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CURRENT SCENARIO OF PHARMACOVIGILANCE IN INDIA

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Abstract: Pharmacovigilance, often considered a key component in an effective drug regulation system, is a dynamic and constantly evolving scientific discipline. It is an umbrella term that describes the processes that are involved in evaluating and monitoring Adverse Drug Reactions (ADR's).1

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 problems."2 It aims to improve patient care and safety with respect to the use of medicines and other medical interventions and also contributes to the risk-benefit analysis of the medicines. At the same time, it encourages the safe, rational and effective use of medicines i.e. both from a therapeutic as well as an economic point of view.

Keywords- Pharmacovigilance, adverse drug reactions, regulatory, clinical, World Health Organization

I. INTRODUCTION

While major advancements in the discipline of pharmacovigilance have taken place in the West, not much has been achieved in India. However, with more clinical trials and clinical research activity being conducted in India, there is an immense need to understand and implement pharmacovigilance. Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and shortterm adverse effects of medicines. As a means of pooling existing data on adverse drug reactions (ADRs), the World Health Organization (WHO) Programme for International Drug Monitoring was started in 1968. Currently, 86 countries participate in the programme, which is coordinated by WHO together with its collaborating centre in Uppsala, Sweden. The origin of pharmacovigilance in India goes back to 1986, when a formal ADR monitoring system consisting of 12 regional centers, each covering a population of 50 million, was proposed for India. The National Pharmacovigilance Program established in January 2005, was to be overseen by the National Pharmacovigilance Advisory Committee based in the Central Drugs Standard Control Organization (CDSCO), New Delhi. This article gives a systematic review of the pharmacovigilance in India from its

origin to the current scenario and also discusses the various strategies and proposals to build, maintain and implement a robust pharmacovigilance system for India in the coming years.[1]

The pandemic of Coronavirus Disease 2019 (COVID-19) has now affected the entire globe which was first surfaced in China in December 2019. In absence of effective therapy to manage COVID-19, repurposed therapies were being used to manage the condition. In view of an urgent need for definitive therapy, multiple repurposed drugs, and investigational drug candidates are being tried in clinical trials which may lead to the emergence of unknown short term and long term adverse drug reactions (ADRs), and hence it is crucial to assess the safety of the tried therapeutic interventions. The lag in the pharmacovigilance activities in the midst of this pandemic fosters under-reporting of ADRs. Difficulty in causality assessment due to factors like wide variations in clinical presentation, concomitant use of multiple drugs, associated comorbidities, drug-drug and drug-disease interaction which forestalls the appropriate causality assessment. Hydroxychloroquine, a repurposed antimalarial drug has been a part of hue and cry at present because of its in-question safety in patients with cardiac disorders. National and International Drug monitoring centers have stressed upon reporting of ADRs and to boost up the process and come up with various recommendations. We can overcome these issues by working cohesively, motivating HCPs and patients to report ADRs electronically, and by setting up dedicated pharmacovigilance rapid response team to tackle the issues at the earliest.[2]

Present article focuses on strategies and current scenario of pharmacovigilance sector in India. It comprises main extract from such sector is adverse drug reactions which describes harm associated with the use of given medications at normal dose. It also includes ICH regulatory guidelines, good clinical practices (GCP) which is considered as an important pre-aspects in the way of transformation from practicing clinical trials to the objective of pharmacovigilance. India is the fourth largest producer of pharmaceuticals in the world. It is emerging as an important Clinical trial hub in the world. Many new drugs are being introduced in our country. Hence present article gives explanation about need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of new drugs. Now a days in India, pharmacovigilance situation has been progressing step by step as what it was in the past. The office of the Drugs Controller General of India has been attempted to implement a pharmacovigilance program in India along with its training modules. Most of pharmaceutical companies stab to regulate and implement an effective system of reporting adverse events of drugs introduced in the Indian market with newly beginning of dedicated parmacovigilance department. This review is aimed to offer a study about necessity of implementation of pharmacovigilance for solving current problems and strategies for upliftment in standards up to the level of developed countries. [3]

Pharmacovigilance (PV) has witnessed several advancements throughout the world over the past few decades. This review provides an overview of the PV system in India, focusing on the current scenario, its development, the challenges faced, and the interventions suggested for its improvement. The Pharmacovigilance Program of India (PvPI) is playing a major role in gathering drug safety related data and adding it to the WHO database. PvPI fulfills the minimum requirements given by the WHO for any functional national Pharmacovigilance system. The Indian Pharmacopoeia Commission (IPC) is the national coordinating center under PvPI. PV in India relies mainly upon the spontaneous reporting of adverse drug

events. The major challenge for PV in India is under-reporting. However, there is an improvement in the number of submitted reports after regular training and awareness programmes, which have been conducted by the IPC. The regular and periodic circulation of the 'PvPI Newsletter' by the IPC has also been instrumental in increasing awareness about PV amongst healthcare professionals and patients. The intensification of PV activities in India demands particular attention in health science curricula. Indeed, a change in mindset is necessary for prescribers, patients, regulatory agencies, and pharmaceutical companies.[4]

Pharmacovigilance is a practice aimed to monitor drug safety in real life conditions and capture adverse drug events during the post marketing phase of drug's life cycle. But under reporting of adverse reactions is a major cause of concern and a threat to the pharmacovigilance systems. The present article looks into the major obstacles affecting the spontaneous reporting of adverse drug reactions (ADRs) in India and the possible solutions. As per available scientific literature, the major impediments to ADR reporting are inadequate knowledge and awareness among health professionals, clinicians' perceptions towards reporting, problems with establishing reporting systems in hospitals and insufficient training to recognize ADRs. Measures to improve the situation include greater involvement of nurses, pharmacists as well as consumers in the reporting of ADRs, making the process simpler and faster through electronic means, introducing educational interventions and training programs for health care providers and spreading awareness about the reporting system amongst caregivers and receivers alike. Providing a momentum to the pharmacovigilance system and ensuring a robust reporting process is a challenge but proper planning, feasible solutions and focussed efforts can help bring about the change ensuring patient safety - the ultimate goal of pharmacovigilance.[5]

Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring & discovery of interactions amongst drugs and their effects in human being. Pharmaceutical and biotechnological products are designed to diagnose, prevent or cure diseases. India is the world's second most populated country with over 1 billion potential drug consumers. Although, India is participating in the Uppsala Monitoring Center (UMC) programme, its contribution to that database is relatively small. Signal assessment is mainly performed to analyse the cause and effect by using World Health Organization (WHO) scale & Naranjo scale of probability. Signal detection and its assessment is very vital and complex process. This article gives a systematic review of the PV in India from its origin to the current scenario and also discusses the various strategies and proposals to build, maintain and implement a robust PV system and to improve the process of ADR reporting in the country[6]

Pharmacovigilance is the pharmacological science associated with the detection, understanding and prevention of adverse effects, especially long-term and short-term adverse effects of medicines. In the present day pharmaceutical scenario, where the development and marketing of an ever-growing array of medicines has rendered their safety and therapeutic efficacy key to determining the success of a drug, pharmacovigilance has come about to play a critical and significant part. While pharmacovigilance, as a system, has witnessed considerable progress and evolution in the West, not as much has been accomplished in India. With India now being recognised as a hub of global clinical trials and with an increasing number of clinical trials and clinical research studies being conducted actively, the need for a dynamic

pharmacovigilance network with an efficient and prudent operation methodology is felt, now more than ever. This article observes the evolution of the pharmacovigilance system in India, with a fundamental overview of the present system in place and also various schemes and proposals to establish and sustain the same. It also examines the challenges faced in the execution of an effective pharmacovigilance network as well as the future prospects with regards to the Indian market.[7]

Adverse drug reactions (ADRs) commonly encountered in daily practice are one of the well-known causes of morbidity and mortality in both hospital and community settings. Ayurveda, the holistic science of herbal medicine that is regarded as the safest medical system, is presently being looked as an important module towards alternative medicine by the world and because of this WHO emphasizes the need for consistent monitoring of its ADRs. Most of the ADRs are preventable with an accomplishment of pharmacovigilance (PV) by the involvement of healthcare providers. To assess the knowledge, attitude, and practices (KAPs) about ADR reporting of Ayurvedic drugs among 60 Ayurvedic practitioners (vaidyas) in Andhra Pradesh. A cross-sectional survey was done by a questionnaire that comprised 15 questions regarding KAP of PV in 60 vaidyas of Andhra Pradesh by WhatsApping them the questionnaire and asking to resend it after answering. The collected data were analyzed using MS Excel 2007 and expressed in percentage (%). Among 60 vaidyas, 55 responded to our survey questionnaire. Only 38% of them were aware of the term, PV, 31% knew about its concept, 25% about National PV programme (NPP), 7% knew about the ADR reporting form and only 2% reported an ADR. Our study indicates that the majority of the Ayurvedic health-care professionals had a poor knowledge and attitude about PV and very few practiced it. Hence, they should be trained properly on ADR reporting to improve the current scenario in the NPP.[8]

Pharmacovigilance in India was initiated way back in 1986 with a formal adverse drug reaction (ADR) monitoring system, under supervision of the drug controller of India. India joined the World Health Organization (WHO) Programme for International Drug Monitoring in 1998, but was not successful. Later, the National Programme of Pharmacovigilance was launched in 2005, and was renamed as the Pharmacovigilance Programme of India (PvPI) in 2010. In consideration of having a robust pharmacovigilance system in India, steps were taken. The National Coordination Centre was shifted from New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. The PvPI works to safeguard the health of the Indian population by ensuring that the benefit of medicines outweighs the risks associated with their use. The culture of reporting of ADRs has achieved remarkable success, with 250 PvPI-established adverse drug monitoring centres all over India and provision of training to healthcare professionals. The programme is striving hard to build trust between the physician and the patient, thereby increasing patient safety and the confidence of people in the country's health system, in addition to the detection of substandard medicines and prescribing, dispensing and administration errors. The IPC-PvPI has now become a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. In spite of these achievements, several challenges are faced by the PvPI, like the monitoring of generic drugs, biosimilars, and disease-specific ADRs of antidiabetic, cardiovascular and antipsychotic drugs and, above all, creating awareness, which is a continual process. At the same time, the PvPI is trying

to address other challenges like counterfeit drugs, antimicrobial resistance, and surveillance during mass vaccinations and other national programmes.[9]

According to WHO, Pharmacovigilance (PV) is characterized as the science and exercises identifying with the recognition, appraisal, comprehension and anticipation of unfavourable impacts or some other medication related issue. It is an important part of our medication guideline framework. As we know, India is the world's second most populated country with very nearly one billion dynamic and potential medication buyers and clients. Though our country is participating in Uppsala Monitoring Centre, its obligation to that data base is by and pretty much nothing. This issue is due to the lack of proper ADR (Adverse drug reaction) monitoring system and awareness among associates of medicines and health workers. PV program mainly aims for patient care, patient safety and monitoring of adverse drug reaction. For the accurate practice of PV in India, there are need of more clinical preliminaries and clinical examinations. For the safe and sensible use of medication, a perfectly working PV system is mandatory. PV will be invaluable in India not only for medical services experts, regulatory authorities, pharmaceutical organizations but also for the consumers to screen the medicines. This article gives a methodical audit of the pharmacovigilance program in India (PvPI) from its starting point to the current situation and furthermore examines the future parts of pharmacovigilance program in India.[10]

Pharmacovigilance (PV) is an integral part of the drug regulation system. PV plays an indispensable role in the identification, assessment, and publicizing of adverse drug reactions (ADRs) through various methods. ADRs account for serious harm to the patients and even lead to morbidity and mortality. The PV databases help in the promotion of safe drug use and protection of public health safety. This article compares the PV system in the USA, Europe, and India, highlighting the challenges and future perspectives to be adapted to widen the horizon of the existing PV structure in India. In India, PV programs are still at the dawning stage when paralleled to the other countries. The National Pharmacovigilance Program and the Pharmacovigilance Program of India are the most recent advancements in this field in the country. The USA and Europe have well-established PV systems in place thanks to technological progress and other resources. India is the largest producer of pharmaceuticals in the world and a major clinical research hub; hence, it requires a more stringent PV setup. With the increase in population and novel drugs in the market each day, there is a need for an effective PV system in India.[11]

Medicines in the current health system hold an indispensable role not only for curing a disease but also for prophylaxis or diagnosis of a medical condition. Medicines are supposed to be harmless but contrary to the belief they do come with adverse effects called as adverse drug reactions (ADRs). ADRs accounts for increase in morbidity, sufferings and in the worst case can culminate into mortality. Apart from them they also lead to hospitalization of patients and tend to increase the economic burden on them. In view of such undesirable consequences, regular monitoring and reporting of ADRs play a crucial role in the prevention of further ADRs. In India, National Coordinating Centre (NCC) at Indian pharmacopeia commission is running a nationwide Pharmacovigilance program of India (PvPI) which suggests monitoring and report the suspected ADRs to them. Healthcare professionals (HCPs) forms a key element in the detection, monitoring and reporting of ADRs. Present scenario in India doesn’t seem to be good enough with regards to ADRs reporting. There are multiple reasons for underreporting of ADR but most crucial is the lack of knowledge

and awareness among the HCPs. NCC-PvPI have taken multiple steps to tackle the situation and there has been improvement in the last few years. We can hope a changed scenario and conducive environment in future for reporting of ADRs and help the patients to have a safe and effective use of medicines.[12]

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