Editorial

India is going through the second wave of COVID during last few months. During this period huge number of our people has expired. During this period the healthcare professionals have tried their best to extend their best services with existing health infrastructure and manpower. But due to non availability of some medicines used for covid treatment in India and poor availability of oxygen the situation was uncontrolled at a time. Due to emergency measures taken by the authorities the situation is a little bit under control. There were non availability of some essential medicines, which was aggravated by black racketeering. Experts opined that this happened due to several reasons- Firstly the health authority could not foresee the consequences of second wave in India having more than 130 crores population. Secondly the health infrastructure is quite inadequate for such huge population as Govt. failed to spend adequate percentage of GDP(at least 6%) for health care. Thirdly health care structure is fragmented and is not working as a team, which is due to ego of superiority of some health cadres. The Drug Control administration is quite neglected by the authority as they are not considered as a part of health care team though they are working as emergency health care staff throughout the year and especially during the pandemic. The infrastructure and man manpower is quite inadequate in India to manage huge production of drugs, huge number of wholesale and retail sale outlets and huge network of supply chain. Hope this will be an eye opener for the policy makers and the administration responsible for implementation to make India able to face such pandemic in future.

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Serum Institute of India seeks DCGI's nod to manufacture Covid vaccine Sputnik V

The Serum Institute of India (SII) has applied to the Drug Controller General of India (DCGI) seeking permission to manufacture the Sputnik V Covid-19 vaccine for examination, test and analysis at its licensed Hadapsar facility in Pune, official sources said on Thursday.

The Pune-based firm has collaborated with the Gamaleya Research Institute of Epidemiology and Microbiology, Moscow for developing Sputnik V at its Hadapsar facility.

On May 18, the SII had also applied to the Review Committee on Genetic Manipulation (RCGM), Department of Biotechnology seeking clearance for the import of strains or seed lots and cell banks and for carrying out research and development, the sources said.

The RCGM has raised certain queries over the SII's application and sought a copy of the material transfer agreement between the Pune-based firm and the Gamaleya Research Institute of Epidemiology and Microbiology.

"The Serum Institute of India (SII) put up an application to the Drugs Controller General of India (DCGI) on Wednesday seeking permission to manufacture Covid-19 vaccine Sputnik V for examination, test and analysis at its licensed Hadapsar facility," an official source said.

Once these approvals are received, the SII plans to seek restricted emergency use permission for the vaccine in India.

Russia's Sputnik V vaccine is currently being manufactured by Dr Reddy's Laboratories in India.

Source: ETEhealth World

Reliance submits proposal for potential Covid drug

Reliance Industries Ltd's R&D arm has proposed the use of Niclosamide - the drug used to treat tapeworm infestation - for treating Covid-19 patients.

Niclosamide, a drug on the World Health Organisation's list of essential medicines, has been used to treat tapeworm infestation for more than 50 years. The oral antiviral drug was also used to treat patients during the SARS outbreak of 2003-04.

"The company submitted a proposal for the application of Niclosamide as a potential drug against Covid-19," the firm's latest annual report said.

The company however did not say if it plans to manufacture the drug or would use it to treat Covid patients at hospitals run by the group.

The government has already given clearance for the Phase 2 clinical trials of Niclosamide in Covid-19 treatment in adult patients.

For details:

India signs deal with domestic vaccine maker Biological-E for 300 million doses

India's government said on Thursday it has inked a deal with domestic vaccine maker Biological-E for 300 million Covid-19 vaccine doses for 15 billion rupees ($205.62 million), the first such order for unapproved shots.

The vaccine, which is currently undergoing phase-3 clinical trials, is likely to be available in the next few months, the health ministry said in a statement.

Biological E., which also has a separate deal to produce about 600 million doses of Johnson & Johnson's Covid-19 shot annually, said on Tuesday it entered into a licensing agreement with Providence Therapeutics Holdings to manufacture the Canadian company's mRNA Covid-19 vaccine in India.

Biological-E will run a clinical trial of Providence's vaccine in India and seek emergency use approval.
India, world's second most populous country has suffered a disastrous second wave of infections that is only now abating.

Health experts India needs to carry out mass vaccination of its 1.3 billion people to reduce the impact of subsequent waves.

Prime Minister Narendra Modi’s government has drawn criticism for a slow vaccine rollout even though India is one of the world's biggest manufacturers of doses.

Earlier in May, Biological-E Managing Director had told Reuters that the company plans producing 75 million to 80 million doses a month from August.

Source: Reuters

**DCGI Exempts Bridging Trials and Batch Testing for Imported Covid-19 Vaccines**

The Drugs Controller General of India (DCGI) has exempted the requirement of conducting post approval bridging clinical trials and the requirement of testing of every batch of the vaccine by the Central Drugs Laboratory (CDL), Kasauli if the vaccine batch or lot has been certified and released by National Control Laboratory of Country of Origin.

This is with reference to the already approved Covid-19 vaccines for restricted use by the US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO emergency use listing.

This has been done in light of huge vaccination requirements in India and in the wake of the recent surge of Covid-19 cases.

This move will cater to the demand for imported vaccines to meet the national requirements even though the domestic manufacturing of Covid-19 vaccines is getting augmented.

As per a DCGI notice, “In partial modification of this office notice of even number dated April 15, 2021 as per the recommendation of National Expert Group on Vaccine Administration for Covid-19 (NEGVAC), it has been decided that the approval of Covid-19 vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) and which are well established vaccines from the stand point that millions of individuals have already been vaccinated with the said vaccines, the requirement of conducting post approval bridging clinical trials and the requirement of testing of every batch of the vaccine by the Central Drugs Laboratory (CDL), Kasauli can be exempted, if the vaccine batch or lot has been certified and released by National Control Laboratory of Country of Origin.”

“However, scrutiny and review of their summary lot protocol and certificate of analysis of batch or lot shall be undertaken by CDL Kasauli for batch releases as per the standard procedures and the requirement of assessment on the first 100 beneficiaries for 7 days for safety outcomes before the vaccine is rolled out for further immunization programme along with other procedures for filing of applications and timelines for processing of the applications etc as laid down in the notice dated April 15, 2021 shall remain the same,” the DCGI notice further stated.

**Government imposes restrictions on export of Amphotericin-B injections**

The government on 2nd June 2021 imposed curbs on the export of Amphotericin-B injections that are used for the treatment of mucormycosis or black fungus infections.

According to a notification issued by the Directorate General of Foreign Trade (DGFT), the export of the injections has been put in the restricted category.

This means that an exporter would need permission or licence from the directorate for its outbound shipments.

"The export of Amphotericin-B injections... is restricted, with immediate effect," it said.

**DCGI approves Covaxin clinical trials for children aged 2-18 years**

The Drugs Controller General of India (DCGI) cleared Bharat Biotech's Covaxin
trials on children from two to 18 years on Thursday (May 13). Bharat Biotech said its phase II and III trials would be carried out on "525 healthy volunteers". The trial will involve two vaccine doses injected on Day 1 and Day 28. This is the first time in India that a COVID vaccine will be tested on children.

**OBITUARY**

During last few months we have lost the following members of IPA- Bengal Branch. May their souls rest in peace. Our heartfelt condolences to the bereaved family!

- Dr. Amal K. Bandyopadhyay
  BEN/LM/0144
- Dr. Moitreyee Mandal
  BEN/LM/0069
- Mr. Dipak Sarkar
  BEN/LM/0242
- Dr. Jayanta K. Das
  BEN/LM/0081
- Mr. Hrishikesh Saha
  BEN/LM/0174
- Mr. Anup Pal
  BEN/LM/
- Mr. R.N. Mani
  BEN/LM/0197
- Mr. Partha P. Das
  BEN/LM/0295

According to a government statement, the drug regulator accepted the recommendation of an expert committee on vaccines after careful thought.