Registration process for MHRA Gateway

A step by step user reference guide to gain access to the MHRA Gateway

Once you have successfully completed registration for MHRA Submissions and received your administrator account, you can register to send and receive Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) through the MHRA Gateway.

You will require access to the MHRA Gateway Maintenance "tile" if you are submitting the following via MHRA Gateway:

- *Individual Case Safety Reports*
- *Suspected Unexpected Serious Adverse Reactions*

Prior to registration, please ensure that:

- **you are registered and have an MHRA submissions account**
- **you are a company administrator with Gateway permissions (MHRA Gateway registration can only be completed by company administrators).**

If your company does not have the capability to transmit and receive ICSRs/SUSARs via the MHRA Gateway, please see the User reference guide for ICSR Submissions.

Step 1:

Select 'PV Gateway Maintenance' from the MHRA Submissions homepage.
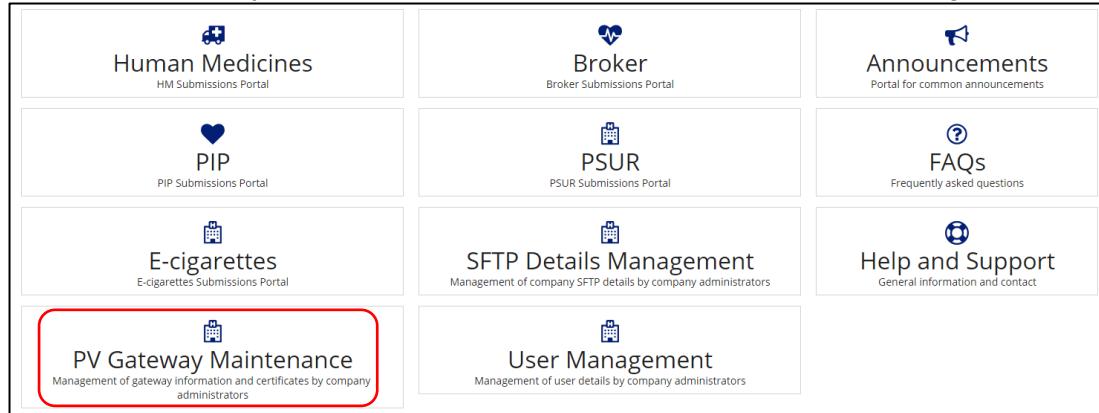
Select 'Register Request'.
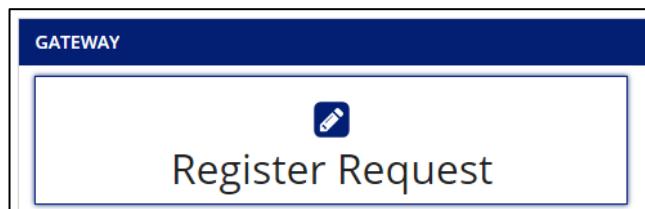
Step 2:

Select the company you would like to register for MHRA Gateway access from the dropdown menu.

MHRA Gateway details, test certificates and production certificates can be downloaded by selecting the relevent link.

Note: If you had not previously registered to send ICSRs/SUSARs directly to the MHRA prior to November 2017 you will see the message 'Production routing ID for the company is not available. Please contact ICSRtesting@mhra.gov.uk.' To register your routing ID, please email your production and testing routing ID (E2B field messagesenderidentifier), company number, email address and postal address to ICSRtesting@mhra.gov.uk. You will receive an email once the routing ID has been set up. You will then be able to continue with the registration process.

If you had previously registered to send ICSRs/SUSARs directly to the MHRA prior to November 2017, a list of versions of configurations will be provided. If you are registering for the first time, no configurations will be present.

Support Details

* Gateway Support Email   2801demo@gmail.com

Support details should be provided so that the MHRA can contact the appropriate individual or mailbox in your company if necessary.

Protocol Details

Instructions — Your test environment sender/receiver ID should be entered manually. Your production sender/receiver ID will be automatically populated.

Test Environment Details   **Production Environment Details**

Routing ID   ACTAVISPR

PV Gateway Type   ---Select a type---   ---Select a type---

AS1 Email Address

AS2 Message and MDN URL

AS2 External static IP Address

After selecting the 'Gateway' type from the dropdown menu (AS1 or AS2), please provide the relevant information in relation to this 'Gateway'.

AS2 MDN Mechanism   ---Select a mechanism---   ---Select a mechanism---

Signature Algorithm   SHA-256

Encryption Algorithm   3DES

Compression Algorithm   None

EDI Data Type   applicati

Encryption information for both AS1 and AS2 Gateways are also required. Appropriate options should also be selected from the drop downs in the 'Encryption Algorithm', 'Compression Algorithm' and 'EDI Data Type' fields.

Public Certificate   UPLOAD Drop file here   UPLOAD Drop file here

Certificate Expiry Date   dd/mm/yyyy   dd/mm/yyyy

Effective Date   dd/mm/yyyy   dd/mm/yyyy

Your test and production encryption 'public certificates' should then be uploaded. Certificates should be uploaded as .cer files. Information on the certificate expiry date and effective date should be entered in the respective fields. Then select 'Submit'.

SUBMIT   CLOSE

Step 3:

MHRA Gateway Details	
Your details has been submitted, MHRA will process your request.	
You will be redirected to a 'details submitted' landing screen. You can close the page.	**CLOSE**
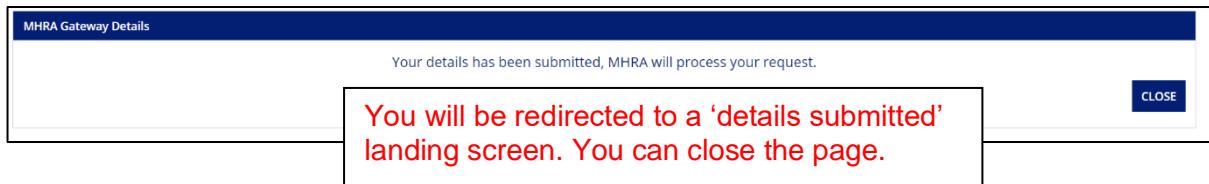
Confirmation of registration and exchange of MHRA certificate

After saving configuration details, this information will be sent to the MHRA for manual review.

If successful, you will receive an email from the MHRA confirming the successful review. We will aim to respond within five working days.

The MHRA will email you if any issues are identified with the provided information or encryption certificate(s).

Once encryption certificates have been successfully exchanged, you will now able to send and receive ICSRs/SUSARs via the MHRA Gateway.

Testing

Once registration is completed, you are encouraged to perform a connectivity test in UAT. You will be able to confirm success via MDN receipt.

Contact Details

If you are experiencing issues sending or receiving ICSRs/SUSARs via the MHRA Gateway following successful registration and exchange of certificates, please email details of your issue(s) to E2B.Support@MHRA.gov.uk.

If your query specifically relates to ICSRs from the MHRA, email: pharmacovigilanceservice@mhra.gov.uk.