Review Article

Pharmacovigilance Program of Unani Drugs in India

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ABSTRACT

Unani is the ancient Greek system of medicine that evolved throughout the ancient world and has been used for the prevention and treatment of diseases for thousands of years. The use of herbal medicinal products and supplements has increased tremendously over the past three decades with not less than 80% of people worldwide relying on them for some part of primary healthcare. Since safety continues to be a major issue with the use of herbal remedies, so as to protect public health the Ministry of AYUSH has started a Pharmacovigilance Program of ASU & H drugs. This review aims to provide the details of the Pharmacovigilance Program of Unani Drugs in India.

Keywords

Pharmacovigilance; Pharmacovigilance Program; Unani Drugs

INTRODUCTION

Indian traditional medicine is based on various systems like Ayurveda, Siddha, and Unani (ASU).[1] Unani medicine has also known as Greco-Arab medicine, its theories and philosophies were conceptualised and developed by Greeks, Romans, and Arab physicians like Hippocrates, Galen, Razes, Avicenna, etc. Unani medicine provides effective treatments and preventive measures for diseases, its holistic approaches include unique principles of diet, lifestyle, and therapeutics, to balance and enrich all aspects of life.[2]

In order to promote AYUSH systems of medicine, the Ministry of Health and Family Welfare, Government of India established a separate Department of Indian Systems of Medicine and Homoeopathy (ISM&H) in 1995, which was renamed in November 2003, as the Department of AYUSH (Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homoeopathy). On November 9th, 2014 the Department of AYUSH was elevated to a full-fledged Ministry of AYUSH and it has a mandate to promote and propagate Indian Systems of Medicine and Homoeopathy, in India and globally.[3] The Ministry of Ayush has a vision of reviving the profound knowledge of ancient systems of medicine and ensuring the optimal development and propagation of the Ayush systems of healthcare.[4]

In 1975 the Drug Control Cell for Ayurvedic and Unani medicines started to regulate the issues of licensing and quality control mechanisms for the manufacturing of Ayush medicines in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and the Drug and Cosmetic Rule 1945.[5] The Drugs & Cosmetics Act, 1940 provides rules for licensing, manufacturing, labelling, shelf-life and testing of Ayush drugs. Both Ayush and

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allopathic drugs are regulated under the provisions of the same Act, the Drugs and Cosmetics Act, 1940, and the regulatory provisions are framed on more or less similar lines. The Central Government is vested with the powers to make and amend the legal provisions of the State Governments. Accordingly, the state governments are responsible for enforcing the legal provisions for Ayush drugs, for which Licensing Authorities / Drug Controllers are appointed. Good Manufacturing Practices and Quality Standards for manufacturing Ayurvedic, Siddha, Unani, and Homeopathic drugs as prescribed in the Drugs & Cosmetics Rules, 1945, and the respective pharmacopeias are mandatory for the manufacturers to follow. Pharmacopoeial Commission of Indian Medicine & Homoeopathy and Pharmacopoeia Committees are in place to lay down quality standards and Standard Operating Procedures for the manufacturing of ASU & H drugs.[6]

Need of Pharmacovigilance

The use of herbal drugs continues to expand across the world with many people now resorting to herbal products for treatment of various health issues. The past decade has witnessed a tremendous surge in acceptance and public interest in natural therapies both in developing and developed countries. It is estimated that more than 80% of the world's population in over 170 of WHO's 194 member states currently use some form of traditional medicine.[7] As the global use of herbal medicinal products grows, public health issues and concerns about their safety are also increasingly recognized. Although some herbal medicines have promising potential and are widely in use, many of them remain untested. It has now become essential, to furnish the general public including healthcare professionals with adequate information to facilitate a better understanding of the risks associated with the use of herbal products and to ensure these medicines are safe and of suitable quality.[8]

Pharmacovigilance is a science relating to the safety of drugs, helps in promoting the safe use of medications, and provides balanced information for the effective assessment of the risk-benefit profile of medicines.[9]

In India, the Pharmacovigilance program for conventional medicine is covered by the Indian Pharmacopoeia Commission (IPC) and Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare, Govt. of India, and IPC was assigned to develop and maintain Pharmacovigilance (PV) database.[10] In 2002, the government signed an agreement to share all Adverse Drug Reactions (ADRs) of the conventional systems of medicine and alternative systems of medicine like Ayurveda, Siddha, Homeopathy, and Unani with the use of WHO terminology. Accordingly, the Ministry of Health and Family Welfare, Govt. of India, under the aegis of IPC & CDSCO established three PV centers; All India Institute of Medical Sciences (AIIMS), New Delhi, King Edward Memorial (KEM) Hospital, Mumbai, and Jawaharlal Nehru Medical College (JNMC), Aligarh Muslim University, Aligarh. The Pharmacovigilance Program of India (PvPI) started under the funding of the World Bank and sponsorship of WHO.[11]

The CDSCO is the national regulatory body for Indian pharmaceuticals and medical devices, it is in collaboration with IPC monitors the safety of medicines and regulatory intervention if required to propagate the medicine safety-related decisions to the stakeholders.[12]

National Pharmacovigilance Program for ASU drugs

World Health Organisation (WHO) emphasizes that traditional medicines should include in the Pharmacovigilance system, and accordingly published 'Guidelines on Safety Monitoring of Herbal Medicines in 2004.[13] To promote the rational use of herbal medicine, based on the guidelines of WHO, Ibn Sina Academy of Medieval Medicine & Sciences (Aligarh), took a novel task of improving the use of Indian originated drugs and their adverse reaction monitoring by establishing a special cell namely, "Centre for Safety & Rational Use of Indian Systems of Medicine" (CSRUISM) in early 2005, and this organisation started receiving ADRs of herbal drugs, which were never reported earlier, and all such reactions were undergone with causal relationships according to WHO Causality Categories and Naranjo ADR Probability Scale Evaluation.[14]

The Society of Pharmacovigilance, India (SoPI), is an Indian national non-profit scientific organization that was constituted and registered in 1999 with multiple aims and objectives to promote Pharmacovigilance in India.[15] The main aim was to promote the study of the use and effects of drugs in the population in a rational way; to determine the risk/benefit ratio of drugs in an individual. SoPI was the first national professional society in the world after the European Society of Pharmacovigilance (ESoP).[16] The first National Symposium on the Relevance of Herbal Pharmacovigilance under the auspices of the Department

of AYUSH, Ministry of Health and Family Welfare, Government of India was held on 4th November 2006, organised at the Department of Pharmacology, JNMC, Aligarh with the collaboration of SoPI and the Ibn Sina Academy, Aligarh. This symposium witnesses the presence of many researchers from JNMC and Ajmal Khan Tibbiya College as well as scientists from the Unani Research Council, particularly the contribution of faculties of Advia, Ajmal Khan Tibbiya College, Aligarh was remarkable in this symposium. A report of the symposium recommending the initiation of an exclusive National Pharmacovigilance Program for ASU drugs was submitted to the Dept. of AYUSH, Ministry of Health and Family Welfare, Govt. of India.[17]

Pharmacovigilance Program on Indian System of Medicine in collaboration with WHO

In the year 2006, Topiwala National Medical College (TNMC) and BYL Nair Charitable Hospital, started the PV program for the traditional medicinal systems of India, and a similar initiative was also taken by Banaras Hindu University, Varanasi to conduct a workshop on PV of Ayurvedic medicine in November 2006.[18,19]

Institute of Post Graduate Teaching & Research in Ayurveda (IPGT & RA), Jamnagar, conducted a two-day national workshop on the 3rd and 4th December 2007 on 'Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations, and Method of Implementation', and resolved to recommend establishing a Pharmacovigilance Cell (PV Cell), first of its kind in India for Ayurveda at IPGT & RA, Jamnagar. Reporting Form for suspected adverse reactions of Ayurvedic formulations was developed, which was vetted by the faculty members, research scholars, and physicians under intimation to Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India.[20]

The National Pharmacovigilance Consultative Committee for ASU Drugs (NPCC-ASU), is comprised mainly of administrative heads of National Institutes, regulatory authorities, and technical persons and is responsible for monitoring and regulating administrative and financial aspects related to the programs.[21] The first National Consultative Committee Meeting for the adoption and implementation of the National Pharmacovigilance Program for ASU Drugs, under the chairmanship of Prof. K. C. Singhal was organized on 29th and 30th August 2008. The meeting was attended by representatives from the ASU research councils (CCRAS, CCRUM) and other consultative committee members. It was suggested to launch a National Program for monitoring safety of ASU Drugs. The national draft protocol was technically reviewed and finalized.[22]

Considering the WHO guidelines for the safety of herbal medicines and to put the pharmacovigilance system for ASU drugs in the proper place, the Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, New Delhi, launched the National Pharmacovigilance Program for ASU Drugs on 29th September 2008. Under this Program, Institute for Post Graduate Teaching and Research in Ayurveda (IPGTRA) Gujarat Ayurved University, Jamnagar, was designated as the National Pharmacovigilance Resource Centre (NPRC) with Prof. M. S. Baghel as Director and Dr. Rabinarayan Acharya as the coordinator. This program was coordinated by the National Pharmacovigilance Consultative Committee for ASU drugs constituted by the Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India. Further, this program is also guided by National Pharmacovigilance Technical Advisory Committee (NPTAC-ASU), a technical committee mainly concerned with reviewing and analysing the ADRs reported at different levels and suggesting proper remedial measures. Under NPRC-ASU drugs, there were eight Regional Pharmacovigilance Centres (RPC), and 30 Peripheral Pharmacovigilance Centres for ASU drugs established to work across the country.[23] Unani medicine was also included as an integral part of this PV program of ASU drugs, accordingly, the National Institute of Unani Medicine, Bangalore – Karnataka was designated as Regional Pharmacovigilance Centres for Unani Drugs and Dr. Tanzeel Ahmed was appointed as coordinator. The Unani colleges identified as Peripheral Pharmacovigilance Centres were Ayurved & Unani Tibbia, College, Karol Bagh New Delhi, Faculty of Medicine (Unani) Jamia Hamdard, New Delhi, Govt. Nizamia Tibbiya College Charminar, Hyderabad. Adverse drug reaction related to any ASU drugs being reported to these Peripheral Pharmacovigilance Centres, in a specially designed ADR reporting form, which are transmitted upwards after proper evaluation at each level.[22]

Central Sector scheme for pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs.

National Coordination Centre, Pharmacovigilance Program of India (NCC-PvPI), IPC (Ghaziabad) invited Ayush stakeholders as participants in a symposium on Pharmacovigilance for Herbal Medicine on

20.11.2017. To maintain the standards and the quality of ASU drugs, the Central Sector scheme for promoting pharmacovigilance of Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) Drugs was introduced. The Standing Finance Committee (SFC) chaired by Secretary (AYUSH) approved the scheme on 1st November 2017 and thereafter, it was rolled out for the implementation of the PV program for ASU &H drugs in the country near the end of the financial year 2017-18. The Ministry of AYUSH signed MoU with NCC-IPC to start the program in March 2018. This program has been restructured by the Ministry of Ayush under the Central Sector Scheme including the Homoeopathy component (i.e., ASU&H drugs) in support and guidance of the Indian Pharmacopoeia Commission (IPC) and concerned program officers of the WHO Country Office, India. The prime objective of the scheme is to develop the culture of documenting suspected adverse drug reactions (ADRs) and undertake safety monitoring of Ayurveda, Siddha, Unani and Homoeopathy drugs and also the surveillance of misleading advertisements related to ASU&H drugs, appearing in the print and electronic media. The scheme intends to facilitate the establishment of a three-tier network at the National Pharmacovigilance Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs). All India Institute of Ayurveda (AIIA), New Delhi is designated as the National Pharmacovigilance Coordination Centre (NPvCC) for implementation of the pharmacovigilance program for ASU & H Drugs, with five Intermediary Pharmacovigilance Centres (IPvCs), two to Ayurveda and one each to Unani, Siddha, Homoeopathy which include, Institute for Post-Graduate Teaching & Research in Ayurveda, Jamnagar; National Institute of Ayurveda, Jaipur; National Institute of Unani Medicine, Bangalore; National Institute of Siddha, Chennai and National Institute of Homeopathy, Kolkata.[24]

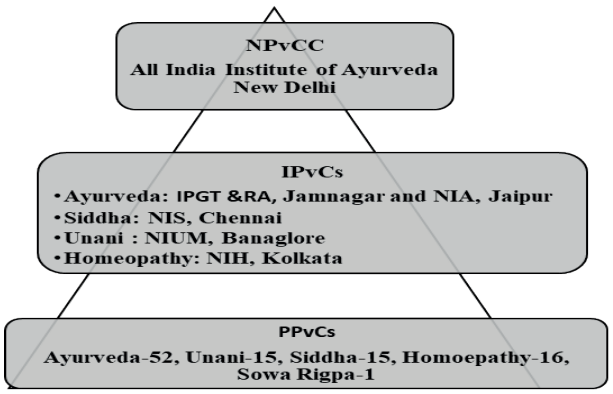

Figure 1: Three-tier network of Pharmacovigilance Program.

NPvCC: National Pharmacovigilance Coordination Centre, IPvCs: Intermediary Pharmacovigilance Centres, PPvCs: Peripheral Pharmacovigilancce Centres, IPGT &RA: Institute for Post Graduate Teaching & Research in Ayurveda, NIA: National Institute of Ayurveda, NIS: National Institute of Siddha, NIUM: National Institute of Unani Medicine, NIH: National Institute of Homeopathy

The National Pharmacovigilance Coordination Centre (NPvCC), AIIA, New Delhi will undertake the pharmacovigilance activities under the guidance and technical support of Indian Pharmacopoeia Commission (WHO Collaborating Centre for Pharmacovigilance), Ghaziabad and Concerned programme officers at WHO Country Office-India, New Delhi. The National Pharmacovigilance Coordination Centre (NPvCC) in consultation with the Pharmacopeial Commission of Indian Medicine and Homoeopathy (PCIM&H), if required, shall conduct the Causality Assessment of the signals received from the Intermediary Pharmacovigilance Centres (IPvCs) and intimate to the Ministry of AYUSH regarding confirmed ADRs and misleading advertisements to enable suitable action.[24]

Unani Pharmacovigilance Program

National Institute of Unani Medicine, Bangalore has been designated as the Intermediary Pharmacovigilance (IPvC) centre for Unani Drugs, and Prof. Mohd Aleemuddin Quamri was nominated officially as Coordinator of this program on 9th January 2018. During the first phase in the year 2018-19, six Peripheral Pharmacovigilance Centres (PPvCs) for Unani drugs have been sanctioned under IPvC, NIUM, Bangalore, viz. 1. National Research Institute of Unani Medicine for Skin Disorders, Hyderabad 2. Central Research Institute of Unani Medicine Lucknow 3. Regional Research Institute of Unani Medicine, Mumbai 4. Regional Research Institute of Unani Medicine, Chennai 5. Regional Research Institute of Unani Medicine, Srinagar 6. Regional Research Institute of Unani Medicine, New Delhi and research officer of respective councils viz. Dr. Javed Inam Siddiqui, Dr. Mahboob us Salam, Dr. Nikhat Shaik, Dr. Noman Anwar, Dr. Shameem Ahmad Rather and Dr. Anwar ul

Islam were designated as coordinators to compile the objective of the program in Unani medicine.

As part of the expansion of the network of PPvCs to ascertain the objectives of the Pharmacovigilance program, in the second phase during the year 2019-20 five more new PPvCs under IPvC NIUM Bangalore have been sanctioned these are 1. Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh 2. Hakim Syed Zia ul Hasan Government Unani Medical College & Hospital, Bhopal 3. Dr. Abdul Haq Unani Medical College, Kurnool 4. Regional Research Institute of Unani Medicine, Kolkata 5. Government Tibbi College & Hospital, Patna, and coordinators of the respective centres are Prof. Tanzeel Ahmad, Prof. Mehmooda Begum, Dr. Sarfaraz Nawaz, Dr. Younis Iftikhar Munshi, and Dr. Md. Tanwir Alam.

In the same year as the third phase of expansion, four more PPvCs were proposed viz 1. Government Nizamia Tibbi College, Charminar, Hyderabad, 2. Regional Research Institute of Unani Medicine Bhadrak, Odisha, 3. Mohammadia Tibbia College & Assayer Hospital Mansoora, Malegaon 4. University College of Unani, Tonk, Rajasthan, and in the year 2021-22 these centres got sanctioned. Prof. Zaibunnisa Begum, Dr. Abdur Rasheed, Dr. Sayyed Minhaj and Dr. Firoz Khan are the coordinators of these respective centres.

Table 1: PPvCs Under IPvC NIUM, Bangalore

PPvCs of Unani Drugs	State/Union Territory
NRIUMSD, Hyderabad	Telangana
CRIUM, Lucknow	Uttar Pradesh
RRIUM, Mumbai	Maharashtra
RRIUM, Chennai	Tamil Nadu
RRIUM, Srinagar	Jammu and Kashmir
RRIUM, Delhi	Delhi
RRIUM, Kolkata	West Bengal
AKTC, AMU, Aligarh.	Uttar Pradesh
HSZH GUMC Bhopal.	Madhya Pradesh
Dr. AHUMC, Kurnool	Andra Pradesh
GTCH, Patna	Bihar
GNTC Charminar, Hyderabad	Telangana
RRIUM Bhadrak	Odisha
MTCH Mansoora Malegaon	Maharashtra
UCU Tonk	Rajasthan

PPvCs: Peripheral Pharmacovigilance Centres, IPvC: Intermediary Pharmacovigilance centres, NRIUMSD: National Research Institute of Unani Medicine for Skin Disorders, CRIUM: Central Research Institute of Unani Medicine, RRIUM: Regional Research Institute of Unani Medicine, AKTC AMU: Ajmal Khan Tibbiya College Aligarh Muslim University, HSZH GUMC: Hakim Syed Zia ul Hasan Government Unani Medical College & Hospital, Dr. AHUMC: Dr. Abdul Haq Unani Medical College, GTCH: Government Tibbi College and Hospital, GNTC: Government Nizamia Tibbi College, MTCH: Mohammadia Tibbia College & Assayer Hospital, UCU: University College of Unani

Ministry of AYUSH, Government of India initiated the Central Sector Scheme for augmenting the quality of AYUSH drugs during the 15th Finance Cycle (2021-22 to 2025-26) by merging the existing Scheme for Pharmacovigilance of ASU&H Drugs with Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY) scheme in the year 2021-22. The Pharmacovigilance Program of ASU&H Drugs is being monitored under the AOGUSY scheme for the growth and development of traditional Indian and Homoeopathic medicines in making them accessible, and safe.[25]

CONCLUSION

Pharmacovigilance Program of ASU&H drugs, working since 2017-18. Presently 99 Peripheral Pharmacovigilance centres are working under five Intermediary Pharmacovigilance centres. 15 Peripheral Pharmacovigilance centres for Unani drugs are being monitored by National Institute of Unani Medicine, Bangalore. Since the inception of the program, the Pharmacovigilance centre has been functioning in line with the defined objectives.

CONFLICT OF INTEREST

The authors declared no conflict of interest

Ethical clearance: Not Applicable

AUTHORS' CONTRIBUTION

Idea owners of this study: Prof. M A Quamri and Dr. Rabia Malik

Study design: Prof. M A Quamri and Dr. Rabia Malik

Data gathering: Dr. Rabia Malik

Writing and submitting the manuscript: Dr. Rabia Malik

Editing and approval of final draft: Prof. M A Quamri and Dr. Rabia Malik

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