Vigilance - MHRA Gateway & ICSR Submissions

This publication was withdrawn on 31 January 2020

23rd October 2019

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Introductions

This webinar

- The requirements and proposals we are presenting are drafts, and do not at this stage represent Government policy.

- The recording of the webinar will be published on the gov.uk site.

- This session is to provide information and can be shared with colleagues.

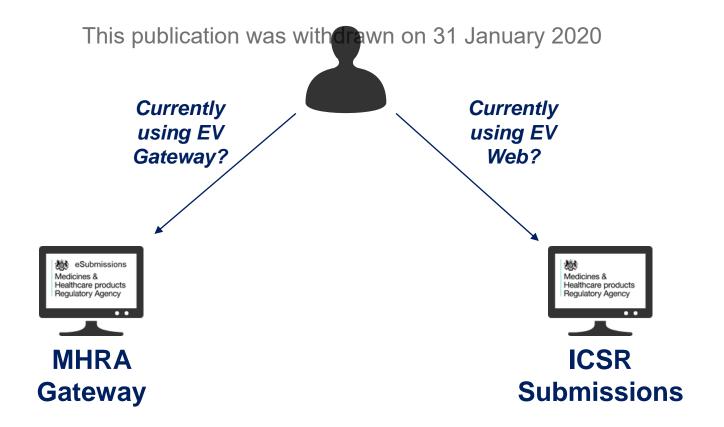- Everything discussed would only be in the event of a no-deal scenario.

The story so far

- We held a general overview webinar in late November 2018 which covered all aspects of the MHRA IT Contingency programme.

- A second webinar on the topic of gaining access to the MHRA Submissions portal was recorded in mid February 2019. This is important as companies submitting ICSRs and/or SUSARs via the Gateway will first need to gain access to the MHRA Submissions portal via a company administrator. This is the first stage of the Gateway registration, testing and setting up process.

- A third webinar on 1st March was to give an overview of the process for gaining access to the MHRA's vigilance reporting solutions: Gateway and ICSR Portal.

- Webinars and guidance is available to view on the gov.uk website

Session purpose

- To provide an overview of the process for gaining access to the MHRA's vigilance reporting solutions: Gateway and ICSR Submissions Portal.

- To clarify what can be submitted via each route.

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- To show video demos of the registration process for both Gateway and ICSR Submissions portal.

- To outline how to receive ICSR notifications.

- To highlight any specific key messages related to submitting SUSARs.

- To outline next steps.

How will I submit my ICSRs/SUSARs after 31st October 2019 for a no-deal Brexit scenario?
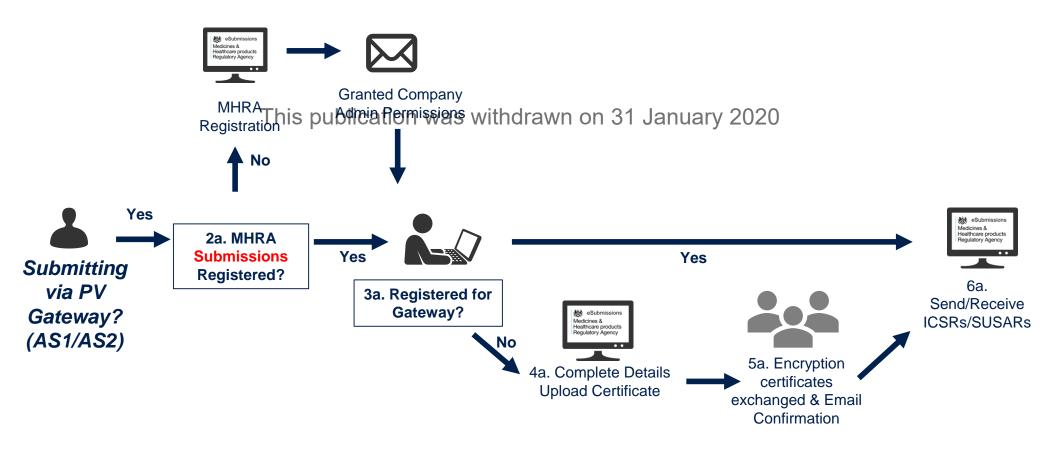
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Currently using EV Gateway?

Currently using EV Web?

MHRA Gateway

ICSR Submissions

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2. Introduction to MHRA Gateway

What is it and who is it relevant for?

- Secure transmission of ICSRs between MAH/ Sponsor database and MHRA database.

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- Intended for MAHs/ Sponsors with systems that allow transmission via AS1/AS2.

Overview of end to end process

Submitting via PV Gateway? (AS1/AS2)

Yes → **2a. MHRA Submissions Registered?**

No → MHRA Registration → Granted Company Admin Permissions

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Yes → **3a. Registered for Gateway?**

Yes → **6a. Send/Receive ICSRs/SUSARs**

No → **4a. Complete Details Upload Certificate** → **5a. Encryption certificates exchanged & Email Confirmation**

Registering with MHRA Gateway

[Registering with MHRA Gateway Demo](#)
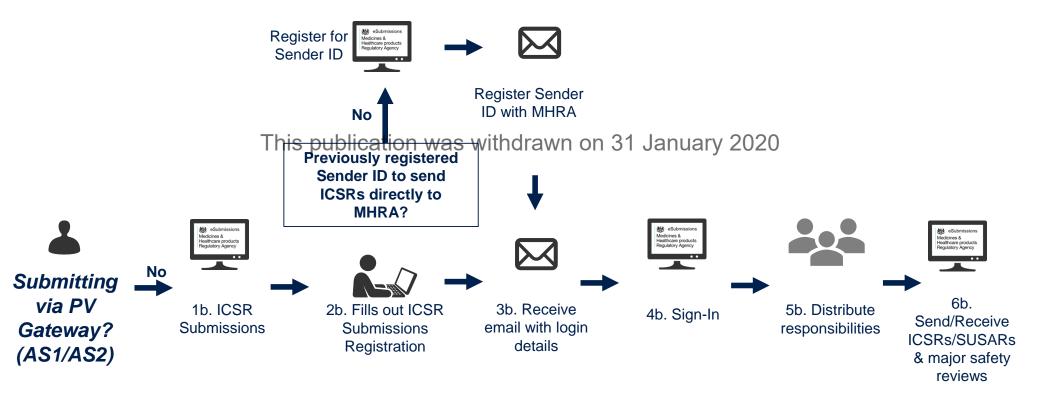
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3. Introduction to ICSR Submissions

What is it and who is it relevant for?

- Online portal to submit ICSRs and/or SUSARs to the MHRA.

- Form to create R2 ICSRs. This publication was withdrawn on 31 January 2020

- Can post R2/R3 XMLs from other systems.

- Major Safety Reviews will also be submitted via ICSR Submissions.

- Intended for MAHs that do not have system capable of sending/receiving via the MHRA Gateway.

Overview of end to end process

Register for Sender ID

Register Sender ID with MHRA

No

Previously registered Sender ID to send ICSRs directly to MHRA?

Submitting via PV Gateway? (AS1/AS2)

No

1b. ICSR Submissions

2b. Fills out ICSR Submissions Registration

3b. Receive email with login details

4b. Sign-In

5b. Distribute responsibilities

6b. Send/Receive ICSRs/SUSARs & major safety reviews

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Registering with ICSR Submissions

[Registering ICSR Demo](#)

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Registering with ICSR Submissions

- Please do so as soon as possible

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- If you have not previously registered with the MHRA prior to centralised reporting we will need your company details

- We will also ask for MedDRA credentials

ICSR Submissions demonstration

ICSR Submission Demo

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ICSR Submissions

- User reference guide - Individual Case Safety Reports (ICSR) submissions

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- FAQs

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4. How to receive your ICSRs

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Individual Case Safety Reports (ICSRs)

- MAHs will receive serious and non-serious UK ICSRs.

- If MAHs are registered with MHRA Gateway, then ICSRs will be sent directly to the MAH system/database.

- If registered with ICSR Submissions, then ICSRs will be received via ICSR Submissions – MAHs will need to login and download.

- If registered to both systems, then ICSRs from the MHRA will be sent to only Gateway.

- Cut-over guidance is online

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5. Suspected Unexpected Serious Adverse Reactions (SUSARs)

SUSARs

- The eSUSAR portal will remain available for academic investigators and as an additional reporting route.

- ICSR Submissions is intended to mimic the process for SUSAR submission via EVWEB.

- It allows for completion of an R2 form, uploading data from an existing R2 from or uploading R2 or R3 forms directly.

- MHRA Gateway allows for database to database transmission of SUSARs.

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6. Pharmacovigilance System Master File (PSMF)

Submitting PSMF/QPPV Details

In the event of a no-deal Brexit the following legal obligations apply:

1. To operate a pharmacovigilance system for UK authorised products.

2. To have an appropriately qualified person responsible for pharmacovigilance (QPPV) that resides and operates in the UK

3. To maintain and make available upon request a pharmacovigilance system master file (PSMF) that describes the pharmacovigilance system for UK authorised products

Two important points to note:

- There is a temporary exemption in place which allows you 21 months beginning with exit day to appoint a UK QPPV that resides and operates in the UK, in the event that you have an appropriately qualified EU/EEA QPPV who is responsible for UK authorised products immediately prior to exit day.

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- You will not need to maintain and make available on request by the MHRA a PSMF covering UK authorised products until such time that a QPPV that resides and operates in the UK is established as long as the conditions described in the following guidance are met.

Detailed guidance available at:

https://www.gov.uk/guidance/guidance-on-qualified-person-responsible-for-pharmacovigilance-qppv-including-pharmacovigilance-system-master-files-psmf-if-the-uk-leaves-the-eu-w#guidance-on-the-uk-psmf

How to request a UK PSMF number in the event of no-deal Brexit

- All UK PSMFs must be registered with the MHRA. You should request a unique UK PSMF number from the MHRA for each pharmacovigilance system that you are operating for UK authorised products.

- A UK PSMF number can be requested via the MHRA Submissions Portal after exit day in a no deal Brexit scenario. You should follow the online instructions for requesting a UK PSMF number and you should receive the number by email immediately upon completion of the online form.

- Where the pharmacovigilance system is shared by several MAHs, a single request for a UK PSMF number should be submitted to the MHRA.

- You are encouraged not to request the UK PSMF number until the UK-resident QPPV and the UK PSMF have been established.

PSMF Number Demonstration

[PSMF Generation Demo](#)

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Next Steps and Timelines

- Regardless of the outcome of the EU negotiations, you should continue to use the current EU solutions until day one post Brexit.

- If we are in a no-deal scenario, you will be able to submit your ICSRs/SUSARs using the new MHRA solutions from day one post Brexit.

- To enable you to be ready to use the new systems from day one, registration has been open since March 2019.

- There are supporting documents to help you and you can raise email enquiries related to this, should you have any questions that are not within the guidance.

- You will not be able to submit or receive ICSRs or SUSARs via these systems until day one.

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