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**Original Research Article**

# Assessment and comparison of adverse drug reactions reporting by USFDA and CDSCO: an audit

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## ABSTRACT

**Background:** Drug safety is a critical component not only during the development of pharmaceutical products but also throughout their post-marketing lifecycle. Pharmacovigilance systems play a vital role in monitoring and evaluating adverse drug reactions (ADRs), with many national programs contributing data to the World Health Organization's Pharmacovigilance Programme headquartered in Uppsala, Sweden.
**Methods:** The present study aimed to assess and compare ADR reports submitted by various stakeholders in the United States and India. Publicly available pharmacovigilance data from both countries were systematically reviewed and analysed, excluding information related to dyes, medical devices, and blood-related products.
**Results:** The comparison indicated that the United States Food and Drug Administration (USFDA) receive a substantially higher number of ADR reports compared to India. However, the number of safety alerts issued over the past four years appears to be relatively consistent between the two countries. Antibacterial agents and drugs acting on the endocrine system were among the most frequently reported therapeutic categories.
**Conclusions:** This study highlights differences in reporting trends and underscores the need for strengthening ADR reporting mechanisms to enhance drug safety monitoring.

**Keywords:** Safety communications, Alerts, PVPI, USFDA

## INTRODUCTION

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.[1] Drug safety alerts play a critical role for multiple stakeholders across the healthcare continuum. For clinicians, they provide timely guidance on risk mitigation, patient monitoring, and therapeutic decision-making. For patients, alerts promote transparency, informed decision, and awareness about the adverse effects. Manufacturers rely on safety alerts to guide post-marketing studies, risk management plans, and regulatory compliance. Regulatory authorities use alerts to protect public health while maintaining access to essential medicines. Pharmacists, nurses, pharmacovigilance professionals, and hospital administrators act as intermediaries, ensuring dissemination and implementation of risk-minimization strategies. It is a vital component of ensuring the safe and effective use of medications, relying on strong systems to monitor and manage drug-related risks. The United States, through its

comprehensive regulatory framework and well-developed reporting infrastructure, plays a leading role in global pharmacovigilance. The U.S. Food and Drug Administration (FDA) actively monitors drug safety and regularly issues timely safety communications to healthcare professionals and the public.[2] In contrast, India, with its vast and diverse healthcare environment, continues to face obstacles in establishing an equally effective pharmacovigilance system although it has quickly picked up from 2010 with few centres to more than thousand centres across the country.[3] The Central Drugs Standard Control Organization (CDSCO), India's national regulatory authority, has taken steps to strengthen its pharmacovigilance initiatives through Pharmacovigilance Program of India (PVPI), but challenges persist.[4]

In light of this, it is interesting to examine drug safety alerts with respect to their frequency, the drug classes involved, the physiological systems affected, and the regulatory actions taken. Such insights can support evidence-based policymaking and help target interventions aimed at reducing drug-related harm. United States has its stringent regulatory grip, while India is taking a leap towards it, we chose to assess these two country's pharmacovigilance programs. This study aimed to assess and analyse drug safety communications issued by the USFDA and CDSCO. By comparing the number, and nature of these communications including the implicated drug classes, affected organ systems, and the regulatory responses.

## METHODS

This study was exempted from review by the Institutional Ethics Committee of Seth GS Medical College and KEM Hospital, Mumbai (EC/OA-156/2022), as it involved analysis of publicly available electronic data. This was a retrospective audit which included all drug safety communications issued by the U.S. Food and Drug (USFDA) and those published by the Drugs Controller General of India (DCGI) on the CDSCO/PVPI website between 2010 and 2024. Communications related to medical devices, dyes, and medication errors were excluded from the analysis.

Drug safety communications were manually searched and downloaded from the official FDA and CDSCO websites.[2,3] Annual performance reports from the Pharmacovigilance Programme of India (PvPI) were also retrieved, and data were entered into a structured spreadsheet.[5] All efforts were made to ensure accuracy and prevent duplication. Additionally, the FDA Adverse Event Reporting System (FAERS) data was also used in this study. The data extraction was done for a period from 2010 to 2024. The following variables were recorded for each safety communication:

Year of publication, drug class involved, affected organ system, regulatory action taken.

Following were the outcome Measures:

Trends of reports received, trends of alerts issued, most frequently reported adverse drug reactions (ADRs), Most commonly implicated drugs, most commonly affected organ systems.

### *Statistical analysis*

A descriptive analysis was conducted. Results were summarized using frequencies, percentages, and ratios where applicable. Software used was MS Excel.

## RESULTS

A total number of 24213335 reports were received by USFDA and a peak was reached during 2022 with 2338092 reports while minimum number of reports during 2010 (Figure 1A). In India total reports received by PvPI were 704562. The maximum reports were received in 2023 with 120289 reports and minimum in the year 2017 with 14491 (Figure 1B).

Total number of safety communications issued by the USFDA were 279. The number of safety communications issued by USFDA to go on reducing in number until 2024. The peak was in 2011 with 62 communications and the lowest of only three communications being issued in 2023 (Figure 2A). A total of 165 alerts were issued by CDSCO. The highest was 37 during 2017 and lowest was six in 2018 (Figure 2B).

The most common broad classes of drugs responsible for the safety communications of USFDA were anti-diabetic/ endocrine drugs (44), antibacterials (19), gastrointestinal/ emetics (15), anti-inflammatory/gout/RA drugs (15), followed by anticancer drugs (12) and drugs acting on the central nervous system (CNS) (13) (Figure 3A).

**Table 1: Distribution of ADRS in PVPI as per gender.**

| Gender | Mean±SD | Median distribution |
|---|---|---|
| **Male** | 50.7±0.8 | 51 |
| **Females** | 46.7±1.6 | 47 |
| **Unknown** | 2.6±1.7 | 2.8 |

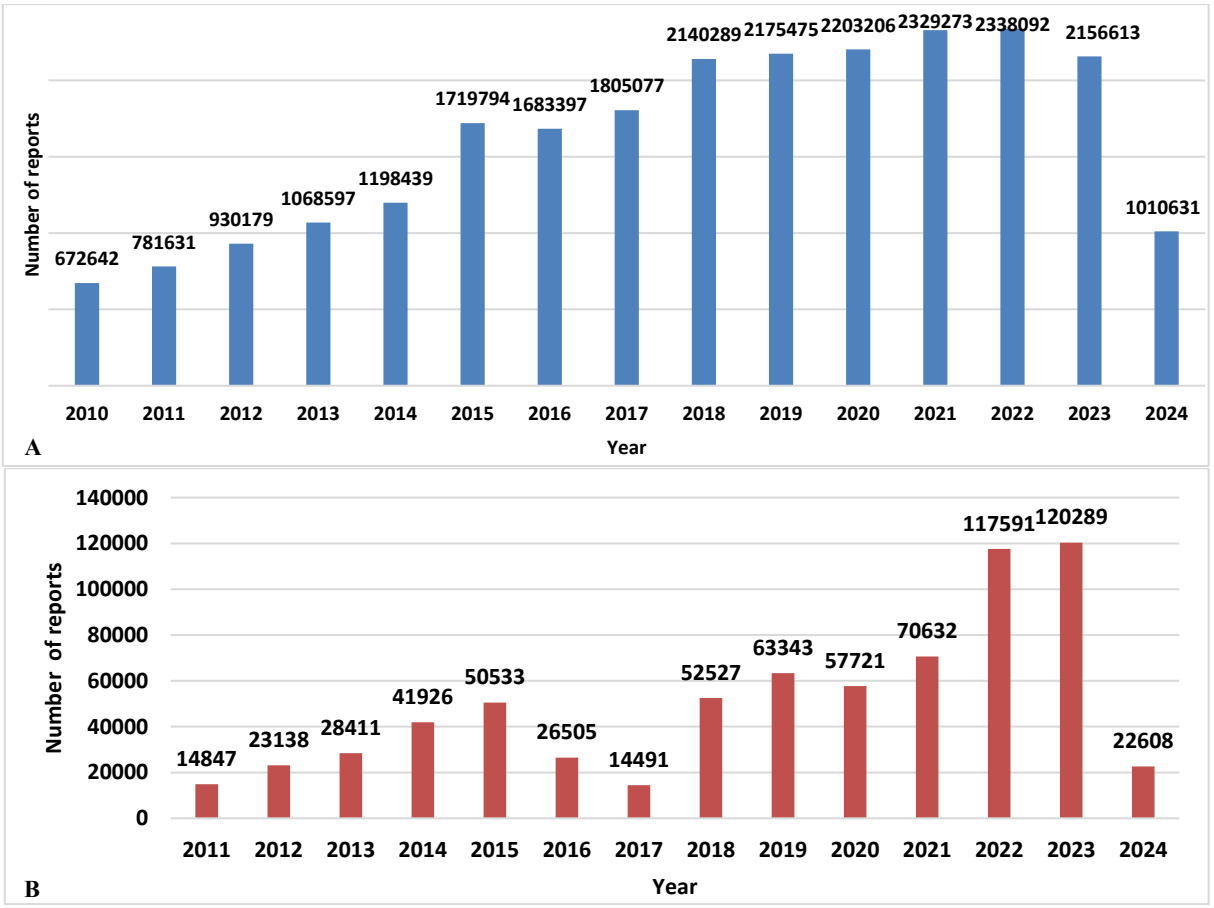


**Figure 1: (A) year wise distribution of fears received by USFDA and (B) year wise trend of ADRS received by CDSCO.**

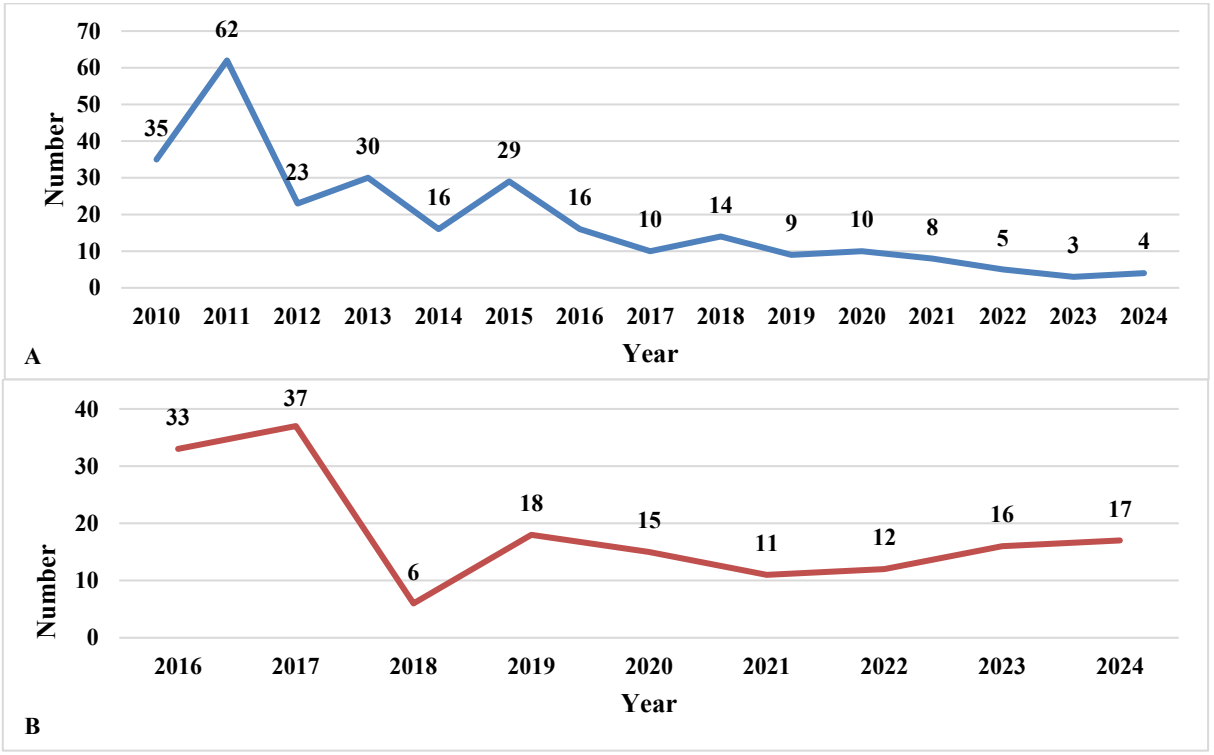


**Figure 2: (A) year wise trend drug safety communications issued by USFDA (n=279) and (B) year wise trend of drug safety alerts issued by CDSCO (n=165).**

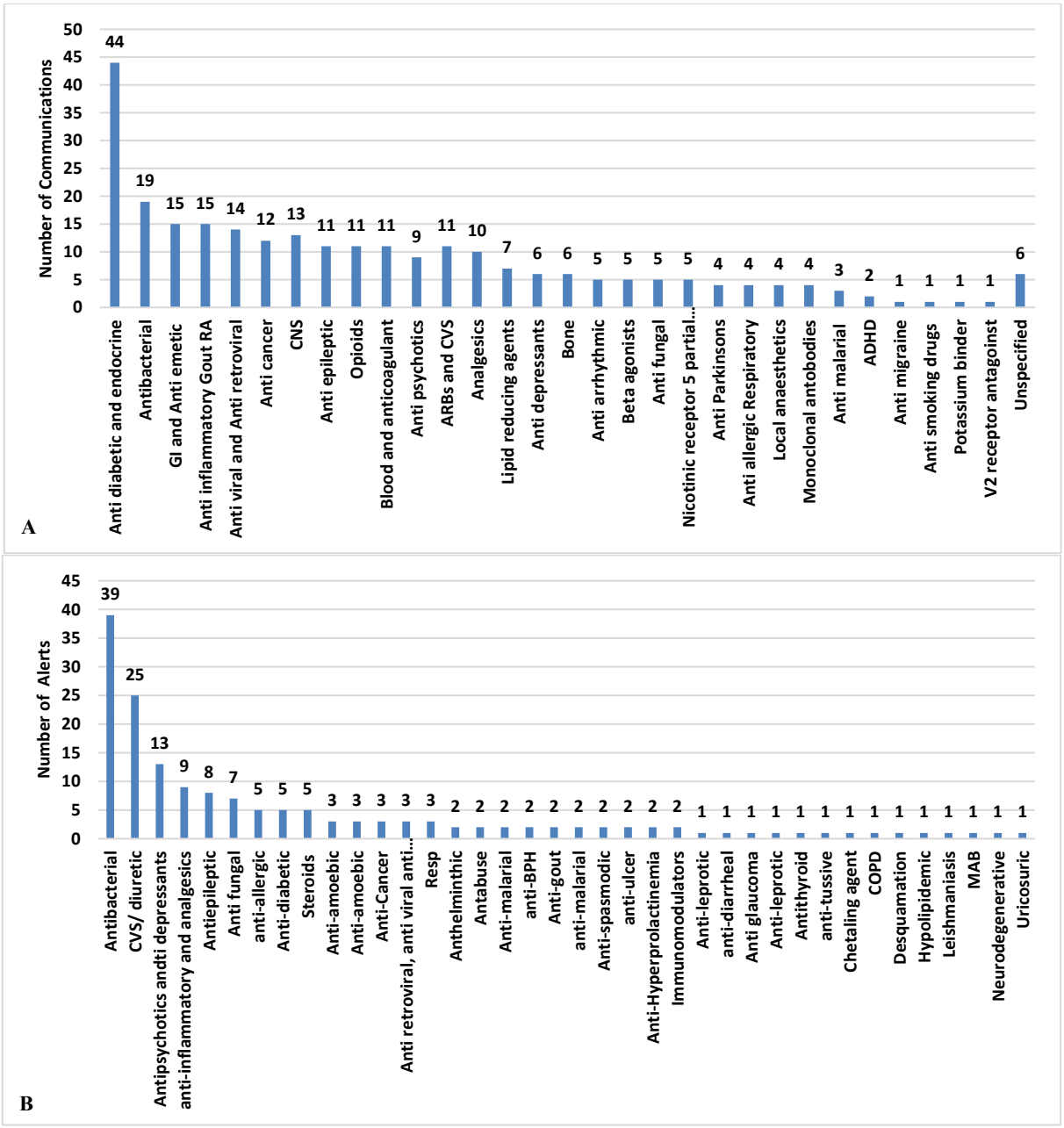


**Figure 3: (A) broad drug classes for which the alerts were issued by USFDA (n=279) and (B) drug classes for which the alerts were issued by CDSCO (n=165).**

**Table 2: Distribution of ADRS as per age in PVPI.**

| Sr. no. | Age | Mean±SD | Median distribution |
|---|---|---|---|
| **1** | 0- 27days | 0.7±1.3 | 0.2 |
| **2** | 28 days - 23 months | 1.4±0.4 | 1.4 |
| **3** | 2-11 years | 3.2±0.9 | 3.2 |
| **4** | 12-17 years | 2.7±0.5 | 2.8 |
| **5** | 18-44 years | 41±5.6 | 39.4 |
| **6** | 45-64 years | 33.6±5.2 | 32 |
| **7** | 65-74 years | 9.5±2 | 9.7 |
| **8** | >75 years | 4.1±1 | 3.5 |
| **9** | Unknown | 9.2±1.8 | 9.8 |

*Note: Data for serial numbers from 1 was missing for the year 2020-21, from 2to 7 was missing from 2014-18 and 8-9 was missing from 2014-19.

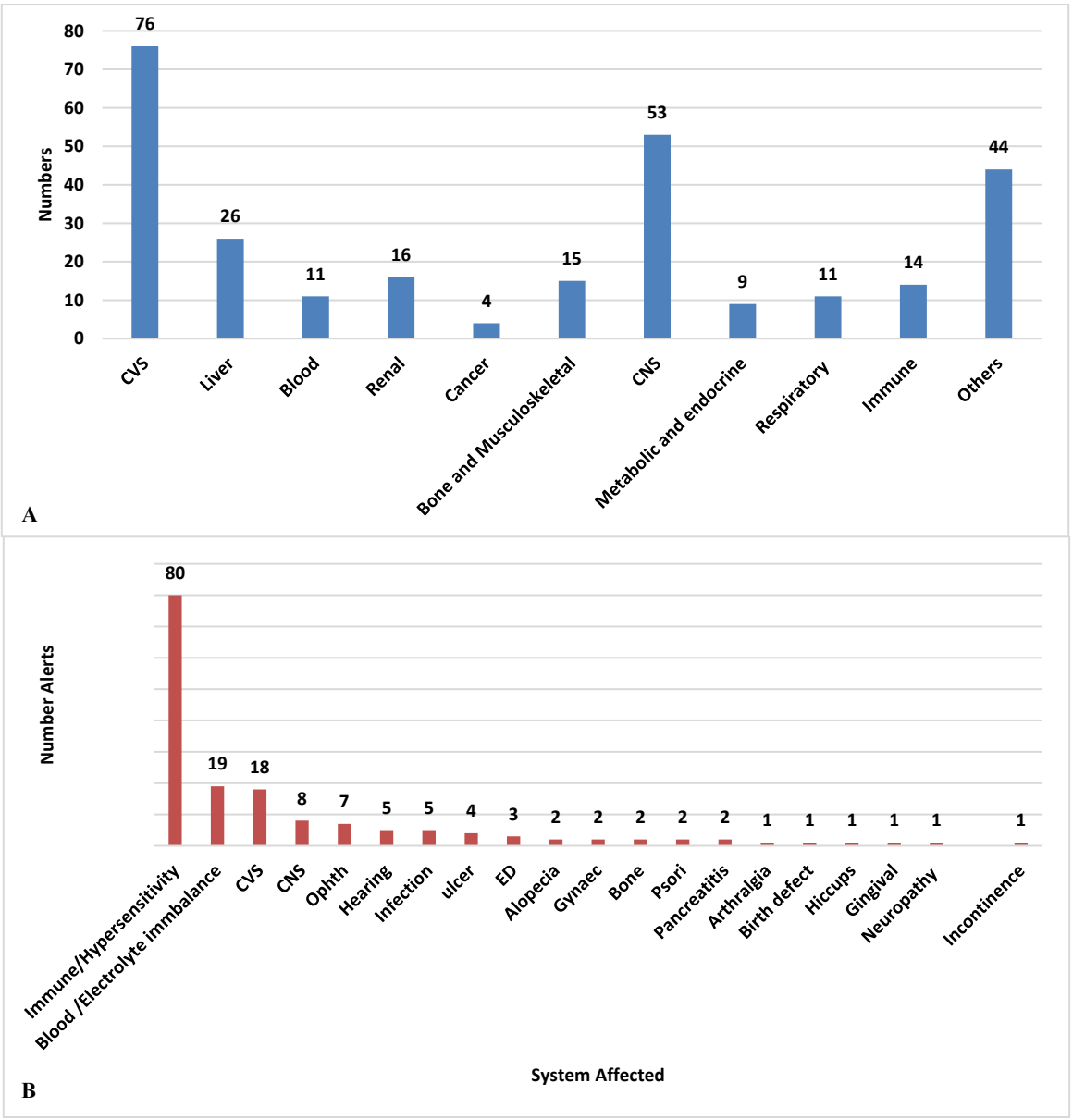


**Figure 4: (A) distribution of affected organ systems affected in USFDA alerts (n=279) and (B) distribution of affected systems affected in CDSCO alerts (n=165).**

**Table 3: Distribution of reporter qualification in PVPI for ADRS.**

| Sr. no. | Reporter qualification | Mean±SD | Median distribution |
|---|---|---|---|
| **1** | Physician | 49.2±8.3 | 50.2 |
| **2** | Pharmacist | 19.9±17 | 15.6 |
| **3** | Other health professionals | 22.9±7.5 | 19.8 |
| **4** | Consumer/ non-health professionals | 17.1±9.8 | 14.4 |
| **5** | Unknown | 0.6±0.4 | 0.4 |

**Table 4: Distribution of ADRS in PVPI based on presence of seriousness.**

| Sr. no. | Seriousness | Mean±SD | Median distribution |
|---|---|---|---|
| **1** | Yes | 25.6±4.1 | 27 |
| **2** | No | 74.3±4.1 | 73 |

*Note: Data from 2014-18 and 2017-18 was missing.

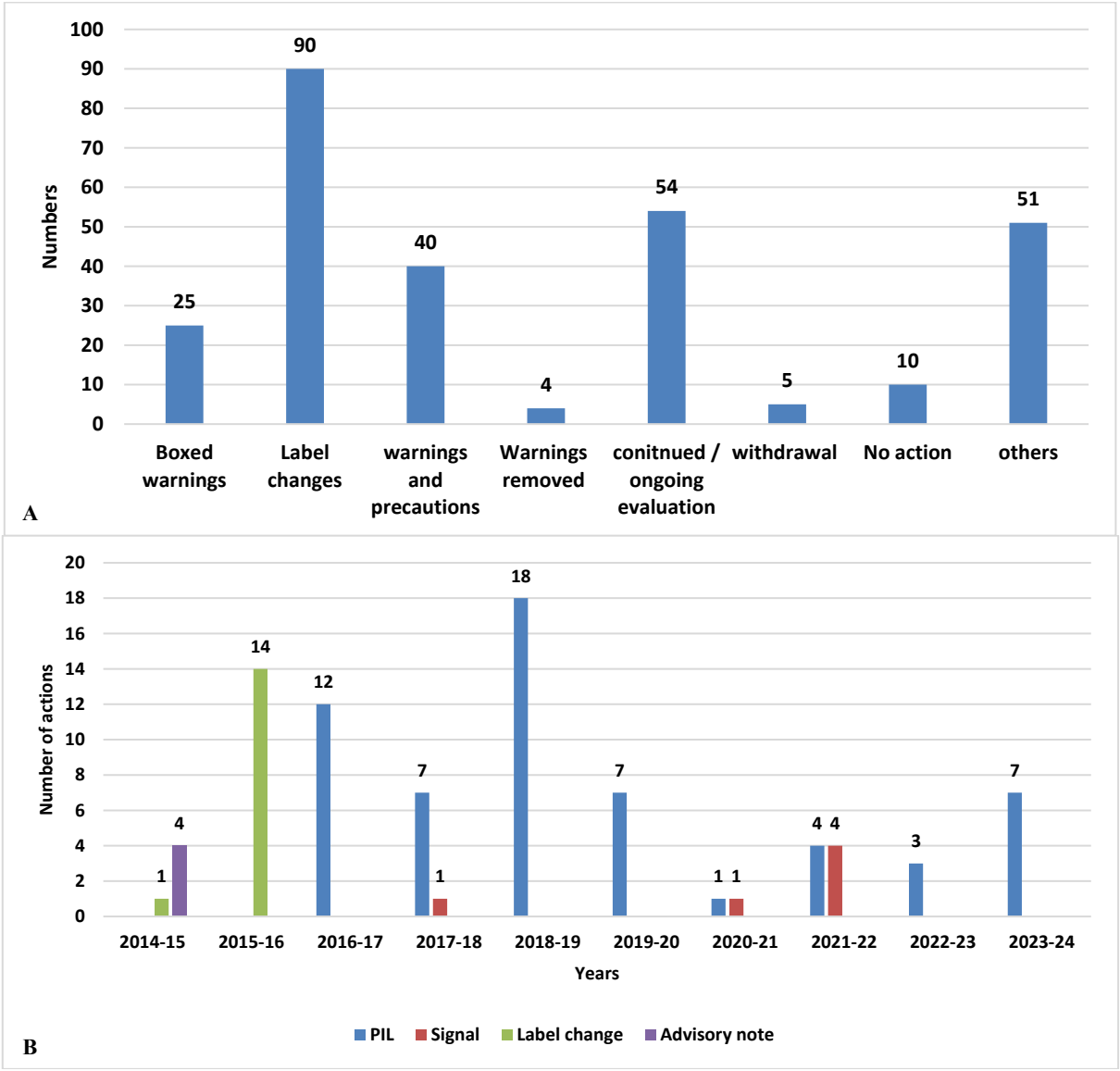


**Figure 5: (A) distribution of actions by USFDA (n=279) and (B) distribution of actions by CDSCO (n=84).**

**Table 5: Distribution of ADRS in PVPI based on seriousness criteria.**

| Sr. no. | Seriousness criteria | Mean±SD | Median distribution |
|---|---|---|---|
| **1** | Prolonged hospitalization | 10.84±2.1 | 10.8 |
| **2** | Death | 4.9±1.36 | 4.5 |
| **3** | Life threatening | 1.52±1.7 | 2.4 |
| **4** | Disabling/incapacitating | 0.23±0.05 | 0.2 |
| **5** | Congenital anomaly/birth defect | 0.03±0.04 | 0.001 |

*Note: Data from 2014 to 2019 (5 years) was missing.

Antibacterials were the most common class for which safety alerts (39) were issued followed by drugs acting on Cardiovascular System (CVS) (25) and antipsychotic/ antidepressants (13) in India by CDSCO (Figure 3B). The most common organ system affected was reported as CVS (76) followed by CNS (53) and Liver (26) by USFDA (Figure 4A). The most common affected system was immune/hypersensitivity type reactions (80), followed by blood/electrolytes (19) and CVS (18) in the CDSCO reports (Figure 4B). The most common action reported by USFDA was Label change (90) followed by continued evaluations (54) and issue of warnings (40) (Figure5A). CDSCO reported Prescription Information Leaflet changes (59) followed by Label change (15). The

year wise distribution is given in Figure 5BUSFDA communication alerts were based on FAERs (35%), Clinical trials/studies (31%) followed by Observational Studies (24%) (Figure 6). Additional analysis of information provided by CDSCO is provided in Tables 1 to 5.

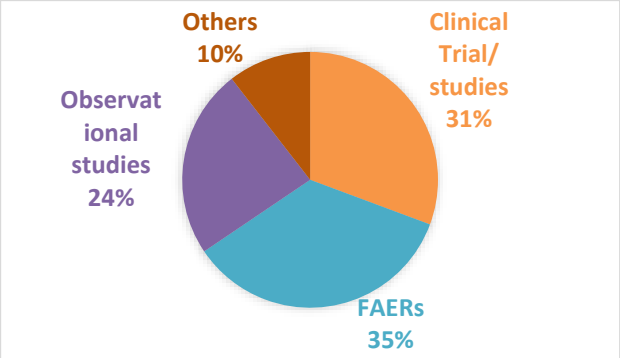


**Figure 6: Additional information provided by USFDA about sources of data (n=279).**

## DISCUSSION

This retrospective audit provides a comprehensive assessment of adverse drug reaction (ADR) reporting and drug safety alert patterns of India's Central Drugs Standard Control Organization (CDSCO) and United States Food and Drug Administration's (USFDA) and over a period of 15 years from 2010 to 2024. The findings reveal substantial quantitative and qualitative differences in reporting volume, drug classes implicated, organ systems affected, and regulatory responses, reflecting broader contrasts in healthcare delivery, drug utilization, and pharmacovigilance system maturity between the two countries. One of the most striking observations of this study is the vast disparity in the volume of ADR reports received by the two regulatory authorities. During the study period, the USFDA received a total of 24,213,335 reports, with a peak of 2,338,092 reports in 2022, whereas India's Pharmacovigilance Programme of India (PVPI) received 704,562 reports, with the highest annual count of 120,289 reports in 2023.

This is despite India having a population nearly four times larger than that of the United States, ADR reporting remains disproportionately higher in the U.S. This discrepancy cannot be explained by population size alone and instead it probably reflects differences in per-capita drug consumption, access to healthcare, reporting mandates, and pharmacovigilance infrastructure, although these have not been evaluated in the present study.[6] The United States has higher prescription drug utilization, widespread long-term therapy for chronic diseases, and extensive use of newer pharmacological agents, including biologics and specialty medicines.[7,8] These factors increase cumulative drug exposure and the probability of identifying adverse events in real-world settings. Furthermore, ADR reporting by pharmaceutical manufacturers to the USFDA is mandatory, contributing substantially to the volume of reports in the FDA Adverse Event Reporting System (FAERS). In contrast, ADR reporting in India is largely voluntary for healthcare professionals, and underreporting remains a recognized challenge due to high patient loads, limited awareness, and lack of integration of reporting into routine clinical workflows.[9] Pharmaceutical industry does report ADRs in India which is in accordance with CDSCO rules, however the data for most years was unavailable. Nevertheless, the upward trend in PVPI reports in recent years indicates improving awareness and participation of important stakeholders.

Interestingly, while ADR reports increased over time, the number of safety communications issued by the USFDA showed a declining trend. A total of 279 safety communications were issued by the USFDA during the study period, with a peak of 62 alerts in 2011 and only three alerts in 2023. In contrast, CDSCO issued 165 safety alerts, with the highest number of 37 alerts in 2017. This divergence suggests that a higher volume of ADR reports does not necessarily translate into a proportional increase in safety alerts. Rather, it reflects differences in signal prioritization, analytical capacity, and regulatory thresholds.[5] The USFDA's system allows aggregation and filtering of large datasets to identify clinically meaningful signals, whereas CDSCO's evolving system may rely on more direct translation of identified concerns into regulatory communications. Distinct differences were also observed in the drug classes responsible for safety alerts. In the United States, anti-diabetic and endocrine drugs were the most frequently implicated class (44 alerts), followed by antibacterials (19), gastrointestinal agents and emetics (15), anti-inflammatory/gout/RA drugs (15), CNS-acting drugs (13), and anticancer agents (12). This distribution reflects the epidemiological profile of the U.S. population, characterized by a high prevalence of diabetes, obesity, cardiovascular disease, and cancer, all of which require prolonged pharmacotherapy.

In contrast, CDSCO safety alerts most commonly involved antibacterials (39 alerts), followed by cardiovascular drugs (25) and antipsychotic/ antidepressant medications (13). The predominance of antibacterials in India likely reflects their widespread use across community and hospital settings, frequent empirical prescribing, and over-the-counter availability. These practices increase the risk of adverse reactions such as hypersensitivity, haematological abnormalities, and electrolyte disturbances, which are more readily identified in acute care settings. The involvement of cardiovascular drugs corresponds with India's growing burden of hypertension and ischemic heart disease, while alerts related to psychotropic medications may indicate increasing recognition and treatment of mental health disorders.

Analysis of affected organ systems further highlights contextual differences between the two countries. In USFDA alerts, the cardiovascular system (76 alerts) was most frequently affected, followed by the central nervous system (53) and liver (26). Cardiovascular adverse events often have serious or life-threatening consequences, making them more likely to prompt regulatory action. CNS and hepatic involvement may reflect cumulative toxicity, drug–drug interactions, and metabolism-related adverse effects associated with long-term therapy.

In contrast, CDSCO alerts predominantly involved immune-mediated and hypersensitivity reactions (80 alerts), followed by blood and electrolyte disorders (19) and cardiovascular system involvement (18). Hypersensitivity reactions are often acute, clinically evident, and more likely to be reported, particularly in hospital settings. The prominence of haematological and electrolyte abnormalities suggests that ADRs detected in India may be skewed toward those identified during inpatient care, where laboratory monitoring is more accessible.

Differences were also observed in regulatory actions taken by the two authorities. The USFDA most commonly implemented label changes (90 alerts), followed by continued evaluations (54) and issuance of warnings (40). This graduated, risk-based approach reflects a regulatory framework that emphasizes ongoing benefit–risk assessment rather than immediate restrictive action. CDSCO, on the other hand, most frequently issued Prescription Information Leaflet (PIL) changes (59), followed by label changes (15), highlighting a strategy focused on improving awareness among prescribers and patients. While PVPI data had additional elements like age, gender and seriousness, a lot of this data was missing or not available as numbers or percentages (only provided in the graphs). A positive angle could be that majority ADRs were not serious. Missing data raises questions on the quality of reporting.

Finally, the observed differences are rooted in the contrasting pharmacovigilance systems of the two countries. The U.S. system benefits from mandatory reporting, advanced analytics, and integration with electronic health records, enabling efficient signal detection and response. India's system, coordinated through PVPI, has expanded significantly since 2010 but continues to face challenges related to underreporting and infrastructure.[10,11] The steady increase in ADR submissions and safety alerts, however, reflects an ongoing progress.

The limitations of this study is missing data and for PVPI there was less uniformity in presenting the data. This led us to include the data that was available in numbers and percentages (data presented in graphs without values /percentages was considered missing). The sources of ICSRs data were available only for the year 2025-16, hence was not analysed.

## CONCLUSION

To conclude, this study assesses and highlights differences in ADR reporting and drug safety alerts of India and United states. PVPI needs to improve the quality of data.

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*Conflict of interest: None declared*
*Ethical approval: The study was approved by the Institutional Ethics Committee of Seth GS Medical College and KEM Hospital, Mumbai, India (EC/OA-156/2022)*

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