# Drug Information Bulletin

*Drug Information Centre (DIC)*
*Indian Pharmaceutical Association*
*Bengal Branch*
*Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com*
*Web Site: http://www.ipabengal.org*
*Contact: 09830136291*

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## Editorial

*The long pending demand of pharmacy professionals for inclusion of Pharmacy subjects in the Indian Administrative Examination (IAS) has been ignored by the concerned authority, creating dissension amongst the pharmacy community.*

*In India most of the students pursuing professional courses like Medical, Engineering courses are getting an advantage in the examination to be qualified for IAS. Pharmacy students are not getting this advantage as Pharmacy subjects are not included in the said examination. Resolutions have been taken in this respect on several occasions by the IPCA in the past but result is yet to be positive.*

*Similar situation is prevailing in case of examination for selecting Patent Examiners in which Pharmacy subject is not included though thirteen subjects like Chemistry, Chemical Engineering, Electric Engineering have been included. It may be noted that patent application on Pharmaceuticals have a major share on the total number of patent application in India. This issue has been raised by a certain quarter before the concerned authority but no positive results are yet visible.*

*In India most of the decisions are taken and executed by the bureaucrats, where the opinions of the technocrats are mostly ignored, absence of bureaucrats with pharmaceutical background is a disadvantage in taking decision in the matter of Pharmaceuticals.*

*These are two issues amongst several such that are deterrent to the development of the profession in our country. Policy makers require think over proper utilization of the huge manpower in pharmaceutical profession in India. IPA is trying its best by submitting memorandum to the concerned authorities and trying to pursue the matter continuously, but expected result is yet to be achieved. Therefore, it is high time for taking up these issues by all of the pharmaceutical professional organizations jointly.*

*Dr. Subhash C. Mandal*
***Editor***
***E mail: subhash.mandaldr@gmail.com***
***Mob. 9830136291***

## Precautions against inappropriate use to prevent resistance

Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) of Japan have announced that the product information for antimicrobials will be revised to include instructions for prescribers to consult the Guidance for Appropriate Use of Antimicrobials to decide if administration of an antimicrobial is appropriate for the case they are treating. The Guidance for Appropriate Use of Antimicrobials was developed in accordance with the National Action Plan on Antimicrobial Resistance 2016- 2020 in Japan. The content of the guidance focuses on patients with acute respiratory tract infections and patients with acute diarrhoea. PMDA examined current package inserts of antimicrobials, and concluded that it is necessary to update the precautions concerning indications to urge prescribers to refer to the guidance to promote appropriate use.

Reference: Revision of Precautions, MHLW/PMDA, 27 March 2018 (www.pmda.go.jp/english/)

## Cefixime risk of mouth ulceration

NCC-PvPI, IPC of India has made a recommendation to CDSCO requesting that the of drug safety label for cefixime is revised to include the risk of mouth ulceration. Cefixime is used for the treatment of otitis media, respiratory tract infections, and uncomplicated UTIs. Between July 2011 and March 2018, NCC-PvPI received 17 ICSRs reporting mouth ulcerations with cefixime use. A review of the cases by Signal Review Panel (SRP)-PvPI, IPC suggested a strong causal relationship between cefixime and mouth ulceration.

Reference: Based on the communication from IPC, NCC-PvPI, India (http://ipc.nic.in)

## Isoniazid potential risk of pancreatitis

Health Canada is working with manufacturers to update the safety information for all isoniazid containing products to include the potential risk of pancreatitis. Isoniazid is indicated to treat tuberculosis. Health Canada reviewed the potential risk of pancreatitis with the use of isoniazid following an update to the product safety information in the United States. Health Canada reviewed three Canadian reports, 14 international reports, and published reports and journals in the scientific literature. Health Canada concluded that there is a rare but potential risk of pancreatitis with the use of isoniazid.

Reference: Summary Safety Review, Health Canada, 10 May 2018 (www.hc-sc.gc.ca)

## Meropenem risk of hypokalaemia

NCC-PvPI, IPC of India has made a recommendation to CDSCO requesting that the drug safety label for meropenem is revised to include the risk of hypokalaemia as an adverse drug reaction. Meropenem is used for the treatment of nosocomial infections such as septicaemia, febrile neutropenia, intraabdominal and pelvic infection, and for cystic fibrosis. Between July 2011 and March 2018, NCC-PvPI received 33 ICSRs of hypokalaemia reported with the use of meropenem. A review of cases by the Signal Review Panel (SRP)-PvPI, IPC, suggested a strong causal relationship between meropenem and hypokalaemia.

Reference: Based on the communication from IPC, NCC-PvPI, India (http://ipc.nic.in)

## Sulfasalazine DRESS syndrome

MFDS of Korea has announced that the package insert for sulfasalazine has been updated to include DRESS syndrome as an adverse reaction. Sulfasalazine is a disease modifying anti-rheumatic drug (DMARD), used for the treatment of rheumatoid arthritis, psoriatic arthritis and arthritis associated with inflammatory bowel disease. Following evaluation of serious adverse events, KIDS reviewed one death case and subsequently suggested a link between the use of sulfasalazine and DRESS syndrome. This recommendation announced by the MFDS was based on investigation results and expert advice.

Reference: Based on the communication from MFDS and KIDS, Republic of Korea, March 2018.

## Methylphenidate, amphetamine best in treating ADHD

UK researchers found that methylphenidate was the safest and most effective attention-

deficit/hyperactivity disorder drug for children, while adults got the biggest benefit from amphetamines. The findings in The Lancet Psychiatry were based on a review of 133 clinical trials involving more than 24,000 children and adults.

Ref. The Guardian

## IPC Issues First 'Standards for Medical Devices - A Reference document' to provide Information on quality parameters

Nearly eight months after the implementation of the Medical Device Rules 2017, the Indian Pharmacopoeia Commission (IPC) has brought out the first reference document for medical devices manufactured and sold in the country. Framed mainly on the basis of MD Rules, the 241-page draft rule book is expected to provide manufacturers, licence holders, regulators and healthcare professionals with requisite information on regulatory and technical requirements under one umbrella.

In addition to the new MD Rules, the document is based on the standards adopted in Indian Pharmacopoeia 2018, British Pharmacopoeia, Japanese Pharmacopoeia, European Pharmacopoeia and the Bureau of Indian Standards.

Currently, India's medical device sector is dominated by multinational companies, which is evident from the fact that about 80 per cent of the sales are generated by imported devices. Though many multinationals have set up operations in India over the years, a majority of them focus on distribution of imported devices and support functions. The MD Rules 2017 were framed around the guidelines of the Global Harmonisation Task Force to ensure that the Indian norms are on par with those in vogue globally. Medical devices, both indigenously produced and imported, now have to conform to the best international practices of manufacturing. Against this backdrop, the new reference document will come in handy since the industry is growing at a rapid pace and there is need for an easy-to-access guidebook on regulations and export-import guidelines.

The draft document is likely to be modified as the IPC has requested industry experts and other stakeholders to submit their comments and suggestions on it. Comments can be submitted till September 1, 2018. The document, reviewed by Pharmabiz, has elaborate sections on classification, registration process, grouping and labelling. More than 20 pages are dedicated for classification of devices and quality parameters.

The reference manual is the latest step from the Union health ministry to ensure the reliability of medical devices available in the domestic market. Plans are afoot to bring all implantable medical devices and other critical medical equipment under the purview of the Drugs and Cosmetics (D&C) Act 1940 and the Central Drugs Standard Control Organisation has notified the list of devices to be regulated under the Act. Apart from all medical implantables, the list includes defibrillators, bone marrow cell separator, dialysis and X-ray machines as well as PET, CT scan and MRI equipment.

While welcoming these positive moves, the domestic industry representatives continue to make a pitch for creating a separate act to regulate medical devices. A draft medical devices regulatory bill has been lying with the health ministry since 2016.

"The law to regulate medical devices needs to be passed and stakeholder consultation for the draft created by the health ministry needs to be expedited as clearly medical electronics are not drugs and a misfit in current legislation of D&C Act," says Rajiv Nath, forum coordinator of Association of Indian Medical Device Industry.

Source: Pharmabiz

## Revision in provisions relating to Blended Edible Vegetable oils and Vanaspati

FSSAI has final notified Food Safety and Standards (Food Product Standards and Food Additives) First Amendment Regulation, 2018 with respect to 'Removal of Boudouin Test and Halphen test requirement for Blended edible Vegetable Oil and Revision of special provisions relating to sale of vegetable oil and fat'. Through this regulation, FSSAI has paved a way for the FBOs to prepare Vanaspati, Interesterified vegetable oil/fat,

Bakery shortening, Bakery and Industrial Margarine, Table Margarine and Fat spreads from any of the edible vegetable oils whose standards are prescribed under FSSR or any other edible vegetable oil with prior approval of the Food Authority. This revised regulation thus does not restrict the preparation of vanspati for the list earlier specified. Furthermore, two provisions relating to Halphen's Test and Baudouin Test are removed as there are other more suitable tests which can be used for testing blending of edible oils. In addition, adulteration of Blended Edible Vegetable Oil will be addressed by the Fatty acid profile of different Vegetable Oils notified by FSSAI. These regulations have been finalised after consideration of the comments received from the stakeholders in this respect and shall immediately come in to force on the date of notification in the Official gazette of India.

Ref. F. No. Stds/O&F/Notification (8)/FSSAI-2017 dtd. 03.07.2018

**Rs 830 crore recovered from drug firms for overcharging: Government**

Government has recovered Rs 830 crore as fine from pharmaceutical companies for overcharging till May 2018. Since the inception of National Pharmaceutical Pricing Authority (NPPA) till May 2018, 1,794 demand notices were issued to drug companies for overcharging patients, Union Minister Mansukh L Mandaviya said in a written reply to the House.

"Demand notices have been issued for a total amount of Rs 6,058.07 crore. Amount to the tune of Rs 829.88 crore has been recovered from the companies...in overcharging cases," he added.

In a separate reply, the minister of state for chemicals and fertilisers said exports of generic drugs in 2017-18 stood at USD 12.9 billion. The global generic market in the same period stood at USD 302 billion.

The total pharma exports including bulk drugs, formulations, herbal products and surgicals stood at USD 17.27 billion in 2017-18, Mandaviya said.

He said the government is taking a lot of steps to encourage use of generic drugs in the domestic market.

"The use of unbranded generics is on the rise in the country and it is now estimated at 7 per cent of the domestic market share," he said.

In another reply, he said the government had constituted an inter-ministerial committee on November 7, 2013 to suggest ways and means to fix the prices of patented drugs in the country.

For details:
https://health.economictimes.indiatimes.com/news/pharma/rs-830-crore-recovered-from-drug-firms-for-overcharging-government/65212809

**Congratulations !**

Dr. B. Suresh for being reelected as President, Pharmacy Council of India

**Pharmacists Day 2018**

**25th September 2018**

Theme:

Pharmacists: Your medicines experts