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RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 22 (PAGES: 48) | 08 TO 14 JUNE 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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

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

Please forward your registrations...

(More details on page No. 5)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
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IDMA BULLETIN

Vol. No. 52 **Issue No. 22** **08 to 14 June 2021**

IDMA ACTIVITIES

GOVERNMENT NOTIFICATION:

GOVERNMENT PRESS RELEASES:

NATIONAL NEWS

INTERNATIONAL NEWS:






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Indian APIs & Formulations for Global Healthcare

ATTENTION MEMBERS

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

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

We enclose herewith the **Agenda** for the **WEBINAR WITH IDMA and ERNST & YOUNG on PLI Scheme for Pharmaceuticals: "What is in it for the Indian Pharmaceutical Industry!"** on **Tuesday, 15th June 2021 - 3.00 p.m. to 5.00 p.m.**

We give below the **Invite and Registration / Joining Link**:-

https://eyenterprise.webex.com/eyenterprise/onstage/g.php?MTID=e396058c158ccaebf7bf0e21160808cb3

KINDLY REGISTER NOW and we look forward to your active participation at this very interesting & informative webinar.

Thanks & regards,

Daara B Patel
Secretary – General

AGENDA

Time	Topics	Speakers
03:00 p.m. – 03:05 p.m.	**Welcome Address**	**Mr. Daara B Patel,** Secretary – General, IDMA
03:05 p.m. – 03:10 p.m.	**Opening Remarks**	**Mr. Yogin Majmudar,** Past National President & Chairman, Bulk Drugs Committee, IDMA & MD, Bakul Aromatics and Chemicals Ltd.
03.10 p.m. onwards	**Technical Sessions by Ernst & Young**	
	Overview of Pharma PLI Scheme from Operational guidelines perspective	
	Capex Agenda	
	Other Incentives	
	Business Considerations ✓ **What factors need to be taken into consideration in deciding whether or not to pursue the Scheme?** ✓ **What factors need to be taken into consideration in deciding which products to enroll?** ✓ **How feasible or achievable is the incentive structure?** ✓ **What are some clarifications that the industry needs to seek?**	
	Operationalisation – How to program manage to fast track commercialisation	
	Questions & Answers Session	**Moderator : Ernst & Young**
05:00	**Summing Up and Vote of Thanks**	**Dr. George A Patani,** Hon. General Secretary, IDMA & Director, INGA Laboratories P. Ltd.

Nutraceuticals - An illusive Pot of Gold at Rainbow End?

Dr R K Sanghavi, *Consultant - Neuro Marketing & Techno Regulatory (Pharma & Nutra)*
Chairman – Nutraceutical Committee (IDMA)

Dear Reader,

In India we are blessed. We have traditional folk medicines, home remedies, besides herbals, Ayurveda, homeopathy and allopathy options, and now the in-roads made by nutraceuticals. The consumer is spoilt for choices and the healthcare providers are flummoxed by the options. What started off as another alternative option, nutraceuticals is fast becoming accepted as a bridge between 'naturals' and drugs. It would be interesting to historically assess how our forefathers have been undergoing treatment down the ages.

- *10000 BC onwards: Era of Siddha system of Medicine*
- *3000 BC onwards: Era of Herbals*
- *2000 BC onwards: Era of traditional Chinese systems of Medicine*
- *1500 BC onwards: Era of Traditional Medicine*
- *500 BC onwards: Era of Unani & Sowa-Rigpa (Tibetan or 'Amchi') Medicines*
- *300 BC onwards: Era of Ayurveda*
- *1700 AD onwards: Era of Homeopathy*
- *1800 AD onwards: Era of Allopathy*
- ***1900 AD onwards: Era of Nutraceuticals***

Nutraceuticals are biologicals and botanicals laced with science! The global Nutraceutical Market is USD $ 300-400 bn and India currently has only 1% slice of the same! Surprisingly Indian Pharmaceutical Market also constitutes mere 2% share of the global drug sales! Then where is the gap? A typical Indian family incurs Rs 50,000/- per year expenses on medical costs but only Rs 2,000 yearly is spent on nutraceuticals – 10 times lesser than global average! The average Indian spend ratio for Nutraceuticals is 4% in comparison to

Dr R K Sanghavi is Mumbai-based privately Consulting Physician since 40 years,who served in Ramakrishna Mission Hospital and many other charitable institutions. He has consulted Ethical & OTC verticals of Healthcare Industry in domains of Medico-Marketing, Training & Dr-lecturing (CMEs), Techno-Legal & Regulatory, and is member of the Subject Review Committee of NFI. Dr Sanghavi has near 200 company-years of exposure, experience and expertise by virtue of advising over 80 small, medium and large Pharma companies, including MNCs. Notable clients have been Themis, Khandelwal, Sun, FDC, Blue Cross, Biochem, Aglowmed, Svizera, Medreich, Abbott and Mankind (in chronological order). He takes credit in pioneering the Nutraceutical vertical of Healthcare in India and was associated in 1990s with first launch of most nutraceutical ingredients (antioxidants, glucosamine-chondroitin, omega-3 fatty acids, evening primrose oil, CoQ_{10}, phytoestrogens, phospholipids, soluble fiber, St John's Wort, etc.) which have wide acceptance - having delivered near 300 lectures in India including overseas Dr CMEs.As Chairman of IDMA's Medical Committee for 15 years Dr Sanghavi had organized 20 conferences; he is currently chairing the Nutraceutical Committee since last one decade. Dr Sanghavi has successfully represented IDMA on all six occasions in various High Courts, and in Supreme Court, pertaining to banning of irrational FDCs (CDSCO) and implementation of an unjustifiable system of Product Approval for nutraceuticals (FSSAI).

Pharmaceuticals versus global proportion of 7%! Therein lies the immediate potential for nutraceuticals.

The nutraceuticals market in India has penetrated just above 10% at all India level – it is albeit 3.5 times bigger in Urban versus Rural India. If the Indian Nutraceutical Market, like global, is to touch 7% of the Pharmaceutical Market the need is to increase penetration to 15% at all-country level and enhance spend for nutraceuticals from current Rs 175/- per month to mere Rs 225/- per month.

Possible to increase reach by 5% and further enhance spend by Rs 50/- per month in India?? Yes – but a thorny path to tread ahead. WHY? I have journeyed through the Nutraceutical vertical of healthcare thus far right from its starting point which is late 1980s. When I commenced my association with Nutraceuticals, there was a mere trickling of nutraceuticals introduced through the 1990s. The market was ignited in the first decade of 21st century when the Pharmaceutical Companies mass-scaled forayed into nutraceuticals; 2010 onwards the products multiplied in all possible channels of distribution when other than the pharmaceutical organizations surfaced. So much so, that today India is responsible for one out of every five nutraceutical launches of in Asia! Then why have the Indians not yet whole-heartedly embraced nutraceuticals? Marketing nutraceuticals in India is not an easy task – challenges being dependence on Dr for their buy-decision, ill-literacy, lack of awareness amongst medical professionals for nutraceuticals, reluctance to advice and spend for preventive health are prime contributory factors. Some of the following aspects pertaining to successful nutraceutical marketing could tip the scale, if addressed.

- *Companies need to be more focused on unleashing the benefits of nutraceuticals rather than on sales. For example, zinc boosts immunity and has antiviral activity albeit as acetate and gluconate salts. However, most brands have sulphate and citrate salts which have no such advantages -how are these expected to really deliver value in coronavirus pandemic? Check your antibodies to ascertain.*
- *Regulators require in their committees knowledgeable professionals and not famed personalities or self-proclaimed experts. Regulators are on unsteady grounds with regards to evaluating nutraceuticals. The DTAB Committee which last evaluated irrational products banished all zinc containing anti-cold formulations questioning its antiviral benefit. Today, vitamin C and zinc are in limelight for their immunity-building benefits! In a current matter of confusion, the FSSAI regulators of a particular state have proclaimed that whether it is cyanocobalamin or methylcobalamin the RDA is same as for vitamin B12! How can one expect to deliver benefits with homeopathic quantities of methylcobalamin being enforced?*
- *Companies should provide beneficial content of nutraceuticals even if the product becomes dearer. In the case of coenzyme Q10 (CoQ10), an expensive ingredient, the brands claim all its benefits whilst providing a mere fraction of minimum 100 mg required per daily serving! Repeat purchase can only be a pipedream.*
- *Nutraceuticals are for life-style and not for organ-health. The consumer needs nutraceuticals to prevent fractures, maintain painless joints movements, ward off cancer, diabetes and heart disease, etc. They do not desire ingredients – he / she wants recipes. Making single ingredient nutraceuticals available like calcium, folic acid, ashwagandha, grape seed extract, etc. is akin to running a grocery shop! The knowledge-challenged buyer prefers refraining from purchasing amongst confusing choices.*

The current FSSAI regulations do not throttle nutraceuticals. They provide ample scope of facilitating the globally projected growth of nutraceuticals equalling 30% of Pharma market. The already cluttered market of nutritional products (vitamins-minerals-proteins) should not be confused as nutraceuticals. The mantra should be: launch nutraceuticals (not nutritionals), conceptualize beneficial combo with optimal amounts, incorporate best ingredient form and ensure 'scientific' promotional messages. Only then will positive health be a stark reality and a Rs 2250 bn golden pot at rainbow end be snatched before 2030 – corona permitting!

Courtesy: Indian Drugs, Editorial, Vol. 58 (03) March 2021

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Notification of the provisions of Section 142 of the Code on Social Security (CoSS), 2020 and status of Aadhaar Seeding : IDMA representation to Additional Central Provident Fund Commissioner - reg.

The Association has submitted the following representation on 9th June 2021 to Shri S. K. Aggarwal, Additional Central Provident Fund Commissioner with the copies to Shri Rajiv Bhist, ACC (F&A), The Central PF Commissioner; Shri Sunil Barthwal, IAS, The Central PF Commissioner and Shri Madan Chaurasia, Under Secretary to the Govt. of India on the above subject :

Dear Sir,

At the outset we would like to state that we highly appreciate the promptness of the authorities with regards to the above mentioned subject matter. Keeping the same in mind, we would like to bring the following points to your notice:

1. The said notification appoints 3rd May, 2021 as the date for the Section 142 of CoSS coming into force. Following this, the message from EPFO states that:"ECR shall be allowed to be filed only for those members, whose Aadhaar numbers are seeded and verified with the UANs, w.e.f. 01.06.2021". This would, effectively mean that after deducting the contribution, the Employer will not be in a position to deposit the same in respect of those members whose Aadhaar seeding is pending.
2. It may please be noted that the EPFO web portal and the allied online features are facilities provided by the government for administrative convenience, to aid the provisions of the Act and not to supersede or hinder with the provisions of the Act.
3. We would like to humbly point out that if the EPFO does not accept the contribution because of the above, it will lead to denial of benefit to the Employees, causing hardship to the Employees and harassment to the Employers. It may also result in the Employees questioning the Employers on the same, causing friction in their relationship.
4. We would now like to highlight, that we have already communicated time and again to our Employees to provide Aadhar details and are still trying our best to inform and encourage the Employees whose Aadhaar seeding is pending, to upload the required details on the EPFO web portal at the earliest. Although there is a provision on the EPFO portal for the Employer to upload the Aadhaar details of the Employees, often times, during such bulk uploads, many of the Aadhaar entries are declined by the portal by displaying the message **"Aadhaar Authentication failed"** and no proper reason is assigned for the same.

In such circumstances, wherein only such a generic statement is made for non-acceptance of the details, the Employer is left with very little information or proper reason for non-acceptance of the Aadhaar details. Here, two possible scenarios can be presumed where there is discrepancy between the details (like name, date of birth, etc.) on the Aadhaar card and the details on the portal:

(a) In cases where the details on the Aadhaar Card are incorrect or incomplete, it is entirely the responsibility of the Employee to get the same rectified by the UIDAI.

(b) In cases where the details on the portal are incorrect, the same needs to be rectified by the EPFO after joint declaration by the Employee and Employer.

In scenario (b) above, it is seen that often times, there is delay in approval of the joint declaration, which subsequently leading to delay filing contribution and compliance. We affirm that we have requested our Employees to fill in their Aadhaar details and/or make the necessary modifications at the earliest as above.

In addition to the above issues, we are also facing a new issue as on the date of this letter, which is that we are not able to file ECR even for some members whose Aadhaar details are already uploaded, and the following messages are being displayed:

(a) Error Aadhaar not seeded against UAN. found on line numbers: [3]

(b) Error Aadhaar not verified against UAN. found on line numbers: [1, 2, 6]

5. In effect, for no fault of their own, the Employers are left vulnerable to be penalized with interest and damages (as per Section 14B and 7Q of EPF & MP Act, 1952).

6. The non-payment of the contribution will also result in further hardship to the Employer, because non- accepted Employee contribution beyond the statutory due date will be deemed to be income in the hands of the Employer and non-accepted Employer contribution beyond the statutory due date will not be considered as business expenditure (as per Section 43B of the Income Tax Act, 1961), thereby stripping away the income tax benefit applicable to these contributions for no fault on the Employer's part.

7. Another issue is that this delay in contribution will also adversely affect the Atmanirbhar Bharat Rojgar Yojana benefit scheme.

8. If any Employer, who because of the pandemic, had faced a financial crunch resulting in non-payment of contribution in preceding months (before June, 2021), the same would also get on hold now for those employees whose Aadhar is not seeded.

9. We would like to further highlight that the CoSS, 2020, is yet to come into effect fully. In view of the same, as only one portion of the Act is being made effective, it is creating unnecessary hardship to the Employers as well as Employees.

10. Furthermore, we would like to bring to your kind notice that EPFO site is very slow and when the Employees are trying to update the details, they are not able to do so and spend lot of time trying to update the details. This issue is pushing back the Employees from updating the details. In this regards, we would like to produce the observations of the Hon'ble High Court of Bombay in Abicor and BinzelTechnoweld Pvt. Ltd. v/s The Union of India and Anr., wherein the court did not hesitate to observe that:

"10. We do not think that these are satisfactory state of affairs. A tax like Goods and Services Tax was highly publicised and termed as popular. We had yet not seen a celebration of New Tax regime, but that has followed with great hue and cry. These celebrations mean nothing. The special sessions of Parliament or special or extraordinary meetings of Council would mean nothing to the assessees unless they obtain easy access to the website and portals. The regime is not tax friendly. We hope and trust that those in charge of implementation and administration of this law will at least now wake up and put in place the requisite mechanism. This is necessary to preserve the image, prestige and reputation of this country, particularly when we are inviting and welcoming foreign investment in the State and the country. We hope and trust that such petitions are rarity and the Court will not be called upon to administer the implementation of the law, leave alone monitoring and supervising the working of the individual officials, howsoever high ranking he may be."

11. As per letter No. BKG-27/7/2020-G/Pt. file dated 01.06.2021 by the EPFO on the subject matter, steps and measures are laid down to be undertaken "to ensure that members and Employers are not adversely affected in the transition phase", which, inter alia, provide for appointment of Nodal officer for coordination and facilitation of issues faced by members and Employers in this regard. Further, the said letter lays down steps and measures to be undertaken for facilitation of Aahdaar seeding on 01.06.2021, which is also the same date beyond which the Employer will not be in a position to deposit the contribution in respect of those members whose Aadhaar seeding is pending. This leaves virtually no time for addressing the abovementioned issues.

12. As per the letter dated 12.05.2021 from the Under Secretary to the Govt. of India, to the ESI Corporation, it is stated that:

"3. Since the other provisions of the CoSS 2020….are yet to be implemented, the requirement for Aadhaar for availing benefits etc. under the existing ESI Act, 1948 may not be mandatory.

5. Though ESIC may start collecting AAdhaar details, but it is made clear that no IP shall be denied any benefit under the existing ESI Act, 1948. "

Therefore, two contradictory views are applied to the same notification with regards to ESIC and EPFO, both of which fall under the purview of the Ministry of Labour& Employment.

We would now like to state that it would not be out of place to draw your kind attention to Para 30(1) of The Employees' Provident Fund Scheme, 1952, which states that:

"The employer shall, in the first instance, pay both the contribution payable by himself (in this Scheme referred to as the employer's contribution) and also, on behalf of the member employed by him directly or by or through a contractor, the contribution payable by such member (in this Scheme referred to as the member's contribution)."

There is no mention of any other condition for payment of the contribution by the Employer. The present notification, therefore, effectively hinders with this provision and with the overall beneficial objective of the EPF & MP Act, 1952.

Under the circumstances explained above, it can be observed that while the EPFO and the Ministry of Labour & Employment have shown exceptional promptness in respect of the subject matter at hand, we hereby humbly request that similar measures be also taken to address the issues that have been raised from time to time regarding the difficulties while accessing the web portal in order to bring it at par with the requirements of the present notification.

Kindly take the above on record and implement the suggestions made herein above, and to your office from time to time. A line of confirmation would be highly appreciated.

Thanking you in anticipation.

Yours faithfully,
For Indian Drug Manufacturers' Association,

Mahesh Doshi
National President

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Appeal for extension of effective date of Indian Pharmacopoeia 2018 Addendum 2021: IDMA representation to Indian Pharmacopoeia Commission - reg

The Association has submitted the following representation on 8th June 2021 to The Secretary-Cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India with the copies of The Drugs Controller General of India, Directorate General of Health Services on the above subject :

Dear Sir,

We congratulate Indian Pharmacopoeia Commission (IPC), the expert members of the Scientific Body and IPC staff for this release of Indian Pharmacopoeia 2018 Addendum 2021. We appreciate the initiative and efforts taken by your good office to release Indian Pharmacopoeia 2018 Addendum 2021 which will strengthen the quality of medicines available in India market.

As we know that India has been among the worst hit countries in terms of absolute COVID-19 numbers. We would like to highlight to your good office that during this challenging time, all the companies are putting their best efforts to fight and provide the medicines to save lives from COVID-19. While having the goal of providing sufficient quality medicines in market, all pharma companies are also facing the practical issue of working with limited manpower.

Also, by knowing the shortage of medicines in market, all pharma companies have shifted their focus to develop COVID-19 specific medicines at the earliest to suffice the market demands. Additionally, we shall also be prepared enough with medicines and supplies in case the next wave strikes our country.

Hence, with this letter, we request you to kindly provide additional transition time of 6 months for implementation of Indian Pharmacopoeia 2018 Addendum 2021, that is 1st March 2022, as release of products in market complying with monographs of IP 2018 Addendum 2021 with current situation of COVID-19 pandemic is extremely difficult and in some cases almost impossible due to the reasons mentioned below.

- IP-2018 addendum 2021 has been brought out incorporating 59 new monographs and 185 revised monographs. Accordingly, ***there is a huge impact on pharma industry with need of evaluation or reformulation for number of products which cannot be completed within the current timeline of 1st October, 2021.***

- Before releasing a product in market with IP claim, lot of work is done by manufacturers within the organization and outside of it. ***Starting from procurement of required materials or equipments, testing as per monograph and in case needed, reformulation of product to make it compliant to monograph of IP. Then, printing of label which takes minimum 20 days.*** Also, in these struggling days, there will also be destruction of packaging inventory for products requiring revision in label claim, which will have financial and environmental impact and is not in national interest.

We would also like to inform you that few of our members have already initiated the evaluation of monographs as appeared in this new edition. However, to evaluate, understand and then to implement the monographs of Indian Pharmacopoeia, will definitely take more efforts and time than usual in this difficult times.

Accordingly, extension is very much required for smooth transition by pharma manufactures to maintain business continuity, and to meet our common objective of ensuring availability of safe & essential medicines in India market.

Additionally, we hereby ensure your good office that all of our members are committed to comply with the Indian Pharmacopoeia and to provide the medicines to Indian market.

Considering all above, and in the best interest of continuous availability of life-saving medicines to the Indian patients, **we hereby appeal to your good office to issue a notice with change in effective date of IP 2018 addendum 2021 as 1st March, 2022 i.e., granting extension of at least another 6 months.**

Thanking you for your kind consideration.

With Best Regards.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Mahesh Doshi
National President

Enclosure:

- Notification of Addendum 2021 to Indian Pharmacopoeia 2018.

Addendum 2021 to Indian Pharmacopoeia 2018

Published By

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health and Family Welfare
Government of India
Sector 23, Raj Nagar, Ghaziabad 201 002, India
Website: www.ipc.gov.in; **Email:** lab.ipc@gov.in

Effective Date

1ST OCTOBER 2021

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3. Amlodipine and Nebivolol Tablets
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1. Allergen Products

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8. Baclofen
9. Benzyl Alcohol
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14. Butyl paraben
15. Calcium Gluconate
16. Calcium Gluconate Injection
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18. Carbimazole Tablets
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65. Gabapentin Capsules
66. Gabapentin Tablets
67. Glibenclamide and Metformin Tablets
68. Granisetron Hydrochloride
69. Granisentron Injection
70. Hydrochlorothiazide Tablets
71. Hyoscine Butylbromide
72. Hyoscine Butylbromide Injection
73. Insulin Zinc Suspension
74. Insulin Zinc Suspension (Amorphous)
75. Insulin Zinc Suspension (Crystalline)
76. Ipratropium Bromide
77. Irbesartan and Hydrochlorothiazide Tablets
78. Isopropyl Rubbing Alcohol
79. Kanamycin Injection
80. Labetalol Hydrochloride
81. Lamivudine and Zidovudine Tablets
82. Lamivudine, Nevirapine and Zidovudine Paediatric Dispersible Tablets
83. Letrozole Tablets
84. Levetiracetam Oral Solution
85. Levocarnitine
86. Levocetirizine Hydrochloride
87. Levocetirizine Tablets
88. Lignocaine Hydrochloride Topical Solution
89. Lithium Carbonate
90. Malic Acid
91. Methadone Injection
92. Methotrexate Tablets
93. Metoprolol Succinate
94. Misoprostol Tablets
95. Modafinil Tablets
96. Montelukast Sodium and Levocetrizine Hydrochloride Tablets
104. Ondansetron Orally Disintegrating Tablets
105. Ormeloxifene Hydrochloride
106. Ormeloxifene Hydrochloride Tablets
107. Oxaliplatin Injection
108. D-Panthenol
109. Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules
110. Pentoxifylline
111. Perindopril Erbumine Tablets
112. Phenobarbitone Injection
113. Phentolamine Injection
114. Phenytoin Oral Suspension
115. Piperacillin and Tazobactam Injection
116. Pirfenidone
117. Polyvinyl Alcohol
118. Prednisolone Tablets
119. Procainamide Injection
120. Promethazine Injection
121. Propofol
122. Propranolol Injection
123. Propylene Glycol
124. Pyrazinamide
125. Quinapril and Hydrochlorothiazide Tablets
126. Rabeprazole Injection
127. Raloxifene Hydrochloride
128. Raloxifene Hydrochloride Tablets
129. Ranitidine Oral Solution
130. Ranitidine Tablets
131. Ritodrine Hydrochloride
132. Ritodrine Injection
133. Ropinirole Prolonged-release Tablets
134. Ropinirole Tablets
135. Serratiopeptidase Tablets
136. Sodium Alendronate Tablets
137. Colloidal Silicon Dioxide
138. Sodium Chloride
139. Sodium Citrate Irrigation Solution
140. Monobasic Sodium Phosphate
141. Sodium Propylparaben
142. Sodium Valproate Gastro-resistant Tablets
143. Solifenacin Succinate Tablets
144. Sorafenib Tosylate
145. Sorafenib Tablets
146. Stearic Acid
147. Streptomycin Sulphate
148. Sulbactam Sodium
149. Sulfasalazine Gastro-resistant Tablets
150. Talc
151. Tamsulosin Hydrochloride

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152. Tazobactam Sodium
153. Telmisartan and Amlodipine Tablets
154. Temozolomide
155. Teneligliptin Hydrobromide Hydrate
156. Teneligliptin Tablets
157. Terazosin Tablets
158. Thiamine Hydrochloride
159. Thiamine Injection
160. Thiamine Tablets
170. Tobramycin Inhalation Solution
171. Torsemide Tablets
172. Tranexamic Acid
173. Tranexamic Acid Injection
174. Tranexamic Acid Tablets
175. Trimethobenzamide Hydrochloride
176. Vancomycin Intravenous Infusion
177. Venlafaxine Prolonged-release Capsules
178. Venlafaxine Prolonged-release Tablets

161. Thiamine Mononitrate
162. Thiocolchicoside
163. Thyroxine Sodium
164. Thyroxine Tablets
165. Ticagrelor
166. Timolol Eye Drops
167. Timolol Tablets
168. Titanium Dioxide
169. Tizanidine Tablets
179. Venlafaxine Tablets
180. Vinorelbine Injection
181. Voriconazole Injection
182. Sterile Water for Injections
183. Zidovudine, Lamivudine and Nevirapine Tablets
184. Zinc Oxide Cream
185. Zopiclone Tablets

Vaccines and Immunosera for Human Use

1. Adsorbed Pertussis Vaccine (Acellular Component)
2. Diphtheria and Tetanus Vaccine (Adsorbed)
3. Diphtheria and Tetanus Vaccine
4. (Adsorbed) for Adults and Adolescents
5. Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed)
6. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed)
7. Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) Vaccine (Adsorbed)
8. Diphtheria, Tetanus, Pertussis (Whole Cell) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed)
9. Diphtheria Vaccine (Adsorbed)
10. Diphtheria Vaccine (Adsorbed) for Adults and Adolescents
11. Haemophilus influenzae Type b Conjugate Vaccine
12. Inactivated Hepatitis A Vaccine (Adsorbed)
13. Inactivated Hepatitis B Vaccine
14. Inactivated Influenza Vaccine (Split Virion)
15. Inactivated Influenza Vaccine (Surface Antigen)
16. Inactivated Influenza Vaccine (Whole Virion)
17. Influenza Vaccine (Human, Live Attenuated)
18. Japanese Encephalitis Vaccine (Human)
19. Japanese Encephalitis Live Vaccine (Human)
20. Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human)
21. Measles and Rubella Vaccine (Live)
22. Measles Vaccine (Live)
23. Measles, Mumps and Rubella Vaccine (Live)
24. Group A Meningococcal Conjugate Vaccine
25. Meningococcal Polysaccharide Vaccine
26. Mumps Vaccine (Live)
27. Plague Vaccine
28. Poliomyelitis Vaccine, Live (Oral)
29. Rabies Vaccine, Human
30. Rotavirus Vaccine (Live attenuated, Oral)
31. Rubella Vaccine (Live)
32. Tetanus Vaccine (Adsorbed)
33. Tick-borne Encephalitis Vaccine (Inactivated)
34. Typhoid Polysaccharide Vaccine
35. Typhoid Paratyphoid A Vaccine
36. Typhoid Vi Conjugate Vaccine
37. Typhus Vaccine
38. Varicella Vaccine, Live
39. Yellow Fever Vaccine

Herbs and Herbal Products

1. Castor Oil
2. Ginkgo Dry Extract
3. Henna Dry Powder

Blood and Blood Related Products

1. Anti-A Blood Grouping Serum
2. Anti-B Blood Grouping Serum
3. Anti-AB Blood Grouping Reagent
4. Anti-D (IgM) Monoclonal Blood Grouping Reagent

Biotechnology Derived Therapeutic Products

1. Filgrastim Concentrated Solution
2. Follicle Stimulating Hormone
3. Concentrated Solution
4. Pegfilgrastim

Radiopharmaceutical Preparations

1. Sodium Chromate (15Cr) Injection

Veterinary Monographs

1. Amprolium Oral Powder
2. Cloprostenol Injection
3. Furazolidone Premix
4. Moxidectin
5. Tylosin Injection

Tamil Nadu IDMA Members Contributes to CMs Corona Relief Fund

President of Tamilnadu Pharmaceutical Sciences Welfare Trust Mr.S. V. Veeramani, President of The Pharmaceutical Manufacturers Association of Tamil Nadu Mr. M D Varadarajan, Chairman of Tamil Nadu State Board of Indian Drug Manufacturers Association Mr. J.Jayaseelan called on Chief Minister Mr. Stalin at the Secretariat and handed over a cheque for Rs. 15 lakh, Rs. 6 lakh and Rs. 29 lakh respectively amounting to a total of Rs. 50 lakh, on behalf of their Associations towards CM's Corona relief fund. Vice Chairman of Tamil Nadu State board of Indian Drug Manufacturers Association Mr. D.Sathish was also present.

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GOVERNMENT NOTIFICATION

Notification number V-16011/01/2017-INI-I dated 24th November 2017 amended - reg

Health & Family Welfare - Other Notification S.O.2245(E), dated 10th June 2021

In exercise of powers conferred by Clause (e) of Section 4, read with Sub-section (3) of Section 6 of the All India Institute of Medical Sciences Act, 1956 (25 of 1956), the Central Government hereby nominates Shri Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare, New Delhi to be a member of All India Institute of Medical Sciences, New Delhi in place of Smt. Preeti Sudan and for that purpose makes the following amendment in the notification of Government of India in the Ministry of Health & Family Welfare, number V-16011/01/2017-INI-I dated the 24th November, 2017, published in the Gazette of India Part II, Section 3, Sub-section (ii) vide S.O.3730(E) dated 24th November, 2017:-

In the said notification, for serial number 2 and the entry relating thereto, the following serial number and entry should be substituted, namely:-

"2. Shri Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare, New Delhi."

F.No.V-16011/01/2021-INI-I

Nilambuj Sharan, Economic Advisor, Ministry of Health and Family Welfare, New Delhi.

Foot Note: *The Principal Notification was published in the Gazette of India (E) Vide S.O.1924(E) dated 16.07.2015 and amended further by:*

(i) S.O. 454(E) dated 12.02.2016
(ii) S.O. 1052(E) dated 11.03.2016.
(iii) S.O. 2722(E) dated 17.08.2016.
(iv) S.O. 1848(E) dated 08.06.2017.
(v) S.O. 3730(E) dated 24.11.2017.
(vi) S.O. 2342(E) dated 7.06.2018.
(vii) S.O. 1711(E) dated 9.05.2019.
(viii) S.O. 2352(E) dated 04.07.2019
(ix) S.O. 3132(E) dated 29.08.2019
(x) S.O. 1457(E) dated 01.04.2021

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Indian Drug Manufacturers' Association
(Tamil Nadu, Puducherry, Kerala State Board)

09.06.2021

HEARTFELT CONDOLENCE

Shri. SARDARMAL CHORDIA
Chairman
Medopharm

We're extremely sorry to hear about **Shri. SARDARMAL CHORDIA, Chairman Medopharm,** passed away today and we extend our sincere condolence on behalf of the **IDMA TNPKSB.**

We extend our heart-felt condolence to the grief struck Family Members, Friends, Relatives and pray the ALMIGHTY for the departed soul to Rest in Peace and give enough strength and courage to the bereaved family members and friends to bear this irreparable loss.

IDMA TNPKSB
Office Bearers & Members

Block D1, "Baid Metha Complex" New Anna Salai, Little Mount, Saidapet, Chennai - 600 015.
Phone: 044-22354432/044-42027624/22355864. email: officeidmatnp@gmail.com

Recommendations of 44th GST Council Meeting

Change in GST Rates on goods being used in Covid- 19 relief and management

The 44th GST Council met under the Chairmanship of Union Finance & Corporate Affairs Minister Smt Nirmala Sitharaman through video conferencing here today. The Council in its meeting has decided to reduce the GST rates on the specified items being used in Covid-19 relief and management till 30th September, 2021.

The meeting was also attended by Union Minister of State for Finance & Corporate Affairs Shri Anurag Thakur besides Finance Ministers of States & UTs and senior officers of the Ministry of Finance & States/ UTs.

The details of recommendations are given below :

S. No.	Description	Present GST Rate	GST Rate recommended by GST Council
A. Medicines			
1.	Tocilizumab	5%	Nil
2.	Amphotericin B	5%	Nil
3.	Anti-Coagulants like Heparin	12%	5%
4.	Remdesivir	12%	5%
5.	Any other drug recommended by Ministry of Health and Family Welfare (MoHFW) and Dept. of Pharma (DoP) for Covid treatment	Applicable Rate	5%
B. Oxygen, Oxygen generation equipment and related medical devices			
1.	Medical Grade Oxygen	12%	5%
2.	Oxygen Concentrator/ Generator, including personal imports thereof	12%	5%
3.	Ventilators	12%	5%
4.	Ventilator masks / canula / helmet	12%	5%
5.	BiPAP Machine	12%	5%
6.	High flow nasal canula (HFNC) device	12%	5%
C. Testing Kits and Machines			
1.	Covid Testing Kits	12%	5%
2.	Specified Inflammatory Diagnostic Kits, namely D- Dimer, IL-6, Ferritin and LDH	12%	5%
D. Other Covid-19 related relief material			
1.	Pulse Oximeters, incl personal imports thereof	12%	5%
2.	Hand Sanitizer	18%	5%
3.	Temperature check equipment	18%	5%
4.	Gas/Electric/other furnaces for crematorium, including their installation, etc.	18%	5%
5.	Ambulances	28%	12%

These rate reductions/exemptions shall remain in force upto 30th September 2021.

Source: 12 June 2021, PIB Delhi (Release ID : 1726525)

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India close to giving indemnity to foreign vaccine makers like Pfizer: Report

India invited Pfizer, Moderna and Johnson & Johnson in April to sell their vaccines after infections rocketed. However, no deal has been signed.

India is close to agreeing to grant foreign COVID-19 vaccine makers such as Pfizer Inc protection against legal liability so that it can use their shots in an immunisation campaign that is facing acute shortages, three government sources told Reuters.

"Indemnity will be granted," said one of the sources. "If one company gets it then all of them get it."

India invited Pfizer, Moderna and Johnson & Johnson in April to sell their vaccines after infections rocketed. However, no deal has been signed.

Pfizer has not sold to any country without obtaining indemnity against legal action over any adverse effects of their product.

India has not granted indemnity to any COVID-19 vaccine maker, but the sources, who requested anonymity, said the government was having a change of heart.

The government has already met one of Pfizer's other key demands by dropping a requirement that foreign vaccines undergo local trials.

Another government official said he expected Pfizer vaccines to be delivered in August. He said initial recipients of foreign shots could be monitored, before a mass roll-out "once we are sure of its efficacy on Indians."

Neither the foreign or health ministries responded to a request for comment.

Pfizer declined to comment on its discussions with the Indian government but said it sought indemnity wherever it supplied its vaccine.

"We seek the same kind of indemnity and liability protections in all of the countries that have asked to purchase our vaccine, consistent with the local applicable laws to create the appropriate risk protection for all involved," a Pfizer spokeswoman said in an email to Reuters.

One of the sources said India was negotiating prices of $10-$12 per dose for foreign shots. The European Union is paying 15.5 euros ($18.86) per dose for the Pfizer vaccine developed with Germany's BioNTech. The Pfizer spokeswoman said the company had offered doses to many countries at a not-for-profit price.

India has administered more than 239 million vaccine doses - mainly a licensed version of the AstraZeneca drug produced locally - the most in the world after China and the United States. But with a population of 1.35 billion people, India's vaccination rate is much lower than many countries.

Source : Reuters, 10.06.2021

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New scheme for services exports soon: Commerce secretary Anup Wadhawan

Under the extant SEIS, the government offers exporters duty credit scrips at 5-7% of the net foreign exchange earned, depending on the nature of services.

Exporters have been awaiting the notification of support for FY20 and FY21 under the Service Exports From India Scheme (SEIS).

The government is in the process of formulating appropriate measures to boost services exports, which will be part of the upcoming foreign trade policy (FTP), commerce secretary Anup Wadhawan said on Thursday.

The statement will likely reassure Covid-hit services exporters about continued policy support, albeit in different forms or structure, amid apprehension that the resource-strapped government may substantially reduce benefits for certain services. Exporters have been awaiting the notification of support for FY20 and FY21 under the Service Exports From India Scheme (SEIS).

Asked if the current SEIS would continue to be a part of the new FTP, Wadhawan told reporters: "When we firm up the new FTP, what we need to do for the services sector will be taken into account, based on stakeholders' feedback and other inputs. And appropriate schemes and measures will be there for services exporters in the new FTP."

Sources had earlier told FE that the commerce ministry was weighing a proposal to overhaul the SEIS to make it more broad-based and fool-proof so that a wider pool of businesses, especially Covid-hit MSMEs, get the succour. This revamped scheme, probably with a new name, could

be part of the new five-year FTP, which would be effective from October 2021, they had said.

Under the extant SEIS, the government offers exporters duty credit scrips at 5-7% of the net foreign exchange earned, depending on the nature of services.

Sources had earlier said the government could also reduce benefits for consultancy and certain other professional services that it thought cornered a sizeable chunk of incentives without commensurate benefits. Moreover, a section of the government believes that since few players are grabbing most of the SEIS incentives, the scheme should be altered in such a fashion that it helps a large number of small businesses as well.

Already, services exporters have urged the government to release SEIS benefits for FY20 at the earliest, which could be to the tune of `3,000-4,000 crore. The SEIS was introduced in the FTP for 2015-20; the validity of the FTP has now been extended up to September 2021.

Services exports dropped almost 6% year-on-year in FY21 to $203 billion due to the pandemic, while merchandise exports contracted by just over 7% to about $291 billion, according to a quick estimate by the commerce ministry. Services trade surplus has been substantially offsetting the merchandise trade deficit. Despite the pandemic, the overall trade deficit dropped to just $13 billion, thanks to an $86-billion surplus in services trade in FY21.

Source : FE Bureau, 11.06.2021

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Data shows trade between Beijing, New Delhi grew in 5 months of 2021

According to the Indian data, imports from China rose 59.13% to $33.49 billion, while exports to China rose 46.09% to $10.41 billion.(Bloomberg)

Trade between India and China soared by around 70%year-on-year to at least $48 billion in the first five months of 2021, latest data from Chinese customs showed Monday.

Publicly available data from India too showed a healthy growth, although the numbers differed from those put out by Chinese state media. According to the Indian data, trade grew 55.83% in the first five months of the year.

The reason for the discrepancy in the data isn't known; both countries denominate the trade in dollars. Calling it a "spectacular growth", Chinese state media interpreted the increase in bilateral trade as a sign of resilience in trade ties between the two countries despite serious conflict at the border and political differences.

"Trade between China and India soared 70.1 % in US dollar terms in the first five months of this year to $48.16 billion, according to Chinese customs data released on Monday. Specifically, Chinese exports to India grew 64.1% year-on-year from January to May, while imports surged 90.2%," the nationalistic tabloid, Global Times reported.

According to the Indian data, imports from China rose 59.13% to $33.49 billion, while exports to China rose 46.09% to $10.41 billion.

The trade volume between the two countries was higher than the trade China conducted with other trading partners in this period, the Global Times report said. The latest statistics were released by China's General Administration of Customs (GAC) on Monday.

As per Chinese data, the trade – or specifically Chinese exports to India – rose sharply between April and May. The rise could be attributed to the increase of exports of Chinese medical goods and equipment by Indian companies to fight the surge in Covid-19 cases in the last couple of months. "If anything, these extraordinary growth rates show that China-India trade has largely shrugged off the impact of the political tensions caused by the border friction last year...," the state media report said.

India-China trade in 2020 declined by 9.1% to $77.66 billion, though China still overtook the US to become India's largest trading partner in 2020.

Those numbers are for the calendar year. India, follows an April to March financial year and according to government data, Indian exports to China saw a 27.53% jump in 2020-21, while China's imports saw a 0.07% contraction. Total India-China trade in the financial year was $86.4 billion, with a $44 billion trade balance in favour of China, a significant 30.15% drop from about $63 billion in 2017-18.

According to the Indian embassy in Beijing, though bilateral trade between the two countries grew exponentially overall – notwithstanding a fall last year because of the Covid-19 pandemic -- India continues to be saddled with a big trade deficit.

The growth of trade deficit with China can be attributed to two factors: narrow basket of commodities, mostly primary, that we export to China and market access impediments for most of our agricultural products and the sectors where we are competitive in, such as pharmaceuticals, IT/IteS, etc. Our pre-dominant exports have consisted of cotton, copper and diamonds/ natural gems," the Indian embassy says on its website under the section "India-China Trade and Economic Relations".

India's Commerce ministry did not respond to an email query on this matter.

According to an Indian official who asked not to be named, the spurt in trade in 2020-21 signified a jump in Indian exports to China and a sharp decline in Chinese imports. "This is a grand success of Make in India and Make for the world aided by competitiveness of Indian industry," the official said requesting anonymity.

To be sure, some analysts also point to the contraction of the Indian economy as the main reason for the fall in Chinese imports last year, although some bit of it was also on account of the situation at the Line of Actual Control.

As for the first five months of this year, people familiar with developments said on condition of anonymity that the numbers likely reflect the spike in imports of medical equipment from China to cope with the second wave of Coronavirus infections. The people, however, added that this shouldn't be perceived as "business as usual" against the backdrop of the dragging border standoff.

In a phone conversation with his Chinese counterpart Wang Yi on April 30, external affairs minister S Jaishankar highlighted the importance of transport corridors and cargo flights remaining open and speedy logistics support from the Chinese side to facilitate the procurement of Covid-19 related products and raw materials.

Source : Sutirtho Patranobis & Rajeev Jayaswal, Hindustan Times, 09.06.2021

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GST Council to meet Saturday, discuss tax exemption on Covid-19 essentials

The council meet is expected to deliberate the exemption and concession on Covid-19 related items

The Goods and Services Tax (GST) Council, chaired by Union Finance Minister Nirmala Sitharaman, will likely consider on Saturday a GST rate cut for Covid-19 relief essentials and drugs for treating the black fungus disease and might leave the vaccines untouched. The meeting is being held following a report submitted by a Group of Ministers (GoM) to the GST Council on Monday.

The GoM, set up by the Council on May 28, was mandated to look at tax exemption and concessions on various Covid items including vaccines, drugs, and equipment.

According to the GoM report, it has not recommended any change in the rates on Covid vaccines. Currently, 5 per cent is levied on domestically manufactured vaccines, while it is 12 per cent for Covid drugs and oxygen concentrators.

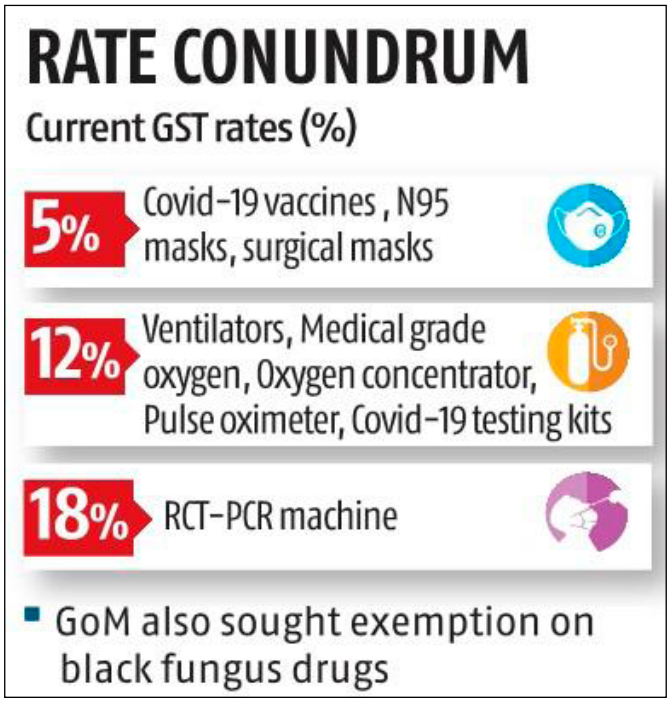
Besides, the GoM has proposed to retain the current rates on items including PPE kits (5 per cent), N95, and surgical masks (5 per cent), and ambulances (28 per cent).

However, it suggested temporarily reducing the rate to nil and 5 per cent on a majority of items including imports and domestic supplies of Covid-19 medicines and material, including medical oxygen, oxygen concentrators, ventilators, pulse oximeters and testing kits. On thermometers and electricity for crematoriums, it suggested 12 per cent each from 18 per cent now.

On unchanged vaccine rates, the GoM said: "The GST rate on vaccines has been the one of the most contentious issues. It examined the issue with utmost care, minutely exploring all options. Apart from the proposals for zero rating or lower rate like 0.1 per cent, the GoM also discussed in detail the proposal for fully exempting GST on vaccines or providing a differential rate structure for vaccine procurements by the Centre, states, and private parties," it said in the report, which Business Standard has reviewed.

"After exhaustive deliberations on the issue, the GoM strongly felt that having a multiple tax rate structure for vaccines for different levels of procurement is not feasible," the report said.

Also taking into account that the vaccine is procured mostly (around 90 per cent) by the Central and state governments, which supply it to the people by and large free, any reduction will not have a direct benefit for the people (who are getting it gratis anyway), or the government (as GST paid by the government comes back to it as tax revenue and the states getting 70 per cent share) or the manufacturer.



It was also noted that in accordance with the decision of the GST Council, imports of Covid-19 vaccines for free distribution, even if imported on the basis of payment, has been exempted from basic customs duty and integrated GST till August 31, which can be extended.

Although the GoM has kept the rate unchanged on vaccines, some states' demand to lower it may be practically met after the change in vaccination policy. The reason is that the Centre will now procure 75 per cent of all the vaccines produced in the country and provide them to states for free. However, the private procurement of 25 per cent of vaccines would require a payment of 5 per cent GST.

With regard to medicines, the GoM was of the view that unlike vaccines, the cost of medicines being used in Covid-19 treatment, in a majority of cases, is borne by the patients. Further, the GoM also took note of the fact that certain medicines used in Covid-19 treatment were expensive and hence reduction in GST rates merit due consideration.

The matter of tax rate cut on Covid-19 related goods and equipment was taken up in the council meeting held on May 28. But, the council decision on taxing these items remained unchanged, as the central government opined that the move may not benefit the common man.

However, on Delhi High Court's directive, the Council had allowed full integrated GST (IGST) waiver on import of specified Covid-19 goods such as medical oxygen, oxygen concentrators, etc till August 31, even if done on payment basis for donation purpose. In view of the rising black fungus cases, IGST was also exempted on Amphotericin B, drug to treat fungus.

Since the Council does not arrive on consensus, it had formed GoM with members include-- Gujarat Deputy CM Nitinbhai Patel, Maharashtra Deputy CM Ajit Pawar, Goa Transport Minister Mauvin Godinho, Kerala Finance Minister KN Balagopal, Odisha Finance Minister Niranjan Pujari, Telangana Finance Minister T Harish Rao and UP Finance Minister Suresh Kumar Khanna.

The GoM felt that the creation of domestic capacity in the short and intermediate run is the key to tackle the pandemic crisis. It also analysed the impact of any change in tax rates on the demand and supply sides, eventual impact on the consumers, revenue streams of the Governments and possible long-term implications of such recommendations made on the GST architecture and taxation structure across all sectors of the economy. Further, it was the endeavour of the GoM to arrive at its recommendations through consensus, the report said.

Source : Shrimi Choudhary, Business Standard, 11.06.2021

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Covid-19 vaccine: Time to test Covishield-Covaxin mix for immune response against D variant

Perhaps it is time for our scientists to test whether a mix of Covishield and Covaxin will increase the chances of a more effective immune response against the D variant

The puzzling question that would arise in most minds is as to how a vaccine that produces less antibodies is more protective against breakthrough infection.

Sibling rivalry between Covishield and Covaxin, which flared briefly at the time of their emergency approvals in January 2021, got sparked again recently when Indian researchers shared pre-publication data on vaccine-induced immune response with the media. The study was conducted on 515 healthcare workers (all doctors) in 22 cities in 13 states, during January to May 2021, following their vaccination.

Vast majority of the participants received Covishield, though the smaller number receiving Covaxin is variably reported as 90 and 93 in the report. Participants were

tested for antibodies against the spike protein of the SARS-CoV-2 virus, after the first dose and the second dose of each vaccine. Breakthrough Covid-19 infections were also recorded. After two doses of both vaccines, 95% showed seropositivity for the tested antibodies.

The researchers report that antibodies against the spike protein were higher in those who received Covishield than among those who received Covaxin. They stated that the former group had 10 times higher antibody levels than the latter, after the first dose. After the second dose, the difference was six-fold. The authors state that among those who 'never had Covid', 97.8% of those who received both doses of Covishield were seropositive for antibodies, compared to 79.3% of two-dose Covaxin recipients.

Breakthrough infections were defined as "testing positive for the virus two weeks or more after the second dose". Here, Covaxin recipients were reported to fare better, with 2.2% of that group testing positive, compared to 5.5% in the Covishield group. The small sample size of the Covaxin group yields wide 95% confidence intervals (uncertainty bands) around the point estimates derived from that group. Even if point estimates appear different, overlapping confidence intervals will not permit conclusions of real differences between the groups.

Media reports of this non-peer reviewed report drew a critical comment from a scientist associated with Covaxin, who pointed out that prior Covid was ruled out only by offered history and not by lab testing for virus or baseline antibodies. The implication was that untested individuals may have had asymptomatic Covid infection resulting in heightened immunogenicity following vaccination. If such persons were more among the numerically much larger Covishield group, higher antibody levels would be a result of the combined effect of the infection and vaccination and not the latter alone.

If only the reported point estimates are relied upon, without concern about the wide uncertainty band, explanations have to be sought for the contrasting effects of the two vaccines on potency and protection. The puzzling question that would arise in most minds is as to how a vaccine that produces less antibodies is more protective against breakthrough infection.

Theoretical grounds do exist, to explain. Covishield carries the code for production of the spike protein in the recipient's body, to trigger strong antibodies against that antigen. Other parts of the SARS-CoV-2 virus are not introduced to the body. Covaxin, on the other hand, is an inactivated virus which offers the body's immune system a larger platter of antigens to react against. As the body's immune response is spread wider, antibody production against the spike protein antigen may be less intense. It is the water jet effect versus the shower effect.

For the same reason, of a widespread immune response, Covaxin may offer a better protection against breakthrough infection by variants that have developed mutations against the spike-protein antibody. The umbrella of protection is larger, as other viral antigens too can be targeted by the broad-band immunity elicited by the inactivated whole virion. Variants may evade spike-protein-specific antibodies, which may be more abundant but less effective after Covishield. Real world evidence, provided recently by Public Health England, shows lowered efficacy of spike-protein-specific vaccines against the A and D variants, both of which were circulating in India during the study period. From January to March, the A variant was quite prominent in several parts of India.

The D variant shared the stage with the A variant in March, but has since cornered the limelight. For us to consider whether the seemingly better protection offered by Covaxin against breakthrough infections calls for better studies, with larger sample sizes and genomic testing added where possible. Baseline antibody levels would have helped. However, what matters in the real world is the answer to the question "how well did the vaccine protect against breakthrough infection and severe Covid-19?". Without adequate data to answer that question, any discussion of comparative efficacy will remain frustratingly futile. History of medicine is replete with studies which produced impressive results on surrogate intermediate variables, but failed to impact meaningful clinical outcomes in trials.

Correlates of vaccine protection are not limited to antibodies alone. T-cells play a very important role too, both in early response and storing memory of the antigens they encounter. After the SARS outbreak (2001-3), none of the survivors has antibodies after six years, while memory T-cells were detected in all after 17 years. While antibodies combat viruses in the blood, T-cells provide protection against intracellular viral infections like Covid-19.

Mixing of vaccines for the two shots is also attracting scientific interest. A recent German study, in 26 young persons, observed that a mix of AstraZeneca and Pfizer shots produced 3.9 times higher levels of neutralising

antibodies against Alpha and Beta variants. Perhaps it is time for our scientists to test whether a mix of Covishield and Covaxin will enhance both potency and protection against the D variant. The siblings can then battle the virus together and not each other.

The author, a cardiologist and epidemiologist, is president, Public Health Foundation of India, Views are personal

Source: K Srinath Reddy, Financial Express, 11.06.2021

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Is the global pharma industry unhappy with India's policies?

The world-class Indian vaccine, with several vaccine manufacturers and an open licence, is attractive for several countries, particularly in the developing world. Indian pharma industry will gain immensely and our country will stand out as a nation helping at the time of need. But dominant global pharma companies stand to lose billions of dollars in profits due to the policies followed and stand taken by the Modi government and this is a strong enough reason for them to be unhappy.

The Drugs Controller General of India, on January 3, granted restricted emergency use authorisation (EUA) for two Covid-19 vaccines — Bharat Biotech's Covaxin and Serum Institute of India's Covishield. Covaxin, developed by the Indian Council of Medical Research and National Institute of Virology in collaboration with Bharat Biotech, is India's first indigenous vaccine against Covid-19. Covaxin has now received EUA from a range of countries and is in the process of obtaining it in 60 other countries. This is an important step by the scientific community to fulfill our dream of Atmanirbhar Bharat .

But the real battle on vaccines had begun earlier, when the original proposal submitted by India and South Africa to the TRIPS Council on October 2 emphasised the need for World Trade Organization (WTO) members to work together to ensure that intellectual property rights (IPR) "such as patents, industrial designs, copyright and protection of undisclosed information" do not create barriers to timely access to affordable medical products. A patent waiver would allow any company with the required capacity to start manufacturing the shot, even without an agreement with the original developer.

However, international developers of Covid-19 vaccines such as AstraZeneca, Pfizer and Johnson & Johnson opposed any waiver for their doses, claiming they were capable of producing adequate jabs to meet global demand. Pharmaceutical companies have reported sharp profit gains during the crisis. The industry's biggest lobby group warned that this unprecedented step would undermine the response of companies and compromise safety. India then revised its proposal, to state that patent protections for vaccines be waived for a limited timeframe to address the concerns of the United States, European Union and others that opposed the original proposal.

The Narendra Modi government made this proposal even before India had developed its indigenous vaccine, which it could manufacture and supply globally at a low cost. With India developing its indigenous vaccine, having the largest vaccine manufacturing capacity in the world, along with its stated intention to waive IPR, the threat to the global pharma industry, particularly to the limited number of companies with vaccine patents, became real. This was aggravated with India's Vaccine Maitri initiative.

India has been one of the pioneers for supply of cheap life-saving drugs under the compulsory licensing (CL) and process patent regime. Under CL, for the purpose of combating a health emergency, a WTO member is allowed to override a patent and "license" a domestic manufacturer to produce a global vaccine. But many experts pointed out that since Covid-19 is a global pandemic, the Indian government may not want to exercise its power under Section 92 and 100 of the Patent Act for manufacturing through CL.

The government, in its affidavit to the Supreme Court, said, "It is earnestly urged that any discussion or a mention of exercise of statutory powers either for essential drugs or vaccines having patent issues would have serious, and unintended adverse consequences in the countries efforts on global platform." Currently, the Centre is involved in finding a diplomatic solution, but it had not ruled out invoking the law at a future date.

The best option is domestic manufacturing using an open licensing policy. The government has given permission to several domestic vaccine manufacturers to manufacture Covaxin.

With an indigenously researched and produced vaccine catering to domestic and global demand, our pharma industry will come of age. This will also end the pharma industry's dependence on manufacture and export of generic medicines alone.

The world-class Indian vaccine, with several vaccine manufacturers and an open licence, is attractive for several countries, particularly in the developing world. Indian pharma industry will gain immensely and our country will stand out as a nation helping at the time of need. But dominant global pharma companies stand to lose billions of dollars in profits due to the policies followed and stand taken by the Modi government and this is a strong enough reason for them to be unhappy.

Gopal Krishna Agarwal is national spokesperson of the BJP

The views expressed are personal

Source: Hindustan Times, 11.06.2021

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Mankind Pharma launches drug to treat black fungus

Mankind Pharma on Thursday, June 10, 2021, said it has launched Posaconazole Gastro resistant tablets, used to treat **black fungus**, in the country.

The company has launched the drug under the brand name Posaforce 100.

"As the cases of black fungus are increasing day by day, the product has been launched to fight against this infection. The drug firm always strives to launch affordable medicines with an endeavour to achieve the best quality standards in the pharmaceutical industry," Mankind Pharma said in a statement.

The country has seen more than 12,000 cases of deadly black fungus (mucormycosis), so far with Gujarat, Maharashtra, Andhra Pradesh, Madhya Pradesh and Telangana, accounting for the maximum number of cases.

DCGI nod

Posaconazole has been found to be a safer and effective drug of choice for the management of the disease. The drug has received approval from the Drug Controller General of India (DCGI), the drug maker noted Besides, AIIMS and ICMR have also recommended use of Posaconazole as an effective option for the management of mucormycosis, it added. The antifungal drug with minimal potential for nephrotoxicity and excellent tolerability profile has been cleared by the USFDA. Black fungus commonly occurs in soil, and airborne spores often produce infections.

Life threatening conditions like severe **COVID-19** infection; prolonged immune suppression or reduced immunity, uncontrolled diabetes mellitus or haematological malignancies and even open wounds contamination with Mucorales can lead to this infection.

Source : The Hindu, 10.06.2021

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CSIR-IICT, Suven Pharma ink MoU for covid drugs Molnupiravir, 2-DG

The antiviral drug initially developed to treat influenza is repurposed to suppress the Covid virus transmission within 24 hours, completely.

Suven Pharmaceuticals Ltd, CSIR-Indian Institute of Chemical Technology (IICT) Hyderabad and CSIR-National Institute of Interdisciplinary Science & Technology, Tiruvananthapuram have entered into an MoU for the process technology transfer and manufacturing of the anti-Covid drug, Molnupiravir.

The antiviral drug was initially developed to treat influenza and is repurposed to completely suppress the Covid virus transmission within 24 hours, according to the study recently published in the Journal Nature Microbiology. Thus, the drug could be a game-changer in the mitigation of the SARS-CoV-2 virus.

The synthetic process for Molnupiravir was sourced from CSIR-NIIST, and CSIR-IICT successfully carried out the scale-up process. The complete technology know-how will be transferred and SPL will manufacture and launch in the market as an effective medication for Covid infected patients.

As per the agreement, CSIR IICT also provides the process know-how for manufacturing new anti-Covid drug 2-DG to treat moderately and severely Covid infected patients to reduce their oxygen dependency, according to a release.

Source : The Hindu Business Line, 10.06.2021

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A premium price cap on Covaxin is inexplicable

The wide variation in price ceilings imposed by the government on vaccine doses of various brands for a private market isn't just a mystery, it also stirs dissonance among the discerning

In the flurry of changes made this week to a vaccine policy marked by inconsistencies and flip-flops, India's

new price caps for privately-given covid jabs would qualify as jaw-droppers. Serum Institute of India's facsimile of AstraZeneca's vaccine, Covishield, can be priced no higher than 780 per dose and the Russian Sputnik-V is capped at 1,145, but Bharat Biotech's indigenous Covaxin can sell for up to 1,410 per shot. What explains these differences? In itself, a private market with profit-seekers serving the relatively well-off is welcome. Under the rules, this market can corner no more than a quarter of our vax output, so diversion from our free-dose public effort need not be a worry if it's policed well. And if fat margins made by vax-makers off premium payers fund their expansion plans and enhance supply, then a high-price market would've served its purpose. There is a caveat, though. While a typical market permits pricing that is demand-driven rather than cost-plus, this one features a virtual duopoly in the midst of a pandemic. This is enough to justify price ceilings. Yet, what glares out from all this is Covaxin's cap. It muddles our vaccination programme's implicit message of 'a jab is a jab', mystifies those who are weighing their options, and stirs dissonance among the discerning.

As Covaxin was developed partly with public money, thanks to Bharat Biotech's partnership with the Indian Council of Medical Research, the need to recoup those expenses cannot justify too large an extra charge. Defenders of multiple caps, however, point to a difference in production costs. An adenovirus vaccine like Covishield can be made cheaply at scale, they say, while a formula like Covaxin's that uses an inactivated virus soaks up greater resources, requires stricter control of quality and does not see its per-unit cost slide quite so sharply as output volumes rise. The claim that adenovirus jabs are cheaper to produce is broadly credible. Unfortunately, we do not have the actual cost per dose calculations of either, but it's likely to be a small fraction of what private customers will be asked to pay. The pertinent point, however, is that price caps in this market should not be a function of production costs in the first place, for that would defy the whole rationale of India's better-off paying sums they can easily afford in order to subsidize the rest.

Whether the caps will create variations in the perceptual value of varied vaccines is unclear. Covishield has World Health Organization (WHO) approval and can boast of efficacy data drawn from globally-accredited studies, with a recent clinical trial having shown a reduced impact on the virus's Delta variant. By contrast, Covaxin is yet to get the WHO's nod, and its third-phase clinical results even for the original strain remain under wraps (they will be put out in July, Bharat Biotech has said). An interim report had claimed a ratio of about five placebo-group infections for every infected fully-dosed Covaxin recipient; if the jabbed and unjabbed samples were equal, that would spell efficacy of some 80%. But these numbers were neither published nor peer reviewed. As for Delta, a small study suggested that Covaxin could trigger an immune response against it (though a weaker one than against other variants), but again, it was not conclusive. A recent comparison on that measure has shown Covaxin lagging Covishield, but this work has not yet been put under peer scrutiny either. We await clearer data. Meanwhile, let's hope that our arbitrary pricing norms don't warp market preferences.

Source : Livemint, 10.06.2021

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Setbacks for SII leave world short of Covid-19 shots

The situation Serum now finds itself in a turnaround. In November, Poonawalla said Serum was aiming to have 100 million doses ready in reserve by the end of December, just a quarter of the amount promised.

Around the world, from Bangladesh to Nepal to Rwanda, vulnerable hotspots have been grappling with stalled Covid-19 vaccination programmes as they run out of doses. Many of those shortages can be traced back to a single company: The Serum Institute of India.

The world's largest vaccine maker, Serum was last year named a top supplier of coronavirus shots to Covax, the World Health Organization-backed initiative aimed at securing an equitable global rollout. But the company has been dogged by setbacks, from a ban on exports to a factory fire, which have hampered its ability to fill orders.

Covax has pledged to send shots to some 92 countries, but has so far received only 30 million of the minimum 200 million doses it ordered from Serum. Serum's travails have now become a cautionary tale for becoming over-reliant on one manufacturer.

Other manufacturers have also had trouble meeting targets, yet Serum's shortfalls are particularly consequential because Covax and emerging countries were counting on it so heavily.

The company has been unable to send any shots overseas since April, when the India banned vaccine exports amid the country's devastating second wave. But some of Serum's problems began long before.

Last year, Serum's chief executive officer, Adar Poonawalla, pledged that his vaccine producing colossus would churn out 400 million doses of AstraZeneca Plc's coronavirus shot for low and middle-income countries by the end of 2020. A month into 2021, he said it had manufactured only 70 million shots because the company had been uncertain about when it would receive a license from India and didn't have enough warehouse space.

A string of nations had also entered into direct contracts with Serum and are now racing to find new suppliers. In Nepal, the government says it has received only half of the 2 million shots it ordered directly from Serum. The rest were supposed to arrive by March.

"We are struggling with the shortage of vaccines," said Tara Nath Pokhrel, the director of the family welfare division at Nepal's health ministry.

The decision to choose Serum as a major Covax supplier "was based, largely, on the company's massive production capacity, ability to deliver at low cost and the fact that its vaccine was one of the earliest to gain WHO emergency use listing," said Seth Berkley, chief executive officer at Gavi, the Vaccine Alliance, which has been facilitating Covax.

Berkley says Serum's manufacturing capacity is now expanding. Still, Covax and many developing countries are scrambling to find new sources after Serum said that exports are unlikely to resume until the end of 2021 given the needs of India. Bangladesh too briefly stopped giving out first vaccination doses after Serum's supply shortages.

The situation Serum now finds itself in a turnaround. In November, Poonawalla said Serum was aiming to have 100 million doses ready in reserve by the end of December, just a quarter of the amount promised. In January, he lowered that to 70 million.

Poonawalla said in January that the shortfalls were due to a lack of warehouse space after slower than anticipated regulatory approvals in India. The company filed their application for an emergency license in early December. Over recent months Poonawalla has also cited US policies for some of his company's problems, spearheading complaints against a de-facto American export ban on some vaccine raw materials.

Meanwhile, in January, a fire broke out at one of Serum's plants. The manufacturer at first downplayed its impact, but it led to losses of equipment and delays in putting on additional manufacturing lines, according to a person familiar with the matter.

"Right now I think they are really, really stuck -- that's a major blow to Covax," said Cleo Kontoravdi, a member of Imperial College London's Future Vaccine Manufacturing Research Hub and Vaccine Research Network.

Serum didn't respond to a list of questions.

There have been shortages in India as well. India's initial order sheet in January was parsimonious -- just 11 million shots at first. But as the second wave swept across the demand shot up, and supplies dwindled.

Source : Hindustan Times, 10.06.2021

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Explained: Mixing Covid-19 vaccines

India is considering whether people can be given a mix of different Covid-19 vaccine doses. What can be the merits of such a programme, and what are the concerns? Which other countries are trying this?

India plans to embark soon on an exercise to investigate if it can immunise people using a "mix and match" of different Covid-19 vaccines. This would mean following up one dose of a particular vaccine with a second dose of a different vaccine. In scientific terms, this is called "heterologous" immunisation.

In India, whose vaccination programme currently uses Covishield, Covaxin and Sputnik V, this practice has not been approved yet. Other countries have already been testing this out.

Why mix and match Covid-19 vaccines?

There are various reasons to try this out.

BETTER IMMUNE RESPONSE: Some scientists believe that using a different vaccine for the second dose could potentially boost the immune response against the virus. This may especially be true for viral vector vaccines like Covishield/AstraZeneca, which use a modified and weakened chimpanzee 'adenovirus' (common cold virus) to deliver the genetic code of the SARS-CoV-2 spike protein to the body. Using the same adenovirus could make the vaccine less effective the second or third time around. "The first time, your body is naive not only to the spike protein, but also to the vector which is injected into your body–in the case of Covishield, it would be the chimpanzee adenovirus. So, while you are developing antibodies against the spike protein, you are also inadvertently developing

antibodies against the adenovirus," said Dr Chandrakant Lahariya, a vaccinologist specialising in public policy and health systems.

This is why Sputnik V uses two different adenoviruses to deliver the spike protein's code to our bodies, according to Dr Srinath Reddy, President, Public Health Foundation of India.

MUTATIONS & VARIANTS: Mixing and matching vaccines of different technologies — for example, a viral vector vaccine followed up with an mRNA vaccine like Pfizer's — might encourage our immune system to build a wider response. "They're all ultimately looking at the same target protein here —the spike protein — but presenting that to the immune system in different ways is potentially a great way of actually generating a better and broader immune response," the Oxford Group's Professor Matthew Snape explained during an episode of The Economist Radio's podcast, The Jab, on May 31. Professor Snape is the chief investigator in the group's Com-COV trials to mix and match Covid-19 vaccines.

Such combinations could potentially provide wider protection against certain mutations or variants of the SARS-CoV-2 virus. "Theoretically, there is an advantage of mixing and matching in this situation, because the AstraZeneca vaccine has less efficacy against the Delta variant, as seen from studies in the UK," Dr Reddy said. "If this is true for Covishield in India, then it makes sense that those who received this vaccine in their first dose receive another vaccine that covers a broader platter of antigens as their second dose. In theory, doing so could extend the body's immunity spectrum against more antigens," he said.

SHORTAGES IN SUPPLY: Current Covid vaccine production cannot sufficiently cater to the existing demand, resulting in stock-outs. In parts of India, government vaccination centres for those in the 18-44 age group had closed down due to limited Covishield and Covaxin supplies.

"In the short term, mixing solves your programme problems, because then people don't have to come again and again to get the dose that they are interested in or the vaccine that they got in their first dose," said Dr Gagandeep Kang, leading vaccine expert and Professor at the Wellcome Trust Research Laboratory in Christian Medical College—Vellore's Division of Gastrointestinal Sciences. "If it's a long-term issue, you want to look at what gives you the best results in terms of what is the best protection that you can get," she added.

SAFETY CONCERNS: Countries like Germany, France, the UK and Canada have halted the use of the AstraZeneca vaccine in younger age groups due to concerns of rare blood clots. Here, mixing and matching allows the completion of immunization while ensuring safety.

What are the concerns?

Many unknowns: The Covid-19 vaccines in use have received restricted emergency use permissions in the last six months after fast-tracked trials, and tests to mix and match them began only a few months ago. Questions about how safe it is to mix and match, and whether the approach can prompt a better immune response, are still being answered.

Even the order of mixing and matching needs to be closely studied — would giving Covishield before Covaxin, for instance, prompt a better immune response than giving Covishield as the second dose?

UNTESTED COMBINATIONS: Some vaccines like Covaxin have not even been administered in a mix and match scenario — save for an incident in May where 20 villagers in East Uttar Pradesh were accidentally given Covaxin as their second dose although they received Covishield first.

DIFFERENCES IN VACCINES: International bodies like the Coalition for Epidemic Preparedness Innovations, which is looking into mixing and matching Covid-19 vaccines, have highlighted certain complexities. These include differences in the shelf life of these vaccines, their shipment and storage conditions and contraindications — some vaccines may have more side-effects or may not work as well as others in people with specific ailments.

SIDE EFFECTS: Studies such as the Com-COV trials show that some combinations, like AstraZeneca with Pfizer vaccines, could lead to an increase in side effects.

THE SILVER LINING: As of now, there are no issues theoretically that could make mixing and matching of Covid-19 vaccines a major safety threat. "Our immune systems are capable of handling a lot — we are seeing an increase in minor side-effects with mixing, but do not expect major side effects," said Dr Kang.

Have vaccines been mixed before Covid?

Mixing and matching of vaccines has been tested for decades, especially for viruses like Ebola. However, most combinations had initially been restricted to vaccines that use the same technology.

In India, combinations of rotavirus vaccines have also been used and tested out. "For the last three years, there has been a study looking at combining two rotavirus vaccines… That was a mix and match of a monovalent and a multivalent vaccine," said Dr Kang. "All the rotavirus vaccines are live attenuated vaccines, but the two vaccines used in the Indian programme are different in that one is a pentavalent vaccine based on a bovine rotavirus and the other is a monovalent vaccine based on a human rotavirus."

Where has mixing of Covid-19 vaccines been tried?

Most mix-and-match tests currently include the AstraZeneca and mRNA vaccines.

Canada, the UK and countries in the EU have offered their younger population the Pfizer or Moderna vaccine as an alternative to AstraZeneca. Spain and South Korea have also been looking into a mix and match of these vaccines.

The UK's Com-COV trials are also studying a mix and match of Moderna's mRNA vaccine and Novavax's protein subunit vaccine and results are expected by August, Professor Snape told The Economist.

Russia and China, too, are looking at a mix and match of other vaccines. Russia, for instance, has been planning on testing a combination of the AstraZeneca and Sputnik V vaccines.

In the US, the Centers for Disease Control in January allowed a mix and match of the Pfizer and Moderna vaccines — both mRNA jabs — under "exceptional" circumstances.

What could set India apart?

The government expects seven or eight Covid-19 vaccines made using vastly different technologies — viral vector, mRNA, DNA and recombinant protein — to be available by December. This gives India an opportunity to test combinations not tried globally. With some of the upcoming vaccines expected to be cheaper and easier to mass manufacture, successful combinations of these vaccines could especially be useful for low-and middle-income countries struggling to get sufficient supplies for standard vaccinations.

Source: Indian Express, 10.06.2021

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Aurobindo installs oxygen plant in Vizag hospital

Hyderabad: Hyderabad-based Aurobindo Pharma has erected an oxygen plant with 0.75 tons per day capacity at MB hospitals in Arilova locality of Visakhapatnam. This initiative is part of Aurobindo pharma's CSR activity to support government's efforts to fight against Covid. The 100 bed hospital with 40 ICU beds is one of the 22 listed hospitals in the Vizag district to treat Covid patients.

"Aurobindo Pharma through its philanthropic arm Aurobindo Foundation has spent Rs 1 crore on procurement of machinery, equipment and converting the nitrogen plant into an oxygen generating plant," Raja Reddy, GM admin said. The equipment and purity certificate are formally handed over to the hospital authorities by the Aurobindo pharma team led by Vice President Suresh Raman on Tuesday in presence of District nodal officer KMP Sarathi. Dr Vishnu Prasad, AVP Aurobindo, Demudu participated.

Amidst the severity of the Covid second wave, the demand for medical oxygen is growing phenomenally across the country. "Aurobindo Pharma through the foundation has taken various measures to support government hospitals across AP and Telangana to meet the demand for medical oxygen," K Nithyananda Reddy Aurobindo Pharma Vice-Chairman and foundation director said. Foundation has donated 100 oxygen concentrators worth Rs 1 crore to the hospitals in Nellore, Srikakulam, and Vizianagaram districts last month. The foundation donated Rs 10 lakh to Anakapalli hospital to increase the number of oxygen beds.

Source : Hans India, 10.06.2021

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Interim data from study supports Favipiravir's safety, effectiveness: Glenmark

Drug firm **Glenmark Pharmaceuticals** on Tuesday said interim data from its post marketing surveillance study on anti-viral drug **favipiravir** in India supports its safety and effectiveness in real world settings with no new safety concerns for COVID-19 patients.

The study, commenced in July 2020, aimed to evaluate safety and efficacy of favipiravir in mild to moderate COVID-19 patients. As on date, a total of 1,083 patients have been enrolled in the prospective, open label, multicenter,

single arm study, Glenmark said in a regulatory filing. A total of 13 sites across Mumbai, Bengaluru, Hyderabad, Nashik, Nagpur and Trivandrum took part in the study, it added.

Interim data presented by the company to the regulator reveals no new safety signals or concerns with the use of favipiravir and already-known side effects which were found to be mild in nature, the filing said.

The time to fever resolution was seen on day 3, while two-thirds of the patients achieved clinical cure on day 7.

Source : Economic Times, 09.06.2021

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Covaxin recipients are being regarded as unvaccinated in many countries

Corporate executives and students who were given the Covaxin jab are facing restrictions when travelling abroad as the developer of India's only indigenously developed covid vaccine is yet to secure approval from the World Health Organization (WHO).

Without the WHO approval, many countries consider even those who have taken both doses of Bharat Biotech's Covaxin jab as unvaccinated.

Countries such as Saudi Arabia, the UK and US are asking travellers vaccinated with Covaxin to undergo lengthy quarantine procedures until they get a WHO-approved vaccine shot.

While healthcare professionals working in Saudi Arabia are exempted from travel restrictions, the Saudi government's covid app, Tawwakalna, which also works as a health passport in the country, only recognizes vaccines made by Pfizer, AstraZeneca and other jabs approved by the WHO. "Those who have taken Covaxin are considered unvaccinated as per government rules and have to undergo mandatory institutional quarantine and testing," said Srivatsan Sridhar, head of transformation at Aster Sanad Hospital, Saudi Arabia.

As countries worldwide open up non-essential travel, lifting travel bans, many of them are only allowing fully vaccinated individuals to enter their country. These measures are inconveniencing students and professionals who have to travel abroad for work or studies.

"A few students who took their first shot of Covaxin and are expected to start their international studies have approached us saying they are ready to take the risk and get a mixed vaccine dose. We have refused such requests," said Hiren Ambegaokar, CEO of Surya Hospitals. Ambegaokar said his hospital has also received similar queries from executives who took Covaxin and are planning to visit the UK and US. These executives now face the prospect of a 14-day quarantine though they are fully vaccinated, he added. The choice for them is either quarantine or get vaccinated again.

"Covaxin uses one of the oldest vaccine technologies but, unfortunately, they have not cleared phase 3 clinical trial. Until the manufacturers get the WHO approval, this status is going to remain," Ambegaokar explained.

Saudi, the European Union, UK and Israel are among nations that have formally initiated the concept of vaccine passports that considers those who have received two doses of vaccines approved by these countries or the WHO being "immune" to covid. Currently, AstraZeneca (including the version made by Serum Institute of India), Pfizer, Moderna, Johnson & Johnson, and Sinovac have received WHO's emergency approval.

Bharat Biotech's Covaxin is yet to publish its phase 3 trial data. The company said it expects WHO approval in September.

Out of the 230 million doses of covid vaccines that have been given in India, nearly 30 million were Covaxin. But going by the norms of travel passports, those who have received even 2 doses of Covaxin will be considered "unvaccinated". An email sent to Bharat Biotech seeking comment remained unanswered.

The EU last month said it will announce a 'Digital Green Passport' that will allow entry of those who have received the last recommended dose of a vaccine that received marketing authorization in the EU or by WHO at least 14 days before arrival. This month, the G7 countries will formally put in action a framework for vaccine passports. India's health minister has opposed the concept of a vaccine passport as only those who received Covishield (made by Serum Institute) will be considered as vaccinated.

Several private hospitals are holding special vaccination camps for people who are expected to undertake travel. These include students, health workers and sportspeople going for the Tokyo Olympics. However, looking at travel requirements, the demand for Covaxin for these categories

of people is extremely low, said medical professionals who were undertaking vaccination for these groups.

Source: Divya Rajagopal, Hindustan Times, 09.06.2021

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Explained: The new drug for Alzheimer's disease

USFDA has approved the first new drug for Alzheimer's disease in two decades. While it raises hope, it's costly, and not a cure — it seeks to slow progression. Dementia, including Alzheimer's, affects 1 in 27 Indians above 60 years.

A new drug for treatment of Alzheimer's disease holds promise, but comes with several caveats. For one thing, it is not a cure, but is aimed at slowing down cognitive decline.

Aducanumab, from the company Biogen, has been approved by the US Food and Drug Administration (FDA) — the first new medication for Alzheimer's to get **FDA approval in nearly two decades**.

What is Alzheimer's disease?

Dementia is an umbrella term for a range of conditions that involve a loss of cognitive functioning. Alzheimer's dementia is the most common type and involves plaques and tangles forming in the brain. Forgetfulness and memory problems are often early symptoms, but as the illness progresses, patients tend to become confused, may lose their way around familiar places, and have difficulties with planning and completing simple tasks. Dr Rajas Deshpande, neurologist at Lilavati Hospital, Mumbai, said the disease is basically an accelerated ageing of certain neurons in the brain that are concerned with storage and processing of memory.

According to World Health Organization (WHO) estimates for 2017, dementia affects approximately 50 million people worldwide, a number that is projected to grow to 82 million by 2030. In India, it is estimated that 5.3 million people (1 in 27) above the age of 60 have dementia in 2020, according to the Dementia in India 2020 report published by the Alzheimer's and Related Disorders Society of India. This is projected to rise to 7.6 million by 2030.

How does the new drug work?

The hallmark of Alzheimer's disease is the accumulation of the debris caused by the breakdown of neurons in the brain, leading to plaque formation. The drug aducanumab, with brand name Aduhelm, is a monoclonal antibody that is designed to reduce the presence of amyloid beta, a protein that forms plaques in the brain.

Aduhelm (aducanumab) aims at altering the course of the disease by slowing the deterioration of brain function.

"The process of regaining memory has not been proven. What has been shown is that it reduces plaque formation," Dr Deshpande said.

How expensive is it?

The company has said the average wholesale cost would be $56,000 (over Rs 40 lakh) per year. Experts, however, said it would not be before a year or two before the drug is available in India. "There are some hyped medicines and it could be possible that when tried on the ground they may not be useful. Still, we are in a desperate situation and hope the drug is useful," Dr Deshpande said.

The drug is to be given as a monthly intravenous infusion. In clinical trials, some patients given the highest dose of the drug experienced brain swelling and had to be monitored. Headache is also a reported side effect of the drug.

How promising is it?

Since there is no treatment so far, the drug that can slow down the process holds much promise and is a ray of hope, said Dr Amit Dias, Assistant Professor, Department of Preventive Medicine, Goa Medical College, and a member of Alzheimer's and Related Society of India. "The drugs we have so far only attempted to improve the function by acting at the level of neurotransmitters," Dr Dias said.

Most doctors agree that the pathophysiology of Alzheimer's disease has not been completely understood yet. Since this is a neuro-degenerative process, there is need for solid proof that something really works to halt it. Hence the process of drug discovery has been slow.

How much is known about its efficacy?

The drug was tested in patients at the earliest stages of Alzheimer's before the disease had a major impact in their ability to care for themselves. It was not tested in people who had progressed to moderate dementia – a state in which the patients lose the ability to care for and feed themselves.

Despite not enough evidence, the drug was approved by the FDA under narrow clinical circumstances. The FDA has asked Biogen to conduct a new trial. It is for people with early-stage Alzheimer's who have had a PET scan confirming the presence of beta-amyloid in their brain.

"It is a novel drug that is designed to slow the progression of Alzheimer's and not a cure. Still, trial results are not convincing," said Dr Manoj Hunnur, Mumbai-based neurologist.

"The development of this drug has been going on for several years with several trials having been conducted and a marginal benefit has been shown in terms of reducing the amyloid load in the early stages of the disease. It is to be noted that these trials were conducted on patients who were in the early stages of the disease," a researcher from the Centre for Brain Research, Indian Institute of Science, Bengaluru told The Indian Express.

"No studies on this drug have been done in India. Considering the fact that the research on use of antibodies as a potential treatment for Alzheimer's has been going on for nearly two decades, there are benefits and drawbacks. It remains to be seen how this drug performs in the phase 4 clinical trials that have been proposed."

How is Alzheimer's currently managed in India?

While there is slow but growing recognition that dementia is a major public health problem, doctors say there are low acceptance levels among families. "A lot of time is spent refuting the problem and taking multiple opinions till such time that the patient worsens and then is taken to the neurologist," said Dr Deshpande.

Sometimes there is no sympathy about the patient not being able to remember anything and their condition is attributed to mental weakness or depression. Once diagnosed after ruling out treatable causes of memory loss, there are usually four types of medications, including blood thinners for vascular blockages, and memory enhancing medicines (which do not increase memory power) to increase conduction between neurons.

Some patients do not tolerate some drugs due to side effects, and these have to be given cautiously as a low dose. There are other medicines that may cause a change in pulse rate and have to be given carefully, Dr Deshpande said.

Source : Anuradha Mascarenhas, The Indian Express, 09.06.2021

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Pfizer, Moderna Vaccines Cut Infection Risk By 91%: US CDC

Taking two doses of the Pfizer-BioNTech and Moderna's mRNA-based vaccines, authorised by the Food and Drug Administration, can reduce the risk of coronavirus infection by 91 per cent, according to a new study by the US Centers for Disease Control and Prevention (CDC).

Even a single dose of the mRNA vaccines can reduce the risk of infection by 81 per cent. These estimates included symptomatic and asymptomatic infections.

"Covid-19 vaccines are a critical tool in overcoming this pandemic," said CDC Director Rochelle P Walensky.

"Findings from the extended timeframe of this study add to accumulating evidence that mRNA Covid-19 vaccines are effective and should prevent most infections -- but that fully vaccinated people who still get Covid-19 are likely to have milder, shorter illness and appear to be less likely to spread the virus to others. These benefits are another important reason to get vaccinated," Walensky added.

The study also showed that mRNA vaccination benefits people who get Covid-19 despite being fully vaccinated (14 or more days after dose 2) or partially vaccinated (14 or more days after dose 1 to 13 days after dose 2).

Fully or partially vaccinated people who developed Covid-19 spent on average six fewer total days sick and two fewer days sick in bed. They also had about a 60 per cent lower risk of developing symptoms, like fever or chills, compared to those who were unvaccinated. Some study participants infected with SARS-CoV-2 did not develop symptoms.

People who were fully or partially vaccinated and then got Covid-19 had 40 per cent less detectable virus in their nose (that is, a lower viral load), and the virus was detected for six fewer days (that is, viral shedding) compared to those who were unvaccinated when infected. This means they were also less likely to spread the virus to others.

In addition, people who were partially or fully vaccinated were 66 per cent less likely to test positive for SARS-CoV-2 infection for more than one week compared to those who were unvaccinated.

While these indicators are not a direct measure of a person's ability to spread the virus, they have been correlated with reduced spread of other viruses, such as varicella and influenza, the CDC said.

For the study, 3,975 participants completed weekly SARS-CoV-2 testing for 17 consecutive weeks (from December 13, 2020 to April 10, 2021) in eight US locations.

Participants self-collected nasal swabs that were laboratory tested for SARS-CoV-2. If the tests came back positive, the specimens were further tested to determine the amount of viral load and viral shedding.

Source : Ahmedabad Mirror, 08.06.2021

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Efficacy of Covaxin, Covishield, Sputnik V more or less equivalent

Data available till now shows clearly that efficacy of all vaccines -- whether Covaxin, Covishield or Sputnik V -- are more or less equivalent, AIIMS Director Randeep Guleria said amid rumours about differentiated abilities of Covid-19 vaccines available in India in terms of production of antibodies or higher seropositivity rate.

"We should not hence say take this vaccine or that vaccine, whichever vaccine is available in your area, please go ahead and get yourself vaccinated so that you and your family are safe," Guleria said while addressing various doubts of people regarding Covid-19 vaccines.

Responding to commonly raised question about enough antibodies after getting vaccinated, Guleria said it is important to understand that we should not judge the efficacy of vaccines only by the amount of antibodies getting generated. The AIIMS Director said that vaccines give many types of protection such as through antibodies, cell-mediated immunity and memory cells (which generate more antibodies when we get infected).

Moreover, Guleria said, the efficacy results which have come so far are based on trial studies, where the study design of each trial is somewhat different.

Source : Hans News Service, 09.06.2021

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Govt panel finds SII's quoted price for inactivated polio vaccine too high, to request health minister to negotiate with firm

New Delhi, Jun 8 (PTI) Emerging as the lowest bidder, Serum Institute of India's (SII) quoted price for each dose of inactivated polio vaccine to be procured under the routine immunization programme is more than double the last purchase rate following which a government purchase committee has decided to request the Union health minister to negotiate the price with the firm.

Pune-based SII has quoted Rs 188 per dose of the vaccine excluding taxes for supplying 180 lakh doses which translates into an increase of 106.65 per cent in the price, official sources said Tuesday.

According to them, meetings of the Integrated Purchase Committee (IPC) was held under the chairmanship of Director General of Health Services (DGHS) on May 28, 31 and June 1 for procurement of 180 lakh doses of IPV (Inactivated Polio Vaccine) for 2021-22 under Routine Immunization Programme.

The IPC found that the lowest price quoted by SII is considerably higher than the last purchase price of Rs 91 per dose excluding taxes and recommended for negotiation with the firm.

The IPC meeting was reconvened on May 31 and the committee asked the representative of SII for justification of price increase.

'The representative of the firm informed that they have participated in IPV tender for the first time and they have already quoted the best possible price of Rs 188.00+ taxes per dose and it is less than UNICEF price,' a source privy to the development said.

The IPC asked the firm to revisit its quoted price following which in a communique to the Union health ministry on May 31, Prakash Kumar Singh, director, Government and Regulatory Affairs at SII said they will not be able to reduce the quoted price and requested the ministry to place order at the earliest so that they can plan the delivery schedule.

The next IPC meeting was held on June 1.

'IPC noted that the firm has not agreed to reduce its quoted price.

'Considering all the facts, the IPC noted that an increase of 106.65 per cent is very high and considering the urgency of this vaccine, decided to request health minister for negotiating with the firm at a higher level,' the source said.

Source : PTI, 08.06.2021

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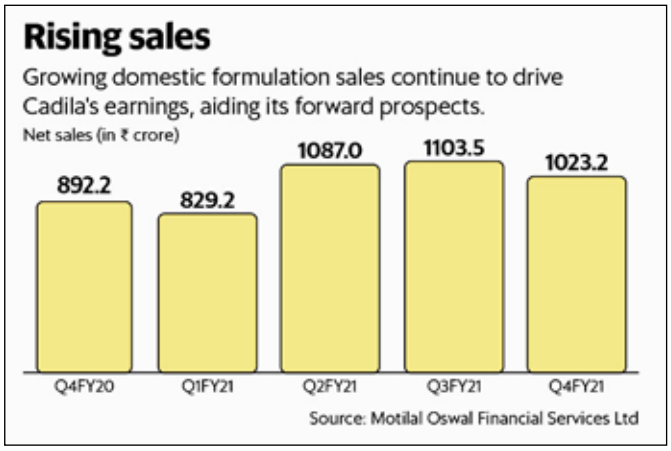
Upcoming Covid portfolio a shot in the arm for Cadila

The Cadila Healthcare Ltd stock has been on investors' radar screens since the company started research and development for covid-19 vaccine and related products. Analysts are of the view that vaccine sales could provide a significant shot in the arm to the company's domestic formulation segment. "The vaccine-related upside is the potential trigger in the near term and is yet to be captured in earnings," analysts at Motilal Oswal Financial Services Ltd said in a report.

Analysts estimate that the company has the capacity to manufacture 10 million doses a month, which can be scaled up to 25-30 million. According to analysts at HDFC Securities Ltd, the covid-19 products further improve the outlook of the company's India business.



Rising sales

"The contribution of covid-19 was negligible in Q4 but it is likely to be significant in Q1FY22. We factor in 13% CAGR for India business for the next two years," said the HDFC report. CAGR is short for compound annual growth rate.

Meanwhile, the company reported decent earnings in the March quarter. Performance was largely driven by strong growth in the Indian market, which negated the impact of weak sales in the US. In Q4FY21, the India business including consumer health and animal health portfolio, which contributed almost half to its overall sales, grew 18% on a year-on-year (y-o-y) basis.

The speciality portfolio also posted robust sales in the March quarter, which helped improve domestic formulations sales by 14.7% y-o-y.

The covid-19 treatment drugs did not contribute much during the March quarter. Analysts said the company's pipeline of novel molecules has the ability to further drive its sales growth.

As far as the company's US business is concerned, it faces intense competition. That, along with weak season for flu and lower-than-expected contributions from its key product Asacol HD, which is used to treat ulcerative colitis, impacted Cadila's Q4 performance.

It should be noted that the company plans to launch 30-40 products in the US to provide growth a fillip in that market.

Apart from that, the company is also developing a range of products in transdermal and hormonal therapy. That said, the approval and launch of these products depends on the regulatory resolution of issues pertaining to its Moraiya manufacturing facility in Gujarat.

Source: Ujjval Jauhari, HT Mint, 09.06.2021

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India pitches for early start to talks on patent waiver for Covid drugs

Members have agreed to discuss both the proposals; the one suggested by India and South Africa and another by the European Union, which backs use of flexibilities within existing frameworks instead of new ones.

In a significant breakthrough, World Trade Organization (WTO) members on Wednesday agreed to engage in a text-based discussion on the proposal for waiver intellectual protection rights for Covid medication.

Members have agreed to discuss both the proposals; the one suggested by India and South Africa and another by the European Union, which backs use of flexibilities within existing frameworks instead of new ones.

India will press for starting text-based discussions on waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for Covid19 medication as soon as mid-June.

"None of the naysayers said no to moving on to text-based negotiations. The TRIPS Council thus, agreed with consensus to go ahead with text based negotiations on our TRIPS Waiver proposal," said an official. The chair of the TRIPS Council concluded that there is no objection from any member to start text-based negotiations.

"Further, the Chair in his conclusion stated, that with no objection from any member to take the deliberations to another level that is the text based negotiations, he will start the consultations process, in this regard he called for open ended TRIPs Council plenary meeting on June 17 to move forward," the official said.

India, which had moved the proposal jointly with South Africa, is keen for early talks.

"The deadline we had suggested was the end of July to conclude negotiations. Chair has suggested reaching a conclusion by July 21, when the General Council is scheduled to meet," the official said, adding that in the meantime, India will engage with all members on the line-by-line text negotiations.

Over the last two days 48 members, including the EU, reiterated their positions and well-known differences but expressed their willingness to engage in a discussion based on the two proposals.

Intense negotiations are expected in the next few weeks as though diverging views persist, the TRIPS Council chair said he did not hear any objections to take the deliberations to another level by engaging in a text-based process.

Another official said the text-based process to find common ground on the intellectual property issue will start from mid of next week and all the proposals including the one by India and South Africa, the EU and any new ones will be taken up.

Members speak: To start with, WTO members will have an informal meeting on June 17 before they move forward in a substantive way and to agree on the needed steps to be taken leading up to the General Council meeting on July 21-22.

South Africa said the revised version signals health products and technologies in general, as the prevention treatment or containment of Covid-19 will not be attained only through vaccines.

On the issue of the proposed three-year duration of the waiver, India stressed it considers the uncertainties surrounding the pandemic, with new variant outbreaks, while also bringing out the temporary nature of the waiver.

"India emphasised that the proponents have no intention of continuing the waiver for an indefinite period and no intention of denying benefits to rights holders," said a Geneva-based official.

Source: Kirtika Suneja, Economic Times, 10.06.2021

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US confirms lifting of ban on vaccine raw material supplies

The US on Wednesday informed India it has lifted all restrictions on exports of materials and components for production of Covid-19 vaccines, raising hopes of supply of raw material sought by New Delhi.

The US on Wednesday informed India it has lifted all restrictions on exports of materials and components for production of Covid-19 vaccines, raising hopes of supply of raw material sought by New Delhi.

This was among a wide range of issues discussed when Daniel B Smith, charge d'affaires at the US Mission to India, called on foreign secretary Harsh Vardhan Shringla here, people aware of the development told ET.

The two officials discussed the impact of the Joe Biden administration's recent decision to remove Defence Production Act priority ratings on AstraZeneca Novavax and Sanofi vaccines.

The move would let companies take their own decision on to whom they want to sell their vaccines. Also, US-based companies that supply these vaccine manufacturers can now make their own decisions on which orders to fulfil first.

The issue of supply of vaccine raw material had figured prominently during external affairs minister S Jaishankar's USA trip last month.

Smith has informed Shringla that supply of vaccine raw materials to India will now be left to devices of the market and that some shortage is being felt because of problems in global supply chains, sources said.

Smith also said the US is working out details of the 25-million first tranche of government-to-government supply of vaccines.

This was the first high level Indo-US meeting since the Biden administration announced to send 25 million doses abroad including seven million for South and Southeast

Asia including India. US NSA had mentioned that India is a priority.

Shringla on his part raised the issue of visas, including student visas, to the USA. It is understood that Smith informed that the USA side is examining opening appointments for students as early as possible to enable timely travel coinciding with university opening.

Following the meeting, an external affairs ministry spokesperson tweeted, "Foreign Secretary @harshvshringla had a productive meeting today with US Acting Ambassador Daniel B. Smith @USAmbIndia about India-US relations, regional issues & cooperation in the UN; also discussed Covid-19 situation, supply of vaccines and cooperation in combating the pandemic.

Source: Dipanjan Roy Chaudhury, Economic Times, 10.06.2021

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Single dose protects well against infection, hospitalisation: Study

"Vaccines are working well! Good against infection (in healthcare settings where there is a high risk of transmission), great against severe disease," Gagandeep Kang, professor of microbiology at CMC Vellore, said. "Next step is to study protection against variants," she added.

The study suggested that the risk of infection among fully vaccinated healthcare workers was significantly lower than those unvaccinated.

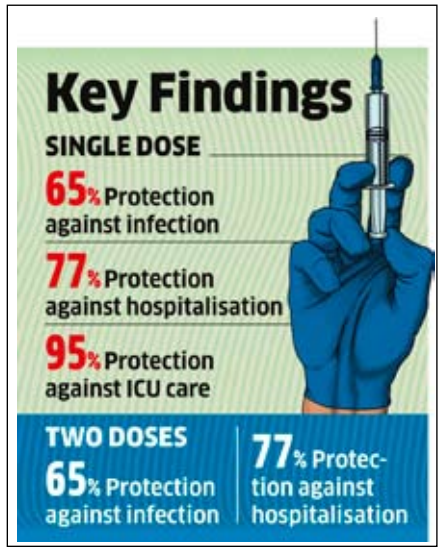
A new study has found that even a single dose of the Covid-19 vaccine gives high protection against infection and hospitalisation even among healthcare workers who are at high risk.

According to the study among healthcare workers at Christian Medical College (CMC) Vellore, a single dose offered 61% protection against infection and 70% protection against hospitalisation.

Among 1,878 healthcare workers who received one dose, 200 (10.6%) were infected, and 22 (1.2%) needed hospitalisation. In comparison, among the 7,080 healthcare workers who received two doses, 679 (9.6%) were infected, and 64 (0.9%) needed hospitalisation.

"Vaccines are working well! Good against infection (in healthcare settings where there is a high risk of transmission), great against severe disease," Gagandeep Kang, professor of microbiology at CMC Vellore, tweeted. "Next step is to study protection against variants," she added.

As per the study, not a single death was reported among those who got vaccinated. "The only staff member who died since the beginning of the pandemic had multiple comorbidities and had not taken the vaccine," it said. The study has been posted on a preprint server and yet to be peer-reviewed.



In the case of those needing oxygen care and ICU admission, the protection offered by a single dose was 94% and 95%, respectively. Among the 7,080 healthcare workers who received two doses of the vaccine, it offered 65% protection against infection, 77% protection against hospitalisation, 92% protection against the need for oxygen, and 94% protection from the need for ICU care.

In total, 8,991 (84.8%) healthcare workers were vaccinated between January 21 and April 30, 2021. Out of this, nearly 8,400 received Covishield. The experts studied the incidence of infection and hospitalisation between February 21 and May 19.

The study suggested that the risk of infection among fully vaccinated healthcare workers was significantly lower than those unvaccinated.

Among the fully vaccinated individuals, infection was seen on average 47 days after the second dose.

Soruce: Teena Thacker, Economic Times, 12.06.2021

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Study on antibody levels produced by vaccines flawed, says Bharat Biotech

Hyderabad-based Bharat Biotech said on Wednesday that a report on a recent study that compared the level of antibodies produced by Covishield and Covaxin after their first and second doses contained "flaws."

The company also said it will be conducting phase-4 trials of Covaxin. Phase-4 trials are conducted after regulatory approvals to monitor long-term safety and effectiveness of drugs in real-world usage situations. The recent comparative study was conducted by independent experts, including 29 doctors from across India.

As reported by ET on Monday, it found that both vaccines — Covishield and Covaxin — work well.

However, it appeared that Covishield may have the ability to produce more antibodies and a higher seropositivity rate amongst recepients.

Bharat Biotech told news agency ANI that it was not a peer-reviewed publication, nor a statistically and scientifically designed study. "The study design and conduct reflect an ad-hoc analysis, rather than predetermined hypothesis. Further, the study was not registered on the CTRI website, nor approved by CDSCO and SEC," it said.

As reported by ET, it found that both vaccines - Covishield and Covaxin - work well.

AK Singh, the lead author of the study, said that he was "appalled" at the company's reaction. "I was sensitive enough not to say that Covaxin evoked a timid antibody response after the first dose. It's not mandatory to register at CTRI for a cross-sectional study nor any prior statistical calculation is required," he told ET.

The company said that once the data from the final analysis of phase-3 studies are available, the company will apply for full licensure for Covaxin. Some experts, on the other hand, said that the study gains significance in the absence of published phase-3 data for Covaxin. Covishield has already published phase-3 data. A public health expert said that an attack by Bharat Biotech is dangerous, and the company "should focus on the integrity of their own research efforts and leave it to independent scientists to critique both their own and others' research".

Source: Teena Thacker, Economic Times, 10.06.2021

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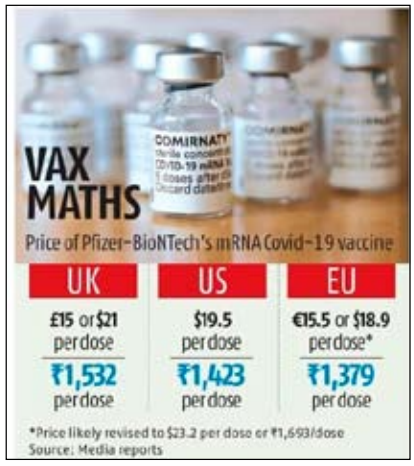
Pfizer's Covid-19 vaccine may cost less than $10 a dose in India

Govt likely to give partial indemnity to company

US pharmaceutical major Pfizer may price its mRNA-based Covid-19 vaccine, co-developed by BioNTech, below $10 (about Rs 730) a dose in India, sources close to the development indicated. This could be the lowest price of the vaccine globally, and almost half the price in developed markets like the US, UK, and EU.

"It is a single-digit price per dose," a source said. "This is a not-for-profit price for the government's immunisation programme."



Pfizer is now in discussions with the Indian government for supplying the vaccine. "Pfizer has offered to make the required doses of our Covid-19 vaccine available at a not-for-profit price for India, as for all low and lower-middle income countries, once we have the necessary regulatory clearance. Currently, as our discussions with the government of India are ongoing and confidential, we cannot provide further details," a Pfizer spokesperson said.

The Pfizer-BioNTech vaccine is sold in the US for $19.5 (Rs 1,423) a dose, while in the UK it costs around $21 (Rs 1,532). Its price in the EU was around $18.9 a dose earlier, but price negotiations are on for a higher price of $23.2 (Rs 1,693) a dose. The Indian price, thus, could be the lowest.

The price of Sputnik V, the Russian Covid-19 vaccine, in India is Rs 995 a dose (inclusive of taxes) in the private market, while Bharat Biotech's Covaxin and Oxford-AstraZeneca's Covishield, made by Serum

Institute of India, are priced at Rs 1,200 and Rs 600 a dose, respectively, when sold to private hospitals. The Centre procures Covishield and Covaxin at Rs 150 a dose at the moment.

Meanwhile, discussions on indemnity are underway between the vaccine maker and the Indian government. The US has provided legal protection to manufacturers like Pfizer and Moderna, except in the cases of "wilful misconduct" by companies. So far, Pfizer has got indemnity (protection against legal suits in the event of any adverse events following vaccination) in the countries where it has launched its Covid-19 vaccine.

"Pfizer seeks indemnity and liability protections in all of our agreements, including the COVAX facility. We seek the same kind of indemnity and liability protections in all of the countries that have asked to purchase our vaccine, consistent with the local applicable laws to create the appropriate risk protection for all involved," a company spokesperson clarified.

Sources close to the discussions told Business Standard that the government was likely to give a partial indemnity to the company.

"Partial indemnity would imply that the company would disclose the known side-effects or contra-indications of its Covid-19 vaccine. However, against any side-effect that is not yet known to the company and it cannot warn against, they would not be liable to be tried in court of law," the source cited above said.

Typically, indemnification is a standard clause in vaccine supply arrangements entered by governments around the world, said Sidharrth Shankar, partner, J Sagar Associates, a law firm.

"Grant of indemnity has an impact on the purchase price of the vaccine offered by the manufacturer. Most countries have kept the terms of the agreements entered with vaccine manufacturers confidential. However, a typical indemnity agreement will have clauses such as representations and warranties, for instance, regarding the government's ability to fulfil the indemnity obligations, ratification of the agreement by the legislature of the receiving country, intellectual property, confidentiality, and protection from liability in case of delayed delivery of vaccines," Shankar said.

None of the domestic vaccine manufacturers has been granted an indemnity by the Indian government till now. "If the government agrees to give an indemnity to select manufacturers, it will open flood gates for other manufacturers to seek similar terms," Shankar said.

Moreover, indemnity clauses usually mention the governing law under which one can be tried -– that is the jurisdiction of the court of law. In the case of US vaccine makers, they are likely to insist to be tried in US courts if the need arises, said industry insiders.

Source: Sohini Das, Business Standard, 10.06.2021

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Hyderabad's Rockwell collaborates with Dr Reddy's Lab for Sputnik V rollout

Rockwell Industries has got orders for 750 Covid19 vaccine freezers from hospitals and institutions.

Hyderabad-based Rockwell Industries, a commercial cold chain appliances player, is partnering with Dr Reddy's Laboratories (DRL) to enable the storage of Sputnik V vaccine in India through their vaccine freezers. Sputnik V was launched in a limited pilot on May 14 and a commercial launch is expected in June.

Rockwell Industries has got orders for 750 Covid19 vaccine freezers from hospitals and institutions. It is now set to start exports of these freezers to various countries including Japan.

The covid19 vaccines are temperature sensitive, hence require the precise temperature to maintain its potency. "The vaccine freezer plays a very critical role in the safety of vaccines and its potency.

Sputnik V vaccine made available in India through Dr. Reddy's requires a temperature range of minus -18 degrees Celsius, to keep the vaccine stable and potent," Rockwell said.

It added that Rockwell has researched on developing vaccine freezers according to WHO PQS (World Health Organisation- Performance, Quality and Safety) standard and after three years of R&D efforts, the final product was tested in Denmark at a WHO authorized laboratory. Two different sizes of this freezer were certified.

"The freezer can handle various harsh usage conditions in rural locations too and maintain desired temperature range, thus breaking the vaccine cold chain hurdle," Rockwell claimed in a statement.

Alok Gupta, MD of Rockwell Industries, said, "Our technology ensures that Sputnik V's storage management at vaccine centres meets the stringent refrigeration standards set forth by Sputnik V manufacturers."

Rockwell is working closely with DRL to develop and provide wireless internet of things (IOT) based controllers and data loggers which can give access to real time data of temperature and performance for the vaccine freezers, Prateek Gupta, director, Rockwell said. He added they can make around 1000 machines per day.

The company further added that hospitals like Apollo, Omega, AIG Hospitals are already using these vaccine freezers for vaccine storage. "We are in the process of exporting our Vaccine Freezers to various developed countries including an initial pilot deal with Japan," Gupta added.

Rockwell has two manufacturing sites in Hyderabad with an annual capacity to make 400,000 units.

According to recent data from the WHO, due to the lack of temperature control or continuous cold chain during vaccine transportation, 5-20 percent of vaccines lose their potency.

Source: Sohini Das, Business Standard, 09.06.2021

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Demand for Ayurvedic stress busters surges amid second wave of Covid-19

With most Indians confined to their houses amid Covid-19, demand for stress reduction merchandise has surged particularly through the second wave of the pandemic.

As per knowledge from main corporations comparable to Emami, Himalaya Drug Company and Dabur, gross sales of balms, anti-stress merchandise and herbs comparable to Ashwagandha grew 50-80% year on-year up to now three months, clocking their highest ever income typically.

For occasion, Zandu Balm, a class chief, doubled gross sales led by 4 to 5 occasions progress in northern India whereas gross sales in Delhi-National Capital Region alone expanded 20 occasions throughout April-May, typically thought-about an low season for the product.

"If sanitisers and immunity boosting products were the hero categories in the first wave, balms and stress related products are for the second wave," mentioned Emami Ltd director Mohan Goenka. He mentioned Zandu Balm clocked its highest ever gross sales in April and May. "Our data suggests over 26 lakh new consumers purchased balms in the last three months," he mentioned.

Companies attributed the surge to elevated ranges of stress, with related signs comparable to headache, ache and lack of sleep which have been extensively reported through the ongoing second wave of the pandemic owing to its impact on a number of households, tales of struggling viral in social media and many individuals utilizing balms for steam inhalation to alleviate Covid-19 signs.

Amrutanjan's chief advertising officer Mani Bhagavatheeswaran mentioned its ache reduction portfolio grew 31% year-on-year in 2020-21 and that the momentum has continued on this monetary 12 months with strong progress in gross sales in April and May.

He attributed the expansion additionally to longer working hours because of the pandemic whereby persons are spending extra time in entrance of the pc without a lot train, main to extend in complications and ache.

Industry executives additionally mentioned there was an elevated consciousness of herbs and that steady impetus to such merchandise by the Ayush ministry has added to the demand.

"Uncertainty, absence of a routine and minimal social interaction can be a few factors that have increased the level of stress and anxiety amongst people of all age groups during this period," mentioned Anil M Jiandani, enterprise director, pharmaceutical division at The Himalaya Drug Co.

Dabur India noticed a big improve in gross sales of stress reduction merchandise through the second wave of the pandemic, mentioned advertising head for ayurvedic ethicals enterprise Durga Prasad, and the corporate just lately entered the ache reduction section.

As per business estimates, the whole ache reduction cream and gel market in India is round `4,900 crore which incorporates ayurvedic, moral and overthe-counter merchandise. Of this, the balms section alone accounts for `1,300 crore and the market until just lately was rising 13-15% yearly. The stress reduction product market has been rising about 30%.

Source : Pehal News, 13.06.2021

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Millions of J&J covid-19 vaccines are at risk of expiring in June

States, hospitals try to reroute such vaccines, while efforts to export them face hurdles

Hospitals, state health departments and the federal government are racing to decide how to use up millions of Johnson & Johnson's Covid-19 vaccine doses that are set to expire this month.

The prospect of so many doses going to waste in the U.S. when developing nations are desperate for shots would add pressure on the Biden administration to share stockpiled vaccines. But there are few practical solutions to administering them quickly in the U.S. or distributing them in time to foreign countries, according to those involved in the vaccination drive.

The stockpile is, in part, an unintended consequence of the U.S.'s decision in April to temporarily suspend administration of J&J doses to assess a rare blood-clot risk. The pause forced states and providers to cancel large blocks of appointments that were never rescheduled, leaving a surplus of supply, and in some areas increasing hesitancy over the J&J vaccine's safety, according to industry officials.

Some hospitals and states say that vaccines from Pfizer Inc. and partner BioNTech SE, as well as Moderna Inc., are due to expire later this summer, but the stockpiles so far are largely of J&J doses. Pfizer's vaccine expires six months after manufacture. Moderna's vaccine can remain frozen for up to six months, during which it can be refrigerated for one month.

Philadelphia has 42,000 J&J doses set to expire, most of which came from a Federal Emergency Management Agency clinic at the city's convention center a few days before the pause, a city spokesman said. Pennsylvania, West Virginia, Oklahoma and Arkansas are among states that report having thousands of J&J doses set to expire this month and have been unable to redistribute them.

"There's no way at the end of June that we're not going to have a couple thousand expiring," said Danielle Hilborn, who helps oversee Covid-19 vaccines for McLaren Health Care Corp. The hospital system based outside Flint, Mich., has more than 3,500 J&J doses set to expire this month, despite having moved doses among its hospitals and shipped 1,100 to a county health department. Hospitals and public-health departments offering the shots have begun special promotions to use J&J's shots before they go bad. Some health systems have redistributed them inside and outside their networks, and some states have rerouted them to physician offices, pharmacies or other states.

The efforts have had limited success because of the nation's slowdown in overall vaccinations and because many states and vaccination sites also have expiring J&J supply and don't see demand for more doses. Just over half of the 21.4 million J&J shots distributed to providers have been administered, according to data from the Centers for Disease Control and Prevention, versus 83% for shots from Moderna Inc. as well as Pfizer Inc. and its partner, BioNTech.

J&J stores doses frozen until shipment by the government, at which point they are refrigerated. Doses can be refrigerated for three months, and the drugmaker is studying whether the shelf life can be extended, a company spokesman said.

Many drugs and vaccines can remain effective for years, but all eventually start to lose potency. Typically, expiring prescription drugs and vaccines for other diseases are sent to other healthcare facilities, overseas or back to manufacturers, hospital officials said.

Covid-19 vaccines come with expiration information, which is determined by manufacturers based on testing data that is later cleared by regulators. Vaccines may still work after the expiration dates, according to manufacturing experts, but data was limited when the vaccines were authorized.

The issue of expiring doses is the latest setback for J&J's Covid-19 vaccine effort. An accident at a contract manufacturer's plant led to the contamination of material that could have yielded up to 15 million doses and led to a halt in production of the J&J vaccine there.

Dr. Bechara Choucair, the White House vaccine coordinator, has briefed governors and local health officials on best practices to maximize supply, according to a White House official, who also cited ongoing U.S. Food and Drug Administration reviews of whether J&J doses may have longer shelf lives. A second administration official said recalling doses that have already been shipped out to vaccination sites to potentially redistribute them would be logistically and legally challenging. One of the administration officials said most Covid-19 vaccines in

the U.S. aren't close to expiring. State health departments and hospital officials say the guidance from states and the CDC is to destroy or discard expired doses. The CDC didn't respond to requests for comment.

In early April, U.S. regulators paused the use of J&J's vaccine after reports of rare but severe blood clots. In response, vaccination sites across the country canceled thousands of appointments and instead offered people Pfizer or Moderna doses. Regulators lifted the pause 10 days later, with J&J and regulators adding language to the vaccine's label warning of a risk of blood clots.

By then, patient demand for Covid-19 vaccines shifted from mass-vaccination to smaller community settings amid lingering concerns about the rare clots, according to industry and state officials. The regulatory pause and overall slowdown in vaccinations has left UofL Health in Louisville, Ky., with more than 6,000 J&J doses that expire this month, after having administered about 2,600 since early April, said Dr. Jason Smith, chief medical officer. "My bet is that we will wind up wasting some of that, unfortunately," he said. To use them, the health system is trying to reach physician offices outside its network, Dr. Smith said. Pennsylvania's Department of Health said it worked with the CDC and Chester County to try to transfer the county's 50,000 expiring J&J doses to Oregon. The deal fell through when Oregon experienced a decline in demand and no longer wanted them, a Pennsylvania health department spokesman said.

The full extent of expiring Covid-19 vaccines is unknown because providers aren't required to report it to the federal government, said Jessica Daley, a pharmacist and executive at Premier Inc., a large group-purchasing organization for hospitals. Premier is asking members whether they have expiring vaccines, and at least a dozen have said they have expiring J&J doses, Ms. Daley said. "It's not as simple as just moving the vaccine somewhere else," she said.

Some states say they have asked the U.S. government whether doses can be shipped to developing nations. Doing so faces significant logistical and legal hurdles, according to the United Nations Children's Fund, because those countries are wary of using vaccines after expiration dates and may not be able to administer them quickly.

Source : Jared S. Hopkins, The Wall Street Journal, HT Mint, 09.06.2021

DEPARTMENT OF BIOTECHNOLOGY, JAYPEE INSTITUTE OF INFORMATION TECHNOLOGY, NOIDA

Organizes

5th International Conference on Advances in Biosciences and Biotechnology

(Theme: Innovations in Life Sciences and Computational Biology)

ICABB-2022

(20^{th} to 22^{nd} Jan, 2022)

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LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.06.2021

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**