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Pharmacovigilance Programme of India: The Beginning, Current Status and Recent Progress

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Abstract

Pharmacovigilance is a crucial part of drug development process which helps in assessing any drug's adverse event profile. Years after the start of WHO's International Drug Monitoring Programme, Government of India launched the Pharmacovigilance Programme of India (PvPI) in 2010. The main function of PvPI is monitoring the Adverse Drug Reactions (ADR) efficiently by setting up various Adverse Drug Reaction Monitoring Centres (AMC) across India and training personnel who can perform this function. PvPI has played an important role in generating awareness amongst healthcare professionals (HCPs) about the importance and the process of reporting ADRs which has led to a multifold increase in ADR reporting. There have been recent developments and advancements overseen by PvPI with a view to further increase the reach of pharmacovigilance across the country, which would further result in betterment in the ADR reporting. In this article, we try to give an overview of the PvPI, with a brief take on the history of the programme along with a look at the necessary steps being taken by the members of PvPI to improve the process of ADR reporting in the country.

Keywords: Adverse drug reaction reporting; Pharmacovigilance; India; PvPI

Introduction

The process of drug discovery and development comprises of multiple pre-clinical and clinical studies. Along with the efficacy data, the researchers and the regulators are keen to recognize the safety data generated at various phases of clinical trial. Post-marketing surveillance is an important step, where drugs used in the real world are monitored for any known or unknown adverse events. Pharmacovigilance is an important aspect of drug discovery and development process which delves in the monitoring and assessment of the adverse events which are associated with drugs.

Pharmacovigilance, according to World Health Organisation (WHO), is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems" [1]. The idea of pharmacovigilance took shape mainly after 1961, after the thalidomide tragedy was reported [2]. After the need for drug monitoring was well established worldwide, WHO's Programme for International Drug Monitoring began in 1968, with Uppsala Monitoring Centre (UMC) in Sweden being the collaborating centre for this global initiative. The main function of this co-ordinating centre was, and rather still is, communication of safety signals recognised through analysis of global data of this Adverse Drug Reactions (ADR). This initiative has gained widespread global acceptance, with a total of 156 countries being the part of the programme currently, contributing a whopping 1.5 crore ADR reports in Vigibase, an ADR database [3].

Advent of Pharmacovigilance Programme of India (PvPI)

A formal and official ADR monitoring system was started in India in the year 1986. In 1997, India became a part of the WHO Programme for International Drug Monitoring, which is managed by the UMC in Sweden. Initially in 1997, there were 6 regional centres in Mumbai, New Delhi, Kolkata, Lucknow, Pondicherry, and Chandigarh selected for ADR monitoring in the country [4]. However, following some poor reporting from majority of these centres, the Government of India launched a National Pharmacovigilance Programme (NPvP) after getting a grant approved from World Bank.

After understanding the need for a better ADR reporting system in India, the health ministry launched a programme called Pharmacovigilance Programme of India (PvPI) in the year 2010 [5]. Under this programme, multiple Adverse Drug Reaction Monitoring Centres (AMC) were set up across various cities in India, in all the medical colleges approved by Medical Council of India (MCI). Currently, there are more than 170 AMCs in India, with addition of many more every year. The main functions of these AMCs are collection of adverse events as per the standard procedure, following up to the completeness of the ADR reports and uploading of reports in the Vigiflow software. These Individual Case Safety Reports (ICSRs) are collected in the standard suspected ADR reporting form, which consists of 4 sections i.e., patient's information, suspected adverse reaction, suspected medication(s), and reporter's information. These ICSRs are then reported to the National Coordinating Centre (NCC) via the Vigiflow software and the causality assessments of ADRs are performed utilising the WHO-UMC causality assessment scale system. The flow of these ADR reports is shown in Figure 1 [4].

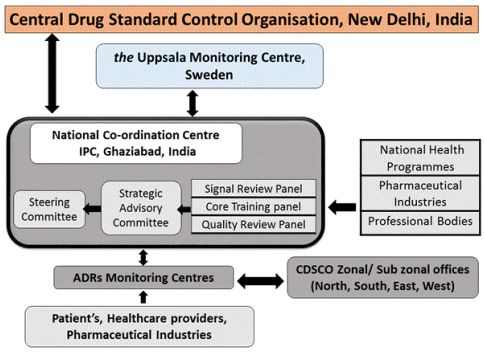

Figure 1: Flow of ADR reports in the Indian pharmacovigilance system.

Recent Developments Related to PvPI

The culture of ADR reporting is being established by the national programme by taking various steps, which include setting up of new AMCs in MCI approved teaching hospitals and corporate hospitals in the whole country. There has been rapid progress in reporting of ADRs by the healthcare professionals in the past 5 years thanks to some changes brought about by the PvPI officials, both in their functioning and their reach. Over a period of 5 years, the NCC has played an important role in generating awareness for the healthcare professionals (HCPs) about the importance and the process of reporting ADRs. The initiatives helped in generating more than 1,49,000 reported ADRs till the end of 2015. The average completeness score for the ICSRs reported by India to the UMC has also increased over the last 5 years [6].

Tuberculosis and HIV infections have a high prevalence in India and the drugs used for their pharmacotherapy are associated with multiple adverse effects. There was a paucity of data related to the reporting of these adverse events and there was always a need to take steps for necessitating the reporting of the plethora of adverse events associated with these drugs. This led to the important collaboration between the Revised National Tuberculosis Control Program (RNTCP), the premier public health programme in India monitoring the treatment of tuberculosis and PvPI on 11th October 2013. On similar lines, the National AIDS Control Organisation (NACO) agreed to collaborate with PvPI on 15th September 2014. The main aim of these collaborations is to set up systems and processes which will help in ADR reporting, analysis as well as monitoring [6].

The PvPI also initiated certain advancements in the modes or ways to communicate the findings to all the stake holders involved in the process-patients and the HCPs. The website of the NCC (www.ipc.gov.in) is regularly updated with all the recent information, just a button-click away from everyone. The NCC also communicates their findings via newspapers and other electronic media regularly. The NCC has also launched a toll-free helpline number (1800 180 3024) for adverse event reporting to ease the participation of the stakeholders in the process of ADR reporting in India.

Mobile phones are being used by everyone now and the NCC-PvPI thought of exploiting this medium to help in increasing the ADR reporting pattern. Therefore, in technical collaboration with NsCB Medical College at Jabalpur, NCC launched a mobile phone application on 22nd May 2015 for the stakeholders, to promote easy and instant ADR reporting [7].

Periodic Safety Update Reports (PSURs) are an important way by which the regulatory authorities in India keep a tab on the marketed medicines in the country. According to the rule by the central drug authority in India which is named the Central Drugs Standard Control Organisation (CDSCO), the Marketing Authorization Holders (MAHs) need to prepare PSURs and see to their submission to the CDSCO twice in a year for the first 2 years and annually for another 2 years after getting marketing approval. Though the PSURs are not directly linked with the PvPI, interactive sessions are being conducted by the CDSCO and the PvPI with an aim to discuss these PSURs and issues involved in reporting the same [6].

There are many countries where patients are not allowed to do ADR reporting [8,9]. However, PvPI started the ADR reporting by patients on 1st August 2014 [6]. The patients can have the following options to report ADRs:

- Use the phone helpline mentioned above;
- Email the same to pvpi.compat@gmail.com;
- Report to the nearest AMC under PvPI by submitting the blue form titled "Medicines Side Effect Reporting form for Consumers" which may be downloaded from the official website of IPC. This form is available in 10 vernacular (local) Indian languages.

The main purpose of the PvPI programme is to expand the culture of ADR reporting as much as possible in India, so that maximum data can be tapped by the system. For this, it is important that more AMCs are opened with properly trained personnel. It has been decided that all the medical colleges under the MCI will be enrolled as AMC by the PvPI. Though the PvPI has launched multiple online sources to report ADRs, it is important that the HCPs and the patients know about these new channels to report the ADRs so that they can use these more easy and efficient reporting systems. The NCC also plans to initiate a co-ordination programme with other countries of South-East Asia for identification of new potential signals [6].

Multiple events and meetings are being conducted by PvPI to extend the reach of the pharmacovigilance programme in India. Recently, in May 2017, the PvPI took a decision of introducing the pharmacovigilance system in the drug-supply chain. This move will help in maintaining quality assurance. The PvPI has also launched its first intensive drug monitoring programme in 2017 with a view to monitor SGLT2 inhibitors, pioglitazone and Sofosbuvir in India, at some designated hospitals [10].

PvPI has stressed on the role of Marketing Authorisation Holders (MAH) in implementing an effective pharmacovigilance system in the country. Various meetings hosted by the officials at PvPI in 2016 and 2017 have recommended how the MAH can play a major role. These recommendations include ways to improve the quality of Individual Case Safety Reports (ICSRs), getting the medical representatives (MR) to participate in the PvPI skill development programme and raising awareness by Public-Private Partnership (PPP) [10].

The Materiovigilance Programme of India (MvPI) was established by the PvPI in 2015 to monitor the adverse events associated with medical devices in the country [11]. The members of MvPI met recently at the IPC in May 2017 to discuss plans to gauge the progress of the ambitious programme. It was decided that biomedical engineers with experience will be recruited and PvPI will provide them with the

necessary training. The MvPI members also suggested that the medical devices manufacturers should be involved in interactive sessions with them. It was also decided that steps will be taken by the MvPI to increase the awareness of the programme and encourage reporting of Medical Devices Adverse Events (MDAEs) [10].

Conclusion

Pharmacovigilance is an important tool to ensure that a marketed drug is safe. PvPI was launched with the main objective of knowing the ADRs associated with the marketed drugs in India so that the necessary steps can be taken, if needed. The members of PvPI are striving hard to increase its reach in India and to fortify the steps for capacity building. Multiple recent steps have been taken by PvPI which prove that pharmacovigilance is moving in the right direction.

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