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Review Article

PHARMAOVIGILANCE: PERSPECTIVES AND FUTURE CHALLENGES IN INDIAN SCENARIO

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ABSTRACT

Pharmacovigilance has been tremendous growth over the past 10 years. For example in Africa, in 2000 there were five countries with good Pharmacovigilance capacity, while at the end of 2010, this figure rose to 34 today 134 countries participate in the programme. Every country need Pharmacovigilance centre because there are differences between countries (even regions within the counties) in the occurrence of adverse drug reaction and other drug related problems. Data derived from pharmacovigilance centre within a country or region may encourage national regulatory decision-making. When information from a region itself is not available, it may take longer before a problem becomes known to drug regulatory authorities, physicians, pharmacists, patients and pharmaceutical companies.

Pharmacovigilance is a process that needs time, vision, dedication, expertise and continuity. A governmental department (health authority, drug regulatory agency) can be a good host for pharmacovigilance centre. However any department in a hospital or academic environment, working in clinical pharmacology, clinical pharmacy, clinical toxicology or epidemiology may suitable starting point for pharmacovigilance. The reporting of adverse drug reaction may start locally, perhaps in one hospital, then extend to other hospitals and family practices in the region, and progress step by step into a national activity. Pharmacovigilance centre is needed for the prevention of drug induced human suffering and to avoid financial risks associated with unexpected adverse effects. In conclusion, pharmacovigilance centre is necessary for continuous monitoring of marketed medicines in every country.

Keywords: Pharmaovigilance.

INTRODUCTION

Pharmacovigilance is concerned with the detection, assessment and prevention of adverse reactions of drugs. Each country has set their own set of guidelines on pharmacovigilance for detection, collection, assessment of adverse events in their corresponding regions.

ADR monitoring programmes are not new to India. In 1982, five centres were established by Drug Controller General of India for nationwide monitoring of Adverse drug Reaction (ADR). In 1987, ICMR had collected about 5,8000 ADR cases through its multi institutional study but they all stopped functioning after few years due to several reasons such as insufficient funds, lack of enthusiasm etc. The present programme may be successful since this has been structured taking into consideration the past deficiency. World has committed to provide US $ 100000 for this project. The success of this programme depends on the continuous active support by Central Drugs Standard Control Organization CDSCO and the dedicated work of pharmacovigilance centres.

The Uppsala Monitoring Center (UMC), Sweden is maintaining the international database of ADR reports received from several national centres. In September 2005 the database had 3.5 million ADR report and 78 countries were participating in this programme. Vigibase online (web based) system is used for submission of ADR reports. Although India is participating in this programme, its contribution to UMC database is very little. This is essentially due to the absence of a vibrant ADR monitoring system and also the lack of a reporting culture among health care workers.

Aim and Objective

- To engage several healthcare professionals and public to participate in pharmacovigilance programme in India
- To gain knowledge about the function of centre in India
- To achieve such operational efficiencies that would make Indian National Pharmacovigilance Programme a benchmark for global drug monitoring endeavors.

Pharmacovigilance Centers in India

India has more than half a million qualified Doctors and15, 000 hospitals having bed strength of 6, 24,000. It 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. Therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the

population from the potential harm that may be caused by some of these new drugs. Since there are considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management – there is a need to engage health-care professionals and the public at large, in a well structured programme to build synergies for monitoring adverse drug reactions. The purpose of the programme is to collect data, analyze it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

Clearly aware of the enormity of task the CDSCO has initiated a well structured and highly participative National Pharmacovigilance Programme. It is largely based on the recommendations made in the WHO document titled “Safety Monitoring of Medicinal Products – Guidelines for Setting up and Running a Pharmacovigilance Centre”.

The National Pharmacovigilance Program was officially inaugurated by the Honorable Health Minister Dr.Anbumani Ram doss on 23 November, 2004 at New Delhi. The Programme aims to foster the culture of ADR notification in its first year of operation and subsequently aims to generate broad based ADR data on the Indian population and share the information with global health-care community through WHO-UMC.

Under the program twenty six peripheral centers, five Regional Centers and two Zonal Centers were established. The Peripheral centers will record the Adverse Events (AE) and send to the Regional Centers. They in turn collect and scrutinize the data received from the Peripheral Centers and submit to the Zonal Centers. The Zonal Centers will analyze the data and submit consolidated information to the National Pharmacovigilance Centre. The Zonal Centre will also provide training, general support and coordinate the functioning of the Regional Centers.

The National Pharmacovigilance Advisory Committee (NPAC) oversee the performance of various Zonal, Regional and Peripheral Pharmacovigilance centers as well as recommend possible regulatory measures based on the data received from various centers.

New Pharmacovigilance Programme for India[9, 10,]

Recognizing the need to restart the national pharmacovigilance programme (NPVP), in a brainstorming workshop jointly organized by Dept of Pharmacology, AIIMS and CDSCO in late 2009, the framework of the new programme was formulated. The programme now rechristened as the Pharmacovigilance Programme for India (PvPI) is scheduled to be operational from mid July 2010.

Framework of new programme

The programme is envisaged to be rolled out in three phases. Phase I would include 40 ADR monitoring centres (AMC) and will be rolled out in 2010. The programme would be expanded in phase II to include up to 140 MCI recognized medical colleges by 2011. Phase III would ultimately cover the healthcare system by 2013. Phase I will be further divided into phase Ia and Ib. Phase Ia will involve upgrading 10 centres in terms of infrastructure (computer and auxiliary). Phase Ib will include the rest of the 40 centres by end of 2010. The centres for phase Ia have been shortlisted based on letter of intent received from interested faculty, duly forwarded by the head of the institution. The AMCs will get operational and logistic support from their respective zonal CDSCO centres, situated at Ghaziabad, Kolkata, Mumbai and Chennai. The zonal CDSCO centres will be under administrative control of the CDSCO headquarter at New Delhi.

The coordinating centre of PvPI will be housed at Dept of Pharmacology, AIIMS, New Delhi and will provide technical support to the CDSCO headquarter. All the centres under the programme will function in accordance with the protocol and SOPs developed by expert committees.

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ADR data flow

ADR reports will be collected at the AMCs. The PV staff at the AMCs will check for validity of the report and if possible conduct provisional causality assessment. The ADR forms will then be dispatched to the coordinating centre as per the SOPs. The AMC staff will also maintain a log of all the centre activities. Selected AMCs will also carry out focused ADR monitoring of drugs in the focused ADR monitoring watch list

The coordinating centre will conduct causality assessment and upload the reports into the PV software. The coordinating centre will prepare a consolidated report of ADRs collected at defined time intervals.

The coordinating centre will also implement and integrate PV activities into public health programmes involving mass usage of drugs, such as for antimalarial, anti-tubercular and anti-retroviral drugs. Lastly, the integrated ADR data will be transmitted through vigiflow interface into the UMC ADR database where signal processing can be carried out.

Future Challenges of Pharmacovigilance

Current pharmacovigilance systems need to be reviewed and developed further in the face ofthese important future challenges. The following summarize some of the priority areas that need to be addressed either at a national or international level:

Detection of ADR: Consider special activities and expertise required for the detection of safety concerns related to vaccines, biological, veterinary medicines, herbal medicines, biotechnology products and investigational drugs. Improve signal detection systems by

facilitating the rapid availability of ADR data that may have international relevance.

Assessment of ADR: Foster collaborative links both at local and international level that could allow countries to assess and respond appropriately to drug safety crises. Consider methods by which information on local patterns of drug use can be integrated with pharmacovigilance information during assessment of benefit and harm at a national level.

Prevention: Integrate pharmacovigilance activities into national drug policies and the activities arising from these like standard treatment guidelines, essential drugs lists etc. Incorporation of pharmacovigilance principles into clinical practice and academic medicine. Improve regulation and pharmacovigilance of traditional and herbal medicines and develop systems which assess the impact of preventive actions taken in response to drug safety problems.

Communication: Improve communication and collaboration between the key partners in pharmacovigilance both locally and internationally. Different solutions are likely to be developed in different countries and regions, and the experience should be shared. Develop sustained and active relationships with the media in order to facilitate effective and accurate communication of drug information to the public. Encourage harmonization of drug regulatory and pharmacovigilance activities by incorporating the wider international community in the development of harmonization policies.

CONCLUSION

India is the fourth largest producer of pharmaceuticals in the world. Many new drugs are being introduced every year so every health care professional must have knowledge about the importance of ADR monitoring and pharmacovigilance. Government of India will make reporting of adverse reaction mandatory for medical colleges across the country. All medical colleges both private and public in the country will be required to monitor the effect of medicines given to their patients and report whether there is any adverse drug reaction. For improving pharmacovigilance in India, a new scheme introduced i.e. 24 hour telephone and online advice in which people can telephone a helpline to report suspected adverse drug reactions.

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