One Message, Three Processes: Managing the Interfaces Between Pharmacovigilance, Product Complaints and Medical Information

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ABSTRACT

Background. A single message can describe a possible adverse reaction, a suspected quality defect and a request for medical information. An exclusive departmental label risks losing one or more of these matters.

Analysis. Drawing on European Union pharmacovigilance law, current good pharmacovigilance practices (GVP), ICH E2D(R1), EU good manufacturing practice (GMP) and recognised Medical Information practice, this paper proposes one preserved source interaction with independently owned functional records. Eight explicitly author-proposed frameworks and controls connect recognition, transfer, acknowledgement, follow-up, closure and reconciliation.

Conclusions. The purpose is coordinated processing, not the merger of Pharmacovigilance, Product Quality and Medical Information. Inspection readiness is demonstrated by reconstructing a real interaction, not by displaying a flowchart.

KEYWORDS

pharmacovigilance · product complaints · medical information · Day Zero · source preservation · reconciliation · artificial intelligence

THECENTRALDECISION

Treat an incoming communication as **one preserved source interaction**, not an exclusive departmental ticket. Route each potentially relevant component without waiting for another function to complete its assessment. Keep the resulting records, clocks, decisions and closure criteria separate.

1. One message is not one process

“The tablets were broken, did not work and made me dizzy. What should I do?” The sender has not selected a corporate workflow. The company must not make that choice on the sender’s behalf.

“Broken” may indicate a physical or packaging defect and perhaps altered administration. “Did not work” may suggest lack of therapeutic efficacy, incorrect use, progression of illness or a quality problem. “Made me dizzy” describes a possible adverse event, not proven causality. “What should I do?” is an unanswered Medical Information enquiry. Medication error and urgent escalation depend on facts not supplied in the sentence. No final classification is justified by it alone.[6,8,11,14]

The first person receiving this message does not need to decide whether an individual case safety report (ICSR) is valid or a batch is defective. That person must preserve the source, recognise potential relevance and make the information available to competent owners.

2. The regulatory floor, and its limits

Directive 2001/83/EC, Regulation (EC) No 726/2004 and Commission Implementing Regulation (EU) No 520/2012, as amended by Regulation (EU) 2025/1466, establish EU pharmacovigilance responsibilities. GVP Module I addresses the pharmacovigilance (PV) quality system and identifies interaction with the product quality defect system as a critical PV process. GVP Module VI Revision 2 addresses the collection, management and submission of reports of suspected adverse reactions. GVP Module IX Revision 1 addresses signal management.[1–7]

ICH E2D(R1) came into effect in the EU on 18 March 2026. The EU implementation strategy permitted an additional transition period until 18 September 2026 and specifies arrangements for patient support programmes and organised data collection systems. Until a revision of GVP Module VI is applicable, the current EU-specific provisions of Revision 2 remain relevant where ICH E2D(R1) refers to regional requirements. ICH E2B(R3) concerns electronic ICSR exchange; the implementation of new E2B(R3) values associated with E2D(R1) is being handled separately in the EU.[6,8–10]

EU GMP Part I, Chapter 8 addresses complaints, possible defects, investigations and recalls. The EU procedure on *Management and classification of reports of suspected quality defects in medicinal products and risk-based decision-making*, version 2, was adopted on 20 April 2026 and entered into force in May 2026. Its stated scope is competent-authority management of suspected-defect reports; its authority-facing timings must not be presented as universal company transfer deadlines. The General Data Protection Regulation (GDPR) governs the processing of personal data, including appropriate access and security controls. The Medical Information Leaders in Europe (MILE) patient-enquiry principles describe recognised practice, but expressly are not binding.[11–14]

The cited instruments do not prescribe one Interaction ID, one database, parallel transfer in every case or a shared closure workflow. The controls below are operational proposals. They do not replace the different legal, guidance and service obligations of the three functions.

3. Separate authority at a shared interface

Table 1. The three functional dispositions. Timing is governed by the applicable function, source and jurisdiction; the table does not assign a common clock.

Function	Authoritative record and decision	Outcome and closure
Pharmacovigilance	ICSR or documented non-case assessment; validity, seriousness, reporting, follow-up and safety context	Submit or document disposition; update on later evidence; close under PV case rules
Product Quality	Complaint and, where warranted, investigation; defect risk, affected scope, root cause, corrective and preventive action (CAPA), market or authority action	Close the complaint and any separate investigation or CAPA under their own criteria
Medical Information	Enquiry and response; exact question, suitable sources, answer scope and referral	Close when the enquiry has been answered or otherwise dispositioned

These differences are not inefficiencies to be designed away. PV cannot delegate a reporting decision to Quality; Quality cannot ask PV to decide whether tablets conform; and forwarding an enquiry does not answer it. The functions are separate but inseparable when one source message concerns all three.[5,6,11,14]

4. One Interaction, Multiple Records

> **One Interaction, Multiple Records**
> Author-proposed framework. Not a regulatory standard.

Give the incoming communication one stable internal Interaction ID and retain the verbatim source under controlled access. It may link an ICSR, product complaint, Medical Information (MI) enquiry, medication-error assessment, sample, investigation, CAPA, authority communication and follow-up plan. Each functional record has its own identifier, owner and status.

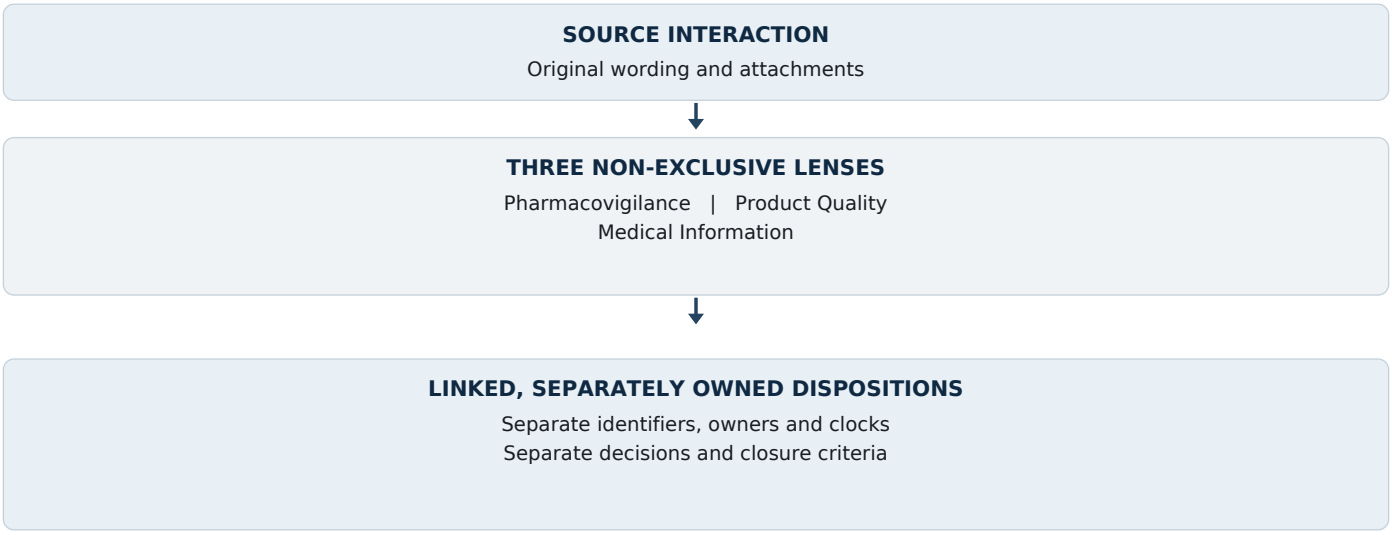

Figure 1. Source-to-record architecture. The figure illustrates traceability, not a required database design or transfer of decision authority.

The Interaction ID is a cross-reference, not a statutory numbering rule or a demand for one database. Limit each function's view to information necessary for its purpose while preserving an authoritative original accessible to authorised personnel. Define retention by record type: closing the interaction index must not delete a PV or Quality record that remains subject to its retention requirements. One message can concern two patients; two messages can concern one case. Document necessary splits, links and duplicate decisions.[3,5,6,13]

5. Intake and Three-Lens Triage

Capture receipt time and time zone, channel, original wording and language, available reporter and patient details, product, strength and dosage form, batch and expiry where known, symptoms, defect description, use, exact question, attachments, country, contact route and permission, urgency, potential-relevance flags, transfer times and acknowledgements. This is a recognition dataset. It is not a demand that intake complete case validation, complaint investigation and the MI response before routing.

Three-Lens Triage
Author-proposed framework. Not a regulatory standard.

Apply three non-exclusive questions: might the message be relevant to patient safety and PV, Product Quality, or Medical Information? Add flags for possible medication error, device issue, falsification, urgent concern, supply, storage or transport, and privacy restrictions. **Route on potential relevance. Confirm final classification within the responsible function.** The opening message reasonably triggers all three lenses. An uncertain complaint referred to Quality and later found unsubstantiated is manageable over-classification. A single-choice “Quality only” label on a message mentioning dizziness is consequential under-classification.

Missing batch or telephone details should ordinarily become targeted follow-up, not a reason to hold urgent referral. ICSR validity and regional reporting requirements are PV determinations, not compulsory fields on every shared-intake form.[6,8]

6. Day Zero is not PV inbox arrival

For a report that meets applicable ICSR criteria, identify when the required information first became available under the relevant EU and source-specific rules. Receipt by Medical Information, Quality, Customer Service, an affiliate or a person acting on behalf of the marketing authorisation holder may be material; a later transfer to PV does not restart an existing reporting clock. If follow-up supplies a missing criterion, document what was received and when. Do not substitute subsequent case validation, database entry, translation, sample receipt, completed Quality investigation or MI response for the relevant first availability of sufficient information.[6,8,9]

Proposed Operational Timestamp Model
Author-proposed framework. Not a regulatory standard.

Retain Interaction Receipt Time, Organisational Awareness Time, Functional Receipt Time, Case Validation Time and Record Creation Time as separate audit fields. Record who knew what, when and through which route. These fields are evidence of a sequence, not alternative regulatory definitions of Day Zero. The opening sentence alone does not prove that every ICSR minimum criterion is met.

Source rules matter. For a digital platform under the marketing authorisation holder’s responsibility, ICH E2D(R1) describes Day Zero in relation to when sufficient information was posted. For a platform outside its responsibility reviewed within an organised data collection system, the relevant point is when review identifies the report and sufficient information. Neither example should be generalised to every website, vendor or unsolicited contact. Apply the EU implementation strategy, contractual scope and jurisdiction-specific requirements.[8,9]

7. Routing and the No-Loss Handover

Parallel Routing Rule
Author-proposed framework. Not a regulatory standard.

Potentially relevant information is routed to each applicable function without waiting for another function’s final assessment. Parallel means concurrent opportunity to act, not identical access, deadlines or conclusions. A documented single route is appropriate for a genuinely single-domain interaction. A technically sequential relay can also work if it does not introduce unsafe delay or conceal ownership.

No-Loss Handover
Author-proposed framework. Not a regulatory standard.

A transfer is not complete merely because it was sent. Distinguish technical delivery, receipt acknowledgement, ownership acceptance, source and attachment completeness, and reconciliation to a functional record or documented no-record disposition. Raise an exception if any stage fails. Case-by-case acknowledgement is proportionate for high-risk transfers; periodic record-level reconciliation can supplement routine flows. Risk sets internal transfer targets. They are not universal regulatory deadlines.

Keep the source evidence: original email, call note, transcript, web form, chatbot exchange or lawful social-media capture, with available photographs, packaging images, timestamps, original language, translation and additive follow-up history. A summary or coded field is an interpretation. A minimised functional view must not overwrite the controlled original.[3,5,6,11,13]

8. Follow-up is coordinated, not centralised

Follow-up Orchestration Plan
Author-proposed framework. Not a regulatory standard.

Link each outstanding question to the Interaction ID, its functional author, contact owner, urgency, sequence, permitted and preferred route, response status and recipients. Combine PV clinical questions, Quality product, sample or photograph questions, and MI clarification where this reduces unnecessary repeat contact. Record remaining gaps and the reason for stopping further contact.

One contact coordinator is practical; that person is not a new scientific assessor. Each function approves its own questions and receives material answers. Urgent safety or quality contact may bypass consolidation. Do not defer case processing or required submission for a combined questionnaire.[6,8,11]

9. What each owner must do

Medical Information records and answers the actual question accurately, specifically and non-promotionally, using appropriate approved product information and other sources permissible for the audience and jurisdiction. It avoids diagnosis, individual treatment decisions, premature causality claims and confirmation of a defect before investigation. Where appropriate, it uses approved urgent referral wording. It forwards potential safety and defect information without waiting to finish its answer and documents the transfer. Forwarding does not itself answer the enquiry.[1,14]

Product Quality records the product and batch, physical and packaging observations, images and samples where appropriate. It assesses immediate risk, possible falsification, distribution scope and whether authority notification or a recall may be necessary. It investigates root cause, CAPA and trends. Quality must not wait for a sample or confirmed defect to forward possible safety information to PV. Wrong strength, contamination, degradation, particles, device failure, wider batch scope or a market action can change PV's assessment and must be fed back. For centrally authorised products, suspected defects that could lead to recall or abnormal restriction of supply have specific EMA reporting implications; for nationally authorised products, the relevant national authority route applies.[6,11,12,16]

Pharmacovigilance preserves the source; assesses ICSR validity, seriousness, outcome, duplicates, coding, narrative and reportability; and follows up and considers signal implications. It assesses lack of therapeutic efficacy, medication errors and other observations in their clinical and regional context. Under ICH E2D(R1), an ICSR can concern an adverse event or reaction, another observation, or both. Standalone lack of efficacy or medication error without an associated adverse event or reaction is reportable as an ICSR only where required by regional or local rules or other authority conditions; E2D(R1) also addresses the exceptional handling of certain reportable near-miss medication errors without an identifiable patient. An invalid ICSR may still require follow-up or a documented PV disposition. PV acts on available evidence without waiting for Quality to confirm a defect; later findings may change its narrative, coding, duplicate assessment or risk interpretation.[3,6–9]

10. Linked closure and reconciliation

Linked Closure Model
Author-proposed framework. Not a regulatory standard.

No functional record closes merely because another closes. Useful source-interaction statuses are Open, functional assessment pending; Open, follow-up active; Controlled, functional records remain open; Controlled disposition complete; and Reopened. "Complete" means every expected functional disposition is accounted for, including an explicit reason why a record was not opened. It does not mean future evidence is impossible. The PV case, Quality complaint, MI response, follow-up plan, investigation and CAPA each close on their own evidence.

Reassess or reopen as appropriate for a changed patient outcome, new seriousness information, corrected product or batch, investigation findings, duplicate split or merge, new complaint trend, ineffective CAPA or corrected MI answer. Show which linked records require renewed assessment.

Three-Way Reconciliation
Author-proposed framework. Not a regulatory standard.

The three "ways" are the PV, Product Quality and MI lenses, not an assertion that every interaction generates three records. Match the source Interaction ID to each expected functional record **or explicit no-record disposition**, receipt and Day Zero evidence where relevant, transfer, acknowledgement, follow-up and closure. Equal aggregate totals can conceal different cases. Log missing records, lost source or attachments, product mismatch, Day Zero conflict, unlinked duplicate, missed flag, fragmented follow-up and closure mismatch. Use event-driven checks for high-risk handovers, frequent exception review for open mixed-domain messages, periodic trend review and samples of apparently MI-only and Quality-only records. Humans resolve material exceptions.

11. Governance across channel boundaries

The intake owner preserves and routes. PV and Local PV own safety decisions and jurisdictional requirements; Product Quality owns complaint investigation; MI owns its response. Quality Assurance tests the interface. The system owner maintains access, links, audit trails and recovery. The privacy function oversees purposeful sharing. A named interface owner resolves unaccepted transfers and orphan interactions. The EU qualified person responsible for pharmacovigilance (QPPV) retains oversight of the PV system; shared intake does not dilute it.[3–5,13]

Map affiliates, distributors, contact and complaint centres, MI and patient-support providers, market-research providers, digital agencies, chatbot operators and translators. Agreements and operating arrangements should address recognition training, source and timestamp preservation, Day Zero assessment, routing, acknowledgement, subcontractors, language, reconciliation, incidents, continuity, audit access and records on exit. Apply the source-specific distinctions in ICH E2D(R1) and its EU strategy. The amendments to Implementing Regulation 520/2012 applicable from 12 February 2026 include subcontract provisions: the required elements are specified in Article 6(3), and a third party must obtain the marketing authorisation holder's written consent before further subcontracting assigned PV tasks under Article 6(4). These provisions do not require a common cross-functional database.[3,4,5,8,9]

12. Five practical route tests

1. "The tablets were broken, did not work and made me dizzy. What should I do?" INT-001: flag PV, Product Quality and MI, with possible dosing error. Follow the approved urgent referral route if the developing facts warrant it. Seek product, patient and reporter details, use, timing, symptom course and batch. Determine PV Day Zero from the applicable validity information, not from specialist receipt. Route and acknowledge each expected disposition. MI answers independently; Quality findings return to PV. Reconcile records, contacts and closure.

2. "The blister was open when I bought it. I took one tablet and later developed a rash." INT-002: PV assesses the rash while Quality investigates pack integrity, storage or tampering. Preserve packaging images; do not wait for a sample before PV transfer. Open an MI disposition only if an enquiry exists or emerges. Capture first valid awareness, share later findings and check linked closure.

3. "The inhaler does not release a dose. I may have used it incorrectly and my breathing is getting worse." INT-003: invoke the approved urgent-safety referral process. Flag PV, possible device or Quality issue, and possible medication error; engage MI if an information need arises. Seek device, administration and symptom details. Parallel specialist assessment must not await a combined questionnaire.

4. "The liquid has changed colour. My child has already taken it, but there are no symptoms." INT-004: Quality assesses appearance, storage, batch and scope. PV assesses the exposure and absence of reported symptoms under applicable special-situation and regional rules, without inventing an adverse reaction. Seek product and follow-up information. Record a reasoned PV disposition even if no reportable ICSR results; sample apparently Quality-only records for missed content.

5. "I received the wrong strength, took it for three days and now feel weak. Can I continue?" INT-005: use the approved urgent referral route where warranted. PV assesses weakness and possible medication error; Quality determines whether supply, packaging or labelling was wrong; MI addresses the question without making an individual treatment decision. Corrected strength findings must reach the linked records.

For each test, trace original wording and attachments, Interaction ID, missing information, awareness and PV Day Zero where applicable, routing and acknowledgement, linked records or no-record decisions, coordinated follow-up, independent decisions, feedback, separate closure and reconciliation. The IDs and workflow are illustrative author proposals, not regulatory designations.

13. Measure the misses, not the forwards

Table 2. Interface measures and their underlying control questions. Targets and sampling schemes require company-specific justification.

Control question	Example measures
Was relevant content recognised?	Three-Lens coverage; independently reviewed PV routing sensitivity; Product Quality routing completeness; MI response completeness
Did the transfer result in an owner?	Time to accepted ownership; missing acknowledgements; orphan interactions; linked-record completeness
Can evidence and decisions be reconstructed?	Source or attachment loss; late Day Zero correction; discrepancies per reconciled interaction; closure mismatch
Was the reporter or reviewer burden controlled?	Avoidable repeat contacts; classifier override; chatbot false negatives; Human Correction Burden

For each measure, define the eligible interaction denominator, numerator, intake or functional data source, relevant product/channel/language/provider segmentation, blind spots, possible gaming and an escalation owner. A fast referral with missing source data is not a success. A high referral count is not proof of sensitivity: independently sample messages that intake classified as needing no PV or Quality action.

14. AI should illuminate the interface

Artificial intelligence (AI) may suggest multiple relevance flags, extract product and symptom information, assist language identification and translation, propose routes and follow-up questions, identify potential duplicates and raise reconciliation exceptions. For each use, assess false positives, false negatives and human correction work; retain the original wording, source-to-field traceability, version history and manual fallback. Test performance by language, channel and message type, including retrospective review of negatives. The Council for International Organizations of Medical Sciences (CIOMS) Working Group XIV published its report in 2025. Its consensus principles do not approve a particular classifier or mandate the autonomy limits proposed here.[15]

In this proposed interface, AI does not autonomously dismiss possible PV relevance; make final ICSR-validity, causality or defect decisions; close a complaint; give individual medical advice; delete source information; resolve a material discrepancy; or decide that no further material follow-up is needed. Until human decisions are stable and measurable, automation only makes a poorly understood boundary faster.

15. Inspection test and staged implementation

Can the organisation reconstruct one selected interaction from original receipt through every transfer, functional decision, follow-up and linked closure?

An audit should establish who first received the source, how each lens was considered, when sufficient PV information became available, what each owner received and acknowledged, who contacted the reporter, which late findings returned to another function and why each record closed. Then select an apparently MI-only record and test whether a safety or complaint trigger was missed. Repeat with a vendor-held interaction, including how it would remain accessible after contract exit.

Proceed in four phases. **Design and risk assessment:** map channels, source rules, clocks, ownership and privacy; stop if urgent transfer or Day Zero ownership is unresolved. **Configure and validate:** test source retention, non-exclusive flags, access, links, failed handovers and audit trails; stop if a critical phrase or attachment can vanish. **Pilot and prove:** choose one controlled mailbox, queue or form; sample negatives, reconstruct real mixed-domain interactions and assess repeat contact and Human Correction Burden; stop if missed content has no detection and recovery route. **Scale and improve:** extend only to channels and providers whose source access, ownership and reconciliation have been demonstrated. Duration and numerical targets need company-specific justification.

16. Conclusions

A communication belongs to the person who sent it before it belongs to any department. Preserve it once; recognise its possible PV, Product Quality and MI content without an exclusive choice. Transfer relevant information early and prove receipt. Let each function keep its own record, clock, assessment and closure. Coordinate contact, then reconcile expected dispositions at interaction level rather than comparing only three aggregate totals.

The inspection failure is not a lack of process boxes. It is the inability to show where an original phrase, an attachment, a reporting clock or a decision went. A system that can answer those questions for one difficult real message is closer to protecting patients than one that merely reports how many messages it forwarded.

SCOPE AND LIMITATIONS

This paper describes an EU-centred post-authorisation operating pattern, not a specific undertaking, patient, product or internal procedure. It is not individual medical advice. Source, market, product, provider role and local legal requirements require assessment before implementation. The eight named frameworks and controls are author proposals and have not been adopted as regulatory standards.

HOW TO CITE

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