NEXTROVE REGULATORY BULLETIN
Staying up to date with the latest regulatory news
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EUROPE

Implementing regulation - EU - 2025/1466 - EN - EUR-Lex

Commission Implementing Regulation (EU) 2025/1466 of 22 July 2025 amending Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

The new European law, Commission Implementing Regulation (EU) 2025/1466 of 22 July 2025 amending Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council, is fully implemented since Feb 12 2026.
The updates aim at strengthening safety oversight, impact signal management, PSMF documentation, vendor management, and product-specific monitoring.

Major updates:

- Quality System: Strengthened internal and external audit rules requiring risk-based auditing to cover all pharmacovigilance activities performed by the Marketing Authorization Holder and its third parties.
- Subcontracting: Enhance requirements for contracts with third parties, requiring clearly defined roles, data exchange methods, and explicit rights for the Marketing Authorization Holder to audit the third party, and for National Competent Authorities to inspect them.
- PSMF: Any major or critical deviations from the pharmacovigilance procedures, their impact and their management shall be documented in the pharmacovigilance system master file until resolved, rather than all deviations.
- PSURs & RMMs: The periodic safety update report shall contain updates on the implementation of the risk minimization measures and the results of effectiveness assessments of risk minimization activities relevant to the risk-benefit.
- PASS Register: Marketing Authorization Holder shall enter the study protocol, the abstract of the final study report and the final study report in the electronic post-authorization study register maintained by the Agency. The marketing authorization holder shall submit electronically to the register the study protocol before the start of the data collection and the abstract of the final study report within one month after the finalization of the final study report.
- Signal Management: Marketing Authorization Holders shall monitor the data available in the Eudravigilance database and use it together with data from other available sources.
- ISO IDMP Standards: Mandatory use of ISO IDMP standards for medicinal products, pharmaceutical products, substances, pharmaceutical dose forms, units of presentation, routes of administration and packaging; identification for the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information.
- Digital Object Identifiers (DOI): Literature references in Individual Case Safety Reports (ICSRs) must now include a Digital Object Identifier (DOI) where available.

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Disabling HTTP access to EudraVigilance

The European Medicines Agency (EMA) is disabling HTTP access to EudraVigilance XML schemas to enhance security and transition to HTTPS (HTTP Secure) for all ICSR submissions (R3 schemas). This mandatory change impacts both Gateway and EVWEB submissions, requiring users to update system configurations to ensure secure data transfer.

The plan includes:

- 15 January 2026: start of the testing phase.
The external test environment for ICSRs accepts both HTTP and HTTPS.
The production environment continues to accept HTTP only for both ICSRs and ACKs.
- 15 April 2026: start of the optional production phase.
Test and production environments accept both HTTP and HTTPS for ICSRs. ACKs reference HTTPS only.
- 15 July 2026: start of full production.
Test and production environments accept HTTPS only for both ICSRs and ACKs.

USA

US FDA Real-time clinical trials collection and monitoring

On April 28, 2026, US FDA announced the launch of the first-ever "real-time" clinical trials (RTCT). RTCT is a cloud-based monitoring system for safety signals and endpoints.

The proof-of-concept (POC) is being performed, focusing on cancer treatments, with AstraZeneca and Amgen participating, with the aim to accelerate drug approvals.

The objective is to accelerate the review time and reduce time-to-approval by increasing efficiencies through the reduction of manual activities and by detecting safety signals earlier.

Rather than waiting for final study reports, the FDA reviewers will monitor the data directly in the cloud-based system as it is collected. This data is captured directly from patient electronic health records (EHRs) and reported instantly to the FDA.

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Draft Guidance – Responding to FDA Form 483 Observations

The United States FDA published a draft guidance titled Responding to FDA Form 483 Observations at the Conclusion of Drug GCMP Inspections.

This document provides recommendations for pharmaceutical manufacturers on how to prepare clear, concise, and effective responses to inspection observations listed in an FDA Form 483.
This draft guidance encourages companies to follow a structured approach when responding to inspection findings, identifying the underlying root cause, assessing potential risks to patients, and implementing appropriate corrective and preventative actions.

The draft guidance is not legally binding. The draft was originally published on March 9, 2026, and was open for public comments until May 8, 2026.

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CANADA

Canada Vigilance: Market Authorization Holders (MAHs) ICSR Download Rule Update

On February 19, 2026, Health Canada published a Notice to Industry, Clarification of Section 4.3 (Regulatory Authority Sources) of the Reporting Adverse Reactions to Marketed Health Products – Guidance Document for Industry, to clarify their expectations on re-reporting when an MAH has downloaded adverse reaction (RA) reports from the Canada Vigilance (CV) database.

Per section C.01.017 of the Regulations, "The manufacturer shall submit to the Minister a report of all information relating to the following serious adverse drug reactions within 15 days after receiving or becoming aware of the information, whichever occurs first."

Due to the administrative burden to comply with this part of the regulation, if an MAH becomes aware of the AR from downloading the report from CV, and the MAH has no additional information, the MAH is not required to re-submit the case.

"In the event a report contains no new information relative to the causality assessment of a health product's safety and effectiveness, MAH reports originating from the Marketed Health Products Directorate (MHPD) sources (e.g., case reports published in the Canada Vigilance Adverse Reaction Online Database, case reports published in the Health Product InfoWatch) are not required to be re-submitted to the Canada Vigilance Program by the MAH as they are already contained within the CV Adverse Reaction Database. Health Canada expects this information will continue to be captured in annual summary reports (ASRs), as highlighted in section C.01.018 of the Regulations."

If the MAH does receive additional information or follow-up information for the case that is relative to the causality assessment of the product's safety and effectiveness, the MAH should include the Canada Vigilance Adverse Event Report (AER) number identifying Canada Vigilance as the source of the report to prevent duplication.

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SOUTH AFRICA

Updated Submission Method for Clinical Trials

Published March 23, 2026, South African Health Products Regulatory Authority (SAHPRA) sent a communication to stakeholders to revise the standard submission method for serious adverse events (SAEs).

In December 2025, SAPHRA originally communicated to stakeholders that E2B reporting was an optional method of reporting SAEs during clinical trials. However, in the communication published March 23, 2026, they have revised their statement, and mandating that as of July 1, 2026, "E2B will be the only acceptable method of reporting SAEs occurring during clinical trial conduct to SAHPRA."

Important information to note:

E2B reports should follow:
- ICH Technical Specifications
- Preferred encoding is ISO-8859-1, but UTF-8 is acceptable
- Each XML can contain up to 100 ICSRs
- Organization Identifier is SAHPRA

Reports can be uploaded in either E2B R2 or E2B R3 standard.

Cover Letter must be attached to an email containing the following information:
- SAHPRA Reference Number
- MRF Number (if applicable)
- Participant ID
- Study Title
- Protocol Number
- Name of the Ssite
- Name of the Investigator/Reporter
- Suspect Study Drug/Device
- Adverse Event
- Type of the Report (e.g., Initial, Follow-up #1, etc.,)
- Outcome of the Adverse Event

All SAEs should be emailed to the appropriate address:
- Medicinal Product Trials: ctcsaes@sahpra.org.za
- Medical Device Trials mdvigilance@sahpra.org.za

All Emails should be structured, as follows, with the appropriate information:
- Email Subject: [E2B_SAHPRA Database Tracking #]_ [Study Protocol Number]_SAE
- e.g., E2B_20260203_NER000_SAE
- XML File should be attached, as it was uploaded to SAHPRA
- Cover Letter should be attached, as previously described.

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NEW ZEALAND

Update to SUSAR Reporting Guidelines for Clinical Trials

As of July 1, 2026, MedSafe, the New Zealand health authority, will no longer require domestic, death/life-threatening SUSARs to be reported within 7 calendar days. The update, published in January 2026, now requires all domestic SUSARs to be submitted within 15 calendar days.

The updates can be found on the MedSafe website.

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