SOCIETY FOR ETHNOPHARMACOLOGY, India (SFE - INDIA) NEWS LETTER

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Contents

Editorial

We are happy to welcome you for the 3rd International congress of the Society for Ethnopharmacology at Raipur. The society is working on dissemination of knowledge for promotion of Ethnopharmacology & Medicinal Plant with its vision on *"Globalization of local knowledge and localization of global technology"* through different local chapters in different parts of India. We are thankful to all the participants, executive board member, board member and coordinators for their hard work. We would like to express our heartfelt thanks to the Local Organizing Committee for organizing the Congress this year. We would like to request you all to join the society and explore the opportunities.

Dr. Pulok K Mukherjee, Secretary, SFE-India
Dr. Pratim Banerji, President, SFE-India
Dr. Debprasad Chattopadhyay, Editor, SFE – India, Newsletter
Dr. Sanmoy Karmakar, Editor, SFE – India, Newsletter
Dr. Subhash Chandra Mandal, Editor, SFE – India, Newsletter

The First Noble Prize from Traditional Medicine.

This year's Nobel Prize for medicine is a tacit recognition of traditional remedies. Dr. Youyou Tu at the Chinese Academy of Traditional Chinese Medicine shared the 2015 Nobel prize in Medicine for isolating the antimalarial principle "artemisinin" from a sweet wormwood (*Artemisia annua*) used in a Chinese since 400AD. Malaria, caused by *Plasmodium falciparum*, a life-threatening disease for antimalarial drug chloroquine. This created an urgent need for new anti-malarial drug. In 1967, a national anti malaria project was started in China with the involvement of the Academy of Chinese Medical Sciences and Dr. Tu to be the Head of a Malaria Research Group. The group investigated more than 2,000 Chinese preparations and identified 640 hits with possible antimalarial activities. About 380 extracts obtained from ~200 Chinese herbs were evaluated against mouse model of malaria without success. The turning point came when an *Artemisia annua* L. (Qinghao) extract showed a promising degree of inhibition against the parasite. The remedies were described in Ge Hong's Handbook of Prescriptions for Emergencies: "A handful of qinghao in 2L water and the juice can cure the disease. This gave Dr. Tu the idea that conventional extraction step used need to be bypassed to get the active principle and the extraction at lower temperature might be helpful to preserve its anti malarial activity.

On 4 October 1971 they obtained a relatively nontoxic neutral extract with 100% efficacy against parasitemia in mice infected with *Plasmodium berghei* and in monkeys infected with *Plasmodium cynomolgi*. This finding represented the breakthrough in the discovery of artemisinin.

Youyou Tu (2011). The discovery of Artemisinin (qinghaosu) and gifts from Chinese medicine. *Nature Medicine* vol. 17 (10): 1217-1220.

Current trend towards the future of smoking cessation treatment: Does paradigm shift from QUIT or SMOKE approach to QUIT or REDUCE HARM direction save smokers lives?

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Human Tobacco consumption is believed to have begun as early as 5000-3000 BC[1] in the form of chewing and smoking during cultural events and religious ceremonies; and by 1700s smoking had become more widespread after the invention of cigarette making machine. Although a few publications on the dangerous health consequences of tobacco smoking had started appearing in the1600s, great attention towards the ill-effects of tobacco smoking was ignited by comprehensive publications released by the Royal College of Physicians (RCP) on "*Smoking and Health*" in 1962 followed by The US Surgeon General report on "*Smoking and Health*" in 1964. Furthermore, in 1979, the World Health Organization published a major report on "*controlling the smoking epidemic*", which received widespread press release.

Unfortunately, among the ~7000 identified chemicals in a puff of cigarette smoke there are about 80 known carcinogens. The majority of the smoking related diseases and deaths were linked to the total aerosol residue (tar) that the smokers inhale from the burning cigarette. In other words, there is no definitive evidence that the smoking related deaths and diseases are caused by nicotine present in the cigarette smoke. It is important to note that the smokers primarily smoke for nicotine, a psychoactive compound present in the tobacco smoke responsible for smoking addiction. It was expressed by Dr. Mike Russell, a pioneer in the smoking cessation field that "*people smoke for nicotine but they die from the tar*"[2]. Since then, the research communities have invested enormous efforts in developing various treatments including nicotine replacement therapy to curtail addiction to smoking. Current smoking cessation treatments available for the addicted smokers are: a) pharmacotherapy (nicotine replacement therapy and non-nicotine medications such as bupropion and varenicline), b) non-pharmacological (self-motivation, counselling and behavioral support) and c) combination of both pharmacotherapy and non-pharmacological treatments. Among the available treatments, the nicotine replacement therapy (NRT) continues to be one of the mainstays of smoking cessation treatment[3] and is the only pharmacotherapy approved for over-the-counter (OTC) sales. Nonetheless, long term success in quit rates remain low in an OTC setting, typically less than 10%.[4, 5] However, the current smoking cessation products have limited effectiveness in keeping majority (65-70%) of the smokers abstained from smoking for long term (more than 1 year).This is evidenced by long term overall success in quit rates under 30-35%[6, 7] using a single product or combined treatments. Incidentally, a recent report on the pharmacokinetics of smoked nicotine using carbon labelled nicotine in humans confirmed that the nicotine from a smoked cigarette reached the brain within minutes and the "*peak effect*" is achieved before the smokers finishes a cigarette[8]. It is evident that the current NRT products lack the speed in delivering the nicotine (nicotine boost) to the smokers' brain with "the unique respiratory tract sensory cues accompanying nicotine inhalation"[8] the way they experience by smoking a cigarette. As a result, smokers relapse from current NRT treatments and resume smoking regular cigarettes leading to unstoppable smoking related morbidity and mortality.

Despite the advent of various pharmacotherapies and behavioral therapies for smoking cessation, it is well established from the recent report published by Centers for Disease Control and Prevention (CDC, USA) that the "*tobacco use is the leading preventable cause of death in the USA*" [9]and cigarette smoking, including second hand smoke, kills more than 480,000 smokers annually (about 1315 deaths per day) in the USA alone. Additionally, WHO warns that "*tobacco use is one of the biggest public health threats the world has ever faced*" and reported an astonishing figure that there were 100 million deaths in 20thcentury due to tobacco use, which is nearly equal to the number of people killed in the World Wars I and II. WHO also cautioned that if immediate actions are not taken, tobacco related deaths will rise to more than "*8 million a year by 2030, and 80% of those deaths will occur in the developing worlds.*"[10]

Hence, it is important to accept the fact that the prevailing smoking cessation treatments are not very effective in combating smoking as it leaves the smokers in a "Quit or Smoke" situation, which leaves the smoker two options, either to "Quit" smoking completely or "Smoke" continuously the burning cigarette due to relapse. It is important to pay close attention to the following critical suggestions of the experts in smoking cessation and public health, namely, "*the circulatory effects of cigarette smoking are probably due to inhalation of nicotine, the most active alkaloid in the smoke.*

If these effects could be matched by inhalation of an aerosol containing nicotine without the other constituents of the smoke, this might help people dependent on cigarettes"[11] and Dr. Walton Sumner wrote that "*even if used very broadly, clean inhaled nicotine might reduce public health problems as much as a very successful tobacco control programme.*"[12] Furthermore, Dr. Neal L. Benowitz, one of the pioneers in the smoking cessation research stated that "*the development of a consumer-acceptable inhaled nicotine delivery system with absorption kinetics similar to those of a cigarette would be an important advancement in pursuing harm reduction through nicotine maintenance.*"[13]

A huge majority of experts in the smoking cessation field support the idea of developing and approving a clean pulmonary nicotine delivery technology as a powerful weapon to combat smoking. Interestingly, in recent years, some emerging products in the consumer market are in line with the experts' view. The most trending one is "electronic nicotine delivery device (ENDD)," which generates a vapor (aerosol) that could be inhaled to have the nicotine delivered to the lungs. The growing body of evidence demonstrates that the ENDD technology has been very successful in helping many smokers to switch from smoking burning tobacco in addition to eliciting a far lower vapor toxicology compared to the smoke toxicology of burning tobacco. It is likely that the ENDD products provide the smokers the nicotine for their addiction with no tar (~7000 chemicals generated during smoking tobacco) thereby reducing harm or risk from smoking. Hence, in order to control or stop the preventable mortality and morbidity caused by tobacco smoking, it is time to work towards the direction of "Quit or Reduce harm" paradigm. Since ENDD technology is currently unregulated due to insufficient scientific data, many sub-standard products under the category of ENDD has found its way into consumer market leading to many controversial reports on the safety and effectiveness of the product. It is therefore a matter of urgency for the research community to accelerate their efforts and conduct aggressive research on various aspects of the ENDD products with main focus on the effectiveness and safety and publish their findings to ease the way for proper regulation and quick approval of harm reduction products to be available to smokers as quickly as possible.

Importantly, it is the time to conceive and appreciate the fact that any alternative and harm reduced product, which deliver nicotine to the smokers' lungs could be better than burning tobacco since majority of the smoking related mortality has been linked to pyrolysis products generated from the cigarette and not due to nicotine. The emerging category of nicotine containing products has the potential to substantially reduce harm and the risk for the smoking population when compared to the conventional cigarette smoking.[14]Therefore, it is the time to change the paradigm from the currently available *Quit or Smoke* approach, which is ineffective for smoking cessation in 70% of smokers. In the near future, the possibility of providing the ENDD as a harm reduction or smoking cessation product to smokers in order to help them switch from conventional cigarettes must be considered as a life saving alternative.

Most importantly, in addition to investing our efforts to stop smoking, it must be our mission to constantly work towards **prevention of initiation of tobacco** (in any form) use in young population. Such a huge and important task can only be achieved with concerted efforts of people from various facets of life. Firstly, the **parents, teachers** and **primary care physicians** being a role model of non-tobacco user and educating the ill consequences of tobacco use. Likewise, the role of **scientists** must be towards researching the trends in the field and publishing the reports in various outlets that could to be accessed and adopted for medical practices. Finally, the **policy makers** should focus their activities in conducting public awareness campaign on the various ill consequences of tobacco use and also make stringent laws to control tobacco use in public places.

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PHYTOPHARMACEUTICAL - A new class of drug : An emerging opportunity for Pharmaceutical Industry

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Investment in Pharma R&D is going down gradually for the past decade in India. There are multiple factors responsible for this downward trend. One important factor is higher input and lower output in Pharma R&D. Combination of the two factors a) existing capability but lower R&D output of Pharmaceutical industry and b) resurgence of interest in herbals but lower R&D input by industry, has created a newer opportunity for Science based products taking lead from traditional medicines, in the form of Phytopharmaceuticals. Ministry of health and Family welfare, Goverment of India on 30th November 2015 introduced a new class of drug (Allopathic) called "Phytopharmaceuticals" which is defined as:

"Phyto-pharmaceutical drug comprises of purified and standardized fraction with defined minimum four bio-active / phyto-pharmaceutical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human being or animals for diagnosis, treatment, mitigation or prevention of any disease and disorder but does not include administration by parental route."

These products would be licensed as new drug defined under rule 122(E) of the Drugs and Cosmetics Rules 1945. Hopefully, new product development time would be reduced from conventionally recognized 15 years to only 4 to 5 years; drug development cost would come down significantly leading to more productive Pharma R&D. This would fulfill the oft repeated and long felt need of inculcating better level of Science in herbal drugs. Introduction of Phyto-Pharmaceuticals, therefore, provides an emerging opportunity to the R&D driven Indian Pharma Industry which is currently struggling to enhance productivity of its Research and Development efforts.

Regulatory News:

Government of India has notified the National List of Essential Medicines (NLEM), 2015 on 23rd December, 2015

The number of drugs included on the National List of Essential Medicines in India has increased from 348 to 376 after several treatments for hepatitis C, HIV/AIDS, cancer and other conditions were added. Updates were based on the 2015 list of essential drugs released by the World Health Organization, as well as on the views of nongovernmental organizations and drug makers. Some industry stakeholders believe the prices of treatments on the list will be controlled, because that's what happened with drugs on the previous list.

Chinese drug maker receives USFDA OK to test herbal drug

The USFDA has allowed China-based Yiling Pharmaceutical to launch clinical tests for its Lianhuaqingwen capsule, an herbal treatment for patients with flu and common cold. The safety and effectiveness of the drug was tested when it was used by nine hospitals in China that joined the international effort to find clinical treatments for the influenza type A H1N1 virus epidemic in 2009. The World Health Organization has recognized the records of the treatment's performance from those hospitals.

Events of SFE-India Local Chapters and Head Quarter

2nd International Congress of Society for Ethnopharmacology, India (SFEC 2015) on "Validation of Medicinal Plants and Traditional Medicines – Global Perspectives", February 20-22, 2015.

The 2nd International Congress of the Society for Ethnopharmacology (SFEC) was organized by the Department of Pharmaceutical Sciences, R. T. M. Nagpur University, Nagpur, India, during February 20-22, 2015. Dr. Prakash R. Itanakr, Coordinator of Nagpur local chapter was the organizing secretary of the 2nd International Congress 2015. The congress was attended by over 1000 delegates from different countries of the world.

1st Regional Seminar on "Pharmacovigilance of Natural Products - A Preliminary Approach", September 26, 2015.

The Guwahati local chapter of SFE-India, organized the 1st Regional Seminar: on "Pharmacovigilance of Natural Products - A Preliminary Approach "during September 26, 2015. This event was organized by Department of Pharmacology, ADR Monitoring Centre, Guwahati Medical College, Guwahati, Assam. More than 250 delegates from different parts of Indian particularly north east India attended the programme.

2nd Convention & National Seminar on "Integrated Approaches for Promotion and Development of Herbal Medicine" December 5-6, 2015.

The 2nd National Convention of the Society for Ethnopharmacology, India on "Integrated Approaches for Promotion and Development of Herbal Medicine." was organized by School of Natural Product Studies, Jadavpur University, Kolkata during December 5-6, 2015. The seminar was attended by more than 300 delegates from different parts of India with above 150 oral/poster presentations.

A Special programme on "Ethnopharmacology & Validation of Traditional Medicine", during ICAAM 2016, January 4, 2016.

In the 1st International Conference: "Advances in Asian Medicines (ICAAM - 2016); a Special Programme was organized by the Pune Local chapter of SFE-India on "Ethnopharmacology and Validation of Traditional Medicine" during January 4, 2016 at Pune, India. More than 300 delegates participated in this event with above 100 scientific presentations, which make this event grand success. SFE-India is thankful to Dr. Sathiyanarayanan L., SFE-India Coordinator, Pune Local Chapter for organizing this event successfully.

A National Conference on "Ethnopharmacology & Validation of Traditional Medicine", January 19, 2016.

Chennai local chapter of SFE-India organized a national conference on "Pharmacovigilance of AYUSH Drugs" during January 19, 2016 at Sri Ramachandra University, Porur, Chennai. This event was a very successful event with the participation of more than 500 delegates from all over the country and above 50 scientific presentations.

NEWS COVERAGE OF SFE-India Event

Intl conference SFEC 2015 from today

Union Minister Nitin Gadkari to grace Business Conclave on February 21

■ Staff Reporter

DEPARTMENT of Pharmaceutical Sciences, Rashtrasant Tukadoji Maharaj Nagpur University, and Society for Ethnopharmacology, India are jointly organising 2nd International Congress of Society for Ethnopharmacology, India (SFEC-2015), 'Validation of medicinal plants and traditional medicine-global perspectives' being organised for the first time in the core of country Orange city and Tiger capital of India, during February 20-22.

The congress will be inaugurated by Former Governor of Chhattisgarh Shekhar Dutt and Former Central Minister Chandreshwar Thakur on Friday at 4:30 pm at Dr Vasantrao Deshpande Hall, Civil Lines.

Chief patron, Vice-chancellor Dr Vinayak Deshpande and Prof Raghunath Mashelkar, Chairman of congress Dr Naresh I Gaikwad, Head, Department of Pharmaceutical Sciences, RTM Nagpur University, Co-chairman Prof Madhukar R Tajne, Convener Dr Pramod G Yeole, Co-convener Dr Kishor Bhonde, Devkinder Gujar and Dr Sudhir Umathe. Organising secretary Dr Prakash Ritankar, Joint organizing secretary Dr Milind J Umekar, Finance secretary Dr Nishikant A Raut and other impending personality from the field of pharmaceutical sciences Dr Dadasaheb Kokare, Dr Rajendra Kakde etc will grace the congress.

A business conclave will be held on February 21 in presence of Union Minister of Road Transport, Highways and Shipping Nitin Gadkari at 12 noon.

The congress is alienated in five different pre-conferences workshops at Department of Pharmaceutical Sciences, RTM Nagpur University, Gurunanak College of Pharmacy, Narl, and workshop session on Panchakarma at Baidyanath Panchakarma centre, near Bishop College, Civil Lines on Friday.

While the poster session, oral presentation etc will be held at Chitnavis Convention Centre, Civil Lines.

On this occasion, Dr C K Kokate, Vice-Chancellor, KLE University, Belgaon, Dr Geoffrey Cordell, University of Illinois, USA and Dr Tikendra Patwardhan, University of Pune will be conferred by awards from the society of Ethnopharmacology for outstanding performance in the field of Ethnopharmacology, informs a press release.

Chennai, Jan 20:

There is an urgent need for evidence based research into adverse effects of AYUSH drugs for their global acceptance said Professor Rabinarayan Acharya of Gujarat Ayurved University while inaugurating a national seminar on "Pharmacovigilance of Ayush Drugs" organised by Sri Ramachandra University in association with Society for today. Ayush drugs should also have clear labels of their content and adverse reactions, he added.

Speaking on the occasion Dr.Pulok K.Mukherjee, Director, School of Natural Product Studies, Jadhavpur University called for collaborations among AYUSH manufacturers, governmental bodies, academia and research institutions to study and establish the side

Jadhavpur and Sri Ramachandra Universities are due to sign an MOU shortly for joint research he added.

Dr.S.P.Thyagarajan, Dean, Research, SRU said to allay international fears about the safety of AYUSH drugs pharmacovigilance should be included in the curriculum, studies should be conducted in Ayush drug safety, adverse reactions and events should be recorded

drug information services should be available for users.

Over 600 delegates from all over the country participated in the seminar. Dr.T.K.Parthasarathy, Chief Advisor, Dr.S.Anandan, Dean, Medical College, Dr. D.Chamundeeswari, Principal, Faculty of Pharmacy, Sri Ramachandra University were among those who participated in the

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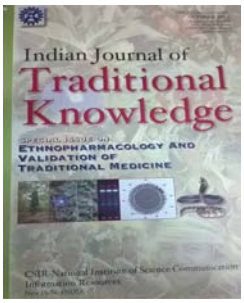

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