

**Review Article****PHARMACOVIGILANCE: DYNAMICS IN INDIAN PHARMA INDUSTRY**

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Keywords:Robust,
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Pharmacovigilance refers to the process of identifying, detecting, and responding to drug safety issue and has witnessed dynamic advancements in pharmaceutical industries throughout the world. The main objective of pharmacovigilance is to extend the safety monitoring and to detect any ADRs that previously got unrecognized in evolution during clinical trial. ADRs monitoring is required for each medicine throughout its lifecycle which includes early stage of drug design, clinical trials, and post marketing surveillance. The emerging trend in pharmacovigilance is to link the pre marketing data with the data collected during post marketing phase that include safety information. India is a vast country with population of over 1.32 Billion with different social economics status, different patterns of disease prevalence it becomes more important to have a standardized and robust pharmacovigilance. Pharmacists, as doctor remark that their involvement may increase the reporting rate and have a greater role to play in the area of pharmacovigilance

Introduction

The word pharmacovigilance (PV) was introduced in mid-70s by a group of French toxicologists and pharmacologist to explain the activities that promotes “The assessment of the risks of side effects potentially associated with drug treatment” [1]. The term originated from Greek word “Pharmakon” means drug and “vigilare” refers to watch. The increasing issue of Adverse Drug Reactions related to drug leads the development of a new branch in pharmacological science known as Pharmacovigilance [2]. PV is defined as the science and activities relating to detection, evaluation, understanding and prevention of adverse effects or ADR. It is the most important and integral part of clinical research and drug development. The main function of PV in the industry is almost same as those of regulatory agencies; that is to protect patient from unnecessary harm by detecting previously unrecognized drug hazards and quantifying risk in relation to benefits [3].

SCOPES OF PV

The discipline of PV has shown a considerable development since the 1972 WHO technical report, and it remains a dynamic clinical and scientific discipline. Now it has become more important to meet the challenges of the increasing range

and potency of pharmaceutical and biological medicines including all types of oral, tropical, parental (vaccine), which carry with them an inevitable and sometimes unpredictable potential harm. When toxicity or the adverse effect appear, especially when previously unknown, it is essential that they are analyzed and communicated effectively to mass population that has the knowledge to interpret the information. This is the role of PV, of which much has already been achieved but many more is required for integration of the discipline into clinical practice and public policy [4].

PHARMACEUTICAL MARKET OF WHOLE WORLD

The pharmaceutical industry is comprised of companies that are engaged in researching, developing, manufacturing and distributing drugs for human as well as for veterinary use [5]. Pharmaceuticals are the 8th largest global product in import and export business. Mainly six types of products are included in pharmaceutical import export business all these came under following HS code- 3004, 3002, 3006, 3005, 3003 and 3001. The product under HS code 3004 (Medicaments consisting of mixed and unmixed products for therapeutic or prophylactic uses) are the most exported and imported pharmaceutical products. Germany is the largest exporter in the world followed by Switzerland, United States of America and

Belgium. Germany pharmaceutical exports represent 15.3% of total export. During the year 2016 Germany record pharmaceutical export of USD 77098405 thousand as per shown in (table 1). USA, UK and Neatherlands are in the list

of top pharmaceutical importer countries [6]. Market research firm Evaluate pharma, through annual World Preview report, projects a global growth rate for the pharma industry of 6.3% CAGR through 2022 [7].

Table 1: Exporter Country

| Exporter Country | Value (USD Thousand) |
|------------------|----------------------|
| Germany | 77098405 |
| Switzerland | 67454988 |
| USA | 47128898 |
| Belgium | 41975129 |
| UK | 32947770 |
| Ireland | 31775741 |
| France | 30126331 |
| Netherlands | 28237527 |
| Italy | 21215394 |
| India | 13042726 |

Table 2: Importer Country

| Importer Country | Value(USD Thousand) |
|------------------|---------------------|
| USA | 92505408 |
| Germany | 49096043 |
| Belgium | 34891600 |
| UK | 32747620 |
| Switzerland | 24674012 |
| Japan | 22067813 |
| France | 21288771 |
| Netherlands | 20971483 |
| China | 20734931 |

*above stats are based on report of 2016

Pharmaceutical Market of INDIA

The Indian pharmaceutical market is third largest in terms of volume and thirteen largest in term of value. The Indian pharmaceutical industry cover up about 20% market and it hold share value of about 1.4% of the Global Pharmaceutical Industry. India's cost of production is approximately 33% less than that of the US. The growth rate of Indian pharmaceutical industry was ranged between 12-14 % till 2015 and now it is expected to grow over 15% per annum during year 2015-2020. According to Pharmaceuticals Export Promotion Council of India (PHARMEXCIL) the growth in export rate of 30% is expected in year of 2017 to 2020 [8]. This growth in pharmaceutical industry leads to emergence as a hub for clinical trials and drug discovery and development [9]. More and more drug entities are being introduced which includes New Chemical Entities, Pharma products, vaccines, dosage form, new routes of drug administration and new therapeutic claims of existing drug moieties. It is demonstrated in the fact that the total number of applications received and processed at CDSCO HQ; New Delhi has increased more than twice from 10,000 in the year 2005 to 22,806 in year 2009 and is still increasing. This includes increase in New Drug Applications, Clinical Trials, Market Authorization of vaccines and biotech products [10]. All this leads to the monitoring of Adverse drug

Reactions (ADRs) for pharmaceutical products over a large population base. Every drug have side effect but some remains unknown even through the drug is in clinical use. It is decisive to study the known and unknown side effects of the drug for better assessment of benefit-risk ratio of the drug. After the ban imposed by CDSCO on some of major drugs like dextropropoxyphene and analgin, pharmacovigilance has become an important asset for assessing the safety profile of the drugs.

SCENARIO OF CLINICAL TRIAL AND REGULATION

Most of the Global pharmaceutical companies have found India to be the better destination for the clinical trials because India's clinical research space, facilities and opportunities are very attractive [11]. As per a recent report of Federation of Indian Chambers of Commerce and Industry (FICCI), scientific feasibility, medical infrastructure, commercialization potential, cost competitiveness, clinical trial experience, regulation are some of the drivers that are responsible for the metamorphosis of Indian Clinical Research growth in past few years.

SWOT Analysis of Indian Clinical Trial Sector:

Strengths

- Large population of over 1.32 billion, which is about 17% of world population.
- Huge pharmaceutical and biotech industry base with mass number of skilled persons [4].
- Third largest country in the world with more than 500 different active pharmaceutical ingredients [12].
- India's cost of production is nearly 33 percent lower than that of the US.
- Labour costs are 50 to 55% cheaper than the western countries.
- Large data mining related to safety profile of drugs possibilities due to large population [13].

Opportunities

- The Indian population is the world largest source of human biodiversity.
- It consist of 4635 culturally and anthropologically well defined populations, expressing a perfect model for study of safety profile of drug, molecular pathology, etiology, disease susceptibility with respect to genetic diversity.
- Excellent potential for skilled human resources needed for an effective PV system because of mass number of recognized medical, dental, pharmacy and nursing college in India [14].

CASE STUDY ON POST MARKETING SURVILLANCE

In spite of the fact that all drug goes through extensive screening before its approval by the food and Drug Administration (FDA), many ADRs may still be missed because of the clinical trials are often small, short, and biased by excluding patients with comorbid diseases. Since premarketing trial do not show the actual clinical use situation for diverse population, thus it is important to have post marketing surveillance. PV has the most important role in the analysis of newly produced drug in post marketing trail [15]. PV research is mainly based on the analysis of "signals". The WHO defines signals as undisclosed assertions on the direct relationship between effects on the living body and a drug to induce adverse effect [16]. PV researchers are now facing problem of delivering knowledge-oriented tools and services that exploit the scope of collecting data. Lastly, the accurate exploration of these data will make the way of improved drug evaluations, critical for pharmaceutical companies [17].

FUTURE PROSPECTIVE

The Indian pharmaceutical market size is expected to grow to US\$ 100 billion by 2025, driven by raising healthcare facilities and PV system. PV systems are capable of detecting new ADRs and taking regulatory actions needed for protection of public health. The emphasis has been put into generating information that can assist a healthcare professional or a patient for making right decision. The communication and gathering of this information is the main goal of PV [17]. PV methods must also be able to describe to describe which patients are at risk of developing ADRs. As per the source of

information the PV system would be consistent with the growing patient involvement in drug safety. At present DCGI is working effectively to improve PV so as to integrate Good Pharmacovigilance Practice (GPP) [18]. The very innovative tool and processes in PV will help to advance pharmaceutical industry to promoting detection and analysis of ADRs by increasing efficiency and providing new analytical capabilities.

Conclusion

The PV in India continues to grow, evolve, and improve with time. India is emerging as an important clinical trial hub and the largest producer as well as exporter of pharmaceutical products in the world. Hence, the need for the professional specialization, a combined view on PGx and clinical requirements are needed which helps to identify the factors that increase the risk of unwanted result from drug therapy and prior to commencing the treatment. Data mining Technology is now part of PV. The PvPI is coordinated at IPC through NCC to generate an independent data on safety of medicines, which will be included in global drug safety monitoring standards. National and Regional PV systems are well adapted bodies for indicating the analysis of ADRs data that further leads to development of new and effective medical products which makes a positive contribution to health and well being of individuals. Hence, PV for medicinal product safety is a collective responsibility of drug regulators, industry and health professionals to ensure the well being of the patients. The financial support to PV system and the increasing clinical trial of drug product should help to achieve a more comprehensive PV activity in India.

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