



Medicines & Healthcare products
Regulatory Agency

Vigilance - MHRA Gateway & ICSR Submissions



Introductions

This webinar

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

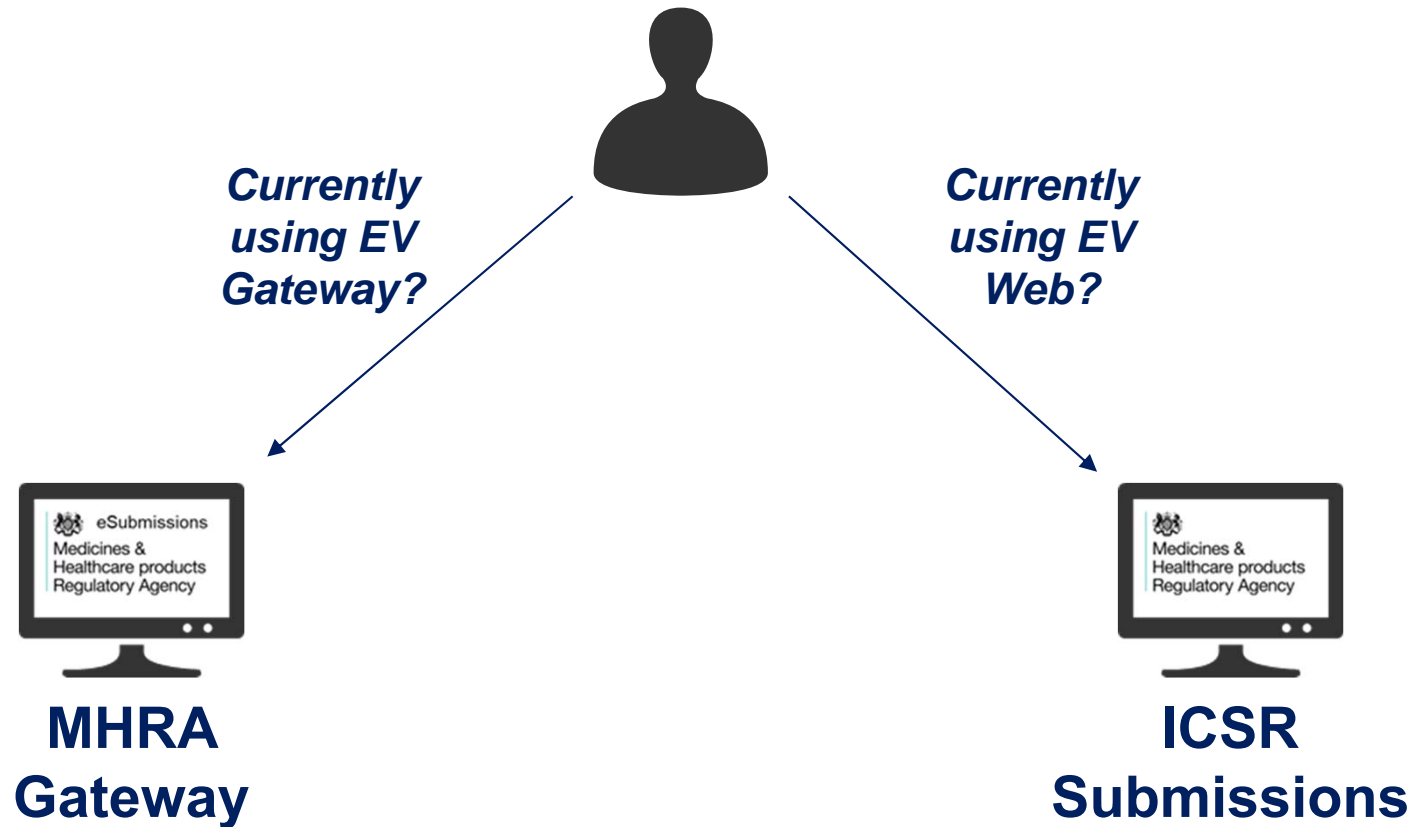
The story so far

- 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 2019 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.
- 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 for UK licences after 31st December 2020?

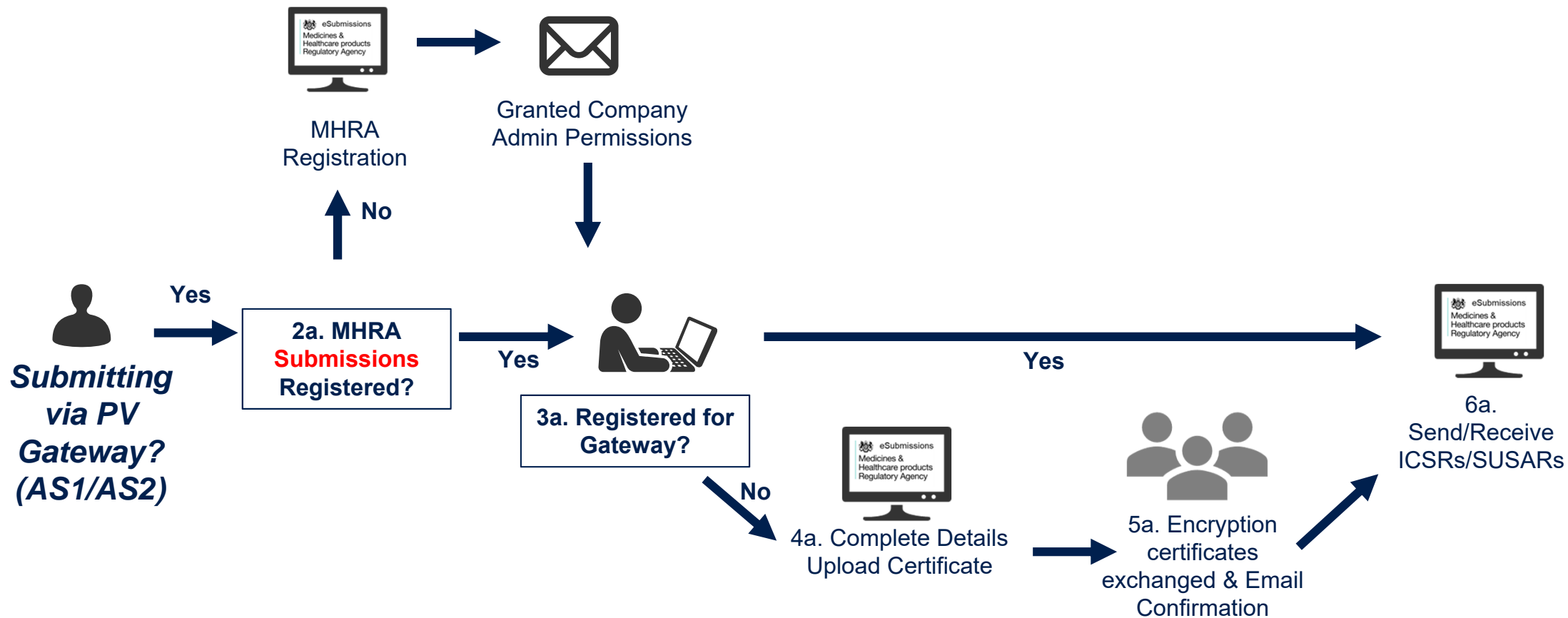


2. Introduction to MHRA Gateway

What is it and who is it relevant for?

- Secure transmission of ICSRs between MAH/ Sponsor database and MHRA database.
- Intended for MAHs/ Sponsors with systems that allow transmission via AS1/AS2.

Overview of end to end process



Registering with MHRA Gateway

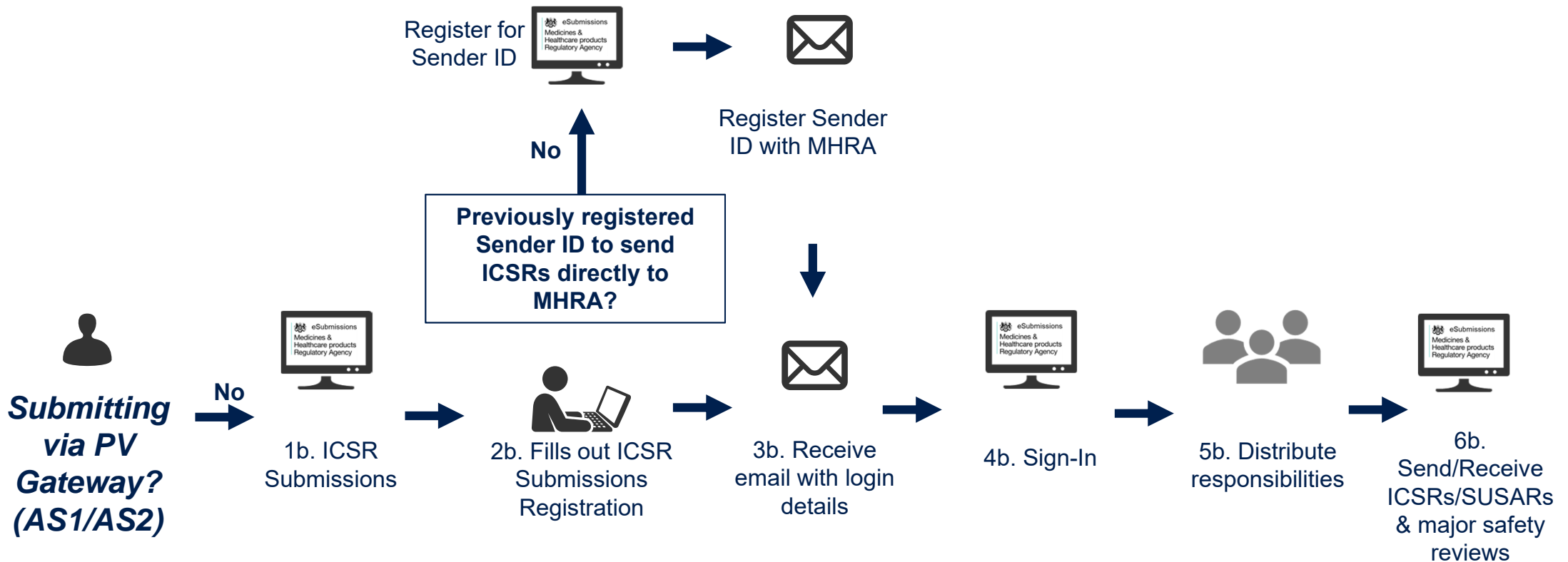
[Registering with MHRA Gateway Demo](#)

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.
- 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



Registering with ICSR Submissions

Registering ICSR Demo

Registering with ICSR Submissions

- Please do so as soon as possible
- 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

ICSR Submissions

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

4. How to receive your ICSRs

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

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.

Next Steps and Timelines

- To enable you to be ready to use the new systems from Jan 2021, 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.

Insert link to MHRA Submission web page

- You will not be able to submit or receive ICSRs or SUSARs via these systems until 1st January 2021