# Drug Information Bulletin

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**Content**



## *Editorial*

*In the recent past the quality, safety and efficacy of herbal products have become an important concern for both the common people and the health authorities round the globe. It necessitates some serious measures needs to be taken. As a result certain stringent measures have already been taken by incorporating / amending laws to ensure quality, safety and efficacy of herbal medicines by different countries like India and international agencies like International Conference on Drug Regulatory Agencies (ICDRA), World Health Organization (WHO), European Commission (EC) etc. India is proactive in this matter and has taken some pragmatic policy decision during the last one decade by introducing new legislation, amendment of existing rules and regulations to ensure quality, safety and efficacy of Ayurvedic, Siddha and Unani (ASU) medicines. New rules to mention the name of ingredients on the label, use of IP grade excipients, restricting heavy metal contents, mentioning expiry date on the label, maintaining records of raw materials used in the formulations, mandatory safety measures are some of the important steps taken besides making GMP mandatory for manufacturing of Ayurvedic medicines. Golden Triangle Partnership project in India will definitely raise this initiative to a greater height. Though some initiatives have been taken by ICDRA, WHO, EC etc. there is dire need of global harmonization of the legislation to get quality, safe and efficacious herbal medicine for the benefit of humanity.*

## Bridge courses to enable ISM doctors prescribe allopathic medicine

The union health ministry's department of Ayush has reportedly asked the Central Council of Indian Medicine (CCIM) to develop bridge courses for Ayurveda, Siddha and Unani doctors to provide them competency to practice preventive, promotive, curative and rehabilitative allopathic medicine in respect to the commonly encountered health problems.

CCIM is the statutory body constituted under the Indian Medicine Central Council Act, 1970. The main object of the council is to prescribe minimum standards of education in Indian Systems of Medicine. Since its establishment in 1971, CCIM has been framing on and implementing various regulations including the curricula and syllabi in Indian Systems of Medicine.

## FDA plans surprise inspections at Indian drug units

India's growing importance as a hub of copycat medicine producers and rising compliance problems in local factories serving the American market have prompted the US drug regulator to consider starting surprise inspections in the country.

The Food and Drug Administration (FDA) plans to follow in India the same system of facility inspections that it follows in the US and other developed countries, including an aggressive surveillance and surprise inspections of manufacturing sites, according to two people aware of the development. Both declined to be named.

"India has become a priority location for the FDA as it houses the largest number of FDA-approved drug manufacturing plants outside the US and it is also emerging as the largest exporter of generic drugs to that country," one of the people said.

Albinus D'Sa, deputy director of FDA's India office, did not respond to queries emailed on 3 October.

"The US regulator, since it has set up an local office in 2009, has been doing site inspections with very short notice. But with more people and infrastructure in various locations, they can (now) manage these quite frequently," said Dilip G. Shah, secretary general of the Indian Pharmaceutical Alliance, a lobby group of Indian pharma firms.

In the past nine months, the US regulator has expanded its inspection team in India from 12 to 19, and opened two more offices, in Hyderabad and Mumbai, in addition to its first office in New Delhi.

Until now, FDA's inspections of Indian pharma plants have always been with prior notice. The surprise checks are being considered because of instances of fabrication of documents and human error in Indian manufacturing units, the two people cited above added.

"The local industry has been trying to comply with the requirements as it can't afford to take risks with the US market. But still, issues can happen as human errors are possible always," Shah added.

The FDA had inducted people with expertise in crime detection and investigation in its team, said the first person cited earlier.

"The FDA has also outsourced such work to consultancy firms led by former officials from the (US) Federal Bureau of Investigation (FBI) and such investigation agencies," added this person, who works in the Indian pharma industry.

Units of Ranbaxy Laboratories Ltd and Wockhardt Ltd were in 2009 and 2013, respectively, barred from exporting to the US. In the recent past, units of Lupin Ltd, Cadila Healthcare Ltd, Aurobindo Pharma Ltd and Strides Arcolabs Ltd have received warning letters from the FDA. Lupin said the issue was resolved in 2010.

India is home to 135 FDA-approved manufacturing units and its Rs.1.1 trillion drug industry, which largely makes generics, exported around Rs.40,000 crore of drugs in 2012, 30% of this value being exported to the US alone, according to the Pharmaceutical Export Promotion Council of India.

The FDA banned two export-oriented manufacturing plants of Ranbaxy at Poanta Sahib in Himachal Pradesh and Dewas in Madhya Pradesh in 2009. In Ranbaxy's case, the FDA found not only serious violations in complying with good manufacturing practices, but also data integrity issues.

The company was also at the receiving end of the US regulator's action regarding the functioning of its third manufacturing site at Mohali in Punjab, in September. In May, Ranbaxy paid a fine of $500 million to the US department of justice after it pleaded guilty on the data integrity issue.

Mumbai-based Wockhardt also faced similar action in June regarding the functioning of its export unit at Aurangabad. These companies are currently in the process of resolving the shortcomings in manufacturing compliance.

"We have initiated the remedial measures to resolve the compliance issue at Aurangabad," a Wockhardt executive said on Thursday. "Leading consultants have been hired to help in the corrective measures." The official declined to be named.

"At this point, I would like to assure you that the issues that were raised by the US FDA in 2012 have been addressed and we have taken stringent steps to ensure that we meet all US FDA concerns," Ranbaxy managing director and chief executive officer Arun Sawhney said by email. "It is important to take cognisance of the fact that since the last inspection by the US FDA at Mohali in 2012, Ranbaxy has strengthened its management, manufacturing and monitoring systems and processes to ensure quality and compliance in all areas."

"The root cause of compliance issues in the Indian units is often linked to human elements, including the culture and the attitude of the people at the facilities and in the senior management (of the companies involved)," said Ajaz Hussain, a former head of the compliance cell at FDA, and currently a consultant to pharma companies in the US on quality issues.

Ref. www.livemint.com

## Success Factors: What can we learn about making progress on women's and children's health?

There has been significant progress worldwide towards Millennium Development Goals (MDGs) 4 and 5a—to reduce child and maternal deaths. Some countries, however, do better than others, despite having similar economic contexts.

To understand what works in reducing maternal and child mortality, a study entitled "Accelerating Progress for Women's and Children's Health", was carried out to identify key drivers of mortality reduction and related strategies used by 'high-performing' countries. The study employed different methods including: a literature review and statistical modeling of data across 144 low and middle-income countries; policy analysis for 10 countries (Bangladesh, Cambodia, China, Egypt, Ethiopia, Laos PDR, Nepal, Peru, Rwanda and Vietnam); and evidence synthesis.

The policy analysis informed the development of a series of Success Factor Country Summaries which highlight lessons learned from a selection of 10 countries that are well on the path to achieving the MDG targets for maternal and child health. These summaries present different types of policies and

programmes that countries use in key areas known to influence the health of women and children.

The lessons learned from the analysis of these 10 countries illustrate:

- Political commitment overcomes challenges
- Evidence guides policy and investment
- Sustainable development accelerates progress
- Strong partnerships achieve goals

The study was coordinated by The Partnership for Maternal, Newborn & Child Health in partnership with: World Health Organization, World Bank, the United States Agency for International Development, Alliance for Health Policy and Systems Research, Johns Hopkins University, Global Health Insights, London School of Hygiene and Tropical Medicine, University of St Gallen, Cambridge Economic Policy Associates and MamaYe–Evidence for Action.

## Europe to combat Antibiotic overuse through child education

Reuters reports that British researchers will be informing eighth-grade children about hygiene, microbes and why the overuse of antibiotics can be bad, starting in January, and aim to implement a nationwide program by September 2014. The European Centre for Disease Prevention and Control designated Nov. 18 as European Antibiotic Awareness Day in an effort to combat the increase in antibiotic-resistant diseases. Details of the peer education initiative were published online Sept. 15 in the Journal of Antimicrobial Chemotherapy.

## Malaria vaccine breakthrough?

A vaccine against malaria could be introduced in the world's worst-hit countries in 2015, after the latest trial of a treatment produced by GlaxoSmithKline (GSK), Britain's biggest drug company, nearly halved the cases of malaria experienced by children aged between five and seven months, the Guardian reports . The vaccine, which will be not-for-profit, was partially funded by the Bill and Melinda Gates Foundation and, if approved, will be the first-ever vaccine against a parasite, according to company officials. The dossier will go to the European Medical Agency next year and if it gets its licence, will go to the World Health Organisation for approval. It is expected that the donor-funded Global Alliance for Vaccines and Immunisation (GAVI) will eventually pick up the bill for vaccine programmes as the treatment is deployed in malarial countries.

## Announcement

**Recommendation for nomination for A.P.C.Ray Memorial Gold Medal Award extended up to 25th October 2013.**

Any member of IPA can recommend name of the person with their detailed Bio-data & Two Page summary of the Bio data for 2013 award, which must reach before 5.30 pm on 25th October 2013 at:

**The Hony. Secretary,**
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## Situation Vacant

**Vacancy for Manufacturing Chemist**

A small pharma unit at Behala is urgently looking for a Drugs approved manufacturing chemist.
Interested persons may send their bio-data to pharmadev.kolkata@gmail.com