National Pharmacovigilance Programme for Ayurveda, Siddha & Unani (NPP-ASU) is the nation wide programme, sponsored and coordinated by the country's National Resource Centre (NPRC) for ASU drugs to establish and manage a data base of Adverse Drug Reactions (ADR) for making uniformed regulatory decisions regarding marketing authorisation of drugs in India for ensuring safety of drugs.

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR ASU DRUGS

Though for centuries ASU drugs are considered as safe drugs, this perception is likely to change in the light of some recent occurrence of incidences of ADR during their use. Thus, it should be considered as the right time to evolve a mechanism to record ADR of ASU drugs. It is a need of hour to design a well-structured programme to build synergies for monitoring adverse drug reactions of ASU medicines. The purpose of the programme is to collect and collate data, analyse it and use the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public.

The National Pharmacovigilance Programme for ASU medicines have the following objectives:

To develop the culture of notification.

To involve healthcare professionals and professional associations in the drug monitoring and information dissemination processes.

To achieve operational efficiencies that would make National Pharmacovigilance Programme for ASU drugs a benchmark for global drug monitoring endeavours. 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. 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.

C.S.M.S.S. AYURVED MAHAVIDYALAY AURANGABAD

Principal
C.S.M.S.S. Ayurved Mahavidyalaya,
Kanchanwadi, Aurangabad.

Structure of pharmacovigilance centre

National Pharmacovigilance Resource centre for ASU (NPRC-ASU)

It is the tertiary pharmacovigilance centre. Large healthcare facilities attached with any of the ASU medical colleges identified by Ministry of AYUSH, Govt. of India may be nominated as NPRC - ASU. It would act as third level centre i.e National Centre in the administrative structure of the NPP for ASU in India. Govt. of India has declared Institute for Post Graduate Teaching and Research in Ayurveda (IPGT & RA), Jamnagar as National Resource centre for this programme. It will also function as First contact ADR data collection unit.

Regional Pharmacovigilance Resource centre for ASU (RPC-ASU)

They are the secondary pharmacovigilance centres. Relatively larger healthcare facilities attached with ASU medical colleges may be identified as RPC - ASU. They would act as second level centres in the administrative structure of the NPPI - ASU (NPP - ASU). They will function as first contact ADR data collection units also. They are identified and coordinated by the NPRC -ASU.

Peripheral Pharmacovigilance Centres for ASU (PPC -ASU)

They are the primary pharmacovigilance centres. Relatively smaller ASU medical Colleges / institutions including individual ASU medical practitioners' clinics, private hospitals, nursing homes, pharmacies etc. may be identified as PPC - ASU. They will function as first contact ADR data collection unit at a health care facility. They would be identified and coordinated by RPCs in consultation with NPRC-ASU.

Coordinator

Designated in-charge of a particular participating Pharmacovigilance centre

Investigator

A healthcare professional involved in investigation of drug related adverse events.

Notifier

Any person who suspects to have experienced / observed an ADR and informs any participating Pharmacovigilance centre about it.

Reporter

A healthcare professional reporting ADR on the ADR S form.

Monitoring

The process of overseeing drug related adverse events at the Pharmacovigilance centre participating in the Pharmacovigilance Programme.

Reporting

The process of providing ADR information by filling in the ADR form appropriately and forwarding the same to the appropriate level.

C.S.M.S.S. AYURVED MAHAVIDYALAY AURANGABAD

Principal
C.S.M.S.S. Ayurved Mahavidyalaya,

Notification

Process of informing by a notifier to any participating pharmacovigilance centre about the occurrence of a suspected ADR. The process may involve informing over telephone, in person, email, fax or any other means of communication-verbal or written. All notifiers must give their contact details.

ADR Form

It's the pre-designed structured form issued by NPRC-ASU to record ADR.

Roles and responsibilities

i Each PPC

To record some ADRs each month. Completed ADR forms shall be forwarded to the concerned RPC at the end of each month under intimation to concerned AYUSH authority.

ii Each RPC

a. To collate and scrutinize the data received from PPC

b. To perform the causality analysis of all the forms received every month.

c. To submit a monthly report prepared in a specific form to be forwarded to National Pharmacovigilance Resource Centre (NPRC -ASU) every month.

d. To report any alarming ADRs with in 24 hrs. to NPRC-ASU along with supporting evidence.

iii NPRC

a. To collate the data received from RPCs and its own centre.

b. To verify / validate the causality analysis.

c. To prepare Monthly Information Sheet (MIS) reports in a specified format.

d. To pass on the final data to National pharmacovigilance Technical Advisory Committee ASU (NPTAC-ASU) for analysis.

e. To pass the analysed data to Department of AYUSH, Govt of India for further necessary action.

Strategies for implementation:

f. To call a meeting of NPCC- ASU as and when necessary.

g. To publish a periodic newsletter

h. To generate awareness by distributing brochures throughout the country particularly in different ventures like CME/ RoTP /Workshops / Seminars etc.

i. To initiate for incorporation of Pharmacovigilance systems as a part of curriculum in UG and PG (particularly in DG / RS & BK subjects) syllabus of Ayurveda.

Coordinator's eligibility at different tiers of NPP for ASU Drugs

For PPC, a teacher of Dravyaguna / Rasashastra, Bhaishajya Kalpana / any clinical department / Agadatantra, allied departments of Siddha and Unani systems of medicines, Research Officer (ASU), for RPC preferably not below

C.S.M.S.S. AYURVED MAHAVIDYALAY * AURANGABAD *

Principal
C.S.M.S.S. Ayurved Mahavidyalaya,
Kanchanwadi, Aurangabad.

the rank of Sr. Lecturer / Assistant professor, attached to an ASU medical college, and Assistant Director (ASU), for NPRC not below the rank of an Asso. Professor.

The mechanism of ADR reporting.

What to report

a. Death
b. Life threatening (real risk of dying)
c. Hospitalisation (initial or prolonged)
d. Disability (significant, persistent or permanent)
e. Congenital anomaly
f. Required intervention to prevent permanent impairment or damage

The prescribed 'Adverse Drug Event Reporting Form For ASU Drugs' shall be used for the purpose of National Pharmacovigilance Programme For ASU.

Who can report

Any health care professional may report suspected adverse drug events. The Programme shall not accept reports from lay members of the public or anyone else who is not a health care professional. Others can report through the physicians under whom he / she had undergone treatment.

Where to report

Consumer may directly report to the concerned PPC / RPC / nearest health centre or physician regarding the suspected ADR. The reporting on prescribed format will be done to any of the Pharmacovigilance centres. The information in the form shall be handled in confidentiality. Peripheral Pharmacovigilance Centres shall forward the form to the respective Regional Pharmacovigilance Centres who will carry out the causality analysis. This information shall be forwarded to the National Pharmacovigilance Resource Centre. The data will be statistically analysed and forwarded to the Ministry of AYUSH, Govt. of India. NPRC will thus be responsible for overall coordination and supervision of all pharmacovigilance activities under the Programme and performance of the various centres involved in this project.

In short this the mechanism of ADR reporting.

C.S.M.S.S. AYURVED MAHAVIDYALAYA AURANGABAD

Principal
C.S.M.S.S. Ayurved Mahavidyalaya,
Kanchanwadi, Aurangabad.