



## Pharmacovigilance: A Necessary Tool for Drug Safety Monitoring Globally

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### Abstract

Pharmacovigilance, which is like a parasol to define the procedures for monitoring and analysing adverse drug reactions (ADRs), is a crucial part of efficient clinical practise, public health initiatives, and drug control systems. The volume of data processed has increased as a result of the rise in reported adverse drug reactions (ADRs), and understanding pharmacovigilance requires a high degree of skill in order to quickly identify medication hazards and defend the product against an unwarranted removal. An impartial method of evaluation would strengthen the present global network of pharmacovigilance centres, which is managed by the Uppsala Monitoring Centre. This would take into account contentious and significant medication safety problems that might have a negative impact on public health across international borders. Pharmacovigilance has recently focused mostly on identifying previously unrecognised or poorly understood adverse medication occurrences. Pharmacovigilance is a crucial and essential component of clinical research, and it is now expanding in many nations. However, with the turn of the millennium, pharmacovigilance confronts enormous hurdles in aspect of improving safety and monitoring of medications. Today, several pharmacovigilance centres are engaged for drug safety monitoring in this global arena. In this overview, we'll talk about medication safety, the function of international pharmacovigilance centres, the advantages and drawbacks of pharmacovigilance, and how it may be used in the future by the healthcare industry.

**Keywords:** Drug safety, Adverse drug reaction, Drug Monitoring, Erice declaration, pharmacovigilance.

## 1. Introduction

Pharmacovigilance and drug safety continue to be active fields of clinical and scientific study. The World Health Organisation (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem." Pharmacovigilance is essential in ensuring that doctors and patients have access to sufficient information to make informed drug treatment decisions. Despite all of their advantages, there is still mounting evidence that some medications can induce serious side effects, which are a prevalent but frequently avoidable source of sickness, disability, and even death. Adverse drug effects are those effects that are unwanted and undesirable and are most likely related to a drug<sup>1</sup>. Adverse drug reactions (ADRs) are among the top 10 main causes of death in various nations. Mechanisms for assessing and monitoring the safety of medications used in clinical settings are essential to avoid or decrease patient damage and hence enhance public health. In the next ten years, pharmacovigilance programmes will briefly outline any potential effects these developments may have on the advancement of research. Pharmacovigilance is currently up against several obstacles as it attempts to improve healthcare systems on a worldwide scale. Globalisation, web-based sales and information, larger safety concerns, public health vs pharmaceutical industry economic expansion, monitoring of existing medicines, new and growing nations, attitudes and perceptions regarding gain from and damage from, results and impacts, and are some of the main obstacles<sup>2</sup>.

Pharmacovigilance (PV) was formally established in December 1961 with the publication of a letter (case report) in the Lancet by W. McBride, an Australian physician who had first hypothesised a connection between thalidomide, a medication used during pregnancy as an antiemetic and sedative, and severe foetal deformities (phocomelia)<sup>3,4</sup>. In order to centralise global data on adverse drug reactions (ADRs), the World Health Organisation (WHO) developed the "Programme for International Drug Monitoring" in 1968. The "WHO Programme" has the specific objective of locating the first PV indications. The term PV was proposed in the mid-70s by a French group of pharmacologists and toxicologists to define the activities promoting "The assessment of the risks of side effects potentially associated with drug treatment".

### 1.1. WHO: Drug Safety Monitoring Historical Perspectives

In 2002, there were pharmacovigilance facilities in over 65 nations. The WHO Collaborating Centre for International Drug Monitoring, often known as the Uppsala Monitoring Centre (UMC), manages membership in the WHO for International Drug Monitoring. Pharmacovigilance today has a solid scientific foundation and is essential to efficient clinical practise. To satisfy the needs of contemporary public health and the expectations of the general public, the discipline must advance<sup>5,6</sup>. The WHO Pilot Research Project for International Drug Monitoring was established as a result of a resolution (WHA 16.36) that was approved by the Sixteenth World Health Assembly. This resolution reiterated the necessity of early action with regard to the quick transmission of

information on adverse drug reactions. The goal of this was to create a system that could be used globally to identify side effects of medications that were either previously undetected or poorly understood.

## 1.2. Teams of Pharmacovigilance around the World

The practise of drug safety monitoring involves a variety of partners in a complicated and crucial connection. The wants and demands of the public, healthcare administrators, policymakers, and politicians must be anticipated, understood, and addressed by these partners in concert <sup>7</sup>.

**The Safety and Quality Assurance:** The Division of Essential Drugs and Medicines Policy of the WHO Health Technology and Pharmaceuticals cluster includes the Safety and Quality Assurance group. The department's goal is to bridge the tremendous gap that exists between the promise that life-saving drugs possess and the millions of people—especially the impoverished and underprivileged—who do not have access to, cannot pay, or misuse these drugs.

**The Monitoring Centre in Uppsala:** Overseeing the global database of ADR reports collected from National Centres is the primary duty of the Uppsala Monitoring Centre. The UMC facilitated international communication and established uniform reporting for all National Centres to promote prompt signal discovery. <sup>8</sup>.

**The National Pharmacovigilance Centres:** National Centres have made the public more aware of the safety of medications. This evolution can be partly attributed to the fact that many national and regional centres are located inside of medical facilities, academic institutions, or poison and drug information centres rather than behind the walls of a drug regulating agency <sup>9</sup>. To gather epidemiological data on adverse medication reactions, major centres in industrialised nations have set up active surveillance projects employing record linking and prescription event monitoring systems (PEM). New Zealand, the United Kingdom, Sweden, and the United States of America have already adopted such systems. The total cost of a pharmacovigilance system is incredibly low when compared to the national spending on medications or the cost of ADRs to the country.

**Hospitals and Universities:** Strict tracking procedures for medication mistakes and bad responses have been put in place by a number of healthcare facilities in their ERs, wards, and clinics. Case-control studies and other pharmacoepidemiological methods are being used increasingly often to evaluate the harm associated with drugs after they have been commercialised <sup>10</sup>. Academic pharmacology and pharmacy centres' clinical services, research, teaching, training, policy development, clinical research, ethics committees (institutional review boards), and clinical research have all made substantial contributions to society.

**Health Care Professionals:** At first, only doctors were asked to report on their experiences using differential diagnosis to determine whether a certain symptom is caused by a disease or medication. Different sorts of healthcare workers may see various drug-related issues today.

**Patients:** The real advantages and hazards of a drug are only known to the patient. Direct patient knowledge and engagement will improve the efficacy of the pharmacovigilance system and offset some of the shortcomings of methods that depend only on reporting from medical professionals <sup>11</sup>.

## 1.3. Pharmacovigilance in International Health

An independent method of review would improve the present worldwide network of pharmacovigilance centres, which is overseen by the Uppsala Monitoring Centre. This would take into account disputed and significant medication safety problems that might have a negative impact on public health across international borders <sup>12</sup>. The Erice Declaration offers a framework of principles and practises for the gathering, evaluation, and subsequent dissemination of information on drug safety concerns. Despite the advancements in pharmacovigilance, the burden of ADRs on public health is still quite high in the modern world. According to pharmacoeconomic research on the costs of adverse responses, governments spend a sizeable percentage of their health budgets to cover these expenditures.

The relationship between socio-political, economic, and cultural issues and the safety profile of medications, which in turn affects access to medications, usage patterns among patients, and public views of them, has come to light more and more recently <sup>13</sup>.

**Drug utilization:** Drug safety is greatly influenced by drug use habits. In one instance, injectable medication usage is more widespread in underdeveloped nations. Prescription drug advertising that directly targets the customer has grown widespread in several nations. Patients feel more equipped to choose their own treatments without help from a doctor or chemist after receiving this information. As a result, more people are self-medicating, more drugs are being sold legally and illegally online, and doctors are over-prescribing medications in response to patient requests. This has significantly impacted the rise in prescriptions. However, these public health initiatives might be utilised to the advantage of the entire population and need not just be centred on patients <sup>14,15</sup>. Partnerships with the media, educational institutions, governmental and non-governmental organisations might considerably aid such awareness-building and educational campaigns, which should also involve children and elderly communities. National pharmacovigilance centres' contributions are essential to the accomplishment of WHO International Drug Monitoring Programmes. A pharmacovigilance centre should ideally exist in each nation.

## 1.4. Pharmacovigilance programme in India

The issue of ADR monitoring has just lately gained attention in India as there isn't a traditional paradigm for drug surveillance there. In India, PV is not a novel idea. This idea did not exist until 1986, when a small number of physicians—mostly from academic institutions—demanded that greater attention be paid to possible prescription drug side effects and prudent medication prescribing <sup>16, 17</sup>. This led to the development of the initial ADR monitoring scheme, which included 12 regional centres with a total population of 50 million but was ultimately unsuccessful. Not much happened until India ten years later, in 1997, when it entered the WHO Adverse Drug Reaction Monitoring Programme, based in Uppsala, Sweden <sup>18</sup>.

The three emphasises for ADR monitoring have been discovered determined; these are based in teaching hospitals and include a National Pharmacovigilance Centre in the Department of Pharmacology at the All India Institute of Medical Sciences (AIIMS), New Delhi, as well as two WHO special centres in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh). It was necessary for these institutions to report ADRs to the drug regulatory authorities in India <sup>19</sup>. The primary responsibility of these facilities was monitoring adverse drug reactions (ADRs) to medications marketed in India. They were ineffectual, nonetheless, because neither the government nor the prescribers supplied funding or

information about the monitoring centres' functions or the necessity of reporting adverse drug reactions. Since this attempt was not successful, on January 1, 2005, the World Bank-funded National Pharmacovigilance Programme (NPVP) for India was established under the sponsorship of WHO<sup>20</sup>.

#### 1.4.1. Current situation of Pharmacovigilance programme in India

The foundation of the new and current programme was developed in a brainstorming session hosted by the Department of Pharmacology, AIIMS, and CDSCO in late 2009 when it became clear that the NPVP needed to be restarted. The Government of India launched the programme, currently known as the Pharmacovigilance Programme of India (PVPI), on July 14, 2010, with the AIIMS, New Delhi serving as the National Coordination Centre (NCC) for tracking adverse drug reactions (ADRs) across the nation in order to protect public health. A total of 22 ADR monitoring centres, including AIIMS in New Delhi, were established under this scheme in 2010<sup>21</sup>. On April 15, 2011, the NCC was moved from the AIIMS, New Delhi, to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh, to facilitate more effective programme execution. The primary goal of the NCC at IPC is to produce independent data on the safety of medications that will be in line with international standards for drug safety monitoring.

In accordance with the input of ADR's in the VigiFlow, the most current report of the AMC's under the PVPI has been reported. In all, NCC received 1,948 Adverse Events Following Immunisation (AEFI) reports and 3,537 Individual Case Safety Reports (ICSRs) from AMCs in May 2014. VigiFlow is now available to seven more centres thanks to UMC, Sweden. A total of 82 of the 97 AMCs where Vigiflow is operational have submitted ADR reports using VigiFlow. In May 2014, 311 ADR reports were submitted by PGIMER, Chandigarh, followed by 225 reports from MMC, Chennai, 216 reports from JSS, Mysore, 184 reports from UCMS-GTBH, Delhi, and 167 reports from LHMC, New Delhi. At NCC, these reports are undergoing (quality and medical) evaluation<sup>22</sup>.

#### 1.4.2. Haemovigilance programme in India

Haemovigilance is the ongoing process of gathering and analysing data on adverse responses to blood transfusions in order to understand what causes them, what happens when they do, and how to stop it from happening again. As part of the PVPI, IPC and the National Institute of Biological Sciences (NIB) in Noida have started the Haemovigilance Programme of India (HVPI), which has two major goals<sup>23</sup>. To assess adverse reactions/events and their frequency related to the delivery of blood products and transfusions, first, and to assist in identifying trends, best practises, and interventions needed to enhance patient care and safety while lowering total healthcare costs, second.

To guarantee patient safety during and after a blood transfusion, transfusion reactions (TRs) must be identified and managed. Acute transfusion responses (ATRs) and delayed transfusion reactions are two categories that each encompasses several subtypes of transfusion reactions. At the onset of the response, it might be challenging to categorise different ATRs because they all exhibit similar signs and symptoms. Additionally, TRs are frequently both under-reported and under-recognized. A national haemovigilance system and a set of national guidelines setting regulations for blood transfusion as well as the identification and management of TRs must be put into place in order to ensure standard practise and safety<sup>24</sup>. In this regard, the hemovigilance initiative, which was introduced on December 10th, 2012, has already engaged 90 Medical Colleges of India as a core component of PVPI. The National Institutes of Health

(NIB) serves as the HVPI's coordination hub for gathering and compiling data on hemovigilance from medical facilities around the nation. The NIB's IT Division created the programme "Haemo-Vigil".

#### 1.5. Clinical trials in India

India has become a favourite location for clinical trials for international pharmaceutical firms as a result of the country's very appealing clinical research environment and prospects. India provides several benefits for conducting clinical trials, including the following:

- Availability of well qualified, English speaking research professionals including physicians.
- Thorough adherence to international standards, including those set forth by the US Food and Drug Administration and the International Conference on Harmonisation (ICH)/World Health Organisation Good Clinical Practise (ICH-GCP).
- Ongoing support and cooperation from the government.
- Lower cost compared to the west.
- Increasing prevalence of illnesses common to both developed and developing countries.
- Availability of good infrastructure.
- Changes in Patent Laws since January 2005.

According to a recent report from the Federation of Indian Chambers of Commerce and Industry (FICCI), some of the growth drivers responsible for the transformation of Indian clinical research in the recent past include scientific feasibility, medical infrastructure, clinical trial experience, regulations, commercialization potential, and cost competitiveness. In comparison to more recent market entries, Indian-born contract research organisations (CROs) were able to provide the benefits of a greater grasp of the Indian context, the ability to deliver services at more affordable rates, and a deeper familiarity with Investigator locations around the nation<sup>25,26</sup>. One of the key factors driving the expansion of clinical research in India is the country's favourable regulatory environment, which complies with international standards. Another is the growing knowledge of good clinical practise guidelines and the execution of those recommendations by doctors.

The National Pharmacovigilance Advisory Committee, which is situated at the Central Drugs Standard Control Organisation (CDSCO), was supposed to manage the NPVP, which was founded in January 2005. To gather data from across the nation and send it to the committee as well as the Uppsala Monitoring Centre (UMC) in Sweden, two zonal centres were established: the South-West (SW) zonal centre (located in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai) and the North-East (NE) zonal centre (located in the Department of Pharmacology, AIIMS, New Delhi). The Mumbai centre will get reports from three regional centres, and the New Delhi centre from two<sup>27</sup>. There would be multiple peripheral centres (a total of 24) reporting to each regional centre in turn. There were three main goals for the programme. Fostering a reporting culture was the short-term goal. Involving a large number of healthcare professionals in the system in information dissemination was the intermediate goal. The program's long-term goal was to serve as a model for worldwide drug monitoring. But this programme also fell short<sup>28</sup>.

## 1.6. SWOT Analysis of Indian Clinical Trial Sector

### Strengths

- With an estimated population in excess of 1.2 billion, or around 16% of the global population, it has a sizable pharmaceutical and biotech sector base and a competent labour pool.
- The third-biggest global players, including 500 distinct active medicinal compounds.
- Currently ranks fourth in the globe and produces 8% of all pharmaceuticals produced worldwide.
- Helpful government measures to capitalise on India's innovative potential.
- Due to the vast population, extensive data mining is possible on the safety profile of pharmaceuticals.

### Weaknesses

- According to predictions for 2021–2022, spending on the health sector accounted for 2.15% of India's overall budget and 0.35% of its GDP.
- The United States, France, Switzerland, and Germany are examples of developed nations that spend around 16%, 11%, 10.8%, and 10.4% of its GDP, respectively.
- Less money available to tackle national priority programmes and concerns like PV.

### Opportunities

- With over 300 medical, 230 dental, >830 pharmacy, and >650 accredited nursing colleges in India, the Indian population is the largest source of human biodiversity.
- It also comprises 4635 culturally and anthropologically well-defined populations, making it an ideal model for studying drug efficacy, disease susceptibility, aetiology, molecular pathology, and safety profile with regard to genetic diversity.

### Threats

- Inadequate ADR reporting.
- Limited financial resources.
- ADR monitoring centres are fewer.

## 1.7. Data mining for Pharmacovigilance programme in India

The science of improving patient care and patient safety with relation to medication usage is known as PV, sometimes known as drug safety surveillance. It involves gathering, monitoring, assessing, and interpreting data from patients and healthcare professionals<sup>29</sup>. According to this perspective, PV may be separated into two stages, such premarketing surveillance, where data on adverse drug reactions is gathered from pre-clinical testing and phases I through III of clinical trials. Due to the enormous amounts and complexity of the data that must be analysed, computational approaches that can effectively detect ADRs in a timely manner have become a crucial part of PV. Traditionally, PV has depended on biological tests or manual evaluation of case reports<sup>30</sup>.

Large-scale compound databases with information on structure, bioassay, and genomics, together with extensive clinical data sets like electronic medical record (EMR) databases, have evolved into the resources that allow for the development of computerised ADR detection techniques.

### 1.7.1. Premarketing surveillance

Early in the drug development pipeline, PV has been devoted to foreseeing or evaluating probable adverse drug reactions (ADRs). Utilising preclinical in vitro Safety Pharmacology Profiling (SPP) by putting substances through biochemical and cellular tests is one of the key techniques. According to the theory, if a substance binds to a specific target, its action might potentially result in an ADR in people. However, in terms of price and effectiveness, experimental ADR detection is still difficult<sup>31</sup>. Developing computational methods to anticipate probable ADRs utilising preclinical properties of the drugs or screening data has been the subject of various research projects. The majority of current research falls into two categories: protein target-based and chemical structure-based techniques. Others have investigated an integrated strategy.

### 1.7.2. Post-marketing surveillance

Even when a medicine is thoroughly examined before the Food and Drug Administration (FDA) approves it, many adverse drug reactions (ADRs) may still go undetected since clinical studies are frequently small, brief, and biased by omitting patients with concomitant conditions. Premarketing studies do not accurately represent real clinical usage scenarios for various groups (like inpatients); hence it is crucial to maintain post-market surveillance. In the post-market evaluation of recently discovered medications, Pharmacovigilance (PV) is crucial. Prior to introducing a new medicine to the market, a lengthy research and development process is enabled by the rivalry among pharmaceutical firms and strict regulatory review procedures. There are several distinctive data sources accessible for post marketing PV.

The examination of "signals" is the foundation of PV research. Signals are unreported claims about the connections between a drug's potential to cause adverse events and impacts on the human body, according to the World Health Organisation (WHO). Clinicians and researchers employ spontaneous reporting systems (SRS) to produce extensive signal databases<sup>32</sup>. There are already electronic SRSs in place in various nations of Europe and the US. Other options are also being carefully investigated, including examination of general practitioners' databases, post-market research, and prescription monitoring, among others. The majority of data, however, is not readily accessible to researchers, which, when combined with other obstacles, substantially restricts signal discovery.

Medication companies are supposed to monitor and handle adverse events reported by doctors, attorneys, or patients; nonetheless, the majority of the detection process depends on the doctor's capacity to identify a specific characteristic as a medication adverse event. Although the issue of gathering and filtering ADR data from several dispersed nodes has already been researched, researchers are still looking for the most effective ways to examine the vast amounts of gathered data in conjunction with other post-drug administration inputs<sup>33</sup>. PV researchers are now challenged with the challenge of providing knowledge-oriented tools and services that take advantage of the breadth of acquired data after data and text-mining algorithms have scavenged millions of electronic medical records. The proper investigation of this data will eventually pave the way for better medication assessments, which are essential for pharmaceutical businesses, regulatory bodies, and researchers<sup>34</sup>.

### 1.7.3. Yellow Card Scheme

Systems for unscheduled reporting were subjected to yellow card schemes (YCS). As a result of the catastrophe of thalidomide, it was founded in 1964. Since then, the system

has grown to be one of the main suppliers of PV energy on a global scale.

The group on Safety of Medicines (CSM), an expert group, and the Medicines Control Agency (MCA), a regulatory body, together manage the Young Clinical Scientists (YCS). A new computer system called ADROIT (Adverse Drug Reaction

Online Information Tracking) has improved the YCS since 1991<sup>35,36</sup>. In contrast to other databases, ADROIT is unique. It also stores the picture of the yellow card in the optical system in addition to the report's specifics. Any yellow card may be viewed on the screen by many people simultaneously. The reports are ranked in order to give priority to significant medication reactions.

Figure 1: Sample Yellow Card<sup>37</sup>

### 1.8. The Erice Declaration

When viewed in the context of these pharmacovigilance reforms, the Erice Declaration constituted a significant advancement. The Declaration calls on all relevant parties—including the public health administration, medical professionals, the pharmaceutical industry, the government, drug regulators, the media, and consumers—to work towards the highest ethical, professional, and scientific standards in order to safeguard and encourage the safe use of medications. The Declaration exhorts governments and other decision-makers to take into account what they say to the general public and patients when making decisions about the value, harm, efficacy, and risk of medications<sup>38</sup>.

**Challenges for the Erice Declaration:** Pharmacovigilance initiatives face a number of obstacles in their quest to fulfil the goals of the Erice Declaration. Like the challenges and dangers of delivering contradictory or divisive messages to the general audience. For instance, during immunisation campaigns, the dissemination of fresh safety issues relating to the vaccine(s) or to programming faults may cause a sharp decline in coverage<sup>39</sup>. However, taking a secretive posture in these situations is likely to weaken public confidence and respect for the people's right to participate in decision-making. Facts and numbers must be made available to the public, but so must the method used to evaluate the data and the decision-making process. Another issue is the need for greater communication between national drug regulatory agencies and national pharmacovigilance centres so that regulatory decisions with potential global repercussions are quickly relayed to regulators, preventing broad public anxiety or panic.

## 2. Challenges of Pharmacovigilance programmes

The PVPI's major problem is the egregious underreporting of negative consequences. This is due to a variety of factors, such as poor national knowledge of PV and a lack of medical experience in drug administration and competent resources in PV. Other difficulties include infrastructure that is still

conservative, a long lag between regulations and laws, a traditional view of new drug research, and essentially non-existent regulatory and PV inspections. Given that India has a highly developed IT industry, the system has to be improved with the assistance of PV professionals working with IT<sup>40</sup>. Since PV deals with a lot of ADRs, it would be a good idea for PV specialists to work with software specialists to create and build a reliable system. Software programmes can be used for data collecting and analysis, trend analysis of drug consumption across a range of disease areas, compliance, medication mistakes, and drug interactions leading to adverse drug reactions (ADRs). Additionally, with more clinical research and PV outsourcing projects being carried out in India, it has been beneficial for the DCGI to invest in a reliable PV system to allow assessors and decision-makers to analyse safety data and take regulatory judgements without having to rely on other nations<sup>41,42</sup>.

On admission, doctors may not always recognise ADRs, and as a result, many patients may die as a result of ADRs. ADRs can come at a significant financial expense to the healthcare system. Patients self-medicate and increasingly convert from prescription-only (POM) to over-the-counter (OTC) medications when new drugs are introduced to the market without long-term safety evaluations by regulatory authorities, which is the major cause of ADR exposure. In the past, medication manufacturers and regulatory organisations in India focused their evaluations of a medicine's safety on long-term user experiences. Numerous Indian businesses have recently increased their R&D spending and improved their ability to create and commercialise novel medicines through in-house research. After a product is launched, more data will be produced, which might change the product's benefit-risk profile. To guarantee the safe use of all goods, a thorough review of the new information created by PV operations is necessary. Therefore, DCGI needs to make some difficult choices, commit to making PV necessary, and establish a culture of PV inspections<sup>43</sup>.

### 3. Future prospects

In order to preserve public health, it is necessary to have PV systems that can identify new adverse drug reactions and implement regulatory measures. Producing data that can aid a healthcare practitioner or patient in making decisions has not received much attention. A major objective of PV is the collecting and dissemination of this data. It's important to know the safety of medication active surveillance. When creating new techniques for active post-marketing monitoring, it's crucial to remember how crucial it is to gather comprehensive and precise information on every major reported incident. Although spontaneous reporting is a valuable method for producing signals, it is less useful for identifying patient features and risk factors due to the generally low number of reports received for a given connection. PV techniques additionally need to be able to identify the patients who are most likely to experience an ADR<sup>44</sup>. The PV method would be in line with the rising patient participation in medication safety as a source of knowledge. Individual risk factors for the incidence of specific ADRs may be identified by the PG. In addition to the more conventional groups, including the health professionals, PV must now focus on the patients as a source of information.

It is therefore necessary for the DCGI to reinforce PV in order to incorporate Good Pharmacovigilance Practise (GPP) into the systems and processes, help ensure regulatory compliance, and enhance post-marketing monitoring and clinical trial safety. A functional PV system is required if drugs are to be utilised carefully. Consumers, pharmaceutical companies, government regulators, and medical experts will all benefit. It supports pharmaceutical companies' risk evaluation of their medicines. Regulating bodies and the industry as a whole today find post-marketing photovoltaics to be a challenging and time-consuming process.

The PV's goal is to make information, work documentation, and expertise available online with a focus on pressing new safety concerns. Even though they are equally often checked, non-serious incidents are given less importance than major ones but are nonetheless crucial for comparing health improvements. GlaxoSmithKline has developed a potent new method for PV that combines case-based, standard PV techniques with tools for data visualisation and disproportionality. These technologies are part of a system structure that enables knowledge management, in-stream evaluation, and monitoring of safety problems. PV will progress thanks to the procedures and this incredibly inventive equipment, which will increase productivity and offer new analytical skills. Pharmaceutical businesses may use a similar strategy to quickly discover and analyse ADRs. Consumer reporting would be strengthened by transparency and communication, which are constructive measures towards incorporating consumers more in PV<sup>45</sup>.

#### 3.1. Other future considerations for international challenges

Several important aspects that could be changed in the future to create better pharmacovigilance practices are as follows:

1. The goal of pharmacovigilance should be to increase safety knowledge rather than to identify damage.
2. Formal decision analysis is applicable to complex risk-benefit choices and is likely to enhance them.
3. A society of scientific advancement should guide the practice of pharmacovigilance. This calls for the proper mix of contributions from different fields, a more robust academic foundation, more accessibility to fundamental training, and resources devoted to scientific strategy.

4. Agreed standards (also known as "good pharmacovigilance practice") should be the basis for developing and implementing an organised audit of pharmacovigilance procedures and results.

**Some Major challenges face pharmacovigilance are as follows:**

**3.1.1. Globalization:** The expansion of the population's access to medications and the globalisation of drug delivery. These include brand-new chemical compounds used to treat symptoms and alter lifestyles, as well as drugs used in underdeveloped nations to reduce the occurrence of pandemic illnesses like HIV/AIDS, malaria, and TB<sup>46</sup>.

**3.1.2. Web-based sales and information:** Along with its numerous advantages, the Internet has made it easier for drugs to be sold unrestrictedly across international borders. Through this medium, drug information in all its forms and with varied degrees of veracity is disseminated globally. Prescription pharmaceuticals, unregistered medications, highly regulated narcotics, and conventional and herbal medications with dubious safety, effectiveness, and quality are all covered by this material.

**3.1.3. Broader safety concerns:** As the variety of pharmaceutical drugs expands, so does the scope of pharmacovigilance. There is an understanding that monitoring, detecting, and evaluating ADRs occurring under precisely specified circumstances and within a certain dosage range are just a small part of medication safety. Instead, it is intimately related to societal drug usage habits. Pharmacovigilance deals with issues such as irrational drug use, overdoses, polypharmacy and interactions, increased use of traditional and herbal medicines in combination with other medications, illegal sales of drugs of abuse over the Internet, increased use of self-medication, substandard medications, medication errors, and lack of efficacy. In order to appropriately meet this enormous breadth, current mechanisms must change.

**3.1.4. Public health versus pharmaceutical industry economic growth:** When addressing public health issues brought on by medication safety concerns, the pharmaceutical sector may have weaknesses and perhaps conflicting interests. The industry must address issues with post-marketing surveillance and clinical trial safety monitoring<sup>47</sup>.

**3.1.5. Monitoring of established products:** The generic pharmaceutical market segment has not completely acknowledged its obligation to regularly check the safety of its goods throughout the globe. There is a false notion that generic medications are always risk-free, especially when they combine with other medications. The main provider of necessary medications is the generic industry.

**3.1.6. Attitudes and perceptions to benefit and harm:** The way that society uses medications has been significantly altered by these changes. Healthcare professionals, patients, and people in general have all responded differently to these changing patterns, as was previously covered in the chapters. Their opinions of the advantages and disadvantages of these rapid developments, in addition to the appropriate level of risk associated with pharmaceuticals, have not received much attention. There is a wealth of research demonstrating the negative effects of drugs. Morbidity and mortality from drug-induced diseases are only just starting to be prioritised in public health agendas in both wealthy and poor countries.

**3.1.7. Outcomes and Impact:** Along with growing public concern over drug safety, there is also growing public interest in how well the regulatory agencies, industry, and health professions are performing. Increased accountability must be followed by further research on the effectiveness of pharmacovigilance and its function in improving public image. Enhancing individual therapy, assisting in the diagnosis and treatment of drug-induced illness, and ultimately leading to a reduction in iatrogenic illnesses needs to be a top focus. It is imperative that patients and healthcare providers alike have access to this information.

## Conclusion:

Given the difficulties that authorities, medication producers, customers, and healthcare professionals must overcome, the PV in India has developed into a significant public health concern. The PV in India is still expanding, changing, and getting better. The world's largest manufacturer of medicines, India is also quickly becoming a major global centre for clinical trials. Evidently, a combined perspective on clinical needs, as well as criteria for professional specialisation, are required. This aids in determining risk factors for unfavourable drug therapy outcomes before starting drug therapy as well as when personalising drug therapy for specific patients. In addition, the PV has used data mining technology while submitting unprompted reports to the national surveillance systems. The PVPI is organised at IPC through NCC under the direction of the Indian Government to produce independent data on drug safety that would be in line with international standards for drug safety monitoring. The comprehensive collecting and analysis of ADR data that results in timely alarms and measures to safeguard public health is a task for which national and regional PV systems are well-suited organisations. Additionally, it is in charge of the whole effort in India to raise awareness of PV and the quantity of ADR reports to the WHO's gold standard level.

The PV system reports unfavourable incidents, and because the reporters may be quickly contacted by phone, email, or text message via mobile devices, the community could gain from these reports. They also speak the same language and are acquainted with the customs and lifestyles of patients as the general public and public health experts. The development of effective and novel medical therapies has a positive effect on people's health and wellness. PV systems need to be enhanced in order to more effectively monitor and handle pharmaceutical safety problems, which will boost their impact on public health. Consequently, with the goal to help patients recover, manage their conditions as best they can, or ideally prevent disease altogether, it is the responsibility of the pharmaceutical industry, the Health and Welfare Ministry, drug regulators, doctors, and other healthcare professionals to make sure that healthcare products are safe. The next measures and financial support are expected to foster a more expansive photovoltaic sector in India.

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