4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1280]

Electronic Submission of Postmarketing Individual Case Safety Reports to the Food and Drug Administration Adverse Event Monitoring System Using International Council of Harmonisation E2B(R3) Data Standards; Regional Data Elements and Implementation Schedule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an updated data standard requirement for the submission of postmarketing individual case safety report (ICSR) submissions for human drug products, biological products, and drug- or biologic-led combination products to the FDA Adverse Event Monitoring System (AEMS) database (formerly FDA Adverse Event Reporting System (FAERS)) via the Electronic Submissions Gateway Next Generation (ESG NextGen). Starting October 1, 2026, postmarketing ICSRs must be reported using the data standards adopted by FDA in the International Council for Harmonisation (ICH) guidance for industry entitled "E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide -- Data Elements and Message Specification" (ICH E2B(R3) Implementation Guidance), which incorporates by reference regional implementation guides (collectively ICH E2B(R3) data standards).

DATES: For postmarketing ICSRs for human drug products, biological products, and drug- or biologic-led combination products submitted via ESG NextGen, beginning October 1, 2026, the ICSRs must be submitted to the AEMS database using ICH E2B(R3) data standards.

FOR FURTHER INFORMATION CONTACT: For information concerning drug products and biological products regulated by the Center for Drug Evaluation and Research: Quocbao Pham,

Center for Drug Evaluation and Research (HFD-430), Food and Drug Administration, 10903 New Hampshire Ave., Building 22, Rm. 4491, Silver Spring, MD 20993-0002, (301)-796-5384, aemsesub@fda.hhs.gov.

For information concerning biological products regulated by the Center for Biologics Evaluation and Research: Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, (240)-402-7911.

SUPPLEMENTARY INFORMATION: FDA is announcing an updated data standard requirement for the submission of postmarketing ICSR submissions for human drug products, biological products, and drug- or biologic-led combination products to the AEMS database via the ESG NextGen. Starting October 1, 2026, postmarketing ICSR submissions for human drug products, biological products, and drug- and biologic-led combination products to the AEMS database via ESG NextGen must be reported using the data standards provided in the ICH E2B(R3) Implementation Guidance (available at https://www.fda.gov/media/81904/download), which incorporates by reference the guidance for industry and technical specifications document entitled "FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products" (ICH E2B(R3) FDA Regional Implementation Guidance) (available at https://www.fda.gov/media/180748/download). The ICH E2B(R3) Implementation Guidance and ICH E2B(R3) FDA Regional Implementation Guidance were issued to improve the quality of data in ICSR submissions and to enable improved handling and analyses of ICSRs. Differences between ICH E2B(R2) and ICH E2B(R3) include, for example: new, changed, and expanded data elements; assessment of seriousness at the event level, rather than the case level; and embedding of attachments in the ICSR rather than providing separately.

FDA postmarketing safety reporting regulations for human drug and biological products require that persons subject to mandatory postmarketing reporting requirements for human drug products, biological products, and drug- or biologic-led combination products submit ICSRs in

an electronic format that FDA can process, review, and archive. See 21 CFR 4.102, 230.220(c)(1), 310.305(e)(1), 314.80(g)(1), 314.81(b)(3)(v)(F)(*1*), 314.98, 329.100(c)(1), and 600.80(h)(1). The regulations explain that FDA will issue guidance on how to provide the electronic submission of safety reports, including ICSRs and ICSR attachments.

In the guidance for industry entitled "Providing Submissions in Electronic Format -- Postmarketing Safety Reports" (eSRR Guidance) (available at https://www.fda.gov/media/71176/download), FDA provides two options for electronic submission of ICSRs and ICSR attachments to AEMS: (1) direct submission through the ESG NextGen, or (2) submission through the Safety Reporting Portal (SRP). The SRP enables submission of ICSRs and ICSR attachments by applicants, specified nonapplicants, and responsible persons for companies with reporting requirements who do not have ICH E2B(R3) data standards capability. This notice regarding the use of ICH E2B(R3) data standards applies only to submission of ICSRs and ICSR attachments through the ESG NextGen. The eSRR Guidance incorporates by reference the technical specifications described in the ICH E2B(R3) FDA Regional Implementation Guidance, which addresses topics such as data elements, electronic transport format, and types of ICSR attachments and is periodically updated. To ensure that you have the most recent version of the technical specifications document and for additional information on electronic submissions to AEMS, check the FDA Adverse Event Monitoring System (AEMS) Electronic Submissions web page at https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/fda-adverse-event-monitoring-system-aems-electronic-submissions.

The technical specifications document entitled "Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments" (available at https://www.fda.gov/media/132096/download) discusses how ICSRs and ICSR attachments should be electronically prepared in accordance with the ICH E2B(R2) data standards, which are the data standards that FDA will continue to accept through September 30, 2026.

In January 2024, FDA began accepting electronic submissions of postmarketing ICSRs for human drug products, biological products, and drug- or biologic-led combination products submitted to AEMS in electronic format using the ICH E2B(R3) data standards and announced that submitters could continue to submit using E2B(R2) standards for an additional two years during the E2B(R3) implementation period. To facilitate implementation and enhance efficiency and alignment with internationally harmonized data standards, FDA is requiring that ICSRs submitted through ESG NextGen must be in the ICH E2B(R3) data standards beginning on October 1, 2026, unless earlier transition to ICH E2B(R3) data standards is needed to accommodate reporting requirements (see, for example, 21 CFR 314.81(b)(3)(v), added by the final rule entitled "Nonprescription Drug Product With an Additional Condition for Nonprescription Use" (89 FR 105288, December 26, 2024)).

We intend to no longer accept postmarketing ICSRs using ICH E2B(R2) data standards for human drug products, biological products, and drug- or biologic-led combination products after September 30, 2026. Once an applicant, specified nonapplicant, or responsible person for a company with reporting requirements has begun submitting ICSRs in the ICH E2B(R3) data standards format, all ICSR submissions are expected to use this data standard. For general questions or assistance, see **FOR FURTHER INFORMATION CONTACT** or contact aemsesub@fda.hhs.gov.

(Authority: (21 CFR 4.102, 230.220(c)(1), 310.305(e)(1), 314.80(g)(1), 314.81(b)(3)(v)(F)(1), 314.98, 329.100(c)(1), and 600.80(h)(1))

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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