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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **Unprecedented increase in the prices of Active Pharmaceutical Ingredients (API) : IDMA Representation to NPPA** *(Page No. 9)*

★ **Press Release: IDMA Recommends Grant of "Voluntary Licenses (VI)" for Vaccines by the Patent Holders to Indian Companies with Sufficient Expertise in this Field** *(Page No. 11)*

★ **IDMA Representation to Minister of State for Chemicals & Fertilizers on PLI Scheme** *(Page No. 13)*

★ **Department of Pharmaceuticals Re-invites application for Production Linked Incentive (PLI) Scheme with the last date of Submission as 28th July 2021** *(Page No. 15)*

★ **Fight Covid with compulsory licensing** *(Page No. 20)*

★ **GST waiver on Covid jabs, drugs will backfire: FM Nirmala Sitharaman** *(Page No. 27)*

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IDMA BULLETIN

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NORTH CAROLINA
DEPARTMENT of COMMERCE

Roy Cooper
GOVERNOR

Machelle Baker Sanders
SECRETARY

April 14, 2021

Dear Pharmaceutical Leader:

As North Carolina's newly appointed Secretary of Commerce, allow me to introduce you to our state's esteemed business-friendly environment, including one of the leading pharmaceutical and manufacturing clusters in the United States. It is supported by a top-rated college and university system and is immersed in a rich and diverse culture.

North Carolina has invested in building its life sciences sector since the mid-1980s. The results are apparent today with 775 companies and a diverse and talented workforce of 67,000. This robust ecosystem also includes approximatively 2,500 specialized support companies and suppliers, and several private-sector organizations.

Pharmaceutical and medicine manufacturing is the largest part of our life sciences cluster, with 30,000 skilled people making specialized pharmaceutical and biological products. We're proud to count Accord Healthcare, Aurobindo, Glenmark, and KriGen among those companies, alongside other major pharmas including Baxter, GSK, Novo Nordisk, and Pfizer.

These companies come to North Carolina — and grow here — because of the state's strong business climate and low operating costs. Our building costs, electricity rates, and cost of living all sit below the national average. North Carolina, in fact, ranks as the nation's best state for business in multiple publications including *Forbes*. A 2020 survey by the Boyd Company found the cost of operating a biopharma manufacturing facility in North Carolina's Research Triangle Region was the lowest in the U.S.

These companies wouldn't succeed without trained talent. Our universities graduate 4,900 people with life sciences degrees annually, along with 4,500 engineers. Our NCBioImpact training partnership aligns coursework at universities and community colleges with industry jobs, supporting a strong workforce pipeline. Our state created the first process technician training program to meet the needs of our biopharma manufacturing companies.

Proof of North Carolina's strengths lies in 10 companies announcing new biopharma manufacturing facilities in North Carolina last year. In total, these companies are investing $2.3 billion in facilities to produce pharmaceuticals and biologics. This year is already off to a great start, with three companies announcing more than $300 million in investment.

As a native North Carolinian, I can also personally attest to the strength of this ecosystem through my own education and career. I graduated from public schools, received a biochemistry degree from a public university and worked for more than twenty years as an executive in the life sciences sector in the state before I entered public service. I know what it takes to manage a successful life sciences operation and I am confident you will find all of the necessary components in a North Carolina location.

I invite you to take a closer look at North Carolina's talented workforce, strong biopharma manufacturing cluster, and low-cost business climate. To explore doing business in our state, connect to the Economic Development Partnership of North Carolina at edpnc.com/India.

Sincerely,

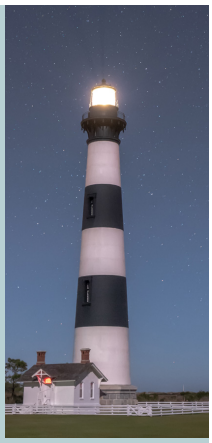
Machelle Baker Sanders

Machelle Baker Sanders
Secretary, NC Department of Commerce

State of North Carolina | Department of Commerce
301 North Wilmington Street | 4301 Mail Service Center | Raleigh, NC 27699-4301
919 814 4600 T





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The EDPNC can connect you with available sites; in-depth workforce, community and infrastructure data; potential supply chain partners; and information on our incentives packages.

Go to EDPNC.com/India or call

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ALL IN NORTH CAROLINA

ECONOMIC DEVELOPMENT PARTNERSHIP of NORTH CAROLINA




THE JOURNEY SO FAR AND THE ROADMAP AHEAD

Dr Gopakumar G Nair, *Editor, Indian Drugs*

Dear Reader,

Current Covid times are introspection times, too. When the Human Genome Project was initiated in 1990, for determining the basic pairs that make up DNA and for identifying and mapping the entire genes of the human genome, the hue and cry made by the Indian NGOs kept India out of the project, at lease officially. Approximately, 20 research institutions globally, including some from China and Russia later, participated during the 13 years of the project, which concluded in 2003. The participating countries and institutions made major contributions and consequently became beneficiaries of great progress and major strides in genomic research.

While China was already participating from 1990 and Russia joined in 2000, India realised the need and importance of moving into this field at the turn of the millennium. The 100K Pathogen Genome Project launched in 2012 in USA and the 100,000 Genomes Project, also of late 2012, by UK carried forward the genome project initiatives. The countries who took early initiatives were immensely benefited through major breakthroughs. For good (or bad?), China outpaced India in genomic research and was rewarded immensely through funding from major global investors. What about India? Better late than never. The DBT in India initiated the Genome India Project in January, 2020 with the aim of collecting a moderate 10,000 human genetic samples from across India to build a reference genome. Fortunately, the vociferous NGO lobbies have probably realised their folly in opposing the genome project participation by India in the 1990s and the Indian project of 2020 will hopefully progress.

India have caught up with China (and even Russia) in biomedical research in recent times. The Haffkine Institute, established in 1899 was indeed a pioneer and named after Dr. Haffkine, inventor of the Plague Vaccine, and a student of Dr. Louis Pasteur. While Dr. Haffkine came to introduce the Cholera vaccine in India which was developed by him in France, he was commissioned to undertake plague vaccine research in Bombay, through the Haffkine Institute jointly with the 33 hospitals in Bombay. He developed the plague vaccine and

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

tested it on himself in 1897. The then residence of Governor of Bombay was handed over to Dr. Haffkine to start the plague research laboratory (and later Bombay Bacteriology Laboratory) which was thereafter named the Haffkine Institute. This institute of a glorious past, fell into political interference and suffered from a loss of goals in the late 1980 to 2000. However, Haffkine Institute still has great potential if allowed to evolve on its strong research fundamentals. Haffkine Institute is currently offering their Bio- reactors for vaccine development in context of the Covid19 pandemic.

In the meantime, post the Patents Act, 1970, the Indian Pharma Industry made major breakthroughs in pharmaceuticals between 1970 and 2020, emerging as a leader not only among the developing countries, but as a "Pharmacy of the World". However, the journey from small to large molecules has been relatively slow in India. A few pioneers like Biocon and Bharat Biotech ventured into Bio-research in the 1990s. While Meril made India proud on Biomedical devices, the Serum Institute of India, Pune made India proud, by leading India's global thrust in manufacturing many vaccines over the years, including now a COVID-19 vaccine COVISHIELD in collaboration with Astra Zeneca-Oxford. COVAXIN from Bharat Biotech jointly developed with ICMR (NIV, Pune) has also entered the global market after final successful trials proving high efficacy. Many more Indian companies like Zydus Cadila (ZyCoV-D) are entering the field. Russia has tied up with six Indian vaccine manufacturers [Gland Pharma, Stelis (of Strides Group), Virchow, Dr. Reddy's, Hetero & others]. The Hyderabad based Biological E has undertaken production of Johnson & Johnson's (single shot) vaccine, which is awaiting regulatory approval.

This leads us to the main theme of this editorial. Pharma research and manufacturing in India has, hitherto been, substantially limited to API (Bulk Drugs) and formulations in the chemical synthesis and small molecular sector with few exceptions. Biologics are the emerging sector. It is time for India to undertake research to add on to the "MABs" (Adalimumab, Rituximab, Trastuzumab, Bevacizumab, Infliximab) the cepts (Etanercept), the "NIBs" (Imatinib, Gefitinib, Erlotinib, Sorafenib, Dasatinib, Sunitinib, Lapatinib, Nilotinib), the GRASTIMS (Pegfilgrastim), Beta Interferons (Alfa) and of course others like Insulin Glargine (Biocon is the pioneer in India). The Mabs, Mibs, Mids, Nabs and Nibs add to the anticancer artillery from the Biologics. Biocon, Cipla, Cadila, Dr. Reddy's and others have moved on to this bandwagon. While formulations of these group of drugs have been taken up by Indian pharma manufacturers, API developments are restricted to a few. It is heartening to note that relatively new comers like BDR are venturing into this challenging sector. There is immense potential for "me-too" molecules in all these breakthrough groups of biologics, which are indeed the "low-hanging fruits to pluck" for the Indian sector. It goes without saying that even "me-too" molecules involve large regulatory processes and require deep pockets and hence the need for intense and intentional industry-academia tie-ups to enable the "lab to market" journey. It is high time the Indian pharma industry revises its strategies to take on the next-gen challenges. The same applies for virology and vaccine research. More and more Indian Pharma companies need to move into these emerging sectors to regain the lost glory of Haffkine, Bengal Immunity and the like and to join the likes of Serum Institute and Bharat Biotech and to diversify like Zydus Cadila and Strides (Stelis) with strategic research and futuristic diversifications.

Courtesy: Indian Drugs, Editorial, Vol. 58 (01) January 2021

Mr. Deepnath Roy Chowdhury, IDMA's Immediate Past National President graces the cover page of QUALPHARMA April 2021 issue

PERSONALITIES

DEEPNATH ROY CHOWDHURY

Managing Director of STRASSENBURG PHARMACEUTICALS LTD

DEEPNATH ROY CHOWDHURY is the Managing Director of **Strassenburg Pharmaceauticals Ltd**, a WHO GMP certified formulation manufacturer, engaged in ethical marketing in the Indian Pharmaceutical Market. Mr Chowdhury is the promoter Director of Cans & Closures Pvt. Ltd. – a leading manufacturer of PET packaging products catering to the Coca Cola chain and the Pharma Industry. He has been an active member of the Indian Drug Manufacturers' Association (IDMA) for many years and has served the Association in various capacities. Mr Deepnath Roy Chowdhury was National President for 3 years (2017 – 2019).

Under his supervision, Strassenburg Pharmaceuticals Ltd. was awarded the 'Economic Times Bengal Corporate Awards – 2015' for Best Financial Performance. **Deepnath Roy Chowdhary** was instrumental along with his brother in launching the largest Stem Cell Banking network in the APAC region -- Cordlife, in India in collaboration with Strassenburg.

Strassenburg was set up in 1987 by a business family based out of Kolkata, then having interests in Metal & Glass Packaging. The unit was designed to produce different oral dosage forms with provision for expansion. Strassenburg launched its product line initially in some states and gradually expanded to cover the entire country. The company has always believed in Core Competence & remained focused on select Therapeutic Categories.

The Company aims to be a leader in therapeutic Categories mainly Gastro & Pain Management where it already has a couple of leading brands. Strassenburg continues to put in best efforts to avail this opportunity to pursue its goal to ensure **'Quality-Safety- Affordability'** adhering to the highest standards of ethics & integrity.

As a Pharmaceutical Producer company motto is 'Patient First'. This is what drives the company aimed at ensuring quality and accessibility. This idea also reflects in our state-of-the-art manufacturing facility & practices.

Facility strives to provide the best to their customers & focus on producing branded generics in various oral & topical dosage forms.

The most important attribute for success in delivering quality medicines is the commitment to quality adhering to the highest ethical standards. Strassenburg quality standards are well defined complying with cGMP standards.

Unprecedented increase in the prices of Active Pharmaceutical Ingredients (API) : IDMA Representation to NPPA

The Association has submitted the following representation on 10th May 2021 to Smt. Shubhra Singh, IAS, Chairperson, National Pharmaceutical Pricing Authority, with a copy to Ms. S. Aparna, IAS, Secretary to the Government of India, Department of Pharmaceuticals, on the above subject:

Greetings from Indian Drug Manufacturers' Association

Vide our representation dated 5th April 2021 (copy attached for your ready reference), we had illustrated the unprecedented increase in the cost of raw materials, packing materials, excipients and transportation costs in the past year. In Paracetamol the rise in API prices was 100% while in the case of Propylene Gycol it was over 300%. However, the prices of raw materials and packing materials, continue to rise unabated. Table I illustrates the increase in prices between March 2021 and April 2021, a period of only one month, shared by our members, and we are told prices are likely to rise further.

Table I Prices of Raw Materials and Packing Materials between March 2021 and April 2021

Item	March 2021 Price/Kg	April 2021 Price/Kg	% One Month Increase
Raw Material			
Ivermectin	18000	54000	200%
Methyl Prednisolone	85000	190000	124%
Meropenem	81000	140000	73%
Doxycycline	7500	12000	60%
Paracetamol	550	800	45%
Azithromycin	10500	14000	33%
Dexamethasone Sodium	40000	50000	25%
Ornidazole	985	1300	32%
Packing Material			
PVC	102	175	72%
Aluminium Foil	45	60	33%
Aluminium Tubes, PP Caps, Flip Off Seals			15-20%
Paper / Board			15%

In our representation dated 5th April 2021, we had highlighted that in the 8 years that Paracetamol has been under price control, its ceiling price has been increased by only 3% for the 125mg syrup and decreased by 3% for the 500mg tablet strengths, while the price of the API of Paracetamol has more than tripled!

Such huge escalation in input and transportation costs have a cascading effect on the entire pharmaceutical value chain, and severely affect its viability. This has been widely covered in the national and international media as this is a genuine problem. While we continue to bear the brunt of this extra ordinary increase in costs, we request you to ease our burden and allow the industry to partly offset the higher costs by allowing under para 19, a price increase of up to 20% for non scheduled formulations, and also allow increase in the prices of scheduled formulations on the basis of consumer price index and not wholesale price index, only for this year.

We request you to grant us a virtual meeting at the earliest so that we can put forth our views and sensitise the authorities to the genuine problems faced by the Indian Pharmaceutical Industry.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association

Mahesh H Doshi,
National President

Current Issues In Exports of Pharmaceutical Goods: IDMA Representation to Minister of State for Ports, Shipping and Waterways & Minister of State for Chemical and Fertilizers – Reg.

The Association has submitted the following representation on 12th May 2021 to Hon'ble Shri. Mansukh L Mandaviya, Minister of State for Ports, Shipping and Waterways & Minister of State for Chemical and Fertilizers. Similar letter was also sent to DGFT on the above subject:

Greetings from Indian Drug Manufacturers' Association.

This has reference to the DGFT Trade Notice No.02/2021-22, dated 26th April 2021 for operationalization of DGFT 'COVID 19 Helpdesk' for International Trade related issues. We are hopeful that this initiative will surely help the pharmaceutical goods exporters significantly in the current awfully challenging time.

We would like to draw your kind attention towards some of the challenges that our members are facing in exporting the pharmaceutical goods.

1. Steep increase in freight charges in the current Covid-19 scenario:

   a) Air freight increased by 7 to 10 times during the Covid-19 period compared to pre-covid-19 rates due to the suspension of several international carriers. Conversely, sea freights during the Covid -19 period remained more or less the same as their pre-Covid-19 period level. This resulted in the shifting of transportation volume from air to sea modes, which caused a huge increase in sea freight rates. A comparison of sea freight rates data in Oct - Nov 2020 and March - April 2021 is shown below for your ready reference. *(Although this increase in freight has impacted all the major locations, we mention the most impacted destination*

Country	Port	Container type	% of increase in Sea Freight from Oct-Nov 2020 to March -April 2021
Nigeria	Apapa	40' reefer	25%
South Africa	Durban	40' reefer	20%
France	Rouen	40' reefer	67%
Russia	Kotka / Moscow	40' reefer	56%
Brazil	Rio de janerio	40' reefer	69%
Myanmar	Yangon	40' reefer	62%
Casablanca	Morocco	40' reefer	55%
Tanzania	Dar-es-salaam	40' reefer	28%
Belgium	Antwerp	40' reefer	105%
Australia	Sydney	40' reefer	67%
Canada	Toronto	40' reefer	55%
USA	New York/ EWR	40' reefer	35%

   b) We anticipated that air freights will be normalized after yearly closing (March 2021); however Airlines are cancelling their flights to India due to prevailing situation, resulting in scarcity of air space with increased air freight rates.

2. Containers issue:

   a) The free period for empty containers provided by shipping line(s) earlier used to be between 10-14 days. The current free period has been reduced to 7-8 days, further impacting the transaction cost.

   b) Worthy containers for pharmaceutical products are still in short supply at many ports, hence shipping lines are taking shelter of such excuses to increase rates.

3) Many vessels are skipping JNPT /Main gate ports (Mumbai, Chennai, Mundra), leading to high detentions, increased lead time and high transit inventory

3. Shipping lines issues / General issues at port:

a) During the Pre-Covid period, several shipping lines were available; however, in the covid-period, only limited options/shipping lines are available. Thus, rates and lead times have increased many fold.

b) Shipping lines have added many surcharges, and there is an increase in basic rates happening almost every month now. The increase is between US$ 1000 to US$1500 per container per month. The overall cost of shipping goods by air /sea modes have gone up by 52 to 55 %.

c) Limited services are available for some ports (such as Sydney, Toronto, Russia), creating a massive backlog at Transit ports. It results in a significant increase in overall lead time.

As we continue to export with above laid down constraints in the current challenging time, we request your kind intervention and issue directions to the concerned in keeping the freight cost under check, and resolution of containers & shipping lines issues. This will help in smoothen the export, which is currently getting hindered.

Thanking you.
Yours sincerely

Mahesh H Doshi
National President

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Press Release:

IDMA Recommends Grant of "Voluntary Licenses (VI)" for Vaccines by the Patent Holders to Indian Companies with Sufficient Expertise in this Field

IDMA Position Paper on Patent Waiver

We refer to newspaper reports quoting forces who are against IP waiver for Vaccines. Indian Drug Manufacturers' Association (IDMA) also agrees that just simple waiving of Patents for Vaccines is not enough for increased and free availability of Vaccines in India. What is more important is grant of "Voluntary Licenses (VL)" by the Patent holders to Indian Companies with sufficient expertise in this field. Example of Astra Zeneca and Serum Institute is already a successful working model. Other Vaccine developers need to come forward and similarly transfer technology to Indian Companies against reasonable Royalties.

At the same time in case of Pharmaceutical Products (including APIs) which are directly or indirectly used for treatment of the present COVID pandemic, there is an urgent need for the IP rights to be waived at the worldwide level to boost their production and ensure there are no shortages anywhere in the world. Global Pharma companies owe at least this much to mankind. Recent shortages of Remdesivir in India is a wake-up call. Capacities of all medicines connected with this pandemic should be ramped up to ensure free availability at reasonable prices.

WTO has also provided provision of Compulsory Licensing (CL) just for tackling such an eventuality. Our Government should not feel shy in invoking this very thoughtful provision in the interest of humanity and our citizens. In view of current suffering of humanity all over the world, urgent action needs to be taken by the world coming together to ensure free flow of technology till the virus is eradicated.

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Seeking kind intervention for creating a mechanism for making environmental clearance (EC) and consent to establish (CTE) a one step process : IDMA Representation to MoEFCC

The Association has made the following representation on 11th May 2021 to Shri Rameshwar Prasad Gupta, IAS, Secretary to the Government of India, Ministry of Environment Forest & Climate Change (MoEFCC) with the copies to Mr. Ravi Agrawal, IAS, Additional Secretary, MoEFCC and Mr. Sharath Kumar Pallerla, Scientist (F), IA Policy Division, MoEFCC on the above subject:

Greetings from Indian Drug Manufacturers' Association.

We refer to the captioned subject and Ministry's above referred office memorandum, we would like to submit as under.

The Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India (GOI) deemed it necessary to expedite prior Environmental Clearances to projects or activities in respect of bulk drugs and intermediates. As a path towards achieving self-reliance in medicines to handle the Novel Corona Virus (COVID-19) outbreak, drug availability in the country and boost domestic production to reduce the import from China, the Ministry deemed it necessary that all projects or activities in respect of bulk drugs and intermediates manufactured are categorized as 'B2' (MoEFCC notification No. S.O. 1223 (E) dt. 27th March 2020).

Government of India initiative to boost domestic manufacturing of APIs/KSMs/and its intermediates.

To boost domestic manufacturing of Active Pharmaceutical Ingredients/KSMs/and its intermediates in the country, Government of India through Department of Pharmaceuticals announced Production Link Incentive (PLI) Scheme.

The scheme intends to boost domestic manufacturing of Active Pharmaceutical Ingredients (APIs), Key starting materials (KSMs) and its intermediates by attracting large investment in the sector, to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/drug intermediates and APIs.

As per MoEF& CC office memorandum F. No. 3-3/2019 IA.III dated 5th February 2020 referred above, one step mechanism was supposed to be created for approval of CTE & EC. This mechanism outlines that, the application made for prior environmental clearance shall be circulated to SEAC (State Expert Appraisal Committee) & SPCB (State Pollution Control Board), so that parallel scrutiny may be carried out by both the departments to reduce separate approval timelines and achieve the Government of India initiative to boost the domestic manufacturing of APIs & intermediates and to contain the outbreak of covid-19.

However, it appears that applications are being circulated to SEAC for approval of the prior environmental clearance, whereas the same is not being circulated with the SPCB for the approval of the CTE, thereby defeating the objective of the one step mechanism and delay in issuance of the CTE by SPCB.

In view of the above facts, we therefore request your kind intervention for the creation and practical implementation of the mechanism for one step approval process of CTE & EC.

Yours sincerely,

Mahesh H Doshi
National President

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IDMA Representation to Minister of State for Chemicals & Fertilizers on PLI Scheme - reg

The Association has submitted the following representation on 12th May 2021 to Hon'ble Shri Mansukh L Mandaviya ji, Minister of State for Chemicals & Fertilizers, Government of India with the copies to Dr. V K Saraswat, Member (Industry) NITI Aayog, Mr. Amitabh Kant, Chairman - Empowered Committee for the PLI scheme on Bulk Drugs & Medical Devices and CEO, NITI Aayog, Ms. S Aparna, Secretary, DoP and Ms. P. Amudha, Addl. Secretary, PMO on the above subject:

Greetings from Indian Drug Manufacturers' Association.

This has reference to the Department of Pharmaceuticals letter No. G – 30013/08/2021 dated 23rd April 2021 in response to the representation made by us on 16th April 2021 for the selection of the applicants in the PLI Scheme (copies attached for kind reference).

While we agree that the selection is done strictly as per the Guidelines but we never imagined that the whole benefit of the Scheme will be allocated / covered by ONLY ONE manufacturer for a product.

The Objective of the Scheme was to encourage Domestic Manufacturers of API and become ATMANIRBHAR, but with these allocations all the Formulation companies will become NIRBHAR on ONLY ONE manufacturer.

This will create a monopoly situation which ultimately will result in Expensive medicines in the hand of Patient. Please refer our earlier representation once again for details. (Attached herewith).

The Scheme was properly designed with a guideline of maximum 4 manufacturers to be granted approval, but it seems that some companies have taken the advantage of the loophole by applying for the entire capacity of the guideline (4 TIMES THE MINIMUM QUANTITY or even more) and quoting the lowest price to grab the entire benefit. By doing this the PLI scheme has GOT RIGGED.

This has left the other companies who are making these products since many years in a very vulnerable situation.

Over the period of time it may lead to stopping their production, as it will be difficult for them to compete with someone who is enjoying the benefit of the scheme. This will / may lead pricing power of medicines in the hands of few companies.

We strongly request you to look into this concern in a bigger picture and the solution lies in awarding the PLI scheme to 2-3 applicants for each product and not to ONLY ONE.

We look forward to your kind consideration and positive response.

Yours faithfully

Mahesh H Doshi
National President

Encl: as above

DoP letter No. G – 30013/08/2021 dated 23rd April 2021 (as reproduced below)

IDMA representation dated 16th April 2021 (published in IDMA Bulletin 21st April 2021 Issue no. 15 Volume no. 52

No. G-30013/08/2021-Scheme
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
*****

Shastri Bhawan, New Delhi
Dated the 23rd April, 2021

To

Shri Mahesh H Doshi
National President
Indian Drug Manufacturers' Association
102-B, Poonam Chambers, A Wing,
Dr. Annie Besant Road, Worli
Mumbai 400 018
Email:- admin@idmaindia.com, idmadelhi@gmail.com

Subject: - Representation of IDMA regarding PLI Scheme for Bulk Drugs - regarding.

Sir,

I am directed to refer to letter no. Nil dated 16.4.2021 received from Indian Drug Manufacturers' Association on the subject mentioned above and to say that the suggestions made therein regarding changes in the PLI Scheme have been considered in this Department.

2. In this regard, it is informed that the selection of applicants has been done strictly as per the Guidelines of the PLI Scheme for Bulk Drugs, which were revised on 29.10.2020 after due consultation with the stakeholders and approval of the competent authority. The Appraisal of the individual applications was done scrupulously by the Project Management Agency (M/s IFCI) and the same were recommended by the designated Empowered Committee (EC) following due procedure. The selection of the applicants was finally done with due approval of the Hon'ble Minister (Chemicals & Fertilizers).

3. It is informed that the selection of the applicants has been done as per the scheme guidelines, which cannot be modified or altered at this juncture. Further, applicants more than that prescribed in the scheme guidelines cannot be approved.

Yours faithfully

(Pankaj Kumar)
Section Officer (Scheme)
Tel. No.:- 23074417
Email: scheme-pharma@gov.in

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Department of Pharmaceuticals Re-invites application for Production Linked Incentive (PLI) Scheme with the last date of Submission as 28th July 2021 –reg.

DO No.31026/16/2020-Scheme, dated 10th May 2021

1. As you are aware, with an objective to attain self-reliance and reduce import dependence in critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country, the Department of Pharmaceuticals had launched a Production Linked Incentive (PLI) Scheme for promotion of their domestic manufacturing by setting up greenfield plants with minimum domestic value addition in four different Target Segments (Fermentation based - 90% and Chemical Synthesis based - 70%), totaling 41 products with a total outlay of Rs.6,940 cr. for the period 2020-21 to 2029-30.

2. The guidelines of the Scheme were issued on 29th October, 2020 and applications invited with a deadline of 30th November, 2020. After appraisal of all the 215 applications received for the 36 products spread across the 4 Target Segments, 46 applications have been approved and selected applicants informed. On conclusion of the selection process, a learning session with all applicants at my level and a workshop of the selected applicants at the level of the Hon'ble Minister of Chemicals & Fertilizers were organized.

3. As few slots are still open, it has been decided to re-invite applications for uncovered/under-covered Target Segments as per the extant guidelines and within the already approved financial outlay. Notice to this effect has already been placed on the website of this Department on 30th April, 2021 with the last date of submission of applications as 28th July, 2021. The Portal for online submission of application has also been made live by M/s IFCI Limited, the Project Management Agency for the Scheme.

4. I seek your active participation in the scheme for building the manufacturing infrastructure in the country for critical KSMs/Drug Intermediates/APIs, reducing the import dependency and giving a fillip to the Make in India' Programme.

Rajneesh Tingal,
Joint Secretary,
Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals,
Shastri Bhavan,
New Delhi.

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DGFT's COVID-19 Helpdesk coordinating and resolving International Trade related Issues

In view of the surge in COVID-19 cases, the 'Covid-19 Helpdesk' of Directorate General of Foreign Trade (DGFT) in the Department of Commerce has from 26.04.2021 onwards started collecting information on the difficulties being faced by exporting community so as to examine and resolve the irritants faced by the trade & industry expeditiously..

Various issues relating to Department of Commerce/ DGFT, Import and Export Licensing Issues, Customs clearance delays and complexities arising thereon, Import/Export documentation issues, Banking matters, Transport/Port Handling/Shipping/Air Movement issues and availability of manpower for running export units etc. are the key areas being examined by the Helpdesk. Trade related issues concerning other Ministries/Departments/ Agencies of Central Government and State Governments are being collated and are being taken up for resolution with the concerned agencies.

Major areas which have been flagged through Helpdesk for support, include-

- Import of Oxygen Concentrators/Oximeters/Covid Related Medical Devices – Regulations & relaxations requested;
- Application Status of licenses incentives;
- Banking related Issues – Shipping Bills not reflecting in RBI EDPMS system.
- Customs Clearance issues
- Documentation issues
- Export Obligation extensions
- Transport/Port Handling/Shipping/Air Movement

Within a period of 15 days, 163 requests have been received seeking support, policy clarity and relaxations etc., out of which 78 have been fully resolved. Major issues which got coordinated/ resolved during the period, include:

- On 6th May 2021, PESO relaxed the norms for registration of imports by way of simplifying online registrations without carrying out the physical inspection of production facilities of global manufacturers before granting registration and approvals for importing oxygen cylinders and cryogenic tankers/containers;
- Issue of mandatory BIS and SIMS requirements for import of oxygen cylinders to India. This would reduce the compliance burden and will waive off the fees to be paid for SIMS registration;
- DGFT took up with RBI issue regarding the Shipping bills not reflecting in the RBI-EDPMS system for the exporters to be able to get their data updated for availing benefits under the FTP;
- DGFT took up the issue with DPIIT regarding the request of some industries for allocation of Oxygen supply for Industrial activities and the support requested for subsidies for establishing the Oxygen Manufacturing plant;
- DGFT successfully addressed issue of lockdown in Karnataka impacting garment manufacturing industry.

Industry can approach the Covid 19 Helpdesk for support and register their issues on the DGFT website (https://dgft.gov.in) or email at dgftedi@nic.in. Department of Commerce is committed to take up all such matters received on priority with other Ministries/Departments and State Governments/UTs.

Source: 10 MAY 2021, by PIB Delhi

DCGI approves anti-COVID drug developed by DRDO for emergency use

An anti-COVID-19 therapeutic application of the drug 2-deoxy-D-glucose (2-DG) has been developed by Institute of Nuclear Medicine and Allied Sciences (INMAS), a lab of Defence Research and Development Organisation (DRDO), in collaboration with Dr Reddy's Laboratories (DRL), Hyderabad. Clinical trial results have shown that this molecule helps in faster recovery of hospitalised patients and reduces supplemental oxygen dependence. Higher proportion of patients treated with 2-DG showed RT-PCR negative conversion in COVID patients. The drug will be of immense benefit to the people suffering from COVID-19.

Pursuing Prime Minister Shri Narendra Modi's call for preparedness against the pandemic, DRDO took the initiative of developing anti-COVID therapeutic application of 2-DG. In April 2020, during the first wave of the pandemic, INMAS-DRDO scientists conducted laboratory experiments with the help of Centre for Cellular and Molecular Biology (CCMB), Hyderabad and found that this molecule works effectively against SARS-CoV-2 virus and inhibits the viral growth. Based on these results, Drugs Controller General of India's (DCGI) Central Drugs Standard Control Organization (CDSCO) permitted Phase-II clinical trial of 2-DG in COVID-19 patients in May 2020.

The DRDO, along with its industry partner DRL, Hyderabad, started the clinical trials to test the safety and efficacy of the drug in COVID-19 patients. In Phase-II trials (including dose ranging) conducted during May to October 2020, the drug was found to be safe in COVID-19 patients and showed significant improvement in their recovery. Phase IIa was conducted in six hospitals and Phase IIb (dose ranging) clinical trial was conducted at 11 hospitals all over the country. Phase-II trial was conducted on 110 patients.

In efficacy trends, the patients treated with 2-DG showed faster symptomatic cure than Standard of Care (SoC) on various endpoints. A significantly favourable trend (2.5 days difference) was seen in terms of the median time to achieving normalisation of specific vital signs parameters when compared to SoC.

Based on successful results, DCGI further permitted the Phase-III clinical trials in November 2020. The Phase-III clinical trial was conducted on 220 patients between December 2020 to March 2021 at 27 COVID hospitals in Delhi, Uttar Pradesh, West Bengal, Gujarat, Rajasthan, Maharashtra, Andhra Pradesh, Telangana, Karnataka and Tamil Nadu. The detailed data of phase-III clinical trial was presented to DCGI. In 2-DG arm, significantly higher proportion of patients improved symptomatically and became free from supplemental oxygen dependence (42% vs 31%) by Day-3 in comparison to SoC, indicating an early relief from Oxygen therapy/dependence.

The similar trend was observed in patients aged more than 65 years. On May 01, 2021, DCGI granted permission for Emergency Use of this drug as adjunct therapy in moderate to severe COVID-19 patients. Being a generic molecule and analogue of glucose, it can be easily produced and made available in plenty in the country.

The drug comes in powder form in sachet, which is taken orally by dissolving it in water. It accumulates in the virus infected cells and prevents virus growth by stopping viral synthesis and energy production. Its selective accumulation in virally infected cells makes this drug unique.

In the ongoing second COVID-19 wave, a large number of patients are facing severe oxygen dependency and need hospitalisation. The drug is expected to save precious lives due to the mechanism of operation of the drug in infected cells. This also reduces the hospital stay of COVID-19 patients.

Source: 08 MAY 2021, by PIB Delhi

DGFT MATTER

Extension of validity of Registration cum Membership Certificate (RCMC) beyond 31st March, 2021.

Trade Notice No.04/2021-2022, dated 10th May, 2021

To

1. Regional Authorities of DGFT,

2. Customs Commissionarates,

3. EPCs and Members of Trade & Industry,

4. Joint Secretary (Customs), CBIC, Department of Revenue.

1. Under para 2.55 & 2.56 of FTP read with paras 2.91 - 2.95 of HBP, 2015-20, Export Promotion Councils (EPCs) have been issuing RCMCs to its members.

2. In view of the current situation due to the COVID-19 pandemic, in continuation of Trade Notice No.60/2019-2020 dated 31 March, 2020, it has been decided that Regional Authorities (RAS) of DGFT will not insist on valid RCMC (in cases where the same has expired on or before 31st March, 2021) from the applicants for any incentive/ authorizations till 30 September, 2021.

3. EPCs will collect the applicable fees for the year 2021-22 on restoration of normalcy.

This is issued with the approval of the competent authority.

F.No.01/93/180/08/AM-19/PC-2(B)/e-11168

S P Roy, Joint Director General of Foreign Trade, Directorate General of Foreign Trade, Commerce and Industry, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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IPR MATTER

EU Split on Covid-Patent Waivers Casts Doubt on U.S. Plan

Spain backed a U.S. proposal to waive intellectual property rights for coronavirus vaccines, breaking ranks with Germany and complicating efforts by the European Union to form a common stance.

"We in the Spanish government welcome Biden's proposal to suspend patents," Spanish Prime Minister Pedro Sanchez said in Porto on Friday ahead of talks with other EU leaders. "But we think it's insufficient and that we have to be more ambitious."

His government sent around a proposal ahead of the meeting calling for accelerating the transfer of technology for making the vaccines to all countries around the world as well as bolstering production and distribution.

Spain's position sets the stage for a tense debate over the bloc's response to the pandemic. The country is at odds with Europe's biggest economy as well as drugmakers, who warned that such a move will harm efforts to stem the pandemic.

While the head of the bloc's executive arm, Ursula von der Leyen, agreed to discuss U.S. President Joe Biden's call to waive patent protections, German Chancellor Angela Merkel dismissed it. Her health minister, Jens Spahn, said the problem is not patents but production capacity and availability, and took a swipe at Washington over its decision to block exports of Covid-19 shots.

"I would be pleased if the United States of America were prepared, just like the European Union, to release doses produced in the U.S. for export," Spahn said Friday in Berlin. "The EU produces for the world, in the knowledge that we are only safe when everyone in the world is safe."

French President Emmanuel Macron said on Friday that while he welcomes the debate over intellectual-property rights, he wants to protect innovation. He also prodded the U.S. and the U.K. to do more to help other countries.

"Today the Anglo-Saxons are blocking many of these ingredients and these vaccines," he said in Porto, adding that France is working closely with Germany on the issue. "What is at stake currently isn't really intellectual property. You can give IP to labs, who don't know how to produce it and they won't produce it tomorrow."

Portugal, which holds the EU's rotating presidency, says suspending patents would be a "very important" step, but also pointed to production issues.

"We must not forget that we have a production-capacity problem and that this has to be resolved," Augusto Santos Silva, Portugal's foreign minister, said on the sidelines of the EU leaders' summit in Porto. "That is why everyone needs to make an effort, because the supply chains of the materials needed for the production of vaccines are global."

The split among EU members and the fierce opposition of drugmakers feed into a prolonged debate on the issue at the World Trade Organization, casting doubt on whether waivers could be deployed in time to help the fight against the pandemic. While EU leaders will discuss the matter at Friday's summit, it's unlikely that concrete decisions are imminent.

A European Commission spokeswoman told reporters in Brussels on Friday that the EU's executive arm hasn't held discussions with the Biden administration since the U.S. proposal was tabled earlier this week. The bloc first needs to define its own position and member states need to give the commission a mandate to negotiate a waiver, the spokeswoman said, adding that this is why the issue will be taken up by EU leaders at their meeting in Porto.

Officials and diplomats in Brussels cautioned that WTO deliberations will take months. Talks will also likely result only in partial waivers, as there's little chance countries such as Germany and the U.S., whose companies pioneered the development of messenger-RNA technology used in some Covid vaccines, will agree to cede intellectual property to competitors such as China.

In any case, most poor countries in the world have neither the capacity nor the expertise to produce such advanced treatments, the officials have said. EU countries are thus expected to continue lobbying the U.S. and the U.K. to allow more exports and share their stock with developing countries.

The need for vaccines is "still enormous," Margrethe Vestager, the EU's competition commissioner, said in Porto. "That is what needs to be in focus -- so not only the patent but also the production and all the things that goes into the production for the vaccines to be delivered."

Source: Nikos Chrysoloras and Rodrigo Orihuela, Bloomberg, 07.05.2021

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DoPT MATTER

Appointment of Shri Vaibhav Bajaj, IRS(C&CE:2009) as Private Secretary to to the Minister for Health & Family Welfare (Dr. Harsh Vardhan) in the Ministry of Health & Family Welfare - reg.

Office Memorandum No. 5/7/2021-EO (MM-1), dated 12th May 2021

1. The competent authority has approved the proposal for appointment of Shri Vaibhav Bajaj, IRS(C&CE:2009) as Private Secretary to the Minister for Health & Family Welfare (Dr. Harsh Vardhan) in the Ministry of Health & Family Welfare at the level of Deputy Secretary with pay at level 12 (Rs. 78,800-2,09,200) of the pay matrix for a period of five years with effect from the date of assumption of the charge of the post or on co terminus basis with the Minister or till he ceases to function as Private Secretary to the Minister or until further orders, whichever event occurs the earliest.

2. The APARs of Shri Vaibhav Bajaj, IRS(C&CE:2009) are returned herewith, receipt of which may kindly be acknowledged.

Khushboo Goel Chowdhary, Deputy Secretary, Department of Personnel & Training, Office of the Establishment Officer, North Block, New Delhi

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Fight Covid with compulsory licensing

If patents continue to determine global access to vaccines and drugs, then fighting Covid-19 will remain a distant dream for most countries

Vaccines are badly required by the world, as are drugs like Remdesivir and Tocilizumab, and medical equipment like ventilators and oxygen concentrators. A large number of countries, particularly low- and middle-income ones, are struggling to access vaccines, drugs and equipment.

There cannot be a more important occasion than the current circumstances for issuing compulsory licences for producing patented health products.

The Covid-19 crisis underpins the importance of flexible global trade rules. Particularly important in this regard are rules linking ownership of intellectual property (IP) to cross-border movement of products involving IP, such as vaccines and medicines. The WTO's rules insist on IP rights being protected in cross-border trade. An implication of the insistence is that health products like vaccines can move from one country to another only after ensuring their developers, i.e. pharmaceutical companies, are commercially compensated for proprietary knowledge. This explains why rich and higher-income countries have been much ahead of others in obtaining vaccines and inoculating their people.

If patents continue to determine global access to vaccines and drugs, then fighting Covid-19 will remain a distant dream for most countries. Global trade rules need to back off from insisting on patent obligations. This doesn't mean that drug and vaccine development becomes a philanthropic exercise. The current global health crisis and high demand for drugs and vaccines means their producers have enough countries and customers to supply to. The large volumes would ensure that they are able to recover the costs on their scientific investments. But what drug developers must avoid is the tendency to make profits by exploiting the helplessness of countries. And profits are indeed pouring in for companies like Pfizer, who have been among the earliest to make vaccines and sell to rich countries through advance purchase agreements.

One of the most effective ways in which global trade rules can contribute to better access of vaccines and medicines is by enabling compulsory licensing. The WTO's rules allow countries to issue compulsory licences to domestic producers for manufacturing patented drugs and other products. This is allowed under situations of serious public health concern.

India's Patents Act of 2005 provides for issue of compulsory licences in public health emergency. In the past, the provision was used for allowing Indian drug-maker Natco to locally manufacture Nexavar, a patented product of the German pharmaceutical firm Bayer, for treating kidney cancer patients. The licence also involved paying royalty to Bayer.

Under normal circumstances, compulsory licences are issued after detailed consultations with the patent holder. Such consultations are lengthy and take time to conclude. The Covid-19 conditions do not allow such luxury on time. Compulsory licences need to be issued fast for enabling Indian companies to make patented vaccines and critical drugs.

The Supreme Court has asked the government to explore the possibility of issuing compulsory licences under the Patents Act of 2005 for locally producing critical drugs like Remdesivir and Tocilizumab for treating Covid-19 patients. A three-judge bench of the Supreme Court described the current conditions as public health emergency and suggested exploring the possibility of issuing compulsory licences while royalty issues are simultaneously sorted out.

Well before vaccines became available for public use, in October 2020, India and South Africa had sought a temporary waiver of patent enforcement obligations by WTO members for enabling easier global access to patented drugs and products. The proposal, unsurprisingly, was resisted by several developed countries, including the US. Major global pharma companies from the US and Europe have always been able to successfully lobby their governments for protecting patent and business interests.

There is no denying that pharma companies need to earn sufficient revenues for recovering their costs of R&D and sustaining the research on drug discovery and new therapeutic applications. But Covid-19 is a situation where this perspective needs to be revisited. Patent rights, and commercial returns on proprietary knowledge, cannot be primary at this stage. The fastest and most cost-effective ways of obtaining vaccines and Covid-19 drugs are imperative now.

For India, there is little option other than authorising compulsory licences. Such licences shouldn't be confined to only local production of patented medicines. These can also explore the option of India-made patented products being exported to countries that require them desperately.

Compulsory licensing provisions under India's Patents Act are WTO-compliant. There shouldn't be any hesitation in using these provisions. At the same time, it is important for India to work with the US, the UK and other countries, which had opposed India's proposal at the WTO, to get the global trade body reach a consensus on allowing the flexibilities in trade rules that India and South Africa had demanded. The recent US decision to work towards ensuring that patents don't obstruct flow of medicines and vaccines for tackling Covid-19 should be of great help in this regard.

Source : Amitendu Palit, Financal Express, 08.05.2021

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Zydus' wrapping up Phase-III trials of three dose vaccine

Says non-needle antidote will provide wider and longer antibody response

Zydus Cadila is optimistic that its three-dose plasmid DNA vaccine, ZyCoV-D, will offer sustained immunity with longer antibody response. The company expects to launch the antidote "very soon", even as it completes the advanced Phase-III clinical trials and submits data to the drug regulator for review.

The Covid-19 vaccines presently in India are two-dose vaccines, and Zydus did encounter questions on the economics and logistic complexities involved in a three-dose vaccine. The company, however, stayed the course with its three-dose vaccine, and even indicated that it would be among the most affordable ones. The vaccine will be administered without a needle, intra-dermally.

Unlike most vaccines, which use a needle to inject the vaccine into the tissue, ZyCov-D will be administered without a needle, but using intra-dermal injection that will push the substance into the dermis.

Sharvil Patel, Managing Director, Zydus Cadila, said, "Currently, we are a three-dose regimen which we believe is more suitable for our vaccine and which will give a wider immune response and longer antibody response which we have seen in our data."

Zydus is also conducting trials on a two-dose vaccine. "If the data are equally good, we will look at it," said Patel ruling out any delay in the first project due to the trials on the two-shot vaccine.

As India's second indigenously-developed vaccine, ZyCoV-D will be affordable, reiterates Patel.

"Currently, we are focussing on completing the Phase-III clinical trials and submitting the outcomes. We will decide the pricing of the vaccine closer to the launch," said Patel.

In an earlier interaction with BusinessLine, Cadila Healthcare founder and pharma sector doyen, Pankaj Patel, had hinted at an affordable price for the company's vaccine. "It is a trying time for the world. We have to ensure that we help people, more than looking at some quick bucks," Patel had told this paper.

Ready for variants

ZyCOV-D is developed using a new technology platform that uses non-replicating and non-integrating plasmid-carrying gene of the virus SARS-CoV2. The platform, with improved vaccine stability and lower cold chain requirement, will be easy to transport to any corner of the country. It can also be modified in just a couple of weeks if the virus mutates. In January 2021, the company had received the Indian regulator's nod to start Phase-III clinical trials for the vaccine on close to 30,000 volunteers. The vaccine was found to be safe, well-tolerated and immunogenic in the Phase I/II clinical trials conducted in 2020.

Throughout the pandemic, Zydus has ensured access to affordable treatment options. It has priced the much-in-demand Remdesivir at ₹899 for a vial, compared to others pricing it at ₹2,450-3,000.

Source : Rutam Vora, The Hindu Business Line,08.05.2021

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Pfizer-BioNTech vaccine is highly effective against variants, studies find

Previous research suggested that B.1.1.7 is more infectious and more deadly than other variants, but that vaccines still worked well against it

The Pfizer-BioNTech coronavirus vaccine is extraordinarily effective at protecting against severe disease caused by two dangerous variants, according to two studies published Wednesday.

The studies, which are based on the real-world use of the vaccine in Qatar and Israel, suggest that the vaccine can prevent the worst outcomes — including severe pneumonia and death — caused by B.1.1.7, the variant first identified in the U.K., and B.1.351, the variant first identified in South Africa.

"This is really good news," said Dr. Annelies Wilder-Smith, an infectious disease researcher at the London School of Hygiene and Tropical Medicine. "At this point in time we can confidently say that we can use this vaccine, even in the presence of circulating variants of concern."

Previous research suggested that B.1.1.7 is more infectious and more deadly than other variants, but that vaccines still worked well against it. But vaccines appeared to be less effective against B.1.351, according to earlier studies.

One of the new studies, which appeared in the New England Journal of Medicine, is based on information about more than 200,000 people that was pulled from Qatar's national Covid-19 databases between Feb. 1 and March 31.

During that time, the variants were widespread there: Sequencing conducted between Feb. 23 and March 18 suggested that roughly half of the coronavirus infections in that period were caused by B.1.351 and 44.5 percent were caused by B.1.1.7.

In multiple analyses, the researchers found that the vaccine was 87 to 89.5 percent effective at preventing infection with B.1.1.7 among people who were at least two weeks past their second shot. It was 72.1 to 75 percent effective at preventing infection with B.1.351 among those who had reached the two-week point.

Even that slightly reduced effectiveness against infection with B.1.351 is still largely good news, one of the study's authors, Laith Abu-Raddad, an infectious disease epidemiologist at Weill Cornell Medicine-Qatar, said. "We're talking about a variant which is probably the nastiest of all the variants of concern," he said. "It's not the 95 percent we were hoping, but the 75 percent is really great."

The vaccine was highly effective at protecting against the worst outcomes. Over all, it was 97.4 percent effective at preventing severe, critical or fatal disease from any form of the coronavirus, and 100 percent effective at preventing severe, critical or fatal disease caused by B.1.1.7 or B.1.351. (This slight difference in effectiveness is likely a result of the fact that the sample sizes were smaller for the subgroups of patients with a documented variant, Dr. Abu-Raddad said.)

The second new study, which was published in The Lancet, was conducted by researchers at the Israel Ministry of Health and Pfizer. It is based on more than 230,000 coronavirus infections that occurred in Israel between Jan. 24 and April 3. During that period, B.1.1.7 accounted for nearly 95 percent of all coronavirus cases in the country, which has vaccinated more than half of its population.

The researchers found that the vaccine was more than 95 percent effective at protecting against coronavirus infection, hospitalization and death among fully vaccinated people 16 and older. It also worked well in older adults. Among those 85 or older, the vaccine was more than 94 percent effective at protecting against infection, hospitalization and death.

As the percentage of fully vaccinated people in each age group grew, the incidence of coronavirus infections in that cohort fell, the researchers found. The declines in infection rates matched the timing of increasing vaccine coverage in each age group better than the start of a nationwide lockdown. The results suggest that Israel's rapid pace of vaccination has been responsible for the decline in infections in the country.

"I'm just really happy to see this data that in the real world these vaccines are having such an amazing impact on curtailing infection and disease," said Akiko Iwasaki, an immunologist at Yale University.

Both studies also reported that two doses of the vaccine provided significantly more protection than one dose did. In the Israel study, for example, one dose of the vaccine was 77 percent effective against death, while two doses were 96.7 percent effective.

"It absolutely emphasizes the need for the second dose," said Dr. Kathleen Neuzil, who directs the Center for Vaccine Development and Global Health at the University of Maryland School of Medicine.

Together, the studies suggest that even with the new variants, vaccination remains a plausible path out of the pandemic, experts said. "If we can get vaccines to the world and get coverage up," Dr. Neuzil said, "I believe we can get on top of this and we can get on top of the emergence of new variants."

Source : Business Standard, 07.05.2021

India to receive between 190-250 million fully subsidised Covid vaccines; $30 million financial assistance: Gavi

Gavi, a global alliance on vaccines, on Friday said that India would receive between 190 and 250 million fully subsidised doses of Covid-19 vaccine and funds up to $30 million for urgent technical assistance and cold chain equipment.

A decision on the matter was taken by the COVAX Board in December, a Gavi spokesperson said.

Gavi, previously called Global Alliance for Vaccines and Immunisation is a public–private global health partnership which is leading the global effort to provide vaccines to low- and middle-income countries.

"Gavi commits its full support to helping India come through its current crisis. In December 2020, the COVAX Board agreed that India would receive approximately 20 per cent of the total doses available to AMC (Advance Market Commitment)- eligible countries through the COVAX Facility – estimated at between 190 and 250 million fully-subsidised doses – subject to vaccine prices and available funds," a Gavi spokesperson told.

"India is also to receive 20 per cent of the total funding available to AMC- eligible countries for urgent technical assistance and cold chain equipment, or $30 million," the spokesperson said.

Responding to a question, Gavi acknowledged that the current crisis in India has impacted its vaccine supply chain given that the country has been a major producer and supplier of vaccines.

Much of COVAX's second quarter supplies were due to be fulfilled by the Serum Institute of India (SII). As SII focuses production towards domestic needs, this has inevitably led to a shortfall for other parts of the world, the spokesperson said.

As a result, COVAX is aiming to address this in the very short term by securing dose donations from high income economies that have a surplus, as well as working towards other short-medium term goals such as diversifying its portfolio of suppliers and decreasing bottlenecks that are currently hampering global production increases, the spokesperson noted.

Gavi welcomed the decision by the United States government to use all mechanisms to increase global equitable access to Covid-19 vaccines.

"We also recognise the significance of the (Biden) administration's commitment to work towards increasing raw material production which will have an immediate impact on alleviating current global supply constraints," the spokesperson said.

It is important now that in the interests of global equitable access, that the US supports manufacturers to transfer not only IP but also know-how in a bid to urgently boost global production, said the spokesperson.

Source : PTI, 07.05.2021

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Govt relaxes procurement norms for health, pharma ministries, DRDO

As per the instructions, when these ministries and departments are undertaking 'single source procurement' of goods or procuring 'non-consultation services' like air and other transportation services, through nomination, then they would not be required to float tender on the GeM portal.

With the world's worst outbreak of COVID-19 severely straining the health system in the country, the government has made sweeping changes in the way departments procure medical supplies, including allowing procurement of the same item at different rates.

Relaxing tendering norms, the Department of Expenditure has allowed global tenders to be floated for less than Rs 200 crore as well.

The Department of Expenditure, under the Ministry of Finance, on April 24 issued special instructions relating to relief operations for COVID-19 pandemic and said that the prevailing health emergency on account of the unprecedented surge in COVID-19 cases across the country requires immediate procurement of certain items in quantities which may not be available with a single supplier and/ or within the time frame in which they are needed.

"The instruction in this Department's OM (Office Memorandum)... dated May 15, 2020... specifying that no Global Tender Enquiries shall be invited for tenders up to Rs 200 crore shall stand relaxed and hence it shall be permissible to invite GTE where necessary," said the instructions, which have been put up on the ministry's website on Monday.

As part of its Aatmanirbhar Bharat package, the government in May last year notified amendments to General Financial Rules (GFR) to ensure that goods and

services valued less than Rs 200 crore will be procured from domestic firms, a move which was aimed at benefitting small and medium enterprises. Rule 149 of GFR provides that procurement of goods and services through the Government's e-marketplace (GeM) will be mandatory for items available on GeM portal.

"In the present situation, vendors under GeM, even if orders are placed, may not always be able to effect deliveries of supplies on time and desired locations, due to the rapidly changing situation on account of the critical pandemic situation which requires extreme flexibility in making available the critical life saving goods to the medical care facilities," as per the instructions, which would be in force till May 31.

In view of the urgency involved, where time is the essence and delay may result in loss of life, these instructions, which are applicable to the Department of Pharmaceuticals, Ministry of Health and Family Welfare (including Department of Health Research) and Defence Research and Development Organisation (DRDO), have been issued for any emergent purchases and transportation of medical and other essential supplies related to COVD-19 operations.

As per the instructions, when these ministries and departments are undertaking 'single source procurement' of goods or procuring 'non-consultation services' like air and other transportation services, through nomination, then they would not be required to float tender on the GeM portal.

The relaxed norms provide that such procurement can also be done from more than one source, if the entire quantity required is not available or is not immediately available from one source. "Such procurement may, if unavoidable, be at different rates," as per the instructions.

"If the entire quantity required is not immediately available from any one method of procurement, the procurement may also be resorted to simultaneously by multiple methods, namely procurement under Rule 166/204, procurement through GeM, and procurement through other procurement methods (including through Indian Missions) and such procurement may, if unavoidable, be at different rates," it added.

While Rule 166 of General Financial Rules (GFR) relates to single-source procurement of goods, Rule 204 pertains to procurement of 'non-consultation services' like air and other transportation services through nomination after consultation with the Financial Advisor of the specific department or Ministry.

India is facing the world's worst outbreak of COVID-19 cases with more than 3 lakh new daily COVID-19 cases being reported for two weeks now. More than 2.46 lakh people in India have died from the virus infection.

Public health system is buckling under the weight of surging infections and deaths with several parts of the country reporting shortage of hospital beds, medical oxygen, medicines and vaccines.

Source : PTI, 10.05.2021

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Vivimed Labs gets DGHS nod to manufacture, market Favipiravir tablets in India

Drug firm Vivimed Labs on Monday said it has received approval from the Director General of Health Services (DGHS) to manufacture and market Favipiravir tablets in India, used for the treatment of mild to moderate cases of COVID-19.

Vivimed Labs in receipt of Government of India (DGHS) approval to manufacture and market Favipiravir tablets in the strengths of 200 mg and 400 mg under Vivimed's own brand name 'Favulous' across India, the company said in a regulatory filing.

It is used for the treatment of mild to moderate cases of COVID-19. Favipiravir is one of the leading oral anti-viral treatment approved in various countries for the potential treatment of patients with mild to moderate COVID-19 disease.

Ramesh Krishnamurthy, CEO of Vivimed Labs said, "With huge spike in COVID-19 cases being reported daily in India, there is an urgent need to provide more treatment options to healthcare professionals. "We are launching Favulous at a competitive price to make the drug accessible to more and more patients thereby ensuring good health and reducing their financial burden. This is in line with Vivimed's commitment to be at forefront in India's fight against COVID-19." The company said it will work closely with the various governments and medical community to ensure availability of Favulous to patients across the country.

Source : The Economic Times, 11.05.2021

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Centre still meandering on Covid-19 vaccine strategy

Its affidavit to SC shows, several missteps later, a well-defined action plan on vaccines still eludes it.

The affidavit does not directly address the specific issue of whether the Centre will revisit the policy to procure 100% of the vaccines.

The Centre's responses to queries put forth by the Supreme Court leave several questions unanswered. Critically, we are still in the dark on the quantum of vaccines that will be available over the next few months. The Centre has said that even if it receives additional permissions and licences by invoking the compulsory licensing of provisions under the Patents Act, the raw materials shortage would prevent any immediate increase in production.

The 200-page affidavit notes that inoculating the country in one stretch is not possible "…due to the very suddenness of the pandemic, limited availability of vaccine doses…". It also says the government is in talks with global drug majors like Pfizer and Moderna for imports though nothing concrete appears to have emerged from these discussions so far. It believes that exercising statutory powers either under the Patents Act 1970—read with TRIPS agreement and Doha declaration, or in any other way—can only prove to be counter-productive.

One hopes the discussions via diplomatic channels yields results. The Centre notes that 'efforts of procurement from other countries have their own challenges as, unlike other vaccines in the past, every country of the world needs vaccines for its domestic use at this juncture". The news on remdesivir, too, isn't good given the shortage of inputs needed to produce the drug.

Indeed, given our population, the Centre should not have exported 66 million doses of vaccines before ensuring Indian citizens had adequate supplies. The affidavit does not directly address the specific issue of whether the Centre will revisit the policy to procure 100% of the vaccines.

Given the severe shortage of vaccines, at this point, it is best the Centre be the sole procurer, buying from all manufacturers, local and overseas. It can then distribute them equitably between the states, apart from apportioning a share for the private sector. A centralised policy alone can ensure equitable allocation; else, financially stronger states could make off with the available stocks, leaving the weaker states stranded.

The government has said in the affidavit it is taking care to see the manufacturers are not 'unduly enriched'. While that is a fair objective—and the Centre has done well to procure the vaccines from SII at Rs 150 per dose—local vaccine manufacturers should not be financially hurt to the extent the business and R&D suffer; if that happens, the country will lose out.

Moreover, there should be no differential pricing; the states and the Centre should be buying from the manufacturer at the same price. It is also unfortunate that the Centre has asked the states to foot the bill for their share of procurements. As this paper has argued, the Centre should be picking up the tab for the entire vaccination drive given we are in the midst of a national catastrophe and that the states are strapped for cash. If the Centre is the sole buyer, these problems of differential pricing will not crop up.

The affidavit says that the vaccination strategy is just, equitable and non-discriminatory, and that any "overzealous" though well-meaning judicial intervention may result in unforeseen consequences. The point is the Centre is way behind the curve on dealing with the second wave; vaccines are in short supply as is oxygen and other drugs. It is not unjustified on the part of the SC to ask for details and clarity. On Saturday, the SC set up a 12-member task force to streamline and ensure the "effective and transparent" allocation of medical oxygen to the states and UTs. Unless we deal with the pandemic in a more efficient way, the damage cannot be contained.

Source : Financial Express, 11.05.2021

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Budget heading for vaccination expenditure does not inhibit Centre from using funds: FinMin

The finance ministry on Monday said provisioning Rs 35,000 crore-expenditure for vaccines in the Union Budget for FY22 under the title 'Transfers to States' does in no way inhibit the central government from using the funds to buy COVID-19 shots.

The finance ministry on Monday said provisioning Rs 35,000 crore-expenditure for vaccines in the Union Budget for FY22 under the title 'Transfers to States' does in no way inhibit the central government from using the funds to buy COVID-19 shots. The amount of Rs 35,000 crore provided in the Union Budget for fiscal year starting

April 1, 2021 (FY22) under the Demand for Grants No. 40, titled 'Transfers to States' has been done for several administrative advantages, including expenditure under such head being exempted from the quarterly control restrictions.

Also, it allows the Union government to procure the vaccines and pass them on to the states as grants in kind. Refuting reports that no provision for expenditure on COVID-19 vaccination has been done by the central government, the finance ministry said, "vaccines have actually been, and are being, procured by and paid for by the Centre through this head of account (Demand for Grants No.40 Transfers to States)".

Since expenditure on vaccine is one-off expenditure outside the normal Centrally-Sponsored Schemes of the health ministry, separate funding ensures easy monitoring and management of these funds, the ministry noted. The amount provided under this head for vaccinations is operated by the Ministry of Health. Vaccines are passed on to the states as grants in kind and the actual administration of vaccines is being done by states, it said. Further, there is enough administrative flexibility to change the nature of the scheme between grants in kind and other forms of grants, it said in a statement. "The use of the Demand titled 'Transfers to States' in no way implies that expenditure cannot be incurred by the Centre," the ministry said. Currently, COVID-19 vaccines are being provided free of cost by the Centre to those who are 45 years of age and above and to all frontline workers.

The Centre has so far provided more than 17.56 crore vaccine doses to states/ UTs free of cost. The Centre has placed total orders of 26.60 crore doses for Rs 3,639.67 crore with the Serum Institute of India which is manufacturing Covishield vaccine while an order for 8 crore doses involving an amount of Rs 1,104.78 crore has been placed with Bharat Biotech for Covaxin. India is facing the world's worst outbreak of COVID-19 cases with more than 3 lakh new daily cases being reported for two weeks now and the new cases reached more than 4 lakh daily over the weekend. More than 2.46 lakh people in India have died from the virus infection. Public health system is buckling under the weight of surging infections and deaths, with several parts of the country reporting shortage of hospital beds, medical oxygen, medicines and vaccines.

Source : PTI, 10.05.2021

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DCGI approves anti-COVID drug developed by DRDO for emergency use

The drug comes in powder form in sachet, which is taken orally by dissolving it in water.

The Drugs Controller General of India (DCGI) has granted permission for emergency use of anti-COVID-19 therapeutic application of the drug 2-deoxy-D-glucose (2-DG) developed by Institute of Nuclear Medicine and Allied Sciences (INMAS), a lab of Defence Research and Development Organisation (DRDO), in collaboration with Dr. Reddy's Laboratories (DRL),Hyderabad.

In a release issued on Saturday, the Ministry of Defence said that as per the order, emergency use of this drug as adjunct therapy in moderate to severe COVID-19 patients is permitted. It added that being a generic molecule and analogue of glucose, it can be easily produced and made available in plenty in the country.

The drug comes in powder form in sachet, which is taken orally by dissolving it in water. It accumulates in the virus infected cells and prevents virus growth by stopping viral synthesis and energy production. Its selective accumulation in virally infected cells makes this drug unique.

Clinical trial results have shown that this molecule helps in faster recovery of hospitalised patients and reduces supplemental oxygen dependence, noted the release.

It further said that higher proportion of patients treated with 2-DG showed RT-PCR negative conversion in COVID-19 patients.

"The drug will be of immense benefit to the people suffering from COVID-19," said the Ministry.

In April 2020, during the first wave of the pandemic, INMAS-DRDO scientists conducted laboratory experiments with the help of the Centre for Cellular and Molecular Biology (CCMB), Hyderabad, and found that this molecule works effectively against SARS-CoV-2 virus and inhibits the viral growth.

The DCGI permitted Phase-II clinical trial of 2-DG in COVID-19 patients in May 2020.

The DRDO, along with its industry partner DRL, Hyderabad, started the clinical trials to test the safety and efficacy of the drug in COVID-19 patients.

In Phase-II trials (including dose ranging) conducted during May to October 2020, the drug was found to be

safe in COVID-19 patients, and showed it led to significant improvement in their recovery. Phase IIa was conducted in six hospitals and Phase IIb (dose ranging) clinical trial was conducted at 11 hospitals all over the country. Phase-II trial was conducted on 110 patients.

In efficacy trends, patients treated with 2-DG showed faster symptomatic cure than Standard of Care (SoC) on various endpoints. A significantly favourable trend (2.5 days difference) was seen in terms of the median time to achieving normalisation of specific vital signs parameters when compared to SoC.

Based on successful results, the DCGI further permitted Phase-III clinical trials in November 2020. The Phase-III clinical trial was conducted on 220 patients between December 2020 to March 2021 at 27 COVID-19 hospitals in Delhi, Uttar Pradesh, West Bengal, Gujarat, Rajasthan, Maharashtra, Andhra Pradesh, Telangana, Karnataka and Tamil Nadu. The detailed data of the phase-III clinical trial was presented to the DCGI. In the 2-DG arm, significantly higher proportion of patients improved symptomatically and became free from supplemental oxygen dependence (42% versus 31%) by Day 3 in comparison to SoC, indicating an early relief from oxygen therapy/dependence.

The similar trend was observed in patients aged more than 65 years, noted the release.

Source : The Hindu, 08.05.2021

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Bharat Biotech commences direct supply of 'Covaxin' to 14 states

The company is now getting requests from other state governments as well, and will be processing them for distribution based on availability of the vaccine

The Centre had announced expansion of the Covid-19 vaccination drive by allowing everyone above 18 years of age to get a jab.

Hyderabad-based vaccine manufacturer Bharat Biotech has been supplying Covaxin — its Covid-19 vaccine — directly to 14 states beginning May 1.

According to a tweet by the company's joint managing director Suchitra Ella, Bharat Biotech has been supplying Covaxin to Andhra Pradesh, Assam, Chhattisgarh, Gujarat, Jammu & Kashmir, Jharkhand, Madhya Pradesh, Odisha, Tamil Nadu, Telangana, Uttar Pradesh and West Bengal.

Ella said in the tweet, "Glad to announce that Bharat Biotech confirms direct supplies of COVAXIN to the following state govt's since 1/5/21, based on the allocations received by the GoI. Requests have been received from other states, and will be processed for distribution based on availability of stocks 24x7."

The company is now getting requests from other state governments as well, and will be processing them for distribution based on availability of the vaccine.

Bharat Biotech had earlier announced a price cut in Covaxin for states to Rs 400 per dose in the last week of April, from the earlier announced price of Rs 600 per dose.

The Centre had announced expansion of the Covid-19 vaccination drive by allowing everyone above 18 years of age to get a jab.

The Centre will continue to procure and distribute vaccines for free for those above 45 years. The states, on the other hand, will procure vaccines directly from vaccine makers based on their plans for inoculation of all above 18 years.

Private sector hospitals, too, are allowed to procure vaccines directly from vaccine manufacturers now.

Both Serum Institute and Bharat Biotech have announced prices of vaccines for state governments and for the private hospitals. While Serum Institute has priced it at Rs 300 per dose for state governments.

Serum Institute did not divulge details on which state governments they are currently supplying directly.

Source: Sohini Das, Business Standard, 11.05.2021

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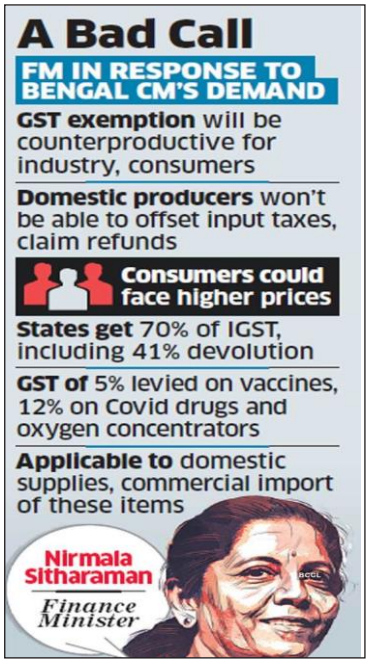
GST waiver on Covid jabs, drugs will backfire: FM Nirmala Sitharaman

In a set of 16 tweets on Sunday, she argued why a nominal GST was in the interest of manufacturers and citizens. GST rates vary from 5% on vaccines to 12% on Covid drugs and oxygen concentrators. It is applicable to domestic supplies and commercial import of these items.

Finance minister Nirmala Sitharaman said exempting vaccines, Covid-related drugs and oxygen concentrators from goods and services tax (GST) would actually raise their prices, as domestic producers of these items would be unable to claim credit for taxes on inputs used.

In a set of 16 tweets on Sunday, she argued why a nominal GST was in the interest of manufacturers and citizens. "If full exemption from GST were given, the domestic producers of these items would be unable to offset taxes paid on their inputs and input services and would pass these on to the end consumers by increasing their price," Sitharaman said in one of the posts, responding to a demand from West Bengal chief minister Mamta Banerjee.

She added that in case of vaccine manufacturers, a 5% GST rate ensures that they can utilise input tax credit (ITC) and in case of overflow of ITC, claim refunds. "Hence, exemption to vaccine from GST would be counterproductive without benefiting the consumer," she noted. GST rates vary from 5% on vaccines to 12% on Covid drugs and oxygen concentrators. It is applicable to domestic supplies and commercial import of these items.



Banerjee has sought the exemption of GST, customs duties and other taxes on items such as remdesivir injections, oxygen cylinders, concentrators, cryogenic storage tanks and containers donated by various organisations. The chief minister had written to Prime Minister Narendra Modi about this on Sunday.

Sitharaman said full exemption from all duties had been provided to remdesivir injections, the remdesivir active pharmaceutical ingredient (API), and a chemical used in the manufacture of the drug, with effect from May 3.

Exemption Available for Medical Oxygen

This exemption is also available for medical oxygen, and equipment used for the manufacture, storage and transportation of oxygen. It's also applicable on equipment used for providing oxygen therapy to Covid patients such as oxygen concentrators, ventilators, non-invasive oxygen masks, inflammatory diagnostic kits, reagents for testing and vaccines among others.

The exemption is also available when items are imported free of cost for free distribution in the country by any entity, state government, relief agency or autonomous body on the basis of a certificate issued by a state government. "In order to augment the availability of these items, the government has also provided full exemption from basic customs duty and health cess to their commercial imports," the minister said.

Full exemption from customs duties, including IGST, is already available to all Covid relief material imported by the Indian Red Cross for free distribution in the country, she added.

Sitharaman argued that much of the integrated GST collected went to the states. "States end up receiving almost 70% of the total revenue collected from vaccines. In fact, a nominal 5% GST is in the interest of the domestic manufacturer of vaccine and in the interest of the citizens," she said.

She added that Covid vaccines were being provided free of cost by the Centre to citizens over 45 years of age and to all frontline workers.

(Originally published on May 09, 2021)

Source: ET Bureau,10.05.2021

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Russia's Sputnik V jabs set to make India debut at private hospitals

A large vaccine consignment is expected from Russia by third week of this month

The journey of Russia's Sputnik V vaccine in India is likely to begin from private hospitals across several cities this month as a large consignment is expected by the third week.

According to private hospitals, Dr Reddy's Laboratories (DRL) is in advanced stages of discussions with many of them and is drawing up a list of hospitals that would receive the first doses of Sputnik V for administering to citizens.

Discussions with the Centre, too, are on for the Sputnik V procurement, which is expected to get a fillip as Indian

Dr Reddy's Laboratories is drawing up a list of private hospitals that will get initial doses of Sputnik V

manufacturing sites start production around August-September. The Indian sites can together make over 850 million doses of the vaccine for both Indian consumption and overseas markets.

A source at a Mumbai-based private hospital said, "We are in talks with DRL to procure Sputnik V. A list is being drawn up of hospitals that would get the dose initially. In May, the Sputnik V inoculation is likely to start from private Covid vaccination centres alone."

As many as 40-50 million doses of Sputnik V are expected to be imported. Of this, a large consignment is expected by the third week of May, an industry source said.

STEPPING UP THE FIGHT

- **Dr Reddy's Laboratories is drawing up a list** of private hospitals that will get initial doses of Sputnik V
- **Indian manufacturing sites may start production** around August–September
- **Sputnik V, developed by Moscow's Gamaleya Institute,** works in a way similar to the Oxford–AstraZeneca jab
- **It gives around 92% protection against Covid-19,** according to late stage trial results published in The Lancet
- **The vaccine requires a temperature range of –18°C to –22°C** to remain stable

DRL did not answer queries sent to it, citing a silent period before the quarterly results.

Sputnik V, a vaccine with 91.6 per cent efficacy -- the highest among Covid vaccines available in India -- requires a temperature range of -18°C to -22°C to remain stable.

"DRL has offered a cold chain solution – a freezer that can maintain minus 12 to minus 18 degrees Celsius. It would come for Rs 15,000 each and going by our vaccination rate, it can hold about a week's stock. Every week the company would replenish the stock," the hospital source added.

For hospitals that already have a sub-zero freezer, this investment would not be necessary.

Around 60-70 per cent of Sputnik V's global production is set to take place in India, DRL has said.

The company will use the government's vaccination cold chain infrastructure, along with its own cold chain capabilities, for last-mile distribution. The firm also has a cold chain for handling critical care products like oncology. DRL has already tested the cold chain infrastructure in India through simulations.

Sputnik V will be imported in the frozen form from Russia this quarter. DRL is responsible for ensuring that the vaccine remains stable and sanctity of the cold chain is maintained — from the manufacturing site in Russia to its cold chain point and eventually to all parts of India, the company has said.

Deepak Sapra, CEO (API and pharmaceutical services), DRL, had said last month that the company had lined up a solution of compact boxes, using which the vaccine would be transported to various parts of India easily through a combination of air and road transport.

Meanwhile, the stability data for the Sputnik V variant that will remain stable at 2-8°C is being generated. "This will take a few more months. After that, we will approach the regulator again to modify the storage condition requirements to 2-8°C. That will make the process of storage and transportation a lot easier," Sapra had said.

The NITI Aayog indicated last week that India would examine the claim that a single dose of Sputnik Light can provide protection from the coronavirus infection. VK Paul, member, NITI Aayog, had noted that if the claim of the vaccine developer was true, it could help double the speed of vaccination in India.

As of now, DRL's contract with the Russian Direct Investment Fund (RDIF) is for 250 million doses for India. However, there is an option to increase the number of doses.

Source: Sohini Das, Business Standard, Mumbai, 10.05.2021

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As demand soars, health & wellness brands expect 35-50% revenue growth in FY22

Many companies have registered an uptick in sales, revenue and are tapping the digital space also

Riding on soaring sales of flagship products with the second wave of Covid-19, Health & Wellness firms are expecting a 35-50 per cent revenue growth in FY 2022.

Maheshwari Pharmaceuticals India Ltd (MPIL), a 25-year-old ayurvedic herbal pharma company based in

Ghaziabad, Uttar Pradesh, sold five million units of its flagship product Amastha Awaleha (AA) in FY21 — up from 3.5 million units the previous fiscal, contributing to 20 per cent of the company's revenue of ₹36.5 crore.

The product, available in three variants and priced at ₹220-385 is described by the company as a 'lung tonic' for chronic bronchitis, bronchial asthma and COPD (chronic obstructive pulmonary disease) which is prescribed by doctors.

Testing & patents

"With the second Covid wave, spurring demand for traditional medicines, we expect a turnover of ₹50 crore led by AA this fiscal," said Nikhil Maheshwari, Director of Operations at MPIL, which offers a range of 300 herbal products, of which 200 products have been certified by the Ministry of Ayush.

All products are available pan India on its own website, Amazon, Flipkart and 1mg.

Nisarga Biotech, which offers 40 natural therapeutic products for chronic diseases, recently launched Nisarga Neem capsules at ₹450 for 60 capsules on its website and on Amazon.

"We conducted double-blind, placebo-controlled, clinical trials last year when the pandemic broke out in collaboration with All India Institute of Ayurveda, New Delhi and ESIC Medical College and Hospital Faridabad for prevention of Covid-19 with comparable efficacy to Vaccines.

"The trials have concluded successfully and our patent-pending Neem formulation has proven to be an effective antiviral with a preventive efficacy rate of 55 per cent," said Girish Soman, founder CEO, Nisarga Biotech Pvt Ltd.

Online health & wellness brand Gaia saw its sales double in FY21 and FY 22 (April) after the lockdown, led by steep demand for its Muesli range, Health capsules and Green Teas. "We are expecting 40-50 per cent growth in revenue this fiscal as demand continues to rise" said Dolly Kumar, founder Director, Gaia.

Revenue boost

Kapiva, a modern Ayurvedic nutrition brand which exited FY21 with ₹65 crore expects to exit this fiscal at ₹150 crore, backed by robust demand for its immunity products. "This sharp increase in revenue run rate we expect this fiscal is linked to demand for our flagship juices range that helps to boost immunity and a slew of new products we will be launching over the course of this fiscal," said Shrey Badhani, co-founder of Kapiva.

Source: Sangeetha Chengappa, Business Line, 10.05.2021

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Jab shortage forces health startups to defer plans to vaccinate India Inc

Enterprises like 1mg, PharmEasy and Practo had drawn up initiatives to inoculate over a million employees from some of the country's top companies

As the government's vaccination drive falters for lack of vaccines, the efforts of healthcare start-ups such as 1mg, Practo and PharmEasy to vaccinate millions of corporate employees have also been delayed for the same reason.

Hyderabad-based healthcare start-up ekincare has partnered with 1mg to facilitate Covid-19 vaccination for the employees of corporates such as Oyo, Flipkart, Swiggy, BlackRock, Micron and KPMG

Hyderabad-based healthcare start-up ekincare has partnered with 1mg to facilitate Covid-19 vaccination for the employees of corporates such as Oyo, Flipkart, Swiggy, BlackRock, Micron and KPMG.

1mg co-founder & CEO Prashant Tandon said the company has set up the network at the back end and the administration capacity – a network of some 2,500 administrators - so that they can vaccinate people at scale.

"Most of the manufacturers are constrained with pre-orders. It could take three to four weeks for the vaccination programme to begin. The only thing stopping us getting started is the access to vaccines," said Tandon.

The company is in talks with all vaccine makers, including international suppliers, for stock. "In every city we will not have ready infrastructure so we are looking at $1.5-2 million investments for additional infrastructure," said Tandon.

Kiran Kalakuntla, founder and CEO at ekincare, said he needs a million doses for the clients that ekincare manages. "One in two corporates are looking to sponsor vaccines for

their employees and dependants. We will be managing the demand side of the vaccination while 1mg will be taking care of the supply side and on ground inoculation," he said. Currently over 500 corporates are in the pipeline for this, he added.

Mumbai-based PharmEasy has said that it aims to vaccinate over 30 million people within the next few quarters via camps and vaccine centres, leveraging its presence across India with over 80,000 partner retailers, 5,000 doctors and a state-of-the-art pharma supply chain facility enabling last-mile delivery of cold chain products. "Our vaccination drive aims to provide ease of access to vaccination which can help us to achieve herd immunity at the earliest. Amidst the rising Covid-19 cases in the second wave, we wanted to contribute our bit in breaking the chain by setting up vaccination camps and centres to facilitate this," Dharmil Sheth, co-founder, PharmEasy, has said earlier.

But these intentions are being thwarted by the vaccine shortage. PharmEasy declined to comment but a person familiar with the matter said: "PharmEasy might get the vaccine stocks by the fourth week of May which will be essentially for large-sized corporates and group housing societies."

Sequoia India backed healthcare start-up Practo is also aiming to vaccinate over 10 million Indians. It has announced 'Corporate Suraksha', a vaccination programme for companies across the country.

Practo said over 500 corporates have expressed an interest in joining the programme in the first phase. "Right now, we are accessing the demand for the vaccines," said a company spokesperson.

Practo will be setting up camps and working with its strong network of hospitals, vaccinators, and supply chain companies to get the drive going. In the coming weeks, its vaccination programmes will be run at hospitals while special camps will be set up at corporate offices in over 30 cities.

Source: Samreen Ahmad, Business Standard, 11.05.2021

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Fixing the vaccine crunch

Besides the two vaccines in use in India, three vaccine candidates look promising

The unprecedented rise in COVID-19 cases has changed vaccine hesitancy to vaccine advocacy. Even as the government has allowed those aged 18 and above to get vaccinated, the availability of vaccines has become an issue. Many extraneous issues such as Centre-State relations have clouded the picture. Given the rise in cases and deaths, COVID-appropriate behaviour has to be strictly implemented from now on and vaccination has to take place on a war footing.

Production capacity

The main issue is of volume of vaccines. Bharat Biotech (BB) was making about 8-10 million doses of Covaxin a month. Serum Institute of India (SII) makes about 70 million doses of Covishield a month. We need about 1,500 million doses (two doses per person) to vaccinate the target population. India has covered about 10% of the target population. BB is expanding its capacity and hopes to reach a target of 50-60 million doses a month in four months. SII has stated that it will push production to 100 million doses a month. Sputnik may chip in with 50 million doses a month in about four months.

Besides these, three vaccine candidates look promising. The DNA vaccine (for spike protein) by Zydus Cadila, the recombinant spike protein (Biological E), and self-amplifying messenger RNA (Sa-mRNA for spike protein) by Gennova can reach field application in four months. All the three may need emergency approval from the DCGI. With the availability of five approved vaccines, with some outside help perhaps, and with an aggressive timeline, India should be able to vaccinate the target population in six months from now.

What are the riders and imponderables? Despite the unfolding tragedy, there are some major outcomes. The DNA vaccine, if successful, will be the first DNA vaccine

that goes into human application for any disease. The 10,000L bioreactor for mammalian cell expansion, to be commissioned by BB, will be largest by global standards. But it is not easy to scale up the micro-carrier technology used by BB. Sa-mRNA, being developed by Gennova, is the first of its kind (uniquely, stable between 2-8°C), even for a mRNA vaccine, already commercialised by Moderna and Pfizer (require -20 and -70°C for stability). Sa-mRNA can amplify itself and so a lower dose may be adequate. In the context of 'variants', mRNA vaccines provide the greatest flexibility to tweak and make a new vaccine in the shortest time. Interestingly, the five vaccines would represent five different platforms and eventually need not be confined to a single company for production. Several research publications have shown that vaccines produced using different platforms are all effective in preventing severity of disease and hospitalisation, although infection may still happen.

The way forward

It is possible that when 60% of the target population is reached in terms of vaccination (in addition to the infected and recovered individuals), herd immunity may kick in and cases may go down drastically. But people and the system may once again get complacent and a third wave may become a reality. We also do not know how long the antibody-mediated protection lasts. We need to look into T-Cell memory and its role in long-term protection. The issue of vaccinating children will become a priority, since, being asymptomatic, they are the largest carriers to spread the disease. This would call for independent trials based on age groups.

A few other public sector units (Haffkine Bio-Pharmaceutical Corporation Limited, Mumbai; Indian Immunologicals, Hyderabad; Bharat Immunologicals and Biologicals Corporation, Bulandshahr) have also been supported for capacity building and can become major vaccine manufacturing centres over time. Viral variants will evolve, especially under vaccine pressure, and pose challenges to vaccine efficacy. Constant tweaking may be needed or a new vaccine strain may be added each year. Vaccines produced using different platforms may be priced differently and it is possible that we may have a poor man's vaccine and a rich man's vaccine since the government may not subsidise the cost forever. One hopes that these efforts will also prepare India for a future pandemic.

Source: G. Padmanaban, The Hindu, 11.05.2021

Get Pfizer in, work out indemnity

WHO experts opine there could be one or more Indian variants of the SARS Cov-2 virus that escape available vaccines.

The vaccination drive is constrained primarily by vaccine supplies. Any company that is willing to sell proven vaccines to India should be welcomed in. mRNA vaccines require special cold chains and are pricier than others. India's larger cities can afford both. If Pfizer and Moderna are willing to manage the logistics or find local partners for that, and the paperwork for individual vaccine recipients to sign off on legally binding indemnity commitments, there is no reason for GoI to stand in the way. If a few crore people opt for these vaccines, those many vaccines from the domestic output would be available for others. At the same time, the government should encourage these companies to set up shop in India and manufacture for the world

WHO experts opine there could be one or more Indian variants of the SARS Cov-2 virus that escape available vaccines. Most vaccines target the spike protein on the coronavirus. If it undergoes significant modifications, the efficacy of the vaccine would come down. It needs to be established if the traditional, inactivated all-of-virus vaccines work against the variants better than vaccines centred on specific proteins of the virus. The deemed advantage of the new mRNA vaccines and virus vector vaccines (in which a DNA encoding the target protein is contained in a relatively harmless virus such as the adenosvirus) is their modular flexibility. Change the mRNA or DNA, to target another protein, while the rest of the vaccine remains the same. The genetic profiling of new variants and identification of target proteins would have to precede new vaccine development. GoI must get this going, in its own labs, and fund a variety of startups of qualified people to do this. Choose young people with their reputation and career at stake to lead such efforts. It is vital to develop new testing kits as well, for accurate, fast detection of the virus. If new mutants show significant vaccine escape, the vaccinated rich world is at risk, too, for all their travel bans. It is a global priority to develop new vaccines effective against new variants. And a company that succeeds in this endeavour would be feted by the world.

Source: Economic Times, 11.5.2021

How Indian pharma companies should have dealt with Remdesivir crisis

Incidentally, pharma companies have been conspicuous by their silence, busy making hay while the sun shines. Except for disseminating helpline numbers or web-links to check the availability of the medicine stock — measures that haven't helped much during the peak of the second wave —the companies did little to stem the crisis. Instead, they became part of the problem as they faltered in their role of patients' outreach and doctor education.

It is rare for a pharmaceutical drug's generic name to become so commonplace among households in a short span of time.

Thanks to the Covid-19 pandemic, the antiviral medicine remdesivir has become such a drug. Right from issues about its efficacy for the treatment of Covid to its shortage, black marketing, price escalation and a drug recall incident, remdesivir has earned itself a bad name, becoming one of the most controversial drugs in the Indian pharmaceutical industry.

Just before the second wave hit, seven companies in India were together manufacturing around 38.8 lakh vials of remdesivir a month. In March 2021, as demand ebbed, Cadila Healthcare reduced the price of the drug from Rs 2,800 to Rs 899 a vial, the lowest in India. As the second wave kicked in, the demand for the drug soared — spurred by people stocking up the drug for contingencies.

By mid-April, the National Pharmaceutical Pricing Authority had to put a cap on its prices at Rs 3,500. However, that did not prevent the drug's price to soar manifold in the black market. Social media has since been full of requests by family members and loved ones of critical Covid patients desperately seeking the drug. Right from the illegal sale of the drug to its illegal manufacturing, unscrupulous opportunists have jumped in to make quick money on the fly. Profiteering, especially, in the healthcare business is worth special contempt, since human lives are at stake.

Far from being a panacea, remdesivir is not a universally prescribed drug for treating Covid. While drug regulators in the US and Europe have validated it for Covid treatment, last November, the World Health Organization (WHO) recommended against the use of remdesivir in hospitalised patients, regardless of the severity of Covid, since it found no evidence about the drug's efficacy to treat the disease. Even as medical professionals in India continue to exhort the dangers of irrational use of remdesivir — and the aspect that the drug proves efficacious for only a small percentage of Covid patients — the drug continues to be popular in treating the disease.

Take Stock of Stocks

Incidentally, pharma companies have been conspicuous by their silence, busy making hay while the sun shines. Except for disseminating helpline numbers or web-links to check the availability of the medicine stock — measures that haven't helped much during the peak of the second wave —the companies did little to stem the crisis. Instead, they became part of the problem as they faltered in their role of patients' outreach and doctor education.

In a country like India with questionable public governance, it is the private sector that is often looked at as the torch bearer of the best practices. However, this time, not only has the government been caught unawares and unprepared for the second wave, but the industry too.

What could the industry have done better? Maintaining transparency tops the list. Structured and coordinated communication on vials manufactured and distributed, as well as stock levels in the supply chain, could be made available real-time to the public through a digital platform. This would help improve access by servicing areas that are running short on the drug. An alert mechanism could be in place to escalate any anticipated shortage in raw materials to state and central governments.

Empower Patients Spreading awareness about the efficacy and safety issues concerning remdesivir would also help empower and inform patients and their families. Rationing the sales and seeking patient information at the point of sale could be another measure of inhibiting the hoarding and black marketing of drugs. Pharma companies not having digitalised supply chains is costing patients dearly. It also leaves room for supply chain malpractices to

continue unabated. A digital supply chain could minimise, if not eliminate, the scope of profiteering and instances of counterfeit drugs.

In 2018, Niti Aayog had announced piloting a real-time drug supply chain using blockchain and Internet of Things (IoT) software, to tackle the problem of counterfeit drugs. However, there has been not much progress by government or industry on this front. People paying heavily inflated prices for buying a fake drug to treat their loved ones in critical condition can never be compensated for.

GoI now supervises the allocation of remdesivir to all states. Thanks to overseas medical assistance, imports and beefing up domestic production, remdesivir will soon be more easily available and the period of scarcity will soon be forgotten. The only hope is that the lessons learnt are imbibed in standard operating procedures and become industry best practices.

Views expressed are author's own

Source: Kiran Kabtta Somvanshi, Economic Times, 08.05.2021

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A tale of two cities

The way Delhi and Mumbai have prepared to take on the pandemic brings out their professional differences

The population of Mumbai under 24 wards of the Brihanmumbai Municipal Corporation (BMC) is around 12.9 million. That of the National Capital Territory of Delhi is about 17.7 million.

This article examines how these two huge metropolises have dealt with the second wave of Covid-19 from February 9 till May 9, 2021. Charts A and B plot the daily data on the number of confirmed cases and Covid-related deaths.

As is apparent, though the Covid wave was significant in both metropolises, Mumbai had a considerably lower number of reported cases of positivity — peaking at 11,206 cases on April 4, 2021. In contrast, Delhi's caseload and, hence, the peak, was way higher: 28,395 cases on April 20, 2021, followed by a second spike of 27,047 cases on April 30, 2021, before starting to reduce.

Similarly, the highest number of certified Covid-related deaths in Mumbai was 90 on May 1, 2021. This was appreciably lower than the average number of mortalities as well as peak death in Delhi — which was 448 on May 3, 2021.

How did Mumbai tightly control the case-spread deaths while Delhi so obviously did not? And what do the answers imply regarding preparedness for the third wave, which will follow as surely as night follows day?

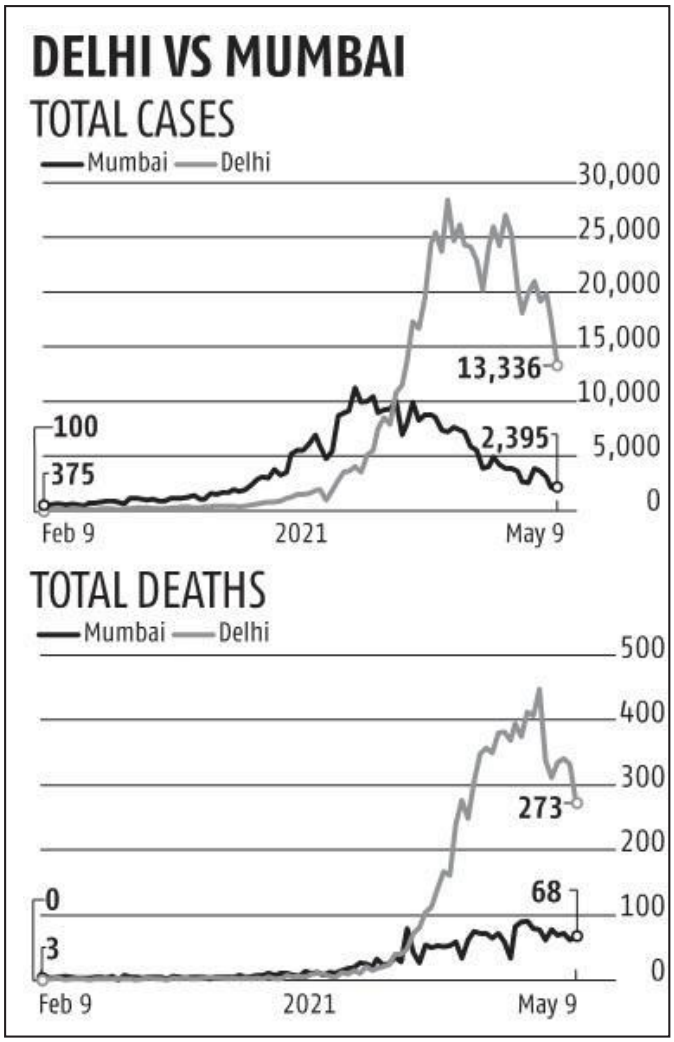
Those who have lived in both Mumbai and Delhi universally recognise a fundamental difference between the two cities. Mumbaikars are more professional and disciplined in everything that they do. I am not referring to only the corporate types. Consider the bais, the ladies who arrive each day to clean homes in Mumbai. They arrive on time, irrespective of whether you are at home or not; do all the housework in a methodical manner; and then leave for the next home. A bai services five to seven homes per day; and does each of them well.

Or take the traffic police. In Delhi, they do nothing other than occasionally catching two-wheelers for jumping a light or not wearing a helmet. Go to Mumbai and see how they coordinate with each other to regularise the enormous flow of commuter traffic between Nariman Point in the south right up to Borivali and Mulund in the north.

For all its infrastructural frailties, Mumbai works. Because Mumbaikars work.

Professional work culture is antithetical to Delhi. In Mumbai, people don't break lines getting on to a bus. In Delhi everyone wants to jump ahead of others. Delhi is about using contacts to get ahead; about dropping names of "important" people; about "fixing" things for one's personal benefit; and about not delivering what was promised by the given date. Delhi is about lawlessness and individual jugaad.

What did Mumbai do? Let me share the facts that have emerged through an excellent article authored by Sucheta Dalal (Moneylife, May 7, 2021) and an interview with Iqbal Singh Chahal, commissioner, BMC (Indian Express, May 10, 2021).



Mr Chahal had the full and unstinted support of his chief minister, Uddhav Thackeray. He didn't have to waste energy in figuring out what his boss might think. Instead, he focused on eliminating panic; decentralising war rooms to slash response times; and building infrastructure.

According to Ms Dalal, the Covid test results were being shared with patients usually by the evening of the test. That caused enormous panic, as Covid-positive patients desperately scurried for hospital beds. Mr Chahal did something controversial. He ordered each testing laboratory not to share the results directly with patients, and instead send these to the BMC.

Before that, he had set up 24 war rooms, one for each ward in the city. Each was a control centre with 30 telephone lines, 10 telephone operators, 10 doctors, medical support staff, and 10 ambulances. These worked 24x7. Each also had 10 dashboards giving updated information on the availability of hospital beds within a ward — or 240 such dashboards for Mumbai.

By 6 am of the following day, the positive test results were routed from the BMC to the wards. By 8 am, each ward started delivering results to patients as doctors and medical staff began to reach homes. The BMC hired 900 doctors and 600 nursing students. Eight hundred SUVs were requisitioned and re-modelled as ambulances. The BMC created a centralised dashboard of 172 hospitals and Covid facilities. When someone required hospitalisation, the ward doctors connected with the hospital dashboard to obtain a bed and transfer the patient. Those with mild cases were advised home-quarantine.

Penultimately, Mr Chahal tied up with IIT (Mumbai) to create a dashboard of the city's 47 crematoriums. This allotted appropriate cremation slots and prevented over-crowding.

Finally, Mr Chahal is preparing for the third wave. He has ensured enough Covid-ready beds in the city with an adequate supply of oxygen. Indeed, he has created an emergency stockpile of oxygen across six places in the city, and is going full speed ahead to set up additional oxygen plants.

Now, that's preparation, management, and execution in a professional city. Compared to this, Delhi has done nothing worthy of note. Neither planning for more beds; nor stockpiling oxygen; nor having a computerised system in place to create method out of madness. Instead, what Delhi has excelled in is having its chief minister wail every day about insufficient oxygen. For a man who once protested by lying underneath a vehicle, should one expect anything more?

The author is Chairman, CERG Advisory Private Limited

Source: Omkar Goswami,IST, May 10.05.2021

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Karnataka Antibiotics & Pharmaceuticals Ltd., Bengaluru

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