

LATAM PV/TV Reform Calendar 2026–2027

Six agencies. One direction. The dates every MAH in the region is now working against.

ALREADY IN FORCE · YA VIGENTE

6 NOV 2025

REGIONAL · PAHO – AEMPS

Memorandum of Understanding, Cartagena

Technical-cooperation framework on regulatory capacity, convergence and reliance across the Americas, coordinating Red EAMI with Red PARF.

20 MAR 2026

BRAZIL · ANVISA

RDC 967/2025 — VigiMed becomes the floor

Mandatory reporting via VigiMed under ICH E2B(R3). MedDRA for medical terms and WHODrug for medicines (incl. vaccines) now required for all MAHs. Amends RDC 406/2020.

4 FEB 2026

ECUADOR · ARCSA

Res. ARCSA-DE-2025-052-DASP published

Substitute technical standard for the National Pharmacovigilance System (R.O. 218). Scope expanded to emergency imports, donations and homologated products. Clocks start here.

19 MAY 2026

MEXICO · COFEPRIS

NOM-137-SSA1-2025 published

Device labeling standard replacing the 2008 NOM: traceability, harmonized symbols, sterility labeling, expanded IVD requirements. Mandatory compliance clock: 360 days.

12 AUG 2026

ECUADOR · ARCSA

Instructivo IE-B.5.1.4-FCV-02 v3.0

e-Reporting Industria is the rule; paper form only by exception. Serious cases: 15 days. Non-serious: 30 days. Zero-case periods must be reported. Sets the Aug 2027 E2B(R3) cut-over.

18 AUG 2026

MEXICO · COFEPRIS

Boletín Nacional FV/TV 2026-I

CENAFyT received 82,993 notifications in 2025. Signal-management results for H1 2026 published. Active reporting is now expected practice, not exception.

REPORTING CLOCKS · QUICK REFERENCE

Ecuador · ARCSA	15 days serious / ESAVI · 30 days non-serious · zero-case report each period
Brazil · ANVISA	Serious AEs via VigiMed, E2B(R3), MedDRA + WHODrug coded
Dictionaries	MedDRA (MSSO) and WHODrug (UMC): licensed, versioned, locally deployed — not APIs
Valid case	Identified patient + suspect product + clinical event + identified reporter

COMING · LO QUE VIENE

4 NOV 2026

ECUADOR · ARCSA

ARCSA-DE-2025-052 in full effect

MAHs must run an in-house or contracted PV unit; designate a Responsable de Farmacovigilancia and alternate (reported annually); keep a PV System Master File; run periodic audits; submit PSUR/PBRER and RMPs on request.

14 MAY 2027

MEXICO · COFEPRIS

NOM-137-SSA1-2025 mandatory

All device labeling and IFUs must comply; 180 additional days to exhaust packaging made under the 2008 standard.

AUG 2027

ECUADOR · ARCSA

E2B(R2) stops being accepted

XML submissions only under ICH E2B(R3). e-Reporting Industria will require registered, current MedDRA (MSSO) and WHODrug (UMC) licences to transmit. Licence procurement is on the critical path today.

2026–2027

COLOMBIA · PERU

INVIMA & DIGEMID tighten periodicity

Signal-management components added to Colombia's technovigilance programme; Peru enforcing documentation and reporting quality across public and private sectors. No new categories of obligation — tighter execution of existing ones.

THE PATTERN UNDERNEATH

More data, more dictionaries, more infrastructure. Compliance is becoming a systems problem, not a knowledge problem. Whatever you build must leave an auditable record a regulator can read without opening the black box.

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SCAN TO SAVE CONTACT

Send me your worst AI pilot. I'll tell you which blast-radius category it's in.

