

Business Continuity Plan for MHRA Gateway and ICSR Submissions

This business continuity plan outlines the expectations on the Medicines and Healthcare products Regulatory Agency (MHRA) and Marketing Authorisation Holders (MAH) during a period of MHRA Gateway or ICSR Submissions planned and unplanned downtime.

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

What to do in case of MAH system failure

Marketing authorisation holders should make sure that business continuity processes and back up systems are in place to deal with system failures. This will ensure that any system failures can be resolved within a short period of time and reporting compliance is maintained.

MHRA does not support the submission of CIOMS I forms via fax or post and these options should not feature in business continuity processes.

In case of a Gateway failure at the sender's side, if the organisation is able to generate valid safety message(s) these can be submitted via a secure transfer mechanism in the first instance or via physical media (USB) if no other route is available. An ICSR Submissions account can also be used to send files securely if Gateway is the normal mechanism.

Guidance on registering for the ICSR Submissions portal can be found at

<https://www.gov.uk/guidance/register-to-make-submissions-to-the-mhra>

Acknowledgement messages for cases received on physical media will be returned via the MHRA Gateway. Since no ICSR-MDN will be generated in this process, the date of despatch of the ICSRs on physical media (with appropriate records) will be sufficient to prove regulatory compliance.

Before initiating this procedure, users should contact MHRA E2B support by email to E2B.Support@mhra.gov.uk to inform them of a systems failure and of the expected timeframe for its resolution, as well as to confirm whether a secure transfer mechanism, ICSR Submissions or physical media will be used. Physical media should be a last resort so relevant justification should be provided if physical media is used.

Failure of message receipt by the MHRA Gateway

In the event of prolonged unavailability of the MHRA Gateway which could affect the sender's ability to meet regulatory reporting timeframes, the report sender can send the ICH E2B(R2 or R3) safety messages to the MHRA when the Gateway becomes available again. Reports submitted within two MHRA business days of the Gateway being made available again will have their reporting compliance calculated against the first day of system failure.

MHRA will provide official dates of when the MHRA Gateway was unavailable.

Failure of the MHRA ICSR Submissions portal

In the event of prolonged unavailability of the MHRA ICSR Submissions portal during MHRA business hours which could affect the sender's ability to meet regulatory reporting

timeframes, the report sender should send the safety messages to MHRA when the portal becomes available again. These reports will be excluded from reporting compliance monitoring as long as they are submitted within two MHRA business days of the MHRA ICSR Submissions portal becoming available again.

MHRA will provide official dates of when ICSR Submissions was unavailable.

Failure of the MHRA Gateway or ICSR Submissions

In the event of an MHRA or MAH systems failure immediately post go live in please contact the MHRA E2B support mailbox, E2B.Support@mhra.gov.uk, before invoking business continuity procedures.