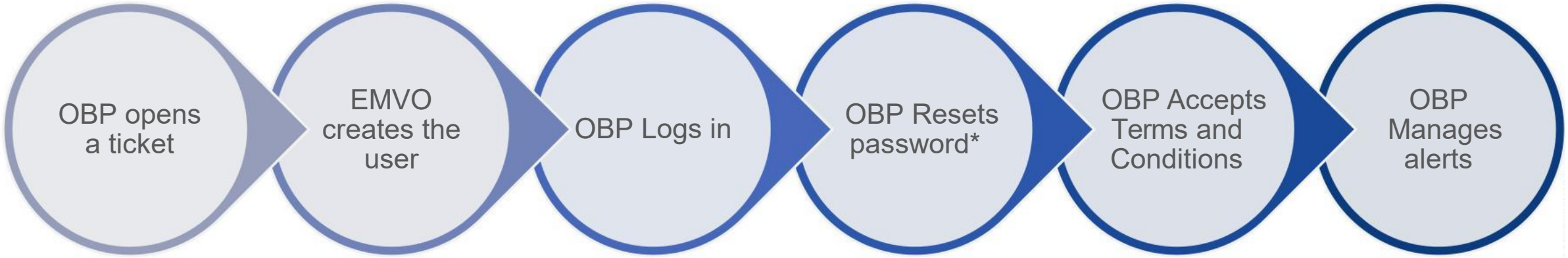
HOW TO JOIN THE EAMS OBP GUIDE

EMVO Team

WHAT IS AND WHY JOIN THE EAMS?

- The EAMS supports EMVS users (OBPs, MAHs, NMVOs and end-users) to change alert statuses and communicate with other parties involved in an alert investigation, depending also on the landscape at national level in each Member State.
- It is composed of the AMS Hub developed by EMVO and the National AMSs.
- The AMS Hub allows the connection among EAMS, national systems and OBPs. It also allows for centralised, anonymous communication between all parties involved in alert investigation in addition to a centralised log of the alert investigation history.
- Synchronisation of alert status between national systems, the AMS Hub and the AMS portal allows OBPs to communicate seamlessly with all connected users respecting the applicable anonymisation rules is in place.
- Each stakeholder can contribute by maintaining his specific “User Specific Workflow Indicator”, but alerts can also be closed according to national rules.
- Option to direct access using defined APIs.

BEFORE PROCCEED TO THE ACTUAL STEPS, PLEASE HAVE A LOOK AT THE HIGH-LEVEL PROCESS



* For security purposes, EMVO will not provide any passwords, the user will be required to reset their password through the log-in page of the AMS Portal before being able to connect to the AMS Portal.

EAMS TERMS AND CONDITIONS

- **Important:** To proceed with the connection, the first user accessing the AMS Portal will be required to accept the EAMS Terms & Conditions (T&C). Please consult them **here**.
- Note that this is a one-off action. Therefore, **we strongly encourage you to ensure that this person is legally allowed to do so on behalf of the OBP.**
- Moreover, the affiliated MAHs represented by your OBP Company will be required to have a **letter of adhesion** in place in order to adhere to the **EAMS Terms & Conditions**. The letter of adhesion should only be provided to EMVO upon request. Be reminded that this process is also followed for the Participation Agreement (PA)
- If the **EAMS Terms & Conditions** are not accepted the AMS Portal will not be accessible;

THERE ARE FOUR DIFFERENT SCENARIOS

Click to go to scenario

SCENARIO 1

The SPOC and/or SPOC Assistant **has** access to the AMS Portal and **is** allowed to sign the T&C

SCENARIO 2

The SPOC and/or SPOC Assistant **has** access to the AMS Portal but is **not** allowed to sign the T&C

SCENARIO 3

The SPOC and/or SPOC Assistant **doesn't have** access to the AMS Portal and is allowed to sign the T&C

SCENARIO 4

The SPOC and/or SPOC Assistant **doesn't have** access to the AMS Portal and **isn't** allowed to sign the T&C

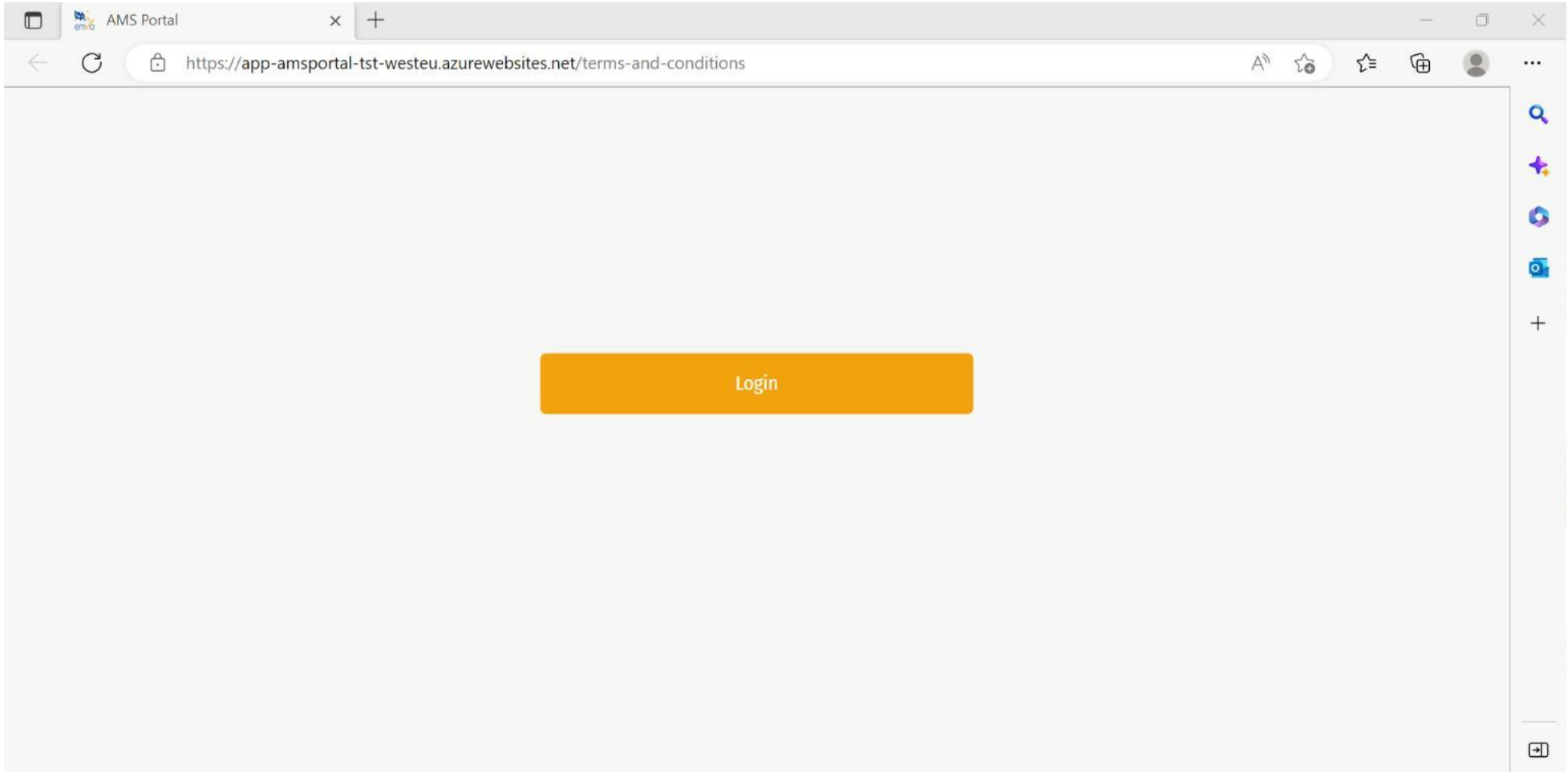
SCENARIO 1

HOW TO JOIN THE EAMS

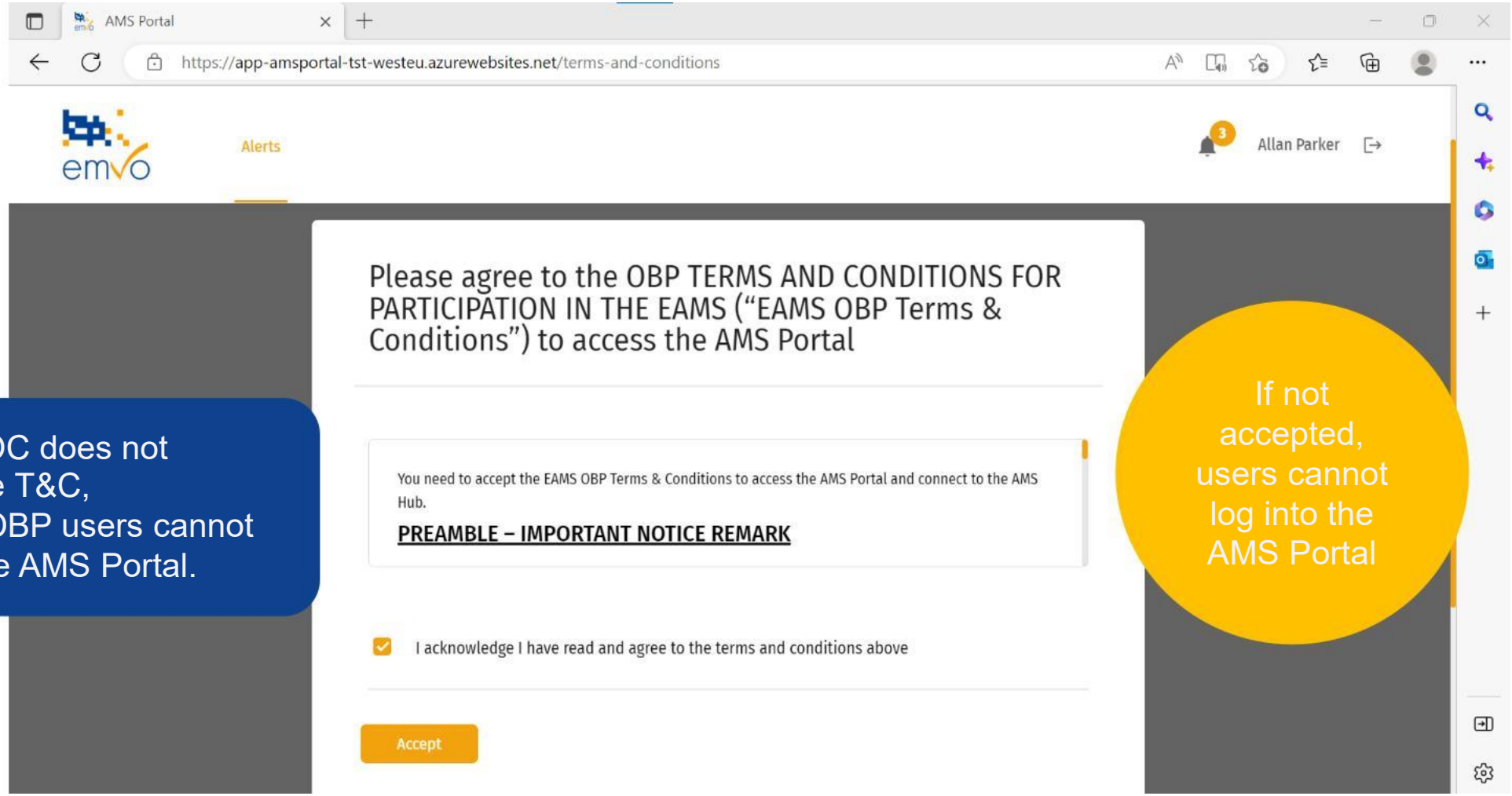
-

The SPOC and/or SPOC Assistant has access to the AMS Portal and is allowed to sign the T&C

STEP 1 THE SPOC AND/OR SPOC ASSISTANT LOGS IN TO THE AMS PORTAL (HTTPS://AMS.EMVO-MEDICINES.EU)



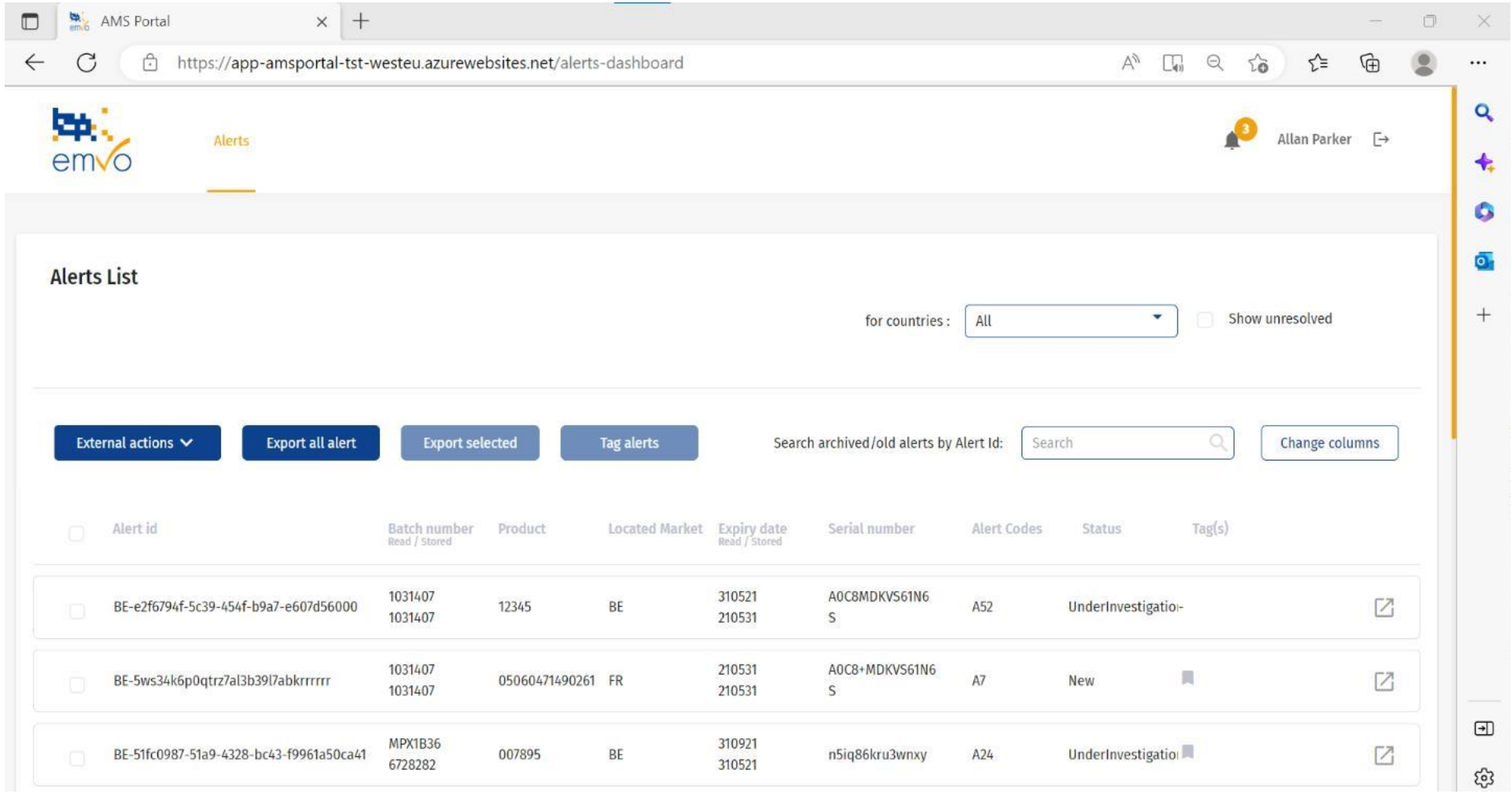
STEP 2 THE SPOC AND/OR SPOC ASSISTANT ACCEPT THE EAMS TERMS AND CONDITIONS



If the SPOC does not accept the T&C, then the OBP users cannot access the AMS Portal.

If not accepted, users cannot log into the AMS Portal

STEP 3 THE SPOC AND/OR SPOC ASSISTANT CAN ACCESS THE AMS PORTAL IN PRODUCTION AND MANAGE THEIR ALERTS



SCENARIO 2

HOW TO JOIN THE EAMS

-

The SPOC and/or SPOC Assistant has access to the AMS Portal but is not allowed to sign the T&C

STEP 1 THE SPOC AND/OR SPOC ASSISTANT REQUEST ACCESS FOR THE LEGAL REPRESENTATIVE

OBP SPOC or SPOC assistant send an email to the EMVO Helpdesk (helpdesk@emvo-medicines.eu) to request the user creation. The email shall contain the following:

- **Subject of the email**:
  - "AMS Access request – OBP Name"

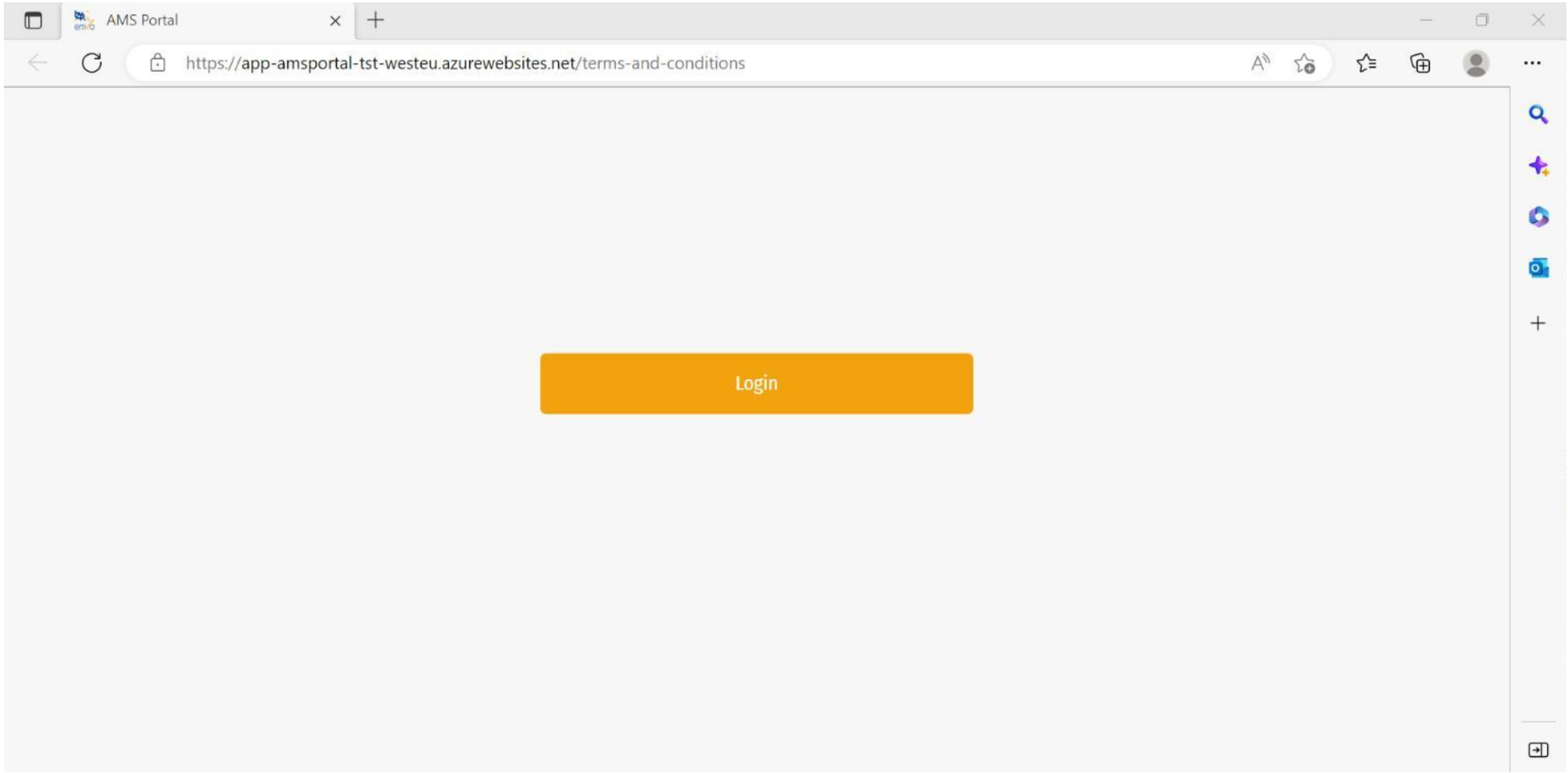
- **Body of the email:**
  - Username
  - User role (Legal Representative)

- **Attachment of the email**:
  - user template filled with the following user's information:
    - User's first name
    - User's Last Name
    - User's Email address
    - User's Organisation ID

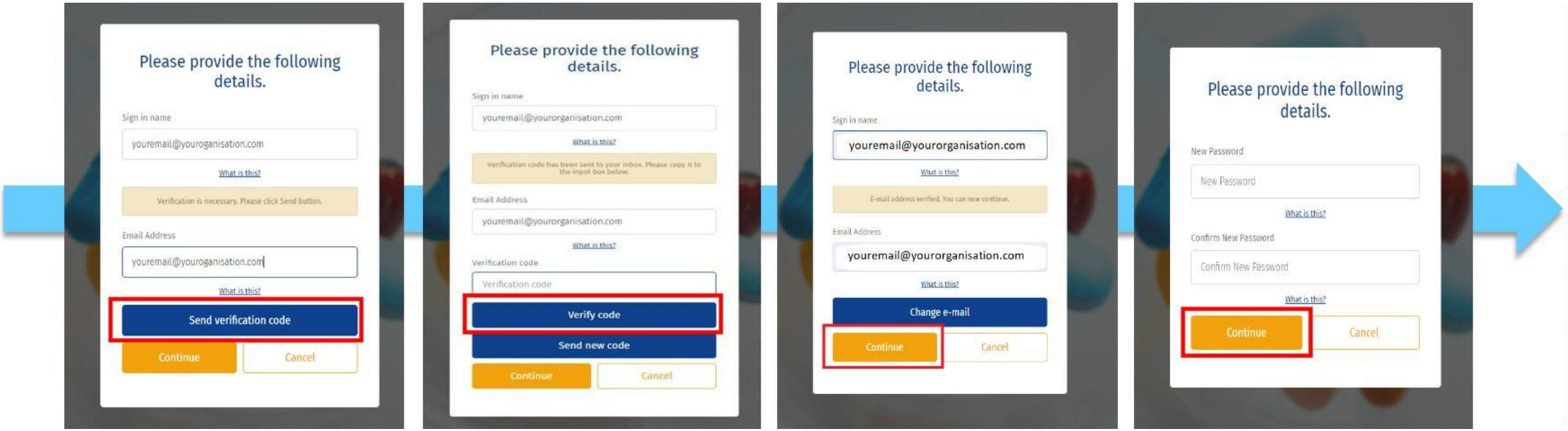
EMVO will take up to 3 days and inform the requestor

Hint: the organisation ID can be found in your OBP Portal under step **4.2.4.1** OR **4.3.4.1**

STEP 2 WHEN CONFIRMED BY EMVO, THE LEGAL REPRESENTATIVE LOGS IN TO THE AMS PORTAL (HTTPS://AMS.EMVO-MEDICINES.EU)

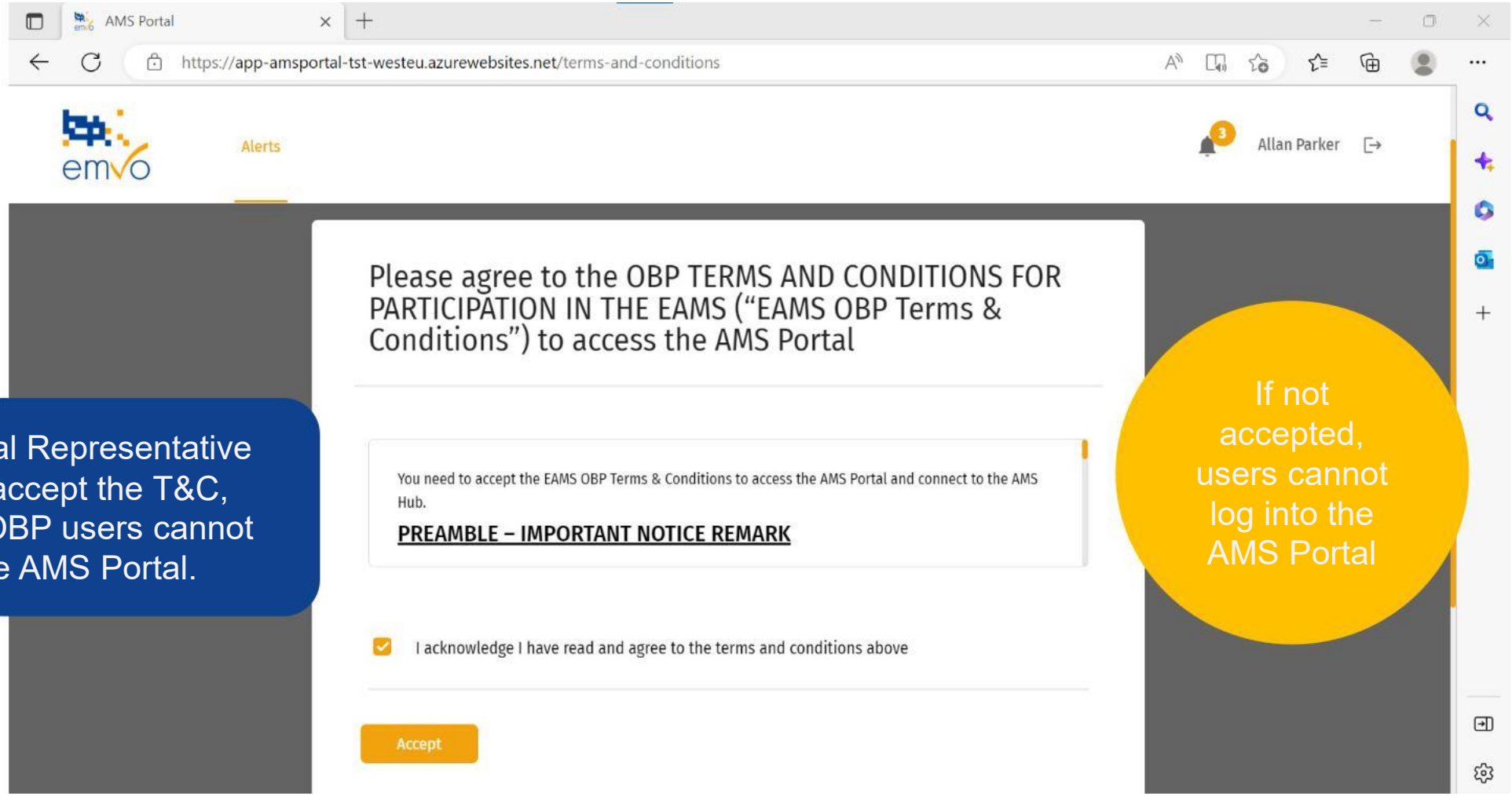


STEP 3 THE LEGAL REPRESENTATIVE CAN RESET THE PASSWORD SUCCESSFULLY AND THEN LOGS INTO THE AMS PORTAL



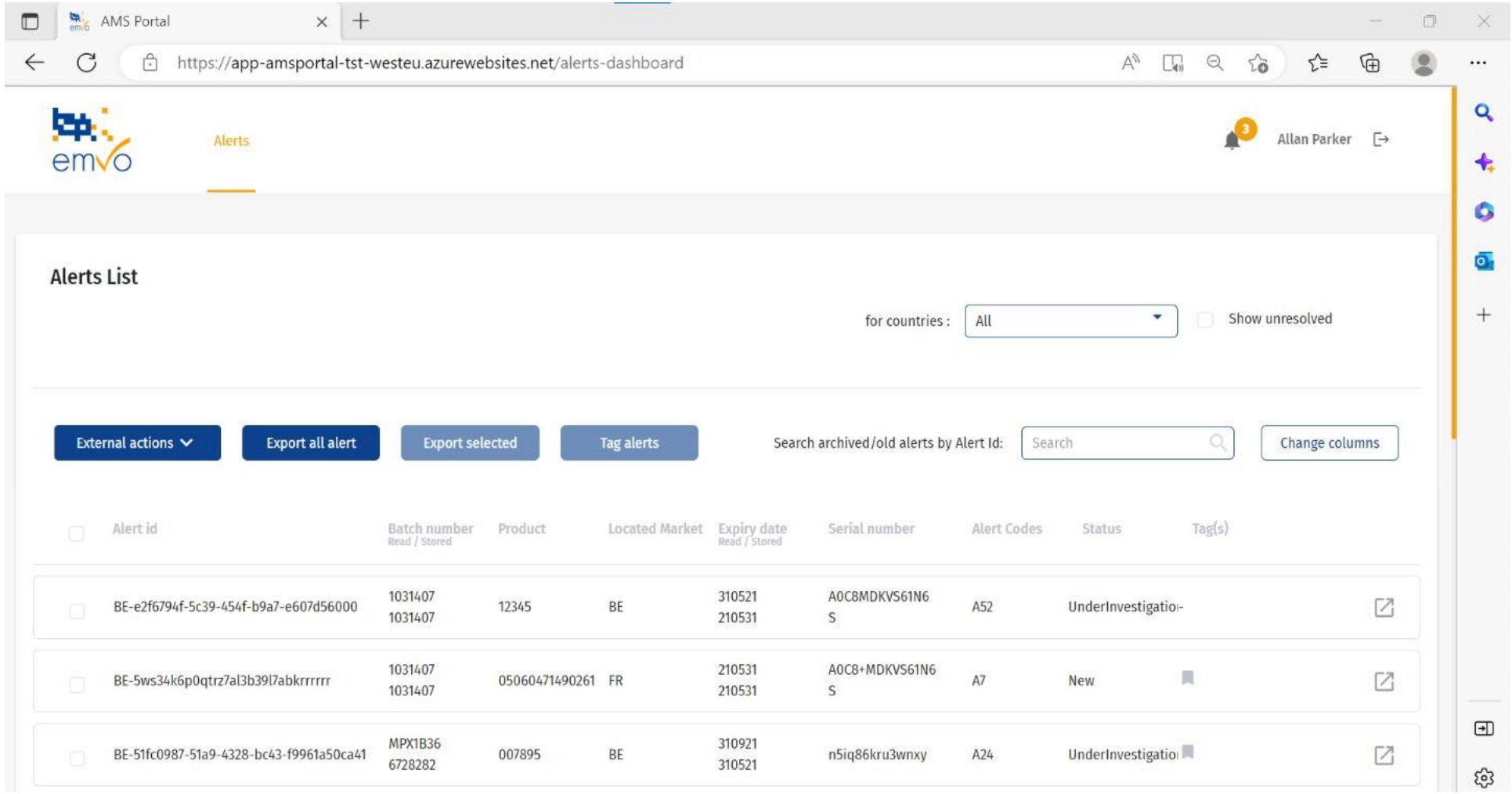
STEP 4 THE LEGAL REPRESENTATIVE ACCEPTS THE EAMS TERMS AND CONDITIONS

If the Legal Representative does not accept the T&C, then the OBP users cannot access the AMS Portal.



If not accepted, users cannot log into the AMS Portal

STEP 5 THE SPOC AND/OR SPOC ASSISTANT CAN ACCESS THE AMS PORTAL IN PRODUCTION AND MANAGE THEIR ALERTS



SCENARIO 3

HOW TO JOIN THE EAMS

-

The SPOC and/or SPOC Assistant doesn’t have access to the AMS Portal and is allowed to sign the T&C

STEP 1 THE SPOC AND/OR SPOC ASSISTANT REQUEST ACCESS FOR THEMSELVES

OBP SPOC or SPOC assistant send an email to the EMVO Helpdesk (helpdesk@emvo-medicines.eu) to request the user creation. The email shall contain the following:

- **Subject of the email**:
  - "AMS Access request – OBP Name"

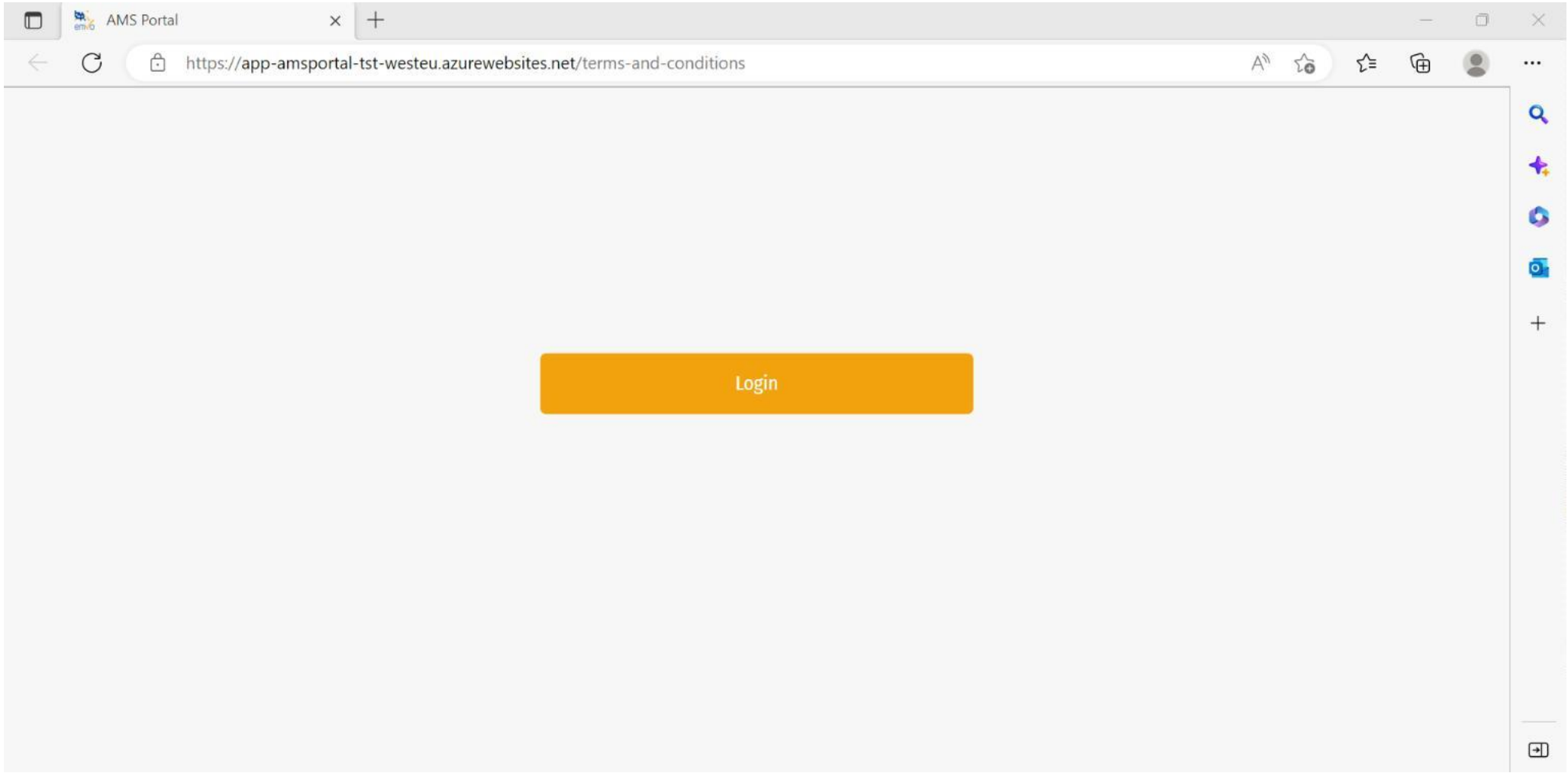
- **Body of the email:**
  - Username
  - User role (SPOC/SPOC Assistant)

- **Attachment of the email**:
  - user template filled with the following user's information:
    - User's first name
    - User's Last Name
    - User's Email address
    - User's Organisation ID

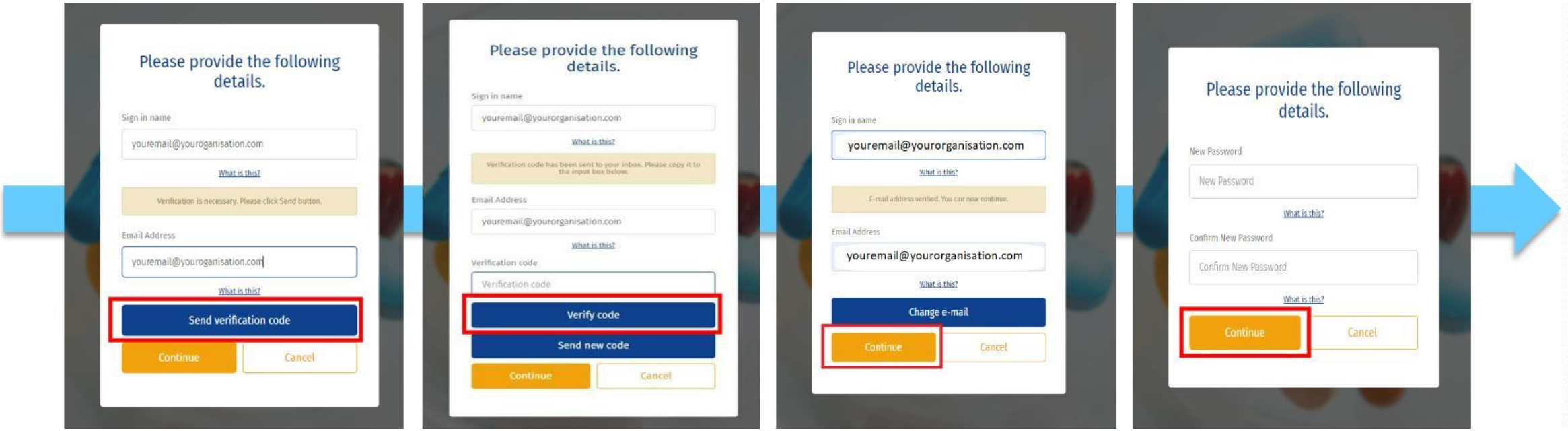
EMVO will take up to 3 days and inform the requestor

Hint: the organisation ID can be found in your OBP Portal under step **4.2.4.1** OR **4.3.4.1**

STEP 2 WHEN CONFIRMED BY EMVO, THE SPOC LOGS IN TO THE AMS PORTAL (HTTPS://AMS.EMVO-MEDICINES.EU)

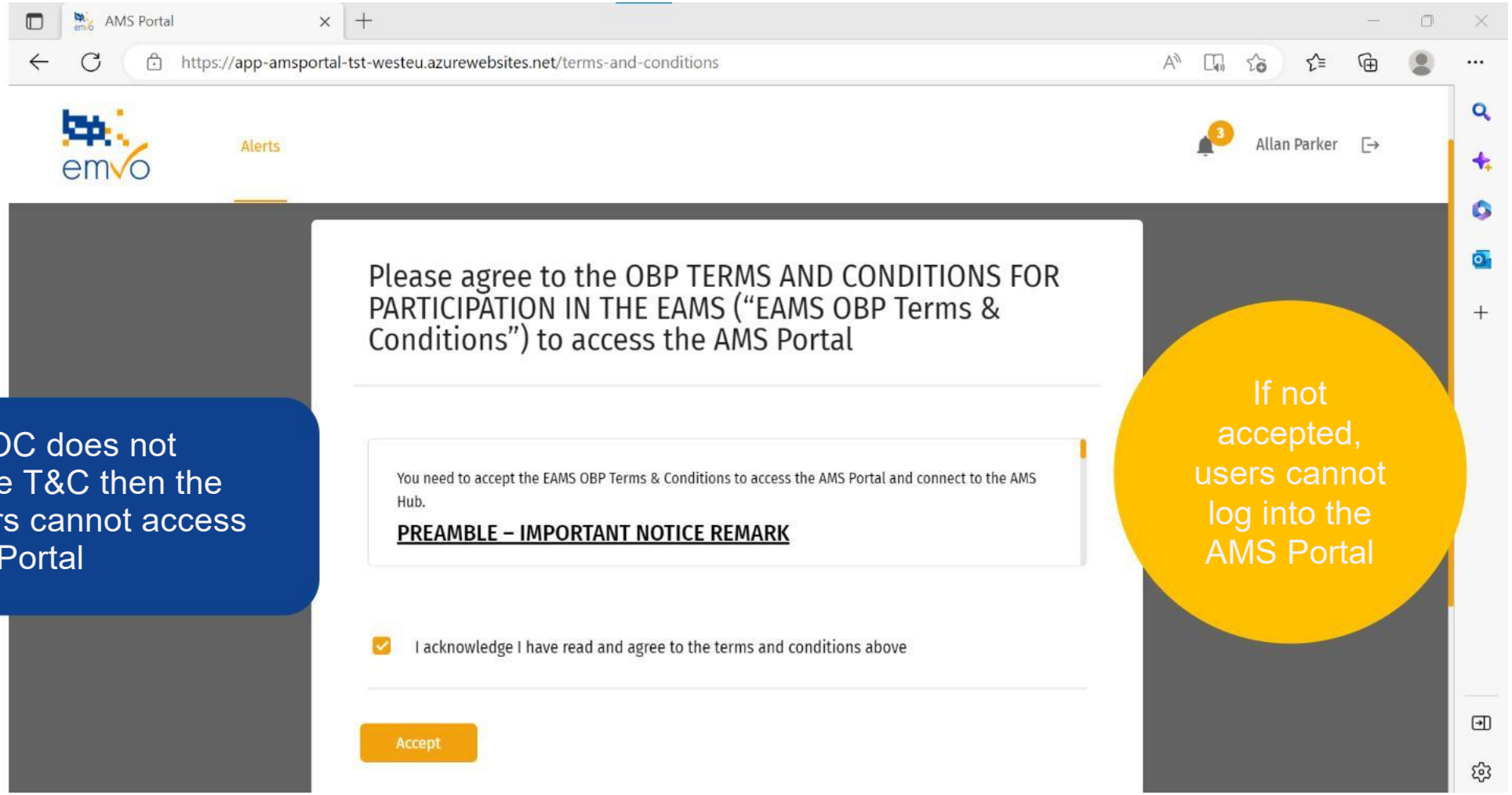


STEP 3 THE SPOC CAN RESET THE PASSWORD SUCCESSFULLY AND THEN LOGS INTO THE AMS PORTAL



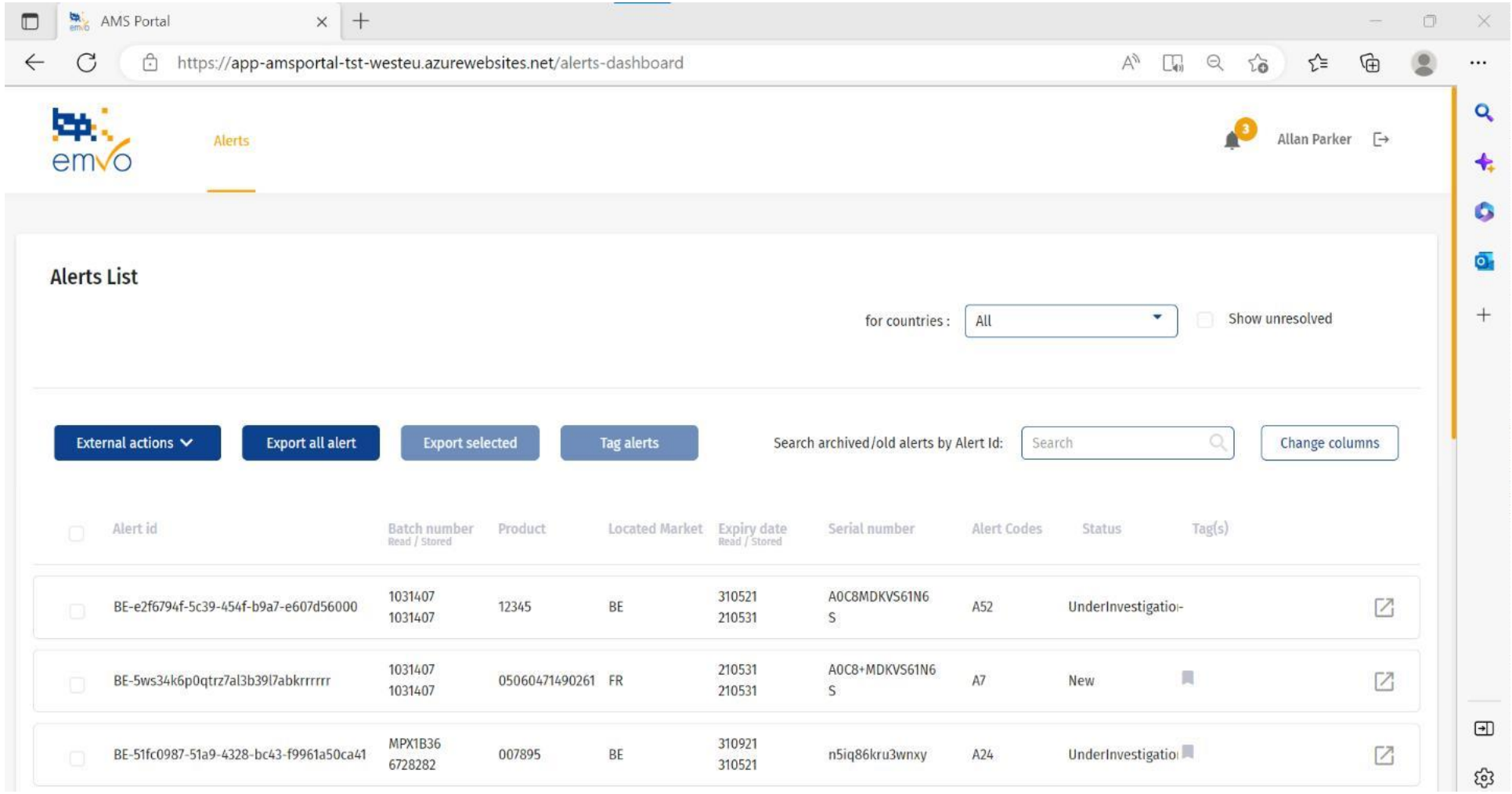
STEP 4 THE SPOC ACCEPTS THE EAMS TERMS AND CONDITIONS

If the SPOC does not accept the T&C then the OBP users cannot access the AMS Portal



If not accepted, users cannot log into the AMS Portal

STEP 5 THE SPOC AND/OR SPOC ASSISTANT CAN ACCESS THE AMS PORTAL IN PRODUCTION AND MANAGE THEIR ALERTS



SCENARIO 4

HOW TO JOIN THE EAMS

-

The SPOC and/or SPOC Assistant doesn't have access to the AMS Portal and isn't allowed to sign the T&C

STEP 1 THE SPOC AND/OR SPOC ASSISTANT REQUEST ACCESS FOR THE LEGAL REPRESENTATIVE AND THEMSELVES

OBP SPOC or SPOC assistant send an email to the EMVO Helpdesk (helpdesk@emvo-medicines.eu) to request the user creation. The email shall contain the following:

- **Subject of the email**:
  - "AMS Access request – OBP Name"

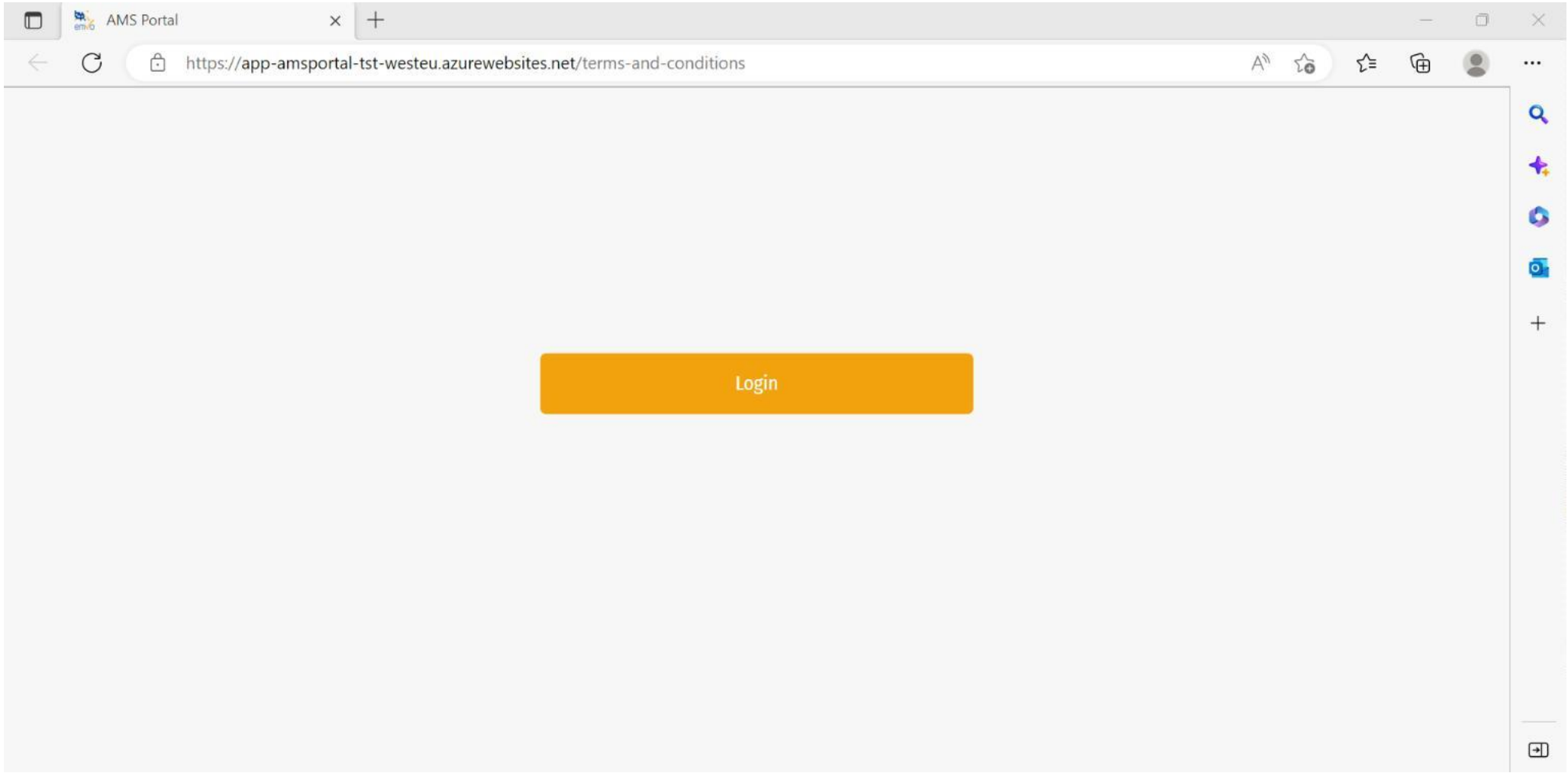
- **Body of the email:**
  - Username
  - User role (SPOC/SPOC Assistant OR Legal representative)

- **Attachment of the email**:
  - user template filled with the following users' information:
    - User's first name
    - User's Last Name
    - User's Email address
    - User's Organisation ID

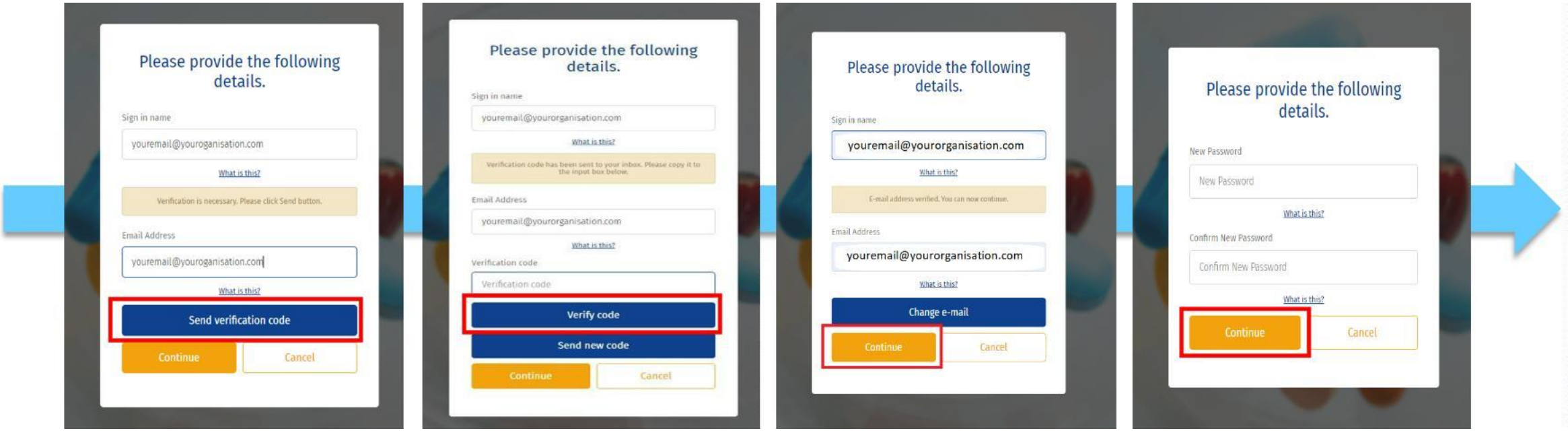
EMVO will take up to 3 days and inform the requestor

Hint: the organisation ID can be found in your OBP Portal under step **4.2.4.1** OR **4.3.4.1**

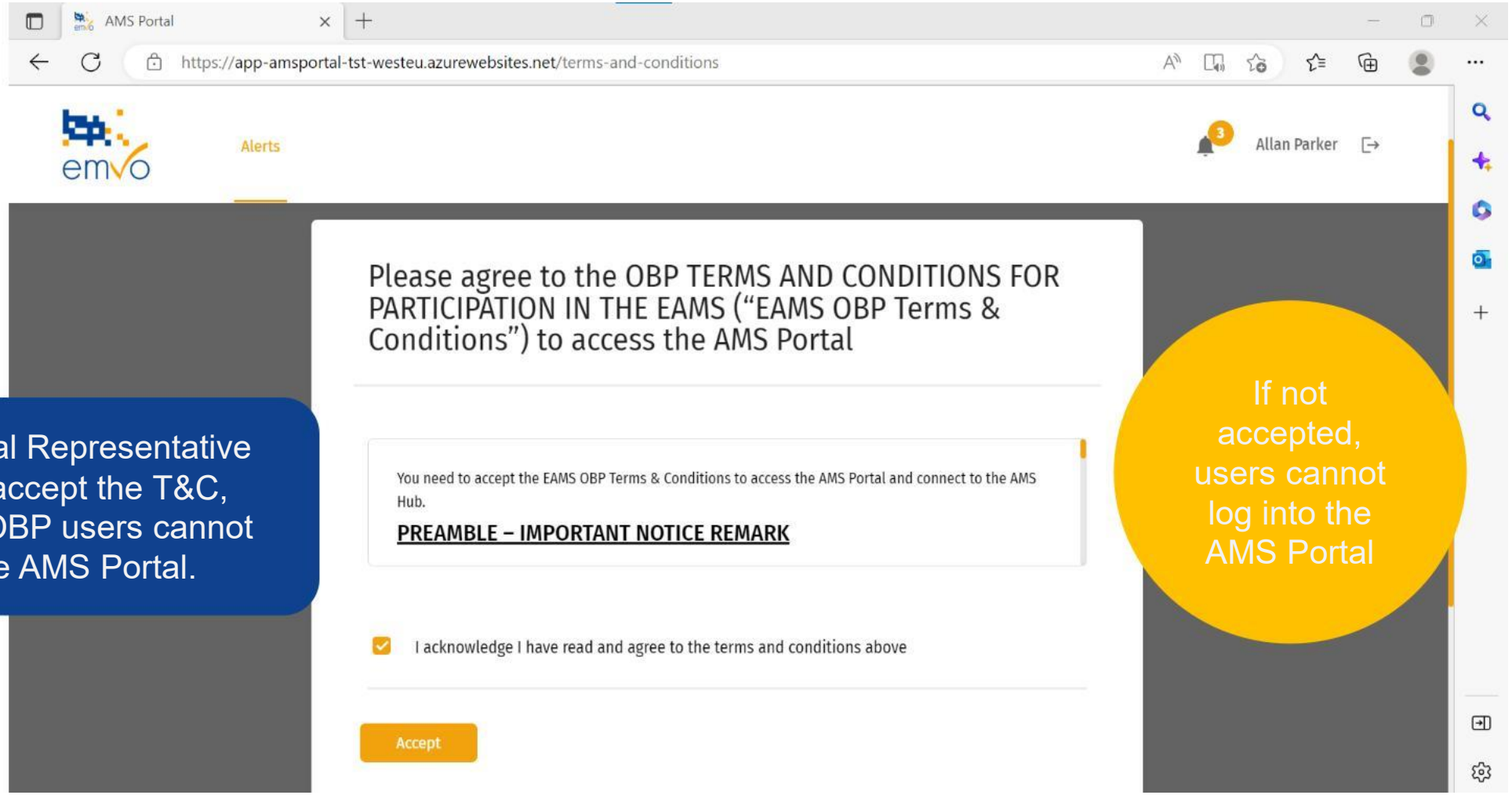
STEP 2 WHEN CONFIRMED BY EMVO, THE LEGAL REPRESENTATIVE LOGS IN TO THE AMS PORTAL (HTTPS://AMS.EMVO-MEDICINES.EU)



STEP 3 THE LEGAL REPRESENTATIVE CAN RESET THE PASSWORD SUCCESSFULLY AND THEN LOGS INTO THE AMS PORTAL



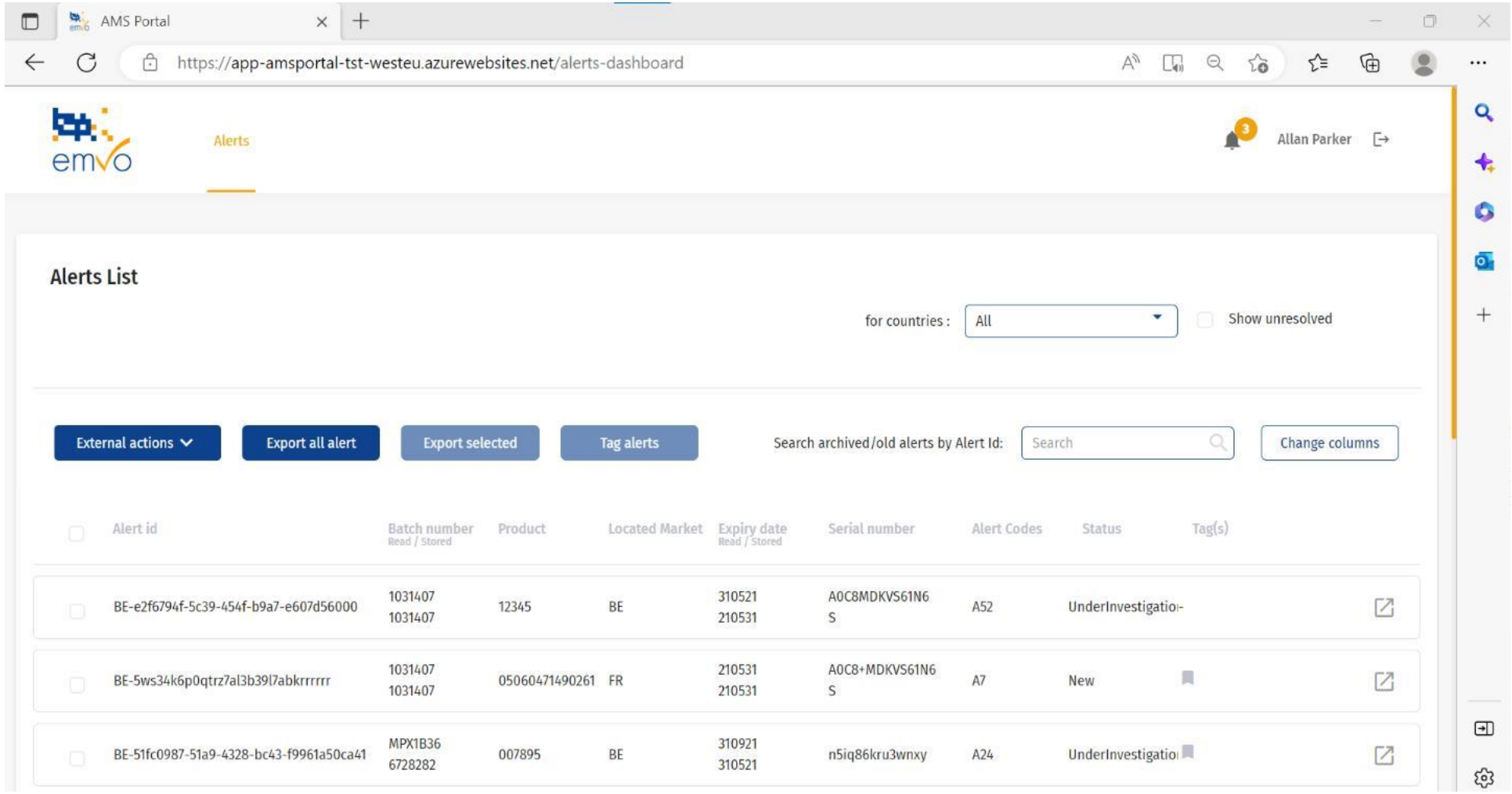
STEP 4 THE LEGAL REPRESENTATIVE ACCEPTS THE EAMS TERMS AND CONDITIONS



If the Legal Representative does not accept the T&C, then the OBP users cannot access the AMS Portal.

If not accepted, users cannot log into the AMS Portal

STEP 5 THE SPOC AND/OR SPOC ASSISTANT CAN ACCESS THE AMS PORTAL IN PRODUCTION AND MANAGE THEIR ALERTS



CONTACTS

For any doubts or questions, please contact the EMVO helpdesk

- helpdesk@emvo-medicines.eu

Thank you

European Alert Management System