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Pharmacovigilance Programme of India

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Abstarct

The monitoring and reporting of adverse drug reactions (ADRs) through pharmacovigilance is vital to patient safety and rational prescribing. In India, Central Drugs Standard Control Organization (CDSCO) initiated Pharmacovigilance Programme of India (PvPI) to report ADRs through ADRs monitoring centres in India. Indian Pharmacopoeia Commission (IPC) is functioning as National Coordination Centre (NCC) for PvPI. The ADRs are reported to NCC through VigiFlow by various centres are evaluated and committed to Uppsala Monitoring Centre, Sweden. The potential benefit of the PvPI is aimed to reducing or eliminating a harm of medicine. Continuous efforts of the healthcare professionals and the patients are expected to make this as one of the most successful and effective programmes. The present article updates the status and future plan of PvPI.

Key words

Pharmacovigilance, ADRs, VigiFlow, Indian Pharmacopoeia Commission, Central Drugs Standard Control Organization

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Introduction

Pharmacovigilance is highly specialized branch of medical science dealing with activities relating to the detection, assessment, understanding and prevention and control of adverse effects or any other possible drug-related problems [1-3]. Its concerns have been widened to include monitoring ADRs associated with herbal products, biologicals including blood and blood related products, recombinant DNA derived therapeutic products, vaccines, medical devices etc. There are differences among countries (and even region within countries) in the occurrence of ADRs and other drug related problems [4]. The reasons could be multiple such as differences in diseases and prescribing practices, genetics, diet, drug manufacturing processes, composition, drug distribution and use including their dose and availability, medication error etc [5-12]. Polypharmacy is also reported as one of the reasons for ADRs [13-15]. India is a country where various systems of medicine are practiced and simultaneous use of medicines of different systems further increases the risk of occurrence of ADRs. ADRs can be monitored through clinical trials but most of the medicines have been assessed short-term safety and efficacy on a limited number of individuals. And also a longer period of drug use or drug interactions with other established medications may not be detected during clinical trials [15,16]. Therefore, Pharmacovigilance is needed for detecting ADRs and specifically to meet the requirements so that the drugs 'not of standard quality' do not find place in the market and also ADRs monitoring ensures that patients obtain safe and efficacious products.

India is the world's fourth largest producer of pharmaceuticals by volume, accounting for around 8% of global production [17]. Clearly aware of the enormity of task and determined to establish a vibrant, sustainable and credible adverse drug reaction monitoring programme in the country, the central drugs regulatory authority-the Central Drugs Standard Control Organization (CDSCO) - has initiated a well structured and highly participative country-wide Pharmacovigilance Programme of India (PvPI) under the aegis of Ministry of Health & Family Welfare, Government of India. Indian Pharmacopoeia Commission (IPC) an autonomous institution, under the ministry of Health & Family Welfare, Government of India, Ghaziabad is functioning as National Coordination Centre (NCC) for PvPI since April 15th 2011. ADRs are collected by various ADR Monitoring Centres across the country and reported to NCC.

Mission of PvPI

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PvPI is functioning with the mission to ensure that the benefits of medicine outweigh the risks and thus safeguard the health of the population. The objective is to

- monitor ADRs in Indian population
- create awareness amongst health care professionals about the importance of ADR reporting in India
- monitor benefit-risk profile of medicines
- generate independent, evidence based recommendations on the safety of medicines
- support the CDSCO for formulating safety related regulatory decisions for medicines

Structure and functions of PvPI

The functional chart of PvPI is given in Figure 1. Pharma industry, healthcare professionals and patients are the major stakeholders of this programme. Any medicine or medicinal products approved for marketing in India by CDSCO, the concerned manufacturer is legally required to become the subject of post-marketing Periodic Safety Update Reporting (PSURs). PSURs are always more than an in-house assessment and directly submitted to CDSCO. The health care professionals collecting data of adverse events related to drugs marketed in India, can report to their respective ADRs Monitoring Centres (AMCs) which in turn is submitted to NCC through VigiFlow. The submitted data is collated and evaluated for quality by the various panels and groups of NCC-PvPI, IPC Ghaziabad. NCC is responsible for committing the reports to Uppsala Monitoring Centre (UMC) in Sweden and to communicate the scientific outcome to CDSCO for their regulatory intervention.

Participation of NCC in WHO-UMC Pharmacovigilance Network

The World Health Organization (WHO) set up its International Drug Monitoring Programme after the thalidomide disaster. Since 1978 the Programme has been carried out by the Uppsala Monitoring Centre (UMC) in Sweden. The UMC is an independent foundation and a centre for international service and scientific research. Its priorities are the safety of patients and the safe and effective use of medicines in every part of the world. UMC provides technical support to more than 100 countries including India worldwide on matters pertaining to drug safety (www.who-umc.org). The NCC, PvPI is responsible for sending Individual Case Safety Reports (ICSRs) to the UMC. UMC identifies and analysis new adverse reaction signals from the case report information submitted by NCC-PvPI. A data-mining approach is used at the UMC to support the clinical analysis made by a panel of signal reviewers.

VigiFlow and VigiBase

VigiFlow is a web-based ICSR management system that is specially designed for use by the authorized national centres in the WHO Programme for International Drug Monitoring. ICSR data can be manually entered into VigiFlow with support from the latest versions of terminologies such as the WHO Drug Dictionary and WHO-ART.

VigiBase is the name of the WHO global ICSR database; it consists of reports of ADRs received from member countries including India. VigiBase is updated with incoming ICSRs on a continuous basis. The VigiBase data resource is the largest and most comprehensive in the world. It is online computerised pharmacovigilance software, in which information is recorded in a structured, hierarchical form to allow for easy and flexible retrieval and analysis of the data. The case reports in the WHO database do not identify the patient or reporter. Its purpose is to provide the evidence from which potential medicine safety hazards may be detected.

Both VigiFlow and VigiBase are developed and maintained by the UMC on behalf of the WHO.

Current Status

As on date, there are 60 AMCs spread across the four zonal offices of CDSCO are functioning under NCC. ADRs related to drugs, biologicals including blood and blood related products, recombinant DNA derived therapeutic products, vaccines and medical devices are being reported to these AMC's, in a specially designed ADR reporting form, which are transmitted to NCC after proper evaluation at each level. As on date, NCC committed total number of 20,750 ADRs to UMC. NCC is analyzing the data on monthly basis and the scientific outcome is communicated to CDSCO.

To develop the culture of voluntary reporting and to involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes, physicians, pharmacists, academicians and other healthcare professionals are being sensitized on the concept of pharmacovigilance and how to report ADRs through PvPI, across the country. As a part of promotional activities, CDSCO Zonal offices have written the letter to Medical and Pharmacy institutions to participate in PvPI. NCC has taken initiative step to publish PvPI Newsletter periodically and to circulate among the stakeholders nationally and internationally. The first Newsletter has been published on 2nd November 2011.

In order to provide training and technical support to the newly inducted AMCs, four Training and Technical Support Centres at regional level were identified by NCC. These include Post Graduate Institute of Medical Education and Research, Chandigarh (North), JSS Medical College, Mysore (South), Institute of Post Graduate Medical Education and Research, Kolkata (East), Seth GS Medical College and KEM Hospital, Mumbai (West). Keeping in view, the significance of this programme, an Appendix has been incorporated in 4th Edition of National Formulary of India 2011 and suspected ADR monitoring form also attached which may be filled in by the healthcare professionals and submitted to appropriate authority for further action. Thus it will help in rational

prescribing and evidence-based regulatory decisions. The professional bodies/associations/organizations are encouraged to upload the suspected ADRs reporting form on their website. It will facilitate the easy availability of the form to the health care professional for ADR reporting.

Future Plan

Steps have been taken to include Medical Council of India approved institutions and pharmacy institutions where having pharmacy practice and Pharm. D courses are being run under the fold of PvPI and further it would be expanded to all hospitals (govt. & private) and centres of public health programs located across India. Sensitization programme would be organized to train and encourage healthcare professionals in reporting of ADRs. Establishment of software for ADR database can be a worthy long-term goal in the Indian context.

Conclusions

The potential benefit of PvPI is aimed to reducing or eliminating a harm of medicine. The success of PvPI lies in its ability to prevent further ADRs on the basis of information received and the regulatory interventions. This can be achieved only when healthcare professionals are vitally alert to the onset or offset of any ADRs and ensure submission of quality data to the NCC, PvPI. Healthcare professionals and patients should come forward and actively participate to improving drug safety through ADRs monitoring in the country. It is also expected that the PvPI data will also contribute significantly in statistical signal analysis of potential harm of medicines at the global level by the UMC.

Conflict of Interest

Nil

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Nil

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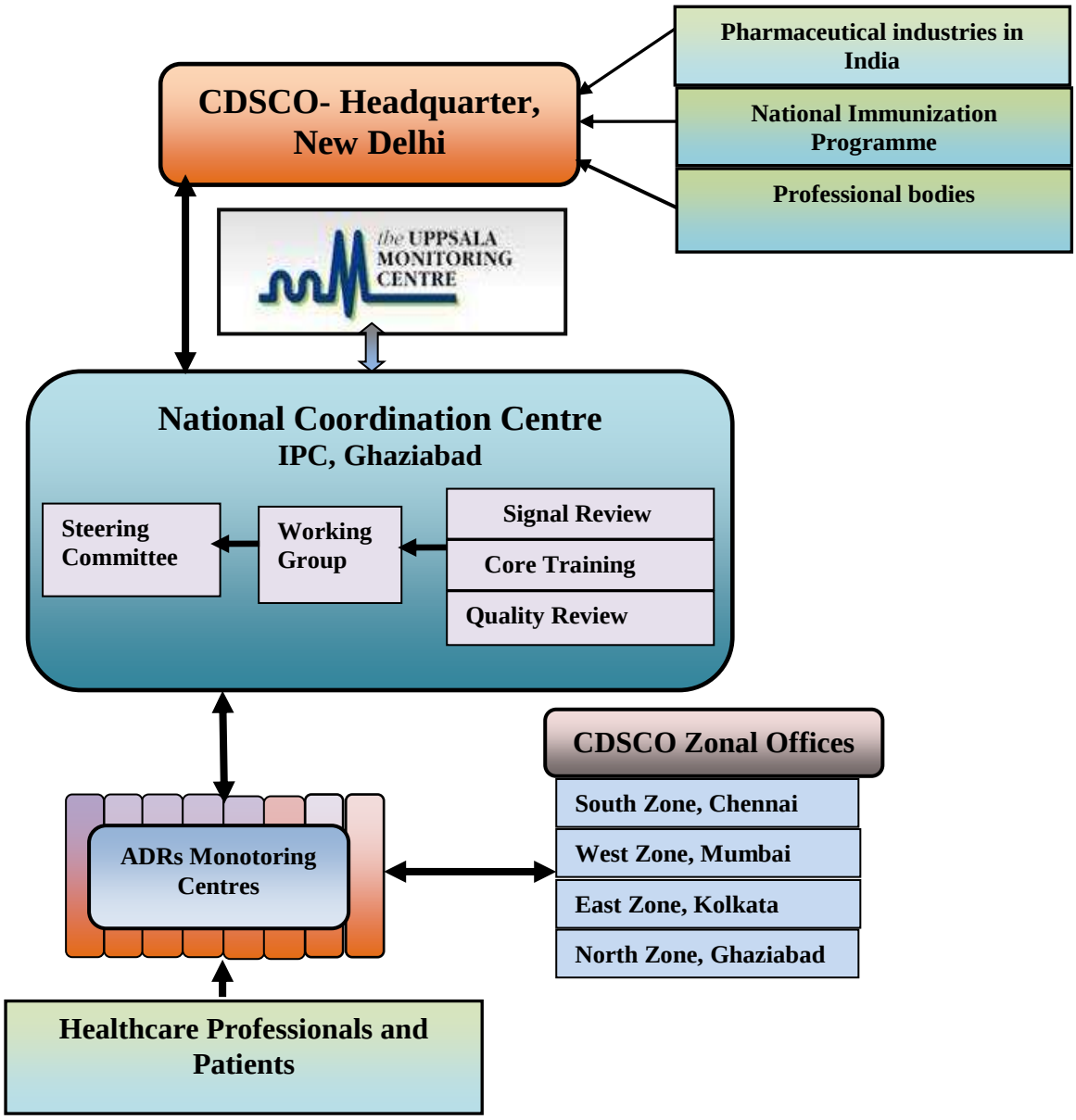

Figure 1: Diagrammatic representation of PvPI