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# **A COMPREHENSIVE ANALYSIS OF GLOBAL PHARMACOVIGILANCE: A STUDY OF INDIA, THE US, AND AUSTRALIA**

**MADDALA BHARATHI<sup>\*1</sup>, VEMURI AKASH<sup>2</sup>**

<sup>1</sup>Student, A. U. College of Pharmaceutical Sciences, Andhra University, Visakhapatnam- 530003, Andhra Pradesh, India

<sup>2</sup>Research Scholar, A. U. College of Pharmaceutical Sciences, Andhra University, Visakhapatnam-530003, Andhra Pradesh, India

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## **ABSTRACT:**

This study provides a comparative analysis of pharmacovigilance systems in India, the US, and Australia, examining regulatory frameworks, organizational structures, ADR reporting processes, data utilization, challenges, and opportunities. It identifies common challenges such as underreporting and resource constraints, while also exploring opportunities for international collaboration and the advancement of patient safety practices globally. Moreover, the study identifies and analyzes common challenges encountered by pharmacovigilance systems in India, the US, and Australia, including issues related to resource limitations, globalization of drug development, emerging technologies, and the need for international collaboration. By synthesizing insights from diverse regulatory environments, healthcare systems, and cultural contexts, this study provides valuable comparative perspectives on global pharmacovigilance practices. It offers recommendations for enhancing pharmacovigilance capabilities, fostering collaboration between countries, and advancing patient safety on a global scale.

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**KEYWORDS:** Pharmacovigilance, ADR, Fostering, Regulatory framework.

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## **INTRODUCTION:**

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other potential drug-related problems." [1]. It is an organized activity in the professional health area with significant social and economic repercussions that aims to evaluate pharmacological risk/benefit ratios while also enhancing patient safety and quality of life. Pharmacovigilance must constantly adjust in response to new medical developments. Pharmacovigilance and all drug safety issues are important to everyone whose life has been influenced in some manner by medical interventions. [2] Pharmacovigilance has developed and will continue to develop in response to the specific needs and strengths of WHO Programme participants. Pharmacovigilance, or the research of pharmacological benefits and dangers in general, is an important part of pharmacotherapeutic decision-making at the individual, regional, national, and international levels. Furthermore, pharmacovigilance is emerging as a distinct scientific discipline. Several developments are occurring in the complicated system of drug development, regulation, and distribution. Pharmacovigilance should be proactive in assessing the potential outcomes. [3] The detection of new adverse drug responses is critical to protecting patients from potential harm caused by medicine. [4] The healthcare system needs new techniques to understand the risk-benefit ratio of medications. [5] In the United States, drug safety monitoring laws were implemented in 1962; in Europe, they were implemented between 1963 and 1964. However, in 1997, India joined the WHO-ADR monitoring program with three countrywide centres. However, an important program has been established by the Central Drugs Standard Control Organization (CDSCO) under the Government of India, a nationwide pharmacovigilance program in July 2010, to monitor ADR in the country to safeguard public health [5]. WHO's Pharmacovigilance team aims to ensure the safety of medicines and vaccines by ensuring the reliable and timely exchange of information on safety issues, promoting pharmacovigilance activities throughout the Organization, and encouraging participation in the WHO Programme for International Drug Monitoring [6]. Pharmacovigilance is a significant and essential component of clinical research. Both clinical trial safety and post-marketing pharmacovigilance are crucial throughout the product's lifecycle, particularly in terms of safety [7].

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## **PURPOSE OF PHARMACOVIGILANCE**

Pharmacovigilance is the process of gathering, monitoring, investigating, assessing, and evaluating information from healthcare practitioners, pharmaceutical firms, and patients regarding the harmful effects of drugs, biologicals, herbal, and traditional therapies.

Pharmacovigilance entails monitoring and assessing drug quality, as well as detecting and preventing side effects. Its objectives include identifying new knowledge regarding potential dangers connected with medicines.

- ✓ To avoid injury to patients.
- ✓ To improve patient care and safety when using medications and performing other medical and paramedical procedures.
- ✓ To evaluate the quantitative aspects of benefit-risk analysis and information dissemination required to improve drug prescribing and regulation. [8]

1. Improve public health and safety when using pharmaceuticals.
2. Educate and instruct the public on pharmacovigilance.
3. Detect and communicate medication-related issues promptly.[9] Improve patient care and safety when using medications and performing other medical and paramedical procedures. Investigate the efficacy of medications and monitor their detrimental effects from the lab to the pharmacy for many years. Pharmacovigilance monitors any adverse effects of medications.[10] The detection of improper prescriptions and administrations. Detecting substantial drug-drug interactions between new medications and co-therapy with agents already on the market, which may only be detected during widespread use.[11]

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## IMPORTANCE OF PHARMACOVIGILANCE

The WHO's pharmacovigilance team works to ensure the safety of pharmaceuticals and vaccines by facilitating the timely and dependable exchange of safety-related information, advancing pharmacovigilance initiatives across the WHO, and fostering involvement in the WHO Program for International Drug Monitoring.[12]

Pharmacovigilance is important for the reasons listed below.

1. Medication safety observation.
2. Drug surveillance.
3. Adverse effects of pharmaceutical preparations.
4. Reporting adverse medication reactions.
5. Post-marketing product surveillance.

Pharmacovigilance is crucial for preserving patient health, fostering public confidence, and upholding the integrity of healthcare systems around the globe.[13]

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## PATIENT SAFETY AND HEALTH PROTECTION

Pharmacovigilance is at the forefront of safeguarding patients' health and safety from the negative effects of drugs. Pharmacovigilance aids in the early detection of safety issues by monitoring and evaluating adverse responses, side effects, and unanticipated medical events connected to medications. This ensures patient safety and reduces potential harm by assisting medical professionals in making educated judgments, changing treatment strategies, or even recalling products as needed.

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## DETECTING PREVIOUSLY UNNOTICED ADVERSE EFFECTS

Because of the small sample size and short duration, certain uncommon or long-term side effects might not be discovered during the clinical trial stage. A platform for identifying and evaluating these side effects is provided by pharmacovigilance after the medication is marketed and a wider population is exposed to it.

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## REGULATORY COMPLIANCE AND MARKET AUTHORIZATION

Before a medication is authorized for commercialization, pharmaceutical companies have to abide by stringent regulatory criteria.

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## BUILDING PUBLIC TRUST AND CONFIDENCE

In the pharmaceutical industry, accountability and openness are promoted by an efficient pharmacovigilance system. Patients and healthcare professionals gain confidence in the healthcare systems and industry when they observe timely actions done to resolve safety concerns.[13]

### WHAT IS PHARMACOVIGILANCE

Drug effects should be monitored before and after successful testing and market launch. Pharmacovigilance is the process of reviewing information provided by healthcare practitioners, pharmaceutical companies, and patients to better understand the risks and benefits of a specific drug. Pharmaceutical corporations spend millions of dollars and take a long time to create new treatments. [14] Pharmacovigilance, often known as drug safety, is a comprehensive phrase that refers to the gathering, analysis, monitoring, and prevention of adverse effects in medications and therapies. It is a completely scientific and process-driven area of pharmaceuticals.[15]

Term	Definition	reference
Clinical trial	A clinical trial is an analysis research that evaluates an alternative medical treatment or a replacement method of administering an existing treatment to determine whether it will be more effective in stopping and screening for illness or treating it.	16

Adverse event	Any unfavorable medical event that may arise during drug therapy but is not always linked to the drug's use is referred to as an adverse event.	7
Post market surveillance	PMS, or post-marketing surveillance, is the process of keeping an eye on a pharmaceutical product's safety after it has been made available to the public.	7
Adverse drug reaction	Any unpleasant, unexpected, and undesirable side effect of a medication that happens at a dose utilized in humans for prevention, diagnosis, therapy, or alteration of physiological function is known as an adverse drug reaction (ADR).	7

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## HISTORICAL BACKGROUND OF PHARMACOVIGILANCE

The safety of drugs was not a major concern in their early history. The thalidomide tragedy of the 1960s prompted drug regulators and other concerned healthcare experts to devise a solution to ensure medication safety. In 1893, The Lancet journal published the first report of a chloroform-related death. Drug safety became a global concern, and different countries launched various programs to protect public health.[17]

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## METHODS OF PHARMACOVIGILANCE

According to the International Conference on Harmonization Efficacy Recommendations 2 (ICHE2E) recommendations, pharmacovigilance approaches can be classified as

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### SPONTANEOUS REPORTING SYSTEM

Spontaneous or voluntary reporting refers to the recording and reporting of clinical findings of a suspected ADR associated with a marketed medicine.<sup>12</sup> There are slight variances between countries, but the principles remain the same. In the United Kingdom, the 'Yellow Card' policy encourages doctors, dentists, and, more recently, hospital pharmacists to report any suspected reactions to new drugs as well as serious suspected responses to old medicines. The safety of drugs is frequently monitored using spontaneous reporting mechanisms.<sup>13</sup> Medical professionals, including physicians, pharmacists, and nurses, utilize standardized forms to report potential adverse reactions to regulatory authorities, as do consumers in some countries. Spontaneous reports are more likely to be effective when items are controlled as medicines and administered by health practitioners who are familiar with the reporting system. Consumers may be unaware of the significance of reporting unpleasant consequences.<sup>15</sup> Spontaneous reporting of adverse drug reactions and adverse events is an important tool for gathering safety information for early detection. Case reports collected by such systems represent the source of information with the lowest level of evidence and the highest level of uncertainty about the casualty. One benefit of spontaneous reporting is that it may be made available as soon as a new medication is introduced, lasts forever, and covers every patient who takes the medication. It is the most likely means of discovering novel, uncommon ADRs and typically produces safety flags that must be investigated further.<sup>17</sup> The main drawbacks are the difficulty in recognizing previously unreported reactions, particularly those that are not typically considered ADRs, and under-reporting, which is varied, sensitive to reporting cues, and difficult to measure. It normally does not confirm assumptions; nonetheless, there are cases where spontaneous reporting data alone allows us to conclude that a signal indicates a true ADR.[7]

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### PRESCRIPTION EVENT MONITORING

PEM is a non-interventional, observational cohort method of pharmacovigilance. PEM studies are cohort studies in which general practitioners complete basic questions after receiving exposure from a centralized provider. Nineteen follow-up forms are sent for certain occurrences. Because PEM includes all events, not only suspected ADRs, PEM cohorts may differ in terms of the distribution of events per person depending on the nature of the medicine being studied. This variation can be attributed to either the disease for which the medicine is prescribed (for example, a condition with high morbidity will have, on average, a higher number of occurrences per person than a condition with low morbidity) or the drug effect itself.[7]

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### TARGETED CLINICAL INVESTIGATION

When significant hazards are detected during pre-approval clinical trials, additional clinical studies may be required to investigate the mechanism of action for the adverse event. In some cases, pharmacodynamics and pharmacokinetics studies may be performed to establish whether a specific dosing instruction puts patients at risk of adverse outcomes. Genetic testing can also help determine which patients are more likely to experience unfavourable effects. Furthermore, specific studies to explore potential drug-drug interactions and food-drug interactions must be done depending on the drug's pharmacological qualities and intended use in general practice. These investigations may include population pharmacokinetic studies and medication concentration monitoring in patients and healthy volunteers.[7]

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## STRENGTHING OF PHARMACOVIGILANCE

To strengthen the PV system, we first need to raise awareness among HCPs. It is the most important aspect of the process since HCPs are the primary source of ADR reporting because they are the ones who spend the most time with patients. We should organize advanced-level training for the involved personnel of all ADR monitoring centres (AMC) in their respective areas. Increase the amount of CME in pharmacovigilance at all AMCs to raise HCPs' awareness of ADR reporting. All accredited medical colleges, hospitals, private and corporate hospitals, and other relevant entities should have their own pharmacovigilance monitoring system. Increase awareness and dissemination of information to the general public about adverse drug reactions, their importance, when to report, what to report, how to report, and where to report through public lectures, media communications, pamphlets, roleplaying, and other means that will reinforce the information to be passed on to them. Newsletters and emails should be sent to HCPs regularly to keep them up to date on developments. They should be congratulated and acknowledged positively when they provide proper ADR reports, which will enhance morale and trust in them. The National Coordinating Centre (NCC) at the Indian Pharmacopoeia Commission in Ghaziabad has taken a few steps to further ease the process of ADR reporting, including the introduction of a toll-free helpline number, an ADR reporting mobile application, the availability of an ADR reporting form in vernacular languages, and the establishment of ADR monitoring centers with a dedicated pharmacovigilance safety associate to monitor, collect, assess, and report ADRs.[20]

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## NATIONAL PHARMACOVIGILANCE PROGRAM IN INDIA

On January 1, 2005, the government of India, under the command of the Central Drug Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India, New Delhi, officially launched the WHO-sponsored and World Bank funded National Pharmacovigilance Program (NPVP) for India, which was largely based on the recommendations made by WHO in its document titled "Safety Monitoring of Medicinal Products - Guidelines for Setting Up and Running a Pharmaco."9 The National Pharmacovigilance Advisory Committee, which is housed at the Central Drugs Standard Control Organization, was to manage the initiative. Prior to the inception of the NPVP, Dr. Ashwani Kumar (Chairman, National Pharmacovigilance Advisory Committee, NPVP), Dr. Brijesh Regal (Advisor, NPVP), and Dr. R. K. Rishi (Senior Scientific Assistance, CDSCO) played important roles in its formation. Under this NPVP, the Department of Pharmacology at the All India Institute of Medical Sciences in New Delhi (led by Prof. S. K. Gupta) was appointed as the National Coordinating Centre (NCC) for monitoring Adverse Drug Reactions (ADR) in the country to protect public health. The NPVP structure is depicted in Figure 1. The South-West (SW) zonal center (located in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai) and the North-East (NE) zonal center (located in the Department of Pharmacology, AIIMS, New Delhi) were tasked with gathering information from across the country and sending it to the committee as well as the Uppsala Monitoring Centre (UMC) in Sweden. Each regional center, in turn, would receive reports from numerous periphery centers (a total of 24). The program had three broad objectives. The short-term goal was to instill a reporting culture, the intermediate goal was to involve a large number of healthcare professionals in information dissemination, and the long-term goal was for the program to serve as a baseline for worldwide drug monitoring. This program, which ran for five years (2005-2010), played a vital role in accumulating ADR data, much like previous WHO Special Centres. Unfortunately, many reputable institutes were not included in the NPVP, particularly ones that had already been sensitized, such as all previous WHO Special Centres.[21] The National Pharmacovigilance Program and the Pharmacovigilance Programme of India are the most recent advancements in this field in the country [22].

### PHARMACOVIGILANCE IN US:

The FDA's Office of Surveillance and Epidemiology (OSE) of the Center for Drug Evaluation and Research (CDER) oversees the pharmacovigilance efforts. Reports of pharmaceutical errors and unplanned adverse events are sent to the FDA. MEDRA, the medical lexicon for regulatory activities, is used to code the reported activities and indications for use [23]. The FDA Adverse Event Reporting System (FAERS) is used to report the adverse occurrences. One centralized source for reports of spontaneous adverse events is called FAERS, and it's quite useful for finding unidentified adverse events that go undetected in clinical trials. Potential demographic groupings and other elements that can raise the risk of a product are identified with the aid of FAERS data. FAERS is limited, nevertheless, by issues like underreporting, reporting bias, missing and incomplete data, and duplicate reporting. It is impossible to gauge the frequency of any particular bad event[24]. Reports are sent directly to the FDA via MED-WATCH, the agency's adverse event and safety information reporting system. Med-Watch offers a number of reporting options for patients, customers, and medical professionals. Every authorized new drug application (NDA) or abbreviated new drug application (ANDA) is required by 21 CFR 314.80 to disclose any adverse medication occurrence. After the first three years, these should be supplied annually, then quarterly. Anyone who is willing can use Med-watch FDAFORM-3500 to voluntarily report the adverse occurrence. Customers can report using Med-Watch FORM-3500B; filling out the form requires following certain steps. All pharmaceuticals that are on the market and therapeutically biological items that can trigger early signal detection of examination of new and major adverse events are routinely monitored for safety by the clinical reviewers in the CDER office.[25]

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## PHARMACOVIGILANCE IN AUSTRALIA

The World Health Organization - external site defines pharmacovigilance as the research and actions involved in identifying, measuring, understanding, and preventing side effects and other medical concerns. The Therapeutic Goods Administration (TGA) gathers and reviews data on the benefit-risk balance of medications in Australia to monitor their safety and, if necessary, take appropriate action. This guidance outlines the pharmacovigilance duties of sponsors of medications listed on the Australian Register of Therapeutic Goods (ARTG) and overseen by the TGA. It describes the necessary reporting obligations and provides recommendations on pharmacovigilance best practices.[26] The Australian Drug Evaluation Committee was established in 1963 in response to reports of thalidomide embryopathy, and pharmacovigilance began formally. Despite many policy and committee name changes, statistics

on adverse events have been collected regularly since then. Pre- and post-marketing surveillance, including pharmacovigilance, is overseen by the Therapeutic Goods Administration (TGA) subcommittee on medicines, which was established in January 2017. Previously, adverse events were reported to the TGA by submitting a 'blue card'.<sup>2</sup> These cards are no longer available in their physical form. Clinicians can now report the TGA of adverse events using the online Australian Adverse Drug Reactions Reporting System.<sup>3</sup> Alternatively, reports can be submitted by phone, mail, fax, or email. The TGA accepts adverse event reports from anybody, including the general public (via a separate online consumer site). A report can be submitted even if there is simply a suspicion that a medicine is producing an adverse impact. It is the TGA's job to investigate and establish the cause. While it is ideal for all adverse occurrences to be recorded, the TGA is particularly focused on those instances. Reporting previously known or common adverse occurrences allows the TGA to continue building a drug safety profile'.<sup>[27]</sup>

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## SHOWING THE BLUE CARD: REPORTING ADVERSE REACTIONS

An adverse reaction reporting system's primary aim is to identify harmful side effects linked with medication use. Since 1964, the Australian system has led to the early detection of numerous drug-related disorders. Healthcare professionals, pharmaceutical companies, and consumers can report suspected adverse drug reactions to the Therapeutic Goods Administration's Adverse Drug Reactions Unit. The reports are evaluated, coded, and placed into a database before being examined for trends in adverse events. Selected reports are given to the Adverse Medicine Reactions Advisory Committee, which can make recommendations ranging from no action to withdrawing a medicine from the market. The Committee's important job is to inform healthcare professionals about the unfavorable impacts revealed by their reports. In Australia, healthcare professionals, pharmaceutical companies, and consumers can all report suspected adverse drug reactions to the Adverse Drug Reactions Advisory Committee (ADRAC). Healthcare practitioners typically submit reports on the 'blue card' that accompanies the Australian Adverse Drug Reactions Bulletin and the Schedule of Pharmaceutical Benefits. Reports can also be sent by letter, fax, or electronically [28].

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## MEDICINE SAFETY UPDATES

Medicines Safety Update (MSU) provides health professionals with practical drug safety information and recommendations, as well as updates on new safety risks. It provides information on adverse event reporting and how health professionals can help with safety monitoring in Australia. [28]

### MEDICAL DEVICE SAFETY UPDATES

Health professionals can find useful information and guidance on medical device safety, as well as information on emerging safety issues, from the Medical Devices Safety Update (MDSU).

It provides information on adverse event reporting and how health professionals can help with safety monitoring in Australia. [29]

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## QUALIFIED PERSON RESPONSIBLE FOR PHARMACOVIGILANCE IN AUSTRALIA

In Australia, you should have a qualified person in charge of all pharmacovigilance activities. Ideally, this person will also serve as the A-PVCP in charge of reporting to the TGA and coordinating our pharmacovigilance communications. The qualified person responsible for pharmacovigilance in Australia (QPPVA) must verify that the sponsor has an efficient pharmacovigilance system in place and meets all legal pharmacovigilance standards.

The QPPVA should be based in Australia, available between 9 am-5 pm AEST Monday-Friday, trained in pharmacovigilance and relevant legislation, and medically qualified (or have access to one). We prefer that this medically qualified individual live and be medically registered in Australia so that they may address adverse reactions, safety concerns, and the benefit-risk balance of drugs in the Australian setting.

The QPPVA should be appropriately experienced and qualified to monitor the safety of your medications. Individual QPPVA characteristics and skills should be tailored to their specific tasks and responsibilities, ensuring that you can achieve your pharmacovigilance standards. The QPPVA must have a thorough awareness of both Australian and global pharmacovigilance processes to effectively oversee the complete pharmacovigilance system.<sup>[30]</sup>

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