Drug Information Bulletin

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Content

Editorial

Wishing you all a happy "festive season"!

Pharmacists of India celebrated 6th 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.

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USFDA approves HPV vaccine for people up to 45 to help prevent HPV-related diseases and cancers

The Food and Drug Administration expanded its approval of the HPV vaccine to include men and women between 27 and 45, an effort to protect more people from several types of cancer caused by the human papilloma virus.

The vaccine, called Gardasil 9, previously was approved for people ages 9 through 26. The vaccine is typically given in two doses several months apart for those who are 9 through 14, and in three doses for individuals 15 through 26. For those older than 26, the recommended regimen will be three doses.

Most sexually active individuals in the United States will become infected with HPV in their lifetimes. In most cases, the virus is cleared by the body's immune system, but when that doesn't occur, HPV infections can lead to cervical, anal, vaginal, penile and throat cancers.

The approval "represents an important opportunity to help prevent HPV-related diseases and cancers in a broader age range," said Peter Marks, director of the FDA's Center for Biologics Evaluation and Research.

Experts say the vaccine, which protects against nine HPV strains, is most effective when administered before the initiation of sexual activity. But data also indicate that the vaccine can benefit the older group. That's because even though many adults have been exposed to some types of HPV, most have not been exposed to all nine types covered by the vaccine.

Merck, which manufacturers the vaccine, requested the expanded age range this year. In June, the FDA granted the application priority review.

The original version of the vaccine, called simply Gardasil, was approved by the FDA in 2006 and covered four strains of HPV; it is no longer available in the United States. Gardasil 9 was approved in 2014. The two versions are manufactured similarly and cover four of the same HPV types.

The agency said it based its expanded age approval on data on the original Gardasil vaccine involving 3,200 women ages 27 through 45. The data, and long-term follow-up, showed that Gardasil was effective in preventing persistent infection, genital warts, various precancerous lesions and cancers related to HPV types covered by the vaccine. The FDA said the effectiveness for men was inferred based on the data for women, a small trial for men ages 27 through 45 and the experience of younger males.

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, which is made up of medical and public health experts who make recommendations on the use of vaccines, is expected to review the expanded age range at its meeting later this month and to vote on it next year. If the CDC committee recommends that the older group receive the vaccine, insurance companies are much more likely to cover the cost.

In August, CDC data for 2017 showed that HPV vaccination rates are rising, although not as fast as medical experts would like. Nearly half of adolescents ages 13 to 17 had received all the recommended doses for HPV vaccination, while two-thirds had received the first dose. For both groups, that was a five-percentage-point increase from the previous year.

But HPV-related cancers also are increasing. More than 43,000 people developed HPV-associated cancer in 2015, compared with about 30,000 in 1999, the CDC said.

Reference:

https://www.washingtonpost.com/health/2018/10/05/fda-approves-hpv-vaccine-people-up/?utm_term=.1ed2afc3765a

E-Commerce sites under scanner for selling spurious cosmetics

Next time you buy cosmetics online, do not forget to check for its authenticity. Leading ecommerce portals like Amazon, Flipkart and Indiamart have come under regulatory scanner for allegedly selling spurious, adulterated and unapproved cosmetics, mainly imported brands, some of which contain harmful ingredients, not permitted for use on humans.

The country's top drug regulator, Drugs Controller General of India (DCGI), issued notices to these companies on Monday after it found these online sites selling various cosmetic products which were imported without registration or manufactured in the country without valid

licence, with most of them containing "ingredients" which are in "the negative list" of BIS (Bureau of Indian Standards).

"Drugs Inspectors from CDSCO have carried out several raids at various locations all over the country (Oct 5-6) and found that, some indigenously manufactured cosmetics without valid manufacturing licence and various cosmetics which were imported without having registration certificate were found to be sold on your ecommerce platform," the notice issued by DCGI S Eswara Reddy to Amazon said.

Similar notices were issued to Flipkart and IndiaMart. TOI is in possession of these notices. IndiaMart said it has not received any show cause notice on the issue as yet. It maintained it is only an "intermediary" and "no transaction of sale and purchase or trade or commerce etc takes place on India-Mart platform". "Our platform only facilitates display or advertises for the person who has listed himself being engaged in certain commercial activities. In case of any unethical activity on the platform, the company takes strict action and removes the listing of the products," an India-Mart spokesperson said.

TOI's queries to Amazon and Flipkart did not elicit any response. The companies have been asked to respond to the notice within ten days, failing which the regulator will initiate action against them.

Source: The Times of India

Doctor not essential to run basic Pathology Labs: Health Ministry directs State and UT Govt. implementation

Doctors would no longer be a necessary component for running a basic pathology laboratory in the country. While a provision for such a policy was recently made in the Minimum Standards for Medical Diagnostic laboratories under the Clinical Establishments Act. 2010, a confirmation to the same comes in the form of a recent letter from the Director NHM, Ministry of Health directing all the states to implement the said provisions.

The letter which was recently written by the Additional Secretary, Ministry of Health And Family Welfare as well as the Mission Director, National Health Mission to the Principal Secretaries, Health in all states and UTs clarifies the stand of the government in the light of implementation of Supreme Court order in the matter of North Gujarat unit of association of self-employed owners (paramedical) of private pathology laboratories of Gujarat versus North Gujarat pathologists association regarding the signing of the Laboratory reports.

The letter refers to the Gazette Notification that has been published by Ministry of Health & Family Welfare, Government of India in respect of Minimum Standards for Medical Diagnostic laboratories under Clinical Establishments Act. 2010. In light the SC order, the letter clarifies the following "States may like to implement the above as appropriate," the letter added.

As per the notification, the laboratories have been classified into three categories, basic composite, medium and advanced. The reports of the medium and advanced categories are to signed by the doctors having a Post-graduate qualification in pathology/biochemistry/micro-biology/laboratory medicine or doctors having MBBS with PhD qualification in any of the above subjects.

For basic composite laboratory, wherever the interpretation of the medical report is required, the same is to be signed by a qualified registered medical practitioner having minimum MBBS degree and the reports which contain only numerical value/result of the test/technical analysis of samples, then signing of the report by MBBS doctors may not be essential.

Alleging that this will allow small labs to be run by nondoctors, will finally promote more quackery in laboratory medicine and will lead to mushrooming of illegal labs in the country, doctors have pointed out that the new rules will eventually put the patient at risk and dilute of the overall quality of care in medical services.

Source: Medical Dialogue

Mumbai-based lawyer files PIL against Drug Regulators for unregulated sale of Prescription Medicines

A city-based lawyer Bharat Kothari has filed a PIL in Bombay High Court against Union of India, Government of Maharashtra, Central Drugs Standard Control Organisation (CDSCO) and the

Drug Controller General of India (DCGI) to address the issue of unchecked sales of high potency antibiotics without prescriptions.

Citing the harmful effects of availability of antibiotics without prescription, the writ petition is meant to seek control the medicines in categories H and H1, sold without prescriptions.

The PIL outlines unchecked sale, consumption of antibiotics as an OTC product, drug resistance and impact on disease control measures, increased pressure on cost of healthcare, insurance research and unchecked access of H, H1 category of antibiotics.

The petition is a result of a survey conducted across 500 pharmacies. Antibiotics in the range of H and H1 were freely available among other OTC products across pharmacies. Listing the critical issues that surfaced due to unchecked consumption of high potency antibiotics such as serious drug resistances among infectious deceases and unauthorized sale, the lawyer believed there was great merit in a PIL.

Over 118 different formulations of FDCs were being sold in India, with just 5 in the United Kingdom and the United States. Of these 118 formulations, 64 percent were not approved by the CDSCO, even though the sale of unapproved new drugs is illegal in India. In contrast to FDCs, 93 per cent of 86 single drug formulation (SDF) antibiotics of the market in India had regulatory approval. Presently, India is the largest consumer of antibiotics in world.

"Temporary suspension of licenses of local pharmacies have failed to control the rising concerns and medicines are continued to be dispensed irresponsibly by shop owners. It's high time that there should be a system in place to not only control these irregularities effectively but severe punishment to be levied against such defaulters," said an activist from Venkateshwar Seva Sanstha.

The petition has outlined citizens rights to health, stated to have been compromised due to indiscriminate OTC sale and unchecked use of prescription medication. It draws attention to the duty of the state to assess and monitor any dependency to the antibiotics and other high potency drugs and to ensure that there is no damage to the consumer's health by use of uncontrolled, unchecked self-medication.

It has been a strategic goal of WHO and many countries to limit antimicrobial resistance. Most countries are taking brisk measures to prevent the production and sale of illegal and unapproved medication, which is critical in case of OTC pharmacies.

Source: Pharmabiz

Forthcoming Events:

- **27th FAPA Congress**
  October 24th-27th, 2018
  Manila, Philipines
- **57th National Pharmacy Week(NPW)**
  18-24th November 2018
  Theme: Pharmacists for a Healthy India
- **70th Indian Pharmaceutical Congress (IPC)**
  21-23 Dec 2018
  Amity University, Noida, NCR Delhi