

Register to make submissions to the MHRA if there is a no-deal Brexit

If there is a no-deal Brexit, submissions related to human medicines would need to be submitted directly to the MHRA.

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The Agency is making preparations to ensure that you can continue to submit regulatory and notification information to the UK.

For applications that you plan to submit to both the EU and the UK (for example, a Marketing Authorisation for both EU and UK markets), you would need to submit the information separately through EU systems and our portals.

The following groups will need to ensure they follow the steps to gain access to MHRA Submissions, so they can make submissions from day one:

- all pharmaceutical companies involved in making medicines regulatory submissions and vigilance activities
- all medicines clinical trial sponsors wishing to make clinical trial submissions (Initial Applications, Substantial Amendments, End of Trial Notifications and Developmental Safety Update Reports (DSURs)) to the Agency
- e-cigarette producers
- brokers of medicinal products

Please note: all current Eudravigilance Gateway users who wish to gain access to the new MHRA Gateway will need to first gain access to MHRA Submissions. The steps for gaining MHRA Gateway access are contained within MHRA Submissions.

MHRA Submissions will not be used to send or receive ICSRs, the process for which can be found below.

Prior to day one, the only areas which will be enabled on the MHRA Submissions home page will be User Maintenance and PV Gateway Management.

Gaining Access to MHRA Submissions

Before getting started - guidance

Ensure that you have watched the videos and have referred to the user reference guides prior to clicking on the link in the Getting Started section.

Three short video demos are provided below which cover all aspects of the user access management process - these steps will enable your organisation to gain access and manage user permissions for using MHRA Submissions. You can [access all three videos on Sharefile](#).

- User registration – the end to end process for adding an initial company administrator
- Add a new user – how to add an internal colleague as a user or company administrator
- Add a new external user – how to add a third party consultant/consultancy as a user or company administrator

There are two user reference guides which contain step by step guidance on the processes:

User Reference Guide – [Gaining Access to MHRA Submissions](#) (PDF, 661KB, 11 pages)

User Reference Guide – [Managing users on MHRA Submissions](#) (PDF, 770KB, 12 pages)

The role of the initial company administrator

The first person in your organisation to complete the registration process outlined here will become the initial company administrator.

There are different factors to consider when selecting this initial company administrator.

For smaller organisations, a company administrator may also be responsible for making submissions or managing a team who will make submissions. It is recommended that each organisation has more than one company administrator.

For larger organisations, you may have different teams or departments who will be making submissions via MHRA Submissions, for example, regulatory affairs, pharmacovigilance units, clinical trials teams etc. You must carefully consider who is best placed in your organisation to be the initial company administrator as this person will be responsible for adding further company administrators and cascade responsibilities down through the organisation.

Unless the organisation is one person only, it is recommended that you have at least one other company administrator.

Getting started

To ensure you are able to make submissions to the MHRA from day one, you can [begin the process for gaining access to MHRA Submissions](#).

This will allow an initial company administrator to gain access to MHRA Submissions and provide access to both colleagues and external consultants for your organisation.

Definition of a company administrator and user

A “company administrator” has the ability to add, edit and disable other users. A company administrator will also be able to see records of submissions made by users.

A “user” cannot add other users and can only make submissions for the organisation they are registered to. They can be added to multiple legal entities if required. A user will not see records of submissions made by other users.

The initial company administrator will have the same permissions as any subsequent company administrators. However, they will be responsible for completing the user access steps for the organisation and setting up the first set of additional company administrators and users.

There are no limits to the number of company administrators and users you can add. However, careful consideration should be given to how you set up access for your organisation. As the company administrator is responsible for adding and removing users once an organisation is registered, you may need to consider who and how many company administrators there are for your organisation.

Note: if adding more than 5 users at a time, the changes will be made but you will be redirected to the homepage rather than the “user maintenance” page. To confirm that your new users have been added, simply navigate back to the “user maintenance” page.

Setting up access for multiple legal entities in pharmaceutical companies

A unique email address is required when registering an organisation for the first time. It is recommended that if you have multiple legal entities under your organisation, you should appoint an appropriate company administrator to register for each of these entities.

For pharmaceutical companies, this relates to the unique 5 digit MHRA company number.

However, it is recognised that larger organisations may have a significant number of legal entities and setting up individual company administrators for each 5 digit number would be complex and time consuming. If an organisation chooses to only create a company administrator for one or few legal entities, there is one area that requires consideration.

MA Holders will have the ability to automatically generate a new Product Licensing (PL) number in MHRA Submissions. As the 5 digit number is part of the PL Number, the organisation must ensure this legal entity is set up with a company administrator prior to performing the generation of the new PLNumber. This will allow the company administrator to select the correct 5 digit number from a drop down menu during the process.

Submission types such as initial applications and variations require a drop down company name/number to be selected. There would be no impact on these submissions being successfully sent via MHRA Submissions, if you use any of your registered numbers. The correct Marketing Authorisation Holder information is contained within the application itself and is not dependent on the drop downs selected. For any future changes, we will aim to ensure there is no dependency on this data when submitting applications.

Successfully completing the user access process

Where to find the MHRA company number

The MHRA company number is a unique number the MHRA assigns to an organisation.

If your organisation has made a submission to the MHRA before, you will find this number on correspondences you have received from us.

- Pharmaceutical industry - this is the first 5 digits of your Product Licensing number
- Clinical trial applicants - this is the first 5 digits of the CTA number from a trial that your organisation has previously submitted. This can be also be found on letter correspondences from the MHRA

- e-cigarette producers - the 5 digit company number is your MHRA account number. This information is available on your invoices - please note, this is not your EU submitter ID
- Brokers - the broker company number is on the Registration document issued by the MHRA
- Paediatric Investigation Plans (PiPs) submitters - if your organisation already holds marketing authorisations, this will be the first 5 digits of any of your product licenses. If you have never submitted to the MHRA before, you will need to be set up as a new company - see below

Third party consultants/consultancies

External users (third party consultants/consultancies) can be added to your organisation as either an additional company administrator or standard user. In order to do this, they must already have a 5 digit MHRA company number before completing the user access process. External users must complete this process before they can be added to your organisation.

This ensures you can provide the appropriate level of access to external users and will also allow external users who work on behalf of multiple organisations, to better manage their submissions.

Where to go for help

Please ensure you read all the information contained with the user reference guides, the video demos and on this page before contacting submissions@mhra.gov.uk.

Only the initial company administrator will need to complete the full user access process. If you attempt to complete the user access process and an initial company administrator already exists for your organisation, you will receive a message outlining this. If you are unaware of who your initial company administrator is, please ask within your company. They can then directly add you as an additional company administrator or user.

If you receive an email indicating that you have already been registered, this means that a company administrator has already set you up as an additional company administrator or user. Look for a confirmation email or contact your company administrator for further clarification.

If you have accidentally entered and selected an incorrect MHRA company number and realise afterwards, please contact submissions@mhra.gov.uk for correction.

If you need to reset your password, click the “Can’t access your account?” link on the Sign-in screen and you will be guided through the appropriate steps. Please note this will be performed via Microsoft and not directly by the MHRA.

Registering to use the vigilance systems: MHRA Gateway and ICSR Submissions

The following sections are relevant to all pharmaceutical companies involved in the submission of ICSRs or SUSARs to the MHRA.

Before getting started, ensure that you have watched the videos and have referred to the user reference guides.

Two short video demos are provided below which cover the MHRA Gateway registration process and ICSR Submissions registration process. These steps will enable your organisation to register to send and receive ICSRs/SUSARs via the MHRA Gateway or ICSR Submissions.

- [MHRA Gateway registration](#) – the end to end process for registering to use the MHRA Gateway
- [ICSR Submissions](#) – the end to end process for registering to use the ICSR Submissions portal

There are two user reference guides which contain step by step guidance on the processes:

[Registration for ICSR Submissions](#) (PDF, 167KB, 4 pages)
[Registration for MHRA Gateway](#) (PDF, 271KB, 4 pages)

Registering for the MHRA Gateway

Once you have completed registration for MHRA Submissions, MHRA Submissions company administrators can register to send both ICSRs or SUSARs via the MHRA Gateway by selecting the 'Gateway Management' tile of MHRA Submissions and following the process in the user reference guide .

On receipt of your registration request, the MHRA will aim to complete your registration within 5 working days.

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

On sending ICSRS/SUSARs via the MHRA Gateway, you will receive an acknowledgement within 48 hours.

If you submit ICSRs or SUSARs to the MHRA via the MHRA Gateway, you will also receive serious and non-serious UK reports from the MHRA via the MHRA Gateway.

Registering for ICSR Submissions

If you do not have the capability to send or receive via the MHRA Gateway, you can send ICSRs or SUSARs to the MHRA via [ICSR Submissions](#).

To register for ICSR Submissions, you should visit the [ICSR Submissions](#), select the 'Request company account' option, and follow the process outlined in the user reference guide .

On receipt of your registration request, the MHRA will aim to complete your registration within 5 working days.

If you submit ICSRs or SUSARs to the MHRA via [ICSR Submissions](#), you will also receive serious and non-serious UK reports from the MHRA via [ICSR Submissions](#).

Transition between reporting to EU and UK systems

In a no-deal scenario, on exit day Marketing Authorisation Holders (MAHs) will be required to submit ICSRs to the UK directly, using the systems described above.

Under current reporting modalities, the European Medicines Agency (EMA) forwards UK ICSRs (individual case safety reports) to the MHRA at the time that they are processed through the EudraVigilance system.

As such Marketing Authorisation Holders should plan on the basis all ICSRs that they have sent to the EMA and are processed before 11pm on exit day will be passed to the MHRA. Cases not processed prior to that point should be submitted via the new MHRA systems.

To assist companies in any reconciliation required, the MHRA intends to publish a list of cases which we received on exit day from the European Medicines Agency. This list will be made available after exit day.

As outlined in legal text, all UK ICSRs (serious and non-serious) and all non-UK serious ICSRs should be transmitted to the MHRA following the UK's exit from the European Union. This includes transmission of follow-up, nullification and downgrade cases where previous versions of that ICSR were sent directly to the EMA. These case types will be automatically processed by the MHRA system, even if previously received from a different sender. Companies should ensure that systems are configured to correctly distribute these cases to the MHRA from exit day.

Business Continuity Plan for MHRA Gateway and ICSR Submissions

This business continuity plan outlines the expectations on the MHRA and MAHs during a period of MHRA Gateway or ICSR Submissions during planned and unplanned downtime.

MHRA will communicate at the earliest opportunity if systems are down, including planned downtime. Please use the following guidance with regards to ICSR reporting unless communications from the MHRA advise otherwise.

[Business Continuity Plan](#) (PDF, 15.9KB, 2 pages)

Where to go for help

If you have not received an acknowledgment within 48 hours of submitting an ICSR/SUSAR, contact E2B.support@mhra.gov.uk, including information on the filename, message number and senderreportID, as well as attaching the XML file.

If you have any other queries about the ICSR/SUSAR process, please email E2B.support@mhra.gov.uk.

Any queries around setting up the gateway company administrator on MHRA Submissions please email submissions@mhra.gov.uk.