



European Medicines Verification Organisation



PGEU GPUE



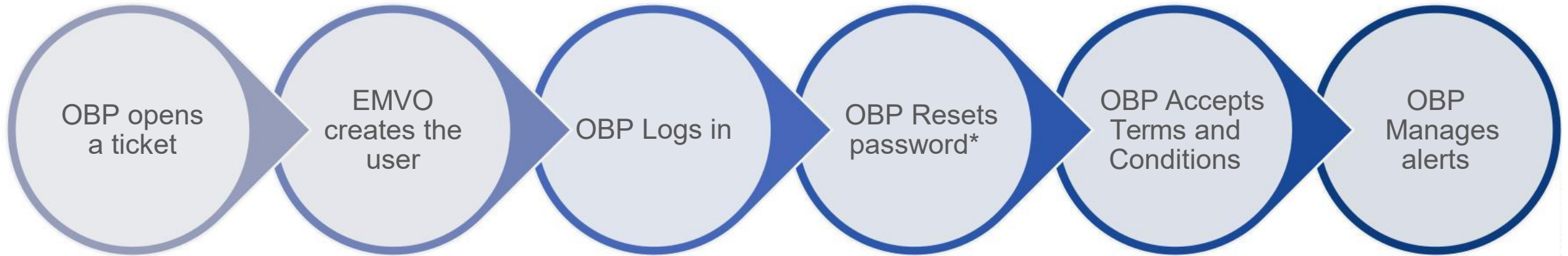
HOW TO JOIN THE EAMS OBP GUIDE

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 PROCEED 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 adherence](#) in place in order to adhere to the [EAMS Terms & Conditions](#). The letter of adherence 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

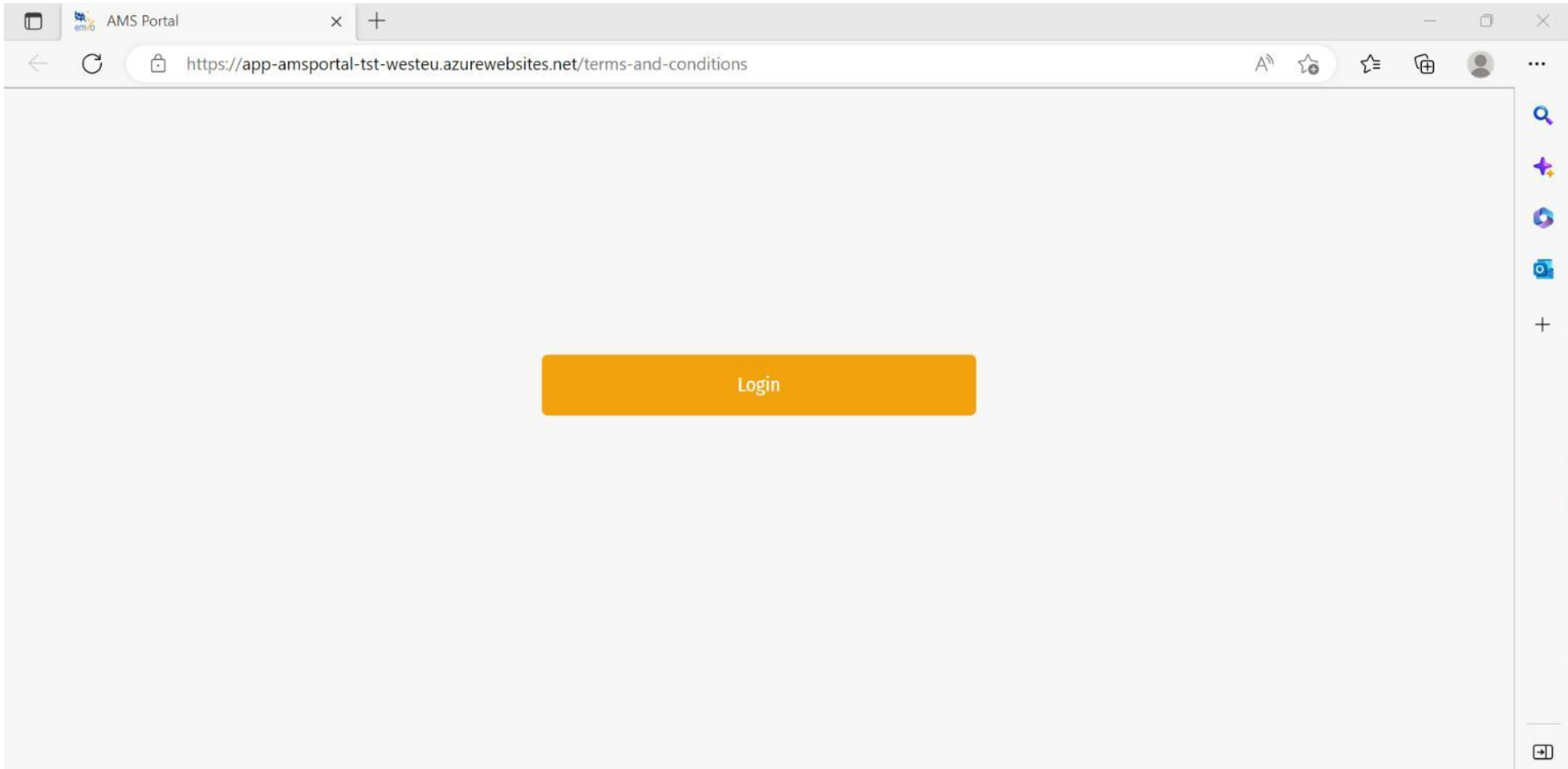
HOW TO JOIN THE EAMS

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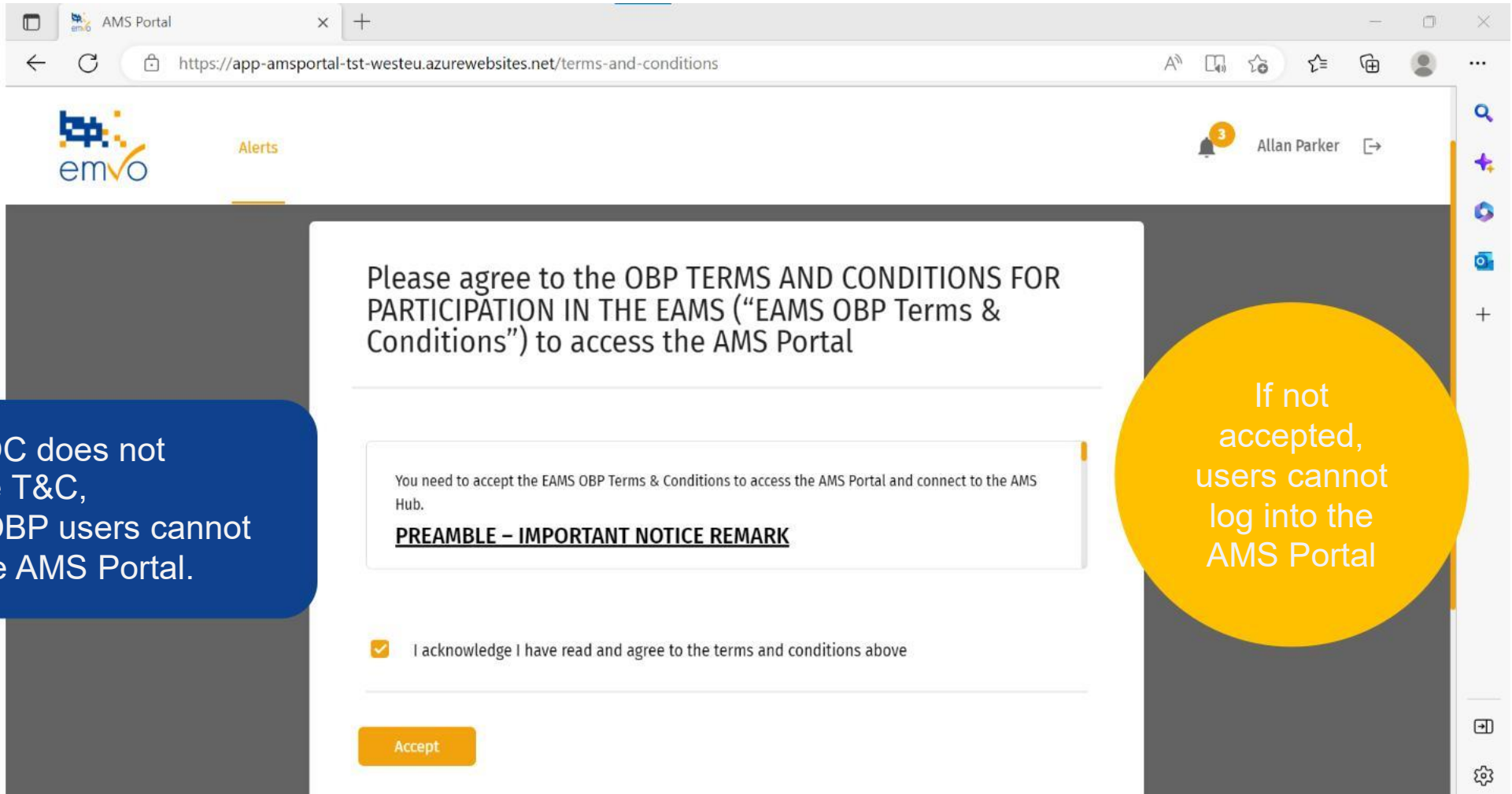
The SPOC and/or SPOC Assistant has access to the AMS Portal and is allowed to sign the T&C



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



AMS Portal

Alerts

Allan Parker

Please agree to the OBP TERMS AND CONDITIONS FOR PARTICIPATION IN THE EAMS (“EAMS OBP Terms & Conditions”) to access the AMS Portal

You need to accept the EAMS OBP Terms & Conditions to access the AMS Portal and connect to the AMS Hub.

PREAMBLE – IMPORTANT NOTICE REMARK

I acknowledge I have read and agree to the terms and conditions above

Accept

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

The screenshot shows the 'Alerts' dashboard in the AMS Portal. The browser address bar shows the URL: <https://app-amsportal-tst-westeu.azurewebsites.net/alerts-dashboard>. The user is logged in as 'Allan Parker'. The dashboard features an 'Alerts List' with a filter for 'countries' set to 'All' and a 'Show unresolved' checkbox. Below the list are buttons for 'External actions', 'Export all alert', 'Export selected', and 'Tag alerts'. A search bar for 'archived/old alerts by Alert Id' is also present. The table below contains three alert entries:

<input type="checkbox"/>	Alert id	Batch number <small>Read / Stored</small>	Product	Located Market	Expiry date <small>Read / Stored</small>	Serial number	Alert Codes	Status	Tag(s)
<input type="checkbox"/>	BE-e2f6794f-5c39-454f-b9a7-e607d56000	1031407 1031407	12345	BE	310521 210531	A0C8MDKVS61N6 S	A52	UnderInvestigatio-	
<input type="checkbox"/>	BE-5ws34k6p0qtrz7al3b39l7abkrrrrrr	1031407 1031407	05060471490261	FR	210531 210531	A0C8+MDKVS61N6 S	A7	New	
<input type="checkbox"/>	BE-51fc0987-51a9-4328-bc43-f9961a50ca41	MPX1B36 6728282	007895	BE	310921 310521	n5iq86kru3wnxy	A24	UnderInvestigatio	

SCENARIO 2

HOW TO JOIN THE EAMS

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**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:

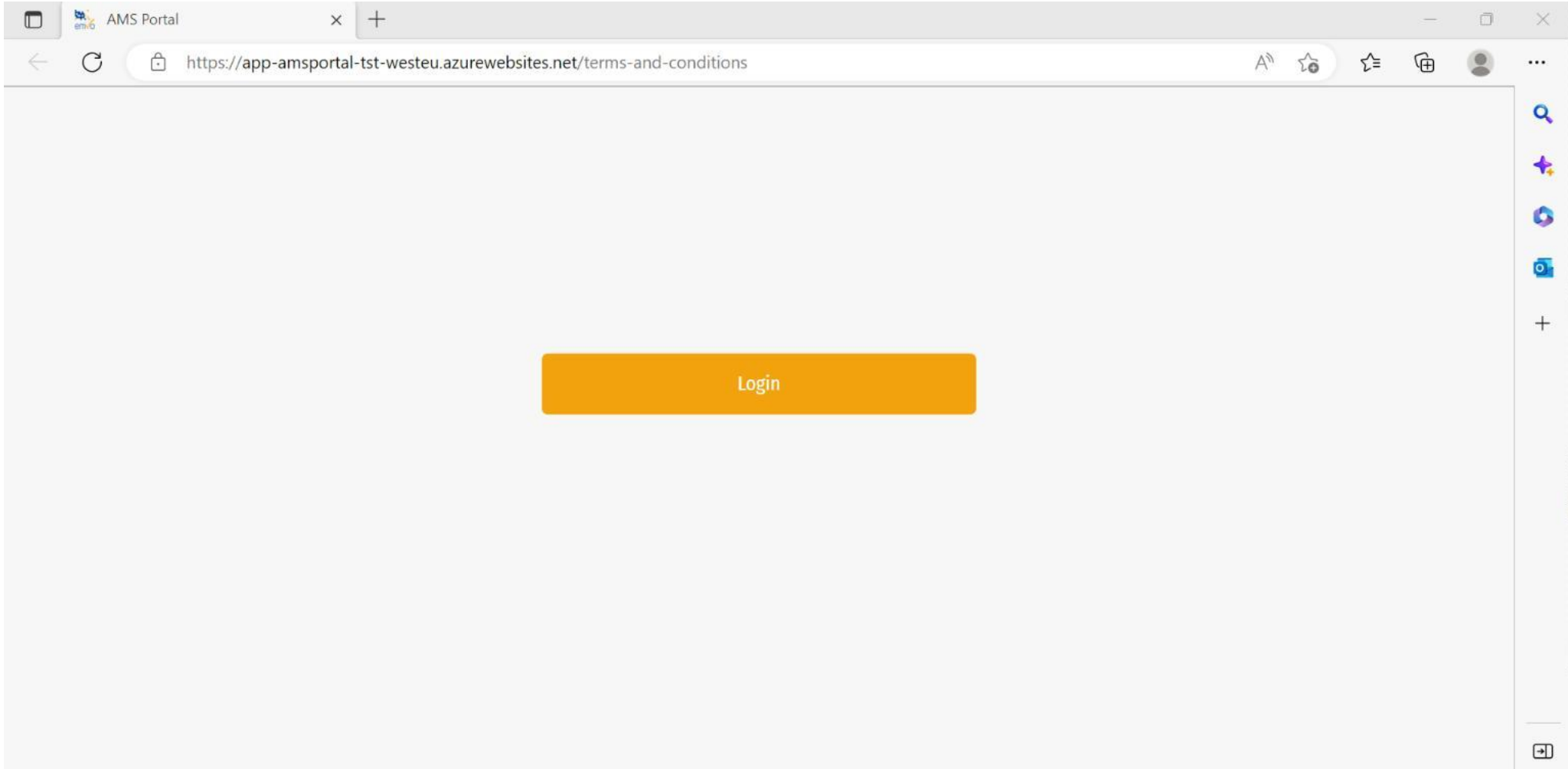
- **Subject of the email:**
 - “AMS Access request – OBP Name”
- **Body of the email:**
 - Username
 - User role (Legal Representative)
- **Attachment of the email:**
 - [user template](#) filled with the following user’s information:
 - User’s first name
 - User’s Last Name
 - User’s Email address
 - User’s Organisation ID

EMVO will take up to 3 days and inform the requestor

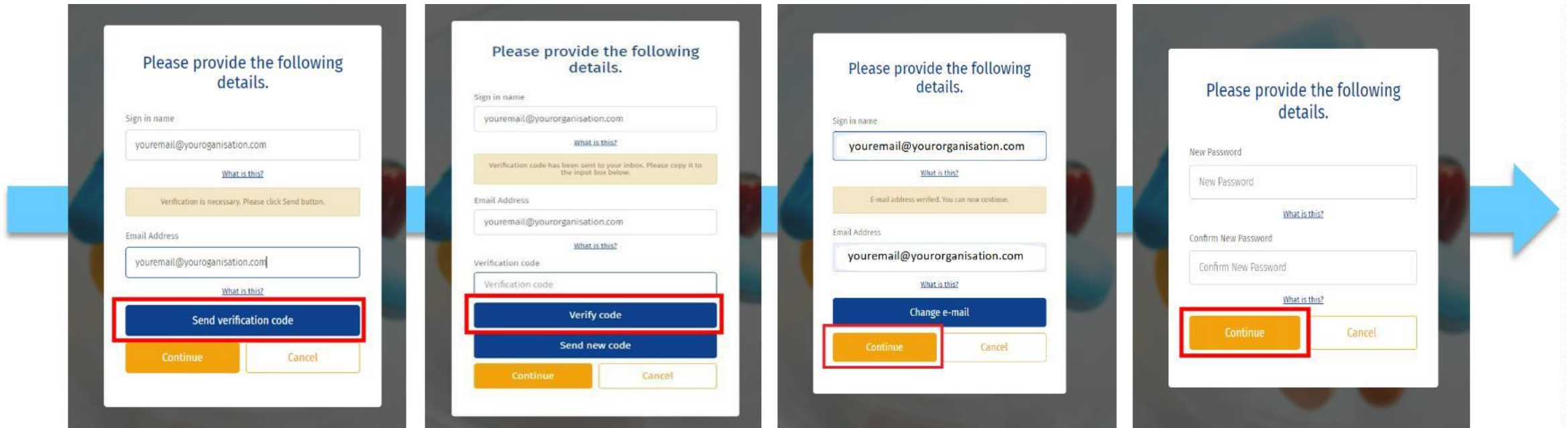
Hint: the organisation ID can be found in your OBP Portal under step 4.2.4.1 OR 4.3.4.1



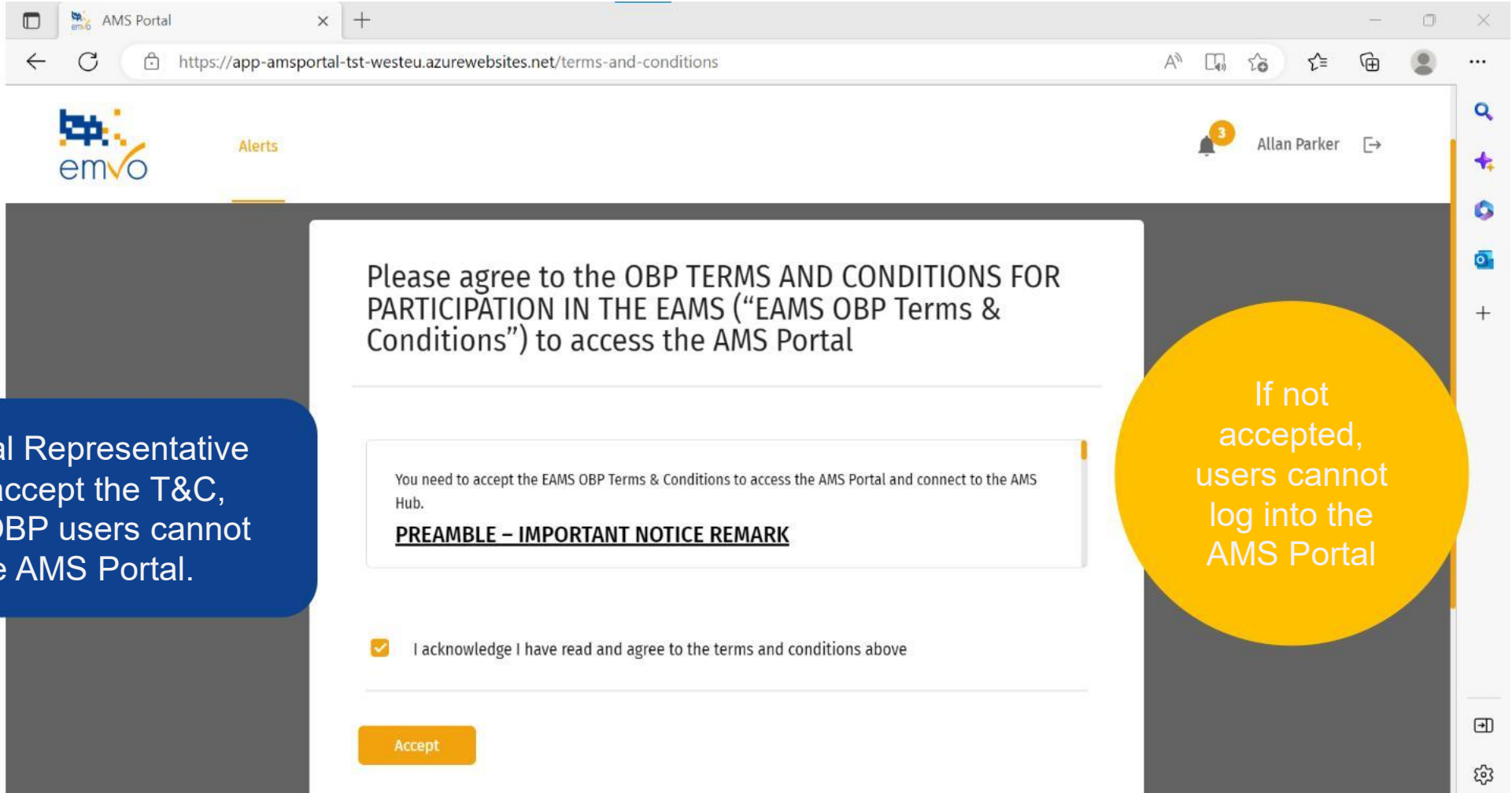
STEP 2 WHEN CONFIRMED BY EMVO, THE LEGAL REPRESENTATIVE LOGS IN TO THE AMS PORTAL (HTTPS://AMS.EMVO-MEDICINES.EU)



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



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You need to accept the EAMS OBP Terms & Conditions to access the AMS Portal and connect to the AMS Hub.

PREAMBLE – IMPORTANT NOTICE REMARK

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Accept

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

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<input type="checkbox"/>	BE-5ws34k6p0qtrz7al3b39l7abkrrrrrr	1031407 1031407	05060471490261	FR	210531 210531	A0C8+MDKVS61N6 S	A7	New	
<input type="checkbox"/>	BE-51fc0987-51a9-4328-bc43-f9961a50ca41	MPX1B36 6728282	007895	BE	310921 310521	n5iq86kru3wnxy	A24	UnderInvestigatio	

SCENARIO 3

HOW TO JOIN THE EAMS

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**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

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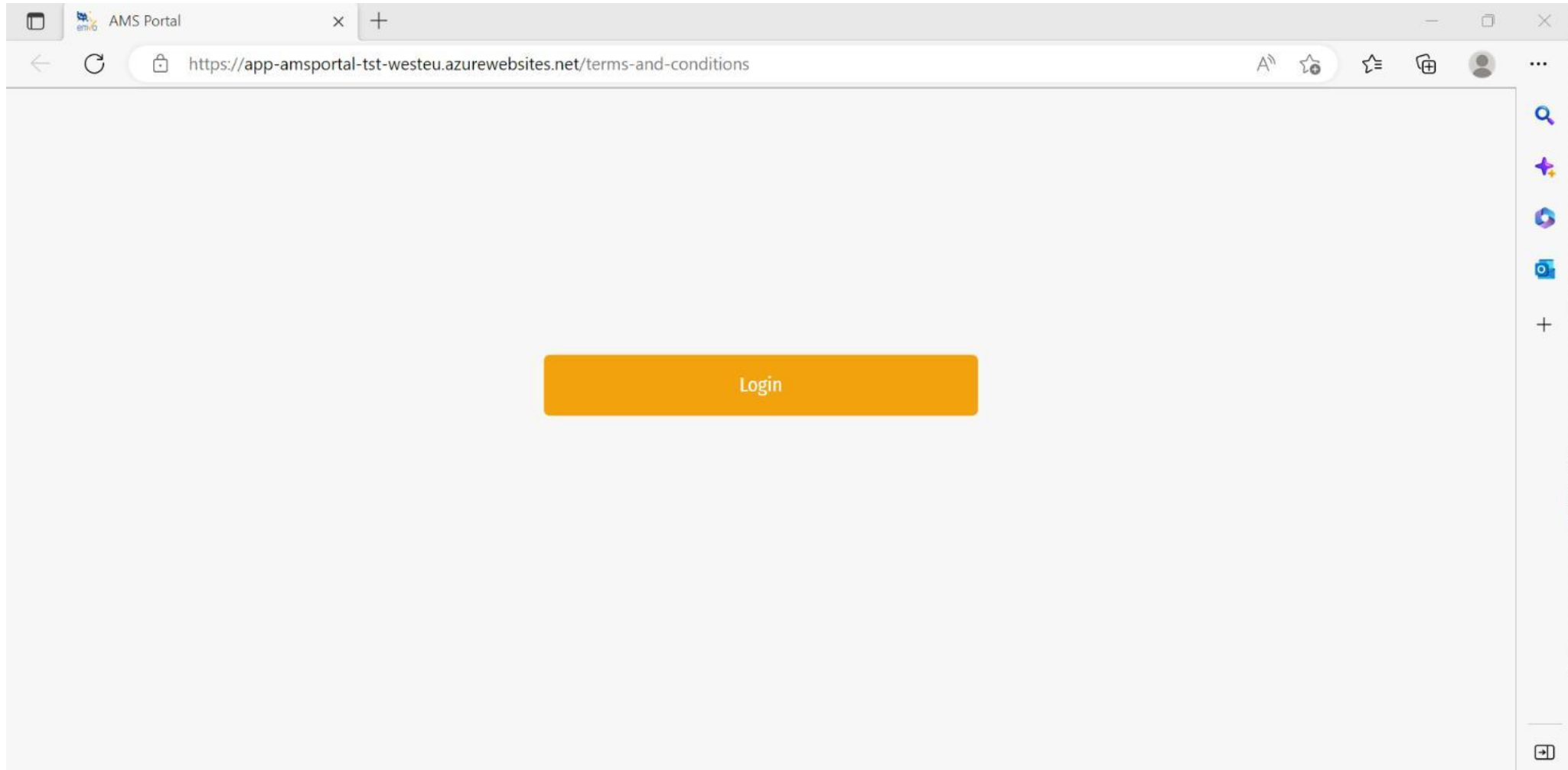
- **Subject of the email:**
 - “AMS Access request – OBP Name”
- **Body of the email:**
 - Username
 - User role (SPOC/SPOC Assistant)
- **Attachment of the email:**
 - [user template](#) filled with the following user’s information:
 - User’s first name
 - User’s Last Name
 - User’s Email address
 - User’s Organisation ID

EMVO will take up to 3 days and inform the requestor

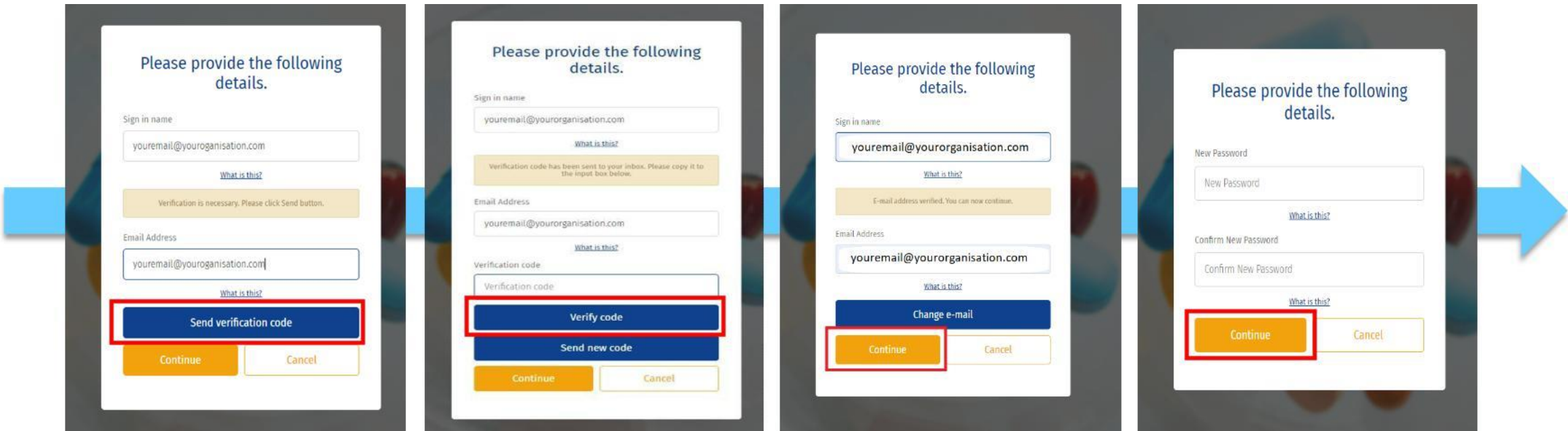
Hint: the organisation ID can be found in your OBP Portal under step 4.2.4.1 OR 4.3.4.1



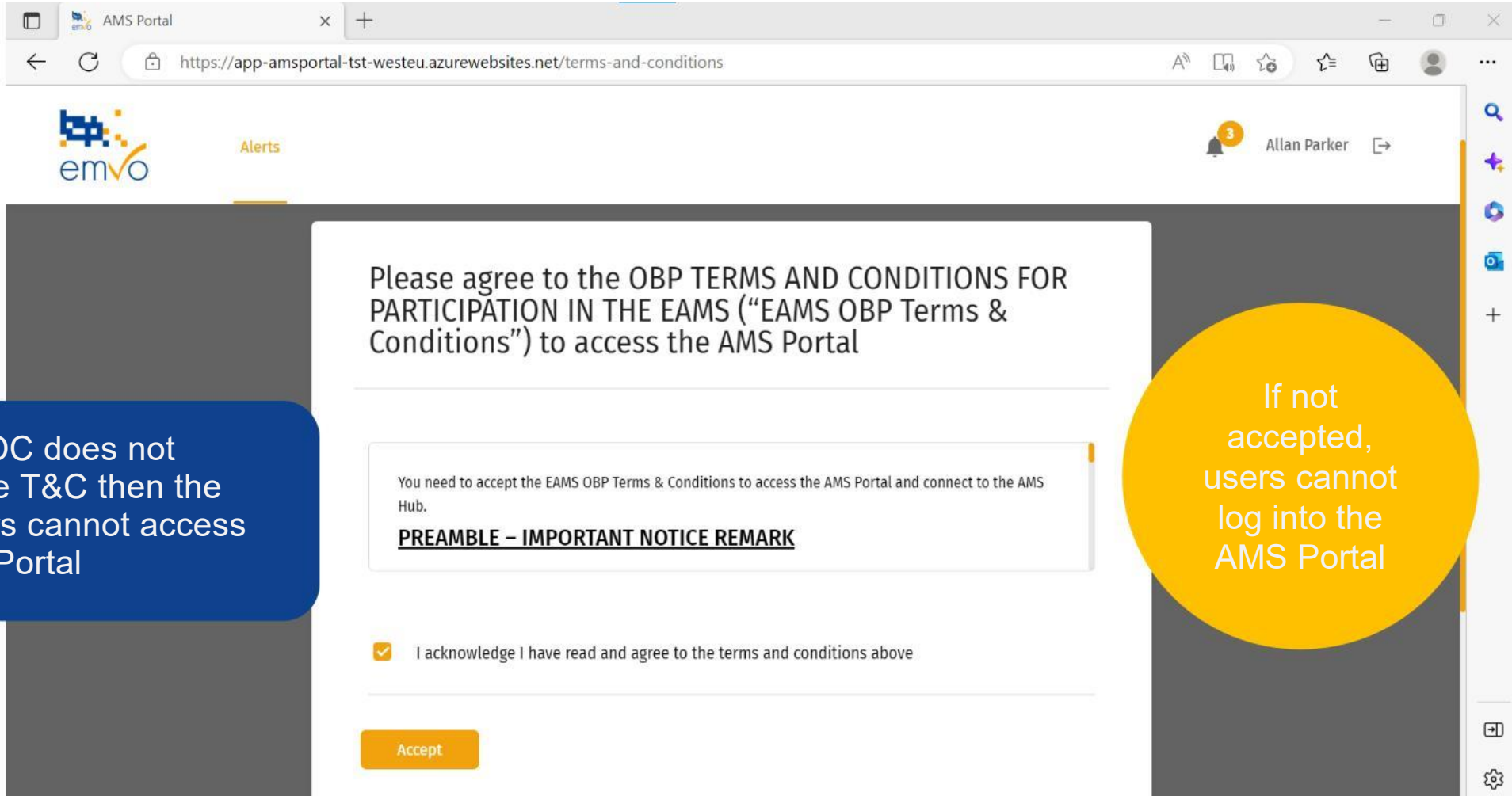
STEP 2 WHEN CONFIRMED BY EMVO, THE SPOC LOGS IN TO THE AMS PORTAL (HTTPS://AMS.EMVO-MEDICINES.EU)



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



AMS Portal

Alerts

Allan Parker

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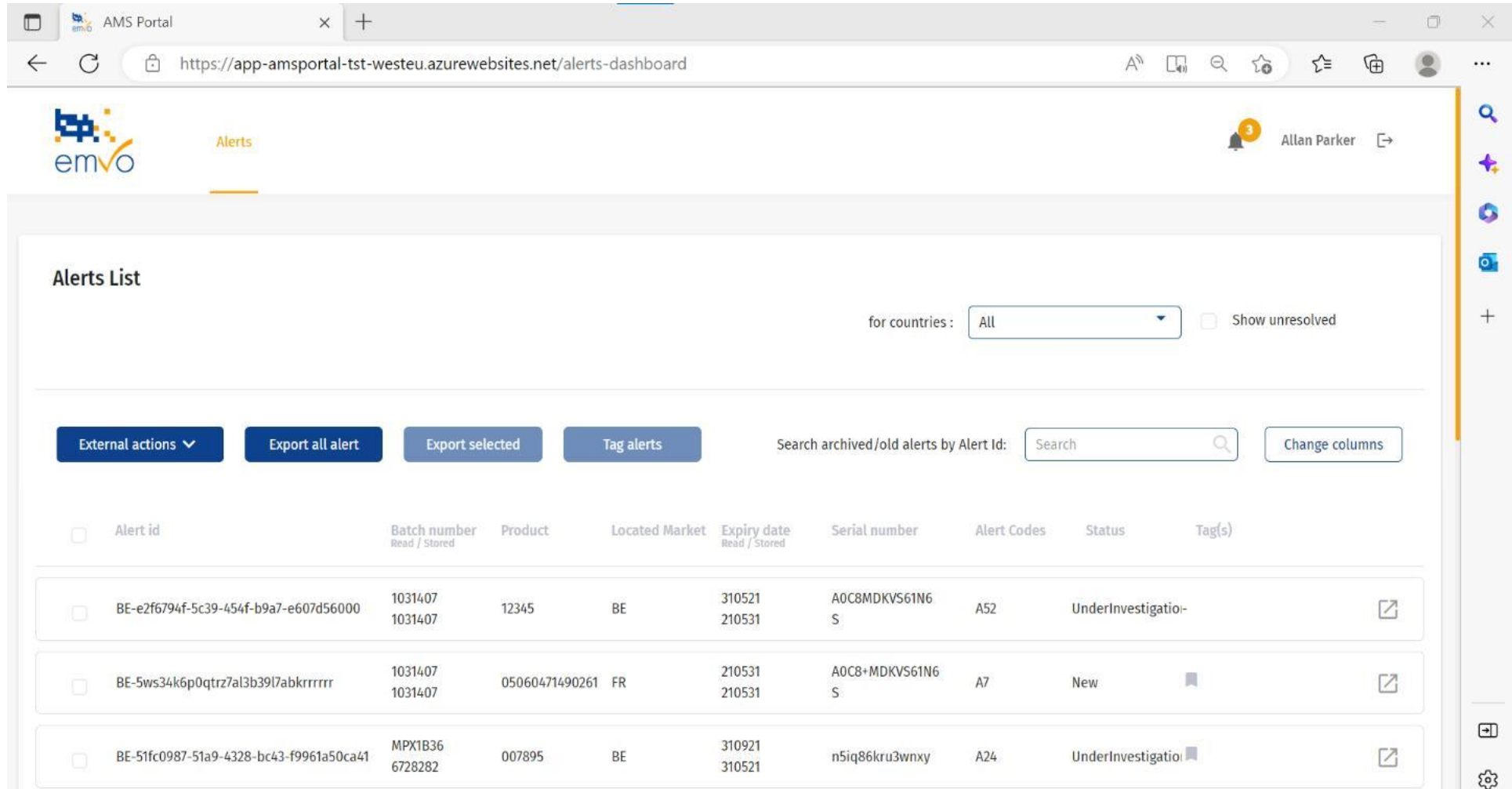
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<input type="checkbox"/> BE-e2f6794f-5c39-454f-b9a7-e607d56000	1031407 1031407	12345	BE	310521 210531	A0C8MDKVS61N6 S	A52	UnderInvestigatio-	
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SCENARIO 4

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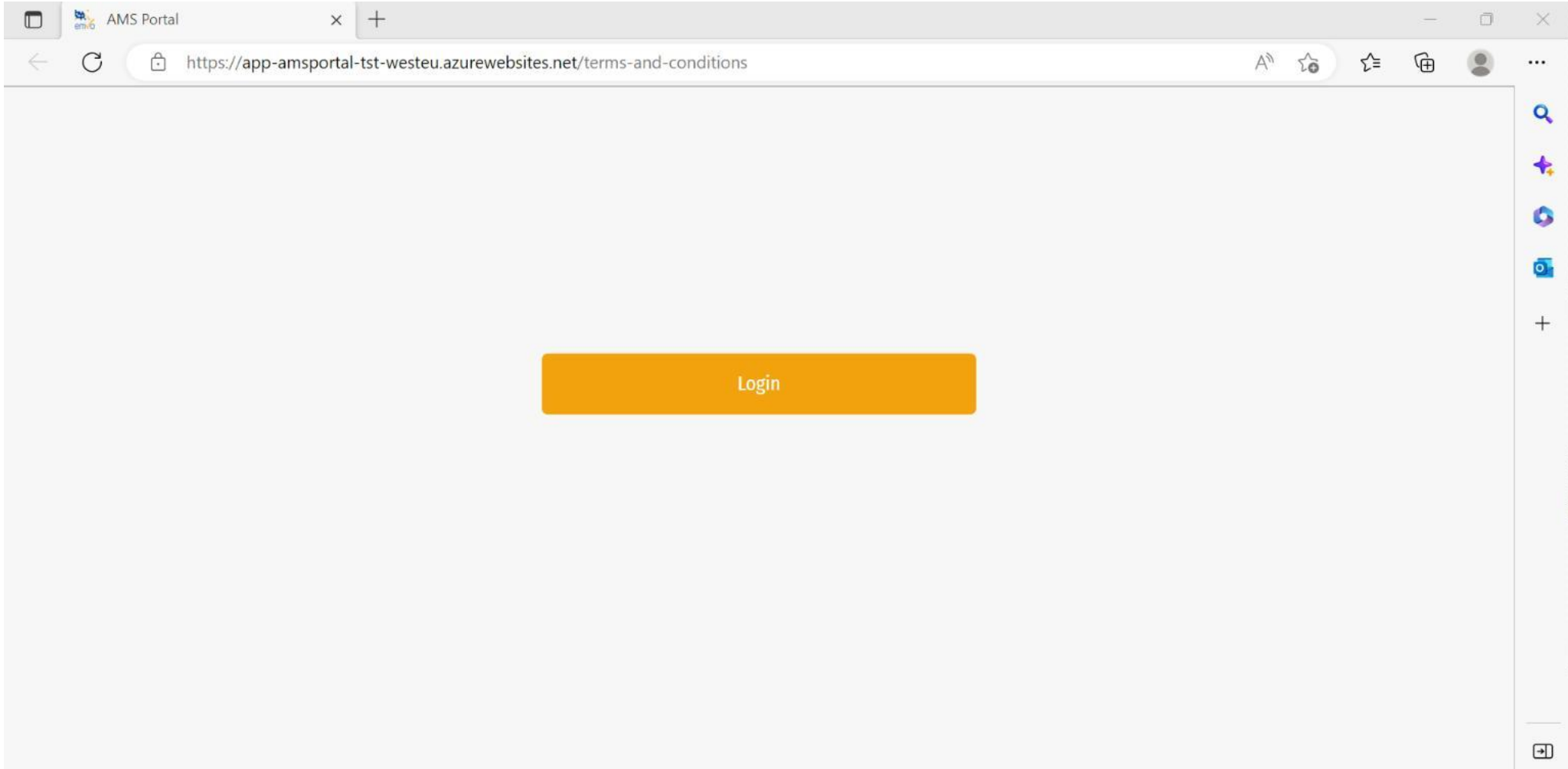
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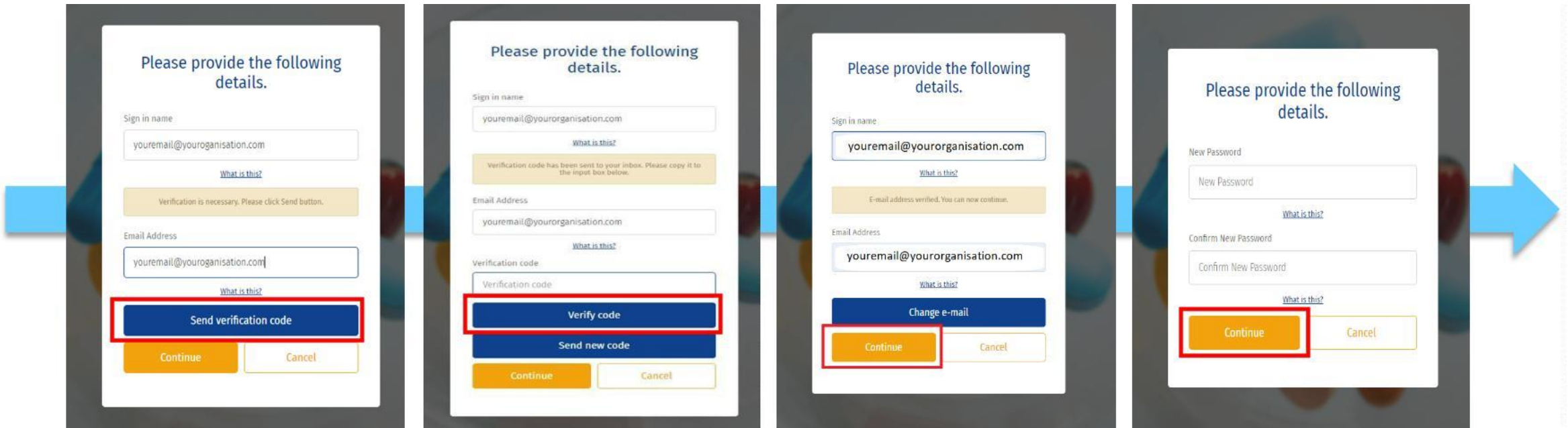
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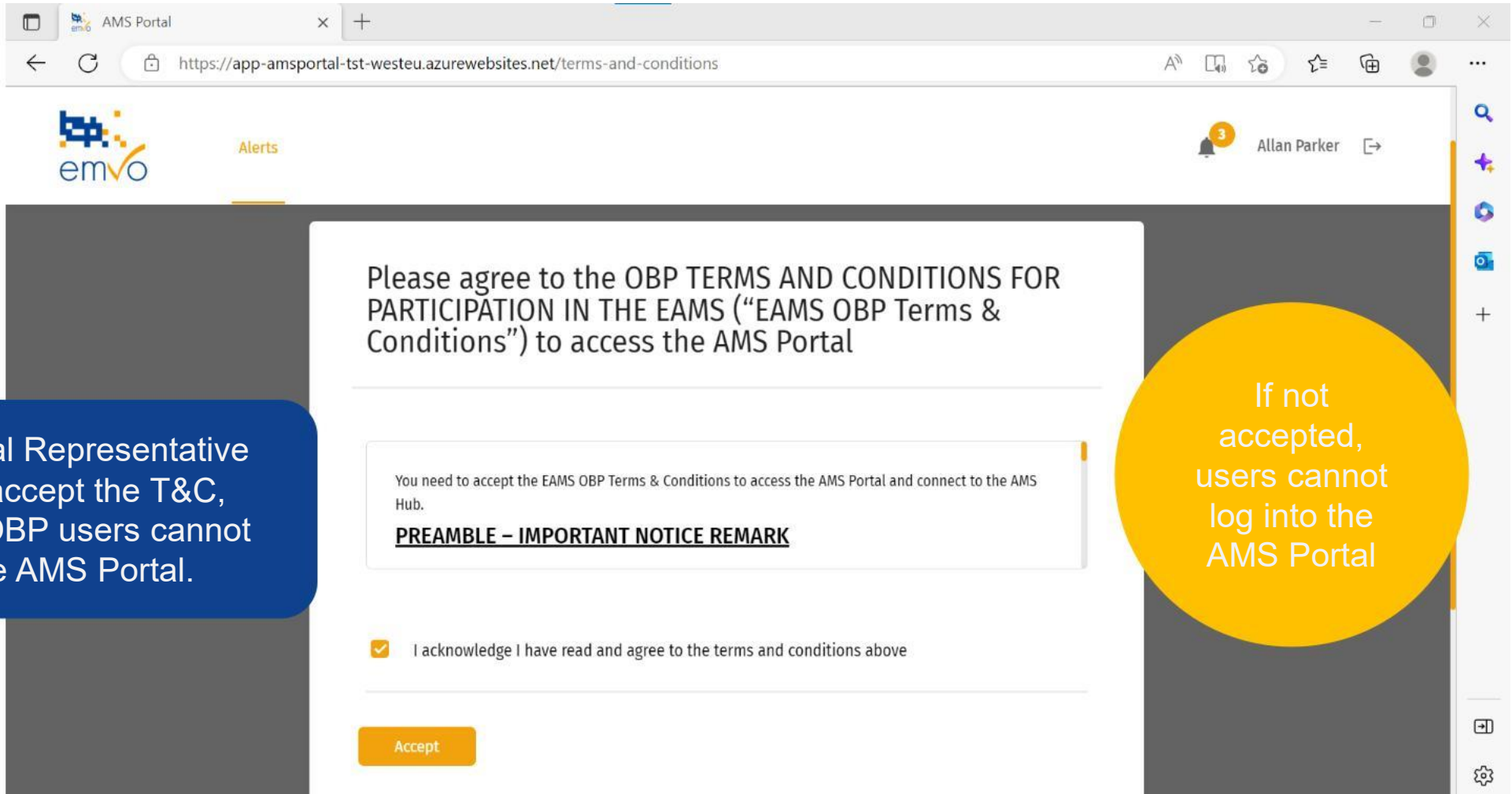
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STEP 5 THE SPOC AND/OR SPOC ASSISTANT CAN ACCESS THE AMS PORTAL IN PRODUCTION AND MANAGE THEIR ALERTS

AMS Portal Alerts

for countries: All Show unresolved

External actions Search archived /old alerts by Alert ID:

<input type="checkbox"/>	Alert id	Batch number <small>Read / Stored</small>	Product	Located Market	Expiry date <small>Read / Stored</small>	Serial number	Alert Codes	Status	Tag(s)
<input type="checkbox"/>	BE-e2f6794f-5c39-454f-b9a7-e607d56000	1031407 1031407	12345	BE	310521 210531	A0C8MDKVS61N6 S	A52	UnderInvestigatio-	<input type="button" value=""/>
<input type="checkbox"/>	BE-5ws34k6p0qtrz7al3b39l7abkrrrrrr	1031407 1031407	05060471490261	FR	210531 210531	A0C8+MDKVS61N6 S	A7	New	<input type="button" value=""/>
<input type="checkbox"/>	BE-51fc0987-51a9-4328-bc43-f9961a50ca41	MPX1B36 6728282	007895	BE	310921 310521	n5iq86kru3wnxy	A24	UnderInvestigatio	<input type="button" value=""/>



CONTACTS

For any doubts or questions, please contact the EMVO helpdesk

- helpdesk@emvo-medicines.eu

Thank you

European Alert Management System