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Editorial

CDSCO has approved Itolizumab injection for marketing under Restricted Emergency Use of the drug for the treatment of Cytokine Release Syndrome (CRS) in moderate to severe Acute Respiratory Distress Syndrome (ADRS) patients due to COVID-19, subject to some conditions like informed consent of patients, a risk management plan, to be used in hospital set up only etc.

“This approval was on the basis of the Phase-II clinical trial data submitted by the firm M/S. Biocon. They have provided details of primary endpoint of mortality, other key end points of lung function such as improvement in PaO2 and O2 saturation were presented. Key inflammatory markers IL-6, TNF etc. were presented to have reduced significantly with the drug thereby preventing hyper-inflammation in COVID-19 patients” –as per press release by the Ministry of Health & Family welfare.

Itolizumab (rDNA origin), a monoclonal antibody is already approved for severe chronic plaque psoriasis and marketed by M/S Biocon since 2013. This is one more addition in the armamentarium to fight COVID with earlier approved Hydroxy Chloroquine tablet, Remdesivir injection and Favipiravir Tablet. Now we are having four medicines to fight against Covid-19 though many serious questions raised by the scientific community about scientific evidence of all four medicines.
Panel Recommends Renaming CDSCO for better International visibility

A high-level committee has recommended renaming India’s drug regulatory authority to give it national and international visibility. The present nomenclature of Central Drugs Standard Control Organisation (CDSCO) does not reflect the "true and extended functional character of the organisation" that regulates cosmetics, medical devices, diagnostics kits, blood banks, other than setting standards of drugs and regulation of imports, the panel said in its report. It has proposed three options — Central Medical Products Administration, India (CMPA), Central Medical Products Regulatory Agency, India (CMPRA), and National Medical Products Regulatory Agency, India (NMPRA) — to rename the agency.

It would be possible to rename CDSCO with an executive order by the government since the nomenclature is not mentioned under the Drugs and Cosmetics Act, 1940, the panel said.

It has also suggested that the organisation should be headed by a Medical Products Controller General of India, which should be at the level of additional secretary. At present the post of Drug Controller General (India) is equivalent to the level of joint secretary. “The changes are required to enhance the visibility and stature of the organisation at a global level,” the committee said in its report ET has seen a copy of the report. The panel has also recommended bringing ayurveda, yoga & naturopathy, unani, siddha and homoeopathy (Ayush) and medical devices under the ambit of the new organisation.

It has recommended five verticals — new drugs, cosmetics and clinical trials; biologicals; AYUSH; medical devices; and legal, enforcement and investigation. Each level should be headed by a controller at the level of joint secretary with decision-making powers for disposal of all technical matters, it said. There should also be a separate cadre for medical devices vertical. The committee has also recommended replacing the archaic 1940 Drugs and Cosmetics Act with a new Drugs and Cosmetics and Medical Devices Act. The government plans a major overhaul of the country’s drug regulatory authority in a bid to bring changes in line with global standards and to deliver services efficiently.

The committee has suggested a slew of measures to reduce the number of regulatory steps and time taken for approvals, to fast track introduction of new drugs in the country, and facilitate coordination between multidisciplinary institutions such as Indian Institute of Science and IITs for promoting innovation in new devices and diagnostic kits. Drug discovery and research in institutes are largely limited to academic purposes rather than translational research, it said.

There is a gap in the ecosystem in respect of research capability, skill, and use of technology, among others as compared to regulatory authorities of other countries like USFDA, TGA (Australia), MHRA (UK), and PMDA (Japan).

Source: Economic Times

Clozapine Risk of serious bowel complications

The FDA has strengthened the existing warning that constipation caused by clozapine (Clozaril®, Fazaclo ODT® and Versacloz®) can progress to serious bowel complications. Clozapine is indicated for schizophrenia. Clozapine affects how the intestines function in the majority of patients. The serious bowel complications can lead to hospitalization or even death if constipation is not diagnosed and treated quickly. Patients should contact a health-care professional if they have symptoms that can be associated with serious bowel problems such as nausea, vomiting or stomach pain. Health-care professionals should avoid co-prescribing clozapine with other anticholinergic medicines that can cause gastrointestinal hypomotility; advise patients frequently of the significant risk of constipation and lifethreatening bowel issues and the need to stay hydrated to prevent constipation; and monitor patients for symptoms of potential complications associated with gastrointestinal hypomotility such as nausea, abdominal distension and vomiting.

**Nitrofurantoin Risk of pulmonary and hepatic impairment and peripheral neuropathy**

Medsafe has announced that the use of nitrofurantoin in patients with significant renal impairment can cause pulmonary or hepatic impairment or peripheral neuropathy. Nitrofurantoin is a bactericidal antibiotic with activity exclusively in the urine. It is indicated for the treatment and prophylaxis of urinary tract infections. Significant renal impairment is a contraindication to nitrofurantoin. Adequate glomerular filtration and renal tubular secretion is needed to achieve an effective therapeutic concentration in the urine. While therapeutic doses of nitrofurantoin are rapidly excreted into the urine in patients with normal renal function, in patients with impaired renal function the plasma concentration increases and there is a higher risk of nitrofurantoin toxicity. The Medicines Adverse Reactions Committee reviewed the evidence for safe use of nitrofurantoin in patients with a greater degree of renal impairment. During the 10-year period to 2019, the Centre for Adverse Reactions Monitoring (CARM) received 150 adverse reaction reports in which nitrofurantoin was a suspect medicine. Of the reports, 46 were on interstitial lung disease, 17 were on hepatic reactions including hepatic cirrhosis and pneumonitis and 3 were on peripheral neuropathy.

Reference: Prescriber Update, Medsafe, March 2020 (www.medsafe.govt.nz/)

**Ondansetron Risk of oral clefts**

The MHRA has announced that exposure to ondansetron (Zofran®) during the first trimester of pregnancy is suggested to be associated with a small increased risk of the baby having a cleft lip and/or cleft palate. Ondansetron, a 5-HT3 receptor antagonist, is indicated for the management, prevention or treatment of nausea and vomiting. Recent epidemiological studies reported a small increased risk of orofacial malformations in babies born to women who used ondansetron in early pregnancy. Key evidence was an observational study of 1.8 million pregnancies in the US. The data were recently reviewed within Europe and considered to be robust. The decision to use ondansetron during pregnancy should be based on professional judgement, and in consultation with the woman who is informed of the potential benefits and risks of use, both to her and to her unborn baby.

Reference: Drug Safety Update, MHRA, 27 January 2020

**India registers 7.4 percent decline in maternal mortality ratio between 2015-17 and 2016-18**

The maternal mortality ratio in India declined from 122 in 2015-17 to 113 in 2016-18, a 7.4 per cent decline, according to a special bulletin released by the Registrar General of India, Union Health Minister Harsh Vardhan said on Friday.

He highlighted that the country has been witnessing a progressive reduction in MMR from 167 in 2011-2013, 130 in 2014-2016, 122 in 2015-17 to 113 in 2016-18.

On India's commitment to Sustainable Development Goals, Vardhan said that with this persistent decline, India is on track to achieving the SDG of 70 per lakh live births by 2030 and National Health Policy (NHP) target of 100 per live births by 2020, according to a health ministry statement.

Maternal mortality ratio (MMR) is the ratio of the number of maternal deaths during a given time period per 1,00,000 live births during the same time period.

The number of states which have achieved the SDG target has now risen from three to five. These five states are Kerala (43), Maharashtra (46) Tamil Nadu (60), Telangana (63) and Andhra Pradesh (65).

"There are 11 states that have achieved the target of MMR set by the NHP which includes the five states and Jharkhand (71), Gujarat (75), Haryana (91), Karnataka (92), West Bengal (98) and Uttarakhand (99)," the statement said.

Vardhan said that three states -- Punjab (129), Bihar (149) and Odisha (150) -- have maternal mortality ratio in between 100-150, while for five states, Chhattisgarh (159), Rajasthan (164), Madhya Pradesh (173), Uttar Pradesh (197) and Assam (215), the MMR is above 150, according to the statement.

The Union health minister congratulated the Rajasthan, which has shown the maximum...
decline of 22 points in MMR, Uttar Pradesh 19 points, Odisha 18, Bihar 16 points and Madhya Pradesh 15 points.

Telangana and Maharashtra have shown more than 15 per cent decline in MMR, while Odisha, Rajasthan, Andhra Pradesh, and Gujarat have shown a decline between 10-15 per cent, Vardhan said, adding that Karnataka, Assam, Jharkhand, Haryana, Madhya Pradesh, Uttar Pradesh and Bihar have witnessed a decline in maternal mortality ratio between 5-10 per cent.

"This success can be attributed to the intensive endeavour of the government in achieving impressive gains in institutional deliveries as well as focusing on quality and coverage of services under NHM through various schemes such as Janani Shishu Suraksha Karyakram, Janani Suraksha Yojana, and newer initiatives like Laqshya and Pradhan Mantri Surakshit Matritva Abhiyan," the minister was quoted as saying in the statement.

The government also envisaging rolling out the overarching SUMAN initiative including the midwifery initiative, assuring the delivery of maternal and newborn healthcare services encompassing wider access to free and quality services, zero tolerance for denial of services along with respectful maternity care, he said. PLB NSD

Ref. ET Health World

Readers Column..............

Dear Dr. Mandal,

Thank you for the newsletter. I liked it very much. Very informative on current topic-Covid. The fine details are presented well.

Regards.

N Sivaprasad
IPA MSB

Dear Sir,

Thank you very much for the issue. I do appreciate your endeavour in bringing out the issue during this adverse situation.

Regards.

Dr. H. K. Sharma
Dibrugarh University

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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.