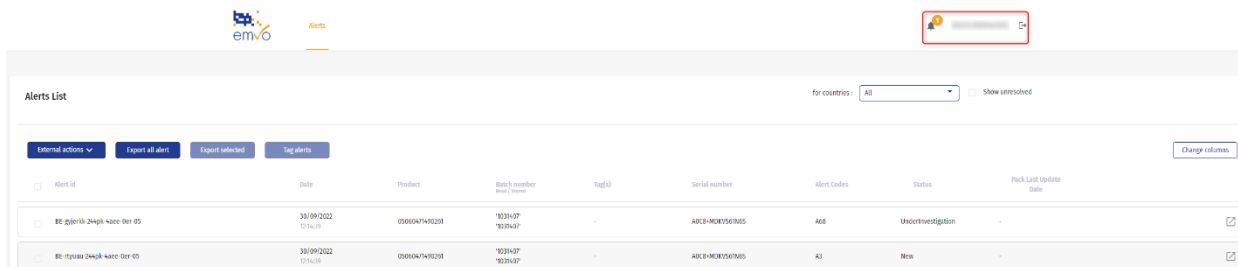


Figure 10.7. Notification icon

Whenever the user executes their actions, they are processed by the AMS Portal. To read the notification, the user can click each notification surrounded by a green line or click **“Mark all as read”**.

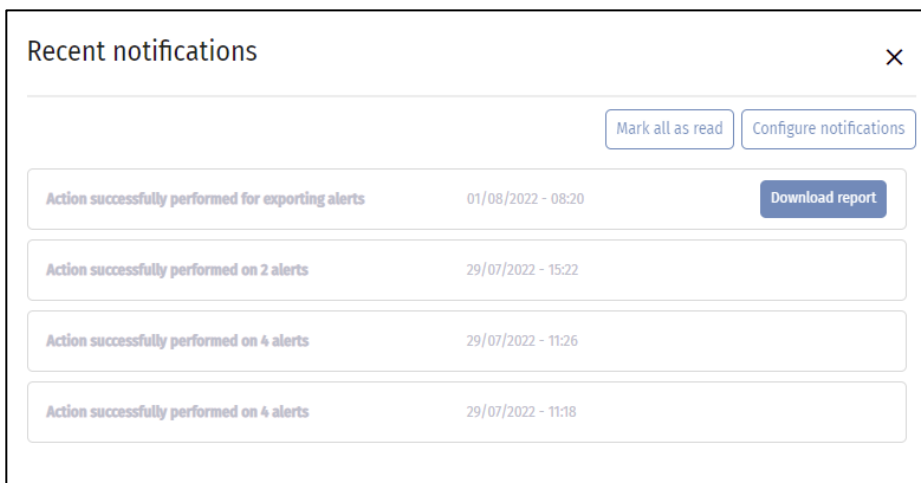



Figure 10.8. Notifications screen

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 46 of 74

Actions resulting in notifications once processed, are:

1. When "Exporting all" alerts from the list. Clicking on the notification icon will give the notifications screen with the possibility to "**Download report**" button.


NOTE: The user can download a report only once.
2. When "Changing Alert status" multiple (bulk) alerts, and the action was:
 - a. Failure. Clicking on the notification icon will give the notifications screen with the possibility to "**See details**" for a list of alerts that failed to be processed and to download a CSV file.
3. When "Changing Investigation status" multiple (bulk) alerts, and the action was:
 - a. Failure. Clicking on the notification icon will give the notifications screen with the possibility to "**See details**" for a list of alerts that failed to be processed and to download a CSV file.
4. When "Importing Investigation status change" with .CSV file and the action was:
 - a. Successful.
 - b. Failed

Recent notifications ×

Mark all as read
Configure notifications

Errors found on batch action on 65 alerts	03/08/2022 - 09:59	See details
Action successfully performed on 65 alerts	03/08/2022 - 07:39	
Action successfully performed on 2 alerts	02/08/2022 - 13:52	
Action successfully performed on 2 alerts	02/08/2022 - 13:31	

Figure 10.9. Notification of failed action

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 47 of 74

< Batch reference 03090000-3aab-000d-6290-08da7536d275

×

Action performed : Change status

N# of alerts : 65

Date/Time : 03/08/2022 - 09:59

Download report (.csv)

✓ 56 alert(s) successfully updated

✗ 9 alert(s) failed to update with error : Alert can not be de-escalated

Tag alerts


Figure 10.10. Download .CSV of failed actions

10.6. Filtering and sorting

By default, when the user logs into the EAMS Portal, it will only display the alerts from the last 31 days with are unresolved. Users have the flexibility to choose any timeframe within a 31-day range. It's important to note that alerts inactive for 180 days or more are automatically archived. For detailed information on this process, please refer to Section 12.Archived alerts. Unresolved means that the system, anytime the user is at the Alerts list, filters alerts with the following criteria:

- OBP Investigation status is:
 - Blank
 - Investigation pending
- Alert status is:
 - New
 - Under Investigation
 - Active

Remaining on the Alert management page, the OBP Users can filter the Alert List by these attributes **"Alert ID", "Product", "Batch Number", "Expiry date", "Serial Number", "Remaining hours", "Alert Code", Alert "Status", "Raised Market",** all **"Investigation Status"** attributes and **"Tag"** by clicking on column header as shown below.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 48 of 74

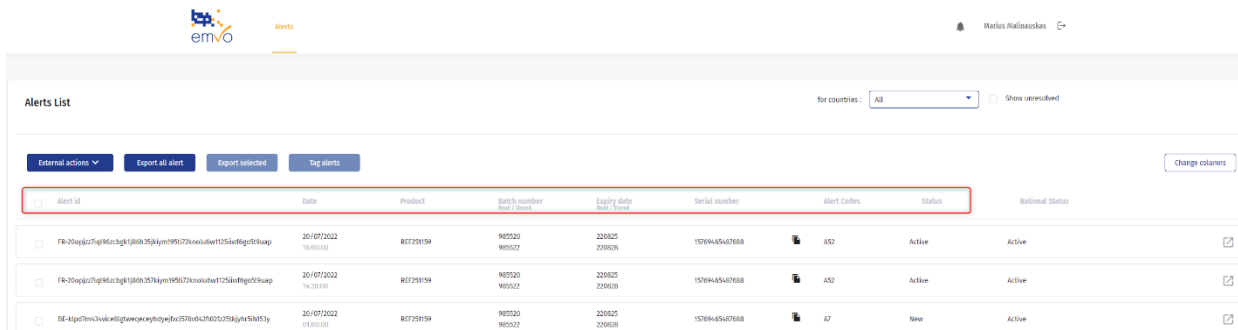


Figure 10.11. Filtering from the header

One of those attributes (as listed above), a filter menu opens, where the OBP Users can choose from different filter options to be displayed in the Alert List.

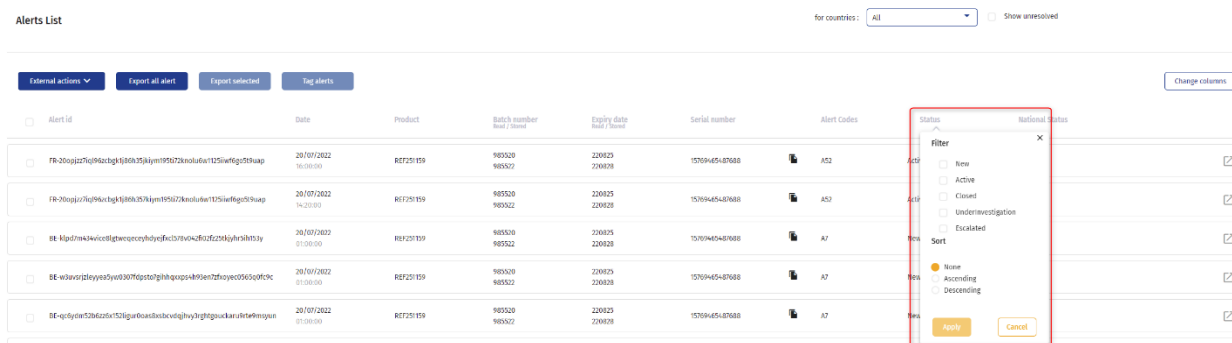


Figure 10.12. Filter menu with options

For example, the OBP wants to filter all alert IDs containing "PT-", to display alerts raised in Portugal. The OBP will type "PT-" in the filter section for alert ID.

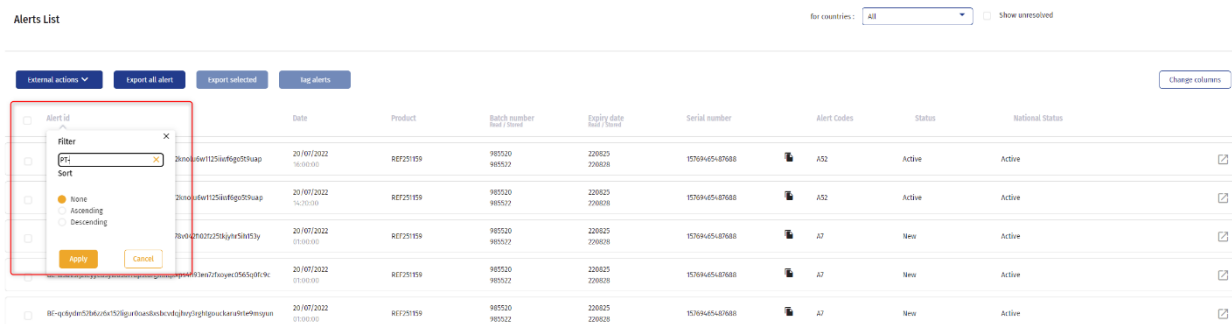



Figure 10.13. Typing in the filters

NOTE: The filters for "Alert ID", "Product", "Batch Number", "Expiry date", "Serial Number" and "Remaining hours" are all fields that have free text fields.

The filters for "Alert Code", Alert "Status", "Raised Market", all "Investigation Status"

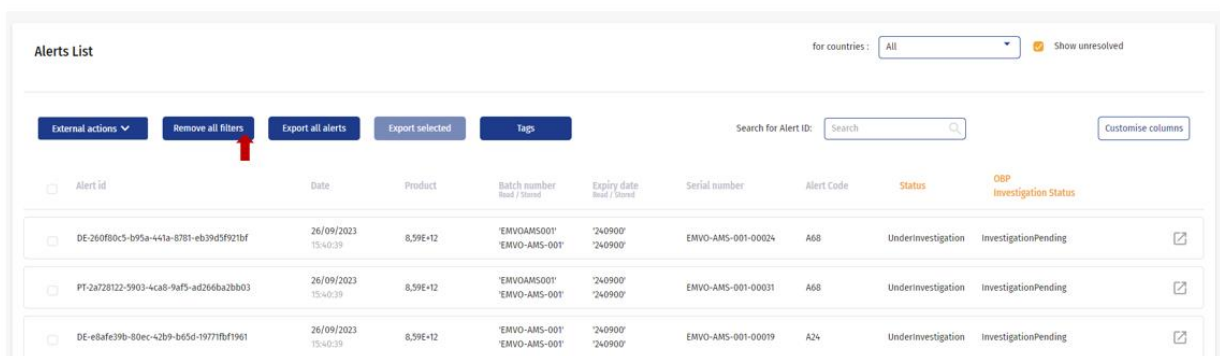
			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 49 of 74

attributes and **"Tag"** have pre-defined values as options to choose.

NOTE: "Alert code" column has unified alert codes: A2, A3, A7, A24, A52, A68, Other.

Once the OBP Users choose the filters they want to be displayed, then they should press **"Apply"** in order for the requested changes to take place.

In case the OBP Users want to undo the filters, then they can press the **"Remove all filters"** button.



The screenshot shows the 'Alerts List' interface. At the top right, there is a dropdown menu for 'for countries:' set to 'All' and a 'Show unresolved' button. Below this, there are several action buttons: 'External actions', 'Remove all filters' (highlighted with a red arrow), 'Export all alerts', 'Export selected', and 'Tags'. A search bar for 'Alert ID' is also present. The main table displays a list of alerts with columns for Alert id, Date, Product, Batch number, Expiry date, Serial number, Alert Code, Status, and OBP Investigation Status. Three alerts are visible, all with a status of 'UnderInvestigation' and 'InvestigationPending'.

Alert id	Date	Product	Batch number Real / Simul	Expiry date Real / Simul	Serial number	Alert Code	Status	OBP Investigation Status
DE-260f80c5-b95a-441a-8781-eb39d5f921bf	26/09/2023 15:40:39	8,59E+12	EMVOAMS001 EMVO-AMS-001	240900 240900	EMVO-AMS-001-00024	A68	UnderInvestigation	InvestigationPending
PT-2a728122-5903-4ca8-9af5-ad266ba2bb03	26/09/2023 15:40:39	8,59E+12	EMVOAMS001 EMVO-AMS-001	240900 240900	EMVO-AMS-001-00031	A68	UnderInvestigation	InvestigationPending
DE-e8afe39b-80ec-42b9-b65d-19771bf1961	26/09/2023 15:40:39	8,59E+12	EMVO-AMS-001 EMVO-AMS-001	240900 240900	EMVO-AMS-001-00019	A24	UnderInvestigation	InvestigationPending

Figure 10.14. Remove filtering

NOTE: The button becomes active only when at least one filter is active. If no filters are active, then the button will not be displayed.


10.7. By default view – Unresolved alerts

By default, OBP users will have visibility into all "Unresolved alerts." These alerts encompass the following status categories:

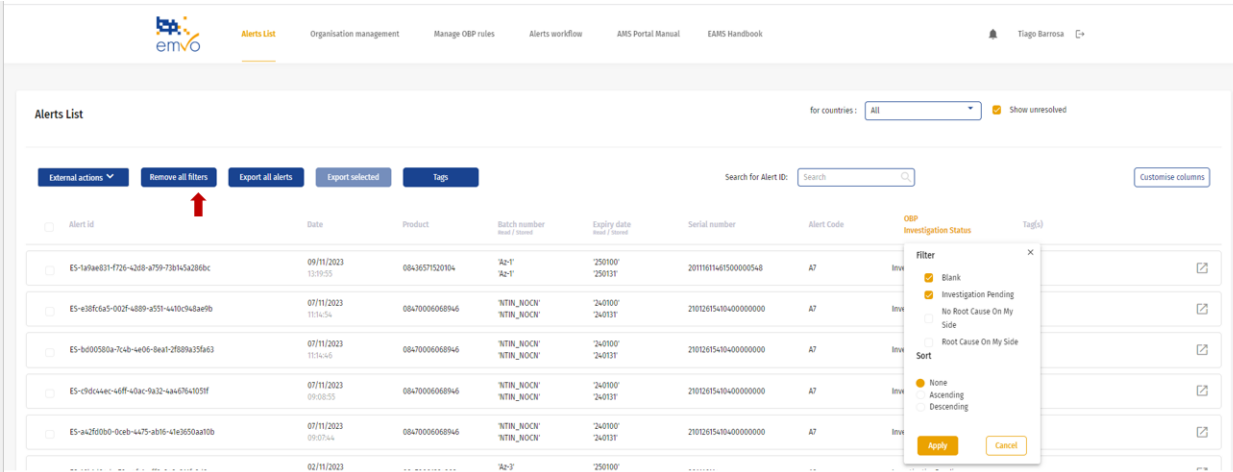
- **New Alerts:** These alerts have recently been generated and have not yet undergone review or assignment for further investigation.
- **Under Investigation Alerts:** Alerts falling under this category are currently being assessed and investigated by OBP users or designated team members. They are actively undergoing scrutiny to determine their validity and potential impact.
- **OBP Investigation Status - Blank:** This status indicates alerts for which the OBP user has not initiated any investigation or taken any action yet. These alerts await attention and input from the OBP user.
- **OBP Investigation Status - Investigation Pending:** Alerts in this category are actively under investigation by the OBP user. This status is used to denote alerts that are currently being examined, with a pending decision or resolution action.

Alerts are categorised based on their new, under investigation, or investigation pending status to streamline the alert resolution process.

Once again, in case the OBP Users want to undo the **"Show Unresolved"** filter, then they can press the

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 50 of 74

“Remove all filters” button.



The screenshot shows the 'Alerts List' page in the EAMS Portal. At the top, there are navigation tabs: Alerts List, Organisation management, Manage OBP rules, Alerts workflow, AMS Portal Manual, and EAMS Handbook. The user profile 'Tiago Barrosa' is visible in the top right. Below the navigation, there are buttons for 'External actions', 'Remove all filters' (highlighted with a red arrow), 'Export all alerts', 'Export selected', and 'Tags'. A search bar for 'Alert ID' is present. The main table lists alerts with columns: Alert ID, Date, Product, Batch number, Expiry date, Serial number, Alert Code, OBP Investigation Status, and Tag(s). A filter dropdown menu is open over the 'OBP Investigation Status' column, showing options: Blank, Investigation Pending, No Root Cause On My Side, and Root Cause On My Side. The 'Sort' dropdown shows options: None, Ascending, and Descending. There are 'Apply' and 'Cancel' buttons at the bottom of the filter menu.


Figure 10.15. Show unresolved alerts

10.8. See connected countries

There is a helpful function for users to filter by countries which use the AMS. When this option is selected, AMS Portal automatically filters the table with the countries subscribed to the AMS Hub. Please note that countries can be subscribed to and not use the EAMS in production. Currently, the countries connected to the AMS are:

- Austria
- Belgium-Luxembourg
- Bulgaria
- Cyprus
- France
- Germany
- Iceland
- Poland
- Slovenia
- Spain

When the option "Countries not using AMS" is selected, then the AMS portal filters the table with countries not subscribed to the AMS hub (inactive) and deactivated. This filter is reflected under "National status" column and is highlighted in orange.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 51 of 74

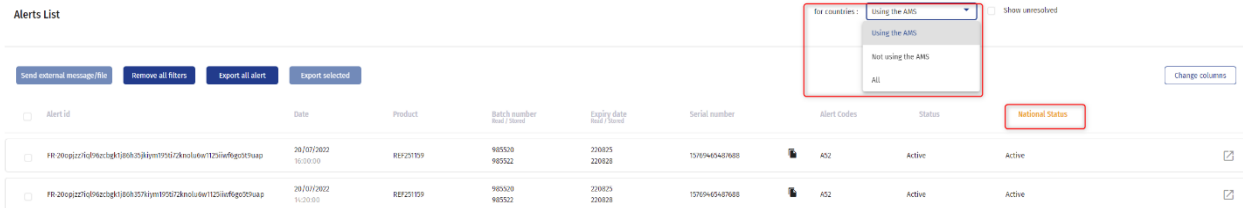


Figure 10.16. Filter National status

10.9. Show mismatches only

Another special filtering is for "Serial Number", "Batch number" and Expiry date columns. When clicking on this column, it will show not only a free text field but also a selectable option to "Show mismatches only". If this is selected, the EAMS Portal will compare the alert values as in the following table:

Column	Check
Serial number	The EAMS Portal will check the alert serial number against the rule set in the "Manage OBP rules".
Batch number	The EAMS Portal will check the alert scanned batch number with the read one.
Expiry date	The EAMS Portal will check if the alert expiry date is correctly formatted. The correct format is based on calendar days and should be within the 5 years after the current date, and cannot be in the past. YY represents the year, MM represents the month, or DD represents the last day of the month (DD is 28, 29, 30 or 31).

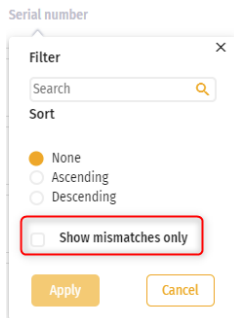




Figure 10.17. Show mismatches only for Serial Number

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 52 of 74

10.10. Alerts with multiple Serial numbers

In cases the alert contains multiple serial numbers, the alert will be displayed as follows. The user can see the full list of serial numbers when clicking on the icon () next to the displayed serial number.

Alert id	Date	Product	Batch number <small>Read / Stored</small>	Expiry date <small>Read / Stored</small>	Serial number	Code	Status
<input type="checkbox"/> EU-kygeap643a82zohzaawdjk8ks2cy6tn	24/11/2021 <small>05:00:00</small>	T2345	PLX1896 14785	42y5yqth5ebw2ykpuc18jey4 m0mk406p9v4h5nllkoxszedj	 15769465487688789124	AS2	New 

Figure 10.18. Multiple serial numbers icon

10.11. Tag alerts – organise alerts by tags

Lastly, the “Tag(s)” column can be filtered only by the values that are created by an OBP admin user, but the “Tag(s)” column with values is visible to all users of that organisation.

Two special operands come with it together: “OR” and “AND”. It is useful when there are multiple tags placed on one alert. If “OR” is selected, then those alerts will be shown that have one or another tag on them. If “AND” is selected, then those alerts will be shown which have the same tags selected at the same time.

For example, if “OR” is chosen and two tags are selected as shown here, the result would show both alerts that have tags “New_tag_example” **or** “New_tag_example2”. If “AND” is chosen with two tags selected as shown here, the result would show only one alert that has tags “New_tag_example” **and** “New_tag_example2”.

Tag(s)
Serial number

Filter
✕

Or And

tag18

tag19


tag21

New_tag_example

New_tag_example2

Apply
Cancel

Figure 10.19. Tags filtering

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 53 of 74

Alert id	Date	Product	Batch number Read / Stored	Tag(s)
<input type="checkbox"/> BE-e2f68947-5j09-4e93-8907-e602dd740670	26/07/2022 08:56:39	05060471490261	1031407 1031407	+ 1
<input type="checkbox"/> BE-e2f68947-5j09-4e93-8907-e602dd740679	26/07/2022 08:56:39	05060471490261	1031407 1031407	

Figure 10.20. Filtering tags with "OR" example

Alert id	Date	Product	Batch number Read / Stored	Tag(s)
<input type="checkbox"/> BE-e2f68947-5j09-4e93-8907-e602dd740670	26/07/2022 08:56:39	05060471490261	1031407 1031407	+ 1

Figure 10.21. Filtering tags with "AND" example

Sorting can be enabled via the header of the chosen column. The list of attributes below can be sorted by ascending or descending order:

"Alert ID", "Product", "Batch Number", "Expiry date", "Serial Number" and "Remaining hours", "Alert Code", Alert "Status", "Raised Market", all "Investigation Status" attributes and "Tag".

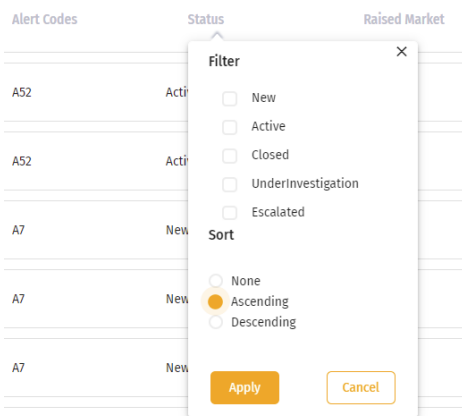



Figure 10.22. Sorting

NOTE: these attributes **"Located market", "Obp Id", "Obp status", "Product code scheme", "Product name", "Error message", "Client id", "Manual entry", "Request target state", "Actual state", "Pack last update location", "Nhrn type", "Pack Last Update Date", "Pack Last Update Market", "Operation" and "Business process"** cannot be filtered or sorted.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 54 of 74

10.12. Exporting alerts

There are two ways of exporting alerts to CSV format from the Alert Management window:

1. Export all alerts,
2. Export selected.

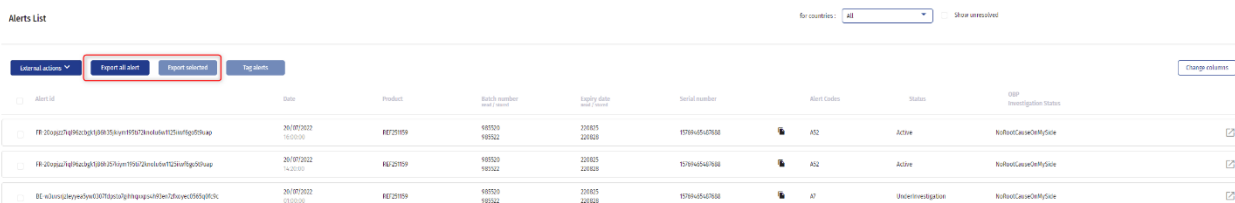


Figure 10.23. Export options in the Alert Management window

When clicking on the “**Export all alerts**” button, it will show a date interval field to choose from which period alerts should be exported (**NOTE**: date interval cannot exceed 31 31-day range).

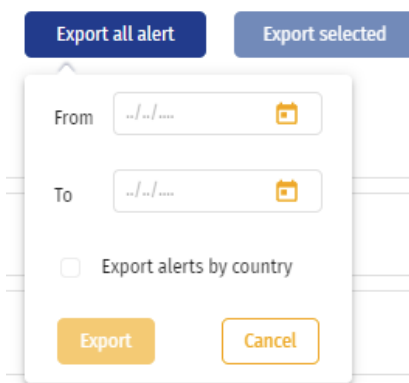


Figure 10.24. Date interval for exporting all alerts action

Then the confirmation window will be presented if the user intends to export for the given period by clicking the “confirm” button.

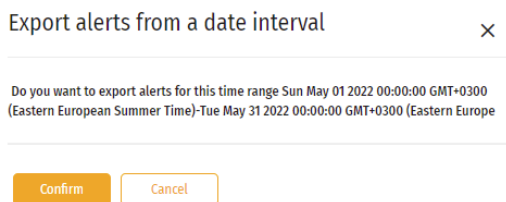



Figure 10.25. Confirm export all alerts action

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 55 of 74

The report generation might take up to a few minutes to be ready to download. The user will see a notification icon under their name in the upper-right corner. Clicking on the notification icon will give the notifications screen with the possibility to **"Download report"** button. **NOTE:** The user can download a report only once.

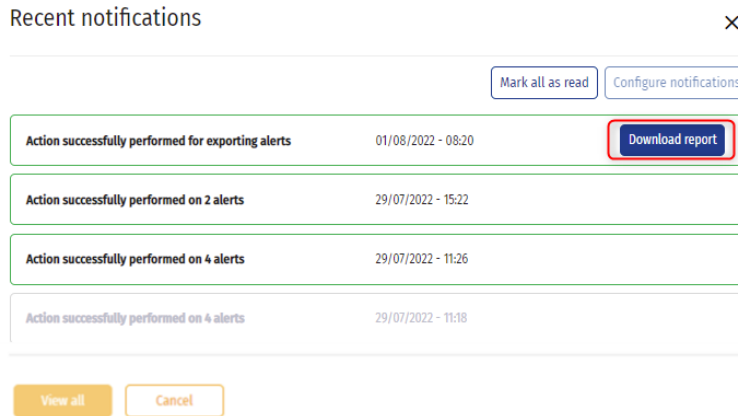


Figure 10.26. Downloading report

Also, from the "Export all alerts" there is a possibility to select **"Export alert by country"** which generates a .zip file containing individual .csv files per country.

Name




-  ams-portal-export-BE-10
-  ams-portal-export-DE-87

Figure 10.27. CSV export by countries example

For the **"Export selected"** action, the user must first select alerts from the list before this action is enabled. The user can select one by one (1) in the list or by clicking the selection square on the **"Alert ID"** column (2), which selects all alerts in the current page.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 56 of 74

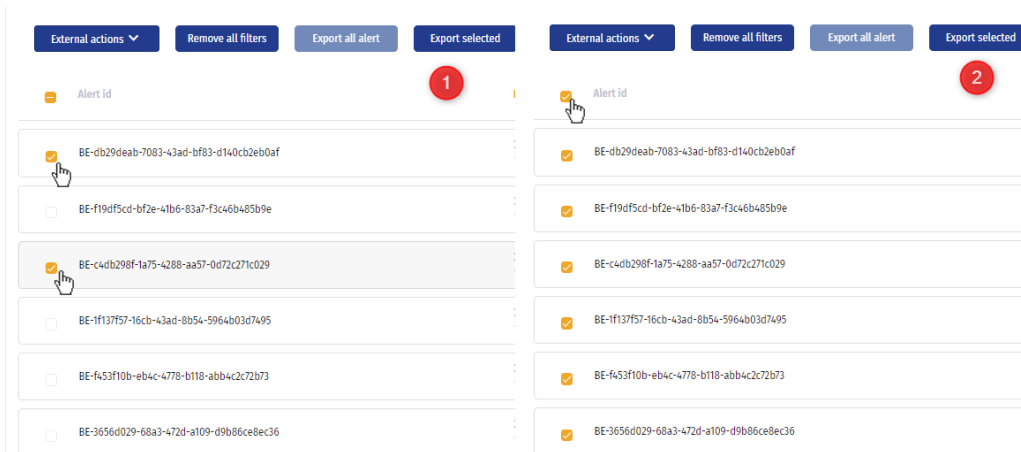


Figure 10.28. Export selected example

When alerts are selected and chosen to be exported by pressing “**Export selected**”, a pop-up will appear to select CSV format. After clicking “**Export**”, a window appears where at least one column must be chosen.

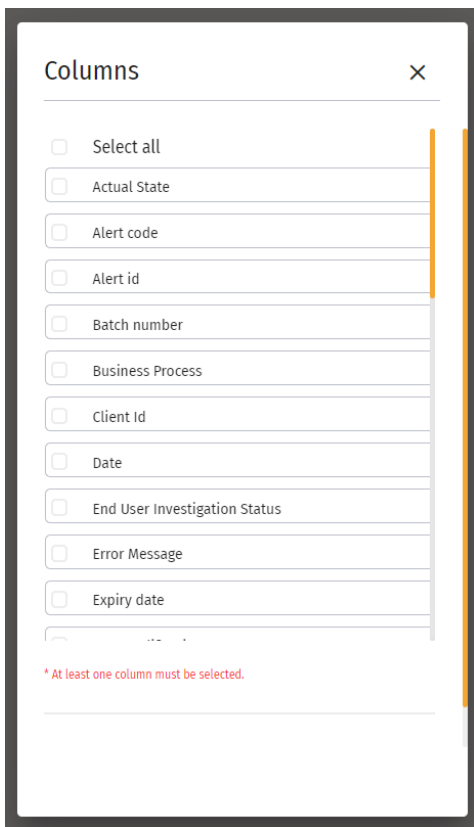



Figure 10.29. Selecting columns for exported alerts report

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 57 of 74

The current release only allows selecting up to 200 alerts.

10.13. Performing external actions

From the Alert Management view, the OBP Users can change the alert status of **multiple** alerts by selecting them and then clicking on **External actions** and pressing the **Change alert status** button.

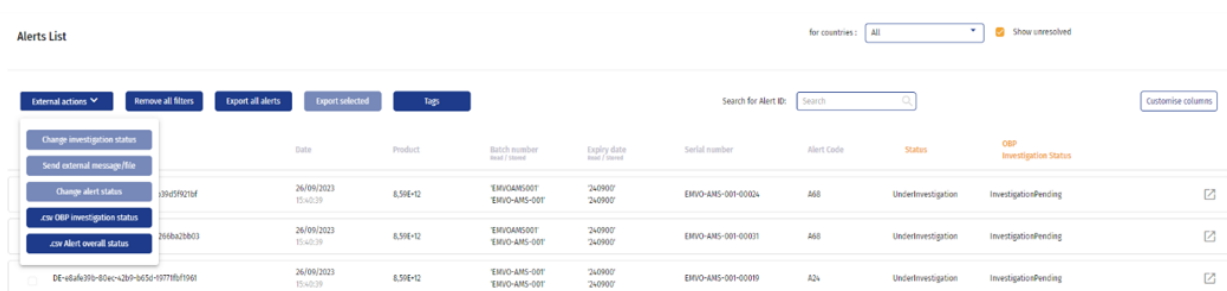


Figure 10.30 See External actions

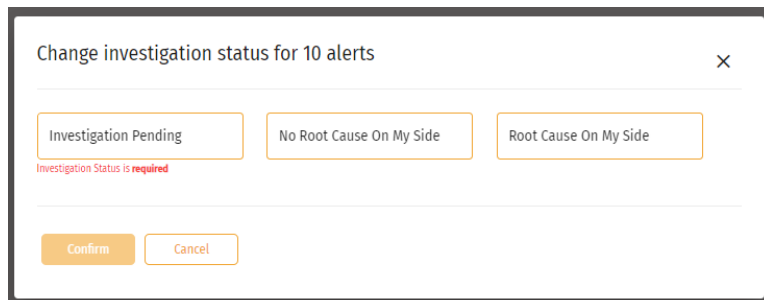
Once pressed, the OBP Users can perform the following actions:

- Change investigation status
- Send external message/file
- Change alert status
- CSV OBP investigation status
- CSV Alert overall status

10.14. Change investigation status

In the above view, OBP users have the ability to modify the OBP investigation status associated with each alert. This status serves as a communication tool among users to provide updates and inform other parties about the progress or status of their activities related to the investigation of a specific alert.

The OBP user should click on **External actions** and press the **Send external message/file** button.




			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 58 of 74

Figure 10.31 - Change investigation status

The Investigation status is unique per organisation type:

- MAH Investigation status
- NVMO Investigation status
- End-user Investigation status
- OBP Investigation status

The possible Investigation statuses can be found below:


- **Investigation pending;** This is to be used by the user when the investigation has started to let other parties know that they are still investigating.
- **No root cause on my side;** This is to be used by the user when the investigation has been completed, and no root cause was identified on their side.
- **Root cause is on my side;** This is to be used by the user when the investigation has been completed, and the root cause has been identified on their side.
- **Blank** – This is not an actual investigation status but an indication that there is no investigation status set yet (only applicable when a new alert appears). Blank is set by the system only.

NOTE: Once the Investigation status is set by the user for the first time for that alert, then the Alert Status is automatically changed by the system to "Under Investigation".

10.15. Send external message/file

From this view, the OBP Users can also add a message to **multiple** alerts by selecting them and by clicking on "**External actions**" and pressing the "**Send external message/file**" button, they can insert some notes, information or questions they might have related to the alerts.

Once the OBP users press the "**Send external message/file**" a pop-up window will open and display an array of pre-defined messages for the OBP Users to choose from, or they can type in their custom message by choosing "**Other (comment)**" at the end of the list. Adding files is also possible by clicking "**Add more files to message**", but that is an optional action.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 59 of 74

Message Text to add for FR-
20opjzz7iq196zcbgk1j86h35jkiym195ti72knolu6w1125iifw6go5t9uap ×

new predefined message for OBP. Please be aware of possible reporting obligations at national level
 new predefined message for OBP. Please be aware of possible reporting obligations at national level
 new predefined message for OBP. Please be aware of possible reporting obligations at national level
 Other (comment)


Custom message is **required**

Figure 10.32. Add external message

NOTE: Please note that there is a 500-character limit on the "Other (comment)" custom message field.


NOTE: Please note that when selecting the "**Other (comment)**" reason/message option, a reason/message should be typed for the "**Confirm**" button to be active.

Users can simply drag and drop files from their computer or click on "**Browse for file**". After all necessary files have been added, the final "Add" button must be clicked so that the files are attached to the external message sent out. The user will see a notification icon under their name in the upper right corner in case

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 60 of 74

of a successful or failed action processed by the EAMS Portal.

Add file(s) to message
×



Drag and drop your file here or

[Browse for file](#)

TEST test.jpg
3.71 KB
🗑️

uml_include_extend.png
68.37 KB
🗑️

Add
Cancel


Figure 10.33. Add file to the external message

NOTE: Please note that one action (sending message for instance) has a limit of 5 attachments with a maximum of 5 Mb size per attachment.

10.16. Change alert status

Changing the alert status will notify everyone involved in this investigation. If the OBP user only wants to change the OBP investigation status, it can be done by changing the Investigation statuses.

To change the alert status, the OBP should (1) choose the new **"Status"** of the alert and (2) the **"Reason"** behind this change. A reason must (3) be selected for the **"Confirm"** button to be active. The user will see a notification icon under their name in the upper right corner in case of a successful or failed action processed by the EAMS Portal.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 61 of 74

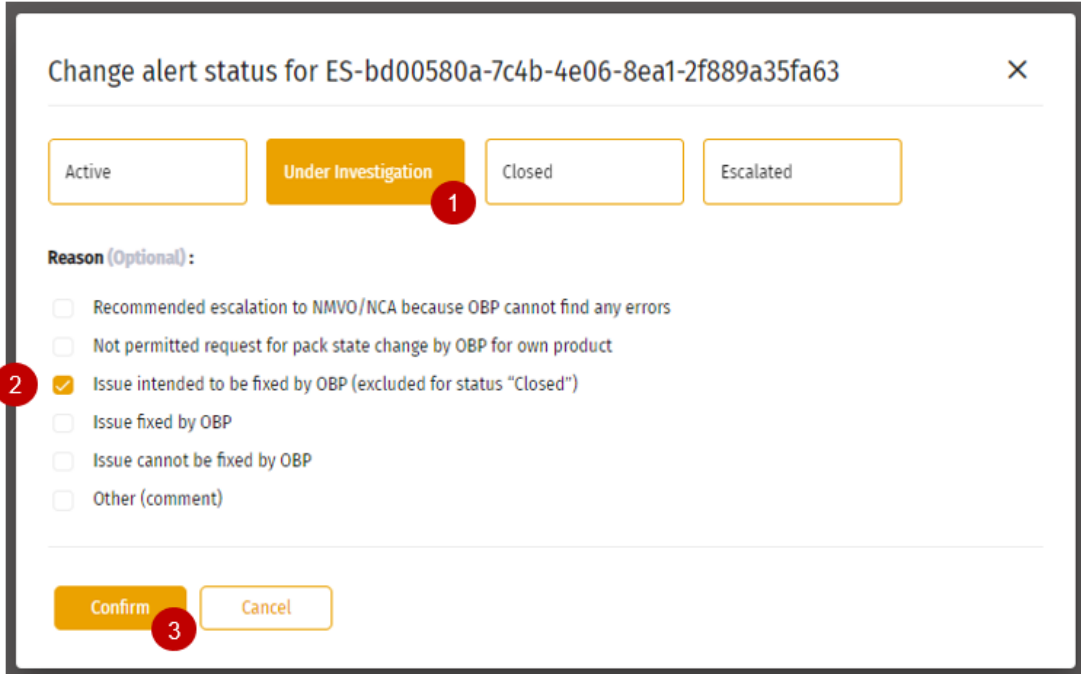


Figure 10.34. Choose Alert status and Reason

NOTE: Please note that the **Status** is always mandatory. **Reason** is also mandatory except in Status **"Under Investigation"** when it is optional.


NOTE: Please note that there is a 500-character limit on the "Other (comment)" reason field.

New – a new alert which has not been modified yet. This is the initial state of an alert. No user can set this alert status, it is automatically set by the system.

Closed – means that the investigation has been carried out on one or more packs, and it has been concluded that there is a technical or procedural root cause for the alert. Hence, the pack is not a suspected falsified pack, and the alert can be closed. OBPs, NMVOs and NCAs may set this alert state from another state. However, OBPs do not have the ability to set an alert as "Closed" when the alert has been marked as "Escalated", only NCAs/NMVOs may do this.

Escalated – means that the investigation has been carried out, but the users could not identify the root cause of that alert, so NCA intervention is required. OBPs, NMVOs and NCAs may set this alert state from any other state.

Under Investigation – means that the alert is currently under investigation. The user may find technical issues with the EMVS, data upload, the person performing the verification or similar technical issues.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 62 of 74

OBDs, NMVOs and NCAs may set this alert state from another state. However, OBDs do not have the ability to set an alert as "Under Investigation" when the alert has been marked as "Escalated", only NCAs/NMVOs may do this.

10.17. Import CSV files for mass-alerts updates

For easier handling of an investigation concerning multiple alerts, there is a function represented for Alert and Investigation statuses that can be manually imported in separate CSV files for each action, as shown below. To change an Investigation status, the user can click on "**External actions**" and press the "**Import investigation status change**" and a pop up window will appear that allows the user to upload a CSV file from their computer or choose a template that can be downloaded and used if needed (press "**download a template**") for importing investigation statuses for specific alerts. The user will see a notification icon under their name in the upper right corner in case of a successful or failed action processed by the EAMS Portal.

Import investigation status change ×

Hi there! Please note that you can also download the template to support you with the import function. You will also find there in the different fields that must be filled in. For any investigation status change, both Alert ID and the Investigation Status are mandatory.


Figure 10.35. Import CSV file for Investigation status

Basic requirements for the file that can be imported to EAMS Portal are:

1. File extension should be .csv (Comma Separated Value)
2. The following two columns are required:
 - a. Alert ID (case sensitive)
 - b. Investigation Status (case insensitive), possible values are
 - i. "investigationpending"
 - ii. "norootcauseonmyside"
 - iii. "rootcauseonmyside"

	A	B
1	Alert ID	Investigation Status
2	BE-kldp7m434vice8lgtweqeceyhdyefjxcl578v042fi02fz25tkjyhr5ih153y	norootcauseonmyside
3	BE-w3uvsrjzleyyea5yw0307fdpsto7gihhqxxps4h93en7zfxoyec0565q0fc9c	norootcauseonmyside

Figure 10.36. Example of CSV file for Investigation status upload

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 63 of 74

To change the Alert status, the user can click on **“External actions”** and press the **“Import alert status change”** and a pop up window will appear that allows the user to upload a CSV file from their computer or choose a template that can be downloaded and used if needed (press **“download a template”**) for importing alert statuses for specific alerts. The user will see a notification icon under their name in the upper right corner in case of a successful or failed action processed by the EAMS Portal.

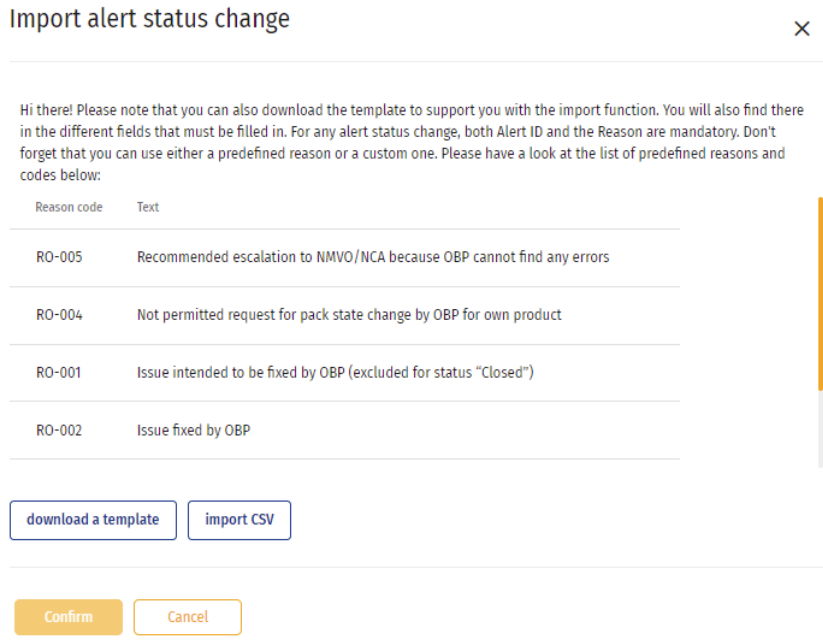



Figure 10.37. Import CSV file for Alert status (when scrolling down the user will see the same reasons as below in "Reason codes and default text")

Basic requirements for the file that can be imported to the EAMS Portal are:

1. File extension should be CSV (comma-separated values)
2. The following four columns are required:
 - a. Alert ID (case sensitive)
 - b. Alert Status (case insensitive)
 - c. Reason code Status (case insensitive)
 - d. Custom reason (only fill in if RC-001 reason code has been chosen, case sensitive)

	A	B	C	D
1	Alert ID	Status	Reason code	Custom reason
2	BE-klpd7m434vice8lgtweqeceyhdyejfxcl578v042fi02fz25tkjyhr5ih153y	escalated	RO-003	
3	BE-w3uvsrjzleyyaea5yw0307fdpsto7gihhqxxps4h93en7zfxoyec0565q0fc9c	escalated	RC-001	Testing custom reason

Figure 10.38. Example of CSV file for Alert status upload

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 64 of 74

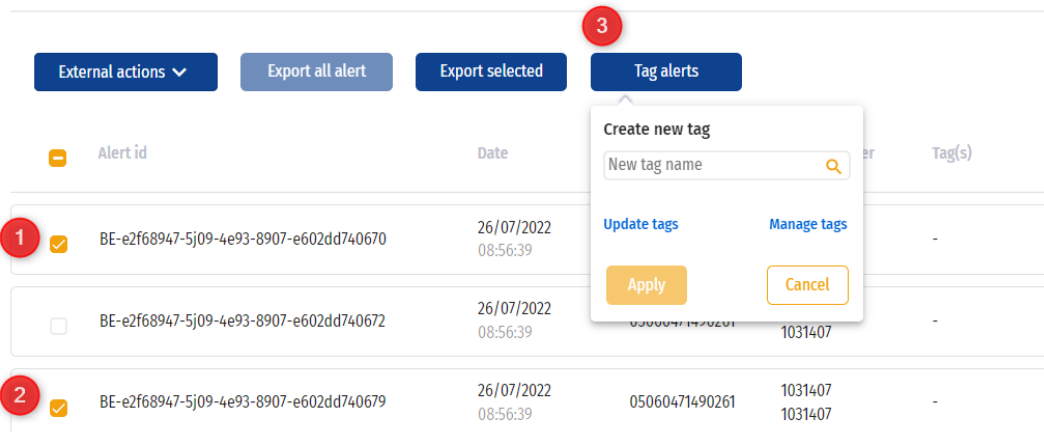
Reason codes and default text:

Reason Code	Text
RO-001	Issue intended to be fixed by OBP (excluded for status "Closed")
RO-002	Issue fixed by OBP
RO-003	Issue cannot be fixed by OBP
RO-004	Not permitted request for pack state change by OBP for own product
RO-005	Recommended escalation to NMVO/NCA because OBP cannot find any errors
RC-001	[Custom reason]

10.18. Grouping alerts by tags

This feature allows users to assign tags to individual cases so they can later work on multiple alerts in the Alerts Management view. The user shall select one (1) or more (2) alerts from the list so that "Tag alerts" button becomes enabled. When clicked (3), it will give a drop down with actions to create, update and manage tags.

Alerts List




The screenshot shows an 'Alerts List' table with columns for 'Alert id', 'Date', and 'Tag(s)'. Three alerts are listed, with the first and third rows selected (indicated by checkboxes and red circles 1 and 2). Above the table, there are buttons for 'External actions', 'Export all alert', 'Export selected', and 'Tag alerts' (highlighted with a red circle 3). A modal window titled 'Create new tag' is open, containing a search field for 'New tag name', buttons for 'Update tags' and 'Manage tags', and 'Apply' and 'Cancel' buttons.

Figure 10.39. Tag alerts

Actions with tags:

- Create tags.** With this action, an entirely new tag is created; hence, a new tag name needs to be entered, and the "Apply" button needs to be pressed. Once the tag is successfully created, it will add a bookmark under the "Tag(s)" column on the selected alert(s) and to the filter.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 65 of 74

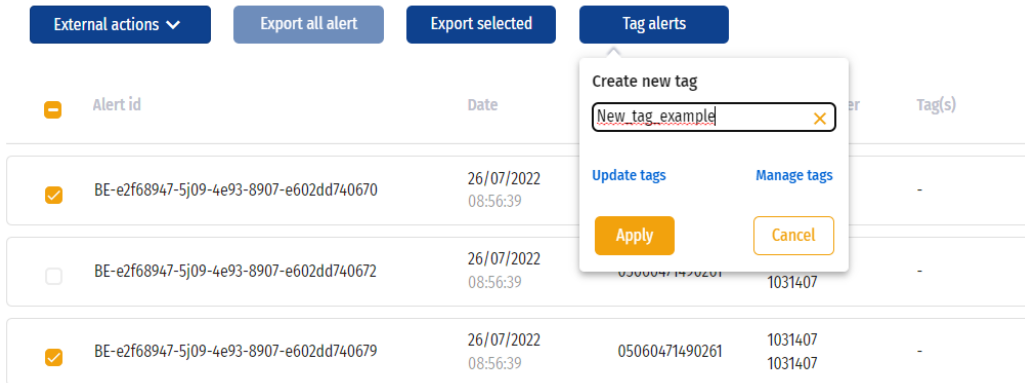


Figure 10.40. Create new tag

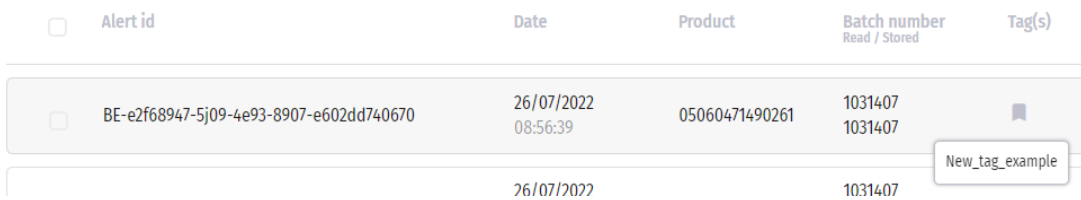


Figure 10.41. Applied tag view

- Update tags.** This option allows the addition or removal of already created tags from the selected alerts that are shown in the list
 - a blank checkbox next to the tag name means there is no tag set on the selected alerts;
 - yellow check mark next to the tag name means there are multiple alerts with such tag set;
 - yellow minus in the checkbox next to the tag name means there is one alert with such tag set. Each marked or unmarked checkbox assigns or removes the tag from the selected alerts, respectively. After the user finishes selecting tags, the "Save" button must be clicked on to reflect the changes.

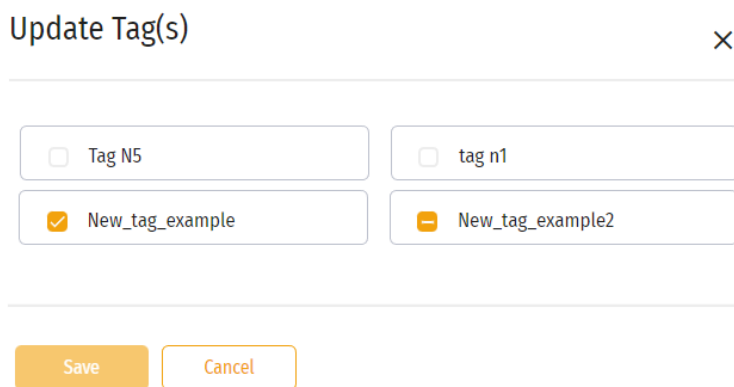





Figure 10.42. Update tags

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 66 of 74

- Manage tags.** This means the user can either rename the tag by clicking on the  icon or delete it by clicking on  icon.

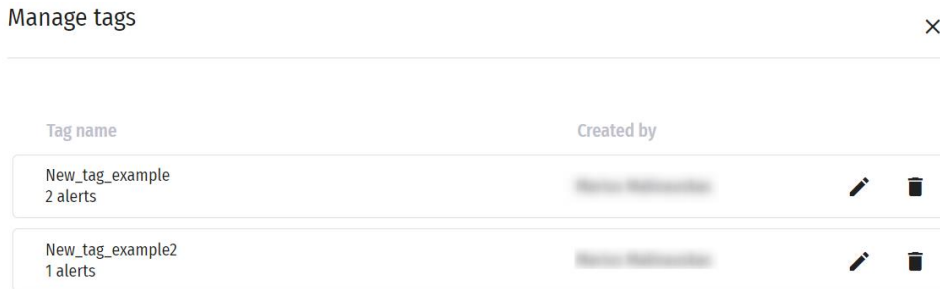



Figure 10.43. Manage tags

NOTE: The creation of a tag can only be made by the OBP administrator role. Users can assign a maximum of 20 tags to one alert. Each organization can create a maximum of 20 unique tags in total.


NOTE: If the OBP administrator creates a new tag with a name that already exists for another tag, the system accepts that but associates it with the already existing tag (whitespace before and after the tag name is ignored).

11. Alert detailed view

Whenever the OBP users want more information regarding an alert, they can press  to obtain detailed information that will help with their investigation.


Alert id	Date	Product	Batch number <small>Real / Simul</small>	Expiry date <small>Real / Simul</small>	Serial number	Code	Status
 EU-kygeap643a8zrohzaawdggk8ks2cy8tn	24/11/2021 05:00:00	12345	PLX1896 14785	4zysyqdh5ewbr2ykpucl8eyl m0mk406p9x4h5nlk0szedj	45769465487688789124	 AS2	New 

Figure 11.1. Go to detailed information of an alert

Once the OBP users press on the  icon, they will be redirected to a new page where they will be able to see the detailed information of the alert.

The information is categorised under 6 Major Categories:

- 1) **Product:** Product Code, Product Code Scheme, Serial Number, Product Name
- 2) **Market:** Packed located in, Alert Raised in:
 - a. If the national system is not subscribed to the EAMS, then the user will see: "[Market ISO Code] - Not subscribed to the EAMS"
 - b. If the national system is deactivated from EAMS, then the user will see: "[Market ISO Code] - deactivated from the EAMS"

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 67 of 74

c. If the national system is subscribed to the EAMS, then the user will see: "[Market ISO Code]"

- 3) **Batch:** Read Batch ID, Stored Batch ID
- 4) **Expiry Date:** Read Expiry Date, Stored Expiry Date
- 5) **Client:** Client ID, Manual Entry Flag
- 6) **Investigation statuses:** MAH Investigation status, NMVO Investigation status, End-user Investigation status, OBP Investigation status,

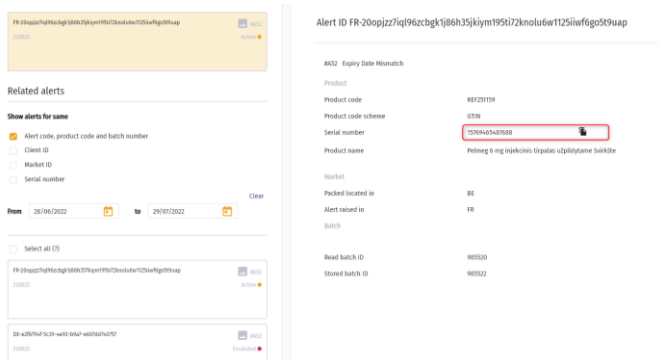



Figure 11.2. Detailed view of an alert

If the alert contains multiple serial numbers, the alert will be displayed. The user can see the full list of serial numbers when clicking on the  icon next to the displayed serial number shows the detailed view of an alert that contains only one serial number.

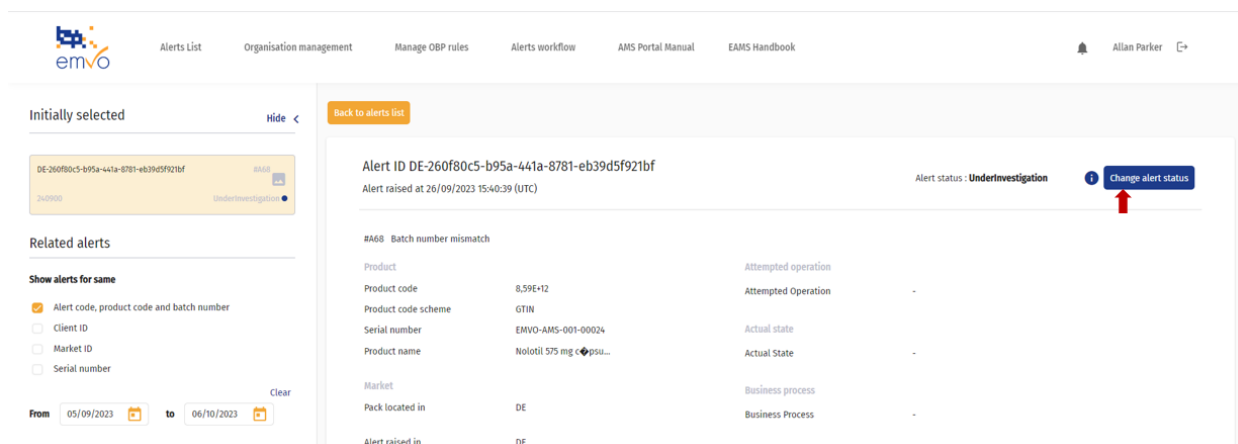



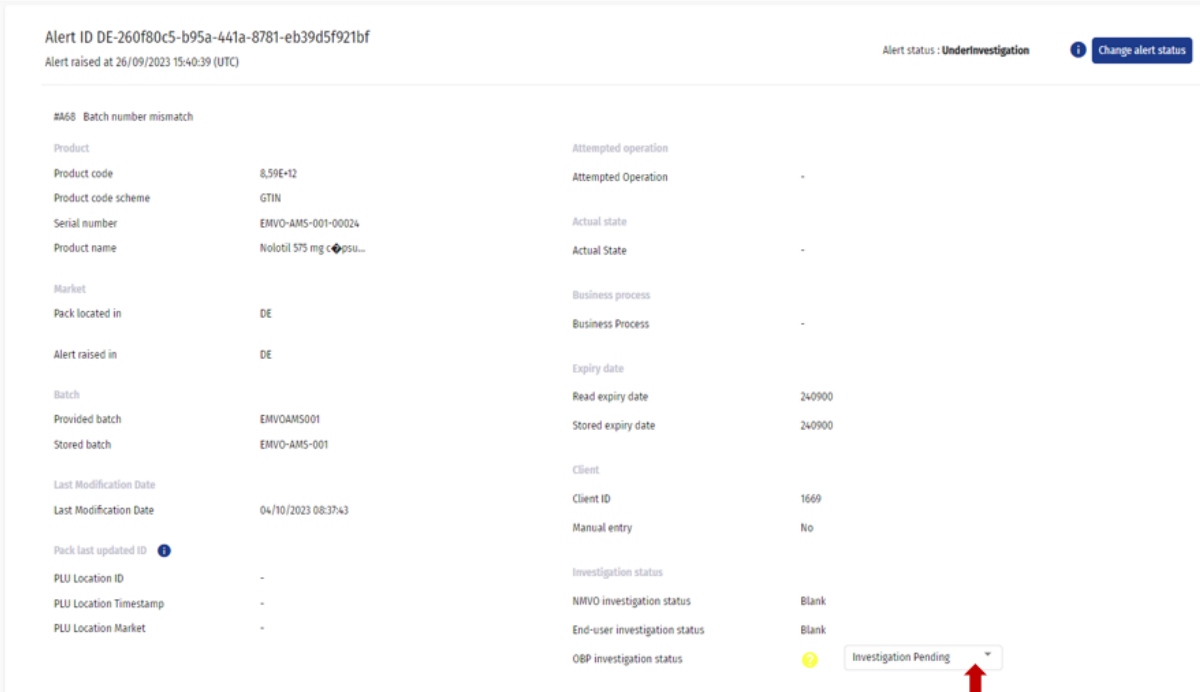
Figure 11.3. Changing alert status through the detailed alert view

11.1.1. Change investigation status

The most frequent action from the detailed alert view is to change the investigation status by selecting the

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 68 of 74

correct value in the **“Investigation status”** area, as shown below.



Alert ID DE-260f80c5-b95a-441a-8781-eb39d5f921bf
Alert raised at 26/09/2023 15:40:39 (UTC)

Alert status : UnderInvestigation Change alert status

#A68 Batch number mismatch

Product		Attempted operation	
Product code	8,59E+12	Attempted Operation	-
Product code scheme	GTIN	Actual state	-
Serial number	EMVO-AMS-001-00024	Actual State	-
Product name	Nolotil 575 mg c...psu...	Business process	-
Market	DE	Business Process	-
Pack located in	DE	Expiry date	-
Alert raised in	DE	Read expiry date	240900
Batch	-	Stored expiry date	240900
Provided batch	EMVOAMS001	Client	-
Stored batch	EMVO-AMS-001	Client ID	1669
Last Modification Date	-	Manual entry	No
Last Modification Date	04/10/2023 08:37:43	Investigation status	-
Pack last updated ID	-	NMVO investigation status	Blank
PLU Location ID	-	End-user investigation status	Blank
PLU Location Timestamp	-	OBP investigation status	Investigation Pending
PLU Location Market	-		

Figure 11.4. Change investigation status through the detailed alert view

11.1.2. Change alert status

From this view, the OBP Users can change the alert status of the displayed alert by pressing the **“Change Status”** button.

Once pressed, the OBP Users should choose the new **“Status”** of the alert and the **“Reason”** behind this change.

11.1.3. Send external message or file

From this view, the OBP Users can also add a message and files to this specific alert by pressing the **“Send external message”** in the “Conversation” section, and insert some notes, information or questions they might have related to the alert.


			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 69 of 74



Figure 11.5. Sending external message through detailed alert view


Once the OBP users press the **"Send external message/file"** button, a pop-up window will be opened and display an array of pre-defined messages for the OBP Users to choose from, or they can type in their custom message by choosing **"Other (comment)"** at the end of the list.

NOTE: Please note that there is a 500-character limit on the **"Other (comment)"** message option and that a message should be typed for the **"Confirm"** button to be active.

11.1.4. Related alerts section

From the detailed alert view, there is additional section on the left side of the window that shows "Related alerts". If there are alerts with the same alert code, product code and batch number, it will show a list of alerts related to the displayed alert (if there are no, the list will be empty), and the system allows to choose other criteria to see a different relation between these alerts.

- Attributes which are mandatory (default selection and cannot be unselect), therefore they are already selected:
 - Same "Alert code"
 - Same "Product code"
 - Same "Batch number"
- Optional attributes:
 - "Serial number"
 - "Start datetime" and „End datetime"
 - "Client ID"
 - "Market ID"

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 70 of 74

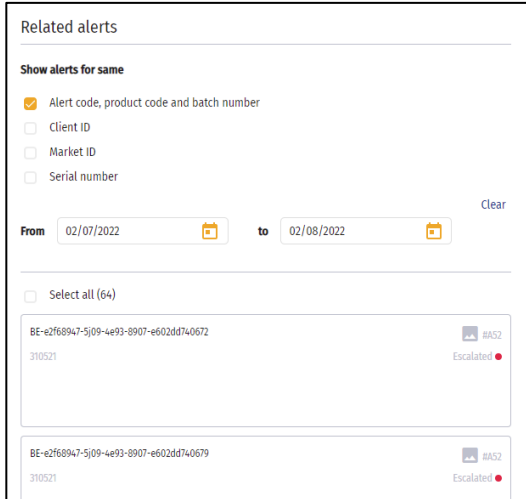


Figure 11.6. Related alerts section

When scrolling down this page, there is an underlined button **“Show more”** which opens a new tab in the browser and shows all alerts that are related to the displayed alert.

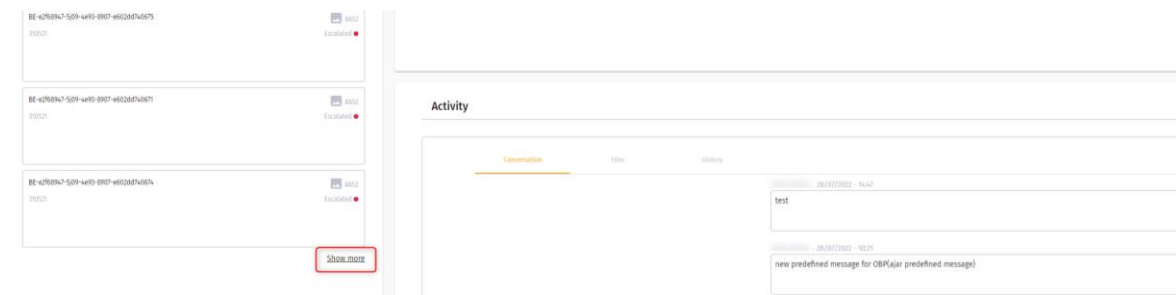



Figure 11.7. “Show more” button in the related alerts section

From the related alert list, the user can do the same actions as described in this paragraph “10.13. Performing external actions” One important note is that it might take a few minutes to process this bulk action, hence it will be shown in a pop-up window, but the bulk action will run in the background.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 71 of 74

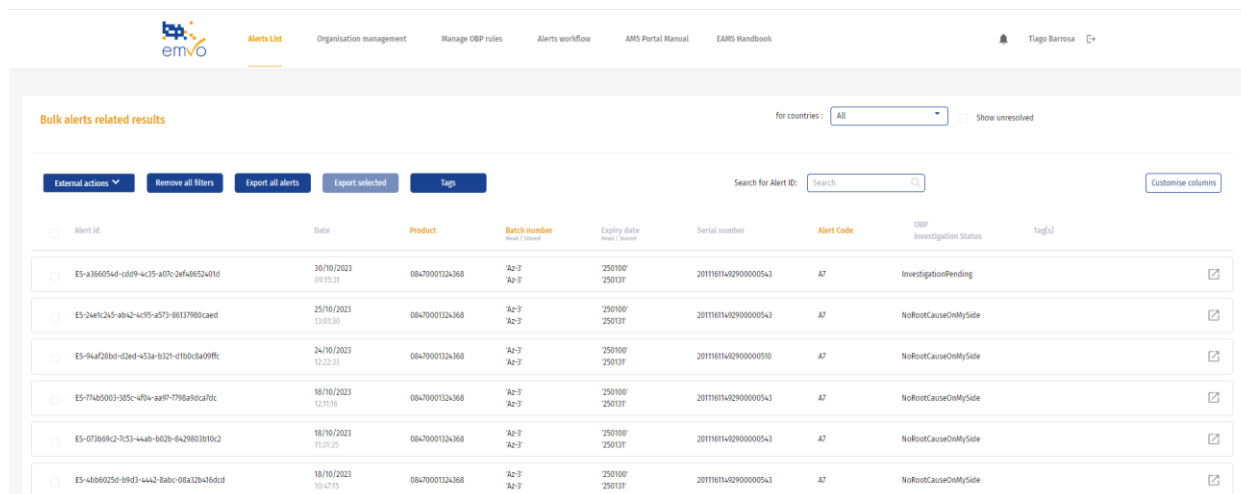


Figure 11.8. Related alerts list view

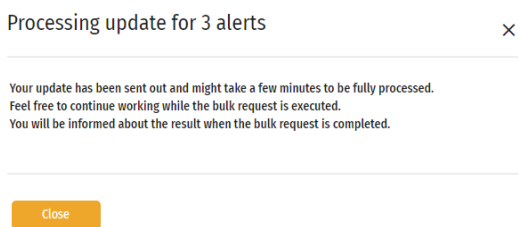


Figure 11.9. Pop up window with information of processing bulk action

NOTE: The “Bulk alerts related results” screen will highlight in yellow “**Product**”, “**Batch number**” and “**Alert code**” as filters. To remove the filters, the user should click on the “**Remove all filters**” button.

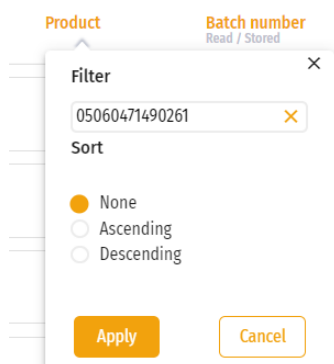



Figure 11.10. Highlighted columns for related alerts as filters

Moreover, to change the investigation or alert status and to send an external message/file for all related alerts in a bulk action, the user can “Select all” by clicking the checkbox in the “Related Alert” section, which replaces the button with the number of selected alerts and allows to make an action.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 72 of 74

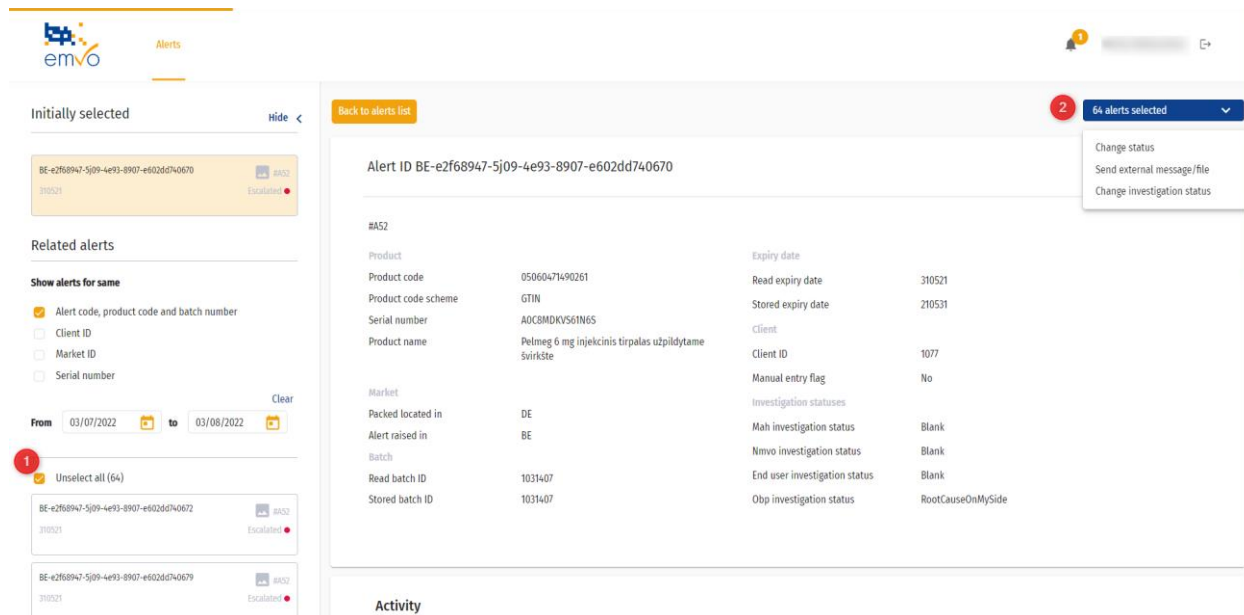


Figure 11.11. Bulk action for related alerts


11.2. Activity view

The OBP Users can navigate to the history of each alert, under the **Activity** section of each alert, where the OBP Users are able to check the Conversation, Files and History for each alert. All changes made in a specific alert will be logged in this section (audit trail will be in this section, under the tab "History").

This section can be found through the alert details pages by scrolling down at the bottom, more to the right of the page.

History: In this tab, the OBP Users can see a list of activities with the following attributes:

- Date/Time in UTC. Please note that this cannot be modified by any user.
- Actor: showing, at a top-level, who took the action – End-User, OBP, NMVO, EMVO – without revealing anything about the identity of the actor.
- Action: Shows all actions taken on the alert.
- Attachment: File/files uploaded and removed for the alert.

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 73 of 74

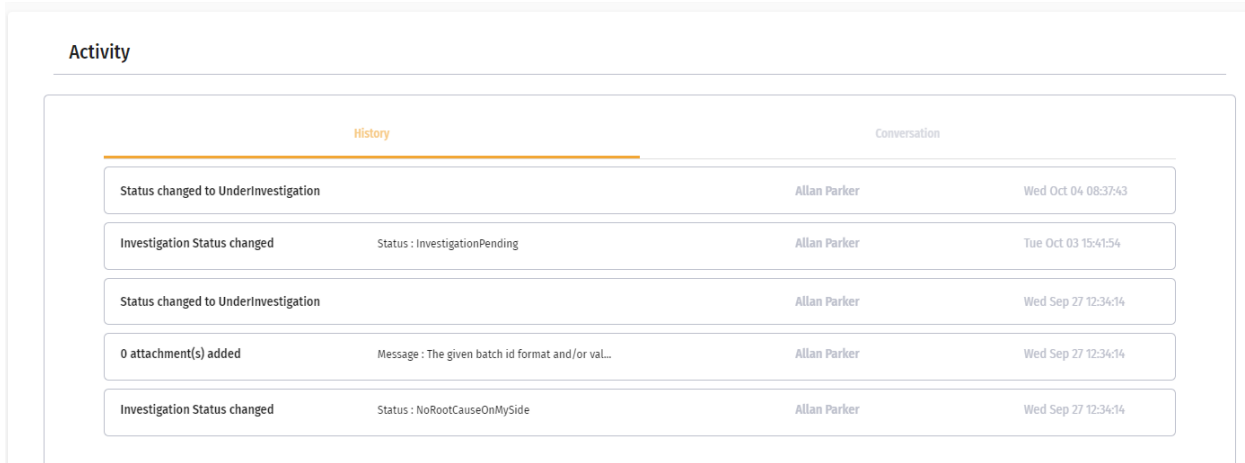


Figure 11.12. Activities history

Conversation: In this tab, the OBP Users can add comments, internal notes, and communication notes with other OBP Users who have access. Please note that this communication is only visible for the OBP users, but not to other stakeholders.



Figure 11.13. Conversation section

Attachments (for example: .jpg, .png, .pdf, .xlsx, etc.) are displayed as icons in the conversation tab. The user can view each one in the browser by simply clicking on it. The user can also right-click and then choose "Save image as" to save the pictures locally. For files like .xlsx or .pdf, there is a button in the top right corner to download them.

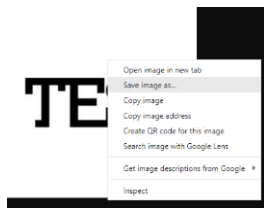


Figure 11.15. Save image as...

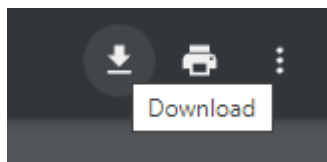



Figure 11.14. Download .pdf, .xlsx files

			
EAMS Portal User Manual			
Document Number	Version	Approval Date	Page No
EMVO-01376	v9.0	18 Feb 2026	Page 74 of 74

Files: In this tab, the OBP Users can see the number of files regarding each alert (files, pictures, etc.)

12. Archived alerts

All alerts from a company should be in the system since the 9th of February 2023, regardless of when the company joined the EAMS.

However, as after 6 months of inactivity (180 days), alerts are archived, those will not be displayed in the Alert List, but you can still search and find them by using the "Search for Alert ID":

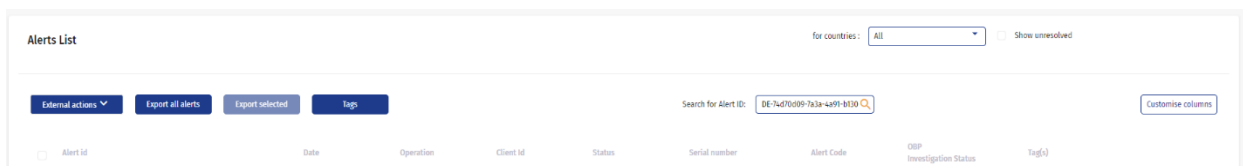


Figure 12.1 - Search for Alert ID

The system will then look for the system and display it accordingly. Please note that these alerts cannot be modified directly. If you want to provide any extra information, this would need to be requested from EMVO using helpdesk@emvo-medicines.eu.