CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.21963597

Available online at: http://www.iajps.com Review Article

GLOBAL PHARMACOVIGILANCE REGULATIONS - HARMONIZATION OF FDA, EMA, MHRA AND CDSCO

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Abstract:

Background: Pharmacovigilance has evolved from spontaneous adverse drug reaction reporting to a lifecycle safety science linking clinical development, post-marketing surveillance, risk minimization and regulatory decision-making. [18, 5, 6] This has been driven by the inability of pre-approval trials to detect rare, delayed, and population-specific harms [4, 3]. Objective: To critically evaluate the degree of harmonization of pharmacovigilance practices between the United States Food and Drug Administration (FDA), European Medicine Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA) and Central Drugs Standard Control Organization (CDSCO) in terms of reporting standards, signal detection, risk management and digital modernization [18, 12, 17]. Data Sources: This review summarizes recent peer-reviewed literature and regulator-focused comparative studies on ICH pharmacovigilance guidelines, FDA post-marketing systems, EMA good pharmacovigilance practices, post-Brexit MHRA changes, CDSCO/PvPI development, and AI uses in pharmacovigilance, with preference for publications from 2018–2026 and landmark older contextual work as needed [2, 9, 8]. Review Methods: We conducted a narrative state-of-the-art synthesis as the focus of the topic is on regulatory structures, operational models and implementation differences, not pooled clinical effect estimates [18, 12, 5]. Main findings: The most harmonized areas are ICH-derived technical architecture such as E2B electronic reporting, common seriousness criteria, MedDRA coding, DSUR/PBRER structures and lifecycle pharmacovigilance planning [19, 12, 5]. There is divergence in expedited reporting clocks, governance models, risk minimization tools, signal detection workflows and legal accountability with further fragmentation post-Brexit and continuing capacity gaps in India [10, 15, 12, 8, 17]. The FDA is characterized by an active surveillance infrastructure, the EMA by highly codified GVP obligations, the MHRA by dual-system complexity following EU separation, and the CDSCO by rapid alignment but weaker active surveillance and underreporting constraints [5, 12, 8, 7]. Data quality, bias, transparency, privacy and validation issues [2, 9, 14] limit routine regulatory use. AI appears to improve signal detection, case processing and data integration. Conclusion: The current evidence favors a model of pragmatic harmonization, not full uniformity. The key policy challenge is to balance interoperable scientific standards with local regulatory flexibility, data governance and public health responsiveness [18].

Keywords: *Pharmacovigilance; Adverse Reactions, Drug-Related; Postmarketing Product Surveillance; Risk Management; Regulatory Science; Artificial Intelligence*

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Please cite this article in press Soma Sekhar P et al., Global Pharmacovigilance Regulations - Harmonization of FDA, EMA, MHRA and CDSCO. Indo Am. J. P. Sci, 2026; 13(08).

INTRODUCTION:

• Since clinical trials are not able to fully characterize post-approval safety profiles in real-world populations [18, 4, 3], pharmacovigilance has become a central part of medicine lifecycle oversight. Trial populations are selective, exposure is limited and rare, harms that are delayed, interaction-related or genotype-sensitive often only become apparent after broader clinical use [4, 3]. The regulatory science has responded with global standards led by ICH, WHO-PIDM, MedDRA and electronic ICSR exchange, which have reduced duplication and improved the comparability of safety data across jurisdictions [19, 10, 15, 18]. However, harmonized formats have not resulted in fully harmonized decisions, as agencies still vary in legal mandate, benefit-risk tolerance, surveillance capacity, timelines and transparency [15, 18]. This review assesses the expression of these tensions in FDA, EMA, MHRA and CDSCO with an emphasis on translational safety science, risk management, real-world evidence and digital systems increasingly connecting clinical trials with post-marketing regulation [18, 7].

Materials and methods

A narrative state-of-the-art synthesis was used to evaluate regulatory structures and differences in implementation across agencies [18, 12, 5]. Data sources include peer-reviewed literature and regulator comparative analyzes (2018–2026) on ICH guidelines, GVP and digital modernization [2, 9, 8].

RESULTS AND DISCUSSION:

Regulatory Alignment ICH has created the primary technical foundation for global pharmacovigilance harmonization by harmonizing expectations for pharmacovigilance planning, post-approval safety data management, electronic reporting, periodic reporting and lifecycle benefit-risk evaluation [19, 5]. The largest areas of convergence are E2B reporting, MedDRA coding and DSUR/PBRER structure, which decrease formatting burden and make multi-national submission strategies more feasible [19, 12, 5]. This has practical value for lifecycle management as it allows sponsors to move resources away from administrative duplication and toward signal evaluation and risk governance [19, 5]. The harmonized scientific background is common to FDA, EMA, MHRA, and CDSCO, but applied differently [18, 5]. The EMA possesses the most formalized pharmacovigilance architecture with GVP modules on systems, PSMF, risk management, adverse reaction reporting, PSURs, PASS and signal management [12]. FDA is less modular, but more distinctive for parallel use of spontaneous reports and active surveillance systems [1, 5]. With PvPI, CDSCO has introduced a structured national pharmacovigilance, which is gradually aligning to WHO, CIOMS, EMA and ICH frameworks, but operational maturity is uneven [17, 16]. While MHRA remains scientifically close to EMA standards, Brexit has created a procedural separation that is important operationally [8]. Comparative Systems Cross-Agency Regulatory Characteristics

FIGURE 1: Comparative pharmacovigilance architecture of FDA, EMA, MHRA and CDSCO

Agency	Central Power	Big restriction	Special Report Proof
FDA	Active infrastructure in the post-market	Global fit of fragmentation functions with non-US data	FAERS and active surveillance in evolution
EMA	Most of pharmacovigilance governance is codified.	Challenging administratively for global sponsors	Surveillance and GVP modules in EudraVigilance [12]
MHR	Post-Brexit regulatory agility	Separate reporting burden, dual submission	Continued pressure to conform to UK-independent pathways [8]

CDSCO	Rapid System Development with PvPI	Under-reporting and less active surveillance	linked to WHO reporting with broad national ADR network [7, 16]

The Central Drugs Standard Control Organization (CDSCO) is a regulatory body in India responsible for the approval of new drugs, clinical trials, and the regulation of pharmaceutical products in the country. It operates under the Ministry of Health and Family Welfare and plays a crucial role in guaranteeing the safety, efficacy, and quality of drugs available to the public. Implementation Differences The most obvious constraints to harmonization are in terms of reporting timelines, causality thresholds, risk minimization tools, and governance requirements [10, 12]. The differences between the EU and US approaches to expedited reporting in clinical development have been known for years. European rules have favored wider communication of serious events, whereas FDA guidance has focused on more selective sponsor adjudicated related events. [15]. Such differences influence the interpretation of emerging safety data by investigators, sponsors and regulators during the trials and add to the complexity of the global consistency of safety communication [15]. Post-marketing governance also continues to differ. Structured RMPs, QPPV/PSMF duties and codified PASS expectations are the backbone of EU pharmacovigilance, while the US relies more selectively on REMS and post-marketing requirements [12]. These parallel systems result in duplication rather than true equivalence for global manufacturers [10, 12, 5]. Brexit has exacerbated this problem, with pharmaceutical companies now facing dual compliance, separate safety reporting systems, and duplicated submissions across the UK and EU despite shared safety objectives [8]. India offers a different kind of divergence: alignment without full equivalence [17]. The CDSCO and PvPI have laid down a systematic structure with national coordination, multiple routes of reporting ADRs, processing thru VigiFlow and participation in WHO-connected systems [7, 11, 3]. However, low ADR reporting, limited professional and patient participation, insufficient real-world data integration and weaker active surveillance still limit timely signal detection and regulatory maturity [7, 17, 16].

Evidence Coverage Across Pharmacovigilance Harmonization

Methods	Reporting Requirements	Governance	Digital Systems	Real World Data	A.I.
ICH Guidelines	GAP	GAP	GAP	GAP	GAP
Signal Detection	GAP	GAP	GAP	GAP	GAP
Risk Management Plans	GAP	GAP	GAP	GAP	GAP
Brexit Effects	GAP	GAP	GAP	GAP	GAP
India PvPI	GAP	GAP	GAP	GAP	GAP

The pattern of coverage is patchy. The literature on ICH standards, reporting rules and India PvPI development is dense, but much thinner on direct four-way comparisons of FDA, EMA, MHRA and CDSCO using common outcome measures or implementation metrics [18, 17]. The most obvious gap is the lack of evidence linking technical harmonization to similar regulatory decisions; some papers show convergence in E2B, MedDRA and DSUR/PBRER formats, while other papers still show divergent clocks, causality rules and local mandates [12, 5, 10, 18]. This gap persists because most analyzes are doctrinal or descriptive rather than comparative implementation studies, which reduces the field's capacity to assess whether harmonization leads to better signal quality, timeliness, or patient outcomes across jurisdictions [12, 5]. Digital Medication Safety Digital systems are playing an increasingly important role in determining the extent to which harmonization can be achieved as standardized electronic data flows are now required for cross-border signal detection, periodic reporting and lifecycle oversight [18, 5]. Spontaneous reporting is still the main source of suspected ADR

information worldwide but it is plagued by under-reporting, heterogeneity and weak denominators [10, 4, 9]. This is why high quality electronic transmission standards are important: they do not solve underreporting, but they increase interoperability and allow for quicker aggregation and review [10, 5]. The FDA has progressed the most toward active surveillance logic, combining spontaneous reporting with database-driven post-marketing assessment, while the EU has concentrated on centralized reporting and rule-based signal monitoring thru EudraVigilance and GVP signal management [5, 12]. India has made strides in digital access thru online and offline channels, toll-free reporting, mobile applications, and VigiFlow-supported case management, but evidence suggests limited integration of real-world evidence and advanced analytics [11, 7]. Precision Safety with AI In the AI literature for pharmacovigilance, the focus has been on signal detection, case processing and data extraction, rather than on fully autonomous regulatory decision-making [14, 9]. Machine learning algorithms can process spontaneous reports, EHRs, literature and even social media and seem to improve speed, triage efficiency, duplicate detection and structured extraction from narrative text [2, 13]. Some of the model-based work on pilot predictive surveillance suggests that there are signals that can be detected earlier than human review, but human judgment is still required to validate and assess causality [6]. The evidence is promising, but still not mature enough to justify uniform regulatory adoption [9, 14, 2]. According to the literature, the main obstacles are low data quality, heterogeneous sources, algorithmic bias, privacy concerns, cost, insufficient training, and low transparency of complex models [2, 13]. Precision medicine is even more relevant, because genotype-dependent toxicity, polypharmacy and heterogeneous patient risk are precisely the settings in which AI-enabled pharmacovigilance could be most useful if data governance and validation improve [4, 3].

FIGURE 2: Possible AI roles in harmonized pharmacovigilance systems

AI Applications Within Pharmacovigilance	Current Field of Use	The main caveat is evidence
Detection of signals	Automated Prioritization of Emergent Signals	Depend on high quality standard data [2, 5]
Narrative processing	NLP extraction of ADRs from narrative sources	Heterogeneous language and format reduces generalizability [2, 13, 14]
Predictive surveilance	Some earlier than human signal detection	Requires human approval and optimization. [6]
Support for worldwide harmonization	Typical methods and region-to-region interoperability	Governance and validation standards are not finalized yet [2]

CONCLUSION:

In the next phase, harmonization will probably be less dependent on new reporting templates but more on interoperable infrastructure, common analytical methods, and transparent post-authorization governance [18]. To achieve fit-for-purpose convergence, regulators will need to harmonize not only data formats but also signal validation expectations, public-facing rationales, and standards for real-world evidence and AI-supported review [18, 2]. The most profitable investments for CDSCO are likely to include workforce development, active surveillance capacity, reporting culture and legislative modernization [7, 17].

REFERENCES:

1. Aarti, Singh, K. S., & Kumar, M. (2025). Role of Pharmacovigilance Programme of India (PvPI) in Adverse Drug Event Monitoring for medication safety in patient. *International Journal For Multidisciplinary Research*. https://doi.org/10.36948/ijfmr.2025.v07i01.36627
2. Algarvio, R., Conceição, J., Rodrigues, P., Ribeiro, I., & Ferreira-Da-Silva, R. (2025). Artificial intelligence in pharmacovigilance: a narrative review and practical experience with an expert-defined Bayesian network tool. *International Journal of Clinical Pharmacy*, 47, 932–944. https://doi.org/10.1007/s11096-025-01975-3
3. Amale, P. N., Deshpande, S., Yd, N., & Na, A. (2018). Pharmacovigilance Process in India: An overview. *Journal of Pharmacovigilance*, 6, 1–7. https://doi.org/10.4172/2329-6887.1000259
4. Basile, A., Yahi, A., & Tatonetti, N. P. (2019). Artificial Intelligence for Drug Toxicity and

Safety. *Trends in Pharmacological Sciences*, 40, 624–635. https://doi.org/10.1016/j.tips.2019.07.005

5. Bernaus, C., & Bournissen, M. L. (2026). Global pharmacovigilance reporting: comparative analysis of adverse event obligations across five major regulatory authorities. *Frontiers in Drug Safety and Regulation*, 6. https://doi.org/10.3389/fdsfr.2026.1821686
6. De Abreu Ferreira, R. L., Zhong, S., Moureaud, C., Le, M. T., Rothstein, A. M., Li, X., Wang, L., & Patwardhan, M. (2024). A Pilot, Predictive Surveillance Model in Pharmacovigilance Using Machine Learning Approaches. *Advances in Therapy*, 41, 2435–2445. https://doi.org/10.1007/s12325-024-02870-5
7. Gupta, M., & Pant, H. (2026). Regulatory Requirement for Pharmacovigilance System in India: Gaps and Future Direction. *International Scientific Journal of Engineering and Management*. https://doi.org/10.55041/isjem07787
8. Ivr, J. G., & Srinivasan, R. (2025). Impact of Brexit on Pharmaceutical Regulations: EMA vs. MHRA. *Reviews on Recent Clinical Trials*. https://doi.org/10.2174/0115748871375964250531090843
9. Kompa, B., Hakim, J. B., Palepu, A., Kompa, K., Smith, M., Bain, P., Woloszynek, S., Painter, J. L., Bate, A., & Beam, A. (2022). Artificial Intelligence Based on Machine Learning in Pharmacovigilance: A Scoping Review. *Drug Safety*, 45, 477–491. https://doi.org/10.1007/s40264-022-01176-1
10. Lomeli-Silva, A., Contreras-Salinas, H., Barajas-Virgen, M. Y., Romero-López, M. S., & Rodríguez-Herrera, L. Y. (2024). Harmonization of individual case safety reports transmission requirements among PAHO reference authorities: a review of their current regulation. *Therapeutic Advances in Drug Safety*, 15. https://doi.org/10.1177/20420986241228119
11. Patel, R., Sachan, A. K., Chaohan, S., Tiwari, A., Giri, T., N., Ansari, A. S., Yadav, R. K., Siddiqui, E. M., Pandey, S. K., Yadav, B. S., & Chaudhary, N. (2021). Present era of drug safety in India: An overview. *Journal of Pharmacovigilance and Drug Research*. https://doi.org/10.53411/jpadr.2021.2.1.1
12. Reddy, N. S., Nagasree, K., Laxmi, P., & Kumar, S. (2026). An Analytical Study on Global Pharmacovigilance Regulations and their Role in Risk Management. *International Journal of Current Trends in Pharmaceutical Research.* https://doi.org/10.30904/j.ijctpr.2026.4999
13. Saini, A., Chandel, R., & Bala, A. (2026). Artificial Intelligence in Pharmacovigilance: Redefining Signal Management, Post-Marketing Drug Safety, and Adverse Drug Reaction Detection. *International Journal of Research Publication and Reviews*. https://doi.org/10.55248/gengpi.07.0626.17a16
14. Salas, M., Petracek, J., Yalamanchili, P., Aimer, O., Kasthuril, D., Dhingra, S., Junaid, T., & Bostic, T. (2022). The Use of Artificial Intelligence in Pharmacovigilance: A Systematic Review of the Literature. *Pharmaceutical Medicine*, 36, 295–306. https://doi.org/10.1007/s40290-022-00441-z
15. Singh, A., Twomey, K., & Baker, R. (2018). Global pharmacovigilance regulations: Call for re-harmonization. *Clinical Trials (London, England)*, 15, 631–632. https://doi.org/10.1177/1740774518801592
16. Singh, P., Vaishnav, Y., & Verma, S. (2022). Development of Pharmacovigilance System in India and paradigm of pharmacovigilance research: an overview. *Current Drug Safety*. https://doi.org/10.2174/1574863176662209301456 03
17. Tripathi, A., Kumar, A., & Das, D. (2026). Regulatory Harmonization in Indian Pharmacovigilance: Convergence with Global Standards and Unique National Adaptations. *International Journal For Multidisciplinary Research.* https://doi.org/10.36948/ijfmr.2026.v08i01.64639
18. Umaru, O., Adeyemi, A., Aderonmu, O., Bhangu, B. S., Dhaliwal, H. S., Lim, H., & Aremu, T. (2026). Global Pharmaceutical Regulation: Comparative Frameworks and Operations. *Pharmacy*, 14. https://doi.org/10.3390/pharmacy14020050
19. Wasiullah, P., Yadav, P., Vishwakarma, P., & Jaiswal, R. P. (2025). ICH Guideline for Pharmacovigilance: A Framework for Global Pharmacovigilance Practice. *International Journal of Pharmaceutical Research and Applications*. https://doi.org/10.35629/4494-100228082814