The National Pharmacovigilance Program for Ayurveda, Siddha and Unani drugs: Current status

Since centuries Ayurveda and other traditional systems of medicine are practised in this continent. They are regarded as the safest medical systems. However with the scientific ethos everything is rejected or accepted in the light of available clinical data only. Hence, to create pharmacovigilance, program for ASU drugs become essential for giving them credibility. One of the primary aims of pharmacovigilance is to prevent the adverse drug reaction that may be due to any medical intervention primarily proposed to cure, treat or diagnose the prevailing morbidity. Adapting internationally acceptable mechanism, in this regards, shall create an impression that these systems are scientific. One of the important present day tasks is the necessity to prove to the world that ASU systems, which are existing since thousands of years, are not only safe but also scientific.

There is very few evidence in defence, when the safety of the drugs of these systems is questioned, except that these systems are in practise since hundreds of years and safety and efficacy of individual drugs are reported in classical texts; although, Ayurveda was the first medical system which considered the situations of adverse drug reactions (ADRs) and incorporated methods to avoid or nullify the ADR. The lists of drugs were classified as toxic, semi-toxic or to be used with precaution etc. Even in certain texts, management for possible ADRs or toxicity have been mentioned in detail. But, it is needed to prove that the drugs of these systems are safe basing upon a comprehensive safety data, basing upon clinical and pharmacological studies. It is to be appreciated that, there is no drug which is devoid of toxicity and that drugs without toxicity are likely to be without any effect. Hence, what is important is to assess the relative safety of administering a drug.

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 Institute for Post Graduate Teaching and Research in Ayurveda (IPGTRA), Gujarat Ayurved University, Jamnagar, as National Pharmacovigilance Resource Centre for Ayurveda, Siddha and Unani Drugs (NPRC-ASU) in India under the Central sector scheme for upgradation to Centre of Excellence since 2008–09 and sanctioned an amount of Rs 57.66 Lacs in this regard. 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 eight Regional Pharmacovigilance Centre (RPC) for ASU drugs. There are 30 Peripheral Pharmacovigilance Centre (PPC) for ASU drugs, which are working under these eight RPCs, across the country. Adverse drug reaction related to any ASU drugs is being reported to these PPC, in a specially designed ADR reporting form, which are transmitted upwards after proper evaluation at each level. Till today, NPCC-ASU drugs met thrice and NPTAC-ASU drugs met once to review the program as well as reported ADRs.

To develop the culture of notification and to involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes, teachers, physicians and pharmacists of ASU systems, were being sensitized on the concept of pharmacovigilance and how to report ADR through CME programs, across the country and till today more than 2000 teachers/physicians and paramedical staff were trained in this regard. Further, pharmacovigilance for ASU drugs is being included as a topic, in the module of each CME and RoTP of Dravyaguna/Rashashastra, coordinated by RAV, New Delhi. A web portal, 'ayushsuraksha.com' has been launched for online registration of ADR related to ASU drugs through an "e format".

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To achieve operational efficiencies that would make National Pharmacovigilance Program for ASU drugs a benchmark for global drug monitoring endeavors, pharmacovigilance has been included in the curriculum of graduate and post-graduate level studies of Ayurveda. Now steps have been taken to open one pharmacovigilance center at each affiliated ASU colleges. Clinical research units of different pharmacies including institutes conducting post graduate and doctoral level research were requested to include pharmacovigilance aspect as one of the criteria in their research projects. Department of AYUSH, Govt. of India, has been requested to instruct the drug licensing authorities to include pharmacovigilance aspect as one of the criteria while giving permission for a new drug.

As a part of promotional activities, brochures on pharmacovigilance for ASU drugs were prepared and being distributed at stall at Arogya / CME etc., Guest lectures were delivered during scientific sessions of different National and International seminars and research scholars and public were informed by putting advertisement related to NPP ASU drugs in different journals and souvenirs. It is high time that different STAKE holders dealing with traditional systems like Ayurveda, Siddha and Unani should come forward and actively participate to make pharmacovigilance program for ASU drugs a successful one.

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