

News and Views

Health Ministry Bans 328 FDCs with Immediate Effect

The Ministry of Health and Family Welfare has prohibited the manufacture for sale, sale or distribution for human use of 328 Fixed Dose Combinations (FDCs) with immediate effect. It has also restricted the manufacture, sale or distribution of six FDCs subject to certain conditions.

Earlier, the Central Government had, through its notifications published on the 10th March, 2016 in the Gazette of India, prohibited the manufacture for sale, sale and distribution for human use of 344 FDCs under Section 26A of the Drugs and Cosmetics Act, 1940. Subsequently, the Government had prohibited five more FDCs in addition to the 344 under the same provisions.

Accordingly, the Ministry of Health and Family Welfare has, in exercise of powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940, prohibited the manufacture for sale, sale or distribution for human use of 328 FDCs through its gazette notifications dated 7th September 2018; it has also restricted the manufacture, sale or distribution of six FDCs subject to certain conditions. These notifications will take immediate effect. However, the matter was contested by the affected manufacturers in various High Courts and the Supreme Court of India. In compliance with the directions given by the Supreme Court of India in its judgment dated the 15th December, 2017, the matter was examined by the Drugs Technical Advisory Board constituted under Section 5 of the Drugs and Cosmetics Act, 1940, which furnished its report on these drugs to the Central Government.

The Drugs Technical Advisory Board recommended, amongst other things, that there is no therapeutic justification for the ingredients contained in 328 FDCs and that these FDCs may involve risk to human beings. The Board recommended that it is necessary to prohibit the manufacture, sale or distribution of these FDCs under Section 26A of the Drugs and Cosmetics Act, 1940 in the larger public interest. With regard to six FDCs, the Board recommended that their manufacture, sale and distribution be restricted subject to certain conditions based on their therapeutic justification. Fifteen FDCs out of the 344 prohibited on the 10th March, 2016, which were claimed to be manufactured prior to 21st September,

1988, have been kept out of the purview of current notifications... (*Press Information Bureau, Ministry of Health and Family Welfare, September, 12, 2018*)

Dairy Consumption Lowers Heart Disease and Mortality Rates

Dairy consumption of around three servings per day is associated with lower rates of cardiovascular disease and mortality, compared to lower levels of consumption, according to data from the Prospective Urban Rural Epidemiological (PURE) global observational study of over 1,30,000 people in 21 countries, published September 10, 2018 in *The Lancet*. Those who consumed three servings of whole fat dairy per day had lower rates of mortality and cardiovascular disease versus those who consumed less than 0.5 serving of whole fat dairy in a day.

Amyotrophic Lateral Sclerosis also Affects the Mind

A new study published online September 12, 2018 in the journal *Neurology* says that amyotrophic lateral sclerosis (ALS) or Lou Gehrig's disease, also affects the mind, especially later in the course of the disease. These patients have problems with thinking skills and behavioral problems such as apathy, changes in eating behaviors and lack of inhibition even at the earliest stages and by the last stage of the disease, only very few people are free of these cognitive and behavioral problems. Hence, these patients should be routinely screened for these problems.

Gestational Diabetes Increases Maternal Risk of Type 2 Diabetes a Decade Later

According to a study published September 11, 2018 in *JAMA*, high blood sugar during pregnancy, even if did not meet cut-off for diagnosis of gestational diabetes were significantly more likely to have developed type 2 diabetes a decade after pregnancy when compared to women who did not have high blood sugar during pregnancy. Children of mothers with high blood sugar were more likely to be obese.

Perception of Quality of Care Lower in Certain Dialysis Settings, Says Study

For-profit operation, free-standing status and large dialysis organization designation were associated

with less favorable patient-reported experiences of care, according to a cross-sectional analysis of 2939 US dialysis facilities published online September 10, 2018 in *JAMA Internal Medicine*.

USPSTF Recommends Ocular Prophylaxis of Newborns to Prevent Gonococcal Ophthalmia Neonatorum

The United States Preventive Services Task Force (USPSTF) recommends prophylactic ocular topical medication (with 0.5% erythromycin ophthalmic ointment) for all newborns to prevent gonococcal ophthalmia neonatorum (Grade A recommendation) in a draft recommendation statement on ocular prophylaxis for gonococcal ophthalmia neonatorum published on its website. The draft is open to public comment till October 9, 2018.

SC Issues Directions to End Stigma Attached to Leprosy Patients

In a bid to remove centuries old stigma attached to leprosy patients, the Supreme Court recently directed the Centre to consider framing separate rules for issuing them disability certificates so that they can avail of reservation and various other welfare benefits. The apex court said that acceptability of leprosy patients in the society would go a long way in reducing the stigma attached to the disease and passed a slew of directions to the Centre and the State governments for launching massive awareness programs.

A bench comprising Chief Justice Dipak Misra and Justices AM Khanwilkar and DY Chandrachud said due attention must be paid to ensure that leprosy affected persons are issued Below Poverty Line cards, so they can avail of benefits under Antyodaya Anna Yojana and other similar schemes, which would enable them to secure their right to food.

The top court said: "The Union and the State Governments must pro-actively plan and formulate a comprehensive community based rehabilitation scheme, which shall cater to all basic facilities and needs of the leprosy affected persons and their families. The scheme shall be aimed at eliminating the stigma that is associated with persons afflicted with leprosy.

"The Union Government may consider framing separate rules for assessing the disability quotient of the leprosy affected persons for the purpose of issuing disability certificate in exercise of the power granted under the Rights of Persons with Disabilities Act, 2016."

It further said that awareness campaigns must inform that a person affected by leprosy is not required to be sent

to any special clinic, hospital or sanatorium and should not be isolated from family members or the community.

It said that awareness campaigns should also inform that a person affected with leprosy can lead a "normal married life, can have children, can take part in social events and go to work or school as normal."

"The Union and the State Governments must ensure that both private and public schools do not discriminate against children hailing from leprosy affected families. Such children should not be turned away and attempt should be made to provide them free education," it said.

Asking the agencies not to use frightening images of people hit by leprosy, the top court said the content and information in the awareness programs should use positive images of cured persons sharing their experiences of becoming healthy.

"The Union and the States are to ensure that drugs for management of leprosy and its complications including the multi-drug therapy (MDT) drugs are available free of cost and do not go out of stock at all Primary Health Centres or public health facilities in the country," it said.

"All-year awareness campaigns should also be run, by the Union as well as the States, to inform the citizenry that under the National Leprosy Eradication Program cases diagnosed through general health care system including NGOs, treatment is provided free of cost to all leprosy," it added.

Second Case of Monkeypox in the UK

A second person has been diagnosed with the deadly monkeypox virus in England, just a few days after the first case was revealed. The patient, who had traveled to Nigeria, arrived at Blackpool Victoria Hospital with symptoms of the disease, Public Health England (PHE) said. They are now being treated at the Royal Liverpool University Hospital, a specialist center. The first case of the disease was recorded on Friday in a Nigerian national staying at a naval base in Cornwall. The patient was transferred to the expert infectious disease unit at the Royal Free Hospital in London. Dr Nick Phin, deputy director of PHE's National Infection Service, said the two cases are not related but added that it was 'unusual' to see two cases in such a short space of time... (*Metro UK, Sept 12, 2018*)

About Monkeypox (WHO)

- Monkeypox is a rare viral zoonotic disease that occurs mainly in central and west Africa, near tropical rainforests.

- The monkeypox virus is similar to human smallpox. Although monkeypox is much milder than smallpox, it can be fatal.
- The case of human monkeypox was identified in 1970 in the Democratic Republic of Congo in a 9-year-old boy in a region where smallpox had been eliminated in 1968.
- Case fatality rate ranges from 1% to 10%.
- Infection of index cases results from direct contact with the blood, bodily fluids or cutaneous or mucosal lesions of infected animals.
- Human-to-human transmission can result from close contact with infected respiratory tract secretions, skin lesions of an infected person or objects recently contaminated by patient fluids or lesion materials.
- Incubation period ranges between 6 and 16 days.
- The infection can be divided into two periods:
 - Invasion period (0-5 days): Fever, intense headache, lymphadenopathy, back pain, myalgia (and an intense asthenia)
 - Skin eruption period (within 1-3 days after appearance of fever) in which rash appears on the body; face (in 95% of cases), and palms of the hands and soles of the feet (in 75% of cases) are most affected. Evolution of the rash from maculopapules to vesicles, pustules, followed by crusts occurs in about 10 days. Three weeks might be necessary before the complete disappearance of the crusts.
- Differential diagnoses: Smallpox (even though it is eradicated), chickenpox, measles, bacterial skin infections, scabies, syphilis and medication-associated allergies. Lymphadenopathy during the prodromal stage of illness can be a clinical feature to distinguish monkeypox from smallpox.
- Diagnosis: Identification of the monkeypox virus in lab.
- There are no specific treatment or vaccines available for monkeypox infection.
- Prevention is by educating the public about risk factors and who to reduce exposure to the virus; healthcare workers should strictly follow standard infection control precautions.

TAVR Associated with Shorter Duration of Hospitalization Than SAVR

According to a new study published Sept. 14, 2018 in *Circulation: Cardiovascular Interventions*, a significantly

greater reduction in the average length of hospital stay was observed in patients who underwent transcatheter aortic valve replacement (TAVR) compared to those who underwent surgical aortic valve replacement (SAVR). They were also significantly less likely to be transferred to a skilled nursing facility.

Biologics Increase Risk of Serious Infections in Patients with Refractory Atopic Dermatitis

Treatment of a refractory atopic dermatitis with a biologic agent doubled the risk of hospitalization for a serious bacterial or opportunistic infection versus high-potency topical steroids or nonbiologic systemic therapy. Infection risk also varied substantially among nonbiologic systemic agents, with cyclosporine posing the lowest risk and azathioprine and mycophenolate the greatest risk. These findings were presented at the ongoing European Academy of Dermatology and Venereology congress in Paris.

¹⁸F-FDG PET/CT Scan may Detect Early Coronary Artery Disease in Psoriasis Patients

In this cross-sectional cohort study of patients with psoriasis assessed with ¹⁸F-FDG positron emission tomography/computed tomography (PET/ct) and coronary computed tomography angiography, aortic vascular inflammation was directly associated with quantitative burden of coronary artery disease, luminal stenosis severity within the coronary arteries, and the prevalence of high-risk coronary plaque beyond traditional cardiovascular risk factors. The study is reported in *JAMA Cardiology* online September 12, 2018.

Eating More Whole Grain Foods Lowers the Risk of Type 2 Diabetes

The study from the Danish Diet, Cancer, and Health Cohort published in the September 2018 issue of the *Journal of Nutrition* says that eating more whole grain foods such as rye bread, whole grain bread or oatmeal/muesli significantly lowers the risk of developing type 2 diabetes among middle-aged men and women.

Pembrolizumab + Pemetrexed + Platinum Chemotherapy Approved as First-line Treatment of Metastatic NSCLC

Based on efficacy and safety data from the phase 3 KEYNOTE-189 trial in patients with advanced disease, the European Commission has approved the combination of pembrolizumab (Keytruda, Merck), pemetrexed (Alimta, Lilly) and platinum chemotherapy for the first-line treatment of metastatic non-small cell

lung cancer (NSCLC). The drug is restricted to patients whose tumors have no epidermal growth factor receptor (EGFR) or anaplastic large-cell lymphoma kinase (ALK) mutations.

NACO Releases HIV Estimations 2017

The National AIDS Control Organization (NACO) has released the report HIV Estimations 2017. It is the 14th round in the series of HIV Estimations under National AIDS Control Programme (NACP). The first round of HIV estimation in India was done in 1998, while the last round was done in 2015.

The report highlights the significant achievement of National AIDS response on prevention as well as on treatment front but has also indicated that there is no place for complacency as country move forward on ambitious goal of attaining the 'End of AIDS' by 2030.

As per the report, in 2017, India had around 21.40 lakh people living with HIV (PLHIV) with adult prevalence of 0.22%. Around 87.58 thousand new HIV infections and 69.11 thousand AIDS related deaths happened in 2017 while around 22,675 mothers needed antiretroviral therapy (ART) for prevention of mother-to-child transmission of HIV. HIV Estimations 2017 corroborate the previous rounds in terms of characteristic of the HIV epidemic in India i.e., national prevalence and incidence remains low, but the epidemic is high in some geographical regions and population group. The report has noted that the rate of decline in annual new HIV infections has been relatively slower in recent years.

The report concludes that, overall, the impact of the programme has been significant with more than 80% decline in estimated new infection from peak of epidemic in 1995. Similarly, estimated AIDS related death declined by 71% since its peak in 2005. As per UNAIDS 2018 report, the global average for decline in new infections and AIDS related deaths from peak has been 47% and 51% respectively... (*Press Information Bureau, Ministry of Health and Family Welfare, September 14, 2018*)

FDA Approves Device for Treatment of Acute Coronary Artery Perforations

The US Food and Drug Administration (FDA) has approved a device intended to treat acute coronary artery perforations, or tears in the blood vessels of the heart. The PK Papyrus Covered Coronary Stent System is the first device approved by the FDA for this indication in 17 years.

Psoriasis Clearance Decreases as the Number of Comorbidities Increases

A study of patients with moderate or severe plaque psoriasis presented at the European Academy of Dermatology and Venereology Congress in Paris reported that overall, 64% of patients had one or more comorbid conditions at the start of treatment, and some of the patients had new comorbid diagnoses during follow-up. The proportion of patients who achieved disease clearance decreased as the number of comorbidities increased.

People with Hangovers have Impaired Cognitive Functions

People with hangovers demonstrate impairment in a variety of cognitive functions and everyday tasks, including driving, according to results of a systematic review and meta-analysis of 19 studies published online August 25 in *Addiction*. Various components of attention, memory and psychomotor performance were impaired during hangovers, including the ability to operate a vehicle

The Second CGRP Blocker Gets FDA Approval for Migraine

Fremanezumab is the second calcitonin gene-related peptide (CGRP) blocker for preventing migraine to be approved by the US FDA. Fremanezumab is a fully humanized monoclonal antibody, which binds to the CGRP ligand and blocks its binding to the receptor.

Patients with Psoriatic Arthritis are at Increased Risk of Type 2 Diabetes

The development of type 2 diabetes in an incident population of psoriatic arthritis (PsA) is significantly higher than in patients with psoriasis alone or in a general population, whereas the increased risk of cardiovascular disease in PsA and psoriasis is similar, says a study published online September 12, 2018 in the journal *Rheumatology*.

First AAP Policy Statement on Care for Transgender and Gender-diverse Children

In a policy statement published September 17, 2018 online in the journal *Pediatrics*, the American Academy of Pediatrics (AAP) has urged support and care of transgender and gender-diverse children and adolescents and states "Transgender and gender-diverse children face many challenges in life, but, like all children, they can grow into happy and healthy adults when supported and loved throughout their development." The statement

aims to help pediatricians and parents navigate health concerns of gender-diverse youth while advocating for ways to eliminate discrimination and stigma.

Topical Ruxolitinib Improves Atopic Dermatitis

A topical formulation of the JAK1/2 inhibitor ruxolitinib (1.5%) administered twice-daily led to dose-dependent improvement of 71.6% in atopic dermatitis in a phase II randomized trial presented at the European Academy of Dermatology and Venereology congress in Paris.

Study Shows Fewer Relapses with Fingolimod vs Interferon beta-1a in Pediatric Multiple Sclerosis

Among pediatric patients with relapsing multiple sclerosis, fingolimod was associated with a lower rate of relapse and less accumulation of lesions on magnetic resonance imaging (MRI) over a 2-year period than interferon beta-1a but was associated with a higher rate of serious adverse events.

New Guideline Recommends Weight Loss Strategies for Sleep Apnea Patients

The American Thoracic Society (ATS) has published a clinical practice guideline for the role of weight management in the treatment of adult obstructive sleep apnea (OSA). The Expert Panel made a strong recommendation that patients with OSA who are overweight or obese be treated with comprehensive lifestyle intervention consisting of a reduced-calorie diet, exercise or increased physical activity and behavioral guidance.

Asthmatic Individuals More Likely to Develop Obesity

A study presented at the European Respiratory Society International Congress in Paris, France has suggested that people with asthma are more likely to go on to become obese. Those who develop asthma as adults and those who have non-allergic asthma are at the greatest risk of obesity.

People Who Walk Just 35 Minutes a Day may have Less Severe Strokes

People who participate in light-to-moderate physical activity, such as walking at least 4 hours a week or swimming 2 to 3 hours a week, were twice as likely to have a mild stroke rather than a moderate or severe stroke compared to people who are physically inactive, according to a study published online September 19, 2018 in *Neurology*.

Infant Walkers are a Major Cause of Serious Injury

Infant walkers remain a dangerous and preventable source of injury for children, despite a US mandatory safety standard, increased public awareness and fewer older walkers in the home, according to a study published online September 17, 2018. Majority of infant walker-related injuries occur when the child falls down the stairs in a walker, with most injuries to the head and neck. The American Academy of Pediatrics (AAP) has called for a ban on the manufacture and sale of infant walkers in the United States.

NIH Funds Study to Prevent, Treat HIV Among Adolescents in Poor Countries

The National Institutes of Health (NIH) has awarded \$7.5 million for an international research program to prevent and treat HIV infection among adolescents and young adults in seven African countries and Brazil. The study, called Prevention and Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings (PATC3H), will support research to develop strategies to identify youth at risk of HIV infection and those living with HIV and to enroll them into medical care programs.

Complications are Common in Neonates Born to Obese Women without Hypertension or Diabetes

Maternal obesity, even in the absence of hypertensive disorders or diabetes, is an independent risk factor for significant neonatal morbidity and neurologic neonatal morbidity, as reported in a study published August 17, 2018 in *Obstetrics & Gynecology*. These neonates were more likely to have hypoxic-ischemic encephalopathy, hypothermia treatment and suspected sepsis.

ASCO Guidelines for Treatment of *C. difficile* Infection in Children with Cancer

The American Society of Clinical Oncology (ASCO) has published a guideline for the prevention and treatment of *Clostridium difficile* infection (CDI) in children and adolescents with cancer and pediatric hematopoietic stem-cell transplantation recipients in the *Journal of Clinical Oncology* online September 14, 2018. The guideline strongly recommends either oral metronidazole or oral vancomycin for the initial treatment of nonsevere CDI and oral vancomycin for the initial treatment of severe CDI. Fidaxomicin may be considered in recurrent CDI.

Nobel Prize in Physiology or Medicine 2018 Jointly Awarded to Cancer Researchers

The Nobel Prize in Physiology or Medicine 2018 was awarded jointly to James P. Allison and Tasuku Honjo "for their discovery of cancer therapy by inhibition of negative immune regulation."

The Royal Swedish Academy of Sciences said, "by stimulating the inherent ability of our immune system to attack tumor cells this year's Nobel Laureates have established an entirely new principle for cancer therapy."

National Initiatives Launched in India Emblematic of Actions Needed to Achieve SDGs: UN Chief

United Nations, India's ambitious programs such as 'Clean India' and "Educate the Girl Child, Save the Girl Child" are "emblematic" of the types of actions needed to achieve the Sustainable Development Goals (SDGs), UN Secretary General Antonio Guterres has said. Guterres, who begins a 3-day visit to India, said that while India still faces challenges, the country has a long history of innovation and leadership in developing programs to further social welfare and tackle inequalities.

"National initiatives such as those being launched in India are emblematic of the types of actions needed to achieve the SDGs, contributing to a common objective of more inclusive development," Guterres told PTI ahead of his first trip to India as the UN chief.

The SDGs, otherwise known as the Global Goals, are a universal call by the United Nations Development Programme (UNDP) for action to end poverty, protect the planet, improve health, education and ensuring that all people enjoy peace and prosperity by 2030. "The initiatives hold promise for expanding the availability of adequate sanitation, empowering women and girls, increasing access to quality education, and reducing inequality by shrinking the digital divide," Guterres said.

He said the various programs launched in India have already achieved impressive results. "I was very impressed to learn that, in the first 2.5 years of implementation, the Clean India campaign supported the construction of over 39 million household toilets working toward an open defecation free India by 2019,"

he said. On the Narendra Modi government's flagship *Beti Bachao, Beti Padhao* (Educate the Girl Child, Save the Girl Child) program, Guterres said the campaign has helped to substantially decrease school dropout rates among girls enhancing gender equality in education.

With the focus on digitisation, the UN chief said access to digital documents in India has never been higher with over 1.7 billion digitized, which can make the distribution of services like food ration cards much easier.

Risk of Subsequent Osteoporotic Fractures is Higher in Men

Men had a three-fold higher risk of sustaining a second fracture within the first year after their index fracture compared with men without a previous fracture (hazard ratio [HR] 3.3, 95% confidence interval [CI] 2.6-4.1), whereas among women with an index fracture, the risk of a second fracture was elevated but to a lesser extent (HR 1.8, 95% CI 1.7-2), according to a study presented at the American Society for Bone and Mineral Research annual meeting.

High Variability of Cardiometabolic Parameters is a Predictor of Mortality

High variability of fasting blood glucose and total cholesterol levels, systolic blood pressure and body mass index was an independent predictor of mortality and cardiovascular events according to a study of more than six million people with a follow-up period of a median of 5.5 years. The risk of outcomes increased significantly with the number of high-variability metabolic parameters. These findings are published October 1, 2018 in the journal *Circulation*.

A Limb Loss and Preservation Registry to be Established in the US

A new database supported by the National Institutes of Health and the Department of Defense aims to establish the number of people in the United States living with limb loss and to provide insight on their challenges and needs. The Limb Loss and Preservation Registry, expected to be operational in 2020 will be the first national registry of people who have lost limbs and promises to collect data that will improve prevention, treatment and rehabilitation efforts for this population.

