



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Regulatory Affairs Division (RAD), IPA

Volume: 12

Number: 14

7th October 2018

Content

- *Editorial*
- *New Drug: USFDA approved the first candidate of a new class - "RNAi" Drug*
- *Study links lipid-lowering drugs to reduced diabetic retinopathy risk*
- *CDSCO seizes Illegal Cosmetics worth ₹ 4 crore*
- *HCFI to launch a campaign against "Antibiotic Resistance" in Delhi*
- *Diabetes is bleeding Indians dry*
- *Recommendation for Acharya P.C.Ray Memorial Gold Medal Award invited*

Editorial

Wishing you all a happy "festive season"!

Path breaking discoveries on cancer treatment awarded Nobel Prize for Medicine or Physiology in 2018. Prof. James P. Allison-from University of Texas, MP Anderson Cancer Centre and Prof. Tasuku Honjo from Kyoto University, won the 2018 Nobel Prize for Physiology or Medicine, by making landmark discoveries on how to manipulate the immune system to fight cancer, which have resulted in new and highly refined therapies for cancer like melanoma and protein CTLA-4, which when blocked, a brake is released, allowing a flood of immune cells to attack tumors. Normally, this protein prevents T cells from attacking the tumors. Prof. Honjo discovered a second protein PD-1, which too acts as an immune system brake but differently, and he found manipulative ways to inhibit PD-1, thus allowing the body's immune system to attack tumors. These discoveries have opened up a multibillion-dollar market for cancer drugs, especially PD-1 blockers offering new hopes to lung and bladder cancer and melanoma patients, as well as a boon to the several million cancer patients.

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New Drug: USFDA approved the first candidate of a new class - "RNAi" Drug

Approval: The product was approved by USFDA on 10.08.2018

INDICATIONS AND USAGE: ONPATTRO contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

DOSAGE AND ADMINISTRATION: • For patients weighing less than 100 kg, the recommended dosage is 0.3 mg/kg every 3 weeks by intravenous infusion. For patients weighing 100 kg or more, the recommended dosage is 30 mg • Premedicate with a corticosteroid, acetaminophen, and antihistamines • Filter and dilute prior to administration • Infuse over approximately 80 minutes

DOSAGE FORMS AND STRENGTHS: Lipid Complex Injection: 10 mg/5 mL (2 mg/mL) in a single-dose vial

CONTRAINDICATIONS: None

WARNINGS AND PRECAUTIONS: • Infusion-related reactions: Monitor for signs and symptoms during infusion. Slow or interrupt the infusion if clinically indicated. Discontinue the infusion if a serious or life-threatening infusion-related reaction occurs (5.1) • Reduced serum vitamin A levels and recommended supplementation: Supplement with the recommended daily allowance of vitamin A. Refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur

ADVERSE REACTIONS: The most frequently reported adverse reactions (that occurred in at least 10% of ONPATTRO-treated patients and at least 3% more frequently than on placebo) were upper respiratory tract infections and infusion-related reactions (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Alnylam Pharmaceuticals at 1-877-256-9526 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Ref. USFDA

Study links lipid-lowering drugs to reduced diabetic retinopathy risk

Japanese researchers conducted a real-world study of people with type 2 diabetes and found that 7.4% of those who received lipid-lowering

medications developed diabetic retinopathy, compared with 11.4% of patients who did not receive the drugs. The study in [Diabetes, Obesity and Metabolism](#), based on two cohorts of 84,808 patients with type 2 diabetes from a health-claims database, also found lipid-lowering medications reduced the need for treatment by 35% among those who already had diabetic retinopathy.

Ref. Medscape

CDSCO seizes Illegal Cosmetics worth ₹ 4 crore

Illegal cosmetics estimated to be worth ₹ four crore have been seized by the Central Drugs Standard Control Organization (CDSCO) during pan-India raids carried out on Friday and Saturday.

The central drug regulator has lodged five FIRs across three cities -- Mumbai, Pune and Delhi -- against manufacturers who were making cosmetics without licence.

The raids revealed the extent of illegal cosmetics in the market, S Eswara Reddy, drug controller general of India said. During the raids, 10 seizures were carried out in Delhi, Mumbai, Pune and Chandigarh.

"The seized goods include mesenchymal stem cell-based creams, glutathione injections, hyaluronic acid injections, botulinum toxin injections, hair serum, peels made with various ingredients, anti-hair loss solutions and skin peel exfoliators among others," Reddy said.

The seized property will be deposited in the respective courts and all the accused will be prosecuted, Reddy said. The drug regulator also cautioned the public and advised them to purchase cosmetics from verified dealers and e-commerce sites only. "Stem-based products are not permitted to be sold as it is in the banned list," Reddy said.

The cosmetics market has been expanding year over year. Aggressive marketing and entry of multi-national companies has further fuelled growth. However, monitoring the safety and quality of products has not got its due share of importance, Reddy explained.

Further, new generation products like stem cell-based cosmetics, serums, skin whitening creams, glutathione injections, hyaluronic acid filler

injections, etc., are being marketed without safety and quality evaluations, Reddy said.

The intelligence cell of CDSCO has carried out a detailed study for three months on the latest trends in marketing of cosmetics. Sales and distribution of cosmetics are exempted from taking licences unlike drugs and therefore the tracking of unscrupulous elements is difficult, he explained.

"However, the advent of e-marketing has made things better as the intelligence cell can track orders online which has led to the identification of a number of distributors of illegal imports and manufacturers of spurious and unlicensed cosmetics manufacturers," Reddy said.

Several cosmetic products contain ingredients which are not permitted for use on humans. "The CDSCO has organised massive raids across the country from Kolkata to Mehsana and Chandigarh to Chennai. Further, 30 teams more teams have been constituted with about 150 officials to raid at around 30 locations in eight states," he said.

Source: PTI

HCFI to launch a campaign against 'Antibiotic Resistance' In Delhi

The Health Care Foundation of India, in collaboration with the National Centre for Disease Control and the World Health Organisation, is set to launch a campaign to raise awareness against the irrational use and prescription of antibiotics at the 'Health Mela' to take place in the city between October 23 and 27.

"During the past 30 years, no new antibiotic molecule has been discovered or invented globally despite research going on in the area. As per the WHO, the most critical group of the resistance species includes multidrug-resistant bacteria that pose a threat in hospitals, nursing homes, and among patients whose care requires devices such as ventilators and blood catheters. These are Acinetobacter, Pseudomonas and various Enterobacteriaceae (including Klebsiella, E. coli, Serratia, and Proteus). They can cause severe, and often deadly infections such as bloodstream infections and pneumonia," said Dr Sujeet K Singh, Director, NCDC.

As per the data, each year, an estimated 750,000 people die from antimicrobial-resistant (AMR) infections, and the death toll will climb unless the

global health community acts decisively. It is estimated that by 2050, as many as 10 million people could die annually from AMR complications. This campaign, therefore, seeks to address this growing concern and focus on strategies to prevent the irrational use of antibiotics in the country.

"Considering the growing incidence of antibiotic resistance, there is an urgent need to raise awareness on the issue. Antibiotics are different from all other classes of drugs in a very important way: the more a person uses them, the less effective they can become. For a country like India, where over-prescription and misuse of antibiotics are rampant, it is only a matter of time before the resistant bacteria win. Several of these medicines can be obtained without a prescription. What further complicates the problem is inequalities in access to medicine and poor sanitation services. Antibiotics should not be given unless absolutely necessary," said, Dr KK Aggarwal, president, HCFI.

In its first global report on antibiotic resistance, the WHO has warned that 'a post-antibiotic era — in which common infections and minor injuries can kill — far from being an apocalyptic fantasy, is instead a very real possibility for the 21st century.'

Ref. Daily News & Analysis

Diabetes is bleeding Indians dry

The total healthcare expenditure on diabetes in India was estimated at \$31 billion in 2017. NEW DELHI: The mounting prevalence of [diabetes](#) with complications like obesity, blood pressure and cholesterol among Indians is leading to spiralling cost of treatment and a massive burden on out-of-pocket expenditure.

The total healthcare expenditure on [diabetes in India](#) was estimated at \$31 billion in 2017 with 86% of rural and 82% of urban populations in India having to bear the costs of disease management through out-of-pocket expenses, a new study published in Lancet shows.

According to the study, the expenditure of an average Indian patient with type 2 diabetes was estimated to be \$95 per year. The costs of care include direct, indirect, and intangible costs.

Though use of low cost drugs and insulin have helped keep the expenditure on diabetes

management under check, the enormous cost is driven by increasing prevalence of diabetes, mainly with complications. Researchers also observed that gradually use of (and thus expenditure on) newer oral drugs and insulins are increasing in India.

Diabetes prevalence has increased by 64% across India over the quarter-century. According to International Diabetes Federation, India's diabetes population totalled 74 million in 2017 and it is estimated to reach 134.3 million people by 2045.

“When complications occur, these costs increase exponentially, particularly when insulin is initiated or admission to hospital or surgery are required...” says Dr Anoop Misra, chairman, Fortis C-Doc. He is one of the authors of the study. Other researchers include Nikhil Tandon from AIIMS and Andrew P Hills from University of Tasmania. The study linked higher spend on the disease management with higher income. In India, infections contribute to 41% of deaths among patients with diabetes.

Source: ET Healthworld

Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2018 invited

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3rd week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.

IPA, Bengal Branch Council select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy. Any member of IPA can recommend name of the person with their detailed Bio-data & Two Page summary of the Bio data for 2018 award, which may be sent by 15th October 2018 to:

The Hony. Secretary,

Indian Pharmaceutical Association, Bengal Branch, 22 B Panchanontola Road, Kolkata – 700029

e-mail: ipabengal@gmail.com

Ref. N.B.: Biodata should include the following points-

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
 - a. Whether member of IPA? If yes, how many years?
 - b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
 - a. President/Vice President / Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
 - b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.

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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.