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NEWS LETTER
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India, US Collaborating in Diagnostics to Fight Covid-19: Ambassador Sandhu

India and the US are working together on combating the deadly coronavirus and collaboration is underway in the areas of diagnostics and therapeutics of the disease, which so far has taken the lives of more than 20,000 people globally, according to the Indian envoy here.

The deadly coronavirus that first emerged in China's Wuhan city has drastically spread around the world, infecting 471,518 people and causing 21,293 deaths, according to the Johns Hopkins coronavirus tracker.

"In the present context of COVID-19 pandemic, close collaboration in the areas of diagnostics and therapeutics of the disease is underway, India's Ambassador to the US, Taranjit Singh Sandhu told PTI. "India and the United States have had a long-standing productive partnership in the healthcare sector, especially between the research institutions and industries of both countries, he said.

Under the existing bilateral collaboration in healthcare sector- the National Institute of Allergy and Infectious Disease in the US shared the important reagents with the Translational Health Science Technology Institute in Gurgaon.

Such cooperation is expected to play a big role in developing new therapeutics and testing reagents for the COVID-19.
In addition, India-based vendors of American companies are in touch with the Indian Council of Medical Research to engage and enhance the capabilities for COVID-19 test in India.

"The US will work shoulder to shoulder with India to combat the COVID19 outbreak. Together, we can safeguard our citizens and people everywhere," Acting Assistant Secretary of State for South and Central Asia, Alice G Wells, said in a tweet referring to the cooperation between the two countries.

The United States, she said, stands united with India and echoes Prime Minister Narendra Modi's call to keep up their fighting spirits. Cooperation and collaboration in the sector of coronavirus was also discussed between the two countries when President Donald Trump met Prime Minister Modi in New Delhi last month.

Trump and Modi also hailed a bilateral Memorandum of Understanding (MOU) that seeks to promote access to high quality, safe, effective, and affordable medications for US and Indian consumers. In 2012, the Center for Disease Control collaborated with National Centre for Disease Control to establish Epidemic Intelligence Service (EIS) Programme.

This post-graduate field-training programme, modelled after the CDC's Epidemic Intelligence Service (EIS), has expanded to two additional hubs at the WHO India Country Office and at the India Council of Medical Research (ICMR) and the National Institute of Epidemiology.

According to the CDC, it has helped strengthen national surveillance for detecting and responding to healthcare associated infections and emerging antimicrobial resistance threats in health facilities in 22 states.

A public-private partnership helped increase capacity to diagnose, treat, and care for multidrug-resistant TB (MDR-TB) patients through virtual platforms. In Mumbai, the CDC helped the municipality and local partners, launch an Airborne Infection Control Unit to reduce healthcare-associated transmission of MDR-TB.

The CDC has helped India in implementing a surveillance system in 35 hospitals and 22 states for healthcare associated infections. It has evaluated 346 laboratory facilities across the country to identify needs and trained more than 1,700 laboratorians on quality diagnostic testing/reporting of priority diseases. (Source: Business Standard)

Pune Lab Gets Approval to Make Hundred Thousand Diagnostic Kits for Covid-19

Pune, India: Pune based molecular diagnostics company Mylab Discovery Solutions and Germany's Altona Diagnostics have been approved by the Indian Council of Medical Research (ICMR) to make diagnostics kits to test people for Covid-19.

The two companies received approval to mass manufacture the kits after they received commercial approval from Indian FDA/ Central Drugs Standard Control Organisation (CDSCO).

"ICMR NIV Pune has completed evaluation of nine non-US FDA EUA/CE IVD kits. Only test kits with 100% concordance among true positive and true negative samples have been recommended for commercial use in India," the council said in a statement.

Currently, the probes required for testing a patient for Covid-19 are procured from the USA and these kits will continued to be used after due approval from Drug and Controller General of India (DCGI) and intimation to ICMR.

"Even early stage infection can be detected with highest accuracy as has been seen during tests at ICMR," Shailendra Kawade, executive director of Mylab, said in a statement.

For the government labs, it would cost nearly Rs 1,200 per test kit, about one-fourth of what ICMR pays, and the terms are still being worked out for private labs, he added.

"The support and immediate action from regulatory bodies (CDSCO/FDA), evaluation centre of ICMR,

NIV, Biotechnology Industry Research Assistance Council (BIRAC) and the central and state governments is commendable," Hasmukh Rawal, managing director, Mylab Discovery Solutions, said. (Source: TNN)

Sun Pharma's Hypertension Drug In Shortage In US Due To Shortfall In Active Ingredients

Drugmaker Sun Pharmaceutical Industries Ltd reported a shortage of its generic version of hypertension drug pindolol in the US due to a lack of pharmaceutical ingredients, but said the shortfall did not stem from China.

Indian companies are the main supplier of generic drugs to the world and procure almost 70 per cent of the active pharmaceutical ingredients (APIs) for their medicines from China.

The coronavirus outbreak has disrupted international businesses dependent on Chinese supplies and industry experts expect Indian generic drugmakers to face supply shortages from China if the epidemic drags on.

"At the moment, we haven't seen any major disruption in API supplies due to the coronavirus outbreak in China," Sun Pharma said in an e-mail on Monday, without giving details on the reasons for the shortfall in pindolol ingredients.

"We have sufficient inventory of API and raw materials for the short term," it added.

Sun Pharma, however, reiterated that there had been some impact on supplies for a few APIs, but did not identify the drugs that might be affected.

Last week, the US Food and Drug Administration announced the first coronavirus-related drug shortage in the US, but declined to name the drug in question, leaving industry players debating which medicines were at risk.

Pindolol, sold under the brand name Visken by Novartis , is an orally administered drug used alone or with other medications to treat high blood pressure.

Other generic drugmakers in India say they currently have enough API supplies from China to cover their operations for up to about three months. (Source: Business Line)

Johnson & Johnson Plans to Conduct Human Trials for Coronavirus Vaccine by September

Washington: Johnson & Johnson has said it had selected a lead candidate vaccine for the new coronavirus that would move to human trials by September and could be ready for emergency use by early next year.

The pharmaceutical company has signed an agreement with the US government's Biomedical Advanced Research and Development Authority to invest $1 billion in the effort, it said in a statement on Monday.

J&J began working on the vaccine under investigation — Ad26 SARS-CoV-2 — in January using the same technology it used to develop a candidate vaccine for Ebola.

Paul Stoffels, the company's chief scientific officer, said his team had combined a common cold virus incapable of replicating with parts of the coronavirus, and hoped it would trigger a human immune response.

"We had several vaccine candidates which we tested in animals in order to choose the best one, that took 12 weeks, from January 15 to today," he said.

They also had to evaluate which candidate vaccine could be upscaled, "to make sure on the one hand it works, and on the other hand, we can make a lot of it," he added.

Though there has never before been a successful human vaccine for any virus belonging to the coronavirus family, Stoffels said he was confident of achieving this milestone because J&J was working with the same team that had developed a candidate vaccine for SARS, which killed almost 800 people between 2002-2003.

The team's work was discontinued once the SARS outbreak was brought under control and interest was lost in bringing the vaccine to market.

"The question is, can you protect for infection or can you protect for severe disease? In many diseases, like in influenza, when you vaccinate on an annual basis, you protect for severe disease, you don't always protect for infection," said Stoffels.

J&J would also need to determine that the vaccine doesn't backfire and give people a higher chance of getting the disease.

The company said it was expanding its global manufacturing capacity both in the US and in other countries, to help it supply more than a billion doses of its vaccine around the world.

J&J is also working on antiviral treatments against the coronavirus.

Separately, the US pharmaceutical Moderna has already moved into human trials for its vaccine candidate, as has China's CanSinoBIO.

There are currently no approved vaccines or treatments for the disease.

Several treatments are being investigated, including the antiviral remdesivir and antimalarial drugs chloroquine and hydroxychloroquine, but it is not yet clear whether they add anything to standard care. (Source: News18)

Anti Malaria Drug Hydrooxychloroquine Now a Schedule H1 Drug

Anti malaria drug Hydrooxychloroquine has now been declared a Schedule H1 Drug by Ministry of Health and Family Welfare after reports of hoarding coming from across the country.

This comes after Indian Council of Medical Research or ICMR approved hydrooxychloroquine as a prophylactic for specific people including healthcare workers and family members in immediate contact of a COVID-19 person.

A Schedule H1 drug means it can only be sold on a prescription by a qualified medical professional. It also means that its box will have a warning label of only prescription sale and against self-medication, and chemists would need to maintain records of sale.

"Whereas, the Central Government is satisfied that the drug 'Hydroxychloroquine' is essential to meet the requirements of emergency arising due to pandemic COVID-19 and in the public interest, it is necessary and expedient to regulate and restrict the sale and distribution of the drug 'Hydroxychloroquine' and preparation based thereon for preventing their misuse."

ICMR's approval for the drug has come under question as most studies on the efficacy of the drug are small. While promising, clinical research of the drug is on going in multiple places, with some studies indicating it could turn toxic. There was also a recent death reported in the US after a man over dosed on the drug. This came after the US President Donald Trump over sold the drug as the most promising. (Source: Dailyhunt)

ICMR Warns Against Using Hydroxychloroquine Sans Prescription

New Delhi, Raman Gangakhedkar, senior scientist at the Indian Council for Medical Research (ICMR), on Tuesday warned against using a drug called hydroxychloroquine against coronavirus without medical prescription.

Speaking to the media at a press conference, Gangakhedkar said, "Do not go for COVID-19 test just on suspicion or consume hydroxychloroquine medicine without a doctor's prescription because the medicine has its side effects. Observe social distancing even at home with your family member's." Gangakhedkar also said that although the ICMR approved to give hydroxychloroquine in some cases but it was still at ean xperimental level.

"The empiric use of hydroxychloroquine for prophylaxis of SARS-Cov-2 infection is recommended only for asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID-19 and asymptomatic household contacts of laboratory-confirmed cases," he said. Gangakhedkar added that the ICMR would not recommend the medicine for children below 15 years and elderly people above 60 years of age as it had many side effects on kidney and heart.

"There is sufficient access to testing so there is no need to panic. It is not just government's responsibility to keep you healthy but you will have to be responsible for your own health. Therefore, follow all the instructions of social distancing given by the government," said the doctor.

There are now 118 government laboratories included in the ICMR network for COVID19 testing. The network has capacity to test 12,000 samples a day. "On an average we have been testing at least 1,350 samples per day," Gangakhedkar informed the media.

Besides this, 22 private laboratory chains with about 15,500 collection centres have been registered with the ICMR till today for conducting tests for novel coronavirus, Gangakhedkar said. According to the mathematical model of transmission of COVID-19, if social distancing is followed sincerely, the threat of coronavirus transmission could be reduced by 62 to 90 per cent in a week, Gangakhedkar said.

Lav Agarwal, Joint Secretary at the Ministry of Health and Family Welfare, was also present at the press conference. He said the ministry has asked states to make dedicated COVID-19 hospitals. "As per the information we've received so far, work has started at the state level in Gujarat, Assam, Jharkhand, Rajasthan, Goa, Karnataka, Madhya Pradesh and Jammu iamp; Kashmir,"- Agarwal said. (Source: IANS)