INDIAN ASSOCIATION FOR THE STUDY OF TRADITIONAL ASIAN MEDICINE पारंपारिक आशियाई स्वास्थ्य परिषद् - भारत



NEWSLETTER

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Connecting Systems; Bridging Disciplines Avurved Unani o Siddha Asian Medicine Yoga

> "We are like islands in the sea, separate on the surface but connected in the deep.".

> > - William James

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P_{RE NOTE}

AYUSH PRODUCTS - NEED OF A REGULATORY STRATEGY

Dr. Narendra Bhatt

The AYUSH industry is besieged with one or the other regulatory issue. The most recent issue is related to 'Drugs and Magic Remedies Act'. An industry veteran Dr. Kativar has shared his observations in this issue.

These issues have hampered not only the true growth of the industry but also the profession and people - the consumer for whom the laws are meant to be created. A careful study of happenings over the last 25 years informs us of a basic flow. We have failed to investigate, identify, define and address the basic needs of the sector, that has now been termed as AYUSH. Time and again we try to either adapt or react to a situation. Even during my early days in the mid-80s, when there was only the department of ISM, there was confusion about product categories and how to handle newer technical happenings. Even after 40 years we are still struggling faced with similar situations, or perhaps even broader and more complex situations. I wish to emphasize the words broader and more complex. Permit me to elucidate further. From 1997 – 1998 the industry faced serious challenges with different types of laws. I clearly remember the discussions. The most logical need that emerged was to address the issues of ASU products at a fundamental level - the basic regulatory approach.

This was always thwarted by the administration with the argument about their inability or rather lack of desire to take up the challenges in order to bring about changes in the basic approach. This inertia, the consequent lack of making efforts to bring in basic changes, has now not only impacted the outcomes making it more complex but has now even ingrained itself into the thought process. In fact, all these efforts have only added more confusion and created greater diversion.

Regulatory Pluralism, Good or Bad?

Medical pluralism in India is unparalleled anywhere else in the world with official recognition of several medical systems. The pros and cons of this is perhaps a subject for a different time. If pluralism is a virtue then it has established weaknesses of diversion, lack of focus and inefficiency when not implemented correctly. Unfortunately, this approach is now reflected in our regulation, particularly when dealing with AYUSH products. Let me cite an example. Ashwagandha, the proclaimed Indian ginseng, could be manufactured under IP, as a Phytopharmaceutical or as Nutraceutical or under FSSAI and of course under AYUSH license; each having its own parameters and permissions. Despite all the exercise and effort the Ashwagandha

March 2020 IASTAM NEWSLETTER sale is nowhere near that of Ginseng. Interestingly, I observe something similar happening to a classical formulation like Triphala. The question I wish to raise is our approach to regulation. What does India as a nation, AYUSH as a process and the consumer gain with this approach?

The present government under PM Modi has shown courage to take on challenges to bring in fundamental changes. AYUSH administration has also shown an eagerness to address basic issues.

The regulatory issues related to AYUSH Industry need to be addressed in a comprehensive manner. Issues involving AYUSH products include classification, manufacturing, standardization, quality control, use by profession or by the consumer, labelling, claims and global promotion which are all interrelated. These require an open debate and deliberations. These cannot be attended to, in a partial manner. We need to evolve and provide a national strategy, nay an Indian Strategy, to AYUSH products rather than partial solutions.

Historically we have been forced to duplicate or imitate an aligned paradigm. Efforts must be made to evolve a system of regulation to do justice to AYUSH systems. *Is it possible? I firmly believe that it is possible.*

What we need is a Regulatory Strategy. We need to identify and address important components to provide the right direction. We need a plan of action designed to satisfy a specific regulatory need so as to ensure development and growth of the sector while providing benefit to the consumer, the patient. The regulatory approach to be taken must be defined in addition to providing its rationale. The regulatory strategy should be good, balanced, practical and implementable to contribute to the growth of the industry and the sector. It must be reiterated that this will need systematic, open deliberations and clarity of objectives amongst all the stake holders including the industry, consumer, profession, technocrats and administrators.

I recollect how IASTAM provided such a platform more than two decades ago to address the issue of the Supreme Court judgment on cross system practice. Perhaps, we could consider such deliberations once again.

I invite suggestions from you.

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Accolades o

Prof. Dr. K. R. Mahadik is Conferred Life Time Achievement Award

by The Indian Pharmaceutical Association, Pune

A supporter and former IASTAM Awardee, Prof. Mahadik is Principal and Professor of Pharmaceutical Chemistry at Bharati Vidyapeeth University Poona College of Pharmacy, Pune. He has been working on promotion of Ayurvedic pharmaceuticals by validating the traditional knowledge through scientific methods emphasizing herbal drug developmental research.



Prof. Dr. K. R. Mahadik

Shri Chandrakant Bhanushali is re-elected as President of ADMA

(Ayurvedic Drug Manufactuers Association)

For the Year 2020-2021

during ADMA AGM on 21st February 2020.

A strong supporter of IASTAM, Shri Chandrakant Bhanushali is a self made dynamic industrialist committed to growth of the sector.



Shri Chandubhai Bhanushali

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PERSPECTIVE Observations on

Proposed Draft of the Drugs & Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020 vide letter no. F No. 11035/133/2014-DFQC/DRS from the Ministry of Health and Family Welfare

By Dr. C. K. Katiyar, Vice President, IASTAM India

The draft of the Drugs & Magic Remedies (Objectionable Advertisements) Amendment Bill, 2020 in the current form would adversely hamper the Ayurvedic Drug Industry.

This is due to the following reasons -

A. Ayurveda has proven medicines for cure of various diseases mentioned in the amended Schedule

Ayurvedic classical and proprietary medicines are formulated as per the age old and time tested recipes of our traditional systems of medicine with rich heritage. These traditional therapies are not only effective and time tested but also available at affordable cost as compared to modern medicines and accessible in the rural part of the country where most of our poor population resides. In view of this, Drugs & Cosmetics Act has provided for exemption of drug sale license for all products classified as Ayurvedic Medicines. By bringing restrictions on the communication of the relevant information to the public, we will be denying them valuable information about the products and services for treating their manageable ailments through self medication. This is bound to reverse the trend of more and more sections of our population reaping the benefits of our age-old traditional medical knowledge and practices.

It is well known fact that there are several conditions/diseases for which allopathic system of medicine lacks treatment but Ayurveda has effective medicines for cure of those conditions/diseases.

For example, as per the amended Schedule the products meant for "Liver disorders" cannot be advertised.

Ayurveda has in its ambit effective and proven medicines for treatment of liver disorders like "Liv 52". When there is a proven medicine available for treatment of a particular ailment under a particular branch of medicine then the restriction of advertisement of a product manufactured under that branch of medicine for that particular disease should not be applicable.

B. Separate guidelines required for Ayurveda Drugs

Amendment proposes to include many of the diseases/conditions mentioned in Schedule J of the Drugs & Cosmetics Rules, 1945 in DMROA Schedule.

Schedule J is currently applicable on modern medicines. It was not made applicable to Ayurvedic medicines considering the fact that Ayurveda had the proven treatment of many of the conditions/diseases mentioned in Schedule J.

For example:

S.No.11 -Change in colour of hair and growth of new hair

S.No.19- Fairness of the skin

S.No.29-Increase in brain capacity and improvement of memory

S.No.34-Jaundice/Hepatitis/Liver disorders

S.No.37-Maintenance or improvement of the capacity of the human being for sexual pleasure

S.No.43-Piles and Fistulae

S.No.44-Power of rejuvenate

S.No.45 - Premature ageing

S.No.46 -Premature greying of hair

S.No.49-Sexual impotence, premature ejaculation and spermatorrhoea

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However, by the current amendment, the conditions/diseases as mentioned in Schedule J are being made applicable to Ayurvedic Drugs and restriction is imposed on the advertisements of products meant for treatment of those conditions/diseases. This restriction is unreasonable considering the fact that Ayurveda has medicines for cure of various ailments/diseases as mentioned in the amended Schedule.

The Indigenous Ayurvedic Drug Industry are competing with multi-national companies of modern medicines and are making available effective medicines to the masses at affordable prices. The Government also wants to promote Ayurveda. But the above amendment would kill the Ayurvedic Drug Industry.

Considering the same, it is our humble request that separate guidelines/provisions be incorporated for Ayurvedic medicines which would cover only those diseases/conditions for which there is no known treatment available and for which self-medication is not advisable.

C. Label declarations to be kept outside the purview of DMROA laws

The manufacturer gives the declarations on the label to educate the consumers about the benefit of the medicine. This is visible to the consumer only when he purchases the product. This, this should not be termed as advertisement and should be kept outside the purview of DMROA.

D. Law in its present form is ambiguous - Ambiguity to be removed

The provision currently is very widely worded and covers even those advertisements which suggest or are calculated to lead to the use of that drug for diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition.

So the claim of "Keeps Liver healthy" can be interpreted by Drug Department that the advertiser is promoting that their product is meant for liver disorders. Hence, it would give rise to unnecessary litigations.

The Government should come up with specific guidelines and illustrations that what can be said in respect of these products and what cannot be said. This would avoid unnecessary litigations and also the advertisers would not be at the mercy of Drug Inspectors.

E. Advertisements of Preventive Medicines should be exempt

Indigenous system of medicine as a preventive measure has been a traditional practice among Indians. Prevention is always better than cure. A major part of Ayurvedic medicines are in the nature of preventive medicines. The preventive medicines are not prescribed by doctors. Hence, for selling the same, the manufacturer has to highlight the properties of the product in an appealing manner so that the customers are attracted to its product. The advertisement of a product like "Keeps Heart Healthy" or "Helps in maintaining healthy sugar levels" should be exempted from the ambit of DMROA.

F. Compounding option to be given to advertisers

The penalty provisions are proposed to be made more stringent by making the offence punishable with both imprisonment and fine.

Presently even in case of first compliance; the matter is filed by Drug Department before Court where the matter is finally decided. This unnecessary loads the Court with cases.

We would humbly like to submit that the advertisers have confusion that what is allowed to be stated and what is prohibited in respect of the medicines mentioned in the Schedule to DMROA Act. Hence, they might make genuine mistakes while giving declarations on their labels/advertisements.

The Act should give option to the advertiser to compound the offence at Department level by paying a requisite amount of fine. This would save harassment of the advertisers as well as valuable time of our judicial machinery. The second and subsequent offence should be punishable with imprisonment and fine.

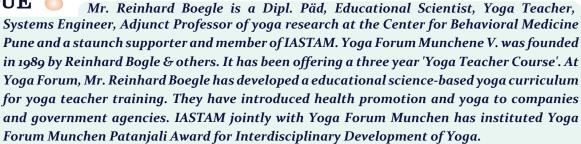
The Ministry of Health and Family Welfare to review the bill.

Further to this observations, it would be a good idea if IASTAM takes lead to provide a neutral platform to initiate the discussions among stakeholders on this issue.

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DIALOGUE



We interacted with him to find out his views and seek suggestions for IASTAM activities.

Q: How long are you associated with IASTAM?

I first heard about IASTAM from Dr. Narendra Bhatt in 1986.

Q: You have been a member of IASTAM International as well, what difference do you find in its activities?

In my opinion, both IASTAM organisations work very well. IASTAM International is mainly interested in science and research, while IASTAM India is very active in hosting meetings, advocacy and networking.

Q: Have you participated at ICTAM conferences, Mumbai? Abroad? Where? How was your experience. Please share your experiences, any memories, specific?

I participated at several IASTAM conferences: Halle, Austin, Bhutan and Kiel. Every conference had its own specific meaning and different topics it focusd on. It was always good to have the personal contact to collegues.

Q: Your views about Objectives of IASTAM. About Activities of IASTAM? How does / will it help, AYUSH, Ayurveda? Yoga? Nationally? Internationally?

The main activities of Ayurveda, Yoga etc. happen

outside IASTAM in the fields of application, medicine, dietary supplements and medicines, magazines, television etc. In most of this fields, IASTAM is unknown. The connection between, Yoga, the Ayurveda researchers and Yoga researchers unfortunately is still weak and more concentrated on language and history. In the future, it would be desirable that IASTAM and IASTAM India work towards promoting the research of Ayurveda as well as Yoga in India, but also in countries like Germany.

Q: What inspired you to give sponsorship for the award? What inspired you to give sponsorship for the award?

We had the strong feeling that there should be a Yoga award.

Q: How did you develop the trust / confidence in IASTAM? Have your expectations been fulfilled?

IASTAM is doing well, but as is usually the case with oganisations there is always more that could be done.

Q: Views about Publications of IASTAM - Chronicle, Proceedings, Newsletter?

The chronicle and proceedings are wonderful.

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5th International Health and Wellness EXPO 2020, Pragati Maidan, New Delhi

3rd Edition of India's Biggest Yoga Contest
The Grand Master of Yoga
The Little Master of Yoga

Presented by The Yogashala & Organised by NAMO GANGE TRUST

Detail information on www.namogange.org/

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REPORT | IASTAM P.J. Deshpande Memorial Fellowship Research Project

"Comparative Assessment of Clinical Efficacy of Apamarga Kshara Taila and Povidone Iodine Solution in the Management of Non-Healing Ulcers"

(Sponsored by Dr. G. V. Satyavati)

IASTAM had received sponsorship from Dr. G. V. Satyavati; our esteemed supporter and previous Prof. K. N. Udupa Awardee for Biomedical Research (1999). The IASTAM P.J. Deshpande Memorial Fellowship Research Project of Rs. 80,000/- was granted to Shalyatantra Department, J.S. Ayurved Mahavidyalaya, Nadiad for 08 months. The Project was initiated by Dr. Foram Joshi. She was selected for Ph. D. at Gujarat Ayurved University in January 2019. Since then the Project was completed by Dr. Hetal Nakarani.

Summary of the project-

This entire research work on "Comparative assessment of clinical efficacy of Apamarga Kshara Taila and povidone iodine solution in the management of non healing ulcers" was performed to evaluate and compare the clinical effect of both the local medicaments in the management of non healing ulcer along with dietary regimen and prescribed internal common medications for a stipulated period.

Apamarga Kshara is one type of caustic preparation that enhances drug absorption rate. Also due to its highly alkaline nature, it helps in tissues debridement. With a view to tissue preventive measure, Kshara Taila has been used for dressing. Moreover, the Til Taila [sesame oil] processed with Apamarga Kshara water and Apamarga Panchanga paste (AFI Formula) becomes more effective. Apamarga Kshara Taila is having favourable physicochemical parameters including pH (7.5), least acid values (0.3559) and high saponification value (226.84).

In this study, total 12 patients were enrolled among which total 10 patients completed the course of treatment. Total Wound size reduction was found 247.20 cm in Group A and 32.17 cm in Group B. Average Unit healing time was found 6.6262 days/cm3 in Group A and 18.1256 days/cm3 in Group B. Maximum 50% patients got marked improvement in healing the ulcers. 40% patients got complete wound healing. 10% patients got moderate improvement in achieving wound healing. In following period of 2 months all the patients achieved complete wound healing.

Both the Apamarga Kshara Taila and Povidone iodine solution are differently effective in the management of non healing ulcer; it is observed that Aamarga Kshara Taila works better than povidone iodine solution in the management of non healing ulcer by its tissue debridement effect. Wound healing was achieved in both the groups in more or less period depending upon various systemic and local factors.

The study drug Apamarga Kshara Taila possesses potent Vrana-Shodhana and Vrana-Ropana [wound cleansing and healing properties. There are no untoward effects found during the course of treatment. It is found better in the management of infected wounds as it provides faster tissue debridement in compare to Povidone Iodine.

By Dr. Manasi Deshpande



ANNOUNCEMENT SCHOLARS, ACADEMICIANS, PRACTITIONERS

CHARLES LESLIE PRIZE

To The Best Original, Unpublished Scholarly Essay On Asian Medicine

The paper should apply methods from anthropology, history, or any other academic discipline to the critical study of Asian medical systems in context, and from any period up to the present. Manuscripts must be in English. Please follow the journal style guidelines for the submission.

Deadline: Entries must be received no later than April 15th, 2020, by the president of IASTAM. Please email submissions to messner@sino.uni-kiel.de.

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News

National Conference was organized by Ayurveda Vyaspeeth at Ganesh Kala Krida Kendra on 11th January 2020

On 11th January 2020, National Conference was organized by Ayurveda Vyaspeeth at Ganesh Kala Krida Kendra.

Around 2000 Ayurveda Practitioners were present for this seminar inaugurated by Vaidya Anant Dharmadhikari. Prof. Emeritus Subhash Ranade was Chairman of the first Scientific session in which Dr. Manoj Nesri gave speech on opportunities for Ayurveda Graduates. Dr. Antonio Morandi from Ayurveda Point (Italy) spoke about Ayurveda Situation in Italy.

In his concluding remarks, Prof. Subhash Ranade explained the work of Ayurveda Globalization being done by International Academy of Ayurveda from 1996. IAA has given opportunities for more than 80 Ayurvedic physicians to visit various Global Centers of IAA for propagation of Ayurveda. At present IAA has MOU with 27 countries Globally.

'National Conference on Role of Sanskrit in Ayurveda - Status and Prospects' on 31st January - 1st February 2020

Prof. Emeritus Subhash Ranade and Dr. Sunanda Ranade (Chairman and Vice-Chairman of IAA) were invited as the Chief Guests at the 'National Conference on Role of Sanskrit in Ayurveda -Status and Prospects' jointly organised by Govt. Ashtang Ayurveda College and Shubhadeep Ayurveda College of Indore, Madhya Pradesh attended by more than 500 national and international delegates.

Both of them were felicitated at the inaugural function of the conference on 31st January 2020. The function was held at Mai Mangeshkar Auditorium in Indore.

Many eminent personalities were present amongst them were- Prof. Hari Shankar Sharma from Japan, Prof. Banvarilal Gaud, Jaipur, Vaidya Harinath Jha of Ayurveda Sankul, Anand, Gujrat; Dr. Tamrakar, Principal of Govt. Ayurveda College, Indore, Shri Anand Mrs. Manisha Sojatia, Director of Shubhadeep Ayurveda College, Indore.





Key Note on 'Health and Happiness through Ayurvedic Science' on 10th February 2020

Prof. Banwarilal Gaur was invited to give a key note at Jaipur National University JNU.

Jaipur National University does not have Ayurved College. The Chancellor off the University Shri Sandeep Bakshi and Education Section Director Prof. Shrimati Kamala Vashishtha had organised this lecture with a view to make the students of different streams become aware of Ayurved and once own health protection.

This shows the increasing importance and acceptance of Ayurved.



'National Seminar on Cancer Prevention and Management through Ayurveda' on 15th February 2020

Prof. Banwarilal Gaur was invited as the Chief Guests at the 'National Seminar on cancer prevention and management through Ayurveda' jointly organised by Ayurveda Parishad and Ayurveda Doctors Club, Kota.

The function was held at UIT Auditorium in Shrinathpuram, Kota. Prof. Gaur gave the Chief Guest address.

March 2020 IASTAM NEWSLETTER

BROADCAST TRADITIONAL MEDICINE PRACTITIONERS, PATIENTS, SCHOLARS

ICTAM X 2021 "Life Stories" Interactive Media Competition

Have you ever had an experience with traditional medicine that profoundly changed the way you practice medicine, seek treatment, think about medical theory, science, or even life?

Looking for precisely such "life stories" told in an engaging and inspiring manner.

This competition invites you to explore a new form of communication: visual storytelling.

Prizes: IASTAM (International) is offering three prizes.

Note: We will accept submissions from teams, each individual may only have one submission to the contest.

For Guidelines and queries refer - http://www.ictam-ashm.com/event.php?id=20

Submission Deadline: May 15, 2020; Winners will be announced by Late Summer 2020

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I *Dr. Vandana Kozarekar* hereby declare that the particulars given above are true to the best of my knowledge and belief.

Dr. Vandana Kozarekar Publisher

Views and opinions expressed in different articles are entirely of the writers and authors

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