Pharmacovigilance Across Multiple Marketing Authorisation Holders

Five governance decisions that determine inspection readiness in the EU/EEA, the United Kingdom and Switzerland

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ABSTRACT

One product may have several marketing authorisation holders (MAHs), one shared safety database and several regulatory reporting routes. The resulting entity boundaries must be mapped, governed and evidenced. This paper examines five decisions: pharmacovigilance-system topology; named-person authority and access; Day 0 across organisational hand-offs; territorial reporting rules; and documented MAH oversight. It closes with a twelve-question inspection-readiness check.

Keywords. Pharmacovigilance · marketing authorisation holder · QPPV · PSMF · inspection readiness · Switzerland · United Kingdom

Scope. Human medicines and post-marketing spontaneous individual case safety reports (ICSRs). Clinical-trial safety reporting and every special reporting scenario are outside scope. Verify authorisation-specific requirements before applying a route or deadline.

1. Why the structure matters

A multi-market pharmacovigilance system is often pictured as one organisation with three regulatory exits. In practice, EU/EEA, UK and Swiss authorisations may sit with different legal entities, while local marketing, distribution and case intake sit elsewhere. UK authorisations require a UK-established holder; Swiss authorisation conditions include a Swiss domicile, registered office or branch and an appropriate establishment licence. [1, 2]

These arrangements are lawful. The risk is that an affiliate or contractor receives a case before the central safety team sees it, while the applicable reporting clock and the MAH’s accountability are already in play. The five decisions below determine whether that boundary is controlled or merely assumed.

2. Decide whether the system is shared

Different MAHs can share a pharmacovigilance system, or they can operate separate systems. The UK regulator recognises both models. A UK pharmacovigilance system master file (PSMF) must describe the system used for UK-authorised products, and each UK system requires its own UK PSMF number. Where several MAHs share one system, they can submit one request for that UK number. [3]

A **shared system** should have documented inter-entity reporting lines, common case-processing and signal-management arrangements, defined access rights and cross-entity oversight. It does not mean one document automatically meets every local PSMF or access obligation. A **separate-system model** requires genuinely distinct operations and a tested route for sharing product-safety information across

the boundary.

Can each MAH show which system applies to its authorisation, which master file describes it, who makes safety decisions and how an issue detected by one entity reaches the other? Choose the model that reflects actual operations rather than drawing a second system on an organisational chart.

3. Match named people to access

Table 1. Named pharmacovigilance roles and practical requirements.

Territory	Named role	Operational requirement
EU/EEA	EU qualified person responsible for pharmacovigilance (QPPV)	Resides and operates in the EU/EEA; the MAH must have the QPPV permanently and continuously at its disposal. [4]
United Kingdom	UK QPPV; potentially the same individual as the EU QPPV	Resides and operates in the UK or EU/EEA. If based outside the UK, appoint a UK-resident and UK-operating national contact person with access to the relevant adverse-reaction reports and UK PSMF. [3]
Switzerland	Responsible Person for Pharmacovigilance (RPV) and qualified deputy	Both must be appointed; neither need be directly employed or resident in Switzerland. Define duties and deputisation in writing. Both must be fluent in at least one official Swiss language; the RPV or deputy must be contactable during business hours on Swiss working days. [5]

For UK-authorised products, the PSMF must be electronically accessible from the UK at the same site at which reports of suspected adverse reactions may be accessed and must be made available upon request. The UK PSMF number is invalidated if the electronic-access address is outside the UK. A single UK PSMF can cover multiple UK-authorised products only if they genuinely use the same system. [3]

The inspection question is not simply whether someone has been nominated. It is whether that person can retrieve records, answer regulator queries, exercise oversight and obtain support when the normal contact is unavailable.

4. Define Day 0 across every hand-off

A valid ICSR requires an identifiable reporter, an identifiable patient, a suspected medicinal product and a suspected adverse reaction. Under EU GVP Module VI, the reporting clock begins when information meeting those criteria first reaches relevant MAH personnel or a contractor acting under an agreement—not when the central safety team later enters the case. A report missing a minimum element still needs prompt follow-up; initial receipt and later validation must be traceable. [6]

Table 2. An illustrative case-intake chain.

Time	Event	Control
Day 0	A local representative receives a valid serious case.	Preserve the first-awareness timestamp and source record.
Days 1–2	The local entity routes the information internally.	Use a measurable forwarding deadline and escalation path.
Day 3	The delegated safety mailbox receives the case.	Do not reset Day 0 to the mailbox date.
Day 4 onward	Triage, medical assessment, quality control and transmission.	Monitor time remaining against the applicable deadline.

Illustrative sequence, not a standard workflow.

Agreements with affiliates, distributors and service providers should name the clock-start rule, prescribe forwarding and escalation deadlines **inside** the regulatory window, require timestamps and

source-document retention, and state who investigates delays. A delegate's deadline set equal to the regulator's deadline leaves no workable margin.

5. Apply each local reporting rule

Similar safety-reporting frameworks do not make submissions interchangeable.

Table 3. Post-marketing spontaneous ICSR reporting: key distinctions.

Route	Reporting position	Qualification
EU/EEA	MAHs submit reportable ICSRs to EudraVigilance; serious cases generally have a 15-day and non-serious EEA cases a 90-day submission period. [6, 7]	EU submission does not itself discharge a separate MHRA or Swissmedic obligation.
United Kingdom	The MHRA requires UK serious and non-serious cases and serious cases from other countries through its own route. [8]	For products authorised for sale or supply in Northern Ireland, applicable EU pharmacovigilance requirements continue alongside relevant UK requirements. Confirm the route against authorisation category, case origin and current MHRA instructions. [8]
Switzerland	Swissmedic requires MAHs to report domestic serious adverse drug reactions (ADRs) within 15 days; domestic non-serious unexpected ADRs within 60 days; ADR clusters within 15 days. [9]	Not every non-serious, already-labelled reaction is individually reportable. Swissmedic says not to send foreign ICSRs through this domestic route. [9]

Swissmedic distinguishes safety information from individually reportable ADRs: medication errors, overdose, misuse and occupational or accidental exposure **without an additional ADR** do not have to be individually reported, although associated signals may still require notification. [5] Apply the exact product-information and case-validity criteria rather than a blanket decision rule.

Emerging safety issues

An EU MAH should notify an emerging safety issue to the EMA **and** competent authorities of Member States where the medicine is authorised as soon as possible and no later than **three working days** after establishing that the issue meets the definition. [10] For a UK-authorised product, MHRA guidance separately requires notification to the MHRA within **three working days**. An EMA notification does not substitute for a UK notification. [8]

For Switzerland, a signal requiring short-term drug-safety measures must be notified immediately and at the latest within **five days**; other serious risks inadequately described in product information have a **15-day** period. These are distinct Swiss signal rules, not interchangeable with the EU/UK emerging-safety-issue definition. [11]

Routes and credentials

The EU, MHRA and Swissmedic use distinct submission arrangements. Swissmedic accepts MAH adverse-reaction reports electronically via its gateway or ElViS; registration is required for either Swiss route. [9, 12] As announced by Swissmedic on **4 September 2026**, ElViS 2.0 is planned to launch on **21 December 2026**, supporting E2B(R3) exchange for MAHs. This is a prospective date: verify Swissmedic's current position before relying on the change operationally. [13]

Maintain an entity-by-entity route inventory, access-owner record, test evidence and contingency procedure. Recheck and retest the relevant route when a portal or format changes.

6. Make oversight visible

Delegating intake, processing or local marketing does not remove the MAH's responsibility for its system. Inspectors can request agreements, audit risk assessments, procedures, safety-review records and evidence of PSMF-described activities. [5, 14] The useful distinction is between a control said to exist and a control that leaves an inspectable record.

Table 4. Evidence-generating oversight controls.

Control	Illustrative risk-based cadence	Evidence to retain
Case-level reconciliation	Monthly at launch; adjust on risk	Matched case lists, exceptions, investigation, resolution and approval.
Performance review	Monthly	Day 0-to-submission latency, on-time rate and open queries, separated by entity, provider and territory.
Risk-based audit planning	Review annually and when risk changes	Approved plan, scope rationale, findings, CAPA owners and closure evidence.
PSMF and agreement maintenance	On change, with periodic review	Current contracts, delegated-activity inventory, versions and change history.

These cadences are a proposed management framework, not uniform statutory frequencies in all three regimes.

Aggregate counts alone cannot demonstrate that both sides hold the **same cases**: two missing cases can be hidden by two extra cases. Reconcile identifiers and receipt dates case by case. Document how a Swiss MAH centrally collects and evaluates safety-relevant information, while keeping the shared global database and local responsibility clear. [15]

7. Rehearse the inspection trail

The MHRA may inspect MAHs and their partners, review the PSMF and underlying documents, interview staff and examine live systems. Inspections can be onsite, remote or hybrid; teams usually comprise one to four inspectors working for two to five days, depending on scope. [14]

Select a genuine case for each material reporting route, starting with one that crosses a legal-entity boundary. Trace the original report, first awareness, validation, inter-entity transfer, assessment, submission and regulator acknowledgement. For every hand-off identify a timestamp, owner and source record; preserve the follow-up history and source-language document. Where the trail breaks, open a corrective action now rather than waiting for a request.

Twelve readiness questions

01. Which legal entity holds the authorisation in each territory?

02. Is each entity's pharmacovigilance system actually shared or separate, and where is that decision recorded?

03. Are inter-entity reporting lines and authority for safety decisions documented and used?

04. Can each named QPPV, RPV, deputy and required local contact access information needed for their role?

05. Is the UK PSMF accessible at the same UK site as the relevant adverse-reaction reports?

06. Have the current submission routes and accounts been checked or tested for each entity?

07. Do all relevant affiliates and external providers have executed agreements defining Day 0, forwarding deadlines and escalation?

08. Does reconciliation match individual cases and record discrepancies to closure?

09. Are timeliness and quality indicators separated by counterparty and territory?

10. Do local decision rules distinguish reportable ICSRs from other safety information, including Swiss non-serious expected cases?
11. Does the signal procedure name all required recipients and distinguish EU, UK and Swiss urgent-notification thresholds?
12. Can the team demonstrate an end-to-end case trail today, including the route across an entity boundary?

8. Conclusion

A multi-entity MAH structure is not itself a pharmacovigilance defect. Unmapped boundaries are. Make the legal holder, system topology, named-person access, clock start, reporting route and oversight evidence explicit for every territory. The same traceability that supports an inspection also helps prevent delayed assessment of a safety signal.

Scope and disclosures

This paper describes a generic structural pattern, not a specific company, client, product or engagement. The tabled periods concern post-marketing spontaneous reports except where Swissmedic's additional cluster rule is expressly identified; other safety data and special situations can have different requirements. Requirements and guidance can change. Check current official sources and authorisation-specific facts before relying on any deadline or route.

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