



Medicines & Healthcare products Regulatory Agency

User reference guide - Registration process for ICSR Submissions

A step by step guide to gain access to ICSR Submissions.

If you wish to submit and receive Individual Case Safety Reports (ICSRs) and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) to or from the MHRA but do not have the capability to use the MHRA Gateway, you will need to register to use ICSR Submissions.

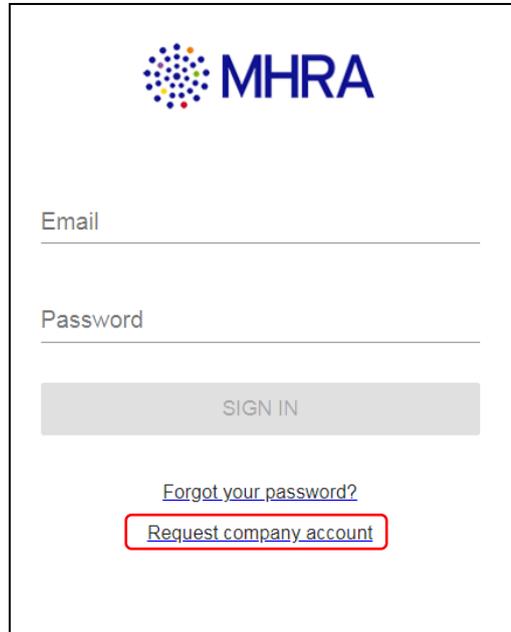
ICSR Submissions can be accessed at <https://icsrsubmissions.mhra.gov.uk/login>.

If you currently submit SUSARs through eSUSAR (<https://esusar.mhra.gov.uk/>) you can continue to do so.

If you wish to transmit and receive ICSR/SUSARs via the MHRA Gateway, please see the User reference guide for MHRA Gateway registration.

Step 1:

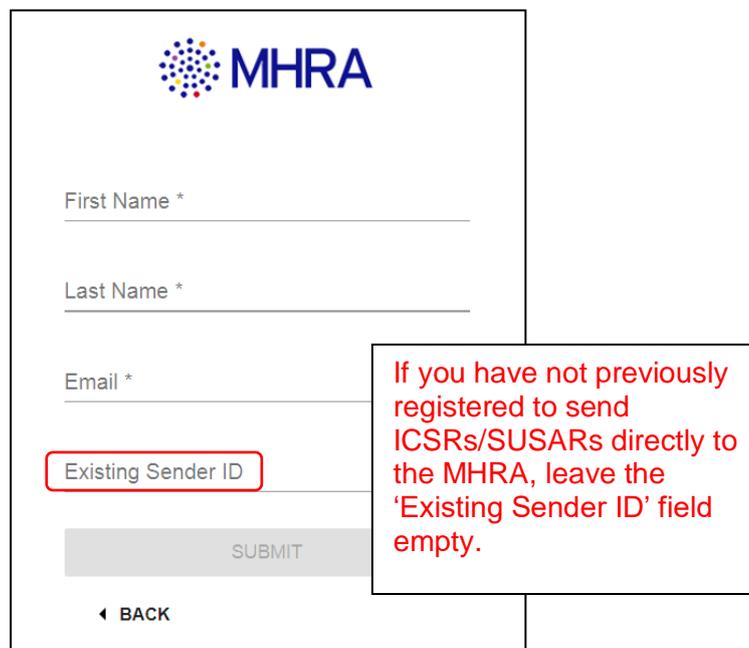
If you are the designated company lead for your organisation, you can initiate registration by visiting ICSR Submissions and selecting the 'Request company account' on the ICSR Submissions login page.



The screenshot shows the MHRA login interface. At the top is the MHRA logo. Below it are two input fields: 'Email' and 'Password'. A grey 'SIGN IN' button is positioned below the password field. Underneath the button is a blue link for 'Forgot your password?'. At the bottom, a red-bordered box highlights the 'Request company account' link.

Step 2:

On the 'Request company account' page, you should enter your first and last name, as well as your contact email address. These fields are mandatory.



The screenshot shows the 'Request company account' page. It features the MHRA logo at the top. Below the logo are three mandatory input fields: 'First Name *', 'Last Name *', and 'Email *'. An 'Existing Sender ID' field is also present, highlighted with a red border. A grey 'SUBMIT' button is located below the 'Existing Sender ID' field. A '← BACK' link is at the bottom left. A red-bordered callout box on the right contains the text: 'If you have not previously registered to send ICSRs/SUSARs directly to the MHRA, leave the 'Existing Sender ID' field empty.'

If the 'Existing Sender ID' field is left empty, upon receiving your request, MHRA will contact you via the email address you provided to confirm your Sender ID, Company number and address, and will set up this Sender ID on the MHRA system.

Note: If you have previously registered to send ICSRs/SUSARs directly to the MHRA, enter your sender ID (E2B field messagesenderidentifier).

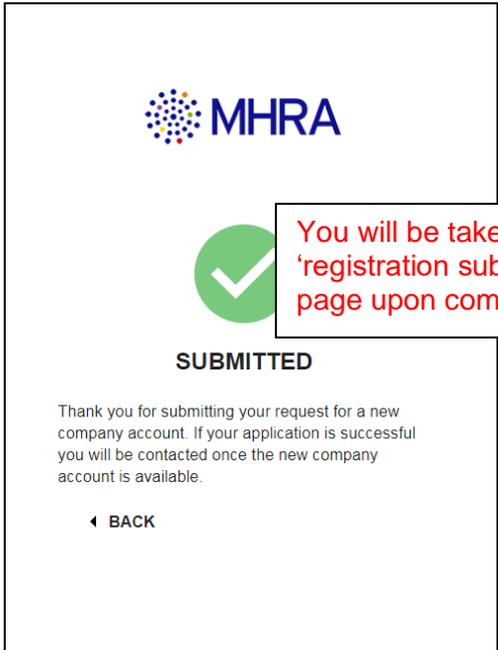
Step 3:



The screenshot shows the MHRA registration form. At the top is the MHRA logo. Below it are four input fields: 'First Name *' with the value 'User', 'Last Name *' with the value 'Name', 'Email *' with the value 'User@email.com', and 'Existing Sender ID' with the value 'SENDERID'. A blue 'SUBMIT' button is highlighted with a red border and a red arrow points from a callout box to it. A 'BACK' link is at the bottom left.

Once you have completed this information, you can submit your request by pressing 'Submit'.

Step 4:



The screenshot shows the 'SUBMITTED' confirmation page. At the top is the MHRA logo. Below it is a green checkmark icon. The word 'SUBMITTED' is displayed in bold. Below that is a paragraph of text: 'Thank you for submitting your request for a new company account. If your application is successful you will be contacted once the new company account is available.' A 'BACK' link is at the bottom left. A callout box with a red border and red text points to the checkmark icon.

You will be taken to the 'registration submitted' page upon completion.

Step 5:

Your request will be sent to the MHRA and we will create an 'Organisation' for your company.

The MHRA will also create an 'organisation lead' account for you based on the details provided in your company account request.

Once these have been created, you will receive an email with your password and login details.

Your organisation has been created using information provided in your request, so you may wish to update organisation information on the 'My Organisation' page.

Further Information:

Your account information can be viewed on the 'My Profile' page.

If you are an 'organisation lead', you are responsible for creating user accounts for others in your organisation who require access to ICSR Submissions.

User accounts can be managed on the 'User Management' page.

Users can be assigned the role of either 'organisation lead' or 'standard user'.

These users are now able to use send and receive ICSRs/SUSARs via ICSR Submissions.

If you require access to ICSR Submissions and your company has already completed registration, contact your company's organisation lead.

For guidance on how to use ICSR Submissions please see the User reference guide for ICSR Submissions.

Testing

You do not need to complete any testing before sending ICSRs/SUSARs to the MHRA via ICSR Submissions.

Contact Details

If you are experiencing issues registering for ICSR Submissions, please email details of your issue(s) to ICSRtesting@mhra.gov.uk. Please include 'ICSR Submissions' in the subject header of your email.