

# IASTAM

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## Connecting Systems; Bridging Disciplines

• Ayurved • Yoga • Unani • Siddha • Asian Medicine •

"The idea of connecting all people to knowledge and each other is enduring."

- Bran Ferren

## Communiqué

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## PRE NOTE

## Blindchase of modern scientific tools for research on Ayurveda may not yield desired dividends

*Dr. C. K. Katiyar - President - IASTAM*

Ayurveda and its products have been facing dichotomy of thoughts on need for research and its proper tools. Few stakeholders say that since Ayurveda is based upon 'Aptopadesh' it does not need any further research but at the same time others opine that while it is true that Ayurveda is based upon 'Aptopadesh' but how can we close eyes on the fact that lot of water has flown down the river and air, water and earth have changed their qualities drastically during last centuries then what is the gurantee that plants/ trees grown today are same as centuries ago? Therefore, Ayurvedic products need to undergo 'Re-search' through 'validation' studies using current scientific tools.

Ayurvedic products, therefore, have been subjected to some or other kind of modern scientific investigations right from the times of Sir Colonel R N Chopra and even before that.

These scientific validation studies have mostly

been conducted using tools of Chemistry and Biology including Pharmacology, Pharmacognosy, Toxicology and clinical trials using bio markers.

While sometimes these efforts actually helped in enriching Ayurveda but most of the time it helped enriching the other sciences using Ayurvedic medicinal plants as a source of new chemical entities, as an example of the same.

A review of Marker Compounds recommended for standardisation of single plant drugs as per the Ayurvedic Pharmacopeia of India/ Indian Pharmacopoeia appears to be application of Chemistry with good intention but when we started applying them in actual practices for standardisation of Ayurvedic products we found that more than half of these Marker Compounds are not appropriate. The reason is that most of these compounds were isolated to identify non-reported, new chemical compounds which can help in publication either for a thesis or a

research paper published in scientific journals and therefore, starting solvent was either Methanol or Hexane. These pure phytochemical compounds were, therefore, not water soluble since they were isolated with intention to standardize Ayurvedic single or compound plant drugs.

Most of the Ayurvedic product manufacturing processes use water as solvent, therefore, compounds used for assays for their standardization should meet solubility in water as first criteria. However more than 50% marker compounds fail on this first criteria itself. For example, lot of work has been done on standardisation of Guggulu with E & Z Guggulsterone as Marker Compounds but when we test most commonly used Ayurvedic Guggulu product like MahayogarajGuggulu, these Marker Compounds are simply not detectable. Similarly, Ayurvedic products with Turmeric as ingredient may fail to show Curcumin during chemical assays.

These are few instances where 'borrowed chemistry' has been found not to be appropriate and conducive to the needs of system of Ayurveda.

It would be good if the Ministry of AYUSH have its own 'Institute of Chemistry and Biology' having experts from main stream Chemistry and Biology but work should be done using basic Ayurvedic process and connotations. For example all the Ayurvedic medicinal plants should be subjected to isolation of Marker Compounds from water extract and they should be soluble in water as first eligibility criteria.

Also, besides search of unique secondary metabolite as Marker Compound, we should not forget the role of primary metabolites. Therefore, language of standardisation should include the ratio of primary and secondary metabolites along with the TLC fingerprint.

Similarly, when it comes to Biology we find a trend of using Bio Assay as quick method of efficacy evaluation. This is a very good example of adoption of modern scientific tools.

However, if we look at the specific needs of Ayurvedic medicines merely blindly following the current methods may not serve the purpose. For example the relevance of direct exposure of herbal extracts to a cell or an enzyme should be debated and experiments should be conducted ex-vivo in addition to in-vitro.

Also we need to ask question on the relevant IC 50 value for Ayurvedic herbal extracts. In case of

synthetic compounds the activity is treated to be potent if the IC 50 value is less than 1 to 2 mcg/mL. But there is no consensus on what should be the dose for herbal extracts which are currently ranging from 20 micrograms to 500 microgram/mL.

To cite another example of in-vivo Pharmacology whenever, a Pharmacologist is testing anti-inflammatory activity of a product on the model of acute inflammation using Carrageenan they mostly test after 30 minutes of giving active drug since that is the protocol for Allopathic drug like Phenylbutazone. But chances are if the same protocol is followed for Ayurvedic products relevant activity may not be detected and product may be labelled as ineffective. While working with Prof Y K Gupta at All India Institute of Medical Sciences, New Delhi, we tried to suitably modify the protocol and started giving herbal drugs 24 hours before the experiments instead of half an hour, and the same product which was showing no-efficacy in 30 minutes, started showing good anti-inflammatory activity.

Multiple similar instances may be cited.

Safety/ efficacy evaluation or Validation of AYUSH products using modern scientific tools is almost mandatory these days. However, AYUSH fraternity needs to discuss with their counterpart the need of suitable modification of the current methods instead of following them blindly and which should enrich Ayurvedic knowledge and wisdom in more positive manner.

Good number of interdisciplinary workshops would be required where AYUSH experts need to share their methods and products and counterparts from hard core science stream to share the currently available scientific tools. They should jointly discuss the modifications required in those tools and publish the same for use of stakeholders of traditional medicines worldwide.

WHO has now set up its global research center on Traditional Medicines in India. It would be good if this issue is discussed on this platform not only to have global inputs but also to ensure global execution for enrichment of knowledge of traditional medicines.

IASTAM may also consider creating a platform for exchange of thoughts on this and other important issues of academic interest in future.

## Pharmacovigilance for ASU drugs- Challenges & Solutions

*Prof. Dr. Manasi Deshpande*

*Professor and HOD, Dravyaguna Vigyan*

Coordinator- Peripheral Pharmacovigilance centre  
Bharati Vidyapeeth, Deemed to be University,  
College of Ayurved, Pune

### Introduction

Pharmacovigilance is defined as the activities relating to detection, evaluation, understanding and prevention of adverse drug reactions or other drug related problems. WHO established its programme for International Drug monitoring in response to thalidomide disaster detection in 1961. The major goal of Pharmacovigilance is namely to improve patient care and safety in relation to drug use, and thus promote rational use of drugs.

### Pharmacovigilance in Ayurved

Although the technical term Pharmacovigilance does not feature in Ayurvedic texts. However, Brihatryee-(Charaka Samhita, Susruta samitha and Ashtanga Samgraha), describes all the adverse reactions to medicines when they are prepared or used inappropriately. Attention is given to factors like the physical appearance of the part of the plant to be used (prakriti), its properties (guna), actions(karma; prabhava), habitat (desha), season in which it grows(ritu), harvesting conditions (grahitam), method of storage(nihitam) and pharmaceutical processing (upaskritam) while selecting the raw material to finish products.

Many classical Ayurvedic formulations contain metals and minerals as or in combination with plants as herbo-mineral formulations. Manufacturing procedures for these medicines are stringent, and adverse reactions are described when precautions are not taken while manufacturing and administering these medicines.

There is several factors to be considered while treating the patients and selecting the medicine such as the constitution of the patient ( prakriti ), age ( vayam ), disease ( vikruti ), tolerance (previous exposure) ( satmya ), psychological state ( satwa ), digestive capacity ( ahara-shakti ), capacity for exercise ( vyayamashakti ), quality of tissues ( Sara ), physical proportions of the body ( sahanan ) and strength ( bala).

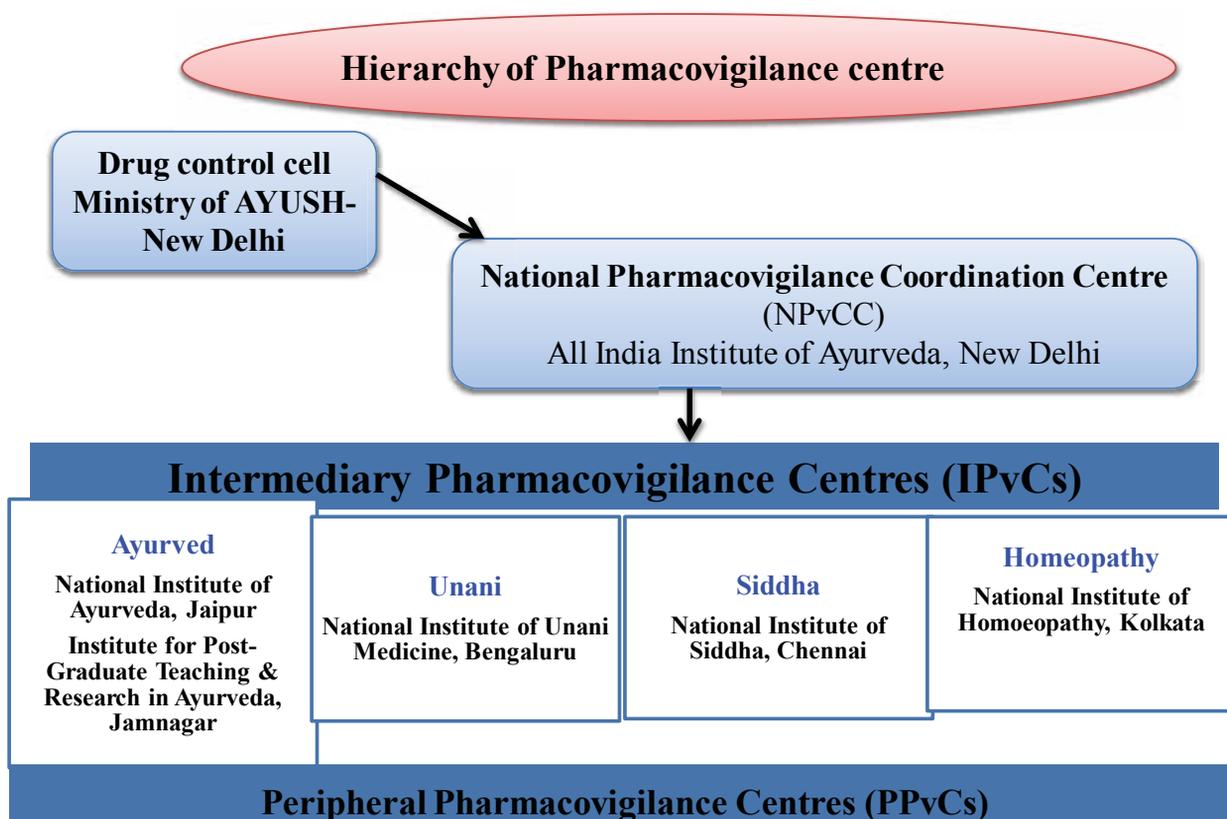
### Pharmacovigilance for Traditional Medicine

The Pharmacovigilance in India evolved with the contribution of many scientists, physicians, and administrators. Pharmacovigilance activities in India were started much before the initiation of National Pharmacovigilance Program of India (PvPI).

### Time line for initiative of Pharmacovigilance for AYUSH drugs

Year	Events
2004	WHO emphasizes that modern Pharmacovigilance should include the traditional medicines in the Pharmacovigilance system and published 'Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems'
2005	Centre for Safety & Rational Use of Indian Systems of Medicine
2006	National Symposium on Relevance of Herbal Pharmacovigilance at the Department of Pharmacology, Jawaharlal Nehru Medical College (JNMC), AMU, Aligarh, under the aegis of Society of Pharmacovigilance, India (SoPI) and CSRUISM of IbnSina Academy, Aligarh
2007	Workshop "Safety Profile of Ayurvedic Dosage Forms at BHU's Institute of Medical Sciences' Department of Rasa Shastra

2007	National Workshop on Herbal Pharmacovigilance- two-day workshop on ‘Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations, and Method of Implementation’ was organized by the Institute of Post Graduate Teaching & Research in Ayurveda (IPGT & RA), Jamnagar
2007	Establishment of Pharmacovigilance Cell (PV Cell), the first of its kind in India for Ayurveda, at IPGT & RA, Jamnagar
2008	National Consultative Meeting for adoption and implementation of National Pharmacovigilance Program for ASU Drugs
2008	National Pharmacovigilance Program for ASU Drugs
2008	One-week ROTP for teachers of Ayurveda -IPGT&RA, Jamnagar
2017	NCC-PvPI and Ministry of AYUSH, Government of India -NCC-PvPI from IPC (Ghaziabad) invited AYUSH industry partners, academicians, regulators as participants in a symposium on Pharmacovigilance for Herbal Medicine
2018	Ministry of AYUSH signed MoU with NCC-IPC- Pharmacovigilance program has been restructured by the Ministry of Ayush under the Central Sector Scheme including Homoeopathy component (i.e. ASU&H drugs) in support and guidance of the Indian Pharmacopoeia Commission (IPC) and concerned program officers of the WHO Country Office, India



## Challenges

- There is a misconception that they are devoid of adverse reactions. But in reality, side effects are not completely absent but they are comparatively less.
- Information related to adverse effects is scattered in Ayurvedic literature
- Non-availability of compendium of ADR's for Ayurvedic medicines
- Ayurvedic formulations are multi-ingredient-fixed dose formulations rarely prescribed. Too many products and multiple ingredient formulations are difficult to monitor
- More over the medicines are not a single molecule or compound, but as a whole from a plant or animal origin
- Lack of quality control to produce standard medicine
- Do not have the actual ingredients as are described in Ayurvedic literature
- Self-medication and home remedies
- Co-administration of Allopathy drugs and other drugs along with Ayurveda drugs
- Lack of knowledge about the concept and importance of pharmacovigilance among Ayurvedic practitioner leads to the improper analysis and

report of adverse effects.

- Application of causality assessment scales for Ayurvedic medicines
- Patients are not adequately aware that Ayurvedic medicines can cause adverse reactions and can take medicines for years on end with no monitoring as they believe that these medicines can do no harm.

## Solutions

- Communication between the academicians, researchers, industry, clinicians, and policy makers
- Encourage studies on drug safety
- Mandatory of reporting of adverse reactions
- Awareness programmes
- Prefer to place less number of medicines and avoid a number of drugs in one prescription.
- Long-term use of herbo-mineral medicines with monitoring hematological and biochemical investigation at regular intervals
- Mixing of multi-ingredient poly herbo-mineral combinations in one prescription should be avoided.
- Physicians must keep on updating information on the ingredients of poly herbo-mineral combinations being used by them.

## Basic information to be known for reporting an ADR

### 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.

### Some common terms used in Pharmacovigilance for ASU Drugs

**Adverse Drug reaction (ADRs) :** 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 modification of physiological function

**Adverse Event/Experience (AE):** Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with the treatment.

**Side Effect (SE):** Any unintended effect of a Pharmaceutical product occurring at doses normally used in man which is related to the pharmacological properties of the drug.

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The Pharmacovigilance for ASU drugs in India has become an important public health issue as regulators, drug manufacturers, consumers, and healthcare professionals are faced with a number of challenges.

There is a need to improve the systems to more effectively monitor and take action on safety issues associated with ASU drugs & formulations to enhance their contribution to public health.

This is a collective responsibility of industry, drug regulators, clinicians and other healthcare professionals.

## Institutional News

Ayurveda- Arthritis Treatment and Advanced Research Center has celebrated its 1st Foundation day On the occasion of world arthritis day 12 Oct 2022, the first ever Ayurveda –Arthritis Treatment and Advanced Research Center (A-ATARC) in Uttar Pradesh has celebrated its 1st foundation day. This center is situated at State Ayurvedic College and Hospital, Lucknow and is functioning since last one year. This is one and only super-specialty center in the state related to Ayurveda and arthritis. The foundation day function was presided by Prof Able Lawrence, Department of Clinical Immunology and Rheumatology, SGPGI, Lucknow and was chaired by Prof PC Saxena, Principal, State Ayurvedic College and Hospital, Lucknow. All faculty members, Medical officers, research scholars and interns were present during the occasion. Speaking as Chief Guest Prof Lawrence emphasized that during the translation, huge amount of knowledge may be lost. So if a real interface between Ayurveda and modern medicine is to be developed, there should be a common language for sharing of information. He also highlighted the importance of quality over quantity when research or patient care is concerned. Subsequently, Prof PC Saxena in his speech expressed his concern to provide optimal quality care to rheumatology patients. Prof Sanjeev Rastogi, Founder-Director of

A-ATARC highlighted the achievements of past one year availed by the center. He presented the statistical data related to patient's inputs, procedures done, research publications, innovative activities and future plans. The center has treated over 1600 new patients in past one year and is now functioning as a dependable referral center for Ayurvedic care in arthritis, he added. The function was also marked by the felicitation of outgoing research scholars of the center for their excellent contribution towards the growth and delivery of Ayurvedic Rheumatology. Dr Preeti Pandey received this certificate of excellence in Ayurvedic Rheumatology on the occasion. The center has also felicitated senior citizens OP Sharma and Asha Rani Nigam who have been the beneficiary of the Center and who subsequently have contributed immensely to float the idea of building a self-help group for extending the benefits of Ayurveda to the people suffering with arthritis. Dr Preeti Pandey, Senior Resident at A-ATARC finally gave the vote of thanks. The occasion was also marked with organization of a free arthritis care camp where over 250 patients were given free consultation and medicines. This was our attempt to connect to the people and let them understand how Ayurveda can be helpful in joint diseases, added Dr Rastogi stating that the country is also observing currently a month dedicated to the theme of connecting Ayurveda with the people.

- By Dr. Sanjiv Rastogi



Congratulations to  
**Vaidya Balendu Prakash** for  
**Dhanvantari Award 2022** conferred by  
Indianvaidyas and hempvaidyas



**Dr. P K Prajapati** appointed as  
Vice Chancellor of **Dr. Sarvepalli  
Radhakrishnan Rajasthan Ayurved  
University, Jodhpur.**  
IASTAM congratulates Dr. Prajapati



Prof. Subash Ranade was conferred  
Ayurveda Brahamarshi Award by Kavi  
Kulguru Kalidas Sanskrit University  
and Dhanvantari Jayanti Mahotsav  
Samiti, Nagpur. Dr. Sunanda Ranade  
was felicitated with Best Nutritionist  
Award by Dr. Subash Waghe Health  
and Humanitarian foundation and  
Dhanvantari Jayanti Mahotsav Samiti,  
Nagpur.  
The award function was held on  
Dhanvantari Jayanti 2022 at Nagpur.



## XIIIth IASTAM ORATION AND AWARDS 2023 NOMINATIONS INVITED

Since 1990 IASTAM has instituted and nurtured the unique tradition of IASTAM Orations and Awards.

With systematic and stringent selection procedure evolved over several years

IASTAM Awards are vastly respected and coveted by experts from various fields.

Suggestions from Members of the Managing Committee, Members of the National Advisory Council and Previous Awardees has helped us increase the quality and reach of these awards.

IASTAM Members are requested to nominate the best of experts for different categories of National Awards.

**Last Date of Nomination - on or before 10<sup>th</sup> November 2022**

For Details - List of Previous Awardees, Award Categories, Criteria and Procedure, Nomination and Selection,

please visit IASTAM website - [www.iastamindia.org](http://www.iastamindia.org)

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To,