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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 51 **Issue No. 19** **15 to 21 May 2020**

Extension of Interest Equalization Scheme (IES) for MSMEs for Pre and Post Shipment credit – reg.

ATTENTION MEMBERS

We are pleased to inform Members that following our representation to DGFT, RBI, Ministry Of Finance, MSME and Secretary, Commerce to extend the ILS scheme. RBI vide its circular dated 13th May, 2020 has extended the ILS scheme by one year upto March 31, 2021 coterminous with the Foreign Trade Policy. RBI Circular and DGFT Trade Notice are reproduced below:

Reserve Bank of India Circular Ref. RBI/2019-20/231, dated 13th May 2020

To
All Scheduled Commercial Banks (excluding RRBs), Small Finance Banks, Primary (Urban) Cooperative Banks, and EXIM Bank;

1. Please refer to the operational instructions for the captioned Scheme contained in RBI circular on Interest Equalization Scheme on Pre and Post Shipment Rupee Export Credit issued vide DBR.Dir.BC.No.62/04.02.001/2015-16 dated December 4, 2015; DCBR.CO.SCB.Cir.No.1/13,05.00012015-16 dated February 11, 2016, DBR.Dir.BC.No.09/04.02.001/ 2018-19 dated November 29, 2018 and DBR. Dir. BC.No.22/04.02.001/201 8-1 9 dated January 11, 2019.

2. in this connection, Government of India has approved the extension of Interest Equalization Scheme for pre and post shipment Rupee export credit, with same scope and coverage, for one more year i.e. upto March 31, 2021. The extension shall take effect from April 01, 2020 and end on March 31, 2021 covering a period of one year.

3. Consequently, the extant operational instructions issued by the RBI under the Captioned Scheme shall continue to remain in force upto March 31, 2021.

DOR.Dr4:.BC.No.69/04.02.001/2019-20

Dr S K Kar, Chief General Manager,
Reserve Bank of India, Mumbai.

DGFT Trade Notice No.11/2020-21, dated 14th May 2020

To
Members of Trade and Industry EPCs/FIEO,
Reserve Bank of India.

1. Attention of Trade and Industry is invited to the Trade Notice No.45 dated 01.02.2019 issued by DGFT. In continuation, it is hereby informed that **Interest Equalisation Scheme for Pre and Post shipment Rupee Export Credit is further extended for one more year i.e. upto 31.03.2021 with same scope and coverage.** RBI has issued Notification No.RBI/2019-20/231 dated 13.05.2020 in this regard which is available at the link: https://www.rbi.org.in/Scripts/NotificationUser.aspx?Id=11887&Mode=0.

2. The Scheme shall remain effective from 01.04.2020 till 31.03.2021 or until further orders, whichever is earlier.

3. Guidelines issued by Reserve Bank of India and Relevant RBI notifications issued from time to time on this subject may be referred.

4. It is requested to make maximum use of the scheme and difficulties, if any, may be brought to the notice of this Directorate.

No. 01/94/180/341/AM20/PC-4

Vijay Kumar,
Additional Director General of Foreign Trade,
Directorate General of Foreign Trade,
Department of Commerce,
Ministry of Commerce & Industry,
New Delhi.

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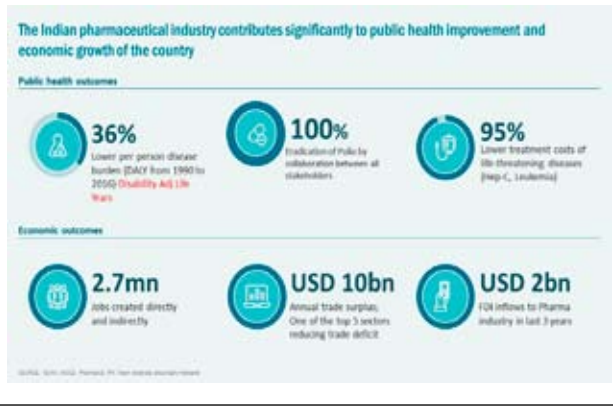
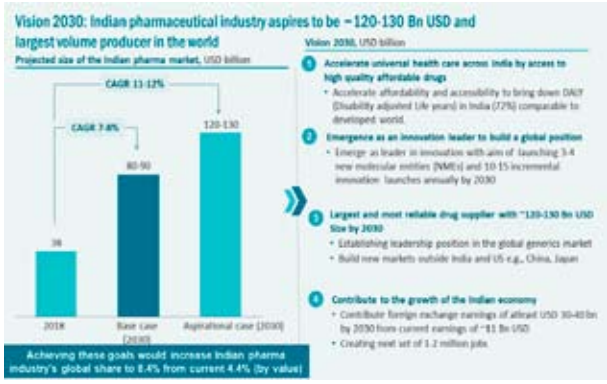
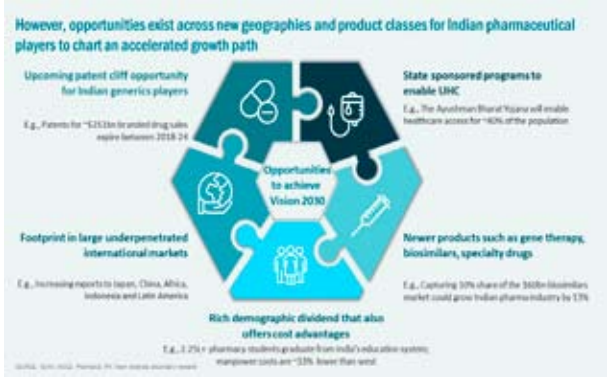
Impact of COVID-19 and Way Forward

*by **Dr Dinesh Dua,** Chairman, Pharmexcil*

Presented at IDMA-GSB Webinar on "Impact of Covid 19 - How the Indian Pharma industry should respond, reset and reshape" on 12th May 2020



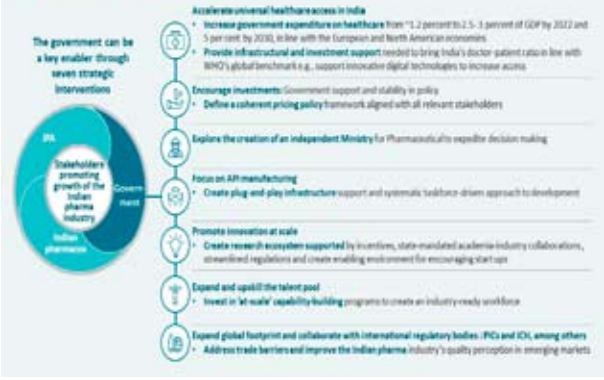




Chinese API growth story and policy interventions to foster innovation highlight what is needed to realize the opportunities

Concerted efforts and strong collaborations between all stakeholders–Indian pharma companies, the government and regulatory agencies & Associations like IPA,IDMA,Fope,Pharmexcil–can help capture these opportunities

Key thrust areas for Vision 2030



Pharma Exports FY19 vs FY20

India's Pharma exports by Month in $Mn

Month	FY19	FY20	Change %	Change in Revenue
April	1,428	1,523	7	95
May	1,518	1,683	11	165
June	1,583	1,830	16	247
July	1,414	1,711	21	297
Aug	1,688	1,671	-1	-17
Sep	1,657	1,790	8	133
Oct	1,513	1,693	12	180
Nov	1,484	1,779	20	295
Dec	1,660	1,866	12	206
Jan	1,586	1,772	12	186
Feb	1,610	1,734	8	124
Mar	1,997	1,533	-23	-464
Total	19,137	20,586	8	1449

Quarter wise Exports ($Mn)

	Fy-19	Fy-20	Change%	Change in Revenue
Apr-Jun	4,529	5,037	11	508
Jul-Sep	4,758	5,172	9	414
Oct-Dec	4,657	5,338	15	682
Jan-Mar	5,194	5,039	-3	-154
Total	19,137	20,586	8	1449

- Q3 has seen sharpest growth @14.63% and a revenue of $5338 million.
- A decline of 23% in Mar decreased the 11.5% growth till 10 months to a mere 7.57% for FY20
- Almost 4.5 -5% of April-Jan Fy-20 Exports is actual loss due to COVID-19. Which is $776 to 866 million when extrapolated to normal circumstances and the total exports could have been $ 21,365- $21,452 Million with a growth over 11.65%.
- India's import of Bulk Drugs declined by 24% due to the pandemic as it relies on china for 70% of its bulk drugs imports & FOR Domestic 90 .

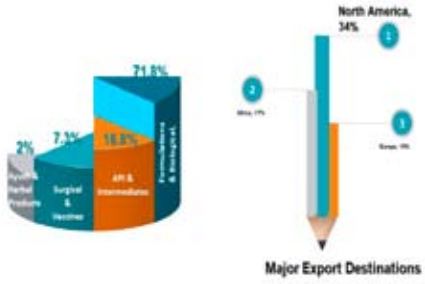
Category wise Exports ($Mn)

Category	Fy-19	Fy-20	Change %	Change in Revenue	Contbn%
Ayush	147	147	-0.04	-0.06	0.71
Bulk Drugs & Drug intermediates	3,895	3,867	-0.73	-28	18.79
Drug formulations & Biologicals	13,504	14,782	9.47	1278	71.81
Herbal Products	301	281	-6.62	-20	1.36
Surgicals	570	630	10.47	60	3.06
Vaccines	720	879	22.05	159	4.27
Grand Total	19,137	20,586	7.57	1449	100

- First time in a FY Bulk Drugs and intermediaries has contributed less then 20%.
- Bulk Drugs export decreased by $168mn (38%) in March 2020.
- Bulk Drugs exports decreased by 14% in African Region, 11% in Asean and 11% in Oceania.

Export Outlook

Over 55% Exports to Highly Regulated Markets



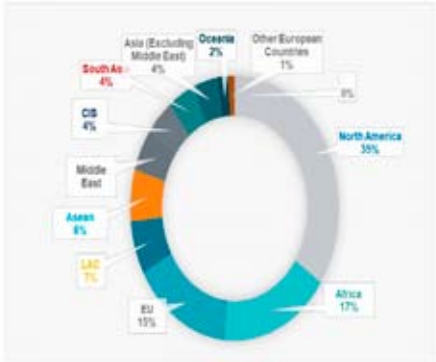
Generic Formulations ($Mn)

Month	FY19	FY20	Change%	Change in Revenue
Apr	983	1,101	12.05	118
May	1,038	1,168	12.48	130
Jun	1,131	1,312	16.04	181
Jul	1,007	1,231	22.23	224
Aug	1,219	1,196	-1.90	-23
Sep	1,190	1,292	8.62	102
Oct	1,072	1,210	12.86	138
Nov	1,061	1,276	20.32	216
Dec	1,164	1,362	17.03	198
Jan	1,117	1,269	13.64	152
Feb	1,149	1,250	8.78	101
Mar	1,373	1,113	-18.89	-259
Total	13,504	14,782	9.47	1,278

- Formulation exports contributed 72% to the total.
- 13% growth in the starting 10 months, changed to 8.8% in Feb and negative growth of 19% in March decreased the total growth to 9.5% for FY20.

Month Wise Exports

Indian Pharma Exports- Region wise



Top Ten Exporting Destinations

Exports in FY-20 ($ Mn)	Growth (%)		Exports in FY-20 ($ Mn)	Growth (%)
6739.43	(15.79%)	01 USA		
		02 SOUTH AFRICA	610.79	(-1.34)
557.66	(-11.48)	03 UK		
		04 RUSSIA	352.41	(13.77%)
504.05	(13.07%)	05 GERMANY		
		06 BRAZIL	473.10	(8.65%)
419.43	(-6.37%)	07 NIGERIA		
		08 CANADA	334.54	(2.65%)
319.29	(55.05%)	09 NETHERLAND		
		10 FRANCE	309.23	(31.77%)

Source: DGCIS

❖ Preference of Pharma Industry for APIs/KSM :

Local Industry or Imports ?

Post Covid era

- With this pandemic not going anywhere for now and the whole world need to practice social distancing, but there are still many day to day activities need to done specially in Pharmaceutical sector to boost it
- With lockdown in many countries the industry needs to find alternate ways of doing there tasks related to regulatory framework as now is the time companies will be expanding their footprints in the different parts of the world so as to ensure that Medicines are reaching every part of the world during this pandemic whilst also maintaining the safety standards to stop the spreading of the virus.
- This is how various activities can be done in the Post Covid era –

1. **Inspections-** As the companies need to go through inspections to approve their product/facility approval from the Regulatory Authority of the country they want to sell in, thus a system can be made where the Authority will check the activities of the plant remotely from their country (24x7 CCTV footage) also a system will be prepared to exchange the documents needed by them on live basis.
2. **Meetings (Internal/External)-** There are several meetings held in a company internally or externally on a day to day basis. This can be turned to a virtual meeting using the various IT tools that are available right now. Companies just need to update there IT infrastructure accordingly.

Pharma Expo/ BSMs/ Conferences

Regulatory Agencies- New Norms

❖ Desktop Audits

❖ Expedited Review & Approvals

❖ Emergency Use Authorisations

Manufacture and stock for sale or distribution of vaccines for prevention and treatment of COVID-19 infection - reg.

Gazette Notification No.S.O.1511(E) dated 18th May 2020

1. Whereas, the Central Government is satisfied that making available suitable vaccines is essential to meet the requirements of emergency arising due to pandemic COVID-19, and in public interest it is necessary and expedient to regulate the manufacture and stock for sale or distribution of vaccines for prevention and treatment of COVID-19 infection;

Now, therefore, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby issues the following notification, notwithstanding anything contained in the Drugs and Cosmetics Rules, 1945 and New Drugs and Clinical Trials Rules, 2019, for the purposes of making available suitable vaccines to meet the requirements of emergency arising due to COVID-19, namely:

a) In case a person intends to manufacture and stock a vaccine for COVID-19, which is under clinical trial for marketing authorisation for sale or distribution, then, such person shall have obtained permission in Form CT-06 to conduct clinical trial of such vaccine and on successful completion of the clinical trial and after obtaining permission in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019, he shall make an application under rule 75 or rule 75A of the Drugs and Cosmetics Rules, 1945, as the case may be, to the concerned Licensing Authority appointed by the State Government along with the permission obtained for conducting clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019, for grant of license to manufacture and stock the vaccine for sale or distribution under the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940)(herein after referred to as the said Act) and the rules made thereunder:

Provided that the requirement of prior permission from the Central Licensing Authority under rule 81 of the New Drugs and Clinical Trials Rules, 2019 to manufacture the vaccine as required under rule 83 of the said rules shall be deferred in public interest to meet the emergent situation arisen out of COVID-19 and such person shall obtain the said permission after successful completion of the clinical trial and submission of application along with fees, data and particulars in accordance with the provisions of the New Drugs and Clinical Trials Rules, 2019.

(b) The Central License Approving Authority may, if satisfied that requirements under the provisions of the said Act and the Drugs and Cosmetics Rules, 1945 and the New Drugs and Clinical Trials Rules, 2019 have been complied with, grant License in accordance with the provisions of rule 68A of the Drugs and Cosmetics Rules, 1945 to manufacture and stock the vaccine subject to the condition that the licensee shall sell or distribute the vaccine only after obtaining permission for such vaccine (new drug) in Form CT-23 from the Central Licensing Authority under the New Drugs and Clinical Trials Rules, 2019.

2. In case of any inconsistency between this notification and any rule made under the said Act, the provisions of this notification shall prevail over such rule in public interest so as to meet the emergency which has arisen due to COVID-19 pandemic.

3. This order shall come into force on the date of its publication in the Official Gazette.

F. No. X.11014/02/2020-DRS

Dr. Mandeep K. Bhandari, Joint Secretary
Department of Health and Family Welfare,
Ministry of Health and Family Welfare, New Delhi.

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Incidence of National Calamity Contingent Duty (NCCD) for calculation of Brand Rate of duty drawback - reg.

Customs Instruction No.5/2020 dated 12th May, 2020

To,
All Principal Chief Commissioners/
Principal Directors General and
Chief Commissioners/
Directors General under CBIC.

1. Please refer to Board's Instruction No.4/2019-Customs dated 11.10.2019 clarifying the position regarding Education Cess, Secondary and Higher Education Cess, Social Welfare Surcharge, Clean Environment Cess (erstwhile Clean Energy Cess) and Stowage Excise Duty levied on inputs used in the manufacture of export goods with regard to their incidence for the purpose of calculation of Brand Rate of duty drawback

2. Subsequent to the above, representations have been received in the Board seeking inclusion of the incidence of National Calamity Contingent Duty (NCCD) levied on the inputs used in the manufacture of export goods in calculation of Brand Rate of duty drawback.

3. The matter has been examined keeping in view the relevant statutory provisions, Customs and Central Excise Duties Drawback Rules, 2017 and Board's Instruction No.4/2019-Customs dated 11.10.2019. NCCD is levied under Section 136 of Finance Act, 2001 as a duty of excise and under Section 134 of Finance Act, 2003 as a duty of customs. These legislations respectively inter-alia provide that provisions of Central Excise Act, 1944, Customs Act, 1962 and rules and regulations made thereunder including those relating to refunds, exemptions etc. shall apply to this levy. Section 75 of the Customs Act, 1962 allows drawback of duties of customs chargeable under the Act. Section 12 of the said Act provides for levy of duties of customs at such rates as may be specified under the Customs Tariff Act, 1975 or any other law for the time being in force. NCCD is also taken into account in the calculation of All Industry Rates of duty drawback by the Drawback Committee.

3.1 It is, therefore, clarified that the incidence of NCCD where applicable, is required to be factored in calculation of Brand Rate of duty drawback.

4. Field formations are requested to deal with applications for fixation of Brand Rate of duty drawback accordingly.

5. A suitable Trade Notice and Standing Order may be issued for the guidance of the trade and staff. Difficulties faced, if any, in implementation of the instruction may be immediately brought to the notice of the Board.

F.No.609/38/2019-DBK

Anand Kumar Jha, Joint Commissioner (Drawback), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

Electronic Sealing-Deposit in and removal of Goods from Customs Bonded Warehouses - reg.

Customs Circular No.25/2020, dated 18th May, 2020

To,
All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (prev),
All Principal Commissioners/Commissioners of Customs & Central Tax,
All Principal Commissioners/Commissioners of Customs/Customs (Prev),
All Principal Commissioner/Commissioners of Customs & Central Tax.

1. Circular-19/2018-Customs dated 18.06.2018 and Circular 10/2020-Customs dated 07.02.2020 provided for

RFID sealing of goods to be deposited in or removed from Customs Bonded Warehouses. The implementation of these Circulars was deferred, vide Circulars No.54/2018-Customs dated 31.12.2018 and 20/2020-Customs dated 21.04.2020.

2. In view of the representations received from stakeholders, Board has decided to review the modalities under the aforesaid circulars.

3. Accordingly, a comprehensive circular is under consideration and shall be soon placed in public domain (cbic.nic.in) to seek inputs/suggestions from all stakeholders before issuance.

4. In view of above, Circular-19/2018-Customs dated 18.06.2018 and Circular-10/2020-Customs dated 07.02.2020 issued previously in this matter and yet to be operationalized, stand rescinded.

F.No.484/03/2015-LC (Vol. II)

Dr. Swati Bhanwala, OSD (Land Customs), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi.

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Health Secretary's meeting with Municipal Commissioners on Covid-19 – reg.

Health Secretary interacts with 30 COVID-19 high case load municipal areas
Reviews measures for Covid-19 containment and management
Recovery rate increases to 35.09%

MoH&FW Press Release dated 16th May 2020

Ms Preeti Sudan, Health Secretary and Shri Rajesh Bhushan, OSD, MoH&FW along with senior officers of the Health Ministry, held a high level review meeting with the Pr Health Secretaries, Municipal Commissioners, DMs and other officials from the 30 Municipal areas which are contributing almost 80% of the country's Covid-19 cases, on 16.05.2020.

These 30 Municipal areas are from the following States/UTs: Maharashtra, Tamil Nadu, Gujarat, Delhi, Madhya Pradesh, West Bengal, Rajasthan, Uttar Pradesh, Telangana, Andhra Pradesh, Punjab and Odisha.

The measures taken by the officials and the staff of the Municipal Corporations for the Management of COVID-19 cases were reviewed. It was informed that fresh Guidelines on Management of COVID-19 in urban settlements are being shared. Highlights of this strategy were discussed. A presentation was made on the present status of COVID-19 infections in the districts while highlighting the high risk factors, indices such as confirmation rate, fatality rate, doubling rate, tests per million etc. They were briefed about the factors to be considered while mapping the containment and buffer zones; the activities mandated in containment zone like perimeter control, active search for cases through house to house surveillance, contact tracing, testing protocol, clinical management of the active cases; surveillance activities in the buffer zone like monitoring of SARI/ILI cases, ensuring social distancing, promoting hand hygiene etc.

It was highlighted that in general the geographic area of containment zones to be defined based on factors like mapping of cases & contacts, geographical dispersion of cases and contacts, area with well demarcated perimeter and enforceability. For Municipal Corporations, residential colony/mohallas/municipal wards or police-station area/ municipal zones/towns etc., can be designated as containment zones, as appropriate. It was advised that the area should be appropriately defined by the district administration/local urban body with technical inputs from local level. Along with the containment zones, buffer zone around containment zone also must be demarcated to break the chain of transmission. Maintaining high vigilance and monitoring in areas of old cities, urban slums and other high density pockets along with the camps for migrant workers are important steps in COVID-19 management in the urban areas.

Regarding management of indicators like high doubling rate, high case fatality rate and high confirmation percentages seen in the containment zones, they were informed about the possible root causes and recommendations were offered on possible actions that could be taken. It was also highlighted that especially in the densely populated urban areas further challenges need to be considered like poor socio-economic conditions, limited health infrastructure, lack of social distancing, issues faced by women among others factors.

Health Secretary also emphasized that along with the containment and management of COVID-19 cases, the issue of continuing all essential non-COVID health services in the urban localities like RMNCHA+N care, cancer treatment, TB surveillance, immunization efforts, vector control measures in view of the ensuing monsoon, etc., need to be ensured. The Municipal Areas were asked to focus on effective risk communication in order to build trust and confidence. They were requested to engage with community leaders and local opinion leaders who could accompany the local surveillance teams to encourage cooperation from the local communities. Mumbai shared its experience of "Containment leaders", who were local community elders and leaders working with the Ward Officers to support the government efforts in encouraging the people particularly in the slum clusters. Role of community leadership was highlighted in finding local solutions, building trust, and for a positive influence on the health workers.

It was also emphasized that added attention needs to be accorded to timely tracing of patients to improve recovery percentage, SARI/ILI Surveillance, and more effective human resource management. It was advised that all health service providers need to be provided with adequate protective gear and communication must focus against the stigmatization of these frontline health workers. Maintenance of sanitation standards of the relief and isolation camps, and waste management from the homes of COVID-19 cases was also stressed upon.

So far, a total of 30,150 people have been cured. In the last 24 hours, 2233 patients were found cured. This takes the total recovery rate to 35.09%. The total number of confirmed cases is now 85,940. Since yesterday, an increase of 3970 has been noted in the number of COVID-19 confirmed cases in India.

For all authentic & updated information on COVID-19 related technical issues, guidelines & advisories please regularly visit: **https://www.mohfw.gov.in/ and @MoHFW_INDIA**.

Technical queries related to COVID-19 may be sent to **technicalquery.covid19@gov.in** and other queries on **ncov2019@gov.in** and **@CovidIndiaSeva**.

In case of any queries on COVID-19, please call at Ministry of Health & Family Welfare helpline no. : +**91-11-23978046** or **1075** (Toll-free). List of helpline numbers of States/UTs on COVID-19 is also available at **https://www.mohfw.gov.in/pdf/coronvavirushelplinenumber.pdf .**

Source: PIB, MoH&FW, 16.05.2020

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Ministry of MSME launches Champions Portal

A Technology driven Control Room-Cum-Management Information System
Based on modern ICT tools the network of control rooms is created in a Hub & Spoke Model
Aimed at assisting Indian MSMEs march into big league as National and Global Champions

Ministry of MSME Press Release dated 12th May, 2020

In a major initiative Union Ministry of MSME has launched Champions portal www.Champions.gov.in, a Technology driven Control Room-Cum-Management Information System. The system utilizing modern ICT tools is aimed at assisting Indian MSMEs march into big league as National and Global Champions.

The Champions stands here for Creation and Harmonious Application of Modern Processes for Increasing the Output and National Strength. Accordingly, the name of the system is Champions.

As the name suggests, the portal is basically for making the smaller units big by solving their grievances, encouraging, supporting, helping and handholding. It is a real one-stop-shop solution of MSME Ministry.

While taking over as Secretary MSME on 30th April evening, Mr A K Sharma had indicated that an ICT based system would be set up to help the MSMEs in present difficult situation and also to handhold them to become national and international champions. Accordingly, a comprehensive system known as Champions was trial launched on 9th May, 2020.

It is a technology packed control room-cum-management information system. In addition to ICT tools including telephone, internet and video conference, the system is enabled by Artificial Intelligence, Data Analytics and Machine Learning. It is also fully integrated on real time basis with GOI's main grievances portal CPGRAMS and MSME Ministry's own other web based mechanisms. The entire ICT architecture is created in house with the help of NIC in no cost. Similarly, the physical infrastructure is created in one of Ministry's dumping rooms in a record time.

As part of the system a network of control rooms is created in a Hub & Spoke Model. The Hub is situated in New Delhi in the Secretary MSME's office. The spokes will be in the States in various offices and institutions of Ministry. As of now, 66 state level control rooms are created as part of the system.

A detailed operating procedure has been issued, officers have been deployed and training has been conducted. On May 9th, Mr Sharma did a trial launching of the champions system amidst his officers and staff. On this occasion around 120 locations of the country were connected through video conference.

While trial launching the system, Mr Sharma said that it is meant for the MSME units and people depending on them. He also said that these units and people need our help badly. We will do everything to help, re-start and rejuvenate them.

Source: PIB, Ministry of MSME, 12.05.2020

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CCI invites public comments regarding examination of Non-compete restrictions under regulation of Combinations

CCI Press Release dated 15th May, 2020

The Competition Commission of India (CCI) has been looking at non-compete restrictions stipulated in mergers and acquisitions while reviewing combinations. Notifying parties are required to furnish information on non-compete restrictions for the purpose of its examination. The CCI has issued a Guidance Note explaining the circumstances under which a non-compete restriction would be regarded as 'ancillary' or 'not ancillary'. The Guidance Note provides that 3 years of non-compete obligation is usually justified in case of transfer of goodwill and know-how and two years in case of transfer of goodwill alone. It further provides that the scope of non-compete shall be restricted to the business sold and the territory where it was conducted. However, a finding that the restriction is not ancillary does not raise any presumption of infringement under the provisions of the Act.

It has been observed that prescribing a general set of standards for assessment of non-compete restrictions may not be appropriate in modern business environments. While it may be possible to conduct a detailed examination on case by case basis, the same may, however, not be feasible considering the timelines followed in combination cases.

The CCI, therefore, proposes to omit paragraph 5.7 of Form I in the Combination Regulations that seeks information regarding non-compete restrictions agreed between the parties to combination and justification for the same. This would allow the parties flexibility in determining non-compete restrictions, while also reducing the information burden on them. However, the parties will be responsible for ensuring that their non-compete arrangements are competition compliant. Competition concerns, if any, that may arise from non-compete restrictions can be looked into under Sections 3 and/or 4 of the Act.

A copy of the draft amendment to the Combination Regulations is available on the website of the CCI (**www.cci.gov.in**). Comments are invited from the public and may be emailed to **combination.cci@nic.in** by June 15, 2020.

Source/Courtesy: PIB, CCI (MCA), 15.05.2020

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Prime Minister's interaction with Mr Bill Gates

PMO Press Release dated 15th May, 2020

The Prime Minister Shri Narendra Modi interacted with Bill & Melinda Gates Foundation co-chair, Mr Bill Gates via video conference. The dignitaries discussed the global response to COVID-19, and the importance of global coordination on scientific innovation and R&D to combat the pandemic.

Prime Minister underlined the conscious approach that India has adopted in its fight against the health crisis - an approach based on ensuring public engagement through appropriate messaging. He explained how this people-centric bottom-up approach has helped win acceptability for physical distancing, respect for front-line workers, wearing of masks, maintaining proper hygiene, and respecting lockdown provisions.

Prime Minister also highlighted how some of the previous developmental initiatives taken by Government - expanding financial inclusion, strengthening last mile delivery of health services, popularizing cleanliness and hygiene through the Swachh Bharat Mission, drawing upon India's Ayurvedic wisdom to enhance people's immunity, etc - had helped increase the effectiveness of India's response to the present pandemic.

Prime Minister appreciated the health related work being done by the Gates Foundation not only in India but also in many other parts of the world, including for coordinating global response to COVID-19. He sought suggestions from Mr Gates on how India's capacities and capabilities could be better leveraged for the general benefit of the world.

Some of the ideas that the dignitaries explored in this context included drawing upon India's unique model of last-mile health service delivery in rural areas, dissemination of the effective contact-tracing mobile app developed by Government of India, and above all by leveraging India's massive pharmaceutical capacity to scale-up the production of vaccines and therapeutics upon their discovery. They agreed that given India's willingness and capacity to contribute to global efforts, particularly for benefit of fellow developing countries, it was important for India to be included in the ongoing global discussions for coordinating responses to the pandemic.

In closing, Prime Minister also suggested that the Gates Foundation could take the lead in analysing the necessary changes in lifestyles, economic organisation, social behaviour, modes of disseminating education and healthcare, that would emerge in the post-COVID world, and the associated technological challenges that would need to be addressed. He said that India would be happy to contribute to such an analytical exercise, based on its own experiences.

Source/Courtesy: PIB, PMO, 15.05.2020

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India calls upon G-20 nations to ensure access to essential medicines, treatments and vaccines at affordable prices

Shri Piyush Goyal, in G-20 Trade Ministers Meeting said, staying true to our tradition of "Vasudhaiv Kutumbakam, India has unconditionally provided medical supplies to over 120 countries to combat this disease. India will emerge stronger after the implementation of the special economic package announced by the Prime Minister, said the Minister. World has to come together to build partnerships among like-minded nations with shared values of democracy, rules-based and transparent business models and concern for humanity as a whole.

MoC&I Press Release dated 14th May 2020

India has called upon the G-20 nations to ensure access to essential medicines, treatments and vaccines at affordable prices. In his Interventions during the 2nd G20 Virtual Trade & Investment Ministers Meeting, held through Video-conferencing, the Commerce and Industry Minister Shri Piyush Goyal asked the G20 members to first focus on immediate and concrete actions that can ease the distress being faced by people all over the world due to Corona pandemic. He said that the unprecedented situation calls for solidarity and a balanced, inclusive and calibrated response. An overriding priority for all countries at this time, is to save precious lives. He strongly called for agreement to enable the use of TRIPs flexibilities to ensure access to essential medicines, treatments and vaccines at affordable prices. He also called upon the G-20 nations to also agree to provide diagnostic and protective equipment, and healthcare professionals across borders where they are most needed.

Shri Goyal said that doing away with the policy instrument of export restrictions is not a panacea that will guarantee access to medical products and food for all. In fact, such a step is likely to lead to a flight of these critical products to the highest bidder, making them inaccessible to the resource-poor. He said that more effective and lasting way to ensure food security of the most vulnerable, would be by agreeing to eliminate the historic asymmetries in the Agreement on Agriculture, and delivering on the long-standing Ministerial mandate to establish permanent, adequate and accessible disciplines

on Public Stockholding for food security purposes by the 12th Ministerial Conference of the WTO.

Shri Goyal said that learning from this extremely distressing experience, the world has to come together to build partnerships among like-minded nations with shared values of democracy, rules-based and transparent business models and concern for humanity as a whole. India wishes to contribute to this global effort. He said "In the last few months, we have embarked upon an ambitious reform agenda under the leadership of Prime Minister Narendra Modi to transform our country. Our future will be crafted on five pillars – a strong and vibrant economy, massive infrastructure development, building modern systems with stable and predictable regulatory practices, leveraging the huge demographic dividend our democracy offers and the growing demand for goods and services of 1.3 billion Indians. We are confident we will emerge stronger after the implementation of the announcement of Prime Minister Modi of a special economic package amounting to around 10% of our GDP."

Sharing a small example of India's capabilities and commitment, Shri Goyal said "When the pandemic broke out, India barely produced a few thousand pieces of Personal Protective Equipment. We had never needed PPEs in large numbers ever before. When we realised that countries were not able to supply enough for our needs, our domestic manufacturers created and ramped up capacities. So much so, that we now produce nearly 300,000 PPEs every day."

The Minister said that widely regarded as the 'Pharmacy of the World', India is also proactively partnering in global efforts to develop vaccines and effective treatment for this disease. He said "We offer full support to any global engagements to further this cause. Staying true to our tradition of "Vasudhaiv Kutumbakam", i.e. the world is one big family, India has unconditionally provided medical supplies to over 120 countries to combat this disease, of which 43 countries received it as a grant. In addition, a USD 10 million COVID-19 Emergency Fund has been created and is being utilised to deliver urgent medical supplies, equipment and humanitarian assistance to our neighbours. We are also sharing our medical and public health expertise and capacity with them, using digital technologies."

Underscoring the wide digital divide between developed and developing countries, the Minister stressed on the urgent need to build the digital skills and capacities of developing countries and LDCs, rather than rushing to make binding rules on digital trade and e-Commerce, which will freeze the extremely non-level playing field against their interests, and deprive them of the opportunity to benefit from the immense potential in these areas. He said that as a result of the pandemic, a large number of professionals, workers and students located overseas are facing difficulty in maintaining their visa status. Describing India as the shining example to have extended benefits to them, he said that we must allow suitable accommodation in their visa status and take other necessary steps to address their distress.

Shri Goyal thanked the Saudi Presidency for organising the 2nd G20 Trade & Investment Ministers Virtual Meeting.

Source/Courtesy: YB, PIB, MoC&I, 14.05.2020

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Dr Harsh Vardhan participates in the 32nd Commonwealth Health Ministers' Meeting through VC

Highlights the timely, graded and pro-active measures taken by India towards COVID-19 management

MoH&FW Press Release dated 14th May 2020

Dr Harsh Vardhan, Union Minister of Health & Family Welfare participated in the 32nd Commonwealth Health Ministers' Meeting through Video Conference. The theme of the meeting was – 'Delivering a co-ordinated Commonwealth COVID-19 response'.

The statement of the Union Health Minister made as part of the intervention at the global meeting is as follows:

"At the outset, while 'Delivering a co-ordinated Commonwealth COVID-19 response', I wish to express

my deepest condolences and concern at the loss of lives due to COVID-19. We acknowledge the tremendous contribution of the numerous frontline health service providers as well as other civic bodies in saving precious lives.

India undertook COVID-19 management with the highest level of political commitment by our Hon'ble Prime Minister Shri Narenda Modi ji under whose guidance, our response toCovid-19 has been pro-active, pre-emptive and graded.

India took all necessary and timely steps including surveillance at points of entry, evacuation of our nationals abroad, surveillance in community through disease surveillance network, health infrastructure strengthening, training and capacity building of health staff, risk communication and community involvement as part of its management efforts.

In implementing the world's largest lockdown to prevent the spread of this pandemic, we are aiming to protect lives by mitigating the explosive growth of the disease and by ensuring that our healthcare system is able to cope up with the growth of the disease. At the same time, we are also mindful of saving lives as well as livelihoods and are therefore keeping all essential services out of the purview of the lockdown.

Our Prime Minister has announced an economic package of more than 265 billion US Dollars to support economic recovery as well to support vulnerable segments of our population. We are gradually easing the restrictions especially in areas where we have managed to contain the disease.

It is critical to build and strengthen core capacities of developing countries particularly the least developed countries for future preparedness, response and resilience.

India has been the first country to urge consolidated global action to fight the challenge of COVID-19. We convened a meeting of SAARC leaders in our region in mid-March in which the need for "coming together, not growing apart; collaboration not confusion; and preparation, not panic", was underlined. These are the elements that signify India's response to this crisis.

India has provided essential medicines such as Hydroxychloroquine to almost 100 needy countries, extending solidarity and support during this time of crisis.

It is important to work on the causes of the pandemic and discover drugs and vaccine to control transmission and prevent recurrence.

It is important to facilitate universal and affordable access to all relevant medical products and technologies, both existing and new. These should be made available in a fair and equitable manner to tackle COVID-19.

Indian scientists are working on discovery of vaccine, drugs as well as development of cost-effective diagnostic kits and various life-saving equipment with the active support of Government of India.

We need to mutually support and share our best practices and explore innovative ways to address new threats and challenges in the post COVID era."

Source/Courtesy: PIB, MoH&FW, 14.05.2020

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US FDA reiterates importance of close patient supervision for 'off-label' use of antimalarial drugs

The U.S. Food and Drug Administration issued a Drug Safety Communication regarding known side effects of hydroxychloroquine and chloroquine, including serious and potentially life-threatening heart rhythm problems, that have been reported with their use for the treatment or prevention of COVID-19, for which they are not approved by the FDA. These risks, which are in the drug labels for their approved uses, may be mitigated when health care professionals closely screen and supervise these patients such as in a hospital setting or a clinical trial, as indicated in the Emergency Use Authorization (EUA) for these drugs to treat COVID-19.

"We understand that health care professionals are looking for every possible treatment option for their patients and we want to ensure we're providing them with the appropriate information needed for them to make the best medical decisions," said FDA Commissioner Stephen M. Hahn, M.D. "While clinical trials are ongoing to determine the safety and effectiveness of these drugs for COVID-19, there are known side effects of these medications that should be considered. We encourage health care professionals making individual patient decisions closely screen and monitor those patients to help mitigate these risks. The FDA will continue to monitor and investigate these potential risks and will communicate publicly when more information is available."

The FDA has issued an EUA to allow hydroxychloroquine and chloroquine products donated to the Strategic National Stockpile (SNS) to be distributed and used in limited circumstances, such as for certain hospitalized patients with COVID-19. These drugs are able to be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. The EUA requires that fact sheets with important information about using these drugs in treating COVID-19, including the known risks and drug interactions, as well as appropriate screening and monitoring, be made available to health care providers and patients.

Hydroxychloroquine and chloroquine are FDA-approved to treat or prevent malaria. Hydroxychloroquine sulfate is also FDA-approved to treat lupus and rheumatoid arthritis. These medicines have not been proven safe or effective for treating COVID-19.

However, clinical trials are underway and additional trials are being planned to determine if these drugs can benefit patients with COVID-19. These trials are also examining whether the drugs can prevent COVID-19 among health care workers, first responders or people who have been in close contact with someone with COVID-19.

Once the FDA has approved a drug, health care providers generally may prescribe or administer the drug for an unapproved use, including in clinical settings not described in the approved labeling. This decision will be based on their assessment of the potential benefits versus the risks for their patient, recognizing that the FDA has not assessed the safety or effectiveness of such use.

For this reason, it is important that health care providers are aware of the risks of serious and potentially life-threatening heart rhythm problems that can occur with these drugs and are included in the drug labels for their approved uses.

As noted in the Drug Safety Communication, the FDA has reviewed - and continues to investigate - case reports in the FDA Adverse Event Reporting System database, published medical literature and the American Association of Poison Control Centers National Poison Data System concerning serious heart-related adverse events and death in patients with COVID-19 receiving hydroxychloroquine and chloroquine, either alone or combined with the antibiotic azithromycin or other medicines.

These adverse events included abnormal heart rhythms such as QT interval prolongation, dangerously rapid heart rate called ventricular tachycardia and ventricular fibrillation, and in some cases, death. Patients who also have other health issues such as heart and kidney disease are likely to be at increased risk of these heart problems when receiving these medicines.

The FDA encourages health care professionals and patients to report adverse reactions or quality problems with any human drugs to the agency's MedWatch Adverse Event Reporting program:

Source: US FDA Press Release, 24.04.2020 (Excerpts)

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Key nose cells identified as likely COVID-19 virus entry points

Two specific cell types in the nose have been identified as likely initial infection points for COVID-19 coronavirus. Scientists discovered that goblet and ciliated cells in the nose have high levels of the entry proteins that the COVID-19 virus uses to get into our cells.

The identification of these cells by researchers from the Wellcome Sanger Institute, University Medical Centre Groningen, University Cote d'Azur and CNRS, Nice and their collaborators, as part of the Human Cell Atlas Lung Biological Network, could help explain the high transmission rate of COVID-19.

Reported today in Nature Medicine, this first publication with the Lung Biological Network is part of an ongoing international effort to use Human Cell Atlas data to understand infection and disease. It further shows that cells in the eye and some other organs also contain the viral-entry proteins. The study also predicts how a key entry protein is regulated with other immune system genes and reveals potential targets for the development of treatments to reduce transmission.

Novel coronavirus disease - COVID-19 - affects the lungs and airways. Patient's symptoms can be flu-like, including fever, coughing and sore throat, while some people may not experience symptoms but still have transmissible virus. In the worst cases, the virus causes pneumonia that can ultimately lead to death. The virus is thought to be spread through respiratory droplets produced when an infected person coughs or sneezes, and appears to be easily transmitted within affected areas. So far the virus has spread to more than 184 countries and claimed more than 180,000 lives.

Scientists around the world are trying to understand exactly how the virus spreads, to help prevent transmission and develop a vaccine. While it is known that the virus that causes COVID-19 disease, known as SARS-CoV-2, uses a similar mechanism to infect our cells as a related coronavirus that caused the 2003 SARS epidemic, the exact cell types involved in the nose had not previously been pinpointed.

To discover which cells could be involved in COVID-19 transmission, researchers analysed multiple Human Cell Atlas (HCA) consortium datasets of single cell RNA sequencing, from more than 20 different tissues of non-infected people. These included cells from the lung, nasal cavity, eye, gut, heart, kidney and liver. The researchers looked for which individual cells expressed both of two key entry proteins that are used by the COVID-19 virus to infect our cells.

Dr Waradon Sungnak, the first author on the paper from Wellcome Sanger Institute, said: "We found that the receptor protein - ACE2 - and the TMPRSS2 protease that can activate SARS-CoV-2 entry are expressed in cells in different organs, including the cells on the inner lining of the nose. We then revealed that mucus-producing goblet cells and ciliated cells in the nose had the highest levels of both these COVID-19 virus proteins, of all cells in the airways. This makes these cells the most likely initial infection route for the virus."

Dr Martijn Nawijn, from the University Medical Center Groningen in the Netherlands, said, on behalf of the HCA Lung Biological Network: "This is the first time these particular cells in the nose have been associated with COVID-19. While there are many factors that contribute to virus transmissibility, our findings are consistent with the rapid infection rates of the virus seen so far. The location of these cells on the surface of the inside of the nose make them highly accessible to the virus, and also may assist with transmission to other people."

The two key entry proteins ACE2 and TMPRSS2 were also found in cells in the cornea of the eye and in the lining of the intestine. This suggests another possible route of infection via the eye and tear ducts, and also revealed a potential for fecal-oral transmission.

When cells are damaged or fighting an infection, various immune genes are activated. The study showed that ACE2 receptor production in the nose cells is probably switched on at the same time as these other immune genes.

The work was carried out as part of the global Human Cell Atlas consortium which aims to create reference maps of all human cells to understand health and disease.

More than 1,600 people across 70 countries are involved in the HCA community, and the data is openly available to scientists worldwide.

Dr Sarah Teichmann, a senior author from the Wellcome Sanger Institute and co-chair of the HCA Organising Committee, said: "As we're building the Human Cell Atlas it is already being used to understand COVID-19 and identify which of our cells are critical for initial infection and transmission.

This information can be used to better understand how coronavirus spreads. Knowing which exact cell types are important for virus transmission also provides a basis for developing potential treatments to reduce the spread of the virus."

The global HCA Lung Biological Network continues to analyse the data in order to provide further insights into the cells and targets likely to be involved in COVID-19, and to relate them to patient characteristics.

Professor Sir Jeremy Farrar, Director of Wellcome, said: "By pinpointing the exact characteristics of every single cell type, the Human Cell Atlas is helping scientists to diagnose, monitor and treat diseases including COVID-19 in a completely new way.

Researchers around the world are working at an unprecedented pace to deepen our understanding of COVID-19, and this new research is testament to this. Collaborating across borders and openly sharing research is crucial to developing effective diagnostics, treatments and vaccines quickly, ensuring no country is left behind."

Waradon Sungnak, Ni Huang, Christophe Bécavin, Marijn Berg, Rachel Queen, Monika Litvinukova, Carlos Talavera-López, Henrike Maatz, Daniel Reichart, Fotios Sampaziotis, Kaylee B Worlock, Masahiro Yoshida, Josephine L Barnes, HCA Lung Biological Network.

SARS-CoV-2 entry factors are highly expressed in nasal epithelial cells together with innate immune genes.

Source: World Pharma News/Science Daily, 23.04.2020 (Excerpts)

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Study reveals most critically ill patients with COVID-19 survive with standard treatment

Clinicians from two hospitals in Boston report that the majority of even the sickest patients with COVID-19 - those who require ventilators in intensive care units - get better when they receive existing guideline-supported treatment for respiratory failure. The clinicians, who are from Massachusetts General Hospital (MGH) and Beth Israel Deaconess Medical Center, published their findings in the American Journal of Respiratory and Critical Care Medicine.

During the COVID-19 pandemic, hospitals around the world have shared anecdotal experiences to help inform the care of affected patients, but such anecdotes do not always reveal the best treatment strategies, and they can even lead to harm. To provide more reliable information, a team led by C. Corey Hardin, MD, PhD, an Assistant Professor of Medicine at MGH and Harvard Medical School, carefully examined the records of 66 critically ill patients with COVID-19 who experienced respiratory failure and were put on ventilators, making note of their responses to the care they received.

The investigators found that the most severe cases of COVID-19 result in a syndrome called Acute Respiratory Distress Syndrome (ARDS), a life-threatening lung condition that can be caused by a wide range of pathogens. "The good news is we have been studying ARDS for over 50 years and we have a number of effective evidenced-based therapies with which to treat it," said Dr. Hardin. "We applied these treatments--such as prone ventilation where patients are turned onto their stomachs--to patients in our study and they responded to them as we would expect patients with ARDS to respond."

Importantly, the death rate among critically ill patients with COVID-19 treated this way - 16.7% - was not nearly as high as has been reported by other hospitals. Also, over a median follow-up of 34 days, 75.8% of patients who were on ventilators were discharged from the intensive care unit. "Based on this, we recommend that clinicians provide evidence-based ARDS treatments to patients with respiratory failure due to COVID-19 and await standardized clinical trials before contemplating novel therapies," said co-lead author Jehan Alladina, MD, an Instructor in Medicine at Mass General.

David R Ziehr, Jehan Alladina, Camille R Petri, Jason H Maley, Ari Moskowitz, Benjamin D Medoff, Kathryn A Hibbert, B Taylor Thompson, C Corey Hardin. Respiratory Pathophysiology of Mechanically Ventilated Patients with COVID-19: A Cohort Study.

Source: World Pharma News, 05.05.2020 (Excerpts)

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Recently recovered COVID-19 patients produce varying virus-specific antibodies

Most newly discharged patients who recently recovered from COVID-19 produce virus-specific antibodies and T cells, suggests a study published on May 3rd in the journal Immunity, but the responses of different patients are not all the same. While the 14 patients examined in the study

showed wide-ranging immune responses, results from the 6 of them that were assessed at two weeks after discharge suggest that antibodies were maintained for at least that long. Additional results from the study indicate which parts of the virus are most effective at triggering these immune responses and should therefore be targeted by potential vaccines.

It is not clear why immune responses varied widely across the patients. The authors say this variability may be related to the initial quantities of virus that the patients encountered, their physical states, or their microbiota. Other open questions include whether these immune responses protect against COVID-19 upon re-exposure to SARS-CoV-2, as well as which types of T cells are activated by infection with the virus. It is also important to note that the laboratory tests that are used to detect antibodies to SARS-CoV-2 in humans still need further validation to determine their accuracy and reliability.

"These findings suggest both B and T cells participate in immune-mediated protection against the viral infection," says co-senior study author Chen Dong of Tsinghua University. "Our work has provided a basis for further analysis of protective immunity and for understanding the mechanism underlying the development of COVID-19, especially in severe cases. It also has implications for designing an effective vaccine to protect against infection."

Relatively little is known about the protective immune responses induced by the disease-causing virus, SARS-CoV-2, and addressing this gap in knowledge may accelerate the development of an effective vaccine, adds co-senior study author Cheng-Feng Qin of the Academy of Military Medical Sciences in Beijing, China.

With this goal in mind, the researchers compared the immune responses of 14 COVID-19 patients who had recently become virus-free to those of six healthy donors. Eight of the patients were newly discharged, and the remaining six were follow-up patients who were discharged two weeks prior to the analyses. Specifically, the researchers collected blood samples and assessed the levels of immunoglobulin M (IgM) antibodies, which are the first to appear in response to an infection, as well as immunoglobulin G (IgG) antibodies, which are the most common type found in blood circulation.

Compared to healthy controls, both newly discharged and follow-up patients showed higher levels of IgM and IgG antibodies that bind to the SARS-CoV-2 nucleocapsid protein, which encapsulates the viral genomic RNA, as well as the S-protein's receptor-binding domain (S-RBD), which binds to receptors on host cells during the process of viral entry. Taken together, these findings show that COVID-19 patients can mount antibody responses to SARS-CoV-2 proteins and suggest that these antibodies are maintained for at least two weeks after discharge.

In addition, five newly discharged patients had high concentrations of neutralizing antibodies that bind to a pseudovirus expressing the SARS-CoV-2 S protein. Neutralizing antibodies prevent infectious particles from interacting with host cells. In addition, all except one follow-up patient had detectable neutralizing antibodies against the pseudovirus.

Compared to healthy controls, five newly discharged patients had higher concentrations of T cells that secrete interferon gamma (IFNγ) - a signaling molecule that plays a critical role in immunity - in response to the SARS-CoV-2 nucleocapsid protein. These are the same patients who had high concentrations of neutralizing antibodies. In addition, three newly discharged patients showed detectable levels of IFNγ-secreting T cells specific to the SARS-CoV-2 main protease - a protein that plays a critical role in viral replication. Meanwhile, seven newly discharged patients showed detectable levels of IFNγ-secreting T cells specific to the S-RBD of SARS-CoV-2. By contrast, only one follow-up patient had a high concentration of IFNγ-secreting T cells responsive to the nucleocapsid protein, the main protease, and S-RBD.

One finding with potential clinical relevance is that the amount of neutralizing antibodies was positively associated with IgG antibodies against S-RBD, but not with those that bind to the nucleocapsid protein. Moreover, S-RBD induced both antibody and T cell responses. "Our results suggest that S-RBD is a promising target for SARS-CoV-2 vaccines," says co-senior study author Fang Chen of Chui Yang Liu Hospital affiliated to Tsinghua University. "But our findings need further confirmation in a large cohort of COVID-19 patients."

Ling Ni, Fang Ye, Meng-Li Cheng, Yu Feng, Yong-Qiang Deng, Hui Zhao, Peng Wei, Jiwan Ge, Mengting Gou, Xiaoli Li, Lin Sun, Tianshu Cao, Pengzhi Wang, Chao Zhou, Rongrong Zhang, Peng Liang, Han Guo, Xinquan Wang, Cheng-Feng Qin, Fang Chen, Chen Dong.

Source: World Pharma News/Science Daily, 05.05.2020 (Excerpts)

Researchers identify four possible treatments for COVID-19

While COVID-19 has infected millions of people worldwide and killed hundreds of thousands, there is currently no vaccine. In response, researchers have been evaluating the effectiveness of various antiviral drugs as possible COVID-19 treatments.

Researchers at the University of Missouri, University of Nebraska Medical Centre, Emory University School of Medicine and Karolinska Institute have found that four antiviral drugs, including remdesivir, a drug originally developed to treat Ebola, are effective in inhibiting the replication of the coronavirus causing COVID-19.

Kamlendra Singh, an Associate Professor in the MU College of Veterinary Medicine, assistant director of the MU Molecular Interactions Core, Bond Life Sciences Center investigator and associate research professor of molecular microbiology and immunology in the MU School of Medicine, and his team used computer-aided drug design to examine the effectiveness of remdesivir, 5-fluorouracil, ribavirin and favipiravir in treating COVID-19. Singh reports that all four drugs were effective in inhibiting, or blocking, the coronavirus' RNA proteins from making genomic copies of the virus.

"As researchers, we have an obligation to search for possible treatments given that so many people are dying from this virus," Singh said. "These antiviral drugs, if they turn out to be effective, all have some limitations. But in the midst of a global pandemic, they are worth taking a deeper look at because based on our research, we have reason to believe that all of these drugs could potentially be effective in treating COVID-19."

The Coronavirus (SARS-CoV-2) that causes COVID-19, like all viruses, can mutate and develop resistance to antiviral drugs. Therefore, further testing in a laboratory setting and in patients is needed to better evaluate how the proposed treatments interact with the virus' RNA polymerase.

"Our goal is to help doctors by providing options for possible treatments of COVID-19, and to ultimately contribute in improving the health outcomes of patients suffering from the infectious disease," Singh said. "As researchers, we are simply playing our part in the fight against the pandemic."

Singh's research is an example of translational medicine, a key component of the University of Missouri System's NextGen Precision Health Initiative. The NextGen initiative aims to improve large-scale interdisciplinary collaboration in pursuit of life-changing precision health advancements and research.

Source: World Pharma News, 05.05.2020 (Excerpts)

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Modi's 'self-reliance' call need of the hour: Pharma industry

The Indian Pharma Industry on Wednesday, 13.05.2020 hailed Prime Minister Narendra Modi emphasising on making India self-reliant and said his speech captured the need of the moment in these trying times. "The Prime Minister's speech captured the need of the hour perfectly. IPA lauds PM's vision on 'Vasudhaiva Kutumbakam' and self-reliance," Indian Pharmaceutical Alliance (IPA) Secretary General Sudarshan Jain said in a statement.

The Government had earlier come out with greater contours of Active Pharmaceutical Ingredient (API) Policy.

During these unprecedented times, the pharmaceutical industry has worked with the Government in an integrated manner and continued to operate with vigour to drive local expertise and truly live up to its title as the 'Pharmacy of the World', he added.

Having said that, providing impetus to domestic manufacturers will strengthen the industry going forward. This will usher a new era for the country's healthcare and pharma sector," Jain said. The Government had earlier come out with greater contours of Active Pharmaceutical Ingredient (API) Policy which is expected to increase self-reliance in fermentation-based API industry, he added.

"IPA is committed to providing quality medicines to the patients in need and we applaud Hon'ble PM's vision for a self-reliant India, Jain said. In similar vein, the Indian Drug Manufacturers' Association (IDMA) also praised Modi's speech on emphasis on self-reliance.

"The PM has very rightly mentioned in his address to nation that it was only the 'local' which came to our help during these unprecedented times," IDMA Executive Director Ashok Kumar Madan said. Whether HCQ or any other formulation, India's uninhibited exports to all nations and its neighbours have again proved India's image as *'Pharmacy of the World'*, he added.

"IDMA with its Membership of Large, Medium and Small Enterprises across the country, reassures the nation of Pharma Industries' commitment to serve the nation and the humanity," Madan said.

Source: PTI, Financial Express, 13.05.2020

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Government still not satisfied with the efficacy of Remdesivir, Favipiravir

The Union Health Ministry is still not satisfied with the efficacy of two antiviral drugs–Remdesivir and Favipiravir–for the treatment of Covid-19 patients

A recent meeting was held by the Joint-Monitoring Group (Technical Committee) at the Health Ministry to discuss the effectiveness of these two antiviral drugs on Coronavirus patients. Experts from ICMR, NCDC, DCGI, WHO representatives, AIIMS, DGHS, Ministry of animal husbandry among others were part of the high-level meeting.

A Senior Government official told: "The technical committee has not found these two antiviral drugs fit for the usage in the covid-19 treatment because there is no concrete evidence to determine the efficacy of the drugs."

"The countries which have used these two antiviral drugs did not show good results on the coronavirus patients. Neither, it reduced the mortality rate nor it reduces the hospitalization time," said the official.

HCQ:

"Till the time, we only recommend Hydroxy-chloroquine (HCQ) as prophylaxis of COVID in selected individuals. It includes asymptomatic healthcare workers involved in the care of suspected or confirmed cases of COVID, asymptomatic household contacts of laboratory-confirmed cases, a combination of HCQ with Azithromycin on patients with severe disease and requiring ICU management," said the official, adding that HCQ has to be given only on the prescription of a Registered Medical Practitioner as per Government Guidelines.

Glenmark is the first company in India to initiate phase-3 clinical trials on Favipiravir for COVID-19 patients in India after the approval from the country's top drug regulator.

US Food and Drug Administration has issued an emergency use authorization for the investigational

antiviral drug remdesivir for the treatment of suspected or laboratory-confirmed Covid-19 in adults and children hospitalized with severe disease.

DCG(I):

"Drug Controller has not received a single application from a pharmaceutical company showing interest to conduct a trial on antiviral drug remdesivir for COVID-19 treatment," said the official.

Earlier this week, Gilead has signed non-exclusive voluntary licensing agreements with five generic pharmaceutical manufacturers based in India and Pakistan to further expand the supply of remdesivir, it said in a statement.

"The countries which have used these two antiviral drugs did not show good results on the coronavirus patients. Neither, it reduced the mortality rate nor it reduces the hospitalization time," said the official.

Source: ANI, The Health Master, 16.05.2020 (Excerpts)

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Enough stock of Hydroxychloroquine in India: Government

The Government said that there is enough stock of Hydroxychloroquine in the country and it is taking all steps to ensure that there is no shortage of the drug in the domestic market. India is the biggest manufacturer of the anti-malarial drug that is being touted as 'game changer' in the fight against the COVID-19 pandemic.

"There is enough stock of Hydroxychloroquine in the country and we are tracking its demand, availability and production on a daily basis," National Pharmaceutical Pricing Authority (NPPA) Chairman Shubhra Singh told.

India is the world's largest manufacturer of the drug, which is used for treatment of rheumatoid arthritis, malaria and lupus, she added. "Ensuring the availability of the drug in the country is our first priority. Only after meeting the demand here, the exports are being done," Singh said.

She, however, cautioned that the medicine should only be taken on the advice of doctors. India manufactures 70 percent of the world's supply of Hydroxychloroquine. Companies like IPCA and Zydus Cadila are the major manufacturers of Hydroxychloroquine in the country. The Indian Pharmaceutical industry earlier this week said there is enough stock of Hydroxychloroquine in the country and drug firms are ready to ramp up the production to meet domestic as well as export requirements.

India currently has an annual installed capacity of around 40 tonnes of Active Pharmaceutical Ingredients (APIs) of Hydroxychloroquine. With this capacity, it can make around 200 million tablets of 200 mg, which can be ramped up, the Indian Drug Manufacturers' Association (IDMA) had said.

The production capacity in the country is sufficient to meet the current demand. If the need arises, the companies are committed to ramp up production, the Indian Pharmaceutical Alliance had earlier told.

India on Tuesday, 12.05.2020 had decided to partially lift the ban on the export of anti-malarial drug Hydroxychloroquine in sync with its global commitment to deal with the Coronavirus pandemic.

Source: PTI, Mathrubhumi, 14.05.2020

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Patent experts urge PMO to set up taskforce to frame IP policy for building strategic stockpile of devices to tackle pandemics such as COVID-19

In a bid to help the country tide over shortage of quality respirator masks, hazmat suits and ventilators covered under patents, patent experts have urged Prime Minister's Office (PMO) to set up a taskforce which will put together an Intellectual Property (IP) policy for building a strategic stockpile for pandemics such as COVID-19.

The taskforce shall consist of public health experts, patent office officials and experts in IP among others.

It should deal with not only existing patents over respiratory masks, hazmat suits and ventilators but also the patents that are likely to be filed very soon for diagnostic kits, drugs and vaccines meant to diagnose or treat COVID-19, said Prashant Reddy Thikkavarapu, Assistant Professor, National Academy of Legal Studies & Research (NALSAR) University of Law, Hyderabad.

Currently, the country is rapidly building up a stockpile that can cater to not just the first-wave of COVID-19 pandemic but also a possible second or third wave that may or may not breakout over the course of the next 12 to 18 months. The cost of such a stockpile is likely to be enormous for a country of 1.34 billion people. While most of the older technology should be out of their patent terms and hence more than affordable (provided there are multiple competitors based in India), the newer technology

is likely to cost the country a king's ransom. This is because most of the newer technology, say even for something like respirator masks required by medical staff dealing with highly contagious diseases such as COVID, are covered by patents, thereby increasing their price, he said.

Taking serious note of this, patent experts appealed to the Central Government to use compulsory licensing under Indian Patents Act to ensure availability of patented medical devices, masks and drugs at an affordable price in the country. The Government can exercise compulsory licensing for patents under three sections of IP Act viz Section 92, Section 100, Section 102.

Under Section 92 of IP Act, the Government can declare a national emergency due to COVID and notify the patents in questions after which any person interested in manufacturing the said patent can make an application to the Controller of Patents who can then issue a compulsory license without following the regular procedure of time-consuming hearings. The patentee will be paid a reasonable royalty rate as fixed by the Controller of Patents, said Thikkavarapu.

Under Section 100 of IP Act, the Government can authorize specific companies to use any patents or patent applications for the "purpose of government". Once the Central Government gives such an authorization to Indian companies, they can begin manufacturing while negotiating royalties with the patentees. In case the Central Government or its authorized company fails to reach an agreement with the patentee, it is up to the High Court to fix the reasonable royalty that is payable to the patentee.

Under Section 102 of IP Act, the government can simply acquire the patents in question from the patentees much like it acquires land for public purpose. Once again if the Central Government and the patentee cannot reach an agreement on the cost of the patents, it is up to the High Court to fix the price of the patents.

In each of these cases, the reasonable royalty is to be fixed with the objective of ensuring the widest possible availability of the patented technology at the most reasonable price for Indian consumers, he said.

In the past the United States has used (or threatened to use) 28 USC 1498 in the times of war and public health crisis, such as the Anthrax scare in 2001, to break patents after paying the owners a reasonable royalty. In the context of the present pandemic, countries like Israel and Equador have either invoked or threatened to invoke compulsory licences for patents that covered potential cures, he added.

Given that compulsory licensing or government acquisition is always likely to raise the hackles of our trading partners, the Government can always consider negotiating either bulk public procurement or technology transfer, while waving the sword of more coercive actions as a negotiating tool. It is a known fact that bulk public procurement can massively reduce the price of even patented products. The question however is whether many of these foreign patentees have the manufacturing capacity to cater, in the short run, to the expected demand from India. If they lack capacity they should be encouraged to transfer technology to Indian companies under reasonable royalty agreements, he stated.

In the past, pharmaceutical companies such as Gilead have licensed their drugs to Indian companies at reasonable royalties.

Source: Laxmi Yadav, Pharmabiz, 14.05.2020

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Manufacturers annoyed over arbitrary and unscientific fixing of RDA value for methylcobalamin by FSSAI

Methylcobalamin manufacturers have once again raked up the contentious issue of arbitrarily fixing of Recommended Dietary Allowance (RDA) value for methylcobalamin by Food Safety and Standards Authority of India (FSSAI) which they claim is not based on scientific rationale with reference to a Government Notification dated January 7, 2020.

Methylcobalamin is widely marketed in the country as a drug for chronic neurological disorders with an RDA of 2000 mcg intramasucular but as per FSSAI it is detrimental for patients when used above 1 mcg for prevention and disease management. Name of some widely sold brands are Locopen capsule, Neugaba M 75 capsule, Nervup 500 mcg injection, Nuroz Forte, Nurofine-2500 injection, Actovis 2500 injection, etc.

RDA for methylcobalamin is currently set at 1 microgram (mcg) for neurological disease management by FSSAI based on data provided by Indian Council of Medical Research (ICMR).

Based on the industry correspondence to share technical details on which 1mcg is specified as RDA for methylcobalamin, FSSAI has maintained that RDA for different essential nutrients for Indians are specified by ICMR which also specifies RDA for vitamin B12

(irrespective of its sources such as methylcobalamine or cyanocobalamine) as 1 microgram (mcg).

"Since revision of RDA does not fall under the scope of FSSAI and any such request may be taken up with ICMR rather than with FSSAI. Moreover, it is to mention that usage of single vitamin B12 (methylcobalamin) at higher doses for patients requires diagnosis by a physician and therefore falls under the scope of CDSCO and not FSSAI," it stated.

"Drug authority has allowed 2000 mcg intramuscular as upper limit but nutraceuticals may be allowed at least 500 mcg RDA for prophalytic use in the interest of patients. One mcg of methylcobalamin to manufacture is of no use," explains Ahmedabad based leading pharma consultant Dr Sanjay Agrawal.

A notification was issued on Recommended Dietary Intake on January 7, 2020 where vitamin B12 RDA was considered as 1 mcg without clarifying the tolerable upper limit (TUL) of each vitamin B12 and individual RDA of each type of vitamin B12. The nutraceutical regulations mention that the quantity of nutrients added to the articles of food shall not exceed the RDA as specified by the ICMR and in case such standards are not specified, the standards laid down by international food standards body, namely, Codex Alimentarius Commission, shall apply. This means that manufacturer of methylcobalamim can manufacture it in 1 mcg strength only.

The issue has been festering due to missing information on tolerable upper limit (TUL) of methylcobalamin from the public domain. Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption. Oral or intramuscular dosages between 1-5 mg are used with no supportive evidence of adverse effect. The usual treatment in PA patient is 1 mg administered intramuscular once every 1-3 month and oral dosages of 300 mcg to 1000 mcg daily could also provide adequate treatment.

"One aspect is body requirement and other is the dose which is to be manufactured. The regulatory authority has considered both as one without giving consideration that only a portion of same will be absorbed. 1 mcg methylcobalamin to manufacture is nothing for Indian public which is already suffering from malnutrition. The FSSAI must take into account that when cynocobalamin is taken only in 1/10 portion, it is absorbed by the body therefore RDA value for each type of vitamin B12 must be different. For prophylactic use atleast 500 mcg methylcobalamin must be allowed to manufacture" elaborated Dr Agrawal.

The FSSAI spokesperson said the differences in the bioavailability of two forms namely, cyanocobalamin and methylcobalamin are also insignificant and may not affect RDA which is very surprising. If that is the truth why water and fat soluble vitamins are given different RDA value," pharma consultant Anshu Yadav argued.

It has been learnt that the FSSAI scientific panel and scientific committee has recommended RDA values in vitamins and minerals for various micro-nutrients using reference from ICMR and Codex in this context.

Methylcobalamin is a form of vitamin B12. It can be used to replace levels in patients who don't have enough and may also be used to treat certain conditions such as neuropathy, ALS and certain types of anemia.

Source: Shardul Nautiyal, Pharmabiz, 14.05.2020

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Gilead gives royalty-free licences for Remdesivir to Indian firms

The Coronavirus pandemic has killed over 2,80,000 people globally, and several drugmakers are racing to develop a viable treatment or vaccine to combat the outbreak.

With no other approved treatment for COVID-19, the respiratory illness caused by the novel Coronavirus, interest in Remdesivir has been growing. To this end, Gilead Sciences Inc has signed a non-exclusive licensing pacts with five generic drugmakers to expand the supply of its experimental COVID-19 treatment Remdesivir.

Out of these, three are based in India:

The licenses are royalty-free until the World Health Organisation declares the end of the public health emergency regarding COVID-19, or until a product other than Remdesivir or a vaccine is approved to treat or prevent the disease. The licensees will also set their own prices for the generic product they produce.

Gilead's antiviral drug Remdesivir earlier this month received the US Food and Drug Administration's emergency use authorisation to treat COVID-19 patients.

The said pacts allow the companies to make and sell the drug in 127 countries, enhancing India's leadership in the global pharmacy market.

At present, Indian Pharma holds a 15 percent share in the world market -- a leadership position. India's drug manufacturing capability is its new soft power. There are three distinct areas of opportunity -- pharmaceutical exports, medical tourism destination, and reaching out to vulnerable nations and offer its knowledge and supplies.

India contributes more than 20 percent by value to the global generics market, and by volume -- supplies more than 40 percent of United States' drugs. Indian drugs have been exported to more than 120 countries in the world.

Also, India co-sponsored a resolution at the United Nations General Assembly. It called for a fair, transparent and equitable access to essential medical supplies and any future vaccines for the Coronavirus. As many as 179 countries have thrown their support behind this resolution now.

Source: Palki Sharma, WION Web Team, 13.05.2020

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USP's revised rules focus on issue of microbial contamination during compounding of sterile preparations

Pharma and biotech industry in India is now making considerable efforts to ensure that there is no microbial contamination during compounding of sterile preparations. This is even as the country gears up as a key supplier of scores of drugs apart from the first line therapy for COVID-19 treatment with hydroxychloroquine (HCQ), azithromycin and paracetamol.

The need to focus on total quality systems came in after the Council of Experts at the US Pharmacopoeia (USP) updated its existing Rules and Procedures on 'Pharmaceutical Compounding – Sterile Preparations'.

Hence USP with a concern on the current Coronavirus infected scenario globally insists that pharma and biotech industry will need to pay attention to maintenance and evaluation of air quality besides avoiding direct or physical contact contamination.

Further USP noted that it is critical for the industry to prevent harm and fatality to patients resulting from microbial contamination, excessive bacterial endotoxins, variability in the intended strength of ingredients exceeding monograph limits and addition of unintended chemical-physical contaminants. Therefore the objective is to protect people's health during the pandemic.

The compounding sterile preparations are potentially hazardous to patients when administered into body cavities, central nervous, vascular systems, eyes, joints, and when used as baths for live organs and tissues.

According to Kaushik Desai, Pharma Consultant, it is imperative to maintain standards while compounding sterile preparations. There is enough technological support available in terms of infrastructure and equipment so as to maintain the area free from microbial contamination. What is needed is robust implementation of quality management systems and trained manpower. Most of the issues arise because of lack of understanding the importance of following systems and procedures. USP's revised rules re-emphasize the issue of microbial contamination in view of increased cases of corona virus globally.

In a country like India there is considerable dependence on HCQ, azithromycin and paracetamol Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs) for formulations that are in demand not just for domestic but export market too.

"We see the need for use of technologies, techniques, materials, and procedures that have been proven to be equivalent or superior with statistical significance. It is here we assert the need for personnel garbing, gloving; personnel training, testing practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring besides disinfection of surfaces," said USP Council of Experts. The revised standards apply to all persons who are engaged in the preparation of compounded sterile preparations. These cover diagnostics, drugs and nutrients that are administered to patients as aqueous bronchial and nasal inhalations, injections, irrigations for wounds, ophthalmic drops and ointments and tissue implants.

Source: Nandita Vijay, Pharmabiz, 14.05.2020

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COVID-19 to cause Rs. 1,500-cr financial loss & 8% jobs in Pharma sector in Kerala unless Government introduces survival package: KPMA survey

A web-based survey conducted by the Kerala Pharmaceutical Manufacturers Association (KPMA) has revealed that 8% of employments in both Pharma manufacturing industry and trade sector in Kerala could be lost due to the COVID-19 pandemic unless Central

and State Governments introduce some survival package for Pharma industry. Further, the survey reports estimate a loss of Rs. 1,500 crore for the entire Pharma sector in Kerala due to the present crisis.

A team of market researchers led by N Purushothaman Namputhiri, President of the KPMA and Managing Director of Chethana Pharmaceuticals in Malappuram district, has carried out the web-based survey which assessed that the Pharma industry and business enterprises are likely to sink if the lockdown situation continues for a long span of time. From the beginning of this year, cash flows to industry from trade sector dried up, and the situation has intensified after the lockdown was imposed. All operations in the industrial units have been disrupted and most of the units are experiencing big financial tension, says the survey.

Briefing Pharmabiz about the survey, Namputhiri said the pharma manufacturing and trade sectors in Kerala provide jobs to about 3 lakh employees in various areas such as industry, distribution, marketing, wholesale and retail. If the national lockdown is not unwound in the near future, there is potential disruption to manufacturers and marketers in pharmaceutical business. The situation can be brought under control if state Government ushers in some significant reforms for survival, he said.

"As per the responses to our survey we find that every month the Pharma sector, both industry and trade, in Kerala spends Rs. 100 crore towards expenditure including salaries to employees. The average income from all sources to the sector comes around Rs. 600 crore. The survey finds that the fallout from the pandemic crisis will continue to affect the industry and the whole pharma business. Hence it has estimated a loss of Rs. 1,500 crore to the sector in the post-COVID period," Namputhiri told.

Expressing concern over the impending after-effects of the lockdown, the KPMA President said the industry can pick up and survive the situation provided it gets labourers on reasonable wages and tax relaxations from Government side. He said job loss in industry during crisis is inevitable as the market is set to shrink. The only way-out is support from Government.

For the survival of the business in the manufacturing sector Government should implement financial packages for the industry covering modernization, infrastructure development, R&D and uninterrupted availability of raw materials on reasonable prices. The trade sector will prosper if ample opportunities are made for availing easy working capital.

The survey suggests that Kerala can become self-sufficient in Pharma production if the government initiates special package for promoting bulk drug industry. Currently, all APIs are coming from China.

Source: Peethaambaran Kunnathoor, Pharmabiz, 18.05.2020

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NIPERs from across country submit research proposals to Government agencies for management of COVID-19

The National Institutes of Pharmaceutical Education and Research (NIPERs) from across the country have submitted research proposals to various government agencies for approval based on its meet with Department of Pharmaceuticals (DoP) Secretary Dr P D Vaghela towards the containment, identification and treatment of COVID-19 patients.

NIPERs at Mohali, Raebareli, Hyderabad, Ahmedabad and Kolkata have submitted proposals to various government agencies towards management of COVID-19.

The key themes of these proposals include design of protease targeting COVID-19 antiviral agents (NIPER-Mohali), computationally guided drug-repurposing using the FDA approved drug-database (NIPER-Mohali and Raebareli), analysis of pro-drug to drug conversion of Remdesvir (NIPER, Mohali), adjuvant-therapy based nasal spray for ailing patients (NIPER-Hyderabad), quantum-dot based and conductivity based biosensor development for rapid COVID-19 (NIPER-Ahmedabad) testing, and an interesting study about the control of strokes incidence during COVID-19.

DoP in consultation with NIPERs have stressed upon priority to licensing and commercialization of solutions developed at NIPERs so that the products reach the market in this hour of need. A large number of multi-faceted research proposals have been submitted by various NIPERs in this direction.

NIPER-Raebareli has also initiated a mega project with IIT and an industrial partner in the development of new immuno-booster formulation utilizing traditionally used shrubs. NIPER Kolkata is working on an indigenous cost effective ICU Ventilator in collaboration with CSIR CECRI and a private manufacturer.

Central Electro Chemical Research Institute (CECRI) is one of a chain of forty national laboratories under the aegis of the Council of Scientific and Industrial Research (CSIR) in New Delhi.

NIPERs are the institutes of national importance under the aegis of the DoP. The seven institutes are functional at Ahmadabad, Hyderabad, Hajipur, Kolkata, Guwahati, Mohali, and Raebareli.

A meeting of all the Directors and Chairmen of the institutions through video conferencing was held under the Chairmanship of Dr Vaghela to review their performance in research and innovation activities especially with regard to the ways in which NIPERs have and can contribute in country's fight against COVID-19 pandemic.

Director, NIPER Guwahati informed about the fabrication of prototypes for 3D printed face-shields, a "hands-free object" for touch-less opening of doors, drawers and elevators, antiviral masks as well as skin friendly herbal sanitizers. He informed that industrial scale manufacturing of these products is being done in collaboration with Hindustan Antibiotics Limited, a departmental PSU.

At NIPER Mohali, in association with the Government of Punjab, steps have been initiated to set-up an RT-PCR based COVID-19 testing facility to expedite COVID-19 confirmatory tests in the state.

Dr Vaghela mentioned that all COVID-19 related research and product development initiatives should be done briskly to provide help to the needy at the earliest. In particular, he stressed that all licensing and commercialization aspects of the developed solutions at NIPERs should be coordinated through regulatory agencies on priority so that the products reach the market in this hour of need. Through these research efforts and societal participation in helping the people, NIPERs are committed to work in solidarity with different groups and serve the country in the best possible way.

Source: Shardul Nautiyal, Pharmabiz, 18.05.2020

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Union Health Minister Dr Harsh Vardhan set to be WHO Executive Board Chairman, say officials

Dr. Vardhan would succeed Dr Hiroki Nakatani of Japan, currently the Chairman of the 34-member WHO Executive Board

Union Health Minister Dr Harsh Vardhan, who is at the forefront of India's battle against coronavirus (Covid-19), is set to take charge as the Chairman of the WHO Executive Board on May 22, officials said on Tuesday, 19.05.2020.

Vardhan would be elected at the Executive Board meeting of the World Health Organisation on May 22, the officials said.

Dr. Vardhan would succeed Dr Hiroki Nakatani of Japan, currently the Chairman of the 34-member WHO Executive Board.

The proposal to appoint India's nominee to the executive board was signed by the 194-nation World Health Assembly, officials said on condition of anonymity.

His taking over the post seems to be a formality after the decision that he will be India's nominee as the WHO's South-East Asia group had unanimously decided last year that India would be elected to the executive board for a three-year-term beginning May.

Dr. Vardhan would be elected at the Executive Board meeting of the World Health Organisation on May 22, the officials said.

The Chairman's post is held by rotation for one year among regional groups and it was decided last year that India's nominee would be the Executive Board Chairman for the first year starting Friday, 22.05.2020.

It is not a full time assignment and the minister will just be required to chair the Executive Board's meetings, an official said.

The Executive Board is composed of 34 individuals technically qualified in the field of health, each one designated by a member state elected to do so by the World Health Assembly. Member States are elected for three-year terms. The Board meets at least twice a year and the main meeting is normally in January, with a second shorter meeting in May, immediately after the Health Assembly.

The main functions of the Executive Board are to give effect to the decisions and policies of the Health Assembly, to advise it and generally to facilitate its work.

Addressing the 73rd World Health Assembly via video conferencing on Monday, Vardhan had said India took all the necessary steps well in time to combat the Covid-19 pandemic.

He had asserted that the country has done well in dealing with the disease and is confident of doing better in the months to come.

India is set to take over the Chairmanship of the Executive Board amid growing calls, including by US President Donald Trump, to investigate how the coronavirus originated in China's Wuhan city and subsequent action by Beijing.

Source: PTI, Business Standard, 20.05.2020

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FMRAI alleges medical reps being forced to work in lockdown; IDMA ignores allegations

The Federation of Medical and Sales Representative Associations of India (FMRAI), which comprises 1.5 lakh medical representatives of various pharmaceutical companies across the country, has alleged that the pharma companies are compelling them to work in the field and in the infection-prone hospital settings in violation of lockdown orders imposed by government and local authorities due to COVID-19 pandemic.

Although the services of medical representatives do not come under the Essential Services Maintenance Act (ESMA) 1968, the manufacturing companies are writing to their brand promotion employees to work as usual because their services form part of the essential services, alleged national leaders of the FMRAI. They further said, all the companies (MNCs, big players and the Small & Medium Enterprises) urge the medical representatives to achieve their targets for not making any deduction in their salaries during this global crisis period.

Meanwhile, industry leaders from various states have informed Pharmabiz that the allegation of FMRAI is not true as no company can force any representative to visit the field in the present extra-ordinary situation. But they said the medical representatives can do whatever they can by sitting at home through online. It is the moral responsibility of the pharma industry to maintain the availability of all medicines in the market in a pandemic crisis.

Mr. Mahesh H Doshi, National President of the IDMA, without commenting much on the issue, has responded that it is the problems of the employees working with the companies and each company has to handle it at individual level.

"Their allegation is unlikely to be correct. No company will force their representatives to work in the field or urge them to achieve their targets. But they are fully paid by the companies even in this lockdown. Very few companies are only making some deductions in the payment. So, as morally responsible employees, the medical representatives can do some work at home to promote the business. Also, they can coordinate with the distribution channel for the business growth," said S K Janimiya, Chairman of Telengana unit of the Indian Drug Manufacturers' Association (IDMA).

Mr. Ramesh Sundar, National President of FMRAI, while briefing their issues, has alleged that the pharma industry is taking advantage of the COVID-19 crisis. He dismissed the argument of manufacturers that sales promotion employees are also part of essential services. He said the companies insist on the employees to work in the field and carry drugs with them while on duty. As per drug rules, medical representatives cannot carry drugs while doing promotion work, they are only brand promoters, he said.

"The pharma industry says that COVID-19 crisis has not affected them, but some of them behave very badly towards the sales promotion employees. Even 50 years old companies want their field staffs to opt for voluntary retirement. Only very few companies make the full payment during this time. Secondly, they want us to work at home. The circumstances at the houses of the field staffs may not be conducive for online promotion work. They are putting tremendous pressure and workload on the representatives and even changing the job profiles. The medical representatives are always working in infection prone areas without any safety measures or protective care. However we are interested to work in the green zones during the lockdown period", said Ramesh.

Mr. S Kandelwal, National Joint Secretary of the medical representatives association from Rajasthan has opined that pharmaceutical product promotion through online is illegal as per norms of the Drugs and Cosmetics Act and the Sales Promotion Employees (Conditions of Service) Act 1976. The medical representatives are supposed to ensure availability of medicines in the market, but the industry should consider the difficulties for work during the present social condition.

Mr. Kandelwal, a fighter for employees' rights, said FMRAI wants life insurance coverage of Rs. 10 lakhs and health insurance coverage of Rs one lakh to their members by the companies. He said the government of India has initiated special insurance coverage for health workers engaged in COVID-19 fight. In the same way the manufacturing companies should come forward with novel schemes to protect their marketing staffs.

Whereas, Mr. K B Kadam, a Mumbai based medical representative and Assistant Secretary of the association, said the companies are forced to pay salaries to their employees, so they want the promotion staffs to work in the market even in the crisis. Although the staffs are making all efforts to promote the products, adverse results are coming due to the situation. The doctors are not willing to meet the representatives.

When Pharmabiz contacted Mr S V Veeramani, Past National President of the IDMA and the Managing Director of Fourrts Laboratories in Chennai, he said no company can force the field staffs to work in the field, but business must go on. “Every company is paying good salary to the product promotion employees. So, whatever possible they must do. They can go to the pharmacies and check if any shortage is there for any product and support the distribution network. Otherwise, difficulty will arise in paying salaries,” he added.

According to Sanjive Rai, President of Bihar Pharmaceutical Manufacturers Association the industry is facing a lot of problems during this time and it cannot take advantage of the COVID-19 crisis. Pharma sector is waiting for the help of government to survive the situation. The medical representatives can maintain the stock availability in the hospital pharmacies and in the community pharmacies over telephone. “We cannot contact the customers directly, it is the duty of the medical representatives to keep touch with them. We are giving salaries to our employees, but our both hands are empty. We are waiting for the mercy of the government,” he said.

Dr Viranchi Shah, President of Gujarat State Board of the Indian Drug Manufacturers' Association (IDMA), said as a moral responsibility it is the duty of the pharma industry to make available all drugs in the market during this time. So, the medical representatives need to be encouraged to check the availability in the market. But no manufacturer will compel them to work; it is their moral responsibility to the company which gives them salary for their livelihood.

Source: Peethaambaran Kunnathoor, Pharmaiz, 16.05.2020

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Government to further revise criteria for classifying "medium" enterprises under MSME definition: Gadkari

Days after changing the definition of MSMEs, the government has decided to further revise the criteria for medium units by enhancing the investment and turnover limits to up to Rs 50 crore and Rs 200 crore respectively, Union Minister Nitin Gadkari said on Tuesday, 19.05.2020.

Unveiling the contours of the Rs 20 lakh crore stimulus package, Finance Minister Nirmala Sitharaman had last last week announced a change in the definition of Micro, Small and Medium Enterprises (MSMEs).

As per the revised definition, any firm with investment up to Rs 1 crore and turnover under Rs 5 crore will be classified as "micro". A company with investment up to Rs 10 crore and turnover up to Rs 50 crore will be classified as "small" and a firm with investment up to Rs 20 crore and turnover under Rs 100 crore will be classified as "medium". The previous criteria for classifying enterprises in the "medium" category was investment up to Rs 10 crore and turnover of up to Rs 5 crore.

"We have taken a decision to raise the up to Rs 20 crore investment (criteria) to up to 50 crore and turnover (limit) to up to Rs 200 crore. So we will issue an order for that," Gadkari said.

The Minister for MSME and Road Transport and Highways, Gadkari said he feels the criteria should be based on investment "or" turnover instead of investment and turnover both as announced, adding that the government "will rectify the same". The minister said he was also open to considering suggestions regarding enhancing the turnover limit to up to Rs 250 crore for medium enterprises, and will take up the matter with the MSME Secretary.

Mr. Gadkari said the Government plans to raise MSMEs contribution to India''s exports to 60 per cent from 48 per cent at present and also boost the sector''s contribution to the country''s GDP from 29 per cent currently to 50 per cent.

"We are planning to create 5 crore new jobs. Until now, we have created 11 crore jobs," said the Minister, adding that he was keen on developing Indian MSMEs of international standards.

Interacting with representatives from an exporters' body, he urged exporters to take advantage of the "blessing in disguise" posed by the global "hatred against China" through cost reduction and encouraging import substitution. Besides, Gadkari said the government wants to make bus ports and is also planning to build logistics parks.

Source: PTI, Outlook, 19.05.2020

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Some widely used drugs in short supply in Bangladesh

Some widely used medicines are already out of market or in short supply in Bangladesh as the Coronavirus crisis hit their productions and supply chain, pharmaceutical industry owners and medicine sellers said.

Medicine manufacturers in Bangladesh is largely dependent on imported raw materials, intermediaries and other associate products the imports of which have been disrupted by the global spread of the new Coronavirus since February, they said.

As countries such as China and India, over the last two weeks, resumed limited scale of exports of pharmaceutical raw materials after a three-month-long lull, prices appeared to have increased manifold as are their shipment charges, they said.

'A crisis is only natural when the import of several thousand molecules on which the existence of pharmaceutical industries depends remained suspended for months,' S M Shafiuzzaman, Secretary General of Bangladesh Association of Pharmaceutical Industries, told. He said that some medicines would be in short supply or might disappear from the shelf if the crisis continued. The widely used vitamin C supplement, marketed as Ceevit and other such brand names are largely out of market, as the Government routinely promoting vitamin intake in order to strengthen immunity to fight COVID-19, the disease caused by the novel Coronavirus.

Supplies of some other drugs used to treat respiratory illness, high blood pressure, cardiac illness, kidney diseases, and cold and fever are reportedly under stress, according to pharmaceutical representatives and medicine sellers. 'Ceevit has been out of supply for more than a month,' said Ripon Kumar, owner of Priya Medical, a medicine shop in Mirzapur, Tangail.

Supplies of other brands of the vitamin C supplement also became scarce, he said. Drugs such as Osartil and Prosan, widely prescribed among heart, kidney and diabetes patients, are also in short supply, he said.

Ripon also reported that cough syrup such as Tusca and Ambrox and antihistamines such as Fenadin also became scarce. 'Pharmaceutical representatives are blaming it on short supply of raw material crisis,' he said. Kumudini Pharma area Manager in Mirzapur Ratan Kuma Sutradhar said that an abnormally increased high demand has stressed the supply of Painil used to treat pain and fever. Ratan used to sell 30 boxes of the drug a month but now he would need 130 boxes and 'now the company is unable to cope with the demand.' General Pharmaceuticals Managing Director Momenul Haq said that a crisis was inevitable for drug producers could normally stock three-month worth of pharmaceutical raw materials.

The last time pharmaceutical company owners in the country imported raw materials were in December last year or early this year, he said. China and India, the countries from where Bangladesh sources 80 percent of its required raw materials, lately opened exports on limited scale while European sources are still inaccessible, he said. 'Pharmaceutical sector is plagued by crises,' he said.

The price of per tonne of isopropyl alcohol, a widely used hand rub ingredient, jumped to $2,100 from $1,100, he said. Per kilogram of azithromycin now sells at $130 though it used to sell at $90 before the pandemic hit, he said. The shipment charge of per kilogram of raw materials from India increased to $8 from $2, he said. 'If the situation does not change immediately many of us may be forced to stop producing drugs,' said Momen.

Bangladesh's Tk 22,000-crore worth drug industry is dominated by 25 companies. Popular hand sanitiser marketed as Hexisol disappeared along with many other cleanliness and disinfectants such as liquid antiseptic Savlon and Dettol in less than a month after the first COVID-19 case had been detected in early March.

The drug administration allowed more than a dozen companies and distilleries to produce hand sanitisers but the crisis for a reliable brand persisted. Drug Administration Directorate General Major General Mahbubur Rahman could not be reached for comments.

DGDA DG Mahbubur Rahman however recently told journalists that the DGDA so far successfully tackled the situation with uninterrupted supply of medicines and that there was no possibility of a drug crisis. Incepta Pharmaceuticals Chairman Abdul Muktadir admitted there were stresses on pharmaceutical industries but he was optimistic about the availability of all kinds of popular drugs. 'We have managed it well so far and hopefully things will start to look up,' he said.

Source: Emran Hossain, https://www.newagebd.net/, 10.05.2020

The challenges of developing a safe and effective COVID-19 vaccine

The goal of a vaccine is to trigger a response that safely protects against an infection and/or the burden of disease. While this is true for all vaccines, the steps leading to a safe and effective product can be different for each infection. In the case of COVID-19, caused by the virus SARS-CoV-2, researchers at Baylor College of Medicine and Texas Children's Hospital have found that vaccine design can face specific challenges and that vaccine development approaches require an understanding of how the immune system naturally responds to a specific infection as well as how vaccines might trigger specific protective responses.

The National School of Tropical Medicine at Baylor and the Center for Vaccine Development at Texas Children's, co-led by Dr Maria Elena Bottazzi and Dr. Peter Hotez, currently are developing Coronavirus vaccines. The researchers are applying their years of experience developing vaccines for neglected tropical and emerging infectious diseases such as SARS and MERS to develop a safe and effective COVID-19 vaccine.

"As we proceed with the designing and testing of vaccine candidates, we felt the need to collaborate with a clinical immunologist, who also is engaged in basic and translational research, so that together we can inform our vaccine development efforts and ensure we evaluate both the protective mechanisms and avoid inducing any undesirable immunological responses that have been associated with some respiratory viruses," said Bottazzi, Professor of pediatrics and of molecular virology and microbiology and associate dean of the National School of Tropical Medicine at Baylor. Bottazzi and Hotez approached Baylor's pulmonologist Dr David Corry, Professor of Immunology, Allergy and Rheumatology and Fulbright Endowed Chair in Pathology in the Department of Pathology & Immunology. He also is a member of the Dan L Duncan Comprehensive Cancer Center.

One of the outcomes of their collaboration is the recent publication of two papers, one in Microbes and Infection and the other in Nature Reviews Immunology. "These publications are the result of an in-depth literature search and analysis that has informed our vaccine development strategy. We highlight experimental and clinical evidence showing some of the challenges toward the development of COVID-19 vaccines -- what we know and what we don't know -- and the critical points we should pay close attention to as we advance and evaluate our vaccine candidates," Bottazzi said.

What does a protective response against COVID-19 look like?

COVID-19 is a new disease and while most of the evidence points to natural infection with the virus generating protective immunity, important gaps still remain. Researchers know, for instance, that the mechanism of protection most likely will need to rely on a robust antibody response with neutralizing capacity, coupled with a balanced cellular response and cytokines or immune proteins. In recent studies, rhesus macaques infected with SARS-CoV-2 have shown to develop protective antibodies and resistance to reinfection. Previous studies from SARS-CoV in 2003 also showed that persistent antibody responses against the virus spike protein - the protein the virus uses to bind and invade a cell - and specifically against a part of the spike protein known as the receptor binding domain, supported immunity.

"We are encouraged by the evidence supporting the likelihood that immunizing against the spike protein's receptor binding domain represents a realistic and viable vaccination strategy. However, many questions remain." said Hotez, who serves as dean of the National School of Tropical Medicine at Baylor, as well as the Texas Children's Hospital Endowed Chair in Tropical Pediatrics.

"Studying the immunological responses triggered in people infected by the virus is one way researchers can select what viral components or antigens are promising candidates to use when designing the vaccine," Bottazzi said. "That, coupled with studies using laboratory models of disease, is how scientists attempt to predict what are the ideal mechanisms of protection triggered by vaccines."

On that basis, the Baylor and Texas Children's teams, in collaboration with the New York Blood Center, developed a vaccine strategy based on this fragment of the viral protein, the receptor binding domain.

How to design a vaccine that safely protects against COVID-19?

Experimental and preclinical observations made during prior attempts to develop vaccines against respiratory viruses suggest that some vaccine formulations may

trigger undesirable responses. Some of these responses may be cell mediated while others may be triggered by antibodies.

Cell-mediated responses:

Preclinical testing of some experimental vaccines followed by viral infection in animal models showed tissue damage caused by cellular infiltrates after the induction of an immune response.

"Some experimental animals developed an inflammatory response in the lung or liver characterized by significant infiltration of immune cells - lymphocytes, monocytes and eosinophils," Corry said. "Our literature search suggests that this cellular infiltration can be associated with IL-6, a cytokine or immune protein that is strongly increased in patients with COVID-19 who experience a cytokine storm, an excessive production of cytokines that can be life-threatening."

"We also found studies that show that type Th17 immune responses likely could account for the cellular infiltrates, including eosinophils, observed in animal models," said Hotez.

This immune infiltration was observed with experimental viral-vectored vaccines. Viral-vectored vaccines use a chemically weakened and different virus to transport components or antigens of the COVID-19 virus into the body to stimulate an immune response.

Although more research is needed to understand the mechanisms of cell-mediated responses and their relevance to clinical outcomes, the potential of significant immune cell infiltration has important implications for COVID-19 vaccine development.

Research also has suggested that the selection of adjuvants - agents traditionally added to vaccines to boost a positive immune response - may impact the type of immune response triggered. For instance, in SARS vaccines, using alum reduces cellular infiltration, indicating that this adjuvant could minimize these undesirable responses.

"Based on prior evidence, we also opted to evaluate and use alum in our COVID-19 vaccine formulation since our goal is to ensure we reduce the possibility of inducing an undesirable immune response," Bottazzi said.

Antibody-mediated responses:

Called antibody-dependent enhancement, this response has been previously observed in dengue and other viral infections.

"Antibody-dependent enhancement in dengue occurs when antibodies bind to the virus and shuttle it inside infection-fighting cells called macrophages. Once the virus coated with an antibody is inside macrophages, it doesn't die. It replicates," Corry said. "The macrophages end up spreading the infection inside the organism as macrophages move around."

Whether this phenomenon is relevant to human coronavirus infection is unclear. In laboratory experiments, antibody-dependent enhancement seems to occur with both non-neutralizing and neutralizing antibodies.

"For this reason, we selected the receptor binding domain of the virus. It excludes the epitopes or sections of viral proteins that might potentially induce antibody-dependent enhancement," Hotez said. "We have not found any evidence that our vaccine triggers antibody-dependent enhancement in laboratory pre-clinical experiments. Experimental evidence suggests that our vaccine against the receptor binding domain leads to the neutralization of the virus," Bottazzi said. "Preclinical studies performed with our partners at the University of Texas Medical Branch, show that the receptor binding domain on alum is indeed a promising vaccine candidate. It can trigger an immune response that is protective and does not induce undesirable cellular immune responses. We are working to advance this approach into the clinic for Phase I studies."

"There are many challenges to overcome but like never before, scientists around the world are working together to develop effective and affordable vaccines," Corry said. "We'll get there, it will just take time to do it right."

"We believe that we need to have many vaccine candidates, platforms and trials, so we can evaluate as many vaccine options as possible to select the ones that are the most appropriate and prove to be the most effective and safe," said Hotez. "We invested almost a decade of research to maximize immune protection and minimize or prevent immune enhancement. Ultimately our goal is that these vaccines are made for the global population, accessible and affordable to all."

Source: Baylor College of Medicine, Science Daily, 12.05.2020

How COVID-19 kills

COVID-19, the disease caused by Cronavirus SARS-Cov-2, has infected over 4 million people in 212 countries, of whom at least 272,000 have died. The ongoing economic and social impact of the pandemic is staggering, but despite a daily flood of news on the disease, few laypeople know that paradoxically, COVID-19 mostly kills through an overreaction of the immune system, whose function is precisely to fight infections.

In a new review article - explicitly targeted to non-specialists as well - in Frontiers in Public Health, a team of experts from Zunyi Medical University review the epidemiology, disease pathway, symptoms, diagnosis, and current treatment of severe COVID-19. They stress the key role of a potentially lethal overreaction of the immune system in the progression of the disease.

They explain step-by-step what is known about how the virus infects the airways, multiplies inside cells, and in severe cases causes the immune defenses to overshoot with a "cytokine storm". This storm is an over-activation of white blood cells, which release too-great amounts of cytokines - inflammation-stimulating molecules - into the blood.

"Similar to what happens after infection with SARS and MERS, data show that patients with severe COVID-19 may have a cytokine storm syndrome. The rapidly increased cytokines attract an excess of immune cells such as lymphocytes and neutrophils, resulting in an infiltration of these cells into lung tissue and thus cause lung injury," explains Author Professor Daishun Liu from Zunyi Medical University, China.

The cytokine storm ultimately causes high fever, excessive leakiness of blood vessels, blood clotting inside the body, extremely low blood pressure, lack of oxygen and excess acidity of the blood, and build-up of fluids in the lungs ("pleural effusion").

White blood cells are misdirected to attack and inflame even healthy tissue, leading to failure of the lungs, heart, liver, intestines, kidneys, and genitals (Multiple Organ Dysfunction Syndrome, MODS). This may worsen and shutdown the lungs (Acute Respiratory Distress Syndrome, ARDS) due to the formation of a so-called hyaline membrane, composed of debris of proteins and dead cells, lining the lungs, which makes absorption of oxygen difficult. Most deaths due to COVID-19 are therefore due to respiratory failure.

Liu *et al* explain how in the absence of a specific antiviral cure for COVID-19, the goal of treatment must be to fight the symptoms, lowering the mortality rate through intensive maintenance of organ function, for example an artificial liver blood purification system or renal replacement therapy to filtrate the blood through mechanical means.

Especially important are methods to supplement or replace lung function, for example through non-invasive mechanical ventilation through a mask, ventilation through a tube into the windpipe (if possible with the refinement of Positive End Expiratory Pressure, PEEP, where the ventilator delivers extra pressure at the end of each breath of keep the lung vesicles open throughout), the administration of heated and humidified oxygen via a tube in the nose ("transnasal high-flow oxygen"), or a heart-lung bypass.

The authors conclude by stressing the importance of preventing secondary infections: SARS-Cov-2 also invades the intestines, where it causes inflammation and leakiness of the gut lining, allowing the opportunistic entry of other disease-causing microorganisms. They advocate that this should be prevented with nutritional support, for example with probiotics - beneficial bacteria that protect against the establishment of harmful ones - and nutrients and amino acids to improve the immune defenses and function of the intestine.

"Because treatment for now relies on aggressive treatment of symptoms, preventative protection against secondary infections, such as bacteria and fungi, is particularly important to support organ function, especially in the heart, kidneys, and liver, to try and avoid further deterioration of their condition," concludes Liu.

Source: Xie Peng, Ma Wanyu, Tang Hongbo, Liu Daishun, World Pharma News, 15.05.2020 (Excerpts)

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