

Overview: Pharmacovigilance and Risk Management

Drug development is an expensive, lengthy, and high-risk business taking 10 to 15 years and is associated with a high attrition rate. Approximately 1 in 10 drugs that start the clinical phase will make it to the market.¹ Research on a new medicine does not end when the discovery and development phases are completed, and the medicine is available to patients. On the contrary, companies conduct extensive post-approval research to monitor safety and longterm side effects, and may also pursue research into new indications for the medicine in different disease areas, age groups, or other patient populations.² Additional clinical value of therapies is realised over time through many different pathways, leading to expanded and improved use of a drug.

One of the most important responsibilities of pharmaceutical companies is assuring the protection of human subjects. The history of egregious failures in this regard means that all stakeholders must remain ever-vigilant. The human experimentation in World War II Germany and Japan, and the Tuskegee syphilis study of 1932 to 1972 in the United States, bear witness to these failings. And it was followed by societal and institutional responses: the Nuremberg Code of 1947, the Declaration of Helsinki of 1964, and the Belmont Report of 1979.³

Pharmacovigilance is relevant for everyone whose life is touched in any way by medical interventions. The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, evaluation, understanding, and prevention of adverse reactions to medicines or any other medicine-related problems.⁴ The assessment of benefit versus risk begins during the preclinical evaluation of a medicinal product and extends throughout its full life cycle. As a result, there is added focus on safety and risk assessment after a product has received regulatory approval, when it is placed in the market and prescribed to large populations.

Risk management is a set of activities performed for identification of risk, risk assessment, risk minimisation or prevention, and risk communication.⁵ Good pharmacovigilance identifies the risks in the shortest possible time after the medicine has been marketed and will help to establish and/or identify risk factors. When communicated effectively, this information allows for intelligent, evidence-based prescribing with potential for preventing many adverse reactions and will ultimately help each patient to receive optimum therapy at a lower cost to the health system.⁶

Operational Aspects of Pharmacovigilance and Risk Management

Pharmacovigilance and risk management are essential part of pharmaceutical product development and commercialisation, the activities of which are highly regulated in many parts of the world. Rare adverse events may not be identified until large number of patients receives the product, so benefit and risk must be continually assessed as more data becomes available about the product through its use. Building pharmacovigilance and risk management capacity requires a systematic approach to ensure that all safety aspects are monitored and addressed properly (see table below).³

Activities currently included in the scope of pharmacovigilance:

Category	Specific Activities/Functions	Phase(s)*
Supporting patient safety during the conduct of clinical trials	Informed consent, institutional review board, data monitoring committee	1 to 4
Selecting the first safe dose; first-in-human	Preclinical data, especially PK/PD parameters	1
Establishing the safety profile	Assessing all phases of development, focusing on dose-limiting toxicity, maximum tolerated dose, AEs of special interest, on-target and off-target toxicities	1 to 4
Communicating information to stakeholders	Maintaining standard formats: Investigator's Brochure, Company Core Data Sheet, package insert, patient package insert, ClinicalTrials.gov	1 to 4
Attending to surveillance activities	Determining relationships between drugs and adverse events through passive and active methods	1 to 4
Monitoring safety-related issues that involve the quality of the manufactured product	Conducting health hazard assessments for manufacturing deviations, complaints	1 to 4
Managing risk: REMS, RMP	Understanding benefit-risk across patient populations and uses	1 to 4
Maintaining inspection readiness	Preparation for scheduled and unscheduled inspections of department activities	1 to 4
Training	Clinical investigators; internal customers throughout the company; vendors	1 to 4
Advertising and promotion review	Assuring consistency with important safety information	4
Providing medical information to health care professionals	Support for professional queries regarding product complaints, AE reports, product use	4
Conducting due diligence	Understanding critical safety information about products being considered for merger, acquisition, or licensing activities	1 to 4

AE = adverse event; PK/PD = pharmacokinetics/pharmacodynamics; REMS = Risk Evaluation and Mitigation Strategy; RMP = Risk Management Plan.

*The phase(s) of the drug development process that include the described activities.

Three core functions of pharmacovigilance are: individual case safety reporting, signal management, and benefit/risk management. There are certain components and capabilities that are essential to have fully functioning pharmacovigilance system, regardless of how a company's safety department is constructed.⁷ These include:

- quality management plan (QMP) including standard operating procedures (SOP) and work instructions (WI)
- safety case processing and review
- safety systems (database) support
- global safety reporting
- medical writing and aggregate reporting
- signal management and risk analysis
- product quality complaints analysis
- a qualified person for pharmacovigilance (QPPV) (Europe)

The global pharmacovigilance market is segmented based on phase of drug development, type of reporting methods, and type of service providers. On the basis of phase of drug development, the market has been segmented into preclinical studies, clinical studies (phase I, II, III), and postmarketing surveillance (or phase IV). On the basis of type of reporting methods, the market has been segmented into spontaneous reporting, intensified adverse drug reactions (ADR) reporting, targeted spontaneous reporting, cohort event monitoring and electronic health records mining.⁸

Following proactive measures could help to achieve effective operational alignment:⁹

- Align operational activities across different functional groups and reorganise it as needed for continuous improvement
- Implement well-defined decision-making models, escalation processes, and communication channels
- Retain key pharmacovigilance personnel with cross-disciplinary expertise and skill sets
- Establish corporate IT platform and have vision for a long term strategy

Risk Management

Overall, risk management should ensure that the benefits of a particular medicinal product exceed the risks by the greatest achievable margin. The risk management plan (RMP; for European Union) and the risk evaluation and mitigation strategy (REMS; for the United States) are now a standard part of pharmacovigilance planning. The guideline intended to aid in planning pharmacovigilance activities (ie, ICH E2E)¹⁰ was originally created to achieve consistency and harmonisation, particularly during the early postmarketing period of medicinal products. Within the past few years, the United States and European regulatory agencies have increased their guidance on benefit/risk assessment and risk minimisation. The intent of both the RMP and the REMS is to minimise risks related to a medicinal product through interventions and to communicate those risks to patients and healthcare providers. Recently, regulatory authorities are emphasising more on effectiveness check of risk minimisation activities.



Additional activities such as active surveillance, other clinical or epidemiological trials, specialised training, or restricted access may be included in the plan. The activities must be sufficient to minimise the likelihood of harm so that benefits still outweigh risks, and to ensure that the risk reduction procedures are communicated and implemented.

Consequences of finding a significant safety issue may include any of the following activities:¹¹

Pre-marketing actions include	Post-marketing actions include
<ul style="list-style-type: none"> • Amending the protocol • Temporarily suspending enrollment • Discontinuing the study • Discontinuing development of the medicinal product • Updating a development RMP/REMS 	<ul style="list-style-type: none"> • Enhanced monitoring • Mechanistic safety studies • Variation of CCSI / SPC / product information leaflet • Post-authorization safety studies (active/passive) • Update of the RMP • Presentation of the signal in the PSUR • Provision of the safety information to HCP and/or patients • Suspension, withdrawal or revocation of the marketing authorization (with recall of the medicinal product)

CCSI = company core safety information; HCP = healthcare professional; PSUR = periodic safety update report; RMP = risk management plan; REMS = risk evaluation and mitigation strategy; SPC = summary of product characteristics

Following proactive measures could help to prepare an effective risk management strategy:⁹

- Develop an objective, data-driven, team-oriented approach to risk monitoring and evaluation
- Determine the pharmacovigilance workload and sufficiently resource the required effort
- Implement workflow management technology to ensure appropriate transparency and accessibility of safety information
- Select a vendor that best matches the pharmacovigilance operating model, business process and vendor/system selection criteria
- Develop risk management action plans based on pre-established risk scoring mitigation processes

Market Overview

Pharmacovigilance has been fundamental to pharmaceuticals industry; however, it has been monitored and followed critically by regulatory authorities and companies. The growing number of drug patient approval has made it tough for companies to monitor pre and post effect of each and every drug on the human. That is a prominent reason behind the splendid growth of the pharmacovigilance outsourcing market.¹¹

The pharmacovigilance market was valued at approximately USD 5.6 billion in 2020, and it is expected to reach 8.6 billion by 2026, registering a CAGR (ie, compound annual growth rate) of nearly 7.54% during the period of 2021–2026.¹² The key factors propelling this market are increasing drug consumption and drug development rates, growing incidence rates of ADR and drug toxicity, and increasing trend of outsourcing pharmacovigilance services. The increasing incidence of lifestyle-related diseases, such as diabetes, hypertension, and cardiac disorders, as a result of sedentary lifestyles, lack of physical activities, changing lifestyle patterns, and poor diets, leads to increased consumption of drugs, which indicates the high demand for drug monitoring and fuels the growth of the market.

With the growing drug consumption, the need for regular monitoring of drugs has also augmented, eventually boosting the pharmacovigilance market.¹² The emergence of COVID-19 has brought the world to a standstill. This health crisis has brought an unprecedented impact on businesses across industries. Rising support from governments and several companies can help in the fight against this highly contagious disease.¹³

The rising demand for drugs has significantly increased the need for new drug development via extensive clinical trials. Manufacturers are now focusing on remodelling their drug development processes to cater to patient needs across the globe. Presence of a competitive milieu has led to improved manufacturing operations, pharmacovigilance system, clinical data management, streamlined research and development (R&D), and medical writing. Manufacturers are rapidly considering outsourcing as a viable cost curbing tool. Moreover, organisations are targeting Asia Pacific countries, such as India and China, to conduct clinical trials owing to a wide presence of skilled labour, lower infrastructure & manufacturing costs, and presence of a large patient pool.¹⁴

Pharmaceutical companies are facing productivity crisis and their R&D investments have increased. Hence, the demand for post-marketing surveillance and safety services is increasing.

Key Factors Driving the Global Pharmacovigilance Market

Growing consumption of medicines: The primary driving factor for growth of the pharmacovigilance market is the significant increase

witnessed in the intake of medical drugs. Besides, increase in prevalence of acute and chronic diseases has consequently led to an increase in incidences of drug consumption, thereby leading to a rise in the number of adverse drug events and drug toxicity cases. This, in turn, has triggered the growth of the pharmacovigilance market globally.⁸

Increasing incidence of ADR and drug toxicity: The global pharmacovigilance market is primarily driven by the rising incidence of ADR, soaring patient awareness regarding safety of drugs, and stringent regulations by various agencies related to drug approvals. Strict guidelines related to clinical trials of new drug therapies and mandatory requirements to keep electronic medical records have propelled the growth of the pharmacovigilance market. Initiatives taken by regulatory agencies, such as the Food and Drug Administration (FDA) and European Medicines Agency (EMA), and global organisations such as the WHO have mounted pressures on several biotechnology and pharmaceutical companies to manufacture safe drugs. This is expected to stimulate the demand for pharmacovigilance.¹⁵

Regulatory burden on manufacturers: The pharmaceutical industry operates in one of the world's most regulated environments. Over the lifecycle of a drug, companies must adhere to both commercial compliance (such as Anti-bribery and Corruption [ABAC]) and industry specific compliance obligations (such as Good Clinical Practice [GCP], Good Pharmacovigilance Practices [GVP], and Good Manufacturing Practice [GMP]). Regulatory authorities continue to increase their compliance oversight and enforcement activities for existing laws. Indeed, those organisations who successfully implement an effective regulatory compliance framework are likely to be able to differentiate themselves from their peers, by articulating to patients the rigor invested in the development, and on-going manufacture and use of drugs, to deliver improved health and quality-of-life outcomes.¹⁶

Introduction of software services: A critical component of good pharmacovigilance practice is centred on acquiring complete quality data from reported source on adverse events. The quality of the reports is critical for appropriate evaluation of the relationship between the product and adverse events. The development and use of standard-based pharmacovigilance system with integration connection to electronic health records and clinical data management system holds promise as a tool for enabling early drug safety detections, data mining, results interpretation, assisting in safety decision making, and clinical collaborations among clinical partners or different functional groups.⁹ The innovations created by the healthcare industry, such as artificial intelligence, next generation sequencing, and telehealth, are being used to combat everyday illnesses and conditions, and play a major role in the ongoing fight with the various diseases.¹⁷

Rising investment in R&D by healthcare companies: With the rising costs seen in the healthcare industry, there has also been a significant rise in health care R&D. In 2016, pharmaceutical firms spent \$156.7 billion globally. Roche and Novartis were the largest investors in this space, spending \$8.7 billion and \$7.9 billion, respectively.¹⁸ Per the Center for Medicare and Medicaid, national healthcare spending in the United States is expected to grow at an average annual rate of 5.4% from 2019 to 2028.¹⁷ The research done by the pharmaceutical companies will lead to better and more innovative healthcare drugs, products, and services.

Partnerships and collaborations: Prominent industry players operating in the pharmacovigilance outsourcing market are LabCorp Drug Development, ICON, Syneos Health, Parexel, PPD, IQVIA, Cognizant, and Tata Consultancy Services.¹⁹ These players are

actively indulged in several strategic initiatives including mergers and acquisitions, business partnerships and collaboration to strengthen foothold over the market and capitalise on market opportunities. In June 2018, Covance's (now LabCorp Drug Development) acquisition of scientific process outsourcing company Sciformix strengthens its position in the later phases of drug development.²⁰ During the same time in 2018, Genpact, a prominent player acquired Commonwealth Informatics, a leading provider of cloud-based drug safety analytics services. This move is expected to help Genpact strengthen its hold over pharmacovigilance artificial intelligence and cloud computing capabilities. Thus, ensure a strong hold over drug safety thereby fostering company's growth.¹¹

Market Restraints

All new medicines introduced into the market are the result of lengthy, costly and risky R&D conducted by pharmaceutical companies.²¹ Regulatory policies vary across countries, thereby making it difficult for pharmaceutical companies to meet the specific requirements. Moreover, pharmacovigilance is a continuously evolving process and, therefore, researchers need to constantly educate themselves in line with the frequent changes in rules and regulations.

Problems resulting from irrational drug use, overdoses, polypharmacy and interactions, increasing use of traditional and herbal medicines with other medicines, illegal sale of medicines and drugs of abuse over the internet, increasing self-medication practices, medication errors, and lack of efficacy are all within the domain of pharmacovigilance. Additionally, the process of pharmacovigilance requires the use of skilled professionals to manage adverse events and clinical-trial activities, and contribute to ensure regulatory compliance.²²

Some of the major challenges faced pharmacovigilance are as follows:²³

- Quality and quantity of information received in post-marketing vary by sources and has inherent limitations – both the factors are challenging to deal with as they are required for critical decision making in risk management
- The globalisation of drug distribution and the increased exposure of massive populations to large volumes of medicines.
- The Internet, in addition to its many benefits, has also facilitated the uncontrolled sale of medicines across national borders.
- The scope of pharmacovigilance continues to broaden as the array of medicinal products grows. There is a realisation that drug safety is more than the monitoring, detection, and assessment of ADRs occurring under clearly defined conditions and within a specific dose range. Rather, it is closely linked to the patterns of drug use within society.
- There are shortcomings and at times conflicting interests within the pharmaceutical industry when dealing with public health concerns arising from drug safety issues.
- The generic sector, which is the largest supplier of essential drugs, has not fully recognised its responsibility to continuously monitor the safety of its products throughout the world. There is the erroneous belief that generic drugs are inherently safe even when they interact with other medicines.
- Current trends have dramatically changed the way in which medicines are used by society. The perception of risk versus benefit for medicines have not been considered in a meaningful way. The harm caused by medicines has been shown to be significant.

Existing systems need to evolve to address this broad scope adequately. A focus must be to empower health practitioners and



patients themselves with useful information that improves individual therapy, aids the diagnosis and management of medicine-induced disease, which leads to a reduction of iatrogenic diseases.

Outsourcing While Building Pharmacovigilance Capacity

Pharmaceutical companies are increasingly outsourcing different activities to vendors as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, new technologies and an unstable economic environment.²⁴ Sponsors must ensure that vendors performing pharmacovigilance and risk management have the experience and capacity to perform required services.

Services that are generally outsourced include performing safety audits; creation of SOPs and study-specific procedures (SSP); medical and safety monitoring; individual case management; creating and maintaining databases; signal management; preparation and updating RMPs/REMS; trend analysis; organising and managing drug safety monitoring board (DSMB), data monitoring board (DMC), and clinical endpoint committee (CEC); and reporting of expedited and periodic safety reports to regulatory authorities, principal investigators, and institutional review boards.⁷

Major information technology companies are actively launching pharmacovigilance software to strengthen their market shares. Pharmaceutical and life sciences companies are forming strategic collaborations with key contract research organizations (CRO) to expand their market presence in various regions. This has also enabled them to gain a better foothold in major regions by effectively positioning their services to new clients.¹⁵

A Look Ahead

The global pharmacovigilance is growing at a rapid pace. Marketing authorisation applicants are encouraged to plan from very early on in a product's life cycle how they will further characterise and minimise the risks associated with the product in the postauthorisation phase.²⁵

Owing to the factors such as high risk associated with data security, lack of global regulatory harmonisation, and lack of data standardisation for adverse event collection, the growth of the pharmacovigilance market is expected to get hindered.¹² Self-medication with over the counter and herbal medicines is a growing area and the possibility of experiencing an ADR or a safety concern following incorrect use should also be recognised. It should be easy to report a suspected reaction, also for individuals who do not obtain their medicines on prescription. With the unexpected apparition of COVID-19 and the search for a vaccine to combat this virus, the increased spending on innovation in the healthcare industry will lead to changes in modern medicine as a whole, transforming the way we currently prevent diagnose and treat disease.¹⁷

Some key points for future consideration which may be improved to make better pharmacovigilance practice:²³

- Pharmacovigilance should be more focused on developing knowledge of safety and not just restrict itself in finding harm.
- Complex risk-benefit decisions are amenable to, and likely to be improved by, the use of formal decision analysis.
- Pharmacovigilance should operate in a culture of scientific development. This requires the right balance of inputs from various disciplines, a stronger academic base, and greater availability of basic training, and resource which is dedicated to scientific strategy.
- Systematic audit of pharmacovigilance processes and outcomes should be developed and implemented based on agreed standards.
- Improvement in signal detection and risk management practices by following risk based approach.

Lastly, policymakers must engage in the difficult conversations about the important issues related to controlling the rising costs of healthcare and sustaining investment in R&D to develop new therapies and technologies. We must ultimately tackle the fundamental question of how much innovation for which we are

willing to pay. This conversation must be informed by the economic realities underpinning the business model of how new drugs and devices are developed. We must also weigh the costs of policies that could either hinder or hurt the development of new therapies and technologies for patients suffering from conditions without any existing treatments. This is where the ability to continue to innovate is critical to driving scientific advancement for patient benefit.²⁶

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