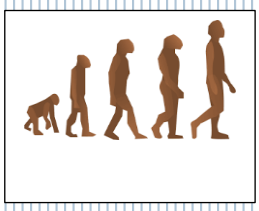
KASTURBA MEDICAL COLLEGE
MANIPAL
(A constituent unit of MAHE, Manipal)

THE DRUG TIMES

Newsletter from Department of Pharmacology, Kasturba Medical College, Manipal
Issue 7, December 2022

Overview

This edition of the drug times focuses on Nobel prizes in 2022, Padma Shri awardee in the field of medicine, and significance of world mental health day. In addition, drug safety alerts, pharmacovigilance week celebration, new drug approvals and growing concern on spurious drugs in the healthcare sector are also highlighted.



Nobel prizes 2022

The Nobel Prize in Physiology or Medicine 2022 was awarded to Svante Pääbo for his discoveries concerning the genomes of extinct hominins and human evolution. Svante Pääbo, through his pioneering research, sequenced the genome of the Neanderthals.

He also made the extraordinary discovery of a previously unknown hominin, Denisova and found that gene transfer had occurred from them to Homo sapiens following the migration out of Africa around 70,000 years ago.

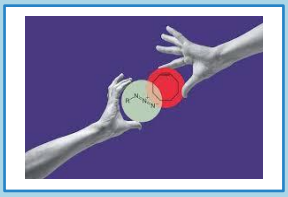
This ancient flow of genes to present-day humans has physiological relevance today, for example affecting how our immune system reacts to infections. What makes us Homo sapiens different from other hominins has always been a pertinent question. Pääbo's seminal research gave rise to a new scientific discipline; paleo genomics.

His discoveries provide the basis for exploring what makes us uniquely human by revealing genetic differences that distinguish all living humans from extinct hominins.

https://www.nobelprize.org/prizes/medicine/2022/press-release/

The Nobel Prize in Chemistry 2022 was awarded to Carolyn R. Bertozzi, Morten Meldal, K. Barry Sharpless for the development of click chemistry and biorthogonal chemistry. Second time Nobel prize winner Barry Sharpless coined the concept of click chemistry in early 2000, which is a form of simple and reliable chemistry, where reactions occur quickly and unwanted by-products are avoided.

Later, Morten Meldal and Barry Sharpless independently of each other – presented click chemistry which encompasses an elegant and efficient chemical reaction that is now utilized in the development of pharmaceuticals, for mapping DNA and creating materials that are more fit for purpose. Carolyn Bertozzi further worked on click chemistry by developing biorthogonal reactions take place without disrupting the normal chemistry of the cell.
Using biorthogonal reactions, researchers have improved the targeting of cancer pharmaceuticals, which are now being tested in clinical trials.



https://www.nobelprize.org/prizes/chemistry/2022/press-release/

PADMA SHRI

One of the awardees of this year's Padma Shri, India's fourth-highest civilian honour is Dr Himmat Rao Bawaskar for his immense contribution in the field of medicine. Hailing from rural Maharashtra, Dr Bawaskar has overcome all odds to complete his medical education. His area of research includes, snakebites, cardiovascular disease and hypothyroidism. His research on the management of scorpion sting especially using prazosin is well known and he has travelled throughout western Maharashtra to train peripheral doctors on how to treat scorpion sting victims. Thanks to his work, fatalities from scorpion sting has dropped from 44% to <1%.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3893974/

WORLD MENTAL HEALTH DAY

World Mental Health Day

World Mental Health Day 2022 was celebrated on 10th October with the theme of "Making mental health and wellbeing for all a global priority" to spread awareness and education about mental health issues across world. Among the mental health disorders, depression is the leading cause of disability worldwide.

Whilst covid-19 pandemic not only disrupted the mental health services but also fueled crisis by 25% rise in depression and anxiety cases combined. A sigh of relief was addition of 2 newer FDA approved drugs to the armory of antidepressants.

(https://www.who.int/health-topics/depression#tab=tab_1).

Newer Drugs

Brexanolone (Allopregnanolone)

The first drug approved by FDA to treat moderate to severe postpartum depression. Brexanolone is a synthetic neuroactive steroid and a positive allosteric modulator of gamma-aminobutyric acid A ($GABA_A$) receptor. It potentiates the effects of $GABA_A$, restores dysfunctional $GABA_A$ transmembrane channels, and mimics progesterone during postpartum. Its administration enhances the inhibitory effects of GABA and reduces depression symptoms. Headache, somnolence, dizziness, sinus tachycardia, fatigue are its reported adverse effects.

https://www.frontiersin.org/articles/10.3389/fpsyt.2021.699740/full

Esketamine

A nasal spray drug for treatment-resistant major depression along with oral antidepressant and patients experiencing acute suicidal ideation or behaviour with major depressive disorder.

Esketamine, is a non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor. The convenience of intranasal is advantageous and fast-onset of action compared to other drugs in the group which takes weeks to produce antidepressant effects. Dissociation from surroundings, sedation, abuse potential, dizziness, nausea, vertigo are its reported adverse effects

https://www.aafp.org/pubs/afp/issues/2020/0315/p339.html

New Drug Approvals

FDA New Drug Approvals (August- December 2022)

	DRUG	INDICATIONS
1.	Olipudase alfa	Acid Sphingomyelinase Deficiency
2.	Spesolimab-sbzo	Flaring of generalized pustular psoriasis
3.	DaxibotulinumtoixnA-lanm	To treat glabellar lines associated with corrugator muscle
4.	Deucravacitinib	To treat plaque psoriasis
5.	Eflapegrastim	Non-myeloid malignancies with clinically significant incidence of febrile neutropenia
6.	Terlipressin	Hepatorenal syndrome
7.	Gadopiclenol	Detect and visualize lesions in MRI and abnormal vascularity in CNS
8.	Oomidenepag isopropyl ophthalmic solution	Open angle glaucoma, ocular hypertension
9.	Sodium phenylbutyrate/taurursodiol	To treat amyotrophic lateral sclerosis (ALS)
10.	Futibatinib	Intrahepatic cholangiocarcinoma
11.	Tremelimumab	Hepatocellular carcinoma
12	Teclistamab-cqyv	Relapsed or refractory multiple myeloma
13	Mirvetuximab soravtansine-gynx	Recurrent ovarian cancer resistant to platinum therapy
14.	Teplizumab-mzwv	Delays onset of stage 3 type 1 diabetes
15.	Olutasidenib	Refractory acute myeloid leukaemia with a susceptible IDH1 mutation

https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022

Teplizumab-mzwv

Dawn in the prevention of
"Diabetes Mellitus type – 1"

Type 1 diabetes is a chronic autoimmune disease that occurs when the cells that produce insulin are destroyed, leading to elevated blood glucose levels. Insulin therapy and monitoring are necessary for survival. This form of diabetes is most diagnosed in children and young adults, but it can occur at any age.

On November 17, 2022, the US Food and Drug Administration (FDA) approved the use of Teplizumab-mzwv injection to delay the onset of advanced stage 3 type 1 diabetes in adults and children aged 8 and older who are currently experiencing stage 2 type 1 diabetes. This treatment received priority review and breakthrough therapy designations from the FDA.

Teplizumab may work by deactivating immune cells that attack insulin-producing cells and increasing the proportion of cells that help regulate the immune response, potentially delaying the progression to stage 3 type 1 diabetes. It is administered by intravenous infusion once daily for 14 consecutive days.

Common side effects of Teplizumab include decreased levels of certain types of white blood cells, rash, and headache. It is important to premedicate and monitor for symptoms of cytokine release syndrome, as well as the risk of serious infections and decreased levels of lymphocytes. There is also a risk of hypersensitivity reactions, and it is recommended to administer all age-appropriate vaccinations prior to starting the drug. Concurrent use of live, inactivated, and mRNA vaccines should be avoided while taking Teplizumab.

https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes

Drug Safety Alerts (PvPI)

Listed below are Suspected and Unexpected Serious Adverse Reactions (SUSARs) from the Pharmacovigilance Program of India (PvPI) database

Suspected Drug	Indication	ADR
Norfloxacin	Antibacterial Wide variety of infection caused by Gram +ve and Gram- ve organisms	Skin Hyperpigmentation

Spurious drugs/ Counterfeit drugs

Spurious drugs or counterfeit drugs, also known as false drugs, are a growing concern in the global healthcare sector. These drugs are deliberately made to look like genuine, brand-name medications, but they often contain little to no active ingredients and may even contain harmful substances. These false drugs are generally sold in both developed and developing countries at a lower price than the genuine medication, can cause side effects or even be fatal to patients.

Government and regulatory agencies in addition with World Health Organization (WHO) are taking several steps to address this issue by implementing stricter regulations on the production and sale of medications, increasing penalties for those who produce and sell fake drugs, raise awareness about the dangers of counterfeit drugs and provide guidance on how to identify and avoid them.

“According to a survey 2020-21, out of 84,874 samples lifted for testing, 2,652 samples were declared not of standard quality while 263 were found to be spurious and people responsible were arrested for the same”.

Recently WHO has linked cough syrup made in India to acute kidney failure, that lead to the death of nearly 70 children in West Africa, Indian authorities acted promptly and shut down the factory where the medicines were made.

In order to check the sales of spurious medicines, the government is in process of making it mandatory for pharmaceutical companies to print bar code on the packages of 300 drug formulations so that information for example manufacturing license and batch number can be accessed upon scanning. Moreover, this will also help in checking the genuineness of the drug.

Overall, spurious drugs are a serious problem that can have harmful effects on those who take them. By being aware of the issue and taking steps to protect ourselves, we can help to reduce the spread of fake drugs and ensure that only safe and effective medication are in circulation.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355878/

https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/300-drug-formulations-to-have-mandatory-bar-codes-on-packages-soon-to-curb-sales-of-spurious-medicines.

Pharmacovigilance Week Celebration

Adverse drug reaction monitoring Centre, Department of Pharmacology, KMC, Manipal had celebrated the 2nd National Pharmacovigilance Week Celebration from 17th to 23rd of Sept 2022. Various activities were conducted by the Centre. To begin with, the flyer was released by faculty members of pharmacology department and the members of pharmacovigilance core committee.

The National Pharmacovigilance Week Celebration posters were displayed in Kasturba Hospital Manipal, Pharmacy, Manipal College of Dental Science, Manipal College of Nursing, and the girls & boy's hostels.

For encouraging active participation of the students, essay writing competition on 'Over the counter drugs-patient safety' was conducted across students of medical, nursing, pharmacy, and health professions colleges under, Manipal. Cash prizes with certificates were awarded to winners.

In the interest of patient safety, an awareness on adverse drug reaction reporting was conducted in the outpatient department of Medicine and Dermatology by Dr Sangita Kamath and Dr Shreya Hegde respectively. A lecture on Pharmacovigilance awareness program was given by Dr Sadhana N Holla to nursing students. Twitter was taken as a social media platform to spread the awareness on pharmacovigilance week celebration.

Dr Meena Kumari and team had participated in the National level Animation Video competition entitled 'Encouraging reporting of Adverse drug reactions by patients' for which Third prize was awarded by the National Coordination Centre, Pharmacovigilance Program of India, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Govt. of India. The participants in the video were Dr Meena Kumari K, Dr Aditya Vinayak, Dr Shivani Singh, Ms. Anisha B and Ms. Arpita Roy.

A valedictory function attended by the faculty members, participants and prize winners was conducted on 23rd September 2022 to celebrate the successful completion of 2nd National Pharmacovigilance Week Celebration 2022.

Tell me and I forget. Teach me and I remember. Involve me and I learn. -Benjamin Franklin

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