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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **Government working to reduce regulatory compliance burden on Pharma Sector: Hon'ble Minister Sadananda Gowda** *(Page No. 30)*

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Felicitation of Mr B N Singh, Executive Chairman, Alkem & Past President, IDMA at Governor House





Mr B N Singh, Executive Chairman, Alkem Laboratories Limited and Past President, IDMA being felicitated at Governor's House - Raj Bhavan, Mumbai on 20th February 2021 for the Humanitarian work done by Alkem Laboratories Limited during the lockdown arising out of COVID-19 Pandemic.

Cabinet approves Production Linked Incentive Scheme for Pharmaceuticals

Union Cabinet Press Release dated 24th February 2021

The Union Cabinet, chaired by the Prime Minister, Shri Narendra Modi has approved Production Linked Incentive (PLI) Scheme for Pharmaceuticals over a period of Financial Year 2020-21 to 2028-29. The Scheme will benefit domestic manufacturers, help in creating employment and is expected to contribute to the availability of wider range of affordable medicines for consumers.

The scheme is expected to promote the production of high value products in the country and increase the value addition in exports. Total incremental sales of Rs.2,94,000 crore and total incremental exports of Rs.1,96,000 crore are estimated during six years from 2022-23 to 2027-28. The scheme is expected to generate employment for both skilled and un-skilled personnel, estimated at 20,000 direct and 80,000 indirect jobs as a result of growth in the sector.

It is expected to promote innovation for development of complex and high-tech products including products of emerging therapies and *in vitro* Diagnostic Devices as also self-reliance in important drugs. It is also expected to improve accessibility and affordability of medical products including orphan drugs to the Indian population.

The Scheme is also expected to bring in investment of Rs.15,000 crore in the pharmaceutical sector. The scheme will be part of the umbrella scheme for the Development of Pharmaceutical Industry. 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.

The salient features of the Scheme are as follows:

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. A sub-group for MSME industry will be made within this group, given their specific challenges and circumstances.

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.

The incentive allocation for Group A and Group C applicants shall not be moved to any-other category.

However, incentive allocated to Group B applicants, if left underutilized can be moved to Group A applicants.

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

Category of Goods:

The scheme shall cover pharmaceutical goods under three categories as mentioned below:

(a): Category 1

Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.;

Complex excipients; Phyto-pharmaceuticals: Other drugs as approved.

(b): Category 2

Active Pharmaceutical Ingredients/Key Starting Materials/Drug Intermediates.

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

Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; I*n vitro* diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

Rate of incentive will be 10% (of incremental sales value) for Category 1 and Category 2 products for first four years, 8% for the fifth year and 6% for the sixth year of production under the scheme.

Rate of incentive will be 5% (of incremental sales value) for Category 3 products for first four years, 4% for the fifth year and 3% for the sixth year of production under 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.

Background:

Indian pharmaceutical industry is 3rd largest in the world by volume and is worth 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 USA, UK, European Union, Canada etc. India has a complete ecosystem for the development and manufacturing of pharmaceuticals with companies having state of the art facilities and highly skilled/technical manpower.

The country also has a number of renowned pharmaceutical educational and research institutes and a robust support of allied industries. At present, low value generic drugs account for the major component of Indian exports, while a large proportion of the domestic demand for patented drugs is met through imports. This is because the Indian Pharmaceutical sector lacks in high value production along with the necessary pharma R&D.

In order to incentivize the global and domestic players to enhance investment and production in diversified product categories, a well-designed and suitably targeted intervention is required to incentivize specific high value goods such as bio-pharmaceuticals, complex generic drugs, patented drugs or drugs nearing patent expiry and cell based or gene therapy products etc.

Source: PIB, Cabinet Press Release, 24.02.2021

● ● ●

'I am sure global Pharma industry will support India's WTO proposal of IP waiver for COVID-19': Goyal

Piyush Goyal said that the developed world is under pressure as a host of WTO members, including least developed countries and African nations, are supporting this proposal host of WTO members, including least developed countries and African nations, are supporting this proposal

Piyush Goyal. File | Photo Credit: M. Vedhan

Commerce and Industry Minister Piyush Goyal on February 25 expressed hope that global pharmaceutical industry will show "big heart" and support India's proposal in the WTO (World Trade Organisation) for relaxing certain provisions in a multilateral agreement on Intellectual Property with a view to containing the pandemic.

In October 2020, India and South Africa submitted a proposal suggesting a waiver for all WTO members on the implementation, application and enforcement of certain provisions of the TRIPS Agreement in relation to the prevention, containment or treatment of COVID-19.

The agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPS came into effect in January 1995. It is a multilateral agreement on Intellectual Property (IP) Rights such as copyright, industrial designs, patents and protection of undisclosed information or trade secrets.

"I am sure the industry will show big heart across the world and support the TRIPS waiver that India has proposed at the WTO so that the entire world can come out of the COVID-19 pandemic much faster and bring back the "V" shaped recovery to the entire world," Mr Goyal said at a FICCI webinar on pharmaceuticals.

He said that the developed world is under pressure as a host of WTO members including least developed countries and African nations are supporting this proposal.

On one hand, the developed countries "talk about supporting each other and multilateral fight against COVID-19 pandemic, but on the other hand, they are looking at protecting the interests of a few companies," he rued.

The Minister said the world is fighting the pandemic which could potentially cost $9 trillion to the world economy and many sectors like tourism, hospitality, and travel have collapsed. He said the proposal of India and South Africa would allow more and more countries to get equitable access to medicines and other products.

The waiver, proposed by the two countries, would cover obligations in four sections of Part II of the TRIPS Agreement — Section 1 (Copyright and related Rights), Section 4 (industrial designs), Section 5 (patents) and Section 7 (protection of undisclosed information). Further Mr Goyal also said following best standards and quality norms would help boost growth of the Pharma industry.

Waiver is a legal instrument provided for exceptional circumstances under the WTO, which is a Geneva-based body dealing with global trade norms and adjudicating trade disputes.

Since COVID-19 pandemic is an extremely exceptional crisis, the proposed limited, temporary and proportionate waiver from certain provisions of TRIPS Agreement, is within the framework of multilateral trading system.

Source: PTI, The Hindu, 25.02.2021 (Excerpts)

Electronic filing and Issuance of Preferential Certificate of Origin (CoO) for India's Exports under India-Mercosur PTA and India-Thailand EHS w.e.f. 25th February 2021 - reg.

DGFT Trade Notice No.43/2020-2021, dated 23th February 2021

To,
All Exporters/Members of Trade,
All Designated Issuing Agencies under FTAs/PTAs.

1. In continuation to the earlier Trade Notice(s) 34/2015-2020 dated 19.09.2019, 41/2019-2020 dated 12.12.2020, 53/2019-2020 dated 02.03.2020, 01/2020-2021 dated 07.04.2020 and 30/2020-2021 dated 13.10.2020, it is informed that the electronic platform for Preferential Certificate of Origin(CoO) is being expanded further to add two (2) more FTAs/PTAs to facilitate electronic application of Preferential Certificates of Origin under the given Trade Agreements.

2. The Preferential Certificate of Origin for exports to countries under the following trade agreements i.e.

I. India-Mercosur Preferential Trade Agreement

II. India-Thailand Early Harvest Scheme

shall also be applied and issued from the CoO e-platform with effect from **25th February 2021**. No manual application for such a CoO should be submitted to an issuing agency from 25th February 2021. Any manual applications submitted prior to the given date may however be processed by the issuing agencies.

3. It is informed that for these applications under the above mentioned Trade Agreements, the e-CoO system shall generate all the existing set of CoO copies besides an additional copy i.e. electronic copy. The electronic copy shall bear the image signature of the officer and stamp of the issuing agency. The exporter may however get the remaining copies duly ink-signed by the issuing officer along with the stamp of the issuing office. The paper copies of the CoOs so issued may be collected by post or in person, for any submission to the Trade Agreement's partner countries authorities.

4. The concerned Indian Exporters may please take note of the following points with regard to the process being notified herewith:

- Digital Signature Certificate (DSC) would be required for the purpose of electronic submission. The digital signature would be the same as used in other DGFT applications;
- The digital signature may be Class II or Class III and should have the IEC of the firm embedded in the DSC;
- Any new applicant exporter would be required to initially register at the portal. The password would be sent on the email and mobile number of the IEC holder. In case the IEC holder desires to update their email on which communication is to be sent, the same may be done by using the 'IEC Profile Management' service on the DGFT website **https://dgft.gov.in**
- Once registration is completed, the IEC branch details would be auto-populated as per the DGFT-IEC database. Applicant is required to ensure that updated IEC details are available in the DGFT system. Necessary steps may be taken to modify the IEC details online, whenever required.

5. For further guidance on registration and application submission, the Help manual & FAQs may be accessed on the landing page at **https://coo.dgft.gov.in** . For any further assistance you may utilize any of the following channels:

- Raise a service request/suggestion ticket through the DGFT Helpdesk service.
- Call the toll-free DGFT Helpdesk numbers.
- Send an email to DGFT CoO Helpdesk at **coo-dgft@gov.in.**

This issues with the approval of the competent authority.

File No.01/02/82/AM-19/EDI

Md Moin Afaque, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

CBIC notifies New Exchange Rates w.e.f. 19th February 2021 - reg.

Notification No.18/2021-Customs (N.T.), dated 18th February, 2021

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.14/2021-Customs(N.T.), dated 4th February, 2021 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 19th February, 2021**, be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	57.70	55.30
2.	Bahraini Dinar	199.70	187.00
3.	Canadian Dollar	58.40	56.30
4.	Chinese Yuan	11.45	11.10
5.	Danish Kroner	12.00	11.55
6.	EURO	89.25	86.10
7.	Hong Kong Dollar	9.55	9.20
8.	Kuwaiti Dinar	248.85	232.90
9.	New Zealand Dollar	53.70	51.35
10.	Norwegian Kroner	8.70	8.40
11.	Pound Sterling	102.65	99.15
12.	Qatari Riyal	20.65	19.40
13.	Saudi Arabian Riyal	20.05	18.80
14.	Singapore Dollar	55.80	53.90
15.	South African Rand	5.10	4.80
16.	Swedish Kroner	8.90	8.60
17.	Swiss Franc	82.65	79.40
18.	Turkish Lira	10.75	10.10
19.	UAE Dirham	20.50	19.20
20.	US Dollar	73.70	72.00

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	70.10	67.50
2.	Korean Won	6.80	6.40

F.No. 468/01/2021-Cus.V

Bullo Mamu, Under Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Increase in Export

Lok Sabha Unstarred Question No: 252

Shri Gopal Chinayya Shetty:

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

(a): whether export has increased during recent times;

(b): if so, the time by which this increase has been recorded;

(c): whether the Government has prepared any outline to increase exports; and

(d): if so, the details thereof?

Answered on 3rd February 2021

A. (a) & (b): The value of India's overall exports (merchandise and services) during first eight months of the current financial year, April-November 2020, was US$ 304.53 billion as compared to US$ 351.83 billion during same period of the previous year, showing a negative growth of 13.45%. During this period, India's overall exports were US$ 44.87 billion in September 2020 as compared to US$ 43.56 billion in September 2019, showing a positive growth of 3%. Merchandise exports were US$ 27.1 billion in December 2020, showing a positive growth of 0.14% as compared to the corresponding month of the previous year.

(c) & (d): Policy making is an ongoing exercise and steps are taken based on the prevailing economic scenario. 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): A 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)

Exports from India

Lok Sabha Unstarred Question No: 248

Shri Dhanush M Kumar:

Shri B Y Raghavendra:

Shri Gajanan Chandrakant Kirtikar:

Shri C N Annadurai:

Shri Gautham Sigamani Pon:

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

(a): the current status of India's exports during April-November in the year 2020;

(b): the details of total export of various commodities, sector-wise during the same period indicating rate of export;

(c): whether the Union Government has extended any assistance/ incentives/facilities to the various States including Tamil Nadu, Karnataka and Maharashtra for creating appropriate infrastructure for the development and growth of exports during the last three years and the current year, if so, the details of contribution made by the State of Maharashtra in the total export of the country during the said period, State/UT-wise;

(d): whether the Government is in the process to diversify the export sectors/destinations and review the ongoing export promotion schemes being implemented; and

(e): the other steps taken by the Government to achieve export target of a trillion-dollar by 2025?

Answered on 3rd February 2021

A. (a) & (b): The value of India's overall exports (merchandise and services) during April-November, 2020 was US$ 304.53 billion as compared to US$ 351.83 billion during April-November, 2019 showing a negative growth of 13.45%. Sector-wise/major commodity-wise details of India's exports during April-November, 2020 along with the percentage change over the corresponding period of the previous year are at Annexure-I*.

(c): The Union Government has provided Rs 245.35 crore during last three years and the current year financial assistance under Trade Infrastructure for Export Scheme (TIES) for projects located in various States/UTs including Tamil Nadu, Karnataka and Maharashtra. The details are at Annexure-II*. Out of India's total merchandise export during April-November, 2020, Maharashtra's export is US$ 33.93 billion (with 19.48% share). The State/ UT-wise share in merchandise exports during last three years and current year is at Annexure-III* and State/UT-wise percentage growth of merchandise exports during last three years and current year is at Annexure-IV*.

(d) & (e): Review of policy is an ongoing exercise and steps are taken based on the prevailing economic scenario. The Government has taken the following key steps to diversify the export sectors/ destinations and increase exports:

(1): The mid-term review of the current Foreign Trade Policy (2015-20) was carried out in December 2017.

(2): Foreign Trade Policy (2015-20) extended by one year i.e. upto 31.03.2021 due to the COVID-19 pandemic situation.

(3): Interest Equalization Scheme on pre and post shipment rupee export credit has also been extended by one year i.e. upto 31.03.2021.

(4): A new Scheme, Remission of Duties and Taxes on Exported Products (RoDTEP), has been launched with effect from 01.01.2021.

(5): Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase FTA utilization by exporters.

(6): A 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.

(7): Promoting and diversifying services exports by pursuing specific action plans for the 12 Champion Services Sectors.

(8): 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.

(9): Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

(10): 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)

(*Annexures I to IV not reproduced here)

Export by Pharmaceutical Manufacturers

Lok Sabha Unstarred Question No: 260

Dr Amol Ramsing Kolhe:

Dr Sunil Dattatray Tatkare:

Shri Kuldeep Rai Sharma:

Dr Subhash Ramrao Bhamre:

Shri D N V Senthilkumar S:

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

(a): whether majority of small and medium pharmaceutical manufacturers in the country are working for bigger pharmaceutical units which export pharmaceutical products under their brand names;

(b): if so, whether there is any proposal to boost the exports of pharmaceutical products by small and medium Pharmaceutical manufacturers under their own brands under Atmanirbhar Bharat initiative;

(c): whether the export of pharmaceutical items from India have declined drastically and if so, the details thereof and the reasons therefor and the steps taken to overcome it;

(d): the present policy of the Government on Foreign Direct Investment(FDI) in the Pharmaceutical sector; and

(e): whether the Government has any regulations for the export of pharmaceutical products and if so, the details thereof and the extent to which these regulations have impacted the volume of exports from the country?

Answered on 3rd February 2021

A. (a) & (b): Manufacturers are required to obtain a license for manufacturing drugs for export from the concerned State Licensing Authority (SLA) under the provision of Drugs and Cosmetic Act, 1940 and Rules made there under. Further, the manufacturer is required to meet the requirements of the importing country.

In the global Pharma supply chain, there are Small, Medium and large manufacturers from India, who are engaged at different levels of the value chain. The measures taken by Government of India to promote exports, including those of small and medium pharmaceutical manufacturers, include various schemes under the Foreign Trade Policy (FTP), assistance under the Market Access Initiative (MAI) scheme, setting up district export hubs, Transport and Market Assistance Scheme etc. Trade delegations/buyer-seller meets with various countries are regularly organized for the benefit of exporters. Airfare support is also provided to the exporters with a turnover of Rs.30 crore and below to encourage participation in business delegations/trade fairs.

(c): India's exports of Pharmaceutical products have not declined and they are growing consistently. During the year 2019-20, India's exports of Pharmaceuticals were USD 20.58 billion with a growth rate of 7.57% over the previous year. Total Pharma exports during Apr-Dec 2020-21 were USD 17.57 billion, registering a growth rate of 12.43% over the same period of the previous year.

(d): As per the extant FDI Policy, 100% foreign investment is allowed under the automatic route in Medical Devices. Foreign investments in pharmaceuticals in Greenfield projects are allowed upto 100% under the automatic route and for Brownfield pharmaceutical projects, foreign investment beyond 74% to up to 100% Government approval is required.

(e): The manufacturers are required to obtain license for manufacturing of drugs for export under the provision of Drugs and Cosmetic Act, 1940 and Rules made there under. The current policy pertaining to the pharmaceuticals products is outlined in chapter 30 of the ITC(HS) Export Policy 2018. Currently, restrictions are placed on export of RT-PCR Kits, VTM Kits, RNA Extraction kits and 12 other laboratory reagents in the context of COVID-19 in accordance with Notification No. 09/2015-2020 dated 10th June 2020.

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

In Rajya Sabha

R&D to reduce dependence on China in Pharma Sector

Rajya Sabha Unstarred Question No. 528

Shri Vaiko:

Q. Will the **MINISTER OF CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the percentage of total imports and quantity of basic formulations and ingredients imported from Chinain the pharmaceutical sector in the last three years and the current year, up to 31st December, 2020;

(b) whether any efforts have been made in research and development (R&D) field to manufacture basic

formulations within the country to reduce dependence on China in pharma sector;

(c) if so, the details thereof including amount being spent on R & D in the country; and

(d) whether any other source of supply was explored as an alternative to China?

Answered on 5th February, 2021

A. (a) As per Central Drugs Standard Control Organization (CDSCO), many raw materials are imported from China, for manufacturing of medicine. As per available data from the various Port Offices of CDSCO, the details of the percentage of raw materials imported from China are as under:-

Year	Percentage (in terms of value)
2017	68.62%
2018	66.53%
2019	72.40%
2020	72.15%

However, drug formulations are not imported in significant number from China.

(b) & (c): The Department does not maintain information regarding Research and Development (R&D) expenditure regarding manufacture of basic formulations within the country.

(d): As per CDSCO, under the provisions of the Drugs and Cosmetics Rules, 1945 various sites of different countries are registered by the CDSCO for import of various Active Pharmaceutical Ingredients (API) which are used in manufacture of drug formulations in the country. CDSCO is reviewing all such applications for import of APIs in an expeditious manner for which India is highly dependent on China.

Minister in the Ministry of Chemicals & Fertilizers Shri D V Sadananda Gowda

Making Pharmaceutical companies Atmanirbhar

Rajya Sabha Unstarred Question No. 529

Shri A Vijayakumar:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the steps taken to make pharmaceutical companies atmanirbhar in the country;

(b) whether the raw materials for pharma sector are mainly imported; and

(c) the steps taken to increase indigenous resources in pharma sector?

Answered on 5th February, 2021

A. (a) & (c): To make pharmaceutical companies atmanirbhar, Department of Pharmaceuticals is implementing two schemes for promoting domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in the country.

(I) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India: Under the scheme, financial incentive will be given for manufacturing of 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940 crore.

(II) Scheme for Promotion of Bulk Drug Parks: This scheme provides for grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs.1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total outlay of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).

The detailed guidelines of the above-mentioned schemes are available on the website **(http://pharmaceuticals.gov.in)** of the Department of Pharmaceuticals.

(b): Yes, Sir.

Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

Production linked incentive scheme for API production

Rajya Sabha Unstarred Question No. 533

Shri K C Ramamurthy:

Q. Will the **MINISTER OF CHEMICALS AND FERTILIZERS** be pleased to state:

(a the details of Production-Linked Incentive scheme being implemented for manufacture of Active Pharmaceutial Ingredients (APIs) in the country;

(b) whether the Ministry has made any request to the Ministry of Finance or GST Council to bring down 18 per cent GST on the manufacture of APIs to 5 per cent as requested by the pharma industry; and

(c) if so, the details thereof?

Answered on 5th February, 2021

A. (a) This Department runs a scheme namely 'Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India' which intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs. The financial incentive under the scheme is provided on sales of 41 identified products in four different Target Segments for a period of six (06) years. The tenure of the scheme is from financial year 2020-21 to 2029-30 with the total financial outlay of Rs.6,940 crore. The Government has already approved five applications under Target Segment-1.

(b) to (c): All the suggestions received from Pharma and Medical Device industry Associations in respect of direct and indirect taxes are duly sent to Ministry of Finance for their consideration.

Minister in the Ministry of Chemicals and Fertilizers (Shri D V Sadananada Gowda)

Regulating cost of cancer medicines

Rajya Sabha Unstarred Question No. 536

Lt.Gen (Dr) D P Vats (Retd.):

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether Government is aware that the number of cancer patients in the country is increasing steadily and it is expected to increase in future;

(b) whether Government is also aware that the medicines for cancer are still very expensive, if so, what steps are being taken by Government in the interest of cancer patients; and

(c) if so, the details thereof and if not, the reasons therefor?

Answered on 05th February, 2021

A. (a) As per the latest National Cancer Registry Programme Report (NCRP) of Indian Council of Medical Research (ICMR) under Ministry of Health & Family Welfare for the year 2020, the annual figures of estimated incidence and mortality of cancer cases are as under:

Year	2017	2018	2019
Estimated incidence of cancer cases	12,92,534	13,25,232	13,58,415
Estimated Mortality of cancer cases	7,15,010	7,33,139	7,51,517

Further, the projected number of incidences of cancer cases in the country is 15.7 lakhs for the year 2025.

(b) & (c): The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling prices of 86 anti-cancer scheduled formulations under the National List of Essential Medicines, 2015 (NLEM, 2015). Further, the NPPA, vide order S.O. 1041(E) dated 27th February, 2019 put a cap on Trade Margin of 42 select non-scheduled anti-cancer medicines under 'Trade Margin Rationalisation' Approach. By this approach, the Maximum Retail Price (MRP) of 526 brands of these medicines have been reduced by upto 90%. This move resulted in annual savings of around Rs. 984 crore to the patients. The details of revised prices are available on website of NPPA, i.e., **nppaindia.nic.in.**

Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

IIT Madras Researchers identify a high-yielding alternative source for anti-cancer drug Camptothecin

Researchers at the Indian Institute of Technology Madras have identified a sustainable and high-yielding alternative source for the anti-cancer drug Camptothecin. This novel microbial fermentation process can be an economically-efficient method of production to fulfill the market demand at large scale.

Topotecan and Irinotecan are two widely used anticancer drugs, which are produced by using Camptothecin as the lead molecule. More than a dozen derivatives and conjugates of Camptothecin are under various stages of Clinical Trials for anti-cancer applications.

Camptothecin is an alkaloid isolated from the Chinese tree Camptotheca acuminata and the Indian tree Nothapodytes nimmoniana. Nearly 1,000 tons of plant material is required to extract just one ton of Camptothecin. Due to extensive overharvesting to meet the market demand both these plants are now critically endangered. The N nimmoniana population has seen more than a 20% decline in the last decade alone.

Camptothecin, the third most in-demand alkaloid, is commercially extracted in India from the endangered plant, Nothapodytes nimmoniana. Endophytes, the microorganisms that reside within plants, are reported to have the ability to produce host-plant associated metabolites. Hence, this research aims to establish a sustainable and high Camptothecin yielding endophyte, as an alternative source for commercial production of Camptothecin.

IIT Madras Researchers have now developed an alternative method of Camptothecin production to meet the demand and conserve the natural sources. To this effect, they developed a microbial fermentation process that can be an economically efficient and sustainable method of production to fulfil the market demand at large scale.

The research was led by Dr Smita Srivastava, Associate Professor, Department of Biotechnology, IIT Madras. This work was recently published in the reputed peer-reviewed international Journal of Scientific Reports (a Nature Research Publication).

Highlighting the applications for this research, Dr Smita Srivastava, Associate Professor, Department of Biotechnology, IIT Madras, and the Principal Investigator of the study, said, "The novelty of the work lies in the fact that unlike other potential microbial strains reported, this strain has been found to show sustainable production even beyond 100 generations."

Cancer has been a leading cause of death worldwide including in India. It is projected that by 2026, the new cancer cases in India annually would reach 0.93 million in male and 0.94 million in female patients, according to a study published in Asian Pacific Journal of Cancer Prevention.

Speaking about the applications of this research, Professor, Suresh Kumar Rayala, Department of Biotechnology, IIT Madras, said, "Preliminary investigations on breast cancer, lung cancer, ovarian cancer and colorectal cancer cell lines revealed that the microbial extract demonstrates a potent cytotoxic effect on lung cancer (H1299), ovarian cancer (SKOV3) and colorectal cancer (HT29; Caco-2) cell lines, comparable to the standard Camptothecin."

Khwajah Mohinudeen, an IIT Madras Ph.D., Research Scholar who worked on this study, said, "Researchers from the Plant Cell Bioprocessing Laboratory at IIT Madras have been able to successfully isolate the highest-yielding strain of Camptothecin reported to date with sustainable production up to reactor level. In addition to isolating a novel microbial source for bioprocess development for the large scale production of Camptothecin, we have also come up with a rapid screening technique for isolation of high Camptothecin yielding microbial strains from plants."

Source: Pharmabiz, 27.02.2021

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JNCASR researchers develop potential drug candidate for Alzheimer's disease

Researchers from the Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bengaluru, an autonomous institute under the Department of Science & Technology (DST), have developed a small molecule that disrupts the mechanism through which neurons become dysfunctional in Alzheimer's disease (AD).

The molecule could be a potential drug candidate to halt or cure the leading cause of dementia (70-80 percent) worldwide. In the Alzheimer's brain, abnormal

levels of naturally forming protein clump together to form plaques that collect between neurons and disrupt cell function. This is caused by production and deposition of the amyloid peptide (Aß) that accumulates in the central nervous system. The multifactorial nature of Alzheimer's disease attributed to multifaceted amyloid toxicity has kept researchers from developing effective treatment.

Professor T Govindaraju, along with his team from JNCASR, have designed and synthesized a set of novel small molecules and identified a lead candidate which they found could reduce the toxicity of Amyloid Beta (Aß) toxicity.

The currently available treatments provide only temporary relief, and there are no approved drugs that directly act on the disease mechanisms of Alzheimer's disease. Thus, there is an unmet need to develop drug candidates to halt or cure Alzheimer's disease, said the statement.

Alzheimer's disease severely affects the patients, families, caregivers and hence is a major societal and economic burden globally. The novel drug candidate TGR63 developed by the JNCASR team has potential as a promising drug candidate for AD treatment, it further added.

The detailed studies established the molecule called TGR63 as the lead candidate to rescue neuronal cells from amyloid toxicity. Remarkably, the molecule was also found to reduce amyloid burden in the cortex and hippocampus, or a complex part embedded deep into the temporal lobe, thereby reversing cognitive decline.

Mice brain affected with Alzheimer's disease when treated with TGR63 showed a significant reduction of amyloid deposits, validating its therapeutic efficacy. The mice also showed reduction of learning deficiency, memory impairment, and cognitive decline as revealed by distinct behavioural tests. These key attributes have validated the potential of TGR63 as a promising drug candidate for the treatment of AD.

Source: Pharmabiz, 25.02.2021

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Researchers reveal genetic predisposition to severe COVID-19

HSE University researchers have become the first in the world to discover genetic predisposition to severe COVID-19. The results of the study were published in the journal Frontiers in Immunology.

T-cell immunity is one of the key mechanisms used by the human body to fight virus infections. The staging ground for cell immunity development is the presentation of virus peptides on the surface of infected cells. This is followed by activation of T lymphocytes, which start to kill the infected cells. The ability to successfully present virus peptides is largely determined by genetics. In human cells, human leukocyte antigen class I (HLA-I) molecules are responsible for this presentation.

The set of six such molecules is unique in every human and is inherited from an individual's parents. In simple terms, if the set of alleles detects the virus well, then the immune cells will detect and destroy the infected cells fast; if a person has a set that is bad at such detection, a more severe case of disease is more likely to be observed.

Researchers from the HSE Faculty of Biology and Biotechnology - Maxim Shkurnikov, Stepan Nersisyan, Alexei Galatenko and Alexander Tonevitsky -together with colleagues from Pirogov Russian National Research Medical University and Filatov City Clinical Hospital (Tatjana Jankevic, Ivan Gordeev, Valery Vechorko) studied the interconnection between HLA-I genotype and the severity of COVID-19.

Using machine learning, they built a model that provides an integral assessment of the possible power of T-cell immune response to COVID-19: if the set of HLA-I alleles allows for effective presentation of the SARS-CoV-2 virus peptides, those individuals received low risk score, while people with lower presentation capability received higher risk scores (in the range from 0 to 100). To validate the model, genotypes of over 100 patients who had suffered from COVID-19 and over 400 healthy people (the control group) were analysed. It turned out that the modelled risk score is highly effective in predicting the severity of COVID-19.

In addition to analysing the Moscow population, the researchers used their model on a sample of patients from Madrid, Spain. The high precision of prediction was confirmed on this independent sample as well: the risk score of patients suffering severe COVID-19 was significantly higher than in patients with moderate and mild cases of the disease.

"In addition to the discovered correlations between the genotype and COVID-19 severity, the suggested approach also helps to evaluate how a certain COVID-19 mutation can affect the development of T-cell immunity to the virus.

For example, we will be able to detect groups of patients for whom infection with new strains of SARS-CoV-2 can lead to more severe forms of the disease," Alexander Tonevitsky said.

(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: National Research University Higher School of Economics, EurekAlert, 23.02.2021

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Researchers discover potential new therapeutic targets on SARS-CoV-2 Spike protein

The COVID-19 pandemic has prompted considerable investigation into how the SARS-CoV-2 Spike protein attaches to a human cell during the infection process, as this knowledge is useful in designing vaccines and therapeutics. Now, a team of scientists has discovered additional locations on the Spike protein that may not only help to explain how certain mutations make emerging variants more infectious but also could be used as additional targets for therapeutic intervention.

"Significant research is underway to examine how the Receptor Binding Domain (RBD) at the tip of the club-shaped SARS-CoV-2 Spike protein attaches to an ACE2 receptor on a human cell, but little is known about the other changes that occur in the Spike protein as a result of this attachment," said Ganesh Anand, Associate Professor of Chemistry, Penn State. "We have uncovered 'hotspots' further down on the Spike protein that are critical for SARS-CoV-2 infection and may be novel targets beyond the RBD for therapeutic intervention."

Anand and his colleagues used a process, called amide hydrogen-deuterium exchange mass spectrometry (HDXMS), to visualize what happens when the SARS-CoV-2 Spike protein binds to an ACE2 receptor. HDXMS uses heavy water or deuterium oxide (D2O), a naturally occurring, non-radioactive isotope of water formed from heavy hydrogen or deuterium, as a probe for mapping proteins. In this case, the team placed SARS-CoV-2 Spike protein and ACE2 receptors in heavy water and obtained footprints of ACE2 on the Spike protein.

"If you put the Spike protein and ACE2 receptor into a solution that's made with D2O, the surfaces and more floppy regions on both proteins will more readily exchange hydrogens for deuterium, compared to their interiors," said Anand. "And footprints of each protein on the binding partner can be readily identified from areas where you see little deuterium and only detect normal hydrogen."

Using this technique, the team determined that binding of the Spike protein and ACE2 receptor is necessary for furin-like proteases - a family of human enzymes - that act to snip off the tip, called the S1 subunit, of the Spike protein, which is the next step in the virus's infection of the cell. The findings published on February 8 in the *journal eLife.*

"The Spike proteins on the surface of the virus swivel to search and latch onto the ACE2 receptor," said Anand. "ACE2 can be likened to a hand holding strands of hair - the Spike protein clusters. Binding to Spike stabilizes it so it can be cut by furin protease scissors. After furin proteases clip the protein, the part that remains - the S2 subunit - is what fuses with the cell's membranes, allowing entry into the cell."

Anand noted that researchers have already learned much about how the Spike protein and ACE2 receptor bind together, but until now no one knew how this binding relayed the message to the furins to cut the protein. He explained that the phenomenon is called allostery, meaning "action at a distance."

"Our findings show ACE2 receptor binding to SARS-CoV-2 Spike protein causes long-range changes and allosterically enhances protease cutting at the distal S1/S2 cleavage site," he said. Anand said that researchers are currently focusing only on therapeutics that block the Spike protein from binding to the ACE2 receptor.

"In this paper, we're suggesting that's not the only vulnerability that can be targeted," he said. "May be the S1/S2 cleavage that is necessary for furin cleavage can serve as a new target for inhibitory therapeutics against the virus. This study also may help in explaining how mutations in emerging variants might alter dynamics and allostery of ACE2 binding, potentially increasing infectiousness of the SARS-CoV-2 virus."

Source: World Pharma News, 22.02.2021 (Excerpts)

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Antibody response may drive COVID-19 outcomes

COVID-19, the source of the current pandemic, may be caused by a single virus, but it has a variety of presentations that make treatment difficult. Children, for example, almost exclusively experience mild or asymptomatic COVID-19, while adults can develop severe or even fatal COVID-19. But children who contract COVID-19 are at risk for a rare but serious syndrome called Multisystem Inflammatory Syndrome in Children (MIS-C). Severe cases of MIS-C can lead to cardiac disease and ventricular failure, and require hospitalization and intense medical support.

Researchers Galit Alter, Ph.D, core member of the Ragon Institute of MGH, MIT and Harvard, and Lael Yonker, MD, Director of the Massachusetts General Hospital Cystic Fibrosis Center, are working to understand why COVID-19 can lead to such distinctly different outcomes in different populations. In a study recently published in Nature Medicine, they and their team identified specific types of antibodies that may be driving these different responses, including one specific to severe disease in adults and another specific to MIS-C in children.

"We noticed children who developed MIS-C after COVID disease or exposure had high levels of a specific type of antibody called IgG," says Yonker. "Normally, IgG acts to control an infection, but with MIS-C, the IgG is triggering activation of immune cells, which may be driving the severe illness seen in MIS-C."

Specifically, explains Yonker, IgG antibodies interact with cells called macrophages, which live throughout the body's tissues. If there are too many IgG bodies activating these macrophages, this could cause inflammation in many different organs and systems, which is seen in MIS-C. These high levels of IgG antibodies were only found in children who developed MIS-C after contracting or being exposed to COVID-19.

Yonker, a pediatric pulmonologist at MGH and Assistant Professor at Harvard Medical School (HMS), runs a biorepository that collects samples from pediatric cystic fibrosis patients. When the pandemic hit, she began to collect samples from children with mild cases of COVID-19. When Yonker and other pediatricians began seeing children hospitalized with what is now called MIS-C, which typically onsets three to six weeks after developing COVID-19, she quickly began collecting those samples too. She wanted to understand how a mild case of COVID-19 could lead to severe MIS-C weeks after recovery.

Seeking a detailed understanding of the immune response, Yonker teamed up with Alter, who is also a Professor at HMS and an immunologist in the Department of Infectious Diseases at MGH. Alter's team used her unique "systems serology" technology to carefully perform a detailed comparison of the immune responses in children--17 with MIS-C and 25 with mild COVID-19--to the responses of 26 adults with severe disease and 34 adults with mild disease.

"We were expecting the children's immune responses to look drastically different from the adults', regardless of the severity of disease," says Alter. "But instead, we found that adults with mild COVID-19 and children with COVID-19 had remarkably similar immune responses. It was only the adults with severe COVID-19 whose immune responses looked different."

For adults with severe COVID-19, Alter explains, they saw increased levels of IgA antibodies, which interact with a type of immune cells called neutrophils and cause the neutrophils to release cytokines. If there are too many IgA antibodies, the neutrophils may be pushed to release too many cytokines, which could contribute to a cytokine storm, one of the symptoms of severe COVID-19.

In both cases, the study shows, it may be a high level of a specific type of antibody causing the disease severity. "In MIS-C, high levels of IgG antibodies may be activating macrophages, which can drive inflammation in organs throughout the body," says Yannic Bartsch, Ph.D, the study's first author and a research fellow at the Ragon Institute. "In adults with severe COVID-19, high levels of IgA antibodies could be driving neutrophils to release too many cytokines, with the potential of causing a cytokine storm."

Identifying the immune mechanisms of multiple, distinct responses to the same virus is the first step to understanding why it mounts different responses in divergent populations. Discovering how the immune system's response shapes the disease and its outcome in both children and adults can help researchers develop treatments that can prevent or modulate the immune response, keeping its protective functions but lessening the unintentional, yet harmful, ones.

Source: Massachusetts General Hospital, Science Daily, 18.02.2021

Could a Nasal Spray Prevent Coronavirus Transmission?

A nasal antiviral created by researchers at Columbia University Vagelos College of Physicians and Surgeons blocked transmission of SARS-CoV-2 in ferrets, suggesting the nasal spray also may prevent infection in people exposed to the new Coronavirus, including recent variants.

The compound in the spray - a lipopeptide developed by Matteo Porotto, Ph.D, and Anne Moscona, MD, Professors in the Department of Pediatrics and Directors of the Center for Host-Pathogen Interaction - is designed to prevent the new Coronavirus from entering host cells.

The antiviral lipopeptide is inexpensive to produce, has a long shelf-life, and does not require refrigeration. These features make it stand out from other antiviral approaches under development, including many monoclonal antibodies. The new nasal lipopeptide could be ideal for halting the spread of COVID in the United States and globally; the transportable and stable compound could be especially key in rural, low-income, and hard-to-reach populations. *(The study published in Science on February 17).*

Ferrets a model for respiratory diseases:

Ferrets are often used in studies of respiratory diseases because the lungs of these animals and humans are similar. Ferrets are highly susceptible to infection with SARS-CoV-2, and the virus spreads easily from ferret to ferret.

In this study, carried out in collaboration with Rory de Vries, Ph.D, and Rik de Swart, Ph.D, at Erasmus in the Netherlands, 100% of the untreated ferrets were infected by their virus-shedding cagemates, approximating a setting like sharing a bed or close living conditions for people.

Porotto and Moscona have previously created similar lipopeptides--small proteins joined to a cholesterol or tocopherol molecule--to prevent infection of cells by other viruses, including measles, parainfluenza, and Nipah viruses. These anti-viral compounds have been challenging to bring to human trials, in large part because the infections they prevent are most prevalent or serious in low-income contexts.

When SARS-CoV-2 emerged, the researchers adapted their designs to the new Coronavirus, collaborating with Christopher Alabi, Ph.D, at Cornell University. "One lesson we want to stress is the importance of applying basic science to develop treatments for viruses that affect human populations globally," Moscona and Porotto say. "The fruits of our earlier research led to our rapid application of the methods to COVID-19."

A paper describing a first generation of the compound and its effect in a 3D model of the human lung first appeared in the journal mBio on October 20. In this human lung model, the compound was able to extinguish an initial infection, prevent spread of the virus within the lung, and was not at all toxic to the airway cells.

Lipopeptides prevent viruses from infecting cells:

The lipopeptides work by preventing a virus from fusing with its host's cell membrane, a necessary step that enveloped viruses, including SARS-CoV-2, use to infect cells. To fuse, the new Coronavirus unfolds its spike protein before contracting into a compact bundle that drives the fusion.

The compound designed by Porotto and Moscona recognizes the SARS-CoV-2 spike, wedges itself into the unfolded region, and prevents the spike protein from adopting the compact shape necessary for fusion.

In the ferret experiments at Erasmus, the lipopeptide was delivered into the noses of six ferrets. Pairs of treated ferrets were then housed with two control ferrets that received a saline nasal spray and one ferret infected with SARS-CoV-2.

After 24 hours of intense direct contact among the ferrets, tests revealed that none of the treated ferrets caught the virus from their infected cagemate and their viral load

was precisely zero, while all of the control animals were highly infected.

Lipopeptides are effective against variants:

Public health officials are concerned about the emergence of several SARS-CoV-2 variants, which appear to be more transmissible and deadly, and could be more adept at evading the antibodies generated by current therapies and vaccines available.

Porotto and Moscona tested the lipopeptide on cells infected with a range of SARS-CoV-2 variants, including B.1.1.7 and B.1.351, and found that the compound prevented the spike protein of all variants from fusing with the cell membrane as effectively as the dominant strain.

Lipopeptides are easily administered:

Porotto and Moscona propose these peptides could be used in any situation where an uninfected person would be exposed, whether in a household, school, health care setting, or community.

"Even in an ideal scenario with large segments of the population vaccinated--and with full trust in and compliance with vaccination procedures--these antivirals will form an important complement to protect individuals and control transmission," Moscona and Porotto say. People who cannot be vaccinated or do not develop immunity will particularly benefit from the spray.

The antiviral is easily administered and, based on the scientists' experience with other respiratory viruses, protection would be immediate and last for at least 24 hours.

The scientists are conducting advanced studies on transmission in animal models and on production and formulation of the peptide. They hope to bring this preventative approach to human clinical trials soon, with the ultimate goal of deploying the therapy to help contain transmission during this pandemic and to support preparedness for future emerging strains and pandemics.

Source: Hina Zahid, Medical Dialogues, 23.02.2021 (Excerpts)

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Industry welcomes PLI 2.0 Scheme, awaits implementation details

Stakeholders highlight that this scheme will help play to our strengths, work towards making the pharma industry more self-reliant, generate employment and usher more affordability in healthcare.

The Union Cabinet's decision to approve the Production Linked Incentive (PLI) 2.0 Scheme for Pharma has been appreciated by the industry and its stakeholders await implementation details. Ramesh Swaminathan, Chief Financial Officer and Head Corporate Affairs, Lupin said, "The scheme provides for a greater thrust on innovation, development of complex and high tech products including emerging technologies.

It would go a long way in making this sector a truly global one in terms of size and stature by paving the way for a marked shift from commodity generics into a truly technology-heavy industry dealing with the latest technologies for patented products across various frontiers of science. This would help us to play to our strengths of a young, well-educated workforce harnessing cutting edge technologies for the progress of mankind as well as the country. We eagerly await finer details of the scheme."

Mr B R Sikri, Chairman, FOPE, and Vice President, BDMA said, "We are very happy that the Government of India has announced PLI II Scheme in the shortest time possible. This will boost domestic production as well as the availability of molecules for overseas markets. The basic Guidelines are yet to come which will clarify the investment criteria. On the whole, it will benefit the Consumer because there will be excess availability of products and competition among Pharma manufacturers."

Mr Mahesh Doshi, National President, IDMA commented, "On behalf of the industry, we welcome the announcement of approval from the Cabinet of PLI II Scheme. We are waiting for further details of scheme implementation. Certainly, this move will benefit the patient and also give a further boost to *Aatmanirbhar Bharat*. With this initiative, it will make our country self-reliant in intermediates and APIs."

"Great intervention by Modi Government at the right time to encourage competition in the Parma sector by announcing PLI 2.0, which should bring down the prices and make healthcare more affordable and accessible under *Ayushman Bharat* and National Health Mission," said Prof Bejon Kumar Misra Founder Patient Safety and Access Initiative.

He further added, "The States should learn from the PLI 1.0 so that they can improve on the infrastructure like more Pharma and Medical Devices Parks to enable existing units to expand, Startups and Entrepreneurs to enter the business and go global in the interest of consumers".

Vivek Padgaonkar, Independent Healthcare Consultant Former-Director, OPPI (Project & Policy), Former GSK (Sales & Marketing) expressed, "The cabinet has now approved the Production Linked Incentive (PLI) Scheme II to incentivise the Indian API industry to invest in the manufacture of APIs, KSMs, and DIs. This is a step towards self-reliance and the industry must appreciate the speed with which the Government has worked to bring PLIs into existence.

While the Government expects entrepreneurs to set up new units for the identified APIs, KSMs and DIs the disbursement of the incentives will be from the second year onwards for chemical APIs and from the third year onwards for fermentation-based ones. However, setting up a unit in India takes much longer, due to delays in getting approvals and permissions from several regulatory bodies like the Pollution Control Board and departments connected with the project."

He recommended that the Government should also look into the following:

- ***Anti-dumping APIs:***

Government will not enter into Economic Partnership Agreements and Free Trade Agreements with other countries, enabling producers therein to dump APIs and raw materials into India, even though they are being produced under the PLI Scheme.

- ***Fiscal measures:***

  (i) Government will not bring any fiscal measures which will dilute the profitability of the setup units.

  (ii) Eliminate fiscal measures by ensuring that GST is made comprehensive by bringing into its fold five petroleum products, electricity, etc.

"Over a seven-year-period, over which the PLI Scheme will payout incentives, it can support the production of about Rs.47,364-crore (assuming an average capacity utilization of 80 percent). This will perhaps offer a healthy

return on Government investment of Rs.6,940-crore, even without considering the additional tax revenue (direct and indirect, including GST) that will accrue to the Government's kitty.

However, from the industry point of view, the incentive amount may not appear to be significant. The total incentive of Rs.6,940-crore being offered to new units over the seven-year-period works out to about less than 15 percent of the turnover likely over the seven years – or about two percent annually.

Considering, the new project starts delivering a minimum of two years from now, and the incentive amount will be paid out from year 3-10, the amount will be eroded by inflation. So, the industry cannot afford to rely on subsidies to ensure competitiveness, but must look to inherent strengths stemming from lowering the project costs, improving the timelines of project implementation, reducing operating costs, use of latest techniques and technologies," added Padgaonkar.

Source: Usha Sharma, Express Pharma, 25.02.2021

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Indian Pharma must grow at 12% CAGR to be $130 billion in size by 2030

The Indian pharmaceutical industry has to reinvent and undertake fundamental reforms to achieve the ambitious target of $130 billion in size by 2030, said a EY-FICCI vision report. To reach that target from the current $42 billion, the Indian pharmaceutical industry will require to double the last decade's growth rate of 6% to 12%. Though the Pharma industry has grown at a Compounded Annual Growth Rate (CAGR) of approximately 13% over the two decades, in the last decade it was 8.5% and has been lower at 6.2% over the past five years.

The overall growth has been driven by the industry's leadership in supplying generic formulations to markets across the globe. In the 2020-2030 period, it is envisaged that the Indian Pharma industry will have to grow at a CAGR of 12% to reach $130 billion by 2030 from $41.7 billion in 2020, said the EY FICCI report titled 'Indian Pharmaceutical Industry 2021: future is now.'

India supplies over 40% of generics in the biggest Pharma market, the US, and about 25% of the prescription drugs in the UK, along with catering to over 60% of the global vaccine demand. While the global formulations trade value is about $652 billion (2019), India's share of exports in the global trade was only about 2.5%. With increased pricing pressure on the global generics trade as well as increased competition in India's established export corridors, the current portfolio of products is expected to further extend this divide. The global pharmaceutical trade is expected to reach a size of $1-1.3 trillion by 2030, the ambition is to garner a global share of 6-7% by value to attain a size of $73 billion, assessed the report.

Innovation-led Research and Development, healthcare delivery (R&D), manufacturing and supply chain, and market access are the opportunities that have emerged to accelerate the growth of Indian pharmaceutical and healthcare industry.

Accelerating research and innovation can help to move up India's share of trade in value. To meet this objective, the industry must consider setting up an overarching regulatory body and a central body to streamline research infrastructure and Financing from all Government bodies. Similarly, exploring new models for Financing R&D to increase private investments and also make available funds for high risk and long term projects, improve industry-academia collaboration and establish a strong innovation ecosystem are key to realise the growth.

Achieving equitable and sustainable healthcare with support of digital healthcare infrastructure and enabling teleconsulting and focusing on preventive healthcare are also important. The focus of manufacturing and supply chain initiatives would be to develop capabilities in Active Pharmaceutical Ingredients (API)s and enable the manufacturing of complex generics.

Besides attracting talent, it is vital to encourage and set up Pharma machine manufacturing facilities in India to lower fixed costs, enable savings in forex and reduce time to set up additional facilities. There is also a need to bolster the logistics infrastructure for connecting the key Pharma hubs in the country in order to facilitate quick and cost efficient movement of goods including cold chain facilities. Improving access to medicines and various global best practices in drug pricing and procurement models can be contextualized for developing geographies Digital marketing of Pharma products too must be considered, said the report.

Source: P B Jayakumar, Business Today, 25.02.2021

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Government working to reduce regulatory compliance burden on Pharma Sector: Sadananda Gowda

Union Minister D V Sadananda Gowda noted that the GDP is estimated by summing up the gross value of different kind of activities plus tax on products minus subsidies on these products. Photo: HT

The Government is continuously working to reduce the regulatory compliance burden on the Pharma industry in a bid to improve ease of doing business in the country, Union Minister for Chemicals & Fertilisers D V Sadananda Gowda said on Thursday, 25.02.2021.

Addressing the inaugural session of 'The India Pharma 2021 & India Medical Device 2021' event, the Minister also emphasised that the domestic Pharma industry has the capability to achieve the target of $130 billion turnover by 2030.

"Under the leadership of Prime Minister Narendra Modi, the Government continues to strive to improve the ease of doing business in the country. Vigorous effort is on to reduce the regulatory compliance burden on the (Pharma) industry," Gowda said. Minister of State for Chemicals and Fertilisers Mansukh Mandaviya said that reforms are being undertaken by the Government especially in the pharmaceutical sector.

"In ease of doing business, we have reached 79th position now from the earlier 145. In the Pharma sector, our ranking has improved to 63. So, it tells that reforms are indeed taking place in the vertical," he noted. Speaking at the event, FICCI Pharma Committee Mentor and Zydus Group Chairman Pankaj R Patel urged the Government to further liberalise the regulatory system, particularly for drug approvals.

Gowda said the country has been serving more than 200 plus countries and territories with its Pharma products and it will continue to grow in value terms. "Indian Pharma industry can achieve the ambitious target which it has set for itself, reaching an annual turnover of $130 billion by 2030. Similarly, the medical device industry in the country has the potential to grow to about $50 billion by 2025," he noted.

He further said: "Along with this growth I am sure the industry will stay committed to the noble cause of providing drugs at an affordable price to the common man." The Minister said the COVID-19 pandemic has exposed vulnerabilities of the global supply chain in the Pharma sector.

In order to take care of that, the Department of Pharmaceuticals (DoP) has launched a Production-Linked Incentive (PLI) scheme for bulk drugs and medical devices with an outlay of ₹6,940 crore and ₹3,420 crore respectively.

"We have been able to approve applications of incentives worth ₹6,564 crore already. Besides, the Cabinet has also approved another PLI scheme for the Pharma sector with an outlay of ₹15,000 crore. We want to support manufacturing units to become global champions, and penetrate the global value chain," Gowda said.

The Government wants to build domestic capabilities in high-end specialized products such as biopharmaceuticals, complex generic drugs and gene therapy drugs, he added. "We want to see India emerge as a global supplier of Active Pharmaceutical Ingredients (API) and intermediates in the future," he added. Gowda said that bulk drug and medical device parks were being set with an outlay of around ₹3,400 crore which would help in realising the vision *Aatmanirbhar Bharat.*

The Minister also sought industry participation in Government schemes like *Ayushman Bharat Yojana and Pradhan Mantri Bhartiya Janaushadhi Pariyojana.* Lauding the role played by the Pharma industry during the COVID-19 pandemic, Gowda said the initiatives have brought laurels to the country and has helped generate goodwill and respect throughout the world.

Zydus Group Chairman Pankaj R Patel said the Pharma industry can grow to USD 80-90 billion in turnover with normal growth rate but with new initiatives from the Government the industry can grow to USD 120-130 billion. To achieve that, higher allocation to healthcare is an important step, he noted.

"Encouraging investment is necessary therefore we need a policy that is clear, coherent and definite and

there should not be much tinkering with the policy. It will ensure sustainable growth for the industry," Patel said. Besides, one of the important steps would be to make a Pharma sector regulatory system of global standards, he added.

"If we want to become a world supplier on a constant basis, Indian regulatory system should be in line with the global regulatory system," Patel said. He also sought a new tax refund scheme in place of the export incentives which are no longer there.

"The API and Pharma industry faces a lot of challenges with the Pollution Control Board. We believe in a healthy environment and pollution control system, but I think expedited approval and removal of unwanted hindrances in approvals would help in the growth of the industry," Patel said. He also urged for a rethinking on important issues like pricing mechanism, support to innovation etc. Patel also sought one Ministry and one Department for the Pharma sector.

FICCI Co-Chair Medical Devices Committee and GE Healthcare South Asia President & CEO Shravan Subramanyam said that in order to achieve the universal goals and make India self-reliant, the first step is to build mutual trust and develop innovative partnership models and Integrate digital technology and tools which can bring in the needed transparency and accountability. Department of Pharmaceuticals (DoP) Secretary S Aparna termed the PLI scheme for pharmaceuticals as a game changer.

Source: PTI, The Live Mint, 25.02.2021

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Indian Healthcare takes on paperless pathway to expedite patient care and vaccination protocols

Indian healthcare is now taking on the paperless pathway to accelerate efficiency in patient care. In the wake of the COVID-19 vaccination protocols, going paperless is a booster shot to monitor the immunisation process.

The health sector which has traditionally relied heavily on paper-based processes, right from prescriptions and reports to discharge summaries and patient records, now recognises the benefits of going paperless.

For instance, one of the leading hospitals in the country opted for smart document solution with us. After the digital transformation, across leading hospitals in the country, doctors can now update patient discharge summaries and provide electronic approvals, wherever needed, through their smart phones. The hospital itself has perceived considerable improvement in operational efficiency. For example, going paperless has resulted in higher bed-turn rates. Needless to mention, they have been able to increase their savings as well with the elimination of paper, Arjit Bhargava, V P, Global Business Development, MSB Docs told.

US-based MSB Docs which is a document digitization major with an Indian presence specializes in e-signatures too. The acceptance of document digitization is seen an indispensable tool across life sciences sector making practices efficient and transparent, he added.

Smart documentation is certainly a boon for patients as well. There is reduced wait-time for admission and discharge from hospitals. A case in point is the Discharge Summary Automation. With digital documentation in place, hospital can automatically generate and route discharge documents and reports. Besides, the communication has been streamlined as barriers have been removed through custom integrations. This assumes greater importance during medical emergencies as reports can be readily accessed.

Also, documents with verified eSignatures can easily be shared for crucial health information. The web forms allow On boarding of patients as an easy task, said Bhargava. As the hunt for Covid-19 vaccine got underway, MSB Docs provided electronic notebooks to the one of the first global manufacturers. It converted the whole paper-based process into a digital signing process.

The chemists could feed in the data related to an experiment directly and the signatures from the witnesses were also achieved through an automated process. The foremost benefits of digital documentation for vaccine manufacturers and distributors have been with regard to quality assurance and control, drug discovery, Clinical Trials, risk assessment, packaging of medicines, facilitating data collection of participants and reports generation of Covid positive cases, said the company.

"What we have seen that paperless mode is a catalyst for the India COVID-19 vaccination programme. Vaccine and even drug development are ridden with cumbersome, time consuming and paper-based processes. While a number of documents need to be scanned, re-scanned, faxed etc, there is added paperwork when signatures and

attestations are to be obtained from the witnesses for proof of discovery and patent defence for a vaccine, he said.

Source: Nandita Vijay, Pharmabiz, 25.02.2021

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IPC to expand PvPI in J&K with focus on North Eastern states in phase wise manner

In order to expand Pharmacovigilance Programme of India (PvPI) in the country to register Adverse Drug Reactions (ADRs) effectively, the Indian Pharmacopoeia Commission (IPC) is planning to expand the PvPI in the Union Territory (UT) of Jammu and Kashmir (J&K) with focus on North Eastern (NE) states.

As of today, India has set up a total of 300 ADR monitoring centres (AMCs). "IPC is in the process of identifying hospitals in J&K as there are only 4 AMCs in the Union Territory (UT) of J&K," according to a senior Health Ministry Official. Intent (LoI) for prospective AMCs for voluntary reporting of ADRs due to COVID-19 drugs by healthcare professionals.

Central Drugs Standard Control Organisation (CDSCO) had launched PvPI in July 2010 with Ghaziabad-based IPC as the National Co-Ordinating Centre (NCC). As per the mandate of PvPI, pan-India ADR information will be taken forward with all district hospitals in the country and implemented at PHC and taluka level health centres. This will augment government's plan to roll out the PvPI at district level hospitals across the country.

Drug Controller General of India (DCGI) in the past had also recommended to explore possibilities of identifying district hospitals in NE states to be developed as AMCs. Medical colleges, hospitals and institutes approved by the Medical Council of India (MCI) can also act as AMCs. Once enrolled, they are assigned to efficiently collect the adverse event information from the patients, do follow up with them to check the completeness of the ADR reports.

IPC has been assigned to update information on ADRs that is being reported in India from across all its centres through Vigiflow software to the Uppsala Monitoring Centre (UMC) in Sweden, which is WHO's collaborating centre for international drug monitoring.

The Union Health Ministry has also mandated AMCs across the country to report SAEs due to medical devices as part of the Materiovigilance Programme of India (MvPI). The MvPI, being coordinated by the IPC at Ghaziabad, was launched in 2015. IPC functions as the NCC and SCTIMST in Thiruvananthapuram acts as the collaborating centre.

Technical support is being provided by the National Health Systems Resource Centre (NHSRC) in New Delhi. The purpose of the programme is to study and follow Medical Device Associated Adverse Events (MDAE) and enables dangerous ones to be withdrawn from the market.

MvPI is meant to enable safety data collection in a systematic manner so that regulatory decisions and recommendations on safe use of medical devices for India could be based on data generated in India.

Source: Shardul Nautiyal, Pharmabiz, 24.02.2021

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IPC releases Guidance document for drafting & formatting of Monographs for Indian Pharmacopoeia

The Indian Pharmacopoeia Commission (IPC) has released the Guidance Document for Drafting and Formatting of Monographs for Indian Pharmacopoeia (IP) to guide the stakeholders including drug manufacturers, analysts and academicians on drafting of drug monographs before their inclusion in the Indian Pharmacopoeia.

In this Guidance Document, emphasis has been given to elaborate IP monographs under the categories of Active Pharmaceutical Ingredients (APIs), dosage forms, pharmaceutics.

IP is a compilation of official standards for drugs manufactured and/or marketed in India. A Monograph states the quality or test parameters, the acceptance criteria and details of the tests that are to be performed to determine compliance with the criteria.

In other words, a Pharmacopoeial monograph provides a reliable basis for making an independent and objective judgement as to the quality of a pharmaceutical substance.

As IP standards are statutory, it is important that the contents of monographs are unambiguous, acceptance criteria are clearly spelt out and the methods of evaluation provide all the details for carrying out the tests and assays,

including the equipment, reagents and other ancillary materials that are to be used.

The Guidance document is a guide for drafting and elaboration of the monographs to the stakeholders of the IP especially industries, testing laboratories and academicians. The aim is to provide guidance for drafting clear unambiguous texts, with similar requirements presented in the same way in each Monograph.

The technical part of pharmacopoeia shall be broadly divided into the following sections like introduction, general chapters, reference data, general tests and general notices. The Scientific Director of the Indian Pharmacopoeia Commission shall approve this part after all the contents of the pharmacopoeia have been finalised. It shall briefly give the background to the edition and describe the salient features including the admissions and omissions from the previous edition.

The Guidance document bears a lot of relevance as there is a need for regular updation of IP to meet essential requirements for Harmonisation of analytical methods in IP with those accepted internationally keeping in view Indian scenario.

Source: Shardul Nautiyal, Pharmabiz, 23.02.2021

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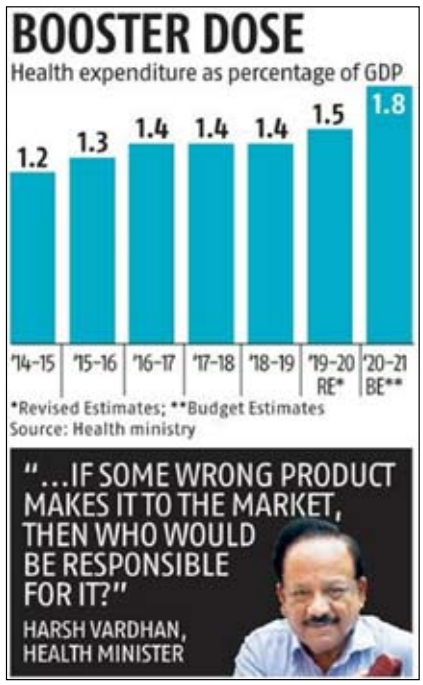
Covid-19 vaccines not ready for open-market roll-out yet, says Government

The Minister said 18-19 vaccines were in various stages of development with a few doing advance Clinical Trials

A month into the vaccination drive, which has covered more than 8.5 million so far, the Health Ministry has indicated that Covid-19 vaccines are not likely to be there in the open market anytime soon.

This is because the government is not willing to take chances with technical protocols and the responsibility of a national vaccine roll-out.

"It is emergency use authorisation and during this time it is the responsibility of the government to keep things under control. That is why it cannot be brought in the open market yet ... If some wrong product comes to the market, then who would be responsible for it?" Union Health Minister Harsh Vardhan said on Monday, 15.02.2021.



The Minister said 18-19 vaccines were in various stages of development with a few doing advance Clinical Trials.

With India likely to start vaccination in March for those above 50, the expert group on vaccines is in the process of finalising the details for this phase, including whether it would be gratis or come at a particular price.

"There is no clear-cut decision in this matter yet. The strategy for the next 270 million is being deliberated by the expert group," the Health Minister told reporters.

On whether emergency use authorisation will be converted into regular market authorisation for the two vaccines, Vardhan said: "There will be an appropriate time for that as well ... All over the world vaccines are currently under emergency use."

He said the Prime Minister had met the Chief Ministers of some states and sought their feedback on the matter. The government is bearing the cost of vaccination for 10 million health functionaries and 20 million front line workers.

The Finance Ministry had allocated Rs. 35,000 crore for vaccination with the assurance that more would come as required.

Expenditure on health as a percentage of GDP has gone up from 1.5 percent in 2019-20 to 1.8 percent in 2020-21, the Health Ministry said.

The committee of experts is yet to finalise the details of vaccinating those with co-morbidities, such as the diseases that would be covered and given priority for the jab.

The Health Minister also said there had been no serious or severe adverse event or death because of the vaccine.

"The smallest of adverse events are being recorded. No death has been found attributable to the vaccine. Even the routine side-effects are negligible. I want to assure the people that vaccines in the public domain are safe and immunogenic," the Health Ministry said.

According to the World Health Organization (WHO) data, in 2020, besides Covid, 60 outbreaks were tackled around the world.

The Indian Council of Medical Research has investigated 1,240 regional outbreaks in the past six years. "We have observed that many other infections dropped because of wearing the mask," Vardhan said.

In the past 28 days there have been no new Covid cases in 76 districts, no fresh cases for the past two weeks in 34 districts, and no new cases for the past 21 days in 21 districts, according to the Health Ministry data.

Source: Ruchika Chitravanshi, Business Standard, 16.02.2021

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Cipla in talks to bring COVID antidotes to India

Expanding into home-testing, point-of-care diagnostics, in the hunt for technology

Cipla is in talks with major vaccine companies to bring vaccines to India, even as it expands its domestic footprint in home-testing or point-of-care diagnostic space, revealed Cipla Managing Director and Global Chief Executive Umang Vohra. "We have offered our services to every potential partner who wants to be in India and doesn't have a partner," Vohra told.

Umang Vohra, MD and Global Chief Executive, Cipla

Cipla's Covid-19 related portfolio spans Remdesivir, Favipiravir and Tocilizumab, and masks and sanitisers, for instance. The drugmaker also has alliances to bring in Covid-19 antibody and antigen testing kits. So vaccines had been the gap in its Covid-offerings.

Vohra reiterates, "We are ready to partner with anyone whose data and science looks good. It could be J&J (Johnson & Johnson), it could be Moderna, it could be Pfizer...," he said, adding that it comes down to, among other things, doing local Clinical Trials on the vaccine, for which the partner company should be comfortable as well.

Self-or home-testing:

"Our vision for diagnostics is that it is going to shift more towards the point of care... where you go to get yourself treated, could be a doctor's chamber or even in your house, for your own self-use," he explains.

In about three-to five years, a CBC profile could be done at home and the results directly fed through microprocessors straight to your doctor, says Vohra, adding "You send in the report one hour before your consult and he has your entire blood parameters. We see an environment like that panning out. That's where we would like to be. So Covid is one area to get into, we see diagnostics as beyond that."

Late last year, the United States Food and Drug Administration authorised for emergency use, the first home-use diagnostic test for Covid-19. "The challenge with India is that, in all the other countries, insurance pays for it, in India the patient pays," he says, indicating that the product needs to be affordable locally. Cipla is looking at bringing in similar diagnostic kits suited to the Indian context, he said, adding that there were internal timelines on both the vaccine and diagnostic plans. "Right now our hunt is more around technology," he said, in terms of where it is available and how it can be suited to the Indian and African context.

Source: P T Jyothi Datta, The Hindu Business Line, 22.02.2021

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Use PLI scheme to attract investment and boost manufacturing, says PM Modi to states

The Centre has announced 13 PLI schemes in wake of the Covid-19 pandemic last year. In February, the Union Cabinet approved the PLI scheme for telecom and networking products worth Rs.12,195 crore.

Stressing the importance for a better coordination and policy framework between the Center and the states,

Prime Minister Narendra Modi has asked states to synchronise their budgets with that of the Centre and take full advantage of the Production Linked Incentive (PLI) schemes to boost manufacturing by tapping the private sector.

Addressing the Governing Council of the Niti Aayog on Saturday, PM said, "The Central Government introduced PLI schemes for various sectors providing an excellent opportunity to increase manufacturing in the country." He urged the states to take full advantage of this scheme and attract maximum investment in themselves and also reap the benefits of reduced corporate tax rates.

Note that the Centre has announced 13 PLI schemes in wake of the Covid-19 pandemic last year. Just this month, the Union Cabinet approved the PLI scheme for telecom and networking products worth Rs.12,195 crore which shall be implemented from April 1, 2021. The Government expects that the scheme will lead to enhanced production of more than Rs.2,44,200 crores of telecom equipment in the country, export worth Rs. 1,95,360 crores, create 40,000 new jobs and generate around Rs.17,000 crore worth of tax revenue in the coming five years.

Last year, in a bid to enhance India's manufacturing capabilities, attract investment and enhance exports, the Government approved Production Linked Incentives for 10 more sectors. The cabinet approved financial assistance of nearly 2 lakh crore rupees for a period of five years to boost domestic manufacturing in the country. The concerned sectors include advance chemistry cell battery, electronic products, automobiles and auto components, Pharma, telecom and networking products, textile, food products, white goods and speciality steel.

The move came in after the Government rolled out Production Linked Incentives for Pharma, medical devices and mobile manufacturing. The 10 champion sectors were identified by Niti Aayog in consultations with various stakeholders. The scheme is aimed at making India a Global Manufacturing Hub and tap companies that are moving out of China.

In his address at the NITI Aayog meet, on the funds allocated for infrastructure in this budget, the Prime Minister said this would help the country's economy to advance the country's economy on many levels. He stressed on the importance of making the states self-reliant and giving momentum to development in their budget.

He announced that there would be a major increase in the economic resources of local bodies in the 15th Finance Commission. He said along with use of technology public participation is also very important in the Local Governance reforms.

Source: FE Bureau, Financial Express, 23.02.2021

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Covishield: Asked to prioritise for India needs, says SII's Poonawalla

The Indian Government has directed vaccine maker, Serum Institute of India (SII) to prioritise for meeting the Covid-19 vaccination needs of India. Adar Poonawalla, CEO, SII tweeted on Sunday, 21.02.2021 urging other Governments that are awaiting Covishield supplies to be patient.

SII has already supplied 20 million doses to the Indian government. Around 30 million doses have been dispatched by the company so far.

SII has been directed to prioritise to cater to the huge needs of India and along with that balance the needs of the rest of the world, Poonawalla tweeted. Serum was trying its best to do this, he said.

The Government has set a target of vaccinating three crore frontline workers in the first phase and 30 crore people with age over 50 years and with co-morbidities in the next phase. The vaccination drive that started on January 14 has now inoculated 1.08 crore people.

SII has already supplied 20 million doses to the Indian Government. Around 30 million doses have been despatched by the company so far.

SII had stockpiled 100 million doses of the Covishield AstraZeneca Oxford vaccine. Serum Institute has capacity to make around 70 million doses a month at present and this capacity would be going up to 100 million doses per month by April 2021 with the addition of a third plant in Pune.

Poonawalla was confident of supplying enough vaccines to meet the needs of the Indian market as well as supplying to other countries. Poonawala had said in an earlier media interaction that India would be priority for the doses and there will be plenty of vaccines for India and other COVAX countries.

Around 50% of SII stock would be going to COVAX countries, Poonawalla had said. He had anticipated some shortage in the first six months of 2021 in the global markets and easing off by August-September 2021 as other vaccine manufacturers started their vaccine supplies.

Serum has committed to supplying 1.1 billion doses of the AstraZeneca – Oxford Covid-19 vaccine to the COVAX facility. Post approval from the WHO, SII is slated to start shipping 20 million doses by end of February 2021 to African countries that are part of GAVI's COVAX facility. SII also tied up with US biotech company, Novavax for manufacturing and selling the Novavax vaccine (NVX-CoV2373) from India.

Novavax had on February 18, 2021 made a joint commitment along with SII to supply 1.1 billion doses to COVAX facility through the GAVI vaccine alliance. SII has got funds of around $ 500 million from the Gates Foundation and other countries for manufacturing the vaccine and scaling up. SII has also put in its own $ 270 million investment for rolling out the Covid-19 vaccines.

Source: FE Bureau, The Financial Express, 22.02.2021

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Modi lauds role of traditional Indian Medicines in COVID fight

A day after the Indian Medical Association (IMA) slammed Yoga Guru Baba Ramdev's Patanjali's claim that its herbal Coronil tablets are effective against the Covid-19 virus, Prime Minister Narendra Modi on Tuesday, 23.02.2021 hailed the contribution of traditional Indian medicines in the fight against the pandemic.

He said that the benefits of domestic spices and decoctions have been noticed by people around the world. "In addition to India's medicines and vaccines, the world has witnessed the contribution of our spices and decoctions as well. Our traditional medicines have established their place in the world," said Modi during a webinar on budget implementation to the health sector.

The Prime Minister's remark comes in the backdrop of amid the controversy surrounding Patanjali's claim that its Coronil tablets are effective against the COVID-19 virus. Patanjali had claimed that its product is the "first evidence-based medicine for Corona".

In his address, PM Modi lauded the efforts of the Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). "Our network of AYUSH has done excellent work in the 'Corona era'. The infrastructure of AYUSH has been useful not just for human research but also for immunity and scientific research," he said.

"The country needs wellness centres, district hospitals, critical care units, health surveillance infrastructure, modern labs and telemedicine. We have to work at every level," Modi added. Modi also hailed the enhanced budget allocated for the health sector by the Centre for this Financial Year.

"The budget allocated for the health sector now is extraordinary. It shows our commitment to this sector. COVID-19 pandemic has taught us a lesson to be prepared to fight similar challenges in the future," said Modi. The IMA on Monday, 22.02.2021 took strong exception to the "blatant lie of WHO certification" for Patanjali's Coronil tablet, which the company claims is an evidence-based medicine to fight Covid-19. The IMA also demanded an explanation from Union Health Minister Harsh Vardhan in whose presence the medicine was launched recently.

The WHO had clarified that it has not reviewed or certified the effectiveness of any traditional medicine for the treatment of Covid-19. Meanwhile, Union Health Secretary Rajesh Bhushan at a press conference said that a total of 1,17,54,788 Covid-19 vaccine doses have been administered in the country till 1 pm Tuesday, 23.02.2021 with 1,04,93,205 getting the first dose and 12,61,583 being given the second dose.

He said that 12 States and Union Territories, including Rajasthan, Uttar Pradesh, Madhya Pradesh, Gujarat and Odisha, have administered first dose of COVID-19 vaccine to more than 75 percent of the registered healthcare workers, while 11 states and UTs,

including Karnataka, Telangana, Delhi, Punjab and Chandigarh, have administered the first dose to less than 60 percent of healthcare workers.

Source: The Pioneer, 24.02.2021

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Government working with four-pronged strategy towards a Healthy India: PM

Prime Minister Narendra Modi has stated that the Government is working with a four-pronged strategy towards a healthy India. Modi was addressing a webinar on effective implementation of budget provisions in the health sector through a Video Conference.

The first is "Prevention of illness and Promotion of Wellness". Measures such as *Swachh Bharat Abhiyan*, yoga, timely care and treatment of pregnant women and children are part of it.

The second is to "provide cheap and effective treatment to the poorest of the poor". Schemes like *Ayushman Bharat* and *Pradhan Mantri Jan Aushadhi Kendras* are working towards the same.

The third is to "increase the quality and quality of health infrastructure and health care professionals". Since last 6 years, expansion of institutions like AIIMS and increasing the number of medical colleges all over the country are attempting this.

The fourth is to "work on mission mode to overcome obstacles". Mission *Indradhanush* has been extended to the tribal and far-flung areas of the country. He said India has advanced its target to eradicate TB by five years to 2025 from the WHO's target of 2030.

Addressing the webinar, the Prime Minister said the budget allocated to the health sector in this year's budget is unprecedented and shows the Government's commitment to provide better healthcare to every citizen.

Modi recalled how the last year was very difficult and challenging owing to the pandemic and expressed happiness for overcoming the challenge and saving many lives. He credited the achievement to the combined efforts of the Government and private sector.

The Prime Minister recalled how, within a few months, the country could set up a network of 2500 labs and how it could reach a milestone of 21 crore tests from a mere dozen tests. The Prime Minister said Corona taught us a lesson that we not only have to fight the epidemic today but also to prepare the country for any such situation in future. Therefore, it is equally necessary to strengthen every field related to healthcare.

He said we have to focus on everything from medical equipment to medicines, from ventilators to vaccines, from scientific research to surveillance infrastructure, from doctors to epidemiologists so that the country is better prepared for any health disaster in future.

This is the inspiration behind the PM *Aatma Nirbhar Swasth Bharat Scheme*. Under this scheme, it has been decided that a modern ecosystem would be developed from research to testing and treatment in the country itself. This Scheme would increase our capabilities in every spectrum.

The Prime Minister said as per the recommendations of the 15th Finance Commission, local bodies will get more than Rs.70,000 crore rupees keeping health services in mind. That is, the Government's emphasis is not only on investment in health care but also to expand the access to health care in far flung areas of the country. He stressed that it should be ensured that these investments not only improve health but also increase employment opportunities.

PM Modi said the world now clearly appreciates the strength and resilience shown by India's health sector owing to its demonstration of its experience and talent during the Corona pandemic. He said the prestige and trust towards the country's health sector has increased manifold all over the world and that now the country has to work towards the future while keeping this in mind.

He said the demand for Indian doctors, Indian nurses, Indian para medical staff, Indian medicines and Indian vaccines will increase across the world. The World's attention would definitely shift towards India's Medical Education System and there would be a huge influx of foreign students to study medicine in India. PM Modi added that a holistic and integrated approach is adopted from Prevention to Cure and also lauded the efforts of the AYUSH sector during the Corona period.

He said "Our AYUSH's infrastructure has also been of great help in the country regarding increasing immunity and scientific research. He said the world is experiencing the impact of traditional medicines and masalas in improving the health along with the vaccine in controlling the COVID-19."

PM Modi stressed that this is the opportune moment to take the accessibility and affordability of the health sector to its next level. He urged the enhanced use of modern technology in the health sector to achieve this goal. He said Digital Health Mission would help the common people to get effective treatment as per their convenience. He said these changes are very much important for *Atma Nirbhar Bharat.*

Modi said that though India has become the pharmacy of the world today but is still dependent on imports for the raw materials. He lamented that such dependence does not augur well for our industry and this is a huge obstacle in providing affordable medicines and health care to the poor.

Source: Pharmabiz, 24.02.2021

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INTERNATIONAL NEWS

Scientists urge for investment now in highly potent vaccines to prevent the next pandemic

As new COVID-19 variants begin to throw vaccine efficacy in question, two leading scientists are calling for health agencies to invest in the development of vaccines that would be broadly effective against many different variants and strains of potential pandemic viruses. In a commentary article published in the journal Nature, Dennis Burton, Ph.D, and Eric Topol, MD, of Scripps Research call for Governments to provide significant funding support for rational vaccine design based on broadly neutralizing antibodies.

Such antibodies provide broad-spectrum potency against viruses, a valuable characteristic that opens the door to vaccines that could provide immunity against the many variants that might evolve from a fast-mutating virus. They could also be used as drugs to prevent and treat infections. Burton and Topol note that the rapid development of effective vaccines against COVID-19 was possible due to certain properties of the SARS-CoV-2 virus--in particular, the spike protein on the virus's surface.

But they warn that the virus driving the next pandemic may not provide such a ready target, which could substantially slow the process of developing a novel vaccine. "Even SARS-CoV-2 could be becoming more problematic for vaccines because of the emergence of new variants," they write. "We call for an alternative approach to pandemic preparedness."

Burton and Topol point to broadly neutralizing antibodies as a promising avenue for developing vaccines and therapies that might be readily adapted to newly emerged pandemic viruses or those that rapidly evolve to evade traditional vaccines.

"Such antibodies could be used as first-line drugs to prevent or treat viruses in a given family, including new lineages or strains that have not yet emerged," the write. "More importantly, they could be used to design vaccines against many members of a given family of viruses." Of particularly concern for future pandemics are viruses that are "evasion-strong," meaning their biological characteristics make them challenging to treat with drugs or prevent with vaccines.

The extreme example of this type of virus is HIV, which can stay in the body for years, hiding from the host's immune system. Burton and his colleagues at Scripps Research and other organizations are currently developing vaccines based on broadly neutralizing antibodies in hopes of producing the world's first truly effective HIV vaccines.

They are also seeking to employ broadly neutralizing antibodies as therapies and vaccines against influenza, another evasive virus and prime contender for future pandemics. "Such pan-virus vaccines could be made in advance and deployed before the next emerging infection becomes a pandemic," Burton and Topol write. "We call for an investment now in basic research leading to the stockpiling of broadly effective vaccines."

(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: Scripps Research Institute, EurekAlert, 09.02.2021 (Excerpts)

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Pharma exports to Arab nations cumbersome, says Sanjay Bhattacharyya

India for trade beyond hydrocarbons

India has urged Arab countries to make it easier to export pharmaceutical products to the region and asked them to tap Indian farms to secure food supplies, as it seeks to diversify the $160 billion trade basket with the Arab bloc beyond hydrocarbons.

"Indian Pharma products enjoy great credibility around the world, [but] we do not have the same kind of recognition in most of the Arab world, because the process through which medicines are brought into your countries are very elaborate and cumbersome at times," said Ambassador Sanjay Bhattacharyya, Secretary (Arab, OIA & CPV), Ministry of External Affairs.

Mr Bhattacharya said market access to Indian Pharma goods could be an 'early harvest' idea ahead of the India-Arab Partnership forum scheduled in the first week of December, after a gap of five years.

"We should look for an early harvest by looking at the US FDA and GMP [Good Manufacturing Practice] - approved drugs that can come in as a first step. India is a large producer of generics, but we also go beyond that," he said at a meeting hosted by FICCI with Ambassadors of several Arab countries on economic opportunities between India and the Arab nations.

India-Arab trade accounts for 20% of India's overall trade, but is still concentrated in Hydrocarbons, the Secretary said, mooting agriculture, technology and tourism as potential areas for diversification.

Agriculture reforms: "Food security is important for India as well as the Arab world, particularly the Gulf region. With the new agricultural reforms in India, there are huge opportunity for many companies in the Arab world to set up base in India where you could have farming and then the produce could go back home," Mr Bhattacharya said. "This could be a win-win situation for both sides," he added.

Source: Special Correspondent, The Hindu, 23.02.2021 (Excerpts)

A Costly Mistake

Government should include pvt sector in vaccine roll-out

Union Health Minister Harsh Vardhan has poured cold water on hopes of an early roll-out of vaccines by the private sector in India. He said on Monday,15.02.2021 that approvals for general use rather than emergency use were not currently foreseen. This is a mistake, and will hold back the control of the pandemic as well as the country's return to normal economic functioning. Mr Vardhan's reasons have little logical foundation. He argued that if the government managed the vaccine roll-out, then there would be less worry about "some wrong product reaching the market". If this is a complaint about the quality of the vaccines, then it is hard to see how whether it is a private or public vaccine makes a difference. Certainly, questions about the indemnification of vaccine companies are important — but unless the government plans to never have private sector sales at all, there is no reason to decide on that issue later when it should be done now.

It is not as if the government is doing particularly well on the roll-out so far. Phase III of the roll-out — when those most vulnerable to mortality if they develop symptoms of Covid-19 are to be inoculated — has not even started. Indeed, proper plans for it have not even been drawn up. The previous phases are running at perhaps 50-60 per cent of effectiveness against their plans. In other words, more than six weeks after regulatory approval for two vaccines was handed out, not a single Indian in the vulnerable age groups has as yet been vaccinated. There is widespread doubt and confusion as to how to sign up to get on a vaccine list, with various state governments and municipalities issuing conflicting instructions. The Co-Win app has not been particularly impressive so far, and there is every reason for fear that it will not be able to handle the registration and tracking of the hundreds of millions of Indians in Phase III. The manufacturers, particularly Serum Institute of India, are producing vaccines faster than India can hand them out. All these points suggest any responsible government would be begging the private sector for help, rather than turning up its nose.

Early approval and quick contracting are essential to get a private sector pipeline up and working swiftly. Multiple players in the pharma industry are willing to put their installations to produce approved vaccines. The sooner they get the go-ahead, the quicker these vital investments can be made. It is unclear, other than a desire for bureaucratic control, why the government is seeking to reduce India's potential vaccine-manufacturing capacity in this manner. In general, it is a bad idea to dis-incentivise private investment at this time through slow approval. But it is even worse when timely private investment in the vaccine chain is the only hope to get India to herd immunity in reasonable time. The government must re-evaluate its strategy and allow private participation at the earliest. Many firms in the private sector are willing to pay for their employees. Expanding the vaccination programme will help strengthen economic recovery. A delay will only increase costs for the economy.

Source: Business Standard, 16.02.2021

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Realisation there in Pharma industry to become self-reliant in API production: IPA

There is a realisation in the domestic Ppharma industry to become self reliant in the production of active pharmaceutical ingredients (APIs) but it will take some time to achieve the goal, a top Indian Pharmaceutical Alliance (IPA) official said on Wednesday, 24.02.2021.

IPA, which represents 24 leading research-based drug firms including Sun Pharma, Dr Reddy's, Cipla and Lupin, noted that Indian industry had the know-how to produce APIs but somehow lost the advantage to countries like China.

Jain however noted that it will take some time for the country to get self reliance in API production.

"Reliance on China for APIs is there. We had the technology of making all kinds of APIs but over a period of time we lost that advantage. But now with Production Linked Lncentive (PLI) scheme which covers APIs and coming up of manufacturing parks we are on the right path," (IPA) Secretary General Sudarshan Jain said during an event.

There is a realisation and some of the companies are taking a big lead and this is clearly one of the agenda where the industry is working together, he added. Jain however noted that it will take some time for the country to get self reliance in API production.

"The overall fundamental point in all this is that there has to be a diversified supply chain. Every manufacturer cannot be dependent on a single supply source. Unfortunately for a long time we have relied too much on one source. We don't have answers at the moment and we continue to source from outside till we create our own capability in the future," he said.

Jain also said that the IPA has been in constant touch with the US Food and Drug Administration (US FDA) regarding the start of inspections. The US Health Regulator since last year has halted nearly all inspections of overseas drug manufacturing plants citing the spread of the Coronavirus pandemic, affecting new drug approvals.

"As far as US FDA inspections are concerned we are having constant meetings. We have been talking to them and checking for the possibility of combining virtual and physical inspection together. The dialogue is on but there are no answers till now as far as this area is concerned," Jain said.

Various organisations have sought for virtual inspection, but it has not been accepted by the US FDA till now, he added. IPA continues to have dialogue because it is important to make sure that products are available and there are choices in terms of drugs with the citizens across the world, Jain said.

He also stated that the production levels have now stabilised across the Pharma sector after witnessing a drop last year due to the COVID-19 pandemic. Jain noted that IPA is closely working with the Pharmacy Council of India for course curriculum and syllabus upgradation of the B Pharm and M Pharm courses to meet latest industry expectations.

The organisation is also working to train the faculty of pharmacy colleges on the latest technological advancements to enhance faculty's practical experience.

Source: PTI, The Economic Times, 25.02.2021

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