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''IMPLEMENTATAIONS OF PHARMACOVIGILANCE PROGRAMME FOR ASU & H DRUGS''

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ABSTRACT-

Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst drugs and their effects in human. Pharmacovigilance is the science which encompasses the activities concerning to the detection, assessment, understanding and prevention of Adverse Drug Reaction (ADRs) or any other possible drug related problems, particularly long term and short-term side effects of medicines. It is the science dedicated to reduce the risk of the drug related harms to the consumers. Pharmacovigilance is a branch that deals with adverse drug reaction, undesired effect of drug, awareness about drug safety, proper doses of drug. Pharmacovigilance in case of visha and upvisha is to remove or lessen the undesired toxic effect and to make the material suitable for use.

KEYWORDS- ***AYUSH System, Healthcare Assessment, Interactions Of ASU&H Drugs, Pharmacovigilance***

INTRODUCTION-

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.

PV was established since 2003 under the control of Central Drug Standard Control Association (CDSCO) under the aegis of Ministry of H & FW, DGHS (Directorate General of Health Service) New Delhi. WHO emphasized that it should include Traditional medicines in PV system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance systems in 2004.[1]IPGT & RA , Jamnagar conducted a two days' workshop on 3rd & 4th December 2007, on "Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations & Methods of Implementation".[2] Based on the recommendations from the workshop, Pharmacovigilance Cell (PV Cell), has been established . Reporting Form for Suspected ADRs of Ayurvedic. Formulations has been developed.

ASU drugs are considered as safe drugs. This perception is likely to change in the light of some recent incidences of ADR during their use. The first National Consultative meet of National Pharmacovigilance Programme for ASU Drugs was organized at Dept. of AYUSH, Ministry of Health & FW, New Delhi on August 2008, sponsored by WHO.[3,4] 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, analyse it and use the inferences to recommend informed regulatory interventions, beside communicating risks to healthcare professionals and the public. 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. 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 .

Aim Of the Pharmacovigilance-

- Improve patient care and safety.
- Improve public health and safety.
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines.
- To promote understanding, education and clinical training.

OBJECTIVES OF PHRMACOVIGILANCE-

Short-term objectives - To develop the culture of notification.

Medium-term objectives - To involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes

Long-term objectives - To achieve operational efficiencies that would make NPP for ASU drugs a benchmark for global drug monitoring endeavours.

MATERIALS AND METHODS-

Pharmaceutical and biotechnological medicines are designed to cure, prevent or treat diseases; however, there are also risks particularly adverse drug reactions (ADRs) can cause serious harm to patients. Thus, for safety medication ADRs monitoring required for each medicine throughout its life cycle, during development of drug such as pre-marketing including early stages of drug

design, clinical trials, and post-marketing surveillance. Since ages Ayurveda, Siddha and Unani systems are being practised in India. Now in this era of globalization certain concerns are raised with regards to their safety. On Indian plants or Indian plant-based products severe toxicity is yet to be reported. Ayurveda 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". There is also a common belief that long term use of a medicine based on tradition, assures both safety and efficacy. Further when traditional (ASU) medicines are used in conjunction with other medicines there is the potential of serious adverse drug interactions. There are also examples of traditional (ASU) medicines being adulterated or contaminated with allopathic medicines, chemicals such as corticosteroids, non-steroidal anti-inflammatory agents etc. Further many ASU drugs are manufactured for global use and they have moved beyond the traditional and cultural framework for which they were originally intended. Currently, the majority of adverse events related to the use of herbal / traditional products that are reported are attributed either due to poor product quality or to improper use.

ASU&H systems of medicines have their own principles, have their own pharmacopoeia, but are practised in the country as OTC drugs and without an authentic prescription. A recent WHO survey showed that around 90 countries, less than half of WHO's member state, currently regulate herbal medicines. Pharmacovigilance practice is the need of hour for all systems of medicine including Indian Systems of Medicine, as it ensures patients safety, more scientific and up to date. Following are certain aspects where more emphasis is needed for better pharmacovigilance practice in ASU system of medicines.

□□Strengthen education, training and publicity.

□□Strengthen the roles of pharmaceutical manufacturers as the main body of ASU&H drugs post-marketing risk management.

□□Promote the rational use of ASU& H drugs.

□□Communicate safety information to the relevant agencies for cooperation to identify the nature of the ADRs

□□Establish an international coordinating database for adverse reactions reporting and promote signal detection.

Pharmacovigilance practice is the need of hour for all systems of medicine including Indian Systems of Medicine, as it helps to prove this system safe, more scientific and up to date in modern terms. It is an absolute requirement to ensure public safety and to promote the healthy development of ASU systems of Medicine. All the stake holders of ASU &H systems of medicine

need to be educated through intensive training and publicity regarding pharmacovigilance aspects of these drugs and Government and pharmaceutical sectors should take initiation in this regard by providing more financed assistance through budgetary provisions. safety of ASU&H drugs is a concern throughout the whole life period of the drug. Quality control remains one of the main issues in ASU&H drugs safety concerns. Standardization and enforcement of GMP and manufacturing guidelines will support any safety initiative. Steps should be taken to strengthen ASU&H pharmaceutical manufacturers' responsibility and awareness of drug quality and of the value of basic research work on their drug products. Clinical use should be regulated by adopting Good Clinical Practice of ASU system to avoid the Adverse drug Reactions.

Cooperation and sharing of information among the related drug regulating agencies should also be promoted. Adverse events reported by PV system potentially benefit to the community due to their proximity to both population and public health practitioners, in terms of language and knowledge, enables easy contact with reporters by electronically. Hence, PV helps to the patients get well and to manage optimally or ideally, avoid illness is a collective responsibility of industry, drug regulators, clinicians and other healthcare professionals to enhance their contribution to public health.

Although a technical term equivalent to "pharmacovigilance" does not feature in Ayurvedic texts, the spirit of pharmacovigilance is vibrant throughout Ayurveda's classical literature. The Brihattrayi and Laghutrayi repeatedly emphasize the major goals of pharmacovigilance, to improve patient care and safety during treatment, and thus to promote rational use of medications. These are recurrent themes of Ayurvedic pharmacology (*Dravyaguna*), pharmaceutics (*Rasa Shastra and Bhaishjya Kalpana*), and therapeutics (*Chikitsa*).[6] It is probable that these basic principles of Ayurveda gave rise to the common belief that Ayurvedic medicines are safe. When new drugs are developed, the pharmacovigilance program with its social perspective requires economic evaluation of all aspects of their use in treatment, including side effects, adverse reactions, and their additional treatment costs, in addition to routine therapeutic evaluation. The pharmaceutical industry also needs to take responsibility for these added facets of pharmacovigilance.

The Ayurvedic literature gives details of drug-drug and drug-diet incompatibilities based on elaborately described qualitative differences in ingredients or quantitative proportions. These factors undoubtedly prevent the onset of many otherwise unfortunate reactions. Ayurveda's *Anupan* therapeutic method and *Shodhan* pharmaceutics principles probably also contribute to

the prevention of many undesired and unforeseen events. Prevention of this kind is a major goal of pharmacovigilance programs.

The pharmacovigilance program promises to close the gap between Ayurvedic drugs' potential and reality. Some Ayurvedic citations use flowery language to describe certain formulations' therapeutic value, for example, the effect of *Grahani Kapat Rasa* on dysentery / diarrhoea; similarly for certain *vajikarna* formulations. There may be a huge gap between claimed and reality, suggesting assessment of their genuine value under pharmacovigilance.

Discussion [7,8]-

- Practise of Indian system of medicine is considered to be safest form of therapy, however incidence of ADR owing to consumption of traditional medicine give rise to necessitates the introduction of Pharmacovigilance of herbal drug.
- The Erice Declaration represented significant progress. It challenges all players, including:
- Public Health administrators
- Health professionals
- The Pharmaceutical industry
- Governments
- Drug regulators
- Media, and
- Consumers
- "To strive towards the highest ethical, professional, and scientific standards in protecting and promoting the safe use of medicines." The declaration charges governments and all involved in determining policies relating to the benefit, harm, effectiveness, and risk of medicines, to be accountable for what they communicate to both the public and patients. It calls for honesty when communicating drug safety information, even when such information is incomplete and investigations are still underway. It further stipulates that patient be transparently informed of all facts, assumptions, and uncertainties concerning safety profiles of their medicines. Considerable effort has subsequently been made to achieve its goals.
- Pharmacovigilance is a science developed as an attempt to reduce the risk of drug related harms, ultimately focusing on patients' safety.

- Human resource development is a key feature for the success of this enterprise. It will be necessary to train Practitioner ASU&H experts in the science of Pharmacovigilance and include them not only in reporting but also assessment of the adverse reactions. More direct involvement of ayurvedic Academic Institutions in the NPVP after appropriate training would be an appropriate first step in this direction. A strong cooperative effort from experts in Pharmacovigilance and ayurveda together can ensure that this system is up and functioning.

- The goals of pharmacovigilance program are to improve: Patient care and safety when using ASU&H medicines and related interventions;

- Public health and safety records of ASU&H medicines

- Assessment of benefit, harm, effectiveness, and risk of ASU&H medicines,

- Encouragement of safe, rational, and more effective (including cost effective) use, and promotion of understanding, education, and clinical training in pharmacovigilance for ASU&H medicines and its effective communication to the public

CONCLUSION-

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 analyse 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.

The success of any pharmacovigilance system lies in its ability to prevent further adverse reactions on the basis of information received. This will be possible only when physicians are vitally alert to the onset or offset of any ADRs. They need to prioritize their contributions to make the pharmacovigilance program for AS U&H medicines a success.

Drug safety is achievable by the three tiers such as detection, monitoring and prevention of adverse events. Pharmacovigilance has a pivotal role in the preventive tier of drug safety. Creating

comprehensive, unbiased and easily accessible information on poisonous drugs used in ASU&H therapeutics can build awareness among physicians, drug manufacturers and patients.

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