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Pharmacovigilance in India: Challenges and Strategies

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ABSTRACT: Pharmacovigilance is a science for identification, evaluation, understanding and prevention of adverse effects, experiencedafter the medicines. Some long-term and short-term goals are also discussed.The main issue is raised about the challenges due to the fact that Indian healthcare professionals have no comprehensive ADR monitoring system or are unaware of reporting concepts. The aims of pharmacovigilance are to enhance the care and safety of patients with regard to medicines and medical products and paramedical procedures, and also assist in the evaluation of medicines' advantages, harms, effectiveness and danger, to promise their safe, efficient use, to promote indulgent education and clinical formation and their efficient communication. This article explains the Indian National Pharmacovigilance Program and addressesthe issues and potential solutions.

Keywords: ADR monitoring centre (AMC), Upsala monitoring centre (UMC), World Health Organisation - Upsala monitoring centre (WHO-UMC), Under reporting (UR), PvPi programme, Central Drugs Standard Control Organization (CDSCO)

I. INTRODUCTION

The term "pharmacovigilance" is derived from the Greek word "pharmacon" which means "drug," and from the "vigilare," which means "to watch or be vigilant." Pharmacovigilance is described as 'pharmacological science in the area of identification, evaluation, understanding and prevention, in particular long and short-term adverse effects of medicinal products' pharmacovigilance [1]. A medication usually undergoes human voluntary trials after discovery and pre-clinical phases. The investigators and the production company closely supervise and monitor the clinical studies. The reporting of all adverse effects in a clinical trial environment within a prescribed time period is obligatory regulatory requirement [2]. In this case, pharmacovigilance has shifted from reactive to proactive pharmaceuticals in the clinical trial environment. The safety of drugs is assessed using a rigorous and well-defined method to detect adverse effects. Pharmacovigilance performs many functions, including identifying, quantifying and documenting substance issues that cause drug-related injuries [3].

Pharmacovigilance in India is not new and has taken place since 1982. When India agreed to join the centre for the control of adverse events. Pharmacovigilance is of concern for regulatory agencies and media; customers are increasingly aware of medicines' advantages and risks. "An unfavourable event is described as a medical occurrence that may occur during medication treatment, but not necessarily related to its use." "Every noxious, unwanted and undesirable effect of medication that occurs at a human dose for prophylaxis, diagnosis, medicines, or physiological function alteration is an adverse reaction to drugs [4]." Spontaneous notification of adverse drug reactions and adverse effects is a valuable tool for the collection of early detection safety information. Many companies in India hasraised their interest in investing in research and development in recent years and are increasing their ability in their own research activities to develop and sell new medicines. Furthermore India, due to its large population, high registration rates, and low costs, becomes the hub for clinical research [5]. In addition, the laggard for the first time in the USA, Europe and Japan or elsewhere on the market in India has decreased significantly, as has the supply of the medication for the first time. Consequently, the long-term safety data for such drugs are not available and marketing time in India. This is evident from the fact that all the newly withdrawn high profile drugs are available on the Indian market. In such situations, Indian regulatory organisations cannot rely on other industry experience to determine a drug's benefit risk balance.

After the very unsuccessful attempts to establish a working pharmacovigilance scheme in India in 1986 and 1997, the WHO funding the National Pharmacovigilance programme in 2004. [6]. The pharmacovigilance programme was

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implemented as the Indian National Pharmacovigilance Program on 23 November 2004 and operational as of 1 January 2005. The programme involved WHO-UMC (the main ICSR database centre), CDSCO headquarters, NCC centre, zonal centres, local centres. In addition, each regional centre has been given many peripheral centres. (as shown in Figure 1) [7].

Figure 2: Different ADR reporting centres in India.

CIOMS

In 1986, the CIOMS formed the first Working Group for Pharmacovigilance to explore ways of co-ordinating and standardising international adverse pharmaceutical reporting to regulatory authorities by pharmaceutical manufacturers. CIOMS is a multinational non-governmental non-profit organisation [8]. It has foreign members, for example the World Medical Association, The International Society for Pharmaco-epidemiology(ISoP) and national members. Moreover, there are associates who do not fulfil all the membership requirements or who choose to be observers.Members may elect representative's memberof CIOMS organisations, participate in the General Meeting as Executive Committee Members, and are aware of the activities and publications of CIOMS, ICH and WHO. The CIOMS member organisations serve a significant part of the global biomedical scientific community by their own members, such as national associations of doctors, the World Medical Association [9]. CIOMS is an exceptionally lean agency, with just four employees in its Geneva secretariat.The commissioned CIOMS Survey, which was presented at CIOMS in 2019, showed that CIOMS lacked the ability to promote itself in public relations, resulting in relatively small general visibilities, but were nonetheless perceived by the participants in CIOMS as "at the peak of the major players in world health and science."[10]

National Pharmacovigilance Programme in India: PVPI

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A national pharmacovigilance programme to protect the health of patients with an enhanced drug security programme is being launched by the Central Drugs Standard Control Organization (CDSCO), the Health Services Directorate under The Ministry for Health & Family Welfare, the Government of India and the Indian Pharmacopoeia Commission (IPC) [11]. The programme is coordinated as a National Coordinating Centre(NCC) by the Ghaziabad Indian Pharmacopeia Board. The centre is supervised by a Steering Committee. On July 14, 2010, Indian Government launched the Indian Pharmacovigilance Program (PVPI) as the National Coordinating Centre for the Monitoring of Adverse Drug Reaction (ADRs) for public health protection in India with the All-India Institute of Medical Sciences (AIIMS), New Delhi. In 2010 this programme established 22 ADR monitoring centres, including AIIMS, New Delhi [12]. The National Coordination Centre was relocated on 15 April 2011 to the IPC, Ghaziabad, Uttar Pradesh to ensure the more successful implementation of this programme.

Guidelines followed by PvPI

In several countries around the world, a systemic safety reporting mechanism is established in order to produce its own PV guidelines. The ICH contains six guidelines on various aspects of pharmaceutical protection. E2A- Management of clinical data: Accelerated concepts and criteria for reporting; E2B- Clinical Safety Data Management: personal safety report data components, E2C- Clinical data management: periodic reports on marketing health; E2D- Post-authorisation safety information management: accredited reporting definitions and requirements, E2E- Pharmacovigilanve planning, and E2F- system creation safety update. Data management: accredited reporting definitions and requirements. Thus, the PV laws of India are governed by Y Schedule of the Act of 1945 under drugs and cosmetics. [13]. Schedule Y also addresses the legislation for preclinical and clinical drug development trials and clinical trial import, manufacture and marketing authorisation standards for new pharmaceutically modified medication in India. The continuing pledge from the Drug Controller General (DCGI) of India to ensure the proper compliance of the pharmaceutical companies with their PV obligations that was revised and amended in Schedule Y on January, 20th , 2005 [14]. An effort was made in the revised Schedule Y to better identify pharmaceutical companies' duties and obligations for their drugs and to report on clinical trial AEs. India has only a limited Schedule Y segment on drug protection, which appears to have numerous shortcomings in view of contemporary global practises. CDSCO must therefore develop comprehensive PV guidance, which is perceived to be essential. More importantly, the guidelines are in line with current international norms to support India's growth like any participant in global clinical trials. [15].

Responsibilities of National centres of pharmacovigilance: Promoting adverse reaction reporting; Records of adverse reactions in cases collected; Evaluation of case reports clinically; Collapse, analyse and assess adverse reaction patterns; Distinguish between "noise" and signs of adverse reactions; Recommend or take regulatory action in response to evidence-based findings; Studies on major suspicious reactions are initiated; to alert regulators, producers and the public to new risks of adverse effects; Share the study with the WHO International Drug Monitoring Programme [16]. Growing public understanding of issues relating to medication safety have been an important part played by national centres. As a result, pharmacovigilance is more and more seen in some countries than regulatory action, as well as a major role in clinical practise and in the implementation of public health policies. This growth is partly because many domestic and regional centre, in cooperation with the Medicines Regulatory Authority (MRA), live in hospitals, medical schools and centres for poison and medication [17]. The scope of the National Centers' operations has been extended to include knowledge for physicians, patients and the public regarding the benefits, harm and efficacy of medicines. The Central Drugs Standard Control Organization (CDSCO) has a national drug monitoring system, as part of the Health Service, the Ministry of Health & Family Welfare and the Government of India. The CDSCO National Pharmacovigilance Centre will coordinate the programme. Under the supervision of the National Pharmacovigilance Advisory Committee, the centers will work to recommend guidelines and suggestions for regulatory action. [18].

The work flow of Adverse Drug Reactions

The government of India initiated the PV programme for India on 14 July 2010. (PvPI). A National Coordinating Centre (NCC), which was designated by all Indian Institutes of Medicine (AIIMS), New Delhi, to work for safety and public health through PvPI monitoring and evaluation.

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There were 22 developed AMCs registered during 2010. In order to ensure that the software is functional and successful, the coordinate centre was transferred from AIIMS, to IPC Ghaziabad on April, 15th 2011 [19]. ADR Monitoring Centers (AMCs) approved a specified number of medical schools, hospitals and centres that meet the necessary eligibility criteria. Those AMCs collect data and conduct the report review protocol from Individual Case Safety Reports (ICSRs). Once it has become obvious that the case obtained is legitimate and is further communicated to the regulatory authority. Currently approximately 250 AMCs were developed under the PvPI (government and non-governmental organisation) [20]. In addition, a total of 20 Anti-Retroviral centre and 17 other National Program centres throughout the country are available for spontaneous ADR reporting. Medical colleges such as Banaras Hindu University are technically assisted and partnered, an approved and accredited ICSR gathering individual and are also responsible for monitoring and integrating the programme into the Vigi-Flow database online. The ADR reports collected from every Community Health Center (CHCs) and Primary Health Center (PHCs) are passed on to the regional centre. The herbal or natural remedy, however, is thought to be more secure and lacking in ADR [21].

The ADRs Monitoring centres selection

The Head of Institutions must send a 'Letter of Intent' to participate in the national drug safety monitoring programme. The relevant centre can be induced under PvPI as AMCs after examination of the appropriateness [22]. Next NCC will provide WHO-Uppsala Monitoring Center (UMC), Sweden with AMC information in order to receive Vigi-Flow login details for uploading ADR (WHO- UMC owns online software).

Currently, The programme actually includes 150 AMCs divided in four areas, namely North, South, East and West (2013 newsletter for the Indian Pharmacovigilance Program (PvPI)). In the coming year, the programme will be made one of the largest pharmacovigilance programmes worldwide by 350 AMCs across the country [23].

All of these AMCs are engaged in monitoring and reporting ADRs to NCC through Vigi-Flow, is an electronic ICSR management system developed specifically for the national centres under the WHO International Drug Monitoring Programme. This system is designed to track and monitor ADRs. With support from recent version of terminologies like the WHO Drug Dictionary and the WHO-Adverse Reaction Terminologies ICSR data can be inserted manually into Vigi-Flow [24].

Other Specialized wings

Pharmacoepidemiology: Drug use and effects on populations are studied in pharmacoepidemiology. Epidemiological methods are being applied in the study of drug use in a broad population, an increasing discipline. Pharmacoepidemiology, as the term suggests, incorporates epidemiology and medication. The analysis of pharmaceutical effects in humans is pharmacology. The drug effect on a patient is to be prevented using pharmacokinetics and pharmacodynamics of a patient. Epidemiology is the study of the factors that decide diseases in populations. Epidemiologists investigate how many diseases are found in a certain region, who gets them, and what unique factors put people at risk. Infectious and chronic disease epidemiology may also be broken down.Drug safety trials are carried out in large populations by pharmacoepidemiologists. They are interested both in normal, predictable, unusual and unexpected drug reactions [25].

Haemovigilance (HvPI): Started with the National Institute of Biologics after 10 December 2012. (NIB). Haemavailability is a series of monitoring processes covering the whole transfusion chain in the collection and processing of whole blood from human blood for separation of components from its recipients with a view to collecting and evaluating information on the unexpected or unwanted effects of labile blood products therapeutic use and preventing their occurrence and repeatability. It is an effective tool in our country to improve healthy blood transfusion practises.

Materiovigilance (MvPI): IPC has been operating as National Collaborating Center (NCC) since 6 July 2015 and will serve the National Coordinating Center& Chitra TirunalCenter for Medical Sciences and Technology. Ministry of Health and Family Welfare, works as a Technical Support and Resource Centro. National Health Systems Resource Centre. The Indian Materiovigilance Program (MvPI) has been established to track the country's safety of medical devices. MvPI is an important measure to ensure the safety of the patient, since medical equipment is as important as medication [26].

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Goals of the Pharmacovigilance Programmers

Pharmacovigilance plays key role as follow, (i) Contribute to the regulatory evaluation of drug risk: benefits, damage, safety, quality and efficient (including cost-effective) use of medicines; (ii) Improving health of patient and safety in medical use in both medical and paramedic procedures. (iii) Enhance trust and efficacy in the use of medicinal products. (iv) Promote pharmacovigilance awareness, education and clinical training and successful public communication. (v) Provide information and monitor the effects of any actions taken to optimise the safe and efficient use of medicines.

Short term objective: Developing and implementing pharmacovigilance in India,to enrol in the programme of North, South, East & West Indian including all MCI accredited medical colleges. To empower health practitioners to record adverse reactions to medications, vaccines, medical equipment and organic products. Case reports & data collection.

Long-term objectives: Expansion of the PV programme to all hospitals and public health centres in India (govt & private). Electronic reporting system establish and incorporate (e-reporting), Develop a culture of reporting among health workers, and ADR reporting should be mandatory for health practitioners [27].

Elements for reporting

The important elements that constitute an adverse event is one of the key concepts of adverse event reporting. The case must contain the "four components" during the triage processing of a possible suspected event report i.e.; an identifiable patient, an identifiable reporter, suspect medicine, suspected adverse event (as shown in Figure 2).

If any of these four component is missing, the case is not considered as non-valid AE report [28].

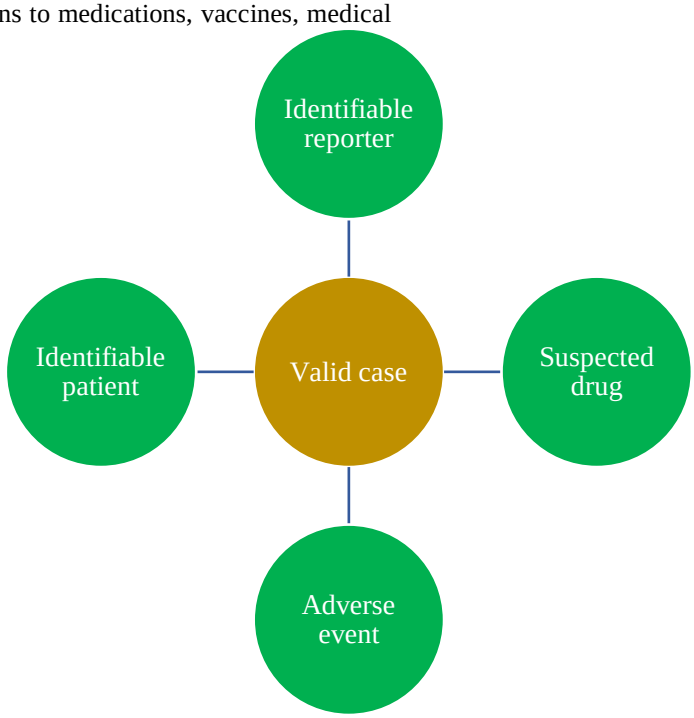

Figure 2 : The 4 main elements for a case to be Valid in Pharmacovigilance.

Reporting in India

Some common methodologies in India for reporting an ADR.

- Helpline number-1800 180 3024 for ADRsreport.
-Mail the filled ADR form directly to pvpi@ipcindia. net or pvpi.ipcindia@gmail.com
- Log on to the http://www.ipc.gov.in, http://www.ipc.gov.in/ PvPI/pv_home.
-Mobile app – ADR PvPI mobile app from the Google Play Store [29].

Causes of lack of pharmacovigilance implementation in India

Numerous challenges and problems have, however, prevented the construction of a comprehensive drug surveillance system outlined below:

1.Not well-funded and systematised pharmacovigilance schemes for the benefit of patients and the public in a large country such as India.

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2. The data gathered from different peripheral centres in the zone centres to date is mostly weak and poorly analysed. Research on ADRs in India is incomplete, so the exact effects of such ADRs are not known.
3. The participation of the medical professions and the expertise and motivation to pharmacovigilance are marginal, both in rural areas and in metropolitan cities and hospitals. There is little incentive by the health department for more training and better reporting among them.
4. There are many consumer associations in India that urge patients to report any adverse events, but patients have no details to report ADRs directly to the regulatory authority [30].

Under reporting

According to Under reporting (UR) of ADRs, pharmacovigilance is generalised and a challenging task (PV). This is because most countries, including India, are following the ADR reporting method spontaneously or voluntarily. There are patient explanations why UR is not recognised as ADR or cannot associate ADR with a medicine. There are no UR reasons for this. The most common explanations for this are shame, fear of lawsuit, ignorance, lethargy, insufficient perception of the risks of newly marketed products, insufficient training to recognise ADRs and an understanding of the PV programme. Similarly, the ability of medical teams to identify ADR or to associate specifically with biochemical, pathological or radiological abnormality also makes ADRs unknown. Intense PV surveillance however enhances ADR identification. Different methods to intensify ADR monitoring have been suggested. Studies show the widespread UR problems in PV but, to define this issue, we did not quote any Indian studies based on evidence. The India PvPI programme has thus continued its emphasis on the UR issue and its potential causes. It is thus the first Indian self-introspection experience the PvPI programme in India [31].

Future strategies

The following solutions can be used in the future after analysing the problems faithful to India's Pharmacovigilance Program in terms of maintaining a stable pharmacovigilance system: (i) DGCI and CDSCO have worked hard to establish a robust framework of pharmacovigilance. However, additional work should be done to ensure that all data are collected as easily and effectively as possible to implement adequate risk-control measures.DCGI may also contact private institutions for the training of pharmacovigilance. (ii) Different stakeholders such as the Ministry of Health, ICMR, Indian Medical Council, the Dental Council, NGOs and the Pharmaceutical Council should meet at regular intervals to discuss the ways to address new issues that emerge when pharmacovigilance is implemented. In addition, thoughts about how to further improve the pharmacovigilance mechanism. (iii) The relatively intertwined pharmacovigilance and pharmacoepidemiology are areas. It is thus essential for a core expert group to develop pharmacoepidemiology guidelines in the field of pharmacovigilance. This core advisory group is made up of MNC leaders, pharmaceutical firms and representatives of the Regulatory Authority. In addition, epidemiologists and doctors may also contribute to the growth of this method and give ideas. (iv) Working with IT to create a stronger and more modern pharmacovigilance scheme, consistent with more mature pharmaceutical markets in pharmaceutical surveillance systems. India houses one of the world's most advanced IT industries. It would therefore be prudent to work together with software professionals to develop an application or framework capable of analysing data sets, determining drug use patterns, error in prescription, etc. (v) During diagnosis and examinations at hospitals, pharmacists should accompany doctors, as they have fundamental knowledge of drug chemistry, drug effects, dosage criteria and products, until medicines are directed to patients. This procedure was followed inpharmaceutical markets and also implement in India to ensure the right medication for patients is administered as per the diagnosis of the disease. (vi) For each pharmaceutical company a common database can be established to list, market and indicate all new drugs and increase the number of monitoring centres for ADRs (AMC) and make them open to areas where these reporting centres are currently unavailable [32].

II. CONCLUSION

A public understanding of ADR reporting was enhanced by the PV programme in India. The underreporting problems are not a concern as a large range of reporting skills like toll-free number, ADR type in different languages, Email IDs for public access are available. In the PV business as an outsource in India, many multinational corporations are creating a good PV environment. Many universities have started PV courses as obligatory or optional subjects in their curriculum in order to make India safe. The Indian government

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must emphasise awareness and enhance knowledge of pharmaceutical workers and grant them facilities and rights to carry out PV activities. In order to track and evaluate ADR, specialised PV cells must be established in every hospital. India will in future become a centre for the outsourcing of photovoltaics and global photovoltaic activities, taking into account the motivational approach of HCP, clinical pharmacists, and progress in the ADR assessment field. Pharmacovigilance agent will play an important role in ensuring potential consumer availability of safe drugs.

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