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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

★ **Phyto-Pharmaceutical Definition under Drug Regulations, India Needs an Urgent Review : By Dr. D B Anantha Narayana** *(Page No. 7)*

★ **Extension in tenure of Shri Amitabh Kant, CEO, NITI Aayog** *(Page No. 11)*

★ **Extension of time limits of certain compliances to provide relief to taxpayers in view of the severe pandemic** *(Page No. 12)*

★ **Here are the tips to reopen offices safely** *(Page No. 15)*

★ **Bengaluru ranked as one of top 5 tech centers in Asia Pacific** *(Page No. 17)*

★ **Surcharges threaten to rock exporters' boat** *(Page No. 23)*

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IDMA BULLETIN

Vol. No. 52 **Issue No. 24** **22 to 30 June 2021**

IDMA ACTIVITIES:

Phyto-Pharmaceutical Definition under Drug Regulations, India Needs an Urgent Review: ***by Dr D B Anantha Narayana*** 7

GOVERNMENT COMMUNICATION:

Operational Guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals — reg. 9

CDSCO MATTERS:

Transfer of CDSCO DDC(I) - reg. 10

DoPT MATTERS:

Extension in tenure of Shri Amitabh Kant, CEO, NITI Aayog - reg. 11

CBDT MATTERS:

Extension of time limits of certain compliances to provide relief to taxpayers in view of the severe pandemic - reg. 12

GOVERNMENT PRESS RELEASE:

Government grants further extension in timelines of compliances 13

NATIONAL NEWS:

CII Prez Seeks Cut in GST Rate on Consumer Goods to Lift Demand 15
Here are the tips to reopen offices safely 15
Covaxin unlikely to get full approval from regulator until next year 16
Piramal Pharma completes acquisition of Hemmo Pharmaceuticals 16
Bengaluru ranked as one of top 5 tech centers in Asia Pacific 17
Glenmark Pharma gets USFDA nod for inhalation drug 18
Cipla gets USFDA nod for inhalation product 18
Explained: Covid-19 vaccine makers and indemnity 19
Mind the gap: Covishield's 2nd jab sets off controversy 20
What is delaying anti-Covid-19 drug by DRDO, Madras HC asks Centre 22
Domestic cold chain biz struggles to keep up volumes to recover investment 22
Surcharges threaten to rock exporters' boat 23
Thyrocare deal: PharmEasy founders out to build Amazon of health care 24
Centre commits to vaccinate all adults by Dec 31 25
Johnson & Johnson Covid vaccine likely to be available in India by July 26
Covid vaccine for kids above 12 likely to be available by July-end or August: Govt 27
Biological E asked to spur vax production 27
10-month gap between AstraZeneca vaccine doses effective, 3rd booster shot ups immunity: Study 28
Centre focusing on developing vaccine for Delta variant says G Kishan Reddy 29
India to take up Covishield absence from EU pass list 30
Second wave impacted 58% of Indian companies: FICCI 30
Big manufacturing firms plan to reopen offices with limited staff 31
Tax department doesn't think sanitiser companies' accounts are clean 32
"With a stake in PharmEasy, I'll be fighting Ambanis and Tatas' 33

Advertisements ..... 2, 4, 5, 6, 35, 36, 38, 39 & 40

How a digital marketplace is catalyzing growth for SMEs

Nobody imagined 2020 would be the way it was. Many global concerns existed even before we were tragically hit by the pandemic. A drop in business registrations, the decline in opportunities, and compressed multiples restricting successful exits were a few of the many problems. Along with a missing generation of new firms, there were critical economic outcomes, mainly employment.

Ranking 2nd in the list of largest MSME base, India has almost 80% of employment generation from this sector. During the pandemic, these enterprises have continued to play a crucial role in the economy as they have adapted with flexibility and speed to ensure digital work. COVID-19 is creating a new norm for all of us, and digitalization is solidifying its presence in the B2B, B2C, D2C, B2G space. Revenues have been affected by the containment measures and the decline in demand due to the pandemic. As a result, many small business owners are left with growth challenges and increased stress about stagnation.

MergerDomo - an Online Global Technology based Investment Banking Marketplace, attempts to help unearth investment opportunities and bring players of the Investment Banking industry together. They are an aggregated team of analysts and advisors committed to delivering transformational solutions by assessing, anticipating, and fulfilling markets to improve operational efficiency, innovate growth strategies, and build customer engagement.

MergerDomo has been founded by Hormazd Charna, a career Investment Banker who quit the corporate world in 2018. Talking about the value addition that MergerDomo as a platform wants to make, Hormazd said, “The vision is to help and facilitate SME and Startups to realize their full potential when it comes to their growth needs, be it strategic (equity) funding, consulting services, GTM, mentorship, JVs, M&As or even complete business strategy overhauls through our empanelled network of Investment Bankers/Consultants. Our mission is to help SMEs based out of Tier I/II/III cities to connect with Domestic/International investors/consultants at a click, thanks to our proprietary algorithm-based online portal.”

MergerDomo is a facilitator for deal sourcing and consulting that matches your requirements through curation with its backend algorithm, speed, and accuracy. Access to such a colossal and competent network available at your fingertips creates an immediate value for all stakeholders.

Why MERGERDOMO for Corporates?

- While it ebbs and flows over time, capital continues to be a massive challenge for SMEs. Traditional debt loans only tend to create additional pressure. Access to immediate liquidity is crucial to keep these businesses solvent as they strive for survival and growth. MergerDomo provides streamlined process to fulfil such monetary requirements.
- India is a highly competitive market with multiple players after the same pie. Differentiation is the key. Scale, cost benefit, quick turnaround, personalized customer service along with curated universe make it a ‘go-to’ platform.
- Be it critical tools like Cash flow modelling, Strategy formulation, Legal or IT aids, Process and Supply chain management for SMEs or Revamp Strategies, Organic / Inorganic growth plan-outs or Turn-around management for Corporates, getting insights from experts in

specialized domains can prove to be a boon. Seeking such advisory helps get an edge over others.

Rajiv Gulati, Strategic Advisor, MergerDomo & past President of Ranbaxy & MD of Eli Lilly said, "In India almost 3-4% of the startups are in pharma & healthcare. This is both a strategic and scalable industry that will put us on the global map. These startups have a potential to add almost 5% to our GDP in the next 4-5 years. We have to nurture them and create the ecosystem which will only catalyze their growth. MergerDomo can be a boon to small and medium companies, especially in Pharma sector, in their quest to grow fast by seeking investments, advice, merger or acquisitions."

Financing your ventures along with developing and updating business strategies are one of the top issues. Ecosystem marketplaces and tech-based platforms are the need of the hour. Higher the scale, higher the probability of sourcing the right businesses.

Engage with Investors and Advisors / Policy makers to scale up and expand into new spectrums. Sign up at Mergerdomo.com, an online global deal sourcing marketplace and partner for your growth journey.

This is 1st of the series, please look out for next editions on advisory services, M&A, funding for the pharma & healthcare industry.

Phyto-Pharmaceutical Definition under Drug Regulations, India Needs an Urgent Review

Dr. D B Anantha Narayana, *CSO, Ayurvidye Trust. Bangalore*

Dear Reader,

An Amendment to the Drugs and Cosmetics Regulations to permit scientifically developed plant based leads as drugs named "phytopharmaceuticals", was notified for the first time in November 2015. This regulation has now been further amended and revised to put it under new drug definitions and provided more provisions for greater clarity in 2019. However, having championed these regulations (as part of the Indian Pharmacopoeia Commission's Expert Committee on Herbals) for nearly a decade a greater number of drugs should have come out through this route given the scientific capability of the Indian drug sector and academia. However, the only information in the public domain as on date is the approval for conducting human clinical trials of a plant based lead for testing the protective or curative potency of Coculous hirsutus against SARS – CoV-2 given by the Drugs Controller General of India. A purified fraction of the stem of this plant commonly called broom creeper has been tested for sinnococculine markers as the lead drug candidate.

In personal discussions, the sector points out that one of the difficulties to enter phytopharmaceuticals development amongst others, is the way it has been defined. To qualify as a phytopharmaceutical, it has to be " a purified and standard fraction, with defined minimum four bio-active or phyto-chemical compounds (qualitatively and quantitatively assessed), of an extract of a medicinal plant or its part……".

Most scientists point out that the definition is not in line with the global regulatory approach and is highly prescriptive. Recognition that the purified fraction needs to be standardized to demonstrate similarity and uniformity of the batches of the fraction produced is acceptable. However, specifying the number and nature of the marker compounds acts as a stumbling block. While theoretically, 4 markers may be present in the raw botanical, as the commercial process progresses to convert the botanical to an extract, and further processed to a fractionate, which is then formulated as a drug in a dosage form in one or

Dr. Anantha Narayana, is the Chief Scientific Officer, AYURVIDYE TRUST, Bangalore. He Championed the Notifications of Supplements and Nutraceuticals Regulations, FSSAI, 2016 Updated in 2017 and Phytopharmaceuticals as Drugs under Drugs & Cosmetics Act & rules, 2016. He is a recipient of Indian Drugs award for Contribution to IDMA and Indian Drugs and is a recipient of Eminent Pharmacist's Award of IPA, 2007. Currently is an expert member, amongst others contributing significantly to 1) Member-Expert committee – Non- Specified Foods & Food Ingredients – FSSAI, 2) Chairman-Expert Committee – Advertisement & Claims – FSSAI, 3) Chairman-Scientific Panel – Nutraceuticals of FSSAI. 4) Chairman – Phytopharmaceuticals & Herbal products of Indian Pharmacopeia Commission 5) Member-Steering Committee of NMPB, Ministry of Ayush. He continues to guide youngsters in research and also guides many startup firms in the area of Supplements/ Nutraceuticals, Foods, herbals and cosmetics.

more steps the same 4 markers may not be present or at detectable and quantifiable levels at each stage. The definition of a phytopharmaceutical to be a purified and standard fraction was put in the regulation historically to differentiate from one step extracts (aqueous, alcoholic, aq-alcoholic) which are in the domain of Ayurvedic drugs in the regulations.

Globally the botanical concentrates or fractions need to be characterized chemically and the methods used to demonstrate similarity / uniformity of the batches produced is to be described in the applications. The nature and number of markers etc. of such quality examination / specifications are left to the applicant which is appropriate science. The document "Guidance to Industry for Botanicals as Drugs", of the United States Food and Drug Administration (USFDA) specifies this approach. The 2 botanical drugs which have been given marketing authorization so far follows such a review and does not insist on the number of markers. The botanical drug Veregen, an ointment for genital warts that is derived from green tea leaves, was standardized to sinecatechins. The second botanical drug is Fulyzaq, which is made from the red sap of the Croton lechleri plant, a South American tree referred to as the dragon's blood tree, standardized to crofelemer. This is for the treatment of diarrhea in HIV/AIDS patients who are on anti-retroviral therapy. An exhaustive review of the approach of testing for marker compounds, the nature and number of markers tested, relevance and relation to the efficacy based on study of all the monographs in European Pharmacopoeia (EP) has been published in 2018. This review by Reinhard Länger, and others published in Planta Medica, a reputed peer reviewed journal is titled "Quality Standards for Herbal Drugs and Herbal Drug Preparations – Appropriate or Improvements Necessary?". This review underscores that most markers tested were analytical markers and not necessarily responsible for biological activity. Most commonly 2 markers have been prescribed for quantitative testing in EP in a large number of plants / extracts under the test for assay. In the Herbal Medicine Compendium of the USP too, most plant extracts are standardized to a single marker compound.

Narayana et al.: Journal of AOAC International Vol. 102, No. x, 2019, titled,

"A Perspective on Additional Approaches Beyond Organic Marker Compounds While Developing Analytical Monographs for Botanicals" showed that additional approaches are coming up in identifying the nature of the marker compounds. Other compounds such as Primary metabolites, minerals, starches, amino acids etc also contribute to the quality, safety and efficacy of the botanicals.

In view of the above and to provide for a globally acceptable science based definition, the definition of phytopharmaceuticals under the Drugs and Cosmetics Rules, India needs an urgent review. The definition while demanding that adequate scientific testing be adopted by the applicant to build similarity / uniformity in batches of the lead fraction, the method of doing so may be left to the botanical drug developer. The committee of experts reviewing applications would apply varying scientific yardsticks during the review process.

There is hence an urgent need to look at amending the definition of the Phytopharmaceuticals in the Drug regulations without diluting the assessment and control of quality of them. Would the office of Drug Controller General of India, and the concerned officials in the Ministry of Health & FW, and Department of Pharma initiate action?

Courtesy: Indian Drugs, Editorial, Vol. 57 (12) December 2020

● ● ●

Operational Guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals — reg.

Corrigendum / Addendum dated 30th June, 2021

The Association have received communication on 30th June 2021 from Mr Venkat H. A., Deputy Director (Policy), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers on the above subject:

The undersigned is directed to refer to the above-mentioned subject and state the following:

1. Clause 2.15.1 may be read as under:

   2.15.1. Expenditure incurred on new Plant, Machinery, Equipment and Associated Utilities: This shall include expenditure on new plant, machinery, equipment and associated utilities. It shall also include expenditure on packaging, freight / transport, insurance, and erection and commissioning of the new plant, machinery, equipment including laboratory equipment and associated utilities. Associated utilities would 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, IT systems as a part of Quality Assurance/Quality Certification/Manufacturing and communication lines for telephone-internet within the establishment. All non-creditable taxes and duties would be included in such expenditure.

2. The contents at table under clause 4.1 and Appendix I & K (wherever applicable) of the operational guidelines may be read as under:

Sr. No.	Group	Selection parameter	Weightage
1	A / B	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 / DMF/CEP, as the case may be, 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%
2	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 / DMF/CEP, as the case may be, 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%
3	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%

3. Clause 6.2.1 may be read as, 'Expenditure incurred on new Plant, Machinery and Equipment as defined in clause 2.15.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.'

4. Clause 6.2.4 may be read as, 'Expenditure incurred on new associated utilities as defined in clause 2.15.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.'

5. 'Clause 6.3.1' therein may be read as `Clause 6.4'

6. 'Clause 6.3.2' therein may be read as 'Clause 6.5"

7. Clause 6.6 is hereby added as under:

'Building: Expenditure incurred on building as defined in Clause 2.15.5 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

F.No. 31026/92/2020-Policy

Venkat H.A., Deputy Director (Policy), Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

● ● ●

CDSCO MATTER

Transfer of CDSCO DDC(I) - reg.

Order dated 28th June 2021

To,

1. *Pay and Accounts Officer, MoHFW, Nirman Bhawan, New Delhi.*
2. *Pay and Accounts Officer, Mumbai through DDC.(1), West Zone, Mumbai.*
3. *DDC(I), CDSCO, West Zone, Mumbai.*
4. *Officers concerned.*
5. *Section Officer, (Drugs) CDSCO(HQ), New Delhi.*
6. *DDO (Cash), CDSCO(HQ), New Delhi.*
7. *JDC(I)s, CDSCO(HQ), New Delhi.*
8. *Sr. PPS to JS(R), MoHFW, Nieman Bhawan, New Delhi.*
9. *PPS to DGHS.*
10. *DCG(I) Secretariat*
11. *Guard File*

1. With immediate effect and until further orders, the following transfers are hereby made in public interest:-

Sr. No.	Nama and Designation	Transferred from	Transferred to
1	Dr. Rubina Bose, DDC(I)	CDSCO, West Zone, Mumbai	CDSCO (HQ), New Delhi
2	Sh. A. Senkathir, DDC(I)	On promotion as DDC(I) w.e.f. 22.06.2021	CDSCO, West Zone, Mumbai

2. The above officers stand relieved with immediate effect and directed to join their new place of posting.

3. This issues with the approval of the competent authority.

F.No. A.32013/03/2017-D(Pt.)

Amit Kumar, Dy. Director Admn. (D), Ministry of Health and Family Welfare, Directorate General of Health Services, Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi.

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Extension in tenure of Shri Amitabh Kant, CEO, NITI Aayog - reg.

F.No. 36/01/2021-EO(SM-I), dated 29th June 2021

To

1. *Cabinet Secretary.*
2. *Principal Secretary to PM*
3. *Secretary to President of India.*
4. *Secretary to Vice President of India.*
5. *Secretary General, Rajya Sabha Secretariat.*
6. *Secretary General, Lok Sabha Secretariat.*
7. *Secretary, Department of Personnel & Training.*
8. *Secretary (Coordination & PG), Cabinet Secretariat.*
9. *All Secretaries to the Government of India (As per standard list).*
10. *PS to Home Minister.*
11. *PS to all Union Ministers.*
12. *PS to MOS (PP).*
13. *Officer concerned*
14. *Chief Secretaries of all States.*
15. *Cabinet Secretariat (Shri Amandeep Garg, Joint Secretary) w.r.t. their Dy.No.01/01/2016-CS(A) dated 29.06.2021.*
16. *DG (M&C), PIB.*
17. *Editor, Civil Services News and Deputy Secretary, D/o Administrative Reforms and Public Grievances.*
18. *PSO to Secretary (P)/PPS to EO/EO(CM)/Guard File.*
19. *NIC, DoPT.*

The Appointments Committee of the Cabinet has approved the extension in tenure of Shri Amitabh Kant, CEO, NITI Aayog for a further period of one year beyond 30.06.2021 i.e. upto 30.06.2022 or until further orders, whichever is earlier, on the same terms and conditions as approved earlier by the ACC.

Srinivas R. Katikithala, Secretary, Appointments Committee of the Cabinet Ministry of Personnel, Public Grievances and Pensions, Department of Personnel and Training, New Delhi.

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

Circular No.12, dated 25th June, 2021

On consideration of genuine hardship being faced by the taxpayers in making various compliances under the Income-tax Act, 1961 (hereinafter referred to as "the Act") in view of severe pandemic, the Central Board of Direct Taxes, in exercise of its power under Section 119 of the Act, provides relaxation in respect of the following compliances as under:

1) **Objections to Dispute Resolution Panel (DRP) and Assessing Officer** under **section 144C of the Act,** for which the last date of filing under that Section is 1st June, 2021 or thereafter, may be filed within the time provided in that Section or by **31st August, 2021,** whichever is later;

2) **The Statement of Deduction of Tax** for the last quarter of the Financial Year 2020-21, required to be furnished on or before 31st May, 2021 under Rule 31A of the Income-tax Rules,1962 (hereinafter referred to as "the Rules"), as extended to 30th June, 2021 vide Circular No.9 of 2021, may be furnished **on or before 15th July, 2021;**

3) **The Certificate of Tax Deducted at Source** in **Form No.16,** required to be furnished to the employee by 15th June, 2021 under Rule 31 of the Rules, as extended to 15th July, 2021 vide Circular No.9 of 2021, may be furnished **on or before 31st July, 2021;**

4) **The Statement of Income paid or credited** by an investment fund to its unit holder in **Form No. 64D** for the Previous Year 2020-21, required to be furnished on or before 15th June, 2021 under Rule 12CB of the Rules, as extended to 30th June, 2021 vide Circular No.9 of 2021, may be furnished **on or before 15th July, 2021;**

5) **The Statement of Income paid or credited** by an investment fund to its unit holder in **Form No. 64C** for the Previous Year 2020-21, required to be furnished on or before 30th June, 2021 under Rule 12CB of the Rules, as extended to 15th July, 2021 vide Circular No.9 of 2021, may be furnished **on or before 31st July, 2021;**

6) The application **under Section 10(23C), 12AB, 35(1)(ii)/(iia)/(iii) and 80G** of the Act in **Form No. 10A/ Form No.10AB,** for registration/ provisional registration/ intimation/ approval/ provisional approval **of Trusts/ Institutions/ Research Associations etc.** required to be made on or before 30th June, 2021, may be made on or before **31st August, 2021;**

7) The **compliances** to be made by the taxpayers such as investment, deposit, payment, acquisition, purchase, construction or such other action, by whatever name called, for the purpose of **claiming any exemption under the provisions contained in Section 54 to 54GB** of the Act, for which the last date of such compliance falls between 1st Apri1,2021 to 29th September, 2021 (both days inclusive), may be completed on or before **30th September, 2021;**

8) The **Quarterly Statement in Form No. 15CC** to be furnished by authorized dealer in respect of remittances made for the quarter ending on 30th June, 2021, required to be furnished on or before 15th July, 2021 under Rule 37 BB of the Rules, may be furnished on or before **31st July, 2021;**

9) The **Equalization Levy Statement in Form No. 1** for the **Financial Year 202021,** which is required to be filed on or before 30th June, 2021, may be furnished on or before **31stJuly,2021;**

10) **The Annual Statement** required to be furnished under **sub-section (5) of section 9A of the Act by the eligible investment fund** in **Form No. 3CEK** for the Financial Year 2020-21, which is required to be filed on or before 29th June, 2021 , may be furnished on or before **31st J uly,2021;**

11) **Uploading of the declarations** received from recipients in **Form No. 15G/15H during the quarter ending on 30th June, 2021,** which is required to be uploaded on or before 15th July,2021, may be uploaded by **31st August,2021;**

12) **Exercising of option** under **sub-section (1) of Section 245M** of the Act in **Form No. 34BB** which is required to be exercised on or before 27th June, 2021 may be exercised on or before **31st July, 2021.**

F. No.225/49/2021-1TA-II

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

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GOVERNMENT PRESS RELEASE

Government grants further extension in timelines of compliances

Also announces tax exemption for expenditure on COVID-19 treatment and ex-gratia received on death due to COVID-19

A. Tax exemption

Many taxpayers have received financial help from their employers and well-wishers for meeting their expenses incurred for treatment of COVID-19. In order to ensure that no income tax liability arises on this account, it has been decided to provide income-tax exemption to the amount received by a taxpayer for medical treatment from employer or from any person for treatment of COVID-19 during FY 2019-20 and subsequent years.

Unfortunately, certain taxpayers have lost their life due to COVID-19. Employers and well-wishers of such taxpayers had extended financial assistance to their family members so that they could cope with the difficulties arisen due to the sudden loss of the earning member of their family. In order to provide relief to the family members of such taxpayer, it has been decided to provide income-tax exemption to ex-gratia payment received by family members of a person from the employer of such person or from other person on the death of the person on account of COVID-19 during FY 2019-20 and subsequent years. The exemption shall be allowed without any limit for the amount received from the employer and the exemption shall be limited to Rs. 10 lakh in aggregate for the amount received from any other persons.

Necessary legislative amendments for the above decisions shall be proposed in due course of time.

B. Extension of Timelines

In view of the impact of the Covid-19 pandemic, taxpayers are facing inconvenience in meeting certain tax compliances and also in filing response to various notices. In order to ease the compliance burden of taxpayers during this difficult time, reliefs are being provided through Notifications nos. 74/2021 & 75/2021 dated 25th June, 2021 Circular no. 12/2021 dated 25th June, 2021. These reliefs are:

1. **Objections to Dispute Resolution Panel (DRP) and Assessing Officer** under **section 144C of the Income-tax Act, 1961** (hereinafter referred to as "the Act") for which the last date of filing under that section is 1st June, 2021 or thereafter, may be filed within the time provided in that section or by **31st August, 2021**, whichever is later.
2. **The Statement of Deduction of Tax** for the last quarter of the Financial Year 2020-21, required to be furnished on or before 31st May, 2021 under Rule 31A of the Income-tax Rules,1962 (hereinafter referred to as "the Rules"), as extended to 30th June, 2021 vide Circular No.9 of 2021, may be furnished on or before 15th July, 2021.
3. **The Certificate of Tax Deducted at Source** in **Form No.16**, required to be furnished to the employee by 15th June, 2021 under Rule 31 of the Rules, as extended to 15th July, 2021 vide Circular No.9 of 2021, may be furnished **on or before 31st July, 2021**.

4. **The Statement of Income paid or credited** by an investment fund to its unit holder in **Form No. 64D** for the Previous Year 2020-21, required to be furnished on or before 15th June, 2021 under Rule 12CB of the Rules, as extended to 30th June, 2021 vide Circular No.9 of 2021, may be furnished **on or before 15th July, 2021**.

5. **The Statement of Income paid or credited** by an investment fund to its unit holder in **Form No. 64C** for the Previous Year 2020-21, required to be furnished on or before 30th June, 2021 under Rule 12CB of the Rules, as extended to 15th July, 2021 vide Circular No.9 of 2021, may be furnished **on or before 31st July, 2021**.

6. The application **under Section 10(23C), 12AB, 35(1)(ii)/(iia)/(iii) and 80G** of the Act in **Form No. 10A/ Form No.10AB,** for registration/ provisional registration/ intimation/ approval/ provisional approval **of Trusts/ Institutions/ Research Associations etc.**, required to be made on or before 30th June, 2021, may be made on or before **31st August, 2021**.

7. The **compliances** to be made by the taxpayers such as investment, deposit, payment, acquisition, purchase, construction or such other action, by whatever name called, for the purpose of **claiming any exemption under the provisions contained in Section 54 to 54GB** of the Act, for which the last date of such compliance falls between 1st April, 2021 to 29th September, 2021 (both days inclusive), may be completed on or before **30th September, 2021.**

8. The **Quarterly Statement in Form No. 15CC** to be furnished by authorized dealer in respect of remittances made for the quarter ending on 30th June, 2021, required to be furnished on or before 15th July, 2021 under Rule 37 BB of the Rules, may be furnished on or before **31st July, 2021**.

9. The **Equalization Levy Statement in Form No. 1** for the **Financial Year 2020-21**, which is required to be filed on or before 30th June, 2021, may be furnished on or before **31st July, 2021**.

10. The **Annual Statement** required to be furnished under **sub-section (5) of section 9A of the Act by the eligible investment fund** in **Form No. 3CEK** for the Financial Year 2020-21, which is required to be filed on or before 29th June, 2021, may be furnished on or before **31st July, 2021.**

11. **Uploading of the declarations** received from recipients in **Form No. 15G/15H during the quarter ending 30th June, 2021**, which is required to be uploaded on or before 15th July, 2021, may be uploaded by **31st August,2021**.

12. **Exercising of option** to withdraw pending application (filed before the erstwhile Income Tax Settlement Commission) under **sub-section (1) of Section 245M** of the Act in **Form No. 34BB,** which is required to be exercised on or before 27th June, 2021, may be exercised on or before **31st July, 2021.**

13. **Last date of linkage of Aadhaar with PAN under section 139AA of the Act**, which was earlier extended to 30th June, 2021 is further extended to 30th September, 2021.

14. **Last date of payment of amount under Vivad se Vishwas(without additional amount)** which was earlier extended to 30th June, 2021 is further extended to 31st August, 2021.

15. **Last date of payment of amount under Vivad se Vishwas (with additional amount)** has been notified as 31st October, 2021.

16. **Time Limit for passing assessment order** which was earlier extended to 30th June, 2021 is further extended to 30th September, 2021.

17. **Time Limit for passing penalty order** which was earlier extended to 30th June, 2021 is further extended to 30th September, 2021.

18. **Time Limit for processing Equalisation Levy returns** which was earlier extended to 30th June, 2021 is further extended to 30th September, 2021.

Source: Posted On 25 Jun 2021 PIB Delhi,
Release ID : 1730346

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CII Prez Seeks Cut in GST Rate on Consumer Goods to Lift Demand

The Confederation of India Industry will discuss with its members the idea of compulsory vaccination as employees return to work, president TV Narendran said, as he called for the fastest possible vaccination, including incentives in the hinterlands, to manage the pandemic.

Narendran, who took over as the president of the industry body last week, batted for a temporary cut in goods and services tax rate on consumer goods to lift demand, and sought measures for healthcare, travel, tourism and more support to the rural employment guarantee scheme.

"Certainly, some of us have discussed that (making vaccination compulsory), but as CII we have to take a view, but the starting point is of course we can only announce that if there are enough vaccines available," he said in an interaction with ET.There is a vaccine task force (at the CII)which is working on this, said Narendran, who is the global chief executive and managing director of Tata Steel. India needs to spend at least 3% of its GDP on healthcare infrastructure, besides addressing the gap in supply of paramedical staff, Narendran said.

RECOVERY AND STIMULUS

The initial indication are that rural markets should be strong and the disruption was not as significant as last year because supply chains were not as disrupted, Narendran said.

The global growth has also been much stronger and the recovery faster which is also helping, he pointed out. "We believe that economic activity will start picking up," he said.

The CII chief wants the government to consider reducing GST rater by 2-3 percentage point for the next six months, look at some measures for services that have been hit hard and see if more support can be given to the rural employment guarantee scheme.

COMMODITY PRICES

Narendran said fixed price contracts were an emerging area of concern for micro, small and medium enterprises, which were suffering because of volatility in the global commodity markets.

The Emergency Credit Line Guarantee Scheme for MSMES can also be extended till March of next year, he suggested.

Source : Nishtha Saloja & Deepshikha Sikarwar, Economic Times, 21.06.2021

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Here are the tips to reopen offices safely

Back to work

With vaccines rolling out, more businesses are weighing how to safely bring employees back to the workplace and if it is worth the risk. With everything we've learned about the virus over the past year, there are some clear, evidence-based steps that employers can take to protect their workers. A guide:

Address the risk of closures

Although Covid-19 is a key health concern, long-term building closures can present risks of their own. Plumbing systems that sit unused, for instance, can be colonised by Legionella pneumophila, bacteria that can cause Legionnaires's disease.

In buildings with lead pipes or fixtures, high levels of lead can also accumulate in stagnant water. Employers can reduce both risks by thoroughly flushing their taps or letting the water run for 15 minutes to an hour, before reopening.

Upgrade ventilation

Because the coronavirus is thought to spread primarily through tiny, airborne droplets, employers should upgrade their ventilation and filtration systems before bringing workers back. Although the ideal ventilation rate varies, employers should maximise the amount of fresh air coming in from outdoors.

Be wary of chemical disinfection

Stay away from fumigators, ionisers, ozone generators or other 'air cleaning' devices that promise to neutralise the coronavirus by adding chemical disinfectants to the air. The compounds that these products emit - which may include hydrogen peroxide, bleach-like solutions or ozone - can be toxic, inflaming the lungs, causing asthma attacks and leading to other kinds of respiratory or cardiovascular problems. And there is not rigorous, real-world evidence that these devices reduce disease transmission.

Reconsider staffing

The benefits of social distancing are minimal in offices in which most people are vaccinated and local case rates are low. Higher-risk workplaces may want to consider de-densification (reducing the number of people who are present at one time) or 'cohorting', which involves creating separate teams of workers that do not have in-person interactions with those who are not on their team.

Back to basics

Regular hand-washing, which can reduce the spread of all kinds of pathogens, is always a good idea. Masks, too, remain effective. If you're someone who's vaccinated and still feeling anxious about going back to work, the best thing is to continue to wear a mask for the first couple of weeks until you feel more comfortable.

Source: Economic Times, 22.06.2021

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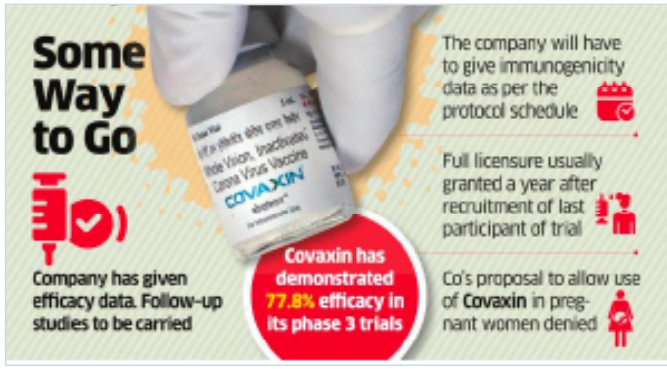
Covaxin unlikely to get full approval from regulator until next year

"The phase-3 trial has not ended yet," said the official, adding that the company needs to carry out follow-up studies. "They have to establish data indicating how much protection the vaccine gives. The duration schedule is defined in their protocol. Till that is established, full licensure cannot be granted," added the official.

Bharat Biotech, the manufacturer of Covaxin, may have to wait till next year to get full approval from the Indian drug regulator for the indigenous vaccine, a senior government official told ET.

"The phase-3 trial has not ended yet," said the official, adding that the company needs to carry out follow-up studies. "They have to establish data indicating how much protection the vaccine gives. The duration schedule is defined in their protocol. Till that is established, full licensure cannot be granted," added the official.

A full licence is usually granted one year after the last trial participant is recruited, another official explained to ET.



Bharat Biotech on Tuesday submitted data from Covaxin's phase-3 trials to the subject expert committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO). However, the SEC did not accept the company's proposal seeking full licensure for Covaxin, and recommended continuation of the vaccine's use under the earlier emergency authorisation.

The data submitted showed that Covaxin had demonstrated 77.8% efficacy in its phase-3 trial, which was conducted on 25,800 subjects. Bharat Biotech has not yet published this data in an internationally recognised, peer-reviewed journal. Earlier this month, the company said it would publish only after the data were submitted to the regulator.

Source : Economic Times, 24.06.2021

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Piramal Pharma completes acquisition of Hemmo Pharmaceuticals

Piramal Pharma has completed the acquisition of Hemmo Pharmaceuticals Private Ltd for cash consideration of Rs 775 crore and earn-outs linked to achievement of milestones.

Piramal Pharma has completed the acquisition of Hemmo Pharmaceuticals Private Ltd for cash consideration of Rs 775 crore and earn-outs linked to achievement of milestones.

In March, Piramal Enterprises, the parent company of Piramal Pharma, had announced the proposed acquisition.

"We wish to inform you that PPL has completed the acquisition of Hemmo on 22nd June, 2021 and the transaction is now closed," Piramal Enterprises said in a regulatory filing on Wednesday.

The development marks Piramal Pharma's foray into manufacturing of peptide APIs (active pharmaceutical ingredients), complementing its existing offerings.

Hemmo is one of the few pure-play synthetic peptide API manufacturers in the global marketplace. With the addition of Hemmo's capabilities, PPS would gain access to the growing peptide API market and enhance its ability to offer integrated services to its customers globally.

Source : Bizz Buzz, 24.06.2021

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Bengaluru ranked as one of top 5 tech centers in Asia Pacific

Gurgaon: Leading diversified professional services and investment management company Colliers has released the growth engines of innovation: How Asia Pacific's technology hubs are reshaping regional real estate report, an in-depth analysis of how the growth of the APAC technology sector is transforming the region's property markets. The report provides a new ranking of the most attractive technology submarkets within major APAC cities, which should serve as a navigation tool for technology groups, as they plan expansion.

Since these submarkets ought to attract strong occupier demand, property owners should also focus on these districts for investment and development opportunities. Arpit Mehrotra, Managing Director, Office Services (South India), commented: "While Bengaluru has been ranked in the top five technology centers in APAC, we also witness Hyderabad in the top 10 list. Offering a compelling balance of infrastructure and talent for occupiers and well-positioned to deliver future growth and investment opportunities for owners, ORR in Bengaluru is the epicenter of commercial leasing. In addition, while smaller than Bengaluru, Hyderabad is also attracting talent and multinational companies to the city. Rents are 15% to 20% cheaper than in Bengaluru.

Overall, we foresee the South India markets leading the pack in terms of office leasing demand for the technology sector." Technology firms both the fastest-growing occupiers of space and a new class of owner-occupier. Today, technology is the most important business sector globally, making up 65% of the world's top 20 public companies by market capitalisation.

Colliers expects technology occupiers to account for 20% to 25% of demand for leased office space in the APAC region over the next five years. Asia's technology giants, in particular, are expanding quickly, and have become a major driver of leasing demand. Many Asian technology companies, especially Chinese technology firms, have also become very active in investment and development of real estate. In 2020 alone, technology companies acquired nearly US$10 billion in APAC real estate assets. Occupiers to expand further in key APAC technology hubs, attracting owner investment Beijing, Shanghai, Bengaluru, Shenzhen and Singapore currently rank as the top five technology centres in APAC; they offer a compelling balance of infrastructure and talent for occupiers, and are well positioned to deliver future growth and investment opportunities for owners.

Other cities are developing strengths in specific areas of technology, e.g., Seoul and Hong Kong in fintech, while new centres such as Hyderabad and Sydney are emerging. Among established technology submarkets in the major APAC cities, we highlight Shangdi in Beijing. Among upcoming submarkets, we highlight Yangpu in Shanghai, Whitefield and North Bengaluru in Bengaluru, Hitec City (Suburban Business District) in Hyderabad as well as Sydney's CBD South.

Siddhart Goel, Senior Director & Head of Research, (India), commented: "Demand from technology occupiers has been the mainstay of Indian commercial real estate. After reaching highs of 65-70% share in annual leasing volumes in the 1990s and 2000s, though the share declined to around 45-50% share in the last decade, technology occupiers are expected to increase their share in the post pandemic period.

Also, Indian office real estate is expected to maintain its competitive advantage over its APAC peers as over 45% of the submarkets in top established and upcoming categories are from the cities of Bengaluru, Chennai, Delhi NCR, Hyderabad and Pune. This is further supported by our

research that shows that about 70% of the tech occupiers are MNCs compared to an average of 30-40% in many other APAC cities." Delhi NCR also ranks in top ten cities by property factors.

In addition to rent and rental growth, a key determinant for technology occupiers to grow is the availability of quality space at competitive rentals. With ample space in new or outlying districts, Bengaluru, Hyderabad, Shenzhen, Delhi NCR and Manila, are the top markets by property factors.

Bhupindra Singh, Managing Director, Regional Tenant Representation (India), commented: "Delhi NCR's micromarkets of Noida Expressway and Golf Course Extension Road in Gurugram have been featured amongst the top ten emerging submarkets in the APAC region for Tech occupiers, which is expected as technology companies are coming out of an extended work from home scenario and raring to go and perform in an office setup. We foresee buoyancy in the Delhi NCR market, and once the restrictions are fully lifted, the market will witness an upswing. Colliers forecasts an increase in uptake from the SME segment, moving towards economical micro-markets in the NCR, like NOIDA and Golf Course Extension."

Source: The Hans India, 24.06.2021

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Glenmark Pharma gets USFDA nod for inhalation drug

According to IQVIATM sales data for the 12 month period ending April 2021, the Brovana Inhalation Solution, 15 mcg/2 mL market2 achieved annual sales of approximately $437.9 million

Glenmark Pharmaceuticals Ltd (Glenmark) has received final approval by the United States Food & Drug Administration (USFDA) for Arformoterol Tartrate Inhalation solution, 15 mcg/2 mL, Unit-Dose Vials, the generic version of Brovana1 Inhalation solution, 15 mcg/2 mL, of Sunovion Pharmaceuticals Inc. Arformoterol Tartrate Inhalation solution, 15 mcg/2 mL, Unit-Dose Vials will be manufactured in the company's North American manufacturing facility based in Monroe, North Carolina, and marks the company's first nebulizer approval. According to IQVIATM sales data for the 12 month period ending April 2021, the Brovana Inhalation Solution, 15 mcg/2 mL market2 achieved annual sales of approximately $437.9 million. Commenting on the launch, Sanjeev Krishan, President, Glenmark North America said, "We are very excited to be one of the first generic companies to receive approval for such an important product for our customers. This also marks our third approval from our state-of-the art manufacturing facility in Monroe in 2021, demonstrating our capability to offer high quality medicines with affordable access across multiple dosage platforms."

Glenmark's current portfolio consists of 172 products authorized for distribution in the U.S. marketplace and 44 ANDA's pending approval with the USFDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

Source : Bizz Buzz, 23.06.2021

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Cipla gets USFDA nod for inhalation product

The approved product is a generic version of Sunovion Pharmaceuticals Inc's Brovana

Cipla yesterday said that it has received final approval from the US health regulator for Arformoterol Tartrate Inhalation Solution, used to treat conditions like chronic bronchitis and emphysema, in the US market.

The approved product is a generic version of Sunovion Pharmaceuticals Inc's Brovana.

The company has received final approval for its Abbreviated New Drug Application (ANDA) for Arformoterol Tartrate Inhalation Solution 15 mcg/2 mL from the United States Food and Drug Administration (FDA), Cipla said in a regulatory filing.

Brovana is used in the maintenance treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema.

Quoting IQVIA (IMS Health) data, Cipla said Brovana had sales of approximately $438 million for the 12-month period ending April 2021.

The product is available for shipping immediately, it added.

Source : Express Pharma News Bureau, 24.06.21

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Explained: Covid-19 vaccine makers and indemnity

In talks over supply of their vaccines in India, Pfizer and Moderna are seeking indemnity against costs of compensation for adverse events. Which countries provide such indemnity, and what is the law in India?

Multiple rounds of discussion have taken place between the government and pharma giants Pfizer and Moderna over the supply of their Covid-19 vaccines in India. What has been contentious is the question of indemnity, and these negotiations are now said to be in the final stages. Globally, the two companies have supplied their Covid-19 vaccines only after indemnities were given against the costs of compensation for adverse effects due to vaccination. This means that they cannot be sued in those countries on account of such effects.

Grant of indemnity does not always mean beneficiaries cannot seek compensation for adverse events, but the bar is very high. A look at how indemnity works in various countries, and why it has been an issue in the companies' negotiations with the Indian government:

What do we know about negotiations between the government and Pfizer?

Details of the negotiations between the government and Pfizer have not been made public. Pfizer and other vaccine manufacturers invoke a confidentiality clause while finalising commercial contracts with countries. The firms say this is to protect sensitive negotiations as well as business-related information.

The head of India's Covid-19 task force, Dr V K Paul, said Pfizer has indicated to India on availability of a "certain amount" of its mRNA Covid-19 vaccine, "possibly starting in July". However, the government is still e examining Pfizer's request of indemnity against the cost of compensation for any severe side effects.

"Similarly, they have requested indemnity from all nations. That is their expectation, that liability should be indemnified. They have expressed this in legal language. We are examining this request and we will make a decision in the larger interest of people and on merits. This is under discussion but there is no decision as of now," Paul said.

Are companies not granted indemnity under Indian law?

The Indian drug regulator has not granted indemnity against the costs of compensation for severe side effects to the manufacturers of any of the three Covid-19 vaccines — Covishield, Covaxin and Sputnik V — to which it has given emergency use authorisation.

For clinical trials, Indian law has laid out rules and a formula for grant of compensation in case of injury or death of any trial subject.

But when a vaccine is approved for commercial use, there is no specific provision under the Drugs and Cosmetic Act for compensation. However, beneficiaries seeking compensation can file petitions before legal forums, such as consumer courts or a High Court. Also, the drug regulator can take action under law for violation of any clause when a registration certificate is granted for import of vaccines.

Which countries have granted indemnity to Covid-19 vaccine manufacturers ?

The US, which began vaccinating its population in December, was the first country to provide such legal protection to Covid-19 vaccine manufacturer. The UK too has granted indemnity to vaccine manufacturers. And the World Health Organization (WHO) has a special compensation programme for low-income countries covered under its COVAX facility.

How does indemnity work in the US?

Pfizer and Moderna, the first two manufacturers to receive emergency use authorisation for their m-RNA Covid-19 vaccines, were granted immunity from liability by the US government. This protects them, until 2024, from lawsuits arising out of any foreseen and unintentional medical complications as a result of vaccination against Covid-19. Sovereign immunity also protects the US Food and Drug Administration; vaccine recipients cannot sue the FDA for approving the vaccine.

Which legal provision enabled such blanket protection?

The Public Readiness and Emergency Preparedness Act (PREP) Act authorises the US Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as vaccines. On February 4, 2020, the Secretary of HHS invoked the PREP Act and declared Covid-19 a public health emergency "warranting liability protections for covered countermeasures". Under the HHS Declaration and its amendments, manufacturers and distributors that are covered, state and local governments that supervise the immunisation programme, and health professionals who administer the vaccine are immune from legal liability for losses due to administration of covered countermeasures against Covid-19.

Immunity under the PREP Act covers "all claims for loss" — death; physical, mental, or emotional injury, illness, disability, or condition; fear of such injury, including medical monitoring costs; and loss of or damage to property, including business interruption loss.

Is there no provision for compensation?

Covid-19 vaccines are covered by the US Countermeasures Injury Compensation Program (CICP), under which individuals who die or suffer serious injuries directly caused by the administration of covered countermeasures may be eligible to receive compensation. Under the PREP Act, CICP can provide benefits to "certain individuals" who sustain "a covered serious physical injury as the direct result of the administration" of the Covid-19 vaccine.

However, the bar for compensation under CCIP is very high, and compensation very rare. Since 2010, CICP has received 1,360 claim filings, of which only 29 claims were compensated, totalling over $6 million.

Covid-19 vaccines are not covered under the US National Vaccine Injury Compensation Program (VICP). To seek compensation under VICP, the beneficiary files a petition with the US Court of Federal Claims, which decides on it based on a review and submissions by the government. VICP covers 16 vaccines, including those for seasonal influenza.

Moderna and Pfizer Covid-19 vaccines sit in a refrigerator at a vaccination site in Cranston, R.I., Thursday, June 10, 2021. (AP Photo: David Goldman, File)

How does the UK provide compensation?

The UK has a Vaccine Damage Payment. This is not a compensation scheme. However, someone severely disabled as a result of vaccination against certain diseases could get a one-off tax-free payment of £120,000, under Vaccine Damage Payment. This covers 19 vaccines, including Covid-19 vaccines.

"Currently, in order to qualify for the payment, it must be accepted, on the balance of probability, that there is a causal link between the vaccine and the claimed disability and that the resulting disability amounts to severe (ie at least 60%) disablement," the UK Department of Health and Social Care states.

How does the WHO special compensation programme work?

In February, the WHO started a "No-Fault compensation programme" for Covid-19 vaccines for 92 low- and middle-income countries. This is the only global vaccine injury compensation mechanism so far, and is funded by a small levy on each dose supported by the Gavi COVAX Advance Market Commitment. The programme is available for rare but serious adverse events associated with COVAX-distributed vaccines until June 2022

It covers serious injury or illness that is suffered by a patient and that: requires hospitalisation or prolongs an existing hospitalisation, and results in permanent impairment; or is a congenital birth injury or illness in an unborn or newborn child of a woman who received a vaccine and results in permanent total or partial impairment; or results in death.

Source: The Indian Express, 25.06.2021

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Mind the gap: Covishield's 2nd jab sets off controversy

Paradoxically, three days after India's May decision, and because of the threat of the Delta variant, the UK reduced the gap to eight weeks

It would benefit us to better understand the controversy surrounding the length of the gap between two AstraZeneca injections -- our Covishield. After all, there's no one over 18 who's not affected. So let me lay out the key facts and explain the complications inherent in them.

When the vaccinations started on January 16, the Covishield gap was set at four weeks, which is what the manufacturers recommended and what was followed in the incomplete bridging trials. However, earlier in December, Britain, on the basis of its own analysis of AstraZeneca's (AZ) trial results and additional information from the company, had unilaterally increased the gap to 8-12 weeks. Then, in February, WHO advised a similar gap. So,

unsurprisingly, questions were asked in India. In response, the government first expanded the gap to 6-8 weeks in March and then to 12-16 weeks in May. Paradoxically, three days after India's May decision, and because of the threat of the Delta variant, the UK reduced the gap to eight weeks.

Now the Indian government's press release says the gap was extended to 16 weeks on the basis of "real-life evidence, particularly from the UK". This created the first controversy. The original UK policy limited the gap to 12 weeks. It doesn't have real world data to cover the additional four weeks. When I questioned Gagandeep Kang, a member of the Covid Working Group which had suggested the 12-16-week gap, she said the additional four weeks was based on AZ's trial results and modelling. Now there's nothing wrong with that except it's not "real-life evidence" from the UK.

Last week, Prof. Andrew Pollard, the chief investigator of AstraZeneca and director of the Oxford Vaccine Group, rationalised the 12-16-week gap differently. He said protection from one dose is extremely good till 12 weeks but doesn't fall off a cliff thereafter. It's reasonable to assume a longer extension and, therefore, extending the gap to 16 weeks is not problematic.

However, this is the lesser controversy. The bigger one has to do with studies suggesting that AZ does not provide adequate protection against the Delta variant. This is of particular concern because AZ constitutes 88 per cent of all vaccinations in India while Delta is the dominant variant. There are probably more cases in India than the rest of the world put together. So, the efficacy of AZ against Delta is critical.

First, Public Health England has said that AZ only provides 30 per cent protection against symptomatic illness caused by Delta. Then, France's Louis Pasteur Institute published a laboratory-based study stating that "a single dose of AstraZeneca will not display an optimal protection against B.1.617.2 (the Delta variant)". Finally, our own National Centre for Disease Control in association with the Institute of Genomics and Integrative Biology published a study of the Delta variant concluding that "partial vaccination is an insufficient impediment to its spread".

Now, do these studies suggest that India's 12-16-week gap leaves people inadequately protected against Delta and we should reduce the gap to eight weeks, as Britain has done? Several experts say yes. They include Srinath Reddy, president of the Public Health Foundation of India, and Arvinder Singh Soin, chairman of Medanta's Institute of Liver Transplantation and Regenerative Medicine. A few newspaper op-eds and editorials echoed this view.

However, this is where we need to pause and understand what precisely the studies are telling us. No doubt one dose of AstraZeneca provides inadequate protection against symptomatic infection, but it provides very credible protection against serious illness and hospitalisation. Public Health England has established -- and, by the way, most of the good research on AZ and Delta comes from Britain, it's only just starting in India -- one dose provides 71 per cent protection, going up to 92 per cent after the second. And that's what really counts.

To explain further, let me rely on what Prof. Pollard said last week. We should not be deterred or deflected by the fact that one dose of AZ gives only 30 per cent protection against symptomatic illness. That usually means nothing more than a cold, cough and fever, which most people can handle. What's important is protection against serious illness, hospitalisation and death.

His second point is more important. The preponderant majority of the Indian population is unvaccinated and, therefore, unprotected at a time when the Delta variant is spreading widely and increasing in threat. In these circumstances, a vaccination policy that covers the largest number, in the quickest possible time, with at least one dose makes sense. This means a gap up to 16 weeks is arguably the right response.

Prof. Pollard also warned against comparing vaccination policies in Britain and India. The circumstances in the two countries are very different. Britain reduced the gap after a substantial proportion of its population was vaccinated. India extended the gap to reach more people. Additionally, there's a shortage of vaccines. We need to make the most of the little we have. We're not in Britain's position of abundant supply.

So now you have the two poles of the debate. Which should we focus on? Inadequate protection conferred by a single dose of AZ against symptomatic illness or the 71 per cent protection against serious illness and hospitalisation? In the last week, the balance has tilted in favour of the government's strategy, which prioritises protection against serious illness and hospitalisation. No doubt, Prof. Pollard's endorsement has hugely helped, but so too has a recent study by the Christian Medical College in Vellore which shows 70 per cent protection against hospitalisation, 94

per cent against need for oxygen and 95 per cent against the need for intensive care after one dose.

Yet two issues remain and they're also unaddressed. Is it wise to leave the elderly and vulnerable inadequately protected for 16 weeks or should the gap be narrowed to eight weeks for them? Second, people who develop symptomatic illness are also carriers and can pass it on. A 12-16-week gap means there could be more such people than if it was just eight weeks.

To the best of my knowledge, this is where the controversy stands today. N.K. Arora, head of the Covid Working Group, has said that any change "will be taken scientifically … on the basis of merit". However, he also added that "if it turns out the current decision is fine, we will continue with it". I guess we'll have to wait and see what happens.

Source: Karan Thapar, Deccan Chronicle, 25.06.2021

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What is delaying anti-Covid-19 drug by DRDO, Madras HC asks Centre

CHENNAI: While people are dying without treatment for covid-19, why did the Union government fail to take steps for mass production of '2-deoxyD-glucose' (2DG), the Covid-19 antiviral drug developed by Defence Research and Development Organisation (DRDO), asked Madras high court on Thursday.

"Why can't you (Union) give permission to at least pharmaceutical companies owned by the central and state governments for immediate mass production of the drug," the bench wondered.

The bench of Justice N Kirubakaran and Justice T V Thamilselvi also directed the Union government to explain as to why only Dr Reddy's Laboratories had been approved for production of the drug.

The court the ordered counsel for the Centre to get instructions from the authorities concerned and file a detailed report by June 25.

According to the petitioner, D Saravanan, DRDO had discovered 2DG oral powder as an adjunctive therapy to standard of care in the acute treatment of moderate to severe Covid-19 patients. Though the drug had received emergency use approval from the Drug Controller General of India (DCGI) during the pandemic, licence to manufacture was granted only to Dr Reddy's Laboratory.

The privately-owned pharma company has planned to sell the drug at 990 per sachet containing 2.34 g of the oral powder, he said.

While Covid-19 is causing huge economic loss to the nation, the policy of granting license to one particular company will create monopolistic trade and give way to price rise, he added.

Claiming that giving the licence to several medical companies might bring down the price of the drug when several lives are being lost, the petitioner wanted the court to direct the authorities to provide the licence to multiple pharmaceutical companies.

He said the inordinate delay caused by the private pharmaceutical manufacturing company in bringing the drug to market has been adversely affecting severely-affected patients in ICUs.

Source: Suresh kumar, Times of India, 25.06.2021

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Domestic cold chain biz struggles to keep up volumes to recover investment

Compared to similar geographies, like Thailand, Malaysia and China, Indian players make just about 1-2 per cent PAT as against 10-15 per cent PAT in these countries

The need for sizeable investment coupled with a well-defined strategy to capture volumes has made cold chain business a tough one despite the market thrown open by the Coronavirus (Covid-19) vaccination drive.

Industry officials are of the view that pharma cold chain alone could grow by about 20 per cent compound annual growth rate (CAGR), while the non-pharma segment by 15 per cent CAGR for the next few years.

The cold chain industry in India, however, is fragmented and has only a few organized players catering to both pharma and non-pharma segments such as confectionaries, fruits and vegetables among others.

Gati Ltd, an old player in the logistic business, sold off its cold chain business Gati Kauser to a private equity player in May. This came at a time when the business had started to look up.

"For the next three-five years, cold chain capacity will fall short of demand for both—pharma and non-pharma segments since in the last four to five years lot of players exited. Private equities want to double money in five years

but that is not possible in cold chain," Sunil Nair, chief executive officer at Snowman Logistics, told Business Standard.

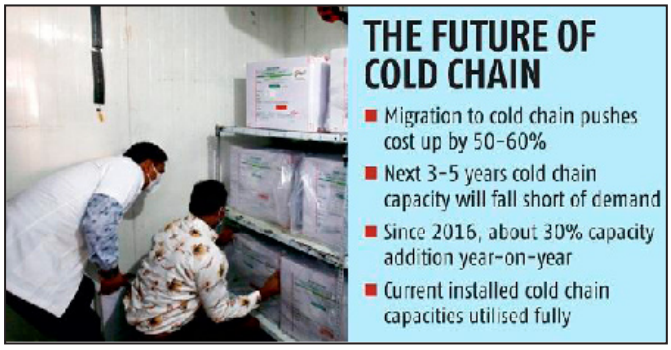
According to Nair, the key to this business lies in its scale which is possible through investment in capacity.

"This has to come with a well chalked-out strategy which allows the cost overheads to be optimised over a period of time," he said.

"Technology requirement is very strong in this segment along with service offerings. It needs a lot of compliance on the ground and a lot of skill is required on ground as well to manage the business," said Kunal Agarwal, director of Kool-ex, a pharma cold chain logistics service provider.

The company has the largest refrigerated (reefer) truck fleet of 450. Most players, however, have 20-30 reefer trucks keeping the industry parched for more capacity.

Coldrush Logistics, Coldman Logistics and RadhaKrishna Foodland are other players in the cold chain market looking to grow in the coming years.



"Demand for vaccines is not the sole reason for growth in the pharma segment. There is a shift happening in FDA (Food & Drug Administration) norms wherein a lot of drugs, which today are stored and transported in normal dry trucks will have to move to the cold chain. This is leading to strong volume visibility in the pharma cold chain logistics," said Nair.

Snowman Logistics is looking to invest Rs 425 crore over the next three years, of which Rs 200 crore would be used to increase pharma capacity. The company has 10 per cent of its total revenue coming from the pharma segment, which it plans to take to 18-20 per cent over the next few years.

As pandemic induced lockdowns lead to consumers stocking up perishable items, this creates more demand for cold chain logistical service. "Even for confectionery, companies are choosing to use cold chain logistics over dry open truck transportation leading to a shift in volumes in the non-pharma category," Nair added.

Industry officials also said that changes in FSSAI Act has led to a volume shift from unorganised to organised segment of cold chain and that since 2016 there has been at least 30 per cent capacity addition year-on-year with currently all the installed cold chain capacities utilised fully.

Still, the cold chain business is considered unattractive as it does not yield adequate returns.

"If you do not own the refrigerated business you cannot be in the cold chain business because the concept of leasing reefer trucks is not developed in the country. Hence it made sense to exit this business," said Bala Aghoramurthy, deputy managing director at Gati Ltd.

Compared to similar geographies, like Thailand, Malaysia and China, Indian players are perhaps making just about 1-2 per cent profit adjusted after tax (PAT) as against 10-15 per cent PAT in these countries. This is because the domestic cold chain industry needs serious price revision, said industry officials.

"Manufacturers have shifted from open body trucks to refrigerated trucks. This migration leads to a huge cost difference as cost goes up by 50 -60 per cent," said Nair. Manufacturers want at least to recover this increase in cost over dry transport and warehousing but they get only a 10-15 per cent premium which is not enough. It will take the next 2-3 years to have prices comparable to Thailand, Malaysia or China, said Nair.

Though there are not many new entrants in the domestic cold chain business at present, once the existing players are able to prove their business model based on sizable utilsation and strong financials, more companies could look to enter the industry going ahead.

Source: Business Standard, 25.06.2021

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Surcharges threaten to rock exporters' boat

Shipping lines to levy up to $1,500/TEU

At a time when exports appear to be the only saving grace for the Indian economy, exporters are

being forced to shell out more to ship goods to global destinations.

Shipping lines have announced surcharges due to the continued disruptions in global container trade following congestion at various ports. The proposed increase is between $500 and $1,500 per twenty-foot equivalent unit (TEU), depending on the destination.

Effective July 7, shipping rates from Nhava Sheva, Mundra, and Hazira ports to Mediterranean will see a rate increase of $500 per TEU, said an Hapag Lloyd advisory. At present, it costs $2,800 per TEU to Barcelona: a $500 surcharge would mean an 18 per cent increase in shipping cost.

The French shipping group CMA CGM will apply a peak season surcharge of $1,250 per TEU for dry cargo to East Coast Central America, the Caribbean and Mexico East Coast from India via Malta. Considering that it costs $5,500 per TEU to Buenos Aires from India, the surcharge adds to the shipping cost by 23 per cent.

The congestion was aggravated after the Suez Canal blockage and the recent suspension of activity at Yantian International Container Terminal (YICT), China.

Suez Canal blockage

Lars Jensen, an industry expert, in a social-media post, said that YICT operated at 30 per cent of capacity in the past month. It will take 82 days to clear the backlog there, said Jensen.

"Importers and exporters are facing huge challenges with port congestion and availability of vessels. We are having to pay three times the normal costs. This is a huge burden for exporters like us who have already contracted the prices with the customers," said Sanjay Lulla, Managing Partner at SM Lulla Industries Worldwide – a leather garment exporter.

An official with a shipping line said they are increasing freight rates to set off steep increase in vessel costs. There is also a serious equipment imbalance, he added.

Maersk, in a bulletin, said that Covid-19 compromised global plans and, in parallel, consumers began asking for more. The knock-on effects of this are widespread and the global trade lacks the resilience needed to cater to this added strain.

Source: TE Raja Simhan, Business Line, 26.06.2021

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Thyrocare deal: PharmEasy founders out to build Amazon of health care

Of the three healthcare baskets that PharmEasy is targeting, it has already created a significant presence in consultation and treatment

(From left) PharmEasy founders Dhaval Shah, Harsh Parekh, Siddharth Shah, Hardik Dedhia, and Dharmil Sheth

API Holdings, the parent company of online pharmacy PharmEasy, announced last week that it would pick up a 66.1 per cent stake in diagnostics firm Thyrocare for Rs 4,546 crore. It is the first unicorn to acquire a listed company.

One of the biggest consolidations in the domestic health care space, the deal was struck in record time at the Mumbai residence of A Velumani, founder of Thyrocare.

The deal is also a milestone for five friends from the Mumbai suburb of Ghatkopar, who called themselves the Ghatkopar Gujju gang, and set up PharmEasy in 2015.

Siddharth Shah, Dhaval Shah, Dharmil Sheth, Harsh Parekh, and Hardik Dedhia are now a step closer to their dream of building India's 'Amazon' in the healthcare delivery platform.

Of the three healthcare baskets that PharmEasy is targeting, it has already created a significant presence in consultation and treatment. With the acquisition of Thyrocare, it will now build the third basket — diagnostics.

Experts feel that with Thyrocare, PharmEasy is not only acquiring a brand and the infrastructure for diagnostics, but also a profitable business. Thyrocare's revenue grew 14 per cent year-on year to Rs 494.6 crore in FY21, with a net profit of Rs 113 crore and Ebitda of 37 per cent.

The acquisition of a profitable business is good news for PharmEasy as it looks at an IPO. Reportedly, the company intends to raise Rs 3,000-3,500 crore via listing in public markets in the next 12-18 months.

For PharmEasy's founders, it all started in 2012 when Siddharth Shah incorporated a company called Dial Health as part of a project during his IIM Ahmedabad days.

While Dhaval is a doctor by profession, Dharmil, and Hardik are engineers by training, and Harsh is an MBA graduate.

It so happened that Dial Health failed miserably. "The only people who believed in us at that time were our parents," said Siddharth Shah during an investor call.

However, the experience enabled the five friends to understand that pharma was a highly fragmented market and that retailers did not have the ability to deliver medicines in a short span of time.

"The only way to make the front end work was to consolidate the backend," said Siddharth Shah. So they went ahead and consolidated the digital and retail business and PharmEasy was born in 2015.

Possibly the largest digital outpatient healthcare ecosystem in the country today, PharmEasy has over 12 million registered users and over 17 million active monthly users. It also has a B2B platform called Retailio which delivers medicines to 90,000 retailers in India spread across 140 cities.

"We are now the proud Students of Thyrocare Technologies (not acquirers/buyers) and are taking the 1st step towards learning to make affordable, reliable and quality testing across the country a reality !!," wrote Dhaval Shah on LinkedIn after the deal was announced.

PharmEasy also plans to invest heavily in technology to give customers a superlative experience. In the works are a recommendation engine to ensure that patients do not do unnecessary tests, a QR-code based verification system to provide end-to-end control of samples, and end-to-end visibility from the time that a customer books a test until the process ends, and so on. The entire process could take 18-24 months, according to company sources.

"Today from a fragmented experience in the OPD value chain, tomorrow you will have an integrated experience, which will be digital-first," asserts Siddharth Shah.

Consolidation

From a gross merchandise value of $1.4 billion last year, the digital healthcare services sector is expected to grow 10 times in the next 4-5 years. And major players such as Tatas, Reliance and Amazon are moving in to cash in on the opportunity.

Last week, Apollo created the country's largest omnichannel digital health platform by merging its online and offline pharmacy businesses (excluding hospital pharmacies) and telemedicine verticals into a single entity called Apollo HealthCo.

While Tata Digital, a 100 per cent subsidiary of Tata Sons, acquired 60 per cent stake in 1MG earlier this month for $270 million, Reliance Industries last year acquired a 60 per cent stake in Netmeds for Rs 620 crore.

Earlier this year, API Holdings also acquired online pharmacy Medlife in a deal of over $200 million. Backed by marquee investors such as Temasek, TPG Growth, Prosus Ventures, and Orios Venture Partners, the company is also planning to venture into the health insurance segment.

Source: Samreen Ahmad, Business Standard, 28.06.2021

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Centre commits to vaccinate all adults by Dec 31

Its SC affidavit exposes slips by Bharat Bio in meeting the vaccine commitments

India's Covid-19 vaccination programme may not be able to sustain the pace that it gathered in the recent days as the supply of vaccines may fall short of expectations of the States and Union Territories.

According to an affidavit filed by the Central government in the Supreme Court on Saturday, the total supply of vaccine doses in July will be 12 crore – hardly enough to clock a target of 40 lakh doses a day.

On June 21, States and UTs were able to vaccinate 88 lakh people, which was a record. States can expect a total

of 12 crore doses of Covishield and Covaxin in July, both in government and private sectors.

Vaccine supply (till June 21)

Quantity (in crore)	Date of purchase order	Timeline of supplies	Supply Status
6.6 (Covishield -5.6 &Covaxin - 1)	4 orders between Jan 10 and Feb 24	January-March 21	Received and utilised
12 (Covishield 10 & Covaxin 2)	March 12	March-May	Received supply barring around 18.37 lakh doses of Covaxin
16 (Covishield 11 & Covaxin 5)	May 5	May-July	Covishield supply received 3.47 crore, balance 7.53 crore. Covaxin yet to start supply

Credit: Health Ministry affidavit to SC on June 26

Fails to meet deadline

Bharat Biotech, the maker of Covaxin, has so far failed to keep to the committed deadlines. As on June 21, the affidavit said Bharat Biotech is yet to supply close to 18.37 lakh committed under a purchase order on March 1.

In addition, Bharat Biotech has not supplied a single dose of 5 crore Covaxin doses it promised between May and July. Stating that the total adult population in the country is approximately 93-94 crore and to vaccinate of them as planned, the affidavit signed by Manohar Agnani, Additional Secretary in the Health Ministry, said the country will require an estimated 186-188 crore vaccine doses till December 31.

Vaccines procured

Of this, the total quantity of vaccines procured till date was 35.6 crore and a delivery of another 16 crore doses – Covishield (11 crore), Covaxin (3 crore) and Sputnik V (2 crore) – is expected by July-end, the Centre said.

The affidavit also said the government has already received 31.5 lakh doses of first component of Sputnik V (meaning first dose) and 60,000 doses of the second component.

As per the government calculation, it is hopeful of getting hold of an additional 135 crore doses of Covid-19 vaccines during five months beginning August 1.

Apart from 50 crore of Covishield and 40 crore of Covaxin, it has counted in 30 crore doses of Biological E subunit vaccine, 10 crore doses of Sputnik V and 5 crore of Zydus Cadila's DNA vaccine.

The affidavit clarified that the estimate of 186.6 crore doses does not include other vaccines that are at various stages of development as on date within the country.

Source: T V Jayan, Business Line, 28.06.2021

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Johnson & Johnson Covid vaccine likely to be available in India by July

Johnson & Johnson's vaccine could arrive in India as early as July, though it will be limited to a few thousand doses initially.

The Johnson & Johnson vaccine does not need to be stored frozen

The Covid-19 vaccine developed by Johnson & Johnson will likely be available in India in small quantities by July this year, sources said.

The Association of Healthcare Providers (India) is in the process of privately procuring the vaccine directly from the US-based manufacturer.

Johnson & Johnson's vaccine could arrive in India as early as July, though it will be limited to a few thousand doses initially. The one-shot vaccine will be priced at $25 in India.

The viral vector vaccine does not need to be stored frozen and is suitable for a country like India, which lacks the healthcare infrastructure for storage of vaccines in sub-zero temperatures in tier-2 regions and beyond.

Johnson & Johnson has already initiated talks with the Union government to authenticate its manufacturing process and specifications in the country. The US pharmaceutical major had approached the Centre earlier in April with the objective of starting a clinical bridging study in India. Now, according to new rules, it is not mandatory for a vaccine approved by the US drug regulator to conduct bridging trials in India. With this, the vaccine is expected to be cleared for use in India in the coming months.

According to the WHO, the J&J vaccine's efficacy was 66.3 per cent for mild to moderate Covid-19 and 76.3 per cent for severe to critical infection. Additionally, it provides 100 per cent protection from hospitalization for Covid-19 28 days after vaccination.

CONCERNS REGARDING J&J VACCINE

The US FDA had authorised Johnson & Johnson's single-dose Covid-19 vaccine for emergency use in February 2021. However, the brisk roll-out of the vaccines has fallen flat in recent weeks after it was linked to a rare but serious blood-clotting disorder.

The vaccine took another hit in June, when regulators told the pharma giant that it should throw out tens

of millions of additional doses produced at a plant in Baltimore because they might be contaminated.

In the UK, which gave emergency use nod to the J&J vaccine last month, infectious disease experts have suggested that a booster shot may be needed due to the increasing prevalence of the more contagious Delta variant.

Moreover, there have been no studies to show how protective the J&J vaccine is against new variants like Delta and Delta Plus. Johnson & Johnson has said it is testing whether the immune response from its vaccine is capable of neutralizing the Delta variant in a laboratory setting, but no data is available yet.

Source : Milan Sharma, India Today, 26.06.2021

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Covid vaccine for kids above 12 likely to be available by July-end or August: Govt

NEW DELHI: The government on Sunday said that Covid vaccination of children in the 12-18 age group may start by the end of July or in August. "Trial for Zydus Cadila vaccine is almost complete. By July end or in August, we might be able to start administering this vaccine to children of 12-18 age group," said Dr N K Arora, chairman of the Covid-19 working group of the National Technical Advisory Group on Immunisation (NTAGI).

Currently, only those who are 18 or above are eligible for vaccination. Commenting on the ICMR study that the third wave is likely to come late, Arora said that in the coming months, the government has targeted to administer 1 crore doses every day to achieve the target of immunising everyone in the country within a time bracket of six to eight months. The NTAGI chief also said that vaccination-related rumours are vague and vaccines in India are 95-96% safe.

"The ICMR has come up with a study which says the third wave is likely to come late. We have a window period of six-eight months to immunise everybody in the country. It is important that people come forward proactively and take the vaccines, that's absolutely necessary. There are several rumours, misinformation which is spreading in the country. Similarly, people have some vague fear in their minds. They think there may be some side effect or vaccine may be unsafe," said Dr Arora.

He further said, "Scientifically, we have been looking at adverse events during vaccination, 95-96% people have only mild fever or local pain, 4-5 pr cent people have been hospitalised due to an allergy or some get anxious and they have to be hospitalised but otherwise these vaccines are absolutely safe". On Saturday, the Centre informed the Supreme Court the vaccine developed by Zydus Cadila will be available soon for children who are 12 and above subject to statutory permissions.

Zydus Cadila is likely to soon apply to the Drugs Controller General of India for emergency use authorisation for its vaccine ZyCoV-D, which it claims can be given to both adults and children. "So, if the Zydus vaccine gets approval, it will be another option," Dr Guleria said. Earlier, AIIMS director Dr Randeep Guleria said that making vaccine available for children will be a milestone achievement and pave the way for reopening of schools and resumption of outdoor activities. He said the data of phase two and three trial of Bharat Biotech's Covaxin on two to 18 years age group is expected by September. The vaccine can be available for children in India around that time following approval from the drug regulator, he said. "If the Pfizer vaccine gets approval before that, then it can also be an option for children," Dr Guleria told PTI on Saturday. " ... if the Zydus vaccine gets approval, it will be another option," Dr Guleria had said.

Source : Times of India, 28.06.2021

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Biological E asked to spur vax production

Minister for Chemicals & Fertilizers D.V. Sadananda Gowda

Biological E's Corbevax is likely to be available in the next few months and the govt has reserved 30 crore doses

Union minister for chemicals and fertilizers D.V. Sadananda Gowda on Sunday urged Hyderabad-based vaccine manufacturer Biological E Ltd to fast track the availability of their covid-19 vaccine to cater to the increasing need in the country.

The minister visited the facilities of Biological E, which has received government support to the tune of 100 crore under Mission Covid Suraksha for the development of an indigenous protein sub-unit covid-19 vaccine.

The vaccine is undergoing phase 3 clinical trials after animal challenge and assay studies were conducted by the company through the department of biotechnology's autonomous institute, Translational Health Science Technology Institute (THSTI), Faridabad.

Biological E's Corbevax vaccine is expected to be available in the next few months and the Union ministry of health and family welfare has finalized arrangements to reserve 30 crore doses, which will be manufactured and stockpiled by Biological-E from August-December 2021. The ministry has paid an advance of 1,500 crore to the vaccine manufacturer.

Covid Suraksha was announced by the Centre under Atmanirbhar Bharat 3.0 Mission to accelerate the development and production of indigenous covid-19 vaccines. This is being spearheaded by DBT and implemented by its Biotechnology Industry Research Assistance Council (BIRAC).

Gowda also visited Covaxin manufacturer Bharat Biotech Ltd to oversee the vaccine's production. The company has set a target of producing 6-7 crore doses per month in July and August and nearly 10 crore doses per month by September 2021.

Hyderabad-based Bharat Biotech and other public sector vaccine manufacturers are being upgraded with infrastructure and technology required for the production of Covaxin.

"Financial support is being provided as grant from central government to the tune of approximately 65 crore to Bharat Biotech's new Bengaluru facility, being re-purposed to increase the capacity of vaccine production. The PSUs being supported by the department for augmentation of covid production are Indian Immununologicals, Hyderabad, Haffkine Biopharmaceutical Corporation Ltd, Mumbai, and Bharat Immunologicals and Biologicals Limited, Bulandshahr," the government said.

Bharat Biotech, Hyderabad has also received support under Covid Suraksha to develop a single dose SARS-CoV-2 intranasal vaccine. "The support is being given for the entire pipeline of vaccine production from phase 1 clinical trials to licensure. This vaccine could be a game changer being a single dose vaccine subject to efficacy and safety," the government said. India's cumulative vaccination coverage exceeded 32 crore on Sunday. The country reported more than 50,040 new covid-19 cases in the last 24 hours with 1,253 deaths. The total tally of covid-19 cases in India has crossed 3 crore and the total number of deaths are nearing 4 lakh.

Source : Neetu Chandra Sharma, HT Mint, 28.06.2021

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10-month gap between AstraZeneca vaccine doses effective, 3rd booster shot ups immunity: Study

The study by Oxford is likely to assist countries in their vaccine roll-out planning. Most nations have recommended a gap of 4 weeks to 12 weeks between AstraZeneca vaccines currently.

The human body's immune response to the AstraZeneca Plc Covid-19 vaccine is likely to be more effective if the gap between two doses is increased to about 10 months, a study by the University of Oxford published on Monday showed. Additionally, a third shot can push up the antibody levels, even more, said the study conducted on the vaccine now known as Vaxzevria.

The study showed that an extended gap between the doses increased the level of protective antibodies. For the third shot, when given the first time after six months post the second dose, the booster was found to have induced a strong response and increased activity against coronavirus variants, the researchers found.

Governments around the world are faced with severe vaccine shortages amid a race to fully vaccinate their population against the infectious disease which has killed at least 3,925,816 people since the outbreak emerged in China in December 2019, according to the AFP.

At least 181,026,780 cases of coronavirus have been registered. The World Health Organization estimates that the pandemic's overall toll could be two to three times higher than official records, due to the

excess mortality that is directly and indirectly linked to Covid-19.

A health worker shows a vial of the AstraZeneca Covid-19 vaccine against the coronavirus disease.(Reuters)

In the last 24 hours, a total of 6,743 new deaths and 325,186 new cases were recorded worldwide.

The countries with the highest new deaths were India with 979 new deaths, followed by Brazil with 739 and Colombia with 664.

Some countries are also trying to tackle questions on booster shots in a bid to avoid overburdening the hospitals in the coming months of winter.

The study by Oxford is likely to assist countries in their vaccine roll-out planning. Most nations have recommended a gap of 4 weeks to 12 weeks between AstraZeneca vaccines currently.

Officials said this study will aid the world's response against the viral disease.

"This is about preparedness," Andrew Pollard, lead investigator on the Oxford vaccine trials, said at a press briefing Monday.

"This data show we can boost responses giving another dose of the AstraZeneca-Oxford vaccine and that's really important. More research on the duration of immunity from two doses and protection against variants would help determine whether booster doses are really needed," Pollard said.

What the study found

The study found that antibodies induced after a single dose survived to some extent after one year. Still, after 180 days the levels were half those seen at the 28-day peak. A second dose increased antibody levels between four- and 18-fold by one month after the shot, however.

Volunteers in the latest study were drawn from Oxford's original early and late-stage trials for the vaccine last year. Thirty participants who only received a single dose in the trial were given a second one about 10 months after the first. An additional 90 participants from those studies received a third dose in March this year. All volunteers were between the ages of 18 and 55, reflecting the recruitment age at that stage of the trials last year.

More than half a billion doses of the Astra-Oxford vaccine have already been sent to 168 countries, according to the researchers.

Source : Arpan Rai, Hindustan Times, 30.06.2021

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Centre focusing on developing vaccine for Delta variant says G Kishan Reddy

Hyderabad : Union Minister of State for Home Affairs G Kishan Reddy said that the Centre was making efforts for the development of a super vaccine to handle any challenges that the Delta plus virus might pose.

Addressing the media on Saturday after inaugurating the oxygen concentrators bank, launched by the Lions Club in Sitarambagh, the Union Minister said the Centre would take a call on vaccinating children below the age of 18 years, after the completion of the second phase trials.

He said some people have approached courts questioning trials on children. But, the courts have dismissed such petitions and allowed the continuation of research.

Appreciating the Lions Club for starting an oxygen bank and providing oxygen concentrators, besides taking up several social services activities, the Union Minister said that many non-governmental organisations in the country have been working along with the government to save people from Covid.

Kishan Reddy said that the Centre has improved about 1 lakh oxygen concentrators and sent the same to the States. In a record time of eight months, he said that 51,000 oxygen concentrators were made operational.

"In addition to providing masks and PPE kits to 85 countries, the Centre has augmented medical oxygen to meet the demand by deploying and running 85 oxygen expresses on the green channel. Also, the Centre had deployed flights to expedite the distribution and supply of oxygen in different parts of the country," he added,

appealing people not to spread fake news on the Delta plus variant of Covid. Later, the Minister distributed hygiene kits and essential commodities to the people at Aghapura.

Source : Hans India, 27.06.2021

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India to take up Covishield absence from EU pass list

India plans to strongly take up with the European Union (EU) the issue of non-inclusion of Serum Institute of India (SII)-manufactured Covishield in the list of approved vaccines for the EU 'Green Pass.' The pass is required for easy travel to and within the EU and will be launched from July 1.

ET has learnt that the ministry of external affairs (MEA) has already raised the matter with the EU drug regulator - the European Medicines Agency (EMA) - as well as with France, which is reportedly one of the first European countries planning to facilitate easy entry for those vaccinated with jabs approved by EMA.

AstraZeneca-manufactured Vaxzevria vaccine has been approved by EMA and those inoculated with it are eligible for the Green Pass. But Covishield, the vaccine made by AstraZeneca's technology partner, SII, which is being widely administered in India and several low- and middle-income countries, does not have EMA approval.

Sources who did not wish to be named said the government was carefully studying the EU's current Green Pass directive, which appeared to be discriminatory and ad hoc. "We are studying how the current status of EU Green Pass impacts third countries in future. There have been informal talks on the matter with EU," said a person familiar with the matter. SII said it will raise the issue through proper diplomatic channels, said a company source.

Covishield non-inclusion a thorny issue

"This has become a political issue. The MEA will have to be involved to resolve the issue," an industry insider said.

As of now, travel from India is restricted by most countries. But once these restrictions are removed, the absence of an Indian vaccine from the list of approved jabs will become a thorny issue. The non-inclusion of Covishield will impact the travel plans of people in several countries.

The SII-manufactured vaccine has been widely distributed by the World Health Organization (WHO) co-sponsored Covax initiative and figures on the list of WHO-approved vaccines.

People familiar with the situation said India will work with EMA and European states to secure approval for Covishield as well as Bharat Biotech's Covaxin. Russia's Sputnik V has already applied to EMA for approval. Sputnik is under a "rolling review" process by EMA, which is the step prior to formal authorisation.

EMA, which is the agency of the European Union responsible for the evaluation and supervision of medicines, has so far approved only four Covid-19 vaccines -

Pfizer, Moderna, Vaxzevria (Oxford-AstraZeneca) and Janssen (Johnson & Johnson). EU members that issue the Green Pass must accept these four vaccines. Individual countries have the freedom to grant entry to travellers who have taken other vaccines as well.

EMA has itself been the subject of some criticism among member states. Italian Prime Minister Mario Draghi, while addressing an EU summit last week, suggested that there was a need for "strengthening and maybe also a reform of EMA" to avoid a repeat of "considerable confusion" over the vaccine rollout. He referred to a "certain discrepancy in pronouncements" over the safety of Covid-19 vaccines between EMA and national medicine bodies.

Traveller information issued by the authorities of the Schengen Zone, which includes EU countries plus several other non-EU European countries such as Norway and Switzerland, states, "As the member states reopen borders for travel from non-EU countries for non-essential purposes, they also intend to issue EU Covid travel certificates to travellers from third countries intending to enter their territory. The commission also intends to accept certificates issued in third countries, which are issued under the same conditions as the ones by the EU. In order for the traveller to be able to get the vaccine, he/she should be vaccinated with one of the EU-approved vaccines."

Source : Dipanjan Roy Chaudhury, ET, 28.06.2021

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Second wave impacted 58% of Indian companies: FICCI

About 58% of respondents cited weak demand as a major challenge in the current environment, the survey conducted this month by Federation of Indian Chambers

of Commerce and Industry (FICCI) and Dhruva Advisors showed.

The second wave of Covid-19 and resultant lockdowns in several states significantly impacted about 58% of Indian companies but India Inc remains optimistic about a strong recovery in the coming months, a private industry survey has said.

About 58% of respondents cited weak demand as a major challenge in the current environment, the survey conducted this month by Federation of Indian Chambers of Commerce and Industry (Ficci) and Dhruva Advisors showed.

While urban demand saw a sharp hit, 37% of firms reported a high impact on sales in rural markets as well, Ficci said in a statement on Monday.

Another industry association, PHD Chamber of Commerce and Industry has urged the government to boost infrastructure spending to support economic recovery and help boost demand. To refuel aggregate demand, the government should front load expenditure under the national infrastructure pipeline, PHDCCI president Sanjay Aggarwal said in a statement on Monday.

As per the Ficci survey, about 56% respondents also cited managing costs as akey challenge for businesses. Yet, most companies are confident about a speedy recovery.

"With the number of new cases ebbing and states getting into the 'unlock' mode, there is hope that business and economic activities would regain normalcy in the months ahead," said Uday Shankar, president of Ficci. Nearly 63% of survey respondents expect capacity utilisation to improve to over 70% in the coming six months to a year. As of now, 40% of companies reported utilisation rates of less than 50% of installed capacity.

According to the survey, the government's top priority to prepare for a third wave of the pandemic should be ramping up investments in healthcare infrastructure in tier two and tier three cities and in rural areas.

To scale up Covid-19 vaccinations, the government should set up a national facility for vaccine manufacturing with government funding, apart from creating more booths at public places, setting up facilities in cooperative societies, and promoting tieups with corporates, Ficci said.

Source: ET Bureau, 22.06.2021

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Big manufacturing firms plan to reopen offices with limited staff

"We are going to start offices by July and will keep the count not more than 30% initially," said Madhu Srivastava, group chief human resources officer at Vedanta.

Several manufacturing companies including Maruti Suzuki, Vedanta, Schneider Electric, Arvind Advanced Materials, TVS Motor, Saint-Gobain, and Ceat Tyres are reopening their offices with less than 30% attendance with new Covid-19 cases continuing to fall and states lifting lockdowns.

Maruti has started its Delhi office while Schneider, Vedanta, and Ceat Tyres plan to resume offices in July, company officials said.

All these companies already have their plants operational and are focusing on reopening offices on a rotation basis.

"We are going to start offices by July and will keep the count not more than 30% initially," said Madhu Srivastava, group chief human resources officer at Vedanta. "While taking all caution, we are gradually looking at taking the numbers up."

Mostly, companies plan to call those employees whose roles are not remote work friendly.

Also, many employees are seeking to return to office for work citing work from home fatigue, officials said.

Ceat Tyres plans to start calling employees from July with an initial cap of 25% attendance. The proposal is under consideration at the group level, a senior official said.

"As a company we do not want to rush the employees to offices," said Milind Apte, senior vice president, HR, at

Ceat Tyres. "However, most employees want to start coming to offices due to WFH saturation."

Schneider Electric is encouraging managers to assess the situation of fatigue that is emerging from working from home on a long-term basis. The company is recommending a voluntary return to office.

Glass manufacturer Saint-Gobain is resuming its offices in cities such as Delhi, Bengaluru, Chennai and Mumbai next month with 20% headcount. "Quite a lot of employees are wanting to come to the office instead of working from home," its CEO B Santhanam said.

Ashok Leyland's HR head Amanpreet Singh said the commercial vehicle maker is still evaluating the pandemic situation and will take a call later.

Arvind Advanced Materials is about to resume office working this month with a roster system. Unlike last year when the shutdown of global markets led to cancellations of orders, this time around the company has export orders that need to be serviced, its CEO Ashish Kumar said. "It is then imperative for business sustenance that manufacturing is allowed to function with required safeguards," he told ET.

The company has vaccinated 75% of its workforce.

HYBRID WORK MODEL

Like most companies in the services sector, many manufacturing firms are embracing hybrid work models.

"We have mastered the way of hybrid work and would continue to follow this for a large part of the workforce," said Rajesh Uppal, member, executive board, at Maruti Suzuki India

Ceat Tyres has a new-age remote working policy in place, encouraging hybrid working, that will continue even after the pandemic ends. "Employees will transition to this policy gradually as situation improves," Apte said.

Due to the severity of the second wave of Covid-19 and possibility of subsequent waves, companies are keen to control the number of employees at a time not only in their offices but also at manufacturing facilities.

Factories at TVS Motor, for example, are open at a maximum capacity of 40%.

"The company is using flexible attendance rosters where some functions are categorised under alternate week patterns while others have alternate days," said R AnandaKrishnan, executive vice president – human resources at TVS Motor Company. The company has vaccinated 95% of its workforce.

Most other companies said employee count at plants is as per the state government norms.

Source: Prachi Verma, Economic Times, 22.06.2021

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Tax department doesn't think sanitiser companies' accounts are clean

Pharmaceutical companies say sanitisers are medicaments, while the taxman considers them disinfectants. The indirect tax department's investigation arm, Director General of GST Intelligence (DGGI), has initiated an investigation in this regard and even sent notices to some companies.

Companies making hand sanitisers and the raw materials used in them have come under scrutiny for allegedly categorising these items incorrectly and escaping tax.

The question is whether sanitisers should be treated as medicaments liable to goods and services tax (GST) of 12%, or as disinfectants or consumer products, on which 18% GST is levied. Under the GST framework, medicaments are broadly medicines, anything that can be used as medicine or used to manufacture medicine. Disinfectants are essentially soap or liquids used as soaps.

Pharmaceutical companies say sanitisers are medicaments, while the taxman considers them disinfectants. The indirect tax department's investigation arm, Director General of GST Intelligence (DGGI), has initiated an investigation in this regard and even sent notices to some companies.

As per a tax notice ET has seen, the DGGI has said "medicaments" consist of mixed or unmixed products for therapeutic or prophylactic use, in measured doses.

Manufacturers argue that hand sanitisers are crucial in the battle against Covid-19, therefore equivalent to medicaments, and should be taxed at 12%.

A group of Gujarat-based pharmaceutical companies had approached the Supreme Court over this matter. The Supreme Court told them to approach a high court against the tax department.

"Rate rationalisation is the effective solution to reduce classification disputes for supplies, which could arguably be covered by two headings with different rates," said Abhishek A Rastogi, partner at Khaitan & Co. "Sanitisers, an essential commodity in this environment, fit within the gamut of medicaments and must be given beneficial treatment in larger public interest." Insiders say hundreds of companies based in Gujarat and Maharashtra are under the tax lens.

Wide DGGI Investigation

These companies include those that either make sanitisers or similar products, or make raw materials for such items. Several companies had switched to making sanitisers after the pandemic began. The DGGI is also said to be looking at pharmaceutical and other companies that supply disinfectants to hospitals. These companies said they have been claiming the lower GST rate even before the pandemic struck. In most cases, these products are liquids used to sanitise hospitals, akin to hand sanitisers, according to DGGI officials, and thereby liable to be taxed higher.

Some of the companies say they are manufacturing 'hand and skin' medicaments that doctors use before an operation, paying an even lower GST of 5%. These products qualify for the 5% slab because they are categorised as 'life-saving drugs.'

Matter of Opinion

Experts say there are two views on the matter whether tax should apply on the basis of the raw materials used in a product or the latter's end use. Some companies that are exporting products treated as disinfectants, or supplying them to hospitals, argue that end use should be considered and not the raw materials. Hence, these should be taxed at the medicaments rate. The tax department, on the other hand, wants to categorise every item as a disinfectant, irrespective of end use.

The manufacturers had told the Supreme Court that sanitisers are currently treated as "insecticides," assuming the coronavirus is similar to an "insect," and that sanitisers are used to kill it. "Given that sanitisers are used as a protection from coronavirus, they should be re-categorised as medicaments," the pharmaceutical companies and manufacturers had told the Supreme Court.

Source: Sachin Dave, 25.06.2021

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"With a stake in PharmEasy, I'll be fighting Ambanis and Tatas'

About five years ago, struck by a personal tragedy, Arokiaswamy Velumani, the Coimbatore born scientist and founder of Thyrocare Technologies Ltd, decided to sell his 25 yr old diagnostics firm. Last week, he found the buyer of his choice in API holdings, parent of upstart digital healthcare platform PharmEasy.

The deal came just weeks after Thyrocare hit a market capitalization of dollar 1 billion. In an interview, Velumani spoke about why it has taken him five years to find the right price for his firm, how he will continue to have stake in the business and what he plans to do next. Edited excerpts

News of Thyrocare's sale came like a bolt from blue. Why did you decide to sell?

Life does not always turn out the way we expect it to. Losing my wife during the eve of the IPO (2016) shattered me and I wondered whether I will be able to run the firm alone. Although she was never at the front end of the business, she was backbone of it. So, for the last five years, I have been thinking of selling Thyrocare and it has taken this long since I wanted to get the best price.

In the last Five years , I have got 25 deals for the acquisition , but none of them was impressive. I was quite surprised when PharmEasy came. I asked for a 30% premium on the shares when they approached me and I got it. The deal with PharmEasy got finalised in a span of 30 days. This kind of deal is not easy to do because Thyrocare as a business is still hale and hearty. But I have never stuck to conventions and took this unconventional route.

What impressed you the most about PharmEasy?

The people who approached me in the last years before PharmEasy wanted to buy only 51% of Thyrocare. This way, they wanted to have a say in business but wanted me to work for them. This formula like *" Malai sab unko, mehnat sab hamara*" (this loosely translate as- while I did the hardwork they only wanted to have the fruit of the hardwork).

But finally, PharmEasy comes- a party that says I should not own a single share and not hold an executive role in the company. That was the clincher and it made me take the decision.

If you had found good executive to run the company, would you still have sold?Arindam Haldar quit as Thyrocare CEO seven months after the appointment that led to rumours about the succession issues?

As a promoter, I can't resist being fully involved in the company even if I have a CEO, managing director (MD) and executives around. I am the kind of person who sees at the end of the day how many customer complaints have come.

To run a business, you also need a thick skin which I could not develop. Also , I think that if the single – largest shareholder has more then 25% in a company, such companies will not be able to grow as much as companies with a pool of shareholders with 2-3% each.

There, the CEO is powerful and the MD is powerful. So, I thought the best thing would be to sell and handover the reins of the business. PharmEasy has a dozen shareholders. So, I am happy that Thyrocare was not purchased by a family but by a holding firm with plenty investors.

The statement said you will separately buy a minority non-controlling stake of less than 5%in API holdings. What role have you or the team envisioned?

My family was shocked when I told them that I want to continue to hold some stake. I think I will do what a lot of investors have been doing. Invest, sit back and if all goes well, get good returns. And by having stake in PharmEasy. I will have a feeling that I am battling out with the likes of Ambanis and Tatas (both have also invested in digital healthcare startups). If I win, I will be happy, if I lose, it is okay as I will be losing to these big conglomerates.

Do you see more instances of newage firms like PharmEasy acquiring traditional healthcare companies?

One thing I gathered during my discussions with PharmEasy is that they want to be health mall. They don't want to be an Amazon of Amazon but an Amazon of healthcare. I see them looking for acquisition of assets that complements their business. I don't know the specifics but their goal is to become the largest healthcare provider in India.

Do you also see large diagnostic companies looking for acquisitions of not just diagnostics firms but also healthtech startups?

I think covid -19 has added a lot of trust towards digital healthcare and I have a reason to believe that everybody in the healthcare space will need to equip themselves with

Arokiaswamy Velumani I Photo Credit: VCCircle

healthtech capabilities. People will wait and watch for some time but they will know that healthtech will be a big factor soon. I am quite surprised to see the buzz this deal has created. This is a marriage that had never taken place in the past. Diagnostics and medicines are complementary and when it comes to chronic illness, we have a very long journey with a patient. In my perception, everybody will try to find match and they will look for a similarly sized beast on the other side.

But there are a lot of challenges to finding the right match if you are expecting something to happen. In the long run, I believe that a dozen such marriages will run the industry of pharma and diagnostics put together. Pharma companies and diagnostics labs will be the kitchens and new – age healthtech companies will be the Swiggys and Zomatos.

Do you plan to make angel investments next?

I plan to relax and tell stories. I haven't done any angel investments so far. An entrepreneur's role is different and an investor's role is different. So far, I have been a 100% entrepreneur and now I will be a 100% investor. I will be looking for those who are creating jobs and not chasing valuations.

Have you left PharmEasy executives with some advice?

The new guys have agreed I will not be in an executive role. If they come for some advice on how to solve a puzzle, I shall help them. But I believe they are very talented and I don't expect them to follow what I say.

Source : Joseph Rai, HT Mint, 29.06.2021

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.

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