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HINDRANCES TO PRESENT PHARMACOVIGILANCE SCENARIO & INNOVATIVE IDEAS TO ENHANCE DRUG SAFETY

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ABSTRACT

In India, there are several consumer groups who encourage patients to report any adverse reactions encountered by them, although there is no information for patients on how to report ADRs directly to the regulatory authority. Direct reports from the patients, the ones who actually experience ADRs, are not accepted by the monitoring centres and by regulatory authorities. To add to this is the total lack of any awareness about ADRs in the general population. So every pharmacist and pharmacovigilance system has a key role in minimising the ADRs and bring awareness about safe usage of drugs in global health care.

Keywords: pharmacovigilance, ADRs, Health care system

INTRODUCTION

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. (1)

Hindrances to present pharmacovigilance scenario

1. It is estimated that adverse drug reactions (ADRs) are between the 4th and 6th largest cause of mortality in some countries. (2) Ten to 20% of hospital admissions are due to such reactions (3-5). As well as threatening the health of patients and consumers of medicines, adverse drug reactions also place a heavy financial burden on health care services. Some countries spend up to 15-20% of their healthcare budget on drug-related problems.
2. The immensity of the problem of ADRs: A number of studies conducted throughout the world have demonstrated that ADRs significantly decrease the quality of life, increase hospitalizations, prolong hospital stay and increase mortality. "A landmark study by Lazarou in 1998 described ADRs to be the fourth to sixth largest cause of death in the USA and ADRs are estimated to cause 3-7% of all hospital admissions." More than half of these ADRs are not recognized by the physicians on admission and ADRs may be responsible for the death of 15 out of 1000 patients admitted. Furthermore, the financial cost of ADRs to the healthcare system is also huge. With more new medicines being approved for marketing more quickly without long-term safety studies by the regulatory authorities and switching of prescription-only medicines (POM) to over-the-counter (OTC) to be used more widely by patients for self-medication, the general public is at risk of exposing itself to ADRs. (6-7)

Current scenario of PV in India

India is a vast country and there is a surfeit of drug brands-more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India is the fourth largest producer of pharmaceuticals in the world and is also emerging as a hub for clinical trials. Traditionally, pharmacovigilance was never done in India in pharmaceutical companies, so there is an immense shortage of knowledgeable people who will be able to advice the DCGI on this matter, as pharmacovigilance is a very complex subject, intertwined with regulations and complex systems. (8)

The information obtained to date in the zonal centres from various peripheral centres is often poor and not well-analyzed. There is insufficient research on ADRs in India, so the exact incidence of specific ADRs is unknown. The reporting forms used by many people engaged in various pharmacovigilance works are different from the reporting form used by the National Pharmacovigilance Program, which makes it extremely difficult to transfer data to the national database, even it has been shared by the various parties. Understanding by healthcare professionals (both in rural areas and urban cities and hospitals) and knowledge and motivation for pharmacovigilance is almost negligible. There is hardly any encouragement from the department of health to provide more training and create more awareness amongst them for better reporting. In India, there are several consumer groups who encourage patients to report any adverse reactions encountered by them, although there is no information for patients on how to report ADRs directly to the regulatory authority. Direct reports from the patients, the ones who actually experience ADRs, are not accepted by the monitoring centres and by regulatory authorities. To add to this is the total lack of any awareness about ADRs in the general population. With more and more clinical trials and other clinical research activities being conducted in India, there is an immense need to understand the importance of pharmacovigilance and how it impacts the lifecycle of the product.

In the past, India's regulatory agencies and drug companies based their safety assessments on experiences derived from long-term drug use in the Western markets and there was no real urgency for the government to establish a strong pharmacovigilance system of its own. In recent years, however, the lag between when a drug is placed in the market and its subsequent availability in India has decreased considerably so that the much needed longer-term safety data is no longer available. In addition, India-based drug companies have increased their capacity to develop and launch new drugs through their own research efforts and this has heightened the importance of developing adequate internal pharmacovigilance standards to detect adverse drug events.

However, what needs to be more important along with the funding is a focused vision and effective strategy for developing the pharmacovigilance systems, especially in the Drug Controller General Ofof India Office, which is lacking. Traditionally, pharmacovigilance was never done in India in pharmaceutical companies, be it Indian or multinational companies (MNCs), so there is an immense shortage of knowledgeable people who will be able to advice the DCGI on this matter, as pharmacovigilance is a very complex subject, intertwined with regulations and complex systems. The need is therefore to engage a completely independent adviser who has extensive and practical knowledge on pharmacovigilance, who can act as a Pharmacovigilance Advisor to the Government of India to effectively implement the systems and policies on pharmaocvigilance. This will help the DCGI to spearhead the activities and implementation of pharmacovigilance.

Innovative ideas to enhance drug safety.

Pharmacovigilance plays an essential role in the early detection of the risks of drugs. Every medicine is tested on a relatively small proportion of the population before it is approved for use by the wider population, where previously undetected reactions can emerge. Each patient is a unique medicines user with a distinctive lifestyle and circumstances, meaning that each person can have a different reaction to the same medicine. Medicines causing serious ADRs need to be re-evaluated or removed from the market to protect public health.

Strategies and proposals to enhance drug safety are**:**

The way forward in India

1. Building and maintaining a robust pharmacovigillance system.
2. Making pharmacovigillance system mandatory and introducing pharmacovigillance inspections
3. High level discussions with various stakeholders.
4. Strengthening the DCGI office with trained scientific and medical assessors for pharmacovigillance.
5. Creating a single country wide specific adverse event reporting form to be used by all.
6. Creating a clinical trial and post- marketing data base for SAS's/SUSAR's and ADR's for signal detection and access to all relevant data from various stakeholders.
7. List all new drugs/ indications by maintaining a standard data base for every pharmaceutical company.
8. Education and training of medical students, pharmacists and nurses in the area of pharmacovigillance.
9. Collaborating with pharmacovigillance organisations in enhancing drug safety.
10. Building a network of pharmacovigillance and pharmacoepidemiologists in India.
11. Interaction with the IT sector in building a robust pharmacovigillance system in India.
12. Drug regulatory agencies

Drug regulatory authorities (DRA) are responsible for assessing applications for a medicine's marketing

approval and monitoring the safety of the medicine once it is on the market. The DRA is responsible for the approval of product information and updates based on new alerts or information. A reporting system want to be established where health personnel can directly or indirectly (via a pharmaceutical company) spontaneously report an ADR.

13. Manufacturers / producers

Manufactures and producers are responsible for the safety of their medicines. The manufacturers do this by receiving reports from the DRAs, which are compiled in periodic safety reports (PSURs) and used as information to DRAs and for updating Summary of Product Characteristics. They are also responsible for monitoring ADRs in clinical trials. Finally, manufacturers want to create risk management plans that are required in the marketing approval process for some new medicines.

Scope and objectives

1.To create a nation-wide system for patient safety reporting
2.To identify and analyse new signal from the reported cases
3.To analyse the benefit - risk ratio of marketed medications
4.To generate evidence based information on safety of medicines
5.To support regulatory agencies in the decision-making process on use of medications
6.To communicate the safety information on use of medicines to various stakeholders to minimise the risk
7.To emerge as a national centre of excellence for pharmacovigilance activities
8.To collaborate with other national centres for the exchange of information and data management
9.To provide training and consultancy support to other national pharmacovigilance centres across globe
10.To promote rational use of medicine

Conclusion

India is now considered to be a hub for clinical research. The DCGI has shown its commitment to ensure safe use of drugs by establishing the National Pharmacovigilance Program. More and more clinical trials are now being conducted in India and business process outsourcing (BPOs) based in India are now also undertaking pharmacovigilance projects from MNCs. Healthcare professionals, consumer groups, NGOs and hospitals should appreciate that there is now a system in place to collect and analyze adverse event data. They should start reporting adverse events actively and participate in the National Pharmacovigilance Program to help ensure that people in India receive safe drugs. With the help and proper coordination of all stakeholders, we can definitely build a world-class pharmacovigilance system in India.

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