Drug Information Bulletin

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Volume: 12 ***Number: 02*** ***22nd April 2018***

Content

Editorial

In order to improve access to health care to the population Government of India has declared a new scheme – "Ayushman Bharat - National Health Protection Mission (AB-NHPM)". The programme targets nearly 11 crore poor families or around 40% of the population. The scheme will provide Rs 5 lakh insurance cover per family and is intended to be extended over time into a universal programme for all citizens. The scheme was considered necessary as in-patient hospitalization expenditure has risen nearly 300% (NSSO-2015) in the last 10 years and more than 80% of the costs are met by out of pocket funds. Moreover, Out Of Pocket (OOP) expenditure in India leads to nearly 6 million families getting into poverty due to catastrophic health expenditures. AB-NHPM will have major impact on reduction of Out Of Pocket (OOP) expenditure. It is expected to increased access to quality health and medication. In addition, the unmet needs of the population which remained hidden due to lack of financial resources will be catered to. This may lead to timely treatments, improvements in health outcomes, patient satisfaction, improvement in productivity and efficiency, job creation thus leading to improvement in quality of life. However, a sector of the health care professionals are skeptical about its implementation.

For details: https://www.india.gov.in/spotlight/ayushman-bharat-national-health-protection-mission

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Drug Safety Alerts released by the Pharmacovigilance Programme of India (PvPI) during January-March 2018

Sl. No.	Suspected Drug	Indication	Adverse Reaction
1.	Levetiracetam	For treatment of myoclonus-generalised epilepsy with photosensitivity, idiopathic epilepsy – control of generalised tonic clonic seizures, postanoxic and post-encephalitic myoclonic epilepsy; epileptic encephalopathies; severe myoclonic epilepsy, absence seizure; rolandic epilepsy	Hypokalaemia
2	Dapsone	For treatment of leprosy, acne vulgaris, dermatitis, pneumocystic pneumonia	Erythema nodosum
3	Cefixime	For treatment of Otitis media, respiratory tract infections, uncomplicated UTIs, effective against infections caused by entero bacteriaceae, H. Influenza species	Hyperpigmentation

Medical colleges to have MDR-TB centres to acquire recognition

In order to prevent tuberculosis deaths and reduce rising cases of multi-drug-resistant tuberculosis (MDR-TB) in the country, the government has issued a mandate to the Medical Council of India (MCI). It has asked the MCI to mandate MDRTB centres while recognising private and government medical colleges.

Subsequently, the MCI has decided that private and government medical colleges will be recognised only if they have (MDR)-TB centres. This decision has been communicated to the health ministry and TB control programme officers. The order has been issued to all the state governments and state health departments. MDR-TB is a form of tuberculosis infection caused by bacteria that are resistant to treatment with at least two of the most powerful first-line anti-TB medications.

Dr Sanjeev Kamble, director of health services, said, “In India, there is a high prevalence of tuberculosis, and the number of MDR-TB patients is rising at an alarming rate. This is a major boost to end TB in the country. According to the order, all government medical colleges will have to set up 10 beds for male and female patients.”

Dr Suchitra Nagre, trustee and director of Maharashtra Institute of Medical Education and Research, added, “There are 21 medical departments in a college and tuberculosis department is one of them. To start any medical college, there already is a provision to have at least 10 beds for TB patients. Earlier it was mandatory that the college has to be started before the hospital. Later on, MCI instructed to start 300-bed hospital and then a medical college.”

Source: Drugs control.org

Probe Into Rajasthan Human Clinical Trial

The Central Drugs Standard Control Organisation (CDSCO) has sent a three-member team to Jaipur to inquire into an alleged unethical human clinical trial conducted by a pharma company at a private hospital in the Rajasthan capital, the Drugs Controller General of India (DCGI) said on Saturday.

Rajasthan Health Minister Kalicharan Saraf also constituted a three-member panel to probe into the alleged incident.

According to State officials, nearly two dozen people hailing from Rajasthan’s Churu and Bharatpur districts were allegedly subjected to the unethical human clinical trial for an osteo-ortho drug at the hospital.

DCGI Dr. S. Eswara Reddy, in Delhi, said, “We have sent a team of three officials to Jaipur to inquire into the matter along with the State drug controller.”

Mr. Saraf said a three-member panel, headed by an additional director-level officer has been constituted to probe the matter.

“Action will be taken, if lapses are found, the Health Minister said.

The panel on Saturday visited the hospital located in Vishwakarma Industrial Area to initiate the probe.

“Principal investigator and patients enrolled in the clinical trial were not available at the site. We have asked the hospital staff to provide necessary documents related to the trial,” Dr. Ravi Prakash Sharma, the head of the three-member probe panel constituted by the State government, said.

Source: The Hindu

WHO recommends testing before use of Sanofi's Dengue Vaccine

The World Health Organization (WHO) said on Thursday Sanofi's vaccine against dengue should only be used after testing on individuals to assess whether they have ever been exposed to the infection.

After a two-day meeting in Geneva, Switzerland, experts at the U.N. agency recommended extra safety measures for the medicine, sold as Dengvaxia.

"We have now clear information that the vaccine needs to be dealt with in a much safer way by using it exclusively in people already infected with dengue before," Alejandro Cravioto, Chair of the WHO's Strategic Advisory Group of Experts (SAGE) on Immunization, told reporters.

"It requires for the people to be tested through a system that is not currently available but that we feel will be developed in the next years," he said.

Sanofi said in a statement: "We are confident in Dengvaxia's safety and its proven potential to reduce dengue disease burden in endemic countries."

Sanofi also said it would "continue to work with the international public health community and endemic countries, to ensure the best usage of the vaccine."

The French drug maker warned in November that Dengvaxia, first approved in late 2015, could increase the risk of severe dengue in some cases in people who had not been previously exposed to the disease.

Mosquito-borne dengue is the world's fastest-growing infectious disease, afflicting hundreds of millions of people worldwide. It causes half a million life-threatening infections and kills about 20,000 people, mostly children, annually.

Dengvaxia, the world's sole licensed vaccine against dengue, is at the centre of a health scare in the Philippines where the government suspended its use last year amid safety fears.

The company has repeatedly said it knows of no deaths resulting from the medicine.

Joachim Hombach, executive secretary of WHO's SAGE group, said: "For us, the primary consideration is to assure our recommendation makes public health sense in terms of ensuring the use of vaccine will maximize public health benefit and minimize risk."

"It is very important we signal ways in which this vaccine could be used," he said, adding that it was up to the company to decide how to deal with this.

Hombach defended the WHO's initial recommendation that the vaccine could be used in children aged 9 and older in places where 70 percent of the population had previously been exposed to the virus, and were likely to benefit from the vaccine.

He said the WHO pointed out a gap in data on the use of the vaccine in people who had never been exposed to the virus, and asked Sanofi to study the impact of the vaccine on children who had never been exposed to the virus.

That study resulted in Sanofi's announcement last November.

Source: ET Healhworld

First novel oral anticoagulant reversal agent gains FDA approval

The FDA approved the use of idarucizumab (Praxbind) , to reverse the effects of the anticoagulant Pradaxa, or dabigatran etexilate

mesylate, in patients experiencing life-threatening or uncontrolled bleeding, undergoing urgent procedures or are in need of emergency surgery. Praxbind is the first reversal agent approved for a novel oral anticoagulant.

Ref. MD Magazine online

First patient enroles in Duchenne muscular dystrophy (DMD)

A Phase Ib trial was launched by Pfizer for its mini-dystrophin drug candidate PF-06939926 to treat patients with Duchenne muscular dystrophy. The company expects to enroll 12 patients in the trial for the drug, which it received as part of its acquisition of Bamboo Therapeutics, and aims to have preliminary results of the study in the first half of 2019.

Duchenne muscular dystrophy (DMD) is a genetic disorder characterized by progressive muscle degeneration and weakness. It is one of nine types of *muscular dystrophy*.

DMD is caused by an absence of *dystrophin*, a protein that helps keep muscle cells intact. Symptom onset is in early childhood, usually between ages 3 and 5. The disease primarily affects boys, but in rare cases it can affect girls.

Ref. Specialty Pharmacy Times

Scientists identify 40 potential drug targets in multiple myeloma study

Forty genes have been identified by investigators from London's Institute of Cancer Research that could become potential therapeutic targets. As reported in the journal Leukemia, the researchers were able to pinpoint coding and noncoding mutations linked to the development of multiple myeloma while examining whole-genome sequencing data from 765 patients.

Ref.: GenomeWeb Daily News

China Announces New Initiatives to Level the Playing Field for Innovative and Generic Drugs

China's Government will launch several incentives to enhance accessibility of innovative drugs, especially imported oncology drugs. The State Council, China's cabinet, has decided not to apply any tariff on imported drugs, and will include imported new drugs (especially urgently required oncology drugs) in the government-funded Basic Medical Insurance on a rolling basis. Companies can use their own testing reports to satisfy the import drug testing requirements and reduce time to clear customs. Innovative chemical drugs will enjoy a 6-year data exclusivity period. New drugs to be launched concurrently in China and globally will be entitled to a 5-year patent term extension.

Meanwhile, the government will encourage research and development of generics and enhance generics' quality and efficacy, the State Council announced on April 3, 2018, in its Circular on *Opinions Concerning Reforms of Policies to Improve the Supply and Utilization of Generics* (the "Circular No.20"). Circular No. 20 outlines a series of reforms to bolster generic drug makers, which will have significant impact on the market dynamics between innovative pharmaceutical companies and generic manufacturers.

These initiatives illustrate the Chinese government's intention to foster an innovation-conducive environment for multinational pharmaceutical companies. On the other hand, the Chinese government is keen to reduce the healthcare burden of Chinese patients by refining the regulatory framework for generics. While many hurdles for regulatory approval of innovator drugs have been eliminated, commercial success will require a sophisticated market access strategy that can fend off pressure from high quality generics. We recommend that multinational pharmaceutical companies carefully assess their competitive advantages and refine their commercialization strategy under these new initiatives.

Ref.: https://www.lexology.com