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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 23** **15 to 21 June 2021**

IDMA ACTIVITIES

COMPANIES LAW AMENDMENTS:

GOVERNMENT COMMUNICATION:

NDPS MATTERS:

IPR MATTERS:

NATIONAL NEWS:

FEATURE:

SITUATIONS VACANT

COMPANY INTRODUCTION

A reputed Group, engaged in manufacture of Pharmaceutical Formulations having Sales of over Rs 200 Cr (Exports constitute more than 50%) and currently modernising/expanding its facilities to EU GMP Standards is looking for suitable candidates to fill up following vacancies.All situations will require the candidates to stay near the factories, located in Maharashtra, within 100 km of Mumbai. Language skills – Marathi, Hindi and English.Looking for Result oriented persons. Production Targets as well as Quality oriented approach.

1. PRODUCTION MANAGER

Educational Qualifications: B. Pharm / M. Pharm

Age: 42-46 years

Work experience: 12-15 years' experience in production of Tablets, Capsules & Powders in a reputed GMP Certified Company. Short term exposure to product development may be an asset.

4-5 years' experience as Assistant production manager or Production Manager in a good sized GMP Company, preferably in an EU GMP or equivalent unit.

FDA Approvals in manufacturing of Tablets, Capsules and/or Powder

Should possess hands on experience in manufacturing. Should be expert in trouble shooting, analysing and solving challenges in formulations, labour handling, planning and coordination. Experience in handling audits from FDA, WHO, EU GMP or UK MHRA is preferable.

Expectations: Must be well versed with equipment, their installations, validations and operations.

2. FACTORY MANAGER

Educational Qualifications: B. Pharm / M. Pharm, with Degree or Diploma in Administration/Management

Age: 45-50 years

Work experience: 15-20 years' experience in production of Formulations at various levels in a reputed GMP Certified Company. Exposure to R&D may be useful.

7-8 years' experience in managerial capacity inProduction management, labour management, General administration and handling Government bodies, in a good sized GMP Company, preferably in a EU GMP or equivalent unit. Out of this, at least 3 years' experience in senior position as General Manager or Factory Manager in medium sized Company in pharmaceuticals.

FDA Approvals in manufacturing of Tablets, Capsules and/or Powder. Experience in handling audits from FDA, WHO, EU GMP or UK MHRA is preferable.

3. QUALITY CONTROL MANAGER

Educational Qualifications: B. Pharm / M. Pharm / M. Sc.

Age: 40-45 years

Work experience: 12-15 years' experience in Quality Control of Oral Dosage Forms in a reputed GMP Certified Company. Short exposure to F&D.

4-5 years' experience as Assistant QC Manager or QC Manager in a good sized GMP Company, preferably in an EU GMP or equivalent unit.

Should possess hands on experience in testing and handling of QC equipment. Should be expert in trouble shooting, analysing and solving challenges in testing, method developments and validations.

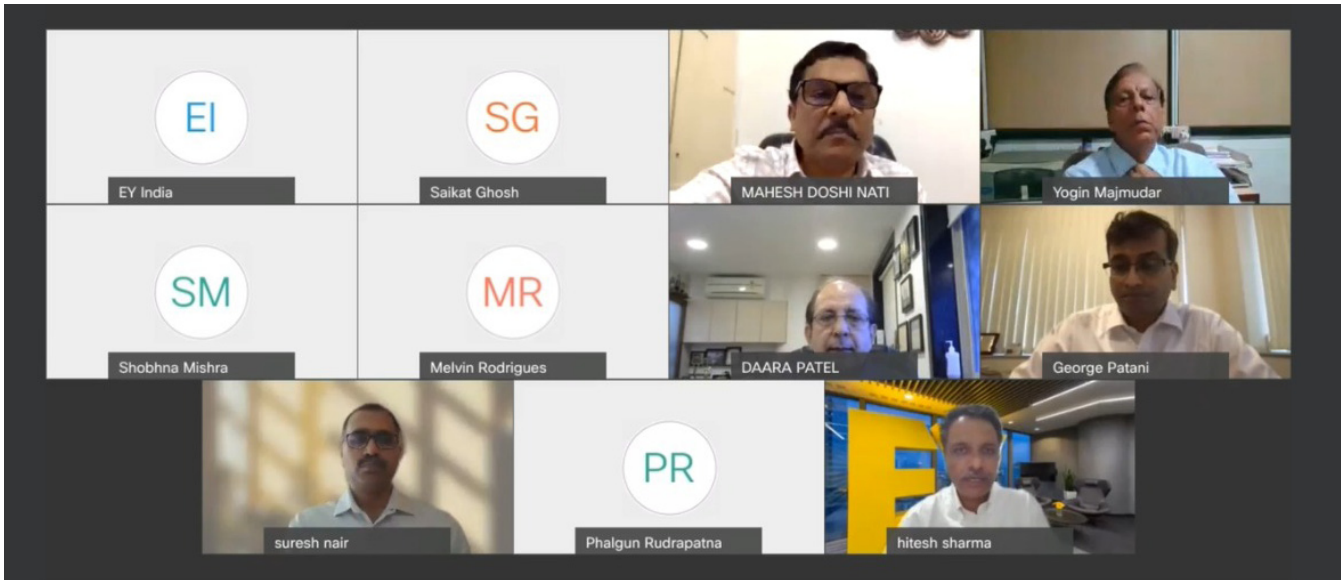
FDA Approvals in Microbiology, Chemical and Instrumental

Experience in handling audits from FDA, WHO/EU GMP, or UK MHRA and multi-national companies is preferable.

Expectations: Must be well versed with QC equipment, their installations, validations and operations.

Interested candidates may please respond to recruitadv2021@gmail.com with full details.

Report on IDMA - ERNST & YOUNG Webinar on PLI Scheme for Pharmaceuticals: "What is in it for the Indian Pharmaceutical Industry!" held on Tuesday, 15th June 2021 from 3.00 pm to 5.30 pm



IDMA along with Ernst & Young organized a webinar on PLI Schemes for Pharmaceuticals: "What is in it for the Indian Pharmaceutical Industry" on Tuesday, 15th June 2021 from 3.00 p.m. to 5.30 p.m.

Mr. Mahesh Doshi, our National President, IDMA gave his good wishes to the organizers and participants. He thanked Mr. Hitesh Sharma and his team for organizing such an excellent webinar and requested the participants to reap benefits from the same.

Mr. Daara B Patel, our Secretary – General, IDMA commenced the webinar by welcoming all the dignitaries, speakers and the participants for this informative, interactive and excellent webinar. Mr. Patel thanked the organizers Ernst and Young, our National President, Mr. Mahesh Doshi and all the participants who were present for this webinar. Approximately 130 participants attended this webinar.

Mr. Patel's speech is reproduced below for your kind perusal and information.

Mr. Yogin R Majmudar, Past National President and Chairman, Bulk Drugs Committee, IDMA delivered his Opening Remarks to the august gathering.

Mr. Majmudar's speech is reproduced below for your kind perusal and information.

Mr. Hitesh Sharma and his team from Ernst and Young proceeded further with the webinar and conducted the technical sessions. They made a very interesting presentation which covered all the aspects of the PLI 1.0 and PLI 2.0 Schemes and the points were also very well explained.

The presentation is reproduced for your kind perusal and information.

The presentation was followed by a question and answer session wherein many questions / clarifications sought by the participants were answered.

Dr. George A Patani, Our Hon. General Secretary, IDMA & Chairman, Publications Committee, IDMA summed up the proceedings in dept and proposed a vote of thanks.

Welcome Address by Mr. Daara B Patel, Secretary - General of IDMA

Good Afternoon Ladies and Gentleman!

Greetings from Indian Drug Manufacturers' Association (IDMA) and Ernst & Young!

It gives me great pleasure and honour to address the august gathering & on behalf of our National President, Mr. Mahesh H Doshi and Mr. Hitesh Sharma from Ernst and Young, I welcome you all to this very interesting webinar titled **PLI Scheme for Pharmaceuticals – What is in it for the Indian Pharmaceutical Industry.**

IDMA had envisaged this long ago and in 2014 IDMA had prepared a white paper titled **"Journey Towards Pharma Vision 2020 and Beyond"** wherein we had presented our justifications and recommendations for development of the API Industry in India to the Government.

But as they say "**Better Late than Never"** and we are indeed very grateful to the Department of Pharmaceuticals under the stewardship of Madam S. Aparna, IAS, Secretary, Department of Pharmaceuticals to interact with the Industry for the success of the PLI Scheme and to make our country Atma Nirbhar as envisioned by Hon'ble Prime Minister.

The Government has had several meetings since 2020 in regards to the PLI Scheme and even at IDMA we have discussed this issues in the special PLI meetings as well as almost every monthly Executive Committee Meeting.

As you may be aware, India's overdependence on China for APIs is a major geopolitical risk and has been flagged by the industry for over 10 years. With a view to increase self-reliance (atma nirbharta) in production and availability of indigenously produced Medicines, the Government has come out with schemes like Production Link Incentive (PLI) Schemes 1.0 & 2.0, which will show some results only after 2-3 years. Meanwhile, we have been recommending to the Government to have a similar scheme for existing manufacturers / plants also for quick results.

The main reason of our dependence on China has been their low cost of production and active support of the Chinese Government. For our manufacturers to compete with China, our costs need to be brought down. One of the ways to achieve savings is by providing common facilities to reduce cost on account of mass scale operations.

Production Linked Incentive (PLI) Schemes for Bulk Drugs and Medical Devices have shown a very positive response from the pharmaceutical as well as the medical device industry.

As we are aware, in the Union Budget 2021-22, the Hon'ble Finance Minister announced an outlay of INR 1.97 lakh crore to be utilized over 5 years for the PLI Schemes in 13 key sectors. The thrust to reinforce India as the **"Pharmacy of the world"** is evident from the PLI Schemes for this sector.

The Indian government announced a production-linked incentive ("PLI 1.0") scheme on 21 July 2020 aimed at boosting India's bulk drug security. This covered identified Active Pharmaceutical Ingredients/Key Starting Materials /Drug Intermediates. The financial outlay for the said PLI scheme was INR 6,940 Cr.

With the aim to further encourage the pharmaceutical industry, to enhance its manufacturing capabilities, to diversify the product mix to complex generics, to enhance patented drugs, for going up the value chain, for bringing investment and creating global champions from India, a new scheme was notified by the government on 3 March 2021 ("PLI 2.0") and its operational guidelines have since been announced on 1 June 2021.

DoP and Invest India had a meeting with all the Associations in regards to PLI – 2 Scheme on 10th June 2021 via an interactive video conference. Whilst the webinar was very successful and interesting as well as interactive not many questions were fielded due to paucity of time. DoP has therefore requested the Associations to collate questions received from their members and forward the same to DoP.

The new scheme is more extensive in its coverage as compared to PLI 1.0 and is expected to offer a total of INR 15,000 cr in incentives to the selected applicants for the identified pharma products.

We have excellent speakers from Ernst & Young who will give us a meticulous & all-encompassing information on PLI Schemes. Not to forget our own Expert, Mr. Yogin R Majmudar.

I wish you all fruitful deliberations and I am sure at the conclusion of this webinar we would all be more enlightened on **"What is in it for the Indian Pharmaceutical Industry"**

Till Then, Stay Safe, Stay Well and Stay Connected.

Thank you.

Opening Remarks by Mr Yogin R Majmudar, Past National President and Chairman, Bulk Drugs Committee, IDMA

Mr. Yogin R Majmudar, Past National President and Chairman, Bulk Drugs Committee, IDMA and also, the Managing Director of Bakul Aromatics and Chemicals Pvt. Ltd. delivered his opening remarks to the august gathering. He began with a few observations on the PLI Schemes in general.

Mr. Majmudar mentioned that it is a good initiative by Government to encourage local production in Pharma Sector. He said that the Pharma has been one of the first Sectors chosen for PLI Schemes. PLI - 1 covered specific 41 products, while PLI - 2 is open ended with 55 participants for products covered under the 3 Categories. For PLI - 1, 41 products were identified from import data as top imported products by value. Outlay for PLI - 1 was Rs.6940 crores while for PLI - 2 is Rs.15,000 crores.

Mr. Majmudar further commented on the short comings in PLI – 1 scheme as per the below mentioned points :-

- Spare capacity of existing P & M was not covered
- Fresh investment was a necessity
- Original sole objective of the Scheme of becoming self-reliant and reduce dependence on China was lost somewhere down the line with emphasis shifting to investment and employment generation becoming the alternate goals
- In spite of our pointing out that the list should be made up of actual KSMs which are presently imported and are being incentivised for local production, mostly API names figure in the list of 41. This did lead to confusion as the APIs are already being produced by import of the KSMs, which the Government is looking at being produced indigenously Indirectly this goal has been achieved by the value addition (70 % & 90%) criteria. But it would have been much simpler to have directly named the actual KSMs in the list
- This has also kept a loophole for someone to get the KSM imported by another entity and then purchase them locally by still falling within the value addition
- Intentionally or unintentionally in many of the 41 products, only 1 applicant has been selected with the lurking danger of Monopoly with no local competition

Mr. Majmudar then gave details of PLI - 2 Scheme. He mentioned that as against PLI - 1 which was only for APIs and KSMs, PLI - 2 Scheme also includes formulations and biologics along with APIs. He said that it was more meant for "bigger players" with almost 90% of the incentive amount allocated to companies with over Rs.500 crores Global t/o 3 Groups based on GMR levels.

He said that another focus was on manufacture of Complex Drugs which are

- difficult to produce
- of high value
- biologics
- disease specific drugs

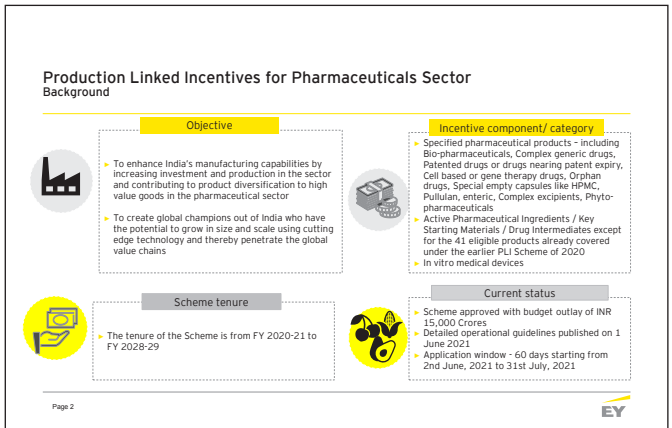
He further added that although the intention was to create global players, MSMEs also find a place in the PLI - 2 with as many as 20 slots reserved out of total 55 participants from this sector. All sectors (including MSMEs) can apply for all 3 Categories. Although, it is not clearly spelled out, the Scheme mentions only word 55 selected applicants. This means that each of the applicant can apply

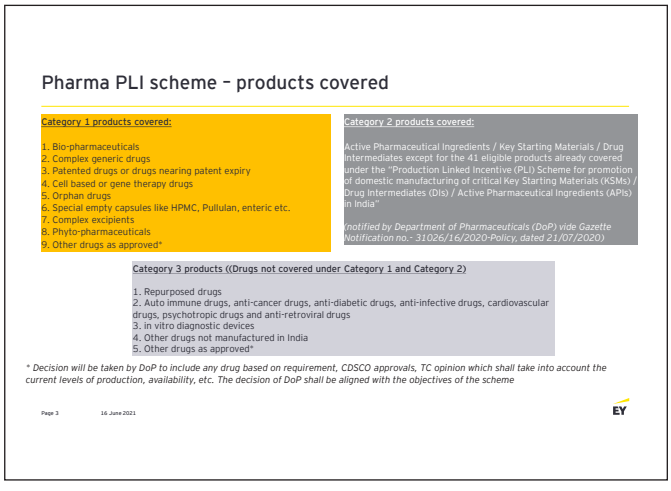
for a basket of products as a single application leading to few hundred products, unlike just 41 in PLI - 1.

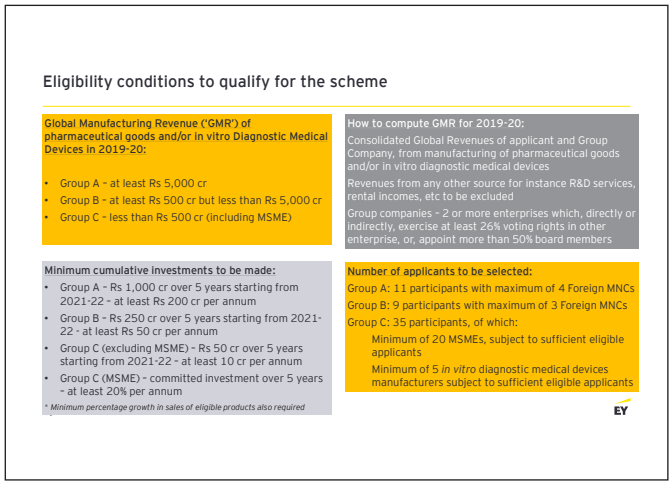
He said that further, there is no value addition criteria as the emphasis is more on value creation, rather than achieving self-reliance. This may be a major oversight, as after investing huge amount of funds, the selected applicants will still be at the mercy of Chinese suppliers of KSMs, if they have not fully backward integrated.

He concluded by saying that the danger of Chinese predatory pricing moves in future once production commences always exits. Just as in PLI-1 Scheme, PLI - 2 is also silent on how Government will proactively support the local manufacturer at the time. Along with PLI Schemes benefits, there is also need to simultaneously address the subjects of high costs of utilities and transaction costs in India as compared to our main competitor China for success of these Schemes

Technical Sessions Presentation by Ernst & Young







Selection criteria for pharmaceuticals *(except in vitro Diagnostic Medical Devices)*

Group	Selection parameter	Weightage
A / B	Gross manufacturing Investment ('GMI') of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021	30%
	R&D expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020	40%
C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021.	30%
	GMR from pharmaceutical goods in FY 2019-2020	40%
C - MSME	Number of manufacturing plants in India owned by applicant/group company and approved by USFDA / EDQM / UK MHRA / PMDA /Health Canada/ TGA or having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021	50%
	Total Investment Committed by the applicant under the scheme	50%

GMI will include gross capital investment in pharmaceutical and in vitro diagnostic medical device manufacturing facilities including capital investments for R&D facilities. Investment in corporate offices, sales offices, residential complex etc will not be included for the purpose of arriving at the GMI.

All eligible applicants shall be ranked on the basis of marks obtained on the basis of evaluation criteria

Selection criteria for in vitro Diagnostic Medical Devices

Group	Selection parameter	Weightage
A / B / C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of manufacturing plants in India owned by applicant/group company having manufacturing license from CDSCO/SLA or approved by USFDA / EU (CE) / UK MHRA / PMDA / Health Canada / TGA / CDSCO as on 01.04.2021	30%
	GMR from *in vitro* diagnostic medical devices in FY 2019-2020	40%

Incentives – eligibility and computation

Eligibility conditions for selected participants to claim incentives:

Minimum threshold sales of eligible products in 2022-23 to be greater than Rs 50 cr for Group A, Rs 10 Cr for Group B, Rs 1 Cr for Group C (except MSME) & Rs 50 lakhs for Group C MSME

Minimum threshold sales from year 2 onwards (2023-24 onwards) – 7% over actual sales of eligible products in previous financial year

Incentive rate to be applied on incremental sales:

Year 1: 2022-23 and year 6: 2027-28

For Category 1 and 2 products – 10% for first 4 years, 8% for year 5 and 6% for year 6

For Category 3 products – 5% for first 4 years, 4% for year 5 and 3% for year 6

Computation of incentive:

'Net Incremental sales' of eligible products * incentive rate

Incremental sales defined to mean sales of eligible products during a financial year less sales in base year ie 2019-20

'Net' means adjusting for sales returns of eligible product. For example if sales of Rs 100 considered for claim processing in year 1, and if sales returns of Rs 100 take place in year 2, sales of year 2 shall be adjusted for sales returns of year 1

Group wise incentive allocation:

Group A - Rs. 11,000 crore

Group B - Rs. 2,250 crore

Group C - Rs. 1,750 crore

If committed investment criteria is not met in any year, incentive will not be eligible for that year. However, the applicant will not be restricted from claiming incentive for subsequent years, provided criteria of minimum cumulative investment and threshold sales criteria are met for such subsequent year.

If the incentive availed by an applicant is less than the maximum available incentive for that applicant in that financial year, the applicant shall not be entitled to claim the differential amount in subsequent financial years.

Incentives computation – illustrative example

- Sale of eligible pharmaceutical products (from category 1 and 2) in 2019-20 was Rs 1000 cr
- Sale of eligible products from above in 2022-23 (year 1) assumed to Rs 1200 cr
- Incentive for year 1 ie 2022-23 would be (1200 -1000)*10% = Rs 20 cr
- In order to be eligible for year 2 ie 2023-24, minimum sales of eligible products in year 2 should be at least Rs 1284 cr ie at least 7% growth over sales of year 1
- Assume sale of eligible products in 2023-2024 (year 2) to be Rs 1300 cr
- Incentive for year e ie 2023-24 would be (1300 -1000)*10% = Rs 30 cr
- Incentives for subsequent years to be computed on similar basis

Note; Incentive rate for category 3 products are different

In vitro medical devices are covered in category 3

Investment - Key considerations

- Eligible investments includes expenses incurred on the following in relation to eligible products:
  - New Plant, Machinery, Equipment and Associated Utilities
  - Research and Development (R&D) and product development including clinical trial costs in India only
  - Transfer of Technology (ToT) agreements - cost of technology and initial technology purchase in relation to the eligible product
  - Product registration - costs incurred for product registration both in India and in other countries in relation to the eligible product which includes renewal charges, bio-availability and bio-equivalence studies, plant inspection charges and patent filing; WHO pre-qualification charges in case of *in vitro* diagnostic medical devices
  - Construction of building where eligible new plant and machinery are installed and expenditure on associated infrastructure limited to 20% of new plant and machinery
- Associated utilities to include essential equipment required in operational areas such as Clean Rooms, cold chain, infrastructure at the manufacturing site, Air Curtains, Temperature and Air Quality Control Systems, Compressed Air, Water & Power Supply and Control Systems. Associated utilities shall also include ETP, incinerators, effluent lines / tanks / treatment, supply lines of water / sewerage / solvents / gases, solvent recovery, solid waste treatment plant, solvent storage tanks, LPG storage tanks, warehousing, electricity lines, power generation facility and communication lines for telephone-internet within the establishment
- Investments made on or after 1.4.2020 to be considered
- All non creditable taxes and duties to be included in the expenditure
- Second hand plant and machinery, raw materials and consumables for manufacturing, not eligible, investment on land excluded
- Date of purchase invoice considered as date of Investment, heads of eligible investment should be capitalised in the books except expenditure on R&D, product registration in the nature of capital / revenue expenditure
- Investments already considered for PLI Scheme for Bulk Drugs or any other PLI Scheme not to be considered again for the purpose of eligible investment under this Scheme

Incentives allocation and computation – additional considerations

- Selected applicant can change the product mix approved to them during the tenure of the scheme with the prior approval of the DoP - However, this option can be exercised up to 5 times only
- Participant shall be eligible to draw incentive within that annual allocation. However, any incentive unutilised by one or more selected participant during a year may be used for paying additional incentive to other selected participants within that Group, provided that:
  - no participant shall receive additional incentive more than 40% of the allocated incentive to such participant for that year
  - no participant shall receive additional incentive more than 20% of the total incentive allocated to such participant over the entire tenure of the scheme, and
  - all approvals of such additional incentive shall not exceed the budget allocated for the respective year and the budgetary outlay for the Scheme
- The ceiling for incentive and additional incentive shall be (Rs Cr)

Group	Incentive ceiling	Ceiling of Additional Incentive, if any	Total incentive Ceiling
A	1000	200	1200
B	250	50	300
C	50	10	60

- Additional incentive is not an entitlement and is contingent upon savings available from unutilized incentive of other participants in that year
- Annual disbursement claims with supporting documents after end of financial year by 30 April
- 75% claim amount to be released if claim found in order and balance 25% to be released after submission of final audited accounts

We have done a preliminary analysis, basis historical data, on the implications for pharma cos, across the Groups

Please note:

- The analysis is based on publicly available data, with no inputs from individual pharma cos
- It is a "conservative" point of view, assuming a constrained vs. a liberal interpretation of the guidelines
- The objective is to illustrate processes in assessing
  - Likelihood of qualifying for the scheme
  - Indicative realization of incentives

Excluding MNCs, 17 Indian pharma cos have a high likelihood of being Group A; and qualify as one of 7 to 11 Indian cos selected for the PLI

Company	A. Domestic FDF (Rs Cr)	B. FDF Exports (Rs Cr)	C. API Exports (Rs Cr)	ANDAs (Orange Book)	APIs (US DMF)	*Tracked Sales (A+B+C) (Rs Cr)* ↓
Sun Pharma	11,784	6,792	1,175	867	247	19,751
Cipla	6,705	6,045	780	286	139	13,530
Lupin	5,463	3,712	778	382	198	9,953
Dr Reddy's	3,501	4,678	1,799	425	220	9,978
Zydus Cadila	5,987	3,644	333	532	123	9,964
Intas	4,337	3,078		270	33	7,415
Glenmark	3,274	3,124	733	296	112	7,132
Alkem	5,092	1,524		203	28	6,615
Macleods	4,136	2,415		163	105	6,551
Aurobindo		4,933	1,585	848	236	6,517
Torrent	4,485	1,999		150	35	6,484
Mankind	5,484	47		19		5,531
Hetero	866	1,738	1,842	172	209	4,447
Jubilant	40	384	1,529	114	97	1,953
Divi's Labs			1,667		37	1,667
Biocon	481	90	794	16	46	1,365
Serum Inst	358	934				1,292

These cos report revenues of more than Rs 5,000 cr; however, clarity is needed on the 3rd party manufacturing revenues being part of GMR – this can make a difference between A & B

The "Tracked Sales" is a useful public domain data point to compare companies; the actual sales, both formulations and APIs, from internal data is critical to specifically arrive at Gross Manufacturing Revenues (GMR), accounting for 3rd party manufacturing and services, both in-bound and out-bound

The 30% weightage for # of regulated market approvals (ANDAs / DMFs equivalent) will impact scores of Torrent and Mankind, and even Alkem and Intas, if the scheme is revised to include a combined # of ANDAs and DMF

Interestingly, Group B is very competitive, with only 9 slots, between the next set of formulations cos, as well as the large regulated market focused API cos

Company	A. Domestic FDF (Rs Cr)	B. FDF Exports (Rs Cr)	C. API Exports (Rs Cr)	ANDAs (Orange Book)	APIs (US DMF)	*Tracked Sales (A+B+C) (Rs Cr)*
Emcure	3,704	1,113		18	98	4,817
Alembic	1,698	1,860	676	251	116	4,234
Ipca	2,092	1,061	973	47	51	4,127
Micro Labs	2,553	1,414		80	37	3,968
Aristo Pharma	3,748	110				3,858
USV	2,844	328	124	12	27	3,296
MSN Labs		541	1,933	63	395	2,474
Aarti			2,319		36	2,319
Ajanta	876	1,184		101		2,061
Granules		1,507	503	63	30	2,010
Cadila Pharma	1,073	423	452	110	32	1,947
Natco	1,090	161	286	43	38	1,536
Wockhardt	1,291	181		122	30	1,473
Piramal	273	505	632	32	36	1,410
Indoco	950	276		19	19	1,226
Nectar		204	825		21	1,029
Laurus Labs			946	10	51	946
Hikal			911	8	26	911
Solara Active			794		90	794
Orchid			491	97	74	491

Domestic & RoW focused formulators have lesser likelihood of selection

MSN's vast US approvals in APIs positions them as a front-runner in Group B

API companies will have higher sales, once the domestic API sales are factored in; for example, companies like SMS, Enaltec, MSN, Symbiotec etc. also have large non-US, non-EU APIs

e.g. Laurus Labs reported > Rs 4,700 cr in FY21

Orchid has been listed given large US approved portfolio

The right starting product mix is critical to maximize year 1 i.e. 2022-23 incentives; the following criteria may be used in a company-specific assessment

I. In-market products (FDFs and APIs, domestic and exports)

- Rs 50+ cr products (in 2019-20) with high growth potential, at least for 2022-23 vs. 2019-20
- New introductions (say, 2019 or later), likely to scale to Rs 50+ cr in 2022-23

II. Products not launched yet, but likely to be commercialized by 2022-23 and scale up to Rs 50+ cr in 2022-23

- Approved ANDAs / DMFs or equivalent, as qualifying for PLI (say, 2017 or later)
- Submitted ANDAs / DMFs or equivalent *(typically not public information)*
- Upcoming high potential pipeline e.g. biosimilars, NCEs, innovative products, not necessarily in US / EU *(typically not public information)*

For both sets above, how intense is the competition? Therefore, are our growth assumptions justified? E.g.

- IQVIA sales for commercialized products (global incl. India)
- Orange Book entries or EMA entries for approved products, not yet commercialized (likewise, for APIs)
- Portfolio (approvals, not submissions) and sales of other Indian companies competing in the PLI e.g. which other Indian companies are anticipated to list the same product in their PLI application?

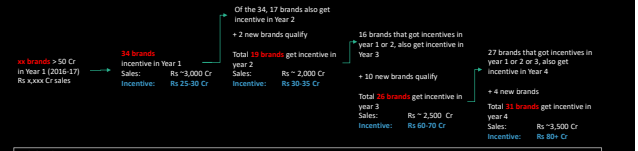
A: 50+ cr, B: 10+ cr, C: 1+ cr, C-MSME: 50+ L

How much incentive are we likely to actually convert?

- **"What if" simulation**... say, PLI was announced in 2016 for incentives in the period 2017-20; applying the current PLI guidelines to two domestic formulations businesses, one in Group A and the other in Group B, how much incentives do the companies get?
- ***High level assessment basis historical data, for illustration only***
- **"Product" = molecule or composition**, separately for formulations and API
  - All SKUs or brands within molecule / composition, considered single product e.g. a 100 mg strength and a 200 mg strength are the same "product", but a mono and a fixed dose combination are two different products
- **Every eligible product needs to be Rs 50+ cr** (Group A) in the year of claiming incentive
  - A less stringent interpretation is that the entire applied-for eligible portfolio needs to be Rs 50+ cr
- **All products in the portfolio and pipeline**, are expected to have been applied for
  - This is a critical activity as you fill the form with the first product mix during application
- **Each eligible product needs to meet 7% growth requirement** – criteria applied to each product, not at category or overall portfolio, therefore Product A and Product B both need to grow at 7%

ILLUSTRATIVE, SIMULATION

Example of a large Group A co. (randomly selected)



INSIGHTS

- Had the PLI taken 2016 as base year and awarded incentives in 2017, 2018, 2019, 2020, then XX's domestic portfolio would have achieved ~ Rs 200+ Cr in cumulative incentives
- Of this, the top 5 molecules would have contributed 35-40% of the incentives: Molecule 1 (Rs 21 cr incentives), Molecule 2 (17 cr), Molecule 3 (16 cr), Molecule 4 (Rs 16 cr), Molecule 5 (13 cr)
- Similar analysis needs to be conducted on sales projections, product-wise, for the PLI period (2019-20 as base, and 2022-23 as year 1, ...)
- Additionally, the formulations exports, by products (molecule / composition) need to be added to their domestic sales, for the right estimation of incentives from formulations
- Similar analysis needs to be done on the API portfolio and pipeline

ILLUSTRATIVE, SIMULATION

Example of a Group B company (randomly selected)

xx brands > 10 Cr in Year 1 (2016-17) Rs x,xxx Cr sales

→ 29 brands incentive in Year 1
Sales: Rs ~600 Cr
Incentive: Rs 5-10 Cr

Of the 29, only 6 brands also get incentive in Year 2
+ 3 new brands qualify
Total 9 brands get incentive in year 2
Sales: Rs ~150 Cr
Incentive: Rs 2-5 Cr

22 brands that got incentives in year 1 or 2, also get incentive in Year 3
+ 10 new brands qualify
Total 32 brands get incentive in year 3
Sales: Rs ~700 Cr
Incentive: Rs 10-15 Cr

11 brands that got incentives in year 1 or 2 or 3, also get incentive in Year 4
+ 4 new brands qualify
Total 16 brands get incentive in year 4
Sales: Rs ~600 Cr
Incentive: Rs 10-15 Cr

INSIGHTS

- Had the PLI taken 2016 as base year and awarded incentives in 2017, 2018, 2019, 2020, then XX's domestic portfolio would have achieved Rs 25-35 Cr in cumulative incentives
- Similar analysis needs to be conducted on sales projections, product-wise, for the PLI period (2019-20 as base, and 2022-23 as year 1, ...)
- Additionally, the formulations exports, by products (molecule / composition) need to be added to their domestic sales, for the right estimation of incentives from formulations
- Similar analysis needs to be done on the API portfolio and pipeline

INPUTS for portfolio selection

- Complete list of products and SKUs, and sales in 2017-18, 2018-19, 2019-20, 2020-21
- Sales projections, for products and SKUs, for as many future years, as available
- List of submitted (not approved) ANDAs and DMFs and equivalent
- List of pending submissions, with indicative year of submission, and target markets, say US, EU, domestic and RoW
- Products and SKUs that we manufacture as third party, for others; incl. sales value
- Products and SKUs that we get manufactured by third parties; incl. sales value
- Point of view of R&D / new product development / strategy etc., for working sessions to align on key assumptions

OUTPUTS for portfolio selection

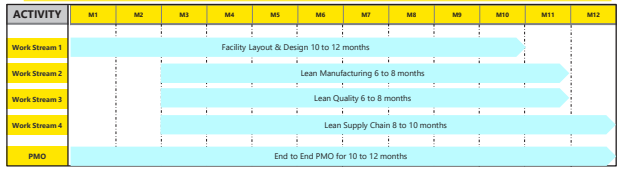
- Product mix to be submitted as part of the PLI application
- High level estimation of the incentive that this product mix is likely to yield, in 2022-23
- Assessment of the competitive intensity in key products
- List of 5-10 products that are not likely to be part of the PLI application, for 2022-23 incentives, but may be included in the product mix subsequently

EY can support in individual workstreams including PMO from facility design to commercialization enabling reduction in overall lead time to commercialization...

Facility Layout & Design	Lean Manufacturing	Lean Quality	Lean Supply Chain
• Plant Site Finalization • Approvals for manufacturing • Lean Layout Finalization • Plant Construction • Utilities set up • Plant Validation • We will use the expertise of SMEs who are empaneled with us for knitting all the aspects together to ensure best possible timeline	• Capacity Finalization basis the demand projections • Equipment Finalization which are Digitally enabled for Smart Factory & Apps • Finalizing Productivity norms (Equipment & Manpower) • Installation, Validation & Approval • Digitally Equipped Smart Factory	• Capacity planning for RM, In-process, FG testing and thus lab design • Lab instruments finalization • Finalizing Productivity norms • Digital Lab – LIMS, QMS, Lab Planning and Lab Analytics • Installation, Validation & Approval • Digitally Equipped Smart Lab	• RM-PM supplier finalization • Vendor qualification • ERP and Systems Setup • Integrated demand and supply planning process setup with digital enablement • Distribution and logistic partner onboarding • Digitally Enabled Supply Chain • Commercialization
Time Line – 8 to 10 months	Time Line – 6 to 8 months	Time Line – 6 to 8 months	Time Line – 8 to 10 months

PMO across all workstream to reduce time to market (End to End) – 10 to 12 months

We will ensure that activities run in parallel so that end to end timeline is reduced... and EY can help in specific areas...



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PMO
Support project management through increased and structured governance process to reduce timeline to commercialization

Strategic Partnership
Tie ups with trusted CRO partners quicker turn around in development phase, Tie ups with technology partner for ERP and planning tool set up

Lean and Digital Deployment
Support in implementing lean principles and Digital in areas of manufacturing line set up, Quality, better plant layout, supply chain planning and KPIs finalization

Manufacturing and Other Operations Warehousing Regulations

Overview

Manufacturing and Other Operations Warehousing Regulations, 2019

Generally, Customs duty is payable at the time of import of goods into India . However, MOOWR, 2019 provides for duty deferment in case of imports, subject to various compliances and procedures.

Governing provisions

- **Section 58** of the Customs Act, 1962, provides for grant of license by the Principal Commissioner/ Commissioner of Customs for private warehouse, for deposit of dutiable goods
- **Section 65** of the Customs Act, 1962 provides for an owner of any warehoused goods to carry on any manufacturing or other operations in a warehouse, subject to permission of the Principal Commissioner/ Commissioner of Customs and various conditions thereon

Basic operational mechanism

- Application to be filed for private bonded warehouse and manufacturing and other operations before the Principal Commissioner/ Commissioner of Customs
- Goods to be imported into India can be deposited in the private warehouse, by way of filing a bill of entry for warehousing, but without payment of any Customs duty
- Further, manufacturing or other operations can be carried out on such goods in the private warehouse
- Clearance of goods can be done for home consumption or export
- The applicant would be required to maintain records with respect of warehoused goods

Benefits

1. Duty-deferment on import of Inputs/ Capital goods
2. No Customs Duty on direct exports from warehouse
3. Pay Customs Duty on domestic clearance of capital goods/ finished or manufactured goods
4. Procurement from DTA permissible*

Unlike Project Import Scheme, import of old machinery is also included under MOOWR, 2019 for deferment/ non payment of Duty

Deferment/ non payment of GST on imported machinery which would otherwise be available as input credit in 10 to 15 years

** GST implications may arise in case of domestic procurement*

EY

Manufacturing and Other Operations Warehousing Regulations, 2019

Figures in INR Crores

Savings on import of CAPEX under MOOWR

Particulars	Amount
Duty payable at the time of domestic clearance	8.25
Less: Present value of duty payable in future (20th year)	1.47
Immediate savings under the MOOWR Scheme - A	6.78
Interest cost saving on BCD and SWS over the period of time (20 years) –B	3.95
Interest cost saving on IGST over the period of time (20 years) – C	11.34
Total Savings on CAPEX on account of MOOWR,2019 (A+B+C)	22.07

Benefit on import of Raw Material under MOOWR

Particulars	Amount
Cost of imported raw material	100
Stock holding period	2 years
Duty paid on domestic clearance	27.74
Net Savings on material on account of MOOWR,2019	3.24

For an investment of 100 Cr. in Plant & Machinery, tentative benefit of 22 Cr. can be achieved through MOOWRs scheme

- *Investment of 100 cr.-relates to Plant & Machinery*
- *Life of assets - 20 years*
- *Estimate stock holding period - 2 years*
- *BCD rate assumed as 7.5%, IGST assumed 18%*
- *Internal rate of return assumed as 0%*

EY

State level incentives in India

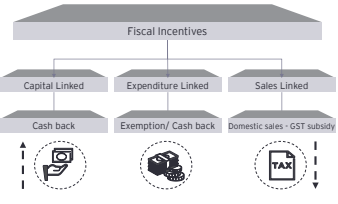
Overview

State incentives in India

Nature and key parameters

Parameters to be considered

- **Location & amount of investment:** To evaluate the maximum benefits that can be availed
- **Sector:** To identify the incentives under sector specific policies
- **Sales pattern:** To identify and quantify incentives available under foreign trade policy and state industrial policy
- **Expenditure:** To quantify the incentives linked to expenditure



Key considerations

- Incentives vary based on location, scale of investment, classification as to new or expansion project
- Investment period is a period within which the investment made is considered for eligibility of incentives
- Operative period is the minimum number of years for which a unit has to be in commercial production
- Tailor-made incentives for projects with substantial investment (usually referred to as Mega Projects)

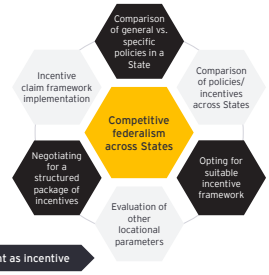
EY

Types of fiscal incentives - indicative

Single window approval and sanction across States

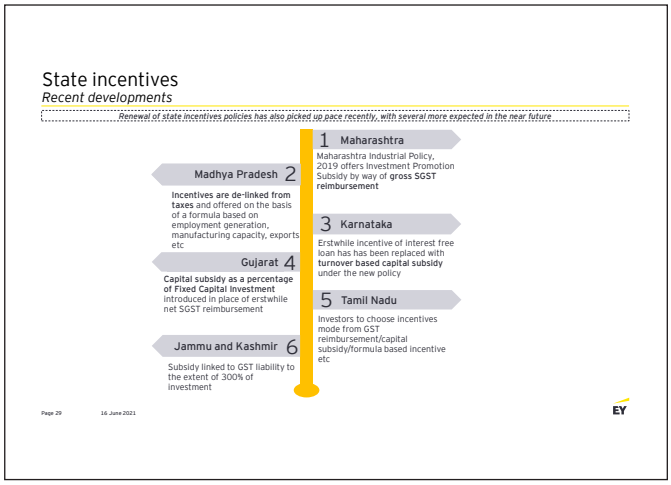
Incentives overview
State goods and services tax (SGST) reimbursement, sales subsidy
Capital subsidy
Electricity duty exemption/tariff concession *
Stamp duty exemption
Interest subsidy
Skill subsidy *
Land concessions including concessional land allotment *
Infrastructure support
Vendor ecosystem

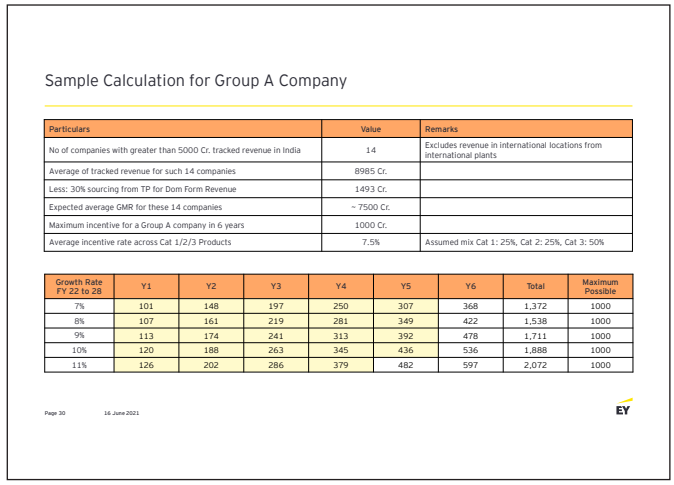
*Relevant for manufacturing and services

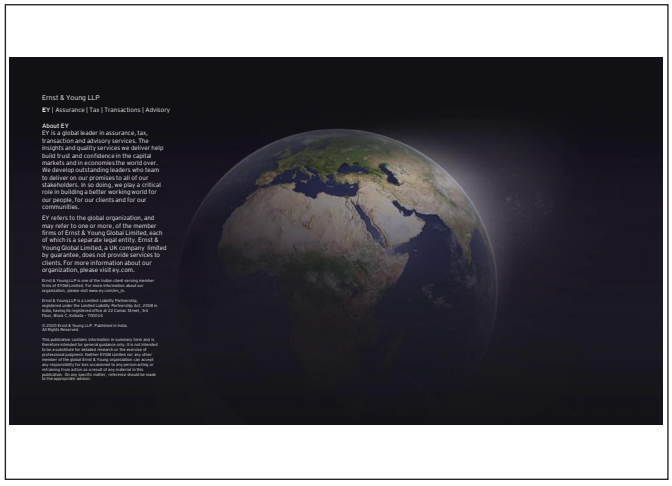


Possibility of negotiating for over 100% of CAPEX investment as incentive

EY







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Questions / Clarifications Sought in Regards to Industry Outreach webinar for PLI 2.0 on 10.06.2021: IDMA representation to DoP – reg.

The Association has submitted following representation to Dr. Sumit Garg, IRS, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers on 17th June 2021 on the above subject:

Dear Sir,

We refer to the very informative and very interactive webinar organized by Invest India and Department of Pharmaceuticals on Industry Outreach for PLI 2.0 on 10th June 2021. We thank you for giving IDMA an opportunity to interact and also raise questions and seek clarifications.

Accordingly, our members have sent a few questions which are given below :

1) What happens when KSM is manufactured by one Group Company and the end API by another? Can investment of both companies will be clubbed, or company has to apply for 2 products as separate ones?

2) Currently company is manufacturing APIs and intermediates under loan-license/job work. Production of the product to be applied will start only in 2022-23 in the new plant to be constructed post

September 2021 as MSME. Whether the product can be considered as eligible to apply under the scheme?

3) The scheme indicates minimum investments for various Groups for the company to be eligible for incentives.

If the company due to certain reasons beyond its control is unable to complete the required investment but has already committed the investment by way of issuance of PO's for purchase of P&M and have also opened LC's / paid advances, then the company should not be denied incentives.

4) (a) If some new product are manufactured for the first time by company in the year 2022-23 with no sales in base year 2019-20, will it be eligible under PLI 2 scheme?

(b) Can examples be provided of Drugs which are included in Bio-pharmaceuticals, Orphan Drugs, Complex Excipients, Phyto-pharmaceuticals?

5) Along with PLI Scheme benefits, there is also need to simultaneously address the subjects of high costs of utilities and transaction costs in India as compared to our main competitor China for success of the PLI Schemes.

6) The scheme indicates minimum investment of R. 200 crores per year for 5 years for Group A bidders and minimum 50 crores per year for 5 years for Group B bidders. If the required investment is not made then, the company is not eligible for incentives.

7) The company due to certain reasons beyond their control could not complete the required investment but have already committed the investment by way of issuance of PO's for purchase of P&M and have also opened LC's / paid advances should be considered as investment and the company should not be denied incentives.

8) ELIGIBLE INVESTMENT (2.15)

2.15.2 EXPENDITURE INCURRED ON R&D.

The scheme objective is to create manufacturing capacities and create global champions. However clinical trials expenses are limited to India only. To be a global player as per the various laws in the respective countries, many countries specifies local clinical trials. Hence all clinical trials relating the eligible product should be considered. Also cost of patent charges if any and other registration charges to enter any market.

Need clarity on expenses incurred for exhibit batches manufactured for getting ANDA etc. from regulated market will be considered as R&D expenditure?

Whether cost of employee's and Chemicals used in R&D will be considered for eligible investment.

2.15.3 EXPENDITURE ON TOT

Only TOT cost incurred initially is allowed. Normally for a TOT subsequent improvements are also transferred at a cost. If such improvements are not available to the Indian company, they may lose out to competition in the International market. Hence all subsequent cost for the eligible product should be allowed.

2.15.4 EXPENDITURE ON PRODUCT REGISTRATION

Here it indicates that WHO pre-qualification charges are allowed in case of in vitro diagnostic medical devices. As you are aware all major formulations procured by global agency for commutable diseases such as, TB, AID etc. insist on WHO pre-qualification. Hence to target international market WHO pre-qualification expenses should also be allowed.

6.1.5

The heads of investment based on which eligibility is being determined should be capitalised in the books of accounts. Many a time though the invoice date prior to closing date, the same is not capitalised as the P&M has not commenced operation. It is declared in Capital Work In Progress. Hence the policy needs to be clear whether Invoice date would be considered Or Capitalisation date.

6.2.3

Plant & Machinery once invested will be utilised for a long period. Additional investment would be required only for capacity expansion or modification. In that case insisting on cumulative investment only on eligible products will make the incentives scheme a dampener.

7.1.1

Clarity on cumulative investment required? Whether only for eligible product or company as a whole in pharma business?

7.2.2

CHANGE OF PRODUCT MIX

a) When the applicant can request for a product mix?

b) Whether the product deleted will be considered for YOY growth % for incentives?

c) After application, in how many days the approval will be given?

d) If approved, from when the new status will be effective?

e) If the whole list of product approved get changed in product mix request, how YOY% of growth will be determined?

We have collated the questions / clarifications forwarded by our members as above and we look forward to your prompt response on the same.

Looking forward to your support and co-operation in regards to the above.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Mahesh H Doshi
National President

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Implementation of Revised GST for Covid Drugs : IDMA representation to DoP – reg.

The Association has submitted following representation to the Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers on 18th June 2021 with the copy to Smt. Shubhra Singh, IAS, Chairperson, National Pharmaceutical Pricing Authority on the above subject:

Respected Madam,

Greetings from IDMA!

We refer to the OM File No. 19(175)/2019/DP/NPPA/Div.II dated 15th June, 2021 issued by NPPA in reference to the lower GST announced for COVID drugs.

We have been approached by many of our members seeking clarification, with respect to Serial No. 5 of Medicines as per the PIB notice dated 12/06/2021 relating to "Recommendation of 44th GST Council Meeting." (Copy enclosed).

The serial No. 5 reads as under :-

Sr. No.	Description	Present GST Rate	GST Rate recommended by GST Council
5	Any other drug recommended by Ministry of Health and Family Welfare (MoHFW) and Dept. of Pharma (DoP) for Covid treatment	Applicable Rate	5%

Since the list of drugs has not been explicitly specified, it can lead to a lot of confusion on account of interpretation of COVID drugs by different States Health Authorities. Hence we request your office to kindly list out the drugs covered under Serial No. 5, so that there is no ambiguity in interpretation.

Looking at the facts referred to above, we seek your clarification at the earliest so that our members are not put into any hardship on account of overcharging and GST violation.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association,

Mahesh Doshi
National President

Encl : Recommendation of 44th GST Council Meeting (reproduced below)

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Ministry of Finance

Recommendations of 44th GST Council Meeting

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

Posted On: 12 JUN 2021 3:39PM by PIB Delhi

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.

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COMPANIES LAW AMENDMENTS

Amendment of Companies (Meetings of Board and its Powers) Rules, 2014

Ministry of Corporate Affairs Notification G.S.R. 409(E), dated 15th June, 2021

In exercise of the powers conferred by sections 173, 177, 178 and section 186, read with section 469 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following rules further to amend the Companies (Meetings of Board and its Powers) Rules, 2014, namely:—

1. (1) These rules may be called the Companies (Meetings of Board and its Powers) Amendment Rules, 2021.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Companies (Meetings of Board and its Powers) Rules, 2014, rule 4 shall be omitted.

F.No. 1/32/2013-CL-V-Part

K.V.R. Murty, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

Note: *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub- section (i), vide notification number G.S.R. 240(E), dated the 31st March, 2014 and subsequently amended as follows:-*

1. G.S.R. 398 (E), dated the 12th June, 2014;
2. G.S.R. 590 (E), dated the 14th August, 2014;
3. G.S.R. 206 (E), dated the 18th March, 2015;
4. G.S.R. 971(E), dated the 14th December, 2015;
5. G.S.R. 309 (E), dated the 30th March, 2017;
6. G.S.R. 880 (E), dated the 13th July, 2017;
7. G.S.R. 429 (E), dated the 7th May, 2018;
8. G.S.R. 777 (E), dated the 11th October, 2019;
9. G.S.R. 857 (E), dated the 18th November, 2019;
10. G.S.R. 186 (E), dated the 19th March, 2020;
11. G.S.R. 395 (E), dated the 23rd June, 2020;
12. G.S.R. 590 (E), dated the 28th September, 2020; and
13. G.S.R. 806 (E), dated the 30th December, 2020.

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ATTENTION MEMBERS

IDMA has received the below communications from Department of Pharmaceuticals requesting IDMA Members to provide requisite information, if any, on the below subjects. Interested members are requested to kindly forward your comments urgently to IDMA Secretariat at idma2@idmaindia.com and/or actadm@idmaindia.com

18th Session of India-Switzerland Joint Economic Commission (JEC) to be held shortly in India or on virtual platform - reg.

F. No. 35022/14/2021-Policy, dated 4th June 2021

To
Pharmexcil, IPA, IDMA and AIMED

1. I am directed to refer on the above mentioned subject and to say that Department of Commerce has informed that 18th Session of India-Switzerland Joint Economic Commission (JEC) to be held shortly in India or on virtual platform.

2. You are requested to provide issues/points for inclusion in the agenda of the 18th Session of India-Switzerland Joint Economic Commission (JEC) urgently (latest by 6th June, 2021) for onward submission to Department of Commerce.

3. This issues with the approval of Competent Authority.

Yours faithfully,

Sanjay Meena, Section Officer, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Shastri Bhawan, New Delhi .

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11th Session of India-Turkey Joint Committee on Economic and Technical Cooperation (JCETC) to be held shortly on virtual platform - Reg.

F.No. 35022/15/2021-Policy, 17th June, 2021

To
Pharmexcil, IPA, IDMA and AIMED

1. I am directed to refer on the above mentioned subject and to say that Department of Commerce has informed that 11th Session of India-Turkey Joint Committee on Economic and Technical Cooperation (JCETC) to be held shortly on virtual platform.

2. You are requested to provide issues/points for inclusion in the agenda of the 11th Session of India-Turkey Joint Committee on Economic and Technical Cooperation (JCETC) urgently (latest by 21st June, 2021) for onward submission to Department of Commerce.

Sanjay Meena,
Section Officer,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
Shastri Bhawan,
New Delhi .

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Temporary Provisions for issue of Provisional CBN Registration Number to the firms dealing in Psychotropic Substances - reg.

Public Notice dated 17th June, 2021

1. Reference is invited towards Rule 65 sub rule 1, of NDPS Rules, 1985 wherein, it is directed to all the firms dealing in Psychotropic Substances to get themselves registered with the Narcotics Commissioner of India, in the form and manner as specified by the Narcotics Commissioner.Also, as per Rule 65 sub rule 2, of NDPS Rules, 1985, the firms having registered with the Narcotics Commissioner or CBN are mandatorily required to submit their quarterly returns in the form and manner as specified by the Narcotics Commissioner.

2. For filing an application for issuance of CBN Registration Number & facility for submitting online quarterly returns, this office had already provided the CBN Online Portal https:\\www.cbnonline.gov.in.However, due to some technical issues the above said website/ online portal is currently not functional and it is expected that it may take some time to become operational.

3. Due to the reason above, the user companies are facing difficulty in submitting their application as well as their quarterly returns. In order to facilitate the user companies during the period of breakdown of the CBN Online Portal, the Central Bureau of Narcotics, Gwalior has initiated some temporary arrangements as under: -

A. Issue of Provisional CBN Registration Number:

1. The firms, not having any temporary CBN Registration Number, may apply for the CBN registration, manually. The proforma of the application and list of documents to be submitted is attached herewith as **Annexure-I.** (After due scrutiny of the application and documents submitted by the firms, this office may issue these firms a **Provisional CBN Registration Number** which will facilitate them to continue their business till restoration of the CBN Online Portal.

2. The **Provisional CBN Registration Number issued** shall be valid only for the period of one year from the date of its issue or till restoration of the CBN Online Portal, whichever is earlier.

3. After restoration of the CBN Online Portal, the companies to whom Provisional CBN **Registration Number has been** issued shall be required to apply on CBN Online Portal for Temporary CBN Registration Number and thereafter shall send the self-attested copy of the print out bearing system generated Temporary CBN Registration Number along with a forwarding letter. However, the previously issued Provisional CBN Registration Number should specifically be mentioned in their forwarding letter. After receipt of the same, after due scrutiny, this office will issue **Permanent CBN Registration Number** to the applicant company. An intimation in this regard shall be sent to the applicant company, accordingly.

B. Submission & Management of Quarterly Returns:-

1. The applicant company should have to file the quarterly returns (in manual forms by post or by hand or by e-mail) strictly in accordance with the time frame given under Rule 65 of NDPS Rules, 1985, failing, which, their registration will be liable to be cancelled. In addition, the company shall ensure preserving the quarterly returns submitted in manual form as record for the period up to the completion of two years from the date of restoration of the CBN Online Portal.

2. The companies who have been registered during the period when CBN Online Portal is not functional, shall have to preserve their manually/ offline sent quarterly returns up to the period 2 years after restoration of the CBN Online Portal. The companies shall provide the information/ detail with regard to their CBN Registration or their quarterly returns, as and when they are directed to do so.

3. immediately after restoration of the CBN Online Portal, all the firms having Permanent CBN Registration Numbers shall file/ update their quarterly returns on the CBN Online Portal which were filed manually/ in offline mode.

F. No. XVI/5/138/Online/ Psy/ 2019-127

Central Bureau of Narcotics, Ministry of Finance, 19,The Mall, Morar, Gwalior (M.P.)

Annexure - I

Application for issue of Provisional Certificate of Registration

(To be submitted by the applicant company involved in the manufacture/ trading/ research of the psychotropic substances)

Temporary CBN Registration Number *(To be filled by the CBN)*	

1. Details of User Type

Name of the firm/ company	
Address of the Corporate office	
Address of Registered office	
Business type of the firm/ company *(Choose one of the following category)* 1. Manufacturer of Bulk/ API of psychotropic substances 2. Manufacturer of preparation(s) of psychotropic substances 3. Other Trader of Bulk/ API of psychotropic substances 4. Other Trader of preparation(s) of psychotropic substances 5. Wholesaler of Bulk/ API of psychotropic substances 6. Wholesaler of Preparation(s) of psychotropic substances 7. Other Institute of Bulk/ API of psychotropic substances 8. Other Institute of preparation(s) of psychotropic substances	
If the applicant is a Manufacturer of Bulk/ Preparation, then, addresses of all the Manufacturing sites of the psychotropic substances of the applicant company	
Jurisdictional GST Commissionerate with full address	
Whether falling under any Special Economic Zone. If yes, details thereof.	

2. Contact details of the authorized signatory

Name	Designation	Tel. No.	Mobile No	Email Id	Remarks

3. PAN details

Name of the PAN Holder	
PAN Number	

4. Certification details

Company Incorporation Certification Details

Certificate Number	
Date of Issue	
Issuing Aurthority	

5. Details of the Importer-Exporter Code issued by the DGFT

IE Code	
Date of Issue	

6. Details of the Psychotropic Substance(s) for which the CBN Registration has been sought

Substance Name	Salt/ Base	Composition/ Brand Name	Generic Brand Name	Unit	Amount of Salt	Domestic Distribution Purpose (Yes/ No)	Import Purpose (Yes/ No)	Export Purpose (Yes/ No)

7. **License Details**
Registration under Central Sales Tax/ VAT

Registration Number	
Date	
Taxpayer Identification Number (TIN)	
Issuing Authority	

8. **Details of the Drug Licenses pertaining to Manufacture/ Trading/ Research & Development activities of the psychotropic substances**

Name of the License	
License Number	
Date	
Validity	
Details of the Issuing Authority with address	

9. **Details of the Certificate Issued by the Ministry of Corporate Affairs**

Certificate Number	
Date of Issue	
Issuing Authority	Ministry of Corporate Affairs

10. **List of Documents to be attached**

Specific Power of Attorney (To be attached with this application in original)
If the applicant is Manufacturer, then, Copy of the Drug Manufacturing License along with complete product list (Duly self-authenticated by the authorized signatory)
If the applicant is other than Manufacturer, then, Copy of the relevant License (Duly self-authenticated by the authorized signatory)
Copy of the PAN (Duly self-authenticated by the authorized signatory)
Copy of the GST registration (Duly self-authenticated by the authorized signatory)
Copy of the Import-Export Certificate (Duly self-authenticated by the authorized signatory)

Signature of the applicant with seal:

Name and designation:

Contact details
(Land line/ Mobile Number and email ID)

Date

WTO talks on Trips waiver from June 30

At the informal meeting of the Trips Council on Thursday, it was also decided that other issues such as duration and implementation of the waiver will be discussed at a later stage depending on the first stage of talks, officials said.

World Trade Organization (**WTO**) members will on June 30 begin talks on the scope and coverage of the waiver of provisions of the Trade-Related Aspects of Intellectual Property Rights (Trips) agreement proposed by **India** and **South Africa** for Covid-related medicines.

"There was agreement on regular Trips Council sessions to push negotiations," said an official.

At the informal meeting of the Trips Council on Thursday, it was also decided that other issues such as duration and implementation of the waiver will be discussed at a later stage depending on the first stage of talks, officials said.

Differences remain on how to ensure rapid and equitable access to vaccines and Covid-related **medical products** for all as the **European Union** and a few others are still opposing a revised proposal by India and South Africa seeking patent waivers on Covid-related medical products for three years, with a provision to review the duration annually.

"There was agreement on regular Trips Council sessions to push negotiations," said an official.

The meeting was the first after the WTO members agreed to engage in text-based discussions on the proposal for waiver of intellectual protection rights for Covid medication.

At the Thursday meeting, the US expressed doubts about starting a discussion on the scope of the waiver instead of focusing on common objectives and said some proposals could be very expensive as they unfold over the next 5-10 years.

The discussions on the proposal will continue on July 6, 14 and 20 between which meetings among small groups would be held. The first consultation period will start soon, leading up to the first open-ended session and stock taking meeting on June 30.

The General Council of the WTO will check the progress of the negotiations on July 27-28, instead of July 21-22 as planned earlier, the official said.

EU seeks parity

The European Union, which has backed the use of flexibilities within existing frameworks such as compulsory licences instead of new ones, sought its submission to be treated on a par with the waiver proposal though India and South Africa argued that the two be discussed separately in parallel tracks.

"While the India and South Africa proposal is based on Article 9 of the WTO Agreement, what the EU has made is not a formal proposal. They can't be treated equally," said an expert on WTO issues.

South Africa argued that from the legal point of view of the discussions, the waiver proposal and the communication by the EU should be addressed on different tracks.

Source : By Kirtika Suneja, ET Bureau, 18.06.2021

Covid-19: On vaccine interval, follow the science

Review of Covishield dose-interval is welcome; to quell controversy, let independent experts appraise evidence cited

Right now, the Centre can't afford further trust deficit over vaccines.

Against the backdrop of senior scientists saying the NTAGI didn't have enough data to back the recommendation to increase the gap between two doses of the Covishield vaccine from 8-12 weeks to 12-16 weeks, chairman NK Arora has said the government is reviewing the move. The scientists were quoted on the inadequate data in a Reuters report earlier this week. The government has denied this, saying the decision was unanimous and there were no dissenting scientists. It has cited the minutes of meetings of the Covid-19 working group of the NTAGI on May 10 and the Standing Technical Sub-Committee of NTAGI on May 13. While the working group' recommendation was "based on real-life evidences particularly from the United Kingdom", increasing the interval between the two doses to 12-16 weeks, the technical sub-committee had talked of "an interval of a minimum three months" (or roughly 12 weeks), as per a government release. The government is yet to clarify whether it had endorsed a gap of 12-16 weeks, and if it didn't, how it settled on 16 weeks as the maximum interval. The example of Spain has been cited with regards to the 16-week gap. However, the fact is Spain recommended the 16-week interval only for those under 60 years of age. The controversy can be quelled if independent experts can examine real-life evidence that the government says corroborates the scientific strength of India's decision. Right now, the Centre can't afford further trust deficit over vaccines. The deadly second wave has had the unfortunate consequence of stoking vaccine hesitancy because of breakthrough infections, despite these being a very small number. As such, even if it manages to get NTAGI scientists to put up a 'unanimous front', it needs to do much more to engender trust.

Around the time the Indian government announced the 12-16 weeks gap, the UK had reduced the interval between two doses of the AstraZeneca vaccine from 12 weeks to 8 weeks at the maximum. This was done in light of the increasing prevalence of the Delta variant—it now accounts for 98% of the cases in the country. Bear in mind, the Delta variant is widely held to have been one of the primary factors behind India's deadly surge. Data from Public Health England analysed by researchers, as Dr Srinath Reddy of PHFI has pointed out in this newspaper, show a single-dose of AstraZeneca—with caveats on the sample size—registers a very low efficacy against Covid-19. Two doses, on the other hand, offer reasonable protection, making a strong case for shortening the dose-gap. Thus, if the government is indeed considering a review of the interval, it is good news. In the interim, it must consider narrowing the interval for those who are more vulnerable to the disease, because of their age or immunocompromised status. Those arguing against further categorisation for targetting vaccines would do well to keep in mind the government only recently created a category for prioritisation of vaccines: students up for admission abroad. The INSACOG episode—Reuters reported how the ministry and some scientists within INSACOG were not on the same page initially regarding the seriousness of the threat from the Delta variant—and now the NTAGI episode underscore the need to let science drive the response to the pandemic, not concerns of the politically-minded.

Source : The Financial Express , 18.06.2021

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Now, PETA urges govt to not use calf serum in Covaxin production

Covaxin does not contain calf serum, but the serum is used in the labs to boost the growth of Vero cells, both the government and Bharat Biotech clarified

Peta has now urged the Drug Controller of India to find an alternative to calf serum for Covaxin production.

A day after the government clarified that Covid-19 vaccine Covaxin does not contain calf serum, People for the Ethical Treatment of Animals (PETA) India on Thursday wrote to the Drugs Controller General of India urging him to replace newborn calf serum with an animal-free chemical solution, reports said. The government on Wednesday explained that Covaxin does not contain calf serum, but calf serum is used at the very first step of the production.

In its letter, PETA said the calves required for this purpose are taken away from their mother shortly after birth which traumatises both the mother and the calf. It also said that there are animal-free alternatives already available.

What is the controversy all about?

Congress's Gaurav Pandhi has recently shared an RTI reply document on social media which says that newborn calf serum is used for the growth of Vero cells.

The government said that claiming that vaccine contains calf serum is twisting and misrepresenting the fact as the final product does not contain any aminal part. It explained that to ensure the growth of Vero cells, calf serum is used as the serum has some properties which boost the growth of Vero cells. These Vero cells, after growth, are washed with water many times to make them free from the calf serum, which is only used as a growth agent.

Why calf serum is used in vaccine production

Calf serum's biological properties make it crucial for rapid cell growth as newborn calf have fewer antibody properties.

On the allegation of animal cruelty

In his tweet, Gaurav Pandhi claimed newborn calves are slaughtered for obtaining serum, which many on social media contested and said there are many ways to get the serum. Importing is also one of them.

Bharat Biotech has not specified how they procure calf serum for their vaccine production, but it has clarified that the use of newborn calf serum is not a secret. The company has been in the vaccine-making business for decades and this is the standard process of producing vaccines.

If calves are not killed, why PETA is opposing

PETA said the Prevention of Cruelty to Animals (Slaughter House) Rules, 2001, prohibits the slaughter of pregnant animals and animals under three months of age. "Therefore, the use of serum obtained by slaughtering a calf younger than 20 days of age for vaccine production should also not be allowed," it said. But even if they are not killed, they are traumatised for being snatched from their mothers just after their birth, PETA said.

It also raised the issue of the risk of contamination in the vaccine, which Bharat Biotech has already addressed and said that Covaxin is pure and there is no trace of calf serum in the finished product.

Source: Poulomi Ghosh, Hindustan Times, 17.06.2021

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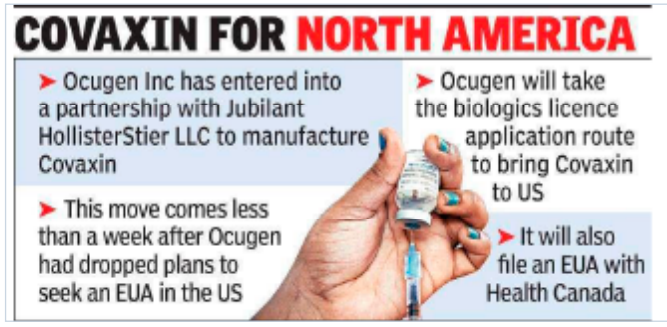
Ocugen ties up with Jubilant to make Covaxin for US, Canada

HYDERABAD: Bharat Biotech's US partner Ocugen Inc has entered into a partnership with Jubilant HollisterStier LLC, a step-down subsidiary of Jubilant Pharmova, for the manufacture of indigenously developed Covid-19 vaccine Covaxin for the United States and Canadian markets, Jubilant Pharmova said in a regulatory filing.



The announcement comes less than a week after Ocugen informed bourses in the US that it had dropped plans to seek an emergency use approval (EUA) from US Food & Drug Administration based on the regulator's recommendation and would be taking the BLA (biologics licence application) route to bring Covaxin to the US market. Ocugen had also said it would be filing an EUA with Health Canada for taking Covaxin to Canada.

Ocugen's senior vice president of manufacturing and supply chain, JP Gabriel, said in a statement that Ocugen was fully committed to bringing Covaxin to the US and Canadian markets because it has the potential to save lives by adding a weapon to the arsenal. "Securing US-based manufacturing capability is a critical step as we prepare to submit our regulatory submissions to the FDA and Health Canada.

Based on Bharat Biotech's strong track record of developing and commercializing vaccines globally and Jubilant's proven track record in manufacturing," Gabriel added. Jubilant Pharma Ltd CEO Pramod Yadav said: "With two facilities in North America working to manufacture multiple Covid-19 vaccines and therapies, we remain committed to supporting efforts to eradicate this global pandemic."

Source : Swati Bharadwaj , TNN, 17.06.2021

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Watchdog tells pharma firms to pass on rate cut benefits to consumers

- Since drug prices are inclusive of taxes, producers and marketing firms should lower the maximum retail price, taking into account the GST rate cut announced last Saturday
- The government had last week lowered the GST on Tocilizumab and Amphotericin B to zero from 5%

The National Pharmaceutical Pricing Authority (NPPA) has urged manufacturers of medicines and medical devices used in treating covid-19 to slash product prices and pass on the benefit of tax rate cuts to consumers.

In an order on Wednesday, the drug pricing watchdog said since the prices are inclusive of taxes, producers and marketing firms should lower the maximum retail price, taking into account the reduction in goods and services tax (GST) rates announced on 12 June.

However, NPPA said that in case of products that have already been dispatched, there was no need to change the price tag on the package, but producers must ensure compliance of the new low price at the retail level by sending a revised price list.

The government had lowered GST on tocilizumab used in treating inflammatory and autoimmune conditions, and anti-fungal drug amphotericin B to 0% from 5%, and anti-viral injection remdesivir and blood thinner heparin to 5% from 12% earlier. The tax cuts covered 18 categories, including medical oxygen and oxygen concentrators. NPPA's order was addressed to both pharmaceutical companies as well as medical device makers.

Following the NPPA order, the All India Organisation of Chemists and Druggists (AIOCD) also advised its members to revise MRPs. "We have requested all pharmaceutical companies manufacturing remdesivir, tocilizumab, heparin and amphotericin B to send us the new prices urgently so that we can inform the trade to follow the gazette notification," said Rajiv Singhal, general secretary, AIOCD.

NPPA mandated pharmaceutical manufacturers and marketing companies to pass on GST rationalization benefits on covid items, including oxygen concentrators, said Rajat Mohan, senior partner at chartered accountant firm AMRG and Associates. "In case of unsold stocks in the market, manufacturers are made liable to ensure prices are reduced by every retailer with immediate effect, irrespective of the old MRP tags. Large stockists of the covid items will experience temporary accumulation of tax credit proportionate to the unsold stocks," he added.

In India, remdesivir is manufactured by seven companies, including Hetero Drugs, Cipla, Dr Reddy's Laboratories and Zydus Cadila, through a voluntary licence issued by Gilead Sciences. Sun Pharmaceutical Industries also makes the drug in partnership with Syngene International Ltd.

The Centre has recently said remdesivir must be used only in select covid-19 patients on supplemental oxygen as it is a reserve drug approved under emergency use authorization based on limited scientific evidence globally.

The government has also asked amphotericin B manufacturers to increase production in view of the rise in cases of mucormycosis, or black fungus, among covid patients.

Tocilizumab, which is being imported from Switzerland by Cipla, costs 40,000- 50,000 for a single dose in India, and helps reduce the inflammatory storm in the respiratory system of severe covid patients.

Source: Neetu Chandra Sharma & Gireesh Chandra Prasad, HT Mint, 17.06.2021

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COVID-19 Has Created An "Ecosystem" Of Innovation In India: Kiran Mazumdar-Shaw

"The whole intent (of the more than a decade old annual India-US bio pharma summit) is to catalyse an innovation ecosystem in India. I think, COVID has actually created the ecosystem," Mazumdar-Shaw told in an interview.

The ongoing COVID-19 public health crisis has resulted in the creation of an "ecosystem" of innovation in India, Biocon chief Kiran Mazumdar-Shaw has said ahead of the annual India-US bio-pharma summit in Boston next week.

Mazumdar-Shaw, 68, is one of the key speakers at the 15th edition of the annual virtual summit on June 22 hosted by the USA India Chambers of Commerce. The other star-studded speakers include Dr Albert Bourla, Chairman and CEO of Pfizer; Dr Francis Collins, Director, National Institutes of Health; Dr Janet Woodcock, Acting Commissioner, US Food and Drug Administration; and Amitabh Kant, CEO of NITI Aayog.

"The whole intent (of the more than a decade old annual India-US bio pharma summit) is to catalyse an innovation ecosystem in India. I think, COVID has actually created the ecosystem," Mazumdar-Shaw told PTI in an interview.

COVID, she, noted, has actually resulted in innovative vaccines being produced, such as Covaxin, Genova mRNA programme, and many other programmes that the Indian vaccine makers have licensed and developed in the country.

"Then, of course, the whole clinical research ecosystem has been created because we"ve had so many clinical trials in India, whether it is for new repurpose drugs or vaccines... basically bridging trials, a lot of clinical trials have also happened in India," said the executive chairperson and founder of Biocon, a top biotechnology company based in Bangalore, noting that clinical trials were banned in India at one stage.

"And then when the whole environment opened up for clinical trials, there were not enough trials going on. Now suddenly, a whole bunch of clinical trials have gone on. A lot of clinical sites have opened. A lot of investigator-initiated studies have started.

"I think the whole understanding that you"ve just got to get into clinical trials and clinical research, to actually address a large number of unmet needs is now beginning to dawn on the Indian innovation system," Mazumdar-Shaw said.

She noted that India has a large number of incubators, where they are developing some very innovative programmes.

"There is VC funding now getting into those programmes. So slowly, that ecosystem has been created," the billionaire entrepreneur said, adding that companies from India have started US operations to raise funding and are becoming a part of the US" innovation ecosystem.

The COVID-19 crisis, she observed, has also brought the pharma companies from India and the US together.

Citing examples, she said, Novavax has partnered with Serum Institute. The Baylor Institute has partnered with Biological-E, Johnson and Johnson has partnered with Biological-E and contracted manufacturing their vaccine.

Then there are many other programmes that have been licensed from US academic centres, Mazumdar-Shaw said.

The nasal vaccine that Bharat Biotech is developing has been licensed from the University of Wisconsin. A lot of that kind of partnership and collaborations are ongoing, she said, adding, "COVID has definitely brought a lot of spotlights on to those kinds of opportunities".

One of the major challenges of the global bio-pharmaceutical industry was the disruption of global supply chains. And one of them was the raw material supply chain required for vaccine production, the Biocon head said.

India, she said, was dependent on the US for raw materials for vaccine manufacturing. Recently, the US and India came together and the ban on supply of the raw materials was revoked, paving the way for Indian vaccine manufacturers to produce the jabs required for global markets.

"Today, India has been recognised as one of the largest producers of vaccines in the world. They (the Indian pharma companies) were limited in terms of their vaccine capacity because of some of these constraints. But now with the US opening up that kind of supply of products to vaccine manufacturers, they have also enabled the production of vaccines for global markets," Mazumdar-Shaw said.

Responding to a question, she said India and the US need to make sure that there is free sharing of knowledge on technologies and products and any kind of export ban be lifted. That would be a very good policy for both the countries to adopt.

"The fact that there"s already a natural collaboration happening between Indian companies and the US companies and academic institutions. Ultimately it is really about having access to each other"s markets, because India is a huge market and so is the US," she said.

Mazumdar-Shaw said while most Indian genetic companies are dependent on the US market, a lot of American companies are also looking at India as a market that is important in the future.

"From that point of view, it"s a symbiotic and win-win kind of an opportunity for both the countries," she said.

Observing that the second wave of COVID-19 is receding and the numbers are coming down very rapidly, Mazumdar-Shaw said India has learned many lessons from this public health crisis.

"Every country has learned lessons in COVID-19. One is that you cannot be complacent. Secondly, there are going to be waves of the pandemic. So just because one wave

recedes, doesn"t mean that another wave won"t happen. Thirdly, you got to be in a state of preparedness all the time. You cannot be complacent.

"Fourthly, you must have very strong surveillance measures. Because that is something which every country has not done very well, and it has got surprised by an outbreak, which has suddenly led to another wave," she said.

Mazumdar-Shaw said any government needs to make sure that it calibrate the opening up of the economy and adopt COVID appropriate behaviour.

"You must be very vigilant about any outbreaks anywhere. Because small outbreaks can really start becoming very serious if you ignore them. These are some of the learnings. But most importantly, the world has realised that by vaccinating dense populations that have high caseload, they"re able to basically bring down and manage the pandemic much better than if you just tried to vaccinate everyone," she said.

Noting that healthcare costs are very challenging right now, Mazumdar-Shaw said products like generics and biosimilars are going to be very helpful and they will also contain the healthcare costs.

"Indian pharma companies will continue to basically address these healthcare needs... From that point of view, I see that right now all the focus has been on COVID, but we"ve also neglected a lot of other disease areas. Now that the economy has opened, hospitals have opened...you"re going to see a huge demand for many, many of these products (generics and biosimilars)," she said.

Source : PTI, 15.06.2021

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Glenmark launches dry powder inhaler Tiogiva in UK

Pharma major Glenmark Pharmaceuticals Ltd on Tuesday said it has launched a bioequivalent version of Tiotropium Bromide dry powder inhaler (DPI) under the brand name - Tiogiva, in UK for the treatment of chronic obstructive pulmonary disease (COPD).

According to Glenmark, COPD is a long-term condition that causes inflammation in the lungs, damaged lung tissue and a narrowing of the airways, making breathing difficult.

There are many different types of the condition, although little is known about what causes this variation and the best way to manage the different versions of the disease.

According to data from IQVIA, Tiotropium DPI had a market size of US$ 450 million in the European Union in the 12 monthAperiod ended September 2020.

Glenmark's subsidiary, Glenmark Pharmaceuticals Europe Limited had entered into a strategic, exclusive in-licensing arrangement for marketing generic Tiotropium Bromide DPI in Western Europe and UK in August 2018.

Glenmark is planning subsequent launches of the product across markets in Western Europe under the brand name Tiogiva in Ireland, Sweden, Finland and Norway; Tavulus in Denmark, Spain and Netherlands and Tiotropium Glenmark in Germany.

Tiotropium Bromide DPI is a bioequivalent version of Boehringer Ingelheim's Spiriva Handihaler and is used in the treatment of COPD, Glenmark said.

According to Glenmark, this is the second inhalation product in-licensed by Glenmark for the European market after StalpexA(Fluticasone/ Salmeterol) dry powder inhaler.

Source: IANS, 16.06.2021

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Bharat Biotech officials to meet WHO assessors next week

A pre-submission meeting provides an opportunity to the company for advice and guidance before submission of the final dossier, as well as an opportunity for them to meet WHO assessors who will be involved in assessing their product.

The World Health Organization (WHO) will hold a 'pre-submission' meeting with Hyderabad based Bharat Biotech regarding the approval of its Covid-19 vaccine Covaxin on June 23.

In May, Bharat Biotech said its Emergency Use Listing (EUL) application had been submitted to WHO, Geneva, and regulatory approvals are expected between July and September.

A pre-submission meeting provides an opportunity to the company for advice and guidance before submission of the final dossier, as well as an opportunity for them to

meet WHO assessors who will be involved in assessing their product.

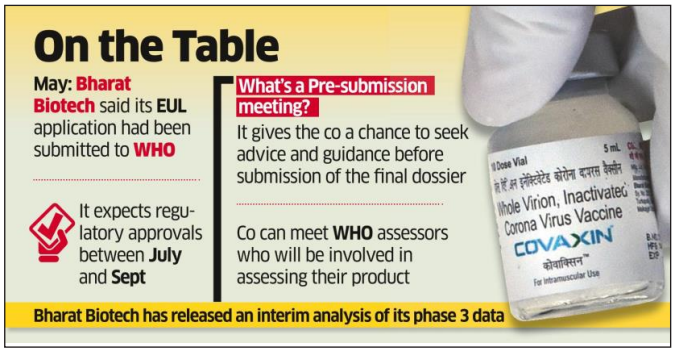
The WHO Emergency Use Listing/Pre qualification evaluation process guidance document dated May 18 posted on the WHO website said Bharat Biotech had submitted its Expression of Interest on April 19 and that more information is required.

"The final dossier and the results of Phase III will be submitted after next week's meeting," a person aware of the development told ET.

Submission of Phase III data along with data on manufacturing quality is mandatory for Emergency Use Listing (EUL). The EUL pathway involves a rigorous assessment of clinical trial data as well as additional data on safety, efficacy, quality, and a risk management plan.

Bharat Biotech has released an interim analysis of its phase 3 data, but it has not yet published full results from phase 3 study in an internationally recognised peer review journal.

Bharat Biotech had earlier said it will make Covaxin's Phase-3 trial data public during July, following which the company will be applying for full licensure of the Covid-19 vaccine in India. It also said it was conducting Phase-4 trials to check the "real-world effectiveness" of the vaccines and to meet scientifically approved standards for safety and efficacy.



An emergency approval from the WHO will allow the company to export its vaccines, and enable easy international travel of Indian citizens who have been administered Covaxin.

The EU and some countries like Saudi Arabia have made it mandatory for travelers to take approved vaccines (those cleared by WHO or the US, UK, and EU regulators) before they can step foot on their shores.

At present, several countries have imposed restrictions on international travel from India but this can become a thorny issue for those who have taken the Covaxin jab once these restrictions are lifted.

Source: Teena Thacker, Economic Times, 18.06.2021

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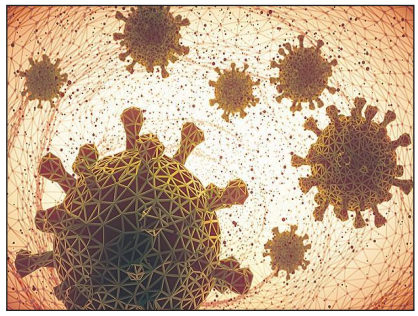
Delta, Delta Plus variants and their response to vaccines

While virologists say theoretically the vaccine that works on Delta should work on the Delta Plus variant as well, more research is needed



Delta and Delta Plus variants of Sars-CoV-2 are causing concern among doctors and researchers as the world tries to map the spread, virulence and potential risks of these mutations. India has said that Delta Plus is not yet a variant of concern. But what are these variants, where did they originate and are vaccines effective against them? Let's find out.

What is the Delta variant of Sars-CoV-2 and what is its origin?

All viruses, including SARS-CoV-2 that causes Covid-19, change over time. Most changes have little to no impact on the virus' properties. However, some changes may affect how easily the virus spreads and the associated severity of the disease, the performance of vaccines, therapeutic medicines, diagnostic tools, or other public health and social measures.

The earliest documented examples of the Delta variant, officially named B.1.617.2, are from India, according to the World Health Organization (WHO).

In April this year, the WHO classified the Delta variant as a "variant of interest" (VOI) — a variant that warranted close monitoring because of its potential risk. But in May, it reclassified it as a "variant of concern" (VOC) — to signify that it posed additional risks to public health.

This strain is thought to be behind the second wave of infections in India.

What is the Delta Plus variant?

The Delta Plus, or Delta-AY.1 variant, is a mutated version of the B.1.617.2 variant or strain. This strain is characterised by the K417N mutation in the spike protein of the SARS-CoV2 virus that causes the Covid-19 disease.

According to reports, the K417N mutation has been associated with "immune escape", which basically means that the virus is less susceptible to — or less responsive to — any drug therapy. The Indian government has said that the Delta Plus variant is not a variant of concern.

Where did Delta Plus originate and in which countries do we find it now?

The Indian government has said that the variant has been seen in Europe since March.

Public Health England, an executive agency of the Department of Health and Social Care in the United Kingdom, has said that the Delta Plus variant has been identified in six genomes from India till June 7. These sequences have been found in genomes from 10 countries so far, some scientists have said. US, Canada, UK, Japan, Portugal, Poland, Russia, Turkey, Nepal and Switzerland are among the countries that have reported this strain.

"The variant prevalent in the US is called Alfa; the one prevalent in South America is Beta and the one in Africa is Theta. And the European countries have seen the prevalence of Gamma, besides Theta," explained Chandrashekhar T, chief intensivist, Fortis Hiranandani Hospital, Vashi, Mumbai.

He added that Delta was by and large prevalent in India and Asia, and has now spread to other nations, too. The Kappa variant was prevalent in Australia. "The Delta variant was there in the first wave as well. However, the coronavirus is in constant mutation, with increasing transmissibility and virulence," the doctor said.

How virulent are these variants?

The Delta Plus variant is said to be resisting the monoclonal antibody cocktail — Casirivimab and Imdevimab — treatment given to high-risk Covid-19 patients in the early stages of this disease. This treatment recently got the nod in India from the drug regulator.

Scientists, however, are not certain if this resistance means that the new variant has a higher transmission rate or that it causes more severe infection compared to the other predominant strains.

Chandrashekhar said that it is believed to be 60 per cent more transmissible than the B.1.1.7 variant (or the alpha variant) and may be associated with an increased disease severity such as hospitalisation risk.

Are Covishield, Covaxin, Pfizer, Sputnik and other vaccines effective against the Delta and Delta Plus variants?

According to Public Health England, Pfizer and AstraZeneca vaccines offer protection against the Delta variant. The protection is more than 90 per cent against hospitalisation or getting severe disease.

Covaxin, the Bharat Biotech vaccine, also offers protection against the Delta variant, the company and the Indian Council of Medical Research have claimed.

Sputnik V's official Twitter handle claimed it works against the Delta variant, too. It said it was more "efficient" than any other vaccine.

A study conducted by the All India Institute of Medical Sciences, Delhi, and the National Centre for Disease Control recently said that the Delta variant can infect partially or fully vaccinated people. The infection does not become severe, however.

While virologists say theoretically the vaccine that works on Delta should work on the Delta Plus variant as well, more research is needed.

Source: Sohini Das, Business Standard, 17.06.2021

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Indians spent Rs 15,000 crore on immunity boosters in a year

Data from the All India Organisation of Chemists & Druggists (AIOCD) showed that in the June 2020-May 2021 period, Indians bought Rs 1,220 crore of antiviral drug Favipiravir and Rs 833 crore of Remdesivir. Sales of antibiotic Azithromycin stood at Rs 992 crore, 38% higher on-year. Sales of Doxycycline almost tripled to Rs 85 crore. Sales of anti-parasitic drug Ivermectin surged over 10 times to Rs 237 crore.

Indians bought nearly Rs 15,000-crore of vitamin supplements and other **immunity boosters** in the twelve months to May, up about a fifth from the same period the preceding year, as sales of drugs related directly or indirectly to **Covid-19 treatment** surged. Prescription antivirals and antibiotics, such as **Favipiravir**, **Remdesivir** and Azithromycin, were also in demand.

Data from the All India Organisation of Chemists & Druggists (AIOCD) showed that in the June 2020-May 2021 period, Indians bought Rs 1,220 crore of antiviral drug Favipiravir and Rs 833 crore of Remdesivir. Sales of antibiotic Azithromycin stood at Rs 992 crore, 38% higher on-year. Sales of Doxycycline almost tripled to Rs 85 crore. Sales of anti-parasitic drug **Ivermectin** surged over 10 times to Rs 237 crore.

Indians also bought immunity-boosting vitamin drugs and mineral supplements worth Rs 14,587 crore, about 20% more than in the preceding year. Sales of vitamin D alone stood at Rs 817 crore, about 40% higher. Zinc supplements sold nearly three times more at Rs 183 crore.

Direct Dispatches not Included

Sales of plain vitamin C on the other hand nearly quadrupled to Rs 340 crore.

To be sure, sales of these categories of drugs could be even higher as AIOCD data do not include company dispatches directly to large hospitals or institutions.

"AIOCD sources data from stockists. Thus, sales of drugs that pharma companies directly sell to the hospitals and other institutions may not get captured in the AIOCD data," said Krishnanath Munde, Associate Director, **India Ratings and Research**.

Sales of leading drug brands sold amidst Pandemic (₹ cr)

Brand	Drug	Company	Yr ended May '21	Yr ended May '20
Fabiflu	Favipiravir	Glenmark Pharma	975	*
Zincovit	Multivitamin	Apex Labs	585	230
Becosules	B Complex + vit C	Pfizer	433	337
Cipremi	Remdesivir	Cipla	309	*
Shelcal	Calcium	Torrent Pharma	279	223
Azithral	Azithromycin	Alembic	259	170
Revital H	Multivitamin	Sun Pharma	200	132
Limcee	Vitamin C	Abbott Healthcare	192	48
Uprise D3	Vitamin D	Alkem Labs	132	72

These drugs were launched after May 2020 Source: AIOCD AWACS

Multivitamins were in demand because of their **immunity booster** properties, said Sheetal Sapale, President – Marketing, AIOCD AWACS. Antivirals Favipiravir and Remdesivir were also in high demand through the second wave because of their direct role in Covid treatment.

Antibacterials such as Doxycycline and Azithromycin and anti-parasitic agents such as Ivermectin reported increased demand due to infections triggered by compromised immunity, said Sapale.

Medicines are largely an out-of-pocket expense item for Indians, and the share of wellness and prescription drugs in total expenses increased for the average household since the onset of the pandemic.

For several companies that rolled out such products on time, sales through the period under review were robust. Glenmark Pharma, the first to introduce Favipirvir in India in June last year, earned Rs 975 crore until May, accounting for four-fifths of the drug's total sales in the country until last month. Glenmark's domestic sales stood at Rs 3,536 crore for FY21.

Cipla and Cadila Healthcare earned Rs 309 crore and Rs 215 crore, respectively, from Remdesivir sales. Similarly, sales of leading vitamin and minerals supplement brand Zincovit of Apex Labs nearly tripled to Rs 585 crore. Limcee, a vitamin C supplement marketed by Abbott Healthcare, saw its sales quadruple to Rs 192 crore.

Vitamin D brand Uprise D3 of Alkem Labs almost doubled its sales from Rs 72 crore to Rs 132 crore. Multivitamin brands A to Z grew 58% and Supradyn 76%. Health supplement brands Revital and Protinex witnessed on-year jumps of 52% and 64%, respectively.

Incidentally, the latest Director General of Health Services (DGHS) guidelines published late last month have dropped Favipiravir, Ivermectin, Azithromycin, Doxycycline and Hydroxychloroquine from the list of drugs to be directly used in Covid treatment. Zinc supplements and multivitamins, too, do not find mention in the guidelines. Also, the use of Remdesivir and Tocilizumab has been restricted to select cases.

Still, experts believe that would not immediately change prescription patterns.

"Lancet or health ministry guidelines do not get widely read and it becomes difficult for physicians to delete these drugs from their prescriptions after it has developed into a deep-rooted ritual," said Dr SP Kalantri, Director and Professor of Medicine, Mahatma Gandhi Institute of Medical Sciences.

Source: Economic Times, 17.06.2021

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Covid-19 vaccine pricing accounts for last-mile delivery, say firms

The cost of logistics is built into the final price of the vaccine, especially when supplying to the private sector

The two Indian vaccine makers —Bharat Biotech and Serum Institute of India — bear the cost of last-mile delivery of their Covid-19 vaccines, executives said.

While supplying to the government this means movement from their plants to states' cold chain points, but for private hospitals, it is delivered at the doorstep.

The cost of logistics is, thus, built into the final price of the vaccine, especially when supplying to the private sector.

A senior executive of Bharat Biotech explained: "When we supply to the government, we dispatch the doses to the state-wise cold chain points.

Each state would have more than one such point. The government takes it from there and ensures distribution to vaccination centers."

According to *PTI*, the government has invited bids for last-mile delivery of vaccines to remote areas through drones.

However, in case of delivering to private hospitals, the vaccine makers have to send it to the specific hospital itself. "Nothing extra is charged from hospitals. This logistics cost, which is significant, is built into the pricing," the executive mentioned.

Cost of logistics is largely determined by the volumes. Supplying a few thousand doses to hospitals thus becomes a challenge, say the vaccine makers.

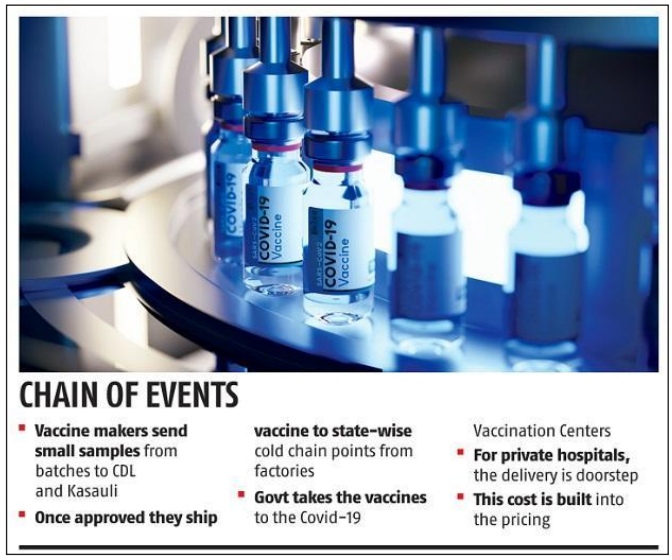
Pune-based SII too follows the same model, sources confirmed. Bharat Biotech charges private hospitals Rs 1,200 per dose for Covaxin, while SII charges them Rs 600 per dose for Covishield.

The cost for the government is much lower at Rs 150 per dose, and the vaccine makers have indicated that this is not sustainable.

Bharat Biotech said on Tuesday that supplying at Rs 150 per dose is not sustainable in the long run.

It has invested Rs 500 crore from internal accruals for development and production of the vaccine and has to pay royalties on sales to the Indian Council of Medical Research, and its adjuvant supplier Virovax of Kansas.

Vaccine logistics has to take into account a few things — spoilage and integrity of the cold chain. Vaccines do not hold their potency for long and thus have to be transported to the last mile within a certain time frame, maintaining the temperature requirements. As a result, commercial cold chain players are seeing an opportunity.



For Sputnik V, which is now available at private hospitals, Hyderabad's Rockwell Industries has partnered with Dr Reddy's Laboratories. Rockwell Industries has got orders for 750 Covid-19 vaccine freezers from hospitals and institutions. It is now set to start exports of these freezers to various countries, including Japan.

Sputnik V requires a temperature range of -18 degrees Celsius to keep the vaccine stable and potent.

Source: Sohini Das, Business Standard, 17.06.2021

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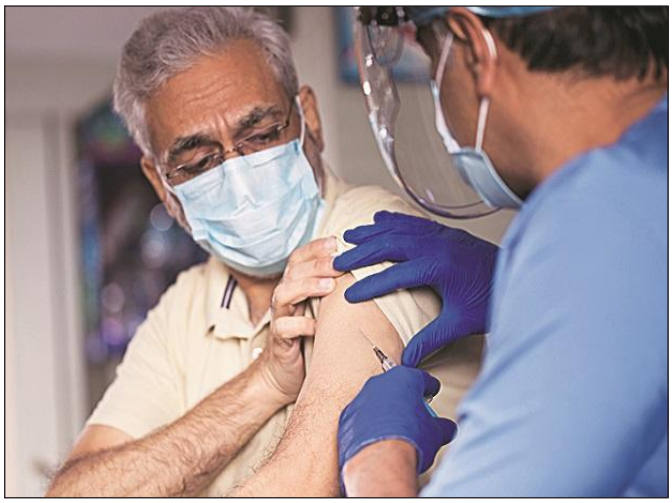
How Biological E could emerge as game changer in India's vaccine race

Company scales up its ambition after government advanced it Rs 1,500 crore for 300 million doses of its vaccine candidate.

A few weeks ago, Hyderabad-based Biological E made headlines by becoming the second created-in-India vaccine player with the government announcing an advance of Rs 1,500 crore for 300 million doses of its candidate Corbevax, which is awaiting the drug regulator's approval. This order is part of a larger vaccine plan by this

73-year-old company, currently the world's largest producer of tetanus vaccines.



The sheer volumes could make Biological E, considered a dark horse in the business, a game-changer, more so because Corbevax is not its only bet. Last year, Mahima Datla, MD and CEO and granddaughter of the founder, told *Business Standard* that the company plans to make 1.5 billion doses of Covid-19 vaccines in 2021. Of this, 500-600 million doses will be contract manufactured for the single shot candidate of US major Johnson and Johnson under the Quad Vaccine Partnership, an alliance between India, the US, Japan and Australia.

By 2022, there is a plan to make an mRNA-technology vaccine, for which it has tied up with Canadian firm Providence Therapeutics. The vaccine, named PTX-COVID19-B, is under development in Canada and the plan includes conducting clinical trials in India. The financial terms of the deal were not disclosed, but Providence will sell up to 30 million doses of PTX-COVID19-B to Biological E and transfer technology to make the vaccine in India, with a minimum production capacity of 600 million doses in 2022 and target capacity of one billion doses.

To put these plans in perspective, Pune-based Serum Institute of India (SII), the world's largest vaccine maker by volume, manufactured 1.5 billion doses in FY 2019-20. This financial year, SII has scaled up annual capacities to over 2 billion doses.

But it is Corbevax that is attracting attention as India's vaccine programme gathers momentum. Currently undergoing Phase 3 clinical trials, the National Expert Group on Vaccine Administration for Covid-19 had conducted due diligence on Biological E's proposal before approving the advance payment.

The government has supported Biological E's candidate since the pre-clinical stage. The Department of Biotechnology extended a grant-in-aid of over Rs 100 crore, and partnered with Biological E to conduct all animal challenge and assay studies through its research centre Translational Health Science and Technology Institute, Faridabad.

In December last year, the Coalition for Epidemic Preparedness Innovations (CEPI), which is backed by 14 governments, the Bill and Melinda Gates Foundation, and UK's Wellcome Trust, chipped in with an initial $5 million and an option to provide more to produce 100 million doses of the vaccine in 2021. CEPI's interest in Biological E's vaccine candidate is crucial because it is one of the three global institutions that are part of the Covax alliance that aim to secure poor countries fair access to Covid-19 vaccines. Gavi, the Vaccine Alliance, and the World Health Organization are the other two. Datla is a Gavi board member.

The global vaccine alliance's interest in Biological E's candidate is due to its scalability. CEPI had indicated that Biological E's vaccine candidate has "the potential to be produced at scale, and characteristics which could make it suitable for broad distribution in developing countries". The Indian government is betting on Biological E for the same reason.

V K Paul, member (health) of the Niti Aayog, has said recently that Biological E will have the capacity to make 75 million doses per month from September, though the Centre's expectation of 300 million doses between August and December assumes a more modest 60 million a month. In comparison, it expects 550 million doses from Bharat Biotech, and 950 million doses from SII (both AstraZeneca's Covishield, which is already being administered, and Covovax, the candidate from US-based biotech company Novavax) for the same period.

Senior virologist T Jacob John, former head of the Department of Clinical Virology and Microbiology at Christian Medical College, Vellore, said that science is predictive. This platform has been used to make the hepatitis B vaccine and the pichia pastoris (a species of yeast) platform has shown good results so far. "Therefore, we can expect that Corbevax will also work. What needs to be seen is whether this is able to induce cell-mediated immune response, or long-term immune response," he said.

SHOT CLOCK

Biological E's Covid-19 vaccine plans

▸ ITS OWN CANDIDATE, CORBEVAX

- Undergoing phase 3 trials; awaiting Indian drug regulator's approval
- Government pays ₹1,500 crore advance for 300 mn doses
- Will supply to the Covax alliance

▸ JOHNSON & JOHNSON'S SINGLE-SHOT CANDIDATE

- To manufacture 500-600 mn doses in 2021
- Will supply under the Quad Vaccine Partnership

▸ PROVIDENCE THERAPEUTICS' MRNA-TECHNOLOGY VACCINE

- Under development by Canadian firm
- Providence will sell up to 30 mn doses to Biological E
- Technology transfer to make minimum 600 mn doses in 2022
- Eventual target: one bn doses

These are certainly big gambles for the Rs 900-1,000-crore unlisted company to take. Are they too ambitious? The company certainly has the experience. Vaccines account for 80 per cent of Biological E's revenues, the result of a strategic reorientation in 2000 with McKinsey, five years after UK's GSK sold its 25 per cent stake to the Datla family. The company had forayed into vaccines in 1962 with diphtheria, pertussis or whooping cough, and tetanus vaccines, but they formed an insignificant part of its revenues. Then Datla decided to exit highly competitive businesses such as tuberculosis drugs and consumer health, and focus on the opportunities thrown up by the government's decision to introduce hepatitis, H1 influenza and pentavalent (or 5-in-one) vaccines.

Today, Biological E has seven WHO-prequalified vaccines in its kitty and supplies to more than 100 countries.It has seven manufacturing facilities — of which two are neighbours of Bharat Biotech at Genome Valley in Hyderabad, and three are in Telangana.

But it's the timeline that's a question mark. A vaccine maker felt that Biological E may miss the 1.5 billion dose manufacturing plan by calendar 2021, but would be able to make significant volumes by the end of the financial year. "The technology platform the company is using is highly scalable, and also it does not require a BSL-3 (biosafety level) facility to manufacture. This makes the huge volumes they are talking about achievable. But, we do not see that happening by December," said the senior official who requested anonymity. He added that the challenge will be bigger when it comes to the mRNA technology platform, which is new to India. "The mRNA platform, too, is scalable with high yields. And thus, once the company masters the technology, it would be able to make large volumes here as well," he added.

John added that any Covid-19 vaccine that comes out now is like an "also-ran" candidate, given that many vulnerable people have already succumbed to the disease for want of vaccine protection.

Another industry insider pointed out that the risks Biological E has taken with Corbevax are also limited, principally because it is based on a similar platform as the hepatitis vaccine, which the company has been making for years. All the same, Datla is taking a jab at a new opportunity. The year 2022 will be the real test.

Source: Sohini Das, Business Standard, 17.06.2021

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FEATURE

Covid vaccination: The race against time

Battered by the second wave of covid-19, the government recalibrates its vaccination strategy in the hope of inoculating India's 900 million adult population by December 31. How realistic is this target?

Raj Chengappa & P.B. Jayakumar

PM Narendra Modi in his address to the nation on June 7, 2021

When word came that Prime Minister Narendra Modi would address the nation at 5 pm on June 7, the pandemic-afflicted nation was at a critical crossroads. On a positive note, the Second Wave was clearly on the wane, with new cases of Covid-19 infection dropping from the daily peak of 400,000 to under 100,000 by June 1. Yet, they were still higher than at the height of the first wave, which meant that the red signal remained on, and the unlockdown process had to be gradual. On the negative side, the carefully-calibrated Covid vaccination programme was threatening to descend into a self-inflicted anarchy.

The liberalised vaccine regime that the central government had announced on April 21 allowing states their own purchase and pricing for vaccinating the 18-44 year age group was failing. Even the Supreme Court termed it "irrational and arbitrary" and asked the Centre to roll it back. As the blame game between the Centre and states intensified, the month of May saw a substantial drop in vaccinations compared to April due to a shortage of doses. While the Centre boasted that India was among the top three nations in terms of total number of vaccinations—behind only China and the US—the fact remained that even after 136 days of vaccinations, as of June 1 only 41 million people, or 3 per cent of the country's population had received both their doses.

The Modi government had also come under flak for its poor handling of the Second Wave. State governments, too, were not spared, especially over the collapse of critical care facilities for severe Covid patients in major cities and in rural areas. The situation was compounded by a deadly shortage of medical oxygen that saw fatalities double in comparison to the First Wave. The long queues outside crematoriums to dispose of the dead only added to the people's anger and anguish. Their loss of faith and trust in the ability of both the central and state governments to handle the pandemic was evident. Worse, a third wave, possibly as devastating as the second, seemed imminent as the vast majority of Indians remained unprotected without inoculation.

The writing was on the wall when Modi began his broadcast. The vaccination strategy needed course correction before the situation spiralled completely out of control. Many states did demand that the vaccination be expanded to younger age groups and the procurement decentralised to permit them to directly purchase vaccines from manufacturers. But the Centre clearly erred in acceding to their requests given its own experience in procuring vaccine doses in the preceding months. So, Modi made a virtue out of necessity and announced that the Centre would now handle the entire procurement of vaccines (which it was doing before it announced the liberalised regime) and in addition would make vaccines available for free for the 18-44 age group as it was for the 45 years and above group. Quoting from the scriptures, he said: "Vijeta aapada aane par usse pareshaan hokar haar nahin maante balki udyam karte hain, parishram karte hain aur paristhiti par jeet haasil karte hain (Winners do not give up in the face of disaster. They work on it and conquer the situation)."

Mission Impossible?

Much remains to be conquered in India's mission vaccination. The Centre had announced a target of inoculating the country's 940 million adult population by December 31. This means vaccinating 900 million people from June onwards at the rate of 8.4 million daily—triple the current rate of 2.7 million. At this rate, the entire population of the US of 300 million would get vaccinated in 71 days. The US, which began its vaccination programme on December 14, had as on June 8 covered 143 million, or 42.3 per cent of its population with a daily vaccination rate of less than a million.

Getting 900 million adult Indians vaccinated by December-end is indeed a humungous task. Not only does the central government have to procure nearly 2 billion doses, it must also mobilise the health infrastructure of the country to inject the numbers required to meet the target. A senior government official says, "It is like a T-20 match where if the side batting second doesn't score the necessary runs in each over, the asking rate mounts." So, if for some reason, the vaccination effort flags in any month, as it did in May, the number of daily vaccinations required could go up to as many as 10 million. Is India's vaccine target a Mission Impossible then?

Dr Vinod K. Paul, chairperson of the National Expert Group on Vaccine Administration for Covid-19 (NEGVAC), the premier body overseeing vaccine procurement and distribution in the country, is confident of accomplishing the target. "It is a mission difficult but it is not a mission impossible," he says. "We have been able to secure the vaccine doses we require to meet the target by December-end and are putting in place the wherewithal to treble our daily capability for inoculations, including in rural areas." Paul has reason to be sanguine. From the perilous position India found itself in May with vaccine shortages being the rule, NEGVAC has worked in the past two months to boost availability to levels that give the country some comfort. For June and July alone, 280 million doses have been purchased already.

The government seems to have paid heed to the criticism that it failed to place sufficient orders, like the US, UK and Europe did, before launching the vaccination programme on January 16. That lapse was responsible for the subsequent shortage of vaccines. In a significant move, a day after Modi's announcement, the government placed orders for 250 million doses of Covishield with the Serum Institute of India (SII) and 190 million doses of Covaxin with Bharat Biotech Limited (BBL), giving both of them 30 per cent advance payment. As an official said, "This should address the carping about the Centre being stingy and disincentivising domestic manufacturers by not placing orders in advance." The supply of this stock should begin from August onward. In addition, the government is expected to place orders for another 250 million doses of Covishield and an additional 200 million doses of Covaxin later this year.

Earlier, the central government, in a departure from the past, paid Rs 1,500 crore in advance to purchase 300 million doses of Corbevax. This is a vaccine being produced by the Hyderabad-based Biological E after scientists at the US-based Baylor College of Medicine's National School of Tropical Medicine developed it. In mid-April, Biological E got approval to start Phase III clinical trials from India's Central Drugs Standard Control Organisation, or CDSCO, Subject Expert Committee (SEC), following successful completion of previous stage trials. The Phase III clinical study is to be conducted in 15 sites across India in about 1,268 healthy subjects in the age range of 18 to 80 years, and there are plans to conduct a larger global Phase III study.

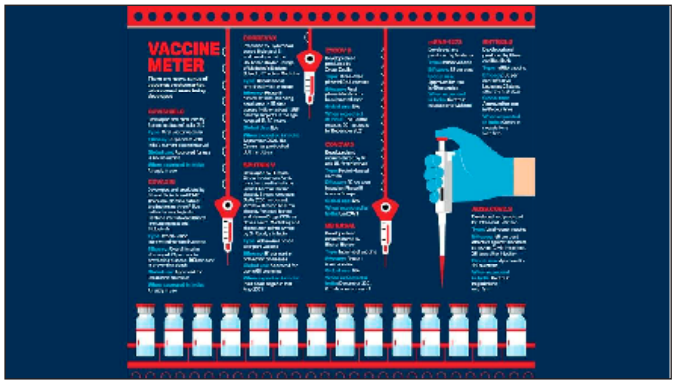
Meanwhile, the government is also expected to purchase close to 150 million doses of Russia's Sputnik 5 vaccine. Dr Reddy's Laboratories has exclusive marketing and distribution rights for the first 250 million doses of the Russian vaccine in India. The Russian Direct Investment Fund (RDIF), which owns the vaccine, has also entered into manufacturing agreements with Indian manufacturers such as Gland Pharma (for 252 million doses), Strides Arcolab's Stelis (200 million), Virchow Biotech (200 million), Panacea Biotec and Hetero Drugs (100 million each) to make over 850 million doses a year from India. SII too got permission recently to make Sputnik V in India.

With all these deals, the central government has got India an assured supply of 1.62 billion doses for the next seven months—just enough to inoculate the entire adult population of the country.

The new vaccines on the block

Meanwhile, the Modi government is already working on procuring a host of newer vaccines to make up for any delays or shortfalls in its assured procurement. That's because one of the major hiccups in India's vaccination plans has been the inability to mass produce and scale up India's first indigenously developed Covid vaccine, 'Covaxin', made by Bharat Biotech. So far, only 20.7 million Covaxin jabs have been given since January 16, or an average of 5.4 million vaccines a month. The company, though, claims that it has made 60 million doses since March. That confusion caused Bharat Biotech to clarify that its vaccine has a lag time of four months, from beginning of production to distribution for vaccination. It means that production batches of Covaxin that were initiated in March this year will be ready for supply only this month. The company is scaling up its production facilities in Hyderabad and Bengaluru to meet the additional requirements.

As Covaxin was co-developed with the support of the Indian government, the Centre entrusted its production to three PSUs—Indian Immunologicals Ltd (IIL), Haffkine



Institute and Bharat Immunologicals and Biologicals Corporation Ltd (BIBCOL)—in a bid to boost production. But these will not yield immediate results. The Maharashtra government-owned Haffkine Institute wants to make 228 million doses of Covaxin a year. The state government says it will require eight months' time to set up the BSL-3 biosafety laboratory, critical in making Covaxin. IIL and BIBCOL are together expected to make 10-15 million doses per month, starting from August or September.

The good news is that several new vaccines being made in India are showing tremendous potential and could provide the necessary back-up in India's vaccine quest. One of the most exciting developments is the made-in-India Covid vaccine from the Ahmedabad-based Zydus Cadila. It is a three-dose DNA vaccine and the final phase trial data for the vaccine will be submitted soon to the drug regulator, with plans of launching it in August. Zydus plans to start with 10 million doses a month initially and double capacity in the following months. The Indian government's calculation is to get 50 million doses before December. "Since it is a DNA vaccine, scale-up is easy and it can resist virus mutations to a large extent," says Pankaj Patel, the group's chairman. The vaccine is also being tested on adolescents aged 12-17 years. This vaccine has a unique advantage—it does not needles to be administered; instead, it is injected intradermally with a special device.

Next is a protein-based Covid vaccine, Covovax, from SII and US biotechnology company Novavax. Its Phase III trial is to begin soon and plans are to launch by September. The vaccine has undergone Phase III trials in Europe. "It has been tested against the African and UK variants of the virus and has an overall efficacy of 89 per cent," says Adar Poonawala, owner and CEO of SII. The firm plans to make about 750 million doses a year in India and 'at risk' trial production has begun. India hopes to get 200 million doses of this vaccine in the first year of production.

Another Indian government-funded vaccine project is from the Pune-based Emcure Pharmaceuticals' biotech subsidiary Gennova Biopharmaceuticals. It is working on India's first mRNA Covid-19 vaccine (similar to Pfizer BioNTech and Moderna vaccines). The vaccine candidate is in Phase I trials, which will be completed in two months. The Phase II and III trials are likely to take another two months and the vaccine is expected to be launched later this year. The government expects Gennova to make 60 million doses available this year and has granted Rs 250 crore for the vaccine development, based on milestones.

As exciting is BBL's intranasal vaccine BBV154 which is now undergoing the first phase of clinical trials. It will be a game-changer, as the vaccine can create an immune response at the site of infection and block both infection and transmission of the virus. "I can easily make one billion doses, as large-scale production is easy," says Dr Krishna Ella, BBL's chairman. The government plans to purchase 100 million doses of this nasal vaccine this year.

Reaching out to big pharma

The Centre is also in talks with top foreign pharmaceutical companies, including Pfizer, Moderna and Johnson & Johnson, who have successfully launched Covid vaccines in the US, UK and Europe. The import of vaccines is expected to gather pace as the Drugs Controller General of India (DCGI) further relaxed rules for importing Covid-19 vaccines last week. The regulator exempted mandatory post-approval bridging clinical trials and testing of each batch of imported vaccines at India's Central Drug Laboratory (CDL) at Kasauli in Himachal Pradesh. The earlier rules for new drugs and vaccines had stipulated that those products which had completed Phase III vaccine studies outside the country should undergo 'bridging' or limited clinical trials on the Indian population to know how the drug works on people of Indian origin.

Since the country has severe shortage of Covid-19 vaccines, this clause was seen as a major impediment and a delaying factor in bringing overseas vaccines into India. On April 15, as per the recommendation of NEGVAC, the DCGI had relaxed the rules to some extent. It allowed Covid-19 vaccines already approved for restricted use by regulatory agencies such as US FDA, EMA (Europe), UK's MHRA, PMDA of Japan or other agencies listed in the WHO Emergency Use Listing (EUL).

According to sources, companies like Cipla and Wockhardt are talking to counterparts like Moderna and Pfizer to import and to manufacture their vaccines in India.

J&J was planning to make its single-shot vaccine in India under the Quad Vaccine Partnership, an alliance by India, the US, Australia and Japan to make over a billion doses for use in the Asia region by the end of 2022. Biological E was looking to contract manufacture about 600 million doses of the J&J vaccine annually, but so far has not revealed plans on starting of manufacturing.

With all these measures, the Centre believes it will deliver on the vaccine front. Dr P.K. Mishra, principal secretary to the prime minister, says, "Vaccinating 130 crore people is a massive undertaking, not just in terms of scale and speed, but also in terms of ensuring efficient and sustained last-mile delivery across multiple supply chains and local constraints. We must recognise that Covid vaccination is under emergency use authorisation and is a more complex operation than the regular immunisation programme, such as for polio. We are looking into several strategies for scaling and diversifying production and encouraging new vaccines approved elsewhere. We are confident that we will achieve the goal of vaccinating all adults by the end of this year and will leave no stone unturned to do so."

Overcoming vaccine hesitancy

While the bottleneck for vaccine supply seems to have been removed, the real issues will be to beef up the number of daily inoculations being done from the current 2.7 million to around 8 million to meet the December 31 deadline. This is, without doubt, an enormous challenge given the inherent vaccine hesitancy in the population. Modi in his speech pointed out that even till 2012, the Universal Immunisation Programme (UIP) for children covered around 60 per cent of the total population. After his government came to power, the prime minister made it a point to mention, it had been pushed to 90 per cent. Now, both the Centre and the state governments have to ensure that at least 90 per cent of the adult population is vaccinated. This will provide the herd immunity required to check the spread of a possible third wave. It will also reduce the severity of the illness in those afflicted and thereby lessen the burden on the health infrastructure. As a senior officer points out, "There are two ways to develop herd immunity. The bad way is for the population to get the disease and build immunity. The best way is to build immunity through a systematic and comprehensive vaccination programme."

Dr Paul of NEGVAC believes that given the experience of conducting elections and the UIP, India is better placed than most to execute one of the world's largest Covid vaccination programmes. "State governments have expressed tremendous confidence in achieving their targets," he says. Already, during the current round of vaccinations, Uttar Pradesh, India's largest state, has showed that it could do about a million vaccinations in June and so is well positioned to meet the demand. Other states like Maharashtra, Andhra Pradesh, Gujarat, Rajasthan and Madhya Pradesh, too, have exhibited similar capabilities. The vast rural health infrastructure has to be galvanised to engage in the vaccine programme. This includes the 1 million ASHA workers and 300,000 ANMs, apart from the 700-odd community health officers. As Bhramar Mukherjee, a professor of epidemiology at the University of Michigan, points out, "We should take vaccines to the people right up to the doorstep if needed so that they don't have to scramble and fight to get vaccines." Paul concurs and says that what is needed is a Jan Andolan to get people to overcome vaccine hesitancy—to induce the same patriotic fervour witnessed when the country is at war.

As important is transparency in procurement and distribution of vaccines for states. The Centre has worked out a formula for distribution of vaccines by the states based on population and age groups. It also needs to ensure vaccine equity. Mukherjee says the Cowin platform for registering requests for vaccination should be made more flexible so that those who are not tech enabled will not be turned away. The private sector is now stepping up to the task. Though the government opened up the private vaccine market in May, it has not gained momentum mainly due to vaccine shortage and the inability of small and medium hospitals to negotiate directly with the manufacturers. This has led to a drop in private hospitals involved in vaccinations from 7,000 to around 2,000. Overall, the private sector accounted for around 23 per cent of the total vaccinations and it is important it maintains that pace. Industry, too, must put its shoulder to the wheel. T.V. Narendran, CEO and managing director of Tata Steel and the current president of the Confederation of Indian Industry, says, "Retaining 25 per cent of the vaccine procurement for the private sector will enable industry to contribute to the vaccination drive and target workers."

The key to avoiding a third wave as devastating as the second is to step up the vaccination drive and ensure that as many people as possible get their shots during the lull before the next storm. "We should not get nationally jubilant as the second wave subsides," says Mukherjee, "but work hard towards preventive measures like vaccines,

apart from strictly observing Covid-appropriate behaviour." The warning comes after massive crowds began mingling again soon after Delhi announced a graded unlockdown. The virus, as an official put it, hasn't gone away. It is still lurking around searching for susceptible people and could cause another surge. The second wave also showed that even if only a couple of states are initially affected, it easily spreads to the rest of the country. So, not only do we need early warning systems, but states also undertake graded lockdown measures. Equally important is testing, tracking and isolating those found to be infectious. The medical infrastructure needs to be beefed up, especially to ensure the availability of oxygen and drugs. Variants will remain a challenge and have the potential of undermining vaccination programmes and causing a fresh surge. Everything rests on our ability to control the virus and prevent a third wave before it overwhelms us. Vaccinations are our only effective shield. The price of failure is just too high for us to be complacent.

Source: India Today Magazine, Cover Story Vaccines, 21.06.2021 (Excerpts)

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