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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

(More details on Page No. 35)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 09** **01 to 07 March 2021**

NORTH CAROLINA'S BIO-PHARMA ADVANTAGE

A top-tiercluster.30,000 people working to manufacture medicines and pharmaceuticals. The most employees of any US State in biologics manufacturing.

Meet North Carolina, home to 130 company sites for biopharma manufacturing and 775 total life sciences companies. Among them are Aurobindo, Glenmark Pharmaceuticals, GSK and Novo Nordisk. Products include oral solid dose and small molecules, as well as biologics and new gene and cell therapies.

North Carolina's leading life sciences cluster grew from significant state support beginning in the 1980s. Support for university research and faculty recruitment created entrepreneurial companies. With targeted support, these companies pushed products to market. Then came interest in manufacturing in North Carolina, with its plentiful water resources, available land, and low-cost business environment.

For its growing biopharma manufacturing cluster, North Carolina built NC BioImpact, a system for training process technicians and quality workers in pharmaceutical methods and cGMP. It includes the NC State University Golden LEAF Biomanufacturing Training and Education Center. The 77,000-plus square foot facility is home to classrooms and a pilot-scale cGMP facility. BioNetwork, part of the NC Community Colleges, offers new worker, incumbent and custom training at a network of sites. The Biomanufacturing Research Institute and Technology Enterprise at NC Central University trains undergraduates and graduates in manufacturing process and drug discovery, with the North Carolina Pharmaceutical Services Network providing targeted short courses for oral solid dose production. In addition, the state's universities award 4,900 life sciences and 4,500 engineering degrees annually.

This leading cluster and job-ready talent continue to attract new companies to North Carolina. Companiesannounced 4,600 jobs in 2020, 2,800 of them in biopharma manufacturing. The list is led by Eli Lilly, which will produce diabetes products in Durham and add 460-plus jobs in the Research Triangle region, already dense with life sciences companies.

In Greenville, Thermo Fisher announced an expansion with 500 new jobs at its facility that produces sterile injectables, tablets and capsules. This facility also supports API and large molecule development. Thermo Fisher is part of the BioPharma Crescent, a group of five North Carolina counties that are home to 10,000 biopharma and support manufacturing employees. More than $3 billion has been invested in this region in the last five years.

North Carolina is also home to the original contract research organization, which is IQVIA today. Today more than 150 clinical research or contract services organizations call North Carolina home. A slate of contract manufacturers also supports product development for pharmaceutical worldwide. Nearly 2,500 support and related companies — from staffing companies to engineering firms -support the growth of this $84 billion industry.

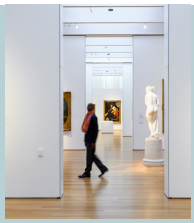
At the center of this ecosystem is the North Carolina Biotechnology Center. NCBiotech keeps the life sciences industry growing by filling gaps in the pipeline and working with individual companies to meet specific challenges. Its services include support for initial and ongoing hiring at manufacturing facilities.

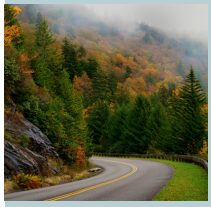
Companies looking to locate or expand in North Carolina should contact the Economic Development Partnership of North Carolina (EDPNC). The EDPNC, which works on behalf of the state of North Carolina, can answer general questions about the state's business advantages or provide specific data on potential sites, communities, and infrastructure.

The EDPNC helps companies find the best site options and assemble the support of public and private partners – including local and state government agencies, customized workforce training programs, colleges and universities, and potential supply chain partners. The EDPNC also connects growing businesses to available incentives.

Indian companies interested in North Carolina should contact Rahul Padmanabha, Director of investment for EDPNC's India office, at **rahul.padmanabha@edpnc.comor +91 914 899 1212.** For more information, visit **EDPNC.com/India**





IT'S ALMOST UNFAIR TO THE OTHER 49 STATES.

Work. Life. And everything that makes both fulfilling. You'll find open minds, open spaces and open opportunities in North Carolina. Ranked #1 for business by Forbes three years running, with the lowest corporate tax rate in the US, low costs of doing business, and cost of living almost 5% below the national average.

Here you'll find a biotechnology ecosystem that runs deep and wide, across more than 775 companies and 67,000 employees, fueled by a highly educated workforce, major research universities and significant private sector R&D investment.

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

Go to EDPNC.com/India or call

Rahul Padmanabha
Director of Investment, India Office
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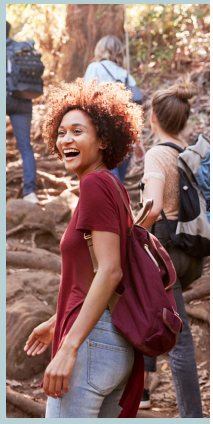



ALL IN NORTH CAROLINA

ECONOMIC DEVELOPMENT PARTNERSHIP of NORTH CAROLINA




Production Linked Incentive Scheme (PLI) for Pharmaceuticals - reg.

Gazette Notification No.31026/60/2020-Policy-DoP, dated 3rd March, 2021

1. Background:

1.1. Indian pharmaceutical industry is the 3rd largest in the world by volume and is USD 40 billion in terms of value. The country contributes 3.5% of total drugs and medicines exported globally. India exports pharmaceuticals to more than 200 countries and territories including highly regulated markets such as the USA, The UK, European Union, Canada etc. India has complete ecosystem for development and manufacturing of pharmaceuticals with companies having state of the art facilities, highly skilled/technical manpower. The country also has a number of renowned pharmaceutical educational and research institutes and a robust ecosystem of allied industries.

1.2. At present a major component of Indian exports are low value generic drugs while a large proportion of the demand for patented drugs is met through imports. This is because the Indian Pharmaceutical sector lacks in high value production along with world class pharma R&D. In order to incentivize the global and domestic players to enhance investment and production in these product categories, a well-designed and suitably targeted intervention is required to incentivise specific high value goods such as biopharmaceuticals, complex generic drugs, patented drugs or drugs nearing patent expiry, cell based or gene therapy drugs.

1.3. Further, looking to the increasing imperative of drug security, continued support to domestic production capability in APIs/KSMs would ensure higher resilience of the Indian pharmaceutical industry to external shocks. These initiatives have the potential to contribute significantly to achieving higher objective of affordable healthcare in the country and globally on a sustained basis.

2. Objective:

The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

3. Salient Features of the Scheme:

3.1. **Target Groups**: The manufacturers of pharmaceutical goods registered in India will be grouped based on their Global Manufacturing Revenue (GMR) to ensure wider applicability of the scheme across the pharmaceutical industry and at the same time meet the objectives of the scheme. The qualifying criteria for the three groups of applicants will be as follows:

(a) **Group A**: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods more than or equal to Rs. 5,000 crore.

(b) **Group B**: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods between Rs. 500 (inclusive) crore and Rs. 5,000 crore.

(c) **Group C**: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods less than Rs. 500 crore. Within this group, a sub-group for MSME industry will be made given their specific challenges and circumstances.

3.2. **Quantum of Incentive**: The total quantum of incentive (inclusive of administrative expenditure) under the scheme is about Rs. 15,000 crore. The incentive allocation among the Target Groups is as follows:

(a) Group A: Rs. 11,000 crore.

(b) Group B: Rs. 2,250 crore.

(c) Group C: Rs. 1,750 crore.

3.3. **Rate of Incentive**: The rate of incentive on incremental sales (over base year) of

pharmaceutical goods covered under Category 1 & 2 will be 10% for FY 2022-23 to FY 2025-26, 8% for 2026-27 and 6% for 2027-28.

The rate of incentive on incremental sales (over base year) of for pharmaceutical goods covered under Category-3 will be 5% for FY 2022-23 to FY 2025-26, 4% for 2026-27 and 3% for 2027-28.

3.4. **Base Year:** Financial Year 2019-20 shall be treated as the base year for computation of incremental sales of manufactured goods.

3.5. **Category of Goods:** The scheme shall cover pharmaceutical goods under three (03) categories as mentioned below:-

(I) Category 1:

1. Bio-pharmaceuticals.
2. Complex generic drugs.
3. Patented drugs or drugs nearing patent expiry.
4. Cell based or gene therapy drugs.
5. Orphan drugs.
6. Special empty capsules like HPMC, Pullulan, enteric etc.
7. Complex excipients.
8. Phyto-pharmaceuticals.
9. Other drugs as approved.

(II) Category 2:

1. Active Pharmaceutical Ingredients/Key Starting materials/Drug Intermediates

(III) Category 3: (Drugs not covered under Category 1 and Category 2)

1. Repurposed drugs.
2. Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti- infective drugs, cardiovascular drugs, psychotropic drugs and anti- retroviral drugs.
3. *In vitro* diagnostic devices.
4. Other drugs as approved.
5. Other drugs not manufactured in India.

3.6. **Selection of participants:** The applicants will be selected based on pre-defined objective criteria to assess their experience, capacity to grow in scale and innovate. The selection criteria shall be elaborated in the scheme guidelines.

3.7. **Eligibility for incentive:** The selected participants in the scheme will be eligible for incentives on incremental sales of pharmaceutical goods based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales as mentioned below:

Group of Participants	Minimum Cumulative Investmentper participant (Rs. Crore)	Minimum Percentage Growth in Sales (Year on Year)
Group A	**Rs. 1,000 crore over 5 years.** FY 2021-22: 200 FY 2022-23: 400 FY 2023-24: 600 FY 2024-25: 800 FY 2025-26: 1000	For first year of production, participants shall have to achieve Minimum threshold sales which will be specified by value for each Group in the scheme guidelines. For subsequent years, the participants have to achieve a minimum percentage growth of 7% Year on Year.
Group B	Rs. 250 crore over 5 years. FY 2021-22: 50 FY 2022-23: 100 FY 2023-24: 150 FY 2024-25: 200 FY 2025-26: 250	
Group C	Rs. 50 crore over 5 years. FY 2021-22: 10 FY 2022-23: 20 FY 2023-24: 30 FY 2024-25: 40 FY 2025-26: 50	
	For MSME participants in Group C, the threshold minimum cumulative investment shall be as committed by the participant in application form.	

3.8. **Tenure of the Scheme**: The duration of the scheme will be from FY 2020-21 to FY 2028-29. This will include the period for processing of applications (FY 2020-21), optional gestation period of one year (FY 2021-22), incentive for 6 years and FY 2028-29 for disbursal of incentive for sales of FY 2027-28.

3.9. **Incentive Outlay:** Total financial outlay of the scheme is Rs. 15,000 crore. The annual incentive outlay is estimated based on projected incremental sales of the identified pharmaceutical goods by the selected participants. The incentives will be paid for a maximum period of 6 years for each participant. Participants may avail of up to one-year gestation period from the date of approval.

3.10. **Incentive ceiling**: Incentive per participant will be subject to ceilings which will be specified in the scheme guidelines.

3.11. **Empowered Group of Secretaries (EGoS):** The Empowered Group of Secretaries (EGoS) comprising of Cabinet Secretary (Chairperson), CEO NITI Aayog (Member), Secretary DPIIT (Member Convenor), Secretary DoC (Member), Secretary DoR (Member), Secretary DEA (Member) and Secretary DoP shall undertake periodic review of the outgo under the scheme, ensure uniformity with other PLI schemes and take appropriate action to ensure that the expenditure is within the prescribed outlay.

3.12. **Technical Committee:** A Technical Committee (TC) of 5-7 members will be formed with representative from CDSCO, experts from industry and academia. The role of the TC along with the scope and manner of its functioning shall be laid down in the scheme guidelines.

3.13. **Project Management Agency:** The Scheme shall be implemented by the Department of Pharmaceuticals through a Project Management Agency (PMA) that will be responsible for providing secretarial, managerial and implementation support and carry out other responsibilities as assigned by DoP within the framework of scheme and guidelines thereof.

3.14. **Approval and Disbursement Process:**

(a) Application under the Scheme can be made by any manufacturer registered in India.

(b) An application, complete in all aspects, will have to be submitted before the due date. Acknowledgement will be issued after initial scrutiny of the application.

(c) The applicants will be appraised and considered for approval, based on predefined selection criteria.

(d) The incentives shall be released to the selected participants under the scheme who meet the annual threshold criteria of minimum cumulative investment and minimum growth in sales and if disbursement claims are found to be in order.

(e) Timely disbursal of incentives by the project Management Agency will be monitored by DoP and reviewed by the EGoS.

(f) The incentive will be disbursed on incremental sales for a maximum period of 6 years for each participant.

(g) The progress in approval of applications and disbursal of incentive shall be monitored on an ongoing basis against the monitoring framework to be specified in the Guidelines.

Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

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MoEF Notification on Pollution load - reg.

Gazette Notification No.S.O. 980(E), dated 2nd March, 2021

WHEREAS, by notification of the Government of India in the erstwhile Ministry of Environment and Forests Number S.O.1533(E), dated the 14th September, 2006 issued under sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986, read with clause (d) of the sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986 (hereinafter referred to as the EIA Notification), the Central Government directed that on and from the date of its publication, the new projects or activities or the expansion or modernisation of existing projects or activities listed in the Schedule to the EIA notification entailing capacity addition with change in process or technology and/or product mix shall be undertaken in any part of India only after obtaining prior environmental clearance from the Central Government or as the case may be, by the State Level Environment Impact Assessment Authority, duly constituted by the Central Government under sub-section (3) of section 3 of the said Act, in accordance with the procedure specified therein;

AND WHEREAS, with core principle of 'no increase in pollution load', the Central Government has amended the EIA notification by notifications number S.O. 3518(E), dated the 23rd November, 2016 and number S.O. 236(E), dated the 16thJanuary, 2020 providing flexibility in change in product-mix; change in quantities within products or number of products in the same category including resultant increase in the production with a cap of 50% for which environmental clearance has been granted; change in configuration of the plant from the environmental clearance conditions during execution of the project;

AND WHEREAS, the Ministry of Environment, Forest and Climate Change is in receipt of requests from processing, production and manufacturing sector for permitting increase in production capacity without having to go through entire environmental clearance process again as long as there is no increase in pollution load;

AND WHEREAS, based on the experience in implementation of the EIA notification as amended by aforesaid notification number S.O. 3518(E), dated the 23rd November, 2016, the Central Government deems it necessary to permit increase in production capacity in respect of processing, production and manufacturing sector with or without any change in raw material-mix or product-mix or change in quantities within products or number of products or any change in configuration of the plant or operations in areas contiguous to the existing area, for which prior environmental clearance has been granted, without the requirement of Prior Environmental Clearance provided that there is no increase in pollution load;

AND WHEREAS, for the purpose of Ethanol Blending Programme with Petrol, a special dispensation was provided for expansion of sugar manufacturing or distillery units, intended for production of Ethanol vide notification number S.O. 345(E), dated the 17th January, 2019 and notification number S.O. 750(E), dated the 17th February, 2020. In view of the Government's commitment to achieve 20% blending of ethanol in petrol by the year 2025, it has been decided to continue further with this dispensation;

Now, therefore, in exercise of powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government, hereby makes following further amendments in the notification of the Government of India, in the erstwhile Ministry of Environment and Forests, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 1533(E), dated the 14th September, 2006, namely:-

In the said notification,:

1. in paragraph 2, for clauses (ii) and (iii), the following clause shall be substituted, namely:-

   "(ii) Expansion, modernisation or any change in the product mix or raw material mix in existing projects or activities, listed in the Schedule to this notification, resulting in capacity beyond the threshold limits specified for the concerned sector in the said Schedule, subject to conditions and procedure provided in the sub-paragraph (ii) of paragraph 7";

2. in paragraph 7,:

   A. in the heading, the words "*for New Projects*" shall be omitted;

   B. in the sub-paragraph (i), the words "***For new***

projects or activities listed in the Schedule to this notification:" shall be inserted as heading to the sub-paragraph;

C. in the sub-paragraph (ii),-

(I) in the clause (a), after the words "*application shall be appraised accordingly for grant of environmental clearance*", the following words shall be inserted, namely:-

"*in respect of projects or activities other than falling in clause (b) and (c)*";

(II) for clauses (b) and (c), the following clauses shall be substituted, namely:-

(b) ***Existing projects (having Prior Environmental Clearance) with no increase in pollution load:*** *Any increase in production capacity in respect of processing or production or manufacturing sectors (listed against item numbers 2, 3, 4 and 5 in the Schedule to this notification) with or without any change in (i) raw material-mix or (ii) product-mix or (ii) quantities within products or (ii) number of products including new products falling in the same category or (iv) configuration of the plant or process or operations in existing area or in areas contiguous to the existing area (for which prior environmental clearance has been granted) shall be exempt from the requirement of Prior Environmental Clearance provided that there is no increase in pollution load (derived on the basis of such Prior Environmental Clearance):*

Provided that such exemption shall be applicable only consequent to:

A. the project proponent furnishing information regarding such changes along with no increase in pollution load certificate, from the environmental auditor or reputed institutions empanelled by the State Pollution Control Board or Union Territory Pollution Control Committee or Central Pollution Control Board or Ministry of Environment, Forest and Climate Change, as per the procedure laid down in Appendix-XIII, on PARIVESH portal as well as to the concerned State Pollution Control Board or Union Territory Pollution Control Committee.

Note: If on verification, the State Pollution Control Board or Union Territory Pollution Control Committee, as the case may be, after giving the project proponent the opportunity of being heard, holds that such change or expansion or modernisation results in increase in pollution load, the exemption claimed under this clause shall not be valid and it shall be deemed that the project proponent was always liable to obtain prior environmental clearance, in respect of such change or expansion or modernisation, as per the clause (a) and the provisions of Environment (Protection) Act, 1986 shall apply accordingly;

B. installation and implementation of Online Continuous Monitoring System (OCMS) with at least 95% uptime, connected to the servers of the Central Pollution Control Board and State Pollution Control Board or Union Territory Pollution Control Committee concerned to report the quantity and quality, of emission and discharges:

Provided further that the provisions of this clause shall not be applicable if such change or increase results in change in category of project or activity from Category-'B2' to either Category-'A' or Category 'B1'.

(c) Any change in configuration of the plant or activity from the environmental clearance conditions during execution of the project after detailed engineering, in respect of projects or activities, falling in any item of the Schedule to this notification, shall not require prior environmental clearance, if there is no change in production capacity and there is no increase in pollution load subject to furnishing particulars of such changes on PARIVESH portal in the format as may be provided by the Government from time to time, before implementing such changes whereupon a system generated acknowledgement will be issued by the concerned Regulatory Authority.

Explanation:- *For the purpose of this sub-paragraph, "Pollution load" shall be determined on the basis of multiplication of quantity and concentration of different components and parameters (as provided or referred in the Prior Environment Clearance or the Environment Impact Assessment Report (EIA) and Environment Management Plan based on which such Prior Environment Clearance has been granted), in respect of emissions, effluents or discharge, solid, industrial hazardous waste and such other parameters notified under the Environment (Protection) Rules, 1986 as amended from time to time.*'

3. in the Schedule, against item 5(g), after the entry in column (5), the following entry shall be inserted, namely:-

"***Note:*** *Expansion of sugar manufacturing units or distilleries, having Prior Environment Clearance and for production of ethanol, to be used as fuel for blending only as certified by the competent authority, shall be appraised as Category 'B2' projects.*";

4. for Appendix-XIII, the following Appendix shall be substituted, namely:-

"Appendix-XIII

Verification of No Increase in Pollution Load

The instant amendment in EIA Notification exempts the requirement of Prior Environmental Clearance for any increase in production capacity in respect of processing or production or manufacturing sectors (listed against item numbers 2, 3, 4 and 5 in the Schedule to this notification) with or without any change in (i) raw material-mix or (ii) product-mix or (ii) quantities within products or (ii) number of products including new products falling in the same category or (iv) configuration of the plant or process or operations in existing area or in areas contiguous to the existing area specified in the environmental clearance of the project. This facility is available to those units which have obtained prior environmental clearance under EIA Notification, 1994 and EIA Notification, 2006. To claim exemption from obtaining Prior Environment Clearance in respect of such cases, the project proponent shall follow the following process:-

1. *The project proponent is required to obtain a certificate of 'no increase in the pollution load' from the environmental auditors or reputed institutions, to be empanelled by the State Pollution Control Board or Central Pollution Control Board or Ministry of Environment, Forest and Climate Change (hereinafter referred to as the Ministry).*
2. *A copy of 'no increase in pollution load' certificate and intimation, as provided by the Ministry from time to time on PARIVESH portal, shall be uploaded by the unit for which system generated acknowledgement shall be issued online;*
3. *The unit shall inform the State Pollution Control Board or Union Territory Pollution Control Committee, as the case may be, in specified format along with:*
   - *i. 'no increase in pollution load' certificate from the Environmental Auditor or reputed institutions empanelled by the State Pollution Control Board or Pollution Control Committee or Central Pollution Control Board or Ministry;*
   - *ii. last Consent to Operate certificate for the project or activity; and*
   - *iii. online system generated acknowledgement of uploading of intimation and 'no increase in pollution load' certificate on PARIVESH Portal;*
4. *The information so received shall be examined by the State Pollution Control Board or Union Territory Pollution Control Committee, as the case may be, who shall take decision on such information, received from the project proponent.*
5. *If on verification the State Pollution Control Board or Union Territory Pollution Control Committee, as the case may be, holds that the change or expansion or modernisation will result or has resulted in increase in pollution load, the exemption claimed under this clause shall not be valid and it shall be deemed that the project proponent was liable to obtain Prior Environmental Clearance before under taking such changes or increase, as per the clause (a) of sub-paragraph* (ii) of paragraph 7 of this notification and the provisions of Environment (Protection) Act, 1986 shall apply accordingly.

Note: *For removal of doubts, it is clarified that it shall be the responsibility of the project proponent to satisfy itself about 'no increase in pollution load' as a result of changes, expansion or modernisation, as the case may be, before under taking such changes or increase, and the project proponent shall be liable for action under the provisions of the Environment (Protection) Act, 1986 if on verification of facts or claim it is found that such change or expansion or modernisation involves increase in pollution load".*

F. No. 22-33/2019-IA.III

Geeta Menon, Joint Secretary, Ministry of Environment, Forest and Climate Change Notification, New Delhi.

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 1533 (E), dated the 14th September, 2006 and was last amended vide the Notification Number S.O.221(E), dated the 18th January, 2021.*

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Clarification on Alternative Methods in the Indian Pharmacopoeia - reg.

Gazette Notification Ref.F.No.T.11013/02/2018-AR&D, dated 26th February 2021

To,

1. *The Drugs Controller General (India);*
2. *CDSCO Zonal Offices;*
3. *All State Drug Controllers;*
4. *Members of the Scientific Body of IPC;*
5. *Members of Sub-Committees of the Scientific Body of IPC;*
6. *Directors of Drugs Testing Laboratories;*
7. *Government Analysts;*
8. *IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations.*

Indian Pharmacopoeia Commission (IPC) has been receiving many enquiries on the subject of use of alternative methods instead of official methods included in the Indian Pharmacopoeia (IP). General Notices of IP (Volume I, Page 12) have the provision to use alternative methods and the same is reproduced below:

1. **Alternative Methods.** The tests and assays described are the official methods upon which the standards of the Pharmacopoeia are based. Alternative methods of analysis may be used for control purposes, provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used. Automated procedures utilising the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorise manufacturer of substance or product.

2. For removal of doubts, it is clarified that the authority competent to authorise manufacturer of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license and approval.

3. All concerned are requested to bring the above clarification to the notice of all authorities under their control.

Dr Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad.

Registration on IPDMS & Filing of Returns/FORMs - reg.

NPPA Circular Ref.D.O.No.19(175)/2020/DP/NPPA/Div-II(Vol-V)/Part file, dated 1st March 2021

To
The President/Chairman/Secretary General,
*All Pharma/Medical Devices Industry Association (*As per list).*

To build a 'Reliable Price Database of Medicines', NPPA has an online Integrated Pharmaceutical Database Management System (IPDMS) to provide a platform to the Pharmaceutical Manufacturers/Marketing Companies/ Importers to file online mandatory returns prescribed in FORM II, FORM III and FORM V prescribed under DPCO, 2013. These Forms are to be filed by the Manufacturers/ Marketing companies on Quarterly/Annual basis/or as and when required for submission of data regarding the formulation manufactured/marketed by them.

*However, it is observed that very few manufacturing/ marketing companies/importers are filing the said forms in IPDMS. This is matter of concern as data facilitates evidence based decision making and information so gathered can help in regulatory processes. This also promotes 'ease of doing business' as IPDMS is an online platform and requires only one time registration by the companies on the IPDMS. There is also a help desk with e-mail id: **nppa@nic.in** and **monitoring-nppa@gov.in** along with phone numbers 011-23360265 and 011-23345177 to resolve any technical and operational issues related to IPDMS.*

We understand that your Association has a large number of members and we would like to use this platform for encouraging the member companies to start using the IPDMS in right earnest. Hence, you are requested to issue an advisory to member companies to register on IPDMS and file mandatory Returns/FORMS. It would be of great help if information regarding member companies registered and regularly filing Returns/FORMS out of total members of your Association can be made available to this office too.

Dr Vinod Kotwal, Member Secretary, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

(*Not reproduced here)

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Branding of Indian Products

Lok Sabha Unstarred Question No: 329

Shri Shivkumar Chanabasappa Udasi:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether the Government has reviewed the branding strategy for export-oriented Indian products and services;

(b): if so, the details and the modes of branding campaign that have been identified and given an opportunity;

(c): whether any roadmap has been drawn by the Government for participation in International Trade Fairs, Expos and Seminars for the next three years; and

(d): if so, the expected target of earnings from taking part in these events?

Answered on 3rd February 2021

A. (a) to (d): The India Brand Equity Foundation (IBEF), established by the Department of Commerce, supports efforts to promote and create awareness in international markets about Indian products and services, through branding related inputs and efforts. IBEF has been working closely with different Departments, Export Promotion Councils, commodity boards and Industry Associations in support of various sectoral branding efforts, including as part of promotional events.

Some of these initiatives include a branding campaign to promote products with Geographical Indicators of India, with a special focus on handicraft, handlooms and agri-based GI Products, and design of an e-brochure showcasing state-wise GI Products. A campaign to promote Indian Handmade Carpets across International markets, which has led to significant interest in the Indian Carpet Expo 20-21, was undertaken.

Branding support is also provided to implementation of annual plans, based on proposals submitted by the Export Promotion Councils/Trade Promotion Organizations, related to participation of exporters in various international fairs and expos supported under the Market Access Initiative (MAI) Scheme.

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

FDI

Lok Sabha Unstarred Question No: 345

Shri Ajay (Teni) Misra:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether the Government is taking concrete steps/ contemplating to increase Foreign Direct Investment (FDI) in the country;

(b): if so, the State-wise details thereof;

(c): whether there is a need to further liberalise the existing FDI policy to increase the potential of FDI in the country; and

(d): if so, the details thereof?

Answered on 3rd March 2021

A. (a) & (b): To promote Foreign Direct Investment (FDI), the Government has put in place an investor-friendly and enabling policy, wherein many sectors are open for 100% FDI under the Automatic route. The intent is to make the FDI climate more investor friendly and remove the policy bottlenecks that have been hindering investment inflows into the country. FDI policy reforms carried out by Government have resulted in increased FDI inflows. The country registered its highest ever FDI Inflow of US $74.39 billion (provisional figure) during the last Financial Year 2019-20

(c) & (d): The policy on FDI is reviewed on an ongoing basis, to ensure that India remains an attractive and investor friendly destination. Changes are made in the policy after rounds of intensive consultations with all stakeholders including apex industry chambers, associations, representatives of industries/groups and other organizations and taking into consideration their views/comments and suggestions.

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

Regional Comprehensive Economic Partnership

Lok Sabha Unstarred Question No: 457

Shri Sisir Kumar Adhikari:

Dr Amar Singh:

Shri Vincent H Pala:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether the Government has estimated the potential impact of rejecting the Regional Comprehensive Economic Partnership (RCEP) on Indian economy and GDP;

(b): if so, the details thereof and if not, the reasons therefor;

(c): whether India's rejection of RCEP will strengthen the Chinese economy by not providing a regional counter balance; and

(d): if so, the reaction of the Government thereon?

Answered on 3rd February 2021

A. (a) to (d): The Government held extensive consultations with the stakeholders such as the domestic industry, exporters, Export Promotion Councils, trade experts, various Ministries/ Departments, academicians etc and received inputs, which were taken into consideration while formulating India's position in the Regional Comprehensive Economic Partnership (RCEP) negotiations. Accordingly, during the 3rd RCEP Leaders' Summit held on 4 November, 2019 in Bangkok, India made it clear that the current structure of RCEP did not reflect the RCEP Guiding Principles or address the outstanding issues and concerns of India, in the light of which India did not join consensus. India's position in RCEP was formulated to achieve equitable outcomes, balanced ambitions and addressing domestic sensitivities of its stakeholders including small entrepreneurs. Further, India had also expressed its stated position that the Act East Policy was the bedrock of India's economic policy and India's engagement with ASEAN countries and other trading partners would continue.

The Minister of State in the Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

In Rajya Sabha

FDI Equity Inflow

Rajya Sabha Unstarred Question No. 539

Shri B Lingaiah Yadav:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether Foreign Direct Investment (FDI) equity inflows into India registered growth in the last few years;

(b): if so, the details thereof in the last three years and the current year, sector-wise; and

(c): if not, the reasons therefor?

Answered on 5th February 2021

A. (a) During the last three years, the Foreign Direct Investment (FDI) equity inflow increased from US$ 44,857 million in 2017-18 to US$ 49,977 million in 2019-20, registering a growth of 11%.

(b) & (c): Sector wise details of FDI equity inflow reported in the last three years and the current year are at Annexure-I. (***Not reproduced here).***

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

Efforts to Increase Exports

Rajya Sabha Unstarred Question No. 540

Shri Narayan Rane:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state;

(a): whether it is a fact that the exports of the country are lesser than the imports, thereby adversely impacting foreign exchange reserve of the country;

(b): if so, the response of Government in this regard; and

(c): the efforts being made by Government at the central level to make exports of the country greater than the imports?

Answered on 5th February 2021

A. (a) & (b): During April-November, 2020-21, India's overall (Merchandise and Services) exports were US$ 304.53 billion, higher than overall imports of

US$ 293.56 billion, resulting in a trade surplus of US$ 10.97 billion.

(c) **:** The following are some of the key steps taken by Government to increase exports:

1. Foreign Trade Policy (2015-20) extended by one year i.e. upto 31-03-2021 due to the COVID-19 pandemic situation.
2. Interest Equalization Scheme on pre and post shipment rupee export credit has also been extended by one year i.e. upto 31.03.2021.
3. A new Scheme, Remission of Duties and Taxes on Exported Products (RoDTEP), has been launched with effect from 01.01.2021.
4. Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase FTA utilization by exporters.
5. Comprehensive "Agriculture Export Policy" to provide an impetus to agricultural exports related to agriculture, horticulture, animal husbandry, fisheries and food processing sectors, is under implementation.
6. Promoting and diversifying services exports by pursuing specific action plans for the 12 Champion Services Sectors.
7. Promoting districts as export hubs by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/manufacturers to generate employment in the district.
8. Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.
9. Package announced in light of the COVID pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

The Minister of State in The Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

Impact of European Union's splitting Trade Agreement with China

Rajya Sabha Unstarred Question No. 543

Shri V Vijayasai Reddy:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state;

(a): the manner in which India looks at European Union (EU) splitting trading agreement with China and signing only trade and investment agreement, and leaving aside investment protection part;

(b): whether it means that if there is a dispute between Chinese investment in EU, weightage be given to domestic laws rather than international arbitration process; and

(c): if so, whether the Ministry sees advantage in this for India while negotiating with EU, UK or US?

Answered on 5th February 2021

A. (a) and (b): EU and China have an in-principle agreement on EU-China Comprehensive Agreement on Investment (CAI).

The text of CAI available on the website of EU as on 01.02.2021 is not a final text and hence the commitments and the manner of dispute settlement be determined at this stage.

(c): Does not arise; since the final text is not available as of now, the advantages cannot be determined.

The Minister of State in The Ministry of Commerce and Industry (Shri Hardeep Singh Puri)

Industrial Parks and Industries in the Country

Rajya Sabha Unstarred Question No. 550

Dr C M Ramesh:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): the number of Industrial Parks and Industries that have been established and functional in different States of the country during the last three years, the State-wise details thereof; and

(b): whether Government proposes to set up more such Parks and Industries in different States in the near future, the details thereof and the funds allocated for the purpose?

Answered on 5th February 2021

A. (a): Industrial Park Scheme-2002, applicable for any undertaking which develops and operates, or, maintains and operates, an Industrial Park for the period beginning 1st day of April, 1997 and ending 31st day of March, 2006, was notified by the Department for Promotion of Industry and Internal Trade on 1st April, 2002.

Data on Industrial Parks that have been established and functional in different States of the country during the last three years is not centrally maintained. However, Department for Promotion of Industry and Internal Trade has built one centralized system of industrial park information which is available at Industrial Information System (IIS) and the details are being updated by the concerned States at regular intervals. A list of States/UT-wise number of Industrial Parks/Estates/Clusters/Nodes entered on Industrial Information System (IIS) is at Annexure*. Industrial park information is also available in the link 'Industrial Information System" on the website of DPIIT **(dipp.gov.in)**

During the last three years, Department for Promotion of Industry & Internal Trade has accorded final approval for setting up of one National Investment & Manufacturing Zone (NIMZ) namely Hyderabad Pharma City NIMZ in Rangareddy District of Telangana.

(b): Setting up of Industrial Park and Industries in different States comes under the purview of the concerned State Government itself. However, Central Government provides support to the States through its scheme/programmes, once the proposal to develop the parks/clusters/industries in a particular region is received from the concerned State Government.

The Minister of State in The Ministry of Commerce & Industry (Shri Som Parkash)

(*Not reproduced here)

Single Window Approval System for Industries

Rajya Sabha Unstarred Question No. 553

Shri T G Venkatesh:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether it is a fact that Government has taken a decision to give all approvals and clearances to the Industries at one go by introducing single window approval system; and

(b): if so, the details thereof?

Answered on 5th February 2021

A. (a) & (b): The Central Government is working on setting up a Single Window System for clearances and approvals of industry in the country. Despite the presence of several IT platforms for investing in India such as in departments of the Government of India and State Single Window Clearances, investors need to visit multiple platforms to gather information and obtain clearances from different stakeholders. To address this, the creation of a centralized Investment Clearance Cell which would provide end-to-end facilitation support, including pre-investment advisory, information related to land banks and facilitating clearances at Central and State level was proposed and the same is also a Budget Announcement 2020-21.

The cell is being planned as a One-stop digital platform to obtain all requisite central and state clearances/approvals required to start business operations in India. The Investment Clearance Cell will be a National portal that integrates the existing clearance systems of the various Ministries/Departments of Government of India and of State Governments without disruption to the existing IT portals of Ministries and will have a single, unified application form. This will eliminate the need for investors to visit multiple platforms/ offices to gather information and obtain clearances from different stakeholders and provide time-bound approvals and real time status update to investors.

The Minister of State in The Ministry of Commerce & Industry (Shri Som Parkash)

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Online Module for Adjudication, Appeal, Review proceedings under FT (D&R) Act, 1992, ('the Act') as amended and FT(R) Rules, 1993, ('the Rules') as amended - reg.

DGFT Trade Notice No.44/2015-2020, dated 1st March 2021

To
Members of Trade and Industry;
All Regional Authorities (RAs) of DGFT/Development Commissioners of SEZs;
All Export Promotion Councils/Chambers of Commerce Foreign Trade Division of Department of Commerce;
All concerned Government Agencies etc.

1. An online module for Adjudication, Appeal, Review proceedings under Foreign Trade (Development & Regulation) Act, 1992, ('the Act') as amended and Foreign Trade (Regulation) Rules, 1993, ('the Rules') as amended has been implemented with effect from 27th February 2021.

Adjudication:

2. The Exporters have to submit prescribed documents evidencing fulfilment of export obligation within the period prescribed indicated in the Authorization/ Foreign Trade Policy/ Procedure. In case of non-submission or incomplete submission of prescribed documents, the Exporter shall be directed to furnish the complete prescribed documents within the period indicated in the letter issued by Regional Authority. In case of non-submission of complete prescribed export documents the Exporter will be issued Show Cause Notice for violations of provisions under 'the Act' as amended and 'the Rules', as amended. Notices for Personal Hearing (PHI) will be issued online to the Noticees to submit their case in the PH or through written submissions which will also be in the online module. PH will be conducted through Video conferencing (VC) or through physical hearings at the time and place indicated in the notice for PH at the discretion of the Adjudicating Authority. Exporters shall submit documents online on DGFT website: dgft.gov.in > login with valid credentials > Services > Enforcement cum Adjudication proceedings. All the correspondences to Exporters will be sent through emails. Therefore, the exporters will keep their details viz. addresses, email IDs, etc. updated on DGFT website. Non receipt of emails etc due to non updatation of details shall be the liability of the Noticee (Exporter).

3. In case of non-submission of prescribed export documents evidencing fulfilment of export obligation, Adjudication Order (Order-in-Original) may be passed for payment of duty and interest thereon, and even enforcing penalty after fulfilling due process. The order will be served online. On receipt of Adjudication Order, the Exporters are required to deposit the penalty amount, Customs duty and interest thereon.

4. Adjudication proceedings for any other violations of DGFT's schemes, Foreign Trade Policy Procedures, any orders issued under 'the Act', and 'the Rules' shall also be initiated and conducted online.

Appeal:

5. The Exporter shall have the facility to file an appeal under Section 15 of the Act against the Adjudication Order within the stipulated period alongwith the proof of having deposited the penalty amount. No appeal can be submitted after the stipulated period and the online system shall automatically block the process of appeal once the time limit expires. The Exporters shall have to submit the appeal online on the DGFT website: dgft.gov.in > login with valid credentials > Services > Enforcement cum Adjudication proceedings. Appellate proceedings will be conducted online viz. service of notice, reply to notice, notices for Personal Hearing (PH), passing of Appellate Order, its service, etc as in the case of Adjudication proceedings. PH will be conducted through Video conferencing (VC) or through physical hearings at the time and place indicated in the notice for PH at the discretion of the Appellate Authority.

5.1 There will be a transition period upto 31st March, 2021 wherein the firm/Appellants wishing to file an Appeal under Section 15 shall be allowed to file Appeals either online or manually. However, subsequent to the filing by the appellant in the manual mode, during the transition period, to the jurisdictional Appellate authority, consequent processing of the case shall be only through the online module.

Review:

6. The Review Proceedings provided in Section 16 of 'the Act' will also be conducted online. The Exporters shall submit Review Petition online. Review proceedings will be conducted online viz service of notice, reply to notice, seeking comments from Adjudication Authority, notices for Personal Hearing (PH), passing of Review Order (Order-in-Review), its service, etc. as in the case of Appeal proceedings. PH will be conducted through Video conferencing (VC) or through physical hearings at the time and place indicated in the notice for PH at the discretion of the Reviewing Authority

7. The online help materials /FAQs are available at dgft.gov.in> Learn > Application Help &FAQs > ECA-Adjudication.

This issues with approval of the DGFT.

File No.18/29/2020-21/ECAI

Dilip Kumar, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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I, **Dr Gopakumar Gopalan Nair, Ph.D., LL.B** hereby declare that the particulars given above are true to the best of my knowledge and belief.

Sd/-
Dr Gopakumar Gopalan Nair
Editor

Date: 07.03.2021

Nanoparticle-delivered COVID-19 vaccine candidate shows promise in preclinical studies

Researchers from Cleveland Clinic's Global Center for Pathogen Research & Human Health have developed a promising new COVID-19 vaccine candidate that utilizes nanotechnology and has shown strong efficacy in preclinical disease models.

According to new findings published in mBio, the vaccine produced potent neutralizing antibodies among preclinical models and also prevented infection and disease symptoms in the face of exposure to SARS-CoV-2 (the virus that causes COVID-19). An additional reason for the vaccine candidate's early appeal is that it may be thermostable, which would make it easier to transport and store than currently authorized COVID-19 vaccines.

"Our vaccine candidate delivers antigens to trigger an immune response via nanoparticles engineered from ferritin--a protein found in almost all living organisms," said Jae Jung, Ph.D., Director of the Global Center for Human Health & Pathogen Research and co-senior author on the study. "This protein is an attractive biomaterial for vaccine and drug delivery for many reasons, including that it does not require strict temperature control."

Added Dokyun (Leo) Kim, a Graduate Student in Dr Jung's lab and co-first author on the study, "This would dramatically ease shipping and storage constraints, which are challenges we're currently experiencing in national distribution efforts. It would also be beneficial for distribution to developing countries." Other benefits of the protein nanoparticles include minimizing cellular damage and providing stronger immunity at lower doses than traditional protein subunit vaccines against other viruses, like influenza.

The team's vaccine uses the ferritin nanoparticles to deliver tiny, weakened fragments from the region of the SARS-CoV-2 spike protein that selectively binds to the human entry point for the virus (this fragment is called the receptor-binding domain, or RBD). When the SARS-CoV-2 RBD binds with the human protein called ACE2 (angiotensin-converting enzyme-2), the virus can enter host cells and begin to replicate.

The researchers tested their vaccine candidate on a ferret model of COVID-19, which reflects the human immune response and disease development better than other preclinical models. Dr Jung, a foremost authority in virology and virus-induced cancers, previously developed the world's first COVID-19 ferret model--a discovery that has significantly advanced research into SARS-CoV-2 infection and transmission.

In this study, the researchers administered an initial dose of the vaccine candidate followed by two booster vaccines given 14 and 28 days later. One group received the vaccines intramuscularly, while another group received them both intramuscularly and intranasally. After the second booster, all vaccinated models produced strong neutralizing antibodies. This suggests that repeated exposure to the RBD antigen successfully prepared the immune systems to rapidly fight the virus.

A few days after the second booster (31 days after the initial vaccine dose), the researchers exposed the models to high concentrations of SARS-CoV-2. Compared to the placebo group that received adjuvant-only vaccines (adjuvants are added ingredients that help vaccines work better), those that received the RBD-nanoparticle vaccine were better protected from clinical symptoms and lung damage associated with infection. The findings suggest the vaccine candidate helped prevent infection and serious disease.

Combination intramuscular and intranasal immunization showed more potent protective immunity and faster viral clearance than intramuscular immunization alone. Both were significantly more effective than the adjuvant-only vaccine. More research will be important to uncover the mechanisms behind these differential benefits. While ferritin nanoparticles are well-characterized for their strong temperature and chemical stability, suggesting the RBD-nanoparticle vaccine may also be thermostable, future investigations will be necessary to validate. The researchers aim to confirm these findings in human Clinical Trials soon.

(*This study was a close collaboration between Dr Jung and researchers from Chungbuk National University in South Korea--including co-senior author Young Ki Choi, Ph.D., and co-first author Young-Il Kim, Ph.D--and was supported in part by the National Institutes of Health. AAAS and EurekAlert! are not responsible for the accuracy of news releases posted to EurekAlert! by contributing institutions or for the use of any information through the EurekAlert system).*

Source: New Cleveland Clinic-led research published in mBio, EurekAlert, 02.03.2021

Assessing a compound's activity, not just its structure, could accelerate drug discovery

Assessing a drug compound by its activity, not simply its structure, is a new approach that could speed the search for COVID-19 therapies and reveal more potential therapies for other diseases.

This action-based focus - called Biological Activity-Based Modeling (BABM) - forms the core of a new approach developed by National Center for Advancing Translational Sciences (NCATS) researchers and others. NCATS is part of the National Institutes of Health (NIH). Researchers used BABM to look for potential anti-SARS-CoV-2 agents whose actions, not their structures, are similar to those of compounds already shown to be effective.

NCATS scientists Ruili Huang, Ph.D., and Wei Zheng, Ph.D., led the research team that created the approach. Their findings were posted online February 23 by the journal *Nature Biotechnology.* "With this new method, you can find completely new chemical structures based on activity profiles and then develop completely new drugs," Huang explained. Thus, using information about a compound's biological activity may expand the pool of promising treatments for a wide range of diseases and conditions.

When researchers seek new compounds or look for existing drugs to repurpose against new diseases, they are increasingly using screening tools to predict which drugs might be good candidates. Virtual screening, or VS, allows scientists to use advanced computer analyses to find potentially effective candidates from among millions of compounds in collections. Traditional VS techniques look for compounds with structures similar to those known to be effective against a particular target on a pathogen or cell, for example. Those structural similarities are then assumed to deliver similar biological activities.

With BABM, however, researchers don't need to know a compound's chemical structure, according to Huang. Instead, they use a profile of a compound's activity patterns - how it behaves at multiple concentrations against a panel of targets or tests - to predict its potential effectiveness against a new target or in a new drug assay. The now-widespread use of quantitative high-throughput screening (qHTS) allows BABM more accuracy in its predictions. qHTS assesses a compound's effectiveness at multiple concentrations in thousands of tests over time. That practice provides far more detail about how a compound behaves than does traditional high-throughput screening, which tests only a single concentration of the compound. The information generated by qHTS creates a stronger biological activity profile - also known as a signature - for each one of millions of compounds.

To test the BABM approach, the researchers tapped the vast pool of data generated by hundreds of qHTS analyses run on NCATS' in-house collection of more than 500,000 compounds and drugs. First, they verified BABM's ability to use activity profiles to identify compounds already shown to be effective against the Zika and Ebola viruses. BABM also identified new compounds that showed promise against those viruses. The scientists then turned to SARS-CoV-2, the virus that causes COVID-19. They applied BABM, a structure-based model and a combined approach to analyze the NCATS library's compounds to find potential anti-SARS-CoV-2 agents. BABM predicted that the activity profiles of 311 compounds might indicate promise against the Coronavirus.

The researchers then had an outside laboratory test those 311 compounds against the live SARS-CoV-2 virus. The result: Nearly one-third of the BABM-backed compounds (99) showed antivirus activity in the test. The BABM-driven prediction hit rate topped that of the structure-based model - and combining the activity-based and structure-based models yielded even better predictive results.

A key advantage to BABM is speed. "This method is very fast - you essentially just run a computer algorithm, and you can identify many new drug leads, even with new chemical structures," Huang noted. In fact, screening the entire NCATS library of half a million compounds for anti-SARS-CoV-2 candidates took only a few minutes.

BABM also is a transferable tool - it's not limited to use in the NCATS compound libraries. "Anyone can use this method by applying any biological activity profile data, including publicly available NCATS data," Huang emphasized. The NCATS researchers predict their activity-based model's impact could extend far beyond the search for COVID-19 treatments and small-molecule drug discovery. Given any substance with an available activity profile, scientists can predict its activity against a new target, for a new indication, or against a new disease.

"In addition to small molecules, this approach can be applied to biologics, antibodies, and other therapies," Huang said. "BABM is for all drug discovery projects."

Source: NIH/National Center for Advancing Translational Sciences (NCATS), Science Daily, 03.03.2021

Arthritis drugs may reduce mortality and time in ICU for sickest COVID patients

Treating critically ill COVID-19 patients with drugs typically used for rheumatoid arthritis may significantly improve survival, a landmark study has found.

The findings, which were announced in January and have now been peer-reviewed and published in the New England Journal of Medicine, come from the REMAP-CAP trial, which evaluates the effect of treatments on a combination of survival and length of time patients need support in an Intensive Care Unit (ICU).

Initial findings reported in November showed that tocilizumab, a drug used to treat arthritis, was likely to improve outcomes among critically ill COVID-19 patients. But the impact on patient survival and length of time on organ support in ICU was not clear at that time.

The full, peer-reviewed analysis shows that tocilizumab and a second drug called sarilumab - both types of immune modulators called IL-6 receptor antagonists - have a significant impact on patient survival, reducing mortality by 8.5%. Furthermore, the treatment also improved recovery so that on average patients were able to be discharged from the Intensive Care Unit (ICU) about a week earlier.

"We are delighted that our full results are now published after peer review. This confirms the robustness of our findings, that tocilizumab and sarilumab can reduce deaths by nearly a quarter, in the sickest patients with COVID," said Professor Anthony Gordon, Chair in Anaesthesia and Critical Care at Imperial College London and a Consultant in Intensive Care Medicine at Imperial College Healthcare NHS Trust.

"We also saw that it helped speed up recovery, so that on average patients were discharged from ICU a week earlier and leave hospital two weeks earlier.

It is great news to know that several thousand patients have already benefited from these drugs being used within the NHS. Other studies have now confirmed our results and so even more patients will continue to benefit.

"We are hugely grateful to all the NHS staff who helped make the trial happen and to all patients and their families who agreed to take part in this trial. Together we are all helping to tackle this dreadful disease."

Tocilizumab and sarilumab are immunosuppressive drugs used to treat rheumatoid arthritis. They were two of several immune modulation treatments included in the REMAP-CAP trial.

At the end of last year, positive early findings on tocilizumab were released before the full data had been collected. With the full analysis now available, researchers are confident the findings will continue to bring clinical benefit for the sickest patients with COVID-19.

Full findings:

At the time of full analysis 353 patients had been assigned to tocilizumab, 48 to sarilumab and 402 to control. The majority of patients were also treated with corticosteroids and were receiving respiratory support. The trial data yielded an odds ratio of 1.64 for a better outcome with tocilizumab, and 1.76 for sarilumab, compared to no immune modulation, with a high degree of statistical certainty (>99.5% probability that both treatments are superior to no immune modulation).

Hospital mortality was 27.3% among patients receiving IL-6 receptor agonists (28.0% for tocilizumab, 22.2% for sarilumab) compared with 35.8% for control group. This means for every 12 patients treated, one life would be saved.

Professor Gordon added: "Previous trials using IL-6 receptor agonists have showed no clear benefit on either disease progression or survival in COVID-19 patients, but those studies included less severely ill patients and started treatment at different stages in the disease course.

"A crucial difference may be that in our study, critically ill patients were enrolled within 24 hours of starting organ support. This highlights a potential early window for treatment where the sickest patients may gain the most benefit from immune modulation treatment."

Study co-author Christopher Seymour, M.D., Associate Professor of critical care medicine and emergency medicine at the University of Pittsburgh School of Medicine (UPMC), said: "As soon as the immune modulator results hit our statistical trigger, these drugs were immediately incorporated at UPMC and other North American REMAP-CAP partners as our standard treatment for patients critically ill with COVID-19.

"In addition, the overall design of REMAP-CAP allows us to test multiple interventions concurrently and over time. So, while we implement new evidence-based care practices, we continue to test other promising therapies in patients with both moderate and severe COVID-19."

REMAP-CAP study is led by Imperial College London and the Intensive Care National Audit & Research Centre (ICNARC) in the UK and University Medical Center Utrecht in Europe. It began investigating treatments for COVID-19 in March 2020, enrolling hospitalised patients with either moderate or severe (requiring ICU care) COVID-19 disease.

The study design randomises patients to multiple combinations of treatments, enabling researchers to evaluate different treatments for COVID-19, including antivirals, drugs which modulate the immune response, and therapies that modulate or support other vital aspects of the body's response to the virus.

To date, over 5,500 patients in 15 countries have been enrolled at more than 290 hospitals worldwide and randomised to multiple treatment combinations. The effects of interventions are assessed separately for moderate and severely ill patients. The latest findings on tocilizumab and sarilumab add to REMAP-CAP findings from earlier this year, which found that hydrocortisone steroid treatment improved recovery among critically ill COVID-19 patients.

This study is one of a number of COVID-19 studies that have been given urgent public health research status by the Department of Health and Social Care. As of February 2021 75% of all study participants had been recruited in the UK through the NIHR's Clinical Research Network (CRN). The study is supported in the UK by the National Institute for Health Research (NIHR) and Imperial College London & ICNARC are partners in the EU funded PREPARE consortium.

(This is an updated press release, based on findings from January 2021 https://www.imperial.ac.uk/news/211514/arthritis-drugs-reduce-mortality-time-icu/)

Source:Imperial College London, EurekAlert, 25.02.2021

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MSME MATTERS

Amendment to Notification S.O.2119(E), dated the 26th June, 2020 - reg.

Notification No. S.O.1055(E), dated 5th March, 2021

In exercise of the powers conferred by sub-sections (1) and (9) of section 7 read with sub-sections (2) and (3) of section 8 of the Micro, Small and Medium Enterprises Development Act, 2006 (27 of 2006), the Central Government hereby makes the following amendments in the notification of Government of India, Ministry of Micro, Small and Medium Enterprises number S.O.2119(E), dated the 26th June, 2020, published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (ii), namely:-

In the said notification,–

(i) in paragraph (5), after sub-paragraph (3), the following sub-paragraph shall be inserted, namely:-

"(4) The exemption from the requirement of having GSTIN shall be as per the provisions of the Central Goods and Services Tax Act, 2017 (12 of 2017).";

(ii) in paragraph (6), after sub-paragraph (8), the following sub-paragraph shall be inserted, namely:-

"(9) In case of any proprietorship enterprise not registered under any Act or rules of the Central Government or the State Government, the proprietor may use his or her PAN for registration of the enterprise in the Udyam Registration portal and for all other types of enterprises PAN shall be mandatory.".

F.No.16/4/2019/P-P & G/Policy (Pt 1)

D K Singh, Addl Secretary, Ministry of Micro, Small and Medium Enterprises, New Delhi.

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii) vide number S.O.2119(E), dated the 26th June, 2020.*

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Hyderabad has potential to become $100-billion Pharma Hub by 2030: Telangana Industries Minister K T Rama Rao

'Life sciences sector attracted ₹3,700-crore investment in one year'

K T Rama Rao, Telangana IT and Industries Minister - The Hindu

As a Pharma and Life Sciences Hub of the world, Hyderabad is poised to grow to a $100-billion business generator by 2030, up from $13 billion (2020), as per the projections made in the Life Sciences report of the Telangana Government.

K T Rama Rao, Telangana IT and Industries Minister, said: "The visit of envoys from 70 countries to Hyderabad, Prime Minister Narendra Modi's visit to a vaccine facility, and former US President Donald Trump's request to India for supply of Covid drug Remdesivir (which is made in Hyderabad) for treatment show the importance the Pharma hub has for the world in Covid treatment and vaccination programme."

The life sciences sector has attracted investments of ₹3,700 crore in the past one year with employment potential of 14,000 people, he said.

'Vaccine capital of the world':

Addressing the inaugural session of the 18th edition of BioAsia, a Life-Sciences and Healthcare forum, Rao said: "Hyderabad's position as a vaccine capital of the world has been further bolstered as the world is looking at it for supplies of vaccines. The year 2020 has had a profound impact on life, economic and social spheres of the world, where we have lost more than 2.5 million lives to the Covid pandemic. Our Scientists and Entrepreneurs have given the Life Sciences sector its moment in spotlight, with accelerated development of vaccines, diagnostics and therapeutics."

The vaccine production capabilities of Bharat Biotech, Biological Evans, Indian Immunologicals, Dr Reddy's Laboratories and Hetero Drugs for Sputnik V vaccines, Aurobindo Pharma (450 million doses), among others, will play a significant role in supply of Covid vaccines, he said.

"As we look at further consolidating the position of Telangana and Hyderabad as a Pharma and Life-Sciences Hub with new facilities, we will soon have a major Pharma City that will house pharmaceutical, life sciences and other medical devices facilities."

Referring to some of the investments and pipeline projects, he said Sai Life Sciences has committed a ₹400-crore investment for and R&D centre and new drug development in Genome Valley; the Syngene campus set up last year is in the process of expanding. GVK Biosciences is set to expand by inducting 600 people; Granules India is coming up with a ₹400-crore vaccine facility; Laurus Labs is setting up a ₹300-core formulations facility.

Ferring Pharmaceuticals has started operations; the $170-million Medtronic medical devices facility is gearing up for commissioning next month, and 40 companies are setting up units at the Medical Devices Park.

Source: The Hindu Business Line, 23.02.2021

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ISCR welcomes CDSCO's move to allow online submission of SAEs arising from Clinical Trials

The Indian Society for Clinical Research (ISCR) has welcomed online submission of Serious Adverse Events (SAEs) arising from Clinical Trials in the country through SUGAM portal saying that it will speed up processes and help meet the regulatory timelines for reporting SAEs.

It will also help in easy traceability of the SAEs and will avoid a situation in which a courier of SAE report submission by the site or Sponsor or an Ethics Committee isn't received by the Central Drugs Standard Control

Organization (CDSCO), thus avoiding its re-submission, says Dr Chirag Trivedi, President, ISCR.

The CDSCO has come out with a training module which will help in the process of this e-submission, he said. Since a reported SAE from a trial will be linked with its Sponsor, Investigator and the Ethics Committee of that site, this e-submission will avoid duplication of the information provided by all three, stated Dr Trivedi.

Though initially, it may feel like the site may have to enter more details when reporting the SAE for the first time, it may be so that for any subsequent follow-up reporting for the same case, only the updated information will have to be provided, said ISCR President.

Since some years, CDSCO has started the process of e-submissions of Clinical Trial applications in its SUGAM portal. This process has helped to ease the submission process and to easily Track and Trace the applications. E-submission of SAEs is thus a part of the evolution of various e-submissions to the CDSCO.

Replying to a query on advantages that the online process brings in the Clinical Trial sector in India, Dr Tivedi said "Online submission does lead to a decrease in the overall timelines and thus helps in faster conduct of the Clinical Trial and enhances efficiencies."

The CDSCO on February 25, 2021 issued a Notification asking all stakeholders involved in Clinical Trials for online submission of SAE reports through SUGAM portal (**www.cdscoonline.gov.in**) from March 14, 2021 to reduce time and transaction cost. It will not accept physical/offline files of SAE reports for processing from March 14, 2021. However, follow up reports of the already submitted SAE reports shall be continued to be submitted in offline mode.

Source: Laxmi Yadav, Pharmabiz, 03.03.2021

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Ayurveda cos in Kerala cannot refrain from depending on Himalayan states for raw drugs: Herbologists

Experts in Herbology, the study of herbs and their medicinal properties, have commented that the Ayurveda drug manufacturers in Kerala can no longer refrain from depending on north Indian states, especially the Himalayas, for availing medicinal plant raw materials for the preparation of classical Ayurvedic formulations.

As of now, there is no replacement for Himalayan plants. The medicines available from Western Ghats are suitable, but they are under conservation. So, for many herbs and plants the manufacturers have to depend on the north Indian states. However, their attempt to cultivate plants as much as they can is appreciable, Herbologists from National Medicinal Plant Board (NMPB) and Ayush sector observe.

Responding to the project of medicinal plant cultivation by the Ayurveda Medicine Manufacturers Organisation of India (AMMOI) and the Mattathur Labourers Cooperative Society in Thrissur district to cultivate medicinal plants for the requirement of state's Ayush industry to reduce dependency on other states for raw drugs, the Herbologists said if they plan to confine within their state for raw materials, they cannot fulfill their demands as per the classical texts. Some major plant species which have the potential to be used as medicinal properties are available only in the Himalayas.

Talking to Pharmabiz, the eminent herbologist, Dr J L N Shasthri, CEO of the NMPB and Secretary of ASUDTAB, said many key ingredients in the classical formulations are Himalayan species. The plants in the Western Ghats have rich medicinal value but they are under conservation. So people in Kerala have to cultivate as much as those medicinal plants in their home premises or in particular gardens. If the listed plants and herbs are not available, the manufacturers will tend to adulterate raw materials.

To avoid adulteration, they have to procure the original materials from north India. Until and unless adequate quantity of plant raw materials is cultivated in Kerala, the Ayush Pharma industry has to depend on Himalayan states as it is the vast storehouse of medicinal plants referred in classical texts for Ayurveda and Siddha formulations.

"We cannot replace the Himalayan species with others. The plants of the Western Ghats are having rich medicinal values, but they are conserved. Unless people in Kerala cultivate the Himalayan plants, the situation will be dull. As far as Kerala is concerned, cultivation is also a problem. In addition to unsuitable climatic conditions and land limitations, labour problems are also a big issue in Kerala. The Ayurveda drug manufacturers cannot stop collecting raw materials from north India in the near future", said Dr Shasthri.

Recently the Union Ayush Ministry appointed Dr J L N Shasthri as the Secretary of the Ayurveda, Siddha,

Unani, Drug Technical Advisory Board (ASUDTAB) in place of Dr D C Katoch.

Supplementing additional suggestions to the medicinal plant farmers in Kerala, another Herbologist from Chennai, Dr T Thirunarayanan who does researches in medicinal plants and herbs used for Siddha medicines, says that the Himalayan and sub-Himalayan herbs are largely used in Ayurvedic preparations, so some of them cannot be replaced. According to him, many substitutions take place in the preparation of Ayurveda and Siddha drugs.

For example, Mattathur labor society is growing Sida rhombifolia for Ayurveda industry, but it is a substitution of Sida cordifolia. This shows that many plants are grown in the Himalayas only which cannot be replaced. But the manufacturers are trying to substitute it with other plants.

He said the Himalayan region is the treasure trove of natural wealth, particularly of medicinal plants and herbs. As far as Kerala is concerned, the soil condition, the geographical condition, frequent heavy rainfall etc become limitations for cultivating the rare species of plants. Besides, land for cultivating medicinal plants is limited in the state. So, the farmers under the Mattathur Labour Society should identify which are the plants they can grow in the climatic conditions of the state and focus on that. He said his organization, Centre for Traditional Medicines & Research (CTMR) can provide Guidance to the farmers and the society for cultivation of medicinal plant species.

Source: Peethaambaran Kunnathoor, Pharmabiz, 03.03.2021

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IPC issues clarification on alternative medicine in IP with reference to use of alternative methods

The Indian Pharmacopoeia Commission (IPC) has issued clarification on alternative medicine in the Indian Pharmacopoeia (IP) with reference to the use of alternative methods instead of official methods.

IPC has been receiving many enquiries on the subject of the use of alternative methods instead of official methods included in the IP. General Notices of IP (Volume-I, Page 12) have the provision to use alternative methods and the same has been reproduced and described.

Alternative methods are the tests and assays described are the official methods upon which the standards of the pharmacopoeia are based. Alternative methods of analysis may be used for control purposes provided that the methods used are shown to give results of equivalent accuracy and enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official methods were used.

Automated procedures utilizing the same basic chemistry as the test procedures given in the monograph may also be used to determine compliance. Such alternative or automated procedures must be validated and are subject to approval by the authority competent to authorize manufacturer of substance or product.

"For removal of doubts, it is clarified that the authority competent to authorize manufacturer of substance or product as mentioned above in the General Notices of IP refers to the licensing authority, either State or Central Drug Regulatory Authority as the case may be, for grant of license or approval. All concerned are requested to bring the above clarification to the notice of all authorities under their control," as per the IPC notice.

Source: Shardul Nautiyal, Pharmabiz, 02.03.2021

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CDSCO directs stakeholders involved in CT for online submission of SAE reports to reduce time & transaction cost

The Central Drugs Standard Control Organization (CDSCO) has directed all stakeholders involved in Clinical Trials (CT) for online submission of Serious Adverse Event (SAE) reports through SUGAM portal (**www.cdscoonline.gov.in)** to reduce time and transaction cost.

In order to implement e-governance effectively, the CDSCO has launched various online services through the SUGAM portal (**www.cdscoonline.gov.in**) on November 14, 2015.

In the latest phase, the development of software for online submission of SAE reports has been completed and stakeholders are requested to avail this facility towards effective time management and optimize transaction cost.

"It has now been decided that the same will be effective from March 14, 2021 and from this date physical/offline files of SAE reports may not be accepted for processing. However, follow up reports of the already submitted SAE reports shall be continued to be submitted in offline mode," according to Drugs Controller General of India Dr V G Somani.

As per "The New Drugs and Clinical Trials Rules, 2019", investigator, sponsor/CT-NOC Holder and ethics committee shall report all SAE's to the Central Licensing Authority (CLA) within a prescribed time bound manner as specified in Rule 42 of the said Rules.

SUGAM is an e-Governance system to discharge various functions performed by CDSCO under the Drugs and Cosmetics (D&C) Act, 1940. The software system developed is an online web portal where applicants can apply for NOCs, licenses, registration certificates, permissions and approvals.

It provides an online interface for applicants to track their applications, respond to queries and download the permissions issued by CDSCO. It also enables CDSCO officials to process the applications online and generate the permissions online and generate MIS reports. It contains step-by-step Guidance to the applicants of the SUGAM portal with screenshots of the workflow for various application submissions.

Following sections which are detailed in Sugam are User Registration and Login, Applicant Dashboard, Managing Sub login Accounts, Form Submission for various processes and Post Approval Changes.

Applications were made in hard copy dossier format to various divisions in CDSCO before the Sugam portal was introduced. The timelines for granting permissions or approvals for applications were almost three times more than what is there in the current scenario.

Source: Shardul Nautiyal, Pharmabiz, 01.03.2021

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Gujarat FDCA introduces online facility for applications for CoPP with QR Code

In order to streamline the process of issuance of WHO-GMP Certification Scheme for Certificate of Pharmaceutical Products (CoPP) through online mode to boost exports, the Gujarat Food and Drug Control Administration (FDCA) has introduced online facility for submission of applications for WHO-GMP CoPP with QR Code for first time in country through its DMLA software.

Since its development in 2011 jointly by Gujarat FDCA and National Informatics Centre (NIC), the DMLA online platform has been able to grant till date manufacturing and sale license online by Gujarat FDCA in the country.

"Gujarat FDCA has started issuing CoPP with QR Code online since the last one week for the first time in the country," according to Gujarat FDCA Commissioner Dr H G Koshia while talking about the new feature in online platform and how it will be able to boost exports.

He further added, "DMLA online platform has been replicated across the country and has been an incentive for Gujarat drug manufacturers in a major way. Gujarat FDCA has also been able to dispose of applications online related to issuing licenses to wholesalers and retailers in a time bound manner since the introduction of online Extended Licensing Node (XLN) system set up in the state in 2007.

Following Gujarat online licensing model for sales licenses, 16 states replicated the model in the country. There are 40,000 plus retail and wholesale licensees in the state of Gujarat. At the time of introduction of the online system, there were 15,000 registered sale licensees in the state in 2007, which have also been digitised.

With the implementation of the online system, the process is now paperless and less time consuming. It is easier for the regulator and licensee to track the process of scrutiny through a seamless online documentation process till final issuance of license.

Gujarat Government has also revised timelines for grant of manufacturing licenses and renewal of licenses to 60 days and that of grant and renewal of sale licenses to 30 days as part of Pharma Vision 2020 under the Right of Citizens to Services for speedy issuance of licenses.

With growing emphasis on boosting SMEs to help meet the regulatory requirements of not only India but also other major markets like US, Europe and Japan, there is an urgent need for the manufacturers who are revised schedule M compliant to upgrade to WHO GMP and those who are WHO GMP compliant to upgrade to US FDA or EDQM compliance.

Source: Shardul Nautiyal, Pharmabiz, 01.03.2021

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Vaccine contendender: Here's a status update

Even as India continues its phase 2 of vaccinations, there are only two companies supplying vaccines for the immunisation programme. However, as vaccination opens up for all adults, there are concerns whether these companies will be able to meet the national demand. India is also playing a key role in vaccine distribution to the rest of the world. There are at least six vaccines in advanced clinical trials and could get approval in the next couple of months. **Teena Thacker & Divya Rajagopal** report.

Sputnik V

VACCINE TYPE: Adenovirus platform combining two strains of Ad 5 and Ad 26

DOSES: ❷

EFFICACY: The Russian vaccine has an efficacy of 94%, which is on a par with Pfizer and Moderna. Dr Reddy's has submitted its phase 2 data to the subject expert committee to market the drug in India on the basis of overseas phase 3 data. The company is expected to submit data in a few week's time for approval.

EFFICACY AGAINST THE NEW VARIANT: Inconclusive evidence on whether the vaccine works against the SA variant. The company is working on a trial find out if the vaccine would work against the new variant.

Zydus Cadila

VACCINE TYPE: DNA platform

DOSES: ❸

TRIALS: The Phase 3 trials for the vaccine are underway and will be tested across 60 locations on 30,000 healthy adult volunteers. Cadila Healthcare aims to supply between 100 million to 150 million doses of its Covid-19 vaccine candidate ZyCoV-D this calendar year. In an interview to brokerage firm Jefferies, the company's CEO Shravil Patil had said the company was looking to price the vaccine along the same lines as Serum Institute of India.

EFFICACY: Not known yet.

Serum-Novova

VACCINE TYPE: Protein based

DOSES: ❷

TRIALS: Phase 2/3 for immunogenicity

The SEC, in January, recommended that SII should conduct a comparator study with the Novavax vaccine. This is similar to what SII did for the AstraZeneca/Oxford vaccine. Novavax is in the process of a rolling review in the UK for an approval. It has signed up with SII for a 1 billion vaccine supply agreement. The SEC has asked the company to submit revised clinical trial protocol for further deliberation.

EFFICACY (UK TRIALS): 91%

Nasal Vaccine by Bharat Biotech

VACCINE TYPE: Vector platform

TRIAL PHASE: Phase 1

The company will look at launching a nasal vaccine that in few studies has shown to work better than the intravenous method. Bharat Biotech has been asked to generate safety and immunogenicity data in Phase-I clinical trial (75 subjects) in the proposed doses as per the protocol. The company had presented animal toxicity and immunogenicity, along with the protocol to conduct Phase I/ II clinical trial of Chimpanzee Adenovirus Vectored COVID-19 Intranasal Vaccine.

EFFICACY: Unknown

J&J/ Biological E

VACCINE TYPE: Adenovirus (26)

DOSES: ❶

TRIAL- Biological E is the manufacturing partner for J&J, however, the companies have not filed any bridging trial application to launch the vaccine in India.

EFFICACY- The vaccine has shown to prevent death and severe illness in 100% of the trial participants, and has shown an overall efficacy of 66% from trial data in the US, South Africa and Brazil.

Genova

VACCINE TYPE: mRNA

TRIAL: Phase 1/2 trial

The Pune-based company is hoping to bring out the mRNA vaccine from India. It is under phase 1/2 trial.

EFFICACY: Unknown

VARANI SAHU

Source: The Economic Times, 04.03.2021

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Indian Pharma faced with complex supply chain ridden with Multi-Channel Distributors: Expert

Indian Pharma is now putting up with complex supply chain situations covering rising price of fuel and increasing labour costs together with the logistics management challenges.

Investments are found wanting in real-time access of stock movement/temperature data loggers across the country. The country also needs a dynamic Single Point of Contact (SPOC) from warehousing to last mile distribution.

Emphasising the need for an advanced cold storage for the Indian Pharma Sector, J B Chowhan, Founder and Chairman, Vardhman Health Specialities Group Companies said that one of the reasons for a complex supply chain environment has been the presence of too many channels of distributions starting from manufacturing hubs, CFAs (Carrying and Forwarding Agent), distributors to retail pharmacies which are all over India.

Medicines are required to be transported to the faraway places with poor connectivity and usage of passive cooling systems. Going by the transport facilities over 25% of the revenues by the Pharma manufacturer have been spent on the transportation only. The problem of poor supply chain management becomes even more severe when the temperature sensitive medications such as vaccines and lifesaving drugs face distance impediments, Chowhan told.

There is a stringent regulatory guidance by the Central Drugs Standard Control Organization (CDSCO) to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. These are not limited to procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices. But what impacts the growth of cold supply chain sector is the lack of required infrastructure and traceability.

During the ongoing COVID-19 pandemic, drug supply chain management in India has seen a humongous growth, with the indispensability of cold storage support for the lifesaving vaccinations. Yet India needs a network of central and multiple regional warehouses which requires investment for inventory.

There is definitely a requirement for end-to-end batch wise traceability, with temperature monitoring, bar coding.

In addition, companies in the cold supply chain arena go through cumbersome agreement protocols with domestic air couriers, snickering, and returns etc. There is major paucity of Good Distribution Practice (GDP) compliant Pharma warehouses. Medicine batch traceability in real time would help keep not-of-standard quality and spurious drugs at bay, pointed out Chowhan.

The global pharmaceutical supply chain management is expected to grow double fold in the coming years. Therefore it is crucial for the cold chain logistics market to look at innovations and investments to research on cold supply chain management in India. Some of these area would be setting up of Super Specialty, Pharma Warehousing and Distribution, last mile connectivity, digital platforms of Internet of Things, Blockchain, secured data management, and annual quality audits.

In addition, the other focused areas include 24×7 Patient Service Focussed, Easy Payment Methods and Online ordering facility, NPI (Name patient Import) of research molecules and an excellent CRM customer relation management with the 1500+ multi speciality hospitals across India, said Chowhan.

Source: Nandita Vijay, Pharmabiz, 27.02.2021

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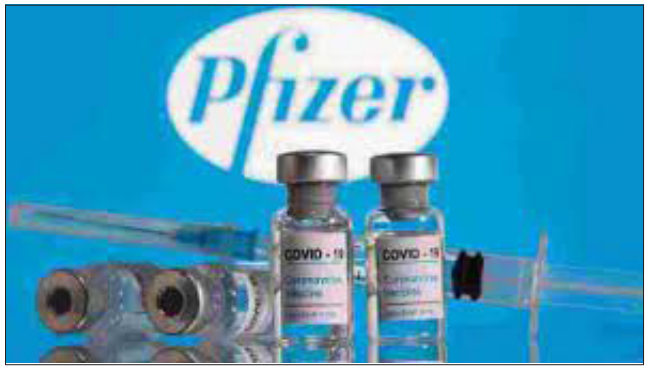
Pfizer-BioNTech shot stops Covid's spread, Israeli study shows

- *The vaccine, which was rolled out in a national immunization program that began December 2020, was 89.4% effective at preventing laboratory-confirmed infections.*
- *Israeli authorities on Saturday said the Pfizer-BioNTech shot was 99% effective at preventing deaths from the virus.*

The Pfizer Inc and BioNTech SE Covid-19 vaccine appeared to stop the vast majority of recipients in Israel becoming infected, providing the first real-world indication that the immunization will curb transmission of the Coronavirus.

The vaccine, which was rolled out in a national immunization program that began December 2020, was 89.4% effective at preventing laboratory-confirmed infections, according to a copy of a draft publication that was posted on Twitter and confirmed by a person familiar with the work. The companies and Israel's Health Ministry worked together on the preliminary observational analysis, which has not yet been peer-reviewed.



Pfizer and BioNTech said they are working on a real-world analysis of data from Israel, which will be shared as soon as it's complete. (Photo: Reuters)

The results, also reported in Der Spiegel, are the latest in a series of positive data to emerge out of Israel, which has given more Covid vaccines per capita than anywhere else in the world. Nearly half of the population has had at least one dose of vaccine. Separately, Israeli authorities on Saturday, 20.02.2021 said the Pfizer-BioNTech shot was 99% effective at preventing deaths from the virus.

The early results on lab-confirmed infections are important because they show the vaccine may also prevent asymptomatic carriers from spreading the virus that causes Covid-19, something that hadn't been clear so far. Stopping transmission in this way is a key factor as countries seek to lift contact restrictions and re-open economies.

Pfizer and BioNTech said they are working on a real-world analysis of data from Israel, which will be shared as soon as it's complete. Spokes people declined to comment on unpublished data.

Four-fifths of the virus cases in Israel during the time period of the study, from January 17 to February 6, were the more transmissible strain first identified in the UK Israel's vaccination drive began just before the so-called B.1.1.7 variant emerged, fueling infections and leading to a third lockdown on January 8.

Through February 6, about 27% of people aged 15 and older in Israel were fully vaccinated, with the Pfizer-BioNTech shot the only vaccine available in the country at the time. People were considered fully vaccinated and included in the analysis if the data collected were more than 7 days after they received their second dose.

Source: Reuters/Bloomberg/Live Mint, 22.02.2021

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Delhi HC asks Serum Institute, Bharat Biotech to disclose capacity to manufacture COVID-19 vaccines

A vial of the AstraZeneca COVID-19 vaccine doses, one of the first 500,000 of the two million, is displayed that Canada has secured through a deal with the Serum Institute of India in partnership with Verity Pharma, Wednesday, March 3, 2021, at a facility in Milton, Ontario. (Carlos Osorio/Pool Photo via AP) (AP).

The Delhi High Court on Thursday, 04.03.2021 directed Serum Institute of India and Bharat Biotech to disclose their capacities to manufacture Covaxin, Covishield vaccines.

The High Court also asked the Centre to explain in affidavit the rationale behind keeping strict control over class of persons who can be vaccinated against COVID-19 currently as under the present system those above the age of 60 years or between 45 to 60 years with comorbidities can receive vaccination.

A bench of Justices Vipin Sanghi and Rekha Palli said the two Institutes -- Serum Institute of India and Bharat Biotech -- have more capacity to provide the vaccines but it seems that they are not exploiting it fully.

"We are not utilising it fully. We are either donating it to foreign countries or selling it to foreign countries and are not vaccinating our own people. So there has to be that sense of responsibility and urgency," the Bench said.

It also asked the Delhi Government to carry out inspection of medical facilities available in court complexes here and to report if COVID-19 vaccination centres could be set up there.

The High Court was hearing a PIL initiated by it to examine the demand of Bar Council of Delhi to declare all people associated with the judicial functioning, including judges, court staff and lawyers as "frontline workers" so that they could receive COVID-19 vaccination on priority and without limitations of their age or physical condition.

Source: PTI, Livemint, 05.03.2021 (Excerpts)

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J Jayaseelan of TN IDMA nominated to Executive Committee of NBA

The President of the Tamil Nadu State Pharmacy Council (TNSPC) and Chairman of the Tamil Nadu, Kerala and Pondicherry Board of the Indian Drug Manufacturers' Association (TN IDMA), J Jayaseelan has been nominated as a member to the Executive Committee of the National Board of Accreditation (NBA), the Autonomous Agency to assess and accredit technical education programmes and institutions.

NBA has been reconstituted with 16 EC members and it will operate with immediate effect for a period of three years, a communiqué issued by the NBA Member Secretary says.

This is the first time a person representing pharmaceutical side becomes a member to the NBA. Jayaseelan is the Managing Director of three Pharmaceutical companies engaged in formulation development, API production and marketing.

A passionate Pharma industry professional with 30 years experience, Jayaseelan became an authentic leader of the pharmaceutical space, both in industry and in education side, and he is loved and admired by all stakeholders. With his entrepreneurial bug to become a successful entrepreneur, he became an undisputed industry leader early in his life.

Since the quality of the pharmacy educational institutions need to be checked by the NBA, the nomination of Jayaseelan as an EC member will be an asset to the accreditation board to assess the quality of the pharmacy colleges in the country, hopes the academic community. The Executive Committee consists of 16 members out of which three members are senior IAS officers holding Secretary ranks in the Department of higher education and two members of Chief Secretary ranks from Uttar Pradesh and Maharashtra.

In addition to the Chairman of the All India Council of Technical Education (AICTE), Vice Chancellors of eminent universities, Directors of Technical Education Board of various universities, Directors of Corporate affairs of multinational companies and Head of Education and Innovation of the Confederation of Indian Industry (CII) have been made members to the NBA Executive Committee.

Commenting on his nomination to the NBA, the former National President of the IDMA, S V Veerramani said, "The entire pharmaceutical sector in Tamil Nadu takes pride in, and the accreditation board can utilize his potential for the quality assurance of the Pharma industry and pharmacy education institutions."

Source: Peethaambaran Kunnathoor, Pharmabiz, 06.03.2021

● ● ●

Extend PLI scheme to all MSMEs, says Niti Aayog

ILLUSTRATION: BINAY SINHA

NITI Aayog has recommended that the production-linked incentive (PLI) scheme be extended across sectors for medium-sized industries with investment above ₹100 crore. This, it said, would provide support to micro, small and medium enterprises (MSMEs) battered by the Covid-19 pandemic.

According to a senior government official, the policy think tank of the Government of India has written to various ministries for expanding the PLI scheme for medium-scale industries to make the country self-reliant and lift domestic manufacturing.

To integrate India's manufacturing ecosystem with global supply chains, the government announced the PLI scheme — that entails providing incentives to firms on incremental sales for five years over the base year of 2019-20 — for 13 sectors.

The recently announced PLI scheme for the telecom sector extended the incentives to MSMEs. The minimum investment threshold has been kept at ₹10 crore (with incentives from 7 per cent to 4 per cent of incremental sales) and ₹100 crore for others (with incentives from 6 per cent to 4 per cent).

The PLI scheme for the pharmaceutical (pharma) sector has also announced incentives for MSMEs by categorising them under a separate category.

The Aayog has suggested that the existing PLI schemes may not be amended, but wherever possible, new guidelines will be issued for expanding its scope to medium-sized industries.

Besides pharma, drug intermediaries, medical devices, mobiles, tablets, electronics, and telecom, the government will announce the PLI scheme for seven more sectors.

"In sectors like electronics, the higher investment threshold and incremental sales target can be reduced, given not many domestic industries have the wherewithal to invest that kind of capital," said the official.

The recommendations from the Aayog have been to extend this for those making fresh investments of a lower quantum. This would help the PLI scheme in covering all levels of businesses, proposed the Aayog.

The biggest challenge continues to be access to capital, said Divakar Vijayasarathy, managing partner at DVS Advisors. The regulatory push through the extension of the scheme for MSMEs can be a game changer, said Vijayasarathy. "Banks would be more forthcoming in advancing loans, and MSMEs may also be able to raise private equity which was difficult earlier," he added.

Priority	Sectors	Implementing ministry/department	Approved financial outlay over a five-year period (₹crore)
1	Advance chemistry cell (ACC) battery	NITI Aayog and Department of Heavy Industries	18,100
2	Electronic/technology products	Ministry of Electronics and Information Technology	5,000
3	Automobiles & auto components	Department of Heavy Industries	57,042
4	Pharmaceuticals drugs	Department of Pharmaceuticals	15,000
5	Telecom & networking products	Department of Telecom	12,195
6	Textile products: MMF segment and technical textiles	Ministry of Textiles	10,683
7	Food products	Ministry of Food Processing Industries	10,900
8	High efficiency solar PV modules	Ministry of New and Renewable Energy	4,500 m
9	White goods (ACs & LED)	Department for Promotion of Industry and Internal Trade	6,238
10	Speciality steel	Ministry of Steel	6,322
	Total		1,459,80

Source: PIB

Source/Courtesy: Nikunj Ohri, Bussiness Standard, 05.03.2021

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Real-world effectiveness of COVID-19 vaccine

The Clalit Research Institute, in collaboration with researchers from Harvard University, analyzed one of the world's largest integrated health record databases to examine the effectiveness of the Pfizer vaccine against COVID-19. The study provides the first large-scale peer-reviewed evaluation of the effectiveness of a COVID-19 vaccine in a nationwide mass-vaccination setting. The study was conducted in Israel, which currently leads the world in COVID-19 vaccination rates.

The results of this study validate and complement the previously reported findings of the Pfizer/BioNTech Phase-III randomized Clinical Trial, which focused on symptomatic infections, and which, with 21,720 vaccinated individuals, could not precisely assess vaccine effectiveness against severe disease in the fully vaccinated. The present study's large size allows a more detailed assessment of the vaccine's effectiveness in preventing a wider range of outcomes, across different time periods and population sub-groups.

The study took place from December 20, 2020, the launch of Israel's national vaccination drive to February 1, 2021. It coincided with Israel's third and largest wave of Coronavirus infection and illness, during which the B.1.1.7 variant gradually became the dominant strain in the country for new infections.

Researchers reviewed data from 596,618 vaccinated individuals aged 16 and over (of whom approximately 170,000 were aged 60+). These individuals were carefully matched with 596,618 unvaccinated individuals based on an extensive set of demographic, geographic and health-related attributes associated with risk of infection, risk of severe disease, health status and health seeking behavior.

Individuals were assigned to each group dynamically based on their changing vaccination status (approximately 85,000 individuals moved from the unvaccinated cohort into the vaccinated cohort during the study). Multiple sensitivity analyses were conducted to ensure that the estimated vaccine effectiveness was robust to potential biases.

The results show that in fully vaccinated individuals (7 or more days after the second dose), the risk of symptomatic COVID-19 decreased by 94% compared with the unvaccinated, while the risk of severe disease decreased by 92%. In the period immediately preceding the second dose (days 14-20 after the first dose), vaccine effectiveness was lower, but still substantial -- the risk of symptomatic COVID-19 decreased by 57% in vaccinated individuals, and the risk of severe disease by 62%. While there was insufficient data to provide an estimate on the reduction in mortality in those who received two doses, data from 21-27 days after the first dose points to a substantial reduction in mortality as well.

As an observational study conducted in a mass-vaccination setting, this study was not designed to systematically assess viral transmission or asymptomatic infections. With the careful matching procedures, multiple outcomes assessed and multiple sensitivity analyses performed, the large sample size in this study also allowed the estimation of vaccine effectiveness in a number of specific subpopulations.

The vaccine effectiveness for preventing symptomatic COVID-19 proved consistent across age groups, including adults aged 70+. The study also evaluated subpopulations with different numbers of comorbidities and found indications that vaccine effectiveness for preventing symptomatic COVID-19 may be slightly lower for individuals with a higher number of co-morbidities, although the difference was not statistically significant.

(The research was conducted by Dr Noa Dagan, Dr Noam Barda, Dr Eldad Kepten, Oren Miron, Shai Perchik, Dr Mark Katz and Prof. Ran Balicer from the Clalit Research Institute, as well as Prof. Miguel Hernán and Prof. Marc Lipsitch of the Harvard T H Chan School of Public Health, and Prof. Ben Reis of Boston Children's Hospital and Harvard Medical School).

"The swift nationwide rollout of Israel's COVID-19 vaccination campaign provided the Clalit Research Institute with a unique opportunity to assess, through its rich digital datasets, the effects of the vaccine in a real-world setting in all population sub-groups," said Prof Ran Balicer, Senior Author of the study, Director of the Clalit Research Institute and Chief Innovation Officer for Clalit.

"These results show convincingly that this vaccine is highly effective against symptomatic COVID-19, one week after the second dose. These results are similar to those reported in the previously published Clinical Trial, despite the challenges inherent in a mass-vaccination setting."

"The results also correlate well with recent population-level trends in Israel, which have seen a sustained decline in hospitalization and severe disease in the mostly-vaccinated older age groups, alongside a delayed decline among younger age groups for whom vaccination began several weeks later.

These data, together with the anticipated impact of the ongoing vaccination campaign in Israel, where nearly half the population has already been vaccinated, have had a significant impact on Government decisions to ease restrictions imposed during Israel's recent third lockdown," explains Prof Balicer, who also serves as Chairman of Israel's National Expert Advisory Team on COVID-19 response.

Prof Miguel Hernán of the Harvard T H Chan School of Public Health, said, "This research is a perfect example of how randomized trials and observational healthcare databases complement each other. The original trial of the Pfizer/BioNTech vaccine provided compelling evidence of its effectiveness to prevent symptomatic infection, but the estimates for severe disease and specific age groups were too imprecise.

This analysis of Clalit's high-quality database emulates the design of the original trial, uses its findings as a benchmark, and expands upon them to confirm the vaccine's effectiveness on severe disease and in different age groups. This combination of evidence from randomized trials and observational studies is a model for efficient medical research, something which is especially important in COVID times."

Prof Marc Lipsitch, Director of the Center for Communicable Disease Dynamics and Professor at the Harvard T H Chan School of Public Health, said, "In all studies of vaccine effectiveness, a major challenge is to ensure that those we are comparing to identify the vaccine's effect are similar in the other characteristics that may predict whether they get infected or ill.

This is especially hard in the context of a rapidly growing, age-targeted vaccine campaign. Clalit's extraordinary database made it possible to design a study that addressed these challenges in a way that provides tremendous confidence in the inferences that come out of the study."

Prof Ben Reis, Director of the Predictive Medicine Group at Boston Children's Hospital and Harvard Medical School, said, "Israel's impressive vaccination campaign, together with Clalit's unique integrated data sources, presented a rare opportunity to study the effects of the vaccine in a real-world mass-vaccination setting."

He continued, "The global scientific cavalry charge that enabled the development of vaccines in record time is now continuing with international collaborations focused on evaluating vaccine effectiveness. The virus doesn't recognize borders, neither should the scientists hoping to fight it. This is how science should be done."

Source: World Pharma News, 25.02.2021 (Excerpts)

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COVID-19 has fast-tracked digital transformation timeline for Pharma industry: Global Data

COVID-19 uncovered a strong need for innovation and the adoption of digital tools, and quite successfully showcased how quickly the industry can embrace changes when it is pressured to do so

Even though the Pharma sector used to display a more conservative stance toward the adoption of new technologies, the COVID-19 pandemic acted as a trigger that forced the Pharma sector to accelerate the digital transformation timeline, says Global Data.

According to a Global Data survey, 35 percent of Pharma industry professionals believe that the COVID-19 pandemic sped up digital transformation in the Pharma industry by more than five years. The respondents coming from Europe and North America seemed to be particularly affected by digitalisation efforts, with 40 percent of respondents highlighting that the digital transformation was accelerated by more than five years.

Urte Jakimaviciute MSc, Senior Director of Market Research, comments, "In a short space of time, the pharmaceutical industry has witnessed years-long digital transformation roadmaps squeezed into weeks in order to adapt to reduced in-person interactions, mobility restrictions and shift towards remote work.

Lockdowns, movement restrictions and social distancing norms have rapidly pushed healthcare services and patient monitoring toward remote options, paving the way for increased usage of telemedicine, digital therapeutics, as well as decentralised Clinical Trials. The pandemic has also changed traditional sales and marketing models, leading to increased demand for online marketing and communication tools."

For example, Doxy.me, a leading telemedicine platform for healthcare providers, saw a significant increase in its monthly visits, from over 250,000 visits in February 2020 to a peak of 23.2 million visits in April 2020. In March 2020, Veeva – a company specialising in cloud-based business solutions for the life sciences industry – started offering its CRM Engage Meeting tool free of charge in order to allow its customers to stay connected with healthcare professionals. More than 64,000 meetings were scheduled using this tool during March 16–21, 2020, at an increase of over 275% compared to the previous week.

Digital transformation is also seen as a positive step towards addressing R&D productivity challenges. Technologies, such as Artificial Intelligence (AI), have already hit significant milestones in drug discovery. For example, in early 2020, Sumitomo Dainippon Pharma and Exscientia announced that an AI-created compound (DSP-1181) would be used in human Clinical Trials for the first time; researchers from Benevolent AI identified Eli Lilly's Olumiant (baricitinib) as a potential treatment for COVID-19. The treatment received Emergency Use Authorization from the FDA for hospitalised COVID-19 patients in November 2020.

Jakimaviciute concludes, "The Pharma sector has been relatively slow in embracing digital transformation. This tendency has been influenced by the need for the industry to concentrate on wide-ranging internal and external factors such as rising R&D costs, drug pricing and reimbursement concerns, increasing regulatory burden, patent expiries and tax reforms. Nevertheless, COVID-19 uncovered a strong need for innovation and the adoption of digital tools, and quite successfully showcased how quickly the industry can embrace changes when it is pressured to do so."

Source: EP News Service, Express Pharma, 05.03.2021

Speakers:

(1) ***Dr Mrunal Jaywant,*** *Senior Director R&D at US Pharmacopeia, Hyderabad, Telangana, India.*

(2) ***Mr Atul Nasa,*** *Deputy Drugs Controller – Delhi.*

(3) ***Mr Daara Patel,*** *Secretary General - IDMA*

(4) ***Dr Diwakar Sukul,*** *Chairman - World Book of Records, London – UK.*

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