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Review Article

Challenges in implementing Pharmacovigilance Programme for ASU & H drugs

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ABSTRACT

Background: *Pharmacovigilance deals with the Adverse Drug Reaction or any Drug related issues. Identification and reporting of Adverse Drug Reaction/ Adverse events and analysis of its consequences have a positive impact on the public health. Implementation of Pharmacovigilance programme for ASU & H drugs is not an easy task; it has come across with many challenges and barriers. This article highlights the challenges faced during the implementation of Pharmacovigilance Program for ASU & H drugs at Peripheral center.*

Methods: *It is an explorative study, wherein personal interviews of health care professionals and peer reviewed journals were collected and evaluated. Already published articles and books were also referred for compilation and interpretation of results.*

Results: *With the span of one year, the centre identifies certain obstacles like signal detection and reporting, collection of the details of the suspected drug, drug regulation etc*

Discussion: *Lack of awareness of ADR reporting among the healthcare professionals is considered as the major problem in implementing the programme. Hence certain considerations are made like Improvement in knowledge of Pharmacovigilance, communication with all sectors of health care system, patient education etc which will definitely help in implementing Pharmacovigilance programme.*

Key words: *Adverse drug reaction, ASU & H Drugs, challenges, considerations, implementation, Pharmacovigilance programme.*

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INTRODUCTION

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems.[1] The World Health Organization (WHO) initiated a program for reporting all adverse reactions possessed not only by drugs but also it included biological products and medical devices. In India, Pharmacovigilance programme for ASU drugs first of its kind was established under Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India in 2007. From 2007 to 2018, IPGT and RA, Jamnagar, was designated as the National Pharmacovigilance Resource Centre for ASU drugs. At present Homeopathic system of medicines are also included under this programme and the National center of Pharmacovigilance for ASU & H drugs is at All India Institute of Ayurveda, New Delhi. In order to maintain a proper documentation, to regulate, monitor and control the activities of Pharmacovigilance 3 tier systems were established throughout the country – 1 National Pharmacovigilance centre (NPvCC), 5 Intermediary Pharmacovigilance centre (IPvCC) and 41 Peripheral Pharmacovigilance centre (PPvCC).

Pharmacovigilance programme for ASU & H drugs is still in its infancy state and has a long way to go to overcome obstacles in order to play an important role in the health care system. With the lack of awareness among the health care professionals regarding Pharmacovigilance, it will face a lot of resistance and challenges to reach its objectives and goals. Further with the rapid increase of patent and proprietary medicines and lack of post marketing surveillance, there is an immense need to address important aspect of Pharmacovigilance to the Ayurvedic Pharmaceutical industry. Also with the prevailing clinical practices in India – Ayurveda, Allopathy, Homeopathy, Unani, Siddha and in view of the complex interactions among these various systems of medicine, the need for an efficient Adverse Drug Reaction (ADR) monitoring system becomes necessary. Adverse drug reactions is the sixth global leading cause of death and the incidence of serious ADRs in hospitalized patients is almost 7 percent. So it becomes important to implement Pharmacovigilance in every health care system for the safe, effective and rational use of drugs and educating the people regarding the consequences of adverse drug effects.

RESULTS

CHALLENGES

There are many prerequisites as well as problems for a Pharmacovigilance Programme has to face. Some of these challenges are discussed here:

1. Administration

In India, Government has a key role to play in planning and sustaining a programme. Without a strong political will this cannot be achieved. It is through the public sector, the programme can reach every nook and corner of the country. A major source of fund to run the programme also comes through the Government. So, it is utmost with its help, the programme cannot reach the pinnacle.[2]

2. Lack of proper education and training

There is a lack of knowledge regarding the concept and importance of Pharmacovigilance among AYUSH practitioners. Many are not aware about the functioning of the Pharmacovigilance programme for AYUSH system of medicines. This hinders the lack of reporting culture among practitioners. Also one of the most challenging aspects is the lack of expertise in performing causality analysis with the Ayurvedic medicines.

3. Signal detection and causality assessment

Signal detection is difficult as there is strong belief about the safety of Ayurvedic medicines leading to lack of reporting of any adverse reactions.[3] There are multiple herbal and herbo-mineral contents are present in Ayurvedic formulations and people often use medicines from different system of medicine along with the Ayurvedic medicines leading to difficulties in assigning causality.

4. Incomplete collection of details of suspected drug

In Government hospitals and dispensaries, often the patients receive the medicines in a loose packets and bottles. Without the label of batch number, manufacturing date, expiry date etc. As the Government hospitals receive the medicines in bulk quantities; there is high chance of mixing up of medicines of previous batch with the new batch. One more difficulty in collecting details is in case of single drug therapy; its safety and efficacy are always questionable. Hence it becomes difficult to complete the ADR reporting form.

5. Drug regulation

Sound drug regulatory arrangements provide the foundation for a national ethos of drug safety and for public confidence in medicines.[4] The methods to study drug safety issues have not evolved adequately in Ayurveda. The lack of quality assurance and control in manufacture of Ayurvedic medicines and the problem of counterfeit and spurious drugs and controversial drugs acts as a confounding factor in diagnosing the adverse reactions.

6. Clinical trial monitoring

In recent years there has been a substantial increase in the number of clinical trials in developed and developing countries.[5] In most of the clinical trials, ADRs that happen are goes unreported and not informed to the concerned authority. With the advent of newer patent and proprietary Ayurvedic medicines in the market, safety profile of the drug is strongly recommended. Thus clinical trials pose a great challenge for Pharmacovigilance programme.

CONSIDERATIONS

1. The Government has to take stringent action to implement Pharmacovigilance programmes effectively in every centers across India.
2. Education regarding Pharmacovigilance should be included in the curriculum itself.
3. Periodic awareness programmes should be conducted among health care professionals and patients.
4. Monthly ADR reporting must be made mandatory in all AYUSH health centers.
5. The prime responsibility of a centre is to have high quality credible and latest medicine information available to health care professional. For this, the centre should have access to up-to-date and comprehensive literature database.[6]
6. A validated scale should be prepared for the reporting of ADR on the basis of Ayurvedic principles.
7. Pharmacovigilance programmes need strong links with drug regulators to ensure that authorities are well educated on safety issues in every day practice that may be relevant to future regulatory action.[7]
8. The laws must be made stringent to the Ayurvedic pharmaceutical industries to submit Periodic Safety Update Reports (PSUR).
9. Clinical trials must have to pass all the phases including post marketing stage. It is now generally accepted that part of the process of evaluating drug safety needs to happen in the post marketing phase.[8]

CONCLUSION

Safety monitoring of medicines should be an integral part of clinical practice. National programme for Pharmacovigilance are perfectly placed for identifying research necessary for better understanding and treatment of drug induced diseases. Implementation of Pharmacovigilance programme for ASU & H drugs is not an easy task. But with the meticulous planning, proactive approach, continuing zeal and motivation of the concerned staff it can be developed.

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