



# Drug Information Bulletin

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**Volume: 08**

**Number: 02**

**26<sup>th</sup> April 2014**

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## Editorial



World health community celebrating World Immunization Week 2014 started on 24<sup>th</sup> April aiming to promote one of the world's most powerful tools for health – the use of vaccines to protect, people of all ages against disease. Immunization is one of the most successful and cost-effective health interventions and prevents between 2 and 3 million deaths every year. India has showed phenomenal success eliminating Small pox and Polio, but a major portion of unvaccinated children are living in India. However, even now, an estimated 22 million infants are not fully immunized with routine vaccines, and more than 1.5 million children under 5 die from diseases that could be prevented by existing vaccines globally. This situation could be improved by promoting the concept of immunization amongst the general people and reducing prohibitive cost of some vaccines. Hope this years' celebration will be successful in this direction.

**Dr. Subhash C. Mandal**  
Editor

## USP revised monograph of Cyclosporine and intended to update four more monographs:

- [Cyclosporine](#) (posted 22-Nov-2013; official 01-Dec-2013; updated 25-Apr-2014)
- [General Chapters and Associated Monographs Affected by Revision of General Chapter <601>](#) (posted 25-Apr-2014)
- [Cefazolin Injection](#) (posted 25-Apr-2014)
- [Ceftriaxone Injection](#) (posted 25-Apr-2014)
- [Levalbuterol Inhalation Solution](#) (posted 07-Feb-2014; updated 25-Apr-2014)

## Karnataka drugs control dept seizes 6 not of standard quality drugs

Karnataka drugs control department has raided a few chemist outlets in the state and seized six not of standard quality drugs. The inspections were carried out over two days in March end and the test reports have been dispatched from the drug test labs recently. These drugs were tested at random during a surprise inspection carried out by the department's team of inspectors.

All drugs which are not of standard quality were tested at its three labs in Bengaluru, Hubli and Bellary. These drugs are flavoured dispersible Amoxicillin Trihydrate manufactured by Minopharm Laboratories at Pernamitta in Andhra Pradesh, Powering by Eifil Pharma in HPSIDC in Baddi, Crispa A Tablets manufactured by Kare Labs in Verna Industrial Area Goa, Enflocin manufactured by B&T Pharmaceuticals, Animal Healthcare, Hyderabad, Medomo manufactured by Medopharm in Malur district in Karnataka and Rabinem DSR by Lifevision Healthcare, in Solan district in Himachal Pradesh.

Source: [pharmabiz.com](#)

## Plants extract effective in rheumatoid arthritis treatment

In a randomized clinical trial, a combination of a plant extract used in traditional Chinese medicine and Methotrexate proved more effective in treating rheumatoid arthritis than either medication separately. About 46% of Methotrexate patients and 55% of those receiving the traditional Chinese medicine *Tripterygium wilfordii* showed improvement after six months, compared to almost 77% of patients given the combination treatment, according to Xuan Zhang of the Chinese Academy of Medical Sciences in Beijing. The study appears in the *Annals of the Rheumatic Diseases*.

Source: [MedPage Today](#)

## Mass ban on painkiller Zohydro reversed by federal judge

Massachusetts Gov. Deval Patrick's effort to prohibit sales of the controversial pain treatment Zohydro was blocked Tuesday by U.S. District Judge Rya Zobel, who said Patrick had no right to ban a drug deemed effective and safe by the FDA. Allowing Patrick's emergency order against the drug to stand "would undermine the FDA's ability to make drugs available to promote and protect the public health," Zobel wrote in a five-page order. "Although the ban may prevent someone from misusing the drug, the ban prevents all in need of its special attributes from receiving the pain relief Zohydro ER offers."

Source: [The Wall Street Journal](#)

## France makes push for biosimilar substitution

The French government introduced a measure that would permit pharmacists

to substitute branded biotech drugs with cheaper biosimilar versions. The proposal, which still requires a decree to take effect, could have sweeping effects, according to Brussels attorney Maarten Meulenbelt. "Depending on how it is implemented, it could have a knock-on effect by encouraging other EU member states to consider whether to do the same," Meulenbelt said.

Source: [Reuters](#)

## **Regulators struggle to oversee India's vast drug industry**

India produces medicines for an estimated 1.2 billion people and exports to nearly 200 countries, but there are only 1,500 inspectors to ensure quality and safety at 10,000-plus manufacturing facilities in the country, according to officials. One government report found that of 48,082 drug samples collected in 2012, 4.5% were determined to be substandard. Manufacturing plants that make drugs for the U.S. market are subject to inspection by the U.S. FDA.

Source: [Deccan Herald \(India\)](#)

## **Maharashtra FDA busts online trade of Viagra**

The Food and Drugs Administration (FDA) has seized Rs 2 crore worth of sildenafil citrate, popularly known as Viagra, from 27 online firms located in Mumbai, Thane and Pune for selling it illegally to African and European countries. The firms did not have the requisite licence from FDA to sell the drug online or were selling them against fake prescriptions.

"We received a tip off on several irregularities in online sale of medicines run by internet pharmacy firms in Maharashtra. We formed teams and conducted raids on these firms, which are mainly concentrated in Mumbai followed

by Thane and Pune, and seized huge quantity of sildenafil citrate worth over Rs 2 crore. A few more raids are in the offing," said state FDA commissioner Mahesh Zagade.

Two online pharmacy firms from Pune located in Kharadi and Salisbury Park were trapped in the FDA raids.

"Like the firms in Mumbai, we found the firms in Pune too were primarily selling sildenafil citrate tablets to people living abroad. The firm based in Kharadi was operating the online sale without a licence. We seized stock worth Rs 3.25 lakh from the firm. The firm at Salisbury Park had obtained the licence but was found dispensing sildenafil citrate against invalid prescriptions hence we cancelled its licence forthright. Further investigation is on," said B R Masal, joint commissioner (drugs), FDA, Pune.

Elaborating, S K Patil, FDA's joint commissioner (drugs) for Greater Mumbai said, "We found the firms were selling large quantities of sildenafil citrate to people living in the US, African and European countries and that they had no buyers in the domestic market. The firms were dispensing the tablets via air courier without obtaining the drug licence from FDA and export licence from the assistant drug controller's office. A few other firms had licences and also the export licence, but were found to be involved in dispensing drugs against invalid and fake prescriptions. Further investigation is on."

Patil said the demand for sildenafil citrate from Indian firms is more, as it is cheaper compared to the price of the same tablets manufactured and sold in US, African and European countries. "Hence there is a lot of illegal sale of these tablets," Patil said.

Source: [Times of India](#)

## Report on the First International Congress "Globalizing Traditional Medicines: Present and Future Prospects" March 7-9, 2014

The first International Congress of the Society for Ethnopharmacology, Kolkata, India (SFE-India) was organized at Sri Ramachandra University, Chennai, India, during March 7-9, 2014. Theme of the event was "Globalizing Traditional Medicines: Present and Future Prospects". The congress was organized by the Faculty of Pharmacy, Sri Ramachandra University, Chennai. The congress has evidenced participation of over 700 delegates from 20 countries with more than 300 scientific presentations.

A pre-conference workshop was organized on "Publishing Your Research in Impact Journals". Eminent editors/editorial board members of various internationally acclaimed impact journals delivered lectures in this workshop. Dr. Pulok K. Mukherjee, Associate Editor, J. Ethnopharmacology, Elsevier; Dr. Michael Heinrich, Editor, J. Pharmacy & Pharmacology, Pharmaceutical Press, UK; Dr. Rudolf Bauer, Editor, Planta Medica, Germany; Prof. Anna Jäger, Copenhagen, Denmark, J. Ethnopharmacology, Elsevier; Dr. Gail B. Mahady, J. Pharmaceutical Biology, Willey; Dr. T. K. Mukherjee, Ex-Editor, Indian J Traditional Knowledge, CSIR and other delivered lectures. This workshop focused on essential techniques for effective writing and presentation of scientific information and highlights some of the important issues related to publishing research works in journals with impact factor.

The congress was inaugurated by Shri Shekhar Dutt, Honorable Governor of Chhattisgarh, Sri V. R. Venkatachallam, Chancellor, Sri Ramachandra University, Chennai. Other respected dignitaries who attended the program were Dr. H. Devaraj, Vice Chairman, University Grants Commission, New Delhi, Prof. Anna Jagar, President, International Society for

Ethnopharmacology UK, Prof. S. Datta, Pro-Vice-Chancellor, Jadavpur University, Kolkata, Dr. Pratim Banerji, President, Society for Ethnopharmacology, Kolkata, Dr. S. P. Thyagrajan, Sri Ramachandra University, Chennai, Dr. Pulok K. Mukherjee, Secretary, Society for Ethnopharmacology, Kolkata, Prof. S S Handa, Former Director Indian Institute of Integrative Medicines, Jammu, Dr. Michael Heinrich, Centre for Pharmacognosy and Phytotherapy, School of Pharmacy, University of London, UK, Dr. D. Chamundeeswari, Organizing Secretary, of the congress.



In the inauguration programme of the congress, a book entitled "Traditional Medicine and Globalization – The Future of Ancient System of Medicine" edited by Dr. Pulok K Mukherjee, Jadavpur University, Kolkata, was released by Sri Sekhar Dutt, Honourable Governor of Chhattisgarh. Felicitation of the eminent scientists were made in is function followed by the special lectures by Prof. S S Handa and Dr. Michael Heinrich. SFE annual awards for outstanding contributions on Ethnopharmacology was awarded in the inaugural function. Dr. Sukhdev Swami Handa received the SFE Lifetime Achievement Award "Bisheswar Saha Memorial Award"; Prof. Michael Heinrich received the SFE Outstanding International Ethnopharmacologist Award "Pranab Banerji Memorial Award"; the SFE Outstanding Indian Ethnopharmacologist Award "Harihar Mukherjee Memorial Award" was conferred to Prof. Y. K. Gupta; Sri

Birendra Kumar Sarkar received the SFE - Best Entrepreneur Award; Prof. S. P. Thyagarajan received the SFE Merit of Excellence Award; Natural Remedies Pvt. Ltd, Bangalore received the SFE - Herbal industry leader award; Dr. D. Chamundeeswari received the SFE Outstanding Service Award.



The Keynote lectures, special lectures and the plenary lectures were delivered on different issues for promotion and globalization of traditional medicine, ethnopharmacology and medicinal plant research by a galaxy of eminent scientists and researchers from all over the world. Some eminent speakers were Dr. Gail B. Mahady, USA, Dr. Pradip Paul, USA, Prof. Rudolf Bauer, Austria; Prof. Elin Yulinah Sukandar, Indonesia; Prof. Anna Jäger, Denmark; Dr. R. S. Ramaswamy, India, Dr. Y. K. Gupta, India, Dr. R. Soundarajan, India, Dr. Ramesh K. Goyal, Dr. Michael Heinrich, UK, India, Dr. S. P. Thyagarajan, India, Dr. Alexander D. Crawford, Luxembourg, Dr. D. K. Mitra, India, Dr. V. Aridhasan, India, Dr. Tuhinadri Sen, India, Dr. S. P. Subramanian, Dr. Sitesh C Bachar, Bangladesh, Dr. K. M. Manikkavasagam, India, Dr. Mukhlesur Rahman, UK, Dr. Debprasad Chattopadhyay, India, Dr. Mukesh Doble, India, Dr. DK Mitra, India, Dr. S. K. Maulik, India, Dr. James Oluwagbamigbe, Brazil, Dr. Ciddi Veeresham, India, Dr. A.K.S. Rawat, India, Dr. Anjan Adhikari, India, Dr. Olatunde Peter Ajagbonna, Nigeria and many other representing 20 countries of the world.

The conference ended with a valedictory programme with the gracious presence of Dr. B. Suresh, President, Pharmacy Council of India and Mr. Sibeswar Saha, Germany, Mentor, SFE, India. Special

recognition was made by SFE-India and the organizers to recognize the services rendered by eminent personalities for their contribution in natural product and ethnopharmacological research, and contribution for the promotion and development of ethnopharmacology in India. Thus the first congress of the society was very successful in every aspect.

SFE-India was formed in 2013, registered under the West Bengal Society Registration act 1961, and affiliated to the International Society for Ethnopharmacology, UK. The society has made its presence through the country, which provides networking opportunity for development and promotion of medicinal plants and natural products. The Society works on dissemination of knowledge in this area through different local chapters made in different parts of India with the major highlights on globalizing local knowledge and localizing global technologies. The 2<sup>nd</sup> International congress of the society will be organized by the Department of Pharmaceutical Sciences, R. T. M. Nagpur University, Nagpur during February 20-22, 2015. We invite all of you to join the society. More information on the activities, awards and membership of the society is available on [www.ethnopharmacology.in](http://www.ethnopharmacology.in). For further information you may please contact Dr. Pulok K. Mukherjee, Secretary, SFE & Director, School of Natural Product Studies, Jadavpur University, Kolkata 700032, India.

### **Forthcoming Event:**

#### **ISPOR 19th Annual International Meeting**

**May 31- June 4, 2014**

**Palais des Congrès de Montréal, Montreal, QC, Canada**

Early Registration Deadline: **April 15, 2014**

Registration Cancellation Deadline: **April 15, 2014**

Edit Registration Deadline: **May 6, 2014**