Drug Information Bulletin

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Content

Editorial

The president of the All India Organization of Chemists & Druggists (AIOCD) has issued a circular dated 18th April 2013 to its members and office-bearers of state associations following the direction of the Competition Commission of India (CCI). It has been mentioned in the circular that it would not be required to obtain NOC for appointment of stockists, and pharmaceutical companies, stockists and wholesalers are at liberty to give discounts to their customers. It would not be mandatory to give product information services (PIS) charge. The PIS services could be availed by manufacturers/ pharmaceutical firms on a voluntary basis. President of AIOCD also assures that there will be no boycott of pharmaceutical companies.

Based on a complaint by a distributor in Orissa, the CCI conducted an investigation and concluded that AIOCD and its associated bodies were infringing Sections 3(3) (A) and 3(3)(B) of the Act. The Commission has found these practices are anti-competitive and ordered the trade body to desist from such activities. Commission has also directed the AIOCD vide order dated 19.02.13 to file an undertaking that the practices carried on by it and its members regarding grant of NOC for appointment of stockist, fixation of trade margins, collection of PIS (product information service) charges and boycott of products of pharmaceutical companies have been discontinued within 60 days from the date of receipt of this order. CCI also imposed a penalty of Rs.47, 40,613 to be paid by AIOCD.

Health care experts feel that this development will eliminate lot of hurdles to reach medicines to the consumers and will help improving access to medicines in India.

Government of India banned 3 drugs recently

Dept. of Health & Family Welfare, Govt. of India has recently banned three drugs due to their severe ADR vide notification dated 18th June 2013. It may be noted that most of them has already banned in US, EU and Australia. Amongst these Analgin are long debated drugs for its ADR, which is banned in most of the countries since long back. Several health care groups in India are demanding its ban for more than 20 years. Three banned drugs are as follows-

1. **Fixed dose combination of Flupenthixol + Melitracen for human use (GSR. 377 E dated 18th June 2013)**
2. **Analgin and its formulations containing Analgin for human use (GSR: 378 E dated 18th June 2013)**
3. **Pioglitazone and its formulations containing Pioglitazone for human use (GSR: 379 E dated 18th June 2013)**

Details are available at
http://www.cdsco.nic.in/html/Notification.html

India imposes a ban on animal testing for cosmetics

Following the footsteps of the European Union and Israel, India on Friday decided to ban animal testing for cosmetics, becoming the first country in South Asia to do so.The Bureau of Indian Standards has now approved the removal of any mention of animal tests from the country's cosmetics standard, according to Humane Society International (HSI), an animal rights organisation that has been running a global campaign to end animal testing for cosmetics. The decision was taken at a meeting chaired by the Drugs Controller General of India (DGCI) Dr GN Singh. M embers of the BIS committee for prescribing safety standards for cosmetics, representatives of cosmetics companies and HSI were also present at the meeting.

""Any manufacturer interested in testing new cosmetic ingredients or finished products must first seek approval from India's Central Drug Standards Control Organization. A manufacturer will be given approval to test only after complying with the BIS non-animal standards,"" an official release from HSI said. Consequently, it will now be mandatory for cosmetics companies to use alternative non-animal tests for evaluating the safety standards of their products. However, the ban has not been extended to products imported from other countries. ""What this means is that if a cosmetics company wishes to test its products on animals in India, it will not be allowed to do so. Essentially, products manufactured in India will be cruelty-free,"" said Alokparna Sengupta, HSI's campaign manager for India, who attended the meeting. ""In February, the DGCI had directed fast-tracking of deletion of the final two animal tests from India's cosmetics safety standard. Subsequently, a draft inviting comments from all stakeholders was put up on the BIS website and was in circulation till May. On Friday, finally, a decision was taken to replace invasive tests on animals with alternative methods.""

According to HSI, animals used for testing in Indian laboratories include rats, rabbits and hamsters. During these tests, chemicals are rubbed on to their skin or dripped into their eyes. In case of lethal dose tests, they are made to swallow huge amounts of chemicals to determine the dose that causes death. ""At the end of a test, the animals are killed, normally by asphyxiation, neck-breaking or decapitation. Pain relief is not provided,"" HSI said.

Source: Economic Times

New Compendium offers freely available public standards to help ensure the quality of herbal ingredients used in Traditional Medicines

With consumers worldwide relying on herbal medicines, a new online resource available from the U.S. Pharmacopeial Convention (USP) will provide freely available public standards to help ensure the quality of the herbal articles used in these products. USP proposes the first 23 herbal articles to be included in the new *Herbal Medicines Compendium* (*HMC*) for comment by all interested stakeholders worldwide at hmc.usp.org. Herbal articles, for the purpose of *HMC*, are herbal ingredients in their entire form as well as their processed forms (e.g., powders, extracts, fractions, not including isolated pure compounds). *HMC* does not include animal origin, synthetic chemical, or biotechnology-derived medicines.

USP is an independent, nonprofit organization that establishes standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. USP's standards for pharmaceuticals are contained in the *United States Pharmacopeia* and the *National Formulary* (*USP–NF*), which are recognized in U.S. law and used throughout the world. Through the new *HMC*, USP now has a forum for advancing standards for herbal ingredients used in herbal medicines worldwide. These ingredients might appear in *USP–NF* or in an associated compendium, the *USP Dietary Supplements Compendium* (*DSC*), but would do so as dietary supplements that are legally marketed in the United States.

"USP believes that public standards are critically important to help ensure the quality of all medicines, including herbal medicines," said Roger L. Williams, M.D., chief executive officer of USP. "Given medicines' key role in maintaining health and treating disease for a majority of the world's population, the importance of public standards for all medicines, including herbal preparations, cannot be overstated. Through the *Herbal Medicines Compendium*, we will now have the ability to better meet the needs of our worldwide stakeholders who seek public standards for herbal medicinal ingredients."

"With herbal medicines increasingly crossing borders in international commerce, it is important to consider the need for global public standards," said Dennis Gorecki, Ph.D., chair of USP's Dietary Supplements and Herbal Medicines Expert Committee, which is part of the USP Council of Experts—the body that makes USP's scientific and standards-setting decisions. "Standards such as those in the *Herbal Medicines Compendium* may be used by regulators and other stakeholders in many countries as a tool against adulterated or poor-quality herbal medicines—which are a growing problem. These standards will advance modern analytical techniques—necessary to deal with the scientific complexities associated with plant-based ingredients."

HMC monographs provide quality specifications—tests, procedures, and acceptance criteria—with validated analytical procedures and allied reference materials that aid in conformity assessment. *HMC* monographs and associated general chapters can help herbal ingredient manufacturers, herbal product manufacturers, regulatory agencies, and other stakeholders to assess conformance of herbal medicinal ingredients with independent public standards and control the quality of herbal articles moving in international commerce. When coupled with sound registration processes and adherence to suitable Good Manufacturing Practices,

standards in *HMC* can become an important part of the safety net that helps ensure access to good quality herbal medicines.

Robust, Public Standards-Setting Process

HMC standards are developed through a public standards-setting process that invites input from all interested parties, and with the collaboration and approval of experts from around the world, via the volunteers who serve on the USP Council of Experts. Proposed monographs on the *HMC* website are initially posted as "*For Development*," which indicates more information is needed before they can advance to the next stage. Once all the information is complete, monographs are advanced for public comment as "*For Comment*" monographs. After addressing public comments, the standards are authorized by the USP Council of Experts and published as "*Final Authorized*."

First Ingredients Proposed for Public Input

USP is proposing these first 23 monographs for comment:

Phyllanthus amarus Aerial Parts
Phyllanthus amarus Aerial Parts Powder
Phyllanthus amarus Aerial Parts Powdered Extract
Rhodiola rosea Root and Rhizome
Rhodiola rosea Root and Rhizome Powder
Rhodiola rosea Root and Rhizome Powdered Extract
Rhodiola rosea Root and Rhizome Tincture
Salvia miltiorrhiza Root and Rhizome
Salvia miltiorrhiza Root and Rhizome Powder
Salvia miltiorrhiza Root and Rhizome Powdered Extract
Ganoderma lucidum Fruiting Body
Ganoderma lucidum Fruiting Body Powder
Ganoderma lucidum Fruiting Body Powdered Extract
Lagerstroemia speciosa Leaf
Lagerstroemia speciosa Leaf Powder
Lagerstroemia speciosa Leaf Powdered Extract
Trigonella foenum-graecum Seed
Trigonella foenum-graecum Seed Powder
Trigonella foenum-graecum Seed Powdered Extract
Trigonella foenum-graecum Seed 4-Hydroxyisoleucine Powdered Extract
Panax pseudoginseng Root and Rhizome
Panax pseudoginseng Root and Rhizome Powder
Panax pseudoginseng Root and Rhizome Powdered Extract

These monographs will be open for a 90-day comment period before they are reviewed and adopted by the USP Council of Experts as authorized monographs. Users will be able to submit comments directly within the website for the USP Council of Experts to consider, and each monograph has an associated discussion forum to allow for real-time exchange among users worldwide. An additional 20 monographs in the *For Development* category also are available on the *HMC* website. After monographs become authorized, comments may still be submitted for consideration by the USP Council of Experts for possible future revisions.

For more information about *HMC*, and to view and comment on the proposed monographs, visit hmc.usp.org.

Forthcoming Event:

Annual General Meeting
of IPA Bengal Branch
Date: 7th July 2013
Time: 5.00 pm
Venue:
IPA Auditorium
22 B Panchanontola Road
Kolkata-700029