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Pharmacovigilance in ASU and H Drugs: Standard in Healthcare

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***Abstract*: Pharmacovigilance (PV) program of India (PVPI) aims to develop a comprehensive PV strategy for the drugs that come under allopathic system of medicine. However, most of the population is still using alternative systems of medicine (ASM) alone or with allopathic medication without knowing the effects. The PV in India is still in its infancy mode due to lack of appropriate clinical data. Our PV initiatives intended in the ASM, which included Ayurveda, Siddha, Unani. This was due to dearth of reports on investigations and research work involving ASM. To assess the current and previously reported toxicities in various ASM, the toxicity data from treatments listed various systems of medicines were collected and listed. Data collated from various research studies suggested that there were many reported toxicities and numerous adverse drug reactions (ADRs), not generally known to many people including the healthcare professionals. Still, high number of such incidences are yet to be studied systematically and taken care of the prophylactic measures and the ultimate goal of uplifting and implementing PV.**

***Keywords*: Ayush system, ASU&H drugs, pharmacovigilance.**

1. Introduction

Pharmacovigilance is the pharmacological field which deals with the Detection, Assessment, Understanding and Prevention of unintended effects, adverse drug side effect or any other possible Medication error, caused by pharmaceutical product. Pharmacovigilance promotes the systemic, rational use and assures the confidence for the safety of drugs. It improves patient care and safety, public health and safety. Although the technical term Pharmacovigilance does not mentioned in Ayurvedic,Unani,Sidha,Homeopathy text, the spirit of pharmacovigilance is vibrant and is emphasized repeatedly in Brihatrayee and Laghutrayee. There is a common perception of people about Hippocrates, one of the founders of Unani System in his famous book, “Materia Medica” has proposed the theory of four humours namely sanguine (Dam), Phlegm (Balgum), yellow choler (Safra) and Melancholic (Sauda) whose proportional balance and disturbance are believed to be the main cause of health and disease. Dioscoridous (70 AD) wrote a comprehensive illustrated book, “De Matria Medica” in which he vividly illustrated the major medicinal plants used in Unani System of medicine for therapeutic uses. Ancient Greek physician Ibn-Sina (980-1037 AD) in his book Encyclopedia „Al-Qanoon“ gave a detailed description of knowledge on pharmacology and therapeutic properties of herbal medicines on clinical observations. On other hand a strong poison can become an excellent medicine if administered properly [1]. Adverse drug reactions (ADRs) are the pharmacological effect(s), other than known/ desired effects, at a particular dose. Sometimes, the ADRs include serious and unknown effects; hence, they must be documented [2]. Pharmaceutical companies are adopting a serious approach to PV of their product to develop more reliable and longterm sustainable product with lesser side effects that needs to be informed to the patient or physician before its use. [3-6].

History of Pharmacovigilance: National Pharmacovigilance Program under the control of Central Drug Standards Control Organization (CDSCO) has initiated during 2003. WHO emphasizes that, traditional medicines are to be included into pharmacovigilance system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance systems in 2004 The nationwide programme under central sector scheme funded by Ministry of AYUSH, New Delhi for ASU & H drugs to establish and manage a data base of Adverse Drug Reactions (ADR) for developing system wise database of adverse drug reactions and evolving evidence based recommendations towards clinical safety of ASU & H Drugs. Besides this; the program also undertake surveillance of objectionable or misleading advertisements. Since ages Ayurveda, Siddha and Unani systems are being practiced in India. In this era of globalization, concerns are being raised with regards to their clinical safety. Unani has categorized toxic plants separately and for their use special processing is essential. There is a wide spread misconception that all drugs of “natural” origin are “safe”.

2. Glossary Used in Pharmacovigilance

Adverse Drug Reactions (ADRs) -A response to a drug which is noxious and unintended, and which occurs at doses

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normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

- *Adverse Event/Experience (AE)* - Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment.
- *Side Effect (SE)* - Any unintended effect of a pharmaceutical product occurring at doses normally used in human which is related to the pharmacological properties of the drug.
- *Serious Adverse Event (SAE)* – Any adverse event which is fatal, life- threatening, permanently disabling or which results in hospitalization.
- *Expected adverse reaction* - As opposed to "unexpected", an event that is noted in the brochure or labeling.
- *Unexpected adverse reaction* - The nature or severity of which is not consistent with the domestic labeling or market authorization, or expected from characteristics of the drug.

3. Pharmacovigilance in Unani System of Medicine

Although the specific term of Pharmacovigilance does not feature in Unani Classical texts, but the concept of Pharmacovigilance is vibrant in the Unani system of medicine [10]. Ibn-i-Sina has done a pioneering work in this regard. An elaborated general and systemic pharmacology of the then existing drugs includes cardio-active drugs, code of recipes and a valuable knowledge on the methods of preparation of more than 2000 simple & compound drugs. Ibn Sina‟s most valuable contribution in Unani medicine is in the form of dissertation on pharmacology and pharmacognosy of various drugs namely, "Al-Qanoon" (the canon of medicine) book of having five volumes, the first volume of which laid out the detailed principles of management of diseases including pharmacotherapy. As per his versatile experience the selection of a particular drug should be based on the following:

- Choice of drug by their quality.
- Choice of drug by their quantity including changes inweight, potency, and properties.
- Time of administration of the drug. Pharmacological and pharmacotherapeutic characteristics of various drugs used in Unani system of medicine (811) were described in detail by Ibn-i-Sina in „Al-Qanoon‟ (The Canon of Medicine) which includes 594 drugs from plant origin, 118 from animal origin and 99 from mineral origin. Pharmacological evaluation of a drug by specific tests and comparative analysis where described in detail. He emphasized upon the need to watch constantly action of drugs in most of the cases and the drug being just in proportion to the nature and severity of the disease both in quality and quantity. He indicated that the experiment on humans should be done at last and not on animals as both have a different temperament [3].

Hence, in different Unani formulations the various reasons, rationality and methods for preparation of drugs are based upon:

1. Rationality underlying combination of various medical plants, minerals, animal products etc.
2. Avoidance of certain diets.
3. Adverse drug effects.
4. Complete drug profile.
5. Adverse, drug-drug and food-drug interactions.
6. Prescribing drugs in senile age, pregnancy, lactation and altered functions of certain organs. Any Adverse or side effects observed and noticed by the Unani Physicians at that period was noted down and communicated to their pupils. In Unani System of medicine the various classical books of drugs (Plant Origin, Animal Origin and Mineral Origin) provide a detailed knowledge about the temperament (Hot, Dry and Moist) based on the years of clinical observation of Unani physicians and use of single or compound drugs for the management of various ailments is governed by various factors such as:

a) Temperament (Mizaj) and pulse examination (Moina-eNabdh) of the patient.
b) Potency/temperamental potency of drugs into four degrees (Darjat-e-Advia).
c) Toxicity minimization of drugs bythe use of various correctives (Tadabir) on the basis of temperament of drug and its effects in minimizing side effects.
d) Use of substitutes (Abdale-Advia) in case of non-availability and cost effectiveness of original drug [7]. According to Ibn-Sina, principle motive of the Pharmacotherapy is that stress must be laid on the particular temperament of the Sina‟s most valuable contribution in Unani medicine is in the form of dissertation on pharmacology and pharmacognosy of various drugs namely, "Al-Qanoon" (the canon of medicine) book of having five volumes, the first volume of which laid out the detailed principles of management of diseases including pharmacotherapy. As per his versatile experience the selection of a particular drug should be based on the following:

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- Har as Hot & Cold, Hot & Dry, Hot & Moist
- Barid as Cold & Hot, Cold and Dry, Cold and Moist
- Yabis as Dry and Hot, Dry and Cold, Dry and Moist.

4. Remedial Measures Required for Proactive Pharmacovigilance of Unani Drugs

To achieve operational efficiencies that would make proactive Pharmacovigilance for the Unani drugs a benchmark for drug monitoring programme, the following measures need to be taken by the governments, regulatory authorities, academicians, prescribers and patients:

1. A separate subject of Pharmacovigilance must be included in the curriculum of graduate & post-graduate level studies in Unani Medicine.
2. Clinical Research units of different pharmacies including institutions conducting postgraduate/doctoral level research should include Pharmacovigilance as one of the criteria in their research projects.
3. Drug licensing authorities of Unani medicines should include Pharmacovigilance as one of the pre-requisites for giving marketing permission for new drugs.
4. Regularity framework governing the manufacturing and licensing of the Unani drugs should be revisited.
5. Manufacturers of Unani drugs should demonstrate the quality, safety and efficacy of their products before marketing

Need of Pharmacovigilance of Asu Drugs: Worldwide movement for the improvement of patient safety gains momentum, the subject of drug safety becomes even more prominent. Pharmacovigilance is the science dedicated to reduce the risk of drug-related harms to the consumers. Looking into the conditions prevailing in the present scenario, it is high time to deliberate regarding the concerns over traditional and classical Ayurvedic, Siddha, Unani and Homoeopathy products and practices. Thus the program is initiated to collect, collate and analyze data to establish evidence for clinical safety of ASU & H drugs in a scientific manner for documenting clinical evidence of safety and to undertake surveillance of misleading advertisements of ASU & H drugs and improper advertisements of ASU & H drugs for regulatory actions. It is observed that few of these ASU drugs are being consumed, by patients, as OTC drug. These are sold as either herbal medicines or herbal products in different health-care settings. Due to inadequate regulatory measures, largely uncontrolled distribution channels either in form of mail order or internet sales and poor quality control systems, improper administration, some adverse events has also been reported.

National Pharmacovigilence Programme: First National Consultative meet of National Pharmacovigilance Programme for ASU Drugs was organized at Dept. of AYUSH, Ministry of Health & FW, and New Delhi on August 2008, sponsored by WHO. Based on the feedback received from the meet, National Pharmacovigilance Programme for ASU drugs was launched on 29th Sept 2008. The purpose of the programme is to collect and collate data, analyses it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

Pharmacovigilance Centers of Asu Drugs: Taking the WHO guidelines for the safety issues of herbal medicines into consideration and to put pharmacovigilance system for ASU drugs in proper place, the Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, New Delhi, took initiation basing upon the activities on pharmacovigilance, recognized by the National Institute of Unani Medicine, Bengaluru, as National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs (NPRC-ASU) in India under the Central sector scheme for up gradation to Centre of Excellence since 2008-09. As per the protocol, the NPRC-ASU Drugs is coordinating this National Pharmacovigilance Program (NPP-ASU) under the aegis of Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, under the guidance of the National Pharmacovigilance

Consultative Committee. For ASU Drugs (NPCC-ASU), which comprise mainly of administrative heads of National Institutes, regulatory authorities and technical persons and have responsibility of monitoring and regulating administrative and financial aspects related to the program. 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 to suggest proper remedial measures. Under NPRC-ASU drugs, there are five Intermediary Pharmacovigilance Centre (IPvC) for ASU drugs. There are 74 Peripheral Pharmacovigilance Centre (PPvC) for ASU drugs, which are working under these Four IPvCs, across the country. Adverse drug reaction related to any ASU drugs is being reported to these PPvC, in a specially designed ADR reporting form. The Structure of India's Pharmacovigilance Program for Asu Drugs: India‟s National Program of Pharmacovigilance for ASU drugs was adopted under the following blueprint in accordance with recommendations of the expert group made at its meeting on 28-29 August, 2008.

5. Conclusion

As self-medication and unrestricted use of asu drugs have increased many folds so it's our responsibility as a common people to report any of the A.D.R of ASU DRUGS that we come to know to the PVPC so that it could be assessed and optimized further pharmacovigilance has been included in postgraduate level of AYUSH curriculum need to introduce it on Bachelors‟ level also, then we can assure safe use of ASU medicaments by professionals.

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[6] Preclinical and clinical trials of the Unani products should be made mandatory. Post marketing surveillance of studies should be a routine for each product.

[7] Information regarding adverse effects, including interactions with other medicine, food, alcohol, disease and so forth, active constituents pharmacokinetics, pharmacodynamics should be brought into the notice of scientific community.

[8] Information regarding use among special patient groups like children, elderly people, and individuals with renal or hepatic disease, pregnant and breast-feeding women and effects of long term use should be notified.