WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 8, Issue 7, 815-821. Review Article ISSN 2277– 7105

PHARMACOVIGILANCE OF HERBAL MEDICINES IN INDIA: A REVIEW

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Article Received on
05 April 2019,

Revised on 24 April 2019,
Accepted on 16 May 2019

DOI: 10.20959/wjpr20197-15095

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ABSTRACT

Pharmacovigilance helps in detection, assessment, understanding and prevention of adverse effects or any other drug related problem.[1] A large number of reports of the adverse events come every year from different countries. And herbal drugs are also the contributor these events.[2] Every country has been following the rules to collect the side effects of herbal medicines as per their regulatory authorities' rule. In India for the adverse events collection of herbal medicines, a three-tier network of National Pharmacovigilance Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCCs) and Peripheral Pharmacovigilance Centres (PPvCC) has been established. These centres will collect the adverse events reporting, will process the reports and will send them to the regulatory authority of the country.[3] As per WHO various national pharmacovigilance program established in various countries to collect, process, understand and report adverse events of the medicines including the herbal medicines.[4] The European medicine agency (EMA) has provided its rule for pharmacovigilance of herbal medicines and provided its reviews of various herbal medicines as per the available data.[7] In India for the pharmacovigilance of herbal drugs the rules of Drugs and Cosmetic Act and Rules (1940 & 1945) and AYUSH pharmacovigilance program are followed.[3,9] Though every possible step is being followed by the regulatory authorities to assess the causality of the events occurred by the use of herbal medicines use yet it is difficult to proper assess the single constituent as causing agent of the adverse effects. New ways can be followed up by the regulatory authorities to access the exact causality assessment of the adverse events occurring by the use of herbal medicines.

KEYWORDS: Pharmacovigilance (PPvCC) herbal medicines.

INTRODUCTION

Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem is known as Pharmacovigilance.[1]

In most cases it is unpredictable accurately the number of adverse effects, medication errors and poor quality products as there is no hundred percent identification of these side effects by patient, caregiver and healthcare person. Also, there is no cent percent reporting of all the side effects. However the day by day reporting shows that there is increasing number of poor quality products, adverse effects and medication errors. Worldwide a large of number of cases have shown this increase, for example; in the report of 2000 of United Kingdom Department of Health, about 85000 adverse events a year which is approximately equal to 10% hospitalization. Countries like Spain, France and Denmark also published incidence studies with nearly same results.[2] These side effects are due to the allopathic drugs, medical devices, herbal drugs and other traditional drugs. In many of the cases in allopathic drugs where the drug has been used as a single drug its causality assessment with the side effects is easy however in certain combination drugs and when they has been used with the other drugs it become little bit difficult task to assess the relatedness of the events with the drug. However in the case of herbal drugs, it is much harder task to determine which component of the herbal medicine has caused the adverse events as there are lots of chemical components present in single herbal drug. In such scenario, it has become very difficult to determine the causality assessment of the side effects. Though there is sophisticated system in many countries to determine the causality assessment of side effects with allopathic medicines as well as proper reporting by healthcare professionals. But the case of herbal drug's adverse effects reporting is little bit different. The reason of less reporting could be the unknown component causing the adverse effect. Even after receiving the side effects reports for the regulatory authorities it is difficult to determine which chemical component could have raised the adverse effects. In FDA, reporting of adverse events occur by the same channel as like of allopathic and medical devices' adverse events. In India, the reporting till before the establishment of Ayush was also reported directly to the regulatory authorities through specified channel. But after the establishment of Ayush, AE reported via the Ayush channel.

Ministry of Ayush

On 09-Nov-2014, for optimal development and propagation Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) systems of healthcare, the ministry of AYUSH was formed. Before that it was known as the Department of Indian System of Medicine and Homeopathy (ISM&H) established in Mar-1995. In Nov-2003, it was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), it focused attention for development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy.[3]

AYUSH pharmacovigilance

On 01-Nov-2017, the Standing Finance Committee (SFC) chaired by secretary (AYUSH) approved the Central Sector scheme for promoting pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs, with the prime objective to develop the culture of documenting adverse effects and undertake safety monitoring of Ayurveda, Siddha, Unani and Homoeopathy drugs and surveillance of misleading advertisements appearing in the print and electronic media. A three-tier network of National Pharmacovigilance Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCCs) and Peripheral Pharmacovigilance Centres (PPvCC) has to be established under this scheme. All India Institute of Ayurveda, New Delhi, designated as National Pharmacovigilance Centre for coordinating various activities of the initiative. Initially five National Institute of AYUSH will work as the Intermediary Pharmacovigilance Centres and forty two AYUSH institutes having clinical facilities will work as Peripheral Pharmacovigilance Centres. These centres will do the work of reporting, documentation, analysis, causality assessment of the adverse reactions and events associated with the consumption of Ayurveda, Unani, Siddha and Homoeopathy drugs. As a mentor and guide Central Drug Standards Control Organisation (CDSCO) and Indian Pharmacopoeia Commission (IPC) are associated with AYUSH pharmacovigilance central scheme.

The safety and quality issues of Ayurveda, Siddha, Unani and Homoeopathy Drugs have been raised from various sources by the peoples and in response to this Ministry of AYUSH felt that it is necessary in the interest of Public Health to oversee the impact of ASU&H Drugs consumed by the people from the perspective of their safety profile. In the same way, publicizing improper drug information in the form advertisements is also a matter of concern which needs to be addressed to safeguard the interest of AYUSH drug consumers.

Pharmacovigilance initiative will facilitate detection of potentially unsafe ASU&H medicines and misleading advertisements for taking regulatory action against them.[4]

Status of herbal pharmacovigilance in world

All over the world, adverse events of the herbal medicines are reported to their regulatory authorities as per their norms. WHO drug-monitoring program contributed a lot for the pharmacovigilance of herbal drugs. AS per WHO international drug monitoring program, national pharmacovigilance centres of the competent health authorities are responsible for collection, detection and evaluation of adverse event case reports.[5]

Fig. 1: WHO drug monitoring scheme.[5]

The Uppsala Monitoring Centre (UMC) maintains the global WHO database in which all case reports received by the national pharmacovigilance centers are sent. The UMC utilises its database to detect signals from the cumulative data and communicate risk assessments back to pharmacovigilance centers and to other parties which are concerned with drugs safety.[6]

In European Union (EU) the process for the regulation of herbal drug is vigorous. For the pharmacovigilance of herbal drugs EU has provided its recommendations and rejections of the use of some herbal drugs based on the available safety data. It provided its reviews on the some medicines as allergy potency of soya protein, risk associated with use of herbal products of Aristolochia species, environmental risk assessment of herbal medicines, use of herbal medicinal products containing asarone, pulegone and menthofuran etc.[7] Though

every necessary step is being followed to cover the safety profile of the herbal drugs yet no exact causality assessment is possible when the drug is used in combination with other drugs.

Current status of herbal pharmacovigilance in India: In India, AYUSH guidelines and Drugs and Cosmetics Act (D and C) 1940 and Rules 1945 regulations for herbal medicines in India have to be followed for the production and adverse event reporting of the herbal medicines. Anyone who is experiencing side effects during use of ASU drugs, suspected as ASU drug has been the cause of the side effect. As per WHO recommended methodologies the causality of the events is assessed with the ASU medicines. All adverse events suspected to be caused by ASU drugs alone or with other drugs needs to be reported and besides this all drug interactions should be reported to the regulatory authority of the country. Any healthcare professional may report suspected adverse events and others can report through their physician whom he/she has undergone a treatment.8 Certificates of GMP has to be followed up by the ASU drugs as per the form 26E-I.9 By following the GMP, some side effects can be reduced which might occurred by the use of improperly processed ASU drugs.

Challenges in Monitoring the Safety of Herbal Medicines

Though every possible step is being followed by different regulatory authorities to know and regulate the safety of herbal medicines yet due to many reasons it is impossible to know the exact cause of the adverse drug reactions in herbal drug usage.

There are various challenges in causality assessment and other parameters in the safety profile of these herbal drugs like

1. Information of herbal drugs is not in electronic form. It is mainly in the traditional literatures.
2. Many of the herbal medicines are of multi-ingredient containing medicines. So to know the causing agent is very difficult.
3. Extract of a herbal medicine contains many chemical entities in it. So when a part of herbal medicinal plant is being used by the patient. Then it is difficult to know that which active substance has caused the event.
4. Lack of expert persons for the causality assessment of herbal medicines.[10]

In addition to this many other factors like under reporting of side effects and myth among the population is that herbal medicines are side effect free drugs leads to escape of many events of the herbal medicines undetected.

CONCLUSION

Side effects of the herbal medicines is a matter of concern over the world. Every country is trying to record the adverse effects of these drugs. Many countries are trying to keep the safety profile of the herbal drugs by following their regulatory authorities' rules. In India the herbal drugs used on a large scale. In India the ministry of AYUSH had been established by the Govt. of India in on 09-Nov-2014. Ministry of Ayush has set a standing committee to regulate the pharmacovigilance of herbal medicines in India. For the causality assessment of herbal medicines India followed the WHO recommended guidelines. To reduce the side effects of herbal medicines, it is mandatory for the manufacturers to follow the Good manufacturing practice as per the form 26E-I. As many chemical entities are present in the herbal medicines, so it makes to find out the adverse effect causing agent. Though there are any ways are being followed to properly assessing the causing agent of the adverse effects, yet there are ways to clear estimation of the causality assessment in the adverse effects of herbal medicines.

CONFLICT OF INTEREST

None reported.

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