



# Drug Information Bulletin

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**Regulatory Affairs Division (RAD), IPA**

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## *Content*

- *Editorial*
- *Prohibition of manufacturing, sale and distribution of Colistin and its formulation for food producing animals, poultry, aqua farming and animal food supplements*
- *WHO, UNICEF: More than 10% of youths globally were unvaccinated*
- *Breakthrough tumor-specific anti-cancer treatment shows promise*
- *Gene Editing: Medical Board Drafts New Laws*
- *Fluoroquinolone antibiotics risk of aortic aneurysm and dissection*
- *Fluoroquinolone antibiotics risk of musculoskeletal and nervous systems damage*
- *Clozapine risk of intestinal ulcer and intestinal perforation*
- *Forthcoming Event*

## *Editorial*

Nutraceuticals, Food supplements, Micronutrients are flooding the market with tall claims. The gullible public is using with or prescriptions. Physicians are prescribing those products to their patients. In most of the cases without evidence of its safety, quality, and not considering drug- food interactions, drug – drug interactions. Possibility of Drug-food interaction and Drug- Drug interaction is many fold more in case of herbal food products. More research must be carried out to develop evidence of safety of such products. Though the Food Safety & Standard Act & Rules 2011 have prescribed measures for ensuring quality, it is yet to be implemented seriously and uniformly, because of weak infrastructure and insufficient manpower in major part of the country. There is overlapping between drugs and food products creating more confusion in case of applying Drugs and Cosmetics Act & Food Safety and Standard Act. Using these loopholes a drug is being marketed as food to circumvent the Drugs & Cosmetic Act and price Control. There is an urgent need to resolve these issues to protect the health of the people.

Qualification for being Food Safety officers and Food Analysts are also not included Pharmacy qualification, which require to included to use best suited person for this job.



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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th July, 2019

S.O. 2607(E).—Whereas, it is brought to the notice of the Central Government that the use of the drug Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements is likely to involve risk to human beings;

And whereas, the Drugs Technical Advisory Board has considered the said matter and recommended for prohibiting the said drug and its formulations for food producing animals, poultry, aqua farming and animal feed supplements;

And whereas, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the manufacture, sale and distribution of the drug Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements;

Now, therefore, in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby—

- (a) prohibits the manufacture, sale and distribution of the following drug with immediate effect, namely:—  
“Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements”; and
- (b) directs that the manufacturer of Colistin and its formulations shall label the container of the drug and mention the words “NOT TO BE USED IN FOOD PRODUCING ANIMALS, POULTRY, AQUA FARMING AND ANIMAL FEED SUPPLEMENTS” in conspicuous manner on the package insert and promotional literature of the said drug and its formulations.

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Dr. MANDEEP K. BHANDARI, Jt. Secy.

**WHO, UNICEF: More than 10% of youths globally were unvaccinated**

The World Health Organization and UNICEF reported that 20 million children, or more than 1 in 10, worldwide weren't vaccinated against measles, tetanus and diphtheria in 2018. The report also showed that global vaccination coverage with three diphtheria-tetanus-pertussis vaccine doses and one measles vaccine dose has remained at nearly 86% since 2010, which is below the 95% target vaccination coverage rate.

Ref. Reuters

**Breakthrough tumor-specific anti-cancer treatment shows promise**

Chinese researchers found that a checkpoint inhibitor nanoparticle with PD-L1-targeting

antibodies combined with a light-activated molecule enabled tumor site infiltration of T-cells and increased tumor sensitivity to checkpoint blockades, as well as stifled lung and lymph node tumor growth and metastasis in mice models. The findings in [Science Immunology](#) also showed that mice receiving the drug combo had nearly 80% survival in 70 days, compared with 100% mouse death in 45 days among those who were only given PD-L1 antibodies.

Ref. [Xinhua News Agency \(China\)](#)

**Gene Editing: Medical Board Drafts New Laws**

Gene editing technology cannot be used for germline engineering or any genetic modifications that can be passed on to the next generation,

according to draft guidelines released by on Friday.

Human germline engineering involves deliberately changing the genes passed on to children, creating genetically modified people. Considered taboo for safety and social reasons, it is prohibited in many countries.

The draft guidelines also prohibit the use of gene editing to induce unnatural advantages like enhanced physical functions or selection of particular traits to create designer babies, according to the draft. "All such applications are prohibited unless scientific or ethical justification can be provided which is acceptable under socio-ethical norms and the laws of the land," the draft says.

The draft guidelines were developed by the Indian Council of Medical Research in consultation with the Department of Biotechnology and the country's apex drug regulator, the Central Drugs Standard Control Organisation. The draft has been put up in the public domain for comments and suggestions for a week until August 1.

"Gene therapy is a fairly new field and in India there are just a few innovations that are at a stage to go into trials. This is a pre-emptive step by the government to ensure that there is a framework in place. These guidelines will streamline the processes and help researchers and scientists as well as the regulatory authorities," one of the people who drafted the guidelines said on condition of anonymity.

These guidelines will be useful in preventing a situation like the one in China where a lax regulatory environment allowed a scientist to alter the genetic makeup of the zygote of a pair of twins last year.

The draft also proposes setting up an independent body of experts in biomedical research and gene therapy called Gene Therapy Advisory and Evaluation Committee (GTAEC) that will oversee scientific and ethical evaluations of proposed therapies.

"These guidelines facilitate the processes; it ensures that when a new drug comes up for clearance, the regulatory authorities know what needs to be done. This needs to be taken up in a big way as it will help us in treating people with

genetic and rare diseases. In fact, the first application for a trial of gene therapy for haemophilia has been submitted by a DBT institute," said Dr Renu Swarup, secretary, department of biotechnology (DBT).

Gene therapy products will be considered "new drugs" under the New Drugs and Clinical Trial Rules, 2019 and the final approval will come from the CDSCO.

"There are clear procedures for the approval of clinical trial and new drugs. Gene therapy is another category of drugs just like nano-pharmaceuticals etc. and we are developing guidelines for all these," said Dr Eshwar Reddy, Drug Controller General of India.

As these therapies will modify genetic makeup, the guidelines recommend that there must be a long-term follow-up for clinical trials, at least five years. It recommends a follow-up of 10 years after marketing.

Disease-specific guidelines will subsequently, be developed as part of standard operating procedures for separate conditions like haemophilia, thalassemia, sickle-cell anaemia, lysosomal storage disorders and cancer. Lysosomal storage disorders are inherited diseases characterized by abnormal build-up of toxic materials in the body because of enzyme deficiencies.

"The guideline was developed after looking at various international regulatory framework. This might lay the groundwork for a future law on gene editing," said one of the committee members.

The United States approved its first gene therapy products in 2017 for the treatment of childhood blindness and blood cancers. Until 2017, almost 2600 gene therapy clinical trials had been conducted in 38 countries, of which 64.9% were in the US, 23.2% in Europe and some 6.5% in Asia.

Source: Hindustan Times

### **Fluoroquinolone antibiotics risk of aortic aneurysm and dissection**

The Therapeutic Goods Administration (TGA) is investigating a rare but serious adverse event of aortic aneurysm and dissection associated with fluoroquinolone antibiotics. Fluoroquinolones are

broad-spectrum antibiotics that are active against both gram-negative and gram-positive bacteria. They include ciprofloxacin, norfloxacin and moxifloxacin in Australia. The TGA's investigation follows conclusions and recommendations made by the US FDA and the EMA's PRAC. The TGA has not received any Australian reports of aortic aneurysm or dissection/rupture associated with the use of fluoroquinolones.

Reference: Medicines Safety Update, TGA, 12 April 2019

### **Fluoroquinolone antibiotics risk of musculoskeletal and nervous systems damage**

The MHRA has announced that new restrictions for the indication of fluoroquinolones are being introduced to reduce the risk of disabling, long-lasting or potentially irreversible adverse reactions affecting the musculoskeletal and nervous systems. Fluoroquinolone antibiotics available in the UK include: ciprofloxacin, levofloxacin, moxifloxacin and ofloxacin. Fluoroquinolone antibiotics are indicated for serious, life-threatening bacterial infections. The restrictions follow an EU wide safety review. Fluoroquinolones can very rarely cause long-lasting, disabling, and potentially irreversible adverse effects, sometimes affecting multiple systems, organ classes, and senses. The first signs of these adverse reactions include: tendinitis or tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy and central nervous system effects. Health-care

professionals should not prescribe fluoroquinolones for non-severe or self-limiting infections, or non-bacterial conditions. Health-care professionals should prescribe with special caution for people older than 60 years and for those with renal impairment or solid-organ transplants, because they are at a higher risk of tendon injury. Also, use of corticosteroids with a fluoroquinolone should be avoided, since co-administration could exacerbate fluoroquinolone-induced tendinitis and tendon rupture.

Reference: Drug Safety Update, MHRA, 21 March 2019

### **Clozapine risk of intestinal ulcer and intestinal perforation**

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for clozapine (Clozaril®) should be revised to include intestinal ulcer and intestinal perforation as adverse drug reactions. Clozapine is indicated to treat resistant schizophrenia. Four cases of intestinal perforation have been reported in Japan in patients treated with clozapine. The MHLW and PMDA have concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Reference: Revision of Precautions, MHLW/PMDA, 19 March 2019

### **Forthcoming Event**

## **IPA Convention 2019**

11-12 September 2019

**Venue:** Vigyan Bhawan, New Delhi

**Organized by:** Indian Pharmaceutical Association (IPA), Delhi Branch

### **DISCLAIMER:**

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.

**Pharmacist Day 2019**

### **GPP Pharmacist Competition**

**Competition for Community Pharmacists**

Greetings from Indian Pharmaceutical Association-Community Pharmacy Division (IPA CPD). World Pharmacist Day 29<sup>th</sup> September is fast approaching. IPA CPD is pleased to announce a competition for community pharmacists. Objective of this competition is to identify and felicitate those pharmacists across the country who are trying to implement Good Pharmacy Practices in their pharmacies.

In 1992, the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading "Good Pharmacy Practice in community and hospital pharmacy settings". This was further endorsed by the WHO in 1997. The Indian Pharmaceutical Association (IPA) developed GPP Guidelines for India in 2002, and followed it up with a GPP Training Manual in 2005, in collaboration with WHO India Country Office and the Central Drugs Standards Control Organisation.

The mission of pharmacy practice is to contribute to health improvement and to help patients with health problems to make the best use of their medicines.

Eligibility for participation: Submit entries at: