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IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 07 (PAGES: 40) | 15 TO 21 FEBRUARY 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 Issue No. 07 15 to 21 February 2021

IDMA ACTIVITIES:

NPPA MATTERS:

GOVERNMENT COMMUNICATIONS:

CCI MATTERS:

DGFT MATTERS:

PARLIAMENT NEWS:

NEW DEVELOPMENTS:

NATIONAL NEWS:

FEATURE:

IDMA & Andhra Pradesh Economic Development Board (APEDB) – Interactive Meeting held on 18th February 2021

The Secretary-General, Mr. Daara B Patel initiated the proceedings and delivered his opening remarks and welcome address on behalf of our National President, Mr. Mahesh H Doshi.

Mr Patel welcomed the below mentioned dignitaries:

- Shri J V N Subramanyam, IAS, Commissioner Industries, Commerce & Export Promotion and CEO APEDB
- Shri Raveen K. Reddy, IRTS - VC & MD APIIC - Andhra Pradesh Industrial Infrastructure Corporation (APIIC)
- Shri Yogin R Majmudar, Past National President, IDMA & Chairman, Bulk Drugs Committee, IDMA
- Shri S M Mudda, Chairman, Regulatory Affairs Committee, IDMA
- Dr. Viranchi Shah, Sr. Vice President, IDMA
- Ms. Lakshmi Prasanna, Director - Regulatory, Pharmexcil

and Officials of the Andhra Pradesh Economic Development Board (APEDB), Members of the Executive Committee, Members of Telangana State Board and its Chairman Shri Shaik Janimiya and all the participants.

He mentioned that IDMA is very keen to set-up a State Board in Andhra Pradesh with the help and assistance of the Officials of APEDB.

He further said that the pharmaceutical industry in India is almost 40 billion plus and is one of the fastest growing industry and is also a huge foreign exchange earner for our country. He said that we have been in dialogue with State Governments and the Centre for the need to smoothen the Environment norms as well as the need to set-up a Common Effluent Treatment Plants (CETP).

Shri Yogin R Majumdar, our Past National President and our Chairman for Bulk Drugs Committee, IDMA briefed us about the requirements of the Industry and IDMA. He said that Manufacturers need to do primary treatment and if there is a Common Effluent Treatment Plant (CETP) around the cluster of manufacturing plants, it will save cost.

Thereafter, Shri S M Mudda, Chairman, Regulatory Affairs Committee, IDMA shared information regarding upgradation of the Pharma Industry from revised Schedule M to WHO-GMP and the costs involved in the upgradation.

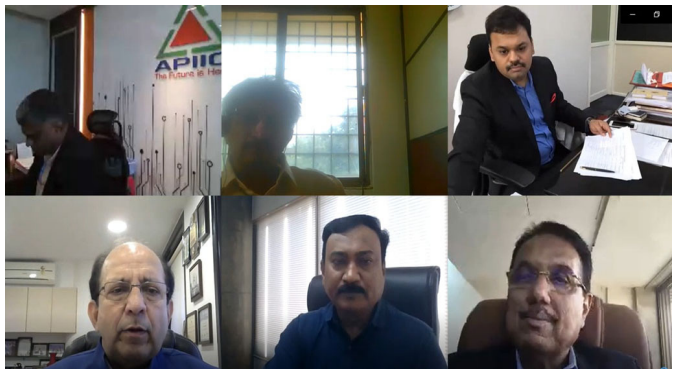
Shri J V N Subramanyam, IAS and Shri Raveen K. Reddy made presentations which covered the following points:-

1. **Brief Industrial Ecosystem of Andhra Pradesh**
2. **Existing Pharma Ecosystem in Andhra Pradesh & incentives that could be offered to the pharma units.**
3. **Initiatives taken by Government of Andhra Pradesh on addressing Environmental Management and reducing Cost & Risk of doing Business in Andhra Pradesh**
4. **Brief on the Pharma Industrial Parks in Andhra Pradesh**
5. **Brief on Export Promotion initiatives by Government of Andhra Pradesh**

The detailed presentations are reproduced in the following pages:

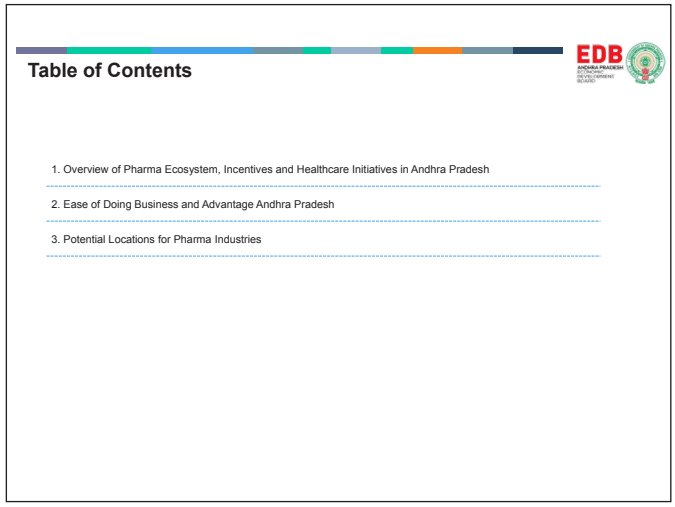
After the presentation, a few questions were answered by Shri J V N Subramanyam, IAS and Shri Raveen K. Reddy.

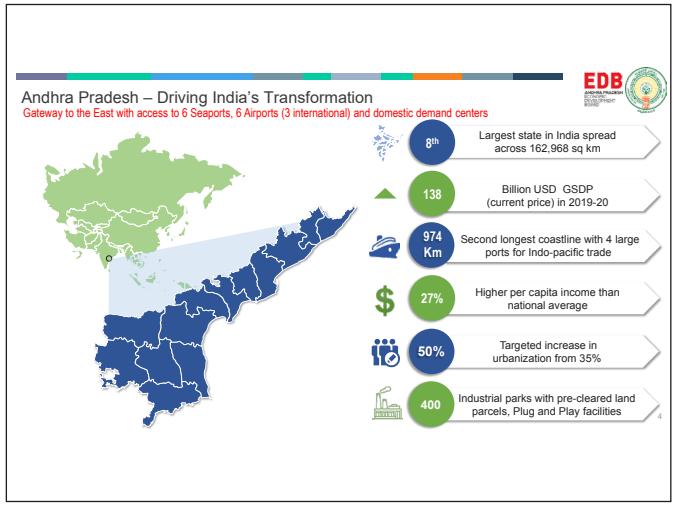
Dr. Viranchi Shah, Sr. Vice President, IDMA delivered the vote of thanks by thanking the APEDB Officials for a wonderful webinar. He thanked Shri Yogin Majmudar, Shri S M Mudda and Mr. Daara B Patel from IDMA for their support and co-ordination. He also thanked Ms. Lakshmi Prasanna and Pharmexcil for their support.



PRESENTATIONS

Delivered by Shri J V N Subramanyam, IAS and Shri Raveen K Reddy at IDMA & Andhra Pradesh Economic Development Board (APEDB) – Interactive Meeting held on 18th February 2021



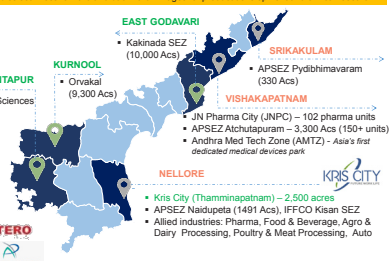


Pharma Ecosystem in Andhra Pradesh

Home to 250+ APIs/Bulk Drug units - 38 WHO approved and 20 USFDA approved

- **16% of India's production value** as on FY 2018-19 i.e., INR 44,000 Cr (USD 6.3 bn)
- **6% of national exports** as on FY 2018-19 i.e, INR 24,538 Cr (USD 3.5 bn)
- **Attracted over INR 18,000+ Cr (USD 2.5 bn)** investments as on date
- Generated about **88,984 direct employment**
- **6%** share of **Pharmaceutical and Medical Devices Sector** in State's GVA
- Constituted **Andhra Pradesh Bulk Drug Infrastructure Corporation (APBDIC)** to set-up bulk Drug Park under PPP
- **IICT-CSIR** as Knowledge Partner

Primary focus of AP's pharma industry has been on Bulk Drugs, while the pharma value-chain in AP enables seamless forward and backward linkages for product development and clinical research



Major Players

Biocon, Granules, Lupin, Hetero, Dr. Reddy's, Mylan, Laurus Labs, Aurobindo

* NEW PHARMA LOCATIONS * EXISTING ECOSYSTEM

Andhra Pradesh Med Tech Zone (AMTZ)

India's 1st Integrated Medical Devices Manufacturing Park

The **Andhra Pradesh Med Tech Zone (AMTZ), setup in 270 acres in two phases**, aims to put India on the global map of high-end medical equipment production and make health care products affordable and accessible

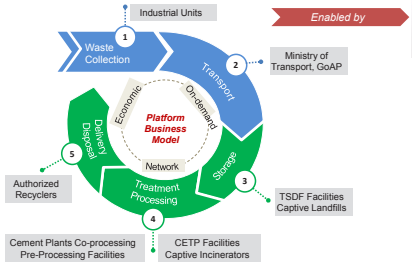
- **85 companies contributing to 14,000 employment**, with production target of USD 3.5 Bn in 3 years
- Presence of **largest federal govt (INR 10 Cr) funded incubation centres**, Medi Valley Atal Incubation Centre, ECRI Institute, Bio Valley Incubation Council
- **WHO Prequalification cell** for IVD manufacturers
- **Common Facilities** – Gamma Irradiation Facility, Biomaterial Testing, Superconducting Magnetic Coil Research & Production, Electro-magnetic center

Major Players

Biosense, primor, TRANSASIA, PHOENIX, omix labs, thinkBD, ZYNA, IDQ, MASS MEDTEK

AP Environment Management Corp Ltd – *Minimizing Cost of Doing Business*

First State to incorporate a government entity to provide effective mechanism for collection, transportation, storage, treatment, processing, delivery and disposal of the industrial and other wastes by Pharma units



Enabled by

Ministry of Transport, GoAP

Online Waste Exchange Platform

2683 Waste Generators,
86 Waste Receivers
980 TPD Waste Generated and Disposed

Salient Features

- 100% tracking of waste generation and disposal
- GPS Vehicle tracking for movement of waste
- Scrutiny and audit of waste
- Safe disposal of toxic waste
- Promote usage of recycled waste
- Promoting 6 R's of waste management – Reduce, Reuse, Recycle, Refurbish, Redesign and Remanufacture to protect environment

To make the waste management market more organized and enhance existing facilities meet the future needs of pharma industries

Waste and Manifest Management – *Service Charges for Waste Management*

With inputs and recommendations from BDMA, Cement Industries Association, CETPS, TSDFs, APFICCI, Pre-Processing units and Oil Reclamation (Recycling) units

Facilities Offered	Current Capacity	Planned Capacity
CETP	30.97 MLD	39.7 MLD
TSDF	10,25,000 MT	10,00,000 MT
Waste Pre-Processing Facility		50,000 MT *(APIIC Atchutapuram)*

#	Hazardous Waste	Service Charge (per Ton/ KL)
1	Utilizable Waste	INR. 100
2	Recyclable Waste	INR. 10
3	Incinerable waste	INR. 200
4	Landfillable Waste	INR. 50

#	Non-Hazardous Waste	Service Charge (per Ton/ KL)
1	Fly Ash	INR. 5
2	Domestic Solid Waste	INR. 1
3	Plastic, Glass	INR. 2

#	Liquid Waste	Service Charge (per Ton/ KL)
1	HTDS	INR. 50
2	LTDS	INR. 25
3	Marine Outfall	INR. 10

Pre-processing Facilities for sending pre-processed waste to cement industries for co-processing – **INR 25 per ton/KL**

AP Industrial Policy 2020-23 & Bulk Drug Special Package Incentives

STAMP DUTY/ TRANSFER DUTY
- 100% Reimbursement

INVESTMENT SUBSIDY
- 15% upto INR. 20 lakhs

LAND CONVERSION
- 25% of Conversion charges

R&D INCENTIVES
- 10% of cost of establishment, limited to INR. 5 Cr
- 50% of registration for Product Approval , upto INR. 25 lakhs

POWER SUBSIDY
- Rs. 1/- per unit for 5 years

NET SGST
- 100% Reimbursement for 10 years, upto 125% of FCI

Composite Lease cum Buy Model to de-risk investments and reduce upfront costs

About **4.9 Lakh** Semi-skilled, **3.1 Lakh** Skilled, and **12,000+** B.Pharm/ M.Pharm/ Chemical Engineers Talent pool is available around potential locations on annual basis

Tailor-made Incentives
For Investment proposals that generate employment for more than 2,000

- Micro – Upto INR 1 Cr ($ 0.14 mn), Turnover - INR 5 Cr ($ 0.7 mn)
- Small – Upto INR 10 Cr ($ 1.4 mn), Turnover - INR 50 Cr ($ 7.2 mn)
- Medium – Upto INR 50 Cr ($ 7.2 mn), Turnover - INR 250 Cr ($ 35.7 mn)
- Large – Upto INR 500 Cr ($ 72.0 mn); Mega: >INR 500 Cr (>$ 72.0 mn)

Industries enjoy competitive advantage in Andhra Pradesh over other leading Indian states in terms of operational cost

Competitiveness Factor	Competing States						
	Andhra Pradesh	Gujarat	Uttar Pradesh	Maharashtra	Tamil Nadu	Telangana	Karnataka
India's coastline with port connectivity	East	West	-	West	East	-	West
Ease of Doing Business Ranking *	1	10	2	13	14	3	17
Water Supply (INR /KL)	50-55	43 - 60	*Depends on the pipe size*	20 -240	45 - 150	Rs.50/kl (0-15Kl) Rs.80/kl (16-100kl) Rs 120/Kl (101-200kl)	25-125
Skilled Labour Wage (INR per day)	233.3	322.6	329.2	312.7	241.4	280.5	314.94
Average Land Cost (in INR mn /acre)	5.0 – 6.0	19.8	19.7	14	21	9.5	15-16
Industrial Power Tariff Per Unit (INR /Kwh) factoring demand charges	*6.00 – 7.00*	8.00	9.04	10.08	8.34	7.00 – 7.50	8.6

** Performance of States on Ease of Doing Business (2018-19) by Ministry of Commerce & Industry, Govt. of India and World Bank*

Healthcare and Public Health Initiatives in Andhra Pradesh

Sector	Healthcare	CoE with Johns Hopkins University in Vizag
Strengths	• **"YSR Kanti Velugu Programme"** in the state to provide free eye care, tests, surgeries, etc ✓ INR 560 Cr (USD 80 mn) allocated for six phases over 3 years, benefitting 5.4 cr people • **INR 200 Cr (USD 30 mn) allocated to medical colleges** with **INR 1600 Cr (USD 230 mn) dedicated for infrastructure development** in hospitals and medical buildings ✓ 25 Medical Colleges – 10 Govt & 15 Pvt ✓ 1145 PHCs, 196 CHCs, 8 UHCs, 243 e-UPHCs	• **Analyses of HIV/TB/COVID program** data to improve quality/ efficiency • **Develop models** for children/adolescents to link to social welfare/protection schemes/education • **Establish clinical research sites in AP** to conduct research related to HIV/TB/COVID and other infectious diseases • **Capacity building workshops** (1-5 days) for AP program staff and students on public health ✓ Population surveillance tools for as part of digital health initiative ✓ Predictive analytics to improve efficiency of programs
Key Initiatives	• **INR 93 Cr (USD 13 mn) budgeted for** improvement of Palasa Kidney Research Center and State Cancer Institute • **Launched 1,088 new ambulances** under 108 and 104 service equipped with modern life support system to address emergency care	

Ease of Doing Business and Advantage Andhra Pradesh

Going beyond Ease of Doing Business

Vision: *Andhra Pradesh to be the most preferred investment destination with sustainable growth*

Beyond EoDB

Minimizing Cost of Doing Business
- Rationalization measures in fees charged, cost of compliances etc.
- AP Environmental Management Corp Ltd, 'Platform-business model' for waste collection and disposal
- Ready Built Factories/ Plug & Play Facilities
- Skill Development

EoDB + Perception

Implementation based rankings
- Implementation of Business Reform Agenda shared by DPIIT,
- Business Process Re-engineering, Time bound service delivery,
- Online payment & status tracking of application

Ease of Doing Business (EoDB)

1st in BRAP 2019 under Ease of Doing Business

2020-21
- **Reducing Risk of Doing Business**
- Lease cum buy model to minimise risk of capital
- "Industries Spandana" Query and Grievance
- Centralized land encumbrance information systems
- Alignment of Relationship Mangers to ensure setting up compliance with all requirements
- Export Promotion Committees at district level
- Reforms in compliance inspection to reduce risk of interruption in operations

2020

2019
- **EoDB | Ranked 1**
- **Perception based rankings**
- Ensure reform implementation at ground level
- Encourage usage of Single Window Portal
- Building capacity of investors and staff on newly implemented systems and reforms
- Kicked Off District Outreach workshop in Jan 2021 at Vizianagaram

2017

2016

2015

Business Re-engineered Reforms – *Minimizing Cost of Doing Business*

Highest
Rating in BRAP 2019 perception survey

130+
Integrated Industrial Parks into APIIC Information Server IIS

1st
State to comply with DBRAP reforms (Received INR 2,500 Crores under enhanced borrowing limit)

The AP Shops and Establishment Act
- Re-engineered to provide Registration of AP Shops & Establishment Act with Trade License through Single Form
- Re-engineered to eliminate the requirement of renewal of Registration of Shops and Establishment Act

The Contract Labour Act
- Introduced SPOT Approval for all registration and licences under Labour Laws
- Introduced auto-renewal of License under The Contract Labour Act on payment of requisite fees

The Factories Act
Introduced Grant of License under Factories Act with perpetual validity eliminating the need for renewal

Legal Metrology
Re-engineered to eliminate the need to submit renewal application. The licensees can now directly pay the fee and extend their license for one more year

Drug Manufacturing License
Introduced retention (auto-renewal) of Drug Manufacturing License on payment of requisite fees

Trade License
Introduced auto-renewal of Trade License on payment of requisite fees

Meetings with Professionals, Industrial Associations and Industrialists

What contributed to highest perception approval?
- Outreach
- Prompt clearances
- Timely Grievances redressal
- Fulfillment of promises
- Building of confidence during crisis (Release of Rs 905 Cr incentives to MSMEs pending since 2014-15

Kicked Off District Outreach workshop on Jan 19, 2021 at Vizianagaram

Seamless Governance and SDP Impact – *Minimizing Cost of Doing Business*

Approvals
- **12,870** online applications approved since April 2019
- **99.03%** applications approved within SLA (21 days maximum)
- **10 days –** average time of approval

Industries
- **5,908 industries** *(5,169 MSME, 291 Large, 448 Mega)* have been registered on Single Window Portal since April 2019

Services & Inspections
- **23 Approval Departments** and 91 Online Services are offered
- **7,800 compliance inspections** were conducted (since 2019) through CIS with online allotment, scheduling and report generation

Process Improvement
- MIS reports and swift feedback paved way for building fee rationalization measures **reducing fee by 40%**
- Documentation requirement **reduced by more than 70%**

INVESTEMENT POTENTIAL INDEX	COMMERCE & INDUSTRIES	GLOBAL COMPETITIVENESS INDEX	LEADS INDEX
# 3rd By NCAER	# 2nd For Industrial Growth	#36th By WEF	#1st By Ministry of Commerce & Industry, Govt of India

Promoting Districts as Export Hubs – *Reducing Risk of Doing Business*

- Created **Export Promotion Committees** at district level
- **Connecting with Embassies** to find buyers for local enterprises
- Preparing District Profiles on export scenario with **EXIM Bank**
- **Capacity building** of DICs for providing handholding support to enterprises
- Touch based with 34 **Export Promotion Councils** to provide handholding support to enterprises
- Collaboration with academia is planned for **design and quality upgradation of exports**
- Creating District Export Promotion **Action Plans** for exportable products in districts
- **Geographical Indicator** Status to our unique products

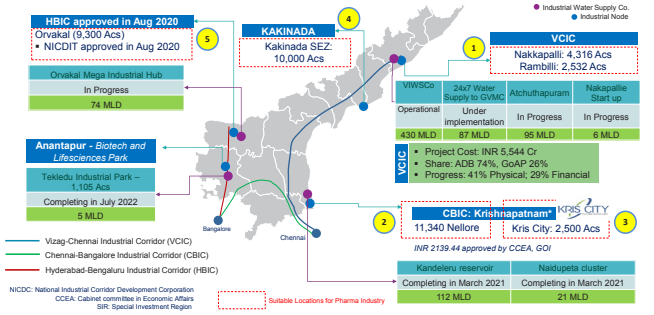
Dedicated Export Policy 2020-23	Revitalize APTPC as Export Agency	Dedicated portal to facilitate ease of exports	Logistic Parks and Processing Infra closer to ports

Potential Locations for Pharma Ecosystem in Andhra Pradesh

18

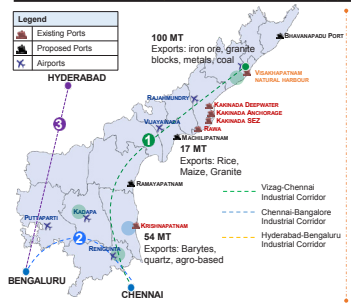
Andhra Pradesh Industrial Corridors and Industrial Water Supply Projects

Only state in India to have 3 National Industrial Corridors, across 48,352 Acres of land bank

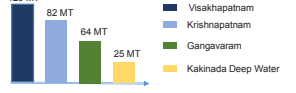


AP Advantage – Logistics and Connectivity

Ranked #2 in Cargo handling capacity in India with 150 MMT of Cargo per annum as on 2018-19, targeted to 326 MMT



Capacity of Ports in MMT



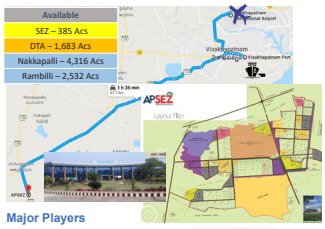
Major Initiatives being taken by AP

A New Ports Planned		▪ Machilipatnam ▪ Ramayapatnam ▪ Bhavanapadu
B Institutional		▪ **AP Maritime Board** for Rapid Development
C Industrialization		▪ **Port Based Clusters** ▪ **Desalination Plants** for Assured Water Supply

20

1. APIIC Atchutapuram, Nakkapalli, Rambilli – Vishakapatnam

Part of the VCIC Industrial Corridor Development



Major Players

LAURUS Labs, Dr.Reddy's, Andhra Organics Limited, VASUDHA PHARMA, Virchow Laboratories Limited, AUROBINDO, Lee Pharma Limited

Power
220/132/33 KV substation for industrial purpose and three 33/11Kv substations

Water
- 95 MLD from Eluru Canal for industries to be extended to further 95 MLD
- Ground water level 30 Ft - 200 Ft

CETP Status and Discharge Availability
- ZLD-based 1.5 MLD CETP available
- Additional 1 MLD CETP is proposed
- EC availed
- Temporary Storage Disposal Facility

Industries Operating
- Pharma and Life Sciences, Textiles, Solar PV, Iron castings, Chemicals, oil refinery, zinc, fertilizers, steel, heavy engineering, ship building

Excellent Connectivity

35 Kms from Gangavaram Port	**40 Kms** from Vishakapatnam Intl Airport	**5 Kms** from NH-16	**17 Kms** From Anakapalle Railway Station
50 Kms from Vishakapatnam Port	**90 Kms** from Bhogapuram Airport	**32 Kms** from Vishakapatnam City	

2. APSEZ and DTA Naidupeta – Nellore

Part of the VCIC Industrial Corridor Development

Power
- 132/33/11 KVA sub-station available in IP, sourced from APSPCL

Water
- 22 MLD supplied from Telugu Ganga project (APIIC – 04)
- Ground Water Level of 100 -150 feet

CETP Status and Discharge Availability
- ZLD-based 1.5 MLD CETP available
- Additional 1 MLD CETP in progress
- EC availed
- Temporary Storage Disposal Facility

Industries Operating
- Pharma, Chemicals, Glass, Mineral-based, Electronics, Batteries, Building materials

Excellent Connectivity

70 Kms From Krishnapatnam Port	**60 Kms** from Tirupati Airport	**13 Kms** from NH-16, connected by State Highway	**10 Kms** from Naidupeta Railway Station
120 Kms from Chennai Port	**130 Kms** from Chennai Airport		

KEY USP
- Well-established ready-made ecosystem with acquired EC and operational CETP
- Presence of 100+ MSMEs catering to Chemical industry such as Oxygen Bottling, Caustic Soda, Chloro Acetic acid, Inorganic Chemicals

Common Utilities – APSEZ Naidupeta

One Stop Center at Menakuru, Naidupeta

Erection of Multiple Evaporator Equipment (MEE)

Top View of 1MLD CETP, Naidupeta

View of MEE, Boiler & Chimney

Trunk Infrastructure – APSEZ Naidupeta

Approaching Road

Internal Road

Existing Units

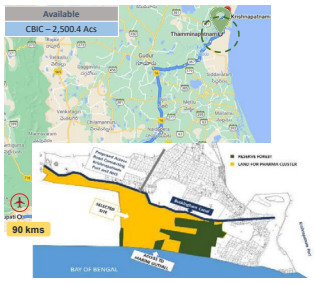
Water Storage Tank

Electrical Sub Station

Vacant Site

3. Krishnapatnam Node (Thamminapatnam) – Nellore

NICDIC Krishnapatnam Industrial City Development Ltd (Kris City) Phase 1



Power
- 133/ 11 KV Substation

Water
- 21 MLD from Sarvepalli reservoir – Telugu Ganga Project
- Ground Water Level of 80 -100 feet

CETP Status and Discharge Availability
- 8 MLD WTP, 5 MLD CETP and 5 MLD STP is proposed
- Access to coast for development of marine outfall

Industries Operating
- Chemicals & Petrochemical, Pharmaceuticals, Leather & Footwear Park proposed on 537 Acs, Power Generation, Mining

Excellent Connectivity

10 Kms	90 Kms	27 Kms	33 Kms
From Krishnapatnam Port	from Tirupati Airport	from NH-5, (Kolkata-Chennai)	from Nellore Railway Station

180 Kms from Chennai Airport

KEY USP
- Access for marine outfall, well connected and established logistics, proximity to Krishnapatnam port
- Proximity to supporting upstream (chemical)/downstream (formulations, generics) and allied industries (enzymes, alkaloids, nutraceuticals)

4. Kakinada SEZ – East Godavari

Part of the new Bulk Drug Park proposal

Power
- 400/220/110/33/11 kV available within the park

Water
- 200 MLD from Samarlakota (66 MLD) reservoir and Polavaram Left Canal (116 MLD)

CETP Status and Discharge Availability
- ZLD-based CETP is to be proposed
- 10 kms far from habitat, as required for obtaining EC

Industries Operating
- Multi-sector industrial park with focus on Chemicals, Petrochemicals, Glass Ceramics, Toys & Games, Food Processing, Apparel, Logistics & Warehousing

Excellent Connectivity

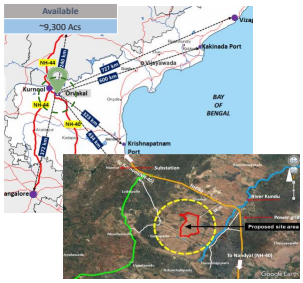
Abutting	70 Kms	4 Kms	12 Kms
Kakinada SEZ port	from Rajahmundry Airport	Annavaram Corridor from KSEZ to NH 216	from Kakinada Railway Station

25 Kms from Kakinada Deep Water Seaport

KEY USP
- Vast availability (10,000 acres) of land, with proximity to marine outfall and sea port
- Proximity to PCPIR, Polymers and Chemical industry such as Bottling, Caustic Soda, Chloro Acetic acid, Inorganic Chemicals

5. Orvakal Mega Industrial Hub – Kurnool

Part of the HBIC Industrial Corridor Development



Power
- Power Grid of 765/400 KVA Capacity
- Nannur Substation 225 KV

Water
- 75 MLD from Srisailam reservoir at Muchumarri village
- Ground Water Level of 100 -150 feet

CETP Status and Discharge Availability
- ZLD-based CETP is to be proposed
- 10 kms far from habitat, as required for obtaining EC

Industries Operating
- Steel based industry, Light engineering, non-metallic minerals, Chemicals, Renewable energy, Textile & apparel

Excellent Connectivity

320 Kms	2 Kms	4 Kms	22 Kms
From Krishnapatnam Port	from Kurnool Airport	from NH-40, (Kurnool-Chittoor)	from Kurnool Railway Station

250 Kms from Hyderabad Airport

KEY USP
- Lower land cost and centrally connected to Bangalore (5-6 hrs) and Hyderabad (3-4 hrs)
- Presence of 100+ MSMEs catering to Chemical industry such as Oxygen Bottling, Caustic Soda, Chloro Acetic acid, Inorganic Chemicals

APIIC – The Future is Here

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Commissioner, Industries & Commerce
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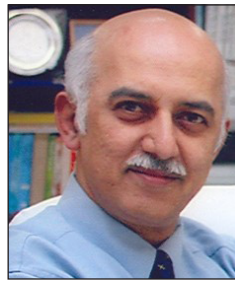
NEED OF THE HOUR FOR INDIA - EVIDENCE-BASED ALL-INCLUSIVE PREVENTIVE NUTRA - NUTRI HOLISTIC APPROACH PRODUCTS BY BOTH PHARMA GIANTS AND CLUSTER STARTUPS

Dr Vish Prakash, Ph.D, FRSC, *Former Director of CFTRI and former Distinguished Scientist of CSIR, Mysore*

Dear Reader,

This Guest Editorial could not have been better timed than now even though it should have given the call nearly ten years back! However, this editorial has become longer than what I envisaged, and seek your patience to read through it in your leisure time.

The positioning of the Indian subcontinent as a leader in the world for Health and Wellness is an important agenda. The paradigm shift of Health to Health and Wellness is the need of the hour. India in its tradition and Wisdom has always related to Food and Wellness as one entity, especially in Ayurveda and the basic concepts governing it. That's not all. If India does not wake up and push the agenda of Wellness strong enough internally and be a Global Champion with its heritage of 5000 years of traditional wisdom in this area, then we are sure to lose out on many Economic fronts too in this sector, especially in the discovery battle of New Drugs. It can emerge as a leader and the Pharmaceutical Industry must aggressively ensure that the huge raw material advantage India has in its resilience of Agriculture and the favorable climate it provides, from North to South and East to West 12 months in a year, is capitalized. We are sitting on a Platinum mine but almost not using it at all?! The need for infrastructure and capacity building for the Wellness Industry to grow is unlimited in India and also in the global market and its huge reach out. It needs a new movement altogether to have a budget allocation from the Pharma Giants to invest in India and the Government's mindset to partner and promote the same, not just by parks but an investment to make it win-win financial enterprises which will thrive with Trillions of Indian Rupees businesses with India as a hub. There are many who have done it boldly and hats off to them. But much much more is needed in the logarithmic phase and scale.



Dr Vish Prakash is currently the President of International Union of Food Science and Technology (IUFoST) and Vice-President of International Union of Nutritional Sciences (IUNS); He was Former Director of CFTRI, Mysore, and was appointed as Distinguished Scientist of CSIR, India. He has received more than 65 National and International awards including one of the high India's Civilian Awards Padmashree, Coveted Bhatnagar Award for Science and Technology of India, Rajyotsava award at State Level and several Lifetime Achievement Awards from various organizations like AIFPA and FICCI, IUFoST (both in India and Abroad). He is a fellow of several Academies in India and Royal Society of Chemistry, UK; IAFoST, Canada and IFT, USA

Dr. Prakash's scientific contribution in the area of Food Science, Food Technology, Chemistry and Biochemistry of Foods and Biomolecules. Nutraceuticals and Nutrition reach out, Nutritionals and Nutraceuticals, Food and Nutrition Safety and Herbaceuticals is vast and in depth with new Innovations and Technologies in the foreground. He has as of date 216 peer reviewed research publications, 55 Patents Filed, nearly 50 Ph.Ds degrees (some are Masters) guided and 810 plus Keynote, Chief Guest and Convocation addresses delivered and is author of 14 Books and 12 more Books are in the pipeline. Dr Prakash has completed Fifty Years of his untiring service and dedication to Chemistry of Proteins and Enzymes and Biomolecules and Nutraceuticals in the larger realm of Academia and Industry Interface and Innovative products to the Market.

Another aspect of focus is documentation and epidemiology for the Health and Wellness network which needs a very quick action to dig out epidemiological evidence of medicines and food-based approach in our long history of at least 5000 years, which is well-documented and established pieces of evidence. Even as it was attempted, many documents are either lost by many invasions or even strategically stolen by the invaders and wars, haunting the subcontinent over 1000+ years. But today, even though we are busy with Whatsapp, Instagram, Facebook, email, etc., which can be used for this dissemination of knowledge, we need to focus to achieve this goal of More from Less for More and More. The Power of Wellness is the profound strength of the matrix of Nutritionals, Nutraceuticals and Herbaceuticals and with the right combination of Lifestyle for promoting wellness. The concept of good health and wellness is a phenomenal limitless market with the right products in place. Nutraceuticals, Nutritionals, and Herbaceuticals are the inner neuronal networking of our body, nurturing one's genes with a food-based approach – topping it up with needed nutrients and bioactives for a healthy life through the Wellness approach. The gut produces these molecules from the food we ingest. However unfortunately, vested interests have reduced nutrition to just Fats, Carbohydrate, and Fats with Vitamins and Minerals, and the remaining biomolecules in the Food are lost in the system of product promotion forever. The need for specialty functional foods with an overall inclusive agenda is missing from both public and private entrepreneurship and it is time we address them in depth in this vibrating ambience of a slowdown in the economy due to the pandemic. Here is a great opportunity, but perhaps we are missing and need rekindling and repurposing to relook at the strategic areas of traditional wisdom of Food be the Medicines including Herbal extractives and Rasayanas and Churnaas. Still, it is not too late yet to move?!.

What is needed as the vaccines for COVID are in the Horizon world over? The role of Information Technology all the way to nutrition and nutraceutical technologies extruded through Innovations to reach out to society cannot be only associated at the social level always and requires a very different approach using the latest tools of chemistry and other scientific areas for well-groomed healthy humans in the next decades. This will perhaps pave the way for the current research to address in terms of newer tools and newer products which can sustain a bright future of the business of Health and Wellness through adaptation of food science to our daily eating habits and understanding the chemistry of foods and their individual components thoroughly. The Future Pharma perhaps is in the Food we eat and how we can leverage the Bioactives from a food based approach to food enriched with such bioactives and all the way to Pharma Sector reaching that molecular matrix with the surgical precision we have today through AI. What are we waiting for? The problem is not having a forceful National Scientific Agenda with daily monitoring like a battle. I would like to give the example of the Nutraceutical Regulations which were Gazetted in India in November 2017 and even today after 3 years I do not see a mega Investment by the major Pharma Industries towards Nutraceuticals and Nutritionals and the long list of nearly 300 Biomolecules cleared for use in Food Products for the first time in the World are almost lying Idle.!? There was hue and cry by the Industry that we don't have regulations for Nutraceuticals and so are a stumbling block for the products. As Chairperson of that committee, I remember we worked overtime and had the document gazetted at a top speed completely based on Science and an evidence-based approach. What is Industry doing sitting on this Treasure??? Are the transformational leadership and translational Science and Technology with the power of Chemistry and Basic Sciences lacking in the Pharma Industry sector? It is not clear what is ailing this sector not to use the opportunity?

Ultimately in any Society: Culture, Science and People will be webbed through tradition and its distilled wisdom and it is time these are integrated and merging of knowledge takes place and that will change the perspective we live in the world all over. The direction and speed towards new goals and lifestyles will also change drastically after the pandemic. This needs to be kept in view of the demand for products beyond market forecasting. It will encompass a whole range of opportunities for science and its business from pediatrics to geriatrics to spring back to the vibrant physical and mental health condition and the unlimited scope of science of nutraceuticals and nutritionals will make many impossibles, possible. This will encompass a lifelong chain of evidence-based products to cater to different levels of personalized preventive molecules matrix with the adaptation of the latest Scientific tools which is the need of the hour. With better sustainable nutrition for Immunity management which has become important of late, the Indian Traditional Foods and Medicines (ITFM) are especially important for those who have chronic diseases like diabetes and other cardiovascular diseases is again a missed opportunity. The need is very urgent for effective Pharma intervention from the bioactives from the plant kingdom and their interactions, which is well documented, but more needs

to be done in the Academia and R and D Institutions too. CSIR and AYUSH have taken some initiatives in this sector and is the only fond hope I have even though the big Pharma giants must have invested much more than what we see in India today. We must congratulate Team India scientists and medical Professionals from all branches of medicine, be it be Ayurveda, Homeopathy, Allopathy, Unani, or Siddha, for their untiring efforts risking their own lives and putting their 24 x 7 into the best they can give impossibles were delivered and many lives saved. Our salutes to all of them.

Dr. Ashok Vaidya's (A leading eminent Globally well-known Scientist in the area which India is proud of) very important message of Reverse Pharmacology has been much quoted but seldom used by the Industry to leverage new and innovative products. This is more so as the single-molecule business from the west dominates the sector rather than a holistic approach of the lifestyle as is well understood from the Prakruti angle (or simplified by a wrong English translation of Ecofriendly!!). It urgently needs a symphony of synchronization and orchestrating the Architecture of Atma Nirbhar Bharat for a totally different emergence of the Pharma sector to a PREVENTIVE mode than along with the curative mode, the lesson that we have learned today in the pandemic year of 2020. India has that richness of knowledge and we must dashingly leverage it without losing time with speed and direction as India is in an advantageous position today. Will we do it?? It is a Trillion Rupees traditional Question? But my confident optimism prevails for a brighter day to be seen in the near-immediate future with India's well-proven knowledge.

Wishing the readership all the very best in the New Calendar Year 2021, perhaps a year where we will be used to certain new hygienic habits and social behavior and will remain as such as the normal way of leading further life. Even if you get a dose of the vaccine, never forget the basic principles of living with a healthy lifestyle and nutritious foods. Nutrition is not a vaccine and a daily dose to boost your immunity against many unknown pandemics and diseases and Coronavirus is only one amongst them for which you are looking to protect yourself with the vaccine!

Courtesy: Indian Drugs, Guest Editorial, Vol. 57 (11) November 2020

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DPCO, 2013: Monitoring of MRP of Medical Devices notified/regulated as 'Drugs' under Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 - reg.

NPPA Office Memorandum dated 16th February 2021

To:

1. *All Manufacturers/Importers of non-scheduled Medical Devices (24 categories)*
2. *Medical Devices Industry Associations namely MTaI, AiMeD, CII, FICCI, USIBC, AMCHAM, AdvaMed with a request to disseminate this O.M. among its Member Companies and enusre complicance of the same.*

1. The Maximum Retail Prices (MRP) of non-scheduled Medical Devices notified/regulated as 'drugs' under Drugs & Cosmetics Act 1940 are governed under the provisions of Para 20 of the Drugs (Prices Control) Order, 2013. Further, Para 25 of DPCO, 2013 provides that every manufacturer/importer shall issue a price list and supplementary price list in Form-V to the dealer, State Drugs Controllers and the Government from time to time.

2. In order the monitor the MRP of the non-scheduled Medical Devices under Para 20 of the DPCO, 2013; NPPA vide OM dated 12th May 2017 had collected price related information for all the 19 categories of non-scheduled Medical Devices for the years from 2014 to 2017. Further, Ministry of Health & Family Welfare (MoH&FW) vide Notifications No. 5980(E) dated 03.12.2018 and 4671(E) dated 27.12.2019 had notified four more Medical Devices as 'Drugs' w.e.f. 01.01.2021. Accordingly, presently 28 categories of Medical Devices are under mandatory regulation as Drugs as per the Drugs & Cosmetics Act, 1940. Of which four Devices namely (i) Coronary Stents (ii) Drug Eluting Stents (iii) Condoms and (iv) Intra Uterine Devices are scheduled Medical Devices.

3. Thus, NPPA in exercise of powers of Para 29 of the DPCO, 2013 hereby directs all manufacturers/ importers of all the 24 (20+4) non-scheduled Medical Devices (Annexure-I & II) to submit price related information in the prescribed formats (Annexure-III & IV), duly certified by practicing Chartered/Cost Accountant, within 2I days of issue of this O.M. A soft copy of the same (in excel format) shall also be sent to the following e-mail id mandatorily: **medicaldevices-nppa@gov.in**

Alok Ranjan, Asst. Director (Med. Dev.), National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

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Submission of Form-I (Application for retail price fixation of new drugs) through e-mail only - reg.

NPPA Office Memorandum dated 12th February 2021

1. The undersigned is directed to refer to NPPA's OM no. 20(08)/17/2020/Div.III/NPPA dated 26.08.2020 regarding 'Development and Implementation of Eco System for timely disposal and monitoring of various applications filed with NPPA" wherein it was observed that most of the new drug applications are received online which has helped in their faster processing in a time bound manner.

2. For further streamlining of the procedure and processing the application in a time bound manner it is clarified that w.e.f 1st April 2021, no application in Form-I for Retail price fixation of new drugs in physical form shall be accepted by NPPA. The application in Form-I for Retail price fixation of new drugs shall only be accepted through e-mail id only (pricing-nppa@gov.in) as mentioned in para 2 of OM No. 20(08)/17/2020/ Div.III/NPPA dated 26.08.2020.

F.No.8(83)/2021/Div.I1/NPPA

S S Ojha, Joint Director (Pricing), National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

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Guidelines for implementing the Provisions of PP (Preference to Make in India) Order (PPO), 2017, revision - Goods & Services in Medical Devices

DoP Communication dated 16th February, 2021

Whereas Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153(iii) of the General Financial Rules 2017, has issued Public Procurement (Preference to Make in India) Order (PPO), 2017 vide no. P 4502/2/2017B.E.-II dated 15.06.2017, which is partially modified by Order no. P-45021/2/2017-PP (BE-II) dated 28.05.2018, Order no. P-45021/2/2017-PP (BE-II) dated 29.05.2019, Order no. P-45021/2/2017-PP (BE-II) dated 04.06.2020 and Order no. P45021/2/2017-PP (BE-II) dated 16.09.2020.

Whereas it is the policy of the Government of India to encourage 'Make in India' and promote manufacturing and production of goods and services in India with a view to enhancing income and employment, and

Whereas DPIIT, in order to facilitate the implementation of the PPO, 2017, vide D.O. No. P-45021/2/2017-BE-H dated 14.08.2017 has identified Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions of the PPO, 2017 relating to goods & services related to Pharmaceuticals Sector. DPIIT vide O.M. no. P-45021/13/2017-PP Section BE-II dated 23.03.2018 has decided that the Nodal department for product category Medical Devices shall be Department of Pharmaceuticals.

Now, therefore, Department of Pharmaceuticals, in supersession of the guidelines issued earlier vide F.No.31026/36/2016-MD dated 18.05.2018, F.No. 31026/36/2016-MD dated 16.10.2018, F.No. 31026/36/2016-MD (Vol-II) dated 12.12.2019 and F.No. 31026/36/2016-MD dated 09.11.2020, issues the following guidelines for implementation of the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017, as revised by DPIIT on 16.09.2020, with respect to public procurement of Goods & Services in Medical Devices:-

1. **Local Content:** 'Local content' means the amount of value added in India which shall be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.
2. **Class-I Local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 50%.
3. **Class-II local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 25% but less than 50%.
4. **Non-Local supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content less than or equal to 25%.
5. **Verification of Local Content:**
   a. The 'Class-I local supplier'/ Class-II local Supplier' at the time oftender, bidding or solicitation shall be required to indicate percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local supplier'/ 'Class-II local supplier', as the case may be. They shall also give details of the location(s) at which the local value addition is made.
   b. In cases of procurement for a value in excess of Rs. 10 crores, the 'Class-I local supplier'/ 'Class-II local supplier' shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content.

c. The following Committee is being formed for independent verification of self-declarations and auditor's/accountant's certificate on random basis and in the case of complaints-

1. Chairman - Joint Secretary (Medical Device) in DoP
2. Member - Director / Deputy Secretary (Medical Devices) in DoP
3. Member - Representative (not below the rank of Deputy Secretary) from M/o Health & Family Welfare / CDSCO
4. Member - Dr. Akshaya Srivastva, Associate Professor, National Institute of Pharmaceutical Education and Research, Ahmedabad
5. Member - Dr. Jitendra Sharma, CEO & MD, Andhra Pradesh Medtech Zone Ltd, Andhra Pradesh

d. In case of reference of any complaint by the concerned bidder, there would be a fee of Rs. 2 lakh or 1% of the value of the medical devices being procured (subject to a maximum of Rs. 5 lakh), whichever is higher, to be paid by way of a Demand Draft to be deposited with the procuring entity, along with the complaint by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld and found to be substantially correct, deposited fee of the complainant would be refunded without any interest.

6. These guidelines shall be applicable to all Central Sector Schemes/Centrally Sponsored Schemes for procurement made by States and local bodies if project or scheme is fully or partially funded by Government of India.

7. All other provisions of Public Procurement (Preference to Make in India) Order 2017, as revised by DPIIT on 16.09.2020, shall be applicable as such and shall be adhered to by all procuring agencies for procurement of any medical device.

8. These guidelines shall remain applicable, until further orders, from the date of issuance.

9. These guidelines will supersede the guidelines issued earlier by DoP vide F.No. 31026/36/2016-MD dated 18.05.2018, F.No. 31026/36/2016-MD dated 16.10.2018, F.No. 31026/36/2016-M_D (Vol-H) dated 12.12.2019 and F.No. 31026/36/2016-MD dated 09.11.2020.

F.No.31026/36/ 2016-MD

Dr Sumit Garg, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

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Public Procurement (Preference to Make in India) Order 2017 (Revision) — to provide purchase preference in respect of Para 3(a) for Medical Devices — reg.

DoP Communication dated 16th February, 2021

1. In pursuance of the Public Procurement (Preference to Make in India) (PPPMII) Order 2017 notified vide the Department for Promotion of Industry and Internal Trade (DPIIT) Notification No.45021/2/2017-PP(B.E.II) dated 15.06.2017 and subsequent amendments dated 28.05.2018, 29.05.2019, 04.06.2020 and 16.09.2020, to promote manufacturing and production of goods and services in India with a view to enhancing income and employment, the following Medical Devices where there is sufficient local capacity and competition are hereby notified by the Department of Pharmaceuticals.

2. In view of the DPIIT's PPP-MII Order Notification No. 45021/2/2017-PP (BE-II) dated 16th September 2020, the Department has issued revised guidelines vide F.No. 31026/36/2016-MD dated 16th February, 2021 for implementation of the Order for Medical Devices Sector.

3. Now, in terms of Para 3(a) of DPIIT's PPP-MII Order Notification No. 45021/2/2017-PP (BE-II) dated

16th September 2020, the Department hereby notifies items of medical devices as per Annexure-I for which only Class-I local supplier shall be eligible to bid irrespective of the purchase value.

4. The list of manufacturers of these items is placed at Annexure-II. This list is only indicative in nature. There may be other Class-I local suppliers also available in the market. Also, suppliers indicated in the list may offer products which do not offer minimum local content requirement for Class-I local supplier. As such procuring entities may follow all prescribed procurement procedure without relying on the published list.

5. This order shall be applicable in respect of the procurement made by attached or subordinate offices or autonomous bodies under the Government of India including Government Companies as defined in the Companies Act, and/ or the States and Local Bodies making procurement under all Central Schemes/ Central Sector Schemes where the Scheme is fully or partially funded by Government of India.

6. This issues with the approval of Competent Authority.

F.No.31026/36/ 2016-MD

Dr Sumit Garg, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

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CCI MATTERS

CCI Public Announcement on Market Survey on Pharma Sector

CCI Public Announcement dated 19th February 2021

The Competition Commission of India ('CCI') is conducting a 'Market Study on the Pharmaceutical Sector in India' with a view to develop a better understanding of the competition landscape in the sector.

As part of the Study, the CCI is conducting consultation with stakeholders (Pharmaceutical companies, stockists, chemists, trade associations, doctors, sector experts and regulators). The idea behind the consultation is to gather insights on issues that may have a bearing on competition in the pharmaceutical market in India.

Any of the aforementioned stakeholders willing to participate in the consultation may please reach out to us at **pharmastudy@cci.gov.in till 19th March, 2021.**

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Amendment of Importer-Exporter Code (IEC) related provisions under Chapter-1 and Chapter-2 of Foreign Trade Policy, 2015-2020

DGFT Notification No.S.O.(E)68/2015-2020, dated 10th February, 2021

1. In exercise of powers conferred by Section 3 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends the IEC related provisions under Chapter-1 and Chapter-2 of Foreign Trade Policy, 2015-2020.

2. Following paragraphs of Foreign Trade Policy, 2015-2020 are amended as below:

Existing Text	Amended Text
1.11 Issue of e-IEC (Electronic- Importer Exporter Code)	1.11 e-IEC (Electronic-Importer Exporter Code)
(a) Importer Exporter Code (IEC) is a mandatory for export/ import from/to India as detailed in paragraph 2.05 of this Policy. DGFT issues Importer Exporter Code in electronic form (e- IEC). For issuance of e-IEC an application can be made on DGFT (http//:dgft.gov.in). Applicant can upload the documents and pay the requisite fee through Net banking. Applicant shall, however, submit the application duly signed digitally.	Importer Exporter Code (IEC) is mandatory for export/ import from/to India as detailed in paragraph 2.05 of this Policy. DGFT issues Importer Exporter Code in electronic form (e-IEC). Application for issuance of e-IEC can be made directly on the DGFT web portal (https//www. dgft.gov.in).
2.05 Importer-Exporter Code (IEC)	**2.05** Importer-Exporter Code (IEC)/(e-IEC)
(c) Application process for IEC is completely online and IEC can be generated by the applicant as per the procedure detailed in the Handbook of Procedure.	(c) Application process for IEC and **updation in IEC** is completely online and IEC can be generated by the applicant as per the procedure detailed in the Handbook of Procedure.

3. The following sub-paragraphs are inserted under para 2.05 of Chapter-2 of Foreign Trade Policy, 2015-2020 as under:

FTP Paragraph no.	Text added (New)
2.05(d)	An IEC holder has to ensure that details in its IEC is updated electronically every year, during April-June period. In cases where thereare no changes in IEC details same also needs to be confirmed online.
2.05(e)	An IEC shall be de-activated, if it is not updated within the prescribed time. An IEC so de-activated may be activated, on its successful updation. This would however be without prejudice to any other action taken for violation of any other provisions of the FTP.
2.05(f)	An IEC may be also be flagged for scrutiny. IEC holder(s) are required to ensure that any risks flagged by the system is timely addressed; failing which the IEC shall be deactivated.

4. The sub paras 1.11(b), 1.11(c) and 1.11(d) of Foreign Trade Policy, 2015-2020 are deleted.

Effect of this Notification: IEC related provisions in Chapter-1 and Chapter-2 of Foreign Trade Policy, 2015-2020 are amended/deleted and new provisions inserted.

This issues with the approval of Minister of Commerce & Industry.

File No 01/93/180/32/AM-19/PC-2[B]/Part-I/E-21759

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

In Lok Sabha & In Rajya Sabha

In Lok Sabha

India's Trade Policy

Lok Sabha Unstarred Question No: 240

Shri Margani Bharat:

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

(a): whether India's Trade Policy has recently been reviewed at WTO;

(b): whether it is also true that US and EU have flagged trade barriers, including increase in import duties, recently;

(c): if so, the details of items on which import duty has been increased and objections raised US and EU thereon;

(d): whether it is true that US and EU have asked the Indian Government to reconsider its agriculture support programme;

(e): if so, the details of agriculture support programme that India is providing and its impact on WTO regulations; and

(f): whether other WTO countries are opposing Indian MSP mechanism and if so, the details thereof and the Government reaction thereto?

Answered on 3rd February 2021

A. (a): Yes, Sir. India's Trade Policy Review (TPR) has been carried out by the World Trade Organization (WTO) under the Trade Policy Review Mechanism, wherein the trade related policies of Member countries are reviewed at regular intervals by the WTO. India's TPR meetings were held on 6th & 8th January 2021.

(b) & (c): USA and the EU have flagged certain trade related issues, including increase in import duties, during the recently held TPR meetings. Applied rates of customs duty in India are determined keeping in view the overall economic and other policy objectives, which include enhancing domestic value addition, creating a level playing field, ensuring availability of raw materials at competitive prices, securing economic interests of the country, ensuring supply of essential items at affordable prices. Import duties have been rationalized across a few sectors, which can be accessed at https://www.cbic.gov.in/.

(d) to (f): Some Member countries, including USA and the EU, raised certain questions regarding MFN applied tariff rates, agricultural support programmes such as MSP, etc. Replies thereto have been given to the WTO. The WTO Agreement on Agriculture provides the rules for trade in agriculture. India's agriculture support programmes, including the support through MSP mechanism, are consistent with India's obligations under the Agreement and are being notified to the WTO as required therein.

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

Trade Deficit between India and China

Lok Sabha Unstarred Question No: 244

Shri Rajendra Agrawal:

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

(a): the steps taken by the Ministry to bridge the trade deficit with China;

(b): if so, the details thereof;

(c): whether there is a target year by the Ministry to bring the trade deficit with China at zero; and

(d): if so, the details thereof and if not, the reasons thereof?

Answered on 3rd February 2021

A. (a) to (d): The details of export/import and trade deficit between India and China during the last three financial years and current financial year are given below:

Financial Year	Trade in Million US$		Trade Deficit
	EXPORT	IMPORT	
2017-18	13333.53	76380.70	63047.16
2018-19	16752.20	70319.64	53567.43
2019-20	16612.75	65260.75	48647.99
2020-21 (Apr-Nov)*	13639.18	38817.90	25178.72

*Provisional (Source: DGCIS)

The Government of India has made sustained efforts to achieve a more balanced trade with China, including bilateral engagements to address the non tariff barriers on Indian exports to China. Through

these efforts, various protocols have been signed to facilitate export of Indian rice, tobacco, fishmeal/fish oil and chilli meal from India to China. The Government has also taken various measures to extend support to exporters by facilitating Buyers Seller Meets between potential importers of China and the Indian exporters to increase exports. In addition, Indian exporters are encouraged to participate in major trade fairs to showcase Indian products.

The Government has taken the initiative to sensitize the Export Promotion Councils/Trade Bodies to enhance export of Indian goods.

The Government has also implemented policies to promote domestic manufacturing through ease of doing business and creating an enabling physical environment for manufacturing, through provision of developed land and infrastructure.

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

In Rajya Sabha

CSR Fund for COVID-19 Crisis

Rajya Sabha Unstarred Question No. 14

Dr Banda Prakash:

Q. Will the Minister of **CORPORATE AFFAIRS** be pleased to state;

(a): whether there has been an increase in the expenditure from Public Sector and Private Sector companies from their Corporate Social Responsibility (CSR) towards the mitigation of the COVID-19 crisis in the country;

(b): if so, the details of the activities carried out from the CSR funds during the last 11 months; and

(c): whether Government has taken any special step to incentivise the companies to increase the utilisation of the CSR funds for the COVID-19 crisis?

Answered on 2nd February 2021

A. (a) & (b): As per the Companies Act, 2013 ('Act'), companies are required to hold Annual General Meeting (AGM) within six months from the end of financial year. Thereafter, financial statements and board report containing disclosure about Corporate Social Responsibility (CSR), are to be filed in MCA21 within 30 days of the AGM. Thus, for the ongoing financial year no filing has been made by CSR mandated companies.

(c): Ministry vide General Circular No.10/2020 dated 23.03.2020 clarified that CSR funds may be spent for various activities related to COVID-19 under item nos. (i) and (xii) of Schedule VII of the Act relating to promotion of health care, including preventive health care and sanitation, and disaster management. Further, Companies (CSR Policy) Rules, 2014 were amended to enable companies to undertake CSR activities in their normal course of business for undertaking research and development of new vaccine, drugs and medical devices related to COVID-19 for three financial years in collaboration with any of the institutes or organisations mentioned in item (ix) of the Schedule VII of the Act.

Answer the Minister of State for Finance and Corporate Affairs (Shri Anurag Singh Thakur)

Vaccination Schedule for Inoculation of Covid-19 Vaccine

Rajya Sabha Unstarred Question No. 81

Shri Harnath Singh Yadav:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): the number of vaccines developed in the country to combat COVID-19 along with the progress of trials, stage-wise; and

(b): whether a triage or vaccination schedule to inoculate 130 crore people of the country has been conceptualized by Government, if so, the details thereof and action taken thereon?

Answered on 2nd February 2021

A. (a): The Central Drugs Standard Control Organization (CDSCO) which is the National Regulatory Authority has granted permission to COVID-19 vaccines in the country as under:

1. M/s Serum Institute of India Pvt., Ltd., Pune for manufacture of the COVID-19 Vaccine for restricted use in emergency situation with various conditions/restrictions.
2. M/s Bharat Biotech International Limited, Hyderabad for manufacture of the COVID-19 Vaccine for restricted use in emergency situation in public interest, as an abundant precaution, in Clinical Trial mode with various conditions/ restrictions.

Further, CDSCO has granted permission to conduct clinical trials of COVID-19 vaccines to various additional manufacturers/Importer in the country. The details along with trials, stage-wise are as under:

Phase I/II Clinical Trial:

1. M/s Bharat Biotech International Limited, Hyderabad for Inactivated Corona Virus Vaccine (Intradermal Route).
2. M/s Biological E Limited, Hyderabad for Receptor Binding Domain of SARS-CoV-2.
3. M/s Gennova Biopharmaceuticals Limited, Pune for mRNA Vaccine for Injection (COVID-19):

Phase II/III Clinical Trial:

1. M/s Dr Reddy's Laboratories Limited, Hyderabad for Gam-COVID-Vac combined vector vaccine.

Phase III Clinical Trial:

1. M/s Cadila Healthcare Ltd., Ahmedabad for DNA based Corona Virus Vaccine.

(b): The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has been established, which provides guidance on all aspects of COVID-19 vaccination including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc.

The prioritized groups comprise Health Care Workers, Front Line Workers, persons above the age of 50 years and persons below 50 years with associated comorbidities.

The COVID-19 vaccination was launched on 16th January 2021 and by 28th January 2021, more than 28.47 lakh Health Care Workers have been successfully vaccinated.

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

Efficacy of COVID-19 Vaccines

Rajya Sabha Unstarred Question No.103

Smt Shanta Chhetri:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): whether the COVID-19 vaccines being administered guarantee complete protection against all strains and variations of the virus;

(b): if not, the details of side effects, if any;

(c): whether Government shall administer the vaccine on the Hon'ble Prime Minister; and

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

Answered on 2nd February 2021

A. (a) & (b): Central Drugs Standard Control Organisation (CDSCO) which is the National Regulatory Authority under the Ministry of Health & Family Welfare has granted permission to manufacture of COVID-19 vaccines in the country as under:

1. M/s Serum Institute of India Pvt., Ltd., for manufacture of the COVID-19 Vaccine for restricted use in emergency situation with various conditions/restrictions.
2. M/s Bharat Biotech International Limited, for manufacture of the COVID-19 Vaccine for restricted use in emergency situation in public interest as an abundant precaution in clinical trial mode with various conditions/restrictions. In case of proposal of M/s Bharat Biotech International Limited, during consultation and evaluation, the Subject Expert Committee (SEC) of CDSCO noted that the Inactivated Whole Virion Corona Virus Vaccine has the potential to target mutated Corona virus strains. The common adverse events which have been reported from COVID-19 vaccines so far include headache, rash, chills, myalgia, fatigue, fever, dizziness, inflammation and pain, swelling or redness at the site of injection, erythema, pruritus etc.

(c) & (d): The priority groups for vaccination have been recommended by the National Experts Group on Vaccine Administration for Covid-19 (NEGVAC). The recommendations of NEGVAC in this regard have been accepted by the Central Government. The vaccine administration across the country is being done following the recommendations of NEGVAC.

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

Selection and Procurement of Covid-19 Vaccines

Rajya Sabha Unstarred Question No.105

Smt Phulo Devi Netam:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): the criteria adopted by Government to select and procure COVID-19 vaccines;

(b): the total quantum of vaccines that have been already procured and the total cost of procurement; and

(c): the total quantum of vaccines for which pre-procurement agreements have been entered into?

Answered on 2nd February 2021

A. (a): The COVID-19 vaccines that have been granted permission for restricted use in emergency situation by the Drug Controller General of India [DCG(I)] have been selected and procured for COVID-19 vaccination drive in the country.

(b): A total of 165 lakh doses of COVID-19 vaccine have been procured of which 110 lakh doses are of Covishield vaccine manufactured by M/s Serum Institute of India and 55 lakh doses are of Covaxin vaccine manufactured by M/s Bharat Biotech International Limited. The total cost of procurement of above mentioned doses of vaccines is INR 350.25 crore (all inclusive).

(c): No Pre-procurement agreements have been entered into.

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

Rush in Approval of Covaxin Vaccine

Rajya Sabha Unstarred Question No.115

Shri Syed Nasir Hussain:

Shri Mallikarjun Kharge:

Shri Sanjay Singh:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): whether it is a fact that Phase-3 trial results of Covaxin vaccine that has been approved recently for emergency uses, have not been made available;

(b): if so, the basis on which Government gave the approval;

(c): the authority responsible in case of any adverse side-effects which come to light post administration of the vaccine, and

(d): the reason for such rush in giving approval?

Answered on 2nd February 2021

A. (a) & (b): Covaxin vaccine is being manufactured by M/s Bharat Biotech International Limited. The firm had submitted interim safety and immunogenicity data of Phase I and II clinical trials carried out in the country along with safety data including Serious Adverse Event (SAE) data of the ongoing Phase III clinical trial in the country. The data was reviewed by Central Drugs Standard Control Organisation (CDSCO) in consultation with Subject Expert Committee (SEC). The committee noted that this vaccine is Inactivated Whole Virion Corona Virus Vaccine having potential to target mutated corona virus strains. The data demonstrated a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which all 25800 subjects have already been enrolled. Moreover, the firm presented the safety and efficacy data from Non-human primate challenge study also to CDSCO, where the vaccine has been found to be safe and effective. After detailed deliberations, the SEC recommended grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. Based on the recommendations of SEC, CDSCO has granted permission to manufacture COVID-19 vaccine to M/s Bharat Biotech International Limited, Hyderabad for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode with various conditions/ restrictions.

(c): As a part of the above permission granted by CDSCO, M/s Bharat Biotech International Limited is required to submit safety data on Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) with due analysis every 15 days for first two months and monthly thereafter to CDSCO. CDSCO, in consultation with Subject Expert Committee, has approved the protocol for rolling out the Whole Virion Inactivated Corona Virus Vaccine (BBV152) in clinical trial mode alongwith factsheet, informed consent form and adverse event form. As per the approval "In case of any serious adverse events, Vaccine recipients will be provided medically recognized standard of care in the government designated and authorized centres/hospitals. The compensation for serious adverse event will be paid by sponsor (BBIL) if the SAE is proven to be causally

related to the vaccine. If any Vaccine recipient develops symptoms of COVID-19, Vaccine recipient will be provided medically recognized standard of care in the government designated and authorized centers/hospitals".

(d): The approval in question has been given by the National Regulator based on the recommendations of the Subject Expert Committee.

The Minister of State in the Ministry of Health and Family Welfare (Shri Ashwini Kumar Choubey)

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NEW DEVELOPMENTS

A machine-learning approach to finding treatment options for COVID-19

When the COVID-19 pandemic struck in early 2020, doctors and researchers rushed to find effective treatments. There was little time to spare. "Making new drugs takes forever," says Caroline Uhler, a computational biologist in MIT's Department of Electrical Engineering and Computer Science and the Institute for Data, Systems and Society, and an associate member of the Broad Institute of MIT and Harvard. "Really, the only expedient option is to repurpose existing drugs."

Uhler's team has now developed a machine learning-based approach to identify drugs already on the market that could potentially be repurposed to fight COVID-19, particularly in the elderly. The system accounts for changes in gene expression in lung cells caused by both the disease and aging. That combination could allow medical experts to more quickly seek drugs for clinical testing in elderly patients, who tend to experience more severe symptoms. The researchers pinpointed the protein RIPK1 as a promising target for COVID-19 drugs, and they identified three approved drugs that act on the expression of RIPK1. The research appears today in the journal *Nature Communications*. Co-authors include MIT Ph.D. students Anastasiya Belyaeva, Adityanarayanan Radhakrishnan, Chandler Squires, and Karren Dai Yang, as well as Ph.D student Louis Cammarata of Harvard University and long-term collaborator G V Shivashankar of ETH Zurich in Switzerland.

Early in the pandemic, it grew clear that COVID-19 harmed older patients more than younger ones, on average. Uhler's team wondered why. "The prevalent hypothesis is the aging immune system," she says. But Uhler and Shivashankar suggested an additional factor: "One of the main changes in the lung that happens through aging is that it becomes stiffer."

The stiffening lung tissue shows different patterns of gene expression than in younger people, even in response to the same signal. "Earlier work by the Shivashankar lab showed that if you stimulate cells on a stiffer substrate with a cytokine, similar to what the virus does, they actually turn on different genes," says Uhler. "So, that motivated this hypothesis. We need to look at aging together with SARS-CoV-2 -- what are the genes at the intersection of these two pathways?" To select approved drugs that might act on these pathways, the team turned to big data and artificial intelligence.

The researchers zeroed in on the most promising drug repurposing candidates in three broad steps. First, they generated a large list of possible drugs using a machine-learning technique called an autoencoder. Next, they mapped the network of genes and proteins involved in both aging and SARS-CoV-2 infection. Finally, they used statistical algorithms to understand causality in that network, allowing them to pinpoint "upstream" genes that caused cascading effects throughout the network. In principle, drugs targeting those upstream genes and proteins should be promising candidates for clinical trials.

To generate an initial list of potential drugs, the team's autoencoder relied on two key datasets of gene expression patterns. One dataset showed how expression in various cell types responded to a range of drugs already on the market, and the other showed how expression responded to infection with SARS-CoV-2. The autoencoder scoured the datasets to highlight drugs whose impacts on gene expression appeared to counteract the effects of SARS-CoV-2. "This application of autoencoders was challenging and required foundational insights into the working of these neural networks, which we developed in a paper recently published in PNAS," notes Radhakrishnan.

Next, the researchers narrowed the list of potential drugs by homing in on key genetic pathways. They mapped the interactions of proteins involved in the aging and SARS-CoV-2 infection pathways. Then they identified areas of overlap among the two maps. That effort pinpointed the

precise gene expression network that a drug would need to target to combat COVID-19 in elderly patients. "At this point, we had an undirected network," says Belyaeva, meaning the researchers had yet to identify which genes and proteins were "upstream" (i.e. they have cascading effects on the expression of other genes) and which were "downstream" (i.e. their expression is altered by prior changes in the network). An ideal drug candidate would target the genes at the upstream end of the network to minimize the impacts of infection.

"We want to identify a drug that has an effect on all of these differentially expressed genes downstream," says Belyaeva. So the team used algorithms that infer causality in interacting systems to turn their undirected network into a causal network. The final causal network identified RIPK1 as a target gene/protein for potential COVID-19 drugs, since it has numerous downstream effects. The researchers identified a list of the approved drugs that act on RIPK1 and may have potential to treat COVID-19. Previously these drugs have been approved for the use in cancer. Other drugs that were also identified, including ribavirin and quinapril, are already in clinical trials for COVID-19.

Uhler plans to share the team's findings with pharmaceutical companies. She emphasizes that before any of the drugs they identified can be approved for repurposed use in elderly COVID-19 patients, clinical testing is needed to determine efficacy. While this particular study focused on COVID-19, the researchers say their framework is extendable. "I'm really excited that this platform can be more generally applied to other infections or diseases," says Belyaeva. Radhakrishnan emphasizes the importance of gathering information on how various diseases impact gene expression. "The more data we have in this space, the better this could work," he says.

Source: World Pharma News, 15.02.2021 (Excerpts)

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One dose of COVID-19 vaccine provokes strong immune response in those previously infected

Although Clinical Trial data are encouraging, real-world evidence with regard to the COVID-19 vaccine remains scarce. In particular, response to the vaccine among those previously infected with SARS-CoV-2 is still not completely understood.

Researchers from Bar-Ilan University and Ziv Medical Center now report preliminary evidence that people previously infected with the virus responded very strongly to one dose of the Pfizer vaccine, regardless of when they were infected and whether or not they had detectable antibodies against COVID-19 prior to receiving the vaccine.

Their study, published on February 11, 2021 in the journal *Eurosurveillance*, was conducted on a cohort of 514 staff members at Ziv Medical Center. Seventeen of them were infected with COVID-19 anytime between one and ten months before receiving the first dose of the vaccine. Antibody levels of the entire cohort were measured prior to vaccination and thereafter to determine response to the vaccine.

The response among those previously infected was so effective that it opens the debate as to whether one dose of the vaccine may suffice. "This finding can help countries make informed decisions regarding vaccine policy - for instance, whether those previously infected should be vaccinated in priority and, if so, with how many doses," says Prof Michael Edelstein, of the Azrieli Faculty of Medicine of Bar-Ilan University, who led the study. "It also offers reassurance that not having detectable antibodies after being infected does not necessarily mean that protection following infection is lost."

The research also provided evidence that immune response was similar across multi-ethnic groups. Ziv Medical Center, where the study was conducted, is staffed by a workforce comprised of Jews, Arabs and Druze, among others. Members of each of these groups responded very similarly to the first dose of the vaccine, a welcome finding considering that the virus itself is known to affect some groups more than others.

The strong response to one dose of the vaccine among those previously infected regardless of the duration between infection and vaccination is good news. However, the researchers emphasize that their findings should be confirmed in a larger cohort before reaching definitive conclusions. The researchers are continuing to follow healthcare workers after their second dose to better understand how long the vaccine will protect against COVID-19 in different groups of people.

Source: World Pharma News, 11.02.2021 (Excerpts)

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Zydus Cadila says 'positive results' from phase 2 studies of COVID-19 drug Desidustat in Mexico

Drug firm Zydus Cadila on Monday, 25.01.2021 said it has received positive results from phase 2(b) studies of Desidustat in COVID-19 patients conducted in Mexico.

In June 2020, Zydus Cadila had received approval from Mexico's regulatory authority Cofepris to test one of its lead research candidate Desidustat in the management of COVID-19.

The company has received positive results from phase 2(b) studies of Desidustat in COVID-19 patients, Cadila Healthcare said in a regulatory filing.

The company has received positive results from phase 2(b) studies of Desidustat in COVID-19 patients, Cadila Healthcare said in a regulatory filing.

Zydus Cadila, which is part of Cadila Healthcare, said: "Patients infected with COVID-19 have been reported to display signs of 'Hypoxia' leading to organ failure and death despite the use of antivirals, anti-inflammatory drugs or ventilators.The phase 2(b) results of this study revealed that Desidustat treatment led to increased red blood cell production and improved oxygen delivery to tissues.

"None of the hospitalised patients required mechanical ventilator in the Desidustat arm, while 25 per cent of COVID-19 patients on the standard of care arm required mechanical ventilation." Pankaj R Patel, Chairman, Zydus Group said, "We are excited to report for the first time, this encouraging data of... Desidustat, showing the potential to help prevent acute respiratory distress syndrome (ARDS) in COVID-19 patients. ARDS is associated with high mortality rate and Zydus remains committed to further develop this novel therapy for patients suffering from ARDS."

Clinical and regulatory development of Desidustat in COVID-19 was executed in Mexico by Avant SantÃ© Research Center S.A. de C.V., a leading Contract Research Organization (CRO) headquartered in Monterrey, Mexico, the company said.

Source: The Economic Times 26.01.2021

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Gujarat FDCA approves 161 & 181 Pharma plants based on MoUs signed in VGS-2017 and VGS-2019

The Gujarat Food and Drug Control Administration (FDCA) has approved and commissioned 161 pharmaceutical plants based on 249 MoUs signed with Pharma companies in Vibrant Gujarat Global Summit (VGGS)-2017 and commissioned 181 pharmaceutical plants based on 273 MoUs signed with Pharma companies in VGGS-2019.

The Gujarat Government signed MoUs worth Rs.15,000 crore with both Indian and International companies in the Pharma sector during Vibrant Gujarat Global Summit- 2017. In VGGS-2017 alone, Australia, Canada, Denmark, France, Japan, The Netherlands, Poland, UAE, UK, USA, Sweden and Singapore were the partner countries in the summit with 1,250 companies.

“Gujarat commissioned 44 pharmaceutical plants in 2011, 79 in 2013 and 160 in 2015 based on VGGS summit MoUs. This has helped promote Gujarat’s Pharma manufacturing strength and align it with Prime Minister Narendra Modi ‘Make in India’ campaign,” according to Gujarat FDCA Commissioner Dr H G Koshia.

Over 3,300 Pharma manufacturing units are located across the state in four large clusters with 5 Special Economic Zones in an area of over 1500 hectares, as per Government of Gujarat data.

Accounting for nearly 40 percent of India’s Pharma production and 28 per cent of Pharma exports, Gujarat saw an increase in Pharma exports in the past one decade with US$ 3,060 million worth of exports in 2016 from a quantum of exports worth US$ 562 million in 2006.

As a part of its broader engagement with organisations and academia to develop medical devices sector, NIPER Ahmedabad is also being developed as a National Centre for Medical Devices (NCMD) which will provide a conducive environment to nurture innovators and industry to further the vision of quality medical device manufacturing.

Source: Shardul Nautiyal, Pharmabiz, 15.02.2021

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S Sridhar elected as President of OPPI

Sridhar is the MD of Pfizer and is heading Pfizer's commercial business in India

The Organisation of Pharmaceutical Producers of India (OPPI) has elected S Sridhar as its next President. The term is for a period of two years and is effective from February 15, 2021. He takes over from Sharad Tyagi, former MD, Boehringer Ingelheim India.

Sridhar is the MD of Pfizer and is heading Pfizer's commercial business in India. Sridhar has been a member of the Executive Committee of OPPI for the past six years and has also chaired its Finance and Taxation Work Group. He was the chair of FICCI's Pharma Committee till recently.

Speaking on the new role, Sridhar said, "I am honoured to take over the responsibility of leading this prestigious organisation at this important juncture for healthcare in India. The COVID-19 pandemic has put a spotlight on the significance of innovation and partnerships to respond to the country's healthcare needs. Healthcare today occupies as a priority agenda for the Government. OPPI stands for research, innovation, access and collaboration to help address the most pressing healthcare needs of the country. I look forward to making a difference to patients, the industry and the country as OPPI works with the Government on policies that are pro-patient, encourage innovation and provide for a positive environment for the industry to grow. I thank members of OPPI Executive Committee for selecting me for this role."

Welcoming Sridhar as President, Tyagi said, "It is a pleasure to welcome Sridhar as the new President. I am confident that under his stellar leadership, OPPI will charter a new path in the emerging healthcare order of the country where research and innovation are taking deep roots as foundations of the economy. It has been an honour to lead OPPI in the year of pandemic when the significance of healthcare sector is reaffirmed, and that I could contribute to the industry and the country in some humble ways.

Sridhar is a Chartered Accountant and has led various finance roles before joining the Pfizer 13 years ago. At Pfizer, he expanded from his role as CFO to Business Unit head, took over the responsibility as the MD of India Commercial Business, a position he has been holding for the past five years.

Source: Express News Service, Express Pharma, 15.02.2021

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Brexit TCA between EU & UK favours Pharma and Medical Devices

Brexit Trade and Cooperation Agreement (TCA) between the EU & UK favours Pharma and medical devices. The pact enforced from January 1, 2021 sees a seamless transition and provides a reassurance for Indian companies in this sector going by the existing trade relations for India with both the UK & EU.

From an Indian Pharma standpoint, in spite of Brexit, UK and EU cannot ignore India in the wake of a falling rupee which depreciated 11% against the British pound sterling, and 8% against the Euro post the Brexit. The rupee depreciation only accelerates exports and boosts the Current Account Deficit.

Observers are of the view that just as UK and EU operate as separate entities, the regulatory regimes for medicines and medical devices in the UK and the EU will need to meet the requirements. Although the TCA has a section on medicinal products for human and veterinary use, several regulatory and trade issues are yet to be looked into.

"UK must optimise their resources and leverage international regulatory reviews from US FDA & EMA for approval and automatic approval. They must innovate and bring in far reaching regulatory reforms and be thought leaders for others. Regulatory science has not kept pace with digital and computational science which can significantly abbreviate development and approval time lines. Accelerated timelines has a huge cost implication which can bring down drug prices. UK has a small window of opportunity to show the way," Kiran Mazumdar-Shaw, Executive Director, Biocon, told.

According to Suresh Khanna, designated Partner, Dossier Solutions, UK has been a big partner for India. Now with the depreciating rupee we can be very competitive because the cost of medicine procurement for the UK will be much cheaper.

"Traditionally for Indian Pharma, UKMHRA approved facilities in the country are another booster shot for exports. India stands to gain irrespective of the Brexit. On an EU perspective, Indian Pharma plants have been

set up in Poland, Switzerland among others with a slew of Mergers and Acquisitions too. For many years, UK has been exporting to the developing world which includes India and Africa. However from an India standpoint we are looked upon as major suppliers and partners in the area of pharmaceuticals. Therefore despite the Brexit, Indian Pharma opportunities are still in plenty," added Khanna.

NSF International in its Brexit Impact Summary states, "The brunt of the UK and EU separation will be felt on new market authorizations of Centrally Authorized Products (CAPs), batch testing and Quality Person (QP) certification of products manufactured in the EU and EEA (European Economic Area) which are Member States of EU and three countries of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway; (excluding Switzerland).

Source: Nandita Vijay, Pharmabiz, 15.02.2021

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NPPA directs manufacturers to submit application online for Retail Price Fixation of New Drugs in Form-I

For further streamlining the procedure and processing of application in a time bound manner, the National Pharmaceutical Pricing Authority (NPPA) has directed manufacturers to submit application online in Form-I for retail price fixation of new drugs.

According to NPPA, with effect from April 1, 2021, no application in Form-I for retail price fixation of new drugs in physical form shall be accepted by NPPA. The application in Form-I for retail price fixation of new drugs shall be accepted through email id only at pricing-nppa@gov.in as mentioned in para 2 of Office Memorandum (OM) dated August 26, 2020. NPPA had mooted a proposal last year in August 2020 to develop an online system for disposing and monitoring of applications filed under various provisions of DPCO-2013 towards ease of doing business.

According to a NPPA notice, "The manufacturers have been directed to refer to NPPA's OM dated August 26, 2020 regarding development and implementation of ecosystem for timely disposal and monitoring of various applications filed with NPPA' wherein it was observed that most of the New Drug Applications are received online which has helped in their faster processing in a time bound manner."

Development and implementation of an ecosystem for timely disposal and monitoring of various applications filed under various provisions of DPCO, 2013 includes submission of Form-I for application for the pricing of new drugs. NPPA has stipulated that the applicant companies need to submit the application with all requisite documents via email at **pricing-nppa@gov.in.**

It has also stipulated Pharma companies to Form-I related to revised prices for scheduled formulations, Form-II related to quarterly return in respect of production/ import and sale of NLEM Drugs and Form-V related to Price List.

Pharma companies should submit these forms on Integrated Pharmaceutical Database Management System (IPDMS) within the prescribed timelines. Besides this, the application for the discontinuation of the production of scheduled formulation with all requisite documents should be sent via email at **monitoringnppa@gov.in.** Applications for special price for packaging under paragraph 11(3) of DPCO 2013 can be submitted at **pricing-nppa@gov.in.**

As per NPPA recommendations, NPPA authority meeting would be preferably held every month. If due to certain circumstances the same could not be held in a particular month, the authority meeting would be held in subsequent months as per requirement. Meeting of the multidisciplinary committee of experts would be held prior to the authority meeting.

All Indian Pharma manufacturer associations should upload the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) on their website including the detailed procedure mentioned in paragraph 10 of the UCPMP regarding lodging of complaints.

A quarterly report mentioning details of the complaint received and the decision taken thereon should be submitted by the concerned association to NPPA within 30 days of the end of the quarter via email to **monitoring-nppa@gov.in.** NPPA has also stipulated timelines for disposal of applications in different categories like in Form-I which is related to new drug prices and the given timeline is within 60 days.

Form-II is used for the revised prices of scheduled formulations and the stipulated timeline to file is within 15 days from the date Notification. Form-III is applied for the purpose of quarterly returns in respect of production/ import and sale of NLEM drugs and the set timeline for

the manufacturer is within 15 days from the date of the end of quarter.

Source: Shardul Nautiyal, Pharmabiz, 16.02.2021

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Drug makers hit hard by increased price of PVC granules

The drug manufacturers and exporters in the country have been hit hard by the increased price of PVC granules since the last few months. The rates of PVC granules went up from Rs.105 per kg in August last year to Rs. 180 per kg in January this year leading to its short supply. The increased cost of PVC material, used in Pharma packaging and medical device sector, has led to a rise in production cost of Pharma products as well as several medical devices such as IV fluid administration set, IV fluid bottles, urine bag, PET bottles etc.

Taking serious note of this, Small and Medium Pharma Manufacturers Association (SMPMA) made a representation to Department of Commerce, Department of Pharmaceuticals, Ministry of Micro, Small and Medium Enterprises (MSME) and Ministry of Health and Family Welfare, urging them to streamline the viable cost of PVC granules including its regular supply.

Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association (SMPMA), said, "PVC value in production of Pharma products is less than 3% of the cost of whole product but the price of PVC resin has increased significantly from Rs.105 per kg in August 2020 to Rs.180 a kg now. This has hit Small and Medium Pharma manufacturers and exporters hard. The industry is already facing several other issues, like GST refunds which are held up despite clearance in Icegate, increasing freight costs of shipping liners, shortage of containers and demand of PVC suppliers for advance payments."

The Department of Commerce had swung into action and wrote to the Department of Chemicals and Petrochemicals (DCPC) to ensure smooth supply of PVC granules in the country. The rate of PVC granules came down slightly to Rs.150 a kg and its supply normalized following the intervention of concerned departments of the Government but exporters are still finding it difficult to ship the consignments due to rising input costs.

Said Sandeep Modi, Secretary, Federation of Pharmaceuticals and Allied Product Merchant Exporter, "The cost of PVC granules has just reduced but not that much. Merchant exporters are affected by the rise in prices of PVC granules which are used in the Pharma packing and medical devices industry. The cost of medical devices made of PVC--IV fluid administration set, urine bags, PET bottles etc has gone up. The increase in the rate of PVC granules is hampering exporters from fulfilling their orders."

Source: Laxmi Yadav, Pharmabiz, 16.02.2021

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Bharat Biotech soon to begin phase-1 trials of world's first intranasal COVID-19 vaccine

The Hyderabad-based Bharat Biotech is getting ready for conducting phase-1 Clinical Trials of world's first intranasal Covid-19 vaccine. Revealing this, the company sources said that as part of its phase-1 Clinical Trials it has selected 75 volunteers, who will undergo safety and efficacy tests for the nasal vaccine.

As announced earlier by Dr Krishna Ella, Chairman and Managing Director of Bharat Biotech, the company in collaboration with Washington University School of Medicine in Saint Louis, USA, has developed the nasal vaccine called 'Chimpanzee Adenovirus Vectored (BBV154)' Covid-19 vaccine.

As per the partnership, Bharat Biotech International will get the needed basic research knowledge and know-how about the vaccine from the Washington University experts, while the company will conduct the lateral research, develop and manufacture the vaccine at its plant in Genome Valley in Hyderabad.

According to the company, it expects the newly developed nasal Covid-19 vaccine is a novel chimp-adenovirus, single dose intranasal vaccine that was already found to be effective in preventing infection in mice susceptible to the novel Coronavirus.

As part of the agreement, it is learnt that if the 3 phases of Clinical Trials for the nasal vaccine succeeds, then Bharat Biotech will have all the rights to market the vaccine across the world except, America, Europe and Japan.

"We are happy to announce that the Subject Experts Committee (SEC) of Drug Control General of India (DCGI) has given its green signal for conducting phase-1 Clinical Trials on the Intra nasal vaccine in India. As part of this, we completing all the necessary formalities to go ahead with the Clinical Trials and have even selected 75 subjects for phase-1 Clinical Trials," informed the CMD. Unlike

the conventional injection based vaccines brought out by various leading Pharma companies, Bharat Biotech's nasal vaccine for Covid-19 will be more cost effective, easy to store, distribute and administer to the people through nose.

"In a country like India where we have a population with more than 1.3 billion people, manufacturing injections, vaccine vials, storing them and distributing it to various parts of the country will cost tremendously. Moreover disposing off such large number of syringes and needles will also pose a great danger to the environment. In view of this, the nasal vaccine will be the best option, as it is a single dose vaccine and can be easily administered through nose," opined Dr Krishna Ella.

Source: A Raju, Pharmabiz, 13.02.2021

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Centre issues draft Notification to include ASTM in product standards for medical devices to enhance competitiveness

The Union Health Ministry has issued draft Notification on Medical Devices Amendment Rules, 2021 to include American Standard Test Method (ASTM) in product standards for medical devices to enhance competitiveness of indigenous medical devices globally.

As per the draft Rules, these rules may be called the Medical Devices (Amendment) Rules, 2021. These Rules shall, unless specified otherwise, come into force on the date of their final publication in the Official Gazette. In the Medical Devices Rules (MDR) 2017, in Rule 7, in Sub-Rule (2), after the words, letters and bracket "the International Electro Technical Commission (IEC)" the words, letters and bracket "or American Standard Test Method (ASTM)" shall be inserted. Rule 7 of the MDR-2017 provides product standards for medical devices. The MDR-2017 was published in the Official Gazette vide Notification Number G.S.R.78(E), dated the January 31, 2017.

The following draft of certain Rules to amend MDR-2017, is done 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 (D&C) Act, 1940 (23 of 1940) and after consultation with the Drugs Technical Advisory Board (DTAB) 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 copies of the Gazette of India containing these draft Rules are made available to public.

The period specified above will be considered by the Central Government; Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs Regulation), Union Health Ministry, Government of India, Room Number 434, C Wing, Nirman Bhavan, New Delhi – 110 011 or emailed at **drugsdiv-mohfw@gov.in.** Drugs Technical Advisory Board (DTAB) after detailed deliberation agreed to the proposal and recommended for necessary amendment in the MDR-2017 in this regard.

Stakeholders and experts have been recommending an urgent need for the Government to align the regulatory regime as per existing global standards to enable Indian medical device manufacturers to enhance their competitiveness and scale towards becoming export friendly. It has been recommended that developed countries have their own certification requirements. Therefore, Indian medical device manufacturers will need to meet the requirements of countries where they export.

As per Rule 7 of MDR-2017, the medical device shall conform to the standards laid down by the Bureau of Indian Standards (BIS) established under Section 3 of BIS Act, 1985 (63 of 1985) or as may be notified by the Union Health Ministry, from time to time. Where no relevant standard of any medical device has been laid down under Sub-Rule (1), such device shall conform to the standard laid down by the International Organisation for Standardization (ISO) or International Electro Technical Commission (IEC) or by any other pharmacopoeial standards. In case of the standards which have not been specified under Sub-Rule (1) and Sub-Rule (2), the device shall conform to the validated manufacturer's standards. Since the ASTM is accepted globally, it was proposed to include the ASTM in the Sub-Rule (2) of the Rule 70 of MDR-2017.

DTAB was apprised that the Union Health Ministry has notified the MDR-2017 on January 31, 2017 under the provisions of the Drugs and Cosmetics (D&C) Act, 1940. New MDR-2017 are effective from January 1, 2018 to regulate the clinical investigation, manufacture, import, sale and distribution of the medical devices in the country.

Source: Shardul Nautiyal, Pharmabiz, 12.02.2021

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Health Ministry to amend NDCT Rules to include provisions related to registration of standalone BA labs

The Union Health Ministry has issued draft Notification on New Drugs and Clinical Trials (NDCT) Amendment Rules, 2021 for inclusion of provisions related to registration of standalone Bioanalytical (BA) laboratories. As per the draft Rules, these rules may be called the New NDCT Amendment Rules, 2021. They shall come into force on the date of their final publication in the Official Gazette. Representations were made that the BA laboratory involved in analysis of the biological samples of BA/BE studies are part of BA/BE Study Centre and hence need to be regulated along with the BA/BE Study Centres.

It was proposed to amend the NDCT Rules-2019 to include the provision of registration of stand-alone Bio-analytical laboratories by inserting the word analytical part in the definition as follows - "BA and BE study centre" means a centre created or established to undertake BA study or BE study of a drug for either clinical part or analytical part or for both clinical and analytical part of such study. In the NDCT Rules, 2019, in Rule 2, in Sub-Rule (1), in clause (g), after the words, 'clinical part' and before the words, 'or for both', the words, 'or analytical part' shall be inserted. The principal Rules were published in the Gazette of India vide Notification number G.S.R. 227(E), dated March 19, 2019.

"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 fifteen days from the date on which the copies of the Gazette of India containing these draft Rules are made available to public," as per the draft Notification.

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), Union Health Ministry, Government of India, Room No. 434, A Wing, Nirman Bhavan, New Delhi – 110 011 or emailed at **drugsdiv-mohfw@gov.in.**

BA of drugs signifies the rate and extent to which their active ingredient is absorbed systemically after dosing. Bioequivalence (BE) establishes generic drugs as interchangeable to the branded ones with similar therapeutic and side effect profiles. As per the Rule 2 (g) of NDCT Rules 2019, "Bioavailability and bioequivalence study centre" is defined as -"BA and BE study centre" means a centre created or established to undertake BA or BE study of a drug for either clinical part or for both clinical and analytical part of such study.

However, this existing definition is not covering stand alone analytical laboratories.

The Union Health Ministry had notified the NDCT Rules, 2019 dated March 19, 2019 under the provisions of the D&C Act, 1940. These Rules are today applicable to all new drugs, investigational new drugs for human use, Clinical Trial, BE study and Ethics Committee. BA laboratory is the laboratory meant for analysis of biological samples received from the BA/BE Study Centres.

Source: Shardul Nautiyal, Pharmabiz, 12.02.2021

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FOPE identifies Section 1(3), 2, 3(c) and 3(h) of D&C Act & Rules as redundant and non-implementable

The Federation of Pharmaceutical Entrepreneurs (FOPE) has now identified certain provisions of Drugs & Cosmetics Act & Rules as redundant. These include Section 1(3), Section 2, Section 3(c) and Section 3(h). In its communication to the Union Government, the Federation has highlighted the unnecessary sections of the drug regulations and cited that these are seen to be non-implementable.

These include Section 1(3) Proviso with reference to Jammu and Kashmir as the rule is redundant after enactment of J&K Reorganization Act, 2019. In Section 2 words Dangerous Drugs Act 1930 has been repealed and therefore needs to be omitted. Section 3 (aaa) in definition of cosmetic word or animal needs to be added after human as now many pet products such as pet shampoo, pet deodorant, etc are manufactured and available in the market, said B R Sikri, Chairman, FOPE. Even Section 3 (c) Government Analyst needs to be redefined as for Analysis of Medical Devices even for State Government Labs Medical Device Testing Officers. Under Section 3 (h) the word patent has no relevance and should be omitted

because it is regulated in another independent Act, he pointed out.

"Though, the intention of such Guidelines was to provide relief to the law-abiding manufacturers against prosecution even for unintentional mistakes, many aspects are not relevant to the current context," Sikri told. However, because of the DCC Guidelines approved in 1993, the regulatory officers are resorting to prosecution strictly based on mathematical consideration. Recently Supreme Court has given the power to Drug Inspector to arrest the accused but this will only aggravate the situation. It is necessary to provide certain statutory support to reflect the principles laid down in the directions issued under Section 33 (p). In view of these, the existing Section 32 (B) should be substituted with new section providing for compounding of all offences except offences related to adulterated and spurious drugs. This will reduce the burden of regulators also, he said.

Further, there is a need to distinguish between formulations, Active Pharmaceutical Ingredients (APIs) and non active ingredients (excipients). Existing definition of Drugs includes bulk drugs and components of drugs like non achieved ingredients or excipients. As a result wherever the term drug appears in the Act, it is construed to include bulk drug as well as excipients and all provisions applicable to formulations also apply to bulk drug. Therefore, there should be separate definition of formulations, active substances and non-active substances. In addition, there should also be independent provisions especially for labelling and manufacturing of formulations, bulk drugs and excipients, said the FOPE Chairman.

Source: Nandita Vijay, Pharmabiz, 08.02.2021

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Industry urges DoP to postpone SOTS scheme to next financial year in the interest of business

The pharmaceutical industry has urged the Department of Pharmaceuticals (DoP) to postpone the proposed Special One Time Settlement (SOTS) Scheme related to Drugs Prices Control Order (DPCO) overcharging cases to the next Financial Year with a deferred payment schedule as the dates proposed for payment are around the end of the Financial Year on March 31, 2021, and this will impact pharmaceutical companies bottom line.

The DoP had earlier proposed to bring the SOTS during the current Financial Year for the settlement of overcharging cases which are pending in various courts to provide a comprehensive platform for out of court resolution of disputes, promote ease of doing business in the consumer and industry interest. It had proposed a draft framework of SOTS on the lines of '*Vivad se Vishwas'* schemes similar on the lines for settlement of disputed income tax dues. Pharma companies have, however, also requested that they should be given an opportunity to be heard by the DoP or the National Pharmaceutical Pricing Authority (NPPA) and thereafter be given the option of SOTS also considering the current situation due to the Covid-19 pandemic.

DoP in the last week of January 2021 had proposed draft framework of SOTS scheme to Pharma companies for fast track recovery of liabilities relating to overcharging cases under DPCO 1979, 1987, 1995, 2013 in exercise of the powers conferred by the DPCO-2013 read with section 3 of the Essential Commodities (EC) Act, 1955, (10 of 1955). As per DoP, SOTS-2021 shall be notified and introduced with effect from March 1, 2021 and shall close on June 30, 2021. The SOTS, 2021 shall cover all active court cases in any Court of Law in the country, as on specified date, relating to overcharging under the provisions of DPCO 1979, 1987, 1995 and 2013. The quantum of settlement offered under the draft SOTS is as follows - where the "Disputed Amount" includes Principal and/or Interest and/or penalty, amount payable by March 31, 2021 is disputed principal amount only and amount payable after March 31, 2021 would be disputed principal amount only + 10% of disputed principal amount.

Where the "Disputed Amount" includes interest and/or penalty only, amount payable by March 31, 2021 is twenty five percent (25%) of disputed amount and amount payable after March 31, 2021 would be thirty percent (30%) of disputed amount. The applicant availing the benefit under the Scheme shall submit an undertaking in the prescribed format provided in the notified Scheme, regarding withdrawal of the legal case(s) and not to avail any legal remedy in future in respect of the such case(s) for which benefit is availed under SOTS. Such undertaking should be furnished before making any payment under the Scheme and would be legally binding on the applicant. The applicant availing the benefit under the Scheme shall withdraw the legal case and submit the appropriate proof of such withdrawal to NPPA in due course of time, as early as possible, for closure of case filed by NPPA.

Source: Shardul Nautiyal, Pharmabiz, 17.02.2021

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LIST OF INSTRUMENTS IN ANALYTICAL DEPARTMENT

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PERD Centre has the following equipment which PERD Centre would like to sell. The list of equipment with its year of purchase and current status of working is given below.

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List of Instruments in Analytical Department

Instrument	Model	Number	Make	Status	Year of Purchase
HPLC	HPLC 1200 Infinity Series	2	Agilent Technologies	Working	2011
HPLC	Liquid Chromatography LC2010 CHT	1	Shimadzu	Working	2011
HPLC	HPLC LC-2010 CHT WITH SPD-M20A	2	Shimadzu	Working	2011
Preparative HPLC	Preparative HPLC UFLC SPD-MZ0A	1	Shimadzu	Working	2011
Semi Preparative HPLC	Semi Preparative HPLC LC-6AD	1	Shimadzu	Working	2011
DSC	DSC Q 20	1	TA Instruments	Working	2000
IR Spectrophotometer	IR Affinity-1 Spectrophotometer	1	Shimadzu	Not working (need repair)	2011
LC-MS/MS*	LC-MS/MS System API 2000	1	MDS SCIEX, Applied Biosystems	Working (LC part need repair)	2002
LC-MS*	LC-MS API 165	1	Perkin Elmer	Not Working	1999

***Instruments were purchased second hand**

Union Health Ministry appoints Dr Rajeev Singh Raghuvanshi as Secretary-cum-Scientific Director of IPC

Union Health Ministry has appointed Dr Rajeev Singh Raghuvanshi as the new Secretary-cum-Scientific Director of the Indian Pharmacopoeia Commission (IPC). IPC is as an autonomous institution under the Union Health Ministry established on January 1, 2009.

Dr Jai Prakash, Secretary-cum-Scientific Director (in-charge) was earlier serving as Secretary-cum-Scientific Director of the IPC. Dr Raghuvanshi completed his Bachelors and Masters from IIT-BHU (Formerly IT-BHU), Varanasi and Ph.D., from National Institute of Immunology, New Delhi.

His Ph.D., work is in the area of extended release formulation of vaccines, a project conceptualized to help reduce the number of injections required to be given for complete immunization. He has also done ISB-Kellogg Global Advanced Management Progamme.

After working for 7 years at National Institute of Immunology, New Delhi, Dr Rajeev moved to join the leading Indian multination pharmaceutical company Ranbaxy Laboratories Ltd where he worked for development, registration and launch of NDDS, generics and branded generics in various global markets.

After having spent 12 years with Ranbaxy Laboratories, Dr Rajeev moved to another Indian multinational, Dr Reddy's Laboratories Ltd, Hyderabad. In his 11 years of stay with Dr Reddy's Labs, 1st eight years was in development of 505b(2) NDA products for US market. In this role, he successfully led the CMC team to get 6 products approved in 1st review cycle by US FDA. During this tenure, he had the opportunity of multiple face to face interactions with US FDA which provided in depth understanding of working of global regulatory agencies.

Apart from US FDA, Dr Raghuvanshi has also had face to face interactions with regulatory agencies of UK, South Korea, Sweden, Romania etc. Last three years at Dr Reddy's has been in a different role of establishing an R&D team for markets like India, China, Russia and other emerging markets in the space of pharmaceutical product Innovation/differentiation, registration and launches. He is widely travelled throughout the world and has worked with team members and partners in countries like USA, UK, China, Russia, South Africa, Romania, Sweden, Canada, France, Australia and Japan.

Dr Raghuvanshi's expertise lies in dosage for design and development, mainly in the domain of pharmaceutical innovation. He has been involved in development of different kind of products like oral solids, oral liquids, topicals, injections, nasal sprays, auto-injectors, sublingual, mouth dissolve, extended release and delayed release for global markets. More than 200 products developed by him and his teams are currently being sold in India, US Europe and emerging markets. Dr Raghuvanshi has 14 granted US patents along with more than 250 published PCTs and Indian patents. He has more than 25 publications in peer reviewed journals and has co-authored 6 chapters in books. He has been visiting faculty at NIPER – Hyderabad and IIT-BHU and has taught students of NIPER-Mohali.

He is a regular speaker at different International and National conferences on Pharmaceutical Innovation. For his contribution, Dr Reddy's Labs has twice awarded him with "Dr Reddy's Excellence Award". Leadership development has been his passion and many of his team members mentored by him are holding leadership roles in Indian and global pharmaceutical companies.

Source: Pharmabiz, 21.02.2021(Excerpts)

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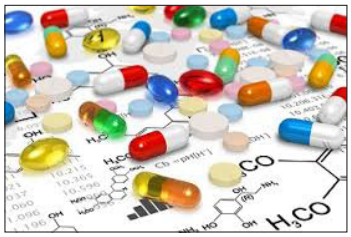
COVID Vaccine can be a game changer for Indian Pharma Industry on a Global Platform

Sumit Peer



We may contemplate that Covid 19 came from Wuhan labs or their wet market; but what is more important is it came from PRC or China. It travelled to 192 countries and infected millions, left a million dead and billions of livelihoods impacted across the world.

Global economy (GDP), which was valued at 90 trillion USD (approx) took a big hit, as all the cogs stopped working and operators went running for cover. An estimated loss to the global economy is currently valued at 15 trillion USD and counting, which is an overwhelming figure of almost 20%. It is like losing 20% of wealth to an invisible enemy who in all probability and likelihood was engineered by someone. Hence, vaccination is the need of the hour across the globe. In India alone, 1.3 billion people need to be vaccinated and each need two shots - 2.6 billion shots. Even if we have all the money in the world, the question remains who is going to give this, as we may argue we are one sixth of humanity. To compound the situation, we need a cold storage chain of -72 degrees, and looking at the map of our country, nobody will believe in implementation possibility, even at a conceptual level.

Our honorable PM announced that he wants to give the vaccine to the whole world; this might sound pure political but with PM Modi, everything has a ROI whether we see it or not. We know Communist China went across the world with 2 billion USD in a suitcase to find some takers for their vaccine which later on revealed 73 side effects. This makes it one of the most unsafe vaccines in the world, close to being fatal. India is one of the three countries in the world to produce this vaccine, only country to have 8 contenders in various stages of development and 5 in phase three of Clinical Trials and 2 already approved with a price tag of 4 USD, leaving aside the unthinkable -72 degrees' cold chain.

Medical and Pharma industry is 7.5 trillion USD as on date with a CAGR of 8% for the next 5 to 10 years. That makes this industry approx 10% of global GDP and it will never have the dearth of markets across the globe. Credibility and affordability will be the two pillars of success. One can imagine with HCQ sent across to 170 countries; and now the world's most trusted and most affordable vaccine will go to the last man in the remotest village of Africa. The person will always remember that the virus came from China and the cure from India. We have already announced free vaccines for 6 neighbouring countries and almost 64 other countries have written to us for the same. We have 8 different vaccines with us and are adding more to our table to choose from.

This vaccines diplomacy and doctrine will be placing Indian Pharma industry on the highest pedestal, vis-a-vis reliability, turn-around time, scalability, production capability and price with a global POC at the time of a dire need. Today, in the world you need to be a superpower in at least one critical area and be globally recognized for it. The vaccination welfare will pave our way to be the Pharma Superpower and powerhouse. We all need medicines from the day we are born till the day we die. Numbers and jobs cannot be counted, it will be a new market created for us, worth 100s of billions dollars which will be sustainable and booming. Back of the envelope calculations say that we can get another trillion or two from here as well. This is not only possible but practically feasible today as well.

An economy of the size of three trillion, another one or two can really make an un-concealable difference to our size, stature and aura in the global arena. *(The author of this article is Sumit Peer, Author & Columnist).*

Source: India Infoline News Service, 15.02.2021

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What's Working in Covid treatments and What Isn't

Sam Fazeli

The arrival of Covid-19 vaccines has put the focus of the pandemic fight on inoculating as many people as quickly as possible. But outbreaks are still raging worldwide, with thousands of new infections every day

and health systems under pressure to care for the sick, a reality that will continue for some time. Vaccine timelines also keep getting more and more stretched. With that in mind, it's a good time to take stock of where we are in treating the disease. The short answer is, there's progress but it's mixed.

For months, Gilead Sciences Inc.'s remdesivir and the generic steroid dexamethasone have been used on the front lines after being shown to reduce hospital stays and improve recovery speeds. Now, as we learn more about Covid-19, more treatments — including some that at first drew skepticism from physicians and scientists — are proving effective in certain circumstances. Others, such as convalescent plasma, are not. Let's take a look:

"Toci": Two arthritis drugs that previously failed in treating Covid-19 — Roche Holding AG's tocilizumab and Sanofi-Regeneron Pharmaceuticals Inc.'s sarilumab — are now showing a meaningful effect in helping reduce the burden of disease in some patients. It seems that when the drugs are used is key. The latest data comes from a trial involving patients who were treated within 24 hours of needing hospital care in an intensive care unit. The drugs reduced mortality, suggesting that seven or eight lives would be saved for each 100 people treated. The hope is that this data will be corroborated in the UK's much larger and pioneering Recovery trial now underway, with more than 3,000 of the 28,000 and rising participants treated with "toci." This will provide the most concrete data behind the drug and will potentially enable global approvals beyond Britain.

"Bam-bam": Next up are new drugs developed by Eli Lilly & Co. and Regeneron, part of a promising group of therapies called monoclonal antibodies that mimic the body's response to infection. Lilly's bamlanivimab, affectionately known as "bam-bam," was the first to gain emergency use authorization by the Food and Drug Administration. Both Lilly's and Regeneron's treatment have now been cleared for high-risk patients to help prevent hospitalization. One obstacle for adoption of these drugs has been the logistics of administering them — they need to be delivered using specialized infusion equipment. This difficulty was compounded in bam-bam's case with a confusing efficacy story and lukewarm comments about it in the Covid-19 treatment guidelines from the National Institutes of Health, resulting in doses piling up on hospital shelves. This situation may be about to change, though, given an early read from a 2,000-patient Mayo Clinic study in which the use of bam-bam was shown to reduce hospitalizations and emergency-room visits by 70%. There are also indications of a reduction in mortality. When data from this study is published, it is likely to drive increased interest in the use of bam-bam, and possibly Regeneron's antibody treatment, too. I do still remain cautious about the broad use of these drugs because of the risk they may hasten development of resistant mutations in the virus, which may, though unlikely, also impact vaccine-induced immunity.

Plasma: Convalescent plasma, a source of hope in the early days of the pandemic, has had a lot of subsequent failures and questions about its use. While not a drug per se, it is supposed to work in a similar way as monoclonal antibodies by giving patients ready-made immunity in a bottle in the form of plasma from recovered patients that is full of antibodies to the virus.

The problem with previous attempts in showing a benefit from this approach was a lack of standardization and its use at the wrong time. Then recent data from a trial in Argentina raised hopes that if you use plasma with high amounts of antibodies early enough, when the infection itself is still active, it does make a difference. Unfortunately, there's since been another setback, and this time a very serious one. The UK's aforementioned Recovery trial has been comparing Regeneron's antibody treatment and convalescent plasma to standard care without those treatments in a very large patient group, making the data and its statistical analysis very robust.

Findings from the trial showed no difference in the mortality of those receiving plasma and those on placebo. We still need to see the data in published form to be able to judge if there were any other potential explanations for the outcome. But if the result is unequivocal, it at least means there will be no more time and money wasted treating patients with an ineffective therapy that carries some risks. In a way, the negative outcome is still a step forward in sharpening treatments of Covid-19.

The end of the pandemic may be in sight, assuming we can control infections and the development of new variants, but it's still many months away. Fortunately, the more we learn, the better we know which treatments are helpful and how to use them. The arsenal is growing. We can use all the help we can get.

Source: https://english.aawsat.com, 24.01.2021

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- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Mr T R Gopalakrishnan — Cell: +98190 35076 (Email: admin@idmaindia.com)/
Mr C K S Chettiar— Cell: +98206 29907 (Email: mail_idma@idmaindia.com)
PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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Website: **www.idma-assn.org www.indiandrugsonline.org**

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