

International Conference on Promotion and Development of Botanicals with International Coordination: Exploring quality, safety, efficacy and regulations

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The international conference on “Promotion and Development of Botanicals with International Coordination: Exploring quality, safety, efficacy and regulations”, was organized on February 25-26, 2005 by the School of Natural Product Studies, Jadavpur University, Kolkata, India jointly with the Indian Institute of Chemical Biology, Kolkata, India. The conference was partially support by the Drug Information Association Foundation (DIA), USA.

Back ground for organizing the conference:

Botanicals or phytomedicines have always been a major component of traditional system of healing in developing countries, which have also been an integral part of their history and culture. Besides wide spread use of botanicals as medicinal products in developing countries, such products are becoming part of the integrative healthcare systems of industrialized nations, known as “complementary and alternative system of medicines” (CAM). Safety and efficacy of the Natural Health Products (NHP) is always a cause of concern to promote and rationalize their use. Quality control of

botanicals, validated processes of manufacturing, customer awareness and post marketing surveillance are the key points which could ensure the safety and efficacy of NHP. Currently there is an urgent need for international collaboration in the development and promotion of operational methodologies that should include variety of standard operating procedures addressing the nomenclature, quality, safety, and efficacy of these products, when used as phytomedicines.

Botanicals are evaluated and marketed in different countries based on their own regulations. International coordination on botanical's development in the context of modern drug development will broaden the use of these products in both developing and industrialized nations. So there is a need for coordination and harmonization of regulations related to research and development of natural products as both pharmaceuticals and food supplements. This conference was organized to emphasize drug development from natural resources including their formulation, safety,

efficacy and regulatory perspectives through international coordination. The program highlighted various facets on promotion and development of natural health products (NHP) globally with a special emphasis on Indian perspectives and provide an open forum for discussing their potentials in different areas related to research and development, ethnobotany, ethnopharmacology, traditional medicine, safety, efficacy and regulatory affairs. It is expected the discussion may lead to promote and facilitate development of herbal drugs and their integration all over the world through international coordination. The conference was initially suggested by the Natural Health Products SIAC of DIA to the DIA foundation. As a member of the DIA's Natural Health product Special Interest Area Community and frequent speaker of the Drug Information Association's annual USA conventions, Dr. Pulok K. Mukherjee, Director, School of Natural product Studies was entrusted by DIA to chair this meeting on natural health products (NHP) in India, which was sponsored by the DIA Foundation.

Objectives:

The international conference on botanicals was organized with the main objectives

To emphasize and explore opportunities in the field of Natural Health Products development with a special focus on botanical products used in Indian system of medicines and other traditional and complementary alternative medicines. The conference highlighted the needs and requirements for research and development of natural products in general and phytomedicine in particular through international coordination and collaboration. Different perspectives highlighted in this international meet were

- Trends in the evaluation of botanicals at global horizon.
- Assessment of the use and value of botanicals within complementary and alternative systems of health care.
- Exploration of ethnobotany and ethnopharmacology in natural product development.
- Perspectives and potential harmonization of regulations and quality control
- Development of International coordination in the field of herbal research.

Participants:

The delegates/participants of the conference included a variety of stakeholders:

Manufacturers of raw materials, phytomedicines, pharmaceuticals, dietary and food supplements; representatives of conventional and traditional health care systems; sellers and distributors; regulatory authorities; standard-setting organizations; contract laboratories and research organizations, NGOs, academicians, scientists, and healthcare practitioners. The conference also provided educational opportunities

for pharmacists, pharmacognosists, physicians, phytochemists, botanists, ethnobotanists, ethnopharmacologists, pharmacologists, toxicologists and others involved in the research, evaluation, development and marketing of botanicals and natural products for use in healthcare. More than 350 delegates from 13 different countries including the scientists/researchers from various organizations in India and abroad participated in the conference from different fields of herbal research.

Brief review of the conference:

Different issues on drug development from natural resources for the promotion and development of botanicals with international coordination was discussed in seven plenary sessions scheduled for two days of the conference along with more than 150 oral and poster presentation in parallel sessions from the young scientists/researchers from different parts of the world. The conference was proved to be helpful for the professionals and researchers working in the field of herbal research and manufacturing botanicals. With the interests of developing botanicals and developing international coordination in the field of herbal research following topics and perspectives were highlighted in the conference through different sessions:

- Botanicals through International Coordination
- Traditional Medicine for Development of Herbal Drugs
- Regulatory Perspective for Development of Herbals
- Impact of Natural (Traditional) Medicines as Health Care resources
- Industrial Perspectives and Development of Phytomedicines
- Ethnobotany and Ethnopharmacology
- Pharmacovigilance Study on Phytomedicine

The international conference was inaugurated by Dr. Surjyakanta Mishra, Honorable Minister of Health and Family Welfare, Government of West Bengal on February 25, 2005 where he highlighted on the development of Indian medicinal plants and its various aspects in management of different diseases. Dr. Pulok K Mukherjee, Organizing secretary of the conference and Director, School of Natural Product Studies (SNPS) welcome the delegates and highlighted the need for safety, efficacy of herbal medicine and the involvement of the School of Natural Product Studies and the Drug information Association in this regard. Dr. Carmen Tamayo, Chairperson, Natural Health Product SIAC of the Drug Information Association, USA attended the function as guest of honor. The inaugural function was presided by Prof. A.N. Basu, Vice Chancellor, Jadavpur University, Kolkata, India where Prof. Basu suggested the usefulness of Indian medicinal system and also threw light on the safety aspects of medicinal plants, which is the need of the hour. Other dignitaries to attend the inaugural function were Prof. Siddhartha Roy, Director,

Indian Institute of Chemical Biology, Kolkata, India, Prof. Samir Bhattacharya, School of Life Sciences, Visva-Bharati, Santiniketan, India, Prof. B. Sa, Head, Department of Pharmaceutical Technology, Jadavpur University Kolkata, India. The inaugural function was followed by keynote address by Prof. Robert Verpoorte, Division of Pharmacognosy, Section of Metabolomics, Leiden University, The Netherlands. Prof. Verpoorte highlighted on New Perspectives of Medicinal Plants in a Globalized World and emphasized on quality safety and efficacy of natural health products. He highlighted the requirements for exploring the biosphere for novel biological active moieties, which may become an important part of modern medicines. Prof. Verpoorte reviewed the instrumentation and other general requirements for the development of quality standards for NHP by exploring and utilizing our biosphere to the maximum extent.

Plenary session I, on “Developing Botanicals through International Coordination”, was scheduled to review possibilities and requirements of collaboration and coordination in the field of herbal research. The session was chaired by Dr. Tulsi Chakraborty, and C. R. Maity, India. Dr. RBS Rawat of Medicinal Plant Board of India highlighted the Indian scenario in the field of medicinal plants and addressed various issues on promotion and development of medicinal plants. As a representative of Medicinal Plant Board, Government of India, Shri Rawat highlighted different initiatives taken by Government of India in development and promotion of medicinal plants in Indian System of Medicine. Dr. Rama Mukherjee, President of Dabur Research Foundation spoke on “Opportunity to Study Herbs and Herbo-mineral Preparations for Human Use, Using Modern Biological Tools and Technologies”. Dr. Mukherjee also highlighted different research activities carried out by Dabur Research Foundation in the field of herbal research. Dr. Carmen Tamayo, delivered her lecture on different key points in the development of botanicals with international coordination. Dr. Tamayo highlighted various priorities, issues, regulatory perspectives on promotion and development of botanicals and addressed different critical issues including clinical trials, labeling, adverse reactions, safety monitoring and related issues on botanicals.

Plenary session II, entitled “Exploring Traditional Medicine for Development of Herbal Drugs”, was chaired by Prof. S. P. Pal and Dr. Vimala Devi. Prof. Peter Houghton from Kings College London, UK, delivered his lecture on ‘Polyvalency - An Important Aspect of *In Vitro* Testing of Traditional Medicines’ and highlighted different aspects of testing traditional medicines by *in vitro* methods. With the examples of various plant derived constituents and their bioactivity testing and emphasized issues to be considered based on polyvalency - an important aspect of *In Vitro* testing of

traditional medicines for their bio-potentials. Dr. F.C. Braga, Laboratory of Phytochemistry and Pharmaceutical Biology Faculty of Pharmacy, Federal University of Minas Gerais (UFMG), Belo Horizonte, Brazil, highlighted *in vitro* screening of inhibitors of angiotensin-converting enzyme (ACE) from plant extracts using various *in vitro* and *in vivo* assay methods. Dr. S.K. Maulik, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi, India, spoke on Botanicals and Ischemic Heart Disease and highlighted the effects of botanicals on various cardiovascular and stress management from natural resources.

Plenary session III on “Regulatory Perspective for Development of Herbals”, was planned to highlight and discuss various issues on regulatory perspectives of botanical and other natural health products. The botanicals are controlled and regulated by different laws and regulations which vary from country to country. To promote and rationalize the use of botanicals, it is required to harmonize these regulatory controls. Dr. P. Pushpangadan of National Botanical Research Institute, Lucknow, India, spoke on the ‘Need for Developing Protocol for Collection/Cultivation and Quality Parameters of Medicinal Plants for Effective Regulatory Quality Control of Herbal Drugs’ and highlighted the Indian scenario on the controls of botanicals. He also discussed various requirements for GAP, GMP and quality controls on botanicals. Prof. S. Sotheeswaran of The University of the South Pacific, Suva, Fiji Islands, reviewed global regulatory perspectives for botanicals and talked on ‘South Pacific Herbal Drugs of Commercial Importance - Analytical and Regulatory Perspectives’ and emphasized the need of harmonization regulatory scenario. Dr. Motlalepula G Matsabisa, Director, IKS Health Lead Programme South African Medical Research Council - Cape Town, South Africa, delivered his lecture on ‘Regulation and Registration of Traditional Practitioners and Traditional Medicines in South Africa’ and highlighted on the folklore medications in South Africa and also discussed various initiatives taken by the South African Government to regulate these indigenous systems of medications and botanicals. Dr. Michael Smith from Natural Health Products Directorate, Canada, highlighted Canadian perspectives on regulations of botanicals through his lecture on ‘Regulation and Development of Natural Health Products: A Canadian Perspective’. He discussed on the need of international collaboration and coordination for regulating botanicals. First day of the conference was adjourned with plenary session III, followed by closing remarks of Prof. M. K. Mitra, Dean, Faculty of Engineering & Technology, Jadavpur University, Kolkata, India and remarks by Dr. Pulok K Mukherjee, organizing Secretary and Director, School of Natural Product Studies, Kolkata. On the dinner arranged at the lake club, Kolkata, interaction

with the delegates and international scientists took place to maximum extent. *Plenary session IV on "Health Care Resources - Impact of Natural (Traditional) Medicines"* was scheduled on second day of the conference. The session was chaired by Dr. P. Banerji, Managing Director, Ulysses Pharmaceuticals and by Prof R.V.K Rao of Auro Pharma India. Prof. Samir Bhattacharya from School of Life Sciences, Visva-Bharati, Santiniketan, India, emphasized on the impact of traditional Indian system of medicines on modern drug development and discussed on various issues for drug development from Indian biosphere. Prof. Wandee Gritsanapan from the Faculty of Pharmacy, Mahidol University, Bangkok, Thailand, delivered a lecture on 'Investigation of Alternative Anthraquinone Sources from Cassia Spp. Growing in Thailand' where she also highlighted on the impact of Thai folklore medicines and natural resources on the herbal drug research. Prof. C.K.Kokate, Ex Vice- Chancellor, Kakatiya University, Warangal, India, spoke on 'Indian Immunomodulatory Herbals for Global Exploitation' and highlighted on different immunomodulatory herbs used in Indian system of medicines. Dr. V. Muthuswamy, Senior Deputy Director General of Indian Council of Medical Research (ICMR), India, highlighted the initiatives taken by the ICMR and Government of India to explore the traditional medicines used in India.

Session V, on "Ethno botany and Ethno pharmacology in Natural Product Development: Global Perspectives", was chaired by Prof. B. K. Gupta and Dr. Anis Ansari. Four speakers highlighted on various aspects of natural product development through ethnobotany and ethnopharmacology. Dr. Willem K. Scholten, Head, Office of Medicinal Cannabis (OMC) Ministry of Health, Welfare and Sport, The Netherlands talked on 'Reliability of Herbal Drugs by Reproducible Cultivation' and emphasized on various issues on cultivation of herbal drugs in varied geographical condition for the production of phytoconstituents. Dr. Xavier Ormancey, France, delivered lecture on 'AROMACOSMETIC- Perspectives of Development of Cosmetics from Herbal Resources'. Other speakers of the session Pankaj Oudhia, India and Dr. Kalpana Sachdev from Sami Labs India highlighted different facets of botanicals development from Indian biosphere.

Session VI on "Pharmacovigilance of Natural Health Products- Evaluating Safety and Toxicity", was scheduled to discuss safety and toxicity issues on botanicals. The session was chaired by Dr. P. K. Paul, USA and Dr. S. Tripathi, India. Dr. Pradip Paul, Director, Global Medical Safety Surveillance, Berlex/Schering AG, USA, Dr. CK Katiyar, Director, Herbal Drug Research, Ranbaxy Laboratories Ltd, India and Dr. Elizabeth Campbell, USA, highlighted different issues on safety, efficacy and quality control of botanicals and the factors to be considered for clinical trials of NHP. Dr. Paul

talked on the 'Safety Monitoring of the Botanical Products- Lessons Learned From Handling of the Traditional Drug Safety'. Dr Freddie Ann Hoffman was not able to come whose lecture was delivered by the Dr. P. K Paul on her behalf on "Safety of Botanical Products: A United States Perspectives". Dr. Elizabeth Campbell highlighted on 'An International Collaboration Model to Evaluate Ayurvedic Compounds Used in the Treatment of Women with HIV' *Session VII on "Industrial Perspectives and Development of Phytomedicines"*, was chaired by Dr. N. K. Chodankar, India and Prof. Peter Houghton from UK. Prof Dr. Michael Popp, Bionorica Corp., Germany delivered his lecture on "Pharmaceutical Aspects of Development and Formulation of Drugs from Plant Extracts" and highlighted on different aspects for the quality safety and efficacy of herbal drugs formulations and raw materials including the clinical efficacy in the perspectives of development of international coordination. Dr. M. Venkateshwarlu, Deputy Director, Drugs Control, India, delivered his talk on "An Approach to Quality of Herbal Medicines and GMP in Biopharmaceuticals" and highlighted various perspectives of herbal drug development from Indian perspectives. Dr. S. Narendar from Lupin Limited, India delivered his lecture on "Patentable Inventions from Botanicals / Traditional Medical Knowledge". The speakers reviewed on industrial perspectives on botanical research and regulations. Besides the plenary session there were 150 presentations from scientists/researchers from different parts of India and abroad. The works of those researches were presented in six different oral sessions where 48 scientists presented their work. 3 poster sessions were organised on both days wherein more than 100 scientists/researchers presented their work and many new findings were presented in their presentation as mentioned in the annexed list with this report. For each oral and poster session there were award from Dr. (Mrs) Manjusree Pal Memorial committee to encourage the young researcher in the field of Natural Health Product research. The valedictory function was on February 26, 2005 at 5:30 pm where Prof. S K Sanyal, Pro-Vice Chancellor, Jadavpur University highlighted different international collaboration on which Jadavpur University is working. Dr Carmen Tamayo, Prof. Robert Verpoorte, Mr HP Chetri and Dr AK Bandyopadhyay were present in the function. Dr Pulok K Mukherjee, organizing secretary expressed his gratitude to all the organizing committee members/ volunteers for their help and assistance in organizing the programme. Prof. Rob verpoorte and Dr. Carmen Tamayo expressed their thanks to the organizing committee and they expressed that the conference was a great success with involvement of researchers/scientists from different parts of world. Most of the participants from India and abroad expressed that such conference should be organized

every two years. The conference ended with the National Anthem of India.

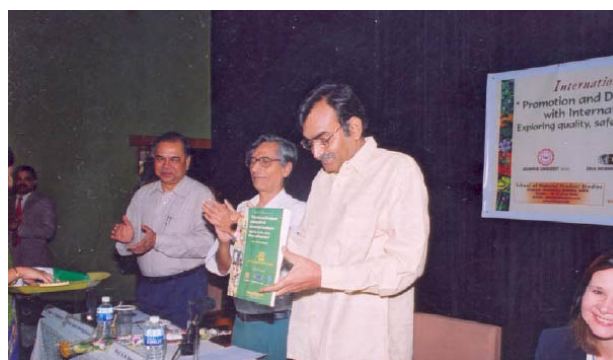
GLIMPSES OF CONFERENCE



Dr. Surjya Kanta Misra, Hon. Health Minister of the State, West Bengal, lighting the lamp



Dignitaries at the inaugural function



Dr. Surjya Kanta Misra, Hon. Health Minister of the State, West Bengal, releasing the scientific abstract of the conference