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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 51 **Issue No. 17** **01 to 07 May 2020**

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Proposed 15% COVID-19 Import Tax on Chemicals will have drastic impact on availability of many formulations: IDMA Representation

The Association has made the following representation on 30th April 2020 to Shri P Raghavendra Rao, IAS, Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi with copies to Dr P D Vaghela, Secretary, Department of Pharmaceuticals, Dr Anup Wadhawan, IAS, Secretary, Department of Commerce, Ms Shubhra Singh, IAS, Chairman, National Pharmaceutical Pricing Authority, New Delhi on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We thank you and the Government of India for your support in the midst of the massive outbreak of COVID-19. We are aligned with the measures taken by the Government of India to contain the spread of Coronavirus and support these initiatives wholeheartedly. The Indian pharmaceutical industry is fully committed to meet the challenges posed by Covid-19.

We understand that there are recommendations from Chemexcil and FICCI for imposing 15% COVID-19 import tax on chemicals and other products from May 2020.

This will have a drastic impact on availability of many formulations as chemicals are important constituents. We request you to consider the following:

1. The increase in import tax on chemicals covered under Chapters 28, 29 and a few other related chapters will increase the cost of inputs significantly. The prices of formulations in India are covered by Drugs (Prices Control) Order 2013 (DPCO) and the prices cannot be increased beyond a stipulated extent. Such an increase in input cost will adversely impact viability of formulations leading to shortages in the market.
2. The notion of import surge and dumping, in the said proposals, is wrongly placed. It is due to lockdown in India and elsewhere that imports of chemicals and other products have been lower in this month. However, once the lockdown is relaxed and full-fledged operations start, there will be normalisation in demand correcting the inventory levels. This may not be construed as dumping by foreign manufacturers.
3. It is not pragmatic administratively to bring together all imports, under various HS Code chapters, for the purpose of levying additional duty much less will it serve the desired objectives mentioned by Chemexcil and FICCI. In case, any dumping takes place, it will need to be handled at micro level for the API or Key Starting Material in question and not by clubbing with other items that include items not even manufactured in India. Instead, monitoring would have to be done on a case to case basis if dumping takes place and will ensure timely imposition of trade measures such as anti-dumping or safeguard duty, as the case may be.
4. Further levying higher duty on all imports of chemicals instead of specific cases will lead to distortion in the market so also misallocation of resources.
5. This has to be looked at from the perspective of exchange rate wherein the dollar has appreciated to the rate of Rs 78 for one dollar today, as against Rs 65 last year.

The Pharmaceutical operations are impacted on account of increase in input cost transportation cost, lower productivity of operations, and increase in import cost due to higher exchange rates. This will be further compounded with additional import duty on chemicals and related products having serious impact on the financial operations of the company in the challenging environment.

The entire Pharmaceutical Industry is united in objecting to this proposal as it will have a significant impact on the viability of Pharma operations and hence availability of medicines in the market, especially in these challenging times."

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IDMA Request to DGFT to allow export of Ethyl Alcohol based Hand Sanitizers - reg.

The Association has made the following representation on 5th May 2020 to Shri Amit Yadav, IAS, Director General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce & Industry, New Delhi with copies to Dr P D Vaghela, Secretary, Department of Pharmaceuticals and Dr Anup Wadhawan, Secretary, Department of Commerce, New Delhi (in response to DGFT Notification No.53/2015-2020 dated 24th March 2020) on the above subject:

"We thank you and the Government of India for your support in the midst of the massive outbreak of COVID-19. We are aligned with the measures taken by the Government of India to contain the spread of Coronavirus and support these initiatives wholeheartedly. The Indian pharmaceutical industry is fully committed to meet the challenges posed by Covid-19.

India is the largest supplier of generic medicines by volume in the world. Due to the pandemic, our economy is dipping. As stated by our Hon'ble Prime Minister Shri Narendra Modiji, we must ensure 'Jaan Bhi, Jahan Bhi' and try our best to revive the economy.

India is the largest producer of sugar after Brazil. The wastage/by product of the sugar industry is molasses. Ethyl Alcohol is produced from molasses. There are about 3000 distilleries in India. For example, there are three small and two big distilleries namely Hamira Distillery (Jagatjit Industries Limited) distillery, Rana Sugar Mill and Pioneer Chemical in Punjab. The small distillery (like Pioneer) is making 125000 litres of Alcohol per day. The estimate of Hamira and Khasa distillery is 10 times more than this. Distilleries are functioning in many states such as Haryana, UP, Gujarat and in South India due to availability of molasses.

During this lockdown sale of alcoholic drinks such as Whisky is low, but the distilleries due to their continuous process continue producing molasses. Now they are full of Alcohol and as the molasses are maturing, the distilleries are overloaded with alcohol and are almost running out of space to store these molasses and alcohol. If the alcohol is not utilized, the lack of storage capacity of the distilleries will compel them to shut down and the molasses will become very hazardous due to enzymatic reactions. This reaction cannot be stopped. The alcohol can be best utilised for hand sanitizers. Isopropyl Alcohol, another base for hand sanitisers has been found to be impure and with many side effects. Hence Ethyl Alcohol is the preferred and ideal base for making hand sanitizers.

Now the presumed shortage of hand sanitizers in India is only a logistics issue with transporters not being able to work to carry goods from factory, couriers not functioning due to lack of staff etc, otherwise there is no shortage of hand sanitizers made of Ethyl Alcohol.

Prohibition of export which does not serve any purpose should be removed. Export of hand sanitizers was prohibited by DGFT Notification No. 53/2015-2020 dated 24.03.2020. The decision to prohibit export was valid in end March as we had to ensure sufficient supplies for our domestic market.

Now with the easing of movement of transporters, the Indian Pharma industry is ready to serve the nation with huge quantities if ordered. Many Pharma companies have export orders from overseas buyers in USA, Europe, Africa etc which need to be fulfilled. With the excess production of molasses as mentioned above and thus availability of Ethyl Alcohol in large quantity, it is the right time to remove the ban on export of hand sanitizers.

We seek your indulgence and request you to allow the pharma industry to export sanitizers made of Ethyl Alcohol. With warm regards".

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Covid-19: New Paradigms For Disease Management

Dr. Vandana B. Patravale, *Professor, Pharmaceutics, Institute of Chemical Technology, Mumbai*

Dear Reader,

The continuing threat of Corona virus Disease 2019 (COVID-19) to global health has posed critical challenges to public health, research, medical fraternity, and governments worldwide. Following the emergence of COVID-19 in the city of Wuhan in the Hubei province of China in December 2019, the number of infected individuals has been on a constant rise outside China with more than a million positive cases. With the centre of global outbreak now shifting to Europe with Italy currently having reported the second highest number of cases (>41,000) and highest mortality (3,405) followed by Spain, Iran (>19,000), Germany (>17,000) and USA (>14,000), the WHO has announced it as a global pandemic. According to the official sources, more than 300 cases have been reported in India with 7 deaths so far. Citing these statistics, several countries have halted flights from COVID-19 hit regions, imposed lockdowns in several cities, suspended major public events, shutdown public places including schools, gyms, museums, clubs, etc and are urging their citizens to self-quarantine.

Corona viruses are comparatively large viruses consisting of a single-stranded positive-sense RNA genome encapsulated within a membrane envelope that has crown-like glycoprotein spikes on its surface, leading to the nomenclature Corona virus.They have four sub-groups viz alpha, beta, gamma, and delta of which alpha and beta forms have been commonly found to infect humans. With its first recognition in mid-1960's, seven coronaviruses have been noted for causing human infection, latest being the beta form of novel coronavirus which causes Severe Acute Respiratory Syndrome (SARS) and is termed as SARS-CoV-2. Recent information suggest that SARS-CoV-2 is the most transmissible/contagious among all. The most common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, multiple organ failure, and even death.

Considering the fact that there are no approved treatments or vaccines for this disease, the current situation demands all hands on deck to combat this COVID-19 pandemic. As an immediate research action, the WHO has emphasized on mobilizing research on rapid point of care diagnostics for use at the community level to quickly identify and treat sick people. Currently, SARS-CoV-2 RNA in nasopharyngeal swab, oropharyngeal swab and/or sputum samples is detected by a reverse-transcription polymerase chain reaction which may take up to 48 hours for confirmation in government approved laboratories.

Dr. Vandana B. Patravale *is currently a Professor of Pharmaceutics at the Institute of Chemical Technology, Mumbai, India. Her areas of research include development of nano-carriers with major emphasis on malaria, cancer and neurodegenerative disorders; medical device development, nano-diagnostics and nano-vaccines. She has over 200 refereed publications, 11 granted patents, 24 patents in pipeline and 2 trademark registries. She has published 2 books and 25 book chapters with international publishers. Dr. Patravale has been active in teaching, research and service throughout her career. She was awarded the Kukreja Oration award 2020, APTI's Dr. Manjushree Pal Best Pharmaceutical Scientist Award 2019, Shri Amrut Mody distinguished researcher award 2018, OPPI women scientist award 2015, Bill Melinda Gates grant award 2015, Best Pharmaceutical Scientist award 2014, VASVIK award 2013, Veneto nanotech award 2013, APTI best teacher award 2012, Fellowship of Maharashtra Academy of Sciences, 2011 and K.H. Garda Distinguished researcher award 2009.*

She is an International advisory committee member of AAPS and Vice President, CRS-Indian chapter. She is actively collaborating with researchers as well as industries within the country and abroad and has completed Indo-Swiss, Indo-Japan, Indo-UK projects. She has been awarded major grants from the Indian Government, focusing on nanotechnology based product development. She has transferred many technologies to various industries including technology on drug eluting stents, which is being marketed in more than 60 countries.

Thus, a lot of research has gone into the development of cutting-edge testing kits that can enable rapid diagnosis of COVID-19. Several countries including the US, China, South Korea, Japan and Italy have been using testing kits that take minutes to a few hours to produce results. Blood tests/finger prick tests that can detect antibodies produced in response to infection, nasal swab tests that detect DNA given off by the corona virus, face mask tests, and breath analyzers that can detect disease-specific biomarkers like DNA, RNA, proteins and fat molecules are currently under trial for rapid detection of COVID-19. In response to the COVID-19 outbreak in India, Indian Council of Medical Research (ICMR)-National Institute of Virology (NIV), Pune served as the apex laboratory to optimize the conventional and real-time PCR assays to test the samples of suspected cases. The Department of Health Research (DHR) / ICMR has commissioned 57 laboratories for COVID-19 testing in India. In addition, following the Indian Government's decision to allow accredited private labs to test for COVID-19, the Drugs Controller General of India (DCGI) has given 8 companies (international and Indian) the test licence to carry out COVID-19 diagnostic tests in the country.

In an attempt to improve the standard of care treatment approaches and evaluate the effect of adjunctive and supportive therapies to find a befitting solution to this pandemic, multicentre clinical trials are going on in multiple countries, the information on which is being constantly updated on the International Clinical Trials Registry Platform on the WHO website. The registry has a total of 508 trials on catering to different aspects of COVID-19 in the database, as of now, with the numbers increasing each day. Severe acute respiratory failure has been the most critical condition responsible for fatal outcomes of the infection and hence major clinical trials are focusing on dealing with evaluation of different therapeutics to manage this condition. Given the lengthy process of new drug development, the current strategy for immediate treatment of COVID-19 is drug repurposing. Glucocorticoid therapy using methylprednisolone, repurposing of anti-retrovirals like lopinavir, ritonavir, ribavirin, danorevir and a combination of these with/without interferon alpha-1b are being tested for their safety and efficacy to treat the pneumonia caused by SARS-CoV-2. Remdesivir, an experimental antiviral drug is being studied in hospitalized adult patients with mild/moderate as well as severe respiratory disease. Favipiravir is another drug which is being tested for its efficacy in COVID-19 caused pneumonia. Use of mesenchymal stem cells alone and in combination with ruxolitinib, recombinant cytokine gene-derived protein injections, recombinant interferons, antibodies, convalescent plasma and immunoregulatory therapy are also being investigated for treating pneumonia arising from COVID-19. Chloroquine, used to treat malaria and amebiasis, and hydroxychloroquine, a less toxic metabolite of chloroquine, used to treat rheumatic diseases, are also being repurposed and investigated for COVID-19 treatment. In addition, numerous traditional Chinese medicines like Lianhua-Qingwen and Jingyebaidu capsules/granules alone, and in combination with western medicines, different hormone doses, and interferon atomization are also proposed for trials and form a major chunk in the prospective registration list with pending trail recruitment. One of the recent findings suggests the use of healed COVID-19 patients' plasma for treating the severe cases. Similar strategies are being followed in India too with the ICMR approving the use of retroviral drugs to treat some of the coronavirus patients after scientific scrutiny. API manufacturer Lasa SuperGenerics has teamed up with the Institute of Chemical Technology, Mumbai to develop the anti-viral drug Favipiravir, which is being tested as a treatment for COVID-19.Cipla has also come forward with Council of Scientific & Industrial Research-Indian Institute of Chemical Technology (CSIR-IICT) to manufacture three promising anti-viral compounds (Favipiravir, Remdesivir and Baloxavir) to treat COVID-19. However, India will not be a participant in the WHO's clinical trials for COVID-19 as of now owing to the very small sample size.

Another major approach to curb this pandemic has been towards the development of a vaccine to protect against COVID-19. The first phase 1 clinical trial evaluating an investigational vaccine, called mRNA-1273, developed by The National Institute of Allergy and Infectious Diseases (NIAID) and a biotechnology company Moderna, Inc., has begun at Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle.This open-label trial involves 45 healthy adult volunteers aged 18 to 55 years and evaluates the safety and ability to induce an immune response at different doses. As per the WHO, 41 candidate vaccines against COVID-19 are being investigated, most of them being in the pre-clinical stage. The developers of these vaccine candidates include major universities like Baylor College of Medicine, University of Oxford, University of Queensland and pharmaceutical companies like ZydusCadila, GlaxoSmithKline/Clover Biopharmaceuticals Inc., Janssen and Sanofi Pasteur to name a few. Pune-based Serum Institute of India has partnered with the US-based drug research company,

Codagenix to develop a live-attenuated vaccine platform against several viral diseases including COVID-19. At the same time, it is important to remember that testing vaccines and drugs without analyzing the safety risks could bring unnecessary setbacks and discouragement during this crisis and in the future.

Every outbreak provides an opportunity to gain important information about emerging and re-emerging infectious pathogens and demands for a coordinated and multi-disciplinary approach to curb it. There is a need for constant surveillance, prompt diagnosis, and better understanding of the pathogenesis of these organisms to develop effective counter measures to avoid another pandemic. The United Nations Foundation and the Swiss Philanthropy Foundation, together with WHO has instituted the COVID-19 Solidarity Response Fund that enables private individuals, corporations and institutions anywhere in the world to come together to directly contribute to global response efforts against the COVID-19 pandemic. Several other medical research foundations like Wellcome and The Bill & Melinda Gates Foundation, National Science Foundation etc have set up seed funding to identify, assess, develop and scale-up treatments for COVID-19. In India, the Intensification of Research in High Priority Areas (IRHPA) program of Science and Engineering Research Board (SERB) has announced a special call for research in COVID-19 and related respiratory viral infections. In addition to the current focus on repurposing of antiviral drugs, the pharmaceutical fraternity should aim for long-term drug development goals to identify inhibitors of the viral entry into host cells, viral replication or infection stages associated with SARS-CoV-2 or other related corona viruses.

As members of this huge Pharmaceutical Fraternity, it is our duty and responsibility to rise to this occasion, which is not only a national but an international crisis and contribute towards it in any capacity possible. Be it intellectual input or financial support, it is a need of the hour to work for the betterment of the society as a whole.

Courtesy: Indian Drugs, Guest Editorial, 57 (03), March 2020

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PRESS RELEASE

PM Jan Aushadi Kendras (PMJAK) are playing a vital role in COVID-19 Situation: Mansukh Mandaviya

Per Day 10 lakh persons are visiting PM Jan Audhadhi Kendras to buy quality medicines at affordable prices

MoC&F Press Release dated 4th May 2020

Shri Mansukh Mandaviya, Minister of State (IC) for Shipping and Chemicals & Fertilisers has said that Jan Aushadi Kendras are playing a vital role in COVID-19 situation as around 10 lakh persons per day are visiting 6000 Jan Aushadhi Kendras to source quality medicines at affordable prices. These Kendras are also selling Hydroxy Chloroquine.

He said Pradhan Mantri Bhartiya Janaaushadi Pariyojana (PMBJP) is a noble initiative by Department of Pharmaceuticals, Government of India and Jan Aushadi Kendras are opened under this Scheme to fulfil the cherished dream of the Prime Minister to make available quality generic medicine at affordable price.

Since assuming office, Prime Minister Shri Narendra Modi has been giving impetus on opening of Jan Aushadi Kendras. In these 5.5 years of governance, about 6000 Jan Aushadi Kendras started operating across the country where at par quality medicines are sold at cheaper price by 50% to 90% of Average Market Price.

He added that apart from selling affordable and quality generic medicines, many Jan Aushadi Kendras have distributed ration kit, cooked food, free medicines, etc., to the needy people during the lockdown period.

In a special situation like COVID-19, the role of Jan Aushadi Kendras has become very important. The 6000 Jan Aushadi Kendras are operating day and night tirelessly to serve the poor and the needy. In April, 2020, around Rs.52 crore worth of medicines have been supplied throughout the country. Jan Aushadi Kendras are also selling Hydroxychloroquine (HCQ), N95 masks, three-ply masks, hand sanitizers, etc., at cheaper price. Acknowledging their important role during Covid-19 pandemic Shri Mandaviya said,

"I appreciate the exemplary and laudable social service rendered by these Jan Aushadi Store owners to the needy people."

Source: RCJ/RKM, PIB, MoC&F, 04.05.2020

PM chairs a meeting of the Task Force on Corona Vaccine Development, Drug Discovery, Diagnosis and Testing

PMO Press Release dated 05th May 2020

The PM took a detailed review of the current status of India's efforts in vaccine development, drug discovery, diagnosis and testing. Indian vaccine companies are well known for their quality, manufacturing capacity and global presence. Today in addition, they have come across as innovators in early stage vaccine development research. Similarly, Indian academia and start-ups have also pioneered in this area. Over 30 Indian vaccines are in different stages of corona vaccine development, with a few going on to the trial stages. Similarly, in drug development three approaches are being taken. First, the repurposing of existing drugs. At least four drugs are undergoing synthesis and examination in this category. Secondly, the development of new candidate drugs and molecules are being driven by linking high performance computational approached with laboratory verification. Thirdly, plant extracts and products are being examined for general anti-viral properties. In diagnosis and testing, several academic research institutions and start-ups have developed new tests, both for the RT-PCR approach and for the antibody detection. In addition, by linking laboratories all over the country, capacity for both these

kinds of tests have been enormously scaled up. The problem of importing reagents for testing has been addressed by consortia of Indian start-ups and industry, meeting current requirements. The current thrust also holds promise for the development of a robust long-term industry in this area. The review by the PM took note of the extraordinary coming together of academia, industry and Government, combined with speedy but efficient regulatory process. The PM desired that such coordination and speed should be embedded into a standard operating procedure. He emphasized that what is possible in a crisis should be a part of our routine way of scientific functioning. Appreciating the scientific coming together of computer science, Chemistry and Biotechnology in drug discovery, the PM suggested that a hackathon be held on this subject, linking computer science to synthesis and testing in the laboratory. The successful candidates from the hackathon could be taken up by the start-ups for further development and scaling up. The PM added that the innovative and original manner in which Indian scientists, from basic to applied sciences, have come together with industry is heartening. This kind of pride, originality and sense of purpose should dominate our approach going ahead. It is only then that we can be amongst the best in the world and not followers, in science.

Source: VRRK/KP, PIB, PMO, 05.05.2020

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CDSCO MATTERS

Extension of validity of BA/BE Study Centres - reg.

DCG(I) Circular No.7-5/2020/Misc/070, dated 30th April 2020

To
All stakeholders through CDSCO website;

To conduct the Bioavailability and Bioequivalence study of New Drugs in human in the country, the centre shall be registered under rule 44 of New Drugs and Clinical Trial (NDCT) Rules 2019. Before the implementation of the NDCT Rules, 2019 on 19/03/2019 the permissions were issued to the study centers to conduct the BA-BE studies having the validity of 3 years. However all such centers permitted by CDSCO before implementation of the NDCT Rules, 2019, need to be registered under the NDCT Rules.

This office has received representations from stakeholders requesting to extend validity of BA/BE study Centers registration whose validities are expiring between now and August 2020 in view of COVID-19 outbreak.

The matter has been examined by committee of CDSCO in light of pandemic COV1D-19, and it is clarified that, in accordance with NDCT Rules, 2019, if application for the renewal of registration of BA/BE study centre in Form CT-08 is received by CDSCO ninety days prior to the date of expiry, the registration shall continue to be in force until order passed by the said authority on the application.

In view of above, the BA/BE study Centres who has already applied or will apply for renewal of the registration 90 days prior to the date of expiry of its existing registration, in Form CT-08 along with requisite fees and documents, the registration of such centers will remain valid until any order is issued by CDSCO otherwise.

Dr V G Somani,
Drugs Controller General (India),
Central Drugs Standard Control Organisation,
(International Cell),
Directorate General of Health Services,
New Delhi.

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Provisional Clearance of Goods under India's Trade Agreements - reg.

Instruction No.04/2020-Customs, dated 04th May, 2020

To
The Principal Chief Commissioner/Chief Commissioner of Customs,
Ahmedabad/Bengaluru/Delhi/Kolkata/Mumbai–I/Mumbai–II/ Mumbai–III Zone.
The Principal Chief Commissioner/Chief Commissioner of Customs (Preventive), Delhi/Patna/Tiruchirapalli.
The Principal Chief Commissioner/Chief Commissioner of Central Goods and Service Tax,
Bhopal/Bhubaneshwar/Guwahati/Hyderabad/ Meerut/Nagpur/Pune/Thiruvananthpuram/Visakhapatnam.

1. Kind reference is drawn to Circular 18/2020-Customs, dated 11.04.2020, which provides an option to clear goods under preferential tariff claim, in terms of section 18 of the Customs Act, 1962, where a Certificate of Origin (CoO) is not available at the time of filing customs documents.

2. This measure has been taken, keeping in view the restrictions imposed globally, which may lead to a situation wherein an exporter in unable to communicate original CoO to the importer or submits a CoO which is not as per the prescribed format (digitally signed/unsigned).

3. Board has also issued necessary guidelines vide Circular No. 38/2016-Customs, dated 22.08.2016, prescribing the manner and amount of security based upon class of importer and nature of import. The Circular covers FTAs/PTAs imports under three categories at S.no.5(a), 5(b) and 5(c).

4. In this regard, it is informed that where original hard copy of CoO has not been submitted or only digitally signed copy or unsigned copy of CoO is submitted, same may be treated at par with category as listed at serial no.5(c) of the Circular No. 38/2016-Customs, provided that the matter is not covered under 5(a), wherein there is reasonable belief that the it involves mis-declaration of origin/value addition.

5. It is requested that the officers under your charge be directed to follow these guidelines while implementing Circular No. 18/2020-Customs.

F.No.15021/10/2020-ICD-(CBEC)

Mandeep Sangha, Joint Commissioner (Customs), Central Board of Indirect Taxes and Customs, International Customs Division, Ministry of Finance, Department of Revenue, New Delhi.

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Government of India Initiative - Survey on Industry 4.0 Readiness of Pharma SMEs – reg.

ATTENTION MEMBERS

IDMA has received an email communication from Indian Institute of Information Technology Sri City Chittoor (as reproduced below). IDMA National President Mr Mahesh Doshi has requested Members to kindly take part in this PAN-INDIA SURVEY conducted by Indian Institute of Information Technology Sri City Chittoor which is sponsored by Ministry of Commerce and Industry, Government of India. This Survey is specially for Need Assessment of SME s to adopt Industry 4.0 in Pharma SMEs. The Survey was emailed to all Members on 30 April 2020 for their compliance.

"Industry 4.0 (I4.0) or fourth industrial revolution is driven by an amalgamation of emerging technologies like the Internet of Things (IoT), Big Data, AR/VR, Artificial Intelligence, Robotic Automation, Additive manufacturing, and Cyber-Physical Systems. It achieves convergence of real and virtual worlds thereby bringing together conventional and modern technologies. I4.0 has a huge opportunity for Pharma SMEs to reduce costs, improve quality and achieve seamless integration with OEMs and partners.

Visit the below website to know more about Industry 4.0 for SMEs: **www.iiits.ac.in**

Do you want Ministry of Industry and Commerce, Government of India to support Pharma SMEs through the following:

14.0 - policies and initiatives

Common resource centers

Funding through 14.0 Clusters

Capacity building through training

Technical service centers at the national /regional levels

Financial Support for adopting 14.0

Please take 10 Minutes of your time to take part in a Pan-India survey conducted by Indian Institute of Information Technology Sri City Chittoor (sponsored by Ministry of Commerce and Industry, Government of India), for Need Assessment of SMEs to adopt Industry 4.0 in Pharma SMEs.

The survey has two parts:

(I) Assessment of overall readiness of all SMEs in the Pharma sector in India for adoption of Industry 4.0

(II) Assessment of adoption of Industry 4.0 in your organization.

Survey Link: https://www.surveymonkey.com/r/Pharma-R

All information provided for this survey will be treated as confidential and used only for research purposes only.

Prof G Kannabiran, Director and Project Lead (14.0), Indian Institute of Information Technology Sri City Chittoor. (Institute of National Importance under an Act of Parliament), 630 Gnan Marg, Sri City, Chittoor (Dt.)- 517646, Andhra Pradesh, India, Phone : **99597 56785** (Off), **http://www.iiits.ac.in**, Email: pharma.smesurvey@iiits.in / **Dr Rinshu Dwivedi,** Phone : **+917978211574** (Off), **http://www.iiits.ac.in**

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Antibodies from llamas could help in fight against COVID-19, study suggests

The hunt for an effective treatment for COVID-19 has led one team of researchers to find an improbable ally for their work: a llama named Winter. The team - from The University of Texas at Austin, the National Institutes of Health and Ghent University in Belgium - reports their findings about a potential avenue for a coronavirus treatment involving llamas on May 5 in the journal Cell. The paper is currently available online as a "pre-proof," meaning it is peer-reviewed but undergoing final formatting.

The researchers linked two copies of a special kind of antibody produced by llamas to create a new antibody that binds tightly to a key protein on the coronavirus that causes COVID-19. This protein, called the spike protein, allows the virus to break into host cells. Initial tests indicate that the antibody blocks viruses that display this spike protein from infecting cells in culture.

"This is one of the first antibodies known to neutralize SARS-CoV-2," said Jason McLellan, Associate Professor of molecular biosciences at UT Austin and Co-Senior Author, referring to the virus that causes COVID-19.

The team is now preparing to conduct preclinical studies in animals such as hamsters or nonhuman primates, with the hopes of next testing in humans. The goal is to develop a treatment that would help people soon after infection with the virus.

"Vaccines have to be given a month or two before infection to provide protection," McLellan said. "With antibody therapies, you're directly giving somebody the protective antibodies and so, immediately after treatment, they should be protected. The antibodies could also be used to treat somebody who is already sick to lessen the severity of the disease."

This would be especially helpful for vulnerable groups such as elderly people, who mount a modest response to vaccines, which means that their protection may be incomplete. Health care workers and other people at increased risk of exposure to the virus can also benefit from immediate protection.

When llamas' immune systems detect foreign invaders such as bacteria and viruses, these animals (and other camelids such as alpacas) produce two types of antibodies: one that is similar to human antibodies and another that's only about a quarter of the size. These smaller ones, called single-domain antibodies or nanobodies, can be nebulized and used in an inhaler.

"That makes them potentially really interesting as a drug for a respiratory pathogen because you're delivering it right to the site of infection," said Daniel Wrapp, a graduate student in McLellan's lab and co-first author of the paper.

Meet Winter:

Winter, the llama, is 4 years old and still living on a farm in the Belgian countryside along with approximately 130 other llamas and alpacas. Her part in the experiment happened in 2016 when she was about 9 months old and the researchers were studying two earlier coronaviruses: SARS-CoV-1 and MERS-CoV. In a process similar to humans getting shots to immunize them against a virus, she was injected with stabilized spike proteins from those viruses over the course of about six weeks.

Next, researchers collected a blood sample and isolated antibodies that bound to each version of the spike protein. One showed real promise in stopping a virus that displays spike proteins from SARS-CoV-1 from infecting cells in culture.

"That was exciting to me because I'd been working on this for years," Wrapp said. "But there wasn't a big need for a coronavirus treatment then. This was just basic research. Now, this can potentially have some translational implications, too."

The team engineered the new antibody that shows promise for treating the current SARS-CoV-2 by linking two copies of the llama antibody that worked against the earlier SARS virus. They demonstrated that the new antibody neutralizes viruses displaying spike proteins from SARS-CoV-2 in cell cultures. The scientists were able to complete this research and publish it in a top journal in a matter of weeks thanks to the years of work they'd already done on related coronaviruses.

McLellan also led the team that first mapped the spike protein of SARS-CoV-2, a critical step toward a vaccine. (Wrapp also co-authored that paper along with other authors on the current Cell paper, including UT Austin's Nianshuang Wang, and Kizzmekia S. Corbett and Barney Graham of the National Institute of Allergy and Infectious Diseases' Vaccine Research Center.) Besides Wrapp, the paper's other

co-first author is Dorien De Vlieger, a postdoctoral scientist at Ghent University's Vlaams Institute for Biotechnology (VIB), and the other senior authors besides McLellan are Bert Schepens and Xavier Saelens, both at VIB.

This work was supported by the National Institute of Allergy and Infectious Diseases (U.S.), VIB, The Research Foundation-Flanders (Belgium), Flanders Innovation and Entrepreneurship (Belgium) and the Federal Ministry of Education and Research (Germany).

Backstory:

The first antibodies the team identified in the initial SARS-CoV-1 and MERS-CoV tests included one called VHH-72, which bound tightly to spike proteins on SARS-CoV-1. In so doing, it prevented a pseudotyped virus - a virus that can't make people sick and has been genetically engineered to display copies of the SARS-CoV-1 spike protein on its surface - from infecting cells.

When SARS-CoV-2 emerged and triggered the COVID-19 pandemic, the team wondered whether the antibody they discovered for SARS-CoV-1 would also be effective against its viral cousin. They discovered that it did bind to SARS-CoV-2's spike protein too, albeit weakly. The engineering they did to make it bind more effectively involved linking two copies of VHH-72, which they then showed neutralizes a pseudotyped virus sporting spike proteins from SARS-CoV-2. This is the first known antibody that neutralizes both SARS-CoV-1 and SARS-CoV-2.

Four years ago, De Vlieger was developing antivirals against influenza A when Bert Schepens and Xavier Saelens asked whether she would be interested in helping to isolate antibodies against coronaviruses from llamas."I thought this would be a small side project," she said. "Now the scientific impact of this project became bigger than I could ever expect. It's amazing how unpredictable viruses can be."

Source: University of Taxes at Austin, Science Daily, 01.05.2020 (Excerpts)

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Can an existing HIV medication slow the spread of COVID-19?

A team of scientists from St. Michael's Hospital, Sinai Health and Sunnybrook Health Sciences Centre have launched a clinical trial to understand whether an existing drug used for HIV treatment and prevention may work to prevent COVID-19 infection.

The trial will examine whether post-exposure prophylaxis (PEP), which is a medication a person takes once they've been exposed to a virus to prevent infection, could halt or slow the spread of COVID-19 in groups of people who have been exposed to a confirmed case. The drug in question - Kaletra (lopinavir/ritonavir as PEP) - has long been used in this capacity to prevent HIV in those who have been exposed to the virus.

"Early studies of the use of this medication as post-exposure prophylaxis therapy in other coronaviruses such as SARS and MERS have been promising," says Dr. Darrell Tan, the study's lead investigator who is also a scientist at the MAP Centre for Urban Health Solutions and an infectious disease physician at St. Michael's. "These are so-called 'cousin' viruses to COVID-19 and we want to understand whether lopinavir/ritonavir as PEP could impact its spread as well."

Dr. Tan, along with his co-leads Dr. Allison McGeer, a senior clinician-scientist at the Lunenfeld-Tanenbaum Research Institute of Sinai Health, and Dr. Adrienne Chan, a clinician-investigator at the Sunnybrook Research Institute, will collaborate with Toronto Public Health to identify confirmed cases of COVID-19. They'll then connect with those exposed to confirmed cases to enroll them in the study.

"A great many people from all across Toronto have worked together to get this study started," says Dr. McGeer. "We know we need to be finding solutions that contribute to stopping the spread of this disease as quickly as possible."

The group of contacts of one patient with confirmed COVID-19 will be identified as a 'cluster.' Entire clusters will be randomized to receive either the medication or no intervention. The team of researchers will then track whether or not participants develop COVID-19 by asking them to complete self-tests for the virus weekly. To limit contact, the research team will rely on courier and virtual or phone meetings with participants.

This type of a study is called a ring trial design and was an effective method of using vaccines to eradicate smallpox and test treatments for Ebola.

"Kaletra is a drug that the HIV community has been using globally for two decades, and has also been commonly used at scale in low-resource settings. This means it could be easily scaleable not just in Canada, but internationally, if we are able to demonstrate its effectiveness in the prevention of COVID-19," says Dr. Chan, who is also

an infectious diseases physician at Sunnybrook Health Sciences Centre.

Participants randomized to receive the study drug will take it for 14 days, as this is the current estimated incubation period for COVID-19. "If this strategy works, it could be a major turning point in our global effort to stop a virus where, as we have seen, the outcomes can be devastating," says Dr. Tan. "We are hopeful that our work will bring us closer to understanding how to slow or contain the spread of COVID-19." This research is funded by the Canadian Institutes of Health Research and the St. Michael's Hospital Foundation. For the purposes of this trial, the medication, Kaletra, has been donated in-kind by AbbVie, a biopharmaceutical company. The CIHR Centre for REACH in HIV/AIDS is also supporting this work

Source: St. Michail's Hospital, EurekAlert, 28.04.2020 (Excerpts)

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DCGI asks drug makers to accelerate production of cardiac & anti-diabetic medicines to overcome short supply

In a bid to tide over the short supply of cardiac and anti-diabetic medicines in the country, the Drugs Controller General of India (DCGI) has directed all state and Union Territory drugs controllers to issue instructions to drug manufacturing companies to accelerate production of these drugs and ensure the replenishment of stocks of medicines through wholesalers, distributors and retailers so as to reach the hospitals and patients timely.

The DCGI has on April 27, 2020 instructed state and UT drugs controllers in this regard following a letter from the National Pharmaceutical Pricing Authority (NPPA).

The NPPA on April 24, 2020 sent a letter to the Central Drugs Standard Control Organisation (CDSCO) about short supply of cardiac and anti-diabetic drugs in the country.

"Cardiac and anti-diabetic drugs including insulin stocks level are below than normal," reads the NPPA letter.

Confirming short supply of anti-diabetic and cardiac drugs, Rajiv Singhal, General Secretary, All India Association of Chemists and Druggists (AIOCD) stated that there is 2-5% shortage of said drugs pan India due to panic buying in the wake of nationwide lockdown. The shortfall of drugs is temporary and it will soon be resolved with fresh stocks arriving in the market shortly.

In order to take stock of production of said drugs in the country, the NPPA has requested CDSCO to provide details about manufacturers and importers of cardiac and anti-diabetic drugs such as insulin, aspirin and atorvastatin and their manufacturing capacity. The CDSCO has also been asked to give data on production of cardiac and anti-diabetic drugs especially insulin, aspirin and atorvastatin for three months—February, March, April 2020 and stock position of said drugs as on March 31, 2020 and April 15, 2020.

Acting on the letter issued by the country's apex drug pricing regulator, DCGI has asked drugs controllers in states and Union Territories to take necessary action urgently to ensure sufficient availability of said drugs at all times to the patients continuously.

The DCGI further directed them to provide requisite information sought by NPPA to central drugs controller's office at the earliest. The DCGI has also written to zonal, sub zonal offices of CDSCO asking them to coordinate with drugs controllers in states and Union territories in this regard.

As per AIOCD AWACS report, in March, sales of cardiac drugs surged 19.8% compared with an 11% increase in February. Sales of anti-diabetes drugs grew 18.2% compared with 11% in February.

Source: Laxmi Yadav, Pharmabiz, 01.05.2020

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Indian pharma needs to adopt smart manufacturing concepts to augment production and profitability: Expert

Technology adoption for the pharma sector in India is pivotal to kick-start pharma manufacturing at a time when access to workforce is difficult due to the COVID-19 lockdown. The current phase has brought a standstill to all industry operations across the country.

Smart manufacturing is a technology-driven approach to automate, monitor operations, increase production performance and ensure profitability.

Just as the Union government categorized pharmaceuticals as an essential service during the COVID-19 lockdown, the pharmaceutical industry faced challenges of logistics, supply chain and workforce absenteeism. In an era of Industry 4.0 which is all about smart manufacturing, there is a need to automate work processes and ensure technology adoption, said Dilip Sawhney, Managing Director, Rockwell Automation.

It was in the last few weeks, when living through the lockdown, practices like social distancing and donning masks emerged. Now this could be the new normal at least for the next 18 months. It is also evident that there is a scale-down of human resources to carry out necessary operations. And pharma manufacturing needs to ensure a high level of productivity with fractional human resource participation, he added.

It is here the pharma industry will need to consider remote collaboration through virtual networking. Concepts like Augmented Reality come to the fore as the industry

across India still needs to carry out the necessary manufacturing operations, noted Sawhney at a webinar on 'Smart manufacturing technologies to be maximized during black swan events like COVID-19'.

Using Augmented Reality, data analytics, machine learning, Internet of Things (IoT) and artificial intelligence, companies can start production operations.

During this lockdown and going forward in the post-COVID-19 phase, deployment of the right resources is the key. With the absenteeism imminent across the plant shop floors, Indian pharma particularly needs to re-imagine the future of manufacturing and how with available employees can collaborate and work. Solutions like virtual collaboration remote assistance can allow the workforce to look at their plant machines from anywhere in the country or the world and make decisions in real-time for uninterrupted production schedules. At the end of the day, it is all about human ingenuity, innovation and resourcefulness, he said.

Digitization rises up to the challenges of the pandemic that the world is going through. Here customers are looking at technology to address the current crisis. This is because technology optimizes productivity, decreases downtime, eases bottlenecks, ensures regulatory compliance and prevents human errors. "Hence Indian pharma needs to adopt smart manufacturing concepts to augment production and profitability, said Sawhney.

Source: Nandita Vijay, Pharmabiz, 01.05.2020

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Biomedical waste needs to be disposed of as per BWM Rules 2016 to safeguard from COVID-19: Experts

Biomedical waste needs to be disposed of as per the guidelines stipulated in the Biomedical Waste Management (BWM) Rules 2016 as improper handling and disposal of medical waste can put healthcare workers at higher risk of infection, experts have cautioned.

Currently, 40 lakh health workers are fighting against COVID-19 in India. Besides this, there is a need for 20 to 25 lakh personal protective equipment (PPE) every day to protect the health workers from the infection. Awareness about post-usage disposal and recycling of protective gears by the medical professionals is therefore very important, they advocate.

A few months back, most of the plastics were facing severe scrutiny from across the globe for their environmental footprint. But, since the COVID-19 outbreak, plastic items like PPE suits, masks, gloves, sanitizers, hand-wash, water bottles, shoe or head cover etc are proving to be the only protective shield for the frontline workers.

According to Prof Ashok Agarwal, President, Indian Association for Hospital Waste Management (IAHWM), "Government should ensure the availability of plastic garbage disposal bags in hospitals, quarantined and general households, so that the waste can be collected and treated (medical waste) or recycled (general waste). All biomedical waste needs to be disposed of in colour-coded categories like yellow, red, white and blue as per the guidelines stipulated in the BWM Rules 2016 and by the Central Pollution Control Board (CPCB). These guidelines must be followed to contain the COVID-19 infection."

Leading medical professionals and scientists have necessitated for sensitization about the essential plastic items to prevent the further spread of COVID-19 virus while ensuring their safe disposal and recycling/treatment afterward.

Dr K K Aggarwal, former President of Indian Medical Association (IMA) and PResident, Confederation of Medical Associations of Asia and Oceania (CMAAO) said, "To protect the medical workers from COVID-19 infection, we need protective gear which is made from an impermeable and non-porous material such as plastics. Hence, the currently used masks, gloves, protective shields for eyes/face, head and shoe cover, apron are made from plastics. Impermeable material stops viruses containing droplets from touching the skin and the viruses stay on the outer surface of the protective gear. It is also essential that healthcare workers change their PPE every 8 hours and regularly decontaminate the hospital surfaces."

Echoing similar views, Dr Vijay Habbu, Adjunct Professor, Institute of Chemical Technology (ICT) said, "The protective equipment such as masks, gloves, PPEs and plastic bags and bottles used in delivering the essentials such as grains, oil, water must not be carelessly thrown away. They must be properly disposed of, so they can be treated or recycled. It is an ideal time to cut down on non-eco-friendly human practices such as littering and utilize this time to strengthen the plastic waste management ecosystem in our country. Scientifically, all types of plastic products or equipment are recyclable. The responsibility

to ensure proper disposal of waste and source segregation is on every Indian citizen. It will help in preventing the highly hazardous practice of waste dumping in landfills or waste bodies for clean environment."

Source: Shardul Nautiyal, Pharmabiz, 01.05 2020

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TB patients face tough challenge as all activities under TB programme come to standstill due to lockdown

The tuberculosis patients in Telangana are having a tough time as majority of them, undergoing treatment in hospitals as well as staying at home, are not getting their prescribed medicines on time due to coronavirus lockdown during the past one month. There are no new TB detections, no diagnosis and access to medicines on time has become very difficult because of which the risk of having more TB cases is increasing in the state.

In fact earlier on March 24, when the state and central governments imposed the lockdown to contain coronavirus, the concerned state TB officers had stocked enough medicines that would have lasted for about one month. However, as the lockdown was further extended up to May 7 in Telangana, the TB patients are facing tough challenge to get their medicines on time.

According to Dr Rajesham, Joint Director of Telangana TB cell, in fact we realized in advance itself that lockdown may have some adverse impact on the TB patients and proposed to the government to supply medicines in advance as additional stocks that would suffice for the next 3 months. Though the state government had agreed and kept everything in place, however with the lockdown we are facing other challenges of supplying the medicines to the TB patients located in different places in the state.

"Realizing the challenges that we may face in advance, we have already ensured enough stocks of life-saving TB drugs are made available at various TB hospitals and supply stock points. However, due to lockdown other challenges have cropped up because of which supplying these drugs to the TB patients located in different places has become difficult. But we have also developed alternative strategy to overcome the lockdown and made sure the TB patients do not suffer due to lack of medicines and had directed all the TB officers to keep in touch with the patients through telephone or any other mode of communication. Even though other outpatient wings are not working full time for other than coronavirus in the state, we have made sure that all the government TB diagnostic facilities are open for patients," informed Rajesham.

While the officials have overcome the difficulty of following up of TB patients and effectively addressing their problems despite the lockdown, there are some other difficulties that have cropped up in the TB control programme. The main problem is that due to lockdown the TB reporting has been severely impacted and TB diagnosis has drastically come down during the past one month.

Source: A Raju, Pharmabiz, 01.05 2020

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Pharma MSMEs gear up for transport pooling to tide over logistics challenges

Upset with the disruption in supply chain despite relaxation in operation of transport and courier services from April 20, the pharmaceutical MSMEs are looking for transport pooling so that several manufacturers in a particular region can load merchandise into a single truck heading for a specific geographic region with multiple points of delivery in that region.

This will help drug makers utilize part of a full-sized container at a reduced rate and supply products to various locations at cheaper rate, said Amit Chawla, general secretary of Madhya Pradesh Small Scale Drug Manufacturers Association.

Even though ministry of home affairs' revised guidelines for extended lockdown has allowed operation of much needed courier service and eased the movement of trucks to ensure smooth supply of goods across the country from April 20, the movement of finished pharmaceutical products and their raw materials is still disrupted due to reduced functioning of transport services, said Chawla who is also General Secretary of Laghu Udyog Bharati Indore unit.

Transport pooling will help overcome disruption in supply chain to a certain extent, he added.

A manufacturer requires around 300 products ranging from raw materials to packing materials for production of medicines. Currently industry is facing short supply of raw materials due to logistics constraints following nationwide lockdown. The transport pooling will also help industry overcome short supply of raw materials, he added.

Despite relaxation, the movement of trucks is hampered by unavailability of drivers. Lakhs of the trucks carrying goods worth crores of rupees were stranded following announcement of nationwide lockdown. Most of the trucks are parked on road unattended as their drivers and cleaners have left for their hometowns since lockdown.

Drivers left the trucks on road and headed for their hometowns when the lockdown was announced. The vehicles are yet to reach their destinations, said a transporter on condition of anonymity, adding, the recent announcement of MHA relaxing movement of trucks is too late, now it is very difficult to get drivers back to work.

Road transport accounts for about 60 per cent of freight traffic in the country, according to the Ministry of Road Transport and Highways.

Though the courier service started operation in metros post relaxation, it is yet to become functional in tier II, III cities thus affecting availability of drugs in those cities and in rural areas.

The operation of courier service depends on operation of transport services which are yet to operate at full throttle. Hence relaxation in operation of courier service hardly makes a difference in availability of drugs in small towns, rural areas until transport service remains non-functional in these areas, said Chawla.

Earlier industry used to dispatch high value drugs in small quantity through courier services. Apart from drugs, requisite documents for government tenders, documents required for import and export were sent through courier.

Source: Laxmi Yadav, Pharmabiz, 30.04.2020

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Experts ask govt to allow industrial mask manufacturers to produce N95 masks as per BIS standards in view of growing demand

In view of the growing demand for N95 masks which is an important component in personal protective equipment (PPE), experts have recommended to the government to allow industrial mask manufacturers to produce indigenous N95 masks as per the standards approved by Bureau of Indian Standards (BIS).

As of today, there are only a few N95 mask manufacturers in the country which are approved by the National Institute for Occupational Safety and Health (NIOSH). As per official estimates, there is availability of only 25 lakh N95 masks in the country and there is a demand for around 2.5 crore such masks.

A representation on the same has been made by the All India Drug License Holders Foundation (AIDLHF) to the Union Health Ministry.

"Evidence shows that people can spread the coronavirus before they are even showing symptoms of infection. To stop the transmission everybody should wear mask. Since commercially available surgical N95 masks are in short supply Government of India (GoI) and Centre for Disease Control (CDC) have also started recommending use of home-made cloth face coverings. In general, thicker, high-grade cotton masks tend to do a better job of filtering out small particles," according to Dr Narendra Saini, Chairman, Scientific committee, Delhi Medical Council (DMC) and Indian Medical Association (IMA)-EDB Corona Committee. The Centre for Disease Control and Prevention is the leading national public health institute of the United States.

NIOSH is a US Federal agency responsible for conducting research and making recommendations for the prevention of work-related disease and injury in healthcare among others.

There are 106 indigenous mask manufacturers approved by the Centre as of today.

Government has also roped in 30 indigenous manufacturers to meet the growing demand of PPE. Orders for 1.7 crore PPEs and 49,000 ventilators have been placed and their supply has begun, according to a Union Health Ministry release.

While addressing the shortage of PPE supply in the country, the Health Ministry has also maintained that use of PPE should be based on the risk profile. "The PPE is meant for high risk profile patients and not for patients with low and moderate risk," it stated in a release.

The PPE is not only coverall, but a mix of boot, coverall, head gear and N95 mask. While high risk patients need full component, for the moderate risk patients mask and gloves were sufficient, the Health Ministry recommends. "We have procured sufficient quantities of the PPE and provided them to the state governments. Rationalisation should be exercised in its usage", the Health Ministry said in a release.

To regulate the production of PPEs among Indian manufacturers in line with the specifications of the World

Health Organisation (WHO) and the Union Health Ministry, Government issued a notification on April 6, 2020.

As per Health ministry guidelines, components of PPE are goggles, face-shield, mask, gloves, coverall/ gowns (with or without aprons), head cover and shoe cover. Coronaviruses target mainly the upper and lower respiratory tracts. Hence protecting the airway from the particulate matter generated by droplets/aerosols prevents human infection. Contamination of mucous membranes of the mouth and nose by infective droplets or through a contaminated hand also allows the virus to enter the host.

Hence the droplet precautions/airborne precautions using masks are crucial while dealing with a suspect or confirmed case of COVID-19/performing aerosol generating procedures. Masks are of different types. The type of mask to be used is related to particular risk profile of the category of personnel and his/her work.

There are two types of masks which are recommended for various categories of personnel working in hospital or community settings, depending upon the work environment - Triple layer medical mask and N-95 Respirator mask.

NIOSH is today working with manufacturers to identify issues and determine necessary corrective action to assure that products on the market are providing the expected level of protection to the end user.

NIOSH is well renowned for its work in respiratory protective device research, certification, and standards development. Since 2011, NIOSH has increased its emphasis on protective clothing where research gaps were evident.

Source: Shardul Nautiyal, Pharmabiz, 30.04.2020

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Ayush Ministry directs states & UTs to give approvals for Ayush Health promotion products to boost immunity against COVID-19

The Union Ayush Ministry has directed the principal secretaries/secretaries (health/Ayush) of all states/UTs, state licensing authorities and drug controllers of Ayush to take immediate measures to give approval to the ASU drug manufacturers to start commercial manufacturing of Ayush health promotion products to boosts immunity against COVID-19.

"Considering the importance of immunity boosting measures in the wake of COVID -19 outbreak, Ministry of Ayush intends to promote the use of following ready-made Ayush formulation in the interest of health promotion of the masses, which has been endorsed by Prime Minister during his address to the nation on the Constitution Day, April 14, 2020," said the letter issued by Ayush Ministry.

The directive comes after Prime Minister Narendra Modi threw his weight behind a ministry advisory urging the use of alternative medicines to strengthen immunity amid the pandemic.

"Dry the ingredients and make a powder and put them in sachets or tea bags each of 3 grams of powder and sell to public to boost immunity," it said. The ministry also suggested a name for the product. The formulation may be manufactured and sold in generic name as 'Ayush Kwath' or 'Ayush Kudineer' or 'Ayush Joshanda'.

This decoction is used across India as a traditional alternative medicine for several diseases like fever, cough and cold.

The state/UT governments are hereby requested to direct the Ayush Licensing Authorities to consider granting license/approval for manufacturing of above-mentioned formulation to the interested licensed Ayurveda/Siddha/ Unani drug manufacturers in accordance with the provisions of Drugs & Cosmetics Rules, 1945.

In a circular issued on March 31, 2020 the ministry of Ayush issued a statement recommending "self-care guidelines for preventive health measures and boosting immunity with special reference to respiratory health." The ministry said these guidelines are "supported by ayurvedic literature and scientific publications".

The recommendations included daily practice of Yoga and meditation, and use of turmeric, cumin, coriander and garlic in cooking for general good health and consumption of chyavanprash and herbal tea to boost immunity.

Source: Neethikrishna, Pharmabiz, 30.04.2020

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Big opportunity for Indian Pharma Companies as more countries look to exit China

India has a big opportunity in pharma manufacturing as the US, South Korea and Japan are preparing their exit strategy from China. India, with its quality, skilled

and English-speaking workforce, stands to gain from this situation, said GG Gurudatta, CEO, Estima Pharma.

The Japanese government has already provided a financial package of US$ 2.15 billion to around 200 companies, including pharmaceuticals, to move out from China. While this is good news for India, two other countries --Vietnam and Taiwan--could also gain from countries exiting China, he added.

While Japan would prefer India for its exports of formulations and Active Pharmaceutical Ingredients (APIs) as India has sound expertise to ensure its products and manufacturing adhere to US and EU regulations, Vietnam and Taiwan will be Japan's choice for its domestic drug consumption needs, Gurudatta told.

Since Japan has close ties with both Vietnam and Taiwan, manufacturing of not just pharmaceuticals but electronics and other goods are expected to move to these two countries because of their competence in mass manufacture. While around 30 percent of the companies are expected to go to Vietnam, the rest will go to Taiwan, he indicated.

Japan and South East Asia will see Indian pharma companies as their choice since they see our country as an entry point into the European Union and US markets. This is true especially for Vietnam, which hardly exports any formulations to the EU and US. Japan, hence, cannot move its pharmaceutical facilities to Vietnam, but could look at Taiwan for APIs since it has the capability of getting US FDA and EUDMF approvals, noted Gurudatta.

In terms of cost, India is on par with Taiwan and Indonesia. But our costs are higher by around 10 to 20 per cent compared to Vietnam and Philippines owing to high cost of skilled labour. Despite a few advantages over India, Taiwan is also hampered by limited English knowledge and the fact that it has very few manufacturers of APIs, he said.

India definitely stands to gain in catering to the manufacturing needs of APIs and key starting materials (KSMs) or formulations. However, the COVID-19 pandemic is not permanent and could subside by the end of June. India had already put in place a framework to step up production of APIs at least 9 to 10 months before the pandemic spread in order to reduce the dependence on China. Now, considering the COVID-19 crisis, India has already cleared funds of Rs. 10,500 crore specifically dedicated to the API industry.

India will benefit in contract manufacturing and research besides proving its expertise in key starting materials which cover the production of intermediates and APIs. However, the cost of API or KSM manufactured in China is lower because of the huge volumes. India may not be able to match that price. With our manufacturing cost likely to be 30 to 40 per cent higher than the Chinese, the cost of APIs may go up by 10 to 20 per cent, said Gurudatta.

Source: Nandita Vijay, Pharmabiz, 29.04.2020

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NGOs urge UN and WHO to operationalise fair and equitable benefit sharing of medical products

A large number of civil society organisations have sent a letter to the UN Secretary-General and the Director-General of the World Health Organization demanding that the world body should operationalise fair and equitable benefit sharing of medical products in the wake of COVID-19 pandemic in the world.

Given the strong possibility of a shortage of medicines and vaccines in developing and least developed countries, the letter to the UN is based on the access and benefit-sharing principles of the Convention on Biological Diversity (CBD) and the Nagoya Protocol.

The CBD and its Nagoya Protocol are binding international instruments based on the principles of fairness and equity, linking access to biological resources with fair and equitable sharing of benefits arising from the utilization of such resources.

These principles are endorsed by WHO Member States as they form the basis of WHO's Pandemic Influenza Preparedness Framework (PIP Framework), a multilateral instrument which recognizes the importance of sharing influenza viruses of pandemic potential on an "equal footing" with benefit sharing, considering both "as equally important parts of the collective action for global public health".

We recognize that sharing SARS-CoV-2 samples as well as sequence information continues to be pivotal for the development of diagnostics, therapeutics and vaccines. But a collective global public health response requires fair and equitable benefit sharing on an equal footing, the NGOs said in the letter.

The NGOs called upon the UN and the WHO to secure binding commitments from biopharmaceutical companies and other manufacturers for the rapid supply of existing and future medical products, especially diagnostics, therapeutics and vaccines to developing and least developed countries at an affordable price.

The NGOs also demanded to the UN to organize open platforms for the widespread and unconditional sharing of technology and knowledge including technical specifications, designs, blueprints and any other know-how to scale-up local/regional manufacturing of medical products required for COVID-19 response including diagnostics, therapeutics and vaccines; and towards that end to secure binding commitments from biopharmaceutical companies and other medical product manufacturers.

The NGOs also called upon the UN and the WHO to proactively coordinate and direct COVID-19 R&D by setting up an open innovation platform for the rapid public sharing of all research outcomes, knowledge gaps and problem solving, and towards that end secure binding commitments from entities and individuals engaged in the R&D. It also sought the UN's intervention to ensure that Intellectual Property Rights do not affect or hinder efforts to curb the COVID-19 outbreak.

Source: Pharmabiz, 29.04.2020

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CSIR to develop immune modulator Sepsivac to limit the spread of COVID-19

The Council of Scientific and Industrial Research (CSIR) is planning to develop immune modulator called Sepsivac to enhance innate immunity of the body to limit the spread of COVID-19 and expedite the recovery of the patients of COVID-19.

Sepsivac is expected to protect the close contacts of COVID-19 patients and healthcare staff by boosting their innate response and thereby preventing them from acquiring the disease and to provide quicker recovery to the hospitalized COVID-19 patients, who are not critically ill. It will also prevent the progression of disease wherein patients will need ICU management.

Clinical trials on the same are now approved by the Drugs Controller General of India (DCGI). They will be randomized, double-blind, two-arm, controlled clinical trials. These clinical trials are in addition to the recently announced trial on evaluating the efficacy of the drug for reducing mortality (deaths) in critically ill COVID-19 patients.

Sepsivac contains heat-killed Mycobacterium W (Mw) and is found to be extremely safe in patients and no systemic side effects are associated with its use. It can be used concurrently with any other therapies required in the management of such critically ill patients without any restriction.

Sepsivac was also developed under the NMITLI programme of CSIR and is manufactured by Cadila Pharmaceuticals Ltd., Ahmedabad.

CSIR has been supporting Cadila Pharmaceuticals, Ahmedabad since 2007 for developing a drug to save lives of critically ill patients suffering from gram-negative sepsis.

Earlier, Union Health Minister Dr Harsh Vardhan held a review with DG CSIR, Dr. Shekhar C Mande and all the CSIR lab directors through video conference of the steps undertaken by CSIR and its constituent 38 labs towards mitigation of coronavirus outbreak in the country. Vardhan, however, also cautioned CSIR scientists to develop COVID-19 mitigation solutions keeping fixed timeframe in mind.

CSIR is a premier national Research and development organization. Its pioneering sustained contribution to S&T human resource development is acclaimed nationally.

Source: Yash Ved, Pharmabiz, 29.04.2020

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DoP contemplating to revive PSU units for producing HCQ tablets in the wake of growing demand

The Department of Pharmaceuticals (DoP) is contemplating to revive the government owned public sector pharma units like the Indian Drugs and Pharmaceuticals Limited (IDPL), Rishikesh for producing hydroxychloroquine (HCQ) tablets in the wake of its growing global and domestic demand due to the outbreak of COVID-19 pandemic.

"It would take a while to assess the competitiveness and revival of the old and sick APIs which would entail a huge capital and human resource in the current scenario of COVID-19," according to a senior DoP official.

Revival plan for API units would again be subject to the requirement for HCQ in the country, a highly placed official on condition of anonymity stated while remarking that it would be an uphill task as there are robust production capacities for HCQ available from private pharma companies like Ipca and Zydus Cadila and the competitive edge they have over other players.

This comes at a time when representation has also been made by the Uttarakhand Government to revive the sick API unit at IDPL, Rishikesh which has a huge capacity to produce chloroquine phosphate. Bengal Chemicals and Pharmaceuticals Ltd which produces anti-malarial drugs like chloroquine phosphate and quinine sulphate is also looking for revival as chloroquine phosphate is one of the ingredients of HCQ.

The Uttarakhand Legislative Assembly Speaker Premchandra Agarwal and other senior political leaders from the opposition have urged Prime Minister Narendra Modi, Union Health Minister Dr Harsh Vardhan and Union Minister of Chemicals and Fertilizers D V Sadananda Gowda to notify IDPL, Rishikesh to manufacture HCQ to meet the demand of the drug in the wake of COVID-19 crisis.

HCQ is a synthetic molecule derived from chloroquine, which as of today is chemically processed quinine. Quinine is also derived from Cinchona barks. Cinchona plantation in Darjeeling is also looking for a revival at a time when India is exporting HCQ to over 28 countries globally.

The Cinchona planters of Darjeeling had, however, started facing a crisis after introduction of synthetic-chemical production of quinine. Now hope floats for cinchona plantation in Darjeeling for its growth in this context due to increase in demand for anti-malaria drugs in the wake of the COVID-19 pandemic.

According to Indian Pharmaceutical Alliance (IP Alliance) President Sudarshan Jain, "Currently, we have adequate supplies of HCQ and big pharma companies are also ramping up production capacities as they have the raw material and infrastructure to sustain both exports and domestic consumption."

In order to contain the COVID-19 pandemic, the US has also begun clinical trials to evaluate the safety and effectiveness of HCQ for treatment of adults hospitalised with COVID-19, according to the National Institutes of Health (NIH).

Source: Shardul Nautiyal, Pharmabiz, 28.04.2020

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Drug research must shift from chronic conditions to infectious diseases: Experts

One of the key lessons that the Indian pharma industry seems to have learnt from the COVID-19 pandemic is that drug research, not just in India but globally too, needs to shift from chronic conditions to infectious diseases. The rapid spread of the virus and the fatality rates stem from the fact that the infection is novel and existing antibiotics can only control early stage infection.

"One of the lessons that the world has to learn is that there is a need to invest in research in acute infectious diseases. COVID-19 will not go away easily. There could be a second wave or it could even come next year in a new form. Hence, we need to ensure investment in research and development," said Dr Viranchi Shah, Managing Director, Sage Laboratories and President, IDMA, Gujarat state board.

Global research is mostly focused on chronic segment like diabetes, cancer and cardiovascular diseases. Countries never felt the need to focus on infectious diseases like malaria and those of bacterial and viral in nature, Shah said.

Another need that the COVID-19 pandemic has triggered is that of strengthening healthcare systems across the world. India is not an exception. Countries will have to heavily invest in healthcare infrastructure and maintain a large pool of essential medicines to fall back on in case something recurs. This will result in a lot of investment and focus on the pharma industry as well and throw up a lot of opportunities, said Dr Shah at a recent webinar by Messe Muenchen and the Indian Pharma Machinery Manufacturers Association (IPMMA), moderated by Kaushik Desai, Advisor, IPMMA.

"The pandemic has also taught us that we should not be a single source supplier but have a comprehensive capability from manufacturing pharma raw materials to packaging. It is only during this COVID-19 phase that we realized and started acting on our dependence on China for APIs and key starting materials," said Paresh Chawla, Managing Director, Alpha Laboratories and President, IDMA, MP state board.

Agreeing with Chawla, Shirish Belapure, Senior Technical Advisor, Indian Pharmaceutical Alliance, said India should wean itself away from its dependence on China. The country now needs to be self-sufficient in

APIs (Active Pharmaceutical Ingredients) as the industry has the capability and it is only a question of time with government support.

Industry experts said there was a need to put in place a disaster management policy for pharmaceuticals supported by a high level committee to constantly evolve new ideas. It is here that collaboration and cooperation are needed. Putting employee safety at the top and ensuring access to resources are vital to tiding over the COVID-19 challenge.

Optimistic about the growth in the pandemic phase, the experts concluded that pharma industry is a green pasture for job generation with a multi-skilling approach in lieu of continuous demand for better healthcare and medicines.

Source: Nandita Vijay, Pharmabiz, 28.04.2020

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The ANDA Feat

The Indian pharmaceutical companies' hegemony over other countries in getting a major chunk of the Abbreviated New Drug Application (ANDA) approvals from the US FDA continues. Despite several headwinds including intermittent warning letters by the US FDA, the Indian research based pharmaceutical companies and their subsidiaries have shown a healthy performance in getting a large number of final as well as tentative ANDA approvals from the US FDA to launch generic drugs in the highly regulated US market during the calendar year 2019. According to a Pharmabiz study, the R&D-based Indian pharmaceutical companies and their subsidiaries received 336 final ANDA approvals from the US FDA out of 837 final ANDAs, accounting for an impressive 40 per cent of total approvals in the year 2019.

In the year 2018, the Indian pharmaceutical companies and their subsidiaries had received 290 final ANDA approvals from the US FDA out of 813 final ANDAs, accounting for a total of 35.7% of total approvals in that year. Similarly, the US FDA approved a total of 165 tentative ANDAs to the Indian companies in 2019, accounting for an envious 49 per cent of total tentative approvals. The Indian companies' ANDA feat is no mean achievement considering the fact that the overall performance of these companies was under tremendous pressure throughout the year in 2019 due to the actions against several Indian pharma companies regarding quality and issuing of warning letters by the US FDA. However, the Indian companies were successful in showing their resilience in successfully resolving these quality issues. Indeed, it is a matter of pride for the Indian companies that they are able to continue their stellar performance in getting a large chunk of ANDAs from the highly regulated market like the US drug market.

The Indian companies' commendable performance in 2019 is not a flash in the pan as the Indian companies and their subsidiaries have established strong presence in the US during the last several years with higher ANDA approvals. The US FDA approved a total of 5,768 final ANDAs during last decade from 2010-2019 and 1,351 tentative approvals. The Indian companies remained a dominant player and grabbed over 35 per cent of these approvals. During the last 10 years, the Indian companies received a total of 2,046 ANDA approvals on account of investments in R&D activities. With higher approvals, Indian players were able to launch new products in leading markets like the US and Europe. It is a fact that the Indian companies have given a tough time to major international players by launching affordable products in these markets. According to the Pharmabiz study, India's leading pharma company, Sun Pharmaceutical Industries, a Rs.28,675 crore plus company, received 30 ANDA approvals from US FDA during 2019 and its subsidiary Taro Pharma grabbed 13 approvals. Aurobindo Pharma, the second largest Indian pharma major with net sales of Rs. 19,226 crore, received 20 ANDA approvals during the year 2019 from the US FDA. Likewise, while Alkem Laboratories received 21 ANDA approvals, another major Indian company Lupin received 20 ANDA approvals during 2019. Another major player Alembic Pharma, a Rs. 3,900 crore plus pharma giant, was successful in getting 22 ANDA approvals from the US FDA in the year 2019. Other prominent names in the list include Cipla, Dr Reddy's Laboratories, Glenmark Pharma, Micro Labs and Gland Pharma. These companies received 12, 14, 15, 14 and 13 ANDA approvals respectively in the year 2019. Besides, Ajanta Pharma received 10, Torrent Pharma received 10, and Cadila Healthcare received 11 ANDA approvals during this period. The Indian pharmaceutical companies have been able to maintain their hegemony on ANDA approvals as these companies have been investing more and more on R&D activities. The Indian companies should now further increase their expenditure on R&D activities to maintain this winning streak.

Source: Ramesh Shankar, Pharmabiz-Editorial, 29.04.2020

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Time to Revive PSUs

Triggered by the outbreak of COVID-19 pandemic, the world at present is facing a healthcare crisis so far unheard of in the human history. The extent of crisis can be gauged from the fact that this highly infectious disease, originated in Wuhan city in the Hubei province of China sometime in December 2019, has trampled upon almost more than 200 nations in the world. In fact, the crisis has wreaked more devastation in the developed nations like the US, UK and the frontline European Union nations like Germany, Italy, France and Spain. This once-in-a-century health crisis has already taken more than 1,65,000 precious lives and is still counting. Besides, more than 2.5 million patients spread across the nook and corner of the world are now battling to save their lives. Consequently, though to date there are no specific vaccines or medicines for this novel disease, the demand for an old anti-malarial medicine, hydroxychloroquine, went through the roof as many pundits and even US President Donald Trump touted the theory that this anti-malaria drug can effectively treat COVID-19. Naturally, the world looked at India, which adorns the epithet of 'the pharmacy of the world', for these drugs, and also for the anti-viral drugs and ICU medicines to control the grave situation. As the COVID-19 pandemic spread further in the world, there were literally distress calls to India from a large number of nations for these drugs.

But unfortunately, as the domestic situation in India was also getting worse with mounting number of COVID-19 cases, the Indian government was forced to impose some restriction on export of hydroxycloroquine, anti-viral drugs and other ICU medicines to ensure their consistent availability in the domestic market. The hard fact is that the country is hoist with its own petard as in a healthcare crisis like this, the pharma PSUs could have played a key role in ensuring uninterrupted supply of quality medicines at affordable prices to meet the domestic as well as the export demand. For instance, one of the PSUs, the Bengal Chemicals & Pharmaceuticals Ltd, has the current production capacity to produce one million hydroxycloroquine phosphate tablets every day. But, as the government had already decided to close down this state-owned company, it is ill-equipped to start production owing to lack of raw materials at its disposal. The situation in other PSUs is not different as the Union government in July 2019 had decided to close down all the major state-owned pharma companies. While the government decided to close down Indian Drugs and Pharmaceutical Ltd (IDPL) and its subsidiary Rajasthan Drugs and Pharmaceuticals Ltd (RDPL), it put two others--Hindustan Antibiotics Ltd (HAL) and Bengal Chemicals and Pharmaceuticals Ltd (BCPL)--on strategic sale. It is an undisputable fact that the PSUs can play a decisive role in developing economies like India, especially in critical areas like healthcare and pharmaceuticals. In fact, these PSUs had played a key role in the development of Indian pharmaceutical industry in the initial years. But down the line, the government lost its vision and subsequently all these state-owned companies turned sick over the years, thanks to the totally indifferent attitude of the ministers who took over the charge of the Union Chemicals Ministry. And ultimately in the 1990s, these PSUs were referred to the BIFR for revival. The see-saw battle between revival and closure of these units continued till last year when the government ultimately took the decision to close them down. Now at this hour of health crisis, the government should understand that healthcare and pharmaceuticals are not the sectors which should be left entirely to the private sector. It should revisit its decision.

Source: Ramesh Shankar, Pharmabiz-Editorial, 22.04.2020,

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Glenmark gets DCGI nod for Clinical Trials of Favipiravir tab

Glenmark Pharmaceuticals said it has become the first company in India to receive approval from Drug Controller General of India (DCGI) to conduct clinical trials of Favipiravir antiviral tablets for the treatment of COVID-19 patients.

Having internally developed the Active Pharmaceutical Ingredients (API) and the formulations for the product, the company filed the product for clinical trials with the DCG(I) and has received approval for conducting the trial on mild to moderate patients, Glenmark Pharmaceuticals said in a statement.

The Mumbai-based company is the first pharmaceutical company in India to be given an approval by the regulator to start the trial on COVID-19 patients in the country, it added. Favipiravir has demonstrated activity against influenza viruses and has been approved in Japan for the treatment of novel influenza virus infections, it added.

As per the clinical trial protocol approved, 150 subjects with mild to moderate COVID-19 will be randomised in the study in a 1:1 ratio to Favipiravir with standard supportive care or standalone standard supportive care, the company

said. Treatment duration is a maximum of 14 days and the total study duration will be a maximum for 28 days from randomisation, it added.

In the past few months, following the outbreak of COVID-19, multiple clinical trials have been initiated on such patients in China, Japan and in the US. The drug firm said its product is a generic version of Japan-based Fujifilm Toyama Chemical Co Ltd's Avigan tablets.

Glenmark Pharmaceuticals Executive Vice President – Global R&D – Sushrut Kulkarni said the company is all geared to immediately begin clinical trials on Favipiravir on COVID-19 patients in India. "The clinical trial will let us know the efficacy of this molecule on COVID-19 patients.

If the clinical trials are successful, Favipiravir could become a potential treatment for COVID-19 patients," he added.

Source: The Health Master, 01.05.2020 (Excerpts)

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Pharma sector requests time-bound relief in DPCO list citing APIs price rise

A significant surge in the prices of Active Pharmaceutical Ingredients (APIs) for drugs like azithromycin, hydroxychloroquine (HCQ), paracetamol, cefixime, Isopropyl Alcohol, Carbomer and Glycerine, along with the APIs used in hand sanitisers, has led the pharma industry to request the government to streamline the supply chain and provide temporary relief from price control of certain medicines. All these are used to fight against the coronavirus (COVID-19). However, industry experts also suspect that these APIs are being hoarded by distributors in the country. Particularly, in the case of azithromycin, which is prescribed to control/ prevent different kinds of viruses in the human body.

The prices of APIs used in hand sanitisers have also jumped significantly

Disruption in the supply chain and lockdown in China during the month of January 2020, especially Wuhan city which exports a majority of APIs and key starting material (KSM), the prices of these APIs increased significantly in comparison to the same period of last year. The prices of these APIs went up further in the Indian market during the nationwide lockdown.

Check the table below to note the significant rise in the API prices in the Indian market from the month of January 2020 to the current month of April 2020.

APIs for drugs	Price in Jan 2020 (per kg)	Price in April 2020 (per kg)
Azithromycin	Rs 7200	Rs 16,000
Hydroxychloroquine	Rs 7800	Rs 75,000
Oseltamivir	Rs 1,00,000	Rs 1,70,000
Paracetamol	Rs 220	Rs 425
Chloroquine Phosphate	Rs 1600	Rs 11,000
Doxycycline	Rs 5,200	Rs 7,500
Cephalexin	Rs 3,300	Rs 4,800
Cefixime	Rs 8200	Rs 10,000

Commenting on this situation, Vinay Pinto, Executive Director, Wallace Pharma said, "To ensure a steady pharma supply chain, all Central Ministries are doing a tremendous job of ensuring bureaucratic challenges are swept away. Most raw material prices are stable except for COVID-19 related materials. Compared with January 20 prices, paracetamol and hydroxychloroquine have spiked nearly 2x and 3-5x respectively. And the government should take note of this as both are price-controlled."

He elaborated, "We continue to face intense transportation challenges at the local and district level and increased transport costs. In the coming weeks, last-mile logistical challenges could very well lead to shortages of medicines in some western and northern states. The government should pass on the savings in petroleum by reducing diesel prices to mitigate increased transportation costs."

Dr Viranchi Shah, National Vice President, IDMA-GSB commented, "There is constant import taking place from China for all these APIs. In this crisis situation, there is a need to watch the stocks of these APIs, imported as well as manufactured in the country, to understand their availability and prevent any hoarding activities. There is also a need to sensitise the supply chain for smooth functioning and availability of these raw materials."

Shah also suggested, "To reduce import burden, the Government should allow the API industry to function at its full strength. And considering the fact that MSMEs do not buy APIs by the truckload, there should be some mechanism in the supply chain, like consolidation of essentials in one truck for the same route. It will be a relief to MSMEs."

Harish Jain, Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association said, "India is heavily dependent on China for API, KSM and Intermediates supply for the manufacture of formulations both for domestic and export. Ever since COVID-19 crisis has erupted, starting with China and now in India, there has been severe supply disruptions. This has resulted in the prices of many APIs skyrocketing and there is a heavy shortage. Lifting of ban on export has further made the situation worse. Added to that, operations and financial statuses, especially of MSMEs, are heavily impacted. We are not only paying higher prices on inputs but are also forced to pay upfront to most suppliers instead of 30 to 60 days of credit norms earlier."

Rahul Bansal, Director, BRD MediLabs said, "Due to various reasons, there is a shortage of some raw materials because of interrupted sale and movement from both inside and outside the country. But the difficulty of operations has led to an increase in the rates of APIs. Also, the operating costs of the units have gone up significantly because of sub-optimal production outputs. Whereas, because of the DPCO, the MRPs of drugs cannot be increased proportionately and therefore, for some of the products, it is difficult to maintain supplies. To avoid this state in the near future, the government should give some time-bound relief to the industry. It could take of these drugs from the DPCO list or offer some alternate solutions."

Mr S V Veeramani, Chairman and Managing Director, Fourrts Laboratories pointed out, "Raw materials prices have gone up by 20 to 30 percent and we are also not getting them freely due to their production problems and transportation issues. Prices of some materials like Isopropyl alcohol (IPA) and other excipients have gone up by 100 per cent. Due to price controls, we also cannot increase the prices of finished formulations. We hope that NPPA will take note of the same and allow a proportionate price increase in genuine cases."

Mr Bhavin Mehta, Director, Kilitch Drugs said, "Within three months, paracetamol prices have skyrocketed without much increase in input costs, many exporters who have bid for tenders had to forgo their bids in order to curtail the losses, India has lost a great opportunity to capitalise the opportunities in these crucial times."

Mr Kuldeep Gupta Director, Vivek Pharmachem India informed, "For every API, which is the basic raw material for manufacturing of the medicines, our country is reliant on China and with China extending the new year holidays due to Coronavirus, there has been a severe shortage of raw material in the market. Due to non-availability of APIs and increase in demand, the rates have escalated by 150% – 1000% depending on the product as well as the demand and supply gaps. Besides, various additives, preservatives and expedients, which are required to prepare a dose form of any medicines are also not available in the market, and contributing to the increase in the prices of these raw materials."

The WHO has recommended the use of hand sanitisers to prevent the spread of coronavirus. As a result, the prices of APIs used in these hand sanitisers have also jumped significantly. Isopropyl Alcohol, Carbomer and Glycerine have registered an increase in the price of per kg. They have risen from Rs 80 to Rs 250, from Rs 400 to Rs 3500 and from Rs 52 to Rs 95 respectively.

Addressing this issue, senior officials from the CDSCO cautioned, "To monitor the supply chain of all the medicines in the country, and prevent hoarding of these APIs, the CDSCO is constantly evaluating their market stock availability, and if anybody is found guilty, strict action will be taken against him/her."

Source: Usha Sharma, Express Pharma, 30.04.2020

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Strides develops antiviral tablets for COVID-19 treatment

Strides Pharma Science Ltd said it has developed and commercialised Favipiravir antiviral tablets and stressed that the drug has demonstrated positive outcomes in COVID-19 treatment globally.

"Favipiravir is an antiviral medication that was initially developed to treat influenza in Japan. In February 2020, post the outbreak of Novel Coronavirus (COVID-19), Favipiravir was studied in China and several other countries as an experimental treatment of COVID-19.

Picture: Pixabay

"The drug has demonstrated positive outcomes, including a reduction in the duration of COVID-19 and improved lung conditions for the patients," the company said in a filing to the BSE.

The filing said Strides is the first Indian company to have commenced export of Favipiravir tablets. The company said it will immediately apply to Indian Drug Authorities to commence necessary studies and make the drug available to Indian patients expeditiously. Strides has developed Favipiravir tablets in 400mg and 200mg strengths for convenient dosage administration.

The product is currently being exported to Gulf Cooperation Council (GCC) countries to treat patients under their treatment programme for COVID-19. "Favipiravir tablets are being manufactured at Strides' flagship facility in Bangalore, India. The facility can produce up to 6 billion units of solid orals annually and is approved by the USFDA, MHRA, WHO, TGA, among others,"it said.

Strides has also entered into a preferred arrangement with a leading Indian API manufacturer for the supplies of Favipiravir API (Active Pharmaceutical Ingredient). "The partner has already commercialised the Favipiravir API from its USFDA, KFDA, PMDA and WHO approved manufacturing facility and has capabilities to manufacture the Favipiravir API from its Key Starting Material (KSM) in-house," it said.

Company's CEO and MD R Ananthanarayanan said: "We are pleased to be the First Indian company to develop and commercially launch Favipiravir tablets for the global markets. This development reinforces our commitment to play a substantial role in the society by bringing affordable and quality healthcare to millions of people around the globe."

Favipiravir has already demonstrated positive outcomes in several studies on COVID-19 patients, and the company is hopeful that the treatment regime with Favipiravir would brace up the fight against this virus, he said. "Favipiravir is a complex drug to make, while we are manufacturing the tablets in-house, we are also excited to partner with the API manufacturer such that our supply chain remains secured up to the key starting material," he added.

Source: The Health Master, 30.04.2020 (Excerpts)

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CSIR identifies top 25 drugs for repurposing: Covid-19

Council of Scientific & Industrial Research (CSIR) has been leading the fight against Covid19 epidemic on multiple fronts, with major emphasis on repurposed drugs as they can be quickly deployed for treatment as

Picture: Pixabay

opposed to new drugs which need almost a decade of development. Globally many drugs are under clinical trials on Coronavirus patients to establish their efficacy against Covid19.

Towards providing drugs for Coronavirus patients in India, CSIR has identified the top 25 drugs/drug candidates for repurposing.

Among these top 25 drugs, Favipiravir a broad spectrum inhibitor of viral RNA polymerase has emerged as of one of the most promising drugs. Favipiravir was developed by Fujifilm Toyama Chemical Ltd.,and is an approved treatment for common influenza and is marketed in Russia, China and Japan.

CSIR-IICT, based in Hyderabad has developed a convenient and costeffective synthetic process for Favipiravir. As a collaborative effort with industry, CSIR-IICT transferred the entire process and significant.

Cipla approached regulatory authority DCGI for approval for Favipiravir to be launched in India. Favipiravir is a generic drug and already being used for treatment of influenza and also is in clinical trials for Covid-19 in many countries such as in China, Japan and Italy. Under the auspices of ICMR, Cipla will conduct a suitable limited trial prior to marketing the product as Ciplenza.

CSIR and Cipla have a long history of working together for affordable drugs in India and globally. Many of the technologies for

HIV generic drugs were established at CSIR labs and Cipla was successful in providing affordable treatment to HIV patients worldwide which led to saving of millions of lives. They have assured the government that they will do same for Favirpiravir.

Source: The Health Master, 01.05.2020 (Excerpts)

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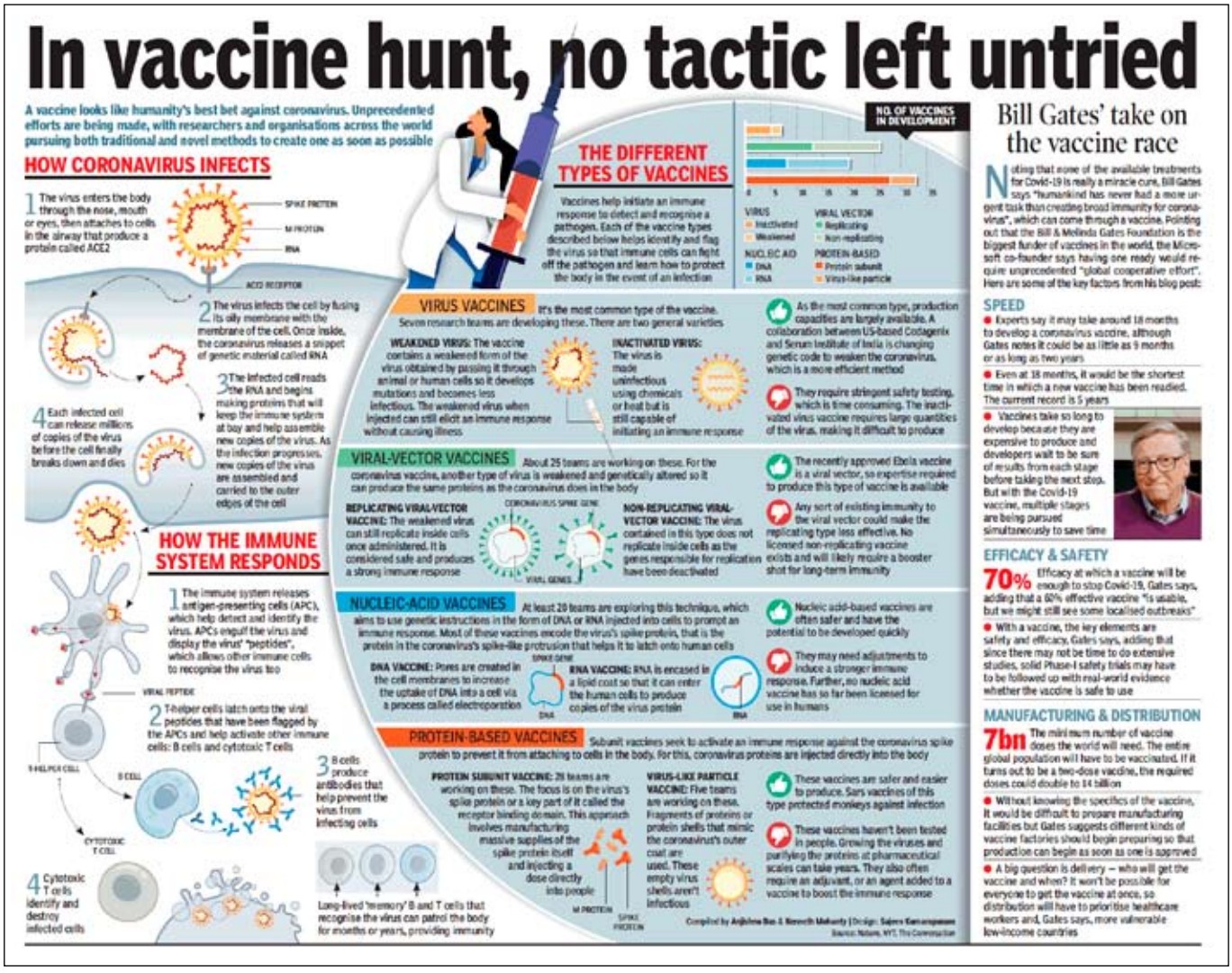

Source: The Times of India, 04.05.2020

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India Exports 50 Million Hydroxychloroquine Tablets to US for COVID-19 Fight: Source

India has shipped 50 million tablets of hydroxychloroquine to the United States, an Indian source with direct knowledge of the exports said, although U.S. regulators warned the antimalarial drug may have harmful side effects in the treatment of COVID-19.

The trade, India's biggest export of the drug to any country, follows a request by U.S. President Donald Trump for New Delhi to release supplies of hydroxychloroquine as a possible treatment for the respiratory disease.

"It amounts to 50 million tablets... Commercial companies are pursuing. It's ongoing," said the source, who declined to be identified due to the sensitivity of discussions with the United States.

The U.S. Food and Drug Administration, the European Union's drug regulator and the Canadian health department have cautioned against the use of hydroxychloroquine, citing side effects such as abnormal heart rhythms and a dangerously rapid heart rate.

However, the health warnings have done little to deter the drug's imports to the United States, where some doctors are continuing to prescribe the drug for the treatment of COVID-19.

"There is high demand for hydroxychloroquine in the international market including U.S.," Dr Viranchi Shah, Senior Vice-President, Indian Drug Manufacturers Association (IDMA), told.

This month India said it would allow some exports of hydroxychloroquine after Trump touted it as a "game changer" and urged Prime Minister Narendra Modi to send supplies. In Modi's home state of Gujarat, 68 new licences have been issued to drugmakers to manufacture hydroxychloroquine formulations, Dr H.G. Koshia, Commissioner, Food and Drug Control Administration (FDCA), Gujarat, told Reuters. "Majority of these licences are for exports," he said.

Teva Pharmaceutical Industries, IPCA Laboratories and Cadila Healthcare are among India's leading suppliers of hydroxychloroquine. Cadila Healthcare recently said it was ramping up production tenfold to 30 metric tonnes per month.

Sales of the decades-old treatment had soared overnight after Trump's advocacy of the drug, raising questions whether political pressure had overridden scientific criteria in the crisis. As the U.S. coronavirus death toll topped 60,000 - the highest in the world - doctors in the United States are desperate for anything that might alter the course of the disease, which attacks the lungs and can shut down other organs in severe cases.

"Pharma companies in Gujarat are continuing to produce and export hydroxychloroquine in large quantities," IDMA's Shah said. The foreign Ministry said India was continuing to supply hydroxychloroquine, and other essential medicines produced in India, to other countries. These supplies were taking place both on a humanitarian and a commercial basis.

(Reporting by Neha Arora in New Delhi and Sumit Khanna in Ahmedabad; Additional reporting by Zeba Siddiqui; Editing by Sanjeev Miglani, William Maclean)

Source: Reuters/The New York Times, 30.04.2020

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FEATURE

Three ways to make Coronavirus drugs in a Hurry

Richard Borge

Mark Denison began hunting for a drug to treat COVID-19 almost a decade before the contagion, driven by a novel coronavirus, devastated the world this year. Denison is not a prophet, but he is a virologist and an expert on the often deadly coronavirus family, members of which also caused the SARS outbreak in 2002 and the MERS eruption in 2012. It is a big viral group, and "we were pretty certain another one would soon emerge," says Denison, who directs the division of pediatric infectious diseases at Vanderbilt University Medical Center.

A virus is an unusual beast. Essentially it is a cluster of genetic material that integrates itself into a cell and takes over some of the cell's molecular machinery, using it to assemble an army of viral copies. Those clones burst out of the cell, destroying it, and go on to infect nearby cells. Viruses are hard to kill off completely because of their cellular integration—they hide within their hosts. And they have explosive reproductive rates. Because total eradication is so hard, antiviral drugs instead aim to limit replication to low levels that cannot hurt the body.

In 2013 Denison and Ralph Baric, a coronavirus researcher at the University of North Carolina at Chapel Hill, identified a vulnerable site on a protein common to all coronaviruses they had examined, a spot that is key to the microbe's ability to make copies of itself. If that ability is hindered, a coronavirus cannot cause widespread infection. Four years later researchers in the two laboratories spotted a compound that acted on this protein site. It was sitting, unused, in a large library of antiviral compounds created by the biotech giant Gilead Biosciences. The scientists got a sample and, in test tube and animal experiments, showed that the drug, called remdesivir, shut down the replicating machinery of several coronavirus variants.

So in early January, when the alarms rang about SARS-CoV-2, Denison and Baric alerted colleagues at Gilead that they were sitting on a potential treatment. Largely because of its activity against other coronavirus strains in Denison and Baric's animal studies, remdesivir was made available to patients for "compassionate use" in January. By March, Gilead had rushed the compound into two human trials, planning to test the drug's safety and most effective doses on about 1,000 ill patients over several months; health authorities in China began two similar trials. While that was happening, Denison, Baric and a group of their colleagues at Emory University identified still another compound,

THREE WAYS TO TREAT COVID-19

Some of the drugs being developed to attack the disease and the SARS-CoV-2 virus that causes it

Block Viral Replication

DRUG	ACTION	COMPANY/LAB	STATUS
Remdesivir	Disrupt viral RNA synthesis	• U. of North Carolina • Vanderbilt University • Gilead Sciences	Clinical trials
EIDD-2801	Disrupt viral RNA synthesis	• Emory University • U. of North Carolina • Vanderbilt University • Ridgeback Biotherapeutics	Clinical trials
Danoprevir-Ritonavir	Inhibit viral protease enzyme	• Ascletis Pharma	Clinical trials
RNAi Experimental Compounds	Block viral RNA synthesis	• Alnylam Pharmaceuticals • Vir Biotechnology	Early research

Prevent Entry into Cells

DRUG	ACTION	COMPANY/LAB	STATUS
APN01	Decoy cell receptor	• Apeiron Biologics	Clinical trials
Multiple Human Antibody Cocktail	Antibodies neutralize virus	• Regeneron	Clinical trials planned for summer
Monoclonal Antibody Candidates	Antibodies neutralize virus	• Vir Biotechnology • Biogen • WuXi Biologics	Clinical trials planned
TAK-888	Modified antibodies against virus	• Takeda	Preclinical

Reduce Hyperimmune Response and Acute Respiratory Distress

DRUG	ACTION	COMPANY/LAB	STATUS
Kevzara (sarilumab)	Antibodies block IL-6 immune cell signal	• Regeneron • Sanofi	Clinical trials
Actemra (tocilizumab)	Antibodies block IL-6 immune cell signal	• Genentech • BARDA*	Clinical trials
Remestemcel-L	Stem cells modulate immune system	• Mesoblast NIH†	Clinical trials
Xeljanz (tofacitinib)	Inhibit inflammatory cells	• Pfizer	Clinical trials

*U.S. Biomedical Advanced Research and Development Authority
†National Institutes of Health

called EIDD-2801, that hits the same viral vulnerability. In early April they published results showing that in mice, the new substance helped breathing and reduced the amount of many coronaviruses. In test-tube experiments with human lung cells, it drastically hindered SARS-CoV-2.

Several labs around the world, like Denison's and Baric's, have logged years of experience poking about the inner workings of coronaviruses because of SARS and MERS. By the time the new coronavirus was genetically sequenced and its structure revealed, scientists already had identified the enzymes and proteins that most coronaviruses use to spread from one infected human cell to another and also understood that the body could create an overly aggressive inflammatory response when the virus infected lung airway cells.

Because of this work, three main strategies for impeding the virus have emerged as the labs have turned to the current threat. One strategy is to find compounds like remdesivir and EIDD-2801 that gum up the virus's reproductive machinery when it enters a target cell. A second is to block the virus, like a bouncer outside a bar, from entering and infecting those cells in the first place. The third approach is to muffle the immune system's dangerously overactive response, a "cytokine storm" that can drown a victim in a mass of congestion and dying airway cells.

To find these drugs, researchers have turned to the Food and Drug Administration's list of some 20,000 compounds approved for human use and crawled through drug patent applications looking for compounds with promising mechanisms of action. The goal has been to find drugs that have been at least partly developed, avoiding years of making therapeutic molecules from scratch. The Milken Institute, a health advocacy think tank, counted 133 experimental COVID-19 treatments in mid-April. About 49 of these therapies are being rushed into clinical trials. Their effectiveness in people is not yet known, and scientists caution that such drugs, like other antivirals, are unlikely to be cures. But they could reduce symptoms enough to give patients' immune systems a chance to beat the virus on their own.

All coronaviruses use the same mechanism to reproduce, which involves an enzyme called viral RNA polymerase, so Baric says that was an obvious target. The polymerase makes lots of mistakes as it copies the virus, and it relies on another enzyme, known as an exonuclease, to "proofread" and fix them. Remdesivir appears to disable the proofreading enzyme. Then the virus's copying factory becomes sloppy and produces fewer new viruses.*

EIDD-2801, the compound with promising animal and test-tube results reported in early April, aims at the same viral enzyme. But unlike remdesivir, which much be given intravenously, EIDD-2801 can be taken as a pill. For this reason, Baric and other researchers investigating EIDD-2801, including George Painter, a Professor of Pharmacology and President of the Emory Institute for Drug Development, which first produced the drug, suspect it may end up being more widely used than remdesivir.

In 2018 Painter and his colleagues identified EIDD-2801's activity during a search for a universal influenza medicine. When SARS-CoV-2 emerged, Painter's group immediately shifted focus. EIDD-2801, like remdesivir, inhibits the coronavirus's self-copying operations, but it also works against virus variants with a mutation that made them resistant to the Gilead drug. In addition, EIDD-2801 is effective against a host of other RNA viruses, so it could serve as a multipurpose antiviral, much as some antibiotics can work against a wide variety of bacteria. For COVID-19, says Wayne Holman, co-founder of Miami-based Ridgeback Biotherapeutics, which has licensed the drug and is planning clinical trials, the goal is to have a pill that can be taken by patients at home early in the course of the disease to prevent it from progressing.

Blocking Infection:

To stop SARS-CoV-2 from penetrating cells in the first place, scientists are trying to develop antibodies that lock onto the viral protein that facilitates cell entry, a part of the virus known as the spike. Some of these neutralizing antibodies, made of a protein called immunoglobulin, may come from the blood of patients who have already cleared the virus. Several medical centers, including Johns Hopkins Hospital and the Mayo Clinic, are harvesting blood plasma from survivors and screening it for antibodies. In a technique known as convalescent therapy, doctors then transfuse it into hospitalized patients with life-threatening acute respiratory distress. Early studies of a few such patients suggest the approach may work—some patients' symptoms improved, and levels of the virus in their bodies dropped—but the work is very preliminary.

Takeda Pharmaceuticals, a Japanese firm, is also collecting plasma from recovered COVID-19 patients to identify antibodies. In that plasma, the company is identifying antibodies that show the most activity against SARS-CoV-2. Using these antibodies as a template, the Takeda researchers plan to synthesize a batch of even more active versions to create a potent cocktail of infection inhibitors, says Chris Morabito, head of research and development of plasma-derived therapies. The therapy—TAK-888—might enter clinical trials by year's end, Morabito says; the number "888" represents "triple fortune" in Chinese. Several other drugmakers, including Regeneron and Vir Biotechnology, are generating their own therapeutic antibodies and say they will also be tested in patients this year. Another blockade strategy focuses on the cellular docking site that the virus uses. Josef Penninger, a molecular biologist at the University of British Columbia in Vancouver and founder of drug company Apeiron Biologics, is trying to lure the virus away from a chemical receptor called ACE2 in the outer wall of lung cells. The coronavirus spike protein binds to this receptor. Several years ago Penninger's lab synthesized a decoy version of ACE2. In test-tube experiments, the scientists found the synthetic molecule—APN01—attracted coronaviruses away from real human airway cells. The virus locked onto the decoy and was marooned there. "We are blocking the door for the virus and, at the same time, protecting tissues," Penninger says. Apeiron is planning clinical trials later this year for APN01, which must be administered in the hospital as an infusion to sick patients.

Overreactions:

In the sickest COVID-19 patients, a mass of mucuslike fluid accumulates in the lungs, preventing cells from absorbing oxygen. These are the patients that need ventilators. The fluid buildup is the result of an overactive immune response that involves a signaling chemical called interleukin-6 (IL-6). Biotech companies, including Regeneron and Genentech, have manufactured synthetic antibodies that can bind to IL-6 and mute the call to action that it sends out.

Northwell Health, a large system of 23 hospitals based in Long Island, N.Y., is one of more than a dozen centers participating in clinical trials of the IL-6 blockers, says Kevin Tracey, Chief Executive of the Feinstein Institutes for Medical Research, which is running the trials at Northwell sites. "The hospitals are being inundated with very sick patients suffering from serious pneumonia and acute respiratory distress," Tracey says. "The IL-6 drugs have a plausible mechanism of action. I'm optimistic they'll work."

None of these approaches are cures. Denison says the drugs under development may "reduce the severity" of an advanced COVID-19 episode, especially if they can be administered when initial symptoms—a mild cough, muscle aches or slight fever—first arise. In a hopeful future, a combination of various therapies may be able to thwart the virus on several different fronts, the way a cocktail of antivirals can beat back an HIV/AIDS infection. By limiting symptoms, drugs may be able to keep some patients out of the hospital and keep hospitalized patients off of ventilators. They can serve as a bridge to survival as other scientists rush to develop the real virus slayer: a vaccine.

Source: Michael Waldholz, Scientific American, 23.04.2020

Corona's Sting: The change we did not see

Amit Khanna

An oft repeated adage ''change is the only constant is perhaps axiomatic and true in most cases. Yet what we will see in the course of the next few months and even years is a ferocity of change humanity has never witnessed. Our history is replete with stories of pandemics and the havoc they wrought across geographies ever so often. While so far only three million people have been infected by the deadly Covid 19 virus and over 2,00,000 have died, it is not by any means anywhere near as deadly as some earlier epidemics and diseases.

For example AIDs infected 75 million people with over 32 million deaths. Or just last year 1.5 million people died from Tuberculosis (TB) and 5 millions of malaria. Plague over the past millennia wiped out millions and the Spanish Flu, a hundred years ago, 50 million. What is it about this Coronavirus strain which is threatening to change the course of human life in the 21st century?

Several leading epidemiologists agree on one thing. While Covid 19 may be less lethal than SARS, MERS or Ebola and other viruses, it is far more infectious. Its transmission, though so far may have been restricted to droplets (as distinct from transmission by air or physical contact), most estimates anticipate that at least 20 percent of the global population is likely to be infected by this virus in the next one year. This is an alarming number and the world is not ready to handle so many sick people at the same time apart from the fact that the scourge of other illnesses, like cancer, strokes, heart attacks and pneumonia etc, continues unabated.

We can take precautions, though. One of the safest means to curb the spread is through social distancing as the virus has a limited range of transmission, around six feet. Since a Covid positive person unknowingly may touch various common facilities like public transport, elevators or other shared facilities, wearing masks and repeated washing of hands is essential. Isolating infected persons is necessary. There are a lot of efforts on at a frenetic pace around the world to develop a vaccine for the virus and it appears that by next year we should have it in use universally. Meanwhile, different treatments are being tried by various doctors around -- from plasma therapy to using other existing drugs and variants.

A few are working new drugs too:

It is now largely accepted that Covid 19 is here to stay in some mutated form for a long time. While the cure and vaccine may ultimately render it less infectious and lethal, the threat of another virus or bacteria will always loom large in people's minds for decades. According to historian-thinker Yuval Noah Harari under the skin surveillance, which includes biometrics, blood reports, x-rays, body scans, and even implants will become commonplace. As he wrote in Financial Times on March 19, "Many short-term emergency measures will become a fixture of life. That is the nature of emergencies. They fast-forward historical processes. Decisions that in normal times could take years of deliberation are passed in a matter of hours". We are entering an age of moments. Nothing will be taken for granted. Sifting sands economic turmoil will swallow men and money alike. Today's world is neither ready nor can it afford such a large-scale upheaval. In the meantime, we will have lockdowns, opening-ups, isolations, quarantines. We must learn to live a sequestered existence alongside our normal lives.

In our hyperconnected world, where travel across national and international borders is no longer a luxury, a pandemic assumes a hitherto unknown scale and dynamics. Since the past few weeks almost the entire planet is in a partial or total lockdown mode. Billions of us live in some kind of social isolation. Yet, never before has there been such a tremendous flow of information -- facts, fiction and ignorance as during the current crisis. The economies of nations lie dishevelled. Individual financial strain varies from extreme penury to a job loss. The conveniences of the 21st century, which we take for granted are suddenly irrelevant or redundant. Simultaneously we are discovering new needs and shortcomings. Life is in a churn no doubt. It's a time of relearning and there are no teachers, people are learning on the fly themselves.

What will life be in the post Corona world? Quite different for sure. How much no one knows:

Let's begin with some obvious changes. Re-emergence of personal hygiene is one such change. A vast majority of the global population still has no or erratic running water. Sanitation, especially garbage disposal, sewerage and drainage are missing or broken. A simple thing like safe

potable water is an issue. Bathing and washing hands either because of water shortage or social habits is not considered essential in many parts of the developing world.

Recent campaigns for improving hygiene -- personal and civic -- have had an impact. The Corona crisis will be a game changer in this regard. The use of masks will become ubiquitous, if not mandatory, at least in public spaces. Social distancing is a reality which will stay. Of course in certain areas, where population density is high, it is impossible to maintain any distance. In many countries, including India, millions of people live cheek by jowl in slums, ramshackle housing and temporary settlements. For many, survival itself is a challenge. In the months to come, it's not economic compulsions but social compulsions which will force an existence under a pall of fear.

The world order itself will change. The last global realignment happened post war in the mid-1940s and a further correction after the fall of the Berlin wall. In the last 10 years, China has emerged the second biggest power. Geopolitics is under rebuild. The left will be left behind and the only way forward will be of compassionate capitalism, inclusive liberalism and aspirationalism. Political ideologies, the entire gamut of isms of the 20th century will fall by the wayside as people and nations seek to overcome instability and look for growth amidst chaos. There is no reason why the concerns of a hundred years ago should matter to the future generations. Baggage of the past, idealism of an era that never existed is dead wood.

This is the age of the moment. Parag Khanna, Founder, FutureMap, sums it up well, "The Coronavirus has proven to be a greater test for leadership than 9/11 and the financial crisis combined, a sobering shock that has shattered complacent assumptions that progress always moves "up and to the right." Evolution, both biological and civilizational, is a much more haphazard and indeterminate process. I expect the rise of domestic markets. Globalisation will be replaced by collaborative enterprises and most transglobal companies will evolve into smaller region-specific entities, each isolated by local regulations.

(Amit Khanna is a writer, filmmaker and social commentator)

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