INTERNATIONAL JOURNAL OF
Clinical and Pharmaceutical Innovations
An International Peer Reviewed Open Access Journal

Review Article

ISSN (Online): 3142-8665
CODEN (USA): IJCPSM

2026, Volume 1, Issue 8, Page No: 28-41.

CHALLENGES IN SAFETY REPORTING PHARMACEUTICAL COMPANIES STANDPOINT IN DRUG SAFETY

Dr. K. Govindarao[1]*, Gompa Gayathri[2]

Professor and Vice Principal, Department of Pharmaceutical Chemistry, Koringa College of Pharmacy, Korangi, Tallarevu, Kakinada, Andhra Pradesh Pin: 533461.

Article Info: **Received:** 12 September 2026, **Revised:** 02 October 2026, **Accepted:** 22 October 2026

***Corresponding Author: Dr. K. Govindarao**

Professor and Vice Principal, Department of Pharmaceutical Chemistry, Koringa College of Pharmacy, Korangi, Tallarevu, Kakinada, Andhra Pradesh Pin: 533461.

DOI: https://doi.org/10.5281/zenodo.23850272

Citation:
Dr. K. Govindarao[1]*, Gompa Gayathri[2]. (2026). Challenges In Safety Reporting Pharmaceutical Companies Standpoint In Drug Safety. International Journal of Clinical and Pharmaceutical Innovations, 1(8), 28-41.

ABSTRACT
Pharmacovigilance plays an essential role in protecting patients by identifying, evaluating, understanding, and preventing adverse effects associated with medicines. Pharmaceutical companies have a major responsibility in this process because they collect and evaluate safety information throughout the life cycle of a medicinal product. Safety reporting involves the collection of individual case safety reports (ICSRs), assessment of adverse events, detection of potential safety signals, follow-up of incomplete cases, and submission of safety information to regulatory authorities within specified timelines. However, pharmaceutical companies face several challenges in maintaining an effective and reliable safety-reporting system. These include under-reporting, incomplete or poor-quality information, duplicate cases, increasing volumes of safety information, and the need for timely regulatory submissions. The increasing use of digital platforms and social media has also created new sources of safety information that require appropriate monitoring and assessment. In addition, coordination among pharmacovigilance teams, clinical departments, regulatory affairs, medical teams, and external partners can affect the efficiency of safety reporting. Technological developments such as automation, artificial intelligence, natural language processing, and advanced data-management systems may help companies manage these challenges more efficiently. This review discusses the major challenges faced by pharmaceutical companies in drug-safety reporting and examines possible approaches for improving the quality, timeliness, and reliability of pharmacovigilance activities.

KEYWORDS: Pharmacovigilance, safety reporting, pharmaceutical companies, adverse drug reactions, ICSR, drug safety, signal detection, regulatory compliance.

INTRODUCTION

Medicines provide significant benefits to patients, but their use can also be associated with unwanted or unexpected effects. Some adverse effects may only become apparent after a medicine is used by a large and diverse population. Therefore, continuous monitoring of the safety profile of medicines is an important part of healthcare.

Pharmacovigilance is the discipline concerned with detecting, assessing, understanding, and preventing adverse effects and other medicine-related problems. Pharmaceutical companies are important participants in

this system because their responsibility for drug safety continues from the development stage through clinical use and, in many cases, for the entire marketed life of the product.[1]

Safety reporting is one of the fundamental activities within pharmacovigilance. Companies receive safety information from healthcare professionals, patients, clinical studies, literature, regulatory authorities, patient-support programmes, and other sources. This information must be reviewed and assessed to determine whether it represents a valid safety case and whether further action or regulatory reporting is required.

However, converting large amounts of real-world safety information into accurate and timely reports is challenging. Reports may contain missing patient information, unclear descriptions of events, incomplete medical histories, or insufficient details about the Introduction.[2]

Medicines provide significant benefits to patients, but their use can also be associated with unwanted or unexpected effects. Some adverse effects may only become apparent after a medicine is used by a large and diverse population. Therefore, continuous monitoring of the safety profile of medicines is an important part of healthcare.[3]

Pharmacovigilance is the discipline concerned with detecting, assessing, understanding, and preventing adverse effects and other medicine-related problems. Pharmaceutical companies are important participants in this system because their responsibility for drug safety continues from the development stage through clinical use and, in many cases, for the entire marketed life of the product.

Safety reporting is one of the fundamental activities within pharmacovigilance. Companies receive safety information from healthcare professionals, patients, clinical studies, literature, regulatory authorities, patient-support programmes, and other sources. This information must be reviewed and assessed to determine whether it represents a valid safety case and whether further action or regulatory reporting is required.

However, converting large amounts of real-world safety information into accurate and timely reports is challenging. Reports may contain missing patient information, unclear descriptions of events, incomplete medical histories, or insufficient details about the suspected medicine. Companies may also receive the same case through multiple sources, creating the possibility of duplicate reports. These issues can affect the quality of safety databases and make case processing more complex.[4]

Another important challenge is the variation in pharmacovigilance requirements across different regulatory jurisdictions. Pharmaceutical companies operating internationally may need to manage different reporting timelines, formats, definitions, and submission procedures. Maintaining compliance while processing a continuously increasing volume of safety information requires trained personnel, well-designed procedures, appropriate technology, and effective quality-control systems.[5]

The development of digital communication has further expanded the sources from which safety information can be obtained. Online patient communities, websites, social media, and other digital platforms can contain valuable information about patients' experiences with medicines. At the same time, identifying relevant safety information from these sources and determining whether it meets reporting requirements can be difficult.

Therefore, pharmaceutical companies need to balance timeliness, accuracy, data quality, regulatory compliance, and efficient use of resources. Understanding these challenges is important for improving safety-reporting practices and ultimately strengthening patient protection.suspected medicine. Companies may also receive the same case through multiple sources, creating the possibility of duplicate reports. These issues can affect the quality of safety databases and make case processing more complex.[6]

Another important challenge is the variation in pharmacovigilance requirements across different regulatory jurisdictions. Pharmaceutical companies operating internationally may need to manage different reporting timelines, formats, definitions, and submission procedures. Maintaining compliance while processing a continuously increasing volume of safety information requires trained personnel, well-designed procedures, appropriate technology, and effective quality-control systems.

The development of digital communication has further expanded the sources from which safety information can be obtained. Online patient communities, websites, social media, and other digital platforms can contain valuable information about patients' experiences with medicines. At the same time, identifying relevant safety information from these sources and determining whether it meets reporting requirements can be difficult.[7]

2. Role of pharmaceutical industries in Pharmacovigilance

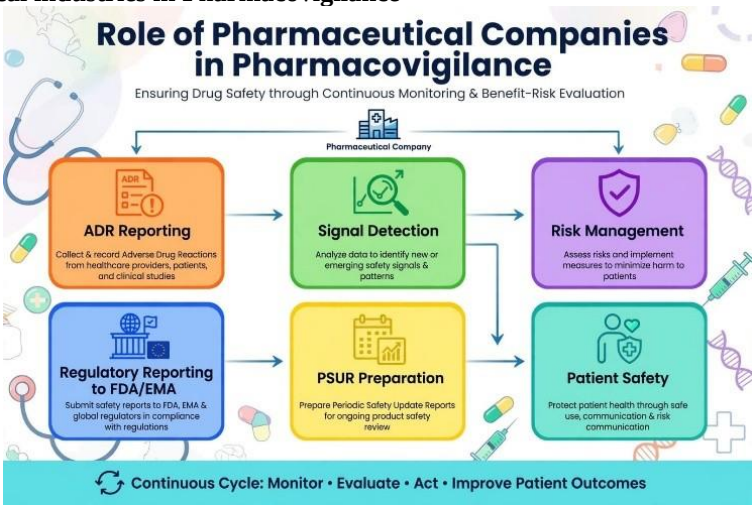

Figure 1: Role of Pharmaceutical industries in Pharmacovigilance and Drug Safety Management.

Pharmaceutical companies have a central role in ensuring the safety of medicines throughout their development and after they are introduced into the market. Their responsibility does not end with obtaining marketing approval. Companies are expected to continuously monitor the safety profile of their products and take appropriate action when new safety information becomes available.[8]

One of the major responsibilities of pharmaceutical companies is the collection of safety information. Reports may come from healthcare professionals, patients, clinical trials, medical literature, regulatory authorities, patient-support programmes, and other sources. The collected information is reviewed by pharmacovigilance professionals to determine whether it represents a reportable adverse event or adverse drug reaction.

Another important responsibility is the processing and assessment of Individual Case Safety Reports (ICSRs). When a valid safety case is identified, relevant information about the patient, suspected medicinal product, adverse event, medical history, and other available details is entered into the company's safety database. The case may then undergo medical review and assessment according to established procedures.[9]

Pharmaceutical companies also perform follow-up activities when important information is missing from an initial report. For example, additional information may be requested regarding the patient's medical history, laboratory results, treatment details, or outcome. Effective follow-up can improve the quality and completeness of a safety report.[10]

3. Safety Reporting Process in Pharmaceutical Companies

Safety reporting is a continuous process through which pharmaceutical companies collect, evaluate, document, and communicate information about possible adverse effects associated with medicines. The process begins when safety information is received from a particular source and continues until the case is assessed, reported when required, and followed up appropriately. A well-organized reporting process is important because the quality of safety information can directly influence the assessment of a medicine's benefit-risk profile.[11]

3.1 Collection of Safety Information

The first step in safety reporting is the collection of information about suspected adverse events. Pharmaceutical companies can receive safety information from many different sources, including healthcare professionals, patients, clinical trials, medical literature, regulatory authorities, patient-support programmes, and business partners.

The information received may vary considerably in its level of detail. Some reports may contain complete information about the patient, suspected medicine, adverse event, treatment history, and outcome, whereas others may contain only limited details. Therefore, companies need established procedures for receiving, documenting, and reviewing safety information from different sources.[12]

3.2 Case Identification and Validation

After receiving a report, pharmacovigilance personnel determine whether the information represents a valid safety case. Basic information such as an identifiable patient, an identifiable reporter, a suspected medicinal product, and a suspected adverse event is generally required for an individual case to be considered reportable.

This step is important because not every piece of safety information received by a company will meet the criteria for an individual case safety report. Careful validation helps prevent inappropriate cases from entering the safety database while ensuring that potentially important reports are not overlooked.[13]

3.3 Data Entry and Case Processing

Once a case has been validated, the available information is entered into the company's pharmacovigilance safety database. Important details may include patient characteristics, medical history, suspected and concomitant medicines, description of the event, dates, investigations, treatment provided, and patient outcome.

The information should be entered accurately because errors or omissions at this stage can affect later medical assessment and regulatory reporting. Pharmacovigilance professionals may also review the case for inconsistencies or missing information.[14]

3.4 Medical Assessment

Medical assessment helps determine the clinical significance of the reported event. Qualified personnel review the available information and consider factors such as the patient's medical history, timing of medicine exposure, clinical course, alternative explanations, and available medical evidence.

In appropriate situations, causality assessment may be performed to evaluate the relationship between the suspected medicine and the reported event. However, the presence of an adverse event in a safety report does not by itself prove that the medicine caused the event.[15]

3.5 Regulatory Reporting

When a case meets applicable reporting criteria, the pharmaceutical company submits the required safety information to the relevant regulatory authority within the applicable reporting timeline. The format, timeline, and requirements can vary depending on the jurisdiction and type of safety information.

Timely reporting is a major responsibility of pharmaceutical companies. Delays or inaccurate submissions can create regulatory compliance concerns and may reduce the efficiency of the overall pharmacovigilance system.[16]

4. Major Challenges in Safety Reporting



Figure 2: Major Challenges in Safety Reporting in Pharmacovigilance.

Safety reporting is one of the most important activities in pharmacovigilance, but pharmaceutical companies face several difficulties while collecting, processing, assessing, and submitting safety information. These challenges can arise from the quality of the information received, the increasing volume of reports, differences in regulatory requirements, limitations in technology, and the availability of trained personnel.[17]

4.1 Under-reporting of Adverse Events

Under-reporting is one of the long-standing challenges in pharmacovigilance. Not every adverse event experienced by a patient is reported to a healthcare professional or pharmaceutical company. Patients may consider an event to be minor or unrelated to their medicine, while healthcare professionals may not always have sufficient time to report every suspected reaction.

Under-reporting can create an incomplete picture of a medicine's safety profile. When fewer reports are received, it may become more difficult to recognize patterns of adverse events, particularly when the event is uncommon.

Pharmaceutical companies therefore depend on multiple reporting channels and awareness activities to improve the availability of safety information. Encouraging healthcare professionals and patients to report suspected adverse events can contribute to a stronger safety-monitoring system.[18]

4.2 Duplicate Safety Reports

A single adverse event can reach a pharmaceutical company through different reporting pathways. For example, a healthcare professional may submit a report

directly to the company while the same case is also forwarded through a regulatory authority.

If these reports are treated as separate cases, the same event could be counted more than once. This may artificially increase the apparent frequency of an adverse event and potentially affect subsequent safety analysis.[19]

Pharmaceutical companies therefore use duplicate-detection procedures to compare reports based on available characteristics such as patient information, event details, dates, suspected medicines, and reporter information.

Modern safety databases and automated matching tools can support duplicate detection, but human review may still be necessary, particularly when reports contain limited or inconsistent information.[20]

4.3 Timeliness of Safety Reporting

Timely reporting is another major challenge for pharmaceutical companies. Certain safety reports must be submitted to regulatory authorities within specified reporting periods. This means that companies need efficient systems for receiving, validating, processing, medically reviewing, and submitting cases.

Delays can occur at different stages. A report may reach the company late, important information may be missing, follow-up may take time, or the case may require additional medical assessment before submission.

Maintaining timeliness while also ensuring accuracy can therefore be difficult. Companies need clearly defined procedures, appropriate workload management, trained staff, and effective monitoring systems to reduce avoidable delays.[21]



Figure 3: Factors Affecting Timely Safety Reporting.

4.4 Challenges in Literature Monitoring

Scientific literature is an important source of safety information. Published case reports and studies can provide information about suspected adverse reactions that may not have been reported directly to a pharmaceutical company.

However, monitoring the large volume of scientific publications can be resource-intensive. Pharmacovigilance teams must identify relevant publications, determine whether the company's medicinal products are involved, review the clinical information, and decide whether an individual case or other safety activity is required.[22]

4.5 Safety Information from Digital Sources

The growth of social media, online discussion forums, websites, and other digital platforms has created additional potential sources of medicine-related safety information.

These sources may provide useful insights into patients' experiences, but they can also contain incomplete, unclear, or unverified information. Determining whether a post contains reportable safety information may therefore be challenging.[23]

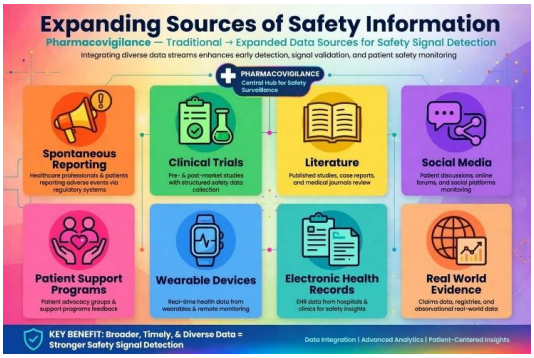

Figure 4: Expanding Sources of Safety Information.

5. Challenges from the Pharmaceutical Company's Standpoint in Drug Safety

Although pharmacovigilance systems are designed to protect patients, pharmaceutical companies face several practical difficulties in maintaining these systems effectively. From a company's standpoint, drug safety requires continuous coordination between pharmacovigilance, medical affairs, regulatory affairs, clinical research, quality teams, information technology, and external partners. The challenge is to maintain accurate and timely safety activities while handling increasing amounts of information and changing regulatory expectations Effectively.[24]

5.1 Managing Global Pharmacovigilance Operations

Large pharmaceutical companies often operate in several countries. Safety information may therefore be received from different regions and processed through both global and local pharmacovigilance teams.

Differences in local regulations, languages, reporting practices, healthcare systems, and submission procedures can increase operational complexity. Companies need to maintain consistency in their overall safety standards while also meeting applicable local requirements.

Effective communication between global and local teams is therefore essential for avoiding delays, inconsistencies, and duplication of work.[25]

5.2 Resource and Workforce Challenges

An effective pharmacovigilance system requires trained professionals who can perform case processing, medical review, signal detection, aggregate-data analysis, quality checks, and regulatory activities.

When safety-report volumes increase significantly, companies may need additional personnel or technological support. At the same time, new employees require appropriate training before they can independently perform safety-related activities.

Workforce planning is therefore an important consideration for pharmaceutical companies. Maintaining adequate staffing and competency can help reduce excessive workload and support consistent safety operations.[26]

5.3 Quality Management and Audit Readiness

Pharmaceutical companies need to demonstrate that their pharmacovigilance activities are being performed according to applicable requirements and established procedures. Quality-management systems help companies monitor processes, identify errors, investigate deviations, and implement corrective and preventive actions when necessary.

Companies may also undergo inspections or audits. Maintaining accurate records, documented procedures, training records, and evidence of appropriate case processing helps demonstrate that the pharmacovigilance system is functioning effectively.[27]

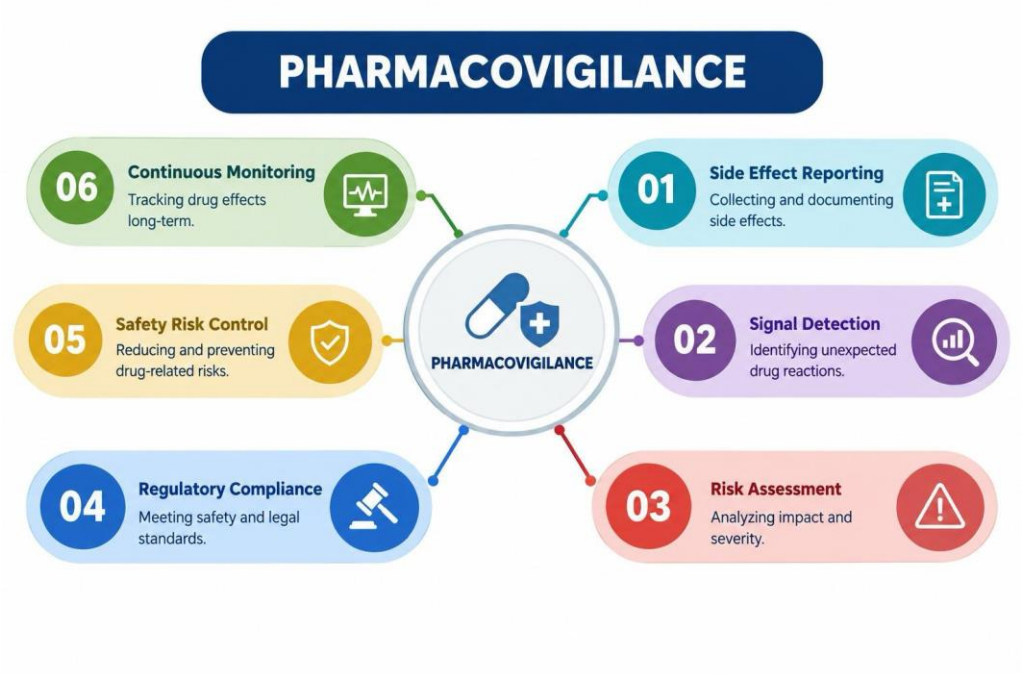

Figure 5: Pharmaceutical Company Drug-Safety Framework.

SUMMARY

From the pharmaceutical company's standpoint, safety reporting involves much more than receiving and submitting adverse-event reports. It requires a coordinated system involve people, processes, technology, quality management, regulatory compliance, and continuous monitoring.[28]

6. Regulatory Requirements and Compliance in Safety Reporting

Pharmacovigilance activities are carried out within a regulatory framework designed to ensure that safety information is collected, evaluated, documented, and communicated in a timely and consistent manner.

Pharmaceutical companies are expected to maintain systems that allow them to identify safety information, assess its importance, report relevant cases to regulatory authorities, and continuously monitor the safety profile of their medicines.

International guidelines provide a common foundation for pharmacovigilance, but reporting requirements can differ between countries and regions. The ICH E2D(R1) guideline provides internationally harmonized recommendations for the management and reporting of post-approval Individual Case Safety Reports (ICSRs), while also recognizing that local and regional requirements may differ.[29]

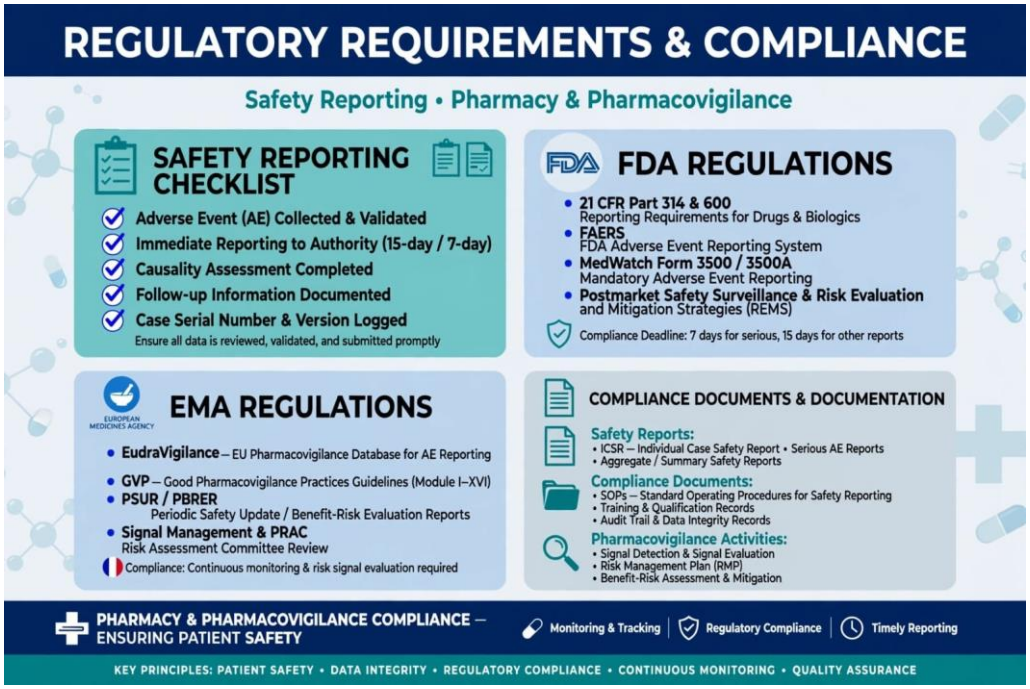

Figure 6: Regulatory Requirements and Compliance in Pharmacovigilance Safety Reporting.

6.1 Importance of Regulatory Compliance

Regulatory compliance is an important part of pharmaceutical safety management. A company must ensure that safety information is handled according to applicable laws, guidelines, standard operating procedures (SOPs), and regulatory commitments.

Compliance involves more than simply submitting an adverse event report. It includes:

- Identifying safety information from different sources;
- Determining whether a report represents a valid safety case;
- Entering and coding information accurately;
- Performing medical and clinical assessment;
- Identifying duplicate cases;
- Conducting appropriate follow-up;
- Determining whether expedited reporting is required;
- Submitting reportable cases within the applicable timeline;
- Maintaining appropriate records;
- Monitoring signals and emerging safety concerns; and
- Maintaining an inspection-ready pharmacovigilance system.

Therefore, regulatory compliance is closely connected with the quality and effectiveness of the company's overall pharmacovigilance system.[30,31]

6.2 International Harmonization of Safety Reporting

The International Council for Harmonisation (ICH) has developed guidelines to promote consistency in pharmaceutical safety management across participating regions.

ICH E2D(R1), adopted in 2025, addresses post-approval safety data and provides definitions and standards for the

management and reporting of ICSRs. The guideline aims to harmonize safety-reporting practices while recognizing that individual regulatory regions may have additional requirements.

ICH Guidelines
↓
Common concepts and standards
↓
Regional Regulatory Requirements
↓
Country-specific implementation
↓
Pharmaceutical Company Pharmacovigilance System
↓
Collection → Assessment → Reporting → Monitoring
↓
Patient Safety[32]

6.3 Individual Case Safety Reports (ICSRs)

An ICSR contains information about an individual patient who experienced an adverse event or suspected adverse reaction associated with a medicinal product.

A safety case generally requires sufficient information to identify:

- An identifiable patient;
- An identifiable reporter;
- A suspected medicinal product; and • A suspected adverse event/reaction.

The ICSR process begins when safety information is received by the company. The information is then assessed, entered into the safety database, medically reviewed, followed up when necessary, and evaluated for regulatory reporting.

ICH E2D(R1) provides updated international recommendations for post-approval ICSR management and reporting.[33]

European union

Under the European Medicines Agency's Good Pharmacovigilance Practices (GVP) Module VI, applicable ICSRs are submitted to EudraVigilance within the relevant reporting timeframe. The guidance identifies 15-day and 90-day reporting timeframes depending on the type and origin of the report.[34]

United States

For certain postmarketing adverse experiences involving approved drugs and biological products, U.S. regulations include a 15-calendar-day reporting requirement for applicable serious and unexpected cases. FDA guidance also describes requirements for follow-up information and maintenance of records relating to unsuccessful follow-up attempts.[35]

India

In India, the Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission (IPC), provides a national system for collection and analysis of adverse drug reaction information. Healthcare professionals and patients can report suspected ADRs through the PvPI system, and pharmaceutical companies can submit product-specific ICSRs to the National Coordinating Centre.[36]

6.4 Differences Between Countries

A multinational company may receive the same safety report in several countries. Different reporting rules, electronic systems, terminology requirements, and submission procedures can increase operational complexity.[37]

6.5 Role of Standard Operating Procedures

Standard Operating Procedures provide standardized instructions for performing pharmacovigilance activities.

- Adverse event intake;
- Case validation;
- ICSR processing;
- Medical review;
- Seriousness and expectedness assessment;
- Coding;
- Duplicate detection;
- Follow-up;
- Regulatory submission;
- Literature monitoring;
- Signal management;
- Safety database reconciliation;
- Quality control; and
- Escalation of safety issues.

Well-designed SOPs help reduce variation between employees and support consistent safety operations. Regular refresher training is particularly important when regulations, company procedures, or safety systems are updated.[38]

6.6 Vendor and Partner Compliance

Many pharmaceutical companies use external service providers for activities such as case processing, literature screening, call-center operations, or technology services.

Outsourcing does not eliminate the company's responsibility for appropriate pharmacovigilance oversight. The company should establish clear agreements defining responsibilities, communication channels, timelines, quality expectations, and escalation procedures.[39]

7. Strategies to Overcome Challenges in Safety Reporting

Pharmaceutical companies face several challenges while collecting, processing, assessing, and reporting drug safety information. These challenges can affect the

completeness, quality, and timely submission of Individual Case Safety Reports (ICSRs). Therefore, companies need a systematic approach that combines trained personnel, suitable technology, clear procedures, and continuous quality monitoring.[40]

7.1 Strengthening Safety Data Collection

The first step in improving pharmacovigilance is to ensure that potential safety information is captured from all relevant sources. Companies should maintain clear procedures for receiving adverse event information from healthcare professionals, patients, clinical trials, medical information departments, literature, digital platforms, and other sources.

Standardized reporting forms and clearly defined minimum information requirements can help reduce incomplete reports. Employees who may receive safety information should also be trained to recognize and forward potential adverse events to the appropriate drug safety team.[41]

7.2 Use of Automation and Artificial Intelligence

Modern pharmacovigilance systems increasingly use automation to manage large volumes of safety information. Automated tools can assist with case intake, duplicate detection, data extraction, case triage, coding, and workflow management.

Artificial intelligence and natural language processing can also help identify potential adverse event information from unstructured sources such as scientific literature and electronic communications. However, automated systems require appropriate validation and human oversight because incorrect identification or classification of safety information may affect the quality of pharmacovigilance activities.[42]

7.3 Importance of a Quality Management System

A strong quality management system (QMS) provides a structured framework for maintaining the quality and compliance of pharmacovigilance activities. It should include appropriate standard operating procedures (SOPs), training programs, documentation practices, quality control, audits, corrective and preventive actions (CAPA), and continuous improvement.

The QMS should also be periodically reviewed to identify weaknesses in the safety reporting process. Lessons obtained from audits, inspections, deviations, and recurring processing errors can be used to improve existing procedures.[43]

8. Role of Technology in Improving Drug Safety Reporting

The increasing volume and complexity of safety information has made technology an important part of modern pharmacovigilance. Pharmaceutical companies receive safety data from multiple sources, including clinical studies, spontaneous reports, scientific literature, healthcare professionals, patients, and digital platforms. Manual handling of large amounts of information can be time-consuming and may increase the possibility of delays or errors. Technological solutions can therefore support the collection, processing, analysis, and monitoring of safety information.[44]

8.1 Digital and Social Media Sources

The increasing use of digital platforms has created additional sources of potential safety information. Patients and healthcare professionals may discuss experiences with medicines through websites, online forums, and social media.

Pharmaceutical companies may therefore consider appropriate digital sources as part of their pharmacovigilance activities. At the same time, information obtained from such sources can be difficult to interpret because reports may lack essential patient or product details. Companies need defined procedures for assessing whether information meets applicable criteria for safety reporting.[45]

Table 1: Applications of Technology in Pharmacovigilance.

Technology	Major application	Potential benefit
Electronic safety databases	Case storage and tracking	Better organization and traceability
Workflow automation	Case routing and processing	Reduced manual workload
Artificial intelligence	Data extraction and classification	Faster processing of large datasets
Natural language processing	Literature and text analysis	Identification of relevant safety information
Machine learning	Pattern recognition	Support for signal detection
Statistical tools	Safety data analysis	Identification of potential trends
Digital monitoring tools	Monitoring online sources	Access to additional safety information
Data visualization	Safety trend presentation	Easier interpretation of complex data

8.2 Challenges Associated with Technology

Although technology provides several advantages, its implementation also creates challenges. Pharmaceutical companies may need significant investment in software, infrastructure, system validation, cybersecurity, and employee training. Poorly designed or inadequately

validated systems can introduce new risks rather than eliminating existing ones.

Another important concern is data privacy and security. Safety databases contain sensitive information, and appropriate controls are required to protect data from unauthorized access or loss.

Therefore, technology should be introduced as part of a controlled pharmacovigilance system rather than being considered a standalone solution.[46]

8.3 Future Perspective

The future of pharmacovigilance is likely to involve greater integration of automation, AI, advanced analytics, and interconnected safety databases. These technologies may help companies manage increasing amounts of safety information more efficiently. However, technological development should be accompanied by appropriate validation, quality control, regulatory compliance, transparency, and human oversight.[47]

9. Impact of Safety Reporting Challenges on Patient Safety

Pharmacovigilance plays an important role in protecting patients from potential risks associated with medicines. The safety information collected from healthcare professionals, patients, clinical studies, and other sources helps pharmaceutical companies and regulatory authorities identify previously unknown or changing risks. When safety reporting is delayed, incomplete, or inaccurate, it may affect the ability to recognize and evaluate these risks effectively.[48]

9.1 Delayed Identification of Safety Signals

One of the major consequences of poor safety reporting is the delayed identification of potential safety signals. If adverse events are not reported or are submitted late, there may be insufficient information available to identify an emerging safety concern at an early stage.

Early identification allows appropriate investigation and, when necessary, risk-minimization measures to be considered.[49]

9.2 Increased Risk of Medication-Related Harm

When important safety information is not adequately captured or communicated, healthcare professionals and patients may not have access to all relevant information about potential medicine-related risks. This may contribute to inappropriate treatment decisions in some circumstances.

Effective pharmacovigilance therefore supports informed benefit–risk assessment throughout the life cycle of a medicinal product.[50]

9.3 Overall Impact

The impact of safety reporting challenges extends beyond the pharmacovigilance department. Problems in data collection, processing, assessment, and reporting can influence the overall safety monitoring system. Strengthening reporting practices can therefore contribute to earlier identification of potential risks, better scientific evaluation, improved regulatory decision-making, and stronger protection of patients.[51]

10. Regulatory and Industry Perspectives on Safety Reporting

Pharmacovigilance activities are carried out within a regulatory framework designed to ensure that the safety of medicines is continuously monitored throughout their life cycle. Pharmaceutical companies are responsible for maintaining appropriate systems for collecting, evaluating, documenting, and reporting safety information. Regulatory authorities, on the other hand, review available safety information and take appropriate action when new or changing risks are identified.[52]

10.1 Responsibilities of Pharmaceutical Companies

Pharmaceutical companies have an important responsibility to maintain an effective pharmacovigilance system. Their activities generally include collecting safety information, processing individual safety reports, conducting follow-up, evaluating potential signals, maintaining safety databases, preparing required safety reports, and implementing appropriate risk-management activities.

Companies also need to maintain suitable procedures and documentation to demonstrate that their pharmacovigilance activities are being performed appropriately.[53]

10.2 Pharmacovigilance Inspections

Regulatory inspections are an important mechanism for assessing whether a company's pharmacovigilance system meets applicable requirements. During an inspection, regulators may examine areas such as standard operating procedures, case processing, reporting timelines, safety databases, training records, quality systems, agreements with service providers, and documentation.

Inspection findings can help identify weaknesses in a company's safety system and may lead to corrective and preventive actions.[54]

10.3 Regulatory Changes as a Challenge

Regulatory requirements can change as scientific knowledge, technology, and safety-monitoring practices develop. Pharmaceutical companies therefore need systems for identifying relevant regulatory updates and incorporating them into their procedures.

Failure to recognize or implement important regulatory changes may result in procedural gaps or compliance problems. Regular training, regulatory intelligence activities, and periodic review of SOPs can help companies respond to changing requirements.[55]

10.4 Collaboration Between Industry and Regulators

Effective pharmacovigilance requires cooperation between pharmaceutical companies and regulatory authorities. Companies provide safety information and scientific assessments, while regulators evaluate the available evidence and determine appropriate regulatory actions within their jurisdiction.

Table 2: Regulatory and Industry Responsibilities in Pharmacovigilance.

Area	Pharmaceutical companies	Regulatory authorities
Safety data collection	Collect and process relevant safety information	Receive and review submitted information
ICSR management	Process and submit applicable reports	Monitor reporting compliance
Signal management	Detect and evaluate potential signals	Independently assess safety concerns
Risk management	Develop and implement appropriate measures	Review and oversee riskmanagement activities
Documentation	Maintain records and procedures	Inspect relevant documentation
Training	Train personnel involved in safety activities	Provide regulatory guidance and expectations

10.5 Future Need for Regulatory Adaptation

The development of new technologies, real-world data sources, artificial intelligence, and digital health platforms is changing the pharmacovigilance environment. Regulatory frameworks may therefore need to evolve alongside these developments.

Future safety-reporting systems are likely to require a balance between technological innovation, data quality, patient privacy, transparency, human oversight, and regulatory compliance.

Overall, cooperation between pharmaceutical companies and regulatory authorities is essential for maintaining an effective drug safety system. Clear responsibilities, appropriate regulatory oversight, continuous training, and adaptation to new technologies can help strengthen pharmacovigilance practices and improve the quality of safety reporting.[56]

11. Future Trends in Pharmacovigilance and Safety Reporting

Pharmacovigilance is continuously changing because of advances in technology, increasing amounts of healthcare data, and changes in the way medicines are developed and used. Traditional safety reporting methods remain important, but newer approaches are being developed to improve the speed, quality, and efficiency of safety monitoring.

11.1 Patient Involvement in Pharmacovigilance

Patients are becoming increasingly recognized as important contributors to medicine safety monitoring. Patients may provide information about adverse effects that may not always be fully captured through healthcare professionals.

Improving public awareness about adverse event reporting and providing accessible reporting mechanisms may help increase the amount of safety information available to pharmacovigilance systems.[57]

11.2 Digital and Mobile Reporting

Mobile applications and online reporting systems may make adverse event reporting more convenient. Digital platforms can allow patients and healthcare professionals to submit information without relying entirely on traditional paper-based processes.

These systems may also support faster transmission of information to the appropriate safety teams.

11.3 Advanced Data Analytics

Pharmaceutical companies are increasingly handling large and complex datasets. Advanced analytical methods can help identify patterns, relationships, and trends that may be difficult to detect through manual review alone.

Combining statistical methods with appropriate clinical assessment may strengthen the process of identifying and evaluating potential safety signals.[58]

11.4 Challenges in Adopting Future Technologies

Although new technologies offer significant opportunities, their implementation may also create challenges. Pharmaceutical companies need appropriate infrastructure, trained personnel, system validation, data-quality controls, cybersecurity measures, and clear governance procedures.

Another important consideration is maintaining human oversight. Technology can support pharmacovigilance professionals, but safety decisions should be based on appropriate scientific evaluation and reliable evidence.

11.5 Future Perspective

The future of pharmacovigilance is likely to involve a combination of human expertise, automation, advanced analytics, and multiple sources of safety information. Rather than completely replacing existing pharmacovigilance processes, emerging technologies are expected to strengthen them.[59]

12. DISCUSSION

Pharmacovigilance is an essential part of ensuring the safe and appropriate use of medicines. Pharmaceutical companies are required to monitor safety information throughout the life cycle of a medicinal product. However, the increasing volume of safety data, multiple reporting sources, regulatory requirements, and the need for timely processing have made safety reporting a complex activity.

One of the major challenges identified in safety reporting is the collection of complete and reliable information. Adverse event reports may contain missing or unclear details, making medical assessment and follow-up difficult. Under-reporting can further limit the amount of information available for identifying potential safety concerns. Therefore, improving awareness among healthcare professionals and patients remains an important aspect of strengthening pharmacovigilance.[60]

12.1 Overall Interpretation

The challenges in safety reporting are interconnected. For example, inadequate training may contribute to incomplete reports, while incomplete information may increase the need for follow-up and consequently increase workload. Similarly, increasing workload may contribute to processing delays if appropriate systems and resources are not available.

Therefore, pharmaceutical companies need to view pharmacovigilance as an integrated system rather than as a series of separate activities. Improvements in one area can support improvements in other areas.[62]

13. Recommendations for Improving Safety Reporting

healthcare professionals, patients, regulatory authorities, and technology providers. Since the challenges associated with safety reporting can occur at different stages of the pharmacovigilance process, improvement strategies should address data collection, case processing, reporting, quality management, and continuous monitoring.

13.1 Improve Awareness About Adverse Event Reporting

Awareness among healthcare professionals and patients can help improve the reporting of suspected adverse events. Educational programs should explain the importance of reporting, the type of information that should be provided, and the appropriate reporting channels.

Simple and accessible reporting procedures may also encourage more individuals to provide safety information.[63]

13.2 Overall Recommendation

The improvement of safety reporting should focus on creating a system in which accurate safety information can be identified, collected, processed, assessed, and communicated without unnecessary delay. Pharmaceutical companies should combine trained personnel, clear procedures, suitable technology, quality management, and effective communication rather than depending on a single intervention.

In summary, strengthening safety reporting is a continuous process. A well-organized pharmacovigilance system can improve the quality and timeliness of safety information and support the early recognition and management of potential medicine-related risks.[64]

14. CONCLUSION

Pharmacovigilance is an essential component of the healthcare system because the safety of medicines needs to be monitored continuously, even after a product has received regulatory approval. Pharmaceutical companies play an important role in collecting, processing, evaluating, and reporting safety information throughout the life cycle of a medicinal product.

This review highlights that pharmaceutical companies face several challenges in maintaining effective safety reporting systems. Under-reporting, incomplete information, increasing numbers of safety cases, reporting timelines, data-quality problems, changing regulatory requirements, limited resources, and coordination between different departments can affect the overall efficiency of pharmacovigilance activities.

The increasing use of technology provides new opportunities to address some of these challenges. Electronic safety databases, automation, artificial intelligence, natural language processing, advanced analytics, and real-world data can support different stages of safety monitoring. However, technological solutions should be appropriately validated and combined with human expertise because medical and scientific judgment remains essential in evaluating safety information.

Improving safety reporting also requires continuous training of employees, standardized procedures, effective quality management, appropriate vendor oversight, and good communication between pharmaceutical companies and regulatory authorities. Greater involvement of healthcare professionals and patients can further improve the availability of safety information.

A strong pharmacovigilance system should therefore focus not only on meeting regulatory requirements but also on maintaining the quality, completeness, and timeliness of safety information. Continuous evaluation and improvement of reporting processes can help pharmaceutical companies identify potential safety concerns more effectively.

In conclusion, effective safety reporting requires a coordinated combination of people, processes,

technology, and regulatory oversight. Strengthening these areas can support better identification and management of medicine-related risks and ultimately contribute to safer use of medicines and improved patient protection.

REFERENCES

1. World Health Organization. The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products. Geneva: WHO, 2002.
2. World Health Organization. Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre. Geneva: WHO, 2000.
3. World Health Organization. Safety of Medicines: A Guide to Detecting and Reporting Adverse Drug Reactions. Geneva: WHO, 2002.
4. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet, 2000; 356(9237): 1255-1259.
5. Aronson JK. Adverse drug reactions—definitions, diagnosis, and management. Br J Clin Pharmacol, 2004; 58(4): 343-344.
6. Waller PC, Evans SJW. A model for the future conduct of pharmacovigilance. Pharmacoepidemiol Drug Saf., 2003; 12(1): 17-29.
7. Mann RD, Andrews EB, editors. Pharmacovigilance. 2nd ed. Chichester: Wiley, 2007.
8. International Council for Harmonisation. E2A: Clinical Safety Data Management—Definitions and Standards for Expedited Reporting. ICH, 1994.
9. International Council for Harmonisation. E2B(R3): Electronic Transmission of Individual Case Safety Reports (ICSRs). ICH, 2012.
10. International Council for Harmonisation. E2D: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting. ICH, 2003.
11. International Council for Harmonisation. E2D(R1): Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports. ICH, 2025.
12. International Council for Harmonisation. E2E: Pharmacovigilance Planning. ICH, 2004.
13. International Council for Harmonisation. E2C(R2): Periodic Benefit-Risk Evaluation Report. ICH, 2012.
14. International Council for Harmonisation. E2F: Development Safety Update Report. ICH, 2010.
15. European Medicines Agency. Guideline on Good Pharmacovigilance Practices (GVP): Module I—Pharmacovigilance Systems and Their Quality Systems. EMA, 2012.
16. European Medicines Agency. GVP Module II—Pharmacovigilance System Master File. EMA, 2017.
17. European Medicines Agency. GVP Module III—Pharmacovigilance Inspections. EMA, 2026.
18. European Medicines Agency. GVP Module IV—Pharmacovigilance Audits. EMA.
19. European Medicines Agency. GVP Module V—Risk Management Systems. EMA, 2017.
20. European Medicines Agency. GVP Module VI—Collection, Management and Submission of Reports of Suspected Adverse Reactions to Medicinal Products. EMA, 2017.
21. European Medicines Agency. GVP Module VI Addendum I—Duplicate Management of Suspected Adverse Reaction Reports. EMA, 2017.
22. European Medicines Agency. GVP Module VII—Periodic Safety Update Report. EMA, 2013.
23. European Medicines Agency. GVP Module VIII—Post-Authorisation Safety Studies. EMA, 2017.
24. European Medicines Agency. GVP Module IX—Signal Management. EMA, 2017.
25. U.S. Food and Drug Administration. Guidance for Industry: Postmarketing Adverse Event Reporting for Pharmaceutical Manufacturers. FDA.
26. U.S. Food and Drug Administration. Guidance for Industry: E2B(R3) Electronic Transmission of Individual Case Safety Reports. FDA.
27. U.S. Food and Drug Administration. FDA Adverse Event Reporting System (FAERS): Overview. FDA.
28. Uppsala Monitoring Centre. WHO Programme for International Drug Monitoring. Uppsala: UMC. 29. Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: a systematic review. Drug Saf., 2006; 29(5): 385-396.
29. Lopez-Gonzalez E, Herdeiro MT, Figueiras A. Determinants of under-reporting of adverse drug reactions: a systematic review. Drug Saf., 2009; 32(1): 19-31.
30. Inman WHW. Monitoring for Drug Safety. 2nd ed. Lancaster: MTP Press, 1986.
31. Inman WHW. Attitudes to adverse drug-reaction reporting. Br J Clin Pharmacol, 1996; 41(5): 434435.
32. Belton KJ, Lewis SC, Payne S, Rawlins MD, Wood SM. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol, 1995; 39(3): 223226.
33. Eland IA, Belton KJ, van Grootheest AC, Meiners AP, Rawlins MD, Stricker BHC. Attitudinal survey of voluntary reporting of adverse drug reactions. Br J Clin Pharmacol, 1999; 48(4): 623-627.
34. Hazell L, Cornelius V, Hannaford P, Shakir S, Avery AJ. How do patients contribute to signal detection? A retrospective analysis of spontaneous reporting of adverse drug reactions in the UK. Br J Clin Pharmacol, 2013; 75(4): 1020-1027.
35. Van Grootheest K, de Jong-van den Berg L. Patients' role in reporting adverse drug reactions. Expert Opin Drug Saf., 2004; 3(4): 363-368.
36. Van Hunsel F, Härmark L, van Puijenbroek E. Improving adverse drug reaction reporting by healthcare professionals. Expert Opin Drug Saf., 2012; 11(6): 867-873.
37. Bäckström M, Mjörndal T, Dahlqvist R. Under-reporting of serious adverse drug reactions in Sweden. Pharmacoepidemiol Drug Saf., 2004; 13(8): 483-487.

38. Alatawi YM, Hansen RA. Empirical estimation of under-reporting in the spontaneous reporting system. Drug Saf., 2017; 40(12): 1199-1208.
39. Venulet J, Blattner R, von Bulow J, Berneker GC. How good are drugs after all? The relationship between efficacy and safety. Eur J Clin Pharmacol, 1986; 30(5): 577-587.
40. Rawlins MD. Spontaneous reporting of adverse drug reactions. I: the data sheet. Br J Clin Pharmacol, 1981; 11(6): 597-600.
41. 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(6): 483-486.
42. Bate A, Lindquist M, Edwards IR, Olsson S, Orre R, Lansner A, De Freitas RM. A Bayesian neural network method for adverse drug reaction signal generation. Eur J Clin Pharmacol, 1998; 54(4): 315321.
43. van Puijenbroek EP, Bate A, Leufkens HGM, Lindquist M, Orre R, Egberts ACG. A comparison of measures of disproportionality for signal detection in spontaneous reporting systems for adverse drug reactions. Pharmacoepidemiol Drug Saf., 2002; 11(1): 3-10.
44. Hauben M, Bate A. Decision support methods for the detection of adverse events in post-marketing data. Drug Discov Today, 2009; 14(7-8): 343-357.
45. Trifirò G, Pariente A, Coloma PM, et al. Data mining on electronic health record databases for signal detection in pharmacovigilance: which events to monitor? Pharmacoepidemiol Drug Saf., 2009; 18(12): 1176-1184.
46. Harpaz R, DuMouchel W, Shah NH, Madigan D, Ryan P, Friedman C. Novel data-mining methodologies for adverse drug event discovery and analysis. Clin Pharmacol Ther., 2012; 91(6): 1010-1021.
47. Bate A, Evans SJW. Quantitative signal detection using spontaneous ADR reporting. Pharmacoepidemiol Drug Saf., 2009; 18(6): 427-436.
48. Sakaeda T, Tamon A, Kadoyama K, Okuno Y. Data mining of the public version of the FDA Adverse Event Reporting System. Int J Med Sci., 2013; 10(7): 796-803.
49. European Medicines Agency. EudraVigilance: European Database of Suspected Adverse Drug Reactions. EMA.
50. World Health Organization. WHO Pharmacovigilance Indicators: A Practical Manual for the Assessment of Pharmacovigilance Systems. Geneva: WHO.
51. World Health Organization. Safety Monitoring of Medicinal Products: Reporting System for the General Public. Geneva: WHO.
52. International Council for Harmonisation. E6(R2): Good Clinical Practice. ICH, 2016.
53. International Council for Harmonisation. E8(R1): General Considerations for Clinical Studies. ICH, 2021.
54. International Council for Harmonisation. M4: The Common Technical Document for the Registration of Pharmaceuticals for Human Use. ICH.
55. Moore N, Kreft-Jais C, Haramburu F, Noblet C. Reports of adverse drug reactions received in the French pharmacovigilance database: analysis of under-reporting. Br J Clin Pharmacol, 1998; 45(4): 315-318.
56. Figueiras A, Herdeiro MT, Polónia J, Gestal-Otero JJ. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. JAMA., 2006; 296(9): 1086-1093.
57. Passier A, ten Napel M, van Puijenbroek E, van Grootheest K. Reporting of adverse drug reactions by general practitioners: a qualitative study. BMC Fam Pract., 2009; 10: 1.
58. Lopez-Gonzalez E, Herdeiro MT, Piñeiro-Lamas M, et al. Effect of an educational intervention to improve adverse drug reaction reporting among healthcare professionals. Drug Saf.
59. Kompa B, Hakim A, Palepu A, et al. Artificial intelligence based on machine learning in pharmacovigilance: a scoping review. Drug Saf., 2022; 45(5): 477-491.
60. Bate A, Reynolds RF, Caudill R, Olson L. Automated detection of adverse drug reactions using natural language processing and machine learning approaches. Drug Saf.
61. Li Y, Tao W, Li Z, Sun Z, Li F, Fenton S, Xu H, Tao C. Artificial intelligence-powered pharmacovigilance: a review of machine and deep learning in clinical text-based adverse drug event detection for benchmark datasets. J Biomed Inform., 2024; 152: 104621.
62. Dsouza VS, Leyens L, Kurian JR, Brand A, Brand H. Artificial intelligence in pharmacovigilance: a systematic review on predicting adverse drug reactions in hospitalized patients. Res Social Adm Pharm., 2025; 21(6): 453-462.

© 2026 Author(s) | Published by IJCPI | Open Access under CC BY 4.0 License |