



A Review on Pharmacovigilance of Herbal Medicinal Products

Tuba Shaikh*, Mukul Sharma, Abhishek Shah, Praveen Sharma and Gajanan N. Darwhekar
Acropolis Institute of Pharmaceutical Education & Research, Indore, (M.P) - India

Abstract

Herbal drugs referred as plants materials or herbalism, involves the use of whole plants or parts of plants, to treat injuries or illnesses. Herbal medicines widely used in health-care in both developed and developing countries. Herbal formulations have reached extensive acceptability as therapeutic agents for several diseases. Standardization of methods and quality control data on safety and efficacy are required for understanding of the use of herbal drugs. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other possible drug-related problems. The aims of pharmacovigilance is to protect patients from unnecessary harm by identifying previously unrecognized drug hazards, elucidating pre-disposing factors and quantifying risk in relation to benefits. A drug is defined as being safe if it causes no known or potential harm to users. Safety is a fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control. A major factor impeding the development of the medicinal plant based industries in developing countries has been the lack of information on the social and economic benefits that could be derived from the industrial utilization of medicinal plants. With the increased use of herbal products, the future worldwide labeling practice should adequately address quality aspects.

Key-Words: Pharmacovigilance, Herbal Medicinal Products, National Pharmacovigilance Centres

Introduction

Health care profession is supreme profession in mankind. It requires regulation safety and purity of herbal component. Many organizations regulate drug safety and efficacy like cGMPs, MHRA, WHO and many others. Herbal medicines needs standardization for improvement and quality control of medicines for the treatment of diseases^[1]. Herbal medicines are nothing but it is a botanical medicine like roots, leaves, barks, flowers and other parts of plant itself. Use of herbs in treatment of diseases called herbalism which has long tradition of use outside of conventional medicines. A drug is defined as a moiety being safe if it causes no known or potential harm to users. Safety is a fundamental principle in the provision of herbal medicines and herbal products for health care, and a critical component of quality control. In recent years, plant derived products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics and are available in health food shops and pharmacies over the counter as self medication or also as drugs prescribed in the non-allopathic systems^[2,3].

Safety and efficacy are the two major concerns about any drug, while efficacy can be detected with relative ease; the same cannot be said about safety because the adverse effect of a drug may be uncommon but very serious. This gave a birth to a new branch of pharmacology called pharmacovigilance^[4,5]. It is a French term referring to identifying side effects of drugs, their treatment, documentation, reportage and regulatory decisions based on them, is a well established science in the developed world. Pharmacovigilance is a discipline involving detection, evaluation and prevention of undesirable effects of medicines. It involves monitoring the safety of drug over a period of time, identification of adverse drug reactions in humans, access risk-benefit ratio^[6].

Aim of the study

The aims of this review is to enhance information of patient care and patient safety in relation to the use of herbal medicines; and providing reliable, balanced information for the effective methodologies of herbal medicines.

Pharmacovigilance of herbal medicines

World Health Organization (WHO) has defined herbal medicines as finished, labeled medicinal products that contain active ingredients, aerial or underground parts of the plant or other plant material or combinations.

* Corresponding Author

E.Mail: tubashaikh0@gmail.com
Mob. +91-9039594651

WHO has set specific guidelines for the assessment of the safety, efficacy, and quality of herbal medicines. WHO estimates that approx 81% of the world populations presently use herbal medicine for primary health care^[7]. It is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961^[8]. Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, WHO promotes PV at the country level. At the end of 2010, 134 countries were part of the WHO PV Programme^[9]. The aims of pharmacovigilance is to protect patients from unnecessary harm by identifying previously unrecognized drug hazards, elucidating pre-disposing factors and quantifying risk in relation to benefits. The purpose of pharmacovigilance is to detect, assess, and understand and to prevent the adverse effects or any other possible drug-related problems, related to herbal, traditionally and complementary medicines^[10]. Herbal medicines are widely used in both developed and developing countries however, in recent years, there are several high-profile herbal safety concerns having an impact on the public health. Herbal medicines are traditionally considered as harmless but as medicinal products they require drug surveillance in order to identify their risks^[11].

Purpose of pharmacovigilance studies

It is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include:

- Herbals
- Traditional and complementary medicines
- Blood products
- Biologicals
- Medical devices
- Vaccines

Other aims of pharmacovigilance studies are to

- Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions,
- Improve public health and safety in relation to the use of medicines,
- Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use, and

- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public^[12].

Action required

For the safety of those using herbal medicines, four complementary actions are needed:

- Clear identification of the nature of adverse events
- Management of the risks
- Institution of measure to prevent adverse events
- Good communication of the risks and benefits of herbal medicines.

Core functions of National Pharmacovigilance centres

Continuous collection of reports of suspected adverse reactions for medicines on the market

Assessment of case reports in respect of:

- Quality of documentation
- Causality assessment
- Coding to international standards using the appropriate medicine classification (the anatomical-therapeutic-chemical (ATC) classification), adverse reaction classification (who adverse reaction terminology (who-art) and the medical dictionary for drug regulatory activities (meddra)
- Clinical relevance
- Quality control, in particular identification

of duplicate reports

Transmission in suitable format of the assessed reports to UMC (WHO Collaborating Centre in Sweden, the Uppsala Monitoring Centre)

Generation of hypotheses or the identification of signals. These activities may be strengthened by a search of the global WHO database (managed by UMC) for similar reports

Communication of relevant safety information to the national and regional regulatory authorities, health professionals, pharmaceutical companies and other players as appropriate

Further investigation of signals, risk factors or pharmacological mechanisms

Receipt and communication as appropriate of safety information resulting from analyses by UMC and from regulatory agencies, case reports and the literature

Provision of feedback to reporters

Timely advice to health-care professionals and consumers on drug safety issues

Education and training

Information sharing at regional and global levels.

Sources of reports

The Council for International Organizations of Medical Sciences (CIOMS) Working Group V has recommended that, as a general guiding principle, emphasis should be placed on the quality of a report and not on its source. Thus, the value of a report lies not in who made it, but in the care and thoroughness with which it is prepared, documented, received, recorded, followed-up, clarified and analysed. However, the source of a report can be an important factor in evaluating the report as it may affect the quality and value of the information. The nature, degree and even feasibility of any follow-up will also be highly dependent on the source^[12].

Reports from health-care professionals

Internationally, adverse drug reaction reporting systems in the post-marketing safety surveillance setting depend primarily on voluntary reporting by health-care professionals, preferably those directly associated with the care of the patient/consumer (i.e. the patient's primary health-care provider or specialist). This is appropriate, since the understanding of adverse drug reactions depends on medical knowledge and such professionals should be aware of the patient's medical history and attuned to the subtleties of clinical differential diagnosis.

Reports from consumers

The involvement of consumers in the use of herbal medicines and herbal products in health care, and their concern regarding possible adverse effects should be valued positively. Consumer reports on adverse reactions should be accepted as a serious source of information, which can contribute to the identification of signals for unknown effects of herbal medicines.

Reports from manufacturer

Manufacturers of herbal medicines could be a source of information on adverse events associated with their products. Some countries include reporting of adverse events by manufacturers as part of their regulatory framework^[12].

Reports from other sources

Problems associated with herbal medicines may be reported as toxicity to the following.

National poisons centres: Where resources are very limited in the national situation and where no pharmacovigilance centre has been established, a poisons centre could play a core role in pharmacovigilance for and safety monitoring of herbal medicines.

Drug information centres: may also be a first point of contact and may provide a wealth of clinical information. National pharmacovigilance centres

should have a good level of communication with such centres.

Consumer organizations: receive complaints about any type of product in the marketplace and may obtain relevant information about herbal medicines

Clinical trials and studies: can also be a source of information.

Data management

Data quality -Strenuous efforts should be made to ensure that there are quality controls on data processing and that the data elements of reports are as complete and accurate as possible. Mechanisms to check for duplications should be instituted.

Data storage- Computer databases should be managed to as high a standard as possible to facilitate access to and use of the data. Software should be selected with expert advice so that analytical needs can be met.

Data analysis-Programmes should be developed to provide for regular analyses and data output appropriate for local needs.

Analysis of the global WHO database-The global WHO database managed by UMC is being improved on the basis of the proposed database management and classification for coding of herbal medicines.

Communication

Communication should be established at many different levels, for example, between:

- The national pharmacovigilance centre and health professionals
- The national pharmacovigilance centre and providers of herbal medicines
- Health professionals and providers of herbal medicines, and consumers and patients
- Providers of herbal medicines and those for other medicines
- The national pharmacovigilance centre and consumers
- The national pharmacovigilance centre and the regulatory authority
- The national pharmacovigilance centre and such centres in other countries, within the region or in other regions
- The national pharmacovigilance centre and UMC
- The national pharmacovigilance centre and the mass media.

Risk communication

Communication strategies should be established to effectively reach all relevant target audiences, such as providers of herbal medicines, other health professionals, manufacturers and patients/consumers. Communication of safety information is a shared

responsibility between national pharmacovigilance centres, national regulatory agencies, manufacturers and health professionals^[12].

Different risk communication vehicles can be considered, including

- Adverse reaction bulletins or articles distributed in reputable journals
- Public advisories or warnings
- Dear health professional" letters.

Various methods of information dissemination can be considered, such as

- Internet posting
- Direct mass mailing to providers of herbal medicines and health professionals
- Briefings to the mass media
- Briefings to patient/consumer associations
- Education sessions at health professional society meetings.

In order to reach consumers and the wide range of providers of herbal medicines successfully, messages should be tailored to suit the recipients, including translation into local languages where appropriate.^[12]

Conclusion

Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from health care providers and prevent patients on the adverse effects of medications, biological products, herbal medicines and traditional medicines. Patient's health is the super most priority of healthcare profession.

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How to cite this article

Shaikh T., Sharma M., Shah A., Sharma P. and Darwhekar G.N. (2014). A Review on Pharmacovigilance of Herbal Medicinal Products. *Int. J. Pharm. Life Sci.*, 5(5):3554-3557.
Source of Support: Nil; Conflict of Interest: None declared

Received: 01.04.14; Revised: 10.04.14; Accepted:22.04.14