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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022, Hotel Sahara Star, Mumbai

(Details on Page: 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 40** **22 to 30 October 2021**

IDMA ACTIVITIES:

GOVERNMENT NOTIFICATION:

GOVERNMENT PRESS RELEASE:

DGFT MATTERS:

NATIONAL NEWS:

INTERVIEW:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
1961 – 2021 (60 Glorious Years)

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Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022
Hotel Sahara Star, Mumbai

We are happy to inform you that our Association will be completing 60 glorious years in 2022. The 60th Year Celebrations will be organized on 7th & 8th January 2022 in Mumbai. We intend to commemorate this historic occasion of the completion of 60 years of our Association, with a two day long celebration consisting of Panel Discussions, Technical Sessions and Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry. The main objectives of the celebrations are:

- Showcasing Pharmaceutical and Allied Industries across the Globe
- Disseminating knowledge on various subjects
- Highlighting the achievements of IDMA

This year at the 60th Year Celebrations, we have invited Eminent National and International personalities to address our members over two days. We will also be recognizing Top Achievers in the Indian Pharmaceutical Industry, who have made India Proud and respected world over as providers of affordable quality medicines.

As part of the Celebrations, the winners of the:

1. IDMA Margi Memorial Best Patent Awards
2. IDMA ACG-SCITECH Research Paper Awards
3. IDMA Corporate Citizen Awards

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been met in the last 60 Years and specially the last two years which have been different, difficult and trying times. You would be pleased to note that during Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government and Regulators. Nevertheless, it is due to your untiring efforts and commitment to the wellbeing and prosperity of our Association that we will be completing 60 years of glorious service to our Pharma Industry and to our great Nation.

We are sure you will be an integral part of the Grand Celebrations.

IDMA 60th ANNUAL PUBLICATION 2022

The IDMA 60th Annual Publication 2022, an up-to-date and most informative compendium will be released at the Annual Celebrations. This Annual Publication will present statistics, vital data and information on the Pharmaceutical industry. This Publication has also come to be recognized as the indispensable reference book of the Indian Pharmaceutical Industry.

AN OFFER NOT TO BE MISSED

Advertisers can, through this single medium, reach their target audience such as Bulk Drug Manufacturers, Formulators, Researchers, Analysts, Traders, Scientists, Students, Consultants, various Government Officials etc and leave an enduring impression on everyone connected with the Industry.

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We invite sponsors for our 60th Year Celebrations as below:

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Sponsors will be provided special benefits & privileges: For details please contact IDMA Secretariat.

REGISTRATION FEES:

To participate in the 60th Year Celebrations, the registration fee would be as under:

Reception Committee Member	Rs.7,500/- plus GST @ 18%
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Mr. Melvin	**Ms. Geeta**	**Ms. Batul**
9821868758	9820161419	9920045226
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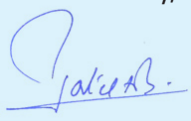
Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

Looking forward to your usual fine cooperation in making this historic event a 'सुपर से भी ऊपर' Success.

Thanking you,

Yours faithfully,



Daara B Patel
Secretary–General

IDMA Congragulates Mr S V Veeramani elected unopposed as Vice-chairman of Pharmexcil

S V Veeramani elected unopposed as vice-chairman of Pharmexcil

Former president of the Indian Drug Manufacturers' Association (IDMA) and the CMD of Fourrts (India) Laboratories, S V Veeramani has been elected unopposed as the vice-chairman of the Pharmaceuticals Export Promotion Council of India (Pharmexcil) after being unanimously supported by all members of the director board.

"It is an honour to be elected unopposed as the vice-chairman of the Pharmexcil and I would like to thank all the members of the administrative board for their support. With everybody's support, I hope Pharmexcil can make big strides in the services for pharma exporters in the years to come," said Veeramani.

Responding to the new assignment given to the veteran pharma industry leader in Chennai, the principal health secretary to the Government of Tamil Nadu, Dr J Radhakrishnan, has informed Pharmabiz that he feels happy and proud to learn about his new position as vice-chairman of the Pharmexcil. He hopes that Veeramani will bring his rich experience to his new endeavor as vice-chairman for the benefit of the industry.

Mahesh H Doshi, president of the Indian drug manufacturers association has opined that Veeramani will further prove to be a great asset for the industry as well as to the Pharmexcil.

Daara B Patel, secretary general of the IDMA, recollected Veeramani's tenure as president of the IDMA and said he is filled with knowledge, administrative skills and leadership qualities. He expects that Veeramani's management skills and knowledge about the international pharma market will enable him to lead Pharmexcil to greater heights.

S K Janimiya, chairman of the Telangana state board of the IDMA said Veeramani is the right person to hold the senior post in the pharmaceutical export promotion council. "He has been working for the welfare of the pharma industry in various positions in different organizations. He knows the requirements of the industry, understands the problems of the entrepreneurs and is always available with everybody for the growth of the industry. The present leadership will give him more confidence to perform much better," he added.

Utpal Moitra, past chairman of the West Bengal state board of the IDMA and director of Emcee Pharmaceuticals Pvt Ltd in Kolkata has commented that Veeramani's new position will help the Indian pharmaceutical industry greatly and the pharmaceutical exporters from West Bengal are proud of him.

Dr Ramanathan, president of the Kerala based Ayurveda Medicine Manufacturers Organisation of India (AMMOI) is expecting more support from Pharmexcil when Veeramani becomes the vice-chairman. He said Pharmexcil can help increase exports of Ayush products from Kerala.

Welcoming the new appointment of Veeramani, the chairman of the Tamil Nadu branch of the IDMA, J Jayaseelan said his new position will be useful for the growth of the MSME companies who are striving for exports. He said Veeramani is always a leader who guides and promotes the small and medium enterprises.

Source: Peethaambaran Kunnathoor, Pharmabiz, 30.10.2021

IDMA Representation on Unprecedented Price Increase in Input Cost -reg.

IDMA has submitted following representation on 20th October 2021 to Hon'ble Shri Mansukh Mandaviya Ji, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India, New Delhi and Dr. Vinod K Paul, Member, NITI AAYOG, Sansad Marg, New Delhi with the copies to Ms. S Aparna, IAS Secretary, DoP and Shri Kamlesh Kumar Pant, IAS Chairperson, NPPA, DoP on the above subject:

Respected & Honourable Minister Shri Mandaviya Ji, / Respected Sir,

India is known as the pharmacy of the world, due to its ability to manufacture quality medicines at affordable prices. When the COVID 19 pandemic severely affected operations of every industry, the Indian pharmaceutical industry braved the colossal challenges and ensured the manufacturing and availability of all medicines at affordable prices. However, this came at a great cost as the prices of raw materials, packing materials and transportation costs, spiraled out of control. The surge in prices of key input materials has continued and had a cascading effect on the viability of the pharmaceutical business in the past one year.

IDMA which represents over 1000 Indian pharmaceutical manufacturers had brought this serious issue to the notice of the NPPA and to the Department of Pharmaceuticals vide representation dated 05/04/21 (**Annexure I**). This was followed up by a detailed power point presentation to the Chairperson NPPA and Member Secretary NPPA on 12/05/2021 (**Annexure II**).

We would again like to emphasize the serious situation which has been exacerbated due to the tremendous escalation in input costs within the last one month which is elucidated in **Table I**. The prices of Active Pharmaceutical Ingredient (API) increased from 11% to 51% and the prices of excipients spiked from 11% to 61%, all within a period of one month.

Table I: Huge Surge in Input Prices in last one month

Description	Price Sep 21 Rs. per Kg	Price Oct 21 Rs. per Kg	One Month Price Increase%	Category
Metformin HCL	248	375	51	API
Paracetamol	599	900	50	API
Guaiphenesin	575	800	39	API
Guaiphenesin	535	700	31	API
Spironolactone (Apr21)	16750	21200	27	API
Phenylephrine HCL	6500	7800	20	API
Ramipril (Feb21)	42000	46750	11	API
Glycerine	171	275	61	Excipients
Citric Acid	125	200	60	Excipients
Sodium Citrate (May21)	94	145	54	Excipients
Aerosil	500	750	50	Excipients
Methylene Chloride	105	154	47	Excipients
Dibasic Calcium Phosphate	121	175	45	Excipients
Propylene Glycol	312	450	44	Excipients
Ceto Stearyl Alcohol (Jul21)	151	210	39	Excipients
Sucralose	3250	4150	28	Excipients
Methylparaben	395	460	16	Excipients
Magnesium Stearate	145	165	14	Excipients
Colloidal Silicon Dioxide	590	660	12	Excipients
Sodium Benzoate	140	155	11	Excipients

The situation becomes more alarming when we compare the spurt in input prices for the past one year period between October 2020 and October 2021, as illustrated in **Table II**. Price of a key API like Paracetamol which is a price controlled formulation has increased by 143% in the last one year whereas the ceiling price was revised by only 0.54% as per the WPI in April 2021. In the last 8 years since Paracetamol is under price control, the API price has increased by more than 300%, but the corresponding ceiling price has been revised by only 3%. Paracetamol is an essential anti-pyretic and analgesic and

is the gold standard for treating fever, but the surge in API prices have made production of Paracetamol unviable. We have been provided indications by the API manufacturers that the price of the API of Paracetamol per kg will soon cross Rs 1000.

Table II: Huge Surge in Input Prices in last one year

Description	Sep 20 Price	Sep 21 Price	One Year Price Increase %	Category
Paracetamol	370	900	143	API
Alpha Lipoic Acid	9000	14350	59	API
Sulfadoxine	4033	6327	57	API
Metformin	230	320	39	API
Myo-Inositol	670	925	38	API
Acetyl Cysteine	2500	3200	28	API
Ambroxol	3600	4600	28	API
Montelukast	41500	50000	20	API
Caffeine	980	1175	20	API
Sulfamethoxazole	750	875	17	API
Thiamine	4200	4900	17	API
Doxycycline	7375	8500	15	API
Nicotinamide	570	640	12	API
Trimethoprim	1675	1875	12	API
Glycerin	76	275	262	Excipients
Tri Methyl Chloro Silane (US$)	4	11	214	Excipients
PHOSPHOROUS PENTACHLORIDE	85	205	141	Excipients
METHYLENE CHLORIDE	53	125	135	Excipients
Citric Acid	110	225	105	Excipients
Diclhloromethane	65	125	92	Excipients
Propylene Glycol	132	242	83	Excipients
Povidone (K30)	650	1100	69	Excipients
Colloidal Silicon Dioxide (Aerosil)	435	720	66	Excipients
TRIPHENYL PHOSPHITE	138	218	58	Excipients
CAUSTIC SODA LYE	30	45	50	Excipients
Beta Naphthol	170	250	47	Excipients
METHANOL	33	45	37	Excipients
ACETIC ACID	89	120	35	Excipients
TRIMETHYL PHOSPHITE	235	315	34	Excipients
CHLOROFORM	30	40	33	Excipients
DIMETHYL FORMAMIDE	174	225	29	Excipients
SODIUM HYDROSULPHITE	86	110	29	Excipients
ISOBUTANOL	128	160	25	Excipients
ACETOXY ETHYL BROMIDE (AEB)	440	535	22	Excipients
Penicillin G (US$)	6	17	175	Intermediate
L-Lysine HCL (US$)	2	3	53	Intermediate
Dibenzo Thiazepine	2350	3500	49	Intermediate
4 CBC	300	445	48	Intermediate
DAPGCH	745	995	34	Intermediate
4 Methyl Acetophenone	450	600	33	Intermediate
L-Proline Benzyl Ester (Lis-3)	1350	1775	31	Intermediate
BCFI	2900	3500	21	Intermediate
GCLE	3400	3875	14	Intermediate
DEMMP	2550	2850	12	Intermediate
Sertralone	850	940	11	Intermediate
PVC Film	133	215	62	Packing Material
Poly Foil	302	432	43	Packing Material
PVDC Film	210	287	37	Packing Material
Blister Foil	410	545	33	Packing Material
Alu Alu Foil	335	425	27	Packing Material
PET Bottles	1615	1890	17	Packing Material
Cartons			12	Packing Material
Corrugated Boxes			11	Packing Material
Container costs			200	Transportation
Import Freight costs			100	Transportation
Local Freight costs			14	Transportation

To summarize Table II, in the past one year, there has been an exceptional rise is input costs in each and every cost head, that has significantly affected the Indian pharmaceutical industry.

1. The prices of key **APIs have** increased between 15% to 130% with the price of Paracetamol increasing by 130%.

2. The prices of **excipients** have risen between 18% to 262%. Glycerin and Propylene Glycol are **solvents** used in every liquid preparation including syrups, oral drops and sterile preparations. The prices of Glycerin and Propylene Glycol have sky-rocketed by 263% and 83% respectively, while the price of a key **chemical** like Trimethyl Chloro Silane has clocked a 214% price increase, and the price of Methylene chloride has increased by 135%. The price of a **pH regulator** like Citric Acid has doubled.
3. The prices of **intermediates** have registered an increase between 11% to 175% with Penicillin G registering a 175% rise in prices.
4. The prices of plastic based material like **PVC, PVDC** and **Poly Foil** have risen between 33 to 62%.
5. The price of **Aluminium foil** is up by 27%.
6. The prices of paper based packing material like **cartons** and **corrugated boxes** have increased by 11 to 12%.
7. The **outward freight** costs have risen by 14%.
8. The cost of **inward freight of imports** has increased by 50%.

Based on the above facts we request **FOUR** recommendations to be implemented urgently within the framework of the existing price control mechanism to help us tide over these extremely exigent woes of the Indian pharmaceutical industry.

Recommendations

1) The increase in input prices has affected all the cost heads like key starting materials, raw materials, packing materials and transportation costs. Hence we request a one time immediate relief to overcome the sudden spurt in prices of inputs by invoking Para 19 of DPCO 2013 due to the prevailing extraordinary circumstances. Please permit the Indian pharmaceutical industry to increase the prices of all non-scheduled formulations by an additional 10% over the 10% allowed for non-scheduled formulations. You may revert to the specified 10% increase in the prices of non-scheduled formulations once the surge abates.
2) Since the prevailing WPI for the period April to September 2021 is over 10%, it is evident that there has been a tremendous increase in input costs, but the increase would be effective from April 2022. Hence we request you to allow the prices of all scheduled formulations to be increased by 10% as per the prevailing WPI, with immediate effect.
3) Please allow scheduled formulations whose retail prices are below the ceiling price, to be raised up to the new proposed ceiling price which includes the 10% WPI increase. Many manufacturers of scheduled formulations are suffering on this count and para 13(2) of DPCO 2013 needs to be relaxed under the current circumstances. We have highlighted in the earlier paragraphs, the case of the dichotomy in Paracetamol where the API price grew by 300% while the ceiling price was allowed an increase of only 3%.
4) Under Para 18(i) of DPCO 2013, re-fixation of ceiling prices for common formulations between NLEM 2015 & NLEM 2021 would be soon undertaken. As a result of Para 18(i) the current ceiling price is much lower than the first ceiling price fixed under DPCO 2013 for many scheduled formulations. We fear, if the re-fixation of ceiling prices exercise is undertaken this year, it may lead to a further reduction in ceiling prices to the tune of 15% to 20%. In light of the current situation, we request that Para 18(i) of DPCO 2013 should be deleted or amended.

We fear that the severe pressure on operating margins could lead to stock outs and shortages even for essential formulations in trade, hospitals and for government institutional supplies. As the input price situation is worsening day by day, we request your urgent intervention and immediate acceptance of our recommendations, to provide partial relief to the Indian pharmaceutical industry. If immediate respite is not provided the Indian pharmaceutical industry would find it very difficult to sustain its manufacturing superiority and that would seriously imperil its position as the pharmacy of the world.

Thanking you.
Yours Sincerely,

For Indian Drug Manufacturers' Association

Mahesh H Doshi
National President

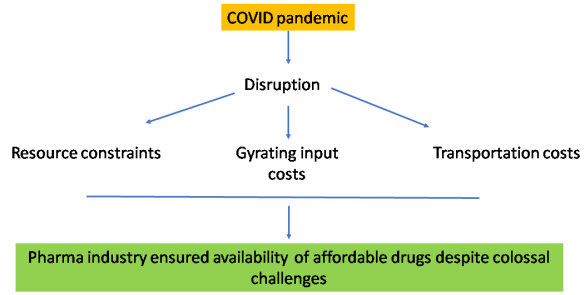
Note: Annexure I published in IDMA Bulletin Vol No. 52, Issue No. 13, 01 to 07 April 2021.

(Annexure II reproduced below)

Indian Pharmaceutical Industry-
Unprecedented increase in input costs.

IDMA- Indian Drug Manufacturers Association 12th May 2021.

Background



Input Cost Rise Last 1 Year

Costs	Item	% Input cost change over last year
Raw material	Paracetamol	100%
	Propylene Glycol	300%
Packing material	PET bottles	40%
	PVC/PVDC	40%
	Paper board	20%
	Corrugated boxes	20%
Freight	Transportation costs	20%

Input Cost Rise last 1 Month

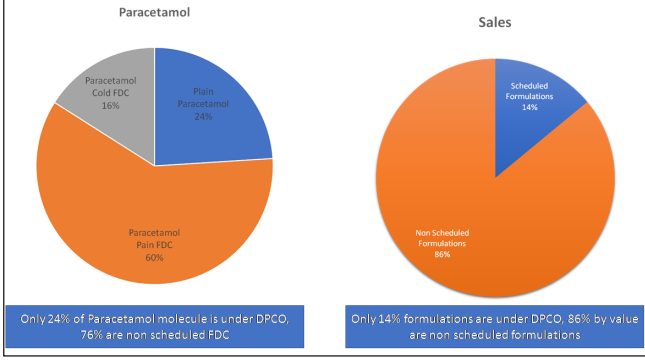
Item	Mar21 Price/Kg Rs	Apr21 Price/Kg Rs	% One Month Increase
Raw Material			
Ivermectin	18000	54000	200%
Methyl Prednisolone	85000	190000	124%
Meropenem	81000	140000	73%
Doxycycline	7500	12000	60%
Paracetamol	550	800	45%
Azithromycin	10500	14000	33%
Dexamethasone Sodium	40000	50000	25%
Ornidazole	985	1300	32%
Packing Material			
PVC	102	175	72%
Aluminium Foil	45	60	33%
Aluminium Tubes, PP Caps, Flip Off Seals			15-20%
Paper / Board			15%

Illustration-Paracetamol Study 2013-21

	Paracetamol Ceiling Price % change between 2013 and 2021	Paracetamol API Price / Kg % change between 2013 and 2021
Paracetamol syrup 125mg / 5ml	+3%	333%
Paracetamol Tablet 500 mg / tablet	-3%	

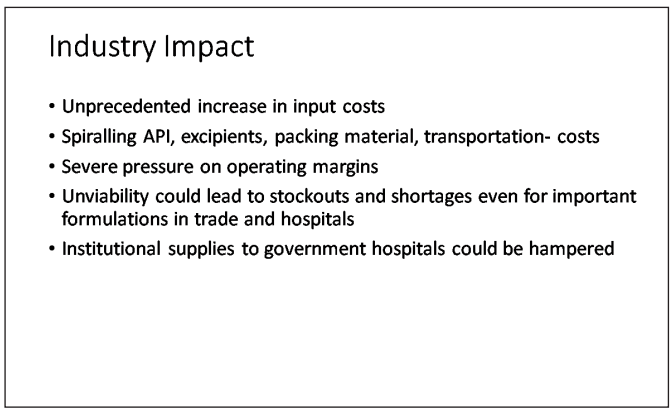
Between 2013-21, Paracetamol ceiling price changed by only -3% to +3% while API prices rose by 333%

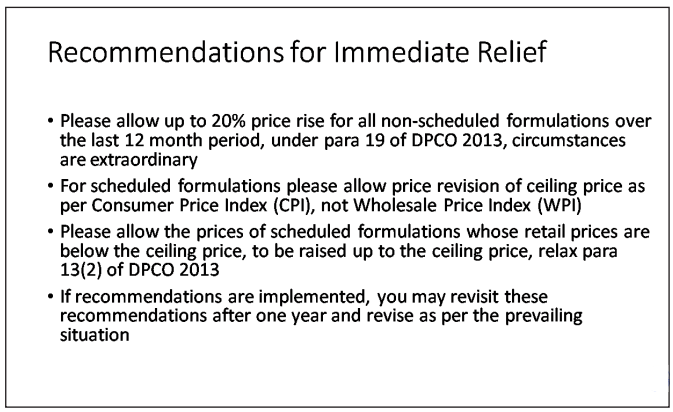
Why Non scheduled formulations



Only 24% of Paracetamol molecule is under DPCO, 76% are non scheduled FDC

Only 14% formulations are under DPCO, 86% by value are non scheduled formulations





Request to permit stockpiling of Medicine/s important for Covid-19 and other disease conditions - IDMA representation to Minister of Health & Family Welfare and Chemicals & Fertilizers, Hon'ble Dr. Mansukh Mandaviya Ji - reg.

IDMA has submitted following representation on 22nd October 2021 to Hon'ble Dr. Mansukh Mandaviya Ji, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India, New Delhi with a copy to Dr. V. G. Somani, Drugs Controller General (India), Central Drugs Standard Control Organization (HQ), FDA Bhawan, New Delhi on the above subject:

Respected & Honourable Minister Dr. Mandaviya Ji,

At the very outset, we would like to extend our compliments to you on India marking a milestone of administering 100 crore vaccines in record time. This is attributed to the extraordinary efforts of the Government, Healthcare workers and Regulators who have all risen beyond the call of duty to manage the pandemic. One of the proactive steps of the Government that helped India achieve this milestone was the decision to stockpile vaccines taken vide SO-1511(E) dated 18th May, 2020 that allowed vaccines to be manufactured and stored in stockpile awaiting regulatory approvals.

Now that the Covid-19 situation with your very timely and notable efforts is under control, we would like to suggest similar steps that would allow India to be in a state of perpetual readiness as far as Nation's drug security is concerned. One such move that we would highly recommend is that, like in the case of vaccines last year, stockpiling should now be immediately considered for other unapproved (New) Covid-19 drugs. We would encourage you to go one step further and consider stockpiling of New drugs in general that are undergoing approval process in general but are yet to be approved as such in the country.

Sir, such a provision would allow the Industry to meet exigencies arising out of any pandemic or other health emergencies. Stockpiling would ensure that the right treatment would be available and could be utilized on short notice after the receipt of the drug approval . Needless to say, drugs approved for stockpiling, would continue to undergo the normal regulatory process and companies/ agencies would be allowed to offer such products for sale only after the same is approved by the authorized Drug regulatory agencies in the country. This provision to pharmaceutical companies to stockpile drugs at their own cost/ risk in the interest of the patients would help save lives.

We hope you will consider our practical request in the interest of the patient.

Thanking you & with best regards,

For Indian Drug Manufacturers' Association,

Mahesh H Doshi
National President

IDMA webinar with NLP Marine Requirement Gathering-reg.

Dear Members,

We had an interesting webinar with the National Logistics Portal (NLP) Team on 19th October 2021 wherein I was joined by Mr. Prakash Rijhwani from Blue Cross Laboratories Ltd., Nashik and Mr. Melvin Rodrigues. The NLP Team is in process of gathering information in regards to NLP Marine Platform.

The NLP Team has attached a brief presentation on the same and has also requested a questionnaire to be filled and forwarded to them .

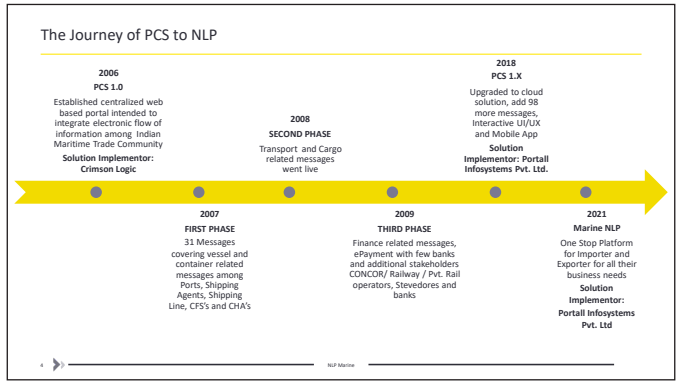
Request you all to kindly respond to the attached questionnaire and forward the same to us at the earliest.

Looking forward to your usual prompt response.

Thanks & regards,

Daara B Patel
Secretary – General

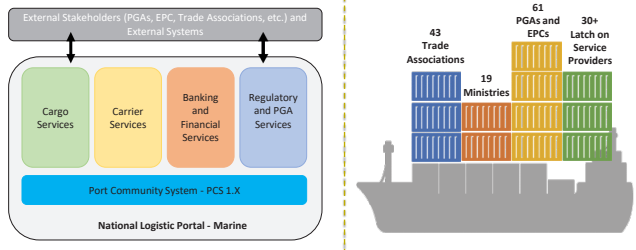
PRESENTATION



Agreement Signing – 01st July 2021

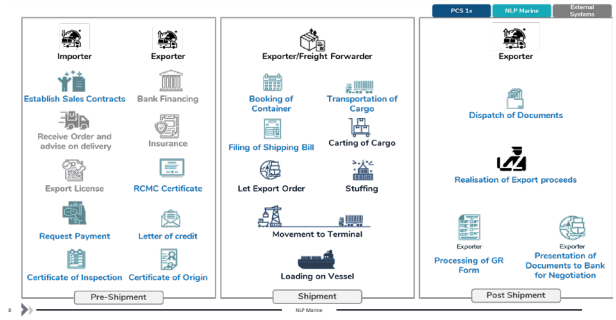
Overview of National Logistic Portal (NLP)

Ministry of Commerce (MoC), Ministry of Ports Shipping and Waterways (MoPS) and Indian Ports Association (IPA) have envisaged a **National Logistics Portal – Marine**, which will integrate further in future, with Air Logistic Portal, Land Logistic Portals and e-marketplace.

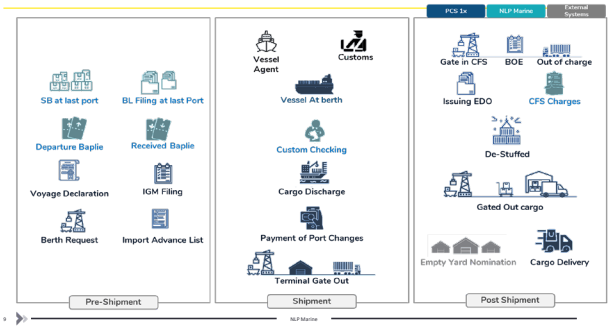


Functional Coverage

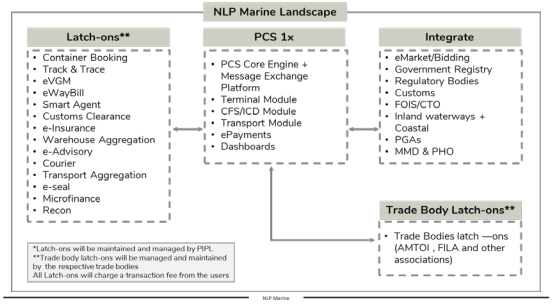
Export Process



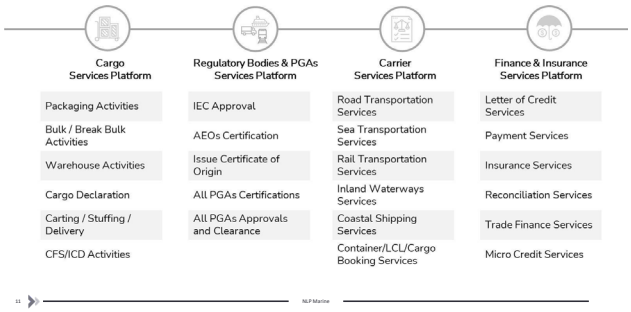
Import Process



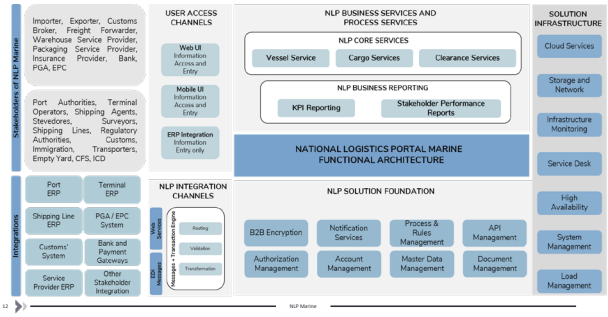
NLP Marine Landscape



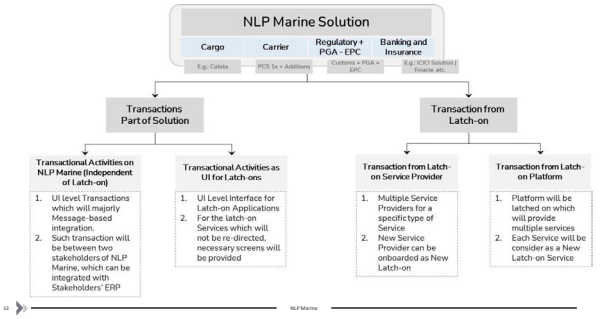
Platform of Platforms



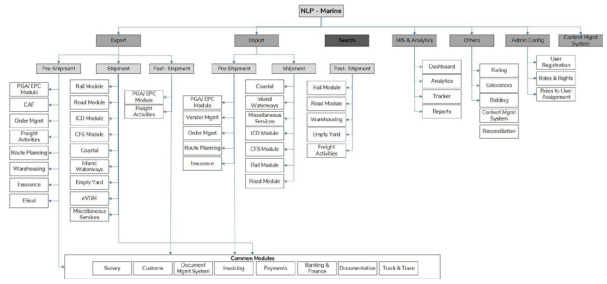
Functional Architecture



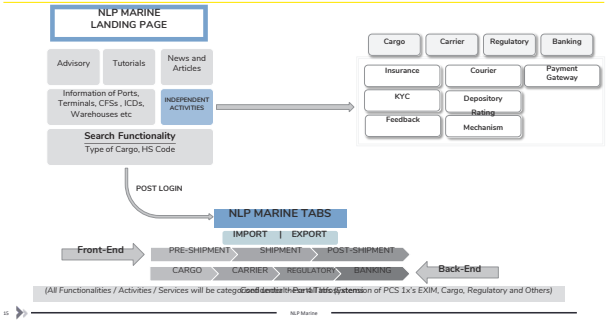
Open Architecture with Latch-on Management Strategy



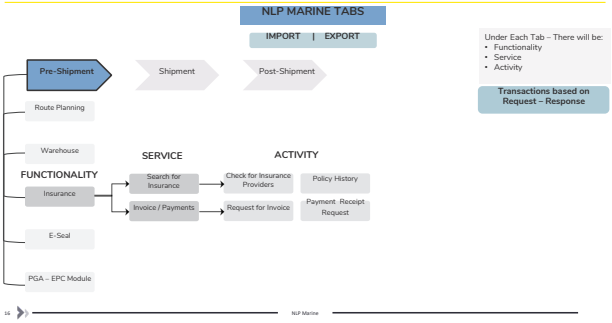
Site Map



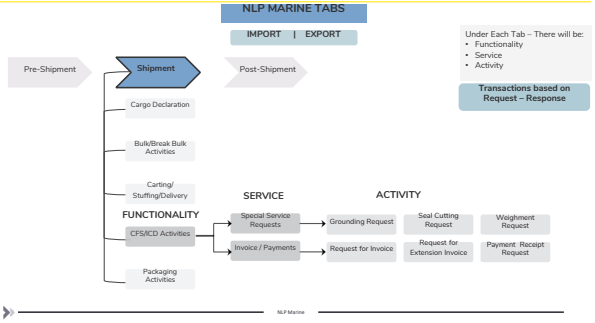
NLP Marine Site Map



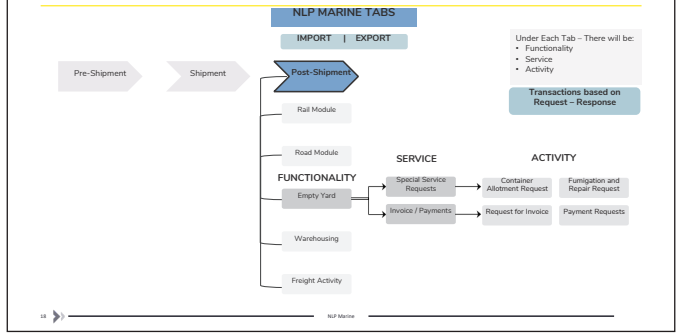
NLP Marine Site Map



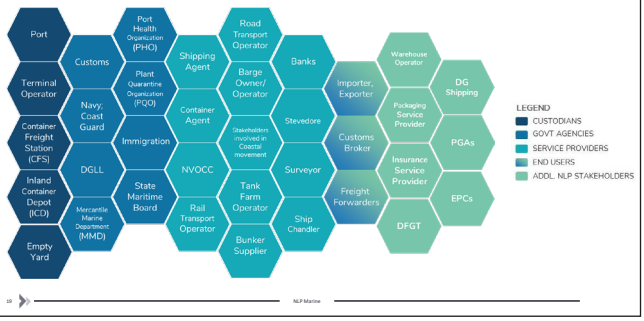
NLP Marine Site Map



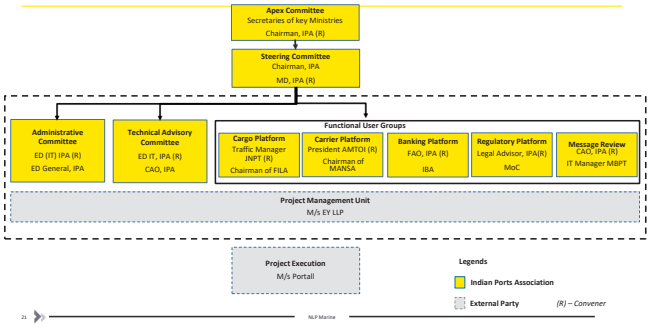
NLP Marine Site Map



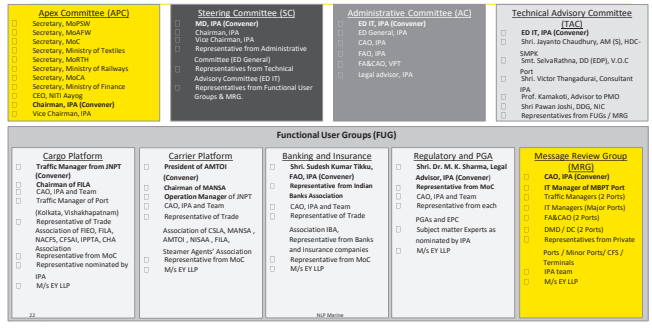
Stakeholder Coverage



NLP Project Governance Structure



Composition of Committees



Roles and Responsibilities (1/2)

- Apex Committee (APC)

  To **monitor the overall project implementation** and **suggest / instruct** suitable course corrections, when required and suggest improvements to the project.

- Steering Committee (SC)

  To **direct and guide project team** for successful implementation of the Project. **Coordinate with external Ministries and stakeholders** to achieve Project objectives.

- Administrative Committee (AC)

  To submit the report for final approval by Steering Committee after **vetting the financial and legal matters** relating to the contract agreement.

- Technical Advisory Committee (TAC)

  TAC should **review all the technological aspects** of the project. TAC shall also review the recommendations/ suggestions/ comments etc. of PMU and **give its feedback to AC / SC.**

Roles and Responsibilities (2/2)

- Functional User Group (FUG)

  To provide **expert advice related to the functionalities of NLP marine** and their inputs and **interactions during the study, testing, and implementation** phases are critical for the success of the Project. They would also **assist in resolving any bottlenecks** related to the NLP Marine community during implementation.

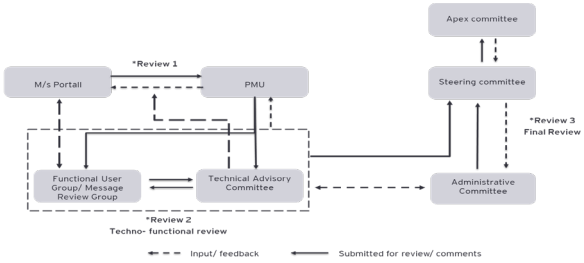
- Message Review Group (MRG)

  To **provide recommendation/ suggestions on Normalizing, simplifying and integrating** PCS 1x messages with NLP Marine. The messages should follow **international standards to enable cross border exchange**. The Message review group should also **create a Dictionary of Data (DOD)** at a national level.

- Project Management Unit (PMU)

  To **assist IPA in project management**, **monitoring and evaluation** during the entire project period to ensure **adherence to the project timelines, specifications, and requirements**. PMU shall ensure that **deliverables are reviewed** for quality management, risk identification etc.

Review Process



*input/ feedback is sent back to M/s Portall after each review, who will re-submit the deliverable after incorporating the feedback

Critical Success Factors

Critical Success Factors

- **Onboarding of all key stakeholders** and ensure their active participation till completion of the project
- **Requirement gathering, and documentation** will be a critical requirement for the project.
- **Functional User Groups and the Message Review Group** identified should work in close coordination with respective technical team of M/s Portall
- **Adherence to finalized meeting schedules** is critical for completion of Business Requirement Study
- Study of the processes of the stakeholders of Indian Maritime community and recommend **re-engineering the processes (TO BE analysis)** along with business process discovery on the implemented platform.
- **Normalize and simplify** the messages of PCS ver 1.x and integrate them with NLP Marine ver 1.0
- All documents of the study should be available in a **common repository,** to be created by M/s Portall
- To work with platforms in the logistics space like **ULIP** in a collaborative manner and **avoid duplication** of efforts.

Project Timelines

T = 15 July'21

Below are the Functionalities planned to deliver in Iterations:

Iteration 1 (T + 80 days)
- Landing Page
- Service Catalogue
- Registration Module
- Login Module
- Business Transaction Support (Grievances) Module
- Common Application Form (CAF) module
- e-VGM (as latch-on with service providers)
- Booking (as latch-on with service providers)
- Transport Module

Iteration 2 (T + 6 Months)
- E-SEAL Module
- Finance Platform
- Insurance Platform
- Documents Exchange Module

Iteration 3 (T + 7.5 Months)
- Empty Yard Module
- Warehouse Module
- Freight Forwarder Module (Full Service)
- Route Planning Module
- Admin Config Module (Profile Extension)
- Content Management
- Vendor Management

Iteration 4 (T + 9 Months)
- Packaging service provider
- Dashboard, Analytics and MIS
- Generated Certificates Module
- Integrated PGA EPC Platform Module (Calista OGA platform video)

Iteration 5 (T + 11 Months)
- Port Module (PCS 1x - Trade)
- E-Berthing Module
- Terminal Module
- Track and Trace Module
- Order Management
- Ratings Module
- Listing Module
- Integrated Regulatory Platform Module (Calista regulatory and advisory platform video)

Iteration 6 (T + 12 Months)
- Coastal Module
- Rail Module (CTO)
- Shipping Line Module
- Inland Waterways Module
- CFS Module
- ICD Module
- Mobile App

National Logistics Portal - Marine Ver 1.0 Questionnaire for Stakeholders (Trade Bodies and Associations)				
Name of Association				
SPOC Name 1				
Mobile Number				
Email Address				
Office Address				
SPOC Name 2				
Mobile Number				
Email Address				
Office Address				
Regulatory Compliance				
	Stakeholder 1	Stakeholder 2	Stakeholder 3	Stakeholder 4
Stakeholder being dealt with (Kindly provide the type of stakeholders that are interacting . E.g. Surveyors, Importers, Exporter, Empty Yards)				
Transactions executed (Kindly provide the type of transactions that are being carried out . E.g. Document Exchange, Regulatory information)				
Documents exchanged (Kindly provide name of documents and attach sample documents e.g. Forwarding Note, Form 13)				
Regulatory Compliance				
Types of Cargo handled				
Compliances involved - (Kindly provide the mandatory compliance that needs to be followed by the members of association . E.g. In Maharashtra state Stamp Duty payment to be verified by Custodian prior allowing the delivery of import cargo)				
Certification required (Kindly provide the certifications that are required for carrying out the cargo operation. E.g. Food items to be cleared from the FSSAI)				
Approval required				
Locations handling maximum traffic (Kindly indicate the type cargo and density of handling of such cargoes. E.g. Cotton bales are being prominently handled in State of Gujarat)				
Operational Details				
When the user starts the first interaction and how?				
Which all information is received / sent to applicant for every service?				

Which are the documents required to be submitted by the users availing various services such as e-BG, Trade Finance, etc.	
Are the documents being processed currently in physical form or digital?	
Timeframes of various services (1st application to service rendered)	
Challenges being faced in executing the operations digitally.	
Regulatory processes, certifications, compliances dealt with.	
List of PGAs, EPCs the involved and the details of these operations.	
Technical Queries	
Online Platforms available and their readiness for API Integration	
Website / ERP details	
Technology used and vendors for the same.	
Preferred integration methods	
Frequency of data exchange	
Linkage with any other agency / authority	
Any interfaces / integrations to external systems. (In use as well as required in future)	
Data field constraints	
Compatibility	
Challenges in adoption	
Organisation Details	
Who are the decision makers for any new process implementation and stages of approval?	
Details of key officials, decision makers, email IDs and contact numbers.	
Details of Nodal Officer for future interaction regarding NLP Marine (Name, Designation, Address, Email Id, Contact Number etc)	
Others	
Please share Standard Operating Procedures and Process Flows	
Various documents required at the time of the request and the documents as generated by the agency.	
Any validation of such certificates / permissions / approvals	
Any payments / financial requirement	
Any dependence of another govt agencies	
Report requirements from the proposed system.	
Any Legal approvals	

Sample templates for documents which are to be digitised.	
Key pain points and suggestive areas for improvement (using technology)	

PGA / EPC
(Kindly provide the contact details / locations of the concerned PGA/EPC with whom are interacting)

Name	Relevant (Y/N)	Transaction details	Documents submitted	Documents received
Pharmaceuticals Export Promotion Council				
Central Drugs Standard Control Organization				
Food Safety and Standards Authority of India				
Wildlife Crime Control Bureau				
Directorate of Plant Protection, Quarantine & Storage				
Animal Quarantine Certification Service				
Committee for the Purpose of Control And Supervision of Experiments on Animals				
Hazardous Substances Management Division				
Central Pollution Control Board				
Department of Animal Husbandry, Dairying and Fisheries				
Central Farm Machinery Training and Testing Institute, Budni, Madhya Pradesh				
Telecommunication Engineering Centre (TEC), Department of Telecommunications				
Central Bureau of Narcotics				
Ministry of New and Renewable Energy				
Textile Committee				
Bureau of Indian Standards				
Legal Metrology Unit				
Directorate General of Civil Aviation				
Archaeological Survey of India				
Chief Controller of Explosives				
Director General of Foreign Trade				
Ministry of Home Affairs				
Vehicle Research and Development Establishment, Ahmednagar				
Ministry of Electronics and Information Technology				
The Export Inspection Council (EIC)				
The Directorate General of Hydrocarbon				
Bureau of Energy Efficiency				
National Authority, Chemical Weapons Convention				
Central Insecticide Board				
The Directorate General of Hydrocarbon				
Plant Quarantine Information System				

Agriculture & Processed Food Products Export Development Authority (APEDA)				
Chemical and Allied Export Promotion Council (CAPEXIL)				
Carpet Exports Promotion council				
Gem & Jewellery Export Promotion Council				
Indian Oilseeds & Produce Export Promotion Council (IOPEPC)				
Apparel Exports Promotion Council				
Basic Chemicals, Cosmetics and Dyes EPC (CHEMEXCIL)				
Coffee Board				
Cotton Textiles Export Promotion Council				
EEPC INDIA (Formerly Engineering Export Promotion Council)				
Electronics and Computer Software EPC				
Export Promotion Council for EOUs & SEZs				
Federation of Indian Export Organisations				
EPC for Handicrafts				
Handloom Export Promotion Council				
Leather EPC				
Plastics Export Promotion Council - PLEXCONCIL				
Power loom Development & Export Promotion Council				
Projects EPC				
Rubber Board				
Services EPC				
Shellac & Forest Products Export Promotion Council				
Sports Goods EPC				
Synthetic & Rayon Textiles Export Promotion Council				
Tea Board				
Telecom & Communication EPC				
Tobacco Board				
Woolen –WWEPC				
Wool Industry Export Promotion Council				
Cashew Export Promotion Council of India				
Coconut Development Board				
Coir Board				
Indian Silk Export Promotion Council				
Jute Products Development and Export Promotion Council				
Marine Products Export Development Authority				
Spices Board				

● ● ●

NIPER-INDUSTRY CONNECT: Strengthening Partnership between NIPER & Industry - reg.

NIPER- INDUSTRY CONNECT: Strengthening Partnership between NIPER & Industry was held on 18th October 2021.

Welcome address made by **Dr Shashi Bala Singh**, Director, NIPER, hyderabad. She said that NIPER as research institute wish to associate with the industry for mutual benefit. She has taken initiatives to interact with the industry and try reach out. She briefed about the facilities available in NIPER.

Dr Preeti Meena, IAS, Director, Drugs control Administration, Telangana spoke and assured that department will extend the support.

Dr Ravi Uday Bhaskar, Director General, Pharmexcil spoke and explained the opportunities in export and suggested NIPER to help the MSME sector by facilitating the regulatory aspects.

Mrs Glory Swarupa, Director General, National Institute of MSME spoke and assured her support for the MSME.

Mr S. K. Janimiya, Chairman, IDMA, Telangana state board spoke and said that the NIPER can support the MSME sector in formulations development by working on Drug. Repurposing, where small manufacturers can work in association with NIPER .This will help the small manufacturers to offer product differentiation which will add value to them also useful for the patient. NIPER can focus on price reduction of products by redesigning the drug, reduce the quantity of drug, work on improving the side effects profile of the drug. Another area where NIPER can focus is .. products going off patent.. NIPER can take DCG(I) approval and can offer product to small manufacturers. Small manufacturers individually cannot afford the cost but can certainly take product from NIPER. This will reduce repetition of work, reduce the cost and time also. He also said that NIPER can offer analytical services to small manufacturers, because it will cost relatively less to them and NIPER with available infrastructure can generate revenue for the institute.

Later **Panel Discussion** on same subject followed, which was moderated by Prof Javed Iqbal, Founder and Chairman, Cosmic Discoveries.

Glimpses of the event


HYDERABAD
NIPER – INDU
Strengthening Partnersh
Shri Bhagwanth Khuba
Minister of State for Chemicals and Fertilizers of India
HYDERABAD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HYDERABAD


NIPER – INDUSTRY CON
Strengthening Partnership between NIPER &
October 18, 2021
11am to 1pm


HYDERABAD
NIPER – INDUSTRY CONNECT
Strengthening Partnership between NIPER & Industry
October 18, 2021


NIPER – IN
Strengthening Part
HYDERABAD


NIPER – INDUSTRY CON
Strengthening Partnership between NIPER &
October 18, 2021
11am to 1pm

OBITUARY

अच्छेद्योऽयमदाह्योऽयमक्लेद्योऽशोष्य एव च ।
नित्यः सर्वगतः स्थाणुरचलोऽयं सनातनः ।।

SHRI DHANANJAY KUMAR SINGH

(Beloved Joint MD of Alkem Labs Ltd)

This individual soul is unbreakable and insoluble, and can be neither burned nor dried. He is everlasting, present everywhere, unchangeable, immovable and eternally the same.

PRAYER CEREMONY

The prayer meet will be held on Monday, 1st Nov, 2021
Nehru Centre Auditorium, Dr Annie Besant Road, Worli, Mumbai
From 3.00 - 6.00 pm.

With Profound Grief

B N Singh - (Father)
Madhurima Singh - (Wife)
Divya Singh & Sreejan Shandilya - (Daughter & Son-in-law)
Aniruddha Singh - (Son)
M K Singh & Seema Singh - (Brother & Sister-in-law)
Archana Sharma & Ajay Sharma - (Sister & Brother-in-law)
Meghna Singh - (Niece)
Shreyshree Anant Singh - (Nephew)

Entire Singh Family, Indchemie & Alkem Family

RSVP: 9920145496 / 9892594125

Dr. Viranchi Shah, Senior Vice-President, IDMA in an interaction with Gujarat Hon CM Shri Bhupendrabhai Patel alongwith Dr H G Koshia and Shri Bhupendrabhai Shah

● ● ●

GOVERNMENT NOTIFICATION

Maleic Anhydride (Quality Control) Order, 2020 amended (2nd Amendment of 2021) - reg.

Chemicals & Fertilizers Order S.O.4500(E), dated 08th October 2021

(Published in the Gazette of India on 29th October, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Maleic Anhydride (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement

(1) This order may be called the Maleic Anhydride (Quality Control) Amendment Order, 2021.

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

2. In the Maleic Anhydride (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following subparagraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II 46016/6/2020-Tech.CPC - Part (1)

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

***Note:** The Principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.4000 (E), dated the 4th November, 2020 and subsequently amended vide number S.O.1693(E) dated 26th April, 2021.*

● ● ●

Acrylonitrite (Quality Control) Order, 2020 amended (2nd Amendment of 2021) - reg.

Chemicals & Fertilizers Order S.O.4501(E), dated 08th October 2021

(Published in the Gazette of India on 29th October, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Acrylonitrite (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement

(1) This order may be called the Acrylonitrite (Quality Control) Amendment Order, 2021.

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

2. In the Acrylonitrite (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following subparagraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II 46016/ 6/2020-Tech.CPC - Part (1)

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.3999 (E), dated the 4th November, 2020 and subsequently amended vide number S.O.1692(E) dated 26th April, 2021.*

● ● ●

Styrene (Vinyl Benzene) (Quality Control) Order, 2020 amended (2nd Amendment of 2021) - reg.

Chemicals & Fertilizers Order S.O.4502(E), dated 08th October 2021

(Published in the Gazette of India on 29th October, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Styrene (Vinyl Benzene) (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement

(1) This order may be called the **Styrene (Vinyl Benzene) (Quality Control) Amendment Order, 2021.**

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

2. In the Styrene (Vinyl Benzene) (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II 46016/ 6/2020-Tech.CPC - Part (1)

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The principal order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.4002 (E), dated the 4th November, 2020 and subsequently amended vide number S.O.1695(E) dated 26th April, 2021.*

● ● ●

Oxytocin API - reg.

GSR 762(E), dated 27th October 2021

In exercise of the powers conferred by section 10A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment further to amend the notification of the Government of India in the Ministry of Health and Family Welfare, number G.S.R. 577(E), dated the 23rd July, 1983, namely:-

In the said notification, in the Table, in the entry at serial number 12, after the words "test and analysis", the following words and letters shall be inserted, namely:-

"and Oxytocin Active Pharmaceutical Ingredient (API) imported exclusively to manufacture formulations for the purpose of export only".

F. No. X.11014/2/2018-DR

Dr. Mandeep K. Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

Note: *The Principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide G.S.R. 577(E), dated the 23rd July, 1983 and lastly amended vide Notification Number G.S.R. 180(E), dated the 16th March, 2020.*

● ● ●

Drugs (5th Amendment) Rules, 2021 - reg.

GSR 766(E), dated 27th October 2021

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of sections 12 and sub-section (1) of 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 533(E), dated the 3rd August, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby,before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 3rd August, 2021;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (5th Amendment) Rules, 2021.

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

2. In the Drugs Rules, 1945, in rule 90,—

(i) in sub-rule(2), for the word and figures "Form 29", the word and figures "Form 30" shall be substituted;

(ii) after sub-rule(2) as so amended, the following sub-rule shall be inserted, namely:—

"(3) The license in Form 29 may be granted by the licensing authority within a period of seven working days from the date of receipt of the application duly completed in Form 30, and in case where no communication is received by the applicant from licensing authority within the said period of seven days, the licensing authority shall be deemed to have granted the license."

F. No. X.11014/2/2018-DR

Dr. Mandeep K. Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

Note: *The Principal Rules were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 716(E), dated the 1st October, 2021.*

● ● ●

New Drugs and Clinical Trials (Amendment) Rules, 2021 - reg.

GSR 767(E), dated 27th October 2021

The following draft of certain rules further to amend the New Drugs and Clinical Trials Rules, 2019 which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the New Drugs and Clinical Trials (.....Amendment) Rules, 2021.

(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the New Drugs and Clinical Trials Rules, 2019, in rule 2, under sub-rule (1), in clause (w), in sub-clause (v), for the words “stem cell derived products”, the words “cell or stem cell derived product” shall be substituted.

F. No. X. 11014/12/2021-DR

Dr. Mandeep K. Bhandari,
Joint Secretary,
Ministry of Health and Family Welfare,
Department of Health and Family Welfare,
New Delhi.

Note: *The principal rules were published in the Gazette of India vide notification number G.S.R. 227(E), dated the 19th March, 2019 and last amended vide notification number G.S.R. …… (E), dated …….*

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Union Health Minister Dr. Mansukh Mandaviya launches the Sixth Edition of National Formulary of India (NFI)

Union Minister for Health and Family Welfare Dr. Mansukh Mandaviya today launched the Sixth Edition of National Formulary of India (NFI). NFI has been published by Indian Pharmacopoeia Commission (IPC) to promote rational use of medicines in the country.

Speaking at the event, Dr. Mandaviya congratulated IPC for coming up with the new edition of NFI. He appreciated the efforts of all the experts, doctors and researchers who contributed in the compilation of new edition. He said that NFI, 2021 would act a guidance document for all the healthcare professionals such as clinicians, pharmacists, nurses, dentists etc. It will play a crucial role in daily clinical practices.

He said that medicines behave differently in different bodies. It is important to know about the content, impact and side effects of medicines. The NFI is published to promote rational use of medicines in the country. It will be very beneficial for Clinicians and Healthcare professionals while prescribing the medicines to the patients.

The 6th Edition of NFI 2021 has been drafted by adopting the principle 'do not miss critical and do not overload' the information by revising the appendices, chapters and drug monographs. The chapters such as Analgesics, Antipyretics and Anti-inflammatory drugs, Antiepileptics, Antacids and Antiulcer Drugs, Antiallergics and Drugs Used in Anaphylaxis, Antidiarrhoeals and Laxatives, Antidotes and Substances Used in Poisoning, Antimigraine drugs, Basics of Medical Emergencies, Dermatological Drugs, Disease Modifying Anti-Rheumatic Drugs (DMARDs) and Drugs for Gout, Diuretics, Drugs in Osteoporosis, Drugs for Inflammatory Bowel Disease, Drugs for Respiratory Diseases, Ophthalmological Preparations and Psychotherapeutics Drugs were revised thoroughly by involving the subject specific experts/ specialist in the country.

The salient feature of this edition includes:

- 34 therapeutic categories chapters including 591 drug monographs and 23 appendices are included in this edition.
- The NFI is aligned with National Health Programmes and National List of Essential Medicines (NLEM).
- Important Weblinks related to NLEM, Drugs banned in India, NHP, Drugs banned in sports, Immunization schedule, wherever necessary are provided for information to readers.
- Special note on "How to use NFI?" and Salient Features of NFI are added in this edition.
- Only indications approved by the Indian drug regulator (CDSCO), clinically relevant and as per standard care are included
- the term 'availability' is now replaced with 'dosage forms and usual strength'
- Only the clinically relevant precautions and contraindications are included
- the common or the serious and clinically relevant adverse effects are included
- Storage conditions for medicines are included for special cases only
- Chapter on Medicines banned in sports in previous edition has been considered under appendices in this edition
- Considering the prevalence of diabetes in the country a separate Chapter on Management of Diabetes is included after revising completely
- New appendix on Good Distribution Practices is incorporated
- Appendix on National Immunization Schedule and IAP Immunization Schedule is revised as per current schedule.

Senior officers of Ministry of Health and Family Welfare and IPC were present at the occasion.

Source: PIB Delhi, 28.10.2021

Amendment in Para 2.76 of Handbook of Procedures (HBP) of the Foreign Trade Policy (FTP) 2015-20 regarding export of SCOMET items from DTA to SEZ/EOU and outside the country - reg.

DGFT Public Notice No.32/2015-20, dated 29th October 2021

1. In exercise of the powers conferred under Paragraph 1.03 of the Foreign Trade Policy (FTP) 2015-20, the Directorate General of Foreign Trade (DGFT) hereby makes amendments in Paragraph 2.76 of Handbook of Procedures (HBP) of FTP 2015-20, with immediate effect.

2. Existing entry at Para 2.76 of HBP of FTP (2015-20) relating to supply of SCOMET Items from DTA to SEZ will be substituted as under:

2.76 Supply of SCOMET Items from DTA to SEZ :	**2.76 Supply of SCOMET Items from DTA to SEZ/ EOU and outside the country**
No export authorization is required for supply of SCOMET items from DTA to SEZ. However, all supplies of SCOMET items from DTA to SEZ will be reported to the Development Commissioner of the respective SEZ by the supplier in the prescribed proforma [Annexure 1 to Appendix-3 to Schedule 2 of ITC (HS) Classifications of Export and Import Items] within one week of the supplies getting effected. An annual report of such supplies from DTA to SEZ shall be sent to SCOMET Section, DGFT (Hqrs), Department of Commerce, Udyog Bhawan, Maulana Azad Road, New Delhi 110011, by the Development Commissioner (DC), SEZ in the prescribed proforma [Annexure 2 to Appendix-3 to Schedule 2 of ITC (HS) Classifications of Export and Import Items]. Report by the DC, SEZ is to be filed by 15th May of every financial year for the supplies effected during the preceding financial year. Export Authorisation is, however, required if the SCOMET items are to be physically exported outside the country from SEZ i.e. to another country (Refer Rule 26 of the SEZ Rules, 2006).	No export authorization is required for supply of SCOMET items from DTA to SEZ/EOU. Export Authorisation is, however, required if the SCOMET items are to be physically exported outside the country from SEZ/EOU, i.e. to another country (Refer Rule 26 of the SEZ Rules, 2006). All supplies of SCOMET items from DTA to SEZ /EOU will be reported to the Development Commissioner (DC) of the respective SEZ/EOU by the supplier in the prescribed proforma [Annexure 1 to Appendix-3 to Schedule 2 of ITC (HS) Classifications of Export and Import Items] within one week of the supplies getting effected. An annual report of such supplies from DTA to SEZ/EOU shall be reported to SCOMET Section, DGFT (Hqrs), Udyog Bhavan, New Delhi- 110011 by the DC of the respective SEZ/EOU in the prescribed proforma [Annexure 2 to Appendix-3 to Schedule 2 of ITC (HS) Classifications of Export and Import Items] by 1 5th May of every financial year, in respect of supplies effected from DTA to SEZ/ EOU during the preceding financial year.

3. Effect of this Public Notice :

Existing entry at Para 2.76 of HBP of the FTP 2015-20 has been modified to bring out clarity on export policy of SCOMET items for supplies/exports from DTA to SEZ/EOU and outside the country.

F. No. 01/77/180/005/AM20/EC(S)

Amit Yadav, Director General of Foreign Trade & Ex-Officio Addl. Secretary, Directorate General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, New Delhi.

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ADB, AIIB processing $2 billion loan for India to buy COVID-19 vaccines

Of the USD 2 billion loan, the Manila-based ADB is expected to finance USD 1.5 billion and AIIB is considering providing USD 500 million, AIIB's Vice President D.J. Pandian said here on Tuesday. "The ADB has agreed to finance USD 1.5 billion and AIIB will supplement with another USD 500 million," Pandian said.

Besides funding various infra projects in India, the AIIB has also granted USD 1.75 billion to India for the COVID-19 relief budget support.

China-based Asian Infrastructure Investment Bank (AIIB) along with the Asian Development (ADB) are currently processing a USD 2 billion loan for India to purchase COVID-19 vaccines.

Of the USD 2 billion loan, the Manila-based ADB is expected to finance USD 1.5 billion and AIIB is considering providing USD 500 million, AIIB's Vice President D.J. Pandian said here on Tuesday.

"The ADB has agreed to finance USD 1.5 billion and AIIB will supplement with another USD 500 million," Pandian said.

The loan is under consideration from the AIIB board, he said, adding that India has applied for it three months ago. About 667 million doses of COVID-19 vaccines were expected to be procured through the loan, according to the Bank.

He said the vaccines will be purchased by the Government of India through a competitive process and the ADB will be administering the purchasing system and implement it under ADB's APVAX, or Asia-Pacific Vaccine Access Facility, mechanism.

India, which produces Covishield and Covaxin, has recently crossed an inoculation milestone of administering 100 crore Covid-19 vaccine doses to its citizens against the deadly virus. India also plans to resume vaccine exports and provide the jabs to a number of countries.

Besides funding various infra projects in India, the AIIB has also granted USD 1.75 billion to India for the COVID-19 relief budget support. Pandian said the Beijing-based AIIB, in which India is the second-largest shareholder after China, has so far approved 147 projects amounting to USD 28.9 billion.

Besides being the second-largest shareholder, India has emerged as its biggest beneficiary by obtaining USD 6.7 billion for 28 projects, he told the media as the bank held its 2021 annual general body meeting through video link.

On Tuesday, the AIIB formally granted USD 356.67 million loans for the expansion of the Chennai metro rail system. The bank is also considering several other infrastructure projects for the development of Chennai city and its suburbs.

Pandian said the AIIB is backing several other infrastructure projects for Chennai. "The USD 400-million Chennai Metro Corridor-5 is already under pipeline at an advanced stage of project approval process. We are also working on a few other transport projects in Chennai, including the Chennai Outer Ring Road project worth USD 300 million," Pandian said.

The energy and transport sectors have received the highest amount of financing from the AIIB, said Pandian who oversees all sovereign and non-sovereign lending for the AIIB in South Asia, the Pacific Islands and South-East Asia.

Significantly, the AIIB sponsored by China has not funded any projects under Beijing's Belt and Road Initiative (BRI) nor its flagship USD 60 billion China-Pakistan Economic Corridor (CPEC).

"We are a multilateral bank. Our job is to do infrastructure development projects. The BRI is different, AIIB is different. To my knowledge nothing has come up from BRI," Pandian said while replying to a question.

India has objected to China over the CPEC as it is being laid through Pakistan-occupied Kashmir (PoK).

Pandian said the bank has a strict policy related to financing projects in the disputed areas. Consent from all sides is required to fund such projects, he added.

In Pakistan, he said, the AIIB has financed seven infrastructure projects amounting to USD 1.5 billion.

Starting with a membership of 57 countries in 2015, the AIIB membership has now grown to 103 countries

spread across the world. The US and Japan, however, have not joined the bank over their reservation of China's sponsorship.

About how the bank has fared since its inception, Pandian said, "I think AIIB has done its job. It's a start-up bank" starting from scratch.

In future, the bank's concentration will be on small countries where more projects, even if they are small, will be undertaken, he said.

He said the Bank has put in an excellent multilateral governance system. It has 12 directors from different countries and has a non-resident board. Its Management was drawn from different countries and followed universal procumbent policy, he said.

Source: Economic Times, 27.10.2021

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Has Pharma reached its peak or preparing to bounce back?

The pharmaceutical industry is one sector that will never go out of demand. For the simple reason - the world will always need doctors and medicines. During the COVID-19 pandemic, the industry witnessed a boost like never before. A rise in demand and safe-haven buying amid a global economic slowdown led to a sharp rally in 2020. But since June 2021, the sector has turned gloomy. Most stocks are trading lower than expectations.

Long-Term Returns

Raamdeo Agrawal, chairman and co-founder, Motilal Oswal Financial Services, in a media interview, explained that the pharma sector is product and molecule-specific, unlike the IT sector, which is in sync with the demand trend. What he meant was that when the demand for some molecules or formulations is high, that stock will rise. Hence, careful selection is mandatory in the pharma space.

In fact, over the past decade, the Nifty Pharma index has reported a 12.3% CAGR compared to Nifty 50 returns of 13.7% CAGR.

This is mainly because of the pharma sector's massive exposure to the US market. Strict US FDA regulations, pricing pressure, and excessive competition reduces pharma's revenues. This directly impacted the stocks and the index performance.

Looking Back!

During the mid-20th century, India relied heavily on foreign countries for its pharma deliveries. Cut to 2021, India stands as one of the leaders of the pharma landscape. While India continues to supply 20% of global exports of generic drugs, why is the pharma space still volatile? Well, it's because of our huge exposure to the US market. Most pharma companies receive their majority revenue from the US, which is a lucrative market. However, strict US FDA regulations, price erosion, and competition make it troublesome to garner revenue from the US market. This is the biggest problem for Indian pharma companies.

Growth prospects

Analysts believe to see sustained revenue growth of 10-15% over the next few years in the pharma companies. The domestic market currently remains hot, on the back of increasing health awareness, a higher number of people reaching the age of 50, lifestyle changes etc. But, catering only to the domestic market won't get as much revenue, and that's the only reason why the pharma companies continue to bear the heat from the US.

How Gloomy Can It Get?

A few weeks back, big bull Rakesh Jhunjhunwala cut his stake in Lupin, which caused an uproar against the pharma space. Since then, Lupin has been on a downtrend just like its peers, but this gloomy period won't last long. Market analysts continue to remain positive on the long-term growth story of the pharma space. They expect it to grow 3x in the coming decade, reaching up to $130 billion. With China taking a step back in the manufacturing space, India is the next-best pharma industry to rely upon.

Future Outlook

Once the market is corrected, and the pharma valuations are back on the line, the appreciation in the share price will begin. Logically, the demand for pharma space will not decline. It will only rise from here, given the increasing level of pollution, lifestyle changes, the prevalence of communicated diseases etc. The long-term benefits of the pharma stocks remain intact, but it is important to choose the best out of the lot. Taking into consideration the industry's competitive nature, it is vital to study the company and its products deeply before investing.

Source: Teji Mandi, Free Press Journal, 27.10.2021

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Private sector looks for ways to liquidate excess vaccine stock

Some hospitals have opened talks with companies to take the unused doses back and distribute them in areas that need them

A leading South India-based corporate hospital chain said that they have around 400,000 unused Covid-19 vaccine doses that can be used no later than next March. Going by their daily rate of vaccination, the hospital chain is confident of liquidating the stock.

Others have opened talks with the vaccine makers to ensure some unused stock nearing expiry dates is taken back and redistributed in areas that have demand. "Some hospitals have opened talks with companies to take the stock back and give it to areas where they see demand. There is no point in wasting the doses," said a senior executive of a Mumbai-based hospital who did not wish to be named.

The situation is similar across the country where demand for paid jabs at private vaccination centers have dropped significantly as free vaccination at government centers is now easily available. In Mumbai, industry insiders estimate there has been an over 70 percent drop in demand from the May-June levels in private sector vaccination. In Maharashtra, average daily rate of vaccination in the private sector is around 25,000 shots.

State government sources say that if the rate of vaccination in the private sector remains low, hospitals may be asked to hand over the excess doses to respective district authorities.

Hospitals, however, are not so sure. "Giving back to the government would be tricky as we have procured these at much higher rates than the government purchase price," said a senior executive of a city-based private hospital.

Dilip Jose, MD & CEO of Manipal Hospitals, India's second largest hospital chain said that they were doing a few thousand vaccine shots now compared to the peak of 50,000 shots a day after the second wave.

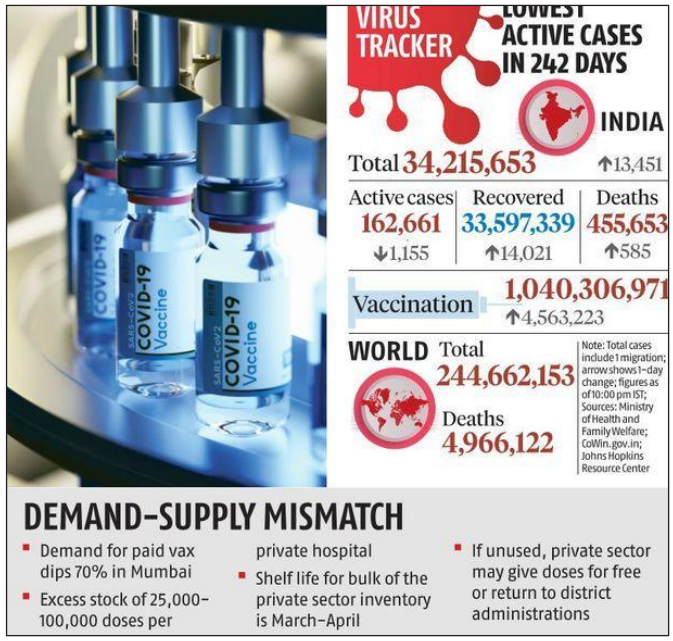
"No vaccine shot should be wasted. If the private sector has excess stock and anyone feels that this cannot be exhausted in time, one should go for out-reach programmes and give it for free if needed," Jose said.

Already some city hospitals in Hyderabad have started giving the vaccines at the cost price without the charging the service fee of Rs 150 per shot.

The Centre has capped the price of Covishield and Covaxin in private hospitals to Rs 780 and Rs 1410 per dose respectively, essentially asking hospitals to take a service charge of Rs 150.

Joy Chakraborty, COO of PD Hinduja Hospital in Mumbai, said that the institute's daily rate of vaccination was down to 300 from a peak of 2,300 or so. It, however, only has a few thousand doses of inventory, and mostly Covishield shots. Chakraborty felt that demand may see a jump if a third booster shot is allowed for healthcare and essential workers.

Various private hospitals are replenishing their vaccine stocks but in smaller numbers due to lower demand for vaccines in their centres. "Covid19 vaccinations are continuing in our hospitals. Vaccination numbers have come down during the past two months. We are ordering vaccines as per demand, and have scaled it down from earlier days, when we had to stock more, to take care of the increased demand," said Bishnu Panigrahi, Group Head, Medical Strategy and Operations, Fortis Healthcare.



The country's largest private hospital chain Apollo Hospitals Group did not comment for this story. Analysts expect a sharp decline in Apollo's vaccination revenue in the second quarter of the fiscal compared to the first quarter.

"We expect Covid-19 vaccination revenue to decline sharply QoQ, driven by a decline in vaccination volumes for private players. Vaccines contributed 5.1 per cent and 5.5

per cent to Q1FY22 revenues and EBITDA, respectively, based on our estimate," Nomura said for Apollo Hospitals recently.

Aakash Healthcare said it had an adequate stock of COVID-19 vaccines for nearly three and half months. "We will be placing the next order 15 days prior," Kousar Shah, chief operating officer, Aakash Healthcare Group said

Source: Sohini Das & Ruchika Chitravanshi , Business Standard, 28.10.2021

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Vaccine maker Bharat Biotech's US partner seeks FDA's approval for Covaxin trials

Hyderabad-based vaccine maker Bharat Biotech's partner in the US, Ocugen, has sought the US FDA's approval to conduct clinical trials for Covaxin.

HIGHLIGHTS

- WHO on Tuesday sought more details from Bharat Biotech to consider EUL for Covaxin
- FDA had in June "recommended" Ocugen to go for BLA route with additional data, instead of EUA
- Ocugen has already sought regulatory approval from authorities for Covaxin to be used in Canada

Ocugen, Bharat Biotech's US partner for COVID-19 vaccine Covaxin, on Wednesday said it has submitted Investigational New Drug Application (IND) to the US Food and Drug Administration to conduct clinical trials.

The development comes a day after the World Health Organisation sought more details from Bharat Biotech to consider its COVID-19 vaccine Covaxin for Emergency Use Listing.

The US firm in a press release said the Phase 3 trial, proposed in the IND, is designed to establish whether the immune response experienced by participants in a completed Phase 3 efficacy trial in India is similar to that observed in a demographically representative, healthy adult population in the USA. The US drug regulator earlier in June "recommended" Ocugen Inc, to go for Biologics Licence Application (BLA) route with additional data, instead of Emergency Use Authorisation (EUA).

The proposed trial can be to people who either have not been vaccinated for COVID-19 or who already received two doses of an mRNA vaccine at least six months earlier in the USA.

"We are very excited to take this next step in the development of Covaxin, which we hope will bring us, closer to introducing a different type of COVID-19 vaccine to the American public. We are hopeful that the study conducted under the IND, if allowed to proceed, will help demonstrate that the data from India will be applicable to the U.S. population, " Dr Shankar Musunuri, Chairman of the Board, Chief Executive Officer, and Co-Founder of Ocugen said.

If the study is allowed to proceed, Ocugen's Phase 3 immuno-bridging study, OCU-002, will seek to enroll several hundred healthy adults in the U.S. Subjects will be randomized to receive either two doses of Covaxin or placebo, 28 days apart.

The Phase 3 study conducted in India by Ocugen's business partner, Bharat Biotech, involved 25,798 participants receiving two doses of Covaxin or placebo, 28 days apart. Ocugen has already sought regulatory approval from Health Canada for Covaxin to be used in that country. Covaxin is a whole-virion inactivated COVID-19 investigational vaccine candidate that uses the same vero cell manufacturing platform that has been used in the production of polio vaccines for decades.

Source: PTI, 27.10. 2021

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Importance of having an EUL for Covid vaccines

An explainer on what emergency-use listing is all about

Much interest and anxiety have been generated by the high-decibel discussions on the emergency-use listing (EUL) of Covid vaccines by the World Health Organization,

and why it is required in some countries. As Bharat Biotech's Covaxin vaccine undertakes the regulatory process to get this emergency tag, a look at what it means, especially since over 11 crore people have taken it already in India.

What is an EUL?

The procedure is a risk-based one to assess and list vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency. It gains significance in countries that do not have an elaborate regulatory mechanism, in which case they can rely on the WHO endorsement.

International travel in many countries requires people to get a vaccine that's on the WHO's approved list.

What is the EUL process?

It is a complex one that takes about 12-24 months generally after submission of a dossier by a vaccine maker. However, in pandemic times, the review process has been faster to meet global requirements. The application and data submitted is reviewed by two groups – the Strategic Advisory Group of Experts on Immunisation (SAGE) and Technical Advisory Group (TAG) – an independent advisory group that provides recommendations to the WHO on whether a Covid vaccine can be listed for emergency use under the EUL procedure.

How many vaccines have an EUL?

As of now, the WHO has six vaccines on the approved list. They are from Pfizer-BioNTech, Moderna Janssen (Johnson & Johnson), Oxford/AstraZeneca and that includes Serum Institute of India's Covishield (AstraZeneca's formulation), Sinopharm and Sinovac.

Is EUL a must for exports?

No. There is no link between EUL and exports. A vaccine maker can export its vaccines, subject to approval of the importing country's health regulator.

However, EUL can augment demand for a particular vaccine as it facilitates easier international travel for people. And an EUL is important if the company wants to supply to the WHO-supported Covax facility that distributes to low- and middle-income countries.

Source : G Naga Sridhar, The Hindu Business Line, 27.10.2021

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Rocketing raw material costs hit India Inc margins in September quarter

Firms resort to other expenditure cuts to offset pressure on operating profit margins

A day after the second-quarter results, Sanjiv Mehta, chairman and managing director of Hindustan Unilever (HUL), India's largest FMCG company, called upon the government to monitor inflation.

Mehta has his reasons. Crude oil (according to the WTI index) is at levels last seen in 2014. Agricultural commodities and metals have seen a surge in prices which is hurting corporate sector profits. Companies across segments such as in FMCG, steel, cement and paints are seeing a margin contraction, despite price hikes and cost cutting measures.

An analysis of September-quarter (Q2) results declared so far shows that 14 of the top 20 companies by revenue (BSE 200) reported a decline in gross margins on a sequential basis and 13 of those reported decline on a year-on-year (YoY) basis.

Gross profit is net sales minus raw material consumed minus stock adjustment minus purchase of finished goods minus power, oil and fuel costs. Eleven of them reported a decline in operating profit margins on a sequential basis while ten saw margins decline on a YoY basis.

Among individual companies, a further analysis shows that while HUL's gross margins declined 159 basis points (bps) on a YoY basis, its operating margins rose 6 bps during the same period, indicating the impact of cost-saving measures taken by the company.

Similarly, in the case of Nestlé, while its gross margins declined 240 bps, its operating margins fell by only 64 bps. While HUL remains cautiously optimistic about the coming quarters, it is guarded on the continued volatility in commodity prices. "Gross margins are likely to remain under pressure. Judicious pricing actions coupled with cost agility and savings programmes will continue," it said following Q2 results.

India's largest paint maker, Asian Paints, is also feeling the pinch of commodity price inflation. While the company

reported a 32.6 per cent increase in consolidated revenue in Q2, its net profit fell by 29 per cent.

MARGINS OF TOP FIRMS — Top 20 companies by revenue

	GPM (%)			PBIDTM (%)		
	Sept'21	QoQ bps	YoY bps	Sept'21	QoQ bps	YoY bps
Reliance Industries	32.3	-315	-344	18.1	-162	-288
JSW Steel	55.1	-1,458	1,313	37.5	-47	1,278
Hindustan Unilever	50.7	109	-159	25.5	88	6
UltraTech Cement	64.6	-259	-147	23.8	-594	-427
Avenue Supermart	14.9	184	42	8.9	400	174
Tata Steel BSL	46.0	-1,013	471	31.3	-1,149	943
Asian Paints	34.7	-368	-966	14.8	-308	-1,057
TVS Motor	32.4	-244	56	11.5	340	-73
Hindustan Zinc*	96.5	657	690	61.2	204	79
Nestlé India*	55.5	-133	-240	25.4	6	-64
ACC	61.3	-369	-88	21.3	-281	59
Havells India	34.2	-150	-605	14.8	-15	-562
Polycab India	22.5	-218	-698	10.5	187	-581
Tata Consumer	42.8	200	194	14.4	32	-6
DCM Shriram	33.8	-189	225	14.6	-88	284
Mahindra CIE	52.0	-247	-75	13.2	-9	181
Supreme Industries	28.6	-357	-580	18.4	-186	-240
Biocon	69.3	406	-7	23.4	176	40
Tata Steel Long*	39.9	-1,692	-431	17.8	-1,533	101
Hatsun Agro*	32.3	188	-98	12.9	127	-183

*standalone; Excludes banks and finance companies; Gross profit = Net sales-raw material consumed-stock adjustment-purchase of finished goods-power, oil & fuel; PBIDTM: Profit before interest, depreciation and tax margin; GPM: Gross profit margin

Source: Capitaline, Compiled by BS Research Bureau

The company's gross margin and operating margin fell by a steep 966 bps and 1,057 bps on a YoY basis. Sequentially, too, these margins were down between 300-370 bps.

"The steep inflation seen in raw material prices since the beginning of this calendar year has been phenomenal and has impacted gross margins across all businesses in the quarter," said Asian Paints MD and CEO Amit Syngle.

Analysts led by Varun Lohchab at HDFC Securities have cut their Ebitda estimates and, consequently, their net profit projections for Asian Paints by 15-16 per cent for FY22 and 6-7 per cent for FY23 and FY24. The company is looking at further price hikes to mitigate the cost impact and is hopeful of a strong rebound in Q3.

In consumer durables, Havells has flagged the risks of commodity price volatility. Its gross margin declined 605 bps in the second quarter due to higher raw material costs. The net profit was down 7 per cent YoY at Rs 302 crore during the quarter.

"The price of zinc, aluminium, and stainless steel is rising since January. Ocean freight rates are up four times compared to December 2019. We will continue to see commodity price pressure till next March," said B Thiagarajan, managing director of air-conditioning major Blue Star.

The firm took price hikes three times this year but has not seen an adverse impact on demand. "Demand has been good. We will have to wait and see how it pans out at Diwali," said Thiagarajan.

Prices of several commodities are up by 30-100+ per cent over last year. Among them, tin and crude oil prices have gained over 100 per cent while those of aluminium, copper and lead are up 40-68 per cent. Palm oil prices have risen nearly 78 per cent.

Steel manufacturers are bearing the brunt of higher coal prices while sharp increases in coal and pet coke prices have dented the profitability of cement companies.

UltraTech, India's largest cement maker, reported a YoY decline of 147 bps and 427 bps in its gross and operating margin, respectively.

Another cement maker, ACC, saw gross margins declining 88 bps, but operating margins rose 59 bps, the latter aided by cost-saving measures.

JSW Steel, which has reported its highest-ever revenue and profit growth in Q2 has also seen the cost impact on its standalone operations. "On a YoY basis, (standalone) Ebita was higher by 108 per cent. The margin was lower QoQ (sequentially) primarily due to elevated raw material prices of iron ore, coking coal and other key inputs like power, natural gas and ferroalloys," said JSW Steel.

The expected revival in construction and infrastructure in H2 of FY22 and increased government spending are positives for the sector.

"While inflation is impacting companies globally, Indian manufacturers have to deal with sectoral challenges too. In the FMCG space, it is the explosion of e-commerce companies while in auto, it is the launch of e-vehicles. The cement sector is being impacted by overcapacity and underutilisation," said G Chokkalingam, founder, Equinomics Research & Advisory.

Firms will have to focus on cost savings and productivity improvements. A good monsoon should also help in broad based growth and demand recovery, added Chokkalingam.

Services are not immune to the heat. While IT services companies are not directly impacted by commodity prices, supply-side constraints (labour) impacted Q2 margins for most top players.

Though TCS reported a 10 bps expansion on a sequential basis, for a traditionally strong quarter the Street was expecting a better performance.

Infosys reported Ebit (earnings before interest and tax) margins of 23.6 per cent down 10 bps. But it managed the supply side pressure well with cost optimisation levers.

At Wipro, the salary impact brought down margins by 10 bps. The company expects margins to be under pressure in the coming quarters. However, despite headwinds, the IT industry players have managed to maintain margins at elevated levels as growth has been robust.

Source: Aneesh Phadnis Shivani Shinde & Aditi Divekar , Business Standard, 28.10.2021

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Power crisis brewing in China likely to hit Indian pharma companies

Delays in consignments, rising prices of key ingredients worry industry

The power crisis brewing in China may throw the Indian pharma market off gear if the situation continues for a few more months, feel sources in the local industry. Indian players roughly import 66-70 per cent of their bulk drug requirements from China.

Already, prices of active pharmaceutical ingredients (APIs), raw materials to make drugs, have gone up significantly and there are delays in shipments to India.

Sudarshan Jain, secretary general of the Indian Pharmaceutical Alliance (IPA), the umbrella organisation of big pharma players in India, said prices of APIs have started going up. "Prices of Penicillin-G from China have gone up from $14 per unit to $26 in just one month," he said, adding that India does not have large capacities to make such fermentation-based APIs.

IPA members account for 60 per cent of the domestic market and about 80 per cent of India's exports of pharmaceutical products.

Jain added that supplies are coming, but there are delays in shipments. "Apart from the power shortage problem plaguing the industry in China, there are also issues with shipping. Consignments are coming, but late. Typically, large pharma players would carry a three-month buffer stock, and the industry at large is trying to maintain a healthy inventory even if it means buying at higher prices," he said.

One of the leading drugmakers of the country, Cipla seems to agree.

Kedar Upadhye, global chief financial officer, Cipla, told Business Standard, "The power crisis in China may impact future supplies of API to India if it continues. Zones where the power shortage is acute are unfortunately the provinces from where Indian formulation makers source their APIs."

He added that Cipla's dependence on imports from China would be around 66-70 per cent, roughly the same level as the overall industry.

"We are carrying buffer stock now," Upadhye added.

"Looking for alternative sources of API would not be easy. The scale (tonnage) of Chinese production is very high, the cost advantage very high, and there is also some technology superiority. There is a gestation period until India can come up to the level of China," Upadhye added.

Mid-sized players may face a bigger challenge. A mid-sized company in Gujarat said overall input costs – packaging material, intermediates and APIs, among others – for formulation makers have gone up in the last few months.

For APIs, there has been a price rise of 25-40 per cent. "While larger players can book bulk volumes, carry inventory, and even afford to pay more, the smaller ones cannot. If the situation continues, we would request the government to look into it, perhaps allow us to take a price hike," the industry source said. He added that prices of key APIs like paracetamol have been going up every year – from Rs 330 per kg around 2013-14 to nearly Rs 850 now.

IPA members account for 60 per cent of the domestic market and about 80 per cent of India's exports of pharmaceutical products.

"As manufacturers, we have hardly taken any price rise for paracetamol, a key drug in Covid-19 treatment, as it is under price control. We don't want to create any panic, but margins of the industry would come under pressure, especially for smaller players," he added.

FACT SHEET

- Indian players import 66-70% of their APIs from China
- Developing alternative sources of API is time-consuming
- Prices of APIs have gone up in the last one month
- There are delays in consignments reaching India
- Firms carry 2-3 months buffer stock of raw material
- Wholesalers and retailers carry 2-3 months of finished product stock

Source: Sohini Das, Business Standard, 28.10.2021

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Indian cos asked to bid for molnupiravir deal

Companies such as Sun Pharmaceutical Industries Ltd, Cipla Ltd, Dr. Reddy's Laboratories, Hetero Pharma, Natco Pharma, and Optimus Pharma are in advanced stages of their clinical trials for molnupiravir.

Unitaid, Unicef want firms to participate in a rolling tender to supply drug

Unitaid, a global health initiative that works with partners to bring about innovations to prevent, diagnose, and treat major diseases in low- and middle-income countries, and Unicef have asked eight Indian generic manufacturers to participate in a rolling tender to supply the experimental covid-19 drug molnupiravir to extend access for the antiviral in low- and middle-income countries.

Molnupiravir, which received emergency approval from the US Food and Drug Administration (FDA) earlier this year, is seen as a breakthrough therapy that has reduced the risk of hospitalization among covid-19 patients.

MSD, which ran the trial for the drug along with its partner Ridgeback Biotherapeutics, has offered the drug to Geneva-based Medicines Patent Pool royalty-free for use in more than 100 middle- and low-income countries. Indian generic makers are keen to play a key role in scaling up of the drug as at least 12 companies, eight of which are officially licensed by MSD, have started running trials for the drug.

Companies such as Sun Pharmaceutical Industries Ltd, Cipla Ltd, Dr. Reddy's Laboratories, Hetero Pharma, Natco Pharma, and Optimus Pharma are in advanced stages of their clinical trials for molnupiravir. The companies are expected to submit their data to Indian regulators by the end of this month. "We hope the eight Indian generic companies will soon go into production of the generic version of molnupiravir. Unicef is running a rolling tender inviting conditional submissions by generic companies. It is conditional because we still need regulatory approval and World Health Organization (WHO) guidance before this can be supplied to national governments," Robert Matiru, director, Unitaid, told Mint.

Unitaid is a not-for-profit organization that works on finding and supporting innovative solutions for infectious diseases in low- and middle-income countries (LMICs).

The companies have been asked to submit their bids early so that organizations can get ahead of the curve by submitting dossiers, including pricing, which is accessible to LMICs, Matiru said.

MSD has announced a price of $700 for the course of treatment, but Indian generic companies that Mint spoke to said that they can offer the drug at less than $15. To encourage companies to manufacture before an official regulatory approval, the Gates Foundation has also announced an insurance policy to start at-risk production, Matiru explained.

In October, the Bill and Melinda Gates Foundation announced that it was making a commitment of up to $120 million to accelerate access to molnupiravir for low-income countries. As part of this commitment, the foundation said it will provide a grant of $2.4 million to speed up generic companies' readiness to apply for WHO prequalification.

Source: Divya Rajagopal, HT Mint, 29.10.2021

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Optimus Group completes phase 3 clinical trial of anti-COVID drug

Molnupiravir is an affordable option to neutralise the disease in minimum time

Optimus Group based in Telangana has announced the successful completion of the much-awaited Molnupiravir oral capsule phase 3 clinical trial on Thursday.

On May 18, the firm had received approval from the Drug Controller General of India (DCGI) to conduct the trial as per the recommendations of the Subject Expert Committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare.

The pharmaceutical company was the first to file for phase 3 clinical trial of Molnupiravir with the Central Licensing Authority. The clinical trial partner of Optimus, JSS Research, was tasked with the execution of the trial at the grass-root level. With 29 study sites across the country, roughly covering 96% of the nation's demographic capital, the trial not only aims to prove the superiority of Molnupiravir over the standard treatment options but also prove the drug's efficacy across India's gene pool diversity, said a press release.

In order to cater to the unmet medical needs of the nation for a front-end cure to SARS-CoV-2 infection, Optimus is well prepared to ensure manufacturing and distribution of Molnupiravir efficiently and effectively.

"With an indigenously developed formulation, Optimus strives to establish its belief in the Make in India initiative of the government. Our aim is to develop a cutting-edge and affordable treatment option for COVID-19 and neutralise the disease in minimum treatment duration. We are fully committed to supporting our business partners across various regions of the world who are counting on us for the supply of Molnupiravir," said chairman and managing director D. Srinivas Reddy.

Optimus submitted the final clinical trial report which highlighted promising results: At study Day 5, 78.4% of patients in the treatment group were recorded RT-PCR negative compared to 48.2% in the placebo group. At study Day 10, 91.5% patients in the treatment group were recorded RT-PCR negative compared to 43% in the placebo group.

"These results are not only a new hope to neutralise COVID but also reinforce our belief in the CLA to ensure a fair and legitimate trial and provide the necessary support for a self-reliant pharmaceutical industry. CDSCO has emerged as a reliable licensing authority in Asia promoting innovation and strict regulatory and quality compliance in the pharmaceutical industry," he added.

Source: The Hindu, 28.10.2021

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Natco Pharma, Hetero seek marketing authorisation for anti-Covid drug molnupiravir

Natco has conducted Phase III trials of molnupiravir and submitted the trial results to the drug regulator this month. "We have submitted phase-III clinical trial results of Molnupiravir to DCGI and we are awaiting for their marketing permission," Natco said in response to an email.

Hyderabad-based Natco Pharma Limited and Hetero have sought marketing authorisation for their anti-Covid drug molnupiravir from the drug regulator, people in the know told ET.

The Subject Expert Committee (SEC) under the drug regulator is likely to take up their applications soon.

Natco has conducted Phase III trials of molnupiravir and submitted the trial results to the drug regulator this month.

"We have submitted phase-III clinical trial results of Molnupiravir to DCGI and we are awaiting for their marketing permission," Natco said in response to an email.

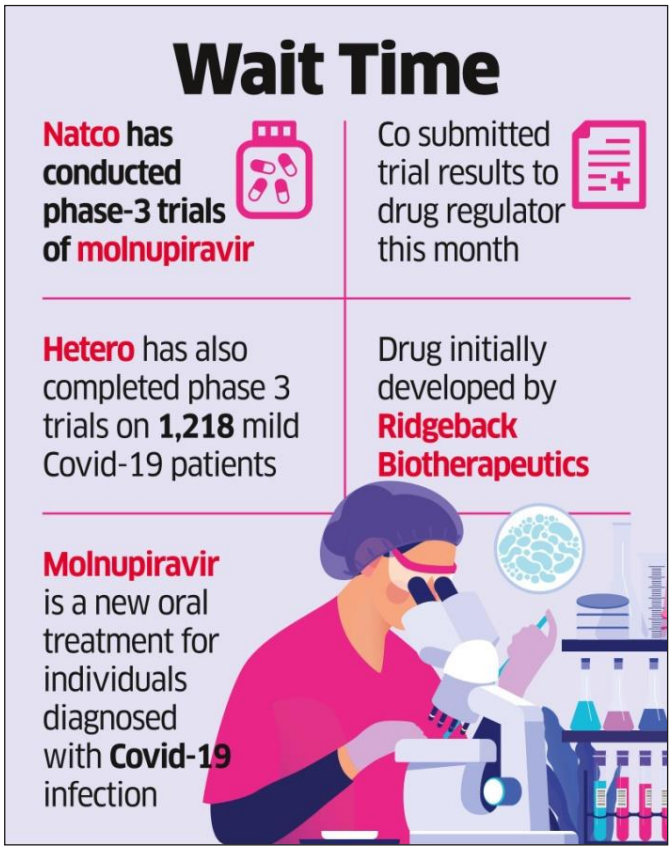
"The trial results show that it helps in early recovery of patients," people quoted above said.

Hetero has also completed phase 3 clinical trials on 1218 mild Covid-19 patients to assess the efficacy and safety of this drug and applied for emergency use authorisation (EUA). During its trials, the company found fewer hospital admissions in Molnupiravir group compared to standard of care alone. Patients in the clinical trial were randomised to receive Molunipiravir 800 mg every 12 hours for five days. In the control arm of the study, the patients received only standard of care.

An email sent to Hetero did not elicit any response till the press time. The drug was initially developed by US-based Ridgeback Biotherapeutics, who later partnered with Merck & Co for further development.

Molnupiravir is a new oral treatment for individuals diagnosed with Covid-19 infection. The experimental antiviral drug is also being evaluated by the US FDA for its effectiveness and safety. The advisory committee of the FDA

will meet on November 30 to take up Merck and Ridgeback's request for granting emergency use authorization (EUA) for molnupiravir to treat mild to moderate Covid-19. In India, Merck & Co. has signed voluntary licensing agreements with Cipla Ltd, Dr Reddy's Laboratories, Emcure Pharmaceuticals Ltd, Hetero Labs Ltd and Sun Pharmaceutical Industries Ltd, for allowing the drug to be manufactured and marketed in India.



Natco has not entered into a licensing agreement with Merck.

Molnupiravir inhibits the replication of multiple RNA viruses including Sars-CoV-2. Merck has claimed that the drug has the potential to eliminate Sars-CoV-2 within five days.

On Wednesday, US drug maker MSD and Medicines Patent Pool (MPP) also entered into a voluntary licencing agreement to facilitate affordable global access for molnupiravir. The agreement will help create broad access for molnupiravir use in 105 low- and middle-income countries (LMICs) following appropriate regulatory approvals.

Source: Teena Thacker, ET Bureau, 28.10.2021

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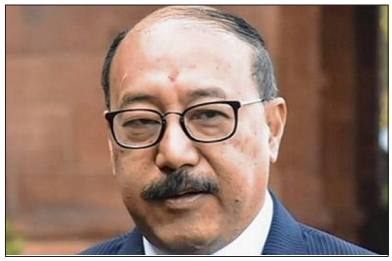
Covaxin may get WHO approval soon as discussions are progressing, says Shringla

The Centre is hopeful that Bharat Biotech's Covid-19 vaccine Covaxin will get WHO approval soon as discussions are progressing, Foreign Secretary Harsh Vardhan Shringla has said.



India has proposed a mutually acceptable Covid-19 vaccine certification framework to its partner countries to ensure a simplified international travel regime and many have agreed to it, Shringla said on Thursday at a briefing on PM Narendra Modi's travel to Rome for the G-20 Summit and to Glasgow for World Leaders' Summit of COP-26 from October 29 to November 2.

"The WHO's technical advisory group, which is a regulatory group, met on October 26. It had asked a few questions to Bharat Biotech. We were informed that they (the company) will give answers at the earliest. Once the queries of the regulatory group are satisfactorily answered, approval for Covaxin should come fast after that," the Foreign Secretary said.

'Recognising certification'

On vaccine certification, the FS pointed out that India had proposed to partner countries that they should recognise India's vaccine certification and India will mutually recognise their vaccine certification. "The advantage is that as we keep adding new vaccines to our stock of national vaccines, one need not go to each country to get their recognition….A number of countries have already agreed to that. We have achieved reciprocal arrangements with a number of countries," Shringla said.

India will take up the proposal with the G-20 and also bilaterally and pluri-laterally with other countries.

G 20 leaders are expected to come out with a concrete outcome in combating the Covid-19 pandemic and similar challenges in the future, Shringla said. Modi is scheduled to call on Pope Francis in the Vatican City and will meet other leaders including Indonesian President Joko Widodo and Saudi Crown Prince Mohammed bin Salman.

India is looking forward to objective discussions and

a balanced outcome from the COP-26 meet, the Foreign Secretary said.

Source: The Team Outreach, 28.10.2021

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India to become best investment destination for pharma sector: Mandaviya

This would create demand for more drugs and medical devices, which would benefit the pharma industries in India.

India strives to become the best investment destination in the world for the pharma sector under the leadership of Prime Minister Narendra Modi, Union Minister for Health and Family Welfare and Chemicals & Fertilizers Mansukh Mandaviya said today.

He was inaugurating the Investor Summit – "Opportunities and Partnerships in Pharmaceuticals & Medical Devices"– via video conferencing.

The summit was organised by the Department of Pharmaceuticals, in partnership with Invest India as part of the vision to further strengthen India's position globally in terms of pharmaceuticals and medical devices.

Mandaviya observed that India was rightly called the pharmacy of the world. It was the largest manufacturer and supplier of generic medicines. During COVID, it supplied medicines to more than 150 countries of the world.

"It shows that the pharma industry is not just a business in India; it is connected with our sentiments. It is not governed with only profit motive but is guided by the Indian philosophy of Vasudhaiv Kutumbkam", he added.

Mandaviya said that under the Make in India Project, Prime Minister Modi has invited investors from all across the world to invest in India. He assured investors that they would be treated fairly in India, given its robust regulatory mechanism, independent judiciary and democratic form of government. He noted that the pharma sector has witnessed a substantial increase in investments.

Enlisting the various policies, schemes and initiatives of the government to encourage pharma industries, Mandaviya said that the Production Linked Incentive (PLI) scheme for the pharma sector would give a boost to the industry and has potential to make India a pharma hub. He underlined the fact that India was going to become a huge market for medicines and medical devices. He added that under Ayushman Bharat-PMJAY, 10 crore families would benefit. This would create demand for more drugs and medical devices, which would benefit the pharma industries in India.

Source: The Statesman, 30.10.2021

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Cipla's 'core' growth offsets weak show in US, Covid portfolio

ET Intelligence Group: **Cipla** posted higher-than-expected profit growth at 7% in the September quarter, aided by a 10% increase in **revenues**.

Contributing over 40% to total revenues, domestic **market** sales grew 16% on a high base of Covid-led drug sales. Sustained growth in the company's core therapies such as respiratory and urology compensated for the normalising contribution of the Covid **portfolio**.

Contributing over 40% to total revenues, domestic market sales grew 16% on a high base of Covid-led drug sales.

Sustained growth in the company's core therapies such as respiratory and urology compensated for the normalising contribution of the Covid portfolio.

The contribution of the Covid portfolio - standing at 5% of the overall revenues - has dipped significantly over the preceding quarter and over the September quarter in the previous year.

US sales have remained relatively flat - growing by 2% year-on-year. The company maintained the momentum from its core products and revenues of Albuterol and Arformoterol even as price erosion impacted the rest of the portfolio. The management is expecting a gradual ramp-up in **market shares** in the US. With certain big launches coming in by the third quarter of next fiscal, the US pipeline will be very well shaped up by the second half of next fiscal.

Besides the Covid portfolio, sales of the active ingredients business also normalised - declining by 9% over the previous year. The trade generics and consumer health business posted strong traction.

The operating margin stood at 22.3% - lower from the year-ago level of 23.5%. Price escalation in the Chinese-sourced raw materials and increase in variable sales expenses impacted the profitability.

With the management looking at exerting more discipline on pricing, savings on cost, and undertaking mix-improvement, it expects a lot of headroom to improve in each business on the margin front. According to the management, the launch momentum is the biggest tailwind while commodity price inflation - especially related to Chinese-sourced materials - is the biggest headwind.

Ramping up the chronic portfolio, improving productivity in India and South Africa, growing the respiratory categories in line with the aspiration of global lung leadership and building a strong US pipeline are the near-term business goals.

Cipla remains a promising bet for pharma investors. However, price erosion in the US market, input cost inflation and ramp-up in the non-Covid portfolio remain the factors to watch out for. The stock has remained range-bound over six months and may remain so in the near term.

Source: Economic Times, 27.10.2021

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NPPA fixes price caps for 12 anti-diabetic medicines

NPPA fixed the ceiling prices for 12 anti-diabetic generic medicines, including glimepiride tablets, glucose injection and intermediate acting insulin solution.

Drug price regulator National Pharmaceutical Pricing Authority (NPPA) on Monday said it has fixed the ceiling prices for 12 anti-diabetic generic medicines, including glimepiride tablets, glucose injection and intermediate acting insulin solution.

In a tweet, the drug price regulator said, "To make it possible for every Indian to afford medical treatment against diseases like diabetes, NPPA has initiated a successful step by fixing the ceiling prices of 12 anti-diabetic generic medicines." These include glimepiride tablet of strength 1 mg, with ceiling price at ₹3.6 per tablet, while that for 2 mg is ₹5.72 per tablet.

The ceiling price of 1 ml glucose injection of 25% strength has been fixed at 17 paise, while that of 1ml of insulin (soluble) injection of strength 40IU/ml is ₹15.09.

Similarly, 1 ml of intermediate acting (NPH) solution insulin injection of strength 40 IU/ml has a ceiling price of ₹15.09, and that of 1 ml of premix insulin 30:70 injection (regular NPH) injection of strength 40 IU/ml is also ₹15.09.

NPPA further said the ceiling price of metformin immediate release tablet of strength 500 mg has been fixed at ₹1.51 per tablet, while that of 750 mg strength is at ₹3.05 per tablet and 1,000 mg strength at ₹3.61 per tablet.

For metformin control release tablet of strength 1000 mg, the ceiling price is ₹3.66 per tablet, NPPA said, adding the same for 750 mg strength is ₹2.4 per tablet and ₹1.92 per tablet for metformin control release tablet of strength 500 mg.

Source: PTI, 25.10.2021

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'China using pandemic as an excuse to block Indian imports'

India has accused China of utilizing the excuse of Covid-19 contamination as a pretext to dam many Indian exports, significantly seafood, and has sought engagement with

Chinese language authorities on discovering methods to bridge the large commerce stability in Beijing's favour.

In its feedback at China's Commerce Coverage Evaluation (TPR), a periodic train on the WTO to weigh the commerce insurance policies of member nations, New Delhi additionally complained about issues being confronted by drug corporations in acquiring registration for his or her formulations in China, based on a Geneva-based commerce official. China's final TPR was in 2018.

Non-transparent insurance policies

"A number of nations criticised China's non-transparent commerce insurance policies and regulatory programs on the nation's TPR. India was significantly essential of the non-tariff obstacles that the nation is constant to erect towards Indian imports, particularly on the time of the pandemic, and its lack of efforts in direction of bridging the commerce hole between the 2 nations," the official stated.

Washington known as on different WTO members to take motion towards China's failure to completely adapt the open, market-oriented insurance policies of the WTO both inside the realm of the multilateral organisation or bilaterally, the official stated. The Australian Ambassador identified that the nation had acquired dependable info on directions being given to Chinese language corporations by the authorities asking them to not buy sure merchandise from Australia.

China's Commerce Minister Wang Wentao participated within the TPR on-line from Beijing with a group of 20 officers from 7 Chinese language authorities companies. The nation acquired over 1,600 written questions from 40 WTO members.

The Indian delegate, on the TPR, stated that it was alarming that through the pandemic, the usage of SPS (sanitary and phytosanitary) measures by China had risen steeply with the "unscientific" use of Covid-19 contamination as a pretext to dam Indian exports, together with seafood.

Indian pharmaceutical corporations, too, weren't in a position to get market approvals for his or her generics in China. The registration of formulations, which takes simply 5-6 months globally, was taking as much as three years in China, the Indian delegate stated.

New Delhi sought a gathering with Chinese language authorities to handle the $46 billion commerce deficit, the very best it has with any buying and selling companion, as the issue was lingering for a very long time. The Indian delegate identified that China had not but fulfilled the promise made in 2001 of offering market entry to 17 farm merchandise. The Chinese language Minister defended the nation's pandemic prevention measures and careworn that these have been scientifically primarily based and had not hit imports to the nation.

Source: Financial News, 25.10.2021

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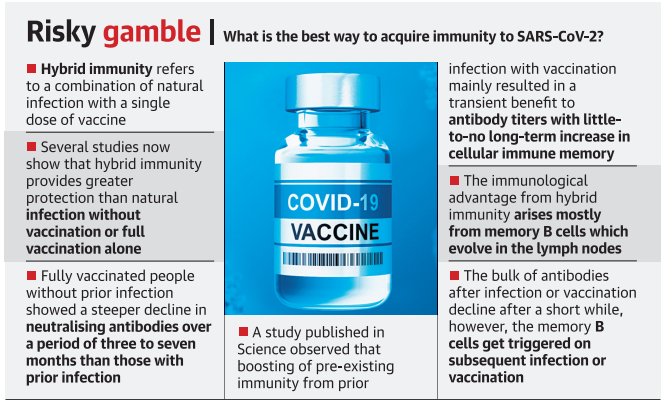
More studies show the superiority of hybrid immunity

Differences between the memory B cells triggered by infection, vaccination might also underlie the heightened responses of hybrid immunity

Yet another study has shown that a combination of natural infection with a single dose of vaccine provides greater immunity than either natural infection without vaccination or full vaccination in infection-naïve individuals. People without prior infection but fully vaccinated with the Pfizer or AstraZeneca vaccine showed a decline in neutralising antibodies over a period of three to seven months. But the decline was much less in vaccinated people with prior infection.



Though 500 health-care workers with or without prior infection were vaccinated, those with hybrid immunity — natural immunity from an infection combined with the immunity provided by the vaccine — had a higher and

more durable neutralising antibody response. The hybrid immunity offers stronger protection than just infection or full vaccination alone.

Neutralising antibodies

The study, posted in the preprint server medRxiv on October 19 (preprints are yet to be peer-reviewed), has found that in 500 health-care workers, the neutralising antibodies were twofold more in people immunised with Pfizer vaccine following natural infection compared with people immunised with Pfizer vaccine but without prior infection.

In the case of people vaccinated with AstraZeneca following natural infection, the neutralising antibodies were threefold more than in vaccinated people with no prior infection.

Early evidence

One of the early evidences of hybrid immunity being better than full vaccination in people without a prior infection came in end-April. The results posted in preprint server medRxiv found that vaccination led to increased levels of neutralizing antibodies against variants in people who had been previously infected compared with those without a prior infection.

An earlier study posted on August 25 in the preprint server medRxiv found that compared with vaccine-induced immunity from two doses of Pfizer vaccine, natural immunity conferred longer lasting and stronger protection against infection, symptomatic disease and hospitalisation caused by the Delta variant in Israel. But naturally infected individuals who were given a single dose of the vaccine showed additional protection against the Delta variant; the protection level conferred by hybrid immunity was even higher than the one offered by natural infection or full vaccination.

Soon after vaccines were rolled out, researchers began to notice higher levels of antibodies in people who were naturally infected prior to vaccination compared with vaccinated people without prior infection. In short, the hybrid immunity from natural infection followed by vaccination provided superior immunity than either natural infection alone or full vaccination.

Contrary point

However, a study published recently in the journal Science observed that "boosting of pre-existing immunity from prior infection with vaccination mainly resulted in a transient benefit to antibody titers with little to-no long-term increase in cellular immune memory".

There is a growing body of evidence that protection from natural immunity can be potent, and researchers are beginning to acknowledge this. However, scientific consensus about the exact strength or durability of the natural immunity post natural infection is not known. Also, the strength and durability of natural immunity might not be uniform and might vary between people depending on the nature and duration of infection (asymptomatic or symptomatic) and severity of disease (mild, moderate or severe).

"Antibody levels are really variable after recovering from infections, and those at the lower end of the spectrum might be more susceptible to reinfections," Deepta Bhattacharya, Professor of immunology at the University of Arizona told NBC News. "But after a single vaccine in people who have recovered from COVID-19, antibodies skyrocket up, including those that neutralize variants of concern."

Researchers at Rockefeller University in New York City looked at how different types of immunity would protect against potential variants. They modified the coronavirus spike protein such that it contained 20 naturally occurring mutations. In the lab, the modified spike protein was tested against antibodies from people belonging to three groups — those who have been fully vaccinated without prior infection, people with prior infection but not vaccinated, and people with hybrid immunity. They found the modified spike proteins were able to evade the antibodies from the first two groups but not antibodies from people with hybrid immunity. The study is posted in the preprint server BioRxiv.

In August, CDC published a study in the Morbidity and Mortality Weekly Report (MMWR) where they showed that unvaccinated people without previous infection are twice as likely to be reinfected compared with vaccinated people with a prior infection. This study prompted the CDC Director Dr. Rochelle Walensky to urge all Americans to take a vaccine even if previously infected. "If you have had COVID-19 before, please still get vaccinated," she appealed.

Immunological edge

The immunological advantage from hybrid immunity arises mostly from memory B cells. While the bulk of antibodies after infection or vaccination decline after

a short while, the memory B cells, which evolve in the lymph nodes, get triggered on subsequent infection or vaccination. So when people who recovered from COVID-19 are re-exposed to the spike protein, the memory B cells are capable of churning out highly potent antibodies.

"Differences between the memory B cells triggered by infection and those triggered by vaccination — as well as the antibodies they make — might also underlie the heightened responses of hybrid immunity. Infection and vaccination expose the spike protein to the immune system in vastly different ways," Dr. Michel Nussenzweig, an immunologist at the Rockefeller University in New York City told Nature.

Dr. Nussenzweig's team isolated hundreds of memory B cells from people at various time points after infection and vaccination. They found that unlike after full vaccination, antibodies produced by natural infection continued to grow in potency and their breadth against variants for a year after infection. According to Nature, unlike after vaccination, the memory B cells formed after natural infection are more likely to make antibodies that block immune-evading variants.

But two studies have found that memory B cells in the fully vaccinated people without prior infection are growing in number and gaining mutations up to 12 weeks after the second dose, which allows the B cells to recognise and neutralise variants.

Source: R Prasad, Financial News, 24.10.2021

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Biocon eyes $30b US insulin market via its biosimilars

With the approval of aspart, Biocon says it will become the first company to receive approvals for two interchangeable insulin drugs in the US, helping it make a strong entry into that market. This also proves that the company has the science and vertical integration required to get to the US market, it said.

Biopharmaceutical major

Biocon has its eyes set on the US insulin market, which is expected to grow to $29.9 billion by 2025, with its interchangeable biosimilar product Semglee that has received approvals and aspart that the company is hoping will be approved by the first quarter of 2022.

Biocon has demonstrated the ability to take very complex biosimilars to the US market...To take five products to the US and succeed is not a joke," Kiran Mazumdar-Shaw, executive chairperson at Biocon, said in an interaction with ET.

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"Biocon has demonstrated the ability to take very complex biosimilars to the US market, first with trastuzumab, pegfilgrastim and Semglee, and soon I hope bevacizumab and aspart. To take five products to the US and succeed is not a joke," Kiran Mazumdar-Shaw, executive chairperson at Biocon, said in an interaction with ET.

"We will be the only company in the US with two interchangeable insulins and therefore it sets us up for a big foray in insulins. I believe that it may end up being a slightly lower-margin business than antibodies, but certainly it is a very attractive business," she added.

Mazumdar-Shaw said Biocon's ability to get approvals for two interchangeable insulins in the US is a major milestone, and that it will add recombinant insulin to the offerings in the country, making for a full-basket of insulin offerings from the company there.

The success of Biocon in getting US regulators to approve its insulin drugs is an example of the company's growing clout in the biosimilars market, which Mazumdar-Shaw said is a "future-proof" business with more opportunities for growth emerging from it. She added that US approvals also set the stage for wider global adoption.

We have a first-mover advantage because right now we're the only company from India that has built the credibility that we have the science and the vertical integration that is required to get to the US market. The US market is the barometer for this. You can be in any other market, but to be in the US market is the hallmark of success," she said.

It also fits into India's pharmaceutical story, which recently received a huge recognition in managing to support the country's administration of 1 billion Covid-19 vaccine doses. A vast majority of the vaccine doses administered by India were manufactured at home, without having to rely on imports at a time when there is a global shortage.

"It was developed here, produced here and used to vaccinate our population, so that's fantastic," said Mazumdar-Shaw, referring to Covid vaccines.

Source: Alnoor Peermohamed & Raghu Krishnan, ET Bureau, 25.10.2021

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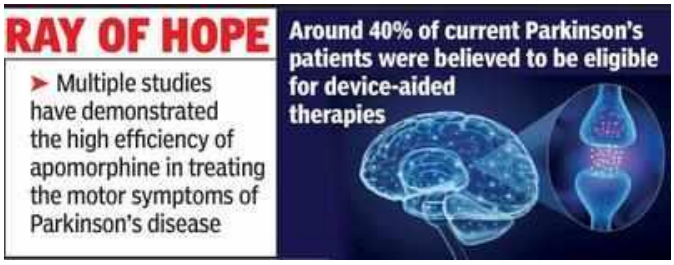
DCGI nod for device-aided therapy for Parkinson's patients



Hyderabad: Drug Controller General of India (DCGI) has given licence for new device-aided therapy for Parkinson's disease.

London-based researchers and Nizam's Institue of Medical Sciences (NIMS) doctors' research paper has revealed that personalised treatment could be done with device-aided therapy using wearable sensors in advanced Parkinson's disease.

Dr Vinod Metta, one of the lead researchers, said, "Parkinson's disease is a movement disorder affecting about 12 lakh people in India. Currently, only oral medications are available in India, and they are not effective in treating the symptoms."

"Oral medications are helpful in the initial years, but as the patient ages, their disease progresses, leaving them crippled and compromising their quality of life. Technology-driven device-aided therapy with apomorphine medicine given as subcutaneous injections and pumps has been a proven therapy for advanced stages of Parkinson's disease and been successfully used in the West," he added.

Multiple studies have demonstrated the high efficiency of apomorphine in treating the motor symptoms of Parkinson's disease."Apomorphine is delivered through devices as an intermittent therapy or continuous infusion therapy. Intermittent therapy is delivered using a pen device similar to that of an insulin pen. Continuous therapy is delivered using a pump which is similar to an insulin infusion pump," Vinod Metta said. "Apo pen injections works within 6-10 minutes and last for 90 minutes, these can be used as a rescue injections whereas Apo pump with continuous infusion is able to help patients as long as infusion in place, ideally most of the patients were given wakeful hours so that they no need to keep pump overnight," the researcher said. Around 40% of current Parkinson's patients were believed to be eligible for device-aided therapies. Apomorphine injection & infusion should be considered before even referring Parkinson's patients to more conventional deep-brain surgeries say experts. Drug Controller General of India permission was given to Hyderabad-based Celera Pharma Private Limited along with Germany-based EVER Neuro Pharma.

Source: U Sudhakar Reddy, TNN, 25.10.2021

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Germany's Boehringer, Indian pharma in legal battle over diabetes drug

The German drug maker has obtained interim injunctions against MSN Labs and Dr Reddy's Lab

German drugmaker Boehringer Ingelheim (BI) has obtained two separate interim injunctions against two Indian drugmakers – MSN Laboratories and Dr Reddy's Laboratories – who launched cheaper, generic versions of their anti-diabetic drug empagliflozin.

BI holds a patent for Empagliflozin under the name Jardiance in India till 2025, the company said

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A Boehringer Ingelheim India spokesperson said that it has obtained two separate orders granting ad-interim injunction that restrains the two domestic pharmaceutical

manufacturers from 'launching, making, using, offering for sale, selling, importing and/ or exporting their respective generic version of Empagliflozin drugs'.

"Boehringer Ingelheim holds a valid patent for Empagliflozin in India until 2025. These orders have been passed based on the prima facie satisfaction of the strength of Boehringer Ingelheim's patent and on the patent infringement by the two domestic pharmaceutical manufacturing companies. Our faith in the Indian Patent system and the enforcement of patent rights is re-affirmed with this ad-interim injunction," the spokesperson added.

DRL and MSN Labs had launched cheaper copies of BI's Jardiance recently.

MSN Labs had said in a statement on October 18 that it has launched India's 'most affordable' empagliflozin tablets under the brand name Empaone priced at Rs 15.9 and Rs 18.9 for each 10 mg and 25 mg tablet.

DRL's brand for empagliflozin is Vicra. These generic drugs are priced at almost one-third the innovator brand Jardiance which costs Rs 51 and Rs 62 for a 10 mg and 25 mg tablet.

DRL, on the other hand, said that it was in full compliance of legal orders.

A company spokesperson told Business Standard that, "We are in full compliance of legal orders. Dr. Reddy's filed a patent revocation petition before the Hon'ble High Court of Delhi on 16th October to challenge the validity of the existing patent. The Hon'ble High Court of Delhi has issued notices accordingly to concerned parties."

The spokesperson went on to add that they believe that the patent that has been asserted is invalid based on legal opinion sought and received.

"We are monitoring the situation closely, and will continue to take all appropriate and timely action. We believe there is a strong case for wider access to this important life-saving drug at affordable prices. In keeping with our purpose, we remain committed to ensuring affordability and access to the patient population in India and across the world in line with our credo of 'Good Health Can't Wait'," DRL said.

MSN Labs said they did not wish to comment on the matter. In its October 18 statement, MSN had noted that Empaone is intended to provide diabetes patients in need an affordable and accessible therapeutic option.

"India being the diabetic capital of the world with over 77 million people suffering from Type 2 diabetes, this medicine will minimize the cost burden on patients and in turn improve compliance," the company had said then.

Jardiance or empagliflozin falls in a generation of anti-diabetes drugs called SGLT-2 (sodium glucose co-transpoter-2) inhibitors. This class of drugs work by preventing the kidneys from re-absorbing glucose back into the blood. This, thereby, allows the kidneys to lower the blood glucose levels and excess glucose in the blood is removed from the body via urine.

Jardiance sales are around Rs 250 crore a year. SGLT-2 inhibitors are a popular and growing category of diabetes medicines valued roughly at around Rs 5000 crore or so.

Gliflozins or SGLT-2 have clocked a strong double digit growth since Johson & Johnson launched its canagliflozin in April 2015. This was followed by AstraZeneca's dapagliflozin in June 2015 and Boehringer Ingelheim's empagliflozin in November 2015. Since then, these companies have partnered with domestic majors to market their drugs. Recently Glenmark disrupted the market with its low-cost innovation remogliflozin. In December, Glenmark partnered with Mankind Pharma to market this drug.

Diabetes is a lucrative category for two reasons – one these are chronic medicines and the pandemic has shown that demand for such therapies hardly wanes, and secondly only 5 percent of this market is covered under the National List of Essential Medicines or is under a price cap.

Source: Business Standard, 26.10.2021

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Cipla launches anti-viral nasal spray Naselin to protect against coronavirus, respiratory tract infections

With powerful antiviral properties, the nasal spray is suitable for wide use, especially by the high risk category of essential service worker

Respiratory tract infections

With powerful antiviral properties, the nasal spray is suitable for wide use, especially by the high risk category of essential service workers. Cipla Health Ltd has launched Naselin Anti-Viral Nasal Spray with Povidone Iodine called as Naselin to protect against coronavirus and respiratory tract infections. With powerful antiviral properties, the spray

Over the years, povidone iodine has been widely used in products such as gargle solution, ointments and creams. However, its usage in a nasal spray format is a disruptive innovation by Cipla Health to ensure potential insulation at grass-root stages of infection.

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Research shows that povidone iodine can act as the first line of defence against the SARS-CoV-2 virus that causes COVID 19. povidone iodine is a molecule with anti-viral, anti-bacterial and anti-fungal properties, which helps to protect from viruses and other germs that cause common upper respiratory tract illnesses like cold, sinusitis or flu.

The Naselin Anti- Viral Spray ensures its relevance beyond the current Covid context to any other respiratory tract discomfort. The 15ml spray bottle priced at Rs 99 is available across 700 Apollo and Medplus pharmacy in Maharashtra, Andhra Pradesh and Telengana as well as online e-commerce platforms such as 1mg and Pharmeasy.

Commenting on the launch of the landmark product, Shivam Puri, CEO, Cipla Health Ltd said, "With a strong commitment to Research & Development, our products have demonstrated effectiveness against a host of health conditions to help people with speedy recovery. In line with this commitment, we are delighted to bring to our consumers one of the most innovative and effective product formulations for preventive care against coronavirus. Adding Naselin Anti-Viral Nasal Spray to our regular routine along with wearing mask, washing hands, and maintaining social distance can definitely help us to fight this pandemic together."

The spray acts by killing the disease causing viruses and bacteria in the nose. Multiple studies have shown that cells lining the nose are a key entry point for SARS-CoV-2. The use of topical antiviral drugs at the nasal region is essential for preventive–care. Through the convenient packaging of Naselin Anti-Viral Nasal Spray, Povidone Iodine offers an easy and powerful means of protection against COVID.

With normalcy returning, health authorities are now emphasizing on following all safety protocols when stepping out of the house. This has spiked the demand for relevant healthcare products; nasal care being one of them. To cater to this demand, Cipla health's Naselin Anti-Viral Nasal Spray is designed as an everyday aid.

Source: FE Online, 27.10.2021

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Progressive Punjab Investors' Summit: Bizmen promise to invest big in edu, textile, automobile, pharma sectors

Trident announces Rs 2K cr, HUL Rs1,200 cr

On the first day of Progressive Punjab Investors Summit, 2021, a galaxy of corporate leaders articulated business plans for the state.

The biggest announcement came from homegrown major Trident Group, who promised aggregate investment of Rs 2,000 crore in the next 18 months, offering employment to around 10,000 people in rural and semi-urban areas. Trident Group Chairman Rajinder Gupta said the group was ready to partner with the state government for setting up a mega textile park in the state under the Centre's PM-MITRA scheme.

Already having presence in the state, Hindustan Unilever Limited (HUL) Chairman and Managing Director Sanjiv Mehta said the company would invest another Rs 1,200 crore in the state in the next five years.

Mahindra Group Chairman Anand G Mahindra also announced to set up its third tractor factory in the state shortly. He said his group was keen on working with the state government in hospitality sector and had plans to set up a five-star resort under Mahindra Holidays entity

at Ranjit Sagar Dam. He also shared his plans to roll out electric three wheelers for last mile connectivity.

Amity University Chancellor Dr Atul Chauhan said he planned to invest another Rs 300 crore in the next two-three years and would set up educational institutes across the state. Amity has already invested around Rs 500 crore in setting up a world class university in Mohali.

Having a manufacturing unit in Mohali, Dilip Shanghvi, Founder and MD, Sun Pharmaceutical Industries Ltd, outlined that his company would continue investing in Punjab. Also, Sanjiv Puri, Chairman and MD, ITC, said the company had already acquired additional land for expansion at the company's food park in Kapurthala. Prakash Hinduja of Hinduja Group assured the state government that he would ask his officials to consider Punjab as a preferred destination.

Kumar Mangalam Birla, Chairman of the Aditya Birla Group, said his group had already committed Rs 1,500-crore investment in the state — Rs 950 crore would be invested in setting up a paint manufacturing unit and the remaining Rs 500 crore in a cement unit in Rajpura.

JK Paper Ltd Vice-Chairman and MD Harsh Pati Singhania has already committed an investment of Rs 150 crore in the state for setting up a corrugated packaging paper manufacturing unit in Ludhiana.

Source: The Tribune, 27.10.2021

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Novartis weighs sale or spinoff of generic drug unit Sandoz

Swiss drug giant's review of generics business comes as it grapples with falling prices for copy-cat medicines

Novartis AG said it is considering the sale or spinoff of its generic drugs business Sandoz, a move that would focus the once-sprawling healthcare conglomerate solely on innovative prescription drugs.

Sandoz, like many generic drugmakers, has struggled with falling prices in the U.S. in recent years. Generic drugs are lower-cost versions of prescription medicines whose patents have expired. While their prices are usually far below those of the branded drugs that they imitate, increased competition has driven those prices even lower in recent years.

In response to greater competition, Novartis has pivoted Sandoz toward higher-value generics, such as biosimilars, which are near-replicas of biologic drugs made using living cells. Sandoz has also become an autonomous unit within Novartis, to give it more flexibility. But the unit, which accounts for around a fifth of total sales for Novartis, has still proven a drag on the company's growth. In the third quarter, Sandoz sales fell 2% at constant currencies to $2.4 billion despite volumes increasing. Sandoz's U.S. sales dropped 20%.

Novartis shares were up 0.9% in early trading.

Chief Executive Vas Narasimhan said Tuesday it was the right moment to review Sandoz's strategic fit within Novartis. The company said it had launched a strategic review of Sandoz that would consider all options, from retaining the business to separating it. Dr. Narasimhan said he expects to complete the review by the end of next year.

Wimal Kapadia, analyst at Bernstein, said in a note that while Sandoz was a reliable cash-generator for Novartis, the unit would be more profitable, and probably generate higher returns on capital, if it were to be sold or spun out into a stand-alone business.

A separation of Sandoz would be the final step toward Novartis focusing solely on innovative drugs. Over the last decade, it has shed units that sold animal medicines, vaccines, drugstore staples, contact lenses and tools for eye surgery.

Since taking the helm in early 2018, Dr. Narasimhan has doubled down on innovative medicines and cutting-edge technologies such as gene therapies and radiopharmaceuticals, drugs that carry radioactive particles to tumors for close-range radiotherapy. He also placed a big bet on cholesterol-lowering drug inclisiran, which Novartis acquired around two years ago through a $9.7 billion deal for The Medicines Company. Inclisiran is currently under

review with the Food and Drug Administration with a decision expected early next year.

The announcement of the Sandoz review came as Novartis reported that third-quarter sales increased 5% at constant currencies to $13.03 billion, driven by strong sales of some of its prescription drugs. Operating income rose 32% to $3.23 billion.

Novartis also boosted its long-term sales expectations for its two top-selling drugs, Entresto for heart failure and Cosentyx for various immunological conditions. It now expects Cosentyx to generate revenue of at least $7 billion a year at its peak, up from earlier guidance of $5 billion. It expects Entresto to make at least $5 billion a year at its peak, up from $4 billion previously.

Source: HT Hint, 27.10.2021

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PM Modi meets Indian Covid vaccine manufacturers; CEOs say his leadership key force in vaccination drive

Modi is likely to emphasise on ways to vaccinate eligible people in India as quickly as possible and also help other countries in inoculating their population as part of the mantra "vaccine for all", an official source said.

Prime Minister Narendra Modi on Saturday met Indian COVID-19 vaccine manufacturers who said his leadership was a key factor in India being able to administer 100 crore doses of the jabs in just about nine months.

During the meeting, Modi discussed various issues including furthering the vaccine research, sources said. Representatives from seven vaccine makers -- Serum Institute of India, Bharat Biotech, Dr Reddy's Laboratories, Zydus Cadila, Biological E, Gennova Biopharma and Panacea Biotech -- participated in the meeting.

Following the meeting, Adar Poonawalla of Serum Institute of India credited Modi's vision for the milestone and said they in the meeting discussed how to take the industry forward and prepare for future pandemics, to continue enhancing the capacity. "All over the world now, countries are going to invest in vaccine production and India needs to stay ahead. We discussed how to do that together with industry and government," he said.

His father Cyrus Poonawalla said, "Had it not been for him (Modi) and (he) driving the health ministry, today India would not have been able to make a billion doses. There is no doubt in my mind about that."

The prime minister was happy that the assurance given by the Serum Institute that it will make India self-sufficient in vaccines at the lowest possible price in the world was fulfilled. "The PM went out of the way and made regulatory people move very fast and they also cooperated," he added.

Pankaj Patel of Zydus, another vaccine maker, said Modi was the "biggest factor" in the development of the DNA-based COVID vaccine.

He praises the prime minister for his encouragement and support and also for mentioning the DNA vaccine at his address at the United Nations.

Union Health Minister Mansukh Mandaviya and Union Minister of State for Health Bharati Pravin Pawar were also present in the meeting.

The cumulative COVID-19 vaccine doses administered in the country have exceeded 101.30 crore, according to the latest health ministry data. On October 21, India achieved a major milestone in its vaccination programme against COVID-19 as the cumulative vaccine doses administered in the country surpassed the 100-crore mark, resulting in celebratory events across various parts.

More than 75 per cent of India's adult population has received at least one dose of COVID-19 vaccine, with nine states and union territories administering the first dose to all eligible people. Over 31 per cent of the country's around 93 crore adults have been administered both doses, according to health ministry officials. So far, all adult population in nine states and union territories -- Andaman and Nicobar Islands, Chandigarh, Goa, Himachal Pradesh, Jammu and Kashmir, Lakshadweep, Sikkim, Uttarakhand and Dadra and Nagar Haveli -- have received at least one dose of the Covid vaccine.

Three vaccines -- Covishield manufactured by Serum Institute of India, Bharat Biotech's Covaxin and Sputnik V -- are currently being used in the country's Covid vaccination drive.

Source: Economic Times, 23.10.2021

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No shortcuts used to develop Covaxin: Dr Renu Swarup, Secretary, Department of Biotechnology

Swarup details how the pandemic has bolstered India's preparedness for various medical eventualities.

Dr Renu Swarup

Renu Swarup, secretary, department of biotechnology, has been at the helm of the government's efforts to boost vaccine development in the country. In an interview with **Teena Thacker** ahead of her retirement on October 31, she discussed Covid-19 vaccine Covaxin, which is struggling to get approval from the WHO, mRNA vaccines and how the pandemic has bolstered India's preparedness for various medical eventualities. Edited excerpts:

What would you say about this journey of one-and-a-half years?

From January of 2020 to where we are today, it has been a remarkable journey, in the sense that we were suddenly faced with this new challenge and the effective response has been so wonderful. The best is that this time, when we completed 100 crore doses, the prime minister said it's a triumph of science, and that truly says everything. Of course, the major role has been played by the citizens- we had to come forward, whether it was for vaccination, adopting Covid-appropriate behaviour, etc. This has given us the confidence that India now has the ecosystem which has responded to this pandemic, and for any future emergency, we are geared up to respond.

What were the major challenges for research work and vaccine development in the times of Covid?

The biggest challenge was when the pandemic came in, we had all the groups working on it, but with the lockdown, supply chain disruptions and travel restrictions, we were not used to virtual connections. We had to identify our gaps, needs, creating an immediate framework and a roadmap and then working on it to be able to come forward. Scientists were used to a different way. Thing changed. For example, the movement of samples... You are using resources and everything is not there where you are. You are doing studies at one place, but need to go to another place for animal studies. So I think that was the bigger challenge.

Did India have enough funds to deal with the situation?

We were given mission Covid Suraksha of ₹900 crore. We could bring together academia, stakeholders, industry and startups. There was another research consortium we put in. The CSIR, DST, Niti Aayog, ICMR - everyone put in the research grants. It's difficult to put a number to it. But it was a whole government approach, together we tried to pool in resources from wherever they were. I think this has been the best that everyone has worked across departments without any boundaries. I can say wherever there was any requirement we have not suffered due to lack of funds. The ecosystem we built in the last 1.5 years has been the most robust.

DBT closely monitored development of vaccines, especially Covaxin. Given the delay in getting WHO approval, do you think corners were cut in developing Covaxin?

Not at all. There's no question of compromise. We have accelerated the response. There's no shortcut. What we have been able to do is help many actions happen in a parallel manner, rather than waiting for it to be done sequentially. Importantly, it was sharing of knowledge and data that made it so much faster. We have shared a lot of data, knowledge and best practices, nationally and globally, and this is the learning that will take us beyond Covid for many others.

If mRNA is so good. Do you think the government has made a mistake by not giving in to the indemnity requirements of Pfizer and Moderna?

We have already got good results from the mRNA we are doing. We have reached late-phase trials. We should be getting it very quickly. This is going to be the only indigenous vaccine that is going to be at 2-8 degrees and has a huge potential.

Source: Teena Thacker, ET Bureau, 30.10.2021

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