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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. 20** **22 to 30 May 2021**

IDMA ACTIVITIES:

UNITED STATES PHARMACOPEIA:

DGFT MATTER:

DoPT MATTER:

GOVERNMENT COMMUNICATION:

IPR MATTER:

NATIONAL NEWS:

SEPCIAL REPORT

Mr. S M Mudda's Keynote Address at 10th Annual Global Pharma Regulatory Summit organsied by CPHI-INFORMA from 25th to 28th May 2021

The 10th Annual Global Pharma Regulatory Summit was held from 25th to 27th May 2021 and the Workshop was held on 28th May 2021. The summit was attended by the regulatory authorities and key regulatory professionals from all over the world. The Summit was organized by CPHI Conferences and Informa Markets.

Mr. S M Mudda, our Chairman, Regulatory Affairs Committee, IDMA and Program Director of APPQM Series 1 & 2 and also, the Managing Director, Misom Labs Limited, Malta (EU) delivered his keynote address at the summit. His Keynote Presentation is reproduced here for your kind perusal, information and education.

Regulatory Strategy for Navigating
Pandemic Disruption

S.M. Mudda
Managing Director, Misom Labs Limited, Malta (EU)
Chairman Regulatory Affairs Committee, IDMA

Discussion Points

- Brutal disruption and Evolution of Regulations
- Remote Inspection Tools - MHRA, EMA, FDA
- Regulatory Flexibilities under Emergency Authorizations
- India Strategy: Strengthening Schedule M and aligning with Global standards

S.M MUDDA, MICRO LABS LTD 2

Pandemic and Its Impact

- We live in an era of brutal disruptions and VUCA world, COVID19 is a great reminder of this fact
- Global community was under-prepared for handling such a catastrophic event that lead to one of the most critical public health challenge of the century
- The statement below reminds us of the scale of the disruption

"There are decades when nothing happens
and
Weeks when decades happen"

S.M MUDDA. 3

Pandemic and Its Impact

Our Learnings

•One thing COVID-19 has given us something previously in short supply: *time to think and reflect.* There's an old saying: 'pain + reflection = progress' This is the reflection time for the regulatory community as well

•We created complexities because we could. Using technological advancement at the expense of human development will continue to pose risk to humanity.

•Reactive measures are too little do deal with the unprecedented challenges of the disruptions.

•The history and evolution of GMP Regulations has shown that the changes were always reactive and were made only after a tragedy impacting human lives.

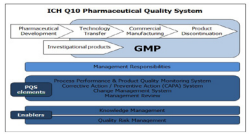
Evolution of Regulations-Reactive

Sulfanilamide disaster occurred in 1937 and killed 107 people US law did not require a comprehensive review of toxicity before bringing a drug product to market	• The Sulfanilamide disaster became a milestone in the history of consumer protection and important precursor to later GMP rules.
Thalidomide Tragedy in 1960 lead to the deformities in more than 10,000 children The medicine was not tested for all possible risks and side effects	• Kefauver Harris Drug Amendment increased safety requirements, laid the foundations for clinical studies and Quality Assurance Measures in Drug Development
1982, Tylenol tragedy , consumers died due to cyanide poisoning	• FDA subsequently issued new rules to prevent such acts . Tamper-resistant Packaging was introduced
2018, Nitrosamine Impurities , classified as possible human carcinogens were found in 'sartans'	• EMA , September 19 'Call for Review' and Q&A for MAHs on CHMP Opinion for the Article 5 (3) , EC 726/2004 referral • Risk Assessment of chemically synthesised APIs and Confirmatory Testing needed

Evolution of Regulations-Proactive

ADOPTION OF QMS APPROACH

- US FDA Initiative: Guidance for Industry issued in September 2006 "Quality Systems Approach to Pharmaceutical CGMP Regulation"
- Recommends Risk-based and Quality system-based approach to be adopted for cGMP regulation by emphasizing **Management Responsibility** for Quality systems



Response of Global Community

1.Emergency Measures for Ensuring Uninterrupted Supply of Medicines

UK MHRA	• Exceptional GMP flexibilities for medicines imported from third countries –Guidelines for QPs • Unexpected Deviations, Relying on information from third parties, re-testing on importation etc. • Handling of calibrations, Handling of GxP documents-working from home
EMA	• Published Q&As on 10.04.20 on regulatory expectations. Article 5(2) ,Product approvals for compassionate use, Article 126(a) , Postponement of renewal Application of MAs, Sunset Clause, Facility GMP Approval extended to December 2021
INDIA –MOH, CDSCO	• April 20- Import of drugs with less than 60%residul life allowed for a temporary period • Notification GSR 354(E) June 20 issued for import and manufacture of unapproved new drugs for compassionate use . • Approval for manufacture of Vaccines and import of Vaccines

Response of Global Community

1.Emergency Measures for Ensuring Uninterrupted Supply of Medicines

US FDA	• suspending routine on-site inspections of domestic and overseas manufacturing facilities and relying solely on reviewing company documents, processes, and past inspection records to ensure safety • reducing data requirements for clinical trials and issuing guidelines for safely conducting such trials while complying with social distancing
US FDA	• facilitating importation of personal protective equipment and medical devices, and • loosening regulatory restrictions for companies that change suppliers or switch medical device components because of manufacturing delays or supply shortages.

Response of Global Community-India

1.Self Reliance in API & Intermediates

PLI Scheme1	• Bulk drugs formed 63% of the total Pharma imports • 27thJuly 2020:Production Linked Incentive Scheme: • Guidelines for promoting Domestic Manufacture of 53 KSMs and APIs ($ 1000 million) • Both synthetic and fermentation based
API PARKS	• 3 API parks of $ 150 million each with common infrastructure, utilities, ETPs • Education and Training centres for capability enhancement

Response of Global Regulators
2. Remote Inspections

MHRA

- MHRA has switched to Remote Inspections from Q1, 2020– Inspection model refined, defined, & embedded into MHRA quality system
- Completed 750 inspections and shared the learnings with PIC/s and ICMRA
- Will continue from March 21 a hybrid of on-site and remote inspections
- Technology can be used effectively , with some inherent restrictions

EMA

- Q&As published on 10.04.20 on regulatory expectations provided fro accepting remote inspections of the API sites by the QPs, distant assessment by the EEA supervisory authority followed by an on=site inspection when the restrictions are lifted
- EMA has published on 15 October 2020, Guidance related to GMP/GDP and PMF distant assessments to facilitate remote audits

Response of Global Regulators
2. Remote Inspections

US FDA

- Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency (April 2021)

US FDA

- FDA will apply risk management methods and tools to determine when to request a facility's participation in a remote interactive evaluation

Response of Global Regulators
2. Remote Inspections

US FDA

- FDA will NOT accept requests from applicants or facilities for FDA to perform a remote interactive evaluation
- Facility should meet these requests or inform FDA of any challenges in meeting these requests as soon as possible.

US FDA

- A remote interactive evaluation does not constitute an inspection for purposes of section 510(h)(3) of the FD&C Act. However, FDA will use information gathered via a remote interactive evaluation to determine the scope, depth, and timing of a future inspection.

Response of Global Regulators
2. Remote Inspections

US FDA

- A written list of observations will be issued and will not be a final Agency action or decision.
- FDA will NOT issue a Form FDA 483, Inspectional Observation

US FDA

- Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers (Updated January 29, 2021)
- Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (March, 2011)

Way Forward- Collaboration to Innovate

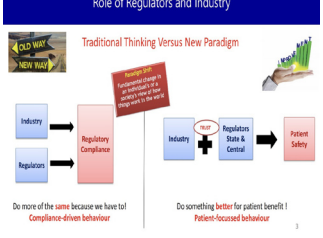
Collaboration of the Industry and Regulators – A new paradigm for patient safety

In todays VUCA world it is imperative for industry and regulators to collaborate and work together to remain at par with the global industry

The foundation of collaboration should be based on sharing of scientific knowledge (subject matter expertise), mutual trust and one common objective of ***BETTER PATIENT OUTCOMES***

Way Forward- Striking the Balance

Role of Regulators and Industry



- Whether to retain these changes wholesale,
- Maintain Status Quo or
- cherry-pick changes worth continuing.

Adopting systems approach for integrating all sub-systems will result in

- ✔ *improved health outcomes, and*
- ✔ *decreased costs to the health care system*

But relaxed/flexible approach such as

- ✔ *fewer routine physical inspections,*
- ✔ *remote clinical trials, and*
- ✔ *the suspension of in-person safety protocols*

may undermine the agency's ability to assess the risks of patient safety.

Way Forward:
Strengthening Schedule M and aligning with Global standards

- A draft notification is published to enhance the GMP requirements specified in Schedule M.
- A number of WHO GMP guidelines (similar to PIC/s and EU GMP guidelines) are proposed to be included in Schedule M.
- Schedule M , being a part of the Drugs and Cosmetics Rules , every provision becomes mandatory in nature .
- The global GMP guidelines are framed in a manner that allows flexibility in the approach to be adopted for compliance with the principles of GMP specified in the Regulations and Directives .
- Adopting the guidelines as regulations themselves in the proposed Schedule M will make compliance with the good practices extremely challenging.
- Distinguish the principles of GMPs from the Guidelines proposed to be included in Schedule M, in line with the framework adopted by European Union, that are aligned with PIC/s.

Our Reflections
Strike the Balance - Technological development & Human development

- New worlds bring new risks - systemic risks in our procrustean pursuit of economic growth at the expense of human development, the products of our "technological advancements."
- We created complexities because we could.
- The World Economic Forum has identified systems thinking skills as one of the top 4 skills needed to make the world better after the COVID-pandemic
- System is not the sum of the behaviors of the parts but the product of their interactions and it cannot be improved by improving a part taken separately
- Directors and CEOs with complex systems thinking abilities can de-risk the society proactively in the face of catastrophic risk
- Don't oversimplify. Sweat the details and create an organizational culture preoccupied with failure.
- THE ONLY PROBLEMS THAT HAVE SIMPLE SOLUTIONS ARE SIMPLE PROBLEMS

Bouncing back stronger

"six to fix" rules to bounce back stronger in PCE

- Rule #1: Make sure you have a "bounce back" culture.
- Rule #2: Excel at brutal simplification.
- Rule #3: Establish an excellent network built on trust and respect
- Rule #4: Implement fast feedback loops.
- Rule #5: Focus on doing the basics to Ph.D. level (exceptionally well!).
- Rule #6: Look after yourself!

Reference Martin Lush, NSF Health Sciences , UK

THANK YOU

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PSUs' increase in prices of Chemicals needed for Manufacture of APIs: IDMA & BDMAI joint submission to the Secretary DoP

IDMA and BDMAI have made a joint submission on 25th May 2021 to Ms. S. Aparna, IAS, Secretary to the Government of India, Department of Pharmaceuticals on the above subject:

We are thankful to you for the kind opportunity to partake in the VC meeting held on 18th May 2021 under your chairpersonship to discuss the production of drugs in the country.

As discussed during the meeting, we are attaching the details of price movement of raw materials/chemicals being procured from the Public Sector Undertakings.

We request for your kind help to take it up with the Hon'ble Minister for Chemicals & Fertilizers to advise the Public Sector Undertakings producing these chemicals not to raise the prices, as it ultimately impacts prices of the lifesaving APIs and raw materials.

Looking forward to your favourable consideration.

Thanking you with best regards,

Mahesh H Doshi
National President, IDMA

V.V. Krishna Reddy
National President, BDMAI

Encl : As reproduced below

Indian Drug Manufacturers' Association & Bulk Drug Manufacturers Association of India

Information on increase in prices of inputs for APIs sourced from PSUs

Sr. No.	Name of the Product	Name of the Company	Oct. 20	Nov. 20	Dec. 20	Jan. 21	Feb. 21	Mar. 21	Apr. 21	May-21	Increase Percentage	Name of the PSU Manufacturers
1	Acetic Acid	Aarti Drugs Ltd.	30.18	34.20	38.18	45.88	56.87	72.00	118.00	118.00	290.99%	GNFC
2	Di Methyl Formamide	Aarti Drugs Ltd.	57.78	57.78	102.16	100.54	100.32	100.32	160.00	180.00	211.53%	RCF
3	Ethyl Acetate	Aarti Drugs Ltd.	59.00	64.75	75.78	73.37	81.82	108.00	114.35	133.00	125.42%	GNFC
4	Aniline	Aarti Drugs Ltd.	75.37	98.66	107.88	111.25	123.62	153.00	200.00	165.00	118.92%	GNFC
5	Benezene	Aarti Drugs Ltd.	34.39	34.35	41.27	48.35	52.32	57.31	67.17	74.63	117.01%	BPCL / IOC
6	Phenol	Aarti Drugs Ltd.	53.25	54.51	58.00	79.00	87.74	108.00	103.00	106.00	99.06%	HOC
7	Formic Acid 85%	Aarti Drugs Ltd.	33.76	41.58	44.21	48.00	48.92	52.00	57.00	59.00	74.76%	GNFC
8	Toluene	Aarti Drugs Ltd.	37.95	46.12	51.94	49.37	50.43	62.00	55.00	60.00	58.10%	BPCL
9	Acetone	Aarti Drugs Ltd.	73.33	74.15	78.83	76.89	75.50	107.00	107.00	109.00	48.64%	HOC

● ● ●

IDMA representation to CBIC, Ministry of Finance on Goods and Service Tax – Key issues and concerns of Pharmaceutical industry for GST Council Meeting- reg.

IDMA have submitted the following representation on 25th May 2021 to Shri. M Ajit Kumar, IRS, Chairman, Central Board of Indirect Taxes and Customs, Ministry of Finance with a copies to Hon'ble Smt Nirmala Sitharaman ji, Minister of Finance & Chairman, GST Council and Dr. Ajay Bhushan Pandey, IAS, Revenue Secretary & Ex-Officio Secretary to the GST Council, Ministry of Finance, on the above subject:

Greetings from Indian Drug Manufacturers' Association (IDMA)!

We, at IDMA, are pleased to note that the office of the Hon'ble Finance Minister Shrimati Nirmala Sitharaman has announced the meeting of the esteemed GST Council on 28th May 2021.

In this regards, IDMA submits the below 19 (nineteen) issues and suggestions for your kind perusal, information and favourable response:

Sr. No.	Subject	Issue	Suggestion
1.	**Classification of Alcohol based Hand Rubs (ABHR)**	GST liability on Hand Sanitizer should be under Drug Category HSN Code 3004 @ 12% – Request to examine the matter and issue a clarification as regards the applicability of GST. The product in question merits classification only under Chapter 30 for the following reasons: (i) The products in question are manufactured under drug license in the capacity as a manufacturer of drug. (ii) The different ingredients which go into the product are all clearly indicated in the label and the label also indicates the application of the product; the methodology with adequate caution symbols and also has the manufacturing license number. (iii) The label clearly indicates that it has to be applied on the palm and the limited time at which it can be applied including the quantity that has to be taken	Members of the Association are manufacturing a product for the society at large at the time of Covid pandemic and thousands of people are risking their life in ensuring that the factory continues to work and the most important product for the society at large at this point of time is continuously available. Further, the profits have dwindled on account of the MRP for the product being reduced and the MRP itself was fixed based on the GST at 12%. At this juncture, it is not possible for the members of the Association to bear any additional impact of GST or to face the pressure being mounted by GST Intelligence and the GST Department in seeking payment of the higher rate of GST. Whereas, The authorities are incorrect in taking the term 'disinfectant' to mean one which is used for antiseptic purpose by human beings. It is submitted that there is an urgent need for the Ministry of Finance / Central Board of Indirect Taxes and Customs

		when it is used as hand disinfectant and when it is used in surgical segment. (iv) The fact that the product is effective against bacterial, virus, fungi, etc. is also specified in the container. (v) The product can be used only for the hands as indicated in the name of the product as well as in the usage instructions. (vi) Chapter 3808 does not cover Medicaments (Heading 3003 or 3004). Given the plethora of decisions on the issue including authoritative pronouncement of the Supreme Court on the issue, the classification of pharma grade alcohol based hand sanitizer manufactured under Drug License issued under the Drugs and Cosmetics Act under Chapter 3808 for the purpose of 18% GST is incorrect and the correct classification would be Chapter 3004 which attracts GST at the rate of 12%.	to examine the matter and issue a clarification as regards the applicability of GST HSN 3004 or 3808. Since the matter is of considerable significance and has implication on the mis-classification of product manufactured by vast section of the industry, it is earnestly requested to instruct the concerned authorities to kindly clarify the issued as early as possible. This would put an end to the prevailing confusion and uncertainty, reduce litigation and ensure uniformity of compliance.
2.	**Spray pumps used in pharmaceutical product are in fact Aerosol Therapy Apparatus which have been wrongly classified under CTH 9616**.	Due to unjust classification from CTH 9019 (Basic Custom Duty 7.5% +SWS 10% + HC 5% + IGST 12%) to CTH 9616 (Basic Custom Duty20% + SWS 10% + IGST 12%), the basic custom duty to be paid on such imported goods has increased which in turn has made the critical drugs more expensive and unaffordable for the needy Indian patients.	Considering the above, we request you to kindly recommend to consider the representation made by us in its right perspective before the concerned authorities so as to make the classification of Aerosol Therapy Apparatus under CTH 9019 instead of CTH 9616. We hope that the misclassification of Aerosol Therapy Apparatus is reconsidered to safeguard the interests of pharmaceutical industry as well as of the needy patients.
3.	**Marketing and distribution expenses - Promotional items or brand reminders – ITC not allowed**.	Companies do provide pen/ paper weight to channels which are brand reminders and not gifts. Hence such credit should be available. We understand that the above expenditures are done in the furtherance of business and are normal business expenditure incurred without which the several Industry can't function.	There should not be any restriction of input credit as long as the goods given are a brand reminder or a brand recall for business purposes. From a business standpoint, the cost of all such items are already factored in the sale price of products on which GST is paid.

4.	**Physician Samples – ITC not allowed**	In Pharmaceutical Industry, it is a common practice to give very limited quantity of physician's samples which are marked "Physician's Samples Not for Sale" to enable the doctors to gain confidence in the efficacy of a particular product. This enables the doctor to personally check the efficacy of the product for his patients, get their feedback and then gives him the confidence to prescribe for others. This expenditure is clearly incurred in furtherance of business. Hence, just as input credit for GST included in other expenses are allowed, it is logical that GST on inputs used in Physician's samples should also be allowed.	Ideally, there should not be any restriction of input credit as long as the goods given free of cost and Free Samples are for business purposes. From a business standpoint, the cost of all such items are already factored in the sale price of products on which GST is paid. We suggest and request through your office to GST Council to accept the proposals of The Law Review committee but there should be no cap as suggested by committee to be fixed at 0.5% of turnover.
5.	**Expiry Goods**	In pharma, due to the peculiar nature of goods and the regulatory requirement, the goods have shelf life and if the goods are not sold till the expiry date, then the said goods are to be destroyed. This is applicable for stock lying not only with manufacturer, but also with distributors, retailers, etc.	It is the need of the hour to amend the exclusion clause of input tax credit and allow the credit w.r.t. goods destroyed due to expiry so that the credit can be availed w.r.t. the input taxes.
6.	**Exemption from filling of Return under form GSTR ITC 04**	When Premises of "Loan Licensee" is registered as Additional Place of Business for the purpose of movement of input materials and dispatch of the final product by the Principal Manufacturer, There should be exemption from filing of return in ITC 04.	The purpose of having Additional Place of Business in the GST Registration is in the view of practical challenges in the pharmaceutical industry is as under :- 1) Multiple usage of the raw and packing material (Common inputs) for different finished products having different strengths (for example: Paracetamol – 100 mg / 200 mg / 500 mg. etc.) 2) Temperature conditions (Sensitive category of inputs) for different type of inputs to avoid contamination. 3) Semi-Finished (work in process) mix of the inputs kept in the vessels / Reactors / compression equipment's awaiting Quality Control Approval for final packing.

			4) Multiple samplings for each receipt and removal mandatory as per Drugs Rules and Regulations. 5) Multiple input materials are supplied against delivery challan for getting the finished goods converted into different forms on continuous basis, the tracking, monitoring and / or reconciliation with each challan is practically impossible as the usage of input material may not be for any specific finished product. We submit in the above scenario there should not be any requirement to follow job work procedure as prescribed under Section 143 of CGST Act read with allied Rules.
7.	**Inverted Duty Structure in Pharmaceutical Industry**	In Pharmaceutical Industry, There is an instance of inverted rate structure where the GST rate of 12% on the final product is lower than GST rate of 18% on raw materials and packing materials. This has created distortions in GST which is a deviation from the basic philosophy of a value added tax. We have long pending issue of rationalisation of the rate of tax on Pharmaceutical products and to do away with the structural anomalies in the GST i.e. Inverted tax structure which has led to distortions. We would like to draw your attention to the prevailing inverted tax structure in respect of Pharmaceutical products and how the same has evolved during the GST period like inverted tax structure in the pre-GST period. Majority of Pharmaceutical products attract GST at 12% and 5% whereas major Raw materials i.e. Active Pharmaceutical ingredients and Most of the Packing materials and consumables, services, capital goods attract 18% GST leading to inversion.	It is the need of the hour to eliminate inversion and such corrections in the GST tax structure should have been carried long ago in order to remove distortions in GST. The GST rates concerning the inverted duty structure are to be realigned under GST, and they have to be corrected from a working capital point of view which helps input suppliers as well as buyers. Such correction would make our domestic manufacturing internationally competitive which would add to our GDP, provide employment and also increase exports. We have learnt that The Committee of Officers on Revenue Augmentation has recommended to calibrate rates so as to correct duty inversion. Further, this issue has been examined by the Committee of Officers and has been deliberated in detail in Fitment Committee. On ABC analysis Fitment Committee as first step recommended rate calibration on four items/sectors i.e. mobile, footwear, textiles and fertilizers but not Pharmaceuticals. Whereas Pharmaceutical Industry also contribute significantly to the total consumption of the country as these four sectors contribute.

		The value addition is about 15 to 20%. As a result, the manufacturer and the consumers both are adversely affected. This inverted structure has been acting as detriment to the growth of Pharma sector and investment in the sector. We hereby recommend for correcting inverted rate structure so as to unshackle Pharma sector from the burden of taxes (accumulated ITC etc.). This would increase the employment opportunities in the Pharma sector and also make our exports competitive. Also we would like to draw your attention towards some of the adverse implications of the inverted duty structure as follows: • Unutilized ITC becomes a cost to the manufacturer • To correct this, refund of unutilized ITC is to be given • Cash-flow issue even if refund is given • No refund of input services and capital goods • Inverted rates greater injury to Small standalone units • Accumulated ITC on capital goods hurts the exporter • Disincentives domestic manufacturing and investment • Consumer not benefited. Unutilized ITC is a dead weight cost • Claiming refund entails efforts, cost and hardship	We hereby request you to consider Pharma sector also for correction in the GST tax structure along with other specific sectors. Meanwhile, the best possible solution for the government is to come up with a special refund mechanism for the taxpayers who are applying for the refund of unutilised ITC under inverted duty structure. Through this mechanism, the government can process refunds related to the inverted duty structure in a faster manner and lessen the burden to the taxpayers.
8.	**Hardship faced by ISD registration holder in distribution of Input Tax Credit (ITC) due to technical glitches on the Common Portal**	Our members are facing problem with respect to distribution of TRAN 1 credit under their ISD registration. While the credit of ITC uploaded under TRAN 1 is appearing in the Electronic Credit ledger, **the Portal does not**	In view of the above, we would like to request and submit that the issue needs to be resolved on priority basis with suitable enabling modification on the common portal so that the GST as system, becomes "GOOD and SIMPLE

		show the balance as "available for distribution" without which, distribution of the available credit under ISD is not possible/ enabled. As per the process laid down for distribution of the ITC under ISD, the tax payers are required to file Return in Form GSTR-6. The said return allows to utilize the balance only if it is auto populated in Form GSTR-6A. Since the ITC under TRAN 1 of ISD registration holder is not getting auto populated, the distribution of the same is not possible on the common portal and therefore, the taxpayers are required to shell out additional cash towards discharge of their GST liability despite they having legitimate ITC balance under ISD registration. Non availability of the facility on the common portal for distribution of TRAN 1 credit under ISD is purely a technical glitch and we believe that it is unintended on the part of Tax authority. However, this has led to denial of legitimate credit of the ITC and has put an undue burden on the cash flow of the taxpayer.	TAX" as per the vision of our Honourable Prime Minister Shri Narendra Modi.
9.	**Exemption for national calamities or Good cause**	In order to fight against COVID 19 virus the purchases of masks, sanitizers and PPE kits for own use in the factory and for free distribution throughout country as social responsibility. Input Tax Credit for the Masks, Sanitizers, PPE kits and essential medicines distributed for social welfare should be allowed.	Considering the gratuitous gesture by Pharma Companies, Exemption Notification should be granted, in regard to Medicines and other items supplied free during National Calamities.
10.	**Centralized Registration & Assessments / Provision of flexibility in the GSTN**	Service tax regime allowed centralized registration of tax payers having multiple places of business but centralized accounting and administration system. Through centralized registration, all the assessments and audits could be conducted seamlessly. It also	It is proposed that for certain large tax payers, say having pan India turnover of more than Rs. 500 crores, the registrations should be centralized and the monthly return should contain state-wise allocation of input tax credit and output tax liabilities. The need to maintain accounts and records at

		alleviated the compliance and administrative cost of maintaining accounts and records separately at different locations. Under GST, the Company has been compelled to take a separate registration in all the States on account of its pan India business operations. This has led to separate audit and assessments with respect to each registration being conducted by the local tax officers. Further, the law mandates maintenance of separate books of account, records and documents at each registered location. Requirement for separate registration under GST in each State has led to drastic increase in the administrative burden and compliance cost on the Company. With multiple tax officers proceeding against the company coupled with widespread disparity in the understanding of the provisions of GST law, the Company is helpless at the whims of the tax officers and is forced to bear the unwanted harassment by such tax officers. It is an unwelcome unfavourable departure from the objective of centralized registration under service tax and incongruous to the Government's policy for ease of doing business. The telecom sector is already adversely impacted. Such requirements have worsened the situation.	various locations must be dispensed with to ease out the administrative burden. Also, the assessments by the tax authorities must be centralized to allow the Company to efficiently and effectively cater to their requests and have the assessments concluded in time. There should be an option to set off the excess tax paid by an entity under one registration in relation to another registration in a different state, when it has the same PAN. Further, In case of closure of one registration, there is no option to set off the balance Input tax credit of an entity under one registration in relation to another registration in a different state, even if it has the same PAN.
11.	**Non reversal of ITC on dividend income**	Dividend income requires ITC reversal resulting in increase in costs for the business. Dividend income is exempt supply under GST. As per Section 17 of the CGST Act, exempted supplies are liable for proportionate ITC reversal.	Dividend income should be excluded from exempted supplies, for alignment with the rules of excluding interest income for proportionate reversal for input credit, since interest and dividend both are financial income.

12.	**ITC admissibility in GST in case of expenses booked towards CSR activities**	As per Section 135 of Companies Act, 2013, a company is required to spend at least 2% of its average net profit for the immediately preceding 3 financial years on Corporate Social Responsibility (CSR) activities subject to its turnover /net worth/ net profit crossing prescribed limits. Accordingly, company incurs expenses for procurement of goods and services while undertaking CSR activities. Since such supplies are procured in course of business activities and as mandated by Statute, availment of ITC of GST charged on such supplies under Section 16(1) should not be in dispute However, there is lack of clarity as to whether company will be called upon to reverse the ITC on the ground that the company has provided such goods and services to the recipient of such CSR activity without charging any consideration and thereby, using such goods and services in undertaking non-taxable supplies, which will be subject to provisions contained in Section 17(2) of CGST Act.	Given that CSR is mandated under Statute and also, in order to encourage CSR spends in excess of mandated limits, it would be appropriate if the taxpayers are not burdened with additional cost of input taxes while undertaking CSR activities. A suitable clarification in this regard and /or an amendment in the CGST Act, may be carried out as it may deem fit.
13.	**Input Tax Credit reversals with Interest**	Section 16(2) of Central Goods and Services Tax Act requires levy of Interest on input tax credit availed in case of non-payment of consideration to the vendor with-in 180 days.	GST council had proposed to not levy interest on such levy, however the same was not part of the GST amendment bill passed. The same needs to be re-considered.
14.	**Availability of GST Input Credit to buyer**	Availability of GST Credit to buyer where buyer procures material/ services on payment of the entire material value + GST, irrespective of default on the part of supplier.	In cases where buyer procures material/services on payment of the entire material value + GST, the buyer should not be barred from availing ITC on such input purchases for non-compliance, if any (which may include non-deposit of the collected GST amount and non-filing of GSTR – 3B) by the seller, as presently Sec 16(c) of the CGST Act requires reversal of such ITC credit availed by the buyer.
15.	**Inclusion of Petroleum products and Electricity under Goods & Services Tax**	Petroleum products such as petroleum crude, high speed diesel, motor spirit (commonly known as	What is important is that Petroleum products which are under VAT regime right now and rate varies from States

		petrol), natural gas and aviation turbine fuel are now covered under both Union List & State List (except in the course of interstate trade) enabling them to be subsumed under GST, however, the same is proposed to be deferred to a later date. GST Council has been empowered to decide the date from which said goods would be leviable to GST. However, tax on consumption and sale of electricity which is covered in the State List (sr. no. 53) will not be subsumed under GST. Since the above taxes would presently not be subsumed under GST, CENVAT credit of the same would not be available and the taxes paid thereon would remain a cost. Considering the huge amount of taxes involved, it would increase the cost of doing business while at the same time breaking the seamless chain of CENVAT credit thereby defeating the purpose and principle of input credit scheme. In the new regime, it will break the chain of input tax credit and substantially increase the cost of doing business.	to States and becoming uncompetitive be brought under GST Regime. Until introduction of GST on Petroleum products, it is recommended that producers of petroleum and natural gas should be allowed to claim credit for GST on all inputs, input services and capital goods being paid by them to be allowed to be set off against excise duty on these products appropriate suitable amendment may be carried out in the CENVAT Rules. Further It is suggested that the inputs, input services and capital goods used in providing the said services be exempted from GST.
16.	**Refund of unutilised Input tax credit under GST in case of Closure of Business / Unit**	As per Section 54(3) of the CGST Act, 2017, a registered person is allowed to claim refund of unutilised input tax credit only in the following scenarios: a) Zero rated supplies made without payment of tax: b) Inverted duty structure In any other cases, refund of unutilized input tax credit is not allowed.	Refund of unutilized input tax credit should also be allowed in case of closure of a Business/ Unit.
17.	**COVID related health essentials –Credit eligibility**	In view of the COVID 19 pandemic, the need of mask and sanitizer has become utmost important • Ambiguity on whether the said credit would be eligible for credit availment as these are in some sense employee expenses	Need for clarification to issued that credit in respect of purchases made relating to health essentials would be allowed.

18.	**Non-functioning of GST Appellate Tribunal**	GST Appellate Tribunals have not been made functional till date.	GST Appellate Tribunal to be constituted and made operational on an urgent basis.
19.	**Revision of Returns**	There is no provision to revise the returns causing difficulties to taxpayers.	Revision of GST Returns to be provided.

We, at IDMA, are of the opinion that the above 19 issues are of considerable significance and would have major implications. Hence, we humbly request you to kindly peruse through these 19 issues and their suggestions thereof.

We look forward to your favourable response.

Thanks and regards,

Mahesh Doshi
National President

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Himachal Drug Manufactures Association Members Contributions Towards Covid Centre Establishment & HP State Disaster Relief Fund

As informed by Dr. Rajesh Gupta of Dallas Pharmaceuticals & Member of National Executive Committee of IDMA that Himachal Drug Manufactures Association contributed Rs.41 Lakh to the State Disaster Relief Fund by handing over the Cheque to Hon'ble Chief Minister Shri Jai Ram Thakurji.

We salute our valuable contributors who willingly contributed Rupees One Lakh per company for this noble cause.

Earlier, 72 Members of Himachal Drug Manufactures Association contributed approx 23 Lakh funds for oxygen Cylinders & Two Covid Centre establishment. Remarkable contribution received from Kala Amb & Poanta sahib.

Hon'ble Chief Minister Shri Jai Ram Thakurji congratulated Dr. Rajesh Gupta and his Team and also, applauded their excellent work.

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UNITED STATES PHARMACOPEIA

Just Released! USP Resources to Combat Substandard & Falsified COVID-19 Treatments

Substandard and falsified medicines pose a threat to global health security and hinder the ability of strong and resilient public health systems to prevent, detect, and respond to infectious disease threats. To help reduce risks from substandard and falsified COVID-19 treatments, and to assist manufacturers, regulators, and quality control laboratories in ensuring quality COVID-19 treatments are being procured, produced, and distributed, U.S. Pharmacopeia (USP) released a suite of resources which include:

- USP Method to Detect Falsified Remdesivir publication
- Minilab's Screening Tools for Dexamethasone
- IMWP draft monographs for Favipiravir

These new methods and tools were created in collaboration with public health organizations, pharmacopeias, regulators, and manufacturers to safeguard quality and improve public trust. The resources are available for download on www.usp.org.

These resources are for informational purposes only. Parties relying on these resources bear independent responsibility for awareness of, and compliance with, any applicable federal, state, or local laws and requirements.

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DGFT MATTER

DGFT Import-Exporter Code(IEC) Services affected due to non-availability of PAN Validation Services from 01.06.2021 to 06.06.2021 – reg.

Trade Notice No. 07/2021-22, dated 26th May, 2021

To,

1. *Exporters, Importers and other Members of Trade*
2. *Regional Authorities (RAs) of DGFT*
3. *Export Promotion Councils, Commodities Boards, Trade Associations and other stakeholders of DGFT.*

1. In reference to the Press release by Central Board of Direct Taxes on "Launch of new e-filing Portal of the Income Tax Department - Non-availability of e-filing services from 01.06.2021 to 06.06.2021", it is informed that some DGFT services wherein CBDT PAN validation services are being consumed in the DGFT IT systems will get impacted during this period.

2. Following DGFT services will not be available from 1st June 2021 to 6th June 2021:

i. Application for a new IEC

ii. Application for Amendments/Modification in an IEC

iii. One-time linking of Aadhaar for e-sign purposes

In view of the above, all stakeholders may therefore plan their activities accordingly.

3. In case of any queries/ issues you may please contact DGFT Helpdesk at 1800-111-550 from 9:00 am to 6:00 pm Monday to Saturday.

4. This issues with the approval of the Competent Authority.

File No. 01/02/29/AM-20/EG&TF

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

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OBITUARY

IDMA mourns the sudden demise of Mr. Nand Kishore Prasad

Mr. Nand Kishore Prasad

Mr. Nand Kishore Prasad, Managing Director, M/s Asklepios Remedies passed away on Monday, 24th May 2021. M/s Asklepios Remedies located at Bihar are IDMA Members.

Mr. Prasad was the Hon. Treasurer of IPGA Bihar State branch and also the Vice President of IPA Bihar. He was an active member of Industries Association and BDMA.

Mr. Prasad was a B. Pharm and was in this profession for more than 25 years.

In his passing away, the Pharma Industry based in Bihar as well as West Bengal have lost an active member & friend.

May his Soul Rest in Peace and may God grant his family the strength to bear this irreparable loss.

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DoPT MATTER

Appointment of Shri B.V.R. Subrahmanyarti, IAS, Chief Secretary, Jammu & Kashmir as Officer on Special Duty in the Department of Commerce - reg.

F.No 36/01/2021-E0(SM-1)(3), dated 27th May 2021

1. The Appointments Committee of the Cabinet (ACC) has approved the appointment of Shri B.V.R. Subrahmanyarti, IAS (CG;87), Chief Secretary, Jammu & Kashmir as Officer on Special Duty in the Department of Commerce.

2. The ACC has also approved his appointment as Secretary, Department of Commerce upon superannuation of Shri Anup Wadhawan, IAS (UK:85), Secretary, Department of Commerce on 30.06.2021.

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

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GOVERNMENT COMMUNICATION

SulphobutylEther Beta Cyclodextrin (SBEBCD), an excipient used in manufacture of Remdesivir, is an eligible product under the new PLI Scheme - reg.

The Association have received the communication on 26th May 2021 from Mr. Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers on the above subject :

It is informed that Sulphobutyl Ether Beta Cyclodextrin (SBEBCD), an excipient used in manufacture of Remdesivir, being a complex excipient, is an eligible product under the new PLI Scheme i.e "PLI Scheme for Pharmaceuticals". The Guidelines of the Scheme will be issued in a day or two.

During the process of ramping up of production of Remdesivir in the country, the availability of SBEBCD was identified as a constraint. The SBEBCD is used for making insoluble drugs soluble. It is requested that all the member companies of your associations desirous of manufacturing this product may be informed that it is one of the eligible products under the new PLI Scheme and they may be encouraged to apply for this product among other eligible products under the scheme.

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Thank India, South Africa for Their Initiative at WTO to Waive IP Protections for Covid-19 Products: WHO Chief

WHO chief Tedros Adhanom Ghebreyesus on Monday thanked India and South Africa for their initiative at the world body to temporarily waive some Trade-Related Aspects of Intellectual Property Rights (TRIPS) rules on Covid-19 products. In his opening remarks to the World Health Assembly, World Health Organisation Director-General Ghebreyesus called on nations to share doses through COVAX and underlined the need to scale-up manufacturing of Covid-19 vaccines.

Covid Vaccine Global Access (COVAX) is an international initiative aimed at equitable access to vaccines. He said the bottom line is that "we need a lot more doses, we need them fast, and we must leave no stone unturned to get them.

While noting that several manufacturers have said they have capacity to produce vaccines if the originator companies are willing to share licenses, technology and know-how, he voiced concern that he finds it difficult to understand why this has not happened yet. "I thank India and South Africa for their initiative at the World Trade Organisation (WTO) to waive intellectual property protections for Covid-19 products, and I thank those countries that are supporting these efforts, he said.

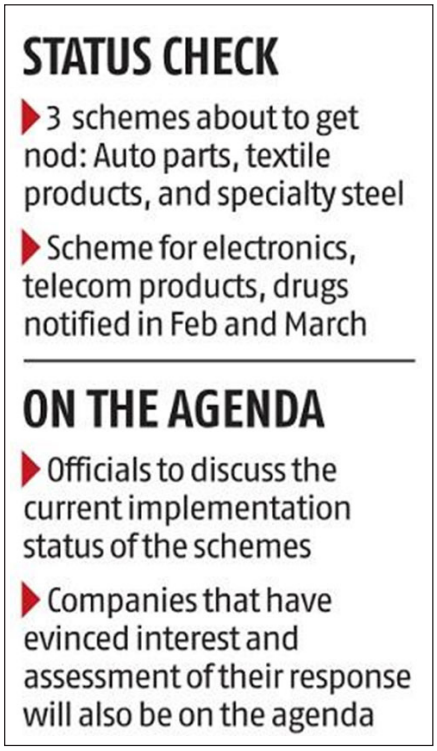
India had worked with South Africa and other partners in the WTO to seek a relaxation in the norms of the TRIPS agreement to ensure quick and affordable access to vaccines and medicines for developing countries during the Covid-19 pandemic. In a major policy change earlier this month, the Biden administration backed the initiative by India and South Africa at the WTO to temporarily waive patent rules on Covid-19 vaccines, seen as a breakthrough in the global fight against the deadly pandemic by potentially expanding the supply of the vaccines and more affordable doses for less wealthy nations. The WHO chief said that the ongoing vaccine crisis is a scandalous inequity" that is perpetuating the pandemic.

More than 75 per cent of all vaccines have been administered in just 10 countries. There is no diplomatic way to say it: a small group of countries that make and buy the majority of the world's vaccines control the fate of the rest of the world. Ghebreyesus noted that the number of doses administered globally so far would have been enough to cover all health workers and older people, if they had been distributed equitably. We could have been in a much better situation.

Source : Yoshita Singh, Financial Express, 24.05.2021

Cabinet secretary Rajiv Gauba to check progress of PLI schemes this week

An empowered group of secretaries, headed by Cabinet Secretary Rajiv Gauba, will conduct meetings over the next one week to review the progress of production-linked incentive (PLI) schemes that have been approved and notified over the past one year, for sectors such as pharmaceutical, electronics, telecommunications, among others.



"Officials will be closely looking at where we stand as far as the implementation of the PLI scheme is concerned. The number of applications for the scheme announced for the respective sectors could also be discussed," said a senior official.

The PLI scheme was announced last year, with India trying to diversify supply chains amid tensions with China and the National Democratic Alliance-led government's persistent efforts to become self-reliant through various initiatives. The scheme also aims at making domestic manufacturing globally competitive, create jobs, and boost exports.

In the Union Budget 2020-21, the finance ministry had already announced an outlay of Rs 1.97 trillion for the PLI schemes for 13 key sectors, including technology, textile, automobile, pharmaceutical, among others, for five years.

Of these, three schemes have been notified, while seven more have been approved by the Cabinet.

The meeting comes in the backdrop of companies, especially electronic manufacturers, requesting the government to relax the targets laid out due to disruption caused by the Covid-19 pandemic. They have also sought a change in the base year from the current 2019-20.

The review meet is also expected to discuss extending the PLI scheme for various sectors to benefit micro, small and medium enterprises.

The official quoted earlier, however, said the relaxation of the terms and conditions are not on the cards yet.

NITI Aayog CEO Amitabh Kant, Commerce Secretary Anup Wadhawan, Department for Promotion of Industry and Internal Trade Secretary Giridhar Aramane, Revenue Secretary Tarun Bajaj, Economic Affairs Secretary Ajay Seth, and representatives from the ministries concerned — food processing industries, electronics and information technology, Department of Pharmaceuticals, telecommunications, heavy industries, and new and renewable energy —will be also be present at the meeting, starting Monday.

Source: Shreya Nandi, Business Standard, 24.05.2021

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Ayurvedic Medicine Touted as Miracle Cure for COVID-19 to be Sent to ICMR To Test Efficacy

The Andhra Pradesh government on Friday decided to send the Ayurvedic medicine, being touted as a miracle cure for COVID-19 and distributed in SPS Nellore district, to the ICMR for a detailed study of its efficacy.

The government also decided to send a team of experts to Nellore for an on-the-spot study of the formulation, popularly known as the 'Krishnapatnam medicine'.

Vice-President M Venkaiah Naidu, who hails from SPS Nellore district, also asked Union Minister for Ayush Kiren Rijiju and Indian Council of Medical Research Director Balram Bhargava to conduct a study on the medicine.

He asked them to come out with a report as early as possible, a release here said.

At a high-level review meeting on COVID-19 here, Chief Minister Y S Jagan Mohan Reddy enquired about the Ayurvedic medicine, which has now become popular as the 'Krishnapatnam medicine, that is being promoted by his party district president and MLA K Govardhan Reddy.

"We have decided to get it studied by the ICMR and other experts to determine its efficacy," Deputy Chief Minister (Health) A K K Srinivas said after the review meeting.

Doctor-turned-bureaucrat P V Ramesh, who previously worked as Principal Secretary (Health) and also Special Chief Secretary to Chief Minister Y S Jagan Mohan Reddy, dubbed the so-called Krishnapatnam medicine "yet another recipe for disaster".

"Governments must stop such epidemics of superstition.

Those preparing and promoting this Krishnapatnam concoction are punishable under the Pharmacy Act, 1948, and Drugs and Magic Remedies Act, 1954," Ramesh, who actively oversaw the AP governments COVID-19 management last year, said.

From tens to hundreds and now thousands, people are flocking to Krishnapatnam village, even violating Covid-19 protocols, to take the medicine being offered by an Ayurvedic practitioner B Anandaiah, who once worked as the village sarpanch and later a member of the mandal parishad.

He began the medicine distribution on April 21.

A team of Ayurvedic doctors from the Department of Ayush visited the village a couple of days ago and enquired about the medicine and submitted a report to the government, saying the medicine preparation, treatment process and the after- effects needs to be studied in a scientific manner.

The team claimed none of those who took the medicine has complained of any ill effects.

It said Anandaiah was preparing five different medicines using natural herbs,honey and spices and giving it to COVID-19 positive patients, suspects and those with lung problems.

"One of the COVID-19 patients saw his oxygen level rise to 95 from 83 in an hour after getting two drops of the medicine administered in his eyes.

We have spoken to the patients," the Ayurvedic doctors said in the report. The SPS Nellore district medical and health officer and Nellore Revenue Divisional Officer were also part of the official team.

The team, however, said no COVID-19 rules were being followed in the village where the medicine was being given.

On Friday, there was a virtual stampede at Krishnapatnam as over 10,000 people thronged there for the medicine, the supply of which was resumed after a break for a few days.

Source: PTI, 21.05.2021

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Cadila to produce up to 30 mn Covid-19 vaccine doses a month

vaccine meant to be given in three doses

India's Cadila Healthcare is aiming to triple monthly production of a Covid-19 vaccine candidate to as many as 30 million doses, its Managing Director said on Monday, as the country battles a massive wave of infections.

The virus has killed nearly 100,000 Indians in May alone according to official figures, although experts say actual numbers are likely many times higher. India's Covid-19 death toll surged past 300,000 on Monday, Health Ministry data showed.

India is also facing a shortage of vaccines. Weekly vaccinations have fallen from a peak of nearly 25 million doses in early April to about 9 million. The government has pledged to make 2.67 billion doses available this year.

Cadila, headquartered in Ahmedabad in western India, is looking to increase monthly production of its vaccine candidate ZyCoV-D to up to 30 million doses in four to five months, from 10 million now, its Managing Director, Sharvil Patel, said in text messages to Reuters.

Reuters reported last month Cadila was seeking emergency use authorisation for the shot from India's regulators in May or June. "We still think we should be able to submit (the vaccine for emergency use authorisation) in May," Patel said on Monday. The company will use both in-house capacity as well as third-party manufacturers to boost production, he said.

ZyCoV-D is a DNA plasmid vaccine, which uses a portion of the genetic code - DNA or RNA - in the virus to stimulate an immune response. It is undergoing late-stage trials in nearly 30,000 adults after being found safe and immunogenic in earlier studies. It is meant to be given in three doses but Cadila is also doing trials on a two-dose regimen, Patel has said previously.

Source: The Hindu Business Line, 25.5.2021

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Delay in second shot of Pfizer vaccine boosts immunity in elderly by over 3 times: Study

Synopsis The finding comes days after the UK government reduced the gap between the two doses of COVID-19 vaccines to eight weeks, while India extended the interval between two doses of the Covishield preventive to 12-16 weeks, up from the previous maximum of eight week

Delay in giving the second dose of the COVID-19 vaccine by 12 weeks increases antibody response in older people by three-and-a-half times compared to those who receive it at a three-week interval, according to a study conducted in the UK.

The finding comes days after the UK government reduced the gap between the two doses of COVID-19 vaccines to eight weeks, while India extended the interval between two doses of the Covishield preventive to 12-16 weeks, up from the previous maximum of eight weeks.

The study conducted on 175 people aged over 80 is the first direct comparison of the immune response in any age group between those who are given the second Pfizer vaccine dose at a three-week interval and those at a 12-week interval.

The Pfizer vaccine was originally authorised for a three-week interval between doses. Several countries, including the UK, chose to expand this to a 12-week interval to allow a higher percentage of the population to receive one vaccine dose quicker.

However, the UK last week cut the gap from 12 weeks to eight weeks in view of the spread of the B.1.617 variant that originated in India. The yet-to-be peer-reviewed research found that extending the second dose interval to 12 weeks increased the peak SARSCoV-2 spike specific antibody response 3.5-fold compared to those who had the second vaccine at three weeks.

The team concluded that extending administration of the second Pfizer vaccine to 12 weeks potentially enhances and extends antibody immunity, which is believed to be important in virus neutralisation and prevention of infection.

"SARS-CoV-2 vaccines have been remarkably effective in providing large-scale protection against infection and symptomatic disease - but many questions remain regarding their optimal delivery for provision of effective and sustained immunity," said study first author Helen Parry, from the University of Birmingham, UK.

"The study is crucial, particularly in older people, as immune responses to vaccination deteriorate with age," said Parry. Understanding how to optimise COVID-19 vaccine schedules and maximise immune responses within this age group is vitally important, the researcher said. "The enhanced antibody responses seen after an extended interval may help to sustain immunity against COVID-19 over the longer term and further improve the clinical efficacy of this powerful vaccine platform," said corresponding author of the study Paul Moss, from the University of Birmingham. "Our research findings may be important in the development of global vaccination strategy as extension of interval of the second vaccine dose in older people may potentially reduce the need for subsequent booster vaccines," Moss said. The research saw the team taking blood samples for analysis in the lab after participants' first vaccine and then again two to three weeks after participants had received their second vaccine. Of the cohort, 99 participants had the second vaccine at three weeks, while 73 had the second dose at 12 weeks. Participants who had previous infection -- 10 in the three-week interval group and five in the 12-week interval group -- were excluded from the analysis as previous infection has been shown to have a major impact on the immune response to vaccination. After their second vaccine, spike protein-specific antibodies were detected in all participants no matter how far apart their doses were. Spike protein helps the virus to infect human cell.

Source: Business Line, 22.05.2021

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Panacea Biotec starts domestic production of Sputnik V vaccine

So far, Sputnik V has received regulatory clearance in 66 countries that have a total population of over 3.2 billion people.

- The firm plans to make test batches of 3 million vaccines at Baddi facility in Himachal
- Local production of Sputnik V will help ease a shortage of vaccines in India at a time when the pandemic continues to claim more lives

NEW DELHI : Panacea Biotec Ltd has started producing Russia's Sputnik V vaccine against coronavirus in a major boost to the ongoing vaccination drive in India.

The first batch of the vaccine is being made at Panacea's facility at Baddi in Himachal Pradesh from where it will be shipped to Gamaleya Research Institute of Epidemiology and Microbiology in Russia for quality control.

Full-scale production of the vaccine is expected to start later this summer, the New Delhi-based vaccine maker and the Russian Direct Investment Fund (RDIF) said in a joint statement on Monday. Russian sovereign wealth fund RDIF is responsible for marketing the Sputnik vaccine globally.

Panacea Biotec will initially make test batches of 3 million vaccines each of the first and second doses, a person with knowledge of the matter said, requesting anonymity. Sputnik V comprises two doses given three weeks apart with each dose having a different strain of viral vector.

While some samples have been sent to Russia for testing the quality of the batch, the rest has been kept in India, the person said. "After fulfilling India's requirement now, the batches produced by Pancea may also be exported," the person said.

Local production of Sputnik V will help ease a shortage of vaccines in India at a time when the pandemic continues to claim more lives. Serum Institute of India and Bharat Biotech International, the only two domestic makers of covid-19 vaccines currently, are also scaling up capacities for their Covishield and Covaxin vaccines, respectively.

Panacea has a a pact with RDIF to manufacture 100 million doses of Sputnik V.

"Launch of production in India in partnership with Panacea Biotec marks an important step in helping the country fight the pandemic. Production of Sputnik V supports efforts of India's authorities to leave behind the acute phase of coronavirus as soon as possible while the vaccine will also be exported at a later stage to help prevent the spread of the virus in other countries around the world," RDIF chief executive officer Kirill Dmitriev said in the statement.

Other Indian companies that RDIF has signed manufacturing pacts for the Sputnik V vaccine are Hetero Biopharma, Gland Pharma, Stelis Biopharma, Virchow Biotech and Shilpa Medicare.

Source : Mint, 25.05.2021

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Dr Reddy's lines up Rs 1,000 cr capex for current fiscal

The drug maker's growth would be primarily driven by organic moves, focusing around pipeline monetisation, productivity enhancement, diversifications.

Drug major Dr Reddy's Laboratories has earmarked a Capex of around Rs 1,000 crore for the current fiscal as it remains positive about sustaining its growth trends in the current fiscal and beyond, as per a top company official.

The Hyderabad based firm invested about Rs 1,000 crore in the 2020-21 fiscal.

"The Capex will be around the same numbers, maybe a bit higher if everything goes through," Dr Reddy's Laboratories CEO Erez Israeli said in an analyst call.

However, it depends on the COVID-situation that how much the company would be able to put in during the fiscal, he noted.

He was responding to a query whether the company's Capex for FY22 would be higher than FY21.

"We had about give or take a little bit less than Rs 1,000 crore of Capex in FY21," Israeli said.

On the growth outlook for the current fiscal, Israeli noted: "While the current business environment continues to remain uncertain owing to the global pandemic, we believe that the foundation is solid and there are multiple growth levers available for us to sustain growth trends in FY22 and beyond".

The drug maker's growth would be primarily driven by organic moves, focusing around pipeline monetisation, productivity enhancement, diversifications and capability ramp-up in marketing and digitalisation, he added.

"Further, our strong balance sheet allows us to continue to invest in the right set of inorganic moves to enable long-term growth," Israeli said. Dr Reddy's has a net surplus cash of Rs 751 crore as of March 31, 2021, he added.

On the company's North America Generics business, Israeli said that as of March 31, 2021, the drugmaker had 95 cumulative filings pending approval with the US Food and Drug Administration (USFDA), which included 92 abbreviated new drug applications (ANDAs) and three new drug applications (NDAs).

"Overall, in the year (2020-21), we launched 28 new products, including one relaunch. We expect the strong new

launches momentum to continue through the current year as well with a similar number of launches," he added. On a full-year basis (2020-21), the North America Generics business sales stood at USD 948 million, a growth of 4 per cent over the previous year (2019-20). The overall revenues of the drugmaker for FY21 stood at Rs 18,972 crore.

Source : Telangana Today, 25.05.2021

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Mucormycosis: Alembic gets Gujarat FDCA licence for anti-black fungal drug Amphotericin-B

"We have issued a licence to APL to make the anti-fungal drug at the company's facility near Karakhadi village, around 40 km from its Vadodara headquarters," said HC Koshia, Gujarat's FDCA Commissioner.

At present, Cipla, Sun Pharmaceuticals, Abbott India, Bharat Serums and Vaccines, and Celon Labs are manufacturing the drug.

Alembic Pharmaceuticals (APL) is all set to manufacture Amphotericin-B, a drug used to treat mucormycosis patients, after receiving a licence to do so from the Food & Drug Control Authority (FDCA), Gujarat.

"We have issued a licence to APL to make the anti-fungal drug at the company's facility near Karakhadi village, around 40 km from its Vadodara headquarters," said HC Koshia, Gujarat's FDCA Commissioner.

Last week, Alembic and five other companies including Natco Pharma, Lyka Labs, Emcure Pharma, Gufic Biosciences and Protech Telelinks, received approval from the Drug Controller General of India's expert panel to begin clinical trials for the drug. "It would take at least a month to start manufacturing the anti-black fungal drug at our Karakhadi facility. We are acquiring necessary raw material and completing other formalities. Initially, the company is targeting 50,000 vials per month," RK Baheti, director – finance & CFO of APL, said.

APL currently has six formulation and three API manufacturing facilities. Of the six formulation facilities, five are in and around Vadodara — three at Panelav and two at Karakhadi — while one is in Sikkim. Alembic currently manufactures general oral solids in Panelav and is setting up oncology oral solids and oncology injectable facilities at the same location. The company's Karakhadi plants are equipped to manufacture injectable and ophthalmic products. APL is the flagship company of the over 100-year-old Alembic Group.

Liposomal Amphotericin-B injections are in huge demand due to a sudden surge in black fungus cases. Currently, the drug is in short supply. At present, Cipla, Sun Pharmaceuticals, Abbott India, Bharat Serums and Vaccines, and Celon Labs are manufacturing the drug.

Source: Financial Express, 25.05.2021

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Roche's antibody cocktail for Covid rolls out in India

Price to a patient, including tax, is ₹59,750

Doctors treating Covid-19 patients will now also have the antibody cocktail – Casirivimab and Imdevimab – for treatment. The first batch of the injectable from Swiss drugmaker Roche has been imported to India from the US, and the second batch is expected by mid-June. Cipla will market the product in India.

Global attention

The antibody cocktail received much global attention last year after former US President Trump was given the drug when he had contracted Covid. A total of one lakh packs are slated for India, but each pack can treat two patients, said the company. The price to a patient is ₹59,750, inclusive of taxes, said the company, with the two-dose pack costing ₹119,500.

With drugmakers facing intense pressure on supplies, given the global demand on a limited supply of products, Roche Pharma (India) Managing Director and Chief Executive Officer, V Simpson Emmanuel, said the idea was to get the product in for treatment as soon as possible, as it would be difficult to match the entire demand, given the scale of the pandemic and size of the population.

Price will always be a factor, but the product was deferentially priced for India, he told *Business Line*, adding that it was substantially less that its price in the US or European Union. Discussions are on to reduce the tax component on the price, the benefit of which could be passed on to the consumer, he said. Bruno Jolain, Medical Director, Roche Pharma (India), explained that a singe dose was to be given to a high-risk patient with mild to moderate Covid-19, to prevent them from getting worse

and hospitalised. It should be given in an out-patient set-up, he stressed, where the patient can be given the drug and can go home after being observed by the doctor, just as the case is with a vaccine.

High-risk patients

It has been shown to help high-risk patients before their condition worsens, reducing the risk of hospitalisation and fatality by 70 per cent and shortening the duration of symptoms by four days, the company said. The risk factors include age (above 65 years), chronic liver or kidney diseases, diabetes and obesity, he said, outlining a few.

Pointing out that there were no major safety concerns, he said the product has an emergency use authorisation in India, and is seen to have a neutralising effect against all known variants in the laboratory set-up. It's effectiveness in the real world settings will also be studied, he said. Surge in demand

Another Covid-19 product from Roche, Tocilizumab, is also marketed in the country by Cipla. The product though is facing a severe supply crunch. The CEO explained that there was an unprecedented demand for the product globally and locally, and the company has entered into alliances internationally to increase supplies. This may not, however, be a solution for the immediate needs, he agreed, adding that India was a priority for the company and plans to address the requirements of the local market were being addressed.

Mechanism of action

Casirivimab and Imdevimab are human immunoglobulin monoclonal antibodies produced by recombinant DNA technology in the lab. Monoclonal antibodies are proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. This product is specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells.

Source : PT Jyothi Datta, The Hindu Business Line , 25.05.2021

● ● ●

Dr Harsh Vardhan asks Baba Ramdev to take back his statements on allopathic medicines

Union Health Minister Dr Harsh Vardhan on Sunday has written a letter to yoga guru Baba Ramdev asking him to take back his statements on allopathic medicines and modern medicine and called it "unfortunate and inappropriate".

"You should be aware that smallpox, polio, Ebola, SARS and TB have been diagnosed and treated by allopathy medicine. In this fight against COVID, vaccination is proved to be an important weapon which is also given by allopathy. In your defence, you said the statement is not against modern science or good doctors. I do not consider the clarification is enough. I hope you will ponder over the topic with seriousness and take back the offensive and unfortunate statement keeping in mind the feeling of corona warriors across the world," wrote the Union Minister in his letter to Baba Ramdev in Hindi. (as reproduced below)

Dr Harsh Vardhan called Baba Ramdev's statement unfortunate and inappropriate which can break the morale of the doctors and can weaken the fight against coronavirus. "As you are a public figure and every statement given by you has high value. I believe you should give the statement keeping in mind time and situation. At this time calling presently practiced treatment as 'Tamasha' you have not only questioned the allopathy but also the ability and motive of the doctors practicing it, which is inappropriate. Your statement can break the morale of the doctors and can weaken our fight against coronavirus," he said.

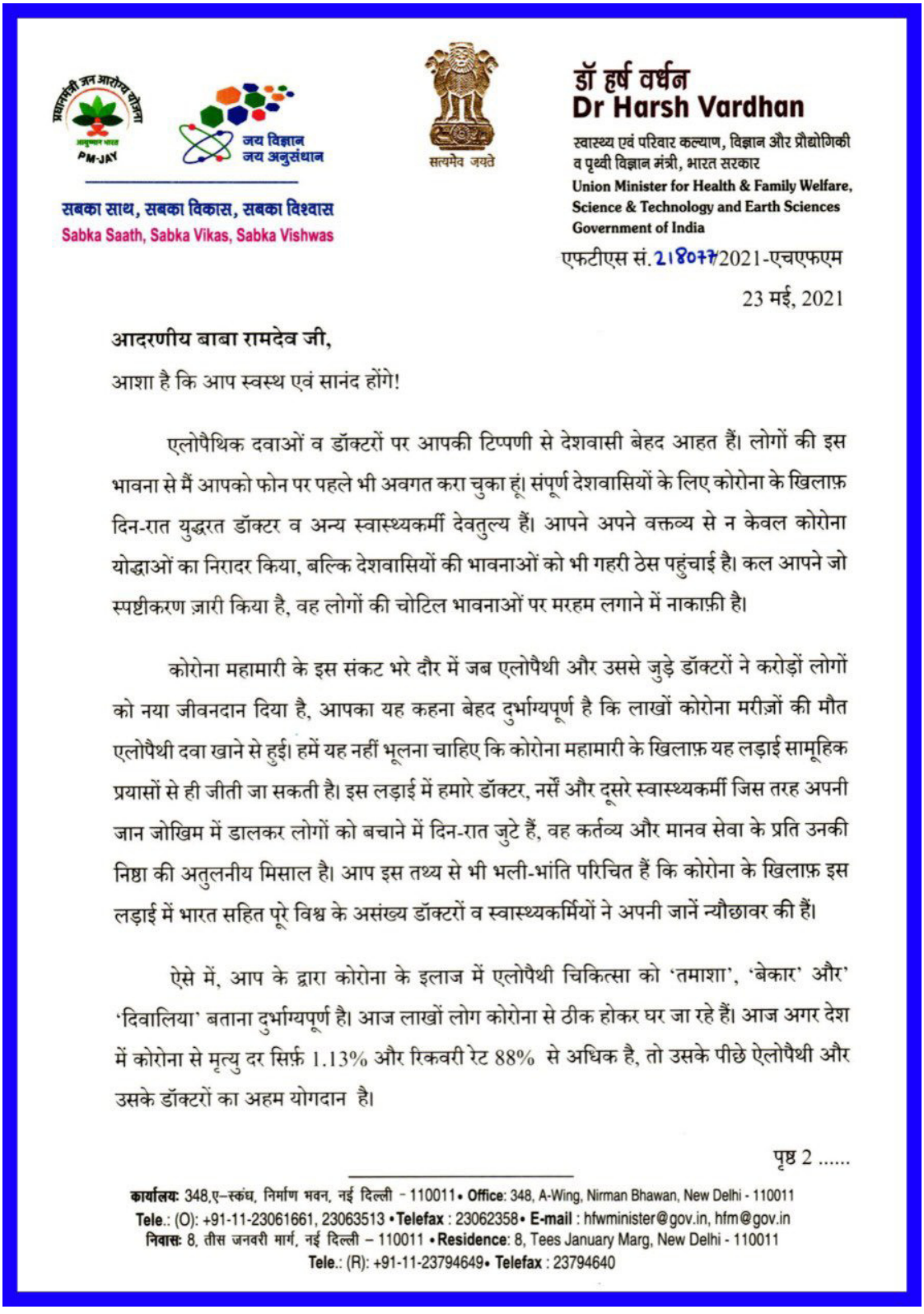
Dr Harsh Vardhan also pointed out that the doctors and healthcare workers are fighting against COVID-19 day and night and are 'godlike' for the public and Ramdev's statement not only disrespected corona warriors but has also hurt the sentiments of the citizens. Counting on the contribution of Allopathic treatment in the world, the Union Health Minister who himself is an allopathic physician said, "By calling Allopathic medicine 'Tamasha', 'Waste' and 'Bankrupt' is unfortunate. Many are going back home after receiving the treatment. In the country, if the death rate is 1.13 per cent and recovery rate is 88 per cent then it is because of the contribution of Allopathic doctors and treatment."

Indian Medical Association (IMA) on Saturday sent a legal notice to yoga guru Ramdev over his alleged statements against allopathy and "defaming" scientific medicine. Patanjali Yogpeeth Trust has denied allegations by the IMA that Ramdev has misled people by making "unlearned" statements against allopathy and defamed scientific medicine.

"IMA brings to the notice of our Health Minister, a video circulating in social media portraying, the celebrated

Yoga Guruji saying that 'modern allopathy ek aisi stupid aur diwaliya science hai' allopathy is a stupid and failed science)," the IMA said in its statement. According to a Haridwar-based Patanjali Yogpeeth Trust statement, Yog Guru Ramdev was reading out a WhatsApp forwarded message in the video that has gone viral on social media.

Source : ANI, 23.05.2021



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सत्यमेव जयते

डॉ हर्ष वर्धन
Dr Harsh Vardhan

स्वास्थ्य एवं परिवार कल्याण, विज्ञान और प्रौद्योगिकी व पृथ्वी विज्ञान मंत्री, भारत सरकार
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एफटीएस सं. 218077/2021-एचएफएम

23 मई, 2021

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एलोपैथिक दवाओं व डॉक्टरों पर आपकी टिप्पणी से देशवासी बेहद आहत हैं। लोगों की इस भावना से मैं आपको फोन पर पहले भी अवगत करा चुका हूं। संपूर्ण देशवासियों के लिए कोरोना के खिलाफ़ दिन-रात युद्धरत डॉक्टर व अन्य स्वास्थ्यकर्मी देवतुल्य हैं। आपने अपने वक्तव्य से न केवल कोरोना योद्धाओं का निरादर किया, बल्कि देशवासियों की भावनाओं को भी गहरी ठेस पहुंचाई है। कल आपने जो स्पष्टीकरण ज़ारी किया है, वह लोगों की चोटिल भावनाओं पर मरहम लगाने में नाकाफ़ी है।

कोरोना महामारी के इस संकट भरे दौर में जब एलोपैथी और उससे जुड़े डॉक्टरों ने करोड़ों लोगों को नया जीवनदान दिया है, आपका यह कहना बेहद दुर्भाग्यपूर्ण है कि लाखों कोरोना मरीज़ों की मौत एलोपैथी दवा खाने से हुई। हमें यह नहीं भूलना चाहिए कि कोरोना महामारी के खिलाफ़ यह लड़ाई सामूहिक प्रयासों से ही जीती जा सकती है। इस लड़ाई में हमारे डॉक्टर, नर्सें और दूसरे स्वास्थ्यकर्मी जिस तरह अपनी जान जोखिम में डालकर लोगों को बचाने में दिन-रात जुटे हैं, वह कर्तव्य और मानव सेवा के प्रति उनकी निष्ठा की अतुलनीय मिसाल है। आप इस तथ्य से भी भली-भांति परिचित हैं कि कोरोना के खिलाफ़ इस लड़ाई में भारत सहित पूरे विश्व के असंख्य डॉक्टरों व स्वास्थ्यकर्मियों ने अपनी जानें न्यौछावर की हैं।

ऐसे में, आप के द्वारा कोरोना के इलाज में एलोपैथी चिकित्सा को 'तमाशा', 'बेकार' और 'दिवालिया' बताना दुर्भाग्यपूर्ण है। आज लाखों लोग कोरोना से ठीक होकर घर जा रहे हैं। आज अगर देश में कोरोना से मृत्यु दर सिर्फ़ 1.13% और रिकवरी रेट 88% से अधिक है, तो उसके पीछे ऐलोपैथी और उसके डॉक्टरों का अहम योगदान है।

पृष्ठ 2 .....

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बाबा रामदेव जी, आप सार्वजनिक जीवन में रहने वाली शख्सियतों में से हैं, ऐसे में आपका कोई भी बयान बहुत मायने रखता है। मैं समझता हूं कि आपको किसी भी मुद्दे पर कोई भी बयान समय, काल और परिस्थिति को देखकर देना चाहिए। ऐसे समय में इलाज के मौजूदा तरीकों को तमाशा बताना न सिर्फ़ एलोपैथी बल्कि उनके डॉक्टरों की क्षमता, योग्यता व उनके इरादों पर भी सवाल खड़े करता है, जो अनुचित है। आपका बयान डॉक्टरों के मनोबल को तोड़ने और कोरोना महामारी के खिलाफ़ हमारी लड़ाई को कमज़ोर करने वाला साबित हो सकता है।

आपको यह पता होना चाहिए कि चेचक, पोलियो, इबोला, सार्स और टी.बी. जैसे गंभीर रोगों का निदान एलोपैथी ने ही दिया है। आज कोरोना के खिलाफ़ वैक्सीन एक अहम हथियार साबित हो रहा है, यह भी एलौपैथी की ही देन है। आपने अपने स्पष्टीकरण में सिर्फ़ यह कहा है कि आपकी मंशा मॉडर्न साइंस और अच्छे डॉक्टरों के खिलाफ़ नहीं है। मैं आपके द्वारा दिए गए स्पष्टीकरण को पर्याप्त नहीं मानता।

आशा है, आप इस विषय पर गंभीरतापूर्वक विचार करते हुए, और विश्वभर के कोरोना योद्धाओं की भावनाओं का सम्मान करते हुए, अपना आपत्तिजनक और दुर्भाग्यपूर्ण वक्तव्य पूर्ण रूप से वापस लेंगे।

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आपका,

(डॉ हर्ष वर्धन)

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Sun may have better served by boarding global pharma talent

ET Intelligence Group: India's largest drugmaker Sun Pharma has onboarded Rama Bijapurkar and Pawan Goenka as independent directors.

These two dignitaries from the consumer and automobile industries, respectively, join Sun Pharma's board that also includes professionals VC Sehgal from the Samvardhana Motherson group, tax expert Gautam Doshi and Rekha Sethi of the All India Management Association.

The latest choices of independent directors seem to have been prompted by the need to have credible names on the board, given Sun's past corporate governance issues.

Sun Pharma has Israel Makov, former CEO of Teva Pharma, as its non-executive chairman; none of its independent directors are from the pharmaceutical industry.

At a time when the company is investing heavily in the speciality drugs business in the US, it could well have incorporated more globally diverse experts from the pharmaceutical industry.

This would also be in line with what the company's peers in India are doing and the current need of the Indian pharma industry to globalise its management.

For instance, earlier this month Cipla roped in Robert Stewart, CEO of a global speciality pharma company, as an independent director. The company already has Peter Mugyenyi, a Ugandan physician specialising in AIDS, as an independent director on the board. AIDS has been an area of specialisation for Cipla.

Dr Reddy's Laboratories has two independent directors — global pharma industry experts Bruce LA Carter and Allan Oberman — among the seven directors without executive responsibilities. The company has an expat CEO Erez Israeli, formerly a Teva executive, who has managed to turn around its performance — both on the ground and the bourses.

Three of the five independent directors on the board of Lupin — Jean-Luc Belingard, Christine Mundkur and Mark D McDade — are professionals from the global pharma and healthcare industry.

As Indian companies grow and globalise, it is important that their boards and managements start reflecting that change. While celebrated names on the board do increase a company's credibility and the confidence of its investors, the need of the hour must also be factored in while making those choices.

Source: Economic Times, 25.05.2021

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A single global tender for vaccine procurement

The scramble by the States is destined to be inequitable and inefficient and portrays lack of coordination

With only 20 million vaccine shots available for the entire month of May for the 600 million people aged 18-44 years in India, many State governments have resorted to floating global tenders for COVID-19 vaccines. This situation is another example of political promises being made without sufficient planning.

It also points to a lack of political will to find sustainable solutions; inadequate coordination between States and the Union government; and a focus on optics during a public health emergency of unprecedented magnitude. Each of these is an indictment of the response to the pandemic in India. If not now, when can the Indian state be more responsive and responsible?

Incoherent on all fronts

There are many cons of the Liberalised and Accelerated Phase 3 Strategy of COVID-19 Vaccination, which began on May 1. We discuss them in this article, particularly in view of the scramble among States at the international stage as a result of this strategy.

First, was the new liberalised strategy primarily intended as a fire-fighting measure in view of limited vaccine supply or as a stable, long-term measure? Reducing Central government monopsony can theoretically increase production. However, it is unlikely to manifest quickly enough to aid in successfully preparing for a third wave through vaccination, especially in the presence of limiting factors like reduced raw materials, which the government has itself admitted to. Supplies are projected to achieve substantial levels only by August 2021. However, considering that past announcements of vaccine production have not met the timelines, can we be assured of even that? Without any increase in supplies, expanding eligibility to the 18-44 years age group will only spread

vaccines thinly, which makes little epidemiological and operational sense.

If it is intended to be a long-term and stable measure, it would exemplify an imprudent and inequitable vaccination strategy by any nation in the face of an unprecedented national emergency.

Second, uniform vaccine prices for all States can prevent exploitation of possible economies of scale. Leaving prices to an oligopolistic market favours unhealthy competition among States. The new vaccination strategy has now forced States to compete in an unfavourable international market, which negates any success at curbing domestic competition. States will have to procure doses at higher rates than a single national purchaser would. As a result of the new strategy, each vaccine dose will be costlier in India than in any other part of the world, until prices come down substantially. Making State governments pay higher prices for the vaccines essentially increases government expenditure, though the burden now has shifted to the States. Overall, the current approach is destined to be highly inefficient on all fronts for a country that is short of resources. The concomitant inequity is self-explanatory.

The solution is to boldly revisit the policy and use the limited vaccine supply for the adult high-risk and vulnerable group, identified as per the target population. This can be a State-specific decision led by subject experts without interference from the political circle. Don't give false hopes to the rest, which can only lead to disillusionment, further diminish trust in government promises and compound other problems. Reconsider opening vaccination for the 18-44 years age group in August 2021, when vaccine supply is likely to stabilise. This can be done earlier if adequate supplies become available.

The current scramble by States on the international stage is not only destined to be inequitable and inefficient, but also propagates a discordant image for a country which, until late, boasted of extending humanitarian aid by exporting vaccines. It only behoves the Central government to bear the costs and provide vaccines to the States. However, the bare minimum that the Central government can do now is to coordinate with the States and on behalf of all the willing States, float a single global tender for vaccine procurement. This is unlikely to yield much as most vaccine manufacturers hardly have any spare capacity for the next few months, but a single powerful purchaser is more likely to tip the balance in India's favour, apart from accomplishing obvious efficiency and equity gains. The benefits of being the single purchaser are not alien to the current government — the Centre's own flagship healthcare programme, the Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana, is an exemplar of such benefits.

More specifically, on vaccination, the Centre-State division of labour has traditionally been one where the Centre procures vaccines and the States administer them. It was effective vaccine delivery that helped the state deal with the public health problem of polio. The Central government procured the vaccines and States dealt with delivery.

An emergency is the worst hour to abruptly disturb this equation and saddle the States with additional procurement responsibilities. The fact that the federal government has provided vaccines free to all even in the United States, which is a poster child of laissez-faire and arguably, an inspiration behind many of India's recent health policy pronouncements, should be an eye-opener.

A rights-based approach

Article 21 of the Constitution is often interpreted as embracing the right to health. The rights-based approach in health in operational terms connotes accessibility, availability and affordability, and the significance of these magnifies multifold during an emergency of the proportions we are seeing today.

In recent times, various Indian courts have looked at COVID-19 vaccines and services from a rights-based approach. A health emergency comes largely within the purview of the Central government. It demands that the government act responsibly to ensure that COVID-19 vaccines are accessible, available, and affordable. It is never too late to take corrective measures.

Chandrakant Lahariya has done extensive work on the vaccination programme of India, is a public policy and health systems expert and the co-author of 'Till We Win: India's Fight Against The COVID-19 Pandemic'; Soham D. Bhaduri is a health policy expert and Chief Editor of 'The Indian Practitioner'

Source: Chandrakant Lahariya & Soham D. Bhaduri, The Hindu, 25.05.2021

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DBS Industry Insights for IDMA – Indian Pharma - Trends and Expectations

Headline options: Key takeaways for the Indian pharma sector in 2021

What are the key trends and expectations for the Indian pharmaceutical sector this year? Radhika Rao, India Economist, DBS Group Research, and Dr Eugene Hong, Executive Director, Group Head for the Healthcare and Pharmaceutical Group, DBS, spoke at a webinar in Mumbai held by the Indian Drug Manufacturers Association (IDMA) to discuss the future growth opportunities for India's pharmaceutical industry. This latest insight article outlines key takeaways for the Indian pharma industry to grow market share and stay competitive.

Emboldened by a vaccine roll-out, the world is slowly moving to recoup lost growth. Sure, hitches remain, including production and logistical challenges, the vaccines' efficacy as the virus mutates, and the ability of lesser developed countries to get the vaccines—but green shoots of optimism are slowly appearing.

Asia is expected to be on a relatively more robust road to economic recovery compared to the West. Enclosed in the optimism bubbling in Asia, DBS's view is that India's pharma sector is a strong performer. Projections by the Indian government indicate that the pharma industry will grow at a CAGR of 12.5 per cent to USD 130 billion by 2030[1].

Here, we outline four key takeaways for the Indian pharma sector in 2021, the third-largest in the world in terms of volume and valued at USD 40 billion[2].

1. India's economy is poised for a robust recovery, along with healthcare and the pharma sector

The Indian Budget for the financial year 2021-22 increases capital expenditure, which is expected to have a multiplier effect on the economy[3]. More recently, India is in the midst of a second Covid-19 wave which has seen the daily caseload surge by unprecedented levels, with the country overtaking Brazil as the second worst-hit country, with the most cumulative cases behind the U.S. We retain our projections for double-digit growth as India's Covid resurgence begins to take an economic bite, partly due to base effects. We also note that the pandemic-related developments are fluid at this juncture and likewise considerable uncertainty bands around the economic projections.

"The second Covid wave and its economic impact will be crucial to monitor in the coming weeks. While overall growth might still stay high due to base effects, there are downside risks emanating due to the state-level restrictions," added Radhika.

What does this mean for sectoral growth? In February 2021, the Indian government cleared a Rs 15,000 crore Production-Linked Incentivise plan meant to enhance India's manufacturing capabilities, drive production capacity to high-value products and create 'global champions' in the pharma sector[4]. Explains Radhika that the Indian government focuses consciously on healthcare investments such as infrastructure (hospital beds), the larger sanitation ecosystem, and making sure the population at large has potable water.

2. The positive impact of President Joe Biden's win for Indian pharma, but U.S. margins will be under pressure

The U.S. is one of the largest export markets for Indian pharma companies. On average, 38 per cent of the revenue of the top 10 Indian pharma companies (in terms of market capitalisation) is from the U.S. markets[5].

Here are some reasons that the Joe Biden win is good news for the Indian pharma sector.

Dilution of 'America First' policy. Economic policies crafted by Biden's presidency will have a less hawkish tone, implying that foreign investment is more welcome than in President Donald Trump's era.

Strengthening the CREATES Act. Biden's administration will strengthen the Creates Act enacted in December 2019. The changes address anti-competitive tactics by branded manufacturers to limit the import of generic products.

"This (obtaining samples of brand products) was not allowed in the past, and this was how the branded manufacturers, the big pharma companies in the U.S., were stopping generics from entering the country," explains Dr Hong. "What this now means is the Indian generic products can continue to be exported to the U.S. market."

Dr Hong's optimism comes with a warning. The U.S. market will be challenging to grow as market growth slows down due to price erosion. According to DBS industry research, at two per cent, the CAGR for North America lags behind the rest of the world, which is growing at six per cent.

Dr Hong cautions,*" It is pretty clear that the growth of the generic market in the U.S. is slowing down. A lot of policies, be it this administration or the previous administration, are all focused on lowering the price, which will be limiting the U.S. market growth."*

As India's biggest pharmaceutical export market slows down, the sector must build partnerships and expand its customer base to regional markets.

3. Handling the China equation—possibilities and competitive threats

The Indian pharma sector is pushing for self-sufficiency on API manufacturing (Active Pharmaceutical Ingredient) but matching the Chinese on price will be no easy task. China produces APIs at a 20 to 30 per cent lower price than the West, and India is heavily dependent on Chinese-manufactured APIs—the Indian pharma sector relies solely on Chinese imports for 8 out of 68 APIs.

Another hindrance to shifting manufacturing from China to India is that drugs like penicillin, and many other biosimilars used by Indian companies, need to be manufactured in cooler climates such as Xindong. Moving manufacturing to warmer Indian cities such as Hyderabad is not feasible.

Dr Hong alludes to a love-hate relationship between China and India, where the competitive threats are worrying, yet untapped profitable market opportunities are there for the taking. Of the ten listed Indian pharma companies, eight have an explicit China strategy, asserts Dr Hong.

China has untapped potential for certain drugs. Rituximab is one such example. The estimated penetration in targeted patients for Rituximab, used in the treatment for a specific kind of cancer, is 15 per cent in China and over 60 per cent in the U.S. Another drug, Trastuzumab, clocks in at around 80 per cent targeted penetration in the U.S. but 28 per cent in China[6].

Foreign clinical trials are now accepted for drugs in national tenders in China. *"These national tenders are winner takes all national tenders, and the volume is tremendous,"* adds Dr Hong. *"I would argue that China is still a long game but worth pursuing."*

4. Evaluate opportunities with Asian counterparts and countries

Radhika and Dr Hong advise that Indian companies evaluate specific geographies in the region to expand to. The penetration rates of targeted therapies are 3 to 5 per cent in Southeast Asia[7]: these low rates imply a significant opportunity. Two countries, Indonesia and Vietnam, show promise.

Indonesia, which has roughly half of Southeast Asia's population, has overhauled its healthcare system. Treatment of non-communicable diseases is driving the growth of prescription drugs at a CAGR of 11.2 per cent[8].

In a switch in policy, the Indonesian government now allows foreign specialists to work in the country. This change will increase the number of specialist doctors, which could turn into a viable market opportunity in time for certain drugs.

Likewise, referencing the example of Vietnam, Dr Hong explains*, "Due to the huge middle class in Vietnam, the country has one of Asia's highest growth rates. The government is unfolding specific policies which can be beneficial for foreign investment into the pharma sector*."

Vietnam imports 55 per cent of medicines annually[9]-a market opportunity for Indian companies. Plus, the government is aiming for 80 per cent local production. A new law incentivises investment in a healthcare enterprise by reducing land lease fees and credit support.

A manufacturing plant in Vietnam gives Indian companies access to the larger Indochine region. The government is passing laws to incentivise some of these healthcare investments, with income tax, to encourage more local manufacturing. The country's biggest telco has recently, because of COVID-19, launched a telemedicine programme. Dr Hong explains that 70 per cent of the population, which lives in rural Vietnam, will benefit from this initiative. Still, moves such as these also are opportunities for Indian companies to get involved in the sector.

Such policy changes send out ripple effects in the economy, which Indian pharma companies can capitalise on.

Realigning to the new normal

Where does the industry go next? The need of the hour is to realign strategy and drug pipeline priorities as needed. Over 70 per cent of the Indian pharma sector's raw materials are supplied by China[10] the sector must diversify its supply chain to reduce overdependence on one country. Although, Dr Hong warns that this is easier said than done.

Companies must also pay close attention to alternate geographies to expand into. As mentioned earlier, Indonesia and Vietnam are potential markets due to their large populations. The investments could be in the form of joint ventures with local companies.

Payors and governments are sharply focused on managing costs while improving patient outcomes, and the pressure is on the pharma sector to match these expectations. The industry will benefit hugely from a move to digitalisation. Disruptive technologies such as the cloud, advanced analytics, and the Internet of Things can drive huge value in the pharma sector.

Continuous monitoring and automation in packaging with IoT have the potential to improve processes. Quality assurance in manufacturing also improves if it's easier to look at the wealth of process data and rectify problems.

But it's not always easy to determine where the focus should be at the beginning of the digitalisation journey. Dr Hong advises that the sector make clear strategic choices for using digital technologies across sales and marketing and patient support.

About DBS

DBS Bank has been present in India for over 26 years, having opened its first office in Mumbai in 1994. DBS Bank India Limited is the first among the large foreign banks in India to start operating as a wholly-owned, locally incorporated subsidiary of a leading global bank. DBS provides an entire range of banking services for large, medium and small enterprises and individual consumers in India. In 2016, DBS launched India's first mobile-only bank – digibank, which now has ~1 million savings accounts. In November 2020, Lakshmi Vilas Bank was amalgamated with DBS Bank India Limited. The bank now has a network of nearly 600 branches across 19 states in India.

DBS provides a full range of services in consumer, SME and corporate banking. As a bank born and bred in Asia, DBS understands the intricacies of doing business in the region's most dynamic markets. DBS is committed to building lasting relationships with customers and positively impacting communities through supporting social enterprises as it banks the Asian way. In Asia, DBS partners with clients in 18 countries and 51 cities.

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