PROTOCOL FOR
NATIONAL
PHARMACOVIGILANCE PROGRAMME
FOR AYURVEDA, SIDDHA
AND UNANI (ASU) DRUGS

National Pharmacovigilance Resource Centre,
for ASU Drugs
Institute for P. G. Teaching & Research in Ayurveda,
Gujarat Ayurved University,
Jamnagar 361008, Gujarat

Department of AYUSH,
Ministry of Health & Family Welfare,
Government of India, New Delhi,
in collaboration with
WHO Country Office for India, New Delhi
2008
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National Pharmacovigilance Consultative Committee
for ASU Drugs (NPCC - ASU)

Chairperson : Director, IPGT & RA Prof. MS Baghel
Member Secretary : Co-ordinator, NPRC Dr. RN Acharya

Members:

1. Director, CCRAS or his representative Dr. GS Lavekar
2. One Director, Dept. of AYUSH
3. Director, National Institute of Ayurveda Prof. MC Sharma
4. Director, National Institute of Unani Medicine Prof. MA Jafri
5. Director, National Institute of Siddha Medicine Dr. Bhupathi Raja
6. Director, PLIM Dr. DR Lohar
7. Dean, Faculty of Ayurveda, IMS, BHU, Varanasi Prof. VK Joshi
8. Chairman, APC Dr. SS Handa
9. Drug Controller of ASU Drugs or his representative
10. Three Experts from concerned subjects Prof. SS Savrikar
    Prof. KC Singhal
    Dr. Urmila Thatte
11. Chairman, PV Centre, IPGT & RA, Jamnagar Prof. HM Chandola
# NATIONAL PHARMACOVIGILANCE PROTOCOL
## FOR AYURVEDA, SIDDHA AND UNANI (ASU) DRUGS

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Preamble

Worldwide movement for the improvement of patient safety is gaining momentum; hence the subject of drug safety becomes even more prominent in the present day scenario. In context of ASU; with increased use of drugs of these systems, the scope for adulteration, preparation of counterfeit drugs and development of formulations which do not have conceptual basis in these systems has increased. Further cultivation of medicinal plants with laboratory generated species is being attempted on the basis of chemical composition and is likely to be used in increased manner for commercial purpose. These changes may have profound impact on the safety and efficacy of the ASU drugs in the market. Hence a mechanism is required to put in place to address them. Establishment of Pharmacovigilance set up is the first required step. Pharmacovigilance is the science dedicated to reduce the risk of drug-related harms to patients. The number of adverse reactions to ASU drugs reported in the National Pharmacovigilance in India is negligible. The strong belief that ASU medicines are safe contributes to a large extent to this situation. To compound this matter is the lack of knowledge about the concepts and importance of pharmacovigilance in ASU systems among ASU practitioners.

In India, National pharmacovigilance programme under the control of Central Drug Standards Control Organization (CDSCO) has already been started since 2003. WHO had emphasizes that it should include traditional medicines in pharmacovigilance system and has published guidelines on safety monitoring of herbal medicines in pharmacovigilance systems in 2004.

Perceptive of the importance of Pharmacovigilance, Institute for Post Graduate Teaching and Research In Ayurveda, Jamnagar has already conducted a two days workshop on 3rd & 4th December 2007, on “Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations & Methods of Implementation”, funded by WHO, Country Office for India, New Delhi. Based on the recommendations of the workshop, a Pharmacovigilance Cell (PV Cell), first of its kind in India for Ayurveda, has been established and a Reporting Form for Suspected Adverse Reactions of Ayurvedic Formulations has been developed and distributed among the faculty members / research scholars / physicians under intimation to the Department of AYUSH, Ministry of Health and F.W., Govt. of India.

To put pharmacovigilance for ASU drugs in proper place in India, formation of a National Pharmacovigilance Centre for ASU Drugs, under the control of Department of AYUSH, is highly essential which would monitor the programme centrally. This programme aims to provide adverse drug reaction data related to

various drugs of herbal, mineral, metallic, animal and other origin available in the country.

The programme is being coordinated by NPRC-ASU under the guidance of National Pharmacovigilance Consultative Committee for ASU drugs being constituted by Department of AYUSH, Ministry of Health and FW, Govt. of India.

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 29th & 30th August 2008, sponsored by WHO, Country Office for India, New Delhi, where the draft protocol was technically reviewed and finalized. The finalized draft was circulated among the experts who attended the meet for their comments and additional inputs, if any. Based on the feedback received, final version of the protocol is prepared and the same is being released as a part of launching of National Pharmacovigilance Programme.

We hope that the data generated through Pharmacovigilance programme will provide some answers to the modern scientific world and better confidence in the users of ASU Drugs, ultimately providing more acceptability of these practices.

IPGT & RA wishes to express their sincere thanks to the Dept. of AYUSH, Ministry of Health & Family Welfare, Govt. of India, New Delhi for their constant encouragement, technical and financial support extended towards the establishment of the National Pharmacovigilance Programme for ASU Drugs.

IPGT & RA also would like to thank WHO, Country Office for India, New Delhi for their initiation and providing a strong background to the National Pharmacovigilance Programme for ASU Drugs.

IPGT & RA finally acknowledges the valuable contribution of all members of different advisory committees, who helped in preparing the protocol.

At last, we welcome the positive technical inputs which strengthens the activities of Pharmacovigilance for ASU Drugs.

Prof. MS Baghel,
Director, IPGT & RA,
GAU -Jamnagar
1. a. Glossary of terms:

National Pharmacovigilance Programme for Ayurveda, Siddha & Unani (NPP - ASU)

The nation wide programme, sponsored and coordinated by the country’s National Pharmacovigilance 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 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 Dept. of AYUSH, Ministry of Health and FW, 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 Centres 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 will be 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 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.
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.

Appropriate and adequate measures must be taken to keep track of the notifier. Any follow up action will be initiated on a notification only after the due verification of the notifier. If the notifier cannot be traced back, it will be recorded on the notification slip before closing the case.

Notification slip

A pre-designed structured form for ADR will be made available by the NPRC - ASU for written communication of a suspected ADR by the notifier duly signed by him/her wherever feasible.

ADR Form

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

Archiving

This is to be done at the NPRC - ASU.

Audit

A systematic and independent examination (conducted by personnel, independent of the centre) of centre’s activities and documents to determine whether centre’s activities were conducted and the data were recorded, analysed and accurately reported according to the protocol and regarding performance of pharmacovigilance centre’s participation in National Pharmacovigilance Programme for ASU.

Confidentiality

In a confidential / secretive manner.
Side Effect

Any unintended effect of a pharmaceutical product occurring at doses normally used in man which is related to the pharmacological properties of the drug.

Comment: This is an old term and is broad enough to include both positive and negative effects of a drug apart from its main properties or indications. Some use the term as synonymous with 'adverse reaction', but the proposed definition will improve clarity of use of this term.

Adverse Event / Adverse Experience

Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

Comment: This is a more recent term which some use interchangeably with 'adverse reaction', but, as indicated, it is better reserved for clinical phenomena occurring during drug treatment where causality cannot be or is not ascertained.

Signal

Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

Comment: This describes the first alert of a problem with a drug. By its nature a signal cannot be regarded as definitive but indicates the need for further enquiry or action. On the other hand it is prudent to avoid a multiplicity of signals based on single case reports since follow up of all such would be impractical and time consuming. The definition allows for some flexibility in approach to a signal based on the characteristics of individual problems. Some would like a 'signal' to include new information on positive drug effects, but this is outside the scope of a drug safety Programme.
Adverse Reaction

WHO Technical Report No 498 (1972); 'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Comment: This basic definition includes all doses prescribed clinically, but is intended to exclude accidental or deliberate overdose. The sub classification of 'unexpected' was included to facilitate understanding of the type of adverse reaction which is most important to report to drug monitoring agencies.

Unexpected Adverse Reaction

An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug.

Serious Adverse Event or Reaction

A serious adverse event or reaction is any untoward medical occurrence that at any dose:

⇒ Results in death
⇒ Requires inpatient hospitalisation or prolongation of existing hospitalisation
⇒ Results in persistent or significant disability/ incapacity
⇒ Is life-threatening

To avoid any confusion or misunderstanding of the difference between the terms 'serious' and 'severe', the following note of clarification is provided:

The term 'severe' is not synonymous with serious. 'Severe' is used to describe the intensity (severity) of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance (such as severe headache). Seriousness (not severity) which is based on patient/event outcome or action criteria serves as guide for defining regulatory reporting obligations.
1b. Most common types of adverse effects

**Type A: Adverse Effects** (Drug actions):
Pharmacological adverse effects
- Common (>1%)
- Dose relationship
- Suggestive time relationship
- Reproducible

**Occurring in special situations** or patients with increased susceptibility
- Organ selective injury
- Late effects
- Carcinogenicity, Mutagenicity
- Interactions
- Risk situations
- Childhood
- Adolescent
- The elderly
- Renal failure
- Haemodialysis
- Pregnancy
- Lactation
- Psychological Effect

**Type B: Adverse Effects** (Patient reactions)
Immunoallergic reactions
- Metabolic intolerance
- Idiosyncrasy
- Rare (<1%)
- Unexpected
- Causality uncertain
- Mechanism uncertain
- No dose relationship
- Not reproducible experimentally
- Characteristic, serious
- Suggestive time relationship
- Low background frequency
Type C: Adverse Effects (statistical effects)

Increased frequency of 'spontaneous' disease
  ⇒ High background frequency
  ⇒ Less typical for a drug reaction
  ⇒ No suggestive time relationship
  ⇒ Often long latency
  ⇒ Mechanism unknown
  ⇒ Difficult to reproduce experimentally

1. Commonly used Causality Assessment terms

Certain

A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure if necessary.

Comment: It is recognized that this stringent definition will lead to very few reports meeting the criteria, but this is useful because of the special value of such reports. It is considered that time relationships between drug administration and the onset and course of the adverse event are important in causality analysis. So also is the consideration of confounding features, but due weight must be placed on the known pharmacological and other characteristics of the drug product being considered. Sometimes the clinical phenomena described will also be sufficiently specific to allow a confident causality assessment in the absence of confounding features and with appropriate time relationships, e.g. penicillin anaphylaxis.
Probable / Likely

A clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfil this definition.

Comment: This definition has less stringent wording than for ‘certain’ and does not necessitate prior knowledge of drug characteristics or clinical adverse reaction phenomena. As stated no rechallenge information is needed, but confounding drug administration underlying disease must be absent.

Possible

A clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear.

Comment: This is the definition to be used when drug causality is one of other possible causes for the described clinical event.

Unlikely

A clinical event, including laboratory test abnormality, with a temporal relationship to drug administration which makes a causal relationship improbable, and in which other drugs, chemicals or underlying disease provide plausible explanations.

Comment: This definition is intended to be used when the exclusion of drug causality of a clinical event seems most plausible.
Conditional / Unclassified

A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data is essential for a proper assessment or the additional data are under examination.

Un-assessable / Unclassifiable

A report suggesting an adverse reaction, which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.

Causality Assessment

Various causality terms are in use but the following are used most widely. Some, however, do not use all the terms, for instance many do not believe that a ‘certain’ classification is possible for a single report and other make no distinction between ‘probable’ and ‘possible’. These definitions are however acceptable to Programme members who do use the terms. Where only ‘possible’ or ‘unlikely’ are used to describe reactions it must be understood that ‘possible’ include those reactions which are called by others ‘probable’ and ‘certain’, as well as ‘possible’.

Whilst ‘conditional/unclassified’ and ‘unassessable /unclassifiable’ are not causality terms, they describe the status of adverse reaction reports and therefore allow for practical communication about ADR issues.

Frequency of adverse drug reactions

Whenever possible, an estimate of frequency should be provided, expressed in standard category of frequency.

It is always difficult to estimate incidence on the basis of spontaneous reports, owing to the uncertainty inherent in estimating the denominator and degree of under-reporting. However, whenever possible, an estimate of frequency should be provided and in a standard form.
The following standard categories of frequency are recommended:

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<tr>
<td>Very common</td>
<td>≥ 1/10 (≥ 10%)</td>
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<tr>
<td>Common (frequent)</td>
<td>&gt; 1/100 and &lt; 1/10 (&gt; 1% and &lt; 10%)</td>
</tr>
<tr>
<td>Uncommon (infrequent)</td>
<td>≥ 1/1,000 and &lt; 1/100 (&gt; 0.1% and &lt; 1%)</td>
</tr>
<tr>
<td>Rare</td>
<td>≥ 1/10,000 and &lt; 1,000 (&gt; 0.01% and &lt; 0.1%)</td>
</tr>
<tr>
<td>Very rare</td>
<td>&lt; 1/10,000 (&lt; 0.01%)</td>
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Precise rates will inevitably be based on studies and limited to the more common reactions. For reactions that are fewer than 'common', estimates of frequency will inevitably be based on spontaneous reports or on very large post-marketing studies or other special studies, and the numbers will be less precise; therefore, the source of the estimates (spontaneous or clinical) should be indicated. Stating the absolute numbers of cases reported may be misleading since they inevitably will become outdated.

**Requisite Infrastructure:**

It includes a room of minimum 100 sq. feet, PC with internet facility, Furniture and other office accessories to run the programme.

**National Pharmacovigilance Technical Advisory Committee:**

This is a technical committee mainly concerned with reviewing and analysing the ADRs reported at different levels and to suggest proper remedial measures.

**ASU Drugs:**

Ayurveda, Siddha or Unani (ASU) drugs includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurveda, Siddha.
National Pharmacovigilance Protocol for ASU Drugs

and Unani systems of medicine, specified in the First Schedule of Drugs & Cosmetics Act 1940.

**Health Care Professional:**

Registered Medical practitioners of ASU Systems and other para medical personnel who are involved in providing healthcare like nurses, pharmacists, primary health care workers etc.

**National Pharmacovigilance Consultative Committee for ASU Drugs (NPCC - ASU)**

This committee shall comprise mainly of administrative heads of National Institutes, regulatory authorities and technical persons and shall have responsibility of monitoring and regulating administrative and financial aspects related to the programme.
2. National Pharmacovigilance Consultative Committee for ASU Drugs (NPCC - ASU)

This committee shall comprise mainly of administrative heads of National Institutes, regulatory authorities and technical persons and shall have responsibility of monitoring and regulating administrative and financial aspects related to the programme.

Chairperson :         Director, IPGT & RA
Member Secretary : Co-ordinator, NPRC

Members:

1. Director, CCRAS or his representative
2. One Director, Dept. of AYUSH
3. Director, National Institute of Ayurveda
4. Director, National Institute of Unani Medicine
5. Director, National Institute of Siddha Medicine
6. Director, PLIM
7. Dean, Faculty of Ayurveda, IMS, BHU, Varanasi
8. Chairman, APC
9. Drug Controller of ASU Drugs or his representative
10. Three Experts from concerned subjects
11. Chairman, PV Centre, IPGT & RA, Jamnagar
3. National Pharmacovigilance Technical Advisory Committee for ASU Drugs (NPTAC - ASU)

This is a technical committee mainly concerned with reviewing and analysing the ADRs reported at different levels and to suggest proper remedial measures.

Chairperson: Director, IPGT & RA
Member Secretary: Co-ordinator, NPRC

Members:

1. Director, CCRAS
2. Drug Controller of ASU Drugs
3. Four members from RPCs. One each from Siddha and Unani. Remaining two from Ayurveda. The representation should for two years.
4. One Advisor from ASU systems. Nominated by Secretary, Dept. of AYUSH

Representatives from Subject Specialties:

5. One representative from Dravyaguna
6. One representative from Agada Tantra
7. One representative from Kayachikitsa
8. One representative from Rasa Shastra
9. One representative from Bhaishajya Kalpana
10. One Representative from Swastha Vritta
11. One representative from Roga Nidana
12. One representative from Pharmacology / Toxicology
13. One representative from Modern Pharmacovigilance
4. NATIONAL PHARMACOVIGILANCE PROGRAMME FOR ASU DRUGS

Objectives:

Though for centuries ASU drugs are considered as safe and innocuous drugs, this perception is likely to change in the light of some recent occurrence of incidences of ADR during their use. This along with increased wide spread use of both at national and international levels is likely to lead to increased interaction of these drugs with diverse genomic profiles. This is likely to more incidences of expression of unexpected effects, which may be useful or adverse in nature. Thus, it should be considered as the right time to evolve a mechanism to record ADR of ASU drugs. Since there are considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of implementing appropriate risk management there is a need to engage health-care professionals and the public at large, in 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 will have the following objectives:

⇒ **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 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. There are also examples of traditional (ASU) medicines being adulterated or contaminated with allopathic medicines, chemicals such as corticosteroids, non-sterodial 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 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.
Inclusion of traditional medicines in Pharmacovigilance systems is becoming increasingly important given the growing use of ASU products and medicines globally. Pharmacovigilance is defined as the detection, assessment and prevention of adverse drug reactions in humans.

It is the process of:

⇒ Monitoring medicines as used in everyday practice to identify previously unrecognised adverse effects or changes in the patterns of their adverse effects.
⇒ Assessing the risks and benefits of medicines in order to determine what action, if any, is necessary to improve their safe use.
⇒ Providing information to users to optimise safe and effective use of medicines.
⇒ Monitoring the impact of any action taken.

5. FRAMEWORK FOR PHARMACOVIGILANCE FOR ASU DRUGS:

The National Pharmacovigilance Resource Centre for ASU Drugs is assigned to coordinate a country-wide Pharmacovigilance programme under the aegis of Department of AYUSH, Ministry of Health & Family Welfare, Government of India.

The programme shall be coordinated at Institute for Post Graduate Teaching & Research in Ayurveda (IPGT & RA), Jamnagar, Gujarat, India. The National Pharmacovigilance Programme for ASU drugs will operate under the guidance of the National Pharmacovigilance Technical Advisory Committee to recommend procedures and guidelines for regulatory interventions.
6. THE NATIONAL PHARMACOVIGILANCE RESOURCE CENTRE AT IPGT&RA

The National Pharmacovigilance Resource Centre, IPGT & RA:

a. Shall monitor the adverse drug reactions of ASU medicines in order to identify previously unexpected adverse drug reactions or indicate that certain reactions occur more commonly than previously believed. This will include the collation, review and evaluation of all spontaneous ADR reports received by the unit on a nation-wide basis. This information will then be keyed into the ADR database for use in aggregate analysis. These reports shall also be submitted to the WHO International Drug Monitoring Programme for international collaboration on drug safety.

b. Shall seek Periodic Safety Update Reports (PSURs) submitted by pharmaceutical companies. Pharmaceutical companies are requested to submit the PSURs of all new patent ASU drugs. PSURs are expected to be submitted every 6 monthly for the first 2 years of marketing in India, and annually for the subsequent 2 years.

c. Shall maintain contacts with international regulatory bodies working in pharmacovigilance and exchange information on drug safety under intimation of Dept. of AYUSH.

d. Shall assess the safety information in order to determine what action, if necessary, needs to be taken to improve safe use. Based on the available data, the Technical Advisory Committee shall make recommendations on product label amendments, product withdrawals and suspension.

e. Shall provide information to end-users through adverse drug reaction news bulletins, drug alerts and seminars.
7. Outline of the National Pharmacovigilance Programme For ASU

The National Pharmacovigilance Programme for ASU drugs aims to provide adverse drug reaction data related to various ASU drugs available in the country. The programme will be supervised by the National Pharmacovigilance Resource Centre for ASU [NPRC-ASU] constituted by Department of AYUSH, Ministry of Health & Family Welfare, Govt. of India. The Programme would comprise of the following steps:

**Step 1:**
Identifying various centres across the country for recording ADR related data.

a. Setting up of 8 **Regional Pharmacovigilance Centres** [RPC] under the programme. Each **Regional Centre** shall provide sufficient space with requisite infrastructure.

b. Identifying **30 Peripheral Pharmacovigilance Centres** [PPC] across the country preferably one in every state.

Eligibility criteria for identifying a PPC are provided in Annexure 1.

**Step 2: Training:**

To ensure harmonized implementation of the Programme efforts shall be made to arrive at a uniform understanding of the operational systems, along with standardized formats to document and analyse ADRs. An induction training programme shall be arranged for healthcare professionals participating in the NPP for
Uniform training will be given to all the participating centres. Intensive interaction/training sessions will be organized for all participants to:

⇒ Clearly define their individual and team roles and responsibilities
⇒ Set operational benchmarks e.g.

**Strategies for implementation:**

i Each PPC

To record some ADRs each month (statistically speaking 30 ADR in about 1000 patients who visit each month would be quite easy to record) 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
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.

⇒ Evolve SOPs for generating and forwarding ADR data and for general conduct of the Programme (NPRC to prepare SOPs which must ensure that the Programme is conducted in compliance with this Protocol).

⇒ Impart relevant skills for carrying out ADR data capture namely:
   a. Appropriate communication skills to elicit ADR related information
   b. For recording ADR information through hands-on training
   c. For meticulous collation and completeness of data
   d. For fostering notification culture.

These training programs and interaction meetings shall be held every 6 months after the initial training. Besides, continuous communication through emails, carrying relevant information related to ADR monitoring methods shall be maintained among the participating centres.

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

PPC:
A teacher of Dravyaguna / Rasashastra, Bhaishajya Kalpana / any clinical department / Agadatantra, allied departments of Siddha and Unani systems of medicines, Research Officer (ASU)
RPC:
A teacher of Dravyaguna / Rasashastra, Bhaishajya Kalpana / any clinical department / Agadatantra, allied departments of Siddha and Unani systems of medicines, preferably not below the rank of Sr. Lecturer / Assistant professor, attached to an ASU medical college, and Assistant Director (ASU)

NPRC:
A teacher of Dravyaguna / Rasashastra, Bhaishajya Kalpana / any clinical department / Agadatantra not below the rank of an Asso. Professor.

All coordinators must obtain official permission, in writing; from their respective head of the institution / chief of the hospital, and submit the document to the NPRC.

NPRC will appoint dedicated Ayurvedic pharmacologist and data managers (project staff). The Ayurvedic pharmacologist must be computer literate. The data manager must have sufficient competence in database designing, data entry and data analysis.

Study population:
Anyone experiencing adverse events suspected to be caused by ASU drugs.

Causality Assessment:
As per WHO recommended methodologies.

Archiving:
All data generated (including reporting forms) will be stored and preserved for the purpose of archiving for a minimum period of 5 years, at the NPRC.

Confidentiality:
Patient's identity is not revealed on the form only the patient identifier is mentioned. Identity of the patients and related data will be used only for research and regulatory purpose and sufficient measures will be taken to maintain confidentiality of such information.
The identity of the notifier / reporter must be recorded in the ADR form or Notification Slip so that in future the data can be verified if needed in future.

**Audit and Monitoring:**

Overall supervision of participating centres of all levels will be done by NPCC -ASU, through NPRC office as per a pre-designed audit protocol, thereby making room for prompt correction of deficiencies so detected. The purpose of the audit activities will be to ensure the quality of ADR information, which must be authentic (including traceability of the patient), complete (all essential data elements filled-in), timeline compliant, and legible. The audit activity will also look into overall compliance with SOPs. The overall cost effectiveness analysis of the Programme will also be evaluated by the audit process. This would refer to regularity of the key personnel, particularly the dedicated Programme staff, and the average time they devote in the project work.

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.

**Financial Assistance:**

There shall be a provision for financial assistance to run the programme successfully.

**Change of centre:**

If the performance of any centre is not satisfactory, the NPCC-ASU is empowered to take decision to relocate the centre.

8. **STEPS FOR FOSTERING “REPORTING CULTURE”**

An electronic newsletter shall be published periodically to exchange the information among the participating centres. Professional bodies and non-government organizations [NGOs] shall be approached for collaboration.
National Pharmacovigilance Protocol for ASU Drugs

Other promotional strategies that may be considered include:

- Posters
- Annual celebration of Pharmacovigilance Day
- Leaflets for patients / doctors
- Integrating pharmacovigilance learning sessions into undergraduate curriculum
- Interface with ASU Associations
- Email / referral system
- Cross links on the websites
- Pharmacovigilance-related articles in the newspapers / health journals
- A dedicated pharmacovigilance web site shall be created by the NPC and it will be hyperlinked with other AYUSH organizations.
- Interactive workshops at RPC level are to be organized at regular intervals inviting information from the sufferers / consumers.

9. WHAT TO REPORT

The National Pharmacovigilance Programme For ASU drugs (NPP-ASU) shall encourage reporting of all suspected drug related adverse events, including those suspected to have been caused by interaction with any other drugs or food incompatibilities. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a widespread prescribing problem.

The programme particularly solicits reports of:

- All adverse reactions suspected to have been caused by ASU drugs alone or along with any other drugs.
- All suspected drug interactions
- Reactions to any other drugs which are suspected of significantly affecting a patient’s management, including reactions suspected of causing:
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.

10. 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.

Drug Related Information Report:

Consumer may directly report to the concerned PPC / RPC / nearest health centre or physician regarding the suspected ADR

11. WHERE TO REPORT

The reporting on prescribed format will be done to any of the Pharmacovigilance centres.
12. WHAT HAPPENS TO THE INFORMATION SUBMITTED

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 Dept. of AYUSH, Govt. of India.

13. QUALITY OF SUSPECTED ADVERSE DRUG REACTION INFORMATION

Only those forms which meet the following criteria shall be analysed:

⇒ Authenticity (including reporter's and patient's traceability)
⇒ Completeness (at least with respect to point no.'s 1, 2, 3, 4, 5 and 11 on the ADR Reporting Form) for ASU drugs
⇒ Legibility

In order to avoid receiving fake unauthentic reports or reports by parties having vested interests against any drug(s), it is important that the reporter's identity is clearly stated in the form so that the reporter can be approached to verify the authenticity of the entire report.
### 14. RESPONSIBILITIES OF CENTRE’S COORDINATORS

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Responsibilities</th>
<th>PPC</th>
<th>RPC</th>
<th>NPRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>To collect ADR reporting</td>
<td></td>
<td></td>
<td>Ö</td>
</tr>
<tr>
<td>2</td>
<td>To fill in the ADR form properly</td>
<td></td>
<td></td>
<td>Ö</td>
</tr>
<tr>
<td>3</td>
<td>To forward duly-filled in ADR forms to next higher level centre</td>
<td></td>
<td>Ö</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>To maintain a log of all ADR notification forms (blank or filled) received and forwarded</td>
<td>Ö</td>
<td>Ö</td>
<td>Ö</td>
</tr>
<tr>
<td>5</td>
<td>To identify, induce PPC / RPC (with concurrence of NPRC - ASU), provide them with general technical support, coordinate and monitor their functioning</td>
<td>-</td>
<td>-</td>
<td>Ö</td>
</tr>
<tr>
<td>6</td>
<td>To identify and deploy a pharmacologist for management of pharmacovigilance tasks</td>
<td>-</td>
<td>-</td>
<td>Ö</td>
</tr>
<tr>
<td>7</td>
<td>To identify and deploy a data manager for data management under NPP</td>
<td>-</td>
<td>-</td>
<td>Ö</td>
</tr>
<tr>
<td>8</td>
<td>To carry out (or review) causality analysis of all ADR forms or review such analysis by the RPC</td>
<td>-</td>
<td>Ö</td>
<td>Ö</td>
</tr>
<tr>
<td>9</td>
<td>To forward all duly-filled ADR forms as per pre-determined time line i.e. first week of every month Information of all serious ADR’s must be conveyed to the NPRC within 2 working days by fax, email, telephone, courier as per stipulated guideline</td>
<td>Ö</td>
<td>Ö</td>
<td>Ö</td>
</tr>
<tr>
<td>10</td>
<td>To report all serious adverse reactions within 24 Hrs.</td>
<td>Ö</td>
<td>Ö</td>
<td>-</td>
</tr>
<tr>
<td>11</td>
<td>To forward periodic reports to next higher centre in first week of every month.</td>
<td>Ö</td>
<td>Ö</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>To liaise with healthcare professionals in order to inculcate / foster the culture of ADR reporting</td>
<td>Ö</td>
<td>Ö</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Acknowledge the cooperation of the notifier</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Share with notifier relevant feedback from higher centres</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>To organize and attend training programs/interactive meetings for all lower level centres</td>
<td>Ö</td>
<td>Ö</td>
<td>Ö</td>
</tr>
<tr>
<td>14</td>
<td>Organize the public campaigns to</td>
<td>Ö</td>
<td>Ö</td>
<td></td>
</tr>
</tbody>
</table>

26
15. IMPORTANT:

RPC and NPRC are acknowledged to have comparable professional competence. Their hierarchical position is only for administrative and management purposes (NPRC has the additional responsibilities for data collation, statistical analysis and archiving). Concurrence for selection of new PPCs / RPCs will be given by the NPRC in consultation with NPCC-ASU. If a new centre is being proposed to replace a non functional PPC or RPC, the NPCC-ASU shall provide their opinion/concurrence in not more than one month.

New centres may join the Programme depending on the need in a particular territory and availability of resources to support new centre(s). The request may be forwarded through the respective RPC / NPRC to the NPCC-ASU which will take a final decision in this regard. In all cases, Head of the Institution desiring to join the Programme must give administrative clearance to this effect.

16. MANAGEMENT INFORMATION SYSTEM

<table>
<thead>
<tr>
<th>SI No</th>
<th>PPC to RPC</th>
<th>RPC to NPRC</th>
<th>NPRC to NPCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Period of report</td>
<td>Period of report</td>
<td>Period of report</td>
</tr>
<tr>
<td>02</td>
<td>Number of reportings</td>
<td>Number of reportings</td>
<td>Number of reportings</td>
</tr>
<tr>
<td></td>
<td>received in the preceding period?</td>
<td>received in the preceding period?</td>
<td>received in the preceding period?</td>
</tr>
<tr>
<td>03</td>
<td>Number of ADR reports</td>
<td>Number of ADR reports</td>
<td>Number of ADR reports</td>
</tr>
<tr>
<td>04</td>
<td>Number of serious ADR reports (if any)</td>
<td>Number of serious ADR reports (if any)</td>
<td>Number of serious ADR reports (if any)</td>
</tr>
<tr>
<td>05</td>
<td>Number of serious ADR reports (if any)</td>
<td>Number of serious ADR reports (if any)</td>
<td>Number of serious ADR reports (if any)</td>
</tr>
<tr>
<td></td>
<td>forwarded within specified time.</td>
<td>forwarded within specified time.</td>
<td>forwarded within specified time.</td>
</tr>
<tr>
<td>06</td>
<td>Number of serious ADR reports (if any)</td>
<td>Number of serious ADR reports (if any)</td>
<td>Number of serious ADR reports (if any)</td>
</tr>
<tr>
<td></td>
<td>forwarded within specified time.</td>
<td>forwarded within specified time.</td>
<td>forwarded within specified time.</td>
</tr>
<tr>
<td>07</td>
<td>Reason for delay</td>
<td>Reason for delay</td>
<td>Reason for delay</td>
</tr>
<tr>
<td>No.</td>
<td>Description</td>
<td>Form 1</td>
<td>Form 2</td>
</tr>
<tr>
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<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>08</td>
<td>Important happenings or developments other than the way they should have happened</td>
<td>Important happenings or developments other than the way they should have happened</td>
<td>Important happenings or developments other than the way they should have happened</td>
</tr>
<tr>
<td>09</td>
<td>Total No. of ADR forms received</td>
<td>Total No. of ADR forms received</td>
<td>Total No. of ADR forms received</td>
</tr>
<tr>
<td>10</td>
<td>No. of ADR forms in which causality assessments ADR</td>
<td>No. of ADR forms in which causality assessments ADR</td>
<td>No. of ADR forms in which causality assessments ADR</td>
</tr>
<tr>
<td>11</td>
<td>Any other observations</td>
<td>New PPC identified and recommended if any</td>
<td>No of recommendations from RPC for new PPC</td>
</tr>
<tr>
<td>12</td>
<td>No. of notifications / reports received from each centre</td>
<td>No. of ADR forms received from RPC in which causality assessment has been ADR</td>
<td>No. of ADR forms received from RPC in which causality assessment has been ADR</td>
</tr>
<tr>
<td>13</td>
<td>No. of reports inappropriately filled by respective PPCs</td>
<td>No. of ADR forms received from RPC in which causality assessment has been verified / reassessed (all SAEs and 10% of all remaining)</td>
<td>No. of ADR forms received from RPC in which causality assessment has been verified / reassessed (all SAEs and 10% of all remaining)</td>
</tr>
<tr>
<td>14</td>
<td>Actions taken / recommended</td>
<td>No. of forms archived</td>
<td>No. of forms archived</td>
</tr>
<tr>
<td>15</td>
<td>Monitoring activities done</td>
<td>Monitoring activities done</td>
<td>Monitoring activities done</td>
</tr>
<tr>
<td>16</td>
<td>Acknowledgments sent in time</td>
<td>No. of notifications / reports received from each centre</td>
<td>No. of notifications / reports received from each centre</td>
</tr>
<tr>
<td>17</td>
<td>CME awareness activities if any</td>
<td>No. of reports filled in inappropriately by respective Regional Centres</td>
<td>No. of reports filled in inappropriately by respective Regional Centres</td>
</tr>
<tr>
<td>18</td>
<td>Any other observations</td>
<td>Actions taken / recommended</td>
<td>Acknowledgments sent in time</td>
</tr>
<tr>
<td>19</td>
<td>Acknowledgments sent in time</td>
<td>Acknowledgments sent in time</td>
<td>Acknowledgments sent in time</td>
</tr>
<tr>
<td>20</td>
<td>CME &amp; awareness activities if any</td>
<td>CME &amp; awareness activities if any</td>
<td>CME &amp; awareness activities if any</td>
</tr>
<tr>
<td>21</td>
<td>Any other observations</td>
<td>Any other observations</td>
<td>Any other observations</td>
</tr>
</tbody>
</table>
17. PUBLICATION OF DATA

ADR data may be published without referring the name of National Pharmacovigilance programme and the patient's identity.

18. PERFORMANCE BENCHMARKS:

It will be the responsibility of the Coordinators of the respective Pharmacovigilance Centres to supervise and monitor the performance. In case of any non-conformance or violation of the Protocol, the supervising Coordinator shall issue (3 reminders at monthly intervals) to the concerned centre in accordance with the governance. If no satisfactory response is received even after 3 reminders - the defaulting Centre shall be assumed to have withdrawn from the programme.

In view of the above RPC gets closed down, NPRC will takeover the functions till a new RPC is established.

19. RESOURCES FOR PHARMACOVIGILANCE CENTRES

Publications related to Pharmacovigilance shall be provided to various centres as identified by the NPCC-ASU:

- Poisonous plants of India
- ASU Official Pharmacopoeia and Formularies
- 7 volumes of Database of medicinal plants published by CCRAS
- Meyler's Side Effects
- AHFS Drug Information hand book
- Martindale / online
- Davies Text Book of ADR
- Physician's Desk reference
- Bhaishajya Ratnavali
- Rasayoga Sagara : 2 volumes
- Unani / Siddha Publications
- List of poisonous plants
NPRC will provide honorarium to Co-ordinator and salary to the following qualified experts having degrees: MD (Ayu) in Dravyaguna / Rasa Shastra, Bhaishajya Kalpana, MD (Unani) in Ilmul Advia / Ilmul saidla, MD (Siddha) in Gunapadam, M. Pharm. (Ayu) / B. Pharm. (Ayu) and a data manager. Untied funds will be made available to the NPRC.

RPC and PPC will be provided funds towards honorarium to the Co-ordinators and untied funds to carryout the activities.

All centre co-ordinators will be provided training on the following issues:

` Skills to foster reporting culture.
` Communications skills for complete and meticulous collection of data.
` Methodology of filling up the forms

How often: At initiation of the programme / centres; subsequently every 6 months

Regional and National centre are acknowledged to have comparable professional competence. Their hierarchical position is primarily for administrative and management purposes (National centre has the additional responsibility for data collation and archiving). Concurrence / selection of Peripheral Centre / Regional Centres will be given by the NPRC.

NPRC to remain at the same venue even if the Coordinator moves to another institution.

If a new institution wants to join the programme, its head has to write to NPRC identifying a coordinator and its intention for joining the programme.
20. Terms of Reference for Engagement of Peripheral Pharmacovigilance Centre under the National Pharmacovigilance Programme for ASU

a  Background

Department of AYUSH, Ministry of Health and Family Welfare, Government of India, New Delhi has initiated the National Pharmacovigilance Programme For ASU drugs. NPRC-ASU is coordinating the country-wide Pharmacovigilance programme for 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 in to the conditions prevailing in the present scenario, it is high time to deliberate regarding the burning issues over traditional and classical Ayurvedic, Siddha and Unani products and practices; it is felt to constitute a National Pharmacovigilance Centre for ASU Drugs in India.

The programme shall be coordinated by NPRC, IPGT&RA, GAU, Jamnagar under the supervision of a National Pharmacovigilance Consultative Committee for ASU which would monitor the programme and also recommend regulatory interventions based on the generated Adverse Drug Reaction (ADR) data.

b  Objectives of the Assignment

Assignment:

To manage the Peripheral Pharmacovigilance centres For ASU Drugs.
The overall objective as per the National Pharmacovigilance Programme For ASU will be:

⇒ To monitor safety of the drugs and provide structured inputs for appropriate regulatory interventions.
⇒ To create awareness about ADR monitoring of ASU drugs in their respective vicinity.

Peripheral centres will be the primary pharmacovigilance centres under the National Pharmacovigilance Programme For ASU.

To carry out the functions as envisaged in the “Protocol for the National Pharmacovigilance Programme For ASU” a Coordinator will have to be designated who will be in-charge of the pharmacovigilance activities at the designated peripheral centre.

By accepting to participate in the National Pharmacovigilance Programme for ASU, all centres explicitly agree that all pharmacovigilance activities at their institutions shall be performed in strict consonance with the National Pharmacovigilance Programme appended here (Coordinators of the centres and heads of the institutions are advised to carefully go through the Protocol prior to joining the programme).

c Outline of tasks to be carried out

The National Pharmacovigilance Programme for ASU, encourages the reporting of all suspected adverse reaction to ASU drugs. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a wide spread prescribing problem.
Peripheral Centre is expected to carry out the following tasks:

1. To maintain a log of all ADR notification forms received and forwarded
2. To receive blank ADR forms and acknowledge receipt
3. To fill or get filled the ADR forms
4. Collect Adverse Drug notifications from own centres
5. Receive Adverse Drug Reaction (ADR) forms and maintain log of all ADR forms received and forwarded.
6. Correspond with Regional Centres for general technical support, and coordination
7. Carry out (and/or review) data causality analysis of all ADRs
8. To forward all duly-filled ADR forms [those generated at the same centre] as per pre-determined time line
9. Forward periodic reports to the RPC centre as per Sl. No. 9
10. Liaise with health care professionals in order to inculcate / foster the culture of ADR reporting / notification by acknowledging the cooperation by the notifier and share with the notifier relevant feedback from higher centre.
11. Attend training programmes / interactive meetings for peripheral centres falling under the respective Regional pharmacovigilance centres
12. To provide updates, reports and such other information as may be required by the National Pharmacovigilance Technical Advisory Committee for ASU and to attend their meetings
13. To conduct special pharmacovigilance projects on various drugs which may be of
special concern or interest to NPRC / Government of India

14. To maintain account of the funds provided under this program as per your institution's systems; To provide a consolidated statement to the regional centre

15. Carryout audits to ensure compliance with the program, enlist non-compliance, establish corrective measures and implement them at peripheral centres

In line with the size & patient intake of the institutions where it is based, the peripheral centre shall ensure a minimum 10 adverse events reporting every month and this number must be increased periodically. This number will be in addition to the number of reports generated by the National and regional centres.

d Schedule of Performance of Tasks:

The duration of the assignment is three years (with a review at the end of the year). The time schedule for performance of various tasks is detailed below:
<table>
<thead>
<tr>
<th>S. No.</th>
<th>Task</th>
<th>Time Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>To maintain a log of all ADR notification forms received and forwarded</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>To receive blank ADR forms and acknowledge receipt</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>To fill or get filled the ADR forms</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Collect Adverse Drug notifications from own centres</td>
<td>Monthly</td>
</tr>
<tr>
<td>5.</td>
<td>Receive Adverse Drug Event (ADR) forms and maintain log of all ADR forms received and forwarded.</td>
<td>Monthly</td>
</tr>
<tr>
<td>6.</td>
<td>Carry out (and/or review) data causality analysis of all ADRs</td>
<td>Monthly</td>
</tr>
<tr>
<td>7.</td>
<td>To forward all duly-filled ADR forms as per pre-determined time line</td>
<td>Monthly</td>
</tr>
<tr>
<td>8.</td>
<td>Forward periodic reports to the NPRC centre as per Sl. No. 9</td>
<td>Monthly</td>
</tr>
<tr>
<td>9.</td>
<td>Liaise with health care professionals in order to inculcate / foster the culture of ADR reporting / notification by acknowledging the cooperation by the notifier and share with the notifier relevant feedback from higher centre.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Organize and attend training programmes / interactive meetings</td>
<td>6 months in addition to induction of training</td>
</tr>
<tr>
<td>11.</td>
<td>To provide updates, reports and such other information as may be required by the National Pharmacovigilance Technical Advisory Committee for ASU and to attend their meetings</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>To conduct special pharmacovigilance projects on various drugs which may be of special concern or interest to NPRC / Dept of AYUSH, Government of India</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>To maintain account of the funds provided under this program as per your institution’s systems; To provide a consolidated statement to the NPRC</td>
<td>Quarterly</td>
</tr>
<tr>
<td>14.</td>
<td>Carry out audits to ensure compliance with the program, enlist non-compliance, establish corrective measures and implement them</td>
<td>Quarterly</td>
</tr>
</tbody>
</table>
e Data Services and Facilities to be provided by NPRC

NPRC shall coordinate the programme and arrange for training for those professionals who are participating in the programme.

f Final Output that will be required

a) Structured pharmacovigilance data, based on the ADR forms collected.

b) A structured annual report describing smooth and efficient operation of the program, in accordance with the Protocol.

g Financial support under the Project:

The following financial support shall be provided by NPRC:

1. One post of Co-ordinator: MD (Ayu) in Dravyaguna / Rasa Shastra, Bhaishajya Kalpana, MD (Unani) in Ilmul Advia / Ilmul saidla, MD (Siddha) in Gunapadam or in any clinical subjects of ASU
   The remuneration for the above post will be as decided by the National Pharmacovigilance Consultative Committee.

2. Expenditure on office operation for peripheral centre: Rs. 15,000.00 p.a. (Rs. Fifteen Thousands Only) is proposed.

3. ADR Reporting forms, various books and periodicals, MIS reporting forms shall be provided by the NPRC, which will also provide funds for Regional / Peripheral centres for interaction meetings and trainings twice a year.
h MIS Formats for Reporting by Proposal Centre to RPC

1. Period of Report
2. Number of notifications received in the preceding period
3. Number of Reports of ADR and number of serious or suspected serious ADR reports, if any
4. Number of serious or suspected serious ADR reports forwarded with in the specified time
5. Number of serious or suspected serious ADR reports not forwarded with in the specified time along with the reasons for delay
6. Important happenings or developments
7. Total number of ADR forms received
8. Number of forms archived
9. Monitoring activities done
10. No. of notifications / reports received from their respective vicinity.
11. Actions taken / recommended
12. Acknowledgements sent in time
13. CME awareness activities if any
14. Any other observations

21. Terms of Reference for engagement of Regional Pharmacovigilance Centre under the National Pharmacovigilance Programme for ASU Drugs

a Background

Department of AYUSH, Ministry of Health and Family Welfare, Government of India, New Delhi has initiated the National Pharmacovigilance Programme For ASU drugs. NPRC-ASu is coordinating the country-wide Pharmacovigilance programme for 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 in to the conditions prevailing in the present scenario, it is high time to deliberate regarding the burning issues over traditional and classical Ayurvedic, Siddha and Unani products and practices; it is felt to constitute a National Pharmacovigilance Centre for ASU Drugs in India.
The programme shall be coordinated by NPRC, IPGT&RA, GAU, Jamnagar under the supervision of a National Pharmacovigilance Consultative Committee for ASU which would monitor the programme and also recommend regulatory interventions based on the generated Adverse Drug Reaction (ADR) data.

b  Objective of the Assignment:

Assignment: To manage the Regional Pharmacovigilance centre for ASU drugs

The overall objective as per the National Pharmacovigilance Programme will be:

1. To monitor safety of the drugs and provide structured inputs for appropriate regulatory interventions
2. To create awareness about ADR monitoring in India

Regional centres will be the secondary pharmacovigilance centres under the National Pharmacovigilance Programme for ASU.

To carry out the functions as envisaged in the “Protocol for the National Pharmacovigilance Programme for ASU” a Coordinator will have to be designated who will be in-charge of the pharmacovigilance activities at the designated regional centre.

By accepting to participate in the National Pharmacovigilance Programme for ASU all centres explicitly agree that all pharmacovigilance activities at their institutions shall be performed in strict consonance with the National Pharmacovigilance Programme for ASU appended here (Coordinators of the centres and heads of the institutions are advised to carefully go through the Protocol prior to joining the programme).
Outline of tasks to be carried out

The National Pharmacovigilance Programme for ASU, encourages the reporting of all suspected adverse reaction to ASU drugs. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a wide spread prescribing problem:

Regional Centre is expected to carry out the following tasks.

1. To maintain a log of all ADR notification forms received and forwarded
2. To receive blank ADR forms and acknowledge receipt
3. To fill or get filled the ADR forms
4. Collect Adverse Drug notifications from Peripheral as well as its own centres
5. Receive Adverse Drug Reaction (ADR) forms and maintain log of all ADR forms received and forwarded.
6. Correspond with Peripheral Centres, provide them with general technical support, coordinate and monitor their functionings.
7. Carry out (and/or review) data causality analysis of all ADRs
8. To forward all duly-filled ADR forms [those generated at the same centre and those received from immediate lower-level centre] as per pre-determined time line
9. Forward periodic reports to the NPRC centre as per Sl. No. 9
10. Liaise with health care professionals in order to inculcate / foster the culture of ADR reporting / notification by acknowledging the cooperation by the notifier and share with the notifier relevant feedback from higher centre.
11. Organize and attend training programmes / interactive meetings for all peripheral centres.
12. To provide updates, reports and such other information as may be required by the NPRC / National Pharmacovigilance Technical Committee / National Pharmacovigilance Technical Advisory Committee and to attend their meetings.
13. To conduct special pharmacovigilance projects on various drugs which may be of special concern or interest to NPRC / Government of India

14. To maintain account of the funds provided under this program as per the institution's systems; To review the account statement received from peripheral centres and provide a consolidated statement to the NPRC

15. Carryout audits to ensure compliance with the program, enlist non-compliance, establish corrective measures and implement them at regional centres and oversee their implications at peripheral centres

In line with the size & patient intake of the institutions where it is based, the regional centre shall ensure a minimum 30 adverse event reporting every month and this number must be increased periodically. This number will be in addition to the number of reports generated by the peripheral centres falling under respective regional centres.

d Schedule of Performance of Tasks

The duration of the assignment is 3 years (with a review at the end of every year). The time schedule for performance of various tasks is detailed below:
<table>
<thead>
<tr>
<th>S. No.</th>
<th>Task</th>
<th>Time Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>To maintain a log of all ADR notification forms received and forwarded</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>To receive blank ADR forms and acknowledge receipt</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>To fill or get filled the ADR forms</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Collect &amp; collate Adverse Drug notifications from Peripheral as well as own centres</td>
<td>Monthly</td>
</tr>
<tr>
<td>5.</td>
<td>Receive Adverse Drug Events (ADR) forms and maintain log of all ADR forms received and forwarded</td>
<td>Monthly</td>
</tr>
<tr>
<td>6.</td>
<td>Correspond with Peripheral Centres, provide them with general technical support, coordinate and monitor their functioning</td>
<td></td>
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<tr>
<td>7.</td>
<td>Identify and delegate a pharmacologist for management of pharmacovigilance tasks</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Identify and delegate a data manager for the data management under National Pharmacovigilance Programme</td>
<td></td>
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<tr>
<td>9.</td>
<td>Carry out (and/or review) data causality analysis of all ADRs</td>
<td>Monthly</td>
</tr>
<tr>
<td>10.</td>
<td>To forward all duly-filled ADR forms [those generated at the same centre and those received from immediate lower-level centre] as per pre-determined time line</td>
<td>Monthly</td>
</tr>
<tr>
<td>11.</td>
<td>Forward periodic reports to the NPRC centre as per Sl. No. 9</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Liaise with health care professionals in order to inculcate / foster the culture of ADR reporting / notification by acknowledging the cooperation by the notifier and share with the notifier relevant feedback from higher centre.</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Organize and attend training programmes / interactive meetings for all peripheral centres falling under the respective regional pharmacovigilance centres</td>
<td></td>
</tr>
</tbody>
</table>
14. To provide updates, reports and such other information as may be required by the National Pharmacovigilance Technical Advisory Committee and to attend their meetings

15. To conduct special pharmacovigilance projects on various drugs which may be of special concern or interest to NPRC / Deppt of AYUSH, Government of India

16. To maintain account of the funds provided under this program as per your institution's systems; To review the account statement received from peripheral centres, and provide a consolidated statement to the NPRC centre

17. Carry out audits to ensure compliance with the program, enlist non-compliance, establish corrective measures and implement them at regional centres and oversee their implications at peripheral centres

e  Data Services and Facilities to be provided by NPRC

NPRC shall coordinate the programme and arrange for training for those professionals who are participating in the programme.

f  Final Output that will be required

i) Structured pharmacovigilance data based on the ADR forms collected under the program participants.

ii) A structured annual report describing smooth and efficient operation of the program, in accordance with the Protocol.

g  Financial support under the Project

The following financial support shall be provided by NPRC:
1. One post of Co-ordinator: MD (Ayu) in Dravyaguna / Rasa Shastra, Bhaishajya Kalpana, MD (Unani) in Ilmul Advia / Ilmul saidla, MD (Siddha) in Gunapadam or in any clinical subjects of ASU
The remuneration for the above post will be as decided by the National Pharmacovigilance Consultative Committee.

2. Expenditure on office operation for peripheral centre: Rs. 25,000.00 (Rs. Twenty Five Thousands Only) is proposed.

3. ADR Reporting forms, various books and periodicals, MIS reporting forms shall be provided by the NPRC

h MIS Formats for Reporting by Regional Centre to National Resource Centre

1. Period of Report
2. Number of notifications received in the preceding period
3. Number of Reports ADR and number of serious or suspected serious ADR reports, if any
4. Number of serious or suspected serious ADR reports forwarded with in the specified time
5. Number of serious or suspected serious ADR reports not forwarded with in the specified time along with the reasons for delay
6. Important happenings or development
7. Total number of ADR forms received
8. Number of recommendations from Peripheral Pharmacovigilance centres for new peripheral pharmacovigilance centre
9. Total no. of ADR forms received from Peripheral Centre in which causality assessments has been ADR
10. Number of ADR forms received from Peripheral Centre in which causality assessment has been verified / reassessed
11. Number of forms archived
12. Monitoring activities done
13. No. of notifications / reports received from
National Pharmacovigilance Protocol for ASU Drugs

each centre

14. No. of reports filled in inappropriately by respective Peripheral Centres
15. Actions taken / recommended
16. Acknowledgements sent in time
17. CME awareness activities if any
18. Any other observations

22. Terms of Reference for functioning as National Pharmacovigilance Resource Centre under the National Pharmacovigilance Programme for ASU Drugs

a  Background

Department of AYUSH, Ministry of Health and Family Welfare, Government of India, New Delhi has initiated the National Pharmacovigilance Programme For ASU drugs. NPRC-ASU is coordinating the country-wide Pharmacovigilance programme for 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 in to the conditions prevailing in the present scenario, it is high time to deliberate regarding the burning issues over traditional and classical Ayurvedic, Siddha and Unani products and practices; it is felt to constitute a National Pharmacovigilance Centre for ASU Drugs in India.

The programme shall be coordinated by NPRC, IPGT&RA, GAU, Jamnagar under the supervision of a National Pharmacovigilance Consultative Committee for ASU which would monitor the programme and also recommend regulatory interventions based on the generated Adverse Drug Reaction (ADR) data.

b  Objective of the Assignment
Assignment:
To manage the National Pharmacovigilance centre
For ASU

The overall objective as per the National Pharmacovigilance Programme for ASU will be:

a. To monitor safety of the drugs and provide structured inputs for appropriate regulatory interventions
b. To create awareness about ADR monitoring in India

NPRC will be the tertiary pharmacovigilance centre under the National Pharmacovigilance Programme for ASU.

To carry out the functions as envisaged in the “Protocol for the National Pharmacovigilance Programme for ASU” a Coordinator will have to be designated who will be in-charge of the pharmacovigilance activities at the designated National centre.

By accepting to participate in the National Pharmacovigilance Programme for ASU the centre explicitly agree that all pharmacovigilance activities at their institution shall be performed in strict consonance with the National Pharmacovigilance Programme for ASU appended here (Coordinators of the centre and head of the institutions are advised to carefully go through the Protocol prior to joining the programme).

c Outline of tasks to be carried out

The National Pharmacovigilance Programme for ASU, encourages the reporting of all suspected adverse reaction to ASU drugs. The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a wide spread prescribing problem:

National Centre is expected to carry out the following tasks:
1. To maintain a log of all ADR notification forms received and forwarded
2. To receive blank ADR forms and acknowledge receipt
3. To fill or get filled the ADR forms
4. Collect Adverse Drug notifications from Regional as well as own centres
5. Receive Adverse Drug Reactions (ADR) forms and maintain log of all ADR forms received and forwarded.
6. Correspond with Regional and Peripheral Centres, provide them with general technical support, coordinate and monitor their functioning.
7. Identify and delegate a Ayurvedic pharmacologist for management of pharmacovigilance tasks.
8. Identify and delegate a data manager for the data management under National Pharmacovigilance Programme
9. Carry out (and/or review) data causality analysis of all ADRs
10. To forward all duly-filled ADR forms [those generated at the same centre and those received from immediate lower-level centre] as per pre-determined time line
11. Forward periodic reports to the higher authority as per Sl. No. 9
12. Liaise with health care professionals in order to inculcate / foster the culture of ADR reporting / notification by acknowledging the cooperation by the notifier and share with the notifier relevant feedback from higher centre.
13. Organize and attend training programmes / interactive meetings for all regional and peripheral centres falling under the NPRC
14. To provide updates, reports and such other information as may be required by the National Pharmacovigilance Technical Advisory Committee and to attend their meetings
15. To conduct special pharmacovigilance projects on various drugs which may be of special concern or interest to NPRC / Dept. of AYUSH, Government of India
16. To maintain account of the funds provided under this program as per the institution’s systems; To review
the account statement received from regional centres, and prepare a consolidated statement and provide the same to Dept. of AYUSH, Ministry of H&FW, Govt. of India.

17. Carry out audits to ensure compliance with the program, enlist non-compliance, establish corrective measures and implement them at National centre and oversee their implications at regional centres.

In line with the size & patient intake of the institutions where it is based, the National centre shall ensure a minimum of 50 adverse event reporting every month and this number must be increased periodically. This number will be in addition to the number of reports generated by the regional and peripheral centres.

d Schedule of Performance of Tasks

The duration of the assignment is 3 years (with a review at the end of every year). The time schedule for performance of various tasks is detailed below:

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<td>Correspond with Regional Centres, provide them with general technical support, coordinate and monitor their functioning.</td>
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8. Identify and delegate a data manager for the data management under National Pharmacovigilance Programme

9. Carry out (and/or review) data causality analysis of all ADRs

10. To forward all duly-filled ADR forms [those generated at the same centre and those received from immediate lower-level centre] as per pre-determined time line

11. Forward periodic reports to the higher authority

12. Liaise with health care professionals in order to inculcate / foster the culture of ADR reporting / notification by acknowledging the cooperation by the notifier and share with the notifier relevant feedback from higher centre.

13. Organize and attend training programmes / interactive meetings for all regional and peripheral centres 6 months in addition to induction of training

14. To provide updates, reports and such other information as may be required by the National Pharmacovigilance Technical Advisory Committee and to attend their meetings

15. To conduct special pharmacovigilance projects on various drugs which may be of special concern or interest to NPRC / Dept of AYUSH, Government of India

16. To maintain account of the funds provided under this program as per the institution's systems; To review the account statement received from regional centres, and provide a consolidated statement to the national centre.

17. Carry out audits to ensure compliance with the program, enlist non-compliance, establish corrective measures and implement them at National centre and oversee their implications at regional centres
e  Data Services and Facilities to be provided by NPRC

NPRC shall coordinate the programme and arrange for training for those professionals who are participating in the programme.

f  Final Output that will be required

i) Structured pharmacovigilance data based on the ADR forms collected under the program participants.

ii) A structured annual report describing smooth and efficient operation of the program, in accordance with the Protocol.

g  Financial support under the Project

The following financial support shall be provided by NPRC:

1. One post of Ayurvedic Pharmacologist: Minimum qualification: MD AYU (Dravyaguna, Rasashastra, Bhaishajya Kalpana) M. Pharm (Ayurveda), B. Phar. (Ayu) Maximum remuneration of Rs. 15,000.00 PM (fixed-proposed)

   Computer Operator / Data Managing Assistant: With suitable qualification and/or experience. Maximum remuneration of Rs. 8,000.00 (fixed-proposed) PM

   All staff members shall be identified and retained by the national centre on contract on year to year basis

2. Expenditure on office operation for National centre: Rs. 40,000.00 (Rs. Forty Thousands Only) p.a. is proposed.

3. ADR Reporting forms, various books and periodicals, MIS reporting forms shall be provided by the NPRC
MIS Formats for Reporting by Regional Centres to NPRC

1. Period of Report
2. Number of notifications received in the preceding period
3. Number of Reports ADR and number of serious or suspected serious ADR reports, if any
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9. Total no. of ADR forms received from Regional Centre in which causality assessments has been ADR
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11. Number of forms archived
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13. No. of notifications / reports received from each centre
14. No. of reports filled in inappropriately by respective Regional Centres
15. Actions taken / recommended
16. Acknowledgements sent in time
17. CME awareness activities if any
18. Any other observations
Annexures
Eligibility criteria for identifying a PPC

i. Ideally ASU medical colleges with interested and initiated teaching staff.

ii. Can provide a small area (approx. 100 sq. feet)

iii. Can deploy a interested clinical / Dravyaguna / Rasa shastra teaching staff for the Programme

iv. Ideally, centres that have internet facility

v. Manned by doctors / pharmacists who are enthusiastic about carrying out research activities e.g. monitoring ADRs

vi. Visited by preferably not less than a total of 50 patients daily in the clinical departments such as Kayachikitsa, Stree Roga & Prasuti tantra, Kaumarabhritya, Shalya, Shalakya, Panchakarma, Manasa Roga and Other specialised OPD if any.
Annexure 2

Duties of Coordinators:

* Supervising / monitoring Pharmacovigilance Centre
* Coordinators should typically look for the following performance parameters:

a. No. of reports per month
b. Non compliance with protocol
c. Violation of protocol
d. Submission of fraudulent data and or other information
e. Publication of data with mention of NPP, without appropriate authorisation from NPAC
f. Any other professional/administrative misconduct concerning the NPP - ASU
# National Pharmacovigilance Programme for ASU Drugs

National Pharmacovigilance Resource Centre for ASU (NTRC - ASU): IPGT&RA, Jamnagar

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Region / Centre</th>
<th>Name of the state</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>North Region</td>
<td>Delhi, Punjab, Himachal Pradesh, Jammu &amp; Kashmir, Uttar Pradesh, Uttarakhand, Haryana</td>
</tr>
<tr>
<td>2</td>
<td>South Region</td>
<td>Kerala, Karnataka, Tamilnadu, Andhra Pradesh</td>
</tr>
<tr>
<td>3</td>
<td>East Region</td>
<td>Assam, West Bengal, Orissa, All north east states</td>
</tr>
<tr>
<td>4</td>
<td>West Region</td>
<td>Maharashtra, Gujarat, Goa, Rajasthan</td>
</tr>
<tr>
<td>5</td>
<td>Central Region</td>
<td>Madhya Pradesh, Chattishgarh, Bihar, Jharkhand</td>
</tr>
</tbody>
</table>
## Regional Pharmacovigilance Centres for ASU Drugs

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Region/organization</th>
<th>Name &amp; address of the Institution</th>
<th>Coordinator's name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>North</td>
<td>Faculty of Ayurveda Institute of Medical Sciences, Banaras Hindu University, Varanasi, UP</td>
<td>Dr Anand Choudhury Reader, Dept. of RS&amp;BK,</td>
</tr>
<tr>
<td>2</td>
<td>South</td>
<td>Govt. Ayurved College, MG Road, Thiruvanathapuram, Kerala</td>
<td>Dr Gopa Kumar, Lecturer, Roganidana</td>
</tr>
<tr>
<td>3</td>
<td>East</td>
<td>Government Ayurved College Jalukbari, Guwahati, Assam</td>
<td>Dr Anup Vaishya Asst. Prof.</td>
</tr>
<tr>
<td>4</td>
<td>West</td>
<td>National Institute of Ayurveda, Madhav Vilas Palace, Amer Road, Jaipur, Rajasthan</td>
<td>Prof Ajay Kr. Sharma Kaya Chikitsa</td>
</tr>
<tr>
<td>5</td>
<td>Central</td>
<td>Pt. Khushilal Sharma Govt. Ayurved Maha Sansthan, Bharat Scouts &amp; Guide Bhawan, Shyamala Hills Road Bhopal, MP</td>
<td>Dr Rajakishore Pati Sr Lecturer, RS&amp;BK</td>
</tr>
<tr>
<td>6</td>
<td>CCRAS</td>
<td>Head Quarters, CCRAS No.61-65, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi</td>
<td>Dr N Srikanth, Asst. Director (Ayu)</td>
</tr>
<tr>
<td>7</td>
<td>Unani</td>
<td>National Institute of Unani Medicine, Kottige Palya, Magadi Main Road, Bangalore - Karnataka</td>
<td>Dr Tanzeel Ahmed Lecturer Dept. of Moalejat</td>
</tr>
<tr>
<td>8</td>
<td>Siddha</td>
<td>National Institute of Siddha, Tambaram Sanatorium, Chennai - Tamilnadu</td>
<td>Dr P. Selva Shanmugum</td>
</tr>
</tbody>
</table>
### Peripheral Pharmacovigilance Centres for ASU Drugs

<table>
<thead>
<tr>
<th>PPC-ASU</th>
<th>Name &amp; Address of the College</th>
<th>Coordinator's name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>North Region:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Delhi</td>
<td>Ayurved &amp; Unani Tibbia, College, Ajmal Khan Road, Reader, Karol Bagh, New Delhi</td>
<td>Dr Mohammad Idris,</td>
</tr>
<tr>
<td>2. Punjab</td>
<td>Dayanand Ayurved College Mahatma Hans Raj Marg Jalandhar City Punjab</td>
<td></td>
</tr>
<tr>
<td>3. Himachal Pradesh</td>
<td>Rajiv Gandhi Rajkiya Government Ayurvedic Post-Graduate College, Paprola Distt. Kangra, HP</td>
<td>Dr Navneet Sharma</td>
</tr>
<tr>
<td>4. Jammu &amp; Kashmir</td>
<td>Jammu Institute of Ayurved &amp; Research Muthi, Nardhani Raipur Ban Talab Road Jammu Tawi, J &amp; K</td>
<td>Dr Debasis Panda Lecturer, Dravyaguna</td>
</tr>
<tr>
<td>5. Uttar Pradesh</td>
<td>Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi, UP State Ayurveda College Lucknow, UP</td>
<td>Dr A K Tripathy Reader, Kayachikitsa Dr P K Mishra, Lecturer, Dravyaguna</td>
</tr>
<tr>
<td>6. Uttarakhand</td>
<td>Govt. Gurukul Ayurved College, Gurukul Kangari Haridwar</td>
<td></td>
</tr>
<tr>
<td>7. Haryana</td>
<td>Gaur Brahmin Ayurved College &amp; Hospital, Village Branmanawas Distt. Rohtak Haryana</td>
<td>Dr Sumer Singh</td>
</tr>
</tbody>
</table>
### South Region

1. Kerala  
Govt. Ayurved College, MG Road, Thiruvananthapuram  
Dr. Gopa Kumar  
Lecturer  
Roga nidana

2. Karnataka  
Karnataka Liberal Education Society Shri Karnataka B.M. Kankanwadi Ayurved Mahavidyalaya, Shahapur Belgaum, Karnataka  
SDM College of Ayurveda  
Dr. Girish

3. Tamilnadu  
Jayendra Saraswati Ayurveda College, Chennai

4. Andhra Pradesh  
Dr. NR Sastry Govt. Ayurved College, Besides VK Super Bazar, Bandar Road, Vijayawada, AP  
Dr. P.H.C. Murthy  
Lecturer, RS&BK

### East Region

1. Assam  
Government Ayurved College, Jalukbari, Guwahati, Assam  
Dr. Anup Vaishya  
Asst Prof.

2. West Bengal  
JB Roy State Ayurved College, 170/72 Raja Dinendra Street Calcutta, WB  
Dr. Prasanta Sarkar  
Lecturer,

3. Orissa  
Gopabandhu Ayurveda, Mahavidyalaya, Puri, Orissa  
Dr. Arun Kumar Das  
Reader, RS&BK

### All 7 North East States
West Region

1. Maharashtra
   Tilak Ayurved Mahavidyalaya
   583/2, Rasta Peth,
   Pune
   Prof. Tanuja Nesri
   Dravyaguna

2. Gujarat
   Govt. Akhandanand Ayurved Mahavidyalaya
   Opp. Victoria Garden Bhadra
   Ahmedabad
   Gujarat
   Prof Haridra Dave
   Shalya

3. Goa
   Bharteeya Sanskrit Prabodhini Gomantak Ayurved Mahavidyalaya & Research Centre, Vajem,
   Shiroda
   Distt. South Goa, Goa
   Dr. Sangram K. Das,
   Sr Lecturer
   Dravyaguna

4. Rajasthan
   National Institute of Ayurveda,
   Madhav Vilas Palace,
   Amer Road
   Jaipur,
   Rajasthan
   Dr P Suresh
   Asso. Prof.
   RS&BK

Central Region

1. Madhya Pradesh
   Pt. Khushilal Sharma Govt. Ayurved Maha Sansthan,
   Bharat scouts & Guide Bhawan
   Shyamala Hills Road
   Bhopal, MP
   Dr R K Pati
   Sr Lect. RS&BK

2. Chattishgarh
   Govt. Ayurved College
   Raipur
   Dr R P Gupta
   Reader D.G.

3. Bihar
   Government Ayurved College Post-Graduate Training & Research Institute, Kadam Kuan
   Patna,
   Bihar
   DR R. A. Singh
   Dravyaguna
4. Jharkhand

Surya Mukhi Dinesh
Ayurved Medical College & Hospital, Dinesh Nagram Booty, Ranchi Jharkhand

CCRAS
Head Quarters, CCRAS No.61-65, Institutional Area, Opp. "D" Block, Janakpuri, New Delhi

Unani
1. National Institute of Unani Medicine, Kottige Palya, Magadi Main Road, Bangalore, Karnataka Dr. Tanzeel Ahmed

2. Faculty of Medicine (Unani) Jamia Hamdard, Hamdard Nagar, New Delhi 62 Dr. Akhtar Siddiqui

3. Govt. Nizamia Tibiya College Charminar, Haidrabad Dr. Mir Yousuf Ali

Siddha
National Institute of Siddha, Tambaram Sanatorium, Chennai Dr. Selva Shanmugum
List of experts participated in the
First National Consultative Meet,
National Pharmacovigilance Programme
for ASU Drugs,
29th & 30th August 2008,
At Dept. of AYUSH,
Ministry of Health & FW, New Delhi

1 Dr. S. K. Sharma
Advisor - Ayurveda, Department of AYUSH
Ministry of H. & F.W., Govt. of India, New Delhi

2 Dr. Manoj Nesri,
Deputy Advisor (Ayu) Department of AYUSH,
Ministry of H. & F.W., Govt of India, New Delhi

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Rajasthan- 302 002
<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Address</th>
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<tbody>
<tr>
<td>8</td>
<td>Prof. M. S. Baghel</td>
<td>Director IPGT&amp;RA, Jamnagar, Gujarat</td>
</tr>
<tr>
<td>9</td>
<td>Dr. G. S. Lavekar</td>
<td>Director, CCRAS, No. 61-65, Institutional Area, Opp. ‘D’ Block, Janakpuri, New Delhi</td>
</tr>
<tr>
<td>10</td>
<td>Prof. M. A. Jafri</td>
<td>Director, National Institute of Unani Medicine, Kottige Palya, Magadi Main Road, Bangalore - 560 091</td>
</tr>
<tr>
<td>11</td>
<td>Prof. V. K. Joshi</td>
<td>Dean, Faculty of Ayurveda, IMS, BHU, Varanasi, UP, 221 005</td>
</tr>
<tr>
<td>12</td>
<td>Dr. Renuka Munshi</td>
<td>Dept. Of Clinical Pharmacology, TNC &amp; BYL, Nair Ch. Hospital Mumbai, 400 008</td>
</tr>
<tr>
<td>13</td>
<td>Prof. H. M. Chandola</td>
<td>Dept. Of Kayachikitsa &amp; Chairman, Pharmacovigilance Cell IPGT&amp;RA, GAU, Jamnagar, 361 008</td>
</tr>
<tr>
<td>14</td>
<td>Dr. Vasudevan Nampoothri</td>
<td>Principal, Govt. Ayurveda College Trivendrum</td>
</tr>
<tr>
<td>15</td>
<td>Dr. A. K. Choudhury</td>
<td>Reader, Dept. of RS &amp; BK, Faculty of Ayurveda, IMS, BHU, Varanasi, UP, 221 005</td>
</tr>
<tr>
<td>16</td>
<td>Dr. G.C. Gaur</td>
<td>Technical Officer (Ay.), Drug Control Cell, Department of AYUSH, New Delhi</td>
</tr>
</tbody>
</table>
17 Dr. Ravishankar,
Head, Pharmacology Cell,
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18 Dr. R. N. Acharya,
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Commission for Scientific &
Technical Terminology, (CSTT)
Ministry of HRD, New Delhi

22 Dr N Shrikanth,
Asst. Director (Ayu),
CCRAS, New Delhi

23 Prof. Abhimanyu Kumar
Dept. of Kaumarabhrtya
National Institute of Ayurveda, Jaipur

24 Ms. Nupur Bahl,
WHO India Office, New Delhi
Reporting Form for Suspected Adverse Reactions to ASU Drugs

Please note: i. All consumers / patients and reporters information will remain confidential.
ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

<table>
<thead>
<tr>
<th>Name</th>
<th>Ethnicity</th>
<th>IPD / OPD</th>
<th>Patient Record Number (PRN)</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Address

<table>
<thead>
<tr>
<th>Village / Town</th>
<th>Post / Via</th>
<th>District / State</th>
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<tbody>
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</table>

2. Description of the suspected Adverse Reactions (please complete boxes below)

<table>
<thead>
<tr>
<th>Date and time of initial observation</th>
<th>Description of reaction</th>
</tr>
</thead>
<tbody>
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</table>

3. List of all ASU drugs including drugs of other systems used by the patient during the reporting period:

<table>
<thead>
<tr>
<th>Medicine Name</th>
<th>Manufacturer Name</th>
<th>Batch no.</th>
<th>Daily dose</th>
<th>Form Route of administration</th>
<th>Date Starting</th>
<th>Date Stopped</th>
<th>Reason for use</th>
</tr>
</thead>
<tbody>
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</table>

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4. Brief details of the suspected ASU Medicine:
   a. Composition of the formulation / Part and form of the raw material used
   b. Expiry date if any:
   c. Remaining part of drug / Product label
   d. Please tick (any one)
      Ayurveda, Siddha, Unani, any other
   e. Adjuvant
   f. Dietary Restrictions if any
   g. Whether the drug is consumed under medical supervision or used as self medication.
   h. Any other relevant information.

5. Treatment provided for suspected adverse reaction

6. Outcome of the suspected adverse reaction
   (please complete the boxes below)

<table>
<thead>
<tr>
<th>Recovered: Not recovered</th>
<th>Unknown:</th>
<th>Fatal:</th>
<th>If Fatal</th>
<th>Date of death:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe: Yes/ No.</td>
<td>Reaction abated after drug stopped or dose reduced:</td>
<td>Reaction reappeared after re introduction</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Was the patient admitted to hospital? If yes, give name and address of hospital

7. Any laboratory investigations done which provides suspicion of drug involvement:

8. Whether the patient is suffering with any chronic disorders?
   Hepatic    Renal    Cardiac
   Diabetes   Malnutrition   Any Others

9. H/O previous allergies / Drug reactions:
10. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)

Name: 

Address: 

Telephone / Email if any: 

Signature of the reporter: Date: 

Please send the completed form to: The centre from where the form is received or

To
The Coordinator, National Pharmacovigilance Resource Centre For ASU Drugs
(O) 0288 2552699 Fax : 0288 2676856
Website : www.ayurveduniversity.com, Email: nprcasu@gmail.com

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Who Can Report?

⇒ Any Health care professionals like ASU Doctors / Dentists / Nurse / Pharmacists etc.

What to Report?

⇒ All suspected adverse reactions, Lack of effects, Resistance, Drug interactions, Dependence and Abuse

Confidentiality

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent. Programme staff will not disclose the reporter's identity in response to a request from the public.

⇒ Submission of report doesn't constitute an admission that, medical personnel or manufacturers or the product caused or contributed to the reaction.
For further information please contact:

Coordinator
National Pharmacovigilance Resource Centre for ASU Drugs (NPRC - ASU)
Aswini Bhawan, IPGT & RA, Gujarat Ayurved University,
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Ph/Fax : 0288-2553936