Pharmacovigilance and Indian System of Medicine: An Overview

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Abstract

Ayurveda- the science of life is oldest repository of medical sciences of ancient India. It has two basic objects i.e. maintenance of health and cure of disorders, for this purpose number of herbal drugs are used. It is a popular perception prevailing throughout the globe that, the traditional systems of medicine (Ayurveda, Siddha, or Unani) do not produce any adverse effect, but today it is not truth. In present scenario, increased globalization of these systems have been raised concerns about safety, efficacy and acceptability of Ayurvedic products. Standardization of drugs means confirmation of its identity and determination of its quality and purity. To tackle these concerns, a system like pharmacovigilance is needed to be established considering this, Department of AYUSH, Ministry of Health and Family Welfare, New Delhi has launched Pharmacovigilance programme for Ayurved, Siddha, and Unani medicines. The present article will provide a brief outlook for standardization and pharmacovigilance concerning Ancient and Modern views.

Keywords: Pharmacovigilance, Standardization, Safety, Efficacy, Indian System of Medicine

Introduction:

Quality control for the efficacy and safety of herbal products are essential. The quality control of phyto pharmaceuticals may be defined as the status of a drug which is determined either by identity, purity, content, and other chemical, physical or biological properties, or by the manufacturing process. Even though global herbal resources have a great potential as natural drugs and are of great commercial importance, they are very often procured and processed without any scientific evaluation, and launched onto the market without any mandatory safety and toxicology studies because there are no effective machinery to regulate manufacturing practices and quality standards. Although most of the herbal medicines are safe, but there is unquestionably a need for more reliable information regarding safety and
efficacy of these drugs. Lack of experience, information, and education about herbs make consumers and physicians easy victims of market exploitation and herbal myths. There is no rational reason behind the tendency to equate “natural” with “harmlessness.” The fact that something is natural does not necessarily make it safe or effective. In addition, a lack of knowledge of photochemistry leads to misinterpretation and misunderstanding. It is very likely that some herbs will have side effects, the possibility of herb-drug interactions is important but “under-research” is an issue. The World Health Assembly in resolutions WHA31.33 (1978), WHA40.33(1987), and WHA42.43 (1989) has emphasized the need to ensure the quality of medicinal plant products by using modern control techniques and applying suitable standards.[1,2,3] There is a lack of open interpretation in the area of safety and efficacy, especially for bibliographic studies. Such interpretations are particularly relevant for herbal medicinal products because they have been used for long periods of time, sometimes over centuries, and a wealth of literature is available. It is desirable that this documented traditional knowledge is exploited in scientific manner so that we can develop a system to ensure that every packet of medicine that is being sold has the correct substance in the correct amount and will induce its therapeutic effect. The authentic, quality and purity of Ayurvedic drugs are established by pharmacopoeial committee. The Pharmacopoeia prescribes numerical structural, analytical and physical standards for the drugs. The important standards mentioned in Pharmacopoeia are as follows-[4-6].

The WHO assembly has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and applying suitable standards[7]. Apart from that the continuous monitoring of the safe use of medicinal product is essential. “The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem is known as Pharmacovigilance[8].

Material & Method

PHARMACOVIGILANCE IN INDIA:

Since the first major drug related disaster involving sulfaanilamide in 1937, which killed 107 children, there have been several cases of severe adverse reactions and even death, for example thalidomide in 1961, Practical In 1974, Benoxaproten and phenformin in 1982 and several others, leading to withdrawals and banning of the synthetic drugs.
Since 1993, seven other drugs were withdrawn from the market due to fatalities and unacceptable side effects. In 1986, an adverse drug reaction (ADR) monitoring system for synthetic drug consisting of 12 regional centers was proposed for India and in 1997 India joined as World Health Organization (WHO) ADR monitoring programme base in Uppsala, Sweden [7-8].

PHARMACOVIGILANCE FOR AYURVEDA, SIDDHA AND UNANI DRUG IN INDIA:

Pharmacovigilance system for monitoring ADR if any of Ayurveda, Siddha and Unani drugs is prevailing being established in India. Considering to this, Institute for Postgraduate teaching and research in Ayurveda, Gujarat Ayurveda University, Jamnagar has taken the bed and conducted workshop during month of December 2007 in the premises of Gujarat Ayurveda University, Jamnagar under the sponsorship of WHO Country Office India. Looking into the active initiation, Director of AYUSH, Ministry of Health and Family Welfare, New Delhi announced establishment of a Pharmacovigilance Cell at the Institute level, which will prepare the protocol and ADR reporting format for implementation of Pharmacovigilance system for Ayurveda, Siddha and Unani Medicines[8].

The draft protocol was discussed and technically analyzed by the experts of the consultative committee during 29th and 30th August 2008 at AYUSH, New Delhi organized under the sponsorship of WHO, Country office India[8].

FRAME WORK OF PHARMACOVIGILANCE FOR AYURVEDA, SIDDHA AND UNANI DRUGS:

The Pharmacovigilance programme is being implemented all over India by following the guidelines provided in the National Pharmacovigilance Protocol for Ayurveda, Siddha and Unani drugs. Out the programme successfully, a three tier system is being implemented, working out in their angle, the below specified centers have been identified across the country preferably at least one in every state[8].

1) National Pharmacovigilance Resource Center (NPRC): One
2) Regional Pharmacovigilance Centres (RPCs): Eight
3) Peripheral Pharmacovigilance Centers (PPCs): Thirty.

The activities of the RPPs and PPCs will be supervised by the NPRC. The administrative and financial aspects related to the programme shall be monitored and regulated by National Pharmacovigilance Consultative Committee to ASU drugs[8].

A part of generating awareness and sensitization of AYUSH personal and common people regarding Pharmacovigilance system, training programmed in the form of (MEs/ROTPs/Workshops will be organized at NPRC/RPU/PPCs levels throughout the country[8].

Discussion:

Success of any health care system always depends upon the availability, authenticity, safety and efficacy levels of the suitable drugs. Opinion about the safety, efficacy, and the appropriateness of medicinal herbs varies widely among medical and health professionals in countries where herbal remedies are used. In most cases the safety and efficacy of drugs of herbal origin cannot be attributed to one single chemical constituent. Various pharmaceutical particulars, including the production and collection of the starting material and the extraction procedures, need to be assessed. Perhaps the major problem with regard to the safety of herbal medicines is related to the manufacturing practice, including contamination, substitution, incorrect preparation and dosage, intentional addition of unnatural toxic substances, interactions involving and the presence of natural toxic contaminants[8-9].

However, this will not be easy, as it requires a thorough search for medicinal plants, proper guidelines for their identification, validation of the scientific methods of isolation of active ingredients, preclinical evaluation of their pharmacological and Toxicological profiles, and clinical evidence of their
usefulness. Clinical trials should be conducted to establish facts such as the average effective dose for any drug, as well as potential side effects a compound may cause. It has now become evident that there is need for a holistic approach to health care, and the untapped potential of traditional medicines should be utilized. In other words it can be said that all health care services will get paralyzed without safety and efficacy. The long history of successful usage of Ayurvedic medicines in different pathological manifestation is the ultimate proof for their safe, efficacious, non-toxic and beneficial effects Different kinds of medicinal preparation explained in ancient Indian classics have helped to bring improved health and longer life to human beings since ages without developing any kind of untoward effects. In Ayurvedic classics the issue of safety has been discussed in detail which provide all the guidelines to avoid the occurrence of any unwanted effects. For this purpose our Acarya’s ascribed the characteristics of best therapy[10].

A drug which cures an ailment but does not produce any another effect, is a whole and complete drug. Above statement was said by Acharya Charaka in reference of some general principles regarding drug[10].

Further Acharya Charaka exclusively focuses on the safe use of a drug and about the toxic effects and says that, improperly known, processed, combined and used will kill the individuals like a thunder belt. Acharya Kashyapa also emphasized on rational use of the drug and states that the disease is cause of trebles and medicines is cause of pleasure. The unknown medicine is like poison, weapon, fire and thunder-balcon the other hand the known are is like nectar. In short properly used medicine becomes nectar and improperly used becomes like a poison[10-12].

Conclusion:

All drugs available in the world are capable to producing good and bad effects. To minimize the bad effects, the drugs are supposed to be used judiciously. For this the pharmacopoeial standards in Ayurvedic Pharmacopoeia of India are adequate enough to ensure the quality of plant material, through the use of approved quality of materials, approved packing materials, standardized and well validated methods of processing and manufacture, complete finished product quality control testing. The science of Pharmacovigilance is very essential to meet different challenges like ADR of the drugs for waging safely.

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