Original Article

Indian herbal pharmacovigilance: The untamed saga

Abstract

Background: The acceptability of herbal formulations as therapeutic agents for numerous diseases has reached to its brim in the latest phytomedicine scenario. Since herbal medicinal products are complex mixtures from biological sources, regulations are necessary to guarantee the constant quality and quantity in order to break the unanimous myth related to herbal medicines consumption. Although the pharmacovigilance program in India has spread its roots in the field of medicines, amazingly there has been no benchmark regulations set up in the herbal segments. **Aim:** As per the latest regulatory scenario, the herbal drug regulation or herbal pharmacovigilance of India is lagging very much behind the highly regulated international herbal markets. The present article serves as a reminder of the fact that it is the high time for the Indian drug regulators to tame the herbal drug market since India has emerged as resourceful of enormous herbal medicines with full proof folk knowledge but is still lacking the specific legislative criteria to establish these herbal products as "medicine." **Conclusion:** This systemic herbal pharmacovigilance will definitely boost up not only the herbal market trend, but also the confidence about using of botanical medicines regarding their safe and rationale use within the ambit of pharmacotherapy.

Key words:
Herbal drug regulations, pharmacovigilance, phytomedicine

Introduction

The term pharmacovigilance has been defined as "the study of the safety of marketed drugs" under the practical conditions of clinical usage in large communities with the basic aim to improve patient care and overall public health and safety in relation to medicinal use.[1] Apart from monitoring medicines, this basic motive of adverse drug event detection and safety monitoring has covered herbals, traditional and complementary medicines, blood products, biological, medical devices, and vaccines.[2,3]

India is a very potential source of herbal plants and the use of herbs as a potential source of medicine is as old as history itself.[4] Since the use of herbal medicines has increased to many folds, there are certain reports of toxicity and adverse events related to the use of medicines from herbal source. The myth that herbal drugs are safe in spite of its unpredictable pharmacodynamics is to be broken in order to establish the faith of end users as most of the herbal drugs are not been subjected to preclinical and clinical safety assessment.[5]

Poor quality, misidentification of herbs, and adulteration has significantly attributed to the on-going problem regarding herbal drug safety.[6] These issues have sparked the need of a strong regulatory enforcement for the herbal drug, which should not compromise with the overall public health status.

Access this article online	
Website: www.ddtjournal.org	**Quick Response Code**
DOI: 10.4103/2394-6555.191173	

Swati Madan, Sumeet Gullaiya

Amity Institute of Pharmacy, Amity University, Noida, Uttar Pradesh, India

Address for correspondence:
Dr. Swati Madan,
Amity Institute of Pharmacy, Amity University, Sector-125,
Noida - 201 301, Uttar Pradesh, India.
E-mail: smadan3@amity.edu

How to cite this article: Madan S, Gullaiya S. Indian herbal pharmacovigilance: The untamed saga. Drug Dev Ther 2016;7:122-4.

Need of Pharmacovigilance in Herbals

The first and foremost issue with herbals as medicines is the undefined toxicological data. Since most of the literature or traditional knowledge is scattered in the case of herbals, it makes the scientific world to access the safety and toxicological profiles of most of the herbs.[7] Standardization of herbal formulations and drugs is essential in order to assess the quality, based on the concentration of their active principles [Figure 1]. The adverse effects of the end users are not being monitored, which leads to chaos in the mind of researchers, which needs to have dose-related effects of the herbal medicines. In view of the same, the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring has recommended the use of proper scientific binomial names for herbs used in medicine in order to track and record the same for further references and researches.[8] This database will certainly lead to significant comparability between various national and international platforms. Moreover, the adulteration in the name of herbals has been consistently reported, which have further reduced the interest of scientific community toward herbals.

There are several countries, which widely accept traditional and experience based evidence in the case of herbals while the others doubt the integrity of such medicines from herbal source. The pharmacovigilance of herbal medicinal products will definitely go a long way in restoring the confidence of researchers and end users for their safety and efficacy.

Regulatory Status of Herbal Medicines in India

The regulatory status of herbals in India is somewhat different from other countries as India have folk and traditional knowledge of time-tested herbs and their use as medicines.[9] What India lacks is the regulatory approvals of these herbal medicines as these herbal medicines are not known with exact safety, efficacy, and quality to support the data from scientific world and the data which are available is not comparable globally in terms of clinical and scientific evidence.[10] There should be a stringent criterion for different nature of herbals, and there should be different divisions to submit toxicity data and clinical trial data.

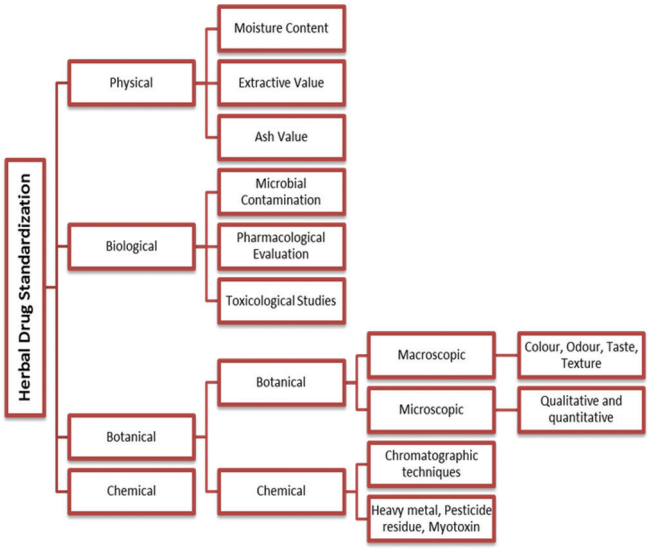

Figure 1: Standardization parameters for herbal drugs

The Emergence of Pharmacovigilance of Herbal Medicines in India

The importance and awareness of pharmacovigilance of herbal medicines have been on the constant rise in India since 2003 with the Constitution of the National Pharmacovigilance Program of India, which is operating under the control of the Central Drug Standards Control Organization.[11] Apart from this, WHO has also emphasized that traditional medicines should be included in pharmacovigilance system and has already published guidelines in 2004 on the safety monitoring of herbal medicines in pharmacovigilance systems.

This move was followed by many government departments in India including the Department of Ayurveda, Yoga, Unani, Siddha, Homoeopathy, Ministry of Health and Family Welfare, Government of India, New Delhi, which initiated pharmacovigilance program for Ayurvedic, Siddha, and Unani drugs also.[12] The list of significant events in the field of herbal pharmacovigilance in India is given in Table 1.

Pharmacovigilance of Herbal Medicines in India Challenges Ahead

The pharmacovigilance program in India is although been practiced and implemented in a war scale status; the practice apparently suffers from many glitches. First, the reporting of adverse events related to herbal drugs is abysmally quite low in spite of multi-initiatives by the government to facilitate these reporting.[13,14] Following the reporting, the detection of adverse events are not significantly done as the names, toxicological profiling, and detections criterion

Table 1: A comprehensive list of significant events in the field of herbal pharmacovigilance in India

Year	Notable events
1983	National Health Policy claims that herbal drugs should be standardized
1995	Creation of Ayurveda, Yoga, Unani, Siddha, and Homoeopathy
2007	WHO Guidance on good manufacturing practices for herbal medicines
2011	Draft guidance for industry: Dietary supplements: New dietary ingredient notifications and related issues

WHO: World Health Organization

are not comparable, and adulterated drugs are creating a nuisance in the same.

To add on to these hindrances, lack of trained and qualified professionals with an inability to correlate the things and misjudging the active ingredient, mechanism of action and toxicological symptoms play an important role.[15,16]

Conclusion

The pharmacovigilance program concept regarding herbals should be introduced at graduate and post graduate levels. Vigilance in terms of adverse drug reaction and adverse event monitoring of herbals and signal generation should be of high priority. Trained pharmacovigilance professionals is an important part of this program and should play an important role in monitoring regulatory control and strengthen the existing pharmacovigilance programs.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References

1. Ang-Lee MK, Moss J, Yuan CS. Herbal medicines and perioperative care. JAMA 2001;286:208-16.
2. Gossell M, Simon OR, West ME. The past and the present use of plants for medicines. West Indian Med J 2006;55:217-8.
3. De Smet PA. The role of plant-derived drugs and herbal medicines in healthcare. Drugs 1997;54:801-40.
4. Dahanukar SA, Thatte UM. Ayurveda Revisited. 1st ed. Mumbai: Popular Prakashan Private Ltd.; 1989.
5. Barnes J. Pharmacovigilance of herbal medicines: A UK perspective. Drug Saf 2003;26:829-51.
6. Dahanukar SA, Thatte UM. Ayurveda Unravelled. New Delhi: National Book Trust; 1996.
7. Farah MH, Edwards R, Lindquist M, Leon C, Shaw D. International monitoring of adverse health effects associated with herbal medicines. Pharmacoepidemiol Drug Saf 2000;9:105-12.
8. Bruhn JG, Holmstedt B. Ethnopharmacology: Objectives, principles and perspectives. In: Reinhard E, Beal JL, editors. Natural Products as Medicinal Agents. Stuttgart: Hippokrates; 1981. p. 405-30.
9. Gadre GK, editor. "13th Adhyaya" Ashtang Hridaya. 2nd ed. Pune: Aryabhushan Printing Press; 1910. p. 65.
10. World Health Organization. The importance of pharmacovigilance: Safety monitoring of medicinal products. Geneva: World Health Organization; 2002.
11. World Health Organization. WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems. Geneva: World Health Organization; 2004.
12. Bowdler J. Effective Communications in Pharmacovigilance: The Erice Report. Birmingham: W Lake; 1997.
13. Available from: http://www.nccam.nih.gov/health/ayurveda/. [Last accessed on 2007 Sep 07].
14. Thatte UM, Rege NN, Phatak SD, Dahanukar SA. The flip side of Ayurveda. J Postgrad Med 1993;39:179-82.
15. Barnes J, Mills SY, Abbot NC, Willoughby M, Ernst E. Different standards for reporting ADRs to herbal remedies and conventional OTC medicines: face-to-face interviews with 515 users of herbal remedies. Br J Clin Pharmacol 1998;45:496-500.
16. Gogtay NJ, Bhatt HA, Dalvi SS, Kshirsagar NA. The use and safety of non-allopathic Indian medicines. Drug Saf 2002;25:1005-19.