



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Editorial

Pharmacists of India celebrated 7th Pharmacist Day on 25th September with great enthusiasm. Pharmacy Council of India has decided that they will celebrate this day as Pharmacists Day in India every year and requested all State Pharmacy Councils, Pharmacy Institutions and professional organizations to celebrate the occasion since 2013.

Pharmacists are one of the three main pillars of the health care systems with Doctors and Nurses. Though Doctors Day and Nurses Day are being celebrated since long back, no Pharmacists day was celebrated earlier till 2013 in India. This celebration will be a boost to the pharmacist as a health care provider and certainly recognition to their relentless service to the mankind.

As per the sources this day was celebrated with great enthusiasm throughout the country. There is information that Pharmacy Council of India, State Pharmacy Councils, IPA branches, several other Pharmacy associations, Pharmacy Colleges, Hospitals has celebrated the occasion in different ways like-Organizing silent procession, interactive discussion, holding health care camps for general public, blood donation camps. Efforts were also made to project the important role played by the pharmacists in health care system to improve therapeutic outcome through print and electronic media. It is expected that this enthusiasm will continue throughout the year and will serve the people.



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Six more categories of Devices will be consider as drugs with effect from 1st December 2019

**[To be published in the Gazette of India, Extraordinary,
Part II, Section 3, Sub-section(ii)]**

**Ministry of Health and Family Welfare
(Department of Health and Family Welfare)**

Notification

New Delhi, the 1st October, 2019.

S.O. ---(E).- In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings or animals as drugs with effect from the 1st day of December, 2019, namely:-

All devices including an instrument, apparatus, appliance, implant, material or other article; whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of -

- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
- (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
- (iv) supporting or sustaining life;
- (v) disinfection of medical devices; and
- (vi) control of conception.

[F.No. X.11035/281/2018-DRS]



(Dr. Mandeep K Bhandari)
Joint Secretary to the Government of India.

Non-steroidal anti-inflammatory drugs (NSAIDs) Risk of cardiovascular adverse events

Medsafe has announced that all nonsteroidal anti-inflammatory drugs (NSAIDs) increase the risk of a cardiovascular adverse event. NSAIDs reduce inflammation by inhibiting the production of cyclo-oxygenase (COX)-1 and 2, and are generally indicated to reduce pain, decrease fever and decrease inflammation. Since the Medicines Adverse Reactions Committee (MARC) previously discussed the cardiovascular safety of diclofenac and ibuprofen, several new studies on the cardiovascular safety of NSAIDs have been published. The MARC reviewed the cardiovascular safety of NSAIDs including two clinical trials and two meta-analyses. MARC concluded that it is currently not possible to differentiate or rank NSAIDs by their individual cardiovascular risk profiles. NSAIDs should be avoided in patients with established cardiovascular disease, and patients should be informed of the risk of NSAIDs. If required, NSAIDs should be used at the lowest effective dose for the shortest duration possible. Reference: Prescriber Update, Vol. 40, No.2, Medsafe, June 2019 (www.medsafe.govt.nz/) (See WHO Pharmaceuticals Newsletter No.4, 2015: Small increased cardiovascular risk with daily doses at or above 2,400mg in Ireland).

Proton pump inhibitors (PPIs) Risk of rebound acid hypersecretion (RAHS)

Medsafe has announced that rebound acid hypersecretion (RAHS) has been reported in patients after stopping prolonged treatment with proton pump inhibitors (PPIs). PPIs (omeprazole, lansoprazole and pantoprazole) inhibit gastric acid secretion and have several indications such as the short-term treatment of benign duodenal and gastric ulcers and the eradication of *Helicobacter pylori* in combination with antibacterials. RAHS is the recurrence of symptoms due to an increase in gastric acid secretion above pretreatment levels after stopping PPI therapy. Symptoms of RAHS may include heartburn, regurgitation or dyspepsia. For many people, short-term PPI use (4-8 weeks) is appropriate. A step-down approach should be considered when stopping PPI therapy. Stepping down involves gradually reducing the dose over

time before stopping the medicine completely. Alternative treatments such as histamine H₂-receptor antagonists or antacids may be useful to manage rebound symptoms.

Reference: Prescriber Update, Vo. 40, No.2, Medsafe, June 2019 (www.medsafe.govt.nz/)

Merck launches AI software pilot to prevent drug shortages

Merck's health care division plans to start testing a software platform using machine-learning algorithms that can analyze information at every phase of the supply chain, including pharmacies, wholesale distributors, and manufacturers. The pilot aims to predict and prevent drug shortages and will begin with immuno-oncology drugs.

Ref.: [The Wall Street Journal \(tiered subscription model\)](#)

241 Gujarat Pharmacists lose registration for renting registration

Gujarat State Pharmacy Council (GSPC) on Wednesday said it has cancelled the registration of 241 pharmacists in the state in the last six months for giving their licenses on rent to drug stores and taking up a job elsewhere, which is 'illegal' as per norms.

Apart from suspending their licenses, the GSPC also imposed fine on these pharmacists for indulging in this malpractice prohibited under the Drugs and Cosmetics Act.

Of these, 103 pharmacists faced suspension very recently following a decision taken in this regard during the executive committee meeting of the GSPC, its president Montubhai Patel said.

Many other pharmacists are also under the scanner and warnings have been issued to them already, he added.

"This is the first time in India when such large number of pharmacists have been penalised. We have also issued warnings to around 3,000 pharmacists who were found guilty of giving their licenses on rent to drug stores and taking up another job, which is illegal," Patel said in a statement.

These erring pharmacists also include employees of several pharma companies, it added.

"Being a pharmacist is a noble profession. A drug store can sell medicines only after consulting a

pharmacist present in the store. However, many of them were found to be working in companies after giving their license to these drug stores. We are in no mood to tolerate such malpractice which is bringing disrepute to this profession," Patel added.

Source: ET Healthworld

CDSCO Mandates Licensing Authorities to get PERs Of 19 specified IVD Tests

The Central Drugs Standard Control Organisation (CDSCO) has mandated Central and State licensing authorities to get performance evaluation reports (PERs) of 19 specified In-vitro Diagnostic (IVD) tests for grant of import and manufacturing licenses.

According to the a CDSCO notice, PERs have to be done on three batches of IVD tests with support from notified labs as per the new Medical Device (MD) Rules, 2017.

PERs mandated for IVD tests include HIV, HBV, HCV, blood grouping reagent, cancer, tuberculosis, malaria, dengue, chikunguia, syphilis, typhoid, influenza, toxoplasma gondii, rubella virus, cytomegalovirus, herpes simplex virus (ToRCH), chlamydia, pneumonia, methicillin resistant staphylococcus aureus (MRSA), enterovirus, marker for congenital disorder for example screen test for Down's syndrome, sexually transmitted agent i.e. Treponema pallidum, neisseria gonorrhoeae, human papillomavirus (HPV), herpes virus and other life threatening infections or agent.

In case of IVDs which are licensed and available in the Indian market for long time and manufactured in lesser number of batches per year, central and state licensing authorities should get PER from the lab for one batch to grant license. This is based on the condition that for the subsequent two consecutive batches, satisfactory PER should be submitted by the

manufacturer to the concerned authority as and when it is manufactured. If there is inability of lab or longer testing time etc., other options are available for testing like any central government or state government laboratory of any hospital or of any institute laboratory accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) or by any hospital accredited by National Accreditation Board for Hospitals and Healthcare Providers (NABH) are also available as provided in the new MD Rules.

CDSCO had recently issued guidelines on performance evaluation of IVD medical devices for grant of manufacturing and import licenses as per new MD Rules, 2017 which is effective from January 1, 2018.

It also issued reference list of laboratories in the country for conducting performance evaluation of IVDs. It had directed notified laboratories to test and evaluate IVD medical devices and issue PERs for the purpose of grant of manufacturing and import licenses.

Import license is issued by CDSCO in India for an individual or industry having wholesale or manufacturing license for medical devices.

Source: Pharmabiz

Forthcoming Event

National Pharmacy Week Celebration

By

Indian Pharmaceutical Association, Bengal Branch

17-24 November 2019

Inauguration on 17.11.2019

Venue:

Gandhi Bhawan, Jadavpur University, Kolkata-700032

Time: 10.00 am

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