ISSN- 2230-7346
Journal of Global Trends in Pharmaceutical Sciences

# PHARMACOVIGILANCE IN INDIA, BHUTAN, AND SOUTH KOREA: A COMPARATIVE EVALUATION OF ADR REPORTING PERFORMANCE AND PHARMACOVIGILANCE SYSTEM MATURITY

**Basavaraj K Somapur*[1], Sai Harshini S R[2]**

[1] Department of Pharmacology, Shantha College of Pharmacy, India

[2] Department of Pharmacology, Rajiv Gandhi University of Health Sciences, India.

Corresponding author E- mail: basavarajksompur@gmail.com

**ARTICLE INFO**

**Key words:**

Pharmacovigilance; Adverse drug reaction reporting; India; Bhutan; South Korea; Comparative evaluation

Access this article online
Website: https://www.jgtps.com/
Quick Response Code:

**ABSTRACT**

**Background:** Pharmacovigilance is essential for detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other medicine-related problems. ADRs impose a substantial burden on morbidity, mortality, and healthcare systems, making effective pharmacovigilance necessary for public safety. **Objective:** To compare pharmacovigilance systems and ADR reporting performance in India, Bhutan, and South Korea using standardized system and reporting indicators. **Materials and Methods:** A cross-sectional comparative study was conducted using secondary data from national pharmacovigilance programme reports, regulatory authority publications, WHO pharmacovigilance resources, and peer-reviewed literature published primarily between 2010 and 2025 [14,18,24,37-43]. The comparison focused on system structure, reporting infrastructure, ADR reporting rates, data completeness, and operational challenges. As the study used publicly available aggregate data and published literature without human participants, ethical approval was not required. **Results:** South Korea showed the highest pharmacovigilance system maturity, with ADR reporting rates of about 420-540 reports per million population and high data completeness supported by advanced electronic reporting infrastructure. India demonstrated moderate performance, with approximately 110-130 reports per million population and expanding national coverage under the Pharmacovigilance Programme of India [20-22,37,38]. Bhutan showed limited reporting capacity, with approximately 60-100 reports per million population and continued dependence on paper-based systems. Under-reporting, limited awareness, technological constraints, and resource limitations were common across settings, though they were more pronounced in India and Bhutan [11-14,17]. **Conclusion:** Pharmacovigilance performance is strongly associated with regulatory capacity, digital infrastructure, stakeholder participation, and reporting culture. Strengthening reporting systems through technological integration, structured training, and improved regulatory support may improve ADR surveillance and medicine safety, especially in resource-limited settings.

## INTRODUCTION:

Pharmacovigilance, defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions and other medicine-related problems, is a core component of medicine safety surveillance. Although

medicines provide major therapeutic benefits, their use is associated with adverse effects that may only become evident after widespread exposure in real-world populations. Pre-marketing clinical trials are limited by sample size, duration, and patient selection, making post-marketing surveillance essential for identifying rare, delayed, or population-specific risks.

ADRs impose a significant public health burden through hospital admissions, prolonged hospital stay, morbidity, mortality, and economic cost. Effective pharmacovigilance systems provide a mechanism for collecting suspected ADR reports, detecting safety signals, and supporting regulatory action such as warnings, label changes, restricted use, or product withdrawal. The importance of pharmacovigilance has increased with expanding drug utilization, increasing complexity of treatment regimens, globalization of pharmaceutical markets, and growing use of biologics and specialized therapies.

The international pharmacovigilance framework is coordinated through the WHO Programme for International Drug Monitoring and supported by national pharmacovigilance centres that contribute individual case safety reports to Vigi Base. However, pharmacovigilance system performance varies widely between countries because of differences in healthcare infrastructure, regulatory maturity, digital systems, human resources, and reporting culture. High-performing systems typically have stronger legal frameworks, electronic reporting mechanisms, better stakeholder participation, and greater use of structured data for signal detection, whereas developing systems often face under-reporting, low awareness, and resource constraints [11-14,17].

India, Bhutan, and South Korea provide a useful comparison because they represent differing levels of pharmacovigilance development in Asia [20-24]. India has substantially expanded its Pharmacovigilance Programme of India (PvPI) and ADR Monitoring Centre network, but under-reporting and uneven system integration remain concerns [20-22,37,38] Bhutan operates a small and developing pharmacovigilance system with limited infrastructure and reporting volume. South Korea has a relatively mature system supported by advanced electronic reporting, structured governance, and broader stakeholder engagement [24,30-32,42,43,].

Comparative evaluation of these three countries can clarify how system design, infrastructure, and governance influence ADR reporting performance. It can also identify transferable practices and priority gaps for strengthening medication safety programmes in low- and middle-resource settings. The present study therefore aimed to compare pharmacovigilance system structure, ADR reporting performance, data completeness, and operational challenges in India, Bhutan, and South Korea using standardized indicators derived from secondary evidence.

## MATERIALS AND METHODS

This study used cross-sectional comparative design based on secondary data. The analysis synthesized information from official pharmacovigilance programme reports, national regulatory authority publications, WHO pharmacovigilance resources, international pharmacovigilance databases, and peer-reviewed literature relevant to India, Bhutan, and South Korea [20-24,37-46].The study focused on the contemporary development period of these systems, with priority given to documents and publications from 2010 to 2025 and use of recent programme statistics where available [35,37-44].

A structured comparative framework was used to evaluate three major domains:(1) pharmacovigilance system structure and organization, including legal framework, regulatory authority, reporting network, and reporting channels;(2) ADR reporting performance, including annual reporting volume, reporting rate per million population, reporter participation, and data completeness; and (3) operational challenges such as under-reporting, technological limitations, training gaps, and resource constraints.

For India, documents from the Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, and

Central Drugs Standard Control Organization were examined [20-22,37-39]. For Bhutan, relevant reports, guidelines, and policy documents from the Drug Regulatory Authority and Ministry of Health were considered. For South Korea, data were extracted from publications and reports of the Ministry of Food and Drug Safety and the Korea Institute of Drug Safety and Risk Management, together with related scientific literature [24,30-32,42-44]. Additional contextual evidence was drawn from WHO programme documents &international pharmacovigilance resources [1,8,9,45-48,54].

Data were extracted into predefined domains covering regulatory framework, institutional structure, reporting infrastructure, reporting modalities, annual ADR volume, reporting rate per million population, stakeholder participation, and report completeness. Information from different sources was triangulated where possible to improve consistency. Because the available data were heterogeneous across countries and not uniformly standardized, narrative synthesis was preferred over meta-analysis.

This study did not involve direct patient contact, interviews, identifiable personal data, or primary data collection. It was based entirely on publicly available aggregate information and published literature. Therefore, ethical approval was not required.

The main limitation of the method was dependence on publicly accessible reports and publications, which varied in detail and methodological transparency across countries. South Korea had the most comprehensive performance data, India had moderate availability, and Bhutan had relatively limited published information [40-43,54]. As a result, some comparisons were necessarily interpretive rather than purely quantitative.

## RESULTS

### Pharmacovigilance System Structure

Clear differences were observed in system maturity and organization across the three countries. South Korea demonstrated the most mature pharmacovigilance structure, supported by the Ministry of Food and Drug Safety and the Korea Institute of Drug Safety and Risk Management, with extensive use of electronic reporting systems and integrated safety databases [24,30-32,42-44]. India operated a broad national system under PvPI with more than 350 ADR Monitoring Centres and multiple reporting channels, including web-based and mobile options, reflecting substantial but still evolving system capacity [20-22,37-39]. Bhutan maintained a developing system under the Drug Regulatory Authority, with more limited institutional reach and continued reliance on paper-based reporting mechanisms.

### ADR Reporting Performance

ADR reporting rates differed markedly between countries. South Korea demonstrated the highest performance, with about 420-540 reports per million population annually, reflecting advanced reporting infrastructure and stronger stakeholder engagement. India showed moderate reporting performance at approximately 110-130 reports per million population annually following expansion of PvPI [20-22,37,38]. Bhutan reported approximately 60-100 reports per million population, indicating more limited reporting capacity. These differences suggest a strong association between system maturity and ADR reporting efficiency.

### Data Completeness and Reporter Participation

Data completeness was highest in South Korea, where electronic systems supported structured submission and validation of reports, with key data fields often exceeding 85-90% completeness. India demonstrated moderate completeness, especially for patient and drug information, but weaker completeness for concomitant medications and outcome details. Bhutan showed lower and less consistent completeness because manual systems limited standardized capture of report elements. Reporter participation also varied, with South Korea showing broader contribution from healthcare professionals, consumers, and industry, whereas India and Bhutan relied predominantly on pharmacists.

### Operational Challenges:

Under-reporting emerged as the most consistent challenge across all three settings [11-14]. India and Bhutan experienced greater

barriers related to lack of awareness, limited training, feedback deficits, infrastructure constraints, and insufficient digital integration. South Korea also faced under-reporting, but its higher reporting rates and stronger infrastructure suggested that these barriers were mitigated more effectively than in the other two countries.

**DISCUSSION:**

The findings indicate that pharmacovigilance system maturity is closely linked to ADR reporting performance. South Korea's stronger performance appears to reflect a combination of regulatory structure, digital reporting infrastructure, broader reporter participation, and better data management. India has made meaningful progress through expansion of PvPI and increasing national coverage, but its reporting performance remains moderate relative to more mature systems [20-22,37,38]. Bhutan's lower reporting rate and limited data infrastructure are consistent with an early-stage pharmacovigilance system facing practical and institutional constraints.

The results align with the broader understanding that electronic reporting systems and structured national coordination improve pharmacovigilance efficiency and report quality. Countries with integrated digital platforms are better positioned to capture complete ADR reports, promote timely reporting, and support early signal detection. In contrast, systems that rely on paper forms or fragmented reporting pathways are more vulnerable to missing data, lower participation, and delayed safety review.

A major strength of this study is its side-by-side comparison of three countries representing different levels of pharmacovigilance maturity within the same regional context. This allows practical interpretation of how infrastructure, governance, and stakeholder participation influence real-world performance. Another strength is the use of multiple evidence sources, including official reports and scientific literature, to build a broader comparative picture [37-46].

Several limitations should be acknowledged. First, the study relied on secondary sources with variable completeness and methodological detail, which may have affected the precision of quantitative comparisons. Second, publicly available data were uneven across countries, especially for Bhutan, limiting deeper benchmarking of indicators such as timeliness, seriousness distribution, and signal detection performance.

Third, the cross-sectional design captures performance over a defined period and cannot establish causal relationships between programme changes and reporting outcomes.

Despite these limitations, the study contributes useful evidence by highlighting practical factors associated with stronger pharmacovigilance systems.

The findings suggest that countries seeking to improve ADR reporting should prioritize digital reporting tools, workforce training, reporter feedback systems, and regulatory reinforcement. Such measures may be especially important in developing pharmacovigilance environments where under-reporting remains substantial.

**CONCLUSION:**

Pharmacovigilance systems in India, Bhutan, and South Korea differ substantially in maturity, reporting infrastructure, and ADR reporting performance [20-24,31,32,37-43]. South Korea demonstrated the strongest overall system performance, India showed moderate but improving performance, and Bhutan remained limited by infrastructure and resource constraints [20-24,31,32,37-43].

Strengthening regulatory support, expanding digital reporting, improving training, and promoting stakeholder participation are likely to improve pharmacovigilance effectiveness and medicine safety outcomes, particularly in resource-limited settings

The following list contains all references included in the manuscript, formatted as a unified, numbered list ready for placement at the end of your paper.

**REFERENCES**

1. World Health Organization (WHO). Pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems. Geneva: WHO; 2015.

2. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA. 1998;279:1200-1205.
3. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ. 2004;329:15-19.
4. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet. 2000;356:1255-1259.
5. U.S. Food and Drug Administration. Guidance for industry: good pharmacovigilance practices and pharmacoepidemiologic assessment. Silver Spring, MD: FDA; 2005.
6. World Health Organization. Pharmacovigilance strategy. Geneva: WHO; 2019.
7. Strom BL. Pharmacoepidemiology. 5th ed. Chichester: Wiley-Blackwell; 2012.
8. World Health Organization. WHO Programme for International Drug Monitoring. Geneva: WHO; 1968.
9. Uppsala Monitoring Centre. VigiBase: the WHO global database of individual case safety reports. Uppsala: UMC; 2026.
10. World Health Organization. Safety monitoring of medicinal products: guidelines for setting up and running a pharmacovigilance centre. Geneva: WHO; 2000.
11. Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29:385-396.
12. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2009;32:19-31.
13. Backstrom M, Mjorndal T, Dahlqvist R. Under-reporting of serious adverse drug reactions in Sweden. Eur J Clin Pharmacol. 2004;60:865-868.
14. Ampadu HH, Hoekman J, de Bruin ML, Pal SN, Olsson S, Sartori D, et al. Organizational capacities of national pharmacovigilance centres in Africa: assessment of resource elements associated with successful drug safety monitoring. Drug Saf. 2018;41:1115-1124.
15. European Medicines Agency. EudraVigilance and pharmacovigilance system report. Amsterdam: EMA; 2023.
16. U.S. Food and Drug Administration. Sentinel Initiative annual report. Silver Spring, MD: FDA; 2023.
17. Isah AO, Pal SN, Olsson S, Dodoo A, Bencheikh RS, Couper M, et al. Specific features of medicines safety and pharmacovigilance in Africa. Ther Adv Drug Saf. 2012;3:25-34.
18. World Health Organization. Pharmacovigilance strengthening report. Geneva: WHO; 2019.
19. Olsson S. The role of the WHO programme for international drug monitoring in coordinating worldwide drug safety efforts. WHO Drug Information. 2010;24:1-7.
20. Central Drugs Standard Control Organization. Pharmacovigilance Programme of India report. New Delhi: CDSCO; 2024.
21. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India annual report 2024. Ghaziabad: IPC; 2024.
22. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance Programme of India: recent developments and future perspectives. Indian J Pharmacol. 2016;48:624-628.
23. Drug Regulatory Authority of Bhutan. National pharmacovigilance programme report. Thimphu: DRA Bhutan; 2023.
24. Ministry of Food and Drug Safety. Korea pharmacovigilance system annual report. Cheongju: MFDS; 2024.
25. Edwards IR. The pharmacovigilance of tomorrow. Lancet. 2000;356:1518-1519.
26. World Health Organization. The WHO Programme for International Drug Monitoring. Geneva: WHO; 1968.
27. Evans SJW, Waller PC, Davis S. Use of proportional reporting ratios for signal generation from spontaneous adverse drug reaction reports. Pharmacoepidemiol Drug Saf. 2001;10:483-486.
28. U.S. Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) public dashboard report. Silver Spring, MD: FDA; 2024.
29. Gupta SK, Nayak RP, Vidyarthi SK. A questionnaire study on the knowledge,

attitude, and practice of pharmacovigilance among healthcare professionals in India. Perspect Clin Res. 2011;2:24-27.
30. Korea Institute of Drug Safety and Risk Management. National pharmacovigilance system overview. Seoul: KIDS; 2023.
31. Kim HJ, Kim Y, Lee E, Park BJ. Current status of pharmacovigilance in South Korea. Drug Saf. 2017;40:1087-1096.
32. Shin JY, Choi NK, Jung SY, Lee J, Kim YJ, Park BJ. Trends in adverse drug reaction reporting and pharmacovigilance activities in Korea. Pharmacoepidemiol Drug Saf. 2016;25:135-142.
33. World Health Organization. Bhutan pharmacovigilance profile. Geneva: WHO; 2022.
34. World Health Organization. Global pharmacovigilance development report. Geneva: WHO; 2019.
35. Strom BL, Kimmel SE, Hennessy S. Pharmacoepidemiology. 6th ed. Hoboken, NJ: Wiley-Blackwell; 2019.
36. Hartnell NR, Wilson JP. Replicability of pharmacovigilance signal detection using proportional reporting ratios. Pharmacoepidemiol Drug Saf. 2004;13:381-387.
37. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India national pharmacovigilance guidelines. Ghaziabad: IPC; 2023.
38. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India annual report. Ghaziabad: IPC; 2024.
39. Central Drugs Standard Control Organization. National pharmacovigilance programme operational framework. New Delhi: CDSCO; 2023.
40. Drug Regulatory Authority of Bhutan. National pharmacovigilance guidelines. Thimphu: DRA Bhutan; 2022.
41. Ministry of Health Bhutan. Bhutan pharmacovigilance programme report. Thimphu: Ministry of Health; 2023.
42. Ministry of Food and Drug Safety. Korea pharmacovigilance system annual report. Cheongju: MFDS; 2024.
43. Korea Institute of Drug Safety and Risk Management. National pharmacovigilance system operation manual and ADR reporting requirements. Cheongju: KIDS; 2023.
44. Ministry of Food and Drug Safety. Pharmaceutical safety information system and ADR reporting infrastructure report. Cheongju: MFDS; 2024.
45. Uppsala Monitoring Centre. VigiAccess database. Available from: https://www.vigiaccess.org.
46. Uppsala Monitoring Centre. WHO Programme for International Drug Monitoring membership and VigiBase statistics. Uppsala: UMC; 2024.
47. World Health Organization. Safety monitoring of medicinal products: guidelines for pharmacovigilance systems. Geneva: WHO; 2004.
48. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: WHO; 2002.
49. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6:e1000097.
50. World Health Organization. WHO global benchmarking tool for evaluation of national regulatory systems of medical products. Geneva: WHO; 2021.
51. Strengthening Pharmaceutical Systems Program. Indicator-based pharmacovigilance assessment tool: manual for conducting pharmacovigilance assessments. Arlington, VA: Management Sciences for Health; 2012.
52. Hauben M, Zhou X. Quantitative methods in pharmacovigilance: focus on signal detection. Drug Saf. 2003;26:159-186.
53. Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of interventions. Version 6.0. London: Cochrane Collaboration; 2019.
54. World Health Organization. Pharmacovigilance indicators: a practical manual for assessment of pharmacovigilance systems. Geneva: WHO; 2015.
55. U.S. Food and Drug Administration. Best practices in pharmacovigilance and signal detection. Silver Spring, MD: FDA; 2018.