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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 52 **Issue No. 06** **08 to 14 February 2021**

PANDEMIC AND "INFODEMIC"

Dr Nagaraj Rao, *Associate Editor, Indian Drugs*

Dear Reader,

With the passage of about one year since the outbreak of the COVID-19 pandemic, huge amounts of scientific research data on COVID-19 are being generated daily and we have thus substantial information and understanding of the disease. While treatment with known anti-viral drugs, monoclonal antibodies, steroids and APIs continues, focus is now on the development and manufacturing of effective vaccines to protect the population at large.

Several Indian companies are already conducting pan-India clinical trials of different vaccines. Bharat Biotech, in cooperation with the Indian Council of Medical Research and the National Institute of Virology, has developed a whole-virion inactivated vaccine on an inactivated platform, which will be administered intramuscularly in two doses (0,28d). Biological E. is clinically evaluating its adjuvant protein subunit (RBD) vaccine on a protein subunit platform, again administered intramuscularly in two doses (0, 28d). Cadila Healthcare has developed a DNA plasmid vaccine on a DNA platform, administered intradermally in three doses (0, 28, 56d). Dr. Reddy's Laboratories, together with the Russian Direct Investment Fund, will be conducting clinical trials of the Sputnik V adenovirus-based vaccine on non-replicating viral vector platform (developed by the Gamaleya National Research Institute). The Serum Institute of India, together with ICMR, is conducting clinical trials of the ChAdOx1-S AstraZeneca-Oxford vaccine on a non-replicating viral vector, also administered intramuscularly in two doses (0, 28d).

Moreover, Indian Immunologicals and Serum Institute are conducting pre-clinical evaluation of their codon de-optimized live attenuated vaccines on live attenuated virus platforms. Bharat Biotech, in cooperation with Thomas Jefferson University, is conducting pre-clinical evaluation of its recombinant deactivated rabies virus containing S1-vaccine on a non-replicating viral vector. It is also planning to manufacture a novel chimp adenovirus, single dose intranasal vaccine after phase I Clinical Trials are successfully conducted at St Louis University in the USA. Cadila Healthcare with its measles vector vaccine and Aurobindo with its VSV-S vaccine, both on replicating viral vector platforms, are the other companies already conducting pre-clinical evaluations. Just as the Indian manufacturing pharmaceutical industry is already playing

Dr Nagaraj Narayan Rao obtained Bachelor's degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with magna cum laude from the University of Tuebingen, Germany, under the guidance of Prof Dr H J Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the "Transactions of the MFAI" for a few years. He contributes a monthly 'Report from India' to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.

Dr Rao is co-founder of the RRR group of Small and Medium Enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.

a crucial role in supplying generics, APIs and vaccines globally, these companies are gearing up to serve the global needs for effective remedies against COVID-19.

Worldwide, research on new vaccines is also focussing on a variety of other strategies using DNA plasmids, virus-like particles, CD8 T cell peptide targeting, mRNAs, influenza A virus, horsepox vector, measles vector, outer Drosophila S2 insect cell expression system VLPs, membrane vesicles, structurally modified spherical particles of the tobacco mosaic virus, oral E. coli based protein expression system of S and N proteins, adenovirus, egg-based inactivated whole chimeric Newcastle disease virus protein and more.

Apart from clinical data generated during the treatment of COVID-19 infected patients, a huge amount of clinical data is being generated during the three-phase Clinical Trials, and the Indian industry has rich experience in conducting clinical research. The race for putting up the first vaccine against COVID-19 is so intense that sometimes serious errors are being committed, such as the "dosing error" recently reported by one of the forefront runners. In the course of time, more information will be available on the interaction of vaccines with other drugs as well as treatment of patients with co-morbidities. The Real-time Reverse Transcription-Polymerase Chain Reaction (RT-PCR) diagnostic method is undergoing refinement to reduce the incidence of false positives. In the areas of formulation of the vaccines, improving shelf-life, pharmacokinetics, administration routes, dosing schedules, ADMET data and packaging, substantial data will have to be generated, evaluated and interpreted to assure stability, efficacy and non-toxicity of the vaccines. The effect of packaging materials such as vials, stoppers, gauzes and syringes needs to be studied in detail. The effect of "temperature shocks" during transport or storage on the vaccine's effectiveness also needs to be studied in detail.

Companies are ramping up their production capacities to be able to meet the demand for vaccines. Shortages in raw material supply for vaccine production, glitches in logistics and distribution and other challenges will be needed to be tackled along the way, not only due to the different cold-storage conditions and the infrastructure needed in different regions and countries.

The Indian government, through the concerned ministries, is doing its best to see that reasonably priced vaccines against COVID-19, reach the citizens, beginning with prioritised categories, at the earliest.

While it is the responsibility of the media to keep the general public informed, it is becoming essential to fight, as the WHO describes it, the "infodemic" related to COVID-19. Responsible and unbiased reporting by the various media is the need of the hour. Just as the media does not and cannot assign any nationality to the SARS-CoV-2 virus, nor does this virus differentiate between different human beings when it infects, similarly, the media would do well by refraining from trying to describe the companies, research laboratories and scientists involved in vaccine development and production by various populistic connotations.

We at Indian Drugs look forward to receiving scientific articles connected to COVID-19!

Courtesy: Indian Drugs, Editorial, Vol. 57 (10) October 2020

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Mr Ranjit Barshikar bestowed with "Quality Champion–GOLD" Award by QCI/NBQP

IDMA Congratulates Mr Ranjit Barshikar

Conferred & Honored with "Quality Champion – GOLD" Award

By Quality Council of India/NBQP - Government of India.

Mr Ranjit Barshikar, a veteran in the Pharmaceutical Industry, has been conferred with ***"Quality Champion – GOLD"*** **Award by Quality Council of India,** a Joint Venture of Government of India & Indian Industries.

This award is in recognition of Mr Barshikar's "outstanding Professional Achievements, Commitments & Contributions in improving Quality in Pharmaceutical Industry".

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Drugs (Prices Control) Order, 2013 amended (1st Amendment of 2021) - reg.

D&C Notification No.S.O.508(E), dated 1st February, 2021

(Published in the Gazette of India on 3rd February, 2021)

In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby makes the following order further to amend the Drugs (Prices Control) Order, 2013, namely;

1. Short title and commencement:

(1) This Order may be called the **Drugs (Prices Control) Amendment Order, 2021.**

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

2. In the Drugs (Prices Control) Order, 2013, in SCHEDULE-I, after the serial number 31 and the entries relating thereto, the following serial number and the entries shall be inserted, namely:-

-32-Medicines for animal use	
32.1	Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine
32.2	Brucella Abortus (S19 strain) Vaccine, Live Freeze Dried

F.No.31026/78/2020-Pricing

Rajneesh Tingal, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

Note:- *The Principal Order was published in the Gazette of India, Part-II, Section 3, Sub-section (ii) vide S.O. No.1221(E) dated the 15th May, 2013 and was subsequently amended vide the following Notifications:-*

(i) S.O. No.686(E) dated the 9th March, 2015;

(ii) S.O. No.1233(E) dated the 8th May, 2015;

(iii) S.O. No.701(E) dated the 10th March, 2016;

(iv) S.O. No.1192(E) dated the 22nd March, 2016;

(v) S.O. No.4100(E) dated the 21st December, 2016; and

(vi) S.O. No.39(E) dated 3rd January, 2019.

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DGFT MATTERS

Introduction of online e-Tariff Rate Quota System for Imports - reg.

DGFT Trade Notice No.40/2020-21, dated 4th February, 2021

To
All RAs of DGFT,
All members of Trade & industry.

1. On the basis of Customs Notifications as applicable, DGFT allocates quota for import of items under the Tariff Rare Quota (TRQ) as per para 2.61 and para 2.107 of the Handbook of Procedure (2015-20). Applications for the TRQ scheme are currently being submitted through the Restricted Item Import Licencing eCom module.

2. As part of IT Revamp, this Directorate has prepared a new online module - e-TRQ System for processing such e-TRQ applications. **With effect from 08.02.2021 onwards**, all applicants seeking Tariff Rate Quota (TRQ) for imports are required to submit their application online under *"*e-Tariff Rate Quota*"* in the Import Management System, through importer's dashboard on the DGFT Website (https://dgft.gov.in á Import Management System a Tariff Rate Quota). For TRQ applications which have already been submitted for FY 2021-22 and are yet to be processed, these applications will be migrated to the new system, for which no action is required by the applicant.

3. Any request for amendment of the TRQ licenses, issued on or after 08.02.2021, is required to be submitted electronically only through the e-TRQ system.

4. Further, licenses for all TRQs would be issued electronically and TRQ License data would be transmitted electronically to the Customs Authorities. No paper copies of the TRQ Import license will be issued by DGFT with effect from **08.02.2021**.

5. For any help and guidance on this new process, the Help manual & FAQs may be accessed on **https://dgft.gov.in** á Learn á Application Help & FAQs. For any further assistance any of the following channels may be assessed:

i. Raise a service request ticket through the DGFT Helpdesk service under Services á 'Complaints & Suggestions'

ii. Call the toll-free Helpline number

iii. Send an email to the Helpdesk on **dgftedi@gov.in.**

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

File No.01/93/180/47/AM-20/PC-II (B)/E-24879

S K Mohapatra, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce & Industry, New Delhi.

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GOVERNMENT PRESS RELEASE

Incentives to Foreign Companies

Ministry of Commerce & Industry Press Release dated 11th February 2021

The Government of India is making continuous efforts under Investment Facilitation for implementation of Make in India action plans to identify potential investors. Support is being provided to Indian Missions abroad and State Governments for organising events, summits, road shows and other promotional activities to attract investment in the country under the Make in India banner. Investment Outreach activities are being carried out for enhancing International cooperation for promoting FDI and improve Ease of Doing Business in the country.

Recently, in addition to ongoing schemes, Government has taken various steps to boost investments in India. These include the National Infrastructure Pipeline, reduction in Corporate Tax, easing liquidity problems of NBFCs and Banks, trade policy measures to boost domestic manufacturing. Government of India has also promoted domestic manufacturing of goods through public procurement orders, Phased Manufacturing Programme (PMP), Schemes for Production Linked Incentives of various Ministries.

Keeping in view India's vision of becoming '*Atmanirbhar*' and to enhance India's Manufacturing Capabilities and Exports, an outlay of INR 1.97 lakh crore has been announced in Union Budget 2021-22 for PLI schemes for 13 key sectors for a period of 5 years starting from Fiscal Year (FY) 2021-22. These 13 sectors include already existing 3 sectors named (i) Mobile Manufacturing and Specified Electronic Components, (ii) Critical Key Starting materials/Drug Intermediaries & Active Pharmaceutical Ingredients, and (iii) Manufacturing of Medical Devices and 10 new key sectors which have been approved by the Union Cabinet recently in November 2020. These 10 key sectors are:

(i): Automobiles and Auto Components,

(ii): Pharmaceuticals Drugs,

(iii): Specialty Steel,

(iv): Telecom & Networking Products,

(v): Electronic/Technology Products,

(vi): White Goods (ACs and LEDs),

(vii): Food Products,

(viii): Textile Products: MMF segment and technical textiles,

(ix): High efficiency solar PV modules, and

(x): Advanced Chemistry Cell (ACC) Battery.

The PLI schemes will be implemented by the concerned Ministries/Departments and will be within the overall financial limits prescribed. Further, with a view to support, facilitate and provide investor friendly ecosystem to investors investing in India, the Union Cabinet on 03rd June, 2020 has approved constitution of an Empowered Group of Secretaries (EGoS), and also Project Development Cells (PDCs) in all concerned Ministries/Departments to fast-track investments in coordination between the Central Government and State Governments, and thereby grow the pipeline of investible projects in India to increase domestic investments and FDI inflow.

This information was given by the Minister of State in the Ministry of Commerce and Industry, Shri Som Parkash, in a written reply in the Lok Sabha yesterday (10.02.2021).

Source: PIB, MoC&I, 11.02.2021

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In Lok Sabha & In Rajya Sabha

FDI in Pharma Sector

Lok Sabha Unstarred Question No: 26

Shri Jayadev Galla:

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

(a): whether it is not true that FDI inflow in drugs and pharma sector has come down from US $ 1500 million in 2014-15 to just US $ 265 million in 2018-19;

(b): if so, the reasons therefor along with the FDI in 2019-20 in the above sector;

(c): the details of remedial measures that the Government has taken/is going to take to attract FDI in this sector;

(d): whether there is any proposal in the Atmanirbhar Bharat Package to attract FDI;

(e): if so, the details thereof; and

(f): the impact on FDI due to Corona pandemic in 2020-21?

Answered on 2nd February 2021

A. (a) to (c): The FDI inflow in pharmaceutical sector, which was about US $ 1500 million in 2014-15, came down to US $ 265 million in the year 2018-19 with year-on-year variations in between. The FDI inflow increased to US $ 518 million in 2019-20. The FDI inflow into the country depends on many factors and no specific reasons may be attributed to increase or decrease of the FDI inflows during the period.

The Government has taken a number of initiatives to attract foreign investment in the last few years. Foreign investment in pharmaceutical brownfield projects, which was 100% under the Government approval route till May 2016, was brought under the automatic route upto 74% w.e.f. June 2016. The Foreign Investment Promotion Board (FIPB), an inter-Ministerial body considering and approving FDI proposals for all the sectors under Government route, was abolished in May 2017 and the responsibility of examining FDI proposals under Government approval route was given to the concerned administrative Ministries/Departments for speedy decision.

(d) to (e): Recently, the Department of Pharmaceuticals has launched two schemes namely, (i) Production Linked Incentive (PLI) Scheme for domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India and (ii) Scheme for Promotion of Bulk Drug Parks, for enhancing India's manufacturing capabilities and exports. Foreign Investors are also allowed under the said schemes.

(f): There has been positive impact in the foreign investment in pharmaceutical sector in 2020-21. Pharmaceutical sector received FDI inflow of US $ 367 million in the first six month of 2020-21, which is about 24% higher than the corresponding period of previous year. Further, the Department of Pharmaceuticals has also approved 16 FDI proposals worth US $ 208 million till December, 2020.

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

Reduction of Drug Prices

Lok Sabha Unstarred Question No: 116

Adv Dean Kuriakose:

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

(a): whether the National Pharmaceutical Pricing Authority (NPPA) has formulated any plan for reducing the prices of drugs to fight against epidemics like Covid19;

(b): if so, the details of drugs whose price has been reduced during the last one year:

(c): if not, the reasons therefor;

(d): whether the Government is aware of the fact that during this pandemic period, the private hospitals have been prescribing expensive medicines with the sole view of making profits through the channeling of commission payouts by the pharmaceuticals and if so the details thereof; and

(e): whether the Government has received any such complaints from the States and if so the details thereof?

Answered on 2nd February 2021

A. (a) to (c): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling prices of scheduled medicines which are specified in the National List of Essential Medicines (NLEM) and are included in Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The ceiling price fixed by the NPPA is applicable on all the branded and generic versions of such formulations alike. The Indian Council of Medical Research (ICMR) under Ministry of Health & Family Welfare has issued revised Clinical treatment protocol for COVID-19 on 13.06.2020 and included Hydroxychloroquine, Paracetamol, Methylprednisolone, Enoxaparin, Dexamethasone medicines under treatment protocol which are part of Schedule-I of the DPCO, 2013. The ceiling price of these medicines have been fixed/revised by NPPA vide S.O. No. 1213(E) dated 25.03.2020. The details of price notifications are available on the website of the NPPA i.e. **www.nppaindia@nic.in.**

Further, NPPA invoking the extra ordinary powers in public interest, fixed the price of Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas) to ease the situation of Medical Oxygen availability throughout the country, especially in distant and far-flung areas. In addition, NPPA revisited the ceiling price of Heparin injection so as to ensure its continued availability during the pandemic.

The Government has notified Masks (2ply, 3ply & N95) and Hand Sanitizers as 'Essential Commodities' under the Essential Commodities Act, 1955 vide Notification dated 13.03.2020. Further, the Government vide Notification dated 21.03.2020 and 24.03.2020 had fixed ceiling prices for Masks (2ply & 3ply) and Hand Sanitizers. Further, based on the Advisory issued by the NPPA, the Retail Prices of N95 Masks were reduced significantly up to 67% by the manufacturers/importers of the N95 Masks.

(d) & (e): No such complaints have been received from State/UT Governments. However, necessary action on complaints received from individuals has been taken by NPPA.

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

Anti-Cancer Drugs

Lok Sabha Unstarred Question No: 148

Shrimati Sumalatha Ambareesh:

Shri Doddaalahalli Kempegowda Suresh:

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

(a): whether the Government has taken note that the number of cancer patients have increased during the last ten years and if so, the details thereof;

(b): whether the Government has any plan to develop anti-cancer drugs to mitigate the problem of patients;

(c): if so, the details thereof;

(d): whether the Government is taking measures to put cap on cancer drugs to make it affordable to cancer patients; and

(e): if so, the details and the response of the Government in this regard?

Answered on 2nd February 2021

A. (a) to (c): 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.

Cancer is a multi-factorial disease, the risk factors of which include aging population, sedentary lifestyles, use of tobacco products, unhealthy diet and air pollution. In Government hospitals, treatment is either free or highly subsidized. Treatment of cancers is also available under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (PMJAY). ICMR-National Institute of Cancer Prevention and Research

(NICPR), Noida. In order to enhance the facilities for tertiary care of cancer, the Central Government is implementing Strengthening of Tertiary Care for Cancer Scheme, under which setting up of 19 State Cancer Institutes and 20 Tertiary Care Cancer Centres have been approved. Further, Oncology is also one of the focus areas in case of new AIIMS and many upgraded institutions under *Pradhan Mantri Swasthya Suraksha Yojana (PMSSY).* The Government has launched www.cancerindia.org with the theme "India Against Cancer", a portal that provides information on the leading cancers in India with a major focus on awareness, prevention and treatment of these cancers.

(d) & (e): 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 the website of the **NPPA i.e. nppaindia.nic.in**.

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

PLI Scheme for Bulk Drugs

Lok Sabha Unstarred Question No: 178

Shri Midhun Reddy:

Shri Adala Prabhakara Reddy:

Shri Magunta Sreenivasulu Reddy:

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

(a): whether the Government has received a favourable response from the Pharmaceutical sector for the Production Linked Incentive (PLI) Scheme for Bulk Drugs and PLI Scheme for Medical Devices;

(b): if so, the details thereof;

(c): the details of applications received in this regard; and

(d): whether the Government has appointed a Project Management Agency for this scheme and if so, the details thereof.

Answered on 2nd February 2021

A. (a) to (c): Yes, Sir. The Department has received a favourable response to the Production Linked Incentive (PLI) Scheme for Bulk Drugs and PLI Scheme for Medical Devices. In total 215 applications have been received for the 4 Target Segments for the PLI schemes for Bulk Drugs and 28 applications for the 4 Target Segments for the PLI Scheme for Medical Devices.

(d): The Department has appointed M/s IFCI Limited, a public sector non-Banking Finance Company as the Project Management Agency (PMA) for smooth implementation and functioning of the Scheme.

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

Cases against Companies in NPPA

Lok Sabha Unstarred Question No: 193

Shrimati Poonam (Mahajan)
Vajendla Rao:

Ms Ramya Haridas:

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

(a): the number of cases, at present, initiated by National Pharmaceuticals Pricing Authority (NPPA) against pharma companies for over-charging of patients on essential medicines and the number of pending cases along with the amount involved therein;

(b): whether the Government has taken any steps for early disposal of such pending cases;

(c): if so, the details thereof; and

(d): the time-frame fixed for disposal of such pending cases?

Answered on 2nd February 2021

A. (a): The National Pharmaceutical Pricing Authority (NPPA) under the Department monitors the prices of both scheduled and non-scheduled formulations on regular basis to check overcharging

by pharmaceutical companies. Whenever companies are found to be overcharging the consumer in sale of medicine, NPPA issues notices to the companies. Till now, NPPA has initiated 2116 number of overcharging cases. At present, 881 numbers of overcharging cases involving a total amount of Rs. 8,184.19 crore under the Drugs (Prices Control) Order (DPCO), 1979, 1987, 1995 and 2013 are pending. Out of which, an amount of Rs. 6,550.37 crore is under litigation in various Courts in respect of 324 cases. The case wise detailed list alongwith amount involved is available on the website of NPPA, i.e., **www.nppaindia.nic.in**.

(b) to (d): The action for recovery of the overcharged amount is a continuous on-going process undertaken as per the provisions of DPCOs. In cases where the demands raised for overcharging have been challenged in courts, the NPPA pursues these cases in the court. In case the demand raised by the NPPA has not been challenged in the court and the concerned company has not deposited the amount, the matter is referred to the respective Collector/ District Magistrate for recovery of the overcharged amount as arrears of land revenue under provisions of the Essential Commodities Act, 1955.

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

Pharma Products in Jan Aushadhi Stores

Lok Sabha Unstarred Question No: 208

Shri Prathap Simha:

Shri Sudhakar Tukaram Shrangre:

Shri Bhagwant Mann:

Shri Sumedhanand Saraswati:

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

(a): the total sales of pharma products through Jan Aushadhi stores during the last three years, year-wise;

(b): the total number of Jan Aushadhi stores across the country, State-wise particularly in Karnataka;

(c): the fresh steps taken by the Government for increasing awareness of people regarding efficacy and quality of Jan Aushadhi medicines, increasing coverage with a focus on remote and rural areas and for ensuring the adequate availability of medicines at each of the Jan Aushadhi stores?

Answered on 2nd February 2021

A. (a): The total sales of pharma products through Jan Aushadhi stores during last three financial years are as under:

(b): As on 22.01.2021, 7167 Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are opened across the country. Out of this, 815 PMBJKs are opened in the State of Karnataka. State/UT-wise list of PMBJKs is enclosed as Annexure*, **(Not reproduced here)***.

(c): The steps taken to increase awareness on Jan Aushadhi generic medicines include advertisements on TV, FM Radio and Cinema, extensive use of social media platforms like Facebook, Twitter etc., display through Auto wrappings, Bus Brandings, State Transport Bus Stands, Audio and Digital Screen Advertisements at Railway Stations and by organizing workshops in various parts of the country. In order to ensure the adequate availability of medicines at the Jan Aushadhi Stores, the logistics system is being strengthened. At present three warehouses are functional at Gurugram, Chennai and Guwahati and fourth one is under construction at Surat. Further, 37 distributors have been appointed across the country to support the supply of medicines to remote and rural areas. Further, additional one-time incentive is given to store owners for opening of stores in aspirational districts, Himalayan, Island territories and North-Eastern States.

Sr. No.	Financial Year	Sales at MRP (Value in Rs. Crore)
1.	2017-18	140.84
2.	2018-19	315.70
3.	2019-20	433.61

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

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CBIC notifies New Exchange Rates w.e.f. 05th February 2021 - reg.

Notification No.14/2021-Customs (N.T.), dated 04st 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.05/2021-Customs(N.T.), dated 21st January, 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 5th 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	56.90	54.50
2.	Bahraini Dinar	199.80	187.50
3.	Canadian Dollar	58.05	56.00
4.	Chinese Yuan	11.50	11.10
5.	Danish Kroner	12.00	11.55
6.	EURO	89.30	86.15
7.	Hong Kong Dollar	9.60	9.25
8.	Kuwaiti Dinar	248.95	233.15
9.	New Zealand Dollar	53.85	51.50
10.	Norwegian Kroner	8.65	8.35
11.	Pound Sterling	101.05	97.65
12.	Qatari Riyal	20.70	19.40
13.	Saudi Arabian Riyal	20.10	18.85
14.	Singapore Dollar	55.65	53.70
15.	South African Rand	5.05	4.70
16.	Swedish Kroner	8.85	8.50
17.	Swiss Franc	82.75	79.45
18.	Turkish Lira	10.50	9.85
19.	UAE Dirham	20.50	19.25
20.	US Dollar	73.80	72.10

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	70.75	68.10
2.	Korean Won	6.75	6.30

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.

How SARS-CoV-2 mutates to escape antibody binding

In a recurring pattern of evolution, SARS-CoV-2 evades immune responses by selectively deleting small bits of its genetic sequence, according to new research from the University of Pittsburgh School of Medicine. Since these deletions happen in a part of the sequence that encodes for the shape of the spike protein, the formerly neutralizing antibody can't grab hold of the virus, the researchers report today in Science. And because the molecular "proofreader" that usually catches errors during SARS-CoV-2 replication is "blind" to fixing deletions, they become cemented into the variant's genetic material.

"You can't fix what's not there," said study senior author Paul Duprex, Ph.D., Director of the Center for Vaccine Research at the University of Pittsburgh. "Once it's gone, it's gone, and if it's gone in an important part of the virus that the antibody 'sees,' then it's gone for good." Ever since the paper was first submitted as a preprint in November, the researchers watched this pattern play out, as several variants of concern rapidly spread across the globe. The variants first identified in the United Kingdom and South Africa have these sequence deletions.

Duprex's group first came across these neutralization-resistant deletions in a sample from an immunocompromised patient, who was infected with SARS-CoV-2 for 74 days before ultimately dying from COVID-19. That's a long time for the virus and immune system to play "cat and mouse," and gives ample opportunity to initiate the coevolutionary dance that results in these worrisome mutations in the viral genome that are occurring all over the world.

Then, Duprex enlisted the help of lead author Kevin McCarthy, Ph.D., Assistant Professor of Molecular Biology and Molecular Genetics at Pitt and an expert on influenza virus--a master of immune evasion--to see whether the deletions present in the viral sequences of this one patient might be part of a larger trend. McCarthy and colleagues pored through the database of SARS-CoV-2 sequences collected across the world since the virus first spilled over into humans.

When the project started, in the summer of 2020, SARS-CoV-2 was thought to be relatively stable, but the more McCarthy scrutinized the database, the more deletions he saw, and a pattern emerged. The deletions kept happening in the same spots in the sequence, spots where the virus can tolerate a change in shape without losing its ability to invade cells and make copies of itself. "Evolution was repeating itself," said McCarthy, who recently started up a structural virology lab at Pitt's Center for Vaccine Research. "By looking at this pattern, we could forecast. If it happened a few times, it was likely to happen again."

Among the sequences McCarthy identified as having these deletions was the so-called "U.K. variant"--or to use its proper name, B.1.1.7. By this point, it was October 2020, and B.1.1.7 hadn't taken off yet. In fact, it didn't even have a name, but it was there in the datasets. The strain was still emerging, and no one knew then the significance that it would come to have. But McCarthy's analysis caught it in advance by looking for patterns in the genetic sequence. Reassuringly, the strain identified in this Pittsburgh patient is still susceptible to neutralization by the swarm of antibodies present in convalescent plasma, demonstrating that mutational escape isn't all or nothing. And that's important to realize when it comes to designing tools to combat the virus.

"Going after the virus in multiple different ways is how we beat the shapeshifter," Duprex said. "Combinations of different antibodies, combinations of nanobodies with antibodies, different types of vaccines. If there's a crisis, we'll want to have those backups." Although this paper shows how SARS-CoV-2 is likely to escape the existing vaccines and therapeutics, it's impossible to know at this point exactly when that might happen. Will the COVID-19 vaccines on the market today continue to offer a high level of protection for another six months? A year? Five years? "How far these deletions erode protection is yet to be determined," McCarthy said. "At some point, we're going to have to start reformulating vaccines, or at least entertain that idea."

(Additional authors on the study include Linda Rennick, Ph.D., Sham Nambulli, Ph.D., of Pitt; Lindsey Robinson-McCarthy, Ph.D., formally Harvard Medical School and now working as a virologist at UPMC Hillman Cancer Center; and William Bain, M.D., and Ghady Haidar, M.D., of Pitt and UPMC. Funding for this study was provided by the Richard King Mellon Foundation, Hillman Family Foundation and UPMC Immune Transplant and Therapy Center.)

Source: University of Pittsburgh, Science Daily, 03.02.2021 (Excerpts)

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'Prescription audit' soon to assess use of drug cocktails in India and check over-medication

The National Pharmaceuticals Pricing Authority (NPPA), India's drug price regulator, has decided to conduct a "prescription audit" to understand the usage of drug cocktails in the country.

This marks the third time in the last three months the authority has expressed concern over increasing approvals to Fixed Dose Combination (FDC) medicines or drug cocktails in India. Since its meeting on 26 October last year, the price watchdog has been noting that most of the retail price applications of new drugs mainly consist of FDCs of two or more drugs.

FDCs are medicines that combine more than one drug in a single pill. The idea is to ease compliance for those required to take multiple medicines as part of long-term treatment or when the combination is proved to have a clear benefit over single-compound drugs.

In October, NPPA expressed concerns over cocktail drugs by highlighting "over-medication" as a potential hazard while also flagging the prospect of "profiteering" by pharma companies. In another meeting, held on 23 December, the authority again noted the trend and said this is "not desirable in the overall public interest and welfare". In its latest meeting on 27 January this year, the NPPA decided to undertake a 'prescription audit'.

"It was discussed and felt that undertaking a 'prescription audit' may throw light on the prescription patterns of various drugs and their usage," according to the minutes of the meeting, recently uploaded on NPPA's website.

The authority was of the view that NPPA may undertake 'prescription audit' as the findings can be of help for decision making, the minutes further mentioned. "We will be starting the process soon. We plan to collect the prescription samples nationwide. However, all these plans are at the preliminary stage of discussion and will be fine-tuned further," said an NPPA official, who did not wish to be named. "We have observed that rationality of use of FDCs is important as information asymmetry exists in this area," the official added.

Trend highlighted before ICMR, Health Ministry:

The Modi government has approved over 2,100 FDCs out of 6,600 reviewed for efficacy since 2016. Many FDCs have also been banned over the years amid questions about their efficacy. Spotting the trend of more FDCs coming in for price fixation approvals, the NPPA in October had "expressed concern that approval of these FDCs may compromise the rationale in the usage of the drugs and may lead to over-medication".

It subsequently said the trend must be highlighted before the country's apex health research agency, the Indian Council of Medical Research. In December, the authority had said a number of public grievances are on the "irrational pack size wherein a consumer is forced to buy more than his/her need". "Thus, looking at the pervasive nature of the issue that may also impact the public health system, it was agreed that these issues may be raised with the Ministry of Health and Family Welfare, Government of India," it said.

Source: Himani Chandna, The Print, 04.02.2021

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Budget gives 200% boost to Pharma sector as Government looks to curb dependence on China

India's first post-pandemic Budget has provided a boost of nearly 200 per cent for developing the pharmaceutical sector to help the country bolster its image as the 'pharmacy of the world'. In the allocation for the Union Department of Pharmaceuticals, which comes under the Ministry of Chemicals and Fertilizers, Budget 2021-22 earmarks Rs. 124.42 crore for initiatives aimed at "Development of Pharmaceutical Industry".

In comparison, Budget 2020-21 set aside Rs. 42.05 crore for the scheme, with the revised estimates pegged at Rs. 34.05 crore. In 2019-2020, the scheme used Rs. 3.29 crore. The big push for the pharma sector can be seen as an attempt by the government to wean India off raw material imports from China that are heavily used in local drug manufacturing.

Indian drug-makers import around 70 per cent of their total bulk drug requirements from China. In 2018-19, the government informed the Lok Sabha in 2019, Indian

drug-makers imported bulk drugs and intermediates worth $2.4 billion from China.

Last February, India found itself on the verge of a shortfall of essential medicines as China — the first country to report novel Coronavirus infections — went into lockdown over Covid-19. The amount under the scheme, according to Budget documents, will go towards providing Production-Linked Incentives (PLI) to promote domestic manufacturing of critical Key Starting Materials (KSM), drug intermediates, and active pharmaceutical ingredients (APIs). KSM, API and drug intermediates are all raw materials required for making drugs. The allocation is also meant to encourage local production of medical devices with a similar PLI scheme.

'Over-dependence on China great threat to drug security':

Last year, several experts had highlighted the fact that an over-dependence on China for medical imports could become "a great threat to the country's drug security and national health". "The pandemic is an eye-opener for the pharma industry, which is heavily dependent on China for Active Pharmaceutical Ingredients and Key Starting Materials (KSMs)," Udaya Bhaskar, Director-General, Pharmaceuticals Export Promotion Council of India (Pharmexcil), had told.

Pharmexcil, which functions under the Ministry of Commerce and Industry, was set up in 2004 to promote pharmaceutical exports. A 2020 report by Hong Kong-based equity research firm Haitong International Securities Group noted that the high level of dependence the Indian pharma industry has on China could impact Indian production of drugs for HIV, cancer, epilepsy, malaria, commonly-used antibiotics and anti-inflammatory drugs during the pandemic. India, a leading supplier of medicines around the world, announced a curb on exports of certain essential medicines last year but it was eased after Chinese supplies resumed.

Pharma industry 'unhappy':

Officials of pharma lobbies — professional associations such as the Indian Pharmaceutical Alliances (IPA) and the India Drug Manufacturers' Association — expressed dissatisfaction with the Budget allocation. Speaking to ThePrint, they said the amount is "negligible".

"If the government is serious in reducing the industry's dependence on China, the investment required is in lakh crores, and not hundred crore. While the hike shows that the government has recognised the need to invest in the pharmaceutical industry, the amount allocated is of no real value," a pharmaceutical industry veteran working with an industry association said. Another official echoed the concerns. "The task of reducing or eliminating dependence on Chinese imports is humongous and needs investments in a similar proportion," the official said. "The allocation in the Budget is a mere formality." Both officials requested anonymity, saying they will release official statements with "overall comments" on the Budget.

Source: Himani Chandna, The Print, 02.02.2021

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Experts recommend India should now focus on Clinical Trials, research, innovation & technology to become the largest Global Health Technology Center

Experts while commenting on Union Budget has recommended that India should now focus on Clinical Trials, research, innovation and technology as there is potential for India to become the largest global health technology center. As an additional opportunity, India can generate employment and be a healthcare service provider for the world."

While commenting on the budget, Dr Prathap C Reddy, Chairman, Apollo Hospitals Group said, "The Covid-19 pandemic was an unprecedented medical crisis and it underlined the importance of building a resilient healthcare infrastructure. Today, the Finance Minister's said health was her first pillar and her announcements to develop primary, secondary and tertiary healthcare systems will provide access to medical care for all in our country, fuel job creation and boost economic momentum.

He further added that India's efforts in managing the pandemic have been exemplary – our frontline workers and scientists have been working tirelessly to save lives and develop indigenous vaccines. Now the allocation of Rs. 35,000 crore for Covid-19 vaccines and more if required, makes our glorious nation stand tall as a model for the world. We must now look at the next crisis of non communicable diseases, which will be responsible for 80% of deaths and cause a US$ 3.8 trillion burden to the country by 2030. It is important to focus on prevention, early detection and possible cure to protect Indian families from grief, financial burden and to help the GDP grow.

On behalf of NATHEALTH, Preetha Reddy, President, NATHEALTH and Executive Vice Chairperson, Apollo Hospitals said, "This will strengthen preventive health and

ensure frontline allied health worker skill building while increasing robust community surveillance of emerging infectious diseases. This announcement reinforces the commitment government made earlier under the Ayushman Bharat programme to strengthen public health and community health through health and wellness centres."

Adding to her comments, Siddhartha Bhattacharya, Secretary General, NATHEALTH said, "Using India's deep experience in digital health, skilled manpower availability, Clinical Trials, manufacturing prowess and proven ability to deliver affordable excellence in healthcare, India can emerge as a global centre of excellence for holistic healthcare weaving the preventive, promotive, curative and rehabilitative spectrums. This can position healthcare as a top employment generating sector while bringing in valuable investments to fund the journey towards universal healthcare, reducing out of pocket investments."

Said Neerja Birla, Founder & Chairperson, Mpower, "We appreciate the measures proposed by Finance Minister Nirmala Sitharaman in the Union Budget to take a holistic approach to healthcare in the Union Budget 2021, by focusing on preventive and curative healthcare in addition to wellbeing. While the allocation to healthcare in this budget has increased substantially, we believe mental healthcare also deserved a special mention. As aptly mentioned by the FM in the Budget speech, last year was an undeniably tough year for our physical and mental well-being. Covid-19 has brought India's mental health crisis to the fore. Unfortunately, the rising number of cases of mental illness has not been accompanied by a parallel rise in the budget allocation for mental healthcare. Amidst the challenging and competitive era that we are living in, it is extremely crucial to acknowledge the importance of mental healthcare and invest in educating citizens to make them aware of mental health services available in India while taking measures to alleviate the stigma associated with it."

Sharing his views, S Purnachandra Rao, the new National President for Indo American Chamber of Commerce (IACC) said, "Growth-oriented and transformative, the Finance Minister's 2021-22 budget includes many welcome signals for entrepreneurship and foreign direct investment. To begin, allowing 74% FDI in the insurance sector is a 'game-changing' reform. The boost to healthcare and infrastructure, areas dear to American companies, will lead to more FDI and better employment opportunities. We specifically laud their decision here to set up seven textile parks. Moreover, we at the Indo American Chamber of Commerce (IACC), welcome the government's encouragement to NRIs to operate One Person Companies of OPCs in India. They've done this by reducing the registration timeline from 182 days to 120 days."

Prashant Narang, co-founder, Agility Venture Partners further added, "The budget looks promising for the start-up industry as measures like an extended tax holiday will help the start-up scenario in the country. Consequently, focus on skill development by partnerships with UAE and Japan, as well as reforms proposed for MSMEs like collateral free loans and funds for MSMEs is a highly encouraging move for the sector. Overall, the new-budget is welcomed for its positive focus on boosting entrepreneurship in India.

Commenting on the Union Budget 2021, Kishore Narne, Head – Currency & Commodities, Motilal Oswal Financial Services Ltd said, "Government has made their intentions clear to put the gold exchange initiative on fast pace by proposing SEBI as regulator for the same. This will now pave way for a new era of gold trading in to India. Government also rationalised the import duty on gold, through some of it was taken back in the form of Agriculture Infrastructure and Development Cess (AIDC), but still the overall duty was reduced by 2.5%. On the otherside they tried to garner more resources to support agriculture through special cess and also initiated few duty hikes like in cotton to protect domestic farmers."

According to Dr Gautam Sen, Chairman & Founder, Healthspring said, "This government ever since it came to power has been giving importance to basic health issues like public health in "Swatccha Bharat" addressing better sanitation for all, Ayushman Bharat by Financing Tertiary Care Expenses for those who are below the poverty line, the 'Pradhan Mantri Jana Aushadhi Yojana" where generic medicines are made extremely affordable and culminating into "Health Policy 2017" where it rightly gives importance to wellness and health and invites all section of healthcare providers to participate in Nation's health outcomes.

Source: Pharmabiz, 03.02.2021

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Experts underline key elements mandatory for upcoming two Covid-19 vaccines in India

Public Health and medical experts underlined the key elements mandatory for upcoming two Covid-19 vaccines in India after Finance Minister Nirmala Sitharaman recently

announced the government's decision to roll out more Covid-19 vaccines soon in India.

"The decision of the Indian government to consider approval for more vaccines is a much needed and timely move, to 30 crore population. Genova Pharmaceutical, Zydus Cadilla and Sputnik V are among the candidates most likely to get approvals soon. It is encouraging to see that The Lancet article confirmed positive outcomes and provided additional data about the safety and efficacy of Sputnik V in different subgroups. According to the study, efficacy of Sputnik V stands at 91.6%. Compare it with Covishield (India) which stands at 62.1%, Sinovac (China) at 50.4%, Sinopharm (China) at 79.3%. The Sputnik V vaccine is relatively easy to produce and transport amidst the expected shortage of vaccines globally and logistical problems in roll-out of vaccines that are temperature sensitive," says Dr Sanjiv Kumar, Chairperson of the Indian Academy of Public Health and Indian Alliance of Patients Group, Former Senior Advisor at UNICEF and Former Director at IIHMR.

"World Health Organization and the Director General of the Indian Council of Medical Research mentions that the vaccination against Covid-19 vaccine should give minimum 50% protection to be recognized as effective. The vaccines that recently cleared the phase III of Clinical Trials, however, have exceeded that expectation. Pfizer, Moderna and Sputnik V had passed the efficacy test with 90+% during phase I and II; Sputnik V, however, is the first adenovirus vector vaccine to achieve the 90% efficacy seen with the two mRNA vaccines after phase III of the Clinical Trials," says Dr. Gajendra Singh, Public Health Expert.

Dr Singh added, "The peer-reviewed journal Lancet published interim analysis data of phase III trials of the vaccine involving over 20,000 adults in Russia and found it 91.6% efficient. It also shows that a sub-analysis of over 2,000 participants aged over 60 years indicates that the vaccine was similarly effective and well tolerated in the elderly as well. Over 98% of volunteers developed humoral immune response and 100% - cellular immune response."

The efficacy of any vaccine is dependent on the technological platform it utilized. Sputnik V is based on human adenovirus platform, a tried and tested one that was used to fight Ebola in the past. AstraZeneca vaccine on the contrary is based on chimpanzee adenovirus is not very popular among the scientific community. Moreover, vaccines such as Covishield and Sputnik V are fit for Indian terrain since they can be stored at +2º+8ºC in contrast with mRNA vaccines with much more extreme temperature regimen of -70º-20ºC, Dr Debkishore Gupta, Consultant Clinical Microbiologist and head of infection control, CK Birla Hospitals, India.

Source: Pharmabiz, 03.02.2021

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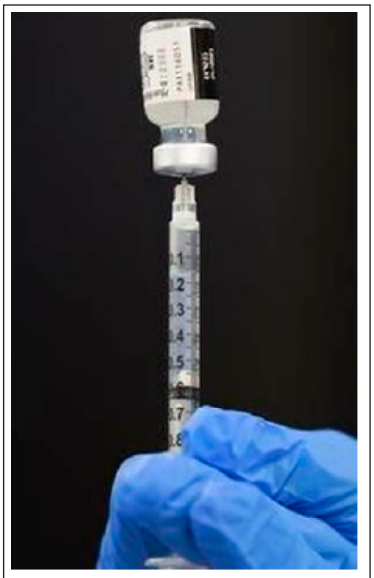
Covid-19 vaccine becoming a reality, says India

India has made a renewed case for Trade Related Intellectual Property Rights (TRIPS) waiver at the World Trade Organization (WTO) pointing out that the worst fears of global shortage in Covid-19 vaccine supplies were becoming a reality, according to a Geneva-based official. There were delays in vaccine rollout programmes in most countries as manufacturing and availability of the vaccine doses were falling short owing to Intellectual Property (IP) barriers, it said at the informal meeting of the TRIPS Council on Tuesday, 19.01.2021.



'Many countries not able to utilize their manufacturing capacities due to IP barriers'

WTO members could not reach a consensus on the proposal by India and South Africa for a temporary waiver of certain TRIPS obligations, made on October 2, 2020, to ensure supplies of essential medication during the Covid-19 pandemic, but they agreed to continue consideration of the suggestions, the official said. "Some members, many of them developed countries, continued to oppose the waiver putting forward their earlier arguments with about 30 members exchanged views on the matter," the official said.

The opposers:

Members such as Japan, the EU and the US had opposed the waiver arguing that it will not serve any purpose in improving medical supplies during the pandemic. The

EU argued that it was unnecessary and pointed out that the expansion of production was already taking place with companies granting licences. New Delhi, however, argued that licensing arrangements for increasing manufacturing of vaccines were not working as much as required. It pointed out that due to new IP barriers, there were many countries that were not able to utilise their manufacturing capacities to produce the vaccines.

South Africa pointed that there was a sharp increase in casualties since the discussion for the proposed waiver had started and evidence was now coming up on how global vaccination would be hindered due to IP barriers to access, the official said.

'Move to next level':

It said members opposing the waiver should reconsider some aspect of the proposal like timeframes and scope. South Africa proposed that no more time should be spent on the evidentiary aspect of the discussion and the next formal TRIPS Council should move to text-based discussions. At the last informal meeting in December 2020, the country presented a paper that had examples of IP creating problems in access to medical products. It included barriers related to trade secrets, industrial designs and know-how. Afghanistan, Pakistan, Zimbabwe, Egypt, Mongolia, Chad, Indonesia, Nepal, Bangladesh, Sri Lanka, Cambodia and Venezuela also spoke in support of the waiver proposal. More clarity on the operation of the waiver was sought by China, Chinese Taipei, Chile, Malaysia, Australia, Colombia and Canada.

Source: Amiti Sen, The Hindu Business Line, 20.01.2021 (Excerpts)

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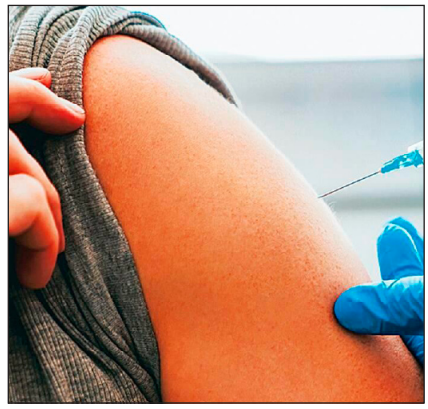
Zydus Cadila starts enrolment for late stage vaccine trial

Late stage human trials of Zydus Cadila's three-dose Covid-19 vaccine begun in the country this week, with the enrolment and vaccination of participants underway, The Indian Express has learnt. This puts the Ahmedabad-headquartered company right behind Dr Reddy's Laboratories in the pipeline of vaccines that the country may be adding to its arsenal against the virus that has killed 1.5 lakh and infected over a crore.

"Enrolment began (at some of the sites) this week," said a person close to the development on condition of anonymity. According to another, some other trial sites are still in the process of site inspections — a check by regulatory authorities of the place where the Clinical Trials will take place, following which clearance is given to enroll and vaccinate participants.



The trials are expected to take place at five sites across four cities — Surat, Nashik, Jaipur and Ahmedabad, according to information from the Clinical Trials Registry of India.

Source: Prabha Raghavan, The Indian Express, 22.01.2021

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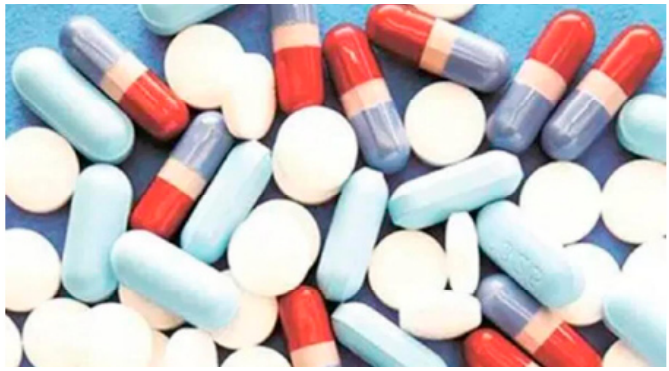
Self-reliance push: 3 Companies to manufacture priority bulk drugs



The firms have committed to a total investment of around Rs. 3,761 crore for setting up these plants, according to the Ministry of Chemicals and Fertilizers, which expects commercial production to commence from April 1, 2023. (Representational)

The Government on Friday, 22.01.2021 gave the green light to three drug makers, including one public sector firm, to set up capacities under the Production-Linked Incentive (PLI) scheme to promote self reliance in critical drug ingredients in the country. The firms — Aurobindo Pharmaceuticals, Karnataka Antibiotics and Pharmaceuticals Ltd (KAPL) and Kinvan Pvt Ltd — will be the first to make select bulk drugs under the recently approved scheme.

India is presently "fully" dependent on imports for these products — penicillin G, 7-aminocephalosporanic acid (7-ACA), erythromycin thiocyanate (TIOC) and

clavulanic acid — which is why they were considered for approvals on priority.

The firms have committed to a total investment of around Rs.3,761 crore for setting up these plants, according to the Ministry of Chemicals and Fertilizers, which expects commercial production to commence from April 1, 2023. The Government would be disbursing up to Rs.3,600 crore in PLI over the agreed six-year period of the scheme. Aurobindo, through subsidiary Lyfius Pharma, will be setting up Greenfield capacities to make penicillin G as well as 7-ACA (used to make cephalosporin antibiotics and intermediates). The Hyderabad firm will also be building capacities to make TIOC through subsidiary Qule Pharma.

KAPL will also be manufacturing 7-ACA, while Kinvan will be making clavulanic acid, according to the Ministry. "Setting of these plants will make the country self-reliant to a large extent in respect of these bulk drugs," said the Ministry in a release about the development.

The Government in March 2020 had announced its intent to launch a PLI scheme for critical bulk drugs, including Key Starting Materials (KSMs), Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The announcement came a couple of months after Covid-19 cases in China had surged, causing the neighbouring country to shut down several bulk drug manufacturing plants in its Hubei province. This led to the Government announcing a restriction on exports of various Key Drug Ingredients.

Over the last three decades, India has slowly grown more dependent on imports from China for such ingredients, leading to firms with indigenous capacity to make these raw materials to shut shop, industry executives earlier told. It relies on China for about 70 percent of its bulk drug imports, as per Government figures.

With rising tension between India and China last year and Prime Minister Narendra Modi's call for India to be more self-reliant in various sectors, the Department of Pharmaceuticals (DoP) last year launched the PLI scheme with a total outlay of Rs.6,940 crore. It sought applications from Indian drug makers to set up Greenfield capacity in 36 bulk drugs by November 30, 2020.

A total of 215 applications were received and were to be processed and decided upon by February 28, 2021, according to the Ministry. While the first four bulk drugs that the Government has given approvals for come under the first of four target segments of key ingredients, applications under the other three segments are proposed to be taken up for approval in the next 45 days.

Source: ENS Economic Bureau, The Indian Express, 23.01.2021 (Excerpts)

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Indian Pharma Market Growth slips to 4.5% in January 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 4.5 percent for the month of January 2021, as against growth of 8.5 percent in December 2020. According to AIOCD AWACS report, the IPM has recorded sales of Rs.1,45,931 crore for Moving Annual Total (MAT) basis during January 2021.

Amongst the top 10 corporates, Cipla exhibited the highest growth of 8.7 percent, followed by Torrent Pharma at 6.6 percent. Amongst the 11 to 25 ranked corporates, Glenmark Pharma exhibited highest growth of 15.7 percent followed by Himalaya at 14.3 percent.

Amongst the 26 to 50 ranked corporates, Apex Lab registered the highest growth of 21.6 percent followed by Boehringer Ingelheim at 12.1 per cent. Amongst the 51 to 75 ranked corporates, Danone registered the highest growth of 34.1 per cent. Amongst the 76 to 100 ranked corporates, Unimed TL exhibited the highest growth at 18.2 per cent, followed by Unison at 9.3 percent.

Cardiac registered a monthly growth of 8.8% in January 2021 as compared to 14.9% in December 2020, while anti-diabetic registered growth of 5.3% in January 2021 as compared to 9.9% in December 2020.

Respiratory segment posted negative growth and slumped to -14.1% in January 2021 as compared to -9.8% in December 2020. Few therapy areas that had slumped in COVID quarters are coming back to normal performance gradually. Post-unlockdown, since June 2020 the struggle for anti-infectives 5.2% in December 2020 continues -2.7% in January 2021 and its associated therapy like gastro exhibits growth of 14.3% as against 16.2% in December 2020. Vitamins have bounced back has growth of 12.2% in January 2021. Pain and analgesics are at 5% in January 2021 as against -6% in December 2020.

Source: Yash Ved, Pharmabiz, 09.02.2021

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Thrust on MSMEs, employment generation to augur well for Pharma Industry: Experts

The Union Government's recent impetus to the Micro, Small and Medium Enterprises (MSMEs) comes as an advantage to the Indian Pharmaceutical Sector in the area of manufacture. This, according to industry observers, makes the case stronger for the creation of a skilling ecosystem to ensure productivity at execution.

India has a robust ecosystem for development and manufacturing of Pharmaceuticals. The Productivity Linked Incentive (PLI) scheme will incentivize the global and domestic players to engage in high value production. The slew of policies announced in the Budget 2021 can make Pharma manufacturers globally competitive, attract investment in the areas of core competencies and infuse advanced technology; ensure efficiencies; create economies-of-scale; enhance exports, making the sector an integral part of the global supply chain, experts say.

All this is definitely aimed to make India a better place to do business and access quality education. The increased focus on job creation will step up production and boost R&D to prepare the workforce for Industrial Revolution 4.0. The outlook to amend the Apprenticeship Act will lead to providing attractive incentives for Small and Medium Enterprises (SMEs), boost skilling and create employment opportunities, said Sumit Kumar, Vice President, NETAP, TeamLease.

Realignment of National Apprenticeship Training Scheme (NATS) and the allocation of Rs.3.000 crore in the Union Budget 2021 will motivate organizations for providing apprenticeship training. Commencing of degree and diploma apprenticeships in the non-technical stream will improve the employability factor for the youth and prepare a productive workforce the country for sectors including Pharma, he added.

Additionally setting up of the Higher Education Commission will help us understand the ground realities of execution of policies like that National Education Policy among other education reforms, and will help in addressing challenges in execution as well, said Kumar. According to P S Srikanta Dutta, President Laghu Udyog Bharati-Karnataka, with specific emphasis on a slew of policy-oriented announcements that target to promote MSMEs, promote job creation will spur overall economic growth as it clearly sets the right tone for overall economic growth.

"With the implementation of the seamless integration of GST, there is growing confidence in the Government's ability to take on difficult reforms in India. The improvement in investor confidence is evident from capital flows as foreign investors continue to bet on India as one of the best destinations for investment across the emerging markets, added Dutta.

Source: Nandita Vijay, Pharmabiz, 04.02.2021

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No violation of data privacy under National Digital Health Mission: Union Health Minister

There is no violation of data privacy of citizens under the National Digital Health Mission as it enables appropriate use of health data with the consent of an individual, stated Ashwini Kumar Choubey, MoS, Health and Family Welfare. The National Digital Health Mission (NDHM) programme was announced by Prime Minister Narendra Modi in his Independence Day speech last year. Choubey said the pilot phase of the mission is active in the Andaman and Nicobar Islands, Chandigarh, Dadra and Nagar Haveli, Daman and Diu, Ladakh, Lakshadweep and Puducherry.

As on January 21, 2021 as many as 6,30,478 Health IDs have been generated. The selection of vendors for NDHM is compliant with various applicable Rules and Policies of the Government. The data is stored in a federated architecture as described in the National Digital Health Blueprint released by the Government of India in 2019. "There is no centralized database of medical records. However, NDHM enables appropriate use of the health data of each individual for his/her own healthcare with his/her consent only," added Choubey.

On steps taken to protect data privacy, Choubey said it is inbuilt in the design of NDHM. "All applicable laws, rules and judgments of the Supreme Court are being followed. Health Data Management Policy has also been approved. Apart from various legal provisions, all technical solutions possible to ensure data privacy and security are being put in place," Choubey said.

One of the key aspects of information security framework under NDHM highlights privacy by design as one of the key guiding principles. "It aims to ensure that health

data and its transfer are always compliant and adhere to all privacy requirements. All the building blocks that require handling personal health records are being designed to comply with such policy ab initio. Further, medical records are made available to anyone only with the consent of the individual or his/her nominee," the Minister said.

Source:Yash Ved, Pharmabiz, 04.02.2021

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Accord 'strategic sector' tag to Pharma industry: Parliamentary Panel

Highlighting the need for strong indigenous Pharma companies, a Parliamentary panel has recommended that the Pharma industry should be categorised as a "strategic sector" and called for a necessary follow-up action in this regard.

In its report, tabled in Parliament on Friday, 29.01.2021 on the review of loss-making central public sector enterprises, the Committee on Public Undertakings chaired by Meenakshi Lekhi observed that the indigenous awareness of healthcare facilities is of paramount importance of any nation. The Committee said it was of the strong opinion that Pharma sector plays a very important role to keep the nation healthy and strong, and this has been quite apparent during the current pandemic when the need for strong indigenous Pharma companies has been realised with more intensity.

"The Committee therefore recommend that Pharma sector should be categorised as a 'strategic sector' and a necessary follow-up action needs to be taken accordingly," the report stated. Besides, in certain other sectors like light and heavy engineering products, the PSUs like SAIL are in dire need of constant technology up-gradation to keep pace with the market demands and compete with the multi-national companies.

The Committee also observed that during the current pandemic when other airlines could not come to rescue, it was only Air India which brought Indian citizens from foreign countries and thus its importance was realised during this crisis in a bigger way. It noted that the aviation sector being of strategic importance, the country needs to have its own national air carrier which could be relied upon during the crisis. "The Committee therefore urges the Government to maintain a fine balance between the national interest of having its own airlines and overall health of national carrier. The Committee would like to be apprised of the progress made so far and the latest developments about the status of Air India," stated the panel's report.

Source: PTI, The Economic Times, 30.01.2021

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DoP to appoint PMA to implement PLI scheme; invites Public Financial Institutions to provide services

The Department of Pharmaceuticals (DoP) will soon appoint a Project Management Agency (PMA) to implement Production Linked Incentive (PLI) scheme for pharmaceuticals. For this purpose, the DoP has invited proposals from public financial institutions for providing the services of PMA. As per a DoP notice, proposals are solicited from public financial institutions (Government companies only) for providing services of a Project Management Agency for the implementation of Production Linked Incentive scheme for Pharmaceuticals.

As per Terms of Reference (ToR), the PMA shall provide implementation support for effective implementation of the PLI Scheme. It shall also be responsible for the development and maintenance of an online portal for receipt of applications. It will prepare operating procedures for processing, scrutiny, appraisal, verification, etc., as per procedure or established practice and getting them approved from DoP.

The PMA shall also process applications against the qualification and evaluation criteria for the purpose of selection of participants. It would receive the application fee or bank guarantee from the participants on behalf of the DoP and deposition of the same to DoP at appropriate time. The proposals will be evaluated through Quality and Cost Based Selection (QCBS) process which gives weighted scores to both the technical proposal (Quality) as well as the financial proposal (Cost).

The notice further stated that DoP is proposing to introduce a PLI scheme for pharmaceuticals in the month of January, 2021 with the objective of enhancing India's manufacturing capabilities by boosting investment and production as well as contributing to product diversification of high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions from amongst domestic players who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains.

Under the scheme, applicants shall apply in three different categories.

The criteria for categorization shall be on the basis of the Global Manufacturing Revenue (GMR) of Financial Year (FY) 2019-20 in each group, details of which will be issued in the scheme Guidelines which are under preparation.

The applications would be received through an online portal. Post the closure of application period, the selection process shall be completed by end of April, 2021. Remaining period of FY 2021-22 will be the gestation period given to the selected participants to set up manufacturing plants, etc. Thereafter, the selected participants shall be given financial incentives based on the incremental sales of pharmaceutical goods covered under the scheme over a period of 6 years. FY 2019-20 is proposed to be the base year for calculation of incremental sales.

PLI scheme which is applicable only for Greenfield projects intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reducing India's import dependence in critical APIs. Under the scheme, financial incentives shall be given for six years based on sales made by selected manufacturers for 41 products which cover all the identified 53 APIs. The tenure of the scheme is from FY 2020-21 to FY 2029-30.

The total scheme outlay will be Rs.15,000 crore which will also include the expenditure for hiring the services of the PMA. The DoP has also recently introduced revised PLI scheme Guidelines for promoting domestic manufacturing of KSMs, DIs, APIs and medical devices, removing minimum investment criteria and incorporating export and sale-based production criteria following an appeal by the Pharmaceutical industry.

Source: Shardul Nautiyal, Pharmabiz, 01.02.2021

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Indian Pharma sector set to grow 3 times in next decade, says Economic Survey

India's pharmaceutical industry, which is currently valued at $41 billion, is expected to grow to $65 billion by 2024 and $120-130 billion by 2030. According to the Economic Survey 2020-21, a significant raw material base and availability of a skilled workforce have enabled India to emerge as an international manufacturing hub for generic medicines. Further, India is the only country with the largest number of US FDA compliant Pharma plants (more than 262 including Active Pharmaceutical Ingredients - APIs) outside of the USA.

At the same time, the Global Pharmaceutical Market is set to exceed $1.5 trillion by 2023, the Survey said. Covid-19 has presented both an opportunity and a challenge for India to emerge as the 'pharmacy of the world'. During April-October, 2020, India's pharmaceutical exports totalling $11.1 billion witnessed an impressive growth of 18%, as against $9.4 billion during the corresponding period a year ago.

This has led to an increase in the share of pharmaceuticals exports in India's total exports from 5.1% in April-October, 2019 to 7.3% in April-October, 2020, making it the third largest exported commodity. "The commitment of provision of Covid-19 vaccine to other countries has made India the epicentre for its manufacturing," the Survey noted.

According to data available from US FDA, Indian Pharma companies have garnered nearly 45% of all New Abbreviated New Drug Application (ANDAs) approvals over the past nine months, which would aid exports growth in the coming years. The pandemic, however, exposed the excessive dependence of Indian Pharmaceutical Industry on China for sourcing Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs). Further, there is a disproportionate dependence of Indian Pharma exports on the USA and generics. To get over this challenge, the Government has identified pharmaceuticals drugs as one of the ten key sectors for introducing Production Linked Incentive (PLI) Scheme for enhancing India's manufacturing capabilities and exports.

This is in addition to the already notified PLI schemes for bulk drugs and medical devices, which aim to provide a boost to domestic manufacturing for critical KSMs/ Drug Intermediates (DIs), APIs and medical devices. Both these schemes have received a very encouraging response from the pharmaceutical as well as the medical device industry. Further, the Government has also announced a scheme for promotion of bulk drugs and medical devices parks.

Source: Mahesh Kulkarni, (DHNS), Deccan Herald, 29.01.2021

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Gujarat FDCA to give boost to MSMEs through series of upskilling programmes

The Gujarat Food and Drug Control Administration (FDCA) is in talks with Central Drugs Standards Control Organisation (CDSCO) and Indian Drug Manufacturers' Association (IDMA) Gujarat State Board to give boost to Micro, Small and Medium Enterprises (MSMEs) through a series of upskilling and training programmes towards adherence and compliance to WHO-GMP standards. Gujarat FDCA recently concluded a virtual meet with US FDA officials and shared experiences of the ongoing Covid-19 pandemic towards equipping Indian regulators and industry on Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Lab Practices (GLP).

According to Gujarat FDCA Commissioner Dr H G Koshia, "We are talking to IDMA and CDSCO Western Zone Deputy Director to start with one training programme towards orienting the MSMEs to upgrade themselves to WHO-GMP so that small Pharma players get the advantage of the evolving global regulatory regime." The Small and Medium Pharmaceutical companies had earlier urged the Centre to expedite implementation of Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) so that they can avail interest subsidy of 6% to upgrade infrastructure and technology to globally accepted standards.

The aim of the scheme is to help Pharma MSMEs improve technology and infrastructure to migrate from Schedule M to World Health Organisation Good Manufacturing Practice (WHO-GMP) standards. For this, the Centre has offered a 6% interest subvention on loan up to Rs.8 to 10 crore for three years. It has earmarked Rs.300 crore for disbursal as interest subsidy for 2020-2022. According to experts, there is a need for risk based inspections and embracing global standards through upgradation of Schedule M units to WHO-GMP compliant units to retain India's position as Pharmacy of the World.

Gujarat has over 700 plus WHO-GMP units and 130 US FDA approved drug manufacturing units in the country. Gujarat also has the distinction of having 28 percent of drug exports to developed markets including the US. The state is aggressively moving towards upgradation of Schedule M units to WHO-GMP compliant drug manufacturing units as part of the global harmonization programme. US FDA-Gujarat FDCA Regulatory Forum which was started in the year 2008 to usher in dialogue between senior leaderships of the US FDA and Gujarat FDCA to take forward the avenues for future strategic collaboration towards effective regulatory compliance has immensely helped Gujarat drug control officials in understanding regulatory requirements of US FDA.

US-based consulting firm World Compliance Seminars (WCS) in 2018 also conducted workshops on subjects like how to be prepared for US FDA inspections and how to develop quality culture in Indian Pharma companies.

A team of US FDA officials last year visited Gujarat FDCA in which Letitia Robinson, Country Director, OIP, India Office, US FDA met Gujarat FDCA Commissioner Dr H G Koshia towards building regulatory compliance in both countries.

Source: Shardul Nautiyal, Pharmabiz, 27.01.2021

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Cluster Development to propel indigenous Pharma manufacture & Access Global Markets: Minister

For the Indian Pharma industry, cluster development approach is the best format to achieve overall economic development and the way forward to achieve the *Atmanirbhar Bharat*, stated Union Minister of State (MOS) for Micro, Small and Medium Enterprises (MSMEs) Pratap Chandra Sarangi. Citing the example of Khadi industry which is now a national movement in textiles, Sarangi said that on similar lines cluster approach will spur employment opportunities and bring the capabilities in manufacturing for Indian Pharma.

At an interactive session organized by *Laghu Udyog Bharati*, Karnataka Chapter (LUB-K) in Bengaluru, Sarangi said, "The MSME industry needs expansion and its scope is enormous. We need to think of ways to provide entrepreneurs their due, to improve market availability and access and to provide technology to them." The Government understands the importance and contribution of MSMEs. Now, the time has come to be a self-reliant country and for this MSME can play a very important role in this mission of nation-building. We are increasing opportunities for this sector to reduce dependence on imports, and able to scale up operations to gain higher market share," he said.

The MSMEs contribute 29.7 percent to India's GDP, accounts for 49.66 percent of exports. And close to 45 percent of the manufacturing output. Though the pandemic

seriously impacted MSMEs, Pharma industry showed its perseverance. However, the Government too announced the *Aatmanirbhar Bharat* package aimed to help MSMEs survive the blow of the COVID-19 by infusing liquidity, he said.

According to Karnataka Minister for Medium and Heavy Industries Jagadish Shettar, the state is working to accelerate further development and job creation. The several initiatives specifically announced for the MSMEs will facilitate investments in advanced manufacturing, Research and Development and innovation as the aim is to create at least 2 million jobs across sector including biotechnology and Pharma. Therefore the state Government will support industries in cluster mode to ensure rapid growth and attract capital.

Stressing on the need for more technology adoption by the MSMEs for better efficiency and competitiveness, P S Srikanta Dutta, President, Laghu Udyog Bharati, Karnataka Chapter (LUB-K), pointed out, "MSMEs face several challenges, including technological obsolescence, supply chain inefficiencies, increasing global competition, uncertain market scenario, and lack of funding. Given these challenges, it is critical to focus on creating tech-efficient MSMEs that they make optimal use of the technology-enabled platforms.

Source: Nandita Vijay, Pharmabiz, 27.01.2021

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Health Ministry to amend Rule 123 to add & delete certain drugs coming under Schedule K

The Union Health Ministry will soon amend Rule 123 of the Drugs & Cosmetics Rules 1945, and will add and delete certain drugs coming under the Schedule K of the Drugs and Cosmetics Rules.

The move comes in the wake of the fact that the Karnataka State Registered Pharmacists Association (KSRPA) had earlier raised objections over Rule 123 and called for its amendment in a time bound manner. Rule 123 read with Schedule K of the D&C Rules 1945 provides exemption from certain rules for certain drugs and Schedule K specifies the extent of exemptions.

In a communication, Somnath Basu, Assistant Drugs Controller, CDSCO stated that after the KSRPA's complaint was examined, the effort to direct a proposal to create a separate provision for the Over-the-Counter (OTC) drugs has been deliberated in various Drugs Consultative Committee (DCC) meetings to create a separate provision for the OTC drugs. This was made at the 52nd meeting held on September 18, 2017, 55th meeting on January 31, 2019 and February 1, 2019 besides at the 57th meeting on August 20, 2019.

"The sub-committee constituted by the DCC had given recommendations on various aspects of the OTC drugs. These are to include definition of OTC, its basic characteristics and classification. It also included the preparation of an initial list of OTC, regulation of prescription (Rx) drugs to OTC drug switch process, regulation of new OTC drug approval, manufacturing and labeling of OTC drugs, advertisement of these over-the-counter drugs and it's pricing," Basu noted in his communication to the KSRPA President, Ashokswamy Heroor.

Further the letter also noted that the DCC in its 57th meeting held in mid August 2019, after considering the recommendations of the sub-committee, suggested for suitable amendment in the Schedule K of the Drugs & Cosmetics Rules to incorporate necessary provisions for such drugs to be exempted from requirements of seeking sale license, and prescription of a Registered Medical Practitioner (RMP).

Now subjected to appropriate conditions, the sub-committee should identify such a list along with the conditions and frame a draft for amendments in the Rules. The communication also stated that further action in this regard would be under consideration by the sub-committee. This order is also being issued with the approval of the competent authority, he said.

"This is a major development for us as the Union Government's Directorate General of Health Services and the CDSCO have comprehended our objection. We are confident that the Government will make the necessary amendments and bring in more clarity on both OTC and the drugs under the Schedule K ambit," Heroor told.

Source: Nandita Vijay, Pharmabiz, 25.01.2021

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PMBJP registers 60% higher sales worth Rs.484 crore in FY 2020-2021

The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) has registered sales worth Rs.484 crore upto January 12, 2021 of the financial year (FY) 2020-2021 with the setting up of new 260 Jan Aushadhi centres taking

the total number of Jan Aushadhi centres to 7,064 centres across the country.

PMBJP scheme has been approved with a budget of Rs. 490 crore for the period 2020-2021 to 2024-2025. Centre also plans to set up 10,500 Jan Aushadi Kendras by end of March 2025.

The figure of Rs. 484 crore in FY 2020-2021 is 60% higher than the corresponding figures of the previous FY 2019-2020 which has led to savings of Rs. 3,000 crore to the citizens of this country. In the FY 2019-2020, the Government of India's grant for the Jan Aushadi Kendras was Rs 35.51 crore while savings to citizens were Rs. 2600 Crore.

PMBJP had faced many challenges in the month of March to June, 2020, regarding shortage of API and other raw material of pharmaceuticals, disturbance in supply of medicines to Jan Aushadhi Kendras from Central and regional warehouses due to non-availability of vehicles for transportation among other issues.

Despite the COVID lockdown and testing times, PMBJP clocked sales turnover of Rs. 146.59 crore in the first quarter of 2020-2021 as compared to Rs. 75.48 crore achieved in the first quarter of 2019-2020. Between July and September 15, 2020, the stores added sales of Rs. 109.43 crore. In the month of July, 2020, BPPI added a sales of Rs. 48.66 crore. The total sales up to July 31, 2020 stood at Rs. 191.90 crore.

The Jan Aushadi Kendras remained functional during lockdown and maintained operations as part of their commitment to ensure uninterrupted availability of essential medicines. They sold about 15 lakhs face masks, 80 lakhs tablets of hydroxychloroquine and 100 lakhs paracetamol tablets, which saved around Rs. 1260 crore of the citizens.

The present basket of medicines sold by these kendras consists of 1,250 medicines and 204 surgical instruments. The target is set to enhance it up to 2,000 medicines and 300 surgical products by the end of March 31, 2024 so that all essential medicines covering therapeutic groups, like - anti-diabetics, cardiovascular drugs, anti-cancer, analgesics and antipyretics, anti-allergic, gastro intestinal agents, vitamins and minerals, food supplements and tropical medicines among others.

The cost of Jan Aushadi medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. These medicines are procured on an open tender basis from WHO-GMP compliant manufacturers only.

The incentive provided to the centre owners has been enhanced from existing Rs. 2.50 lakh to up to Rs. 5 lakh to be given @ 15% of monthly purchases made subject to a ceiling of Rs. 15,000 per month.

One-time incentives of Rs. 2 lakh is to be provided to the PMBJP Kendras opened in North-Eastern States, Himalayan areas, Island territories and backward areas mentioned as aspirational district by NITI Aayog or opened by women entrepreneur, Divyang, SC and ST in the form of furniture and fixtures.

Source: Shardul Nautiyal, Pharmabiz, 25.01.2021

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PLI scheme for bulk drugs positive for Indian Pharma industry, say experts

The Government has approved the applications of Aurobindo Pharma and Karnataka Antibiotics and Pharma. The approval is for four products and for both companies, the total investment is Rs.3,700 crore. Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance and Nithya Balasubramanian, Director, Sanford Bernstein discussed the development.

"It is a great positive step for the Indian pharmaceutical industry. This scheme covers not only companies but we are also talking of the pharmaceutical clusters. We will also have three clusters in the country which will be announced in due course of time. Rs.6,940 crore have been kept for APIs and Rs.3,000 crore has been kept for pharmaceutical clusters.

We need to create an overall ecosystem for this that will encourage the production of APIs in this country. This is a very positive step both from the industry point of view, from the country point of view and overall world point of view because we are talking about diversified supply chain from the world today," Jain said.

Sanford Bernstein's Balasubramanian said, "I think the Production-Linked Incentive (PLI) scheme should definitely give a kicker to the Active Pharmaceutical Ingredient (API) industry. The biggest challenge for Indian companies has been their ability to match the scale that Chinese companies have built over the last several years. The PLI scheme should definitely support as long as the incentives last. It can level the playing field."

A shift to India from China as the main source of supply in API is possible, Balasubramanian said. "In most products, we are talking about 15-20 percent kind of price difference between Chinese API and the India APT and the incentives can definitely go a long way towards reducing that differential. I do believe in the next three-four year timeframe we will start seeing customer shift to India as the main source of supply," she said. On the valuations front, she said, "Valuations have gone up more than what I would be comfortable with."

Source:www. cnbctv18.com, 28.01.2021 (Excerpts)

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DoP proposes one-time settlement scheme to settle disputes relating to overcharging

The Department of Pharmaceuticals (DoP) has proposed draft framework of Special One-Time Settlement (SOTS) scheme to pharma companies for fast track recovery of liabilities relating to overcharging cases under Drugs Price Control Order (DPCO) 1979, 1987, 1995, 2013 in exercise of the powers conferred by the DPCO-2013 read with section 3 of the Essential Commodities (EC) Act, 1955, (10 of 1955).

SOTS-2021 shall be notified and introduced with effect from March 1, 2021 and shall close on June 30, 2021. The SOTS, 2021 shall cover all active court cases in any Court of Law in the country, as on specified date, relating to overcharging under the provisions of DPCO 1979, 1987, 1995 and 2013.

The DoP proposes to bring the SOTS during the current financial year for the settlement of overcharging cases which are pending in various courts to provide a comprehensive platform for out of court resolution of disputes, promote ease of doing business in the consumer and industry interest. It has proposed a draft framework of SOTS on the lines of Vivad se Vishwas schemes for settlement of disputed income tax dues.

The quantum of settlement offered under the draft SOTS is as follows - where the "Disputed Amount" includes Principal and/or Interest and/or penalty, amount payable by March 31, 2021 is disputed principal amount only and amount payable after March 31, 2021 would be disputed principal amount only + 10% of disputed principal amount.

Where the "Disputed Amount" includes interest and/or penalty only, amount payable by March 31, 2021 is twenty five percent (25%) of disputed amount and amount payable after March 31, 2021 would be thirty per cent (30%) of disputed amount.

The applicant availing the benefit under the Scheme shall submit an undertaking in the prescribed format provided in the notified Scheme, regarding withdrawal of the legal case(s) and not to avail any legal remedy in future in respect of the such case(s) for which benefit is availed under SOTS. Such undertaking should be furnished before making any payment under the Scheme and would be legally binding on the applicant.

The applicant availing the benefit under the Scheme shall withdraw the legal case and submit the appropriate proof of such withdrawal to National Pharmaceutical Pricing Authority (NPPA) in due course of time, as early as possible, for closure of case filed by NPPA.

Already closed overcharging cases cannot be considered again in any circumstances under SOTS and are out of the purview of the Scheme. Further, no request for review or reopening of any case closed under the Scheme shall be entertained by NPPA. There shall be no refund of any amount under the scheme. A clause for this purpose shall be included in the undertaking to be furnished by the applicant.

The payment due as per scheme shall be made online by the applicant in the manner prescribed in the notified Scheme. The applicant shall provide the proof of payment to NPPA for verification of the payment. Detailed procedure shall be described in the notified Scheme. SOTS offers resolution based on demand currently sub-judice on ás is where is basis'. No revision in the disputed amount based on new/pending request will be applicable.

Any earlier payment or part payment made by the applicant, before submission of application under the scheme, in respect of case(s) under SOTS, shall be adjusted from the amount to be paid under SOTS, and balance amount, if any, shall be payable by the applicant.

In case applicants made part payments on or before March 31, 2021 under the scheme but couldn't discharge the whole overcharge amount or interest as the case may be, then such applicants will be considered only for 'quantum of relief available after March 31, 2021. However, in case part payment is made and balance payment is not made

by June 30, 2021, then the case would be dealt under the extant provisions of DPCO and applicant would not be entitled to any benefit under SOTS.

The scheme will be applicable only in respect to disputed amount currently under litigation. It does not preclude raising subsequent demand based on extant provisions. The settlement under SOTS shall not decide any judicial issue. It only provides for a dispute resolution mechanism in respect of disputed amount only involved in the litigation case.

It shall not be lawful for NPPA or the applicant to contend in any appeal/WP/SLP that the other party (NPPA or applicant) has agreed to the decision of the disputed issue by settling the issue under SOTS. Only the disputed amount given in the undertaking will be settled without any prejudice to the issue pending in same or other cases.

The list of court cases up to the specified date, under SOTS being offered for dispute resolution will be available on NPPA website. The scheme will be implemented on-line, including payments made. The DoP, being administrative department of NPPA, shall finalize the scheme and operational mechanism for implementation of the scheme will be finalized by NPPA.

Source: Shardul Nautiyal, Pharmabiz, 29.01.2021

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INTERNATIONAL NEWS

Vietnam offers significant opportunities for Indian Generic Drugmakers: Fitch Solutions

Indian generic drugmakers have immense potential for growth in Vietnam which currently meets bulk of the domestic demand by importing medicines, Fitch Solutions Country Risk and Industry Research said in a report on Monday, 25.01.2021. Vietnam's domestic pharmaceutical industry is currently able to meet just 53 percent of the country's demand, representing significant opportunities for Indian drug makers as the country is among the leading global producers of generic medicines, the report noted.

"There is an enormous potential for Vietnam to purchase generic medicines from India, but the former is actively trying to get Indian pharmaceutical companies to manufacture in Vietnam instead of importing," it added. India is Vietnam's third largest supplier of pharmaceutical products, with an export turnover of USD 198 million in the first nine months of 2020.

In addition to finished products, the country also provides raw pharmaceutical materials, and generic medicines for the Vietnamese market. The medicines and raw materials imported from India are reasonably priced and meet the diverse needs of Vietnamese, especially those living in remote areas, Fitch Solutions said. Vietnamese pharmaceutical firms want to cooperate and call for investment from foreign companies, including those from India to attract capital, technology and high quality human resources, it added.

"Therefore, there is room for cooperation between Vietnamese and Indian businesses in the field," it added. Fitch noted that Vietnam's generic drug market will post robust growth rates over the coming years, driven by the services. Domestic medicine production will remain firmly within the generic drug sector given the lack of scientific expertise for innovative drug development, but primarily due to the significantly higher demand for generic drugs in the country as a whole, it added.

In addition, while the development of healthcare services in Vietnam will increase the ability for patients to access higher quality medicines, affordability levels remain low and as such opportunities for patented drug makers will remain severely restricted, the report said.

"Generic drugs will continue to account for the majority of prescription drug sales with a value estimated at VND 66 trn (USD 2.9 billion) in 2020. We expect this to grow to VND 171 trn (USD 6.7 billion) by 2030," Fitch said. This is a ten-year Compound Annual Growth Rate of 10 percent in local currency terms and 9 percent in US dollar terms, it added.

Source: The Economic Times, 26.01.2021

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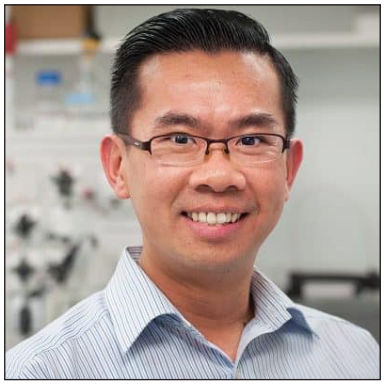
How is a vaccine engineered?

Dr Tuck Seng Wong



Dr Tuck Seng Wong, Director of International Student Recruitment and Senior Lecturer, Department of Chemical and Biological Engineering, the University of Sheffield, UK Engineering points out that engineering a vaccine is a complex process. He also highlights that to ensure future medicine security it is vital to train next-generation engineers to support Pharma manufacturing sector and encouraging more young people into STEM education.

Vaccines are among the most effective means of preventing infectious diseases. Vaccines train our immune system to mount a defence against pathogens by creating antibodies. English physician Edward Jenner pioneered the smallpox vaccine that is widely regarded as the world's first vaccine. Smallpox was once among the world's deadliest diseases known to man, claiming an estimated 300 million lives in the 20th century. Smallpox raged through India in the mid-1970s, with over 100000 reported cases and at least 20000 deaths. Thanks to vaccination, smallpox was declared eradicated in 1980 by WHO.

With COVID-19 now causing widespread disruption and plunging the global economy into the worst recession since World War II, we are once again racing against the clock to roll out mass vaccination. The positive impacts of vaccines are indisputable. We can view the benefits derived from vaccines through different lenses. The health impact is obvious, measured primarily through the reduction of morbidity and mortality. From an economic standpoint, vaccination leads to cost saving in healthcare and productivity gain, among others. Socially, vaccination improves life quality, restores social interaction, and prolongs life expectancy. Healthy individuals are key drivers of our economic and social growth.

At the start of the COVID outbreak in the UK, I led a downstream processing team to manufacture SARS-CoV-2 spike proteins for the Northern General Hospital and the Royal Hallamshire Hospital in Sheffield to develop a serological test for antibody. The SARS-CoV-2 virus is studded with the so-called spike proteins that it uses to enter the human cells. COVID-19 vaccines that have been approved in the UK and many other countries, such as the Pfizer-BioNTech vaccine, the Moderna vaccine and the Oxford-AstraZeneca vaccine, are all based on the virus's genetic instruction for making these spike proteins or vaccine antigens. My lab in Sheffield focuses on engineering and manufacturing proteins for industrial and Pharma applications, providing the basis for this commentary.

As we are vaccinating our way out of the COVID-19 crisis, I see the necessity to address the question '*How is a vaccine engineered*'. Why should we care? Two reasons; First, ramping up vaccine production is not a trivial task. It requires engineering inputs on multiple fronts, from vaccine design through to vaccine distribution. I salute all my fellow engineers who have contributed to vaccine manufacturing. These unsung heroes deserve to be celebrated for their contribution. Second, we must immediately embark on a journey to ensure future medicine security. Fundamental to this endeavour is training the next-generation engineers to support our Pharma manufacturing sector and encouraging more young people into STEM education.

Engineering a vaccine goes far beyond just identifying the right antigen that triggers an immune response and the mechanism of presenting an antigen (the Pfizer-BioNTech vaccine and the Moderna vaccine use mRNA as the genetic instruction for the vaccine recipient's own cells to produce the vaccine antigens). More often than not, adjuvants are added to a vaccine to boost the immune response to produce more antibodies and longer-lasting immunity, thereby minimising the dosage required. Stabilisers are used to help the vaccine maintain its efficacy during storage. Above all, one needs to consider the manufacturability of the vaccine, *i.e.*, manufacturing with the lowest cost, the highest quality, and the quickest time to ensure stable and sustainable production.

Quality control during vaccine manufacturing is integral to vaccine safety. Manufacturing is not complete until the vaccine is bottled into glass vials for cold storage and transport. Successful immunisation programmes are also built upon functional, end-to-end supply chain and logistics systems. Viruses such as SARS-CoV-2 are constantly mutating, presenting yet another challenge to engineers.

India is the world's biggest vaccine maker, accounting for more than 60 percent of all vaccines sold across the globe. The Oxford-AstraZeneca vaccine is also being manufactured locally by the Serum Institute of India, the world's largest vaccine manufacturer. India's leadership effort in COVID-19 vaccine manufacturing is widely praised. Having the world's second-largest population with unmatched talents and culture, India is poised to become a powerhouse for both vaccine development and manufacturing provided STEM education is introduced at a much larger scale and the gender gap in STEM career is closed. Instead of producing a workforce to work in factories, Indian students need an engineering education that produces independent thinkers and innovators to take full advantage of India's manufacturing capability.

At the University of Sheffield, we train our chemical engineering students at the interface of engineering and biology. With a curriculum designed to meet the industrial demands of the 21st century, our graduates tackle grand challenges to create a sustainable future for our society, such as the global health issue. We also offer specialist M.Sc., Pharmaceutical Engineering programme to develop the knowledge and the skills our students need to stand out in the Global Pharma Market.

Source: EP News Services, Express Pharma, 25.01.2021

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Can India offset Chinese influence through its vaccine diplomacy?

Pinak Ranjan Chakravarty

Peaceful international partnerships in crucial sectors, like healthcare, continue to inspire India's global vision

Workers unload cartons of a Covid-19 Coronavirus vaccine being delivered from India to Myanmar in Yangon (Getty)

As India ships out the COVID vaccine to various countries, it is only natural that the first recipients will be India's neighbouring countries. This, not only underlines India's firm commitment to her 'Neighbourhood First' policy, but also harks back to India's foreign policy goals that firmly anchored itself in development cooperation with newly independent countries in Asia and Africa, during the formative period of crafting Indian foreign policy, in the early years after independence.

Peaceful international partnerships in crucial sectors of development, like healthcare, continue to inspire India's global vision.

India is today regarded as the 'pharmacy of the world', in recognition of its established capacity as a producer of medicines. India produces over 60 percent of the global vaccine requirement.

India's Humanitarian Outreach & Development of Indian Technical & Economic Cooperation Programme:

India remained a net recipient of international aid till late 1990s. Subsequently, India's economic growth, powered by the economic reforms in 1990s, has since made it a net donor. Notwithstanding the Chinese-origin COVID-driven viral pandemic and the consequent economic downturn, India has reached out with assistance in the healthcare sector to over 150 countries and has announced that she will provide vaccines across the world when sufficient quantities become available for use. At the UN

General Assembly, PM Narendra Modi has declared that India would use its "vaccine production and delivery capacity to help all humanity in fighting the Coronavirus crisis."

India's freedom struggle was a beacon of hope for many Asian and African countries struggling to break free from colonial bondage. Independent India had resolved to assist, not only in the freedom struggle of many countries, but also formulated a policy of assisting them, despite her parlous economic condition:

For instance, the Indian Technical and Economic Cooperation programme [ITEC], which was founded in 1964 to provide technical assistance to newly independent developing countries, predicated on the belief that "it was necessary to establish relations of mutual concern and inter-dependence based not only on commonly held ideals and aspirations, but also on solid economic foundations. Technical and economic cooperation was considered to be one of the essential functions of an integrated and imaginative foreign policy."

Over subsequent decades, ITEC, fully funded by the Indian Government, has evolved into an integral part of India's foreign policy, functioning as an important plank of India's 'soft power' diplomacy, a phrase that entered the international diplomatic vocabulary years in the 1980s.

India's Vaccine Potential: Demand for Vaccines from India are piling up; India may also make others like Sputnik after Approval:

The global war against COVID is now well underway. India has already shipped initial dosages of the two vaccines, COVAXIN and COVISHIELD [AstraZeneca], all over India, to fuel the world's biggest vaccination campaign. India has begun airlifting vaccines to Bangladesh, Bhutan, Maldives, Nepal and Seychelles, followed by shipments to Afghanistan, Mauritius and Sri Lanka. India's vaccine diplomacy had begun earlier in 2020, after the pandemic struck South Asian countries. India had supplied Hydroxychloroquine, Remdesivir, Paracetamol, masks, gloves, PPE suits, diagnostic kits and other medical supplies to neighbouring countries. India also organised several training programmes for medical workers to enhance their clinical skills.

Pakistan has not approached India, so far, for the supply of any vaccine. Nor has Iran. Both countries may depend on China, since both countries are increasingly beholden to China for all kinds of aid:

India's acknowledged ability to produce quality, affordable and easily transportable vaccines has led to demand piling up from countries across the world. India's readiness to provide the vaccine globally is a linear progression of the ethos that underpinned the ITEC programme.

Other vaccines like the Russia's SPUTNIK will also be produced in India after ongoing trials and the Pfizer vaccine is awaiting clearance of India's drug authorities. Upon availability of these vaccines will augment the capacity to fight the pandemic more effectively.

India's vaccines will have an advantage over the others because of cost and portability:

Other vaccines require ultra-low storage facility and cold chain delivery system which are logistical hurdles for most developing countries. Apart from the Indian Government's free supply of vaccine dosages, recipient countries are also tying up for commercial supplies from the Serum Institute of India and Bharat BioTech, the two manufacturers of the vaccines.

Why China is scrambling to recover lost Ground through Vaccine Diplomacy:

As anticipated, China is competing in vaccine diplomacy and its vaccine SINOVAC has been delivered to several countries. China has a strong motivation to engage in vaccine diplomacy to overcome the global perception that it was responsible for spread of the pandemic, to the rest of the world because it was opaque and tried to hide its culpability.

Suspicion about China's role has been heightened by its prevarication in cooperating with the WHO in investigating the origin of the outbreak in Wuhan. China's dilatory and non-transparent behaviour has sown doubts about its diversionary tactics has cast a shadow on its approach, as have its attempts to divert attention from itself, by publishing motivated medical research which has attempted to point fingers at sources of the virus to other countries.

China's ham-handed attempt to obfuscate its culpability and its 'Mask and PPE' diplomacy left many countries unhappy about China's mercantile profiteering by sacrificing quality. It is now scrambling to recover lost ground via vaccine diplomacy:

Brazil and Indonesia are among major countries that have received the SINOVAC vaccine. Thailand has bought 2 million doses of SINOVAC. China has promised to donate a total of 800,000 doses to the Philippines and Myanmar. Cambodia, an ally of China, which had received a donation of the Chinese vaccine, has now reached out to India for more vaccines.

Vaccine Diplomacy Fallout: Increasing Divide Between Developed & Developing World:

Vaccine diplomacy has also brought the divide between developed and developing countries into the public domain. WHO has not covered itself with glory, in the fight against the COVID pandemic and is now carping about that developed countries, having not cooperated in a fair distribution of the vaccine to the rest of the world.

WHO has alleged that drug manufacturers have given priority to profit, by getting regulatory approvals in rich countries rather than cooperate with the WHO-backed COVAX initiative which seeks to supply vaccines to developing countries that cannot afford the high prices being charged by the drug manufacturers. COVAX has planned to distribute 2 billion doses by end of 2021 in all participating countries.

India's vaccine diplomacy has raised the predictable opposition by bringing up the question of India's requirement to be met first:

Clearly, the Government has kept the domestic demand that is likely to grow since the rollout of the vaccination programme on 16 January.

The opportunity to leverage vaccine diplomacy to remind India's neighbours that the first port of call in a disaster situation, India will remain the first responder. India's vaccine diplomacy is also designed to create more space for India as China pushes to expand its influence in South Asia.

Source: Observer Research Foundation/The Quint, 22.01.2021 (Excerpts)

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