Pharmacovigilance in a multi-entity marketing authorisation structure: five decisions that determine inspection readiness across the EU, the United Kingdom and Switzerland

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Abstract

Background. Where authorisations in different markets are held by different legal entities, pharmacovigilance responsibilities cross legal and operational boundaries. UK and Swiss establishment rules are relevant to authorisation, but do not prescribe a single group operating model. [1–3]

Analysis. This paper uses publicly available legislation, agency guidance and published inspection information to examine five decisions: system topology; named-person roles and access; Day 0 across delegated intake; local reporting and notification; and evidence of oversight. Organisational arrangements are composite teaching examples, not an account of any undertaking.

Conclusion. The proposed twelve-question framework tests whether responsibilities, information flows and documentary evidence align. Recommended frequencies and controls are distinguished from legal reporting obligations.

Keywords. pharmacovigilance · marketing authorisation holder · QPPV · PSMF · Windsor Framework · Swissmedic · inspection readiness · safety data exchange agreements

1. Introduction

A group may hold marketing authorisations through more than one legal entity while performing safety activities through shared or delegated functions. The important question is not how many boxes appear on the group chart but whether each MAH can demonstrate control over the pharmacovigilance system applicable to its authorisations. MHRA guidance expressly contemplates both several MAHs sharing a system and one MAH operating multiple systems. [5,11]

The model presented below is a composite educational scenario. Individual elements may occur in practice, but their combination is not intended to depict any particular undertaking. Its questions arose in a professional teaching context; the regulatory analysis and legal claims are grounded in the public sources cited. Reporting periods discussed concern post-marketing individual case safety reports (ICSRs); clinical-trial reporting is outside scope.

2. Why boundaries arise

The holder of a UK marketing authorisation must satisfy UK establishment requirements. Swiss authorisation requires a domicile, registered office or branch in Switzerland and, under Article 10 HMG, an appropriate establishment licence. The relevant Swiss licence and its technical and quality arrangements are separate questions from the pharmacovigilance system. These requirements may lead to different authorisation holders across markets; they do not dictate which group function processes cases or whether intake is internal or external. [1–3]

A conceptual system should therefore distinguish the legal holder, any other commercial interface and the function receiving safety information. No fixed number of entities, interfaces, providers or master files follows from the three jurisdictions. The possible arrangements in Figure 1 are alternatives rather than one continuous route.

Regulatory accountabilities (examples)	Possible information interfaces — select only those applicable
EU/EEA MAH · UK MAH · Swiss MAH (roles may be held by distinct eligible entities)	Local affiliate or commercial partner → relevant MAH / PV function
Each holder defines its applicable PV system and local obligations	Internal intake or external service provider → relevant PV function
Shared group PV function or separate functions	Optional cross-entity safety exchange ↔ other responsible MAH

Figure 1. Conceptual anatomy of a multi-entity marketing authorisation structure. The figure combines regulatory and operational features that may occur in different configurations. It does not represent the complete structure of any particular organisation. Arrows denote possible, not mandatory, pathways.

3. Decision one: system topology

The organisation should first determine whether its MAHs use a shared pharmacovigilance system or genuinely separate systems. This represents a recurring structural vulnerability in multi-entity pharmacovigilance systems: a shared process is described as separate, or separate processes are assumed to be covered by one file. UK guidance allows several MAHs to share a system and requires each UK system to have the appropriate unique UK PSMF number; a UK PSMF must accurately describe the system used. EU PSMF content and QPPV obligations also attach to the system actually operated. [4,5]

In a shared-system model, establish and document which MAHs are covered, the reporting lines, the QPPV's oversight and any local UK PSMF obligations. In a separate-system model, document the distinct procedures, responsible persons and master files, and define how relevant product safety information crosses systems. These are alternative governance designs, not claims that every group must operate a single QPPV or exactly two PSMFs. The practical test is whether the chosen design matches records, agreements and real work. [4,5]

4. Decision two: residence, reachability and access

The named-person requirements vary by jurisdiction. Table 1 separates explicit requirements and agency guidance from proposed operational controls. The same individual may hold both EU and UK QPPV roles if the respective conditions are met. [1,4,5,9]

Role / issue	EU/EEA	United Kingdom	Switzerland
Named person	EU QPPV; resident and operating in EU/EEA. [4]	UK QPPV; resident and operating in UK or EU/EEA. [1,5,9]	Qualified person responsible for PV; no Swiss residence requirement. [6]
Availability / contract	MAH must have QPPV permanently and continuously at its disposal. [4]	MAH must have QPPV permanently and continuously at its disposal. [1,5]	May be external; responsibilities in writing. Person or deputy reachable at least on Swiss working days in business hours. On-call cover outside hours is recommended by Swissmedic. [6]
Local access	Applicable EU PSMF / oversight rules. [4]	If QPPV is EU/EEA-resident rather than UK-resident, appoint a UK-resident national contact person who reports to QPPV and has access to UK reports and PSMF. UK PSMF accessible electronically at the same UK point as reports. [5,9]	Document access sufficient to meet reporting, assessment and availability duties; exact arrangement is system-specific. [6,7]

Table 1. Named post-marketing PV roles. Requirements and agency expectations are cited in the relevant cells; the final Swiss access statement is an implementation recommendation, not a specified architecture.

In particular, the UK PSMF must be permanently and immediately available at its stated UK access point, the same point from which suspected adverse reaction reports can be accessed. An address outside the UK invalidates the UK PSMF number and submissions using it are not accepted. A single UK PSMF may cover products only if they use the same system. These are MHRA requirements, not a recommendation to host case data on a particular server. [5]

EU/EEA-resident UK QPPV	UK-resident UK QPPV
UK national contact person required; ensure access to UK reports and PSMF. [5,9]	No additional national contact person required on residence grounds; UK access rules for PSMF and reports still apply. [5]

Figure 2. Alternative UK role arrangements determined by QPPV residence. This is a regulatory decision tree, not a staffing diagram for any organisation.

5. Decision three: when Day 0 begins

For a valid report, EU GVP Module VI starts the reporting clock when the MAH or personnel acting for it, including contractors, first receive the minimum information; later transmission to a central safety function does not restart the clock. Apply the relevant jurisdiction’s rule to the actual reporting route. A receiving agreement should therefore capture first awareness, define ownership of validation and forwarding, and provide time for assessment and submission before the applicable deadline. [12]

The following hypothetical sequence was constructed solely to demonstrate how internal forwarding delays can reduce the time remaining within a regulatory reporting period. It does not represent an actual case, organisation or documented timeline. The 15-calendar-day period shown is the applicable serious-ICSR reporting period in the relevant regimes; the intermediate steps and intervals below are invented teaching values. [6,7,9,12]

Illustrative elapsed day	Hypothetical event
Day 0	An authorised local commercial partner acting for an MAH first receives minimum information for a valid serious ICSR; start the applicable clock.
Day 1	Partner sends the report to an internal coordinator (optional route, not an assumed operating model).
Day 2	Coordinator forwards the case to the designated internal or external PV intake function.
Day 3	Safety team validates routing and begins assessment. The clock remains anchored to Day 0.
Days 4–15	Time available for assessment, follow-up as needed, quality checks and submission within the applicable 15-calendar-day deadline.

Table 2. Entirely hypothetical forwarding sequence. Elapsed days are illustrative, not case dates or contractual service levels. Day 0 does not move when a case crosses an internal or delegated interface. [12]

An agreement that gives a delegate the whole statutory period leaves no assured time for the MAH's final checks and submission. As proposed good practice, set risk-based contractual milestones materially inside the relevant regulatory limit, including arrangements for weekends, urgent escalation and missing information; do not treat those proposed milestones as statutory periods. [12]

First valid awareness	Forwarding / triage	MAH review / submission
Day 0 → regulatory clock starts	Contractual milestones set inside the deadline (illustrative)	Regulatory deadline: e.g., serious ICSR by day 15 where applicable

Figure 3. Conceptual timeline cascade. The contractual stages are deliberately not assigned actual service-level intervals; the statutory deadline is not altered for illustration. [12]

6. Decision four: local reporting precision

6.1 Individual-case scope

EU/EEA serious ICSRs and UK serious ICSRs are generally reportable within 15 calendar days; non-serious reportable cases have a 90-day period subject to the relevant territorial and licence-category rules. The UK Windsor Framework guidance distinguishes UK Category 1, Category 2 and Northern Ireland authorisations when specifying which cases also reach EudraVigilance; a UK submission does not automatically discharge an EU submission obligation. [9,10,12]

In Switzerland, serious adverse reactions and unknown non-serious adverse reactions are individually reportable; Swissmedic specifies 15 days for serious and 60 days for non-serious reportable reactions. Medication errors, overdose, misuse and occupational or accidental exposure without an adverse reaction do not in themselves require individual ADR reporting, although associated safety signals can require attention. The Swiss scope rule should be checked before simply importing an EU or UK reporting matrix. [6,7]

6.2 Accelerated safety notifications

EU GVP Module IX instructs MAHs to notify an emerging safety issue in writing to EMA and competent authorities of the Member States where the product is authorised as soon as possible and no later than three working days after establishing that it meets the definition. The UK has its own emerging-safety-issue notification route to MHRA; EU notification does not replace it. Swiss law has distinct immediate notification, at the latest within five days, for a safety signal requiring short-term measures, and a 15-day period for other specified serious risks. Check the applicable definition and recipient separately; these triggers are not interchangeable. [7–9]

6.3 Routes and access

EU MAHs use EudraVigilance for the EU ICSR reporting route. UK and Swiss routes must be managed according to their own requirements; the relevant MAH should verify its submission access, credentials, acknowledgement handling and contingency arrangements. A separate credential for every legal entity is not asserted as a universal rule: account design depends on the authority's registration and the implemented sender arrangements. [6,9,10]

Swissmedic provides gateway and ElViS reporting options for MAHs. As announced on 4 September 2026, ElViS 2.0 is planned for 21 December 2026, not yet an operating portal at this paper's date. A proposed control is to re-test a changed route before relying on it for live reporting. [6]

Regime	Serious ICSR	Non-serious ICSR	Accelerated safety issue
EU/EEA	Generally 15 calendar days. [4,12]	Generally 90 calendar days for applicable EEA cases. [4,12]	Emerging safety issue: EMA + relevant national authorities, ≤3 working days after establishment. [8]
UK	15 calendar days for reportable UK / third-country serious cases. [9]	90 calendar days for reportable UK cases. [9]	Separate MHRA notification of emerging safety issue; assess UK-specific guidance. [9]
Switzerland	15 days for serious ADRs. [6,7]	60 days only for individually reportable unknown non-serious ADRs. [6,7]	Immediate / ≤5 days for signal requiring short-term measures; other specified serious risks ≤15 days. [7]

Figure 4. High-level post-marketing reporting matrix, not a complete product-specific decision rule. Territorial origin, licence category, case validity and the applicable trigger must be assessed for each route. [4,6–9,12]

7. Decision five: evidence of oversight

Delegation of work does not remove an MAH's pharmacovigilance responsibility. The PSMF should accurately reflect relevant organisational arrangements, outsourced activities and agreements; Swiss law requires safety-relevant information to be centrally collected and evaluated. A central collection point need not dictate one technology or ownership model. Published MHRA inspection guidance states that partner and service-provider agreements, SOPs and activity outputs may be requested. [4,5,7,11]

Table 3 is a proposed risk-based control model, not a schedule imposed by all three regulators. Frequencies and sample artefacts should be adjusted to case volume, risk, delegated scope and change history while preserving the evidence necessary to demonstrate compliance.

Proposed control	Illustrative risk-based cadence	Example evidence
Case-level reconciliation	Monthly during a new hand-off; quarterly once stable, or more often if risk warrants.	Compared case IDs, exceptions, investigation, resolution and dated approval.
Performance review	Monthly initially; then according to risk.	Day-0-to-submission latency, overdue cases and queries separated by route and counterparty.
Delegate audit / review	Risk-based schedule; no universal annual rule implied.	Audit or assessment plan, findings, corrective actions and closure evidence.

Proposed control	Illustrative risk-based cadence	Example evidence
PSMF / agreements check	At material change and periodic review.	Current descriptions of applicable MAHs, functions, delegated tasks and contracts, consistent across the PSMFs actually required.

Table 3. Suggested oversight mechanisms and documentary artefacts. Cadences are proposals, not statutory minimum frequencies; there is no assumption of two PSMFs or of a particular outsourced vendor.

System A	System B	What a control must compare
3 case identifiers received	3 case identifiers recorded	Matching totals do not establish that the same cases are present; compare identifiers and resolve discrepancies.

Figure 5. Conceptual case-level reconciliation illustration. Numbers are invented solely for explanation and are not performance figures.

8. Inspection exposure

MHRA guidance describes routine inspection planning as risk-based, permits triggered inspections on specific risk information, and explains that inspection teams may review the PSMF, agreements, activity records, systems and personnel. The authority publishes inspection metrics on common finding categories. These are published practices and evidence, not findings about the scenario in this paper. [11]

Avoid assuming that a newly established entity has already been inspected, or that an initial inspection will have a particular outcome. Published UK metrics are population-level observations and should not be converted into a prediction for any hypothetical MAH. A more reliable readiness test is to demonstrate a complete evidence trail through each actual submission route. [11]

As proposed good practice, rehearse one appropriately selected genuine case internally per material route: source receipt, first valid awareness, forwarding, validation, assessment, submission, acknowledgement and any follow-up. Protect patient data and use redacted or controlled evidence in external training or publication. The diagram below is a generic process map, not a record from an inspection. [11,12]

Receipt / Day 0	Routing	Assessment	Submission	Acknowledgement / follow-up
Timestamp and source	Handoff records	Medical and QC record	Destination and time	Receipt, exception and closure evidence

Figure 6. Conceptual end-to-end traceability demonstration. Actual inspection scope varies; this is a suggested internal readiness exercise, not a claim that every inspector requests this exact sequence. [11]

9. Twelve-question readiness framework

No.	Question
1	For each jurisdiction, which eligible entity holds each authorisation, and what PV system applies?
2	Are the applicable systems shared or separate, and where is that determination recorded?
3	Are inter-MAH reporting lines and product-safety exchanges documented and operating?
4	Are the required QPPVs and, where applicable, the UK national contact person appointed, available and appropriately connected?
5	Are the applicable PSMFs accurate and accessible at their required locations, including the UK access point?
6	Are actual submission routes, authorised senders, access arrangements and acknowledgements tested and controlled?
7	Do relevant delegate and partner agreements define first valid awareness, forwarding, escalation and time within regulatory deadlines?
8	Is case-level reconciliation performed and evidenced at a risk-based frequency?
9	Are performance indicators separated by route and counterparty so that delays can be investigated?
10	Does each local reporting matrix capture scope, origin, validity, seriousness and relevant licence category?
11	Are accelerated safety-issue triggers, distinct recipients and owners identified for each applicable regime?
12	Can an appropriately selected case be traced end to end through each material route, including any actual entity boundary?

Table 4. Proposed twelve-question inspection-readiness framework. It is a professional assessment tool, not a statutory questionnaire.

10. Conclusions

A multi-entity authorisation structure need not be a compliance defect. The inspection-readiness question is whether each applicable legal obligation has an owner and whether information can move across the boundaries that actually exist. First define the system; then validate named-person access, the clock start, each local reporting route and the evidence of oversight. The five decisions translate regulatory duties into a demonstrable operating model without treating any conceptual example as a description of one organisation.

Scope and limitations

This paper presents a generic regulatory and governance analysis based on publicly available legislation, regulatory guidance and published inspection information. Generic educational questions also arose through professional teaching experience. The organisational configurations, timelines, examples and diagrams are illustrative composite models prepared for educational purposes; they do not reproduce the complete pharmacovigilance system, products, procedures, contractual arrangements, inspection history or operating model of the author’s employer, a client, a training participant or any other identifiable organisation. No company names, product names, personal data, confidential documents or proprietary system identifiers are reproduced or disclosed in this publication.

It is an independently authored, company-neutral white paper based on public regulatory sources and composite educational scenarios, not an employer publication, a client deliverable or a description of a

training participant. The views and proposed framework are those of the author. Reporting guidance can change; verify current primary sources and product-specific obligations before implementation.

Conflicts of interest and independence

The author is employed in the pharmaceutical industry and additionally provides independent audit, consultancy and training services in pharmacovigilance governance. This paper was prepared independently and does not represent the views, systems or practices of the author's employer, any client or any training participant. The regulatory analysis is based on publicly available sources. No company names, product names, personal data, confidential documents or proprietary system identifiers are reproduced or disclosed. No external funding was received for the preparation of this white paper.

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