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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA - ERNST & YOUNG Webinar on PLI Scheme for Pharmaceuticals: "What is in it for the Indian pharmaceutical industry!"

Tuesday, 15th June 2021 – 3.00 p.m. to 5.00 p.m.

Please forward your registrations…

(More details on Page No. 4)

HIGHLIGHTS

★ **"Old is the New normal" by Dr. Gopakumar G Nair** *(Page No. 5)*

★ **Pharma next big thing for IT cos** *(Page No. 27)*

★ **No shortage of Covid drugs: IDMA** *(Page No. 35)*

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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

ATTENTION MEMBERS

IDMA – ERNST & YOUNG Webinar on

PLI Scheme for Pharmaceuticals:

"What is in it for the Indian pharmaceutical industry!"

Tuesday, 15th June 2021 – 3.00 p.m. to 5.00 p.m.

IDMA along with Ernst & Young proudly presents the First Virtual Webinar on **PLI Scheme for Pharmaceuticals** to be held on Tuesday, 15th June 2021 from 3.00 p.m. to 5.00 p.m.

Please Block Your Calendar.
Detailed Agenda, Speakers & Link Follows.

KINDLY NOTE THAT THERE IS NO REGISTRATION FEE But Prior Registration is Necessary

For Registrations kindly contact :

Mr. Melvin Rodrigues – actadm@idmaindia.com
Ms. Parivaz Irani – mail@idmaindia.com

Request you to kindly rush in your registrations in the below format:

Sr. No.	Name of the Participants & Designation	Mobile No.	Email id

Looking forward to your active participation at this very interesting and informative webinar.

Thanks & regards,

Daara B Patel
Secretary – General

"Old is the New normal"

Dr Gopakumar G Nair, *Editor, Indian Drugs*

Dear Reader,

"Every cloud has a silver lining". A few "side effects" of the Covid era are welcome for diverse reasons. The "webinars explosion" on the internet and the new normal experience of "work from home" and online operations have produced "travel-saving", "time-saving" and "overhead saving" economics in corporate and academic environs. More particularly, the new "innovation culture" that has emerged in the small-medium pharma sector as the response to the patient needs in the pandemic tsunami is a welcome development. In the wake of this repurposing spree, many "grandfather" drugs have found renewed interest. The revival of HCQ has been relatively short-lived compared to the "evergreen" Paracetamol which is being dispensed both to Covid patients in early stages and post vaccination to one and all. The medical profession as well as clinical researchers have taken to these proven remedies with low but well known (often nil) side effects. There are many examples. Recent research was shown that "Budesonide" inhaler (and the Budesonide and Formoterol inhalation) is an effective prophylactic as well as early stage Covid-19 therapy.

Colchicine is another drug reported in use from 1500 B.C. It was approved for medicinal use, though in a narrow safety efficacy range, since 1961. In recent times, Colchicine has emerged as the most commonly prescribed medication in USA, even before the outset of Covid. The modest "gout" drug has now been rediscovered in its new "Avtar" and has reborn in treatment of moderate symptomatic Covid-19 patients. Dexamethasone and Hydrocortisone have also emerged as useful agents in Covid therapy. The "Recovery Trial" found dexamethasone useful for patients on respiratory support. Hydrocortisone has also been used in managing septic shock in Covid patients. Indian Pharma Industry has been responding amazingly well by repurposing known drugs for affordable treatment of the alarming resurgence of Covid-19 extending from 2020 to 2021.

The "start-up" era of recent origin has been quick to reorient and reinvent themselves in responding

Dr. Gopakumar G. Nair is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.

Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai

to pandemic times. Newer medical devices and need-based diagnostic processes and products have come up through breakthrough innovations in recent times.

However, academic research institutions, except through some venture centres and start up initiatives, have not been forthcoming adequately to take advantage of these innovation opportunities. Low-hanging fruits in the form of incremental innovations (based on internet search of prior arts) are available as research topics, needed for immediate commercialization in industry. New drug delivery systems are also open for remodelling the repurposed drugs for current needs. The lack of adequate linkages with clinical research groups and investigators have kept the academic research institutions away from pursuing "me too" molecules, which could be extensions of newer large biological drugs like "mabs", "nibs" etc. This brings us back to our earlier clarion call to enhance and enlarge tie-ups and research cooperation between Industry-academia, clinical research, medical profession, medical devices and engineering research industry groups. The "silver lining" emerging from the "Covid cloud" is ideal for pharma-bio researchers to ride on by undertaking need-based innovation projects to meet current market expectations.

Further to the mad rush for Remdesivir, Gilead has issued a press release on availability of Remdesivir, even though Remdesivir is acknowledged as only helping to cut the hospital stay by 5 days. Of late, considerable interest has emerged among Researchers, Clinicians, pharma industry and physicians on MOLNUPIRAVIR, an oral drug for treatment of Covid-19 and the variants / mutants. There is opportunity for pharma researchers in the academic corridors to undertake work on newer formulations of useful molecules like Molnupiravir.

Courtesy: Indian Drugs, Editorial, Vol. 58 (02) February 2021

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"Standard Operating Procedures to be followed in all the Industrial Commercial Establishments / Work Sites" at Sikkim : IDMA representation to the Secretary DoP - reg.

The Association have submitted the following representation on 2nd June 2021 to Ms. S. Aparna, IAS, Secretary to the Government of India, Department of Pharmaceuticals with the copy to the Department of Labour, Government of Sikkim, on the above subject:

Greetings from Indian Drug Manufacturers' Association (IDMA)!

We refer to the **circular no. 53 dated 28/05/2021 on "Standard Operating Procedures to be followed in all the Industrial Commercial Establishments / Work Sites"** issued by the Department of Labour, Government of Sikkim.

We are pleased to inform you that IDMA has about 25 member companies who have their factories/plants at Sikkim. We thank the Sikkim Government for all their support and co-operation extended to our members.

However, the above mentioned circular issued by the Department of Labour, Government of Sikkim asking all pharma companies to continue operations by accommodating the work force within the plant premises or in neighbouring schools / housing facilities can have damaging consequences to the functioning of pharma companies in Sikkim and hence not advisable. It would put the workforce in grave danger of Covid-19 pandemic spread affecting their colleagues, families and neighbours. This will further result in adversely affecting

the manufacturing facilities and ultimately resulting in shortages of medicines.

We therefore request the Government to take into consideration the following:-

1) There aren't enough facilities like schools or hotels which can accommodate all employees of all Pharmaceutical companies in the vicinity of the plant. Further, schools will not have the required infrastructure like number of toilets, dining areas and support structure for following the covid-19 protocols.

2) During the last pandemic many companies had tried to accommodate employees within the plant premises which led to large outbreaks and subsequently the plants were declared containment zones limiting movement of people and materials.

3) Also, there was unrest within the units where individuals who are not infected wanted to leave the plant, but were not allowed to leave by the Government. Similar consequences can be expected if employees are kept in such facilities. This will have long-term consequences for production.

4) It may also lead to employees resorting to large scale absenteeism due to the fear of getting infected.

We would like to submit that our member companies have updated screening methods and SOPs to be followed to ensure total adherence to the covid-19 protocols. Screening for signs and symptoms are done from pickup point itself and also during entry into the plant. This results in quick identification and isolation of those found to be infected. The Plant section is then sanitized and shut down for 48 hours, rest of staff are screened for symptoms before resumption of production. This ensures continuity of production as well as safety of the staff.

We request your quick intervention in this matter and to ensure the necessary support to the manufacturing units thereby ensuring continuous production of medicines.

Thanking you,

Yours faithfully,
For Indian Drug Manufacturers' Association,

Mahesh Doshi
National President

● ● ●

IDMA Congratulates Prof. Vandana B. Patravale

PROF. VANDANA B. PATRAVALE , Ph.D
Professor of Pharmaceutics
Department of Pharmaceutical Sciences and Technology, ICT, Mumbai
Member of Editorial Advisory Board, Indian Drugs

Congratulations to Prof. Vandana Patravale for being inducted as Independent Director on the Board of Directors of Sahajanand Medical Technologies Limited, a company which has introduced coronary stents in more than 65 countries based on technology suggested by VBP research group.

● ● ●

IDMA & IPGA donated Covid treatment Medicines to Poor and Needy

Cyberabad CP Shri. VC Sajjanar, IPS., appreciated IDMA & IPGA association member companies for the Good Cause

Cyberabad: As part of the COVID relief activities to help the poor and needy people in the pandemic situation Indian Drug Manufacturers' Association (IDMA) & Indian Pharmacy Graduates Association (IPGA) have donated COVID treatment Medicines to Cyberabad Police under CSR activities on 29.05.2021. Medicines were handed over to Shri VC Sajjanar, IPS, Commissioner of Police Cyberabad by Shri Shaik Janimiya, Chairman, IDMA Telangana State Board and Shri. G. Koteswara Rao, Indian Pharmacy Graduates Association (IPGA) Telangana Branch along with other members of the Association. On behalf of the Cyberabad Police and Society For Cyberabad Security Council (SCSC) Cyberabad CP Shri VC Sajjanar, IPS appreciated Indian Drug Manufacturers' Association (IDMA) and Indian Pharmacy Graduates Association (IPGA) Telangana Branch and its Association members like Suraksha Pharma, Crescent Formulations, Pulse Pharmaceuticals, Indu Drugs, Serene Formulations, Medmenar Organics, Sain Medicaments, Euro Medicare, Vaibhav Drugs, Navya Pharmaceuticals, Vasanth Biotech, Dr. Guda Ramana Reddy, Krishcare Formulations for organizing these donations and motivating their members for this great contribution.

● ● ●

TRIBUTE TO DR K K AGGARWAL

The Virus In COVID-19 Needs Always TO BE Cornered & Checkmated Expressly With Mahabharat Strategy

1st June 2021

THE DEADLY CORONA CANNOT BE DEALT WITH KID GLOVES

Dr R K Sanghavi

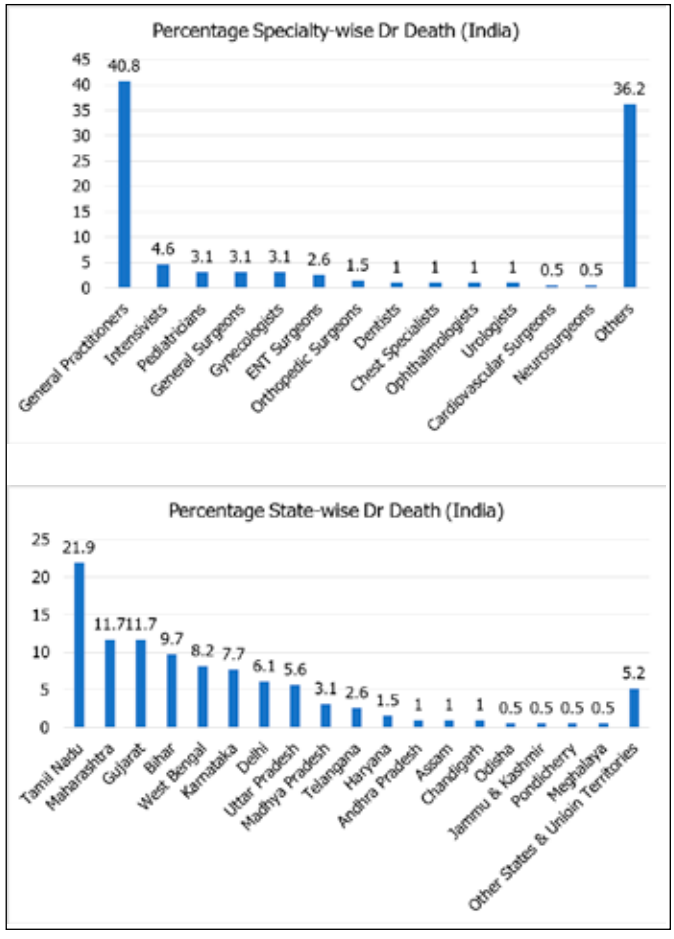
Dear Reader,

The 2019-discovered novel coronavirus-2 (2019-nCoV) or SARS-CoV-2 has thus far infected near 3 crore Indians of which the unfortunate ones have been over 3 lakhs. The total number of doctor fatalities have been approximately 1000 during the pandemic, which is 0.5% of the medical professionals engaged in COVID-19 management.

Hence, 1% of infected Indian population die of COVID-19 but, in the case of Indian doctor, 1 out of 3 SARS-CoV-2 afflicted medical professional have been pushed to their grave!! This is alarming and indeed calls for an all-out war against the pandemic-causative virus to save our fellow Dr brethren.

THE UNFOLDING OF COVID-19 SEQUENCE OF EVENTS

1. The SARS-CoV-2 first lodges in the nasal and mouth passages because of entry via floating droplets emanating from the carrier person with whom one interacts, sans maintaining social distancing and / or masking up. This causes symptoms.
2. When symptoms persist, or there is strong suspicion of contact with a carrier, a RT-PCR testing must be done usually after 4 days following exposure or symptoms occurrence to confirm presence of SARS-CoV-2 infection.
3. The SARS-CoV-2 remains alive seemingly up to 10 days post-entry into the human body. The virus needs to be killed efficiently and promptly by drugs and / or immune defences.
4. If the virus is not promptly killed, dangerous chemical mediators like IL-6 and NLRP3 are liberated by the defence cells of the human body in an effort to destroy the enemy SARS-CoV-2. NLRP3 is first released followed by IL-6 production. 10% of COVID-19 patients have a raised IL-6 by day 4 or 7 or 11 - an indicator of an upcoming cytokine storm syndrome (CSS). Unfortunately, at present, NLRP3 is not being estimated and hence there is no earlier and hence there is no earlier 'premonition' of the CSS other than IL-6 estimation!
5. The CSS has been initiated to kill the persistent SARS-CoV-2 but the liberated IL-6 and NLRP3 cause collateral damage. Usually the damaged lungs release LDH and there is a rise in D-dimer blood concentrations, besides higher serum ferritin levels - all of these are markers to indicate CSS.
6. High D-dimer values could predict COVID-19 disease severity, lung complications as well as blood clot formation potential even before these consequences occur.



7. If there is recovery because of appropriate and effective antiviral drugs, the dead SARS-CoV-2 RNA continues to remain in cells and could be detectable by RT-PCR even 1-2 months after the infection! (This is false positive RT-PCR test.)

Thus, the aim has to be to kill the SARS-CoV-2 before the body's defence cells kick-starts the CSS in an effort to eliminate the virus. It is important to remember that the virus is dead in less than 10-14 days but the consequences of critical condition in hospitalised patient and fatalities are all the outcome of the already initiated CSS - the virus is no-way in the picture at that point of time!

TIME FOR MEDICAL MAHABHARAT

Not only our dear patients but we as doctors need to protect our right to life. This SARS-CoV-2 just cannot be allowed to overwhelm us and render us helpless and push us in dire striates. The need of the hour is not to be reactive but proactive. After all, as stated, one out of every 3 doctors with COVID-19 disease can have a catastrophic ending.

A high blood CRP, which will invariably rise in all patients in 2-3 days post SARS-CoV-2 infection, can only re-confirm COVID-19 status in a positively RT-PCR tested patient. CRP values can guide regarding the severity of infection, and in no way can assist in personalising a comprehensive drug regimen. What is more important, once positive RT-PCR and an abnormal high CRP are detected, is:

Kill the virus with specific antivirals - so that the deadly CSS waves initiating chemical mediators are NOT generated.

Kill the virus decisively with combination of antivirals - depending upon the severity should be the choice of specific antivirals.

Prevent and, if necessary, tackle the COVID-19 - associated disasters with appropriate preventive regimens - when IL-6 and associated complication markers indicate possible onset of CSS.

Do not hesitate to start antivirals promptly: it could be a single agent or 2 drugs; or it could be tablets or injection (as per patient condition). The other treatment measures are secondary and complimentary.

WHICH ANTIVIRALS & WHY?

A little information on SARS-CoV-2 mechanism in thriving and causing infection would be enlightening. The 2019-CoV-2 has:

1. Structural proteins: M, E & N proteins
2. Host cell docking protein: S protein

In addition to the above, there are accessory proteins and an enzyme called RNA-dependent RNA polymerase (RdRp) which is essential for RNA replication. For the virus to be infective the S protein needs to bind with corresponding S protein ligand (docking point) present on host cell; similarly RdRp needs to interact with RdRp ligand of human cell for facilitating viral replication.

Thus, for antivirals to beneficially prevent the SARS-CoV-2 from infecting and multiplying, the S protein and the RdRp as well as their respective ligands must be inhibited. The result of blocking docking (of the S protein / RdRp of SARS-CoV-2 as well as the interacting respective ligands of the host cell) are expressed as MolDock score.

SARS-COV-2 ANTIVIRAL	S PROTEIN	S PROTEIN-LIGAND	RdRp	RdRp PROTEIN-LIGAND
	MolDock Score (Kcal/mol)			
Ivermectin	-140.584	-139.371	-149.9900	-147.608
Remdesivir	-111.007	-122.699	-160.418	-173.270
Favipiravir	-54.595	-68.539	-63.408	-77.835

Higher the negative value better is the inhibitory action and more superior is the outcome of antiviral drug. Doxycycline has a MolDock score of -115.46.

Since ivermectin has higher MolDock score than doxycycline it should be preferred in combination with favipiravir as far as swallowing antiviral pills are concerned. Why combine the latter two when favipiravir is weaker? This is because ivermectin acts on 4 amino acids (threonine, isoleucine, glutamic acid & asparagine) whilst favipiravir has unique binding action on arginine which compliments that of ivermectin. Injection of remdesivir is more suitable for the severe COVID-19 patients and those who are hospitalised.

WHY YET FAVIPIRAVIR - A Weak MolDock Scorer?

Furin is a widespread enzyme in the body, potentially granting SARS-CoV-2 countless opportunities to infect cells. One cannot, in fact, live without possessing furin enzyme! Inhibiting furin is a more beneficial mechanism than spike protein S blocking.

In order to invade the body, the spike of SARS-CoV-2 must first be snipped at a specific point by the furin protease enzyme following which the virus can then latch onto a cell's ACE2 receptor to thereby cause infection. The spike protein as well as the SARS-CoV-2 docking site on the cell have an amino acid sequence - arginine-arginine-alanine-arginine. Favipiravir (as tablets) and remdesivir (as injection) both inhibit furin because of binding to arginine (unlike ivermectin) but remdesivir is stronger in its action. However, when antiviral tablets are necessitated favipiravir is preferable since it has higher affinity than ritonavir and lopinavir for furin enzyme as compared to S protein and RdRp and their corresponding ligands. Thus, there is always an implied and urgent necessity to advocate a combination of ivermectin with favipiravir in positively tested RT-PCR patients.

CONCLUSION

Favipiravir or remdesivir, when paired with doxycycline or ivermectin, can substantially and rapidly clear SARS-CoV-2 from nasal secretions if it was started relatively early (day 1) or latest by day 7 of confirmed COVID-19 infection. If this antiviral is given within the first few hours of infection, then the SARS-CoV-2 virus is possibly cleared in 7 days sans complications!

For prevention of CSS, corticosteroids can be initiated by day 5, or earlier if pulmonary symptoms are present or co-morbidities co-exist, in a COVID-19 sufferer. Abnormally high D-dimer values naturally signal institution of anti-clotting medication.

Thus, to defeat the SARS-CoV-2 in fighting the COVID-19 the Mahabharat - like forces are:

1. Yudhistira - The advising Dr
2. Arjuna - The sharp-shooter antiviral
3. Bhima - The bull-dozer corticosteroid
4. Nakula - The immunity supporters - Vitamins C & D, zinc (acetate, gluconate)
5. Sahadeva - The strategist anticoagulant

We doctors need to win COVID-19 war without ultimate sacrifice. Why risk and leave the outcome to destiny and good wishes and faith. We must ensure no loose ends are left and all therapy gaps filled. Under the guidance of one of our more trusted but aggressive Dr guru we must adopt the Mahabharat strategy.

REMEMBERING DR K K AGGARWAL

We have paid the price with over 1,000 of our colleagues falling in the battle, including our beloved physician and cardiologist Dr Krishan Kumar Aggarwal who was President of Confederation of Medical Association of Asia and Oceania (CMAAO) as well as Heart Care Foundation of India (HCFI) & Past National President of Indian Medical Association (IMA) - besides being a Padma Shri and B C Roy National award recipient.

My tryst with Dr K K Aggarwal was first in the month of August 2020 as we planned a special one-hour session on CSS for his MedTalks series. This was possibly the first time ever, as Editor-in-Chief of MedTalks Dr K K Aggarwal facilitated an elaborate PowerPoint presentation, at my request, on his 7 pm 11th September 2020 show titled - Chemical Mediators Causing Cytokine Storm In Viral Infections: MedTalks with Dr K K Aggarwal. He was possibly the first medical professional with whom I had willingly ever given my presentation knowing fully well that Dr K K Aggarwal will be most enthusiastic in wide-spreading my data on a broader-based platform so as to benefit both Indian and overseas doctors. The very next day I was invited by Dr K K Aggarwal to explain a few of my slides in a COVID-19 - related meeting of CMAAO and I will always be grateful for this opportunity.

Dr K K Aggarwal had immense following of his thrice a day YouTube video talks uploads pertaining to different aspects of corona pandemic. His crystal clear views on coronavirus pandemic, and lucid presentation of the same, enabled percolation of COVID-19 knowledge even to the layman. He will forever be remembered.

The second wave of COVID-19 is scary because of its 80-90% virus transmissibility rate from contacts in comparison to 30-40% in first wave! Most health workers would not seemingly be able to escape getting infected with SARS-CoV-2 - preventive measures and vaccination notwithstanding! Be mind-tuned to hit hard the virus if it attacks. We cannot afford to lose another luminary from amongst medicos.

God Bless the warring Doctors.

Dr R K Sanghavi, *Chairman : Nutraceutical Committee (IDMA) Prophesied Enabler, Experience & Expertise: Clinician & Healthcare Industry Adviser*

OBITUARY

IDMA mourns the sudden demise of Mr. T S Jaishankar

IDMA and its members all over India sadly mourn the sudden demise of veteran pharma leader Mr. T S Jaishankar who passed away on May 31, 2021 in Chennai.

Mr. Jaishankar was the founder of the pharmaceutical manufacturing firm Chemech Laboratories Ltd and the clinical research services organization, Quest Lifesciences.

A senior pharma industry captain in the country, Mr. Jaishankar held various positions in several pharmaceutical industry associations including Indian Drug Manufacturers' Association (IDMA), Confederation of Indian Pharmaceutical Industry (CIPI) and Tamil Nadu Pharmaceutical Manufacturers Association (TN PMA). He was the Past President of CIPI and Past President of TN PMA. He was also one of the Advisory Board Members of Pharmabiz.

Mr. Jaishankar would always be remembered for his hard work and commitment towards the growth of the pharma Small and Medium Enterprises (SMEs) in the country. In Tamil Nadu, he was part of all associations and activities connected with the pharmaceutical sector.

Mr. S V Veeramani, Past President of the Indian Drugs Manufacturers' Association and MD of Fourrts Laboratories said that Mr. Jaishankar was one of the founder leaders of CIPI and was also President of the confederation for a term. While he was the President of CIPI, he brought all the pharma SME units under one umbrella. With his sudden death the Indian pharma industry has lost a great supporter and a big leader.

Mr. J Jayaseelan, Chairman, IDMA Tamil Nadu, Kerala & Puducherry State Board said that Mr. Jaishankar's services to the pharma sector were unparalleled and he was a pillar of the Indian pharma industry always. He worked hard for the SME sector and was part and parcel of all activities and conferences on pharma in Tamil Nadu. Personally he was a very nice person.

Mr. M Rajaratinam, Executive Committee Member of IDMA and MD of MMC Pharmaceuticals Ltd. said that Mr. Jaishankar was the pioneer of the biotechnology industry in Tamil Nadu and his efforts in that area had helped the pharma industry grow so much.

In his passing away, the Indian Pharma Industry has lost a Senior Pharma Leader, an active Supporter, a very warm human being and brilliant professional.

May his Soul Rest in Peace and May God grant his family the strength to bear this irreparable loss.

NPPA fixes the Retail Price of Specified 12 Formulation/Brand Name under the Drugs (Price control) order, 2013-reg.

NPPA Order S.O.2119(E), dated 01st June 2021

In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O.1394(E) date d the 30th May, 2013 and S.O.701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of goods and services tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

TABLE

Sr. No.	Name of the Formulation/ Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Ivabradine Hydrochloride + Metoprolol Tartrate Tablet	Each film coated tablet contains: Ivabradine Hydrochloride eq. to Ivabradine 5 mg + Metoprolol Tartrate IP 25 mg	1 Tablet	M/s Archimedis Healthcare Pvt. Ltd./ M/s Lupin Limited	15.75
2.	Ivabradine Hydrochloride + Metoprolol Tartrate Tablet	Each film coated tablet contains: Ivabradine Hydrochloride eq. to Ivabradine 5 mg + Metoprolol Tartrate IP 50 mg	1 Tablet	M/s Archimedis Healthcare Pvt. Ltd./ M/s Lupin Limited	18.14
3.	Telmisartan, Cilnidipine & Metoprolol (ER) Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Neomac Pharmaceuticals Pvt. Ltd.	10.16
4.	Telmisartan, Cilnidipine & Metoprolol (ER) Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Neomac Pharmaceuticals Pvt. Ltd.	12.41
5.	Doxycycline & Lactic Acid Bacillus Capsule	Each hard gelatine capsule contains: Doxycycline hyclate IP eq. to Doxycycline (as pellets) 100mg Lactic Acid Bacillus (As enteric coated pellets) 5 Billion Spores	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd.	6.94
6.	Doxycycline & Lactic Acid Bacillus Capsule	Each hard gelatine capsule contains: Doxycycline hyclate IP eq. to Doxycycline (as pellets) 100mg Lactic Acid Bacillus (As enteric coated pellets) 5 Billion Spores	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s Glensmith Labs Pvt. Ltd.	6.94

7.	Darunavir + Ritonavir Tablet	Each film coated tablet contains: Darunavir Ethanolate eq. Darunavir IP 600mg Ritonavir IP 100mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Cipla Limited	145.70
8.	Povidone-Iodine gargle 0.5% w/v	Contains: Povidone Iodine IP 0.5% w/v (available Iodine 0.05% w/v)	1 ML	M/s Stedman Pharmaceuticals Pvt. Ltd.	0.66
9.	Teneligliptin + Metformin HydrochlorideIP (SR) Tablet	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HydrochlorideIP (As Sustained Release) IP 500mg	1 Tablet	M/s Windlas Biotech Pvt. Limited/ M/s Abbott Healthcare Limited	11.00
10.	Teneligliptin + Metormin HCL (ER) Tablet	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin hydrochloride (As Extended Release) IP 500mg	1 Tablet	M/s Morepen Laboratories Limited	10.96
11.	Teneligliptin + Metormin HCL (ER) Tablet	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin hydrochloride (As Extended Release) IP 1000mg	1 Tablet	M/s Morepen Laboratories Limited	11.48
12.	Teneligliptin + Metformin Hydrochloride IP (SR) Tablet	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HydrochlorideIP (As Sustained Release) IP 1000mg	1 Tablet	M/s Windlas Biotech Pvt. Limited/ M/s Abbott Healthcare Limited	11.48

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(e) The above mentioned retail price is applicable only to the individual manufacturer/marketer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation/revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.

(f) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(g) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/219/87/2021/F/F.No.8(87)/2021/D.P./NPPA-Div.-II

Prasenjit Das, Deputy. Director, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers Department of Pharmaceuticals, New Delhi.

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Amendment in Export Policy of Amphotericin-B injections

DGFT Notification No.07/2015-2020, dated 01st June 2021

1. In exercise of powers conferred by Section 3 of the Foreign Trade (Development & Regulation) Act, 1992 (No.22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes the following amendment in Schedule 2 of the ITC (HS) Export Policy, 2018 related to export of Amphotericin-B injections:

Sr. No.	ITC HS Codes	Description	Present Policy	Revised Policy
207AB	Ex 30049029 Ex 30049099	Amphotericin-B injections	Free	Restricted

2. The provision under Para 1.05 of the Foreign Trade Policy (FTP) 2015-20 regarding transitional arrangement is not applicable for this notification.

3. **Effect of this Notification:** The export of Amphotericin-B injections falling under the ITCHS Codes specified above or falling under any other HS Code is restricted, with immediate effect.

File No.01/91/180/24/AM22/EC/E-27724

Amit Yadav, Director General of Foreign Trade, Ex-Officio Additional Secretary, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, New Delhi.

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Government issues Operational guidelines for Production Linked Incentive Scheme of Pharmaceuticals

Applications invited from industry

With an aim to enhance India's manufacturing capabilities by increasing investment and production in the sector and to contribute to product diversification to high value goods in the pharmaceutical sector, Department of Pharmaceuticals notified the 'Production Linked Incentive (PLI) Scheme for Pharmaceuticals' vide Gazette Notification No.31026/60/2020-Policy-DoP dated 3rd March, 2021. The approved outlay of the scheme is Rs 15000 crore. The scheme envisages to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. Based on a series of consultations with pharmaceutical industry and stakeholders in the Government, the operational guidelines for the scheme have been prepared and issued on 1st June. The scheme is now open to applications from the industry.

The applications are invited in three groups based on the Global Manufacturing Revenue of FY 2019-20 of the applicants. A special carve out for MSMEs has been kept under the scheme. All the applications will be submitted through an online portal maintained by SIDBI, the Project Management Agency for the scheme. Application can be made on the online portal, URL of which is https://pli-pharma.udyamimitra.in. **The application window is for 60 days staring from 2nd June, 2021 to 31st July, 2021 (Both dates inclusive)**

The eligible products have been categorized into three categories. The products covered under the scheme are formulations, biopharmaceuticals, active pharmaceutical ingredients, key starting material, drug intermediates, in-vitro diagnostic medical devices, etc. The category-1 and category-2 products attract 10% incentive and category-3 products attract 5% incentive on the incremental sales. Incremental sales of a product mean sales of that product in a year over and above the sales of that product in FY 2019-2020.

Based on clearly laid out selection criteria given in the guidelines, a maximum of 55 applicants will be selected under the scheme. An applicant, through a single application, can apply for more than one product and the products applied by an applicant can be in any of the three categories. The applicants will be required to achieve minimum cumulative investment per year over a period of 5 years as prescribed under the scheme. The investment could be under new plant and machinery, equipment and associated utilities, research and development, transfer of technology, product registration and expenditure incurred on building where plant and machinery are installed. Investment made on or after April 01, 2020 will be considered as eligible investment under the scheme.

Thereafter, the selected manufacturers will be able to receive production linked incentives based on incremental sales of pharmaceutical products for a period of 6 years. A selected participant will be able to get a maximum incentive of Rs 1000 crore, Rs 250 crore and Rs 50 crore respectively depending upon its group over the period of the scheme. Additional incentive will be available based on performance but subject to certain conditions. In no case, the total incentive including additional inventive, would be more than Rs 1200 crore, Rs 300 crore and Rs 60 crore per selected participant respectively for the three groups over the period of the scheme.

An Empowered Group of Secretaries will undertake periodic reviews of the scheme to ensure its smooth implementation along with the other PLI schemes of the Govt. of India. A Technical Committee will assist the department in all technical issues which arise during the implementation of the scheme. SIDBI, the Project management Agency selected for this scheme, will be responsible for implementation and will be the interface with the industry for all issues with respect to online applications, selection of applicants, verification of investments, verification of sales and disbursal of incentives etc.

The pharmaceutical and the in-vitro diagnostic industry is expected to actively participate in the scheme and contribute to further strengthening the sector.

Source: PIB, 01.06.2021

Recommendations of 43rd GST Council meeting

Amnesty Scheme to provide relief to taxpayers regarding late fee for pending returns ; Late fee also rationalised for future tax periods

COVID-19 related medical goods including Amphotericin B for free distribution given full exemption from IGST upto 31.08.2021

Custom duty exemption also given to Amphotericin B

Simplification of Annual Return for Financial Year 2020-21

The 43rd GST Council met under the Chairmanship of Union Finance & Corporate Affairs Minister Smt. Nirmala Sitharaman through video conferencing here today. The meeting was also attended by Union Minister of State for Finance & Corporate Affairs Shri Anurag Thakur besides Finance Ministers of States & UTs and senior officers of the Ministry of Finance & States/ UTs.

The GST Council has made the following recommendations relating to changes in GST rates on supply of goods and services and changes related to GST law and procedure:

COVID-19 RELIEF

- As a COVID-19 relief measure, a number of specified COVID-19 related goods such as **medical oxygen, oxygen concentrators and other oxygen storage and transportation equipment, certain diagnostic markers test kits** and COVID-19 vaccines, etc., have been **recommended for full exemption from IGST**, even if imported on payment basis, for donating to the government or on recommendation of state authority to any relief agency. This exemption shall be valid upto 31.08.2021. Hitherto, IGST exemption was applicable only when these goods were imported "free of cost" for free distribution. The same will also be extended till 31.8.2021. It may be mentioned that these goods are already exempted from Basic Customs duty. Further in view of rising **Black Fungus cases, the above exemption from IGST has been extended to Amphotericin B.**

Further relief in individual item of COVID-19 after Group of Ministers (GoM) submits report on 8th June 2021

- As regards individual items, it was decided to constitute a Group of Ministers (GoM) to go into the need for further relief to COVID-19 related individual items immediately. The GOM shall give its report by 08.06.2021.

OTHER RELIEFS ON GOODS

- To support the LympahticFilarisis (an endemic) elimination programme being conducted in collaboration with WHO, the GST rate on Diethylcarbamazine (DEC) tablets has been recommended for reduction to 5% (from 12%).
- Certain clarifications/clarificatory amendments have been recommended in relation to GST rates. Major ones are, -
    - o Leviability of IGST on repair value of goods re-imported after repairs
    - o GST rate of 12% to apply on parts of sprinklers/ drip irrigation systems falling under tariff heading 8424 (nozzle/laterals) to apply even if these goods are sold separately.

SERVICES

- To clarify those services supplied to an educational institution including anganwadi(which provide pre-school education also), by way of serving of food including mid- day meals under any midday meals scheme, sponsored by Government is exempt from levy of GST irrespective of funding of such supplies from government grants or corporate donations.
- To clarify these services provided by way of examination including entrance examination, where fee is charged for such examinations, by National Board of Examination (NBE), or similar Central or State Educational Boards, and input services relating thereto are exempt from GST.
- To make appropriate changes in the relevant notification for an explicit provision to make it clear that land owner promoters could utilize credit of GST

charged to them by developer promoters in respect of suchapartments that are subsequently sold by the land promotor and on which GST is paid. The developer promotor shall be allowed to pay GST relating to such apartments any time before or at the time of issuance of completion certificate.

- To extend the same dispensation as provided to MRO units of aviation sector to MRO units of ships/vessels so as to provide level playing field to domestic shipping MROs vis a vis foreign MROs and accordingly, -
  - GST on MRO services in respect of ships/vessels shall be reduced to 5% (from 18%).
  - PoS of B2B supply of MRO Services in respect of ships/ vessels would be location of recipient of service
- To clarify that supply of service by way of milling of wheat/paddy into flour (fortified with minerals etc. by millers or otherwise)/rice to Government/ local authority etc.for distribution of such flour or rice under PDS is exempt from GST if the value of goods in such composite supply does not exceed 25%. Otherwise, such services would attract GST at the rate of 5% if supplied to any person registered in GST, including a person registered for payment of TDS.
- To clarify that GST is payable on annuity payments received as deferred payment for construction of road. Benefit of the exemption is for such annuities which are paid for the service by way of access to a road or a bridge.
- To clarify those services supplied to a Government Entity by way of construction of a rope-way attract GST at the rate of 18%.
- To clarify that services supplied by Govt. to its undertaking/PSU by way of guaranteeing loans taken by such entity from banks and financial institutions is exempt from GST.

MEASURES FOR TRADE FACILITATION:

1. Amnesty Scheme to provide relief to taxpayers regarding late fee for pending returns:

To provide relief to the taxpayers, late fee for non-furnishing FORM GSTR-3B for the tax periods from July, 2017 to April, 2021 has been reduced / waived as under: -

i. late fee capped to a maximum of **Rs 500/- (Rs. 250/- each for CGST & SGST) per return** for taxpayers, who did not have any tax liability for the said tax periods;

ii. late fee capped to a maximum of **Rs 1000/- (Rs. 500/- each for CGST & SGST) per return** for other taxpayers;

The reduced rate of late fee would apply if GSTR-3B returns for these tax periods are furnished between 01.06.2021 to 31.08.2021.

2. Rationalization of late fee imposed under section 47 of the CGST Act:

To reduce burden of late fee on smaller taxpayers, the upper cap of late fee is being rationalized to align late fee with tax liability/ turnover of the taxpayers, as follows:

A. The late fee for delay in furnishing of **FORM GSTR-3B** and **FORM GSTR-1** to be capped, per return, as below:

(i) **For taxpayers having nil tax liability** in **GSTR-3B** or nil outward supplies in **GSTR-1**, the late fee to be capped at Rs 500 (Rs 250 CGST + Rs 250 SGST)

(ii) **For other taxpayers:**

a. For taxpayers having Annual Aggregate Turnover (AATO) in preceding year upto Rs 1.5 crore, late fee to be capped to a maximum of Rs 2000 (1000 CGST+1000 SGST);

b. For taxpayers having AATO in preceding year between Rs 1.5 crore to Rs 5 crore, late fee to be capped to a maximum of Rs 5000 (2500 CGST+2500 SGST);

c. For taxpayers having AATO in preceding year above Rs 5 crores, late fee to be capped to a maximum of Rs 10000 (5000 CGST+5000 SGST).

B. The late fee for delay in furnishing of FORM GSTR-4 by composition taxpayers to be capped to Rs 500 (Rs 250 CGST + Rs 250 SGST) per return, if tax liability is nil in the return, and Rs 2000 (Rs 1000 CGST + Rs 1000 SGST) per return for others.

C. Late fee payable for delayed furnishing of FORM GSTR-7 to be reduced to Rs.50/- per day (Rs. 25 CGST + Rs 25 SGST) and to be capped to a maximum of Rs 2000/- (Rs. 1,000 CGST + Rs 1,000 SGST) per return.

All the above proposals to be made applicable for prospective tax periods.

3. COVID-19 related relief measures for taxpayers:

In addition to the relief measures already provided to the taxpayers vide the notifications issued on 01.05.2021, the following further relaxations are being provided to the taxpayers:

A. **For small taxpayers (aggregate turnover upto Rs. 5 crore)**

i.a. March & April 2021 tax periods:

ii. NIL rate of interest for first 15 days from the due date of furnishing the return in **FORM GSTR-3B** or filing of PMT-06 Challan, reduced rate of 9% thereafter for further 45 days and 30 days for March,2021 and April, 2021 respectively.

iii. Waiver of late fee for delay in furnishing return in **FORM GSTR-3B** for the tax periods March / QE March, 2021 and April 2021 for 60 days and 45 days respectively, from the due date of furnishing **FORM GSTR-3B.**

iv. NIL rate of interest for first 15 days from the due date of furnishing the statement in CMP-08 by composition dealers for QE March 2021, and reduced rate of 9% thereafter for further 45 days.

b. **For May 2021 tax period:**

ii. NIL rate of interest for first 15 days from the due date of furnishing the return in **FORM GSTR-3B** or filing of PMT-06 Challan, and reduced rate of 9% thereafter for further 15 days.

iii. Waiver of late fee for delay in furnishing returns in **FORM GSTR-3B** for taxpayers filing monthly returns for 30 days from the due date of furnishing **FORM GSTR-3B**.

B. **For large taxpayers (aggregate turnover more than Rs. 5 crore)**

i. A lower rate of interest @ 9% for first 15 days after the due date of filing return in **FORM GSTR-3B** for the tax period May, 2021.

ii. Waiver of late fee for delay in furnishing returns in **FORM GSTR-3B** for the tax period May, 2021 for 15 days from the due date of furnishing FORM GSTR-3B.

C. **Certain other COVID-19 related relaxations** to be provided, such as

1. Extension of due date of filing **GSTR-1/ IFF for the month of May 2021 by 15 days.**
2. **Extension of due date of filing GSTR-4 for FY 2020-21 to 31.07.2021.**
3. Extension of due date of filing **ITC-04 for QE March 2021 to 30.06.2021.**
4. **Cumulative application of rule 36(4)** for availing ITC for tax periods April, May and June, 2021 **in the return for the period June, 2021.**
5. Allowing filing of returns by companies using Electronic Verification Code (EVC), instead of Digital Signature Certificate (DSC) till 31.08.2021.

D. Relaxations under section 168A of the CGST Act: Time limit for completion of various actions, by any authority or by any person, under the GST Act, which falls during the period from 15th April, 2021 to 29th June, 2021, to be extended upto 30th June, 2021, subject to some exceptions.

[Wherever the timelines for actions have been extended by the Hon'ble Supreme Court, the same would apply]

4. **Simplification of Annual Return for Financial Year 2020-21:**

i. Amendments in section 35 and 44 of CGST Act made through Finance Act, 2021 to be notified. This would ease the compliance requirement in furnishing reconciliation statement in FORM GSTR-9C, as taxpayers would be able to self-certify the reconciliation statement, instead of getting it certified by chartered accountants. This change will apply for Annual Return for FY 2020-21.

ii. The filing of annual return in FORM GSTR-9 / 9A for FY 2020-21 to be optional for taxpayers having aggregate annual turnover upto Rs 2 Crore;

iii. The reconciliation statement in FORM GSTR-9C for the FY 2020-21 will be required to be filed by taxpayers with annual aggregate turnover above Rs 5 Crore.

5. Retrospective amendment in section 50 of the CGST Act with effect from 01.07.2017, providing for payment of interest on net cash basis, to be notified at the earliest.

OTHER MEASURES

GST Council recommended amendments in certain provisions of the Act so as to make the present system of GSTR-1/3B return filing as the default return filing system in GST.

Note: The recommendations of the GST Council have been presented in this release in simple language for information of all stakeholders. The same would be given effect through relevant Circulars/Notifications which alone shall have the force of law.

Source: PIB, 28.05.2021

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CBDT MATTER

Extension of time limits of certain compliances to provide relief to taxpayers in view of the severe pandemic - reg.

Circular No. 9 of 2021, dated 20th May 2021

The Central Board of Direct Taxes, in exercise of its power under section 119 of the Income-tax Act, 1961 (hereinafter referred to as "the Act") provides relaxation in respect of the following compliances:

1) **The Statement of Financial Transactions (SFT)** for the Financial Year 2020- 21 , required to be furnished on or before 31st May 2021 under Rule 114E of the Income-tax Rules, 1962 (hereinafter referred to as "the Rules") and various notifications issued thereunder, may be furnished on or **before 30th June 2021;**

2) **The Statement of Reportable Account** for the calendar year 2020, required to be furnished on or before 31 st May 2021 under Rule 114G of the Rules, may be furnished on or **before 30th June 2021 ;**

3) **The Statement of Deduction of Tax** for the last quarter of the Financial Year 2020-21 , required to be furnished on or before 31 st May 2021 under Rule 31A of the Rules, may be furnished on or **before 30th June 2021 ;**

4) **The Certificate of Tax Deducted at Source in Form No 16,** required to be furnished to the employee by 15th June 2021 under Rule 31 of the Rules, may be furnished on or **before 15th July 2021 ;**

5) **The TDSITCS Book Adjustment Statement in Form No 24G for the month of May 2021**, required to be furnished on or before 15th June 2021 under Rule 30 and Rule 37CA of the Rules, may be furnished on or **before 30th June 2021;**

6) **The Statement of Deduction of Tax** from contributions paid by the trustees of an approved superannuation fund for the Financial Year 2020-21 , required to be sent on or before 31 st May 2021 under Rule 33 of the Rules, may be sent on or **before 30th June 2021;**

7) **The Statement of Income paid or credited** by an investment fund to its unit holder in Form No 64D for the Previous Year 2020-21 , required to be furnished on or before 15th June 2021 under Rule 12CB of the Rules, may be furnished on or **before 30th June 2021.**

8) **The Statement of Income paid or credited** by an investment fund to its unit holder in **Form No 64C** for the Previous Year 2020-21 , required to be furnished on or before 30th June 2021 under Rule 12CB of the Rules, may be furnished on or **before 15th July 2021 ;**

9) **The due date of furnishing of Return of Income** for the Assessment Year 2021-22, which is 31st July 2021 under sub-section (1) of section 139 of the Act, is **extended to 30th September 2021 ;**

10) The **due date of furnishing of Report** of Audit under any provision of the Act for the Previous Year 2020-

21, which is 30th September 2021, is **extended to 31st October 2021 ;**

11) **The due date of furnishing Report from an Accountant** by persons entering into international transaction or specified domestic transaction under **section 92E** of the Act for the Previous Year 2020-21, which is 31st October 2021, is **extended to 30th November 2021 ;**

12) The **due date of furnishing of Return of Income** for the **Assessment Year 2021-22,** which is 31st October 2021 under Sub-section (1) of section 139 of the Act, is **extended to 30th November 2021;**

13) The **due date of furnishing of Return of Income** for the **Assessment Year 2021-22,** which is 30th November 2021 under sub-section (1) of section 139 of the Act, is **extended to 31st December 2021;**

14) The **due date of furnishing of belated/revised Return of Income** for the Assessment Year 2021-22, which is 31st December 2021 under sub-section (4)/sub-section (5) of section 139 of the Act, is **extended to 31st January 2022.**

Clarification 1: It is clarified that the extension of the dates as referred to in clauses (9), (12) and (13) above shall not apply to Explanation 1 to section 234A of the Act, in cases where the amount of tax on the total income as reduced by the amount as specified in clauses (i) to (vi) of sub-section (1) of that section exceeds one lakh rupees.

Clarification 2: For the purpose of Clarification 1, in case of an individual resident in India referred to in sub-section (2) of section 207 of the Act, the tax paid by him under section 140A of the Act within the due date (without extension under this Circular) provided in that Act, shall be deemed to be the advance tax.

F. No.225/49/2021-ITA-II

Prajna Paramita, Director, Central Board of Direct Taxes, Ministry of Finance, Department of Revenue, New Delhi.

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Stalling negotiations on waiver will harm WTO's credibility, warns India

India on Monday said the co-sponsors of the proposal recognise that intellectual properties (IPs) are not the only barrier to augmenting manufacturing and addressing supply side constraints.

The warning came after the EU, UK, Australia and Singapore opposed negotiations at the WTO for such a waiver

With countries of European Union, United Kingdom, Australia and Singapore opposing text-based negotiations for intellectual property waiver for covid-19 vaccines and drugs, India on Monday cautioned this will do more harm to the credibility of the World Trade Organisation (WTO) and the collective failure will be remembered by posterity.

"We often hear that the WTO is losing its relevance and credibility, well, if WTO does not deliver during the pandemic on the issues and agreements for which it bears responsibility, and to think that by concluding the fisheries negotiation alone amidst these difficult times will the WTO reinstate its credibility and relevance, would be a grave mistake. Not allowing text-based negotiations will do more harm to WTO's credibility and this collective failure will be remembered by posterity," India said during the informal TRIPS (Trade-Related Aspects of Intellectual Property Rights) Council meeting on Monday.

The co-sponsors of a patent waiver to boost supplies of life-saving drugs and vaccines for covid-19, pioneered by India and South Africa presented a revised proposal on 21 May seeking that the temporary waiver be in place for at least three years, given the uncertainty regarding vaccine effectiveness for children and against new variants. However, the proposal has hit a roadblock even though the US last month, came out in the open supporting the idea and expressing its readiness for text-based negotiation at the WTO.

Dissenting economies have questioned the effectiveness of TRIPS waiver for fast-tracking access to covid vaccines across the world. In a meeting on 23 February they asked co-sponsors such as India and South Africa if spare manufacturing capacity is available to produce vaccines even if a waiver is granted.

EU said while it agrees that the ramping up of manufacturing capacity is a clear priority now and any available manufacturing capacity anywhere in the world should be used to the full extent, "any indication of where underused capacity exists as indicated by some members would be very welcome".

India on Monday said the co-sponsors of the proposal recognise that intellectual properties (IPs) are not the only barrier to augmenting manufacturing and addressing supply side constraints.

"However, we do believe that IPs are the biggest barrier in addressing supply side constraints, and thus need to be addressed on priority. The waiver is not sufficient but rather necessary element of a multipronged strategy. The TRIPS waiver is a necessary, proportionate and temporary legal measure for removing IP barriers and paving the way for more companies to produce COVID-19 vaccines, therapeutics or diagnostics by providing them freedom to operate without the fear of infringement of IP rights or the threat of litigation," it added.

The IMF in a recent paper has calculated that an immediate investment of $50 billion by developed countries for global vaccination efforts would yield a whopping $9 trillion in economic growth by 2025, holding that this could be the highest return on public investment in modern history.

"We have been presenting similar arguments in our previous statements emphasising upon the need for urgent steps for containing the pandemic by augmenting vaccine production to salvage the loss of $9.2 trillion in economic output and additional burden of $26 trillion in crisis support to the global economy. With IMF echoing similar sentiment we hope that the members will pay more heed," India said.

Source: HT Mint, 02.06.2021

Indemnity, a 'standard process' followed in other countries for vaccines: Wockhardt

In discussion to bring to India next-gen 'multi-variant' vaccines

Even as drugmaker Wockhardt explores multiple options for next-generation Covid-19 vaccines, its founder-Chairman Habil Khorakiwala says the "indemnity" being sought by foreign vaccine makers is a "standard approach" in other countries, and not a request being made just in India.

This exemption is specific to vaccines, and would not set a precedent for pharmaceutical or biological products, Khorakiwala told *Business Line*. His statement came against the backdrop of foreign companies, including Pfizer and Moderna, seeking indemnity against litigation for their Covid-19 vaccines. For decades now, such protection has been extended by the US, he said, adding that there was a sense of urgency now because of the pandemic.

The pharma veteran is busy with discussions on second generation "multi-variant" vaccines being developed by research companies, besides nasal vaccines that are also easier to administer. The companies involved with both products were still in the early phase of clinical trials, he said, but added the pandemic would quicken the development timelines.

First off the blocks, though, is another tech-transfer deal that he expects to announce in a month. Without divulging names, he said, about 500 million doses will be supplied by October, and its distribution to different markets would depend on the original company.

The product would be made at Wockhardt's facility at Aurangabad, and if other alliances come through, he said, they would scale up capacity to meet the requirement. The company can make all three types of vaccines in circulation — vector-based, protein-based and mRNA vccines, he said. But Covaxin is not a vaccine they would be able to make, as it requires required a Bio Safety- Level 3 facility, he said. The company has also offered its services to the Government, to make affordable vaccines for the country, he said.

Wockhardt has an alliance with the British government up to August 2022 to make 100 million doses of the AstraZeneca vaccine, at its UK facility.

Source: PT Jyothi Datta , The Hindu Business Line, 03.06.2021

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Centre to find partner to operationalise Chengalpattu vaccine complex; TN CM against any further delay

M.K. Stalin wrote to Union Health Minister Harsh Vardhan on Wednesday, assuring him of "unflinching and wholehearted support" from his government in putting this national asset to its full use

The Tamil Nadu government has been informed that the Union government will find a partner to operationalise the Integrated Vaccine Complex (IVC) at Chengalpattu, established by HLL Bio-Tech Ltd. However, Tamil Nadu Chief Minister M.K. Stalin on Wednesday urged the Union government to ensure against any further delay in the process.

In response to the **Tamil Nadu government's repeated requests** and its representatives personally calling on multiple Union Ministers in Delhi last week over the proposal to hand over the facility to the State government, the Stalin-led government has been informed that the Union government intends to bring in a partner on its own to operate the plant.

"While I would like to reiterate our earlier request, I wish to highlight to you the urgency of the moment, given the need for immediate commencement of production. Irrespective of whether it is the Union government or the State government, which is to find the partner to operationalise the plant, the need of the hour is to ensure that there is absolutely no further delay in the process," Mr. Stalin wrote to Union Health Minister Harsh Vardhan on Wednesday.

In his letter (a copy of the communication was circulated to the media), Mr. Stalin assured the Union Minister of "unflinching and wholehearted support" from his government in putting this national asset to its full use. He also recalled his earlier letter to Prime Minister Narendra Modi in this regard.

Stalin urges for more vaccines, swift supply

The TN CM also pointed out that the COVID-19 vaccine supply to Tamil Nadu was almost exhausted and went on to request the Centre to prioritise Tamil Nadu and frontload the June month's supplies from the first week itself. "This would help us to recommence our vaccination drive and sustain the momentum generated by us in the last fortnight."

Mr. Stalin also recalled his communications earlier over COVID-19 vaccines, which were not in proportionate to the State's population and caseload and contended it could be corrected only by a special allocation of 50 lakh doses each under the Government of India channel and Other than Government of India channel.

The CM thanked the Centre for the allocation of 25.84 lakh doses under the former and 16.74 lakh doses under the latter. "Meanwhile, I would also like to point out that this allotment is just commensurate with the broader increase at the national level and our request for a special allotment to correct the earlier lower allocation is still to be addressed."

Mr. Stalin reiterated the request to the Centre to look into this issue and ensure that Tamil Nadu was allocated vaccines at levels comparable to comparable States.

Source : The Hindu, 02.06.2021

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India may consider indemnity request to vaccine makers

India has not provided indemnity to any vaccine makers so far, including Indian vaccine makers Serum Institute of India, which makes a version of the AstraZeneca/Oxford shot locally, and Bharat Biotech, which makes Covaxin.

India may look at providing indemnity, under certain conditions, to foreign Coronavirus disease (Covid-19) vaccine makers, even though no final decision has been taken on this, people familiar with the matter said on condition of anonymity.

Pfizer and Moderna have both reportedly sought protection from lawsuits related to unforeseen complications from their vaccines, much like the indemnity they have been provided in the US and the UK, and it is believed that this issue is holding up their entry into India, which is short of vaccines to protect its huge population.

India has not provided indemnity to any vaccine makers so far, including Indian vaccine makers Serum Institute of India, which makes a version of the AstraZeneca/Oxford shot locally, and Bharat Biotech , which makes Covaxin.

During the Carnegie India's Global Tech Summit 2020 in December, SII CEO, Adar Poonawalla, also talked about the need for the government to provide indemnity to vaccine manufacturers against frivolous complaints.

"No formal decision has been taken on the matter yet but the request is being seriously considered by experts, especially the conditions under which it should be allowed -- probably only during a pandemic. It is a big decision, and needs to be thought through. They might agree eventually with certain riders but at this stage nothing can be said for sure," said one of the people cited in the first instance.

Dr VK Paul, member (health), Niti Aayog, who heads the empowered group responsible for procurement, manufacturing, import, logistics, daily supply, and utilization of vaccines id not respond to queries.

In a media briefing last wee Paul said Pfizer's request for an indemnity is being examined.

India has already waived for vaccines approved by regulators of some countries (such as the US and UK) or WHO, local bridging trials and the need for testing every vaccine batch at the central drugs laboratory. The national drugs regulator, VG Somani, formally issued an order in this regard on Tuesday.

According to media reports, Pfizer indicated the availability of 50 million doses of its Pfizer-BioNtech vaccine between July and October. A Pfizer spokesperson said in a statement on May 25 that the company was in talks with the Indian government.

"Pfizer remains committed to continuing our engagement with the Government of India towards making the Pfizer BioNTech Covid-19 vaccine available for use in the country. Since the ongoing discussions are confidential, we cannot provide any further comments."

In another statement on May 25, it said, "...during this pandemic phase, across the world, Pfizer is supplying its Covid-19 vaccine only to central Governments and supra-national organizations for deployment in national immunization programs. Neither Pfizer Inc nor any of its affiliates globally, including in India, have authorized anyone to import/market/distribute the Pfizer-BioNTech Covid 19 vaccine. We continue to have ongoing discussions

with the Government of India towards making our vaccine available for use nationally."

Indian generics giant Cipla Ltd, is also working on importing the Moderna vaccine to India. HT learns that Cipla is seeking fast-track approvals to bring Moderna's single-dose Covid-19 booster vaccine into India expeditiously.

The company has refused to disclose any details of the ongoing discussion except for the fact that it is seeking seeking clarity and guidance from the government.

"Cipla has been at the forefront of Covid care. We are in the process of seeking clarity & guidance from the Government of India for exploring the possible roadmap for vaccine importation to India. At this stage, no definitive terms have been finalized and hence, the Company cannot comment further," the company said in an email on Tuesday.

Source : Hindustan Times, 03.06.2021

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Medium & Small hospitals will take a while to offer Covid vaccine shots

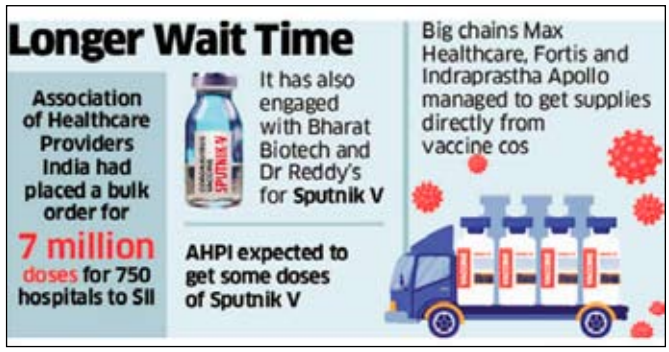
These hospitals under the umbrella of Association of Healthcare Providers India (AHPI) had approached SII to place orders in bulk. "SII has said it will send the list to the government for approval and it will revert after it gets approval," said Girdhar Gyani, director general of the AHPI.

Medium and small hospitals have been told by Serum Institute of India (SII) that they will have to take approval from the government before it starts supplying Covishield vaccines to them, said industry executives.

These hospitals under the umbrella of Association of Healthcare Providers India (AHPI) had approached SII to place orders in bulk. "SII has said it will send the list to the government for approval and it will revert after it gets approval," said Girdhar Gyani, director general of the AHPI.

SII has said after the government approves the list of hospitals, it will take another six weeks before supplies begin.

"During our discussions with SII on June 1, the company said delivery in six weeks after government's approval and confirmation of payment was the best-case scenario. It takes four weeks for every batch of vaccines to get cleared," said Jogesh Gambhir, president, AHPI, Jharkhand chapter. SII did not respond to email queries sent by ET.



AHPI had placed a bulk order for 7 million doses for 750 hospitals to SII. It has also engaged with Bharat Biotech (BB) for Covain and Dr Reddy's Laboratories for Sputnik V. While it expects to get some doses of Sputnik V, the Indian manufacturers are yet to commit.

A few big hospital chains like Max Healthcare, Fortis and Indraprastha Apollo have managed to get supplies directly from the vaccine makers, while medium and small-sized hospitals such as Narayana Hrudayalaya and the Indian Spinal Injuries Centre, among others, are yet to get their quota of vaccine supplies.

Gambhir said that the delay in the supplies will have an adverse effect on the vaccination drive.

"It will have an adverse impact. The bigger hospital chains will keep on making profits. Association of Healthcare Providers India has committed to give it to people under Rs 800. Our apprehension is that the consequences would be counter-productive as there will be not enough competition," he added.

Gyani said that AHPI is trying to help small hospitals as they can run the vaccination drive in smaller towns. "For Serum, it is easy to ship bigger quantity to a few sources but then the whole objective is lost," he said.

The AHPI has been in discussion with SII for the last three weeks. "Now they are saying they have to take permission from the government before supplying. A lot of time has already been wasted," said Gambhir.

Source : Economic Times, 03.06.2021

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Foreign-approved vaccines no longer need bridging trials in India: DCGI

New Delhi: India's apex drug regulator has waived the requirement of testing every batch of foreign-made COVID-19 vaccines by the Central Drugs Laboratory, Kasauli and post-launch bridging trials for such firms, a move that will bolster the availability of vaccines.

The decision by the Drugs Controller General of India (DCGI) comes in the backdrop of Pfizer and Cipla putting forth similar demands during negotiations to supply imported vaccines to India.

These exemptions have been made in light of the huge vaccination requirements in India in the wake of the recent surge of COVID-19 cases and the need for increased availability of imported vaccines to meet national requirements, according to DCGI.

"It has been decided that for approval of COVID-19 vaccines in India for restricted use in an emergency situation which is already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing and which are well-established vaccines from the standpoint that millions of individuals have already been vaccinated with the said vaccines, the requirement of conducting post-approval bridging clinical trials and of testing every batch of vaccine by CDL, Kasauli can be exempted, if the vaccine batch/ lot has been certified and released by National Control Laboratory of the country of origin," it said.

However, scrutiny of their summary lot protocol and certificate of analysis of batch or lot shall be undertaken by CDL, Kasauli for release as per standard procedures and requirement of assessment on the first 100 beneficiaries for seven days for safety outcomes before the vaccine is rolled out for further immunisation programme, the DCGI said in a notice issued on June 1.

Source : Millennium Post, 03.06.2021

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Haffkine Biopharma to produce 22.8 cr Covaxin doses a year

Making Covaxin at Haffkine is part of the government's plans to accelerate domestic vaccine production by using the capacities of the public sector units.

The department of science and technology had approved Haffkine in April 2021 to produce Covaxin.

Haffkine Bio-Pharmaceutical Corporation, a Maharashtra government undertaking, will manufacture 22.8 crore doses of Covaxin per annum under a technology transfer arrangement with Bharat Biotech. The company has received funding of ₹159.80 crore for producing Covaxin.

Haffkine BioPharma MD Dr Sandeep Rathod said the company has been provided with a grant of ₹65 crore by the Centre and ₹94 crore from the Maharashtra government. "We have been given a timeline of eight months and the work is being executed on a war footing," Rathod said. The company had earlier estimated around a year to make the vaccine.

Vaccine production will be done at the firm's Parel complex in Mumbai. The process would involve two stages – drug substance and final drug product. For the production of drug substance, Haffkine would need to build a Bio Safety Level 3 (BSL 3) facility. BSL 3 is a safety standard applicable to facilities where work involves microbes that can cause serious disease via the inhalation route. It already has a fill-finish facility.

Making Covaxin at Haffkine is part of the government's plans to accelerate domestic vaccine production by using the capacities of the public sector units. Apart from Haffkine, these vaccines will also be made at Indian Immunologicals, Hyderabad and Bharat Immunologicals & Biologicals, Bulandshahar, Uttar Pradesh.

'Enhancing vaccine production capacity using public sectors assets will go a long way in building production capacity of vaccines in our country to support the massive vaccination drive," said Renu Swarup, secretary, department of biotechnology and chairperson, Biotechnology Industry Research Assistance Council.

The department of science and technology had approved Haffkine in April 2021 to produce Covaxin. Haffkine Biopharmaceuticals had asked for around 12 months to complete this task. The central government wanted them to expedite and complete the task urgently within six months. Now the timeline has been set at eight months.

The pharma company is an offshoot of the 122-year-old Haffkine Institute, one of the oldest biomedical research institutes in the country and focuses on research and manufacturing of polio vaccines. Haffkine has installed capacity to make 22.8 crore vials a year. A committee formed by the Maharashtra state government under the chairmanship of scientist, Raghunath Mashelkar,

had recommended allocations of around ₹1,100 crore to implement projects over five years for the revival of Haffkine.

Source: Financial Express, 03.06.2021

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Telangana: Biological E starts at risk manufacturing of Corbevax

HYDERABAD: Vaccine maker Biological E has begun at risk manufacturing of its recombinant protein Covid-19 vaccine – Corbevax that it is developing in tie-up with Texas-based Baylor College of Medicine (BCM), TOI has learnt.

The company has already begun churning out doses of the vaccine as part of plans to create a stockpile ahead of an emergency use approval (EUA), sources said. However, the actual quantum of doses that has been manufactured so far could not be ascertained.

Corbevax, which is slated to be the most affordable vaccine to hit the market with an estimated production cost of around $1.5 per dose, is expected to be available for use in the country by August. Biological E is looking at hitting a capacity of 75-80 million doses per month for this vaccine candidate from August this year.

"It's a significant capacity and we have already scaled up. We have confidence in our manufacturing capabilities to be able to deliver that number from August onwards," Biological E managing director Mahima Datla had told TOI earlier.

At present, only three vaccines have got EUA in the country – Bharat Biotech and ICMR-NIV's Covaxin, AstraZeneca-Oxford vaccine being made by Serum Institute of India (SII) under the Covishield brand and Russian vaccine Sputnik V. The vaccine candidate is currently undergoing phase-III trials on 1,268 healthy volunteers in the 18-80 years age group at 15 centres across the country as part of a larger global Phase III study to evaluate the immunogenicity and safety of the vaccine against Covid-19.

Apart from the two-dose Corbevax, Biological E has just joined hands with Providence Therapeutics Holdings Inc of Canada for licencing the latter's mRNA vaccine candidate PTX-COVID-19-B for the Indian market as well as some other markets. The Hyderabad-based vaccine maker will be manufacturing up to 1 billion doses per annum of the mRNA vaccine in 2022.

Source : Swati Bharadwaj , TNN , 03.06.2021

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Pharma next big thing for IT cos

Healthcare sector will also offer big growth opportunity for software firms

LIFE sciences and pharmaceutical vertical is slowly emerging as the next growth spot for the IT services industry with growth opportunities spanning over the next decade.

Experts and company officials are of the opinion that ongoing pandemic has brought healthcare as one of the top priorities of countries, leading to higher public and private investment in life sciences and pharmaceutical sector.

As the pandemic is going to remain here for some years, the application of software services in life sciences sector will grow over the years.

"The technology spend of life sciences and pharmaceutical vertical has increased manifold during this Covid period. Therefore, tier-I IT services players, engineering services companies that are into medical devices design and development and BPM players have benefitted from this rising spend. As nations increase their healthcare spend, this is a growth story for the next decade," said Pareekh Jain, an IT outsourcing advisor and founder of Pareekh Consulting.

The growth in spend has already been visible in the fourth quarter earnings of IT services firms. For instance, Infosys witnessed a year-on-year growth of 18.3 per cent (constant currency term) in the Q4 of FY21 in its life sciences vertical. Out of 23 large deals the company won in January-March period, three came from life sciences vertical. Similarly, Tata Consultancy Services saw its life sciences vertical growing 19.3 per cent in the fourth quarter of this fiscal year.

Cognizant Technology Solutions, which is considered one of the big players in healthcare technology space, witnessed 7 per cent rise in CC term. This growth came from increased demand for its integrated payer software solutions and continued strong demand among its life sciences clients.

Apart from IT services players, even engineering services companies such as L&T Technology Services, Cyient, Tata Elxsi and others operating in designing of smart healthcare devices are also witnessing higher demand from this sector. For instance, L&T Technology Services' medical devices vertical grew 21 per cent YoY in Q4 of FY21, making it the best performer among all verticals.

Amid the Covid pandemic, pharmaceutical companies are spending more on technology to reduce time for vaccine trial and its subsequent release. Many IT firms have collaborated with vaccine producers to create technology platforms for interpretation of data coming out of vaccine trial.

Not only IT firms and engineering services companies, even BPM (business process management) service providers operating in the healthcare segment like telemedicine and insurance have also seen surge in demand. "Bioinformatics is the other area which will see rising spend in the coming years. Though it is there for quite some time, there will be greater momentum this time around. So, while the pandemic creates demand for IT companies with domain knowledge, it also enables technology firms to provide various digital technology-powered solutions to healthcare players," said Jain of Pareekh Consulting.

Though the growth of life sciences vertical will support the overall revenues, the supplementary impact will not be that big as this vertical typically contributes around 10 per cent of the total revenues of most IT firms, experts said

Source : Debasis Mohapatra, Hans India Bizz Buzz, 02.06.2021

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Govt restricts export of Amphotericin-B drug

Mucormycosis cases are on the rise in the country

The government has imposed curbs on the export of Amphotericin-B drug used in the treatment of black fungus disease, according to the notification of the Directorate General of Foreign Trade. Now, under the revised policy, export of Amphotericin-B is under the restricted category.

Rise in cases

The decision comes in the backdrop of rising cases of Mucormycosis in the country. It may be recalled that the GST Council, at its 43rd meeting, had recently included it in the GST exemption list of imported items.

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

Meanwhile, DV Sadananda Gowda, Chemicals & Fertilizers Minister, said on Tuesday that 2,70,060 vials of Amphotericin-B have been allocated to States/UTs and Central institutions from May 11 to May 30. This is in addition to the 81,651 vials that were allocated to the States in the first week of May.

In addition, a total of 98.87 lakh vials of Remdesivir were allocated to States, UTs and Central institutions from April 21 to May 30, the government informed on Tuesday, while further adding that its production has been ramped up 10 times, leading to enough supply than the demand. The government is also planning to supply up to 91 lakh vials till June-end.

Gowda further informed that Cipla has imported 11,000 vials of 400 mg and 50,000 vials of 80 mg of Tocilizumab from April 25-May 30. In addition, the Health Ministry received 1,002 vials of 400 mg and 50,024 vials of 80 mg via donation in May. Further, 20,000 vials of 80 mg and 1000 vials of 200 mg are likely to arrive in June, he said.

Supply of Covid drugs

The production, supply and stock position of other drugs used in the treatment of Covid, such as Dexamethasone, Methylprednisolone, Enoxaparin, Favipiravir, Ivermectin and Dexamethasone tablets, are also being reviewed weekly.

The production has been augmented and stocks are available to meet demand, Gowda further stated.

Source : The Hindu Business Line, 01.06.2021

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Regulator Looks for Alternative Medicines to treat Black Fungus'

India's drug regulator is examining the use of alternative drugs for the treatment of mucormycosis, the fungal infection which has become the latest health worry, said people with knowledge of the matter. India's drug regulator is examining the use of alternative drugs for the treatment of mucormycosis, the fungal infection which has become the latest health worry, said people with knowledge of the matter. A large number of cases has led to a shortage

of Amphotericin B, the medicine commonly used to treat the affliction.

With the unprecedented surge in mucormycosis infections causing a clamour for the anti-fungal drug, the drug regulator is reviewing the use of alternative drugs, notably those used at present to treat 'Kala Azar'. "In a bid to bridge the gap between demand and supply, while this is the preferred drug, the drug regulator is looking at alternatives especially those drugs which are used to treat Kala Azar. The decision is likely to come soon," added the same people.

The government is also considering releasing a clinical management protocol with guidelines regarding the use of Amphotericin B. "The experts are looking to recommend use of Amphotericin B only in severe cases and less severe cases be treated with alternative medicines. Guidelines regarding the use of Amphotericin B will soon be out, too," added the people.

Amphotericin B, an antifungal drug, is used to treat mucormycosis which can cause blindness, organ dysfunction, and can be fatal if not treated in time. Certain parts of India are seeing a large number of cases of black fungus. Some experts blame it on the overuse of steroids during Covid. Those with diabetes are believed to be particularly susceptible to the disease.

Doctors have said that while they would previously see 10-15 cases a year, they now have close to a 100 in a matter of weeks.

The number of cases of rhino-cerebral mucormycosis is showing no respite. Many patients are presenting themselves in advanced stages. They are being treated by endoscopic debridement followed by antifungals, " said K K Handa, chairman, department of ENT and head neck surgery, Medanta Medicity.

Union minister for chemicals and fertilizers Sadananda Gowda said that domestic production has been ramped up. "Over 1.63 lakh vials are available from existing domestic manufacturers in May which is about 260% higher than the production in April, "he tweeted.

On Tuesday the centre allocated more than 2.5 lakh vials of Amphotericin B to the states and UTs. "This is in addition to the supplies of 81,651 vials that had been made available by manufacturers to states in the first week of May," Gowda further tweeted.

Source : Economic Times, 02.06.2021

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Biological E ties up with Canadian firm Providence for mRNA Covid vaccine

The vaccine, named PTX-COVID19-B, is under development in Canada; the deal assumes significance as this gives India access to the mRNA tech

Hyderabad-based Biological E tied up with Calgary-based Providence Therapeutics to manufacture its mRNA technology-based Covid-19 vaccine and do clinical trials in India. The deal assumes significance as this gives India access to the mRNA technology.

The vaccine, named PTX-COVID19-B, is under development in Canada at the moment. Providence announced data from the phase 1 trials in May and will begin the phase 2 trials soon.

"The mRNA platform has emerged as the front runner in delivering the first vaccines for emergency use to combat the COVID-19 pandemic.

Biological E. is very pleased to be able to work with Providence on its promising mRNA vaccine candidate. We hope to provide India and other countries yet another option to ramp up their efforts towards achieving herd immunity against COVID-19," said Mahima Datla, Managing Director of Biological E Limited.

While the financial terms of the deal were not disclosed, Providence will sell up to 30 mn doses of its mRNA vaccine to Biological E. It would also provide the necessary technology transfer to make the vaccine in India, with a minimum production capacity of 600 mn doses in 2022 and targets capacity of 1 bn doses.

"Biological E will be responsible for all clinical development and regulatory activities for the mRNA vaccine in India and other jurisdictions licensed by Biological E," the company said.

"This initiative is an important commitment by a Canada-based company to help India and other nations vaccinate their citizens against COVID19. Providence was founded to serve patients, and this commitment by Biological E allows us to achieve that essential goal," indicated Brad Sorenson, CEO of Providence.

Biological E already has a deal in place to make over 500 mn doses of the single dose Johnson and Johnson (J&J) vaccine. J&J's is a viral vector based vaccine which uses human adenovirus Ad26.

India already has one mRNA vaccine in development by Pune-based Gennova Biopharmaceuticals which is in phase 1 clinical trials.

In a May 12 press statement, Providence has said that its phase 1 studies on 60 subjects have shown PTX-COVID19-B to be generally safe and well tolerated. It exhibited "strong virus neutralisation". It already has an agreement in place to supply 2 mn doses of PTX-COVID19-B to the government of Manitoba in Canada.

According to media reports, Providence was planning to move the clinical trials out of Canada.

Apart from the J&J and Providence Covid-19 vaccine deals, Biological E also has under development a third candidate with Baylor College of Medicine. The Baylor College of Medicine – Biological E vaccine is set to begin phase 3 clinical trials in June. This is a protein sub-unit technology based vaccine, a technology that Biological E already had. This technology is used to make Hepatitis B vaccines.

The Indian government has indicated that in the second half of the year, it expects to receive 300 mn doses of the Biological E vaccine.

India is already in talks with US players Pfizer and Moderna for bringing their USFDA-approved mRNA Covid-19 vaccines to India. Canada is using both Pfizer and Moderna vaccines to inoculate its citizens.

Source: Sohini Das, Business Standard, 02.06.2021

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Eli Lilly's antibody cocktail drug gets emergency use nod in India

Eli Lilly and Company India on Tuesday announced that it has received emergency use approval in the country for its monoclonal antibody drug combination used for treating Covid-19 patients with mild to moderate symptoms.

The drug, a combination of Bamlanivimab 700 mg and Etesevimab 1400 mg has been approved for use in the country by the Drugs Controller General of India (DCGI).

This will be the second cocktail drug approved by DCGI for emergency use, after the drug regulator gave its nod to the antibody cocktail Casirivimab and Imdevimab developed by Roche.

"We are pleased that we have another innovative treatment option to offer India's healthcare providers who continue to be at the forefront of the battle against Covid-19. Lilly is committed to contributing to the alleviation of the Covid-19 pandemic in India and around the world. We will continue to assess and evaluate how our existing portfolio and ongoing research can benefit patients with Covid-19," said Luca Vasini, Managing director, India subcontinent, Lilly India.

Bamlanivimab and Etesevimab together can be administered via injection in a restricted manner to adults and paediatrics patients (12 years and older, weighing at least 40 kg) in emergency situations at hospitals to treat mild to moderate Covid-19.

According to the company statement, Lilly is engaging in active dialogue with the India government and regulatory authorities to donate Bamlanivimab and Etesevimab in order to speed up access and provide more treatment options for patients with Covid-19. (ANI)

Source: Shalini Bhardwaj, ANI, 01.06.2021

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Changing GST rates for Covid-supplies no panacea

The solution lies in ensuring adequate supply and not making ad hoc changes to GST rates

As there is market failure due to high externality, the responsibility to vaccinate and financing the expenditures from the Consolidated Fund falls squarely on the government.

The 43rd meeting of the GST Council convened on May 28 to decide on matters including tax treatment of Covid-19 supplies, dealing with inverted duty structure for certain items and extension of relief to small taxpayers, and extension of compensation period beyond June 2022, when the current scheme comes to an end. With as many as eight finance ministers from Opposition-ruled states, the deliberations of the Council were not expected to be smooth, and it is not surprising that key decisions have been deferred.

The most urgent issue was lowering tax rates on Covid-19 related supplies such as vaccines, drugs and medicines, oxygen cylinders and concentrators, and other material and equipment required for Covid-care. Some states have asked for exempting vaccines (currently taxed at 5%), but given the higher rates on inputs, this would make them ineligible for availing input tax credit, and that may actually increase prices.

Some have suggested zero-rating of the tax and some others have suggested levying a small rate of 0.1% to enable input tax credit. However, zero rating is done only for exports and levying a low rate would cause heavy refunds to be made. Considering the differences, the Council constituted an 8-member panel headed by the Meghalaya CM to deliberate and submit a report by June 8 on the matter.

The important point that is missed in the discussion is that tax component is not a major determinant of the price of the vaccine today; it is the convoluted vaccine policy, combined with the supply-demand mismatch. As there is market failure due to high externality, the responsibility to vaccinate and financing the expenditures from the Consolidated Fund falls squarely on the government.

The Constitution places prevention and containment of contagious diseases in the Concurrent List (Entry 29), and the Union Government should take the responsibility of financing the programme, and the states as well as the private sector should be involved in administering the vaccine. The government should have assessed the requirements when the pandemic was raging, and considering the capacity constraint of the two domestic producers, it should have opened the market for imports.

Instead, the decision to import was delayed, and the Centre simply asked the states to vaccinate 590 million people in the 18-45 age group that would require 1.22 billion doses. Monopsonistic procurement of vaccine by the Centre and its distribution among the states would have helped bring down the prices instead of States going for global tenders. Even for the domestic manufacturers, the initial price was relaxed, and Covishield is now priced at Rs 300/dose to the states and Rs 600/dose to the private sector. Covaxin is priced at Rs 400/dose to the states and Rs 1200/dose to the private sector. Even now, it is not too late to reverse the decision. In the case of Covid-19 drugs and other supplies, the common man is made to pay black-market prices due to scarcity. The solution lies in ensuring adequate supply and not making ad hoc changes to GST rates.

Compensation to the states for the shortfall in revenue collections has been a vexed issue. In FY21, the shortfall was estimated by assuming that the states' GST collections will increase by 7%, and the states were given a loan of Rs 1.1 trillion after adjusting the shortfall with estimated collections from compensation cess. The actual collection was lower than the previous years by 3.3%, and the states are concerned. For FY22, too, 7% 'as-normal' growth has been assumed, pegging the shortfall at Rs 2.7 trillion and, after adjusting the revenue of Rs 1.1 trillion from the compensation cess, the compensation payment is estimated at Rs 1.58 trillion; the Centre is supposed to borrow this amount and on-lend it to the states. Given the dire need for resources, the states will be left with no choice but to accept. However, the entire episode of GST compensation has left the states helpless and eroded their trust, and this could make them wary of future reforms.

The issue of compensation in the future after the present agreement ends in June 2022 is another major concern for the states. The problem would not have arisen if GST had been a money machine as was promised. Thankfully, as the technology platform has stabilised, the monthly collections have consistently exceeded Rs 1 trillion since October 2020. Unfortunately, due to the second wave, the estimated 17% increase over FY21 RE may not accrue. The future collections will depend upon economic recovery.

In 2017, when GST was introduced, the Centre agreed to a generous compensation scheme to clinch states' assent. Now that states have nowhere to go, it remains to be seen how the Centre will address the matter. The entire process is likely to place severe challenges in Union-state financial relations, and it remains to be seen how these will be navigated.

(M Govinda Rao- Chief Economic Adviser, Brickwork Ratings, and former director NIPFP)

Source: M Govinda Rao, Financial Express, 02.06.2021

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Seeking clarity, guidance from govt for vaccine import: Cipla

The statement came after a report by PTI on Monday said the company is seeking fast-track approvals to expeditiously bring Moderna's single-dose COVID-19 booster vaccine into India.

Pharma major Cipla on Tuesday said it is seeking clarity and guidance from the government on the possible roadmap to import vaccine, while stressing that it has been at the forefront of COVID-19 care.

The statement came after a report by PTI on Monday said the company is seeking fast-track approvals to expeditiously bring Moderna's single-dose COVID-19 booster vaccine into India.

The report quoting sources said Cipla has requested the government for indemnification and exemptions from price capping, bridging trials and basic customs duty, while stating that the firm is close to committing over USD 1 billion as advance to the US major.

In a regulatory filing, the pharma firm said, "Cipla has been at the forefront of COVID care. We are in the process of seeking clarity and guidance from the Government of India for exploring the possible roadmap for vaccine importation to India". At this stage, no definitive terms have been finalised and hence, the company cannot comment further, it added.

Source : PTI, 01.06.2021

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India halts vax exports, may resume in future

The MEA has also made it clear that in future; supplies (export) would be undertaken, keeping in view of the domestic production and the requirements of the national vaccination programme Pune

In a relief of sorts, from May 5, India has apparently halted the contentious doles and exports of vaccines which has erupted into a massive political furore across the country, as per an RTI reply released here on Monday. In a response to the RTI query filed by Pune-based activist Prafful Sarda, the Ministry of External Affairs (MEA) has provided details of the vaccines exported in different categories to 95 countries till May 5.

To a question, the MEA has also made it clear that in future; supplies (export) would be undertaken, "keeping in view of the domestic production and the requirements of the national vaccination programme".

The IANS had first reported the vaccines exports details on April 27, (Centre's Covid jab for world spells 'ouch' in India!), triggering a massive political furore. All major parties in the country including Congress, Nationalist Congress Party, Shiv Sena, Aam Aadmi Party, the Left and other opposition parties had repeatedly slammed Prime Minister Narendra Modi and the Bharatiya Janata Party-led central government on the issue. "However, barring the basic export data, the government has kept mum on many other related info but critical aspects pertaining to the exports of such a huge quantity of doses which deprived Indians in a big way," Sarda told IANS.

For instance, the Centre has said it has no record or documents if any committee was formed by the government to decide on the vaccines export, its members, the details and minutes of the meetings if any of such a committee.

"This is quite mysterious. Which ministry has actually taken the decision for the massive donations or exports especially since at least two key ministries – Health and MEA – could be directly involved in the process," Sarda pointed out. The RTI reply has mentioned in passing that the vaccines were procured for the export purposes – as Grant, contractual supplies and under the Covax facility – as per the authorization from the Ministry of Health & Family Welfare.

However, it throws no light on who took such a critical decision when the country is reeling under the massive second wave of the Covid-19 pandemic, said Sarda.

As per the official data, the Centre has given away a whopping 107.15 lakh vaccines free as 'Grant' to 47 countries, sold 357.92 lakh doses at commercial rates to 26 nations, and under the Covax programme sold 198.63 lakh vaccines to another 47 countries – totaling to a staggering 663.70 lakh doses.

Till May 31 (today), India has vaccinated a total of 21,31,54,129 people under various approved categories, including those who got their second dose. "This proves that the government has virtually sent away more than 6.60 crore doses abroad that could have, for instance, vaccinated by now the entire adult population of Maharashtra - which is the country's worst-hit in terms of infections and fatalities," Sarda said.

For the 'Grant', the government had purchased the vaccines from Pune-based Serum Institute of India Ltd (SII) at Rs 200+GST per dose, and from Hyderabad-based Bharat Biotech International Ltd at Rs 295+GST per vaccine, said the RTI reply.

Source : Quaid Najmi, Hans India Bizz Buzz, 01.06.2021

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Covid drugs rates brought down, NPPA tells Telangana high court

HYDERABAD: Amid charges of exploitation of Covid-19 patients by private hospitals by collecting exorbitant bills, the National Pharmaceutical Pricing Authority (NPPA) said the prices of Covid-19 management drugs like remdesivir have been brought down following

the intervention of the Centre. The price of remdesivir was brought down to Rs 3,500 from Rs 5,400 per vial, it said.

The drug manufacturing companies have volunteered to bring the rates down following the intervention of the Centre, the NPPA said in its affidavit before the Telangana high court which made NPPA a respondent in the ongoing case on Covid-19. The court, while hearing a batch of PILs on Covid-19 questioning the high charges on one hand and failure of the authorities on the other, had asked the NPPA to file an affidavit specifying its efforts to contain the exploitative practices of the hospitals.

NPPA deputy director T Rajesh Kumar said in his affidavit that manufacturers of non-scheduled drugs cannot increase the maximum retail prices of their drugs by more than10 per cent in a year. "Remdesivir is a non-scheduled drug. NPPA is monitoring the situation in respect of nonscheduled drugs used in the management of Covid-19 to ensure that the manufacturers do not increase the prices beyond10% per annum," he said.

For Covid-19 drugs, the NPPA is monitoring the situation regardless of the classification of the drug, scheduled or non-scheduled. "The NPPA is also coordinating with the All India Organisation of Chemists and Druggists (AIOCD) for removing bottlenecks in the supply chain," Rajesh Kumar said. NPPA issued an office memorandum on April 17 notifying the reduced prices of the drugs used in Covid-19 with a direction to drug controllers in the states to ensure that these drugs were available at reduced rates, he said.

The central agency's affidavit said NPPA fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013, known as DPCO. Manufacturers of scheduled drugs will have to sell their products within the ceiling price and GST can be added to this. However, the price fixation methods are not the same for all drugs.

Source : Sagar Kumar Mutha, TNN , 01.06.2021

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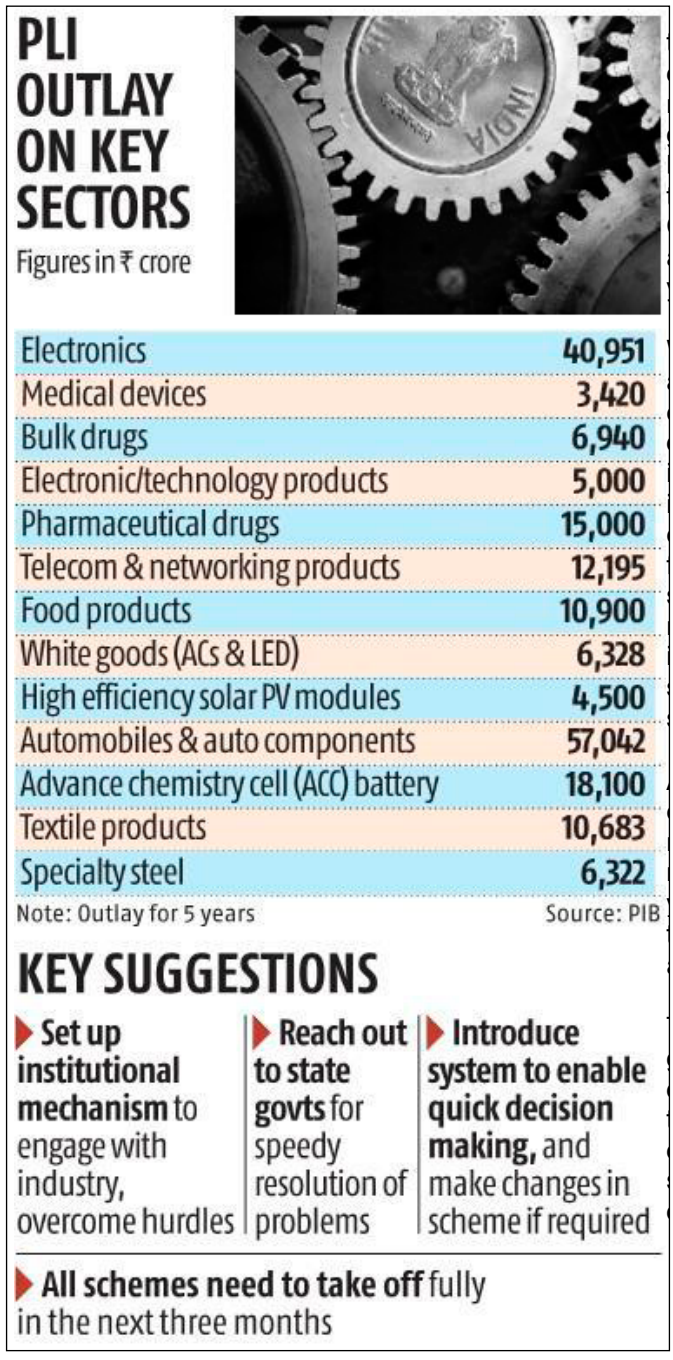
Cabinet secy-led panel wants PLI scheme revamp to boost manufacturing

Suggests institutional mechanism, regular hand-holding for firms

A high-level committee headed by Union Cabinet Secretary Rajiv Gauba has suggested a revamp of the production-linked incentive (PLI) scheme to boost domestic manufacturing and make the initiative more investor-friendly by "regular hand-holding" and removing hurdles at the earliest.



The panel, in a recent meeting with different ministries, called for setting up an effective "institutional mechanism" to constantly engage with companies that have decided to participate in the Rs 1.97 trillion scheme, an official aware of the matter said.

The mechanism will focus on addressing challenges faced by investors, including global giants, which have shown interest in participating in the National Democratic Alliance government's flagship scheme, the official said.

Last year, the Centre announced the PLI scheme now extended to 13 key sectors such as telecom, textile, automobile, white goods, and pharmaceutical drugs -- to improve cost competitiveness of locally produced goods, create employment opportunities, curb cheap imports, and boost exports. The scheme offers incentives to companies on incremental sales of goods manufactured in India for a period of five years.

"The idea is to engage with industry regularly, monitor various milestones achieved (as part of the scheme). There should also be regular hand-holding for companies," the official cited above said.

A system will have to be introduced to enable prompt decision making and look into the "legitimate requirements" of the companies availing of incentives under the scheme, suggested the panel, which also includes senior officials of the NITI Aayog, finance ministry, and commerce and industry ministry.

The development comes against the backdrop of several companies, especially electronic manufacturers, requesting the government to relax the targets laid out under the scheme owing to disruptions caused by the Covid-19 pandemic. They have also sought a change in the base year from 2019-20.

While there has been no formal announcement regarding the easing of norms, a process-driven method to address the industries' woes can boost investor confidence and promote ease of doing business. Apart from this, constant support from state governments will be required to resolve issues, including speedy clearances for setting up new units, the official said.

According to the government's estimates, the PLI scheme will result in minimum production of more than $500 billion in five years in India. Besides, India is trying to diversify supply chains, amid tensions with China.

The panel has asked government departments to devise ways to reduce the timeframe for the implementation of the scheme. Besides, all schemes need to take off fully over the next three months. Out of the 13 schemes, three schemes have been notified; seven have been approved by the Cabinet; and three – automobile, steel, and textile – are yet to get the Cabinet's nod.

Source: Shreya Nandi, Business Standard, 03.06.2021

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View: How financial incentives for innovation can play a significant role in vaccine development

Angela Merkel opposed this move, warning that it would discourage production of important vaccines. Merkel is right. Monetary incentives for innovation are critical to stimulating and growing innovation.

Virtues of the reward system include providing incentives to innovate without granting monopoly power over price, or nonoptimally restricting the use of essential innovations.

The world has witnessed an unprecedented race by the private sector to develop and produce Covid-19 vaccines. Since the outbreak of the pandemic, at least five different vaccines have proven effective against the virus. Vaccine development is a risk-intensive process.

It requires substantial investments in pre-clinical research, human clinical trials, regulatory submissions and market creation, with relatively low likelihood of product success and market entry. So, what incentivised private pharmaceutical companies such as Pfizer, Moderna, AstraZeneca Johnson & Johnson and Bharat Biotech to spend hundreds of millions of dollars in mobilising resources and capabilities for vaccine R&D? No doubt the desire to do good. But these companies also have afiduciary duty towards their investors and an equally important, if not more important, incentive for innovation is provided by potential profits from the sale of these vaccines to billions around the world.

Profits are only possible if pharma companies are allowed to sell their vaccines at a price that covers not just the marginal cost of production, but also the significant initial costs incurred during R&D. This can only happen if companies are granted some monopoly power either through patent protection, where innovators have exclusive rights to market the vaccines they develop, or by regulation that limits generic drug manufacturers from reengineering the manufacturing process at lower costs of ownership and selling those generic equivalents at slightly above marginal costs of production.

Yet, granting monopoly power to pharma firms, while providing incentives to innovate, allows a large number of people who could have obtained life-saving vaccines, especially in poorer countries, to suffer and perhaps die.

Such monopoly power also hinders improvements and subsequent innovations if patent holders disallow that. This is the dilemma we currently face. In response to mounting pressure from Democrats and nearly 100 countries, Joe Biden waived patent protection for Covid vaccines being produced in the US.

Angela Merkel opposed this move, warning that it would discourage production of important vaccines. Merkel is right. Monetary incentives for innovation are critical to stimulating and growing innovation.

Economists have implicated the significant gap between private and social returns to research in limited development of vaccines for diseases like malaria and tuberculosis that plague developing countries. While waiving patent protection for the Covid vaccine, it is important to design an alternative system that rewards innovators for this critically important quest. Economists and intellectual property advocates, including Joseph Stiglitz, have long emphasised rewards paid by the government to innovators — such as prizes and purchase commitments — as an alternative to patents in spurring innovative activity.

Virtues of the reward system include providing incentives to innovate without granting monopoly power over price, or nonoptimally restricting the use of essential innovations. A prize could compensate the innovator and then render the innovation open source so that it can be produced and distributed widely. What should be the size of the prize? Who should fund it? How should it be administered? In the 2006 paper, 'Regulation of Natural Monopolies', MIT economist Paul Joscow's suggests that a lump sum prize to compensate for initial R&D costs, along with licensing fees for production paid by government and philanthropic organisations, would provide the right incentives. Further, vaccine R&D is a global public good. So, each country has the incentive to free-ride research financed the governments of other countries.

Governments (read: taxpayers) and philanthropic organisations must pay for the right outcome, with richer countries with greater willingness to pay contributing more towards R&D costs. In effect, richer countries can purchase vaccines at near-monopoly price they would have paid for their populations during the period of patent protection. Thereafter, they should distribute or sell these at near-marginal costs of production, or subsidise for poorer and more needy populations. At the same time, the underlying technologies could be open-sourced for anyone else to use, copy or modify, including the innovating company, so that the most efficient producers can produce it in large quantities.

If there is more than one innovator, as is currently the case with Covid vaccines, an auction mechanism could be instituted that will facilitate price discovery through information aggregation about potential demand and costs of production.

To encourage organisations to invest in cures for future public health crises, intrinsic motivation alone will not suffice. We must provide financial incentives for innovation, and keep financial incentives intact, even as we unshackle ourselves from its limitations by judicious use of public and philanthropic funding.

Source: Bhagwan Chowdhry & Deepa Mani, Economic Times, 01.06.2021

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No shortage of Covid drugs: IDMA

Seeks cut in taxes on medicine; hails PLI scheme for pharma sector

The pharmaceutical experts have said that industry has managed to manufacture required quantity of essential drugs in the country during Covid-19 second wave. The Indian Drug Manufacturers Association (IDMA) said that the sector was able to produce both Covid and non-Covid related drugs despite various challenges including shortage of on-site workforce and restrictions in supply chain.

Viranchi Shah, Senior Vice-President, IDMA, told Bizz Buzz, that upon realising the surge in Covid cases, pharma companies scaled up their manufacturing capacities. He said that critical Covid related drug such as remdesivir saw increase in production from 38 lakhs injections/month to 1.2 crore injections/month since April and May. Similarly, Shah claims that given the surge in cases of black fungus in Covid patients, Amphotericin b drug production has also been increased by Ambalal Sarabhai Enterprises (ASE) by four times this year. The industry expert had said that they do not assume any significant long-term term losses for the pharma manufacturers, with some setback in the first quarter of Financial Year 2021-22.

"We had two major impacts. Number one was in Covid-related drugs, because of the sudden demand, the Active Pharmaceutical Ingredients (APIs) went up, and that's where our margins were hit. Companies continued with the standard price. We can't go to the government and use the arm-twisting technique. We had meetings with the government. And the government also said that increasing the prices would not give the right message to the society. So, you (manufactures) have to find the way to sustain for some months, it said. And we acceded to the government's request," said Shah

"It is not the right time to escalate the prices. Although all of us have suffered losses and profits were gone. So, that was one of the impacts where our bottoms lines will definitely be impacted. Everybody's profits get eroded as input prices are the same but the output is doubled," he added.

The IDMA vice-president explained that although the industry was impacted for the month of April-May, since workers could not come to the plants and manufacturing could not go on, the situation wasn't as severe as previous year's lockdown where supply chain was completely disrupted. **Given the ongoing high demand of essential medicines, the Ministry of Chemicals and Fertilisers gave its nod to 46 companies for domestic manufacturing of critical Key Starting Materials (KSM) or drug intermediates and active pharmaceutical ingredients (APIs) under the Production Linked Incentive (PLI) Scheme.**

Shah said that the decision will give a boost to the industry in the next two to three years and reduce the dependency on imports of essential drugs from countries such as China and Europe. According to him, out of about $ 9-10 billion industry of APIs, India is importing close to $ 3.5 to 4 billion of APIs directly. Out of total the import of KSM (out of which the APIs are manufactured), 67 per cent of those KSM and APIs come from China and rest from Europe and South-East Asian countries.

The IDMA however sought relief on customs duty on essential drugs. At present, the custom duty on medicine in India stands at 23.2 per cent after GST.

Source: Archana Rao, Bizz Buzz, 07.06.2021

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INTERNATIONAL NEWS

India's Covid Vaccine Rollout "Rescued The World": Top US Scientist

Dr Hotez, an internationally-recognised physician-scientist in neglected tropical diseases and vaccine development, said that the COVID-19 vaccine rollout is "India's gift" to the world in combating the virus.

Houston:

The rollout of the COVID-19 vaccines by India in collaboration with leading global institutions has "rescued the world" from the deadly coronavirus and the contributions by the country must not be underestimated, a top American scientist has said.

India is called the pharmacy of the world during the COVID-19 pandemic with its vast experience and deep knowledge in medicine. The country is one of the world's biggest drug-makers and an increasing number of countries have already approached it for procuring coronavirus vaccines.

Dr Peter Hotez, Dean of the National School of Tropical Medicine at Baylor College of Medicine (BCM) in Houston during a recent webinar said that the two mRNA vaccines may not impact the world's low and middle income countries, but India's vaccines, made in collaboration with universities across the world such as BCM and the Oxford University, have "rescued the world" and its contributions must not be underestimated. During the webinar, "COVID-

19: Vaccination and Potential Return to Normalcy - If and When", Dr Hotez, an internationally-recognised physician-scientist in neglected tropical diseases and vaccine development, said that the COVID-19 vaccine rollout is "India's gift" to the world in combating the virus. India's drugs regulator gave emergency use authorisation to Covishield, produced by Pune-based Serum Institute of India after securing licence from British pharma company AstraZeneca, and Covaxin, indigenously developed jointly by Hyderabad-based Bharat Biotech and Indian Council of Medical Research scientists. The webinar was organised by Indo American Chamber of Commerce of Greater Houston (IACCGH).

"This is something very special and I see it myself because I'm on weekly teleconferences with our colleagues in India, you make a recommendation, and within days it's done and not only done, but it's done well and with incredible rigor and thought and creativity," Dr Hotez said, stressing that he felt compelled to make this statement because "India's huge efforts in combating global pandemic is a story that's not really getting out in the world." Dr Hotez, considered as the authority on vaccinations, is working on an affordable coronavirus vaccine in collaboration with Indian pharmaceutical companies.

There is increasing evidence that vaccines not only "interrupt symptomatic illness and keep you out of the hospital" but halts asymptomatic transmission as well. However, the troubling news is that the vaccines work well against the UK B.1.1.7 variant, which is now accelerating across the US, but doesn't work quite as well against the variant coming out of South Africa. It is likely that all the vaccines will require a booster for two reasons: the durability of protection for the vaccines is unknown and to create an added immune response that's better tailored towards the South African variant.

Consul General of India in Houston, Aseem Mahajan, along with a distinguished panel of doctors participated in this webinar, that tracked the possibilities of a return to some semblance of normality due to the accelerated roll out of vaccines across the country. Appreciating Dr. Hotez for commending India's efforts in getting vaccines to the world, Consul General Mahajan, said, "in keeping with "our tradition of sharing with the world," India has exported vaccines to many countries across the world. India has provided 56 lakh doses of coronavirus vaccines under grants assistance to a number of countries. The vaccines were sent to Sri Lanka, Bhutan, Maldives, Bangladesh, Nepal, Myanmar and Seychelles.

There has also been a boost in the collaborative medical partnerships emerging between the US and India during this pandemic. In addition, India is one of the fourth largest destinations in Asia for medical devices manufacturing and many US companies have expressed interest in collaborating on this front," Mr Mahajan said. IACCGH Founding Secretary/Executive Director Jagdip Ahluwalia said that "India's response to the COVID crisis, as acknowledged by Dr Hotez, falls in line with Chamber's vision. Since its inception, 21 years ago, India would be a future global player in key areas like technology, medicine, manufacturing and international trade. This belief has been proved time and again particularly in the last decade." Chamber President Tarush Anand expressed pride that India has risen to this global challenge by leveraging the brilliance of its scientific community and extensive manufacturing capabilities in the most efficient manner to help the world recover from a deadly pandemic.

Source : PTI, 08.03.2021

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