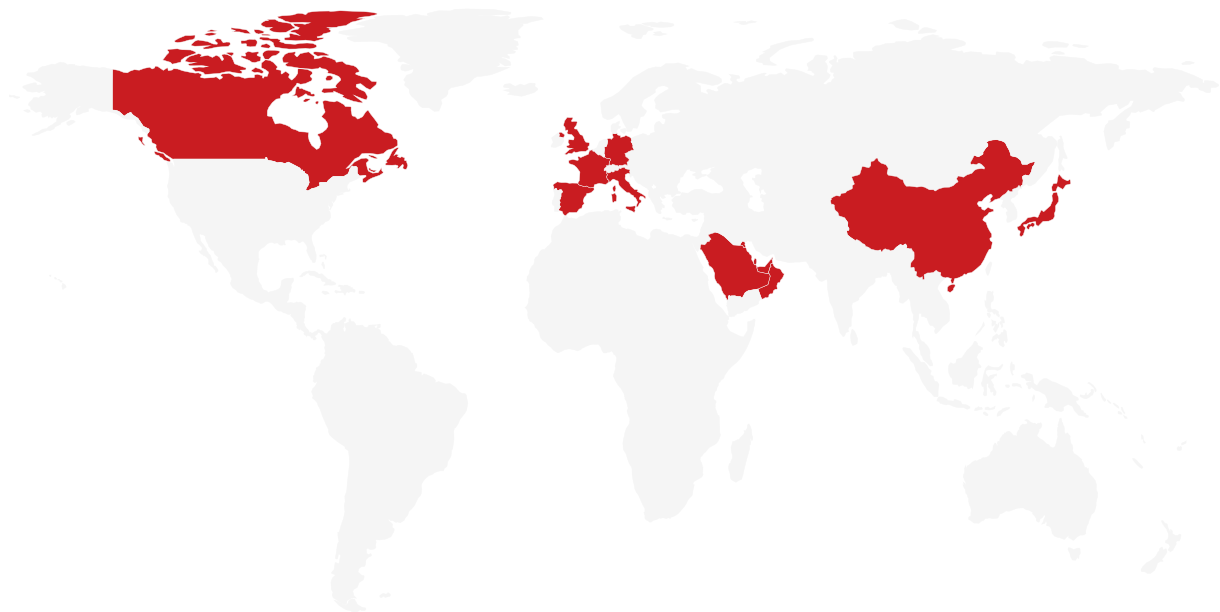


Global Pharmacovigilance Compliance Fact Sheet



Navigating Local PV Requirements Across Japan, EU5, China, GCC & Canada

As biopharmaceutical companies expand globally, pharmacovigilance (PV) compliance becomes increasingly complex. While many organizations operate under a centralized global safety model, regulatory authorities continue to require local oversight, local language capabilities, country-specific reporting processes, and in-country pharmacovigilance representation. For companies launching products simultaneously across multiple regions, failure to establish compliant local PV infrastructure can create significant regulatory, operational, and reputational risks.



PrimeVigilance supports pharmaceutical and biotechnology companies with a global network covering more than 170 countries, helping ensure local compliance while maintaining global oversight.

+170

countries covered

5

major launch regions

local PV

experts worldwide

Market-by-Market Compliance Overview

Market	Regulatory Authority	Key Local PV Requirements	Common Challenges
Japan	PMDA	Local safety contact, Japanese literature monitoring, periodic reporting, post-marketing surveillance	Language requirements and strict post-marketing obligations
EU5 + UK	EMA + National Authorities	Local literature monitoring, local PV contacts, PSUR/PBRER activities	Multiple national requirements despite centralized approval
China	NMPA	Local PV system, Safety Representative, Chinese reporting requirements	Independent PV infrastructure required
GCC	SFDA, UAE MOHAP, GCC Authorities	Local representation, local reporting pathways	Variable country-specific requirements
Canada	Health Canada	Local compliance oversight, bilingual communication capability	Distinct requirements from FDA processes

JAPAN

PMDA

Key Requirements

☐ Local pharmacovigilance contact

☐ Japanese-language adverse event intake

☐ Japanese literature monitoring

☐ Post-marketing surveillance activities

☐ Re-examination and risk management obligations

☐ Periodic safety reporting

Typical Risks

• Delayed case intake due to language barriers

• Insufficient local literature surveillance

• Limited understanding of PMDA expectations

• Difficulty scaling local operations during indication expansion

How PrimeVigilance Supports

- | | |
|---|---|
| ☒ Japanese-language literature monitoring | ☒ Local PV contact services |
| ☒ Local case processing support | ☒ Risk management support |
| ☒ PMDA-compliant reporting | |

EU5 & UNITED KINGDOM

EMA + NATIONAL AUTHORITIES

Key Requirements

- ☐ Local language literature monitoring
- ☐ Country-specific authority interactions
- ☐ Local safety contact capability
- ☐ PSUR/PBRER support
- ☐ Label variation implementation
- ☐ Additional risk minimization activities

Common Challenge

Many organizations assume EU approval equals centralized PV management. In practice, local language surveillance and country-specific obligations remain critical.

PrimeVigilance Advantage

- | | |
|---|---|
| ☒ Established EU-wide local affiliate network | ☒ Country-specific regulatory expertise |
| ☒ Native-language literature monitoring | ☒ Local safety contact support |

CHINA

NMPA

Key Requirements

- ☐ NMPA-compliant PV system
- ☐ Local Safety Representative
- ☐ Chinese literature monitoring
- ☐ China National PV System (CNPVS) reporting
- ☐ Local inspections readiness

Common Challenge

- Establishing local governance
- Building compliant reporting processes
- Managing local language safety information
- Regulatory inspection preparedness

PrimeVigilance Support

- | | |
|--|--|
| ☒ NMPA-compliant system implementation | ☒ Chinese-language intake and monitoring |
| ☒ Safety Representative services | ☒ Local inspection support |

Key Requirements

- ☐ Local pharmacovigilance representation
- ☐ Country-specific reporting obligations
- ☐ Arabic-language literature surveillance
- ☐ Authority interactions

Common Challenge

Companies often lack established affiliates while commercial activity is rapidly increasing.

PrimeVigilance Support

- ☒ GCC-wide local representation
- ☒ Local authority engagement
- ☒ Arabic literature monitoring
- ☒ Regional compliance management

Key Requirements

- ☐ Health Canada reporting obligations
- ☐ Local compliance oversight
- ☐ Bilingual communications capability
- ☐ Post-market surveillance support

PrimeVigilance Support

- ☒ Canadian PV compliance services
- ☒ Reporting support
- ☒ Literature monitoring
- ☒ Inspection readiness

Questions Every Global PV Leader Should Ask

- ☐ Do we have local-language literature monitoring in every launch market?
- ☐ Can we demonstrate country-level compliance during inspection?
- ☐ Are local reporting pathways documented and tested?
- ☐ Do we have qualified local PV contacts where required?
- ☐ Can our current global model scale to support simultaneous launches?

If the answer to any of these questions is uncertain, a local PV gap assessment may be warranted.



Planning Expansion into Japan, China, EU5, GCC or Canada?

**Don't wait until launch preparation
uncovers compliance gaps.**

**PrimeVigilance's global network
of local PV experts supports
organizations in more than
170 countries, helping them
establish compliant, scalable
pharmacovigilance operations
from development through
commercialization.**

Schedule a Global PV Readiness
Assessment today to identify
potential risks, strengthen local
compliance, and accelerate
launch readiness across
your priority markets.

primevigilance.com/contact-us