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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

HIGHLIGHTS

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Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 28** **22 to 30 July 2021**

IDMA ACTIVITIES:

INDIAN PHARMACOPOEIA:

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DoP MATTERS:

NPPA MATTERS:

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USP Education

Dear Valuable Customer,

USP India Education team is pleased to announce our upcoming live webinar courses for the month of July 2021. Please find the details as below. Kindly register yourself and nominate your team for this course.

Course 1

Course Title: **Customer Complaint Handling**
Date: Thursday, 29 July 2021
Duration: 3 hrs
Time: 10:00AM - 01:00PM (IST)
Fee: INR 3,000.00+GST = Rs.3,540.00 per person

USP Approved Speakers:
Raghunandan HV, Ph.D.
Mr. T Lakshmana Murthy

Description :
This three-hour course explains customer complaint handling related to regulatory guidelines, classification of complaints. An overview of root cause analysis (RCA) and CAPA will provide insights into the complaint handling process, responsibilities, and investigations.

Upon completion of the webinar, you will be able to understand:
- Explain market complaints including various triggers, categories and importance
- Describe regulatory guidelines for handling of market complaints
- Demonstrate knowledge of root cause analysis tools and their application for handling of market complaints through case studies
- Explain regulatory observations pertaining to market complaints

Course 2

Course Topic: **Audit fundamentals**
Date: **Saturday, 31 July 2021**
Duration: **3 hrs**
Time: **10:00 am - 01:00 pm (IST)**
Fee: **INR 3000.00+GST = Rs 3540.00 per person**

USP Approved Speakers:
Raghunandan HV, Ph.D.
Mr. T Lakshmana Murthy
Jaya Prakash Didugu, Ph.D.

Description:
This three hour course introduces the audit process, planning, data review, reporting and CAPA. Participants will experience applicable template based discussions on theoretical aspects of audit fundamentals.

Upon completion of webinar, you will be able to understand:
- Explain requirements of self -inspections and process audits
- Describe requirements of the audit process
- Summarize how audits are conducted and how audit reports are prepared.

Target audience:
Quality Assurance, Quality Control, Analytical, Regulatory Affairs, Engineering, Manufacturing, personnel working in Pharma and allied industries.

After completion of the course participants will get USP certificate (soft copy) on their e-mail id provided.

Speaker biographies:

Raghunandan HV, Ph.D. (Kuvempu University)
External faculty
USP consultant faculty since 2018

Dr. Raghunandan is a Pharmacist with over 25+ years of progressive experience in Pharmaceutical Quality Assurance, Quality Control, Regulatory affairs, Manufacturing of formulations/API's/Biological, Contract Manufacturing and Pharmaceutical Technical Consultation,(Reg. affairs, Product Development and Quality), Research and Pharmaceutical Education.

He is an experienced Quality Auditor and has good Knowledge and know how of Quality audits at site functional level and corporate Quality Management level. Has also experienced in academics in the leadership role as Deputy Director and Professor at JSS Academy of Higher Education and Research. Connected Pharmaceutical Industries with Institute for student exchange and faculty Interactions. Having around 17 years of Pharmaceutical/Consumer Health Care Industry work experience both at site Leadership and corporate. He has worked with Cipla Limited, GSK Pharmaceuticals India, GSK Consumer Health Care India, GSK Philippines and Biocon India in the past.

He is an expert on the stability studies for API's, Formulations, and Biotechnology Products. Working as an independent Pharmaceutical Consultant / Auditor from Nov 2011 till date Supported few Pharmaceutical Companies for Regulatory Filings (ANDA) & IND, Due Diligence, Training and Formulation Development.

Lakshmana Murthy T, PG degree in Synthetic Organic Chemistry, Diploma in Integrated Chemistry & Chemical Engineering, Certified Pharmaceutical GMP Professional (CPGP), Certified Quality Auditor (CQA) by ASQ & ICH Q7 Auditor by API Compliance Institute in Europe
Director, Quality Assurance,
United States Pharmacopeia
USP employee since 2010

Lakshmana Murthy serves as Director Quality Assurance at USP-India. Lakshmana has been associated with USP for nearly ten years and is currently responsible for overall quality operations at USP-India. Lakshmana also oversees a group of GMP auditors from Verification Program and USP's flagship PQM program.

Lakshmana is also the subject matter expert and chief designer of USP education courses on Pharmaceutical Quality Assurance Practices and Data Assurance. He had approximately 20 years of experience in development quality assurance, GMP auditing, quality assurance and regulatory compliance functions. He previously held key positions in Actavis Pharma Research and Development Centre and Dr. Reddy's before joining USP in September 2010.

Jayaprakash Didugu, Ph.D Computational Chemistry, MBA in Total Quality Management
GMP Auditor, Verification Programs
United States Pharmacopeia
USP Employee since 2015

Jaya Prakash has been associated with USP for more than five (5) years and is currently responsible for conducting GMP verification audits across Asia-Pacific region and occasionally in USA. Prakash conducted several audits of pharmaceutical, nutraceutical and excipient manufacturers in US, Australia, China, Taiwan, Thailand and India. Prakash is also the subject matter expert and supported to design the USP education courses on Pharmaceutical Quality Assurance Practices and Data Assurance. Prior to joining USP, Prakash worked in the pharmaceutical industry for more than thirteen (13) years in QA, Regulatory Compliance, and GMP Auditing with Pharma majors such as Granules India, Aurobindo Pharma, Dr. Reddy's and Adcock Ingram.

Prakash holds a Ph. D in Computational Chemistry, and MBA in Total Quality Management. He is also a Certified Pharmaceutical GMP Professional (CPGP) and Certified Quality Auditor (CQA) by American Society for Quality (ASQ) and Preventive Controls Qualified Individual (PCQI) by FSPCA.

Payment details:
Fee payment can be done online through UPI payment, paytm, Gpay etc. we will share the link to join the webinar after the payment for the course.
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Kindly reach out to us on **narayan.srivastav@usp.org/ hina.ansari@usp.org** or call on 7893733699 / 9154030360 for any difficulty in registration or to get more information about the course, we will be glad to assist you.

Virus Attenuation Device (Shycocan Brand) Sponsored by JBCPL

Mr. Bharat Shah, Chairman, IDMA 60th Year Celebrations Committee along with his team Mr. Mehul Shah, Mr. Mahesh H Doshi, Mr. Daara B Patel, Dr. Viranchi Shah and Mr. B G Barve standing below the ***Viral Attenuation Device (Shycocan brand)*** *gifted by* ***M/s. J B Chemicals and Pharmaceuticals Ltd.*** *courtesy their* ***CEO Mr. Nikhil Chopra.***

IDMA GSB team welcoming Shri Manoj Aggarwal, Additional Chief Secretary, H & FW Dept on July 08, 2021 at Gandhinagar

● ● ●

INDIAN PHARMACOPOEIA

IDMA thanks Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC for Three Months Extension for Implementation of IP Addendum 2021 - reg.

F. No. T.11014/01/2019-AR&D, dated 26th July 2021

To

1. *The Drugs Controller General (India)*
2. *All Zonal Offices/Port Offices of CDSCO*
3. *All State Drug (Controllers)*
4. *Directors of Central Drugs Laboratories*
5. *Directors of State Drugs Laboratories*
6. *Members of the Scientific Body of IPC*
7. *Government Analysts*
8. *IDMA/BDMA/OPPI/FSSAI/Small Scale Industry Associations*

Considering the impact of the current COVID-19 pandemic, one time extension of three months in the effective date of Addendum 2021 to the Indian Pharmacopoeia (IP) 2018 is being provided to the stakeholders for implementation of the standards included therein. IP Addendum 2021 shall be effective from **31st December 2021.**

All concerned are requested to bring it to the notice of all authorities under their control for the compliance.

Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Sector 23, Raj Nagar, Ghaziabad 201 002 (U.P.), India

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

CSR Funds of Corporate Houses Question

Lok Sabha Unstarred Question No. 83

Shri Asaduddin Owaisi:

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

(a) whether it is a fact that corporate houses spend a huge sum on Corporate Social Responsibility(CSR) for the welfare of workers and local people in the country and if so, the details thereof;

(b) whether due to corona virus corporate houses changed their strategy by setting up hospitals, oxygen plants in the area of their operation and if so, the details thereof;

(c) whether the Government has asked the corporate houses to establish hospitals, testing facilities and other health facilities for their workers and local people;

(d) if so, the instructions issued by the Government to corporate houses to take up health infrastructure under CSR; and

(e) the number of corporate houses that have helped the local people in fighting the disease?

Answered on 19th July 2021

A. (a) to (d): Section 135 of the Companies Act, 2013 ('Act') mandates every company having net worth of Rs. 500 crore or more, or turnover of Rs. 1000 crore or more, or net profit of Rs. 5 crore or more during the immediately preceding financial year to undertake Corporate Social Responsibility (CSR) activities. CSR is a Board driven process and the Board of the company is empowered to plan, decide, execute and monitor the CSR activities of the company based on the recommendation of its CSR Committee. All data related to CSR filed by companies in the MCA21 registry is available in public domain at www.csr.gov.in. On the basis of filings made by the companies in MCA21 registry, CSR amount spent by various companies in the financial years 2017-18, 2018-19 and 2019-20 respectively are given below:

	Financial Year 2017-18	Financial Year 2018-19	Financial Year 2019-20
No. of Companies	21,455	24,965	21,349
CSR expenditure (in Rs. Crore)	13,909	18,728	21,231

(Data upto 31.03.2021) [Source: National CSR Data Portal]

Ministry vide General Circular no.10/2020 dated 23.03.2020 clarified that CSR funds may be spent by the companies for various activities related to COVID-19 under item nos. (i) and (xii) of Schedule VII of the Companies Act, 2013 ('Act') which relates to promotion of health care, including preventive health care and sanitation, and disaster management. Further, Ministry vide General Circular no.05/2021 dated 22.04.2021 and General Circular no.09/2021 dated 05.05.2021 clarified that spending of CSR funds by the companies for setting up makeshift hospitals and temporary COVID care facilities and 'creating health infrastructure for COVID care', 'establishment of medical oxygen generation and storage plants' 'manufacturing and supply of Oxygen concentrators, ventilators, cylinders and other medical equipment for countering COVID-19 respectively, are eligible CSR activities.

(e) As per the Act, financial statements and board report containing disclosure about CSR, for the ongoing financial year 2021-22, are required to be filed only after the end of financial year.

Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning and Minister of State in the Ministry of Corporate Affairs [Rao Inderjit Singh]

Separation of Chairman and Managing Director Posts Question

Lok Sabha Un-Starred Question No. 210

Shri Balashowry Vallabhaneni:

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

(a) whether it is true that SEBI rules mandates separation of Chairman and Managing Director posts before the end of this fiscal;

(b) if so, the details of companies that have implemented this rule so far and the status of remaining companies;

(c) the status of separation in Central Public Sector Enterprises (CPSEs); and

(d) the measures likely to be taken by the Government to address the apprehension in some quarters of corporate world that this arrangement would weaken the position of promoters?

Answered on 19th July 2021

A. (a): Yes Sir, in terms of Regulation 17(1B) of SEBI (Listing Obligations and Disclosure Requirements), Regulations, 2015 ("LODR"), the top 500 listed entities by market capitalization are mandated to comply with the requirement of separation of the roles of Chairperson of the Board and MD/ CEO with effect from April 01, 2022.

(b) and (c): SEBI has informed the status of applicability of Regulation 17(1B) and the status of implementation of Regulation 17(1B)(a) and 17(1B)(b) for top 500 companies, including CPSEs as under:-

	BSE		NSE	
No. of entities to which Regulation 17(1B) of LODR is applicable	486		487	
No. of entities that have non-executive director in terms of Regulation 17(1B)(a) of LODR	CPSE	OTHER	CPSE	OTHER
	6	274	6	273
No. of entities where Chair-person is not related to MD/CEO have implemented Regulation 17(1B)(b) of LODR	12	275	12	278

(d): The separation of post of Chairperson from MD/CEO is considered to enhance corporate governance, therefore, apprehension that it would weaken the position of promoters is misplaced.

Minister of State (Independent Charge) of the Ministry of Statistics And Programme Implementation; Minister of State (Independent Charge) of The Ministry of Planning; and Minister of State for Corporate Affairs [Rao Inderjit Singh]

AMENDMENT TO CSR RULES QUESTION

Lok Sabha Unstarred Question No. 212

Shri Sanjay Bhatia:

Shri Brijendra Singh:

Shri Nayab Singh:

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

(a) whether the Government has made any changes in the laws governing Corporate Social Responsibility (CSR);

(b) if so, the details of the changes made therein and the reasons therefor;

(c) whether the Government proposes to carry out radical changes in the laws governing CSR;

(d) if so, the details thereof; and

(e) the details of the total CSR spending by the Public Sector Undertakings during the period from March, 2020 till date State/UT-wise?

Answered on 19th July 2021

A. (a) to (d): Yes sir. In pursuance of the Amendments to Section 135 of the Companies Act, 2013 ('Act') by Companies (Amendment) Act, 2019 and Companies (Amendment) Act, 2020, the Companies (CSR Policy) Rules, 2014 have been amended on 22nd January 2021. These amendments aim at strengthening the Corporate Social Responsibility (CSR) ecosystem by improving the disclosures, simplifying the compliances, bringing in more objectivity and transparency, and entrusting more responsibility on the Board of the company. These amendments, inter-alia, include mandatory registration of implementing agencies with the Ministry, flexibility to board for spending as per project requirements, treatment of unspent amount as well as set-off of excess amount spent under CSR, impact assessment of CSR projects, modalities for creation and acquisition of capital assets through CSR etc.

(e): As per the Companies Act, 2013 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 CSR, are to be filed in MCA21 within 30 days of the AGM. Thus, the CSR data for the Financial Year 2020-21 is not available.

Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning and Minister of State in the Ministry of Corporate Affairs [Rao Inderjit Singh]

GST ON COVID RELIEF GOODS

Lok Sabha Unstarred Question No.216

Shri Anurag Sharma:

Q. Will the Minister of **FINANCE** be pleased to state:

(a) whether it is a fact that the Government has brought down the Goods and Services Tax (GST) on 14 Covid relief goods;

(b) if so, the details thereof;

(c) whether it is also true that the relaxation given will remain till September, 2021 and if so, the details thereof; and

(d) whether it is also true that this met with the demands of the many States in this regard and if so, the details thereof?

Answered on 19th July 2021

A. (a) : In order to ensure the availability and affordability of the items necessary for treatment and management of COVID-19 situation, Government has reduced the GST rates on such items.

(b): The details of goods for Covid relief on which GST rate has been reduced is enclosed.

(c) : The above stated concessions are effective upto and inclusive of 30th September, 2021.

(d): GST rates are prescribed on the basis of recommendations of the GST Council as made from time to time. GST Council is a constitutional body having Ministers of all the states and Union Territory having legislature as its member. The recommendations, in this regard, were based on suggestions received from many State Governments.

ANNEXURE

Covid Relief Goods on which GST rate has been reduced

S. No.	Description	From	To
	A. Medicines		
1.	Tocilizumab	5%	Nil
2.	Amphotericin B	5%	Nil
3.	Anti-Coagulants like Heparin	12%	5%
4.	Remdesivir	12%	5%
	B.Oxygen, Oxygen generation equipment and related medical devices		
1.	Medical Grade Oxygen	12%	5%
2.	Oxygen Concentrator/Generator, including personal imports thereof	12%	5%
3.	Ventilators	12%	5%
4.	Ventilator masks/canula/helmet	12%	5%
5.	Bi PAP Machine	12%	5%
6.	High flow nasal canula (HFNC) device	12%	5%
	C.Testing Kits and Machines		
1.	Covid Testing Kits	12%	5%
2.	Specified Inflammatory Diagnostic Kits, namely D- Dimer, IL-6, Ferritin and LDH	12%	5%
	D. Other Covid-19 related relief material		
1.	Pulse Oximeters, including personal imports thereof	12%	5%
2.	Hand Sanitizer	18%	5%
3.	Temperature check equipment	18%	5%
4.	Gas/Electric/other furnaces for crematorium, including their installation, etc.	18%	5%
5.	Ambulances	28%	12%

Minister of State in the Ministry of Finance
Sh. Pankaj Choudhary

CSR Funds Question

Lok Sabha Unstarred Question No. 230

Shri Annasaheb Shankar Jolle:

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

(a) the yearly expenditure of CSR funds under legally mandated law;

(b) whether the changes in its administration and utilisation is evaluated against the funds spent;

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

(d) whether the data is available on the same is district and State-wise expenditure for proper planning and analyzing; and

(e) if so, the details thereof and time by which the same will be available in near future?

Answered on 19th July 2021

A. (a) to (e): Section 135 of the Companies Act, 2013 ('Act') mandates every company having net worth of Rs. 500 crore or more, or turnover of Rs. 1000 crore or more, or net profit of Rs. 5 crore or more during the immediately preceding financial year to undertake Corporate Social Responsibility (CSR) activities. CSR is a Board driven process and the Board of the company is empowered to plan, decide, execute and monitor the CSR activities of the company based on the recommendation of its CSR Committee. The entire CSR architecture is disclosure based and CSR mandated companies are required to file details of CSR activities annually in MCA21 registry. The existing legal provisions such as mandatory disclosures, accountability of the CSR Committee and the Board, provisions for statutory audit of accounts of the company etc. provide sufficient safeguards. Whenever any violation of CSR provisions is reported, action against such non-compliant Companies are initiated as per provisions of the Act after due examination of records and following due process of law.

All data related to CSR filed by companies in the MCA21 registry including district- wise and State-wise is available in public domain at www.csr.gov.in. The State-wise CSR spent by all the companies for the financial years 2014-15, 2015-16, 2016-17, 2017-18, 2018-19 and 2019-20 respectively is at Annexure.

Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning and Minister of State in the Ministry of Corporate Affairs [Rao Inderjit Singh]

Annexure

Annexure Referred to In Reply to Lok Sabha Unstarred Question No. 230 For 19.07.2021

STATE/UT-WISE CSR EXPENDITURE DETAILS (IN RS. CRORE)							
States/UT	**Amount Spent FY 2014-15**	**Amount Spent FY 2015-16**	**Amount Spent FY 2016-17**	**Amount Spent FY 2017-18**	**Amount Spent FY 2018-19**	**Amount Spent FY 2019-20**	**Total**
Andaman And Nicobar	0.29	0.55	0.83	0.75	0.43	0.68	3.53
Andhra Pradesh	414.27	1,294.28	753.52	275.27	644.83	679.19	4061.36
Arunachal Pradesh	11.04	1.48	24.04	12.13	24.50	16.83	90.03
Assam	134.78	164.60	269.91	86.23	206.01	753.73	1614.26
Bihar	36.68	124.61	100.77	47.49	136.47	138.15	584.17
Chandigarh	1.77	5.34	21.98	20.51	11.72	14.24	75.57
Chhattisgarh	161.30	241.16	84.94	71.79	146.66	156.64	862.48
Dadra And Nagar Haveli	4.41	12.02	7.58	6.93	13.48	18.92	63.33
Daman And Diu	20.05	2.42	2.63	20.09	6.23	8.60	60.02
Delhi	237.43	493.34	521.16	558.33	674.17	643.99	3128.41
Goa	27.11	30.15	37.89	53.34	46.74	43.71	23.93
Gujarat	313.44	551.42	870.84	775.90	1,065.90	910.13	4487.63
Haryana	187.40	375.61	390.07	266.09	334.53	474.43	2029.14
Himachal Pradesh	10.94	52.28	24.03	60.60	79.97	76.09	303.92

Jammu And Kashmir	43.70	107.80	42.84	46.44	35.34	24.93	301.06
Jharkhand	79.56	117.03	95.69	45.92	70.30	139.04	547.54
Karnataka	403.46	784.66	887.68	1,034.33	1,224.92	1383.65	5718.69
Kerala	68.23	148.13	135.47	167.24	387.17	250.02	1156.25
Lakshadweep	0	0.30	0	2.07	0.39	1.00	3.76
Madhya Pradesh	141.88	185.50	290.60	147.25	247.15	165.47	1177.84
Maharashtra	1,445.91	2052.23	2492.11	2,565.59	2,864.04	2,751.21	14171.09
Manipur	2.44	6.27	12.35	4.03	7.64	10.87	43.61
Meghalaya	3.53	5.58	10.97	5.49	17.99	17.29	60.85
Mizoram	1.03	1.07	0.08	0.23	0.11	0.25	2.77
Nagaland	1.11	0.95	0.92	0.36	2.11	1.64	7.09
Odisha	252.18	624.04	316.72	472.58	682.87	679.43	3027.83
Puducherry	2.02	6.46	7.42	6.53	8.30	8.63	39.37
Punjab	55.60	69.92	75.83	89.32	164.58	176.06	631.31
Rajasthan	299.75	502.95	325.15	263.83	549.02	696.77	2637.47
Sikkim	1.19	1.98	6.83	6.84	4.58	3.94.	25.37
Tamil Nadu	539.63	633.23	550.94	627.75	829.27	919.05	4099.88
Telangana	101.96	265.40	259.88	293.53	422.39	404.97	1748.13
Tripura	1.33	1.47	1.25	1.83	23.06	4.34	33.29
Uttar Pradesh	148.90	423.79	328.31	302.91	479.88	496.13	2179.93
Uttarakhand	74.79	73.16	102.52	86.65	173.32	105.34	615.78
West Bengal	194.85	415.41	290.35	299.77	369.50	390.51	1960.39
NEC/ Not mentioned	26.94	0	7.63	132.04	3.68	3.42	173.72
PAN India*	4,615.03	4,740.61	4,990.68	5,050.79	6,767.74	8,662.86	34827.72
Grand Total (in Cr.)	10,065.93	14,517.20	14,342.45	13,908.79	18,728.01	21,231.15	92793.54

(Data upto 31.03.2021) [Source: National CSR Data Portal]

**Companies either did not specify the names of States or indicated more than one State where projects were undertaken.*

TAX Exemption on Import of Medical Items

Lok Sabha Unstarred Question No.104

Shri Kuruva Gorantla Madhav:

Q. Will the Minister of **FINANCE** be pleased to state:

(a) whether the Government has granted tax exemptions on the import of essential medical items to combat Covid-19;

(b) if so, the details thereof;

(c) whether the GST council has constituted a Group of Ministers to examine the requirement for GST concessions/exemption for items used as Covid-19 relief material; and

(d) if so, the details of the report or the recommendations of the committee in this regard?

Answered on 19th July 2021

A. (a) and (b): In order to ensure the availability and affordability of goods being used for Covid-19 relief and management, the Government has for specified

period provided the following indirect exemptions/ concessions on imports of such items:-

(i) Customs Duties including cesses, wherever applicable, has been exempted on (a) medicines such as Remdesivir injection, Remdesivir API, Amphotericin B and specified inputs for their manufacturing (b) oxygen and oxygen related equipment (c) Covid-19 Vaccines (d) specified inflammatory diagnostic kits, etc.

(ii) Specified Covid relief items have also been exempted from payment of IGST when imported for donation to Central Government, State Government or any relief agency, entity or statutory body for free distribution.

(iii) GST rate has been reduced on imports of specified goods like Covid-19 related medicines, oxygen, oxygen related equipment, specified Covid-19 testing kits, Pulse oximeters, hand sanitizers, temperature check equipment, Gas/electric furnace for crematorium and ambulances.

(c) and (d): GST Council in its 43rd meeting decided to constitute a Group of Ministers (GoM) to examine the issue of GST exemption/concession on Covid relief material. The GoM made recommendations for reducing GST rates on specified Covid relief items. These recommendations were discussed in 44th meeting of GST Council. Council made recommendation for reduction of GST rates, on Covid relief items taking into account the recommendations of GoM. On the recommendation of Council, the concessional GST rates on items mentioned at item no. (iii) in reply part (a) and (b) above were notified.

Minister of State in the Ministry of Finance Sh. Pankaj Choudhary

TAXES On Medical Equipments

Lok Sabha Unstarred Question No.18

Shri Nitesh Ganga Deb:

Q. Will the Minister of FINANCE be pleased to state:

(a) whether the Government has waived taxes from articles and medical equipments used for corona treatments in the country; and

(b) if so, the details thereof?

Answered on 19th July 2021

A. **(a):** In order to ensure the availability and affordability of goods being used for Covid-19 relief and management, the Government has for specified period provided the following indirect exemptions/ concessions on such items:-

(i) Customs Duties has been exempted on (a) medicines such as Remdesivir injection, Remdesivir API, Amphotericin B and specified inputs for their manufacturing (b) oxygen and oxygen related equipment (c) Covid-19 Vaccines (d) specified inflammatory diagnostic kits, etc.

(ii) Specified Covid relief items have also been exempted from payment of IGST when imported for donation to Central Government, State Government or any relief agency, entity or statutory body for free distribution.

(iii) GST rate has been reduced on specified goods like Covid-19 related medicines, oxygen, oxygen related equipment, specified Covid-19 testing kits, Pulse oximeters, hand sanitizers, temperature check equipment, Gas/electric furnace for crematorium and ambulances.

(b) : The list of Covid-19 relief goods on which GST/ Customs duty has been reduced is enclosed.

Minister of State in the Ministry of Finance Sh. Pankaj Choudhary

ANNEXURE

A. Exemption/ Reduction in GST and IGST (on imports) on COVID-19 relief goods

S. No.	Description	From	To
A. Medicines			
1.	Tocilizumab	5%	Nil
2.	Amphotericin B	5%	Nil
3.	Anti-Coagulants like Heparin	12%	5%
4.	Remdesivir	12%	5%
B. Oxygen, Oxygen generation equipment and related medical devices			
1.	Medica lGrade Oxygen	12%	5%
2.	Oxygen Concentrator/Generator, including personalimports thereof	12%	5%
3.	Ventilators	12%	5%
4.	Ventilator masks/canula/helmet	12%	5%

5.	BiPAP Machine	12%	5%
6.	High flow nasal canula (HFNC)device	12%	5%
C. Testing Kits and Machines			
1.	Covid Testing Kits	12%	5%
2.	Specified Inflammatory Diagnostic Kits, namely D-Dimer, IL-6, Ferritin and LDH	12%	5%
D. Other Covid-19 related relief material			
1.	Pulse Oximeters, including personal imports thereof	12%	5%
2.	Hand Sanitizer	18%	5%
3.	Temperature check equipment	18%	5%
4.	Gas/Electric/ other furnaces for crematorium, including the irinstallation, etc.	18%	5%
5.	Ambulances	28%	12%

B. Full Exemption from Customs Duty on import of COVID-19 relief goods

S. No.	Description of goods
1.	Remdesivir Active Pharmaceutical Ingredients (API)
2.	Beta Cyclodextrin (SBEBCD) used in manufacture of Remdesivir, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.
3.	Injection Remdesivir.
4.	Inflammatory Diagnostic (marker) kits, namely-IL6, D-Dimer, CRP(C-Reactive Protein), LDH (Lactate De-Hydrogenase), Ferritin, Pro Calcitonin (PCT) and blood gas reagents
5.	Medical Oxygen
6.	Oxygen concentrator including flow meter, regulator, connectors and tubings.
7.	Vacuum Pressure Swing Absorption (VPSA) and Pressure Swing Absorption (PSA) oxygen plants, Cryogenic oxygen Air Separation Units (ASUs) producing liquid/gaseous oxygen.
8.	Oxygen canister.
9.	Oxygen filling systems.
10.	Oxygen storage tanks
11.	Oxygen generator
12.	ISO containers for Shipping Oxygen
13.	Cryogenic road transport tanks for Oxygen
14.	Oxygen cylinders including cryogenic cylinders and tanks
15.	Parts of goods at S.No.6 to 14 above, used in the manufacture of equipment related to the production, transportation, distribution or storage of Oxygen, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.
16.	Any other device from which oxygen can be generated
17.	Ventilators, including ventilator with compressors; all accessories and tubings; humidifiers; viral filters (should be able to function as high flow device and come with nasal canula).
18.	High flow nasal canula device with all attachments; nasal canula for use with the device.
19.	Helmets for use with non-invasive ventilation.
20.	Non-invasive ventilation oronasal masks for ICU ventilators.
21.	Non-invasive ventilation nasal masks for ICU ventilators.
22.	COVID-19 vaccine
23.	Amphotericin B
24.	6 specified API/ excipients for manufacturing Amphotericin B
25.	Raw materials for manufacturing COVID test kits

Bulk Drug Park

Lok Sabha Starred Question No. 114

Shri Anurag Sharma:

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

(a) whether the Government has received any proposal for construction of Bulk Drug Park (Pharmaceutical Park) in Lalitpur, Uttar Pradesh;

(b) if so, the details thereof;

(c) the funds released for construction of the said park; and

(d) the time by which the construction of the said park is likely to be completed?

Answered on 27th July 2021

A. (a) to (d): A statement is laid on the Table of the House.

Statement Reffered to in Reply to Parts (A) to (D) of Starred Question No. 114 For Reply On 27.07.2021

(a) to (b): Department of Pharmaceuticals has received a proposal from the Government of Uttar Pradesh for establishment of a Bulk Drug Park under the scheme for "Promotion of Bulk Drug Parks". The proposed site for the bulk drug park is located in Saidpur Village (Mehrauni Tehsil) of Lalitpur District. The appraisal of all the proposals received under the scheme has been initiated.

(c): No, Sir.

(d): No such time has been decided.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Covid-19 Pandemic

Lok Sabha Unstarred Question No. 1184

Shri Parvesh Sahib Singh Verma:

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

(a) whether the Government is preparing in advance for future wave of Covid-19 pandemic;

(b) the steps taken by the Government to enhance production and maintain sufficient supply of critical drugs and medicines with regard to treatment of COVID19; and

(c) whether the Government has taken any steps to check and prevent black-marketing and duplication of life saving drugs and if so, the details thereof?

Answered on 27th July 2021

A. (a): Yes, Sir. Ministry of Health and Family Welfare has prepared the guidelines for Buffer Stock Management of COVID-19 on importance of maintenance of sufficient buffer stocks of essential drugs used in management of COVID-19 cases and their sequelae. Ministry of Health and Family Welfare has identified a suggestive list of drugs to be a part of the buffer stock to be maintained by the State/UT Governments as well as the Central Government. Further, inter-alia, the Guidelines also provide that the States/UTs may suitably customize the list in accordance with their local needs and requirements for treatment/management of COVID-19 and its sequelae such as COVID-19 Associated Mucormycosis (CAM) and Multisystem Inflammatory Syndrome in Children (MIS-C).

(b) Government has taken various steps to enhance production and maintain sufficient supply of critical drugs. The measures included expeditious approvals to increase the number of manufacturing sites of Remdesivir and Amphotericin-B. There was regular engagement with the manufacturers of COVID-19 drugs to monitor their production. The export of Remdesivir and Amphotericin-B was also prohibited to maintain adequate domestic supply. The Ministry of External Affairs also assisted the manufacturers for import of raw materials and COVID-19 drugs. To ensure equitable distribution of drugs across the country, allocation of Remdesivir, Tocilizumab and Amphotericin-B was done to States/UTs based on rational and transparent allocation criteria. Daily monitoring of supply of allocated drugs by National Pharmaceutical Pricing Authority (NPPA) was done for ensuring timely supply of drugs through coordination with nodal officers of States and liaison officers of manufacturers. Monitoring of availability of the drugs was also done regularly by the Central Drugs Standard Control Organisation (CDSCO) and the NPPA.

(c) Amidst reports of black-marketing / hoarding / overcharging of COVID-19 management drugs, CDSCO has requested Licensing authorities of all States/UTs through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against the offenders by conducting special drive of monitoring and investigation. As per information available from various State Licensing Authorities, in cases of black-marketing / hoarding/overcharging of COVID-19 management drugs, various enforcement actions like drug seizure, arrests of accused persons / registration of FIRs etc. have been carried out by the State Licensing Authorities.

The NPPA vide letter dated 08.04.2021 addressed to all State Drug Controllers, had directed to closely monitor the production and availability of COVID-19 drugs to prevent black marketing and hoarding.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Affordable Medical Devices

Lok Sabha Unstarred Question No.1194

Shri Kanumuru Raghu Rama Krishna Raju:

Shri Manoj Kotak:

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

(a) whether the Government has any proposal to provide affordable medical devices/equipments and surgical items in the country, if so, the details thereof;

(b) the details of the steps taken by the Government to make surgical items affordable in the country;

(c) whether the Department of Pharmaceuticals has launched any Umbrella Scheme in this regard; and

(d) if so, the details thereof and the progress regarding the implementation of the said Scheme?

Answered on 27th July 2021

A. (a) and (b) :The Government has taken various measures to provide affordable medical devices/ equipments and surgical items to the citizens in the country.

With an objective of making quality generic medicines, surgicals & consumables available at affordable prices to all the citizens, especially to the poor and the deprived ones, Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals. Under the scheme, more than 7,900 dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJK) have been opened in all the districts of the country. The product basket of PMBJP presently comprises of 1,451 medicines and 204 surgicals & consumables.

Further, the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has fixed the ceiling prices of the Coronary Stents and Knee Implants under Para 19 of the DPCO, 2013 vide Notifications dated 13th Feb 2017 and 16th August 2017 respectively in the larger public interest. Further, NPPA has extended ceiling price of four medical devices, which have been included in the National List of Essential Medicines (NLEM) and in Schedule-I of the Drugs (Prices Control) Order, 2013(DPCO, 2013), viz., Cardiac Stents, Drug Eluting Stents, Condoms and Intra Uterine Devices (Cu-T).

Recently, NPPA invoked Paragraph 19 of the DPCO, 2013 to regulate the price of Oxygen Concentrators vide Notification dated 03.06.2021, and prices of (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer under 'Trade Margin Rationalisation' Approach vide Notification dated 13.07.2021, in view of the extraordinary circumstances arising due to COVID pandemic and with the aim of making these medical devices affordable during the evolving pandemic.

NPPA also monitors prices of 28 notified medical devices under compulsory licensing framework under Para 20 of the DPCO, 2013 to ensure their MRP is not increased more than 10% in preceding twelve months.

(c) & (d): As part of the Umbrella Scheme on 'Development of Pharmaceutical Industry', there is a sub-scheme, viz., 'Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices' with an outlay of Rs. 3,420 cr. to boost domestic manufacturing and attract large investments in the Medical Devices Sector. Under the Scheme, financial incentive is given to the selected companies at the rate of 5% on incremental sales of medical devices manufactured. Under the Scheme, 13 applications have been approved with a total Committed Investment of Rs.798.93 crore. Another sub-scheme under the Umbrella Scheme for 'Promotion of Medical Device Parks' with an outlay of Rs. 400 cr. provides support for creation of common infrastructure facilities to provide easy access to standard testing and infrastructure facilities through creation of world class common infrastructure facilities for medical devices.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Shortage of Antiviral Drugs

Lok Sabha Unstarred Question No. 1223

Shri Kumbakudi Sudhakaran:

Shri Mohammed Faizal P.P.:

Shri D.K.Suresh:

Shri Gaurav Gogoi:

Dr. A. Challakumar:

Shri Pradyut Bordoloi:

Dr. Amar Singh:

Shri M. Selvaraj:

Shri Sisir Kumar Adhikari:

Shri Saptagiri Sankar Ulaka:

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

(a) whether the Government has taken cognisance of shortage of antiviral drugs such as Remedesivir and Tocilizumab;

(b) if so, the details thereof and action taken to address this shortage;

(c) whether the Government, exercising its powers under the Patents Act intends to issue compulsory licenses to generic pharmaceutical companies for manufacturing of low cost versions of Remdesivir and Tocilizumab;

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

(e) the number of Remdesivir manufacturers in the country and their production capacity, since 2019 till date; and

(f) the number of Remedesivir and Tocilizumab manufacturing units set up between March 2020 and May 2021?

Answered on 27th July 2021

A. (a) to (b): Yes, Sir. Shortages were noticed in the months of April and May, 2021 in case of Remdesivir and Tocilizumab due to the sudden surge in demand of these drugs for managing COVID-19 patients. It may be noted that both these drugs are patented drugs. Remdesivir is manufactured in India whereas Tocilizumab is available in India through imports only. To address the shortages, government immediately started working on augmenting supply of these drugs by augmenting domestic production in case of Remdesivir and by making efforts for increased quantity of imports in case of Tocilizumab. Due to collective efforts made in this direction by seven domestic manufacturers of Remdesivir and with the grant of expeditious approvals by Drug Controller General of India, the number of licensed manufacturing sites of Remdesivir in India increased from 22 in mid-April, 2021 to 62 at present. The domestic production capacity of Remdesivir increased from 38 lakh vials per month in mid-April, 2021 to 122 lakh vials per month now. Similarly, in case of Tocilizumab, the imported quantity was maximised due to persistent efforts of the Government with the sole manufacturer of Tocilizumab.

Further, in order to secure domestic supply of Remdesivir, the export of Remdesivir Injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from 11th April, 2021. In addition, Department of Pharmaceuticals (DoP) and Ministry of Health and Family Welfare (MoH&FW) jointly undertook an exercise for allocation of available stocks of Remdesivir and Tocilizumab to all the States/UTs of the country in a move to mitigate shortage and to ensure fair and equitable distribution across the country. The total allocation and supply of these two drugs is given as under:

Sr. No.	Name of the drug	Allocation to States/ UTs and Central Institutions (in vials)	Supply till 18.07.2021 (in vials)
1.	Remdesivir Injection	98,87,000	97,03,393
2.	Tocilizumab (400 mg) Injection	9,900	9,578
3.	Tocilizumab (80 mg) Injection	65,000	53,284

In addition to the above allocation of commercial supplies to States/UTs, the MoHFW has also distributed the following, free of cost, to the States/ UTs:

- 21,86,936 vials of Remdesivir purchased from the domestic manufacturers.
- 8,23,862 vials of Remdesivir sourced from outside India through donation and commercial purchases.
- 1,001 vials of Tocilizumab (400 mg) received in donation from Oman have been distributed to States/UTs.
- 27,381 vials of Tocilizumab (80 mg) received in donation from Roche have been distributed to States/UTs.

As on date, the demand of Remdesivir has come down considerably and the demand supply gap

has reversed in the sense that supply is much more than the demand. Accordingly, Remdesivir has been moved from Prohibited to Restricted Category of Exports on 14th June, 2021. Similarly, the demand-supply position for Tocilizumab has stabilized considerably and some States are not placing purchase orders with the company marketing Tocilizumab as per quantities allocated by Central Government to them. The States and UTs have been advised to procure buffer stocks to deal with any future requirements.

(c) to (d): No sir. There is no application filed for invoking compulsory licensing under Section 84 of the Patents Act with central Government by manufacturer or party intending to manufacture Remdesivir or Toculizumab. Further, the manufacturing capacity of Remdesivir, a patented drug has been ramped up from 38 lakh vials per month to 1.22 crore vials per month now, by the seven domestic manufacturers that have been licensed in 2020 by Gilead Sciences Inc, a USA based multinational company, holding the patent for Remdesivir. Tocilizumab is also a patented drug of Hoffman La Roche, a Switzerland based multinational company and is not manufactured in India. It is pertinent to note that the Central Drugs Standard Control Organisation (CDSCO) under MoHFW, has on 12th May, 2021 given permission to one Indian pharmaceutical company for conducting phase three clinical trials for a bio-similar drug.

(e) to (f): As per CDSCO, Remdesivir injection was approved on 20.06.2020 in the country. Presently, 62 manufacturing sites of 7 manufacturers are approved for manufacturing Remdesivir injection with total monthly installed capacity of 122 lakh vials/month. Presently Tocilizumab is not manufactured in India but marketed in India only by way of imports.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Registered Drug Manufacturer

Lok Sabha Unstarred Question No: 1255

Shrimati Sarmistha Sethi:

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

(a) the details of the manufacturers of generic drugs and the companies registered for their manufacture in the country;

(b) whether these manufacturers are associated with Food and Drug Administration (FDA); and

(c) if so, the detailed list of the drugs manufactured by the aforesaid companies?

Answered on 27th July 2021

A. (a) to (c): As per Central Drugs Standard Control Organisation (CDSCO), the details of number of pharmaceutical drug manufacturers, State/UT-wise, in the country as on 29-05-2020 are attached as per Annexure. The manufacture for sale of any drug in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder. Licenses for manufacture of sale are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments.

Annexure

Number of Pharmaceutical Units present in States and UTs as on 29-05-2020

S. No.	Name of the State/UTs	No. of Pharma Units
1.	Andhra Pradesh	261
2.	Arunachal Pradesh	NIL
3.	Assam	25
4.	Bihar	89
5.	Chhattisgarh	31
6.	Goa	51
7.	Gujarat	3332
8.	Haryana	31
9.	Himachal Pradesh	555
10.	Jammu & Kashmir	55
11.	Jharkhand	44
12.	Karnataka	376
13.	Kerala	100
14.	Madhya Pradesh	267
15.	Maharashtra	929
16.	Manipur	NIL
17.	Meghalaya	NIL
18.	Mizoram	NIL
19.	Nagaland	NIL
20.	Odisha	18
21.	Punjab	156
22.	Rajasthan	128
23.	Sikkim	45
24.	Tamil Nadu	514
25.	Telangana	523
26.	Tripura	6

27.	Uttarakhand	220
28.	Uttar Pradesh	408
29.	West Bengal	180
30.	Pondicherry	86
31.	Andaman & Nicobar Island	NIL
32.	Chandigarh	5
33.	Delhi	63
34.	Dadra & Nagar Haveli and Daman & Diu	34
35.	Lakshadweep	NIL
	Total	8532

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Medicine Price Monitoring

Lok Sabha Unstarred Question No. 1256

Shri Manoj Kotak:

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

(a) whether the Department of Pharmaceuticals has any scheme to monitor the prices of medicines especially after the Coronavirus outbreak;

(b) if so, the details thereof;

(c) the steps taken by the Government for price control of medicines in the country during recent years and at the peak of Coronavirus pandemic this year; and

(d) if so, the details thereof?

Answered on 27th July 2021

A. (a) & (b): Yes, Sir. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals, as an on-going process, with the help of Price Monitoring & Resource Units (PMRUs) and State Drug Controllers (SDCs) undertake activities related to market-based data collection, monitoring of the notified prices of medicines and detection of violation of the provisions of Drug (Price Control) Order, 2013 (DPCO, 2013).

(c) & (d): NPPA fixes the ceiling prices of scheduled formulations as per provisions of DPCO, 2013 and monitors the prices of non-scheduled drugs so as to ensure that their prices do not increase beyond 10 percent in a year. NPPA has fixed ceiling prices of 355 medicines and 882 formulations for medicines under National List of Essential Medicines, 2015 (Schedule-I of DPCO, 2013). Most of the drugs that are part of COVID management protocol have ceiling prices, viz., Paracetamol, Dexamethasone, Methyl Prednisolone, IVIGs, Enoxaparin, Budesonide, Heparin and Amphotericin etc. In the case of few non-scheduled medicines like Remdesivir, which are part of COVID protocol and are non-scheduled, on Government intervention, MRPs of various brands of Remdesivir have been reduced voluntarily by the major manufacturers/marketers of the Remdesivir Injection (lyophilized). Inter-brand MRPs that varied up to Rs 5400/ per vial were brought down to less than Rs 3500/-.

Furthermore, to facilitate availability and ensure affordability, NPPA has capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level vide notification dated 3rd June, 2021 and on Pulse Oximeter, Glucometer, BP Monitor, Nebulizer and Digital Thermometer vide notification dated 13th July, 2021.

In addition, Retail prices for 1,640 formulations have been fixed under DPCO, 2013 till date and in recent years exercising extraordinary powers under DPCO, 2013 in public interest, NPPA has fixed the prices of following drugs and medical devices:

(i) Ceiling price of Stents in February, 2017

(ii) Ceiling price of Knee Implants in August, 2017

(iii) Capped trade margin on selected 42 anti-cancer drugs in February, 2019.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Availability of Medicines

Lok Sabha Unstarred Question No. 1263

Shri Parbhubhai Nagarbhai Vasava:

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

(a) the details about the scheme being prepared by the Government to ensure that there will be no shortage of medicines during the third probable wave of the coronavirus in the near future;

(b) the number of vaccine doses being produced in the country per day for the prevention of coronavirus; and

(c) the detailed regarding both of the above important information for public concerns?

Answered on 27th July 2021

A. (a) Ministry of Health and Family Welfare vide its D.O.No.X.11035/178/2021-DRS on dated 13.07.2021 issued "Guidelines for Buffer Stock Management of COVID 19" to State Governments/ UT administrations requesting them to initiate the necessary procurement process on priority, with a view to ensure continuous availability of drugs for any possible future surge in cases.

(b) & (c) The National Covid-19 Vaccination Programme is built on scientific & epidemiological evidence, WHO Guidelines and Global Best Practices. It is expected that beneficiaries aged 18 and above will be vaccinated by December 2021.

The National Covid-19 Vaccination Programme commenced with vaccination of Health Care Workers, free of cost. The Programme was expanded with time to include vaccination of Front Line Workers, citizens more than 60 years of age, citizens more than 45 years of age and eventually, citizens more than 18 years of age. Government of India procures and provides vaccine free of cost to the States/UTs. In addition, 25% of the monthly production of vaccine manufactured is available for procurement by private hospitals.

Government of India has made pro-active arrangements to augment the production capacities of domestic vaccine manufacturers by facilitating technology transfer, providing financial assistance, providing advance payment against supply orders and by streamlining the Regulatory pathway for approval of vaccines. Government of India has further placed procurement orders to ensure adequate supply of vaccines to facilitate vaccination of eligible adult citizens.

States/UTs are provided advance visibility of vaccine doses that would be supplied to them 15 days in advance to enable them to plan vaccination in accordance with availability of doses and to maximize the convenience of the beneficiaries.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Price Reduction of Drugs

Lok Sabha Unstarred Question No. 1317

Shri M.K. Raghavan

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

(a) whether National Pharamaceutical Pricing Authority (NPPA) makes any efforts to stabilize the pharmaceutical prices in the country;

(b) if so, the details thereof;

(c) whether the NPPA has asked Pharma manufactures to reduce the prices on medicines in lieu of reduction in GST by the Government; and

(d) if so, the details regarding the same and the list of medicines for which prices have been reduced?

Answered on 27th July 2021

A. (a) & (b): Yes, National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes / revises the ceiling prices of the scheduled formulations as per the provisions of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). Further, NPPA also monitors the Maximum Retail Price (MRP) of scheduled formulations so as to ensure that the MRP of such formulations are within the range of ceiling price and that of non-scheduled formulations to ensure that MRP does not increase by more than 10% of MRP during the preceding twelve months. The details of ceiling / retail prices fixed/ revised by NPPA are available on NPPA's website, www.nppaindia.nic.in.

(c) & (d): NPPA has issued detailed guidelines on 13th April, 2016 for compliance of revised prices by the manufacturers / marketing companies due to change in the Tax/ GST rates. Recently, the GST Council in its 44th meeting held on 12th June, 2021 has reduced GST on goods being used in COVID-19 management. A copy of the press release issued by the Ministry of Finance indicating the details of medicines and medical devices used for COVID management, on which GST rates were revised, is enclosed.

In order to pass the benefit of reduction in GST rates to the consumers, NPPA has issued instructions on 15th June, 2021 to all the manufacturers and marketing companies of drugs/formulations and medical devices to revise the MRP of drugs/ formulations on which Tax/GST rates have been reduced. A copy of OM dated 15th June, 2021 of NPPA is enclosed.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

File No. 19(175)/2019/DP/NPPA/Div.II
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

3rd and 5th Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi -110001

Dated: 15th June, 2021

OFFICE MEMORANDUM

The undersigned is directed to refer to the queries from some of the manufacturers/marketing companies regarding implementation of MRP on the drugs due to change in the Tax/GST rates.

2. In this regard, reference is invited to the O.M. No. 25(5)/2014/Div-V/NPPA dated 13th April, 2016 (copy enclosed) issued by NPPA which contains detailed guidelines for compliance of revised prices by manufacturers/marketing companies.

3. The change in Tax/GST rates has an impact on the fixation of MRP of items attracting Tax/GST. As per DPCO, 2013 MRP of drugs/formulations is inclusive of Taxes/GST. Therefore, any downward change in Tax/GST rates should be reflected in MRP and benefit of Tax/GST reduction should be passed on to consumers.

4. In view of the above, all the manufacturers and marketing companies are required to revise the MRP of drugs/formulations on which Tax/GST rates have been reduced taking into effect the revised rates of Tax/GST. Recalling or re-labelling or re-stickering on the label of container or pack of released stocks in the market prior to date of notifications, is not mandatory, if manufacturers are able to ensure price compliance at the retailer level through issuance of a revised price list.

15/06/2021

(S. S. Ojha)
Director (Pricing)

To,

All the manufacturers and marketing companies of drugs/formulations and medical devices for compliance.

Copy to:

1. PPS to Hon'ble Minister (HCF)
2. PPS to Hon'ble Minister of State (HCF)
3. Secretary (Pharma), Government of India
4. Secretary (Health), Government of India
5. Principal Health Secretaries (All States/UTs)
6. Drug Controller General (India)
7. All the Drug Controllers / Food & Drug Administration of all the State / UT Governments.

44th Meeting of the GST Council
12th June, 2021

PRESS RELEASE

(Change in GST Rates on GST on goods being used in Covid-19 management)

The GST Council in its 44th meeting, held on 12th June, 2021 through Video Conference, decided to reduce the GST rates on the specified items being used in Covid-19 relief and management till 30th September, 2021, as detailed below, -

S. No.	Description	Present GST Rate	GST Rate recommended by GST Council
A. **Medicines**			
1.	Tocilizumab	5%	Nil
2.	Amphotericin B	5%	Nil
3.	Anti-Coagulants like Heparin	12%	5%
4.	Remdesivir	12%	5%
5.	Any other drug recommended by Ministry of Health and Family Welfare (MoHFW) and Dept. of Pharma (DoP) for Covid treatment	Applicable Rate	5%
B. **Oxygen, Oxygen generation equipment and related medical devices**			
1.	Medical Grade Oxygen	12%	5%
2.	Oxygen Concentrator/ Generator, including personal imports thereof	12%	5%
3.	Ventilators	12%	5%
4.	Ventilator masks / canula / helmet	12%	5%
5.	BiPAP Machine	12%	5%
6.	High flow nasal canula (HFNC) device	12%	5%
C. **Testing Kits and Machines**			
1.	Covid Testing Kits	12%	5%
2.	Specified Inflammatory Diagnostic Kits, namely D-Dimer, IL-6, Ferritin and LDH	12%	5%
D. **Other Covid-19 related relief material**			
1.	Pulse Oximeters, incl personal imports thereof	12%	5%

S. No.	Description	Present GST Rate	GST Rate recommended by GST Council
2.	Hand Sanitizer	18%	5%
3.	Temperature check equipment	18%	5%
4.	Gas/Electric/other furnaces for crematorium, including their installation, etc.	18%	5%
5.	Ambulances	28%	12%

These rate reductions/exemptions shall remain in force up to 30th September 2021.

PLI Scheme in Pharmaceuticals Sector

Lok Sabha Unstarred Question No. 1364

Shri Bidyut Baran Mahato:

Shri Ravi Kishan:

Shri Sanjay Sadashivrao Mandlik:

Shri Ravindra Kushwaha:

Shri Subrat Pathak:

Shri Shrirang Appa Barne:

Shri Chandra Sekhar Sahu:

Shri Sudheer Gupta:

Shri Prataprao Jadhav

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

(a) whether the Government has approved Production Linked Incentive Scheme (PLI) for Pharmaceuticals sector in the country;

(b) if so, the details and the salient features of PLI scheme;

(c) whether the Government has made any assessment to find out the expected promotion of the production of high value products, which are likely to be added in exports of the country in the coming years;

(d) if so, the details thereof;

(e) the details of the investments, employment opportunities which are likely to be increased in the country after the implementation of PLI Scheme in Pharmaceuticals sector;

(f) whether at present, low value generic drugs account for the major component of Indian exports, while a large proportion of the domestic demand for patented drugs is met through imports; and

(g) if so, the manner in which the existing trend is likely to be change from the scheme?

Answered on 27th July 2021

A. (a) to (b): Yes, Sir. The Government has approved the Production Linked Incentive Scheme for Pharmaceuticals on 24.02.2021 which was notified in the Gazette on 03.03.2021. The Operational Guidelines containing the details of the scheme on each aspect and the process of making applications were issued on 01.06.2021. These operational Guidelines can be found on the website of the Department and can be accessed at https://pharmaceuticals.gov.in/schemes.

(c) to (d): The scheme estimated the export generation potential of Rs 1,96,000 crore over a period of 6 years in all the three categories of products under the scheme which includes high value products as well.

(e) The PLI scheme estimated the investment potential of around Rs 15,000 crore and the generation of employment potential of 20,000 direct and 80,000 indirect jobs as a result of the growth in the sector over the period of the scheme.

(f) to (g): Yes Sir, at present low value generic drugs account for the major component of Indian exports. As far as patented drugs are concerned, the same are imported as well as manufactured in the country. The scheme incentivizes the manufacturing of patented drugs and other high value drugs at an

incentive rate of 10% of incremental sales which is highest amongst the product categories under the scheme.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

NIPER Council

Lok Sabha Unstarred Question No.1373

Dr. Sukanta Majumdar:

Shri Rajveer Singh (Raju Bhaiya):

Shri Raja Amareshwara Naik:

Shrimati Sangeeta Kumari Singh Deo:

Shri Vinod Kumar Sonkar:

Dr. Jayanta Kumar Roy:

Shri Bhola Singh:

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

(a) whether the Government is planning to bring a legislation the NIPER (Amendment) Bill 2021 to establish the NIPER Council and if so, the details thereof;

(b) whether the Government has reviewed the functioning of the NIPER and if so, the details of achievements made and funds spend so far, Institutewise;

(c) whether the Government propose to set up four new NIPER and if so, the details thereof;

(d) the details of vacancies of posts in NIPER, Institute-wise;

(e) whether same NIPER do not have its own campuses and are running in temporary buildings and if so, the details thereof; and

(f) the other steps being taken by the Government to strengthen the NIPER?

Answered on 27th July 2021

A. (a): Yes Sir. Government has introduced NIPER (Amendment) Bill 2021 in the Lok Sabha on 15th March, 2021. The provisions of the Bill include setting up a NIPER Council under the chairmanship of Hon'ble Minister (Chemicals & Fertilizers) to coordinate the activities of various NIPERs and ensure planned and coordinated development of pharmaceutical education and research and maintenance of standards thereof.

(b): NIPERs are autonomous institutions having their own Board of Governors, which are responsible for the general superintendence, direction and control of the affairs of the Institute. As the institutes are mainly funded by the Government, it periodically reviews their functioning. The annual accounts of the Institute are also audited by the office of CAG. A third-party evaluation of NIPERs through a private party has also been conducted. Further, the Expenditure Finance Committee (EFC) under the Ministry of Finance also appraise the functioning of NIPERs for their continuation/ expansion.

Ministry of Education publishes annual National Institutional Ranking Framework (NIRF) ranking public and private Higher Education Institutes (HEIs) in the country under various categories. The ranking of NIPERs under the "Pharmacy" category during last four years is as under:

NIPERs	2017	2018	2019	2020
Mohali	2nd	1st	3rd	3rd
Hyderabad	5th	6th	6th	5th
Ahmedabad	-	14th	9th	8th
Guwahati	-	-	-	11th
Raebareli	-	-	-	18th
Kolkata	-	-	-	27th

The institute-wise details of students passed out, research papers published, patents filed and MOUs signed are as under:

NIPER	Students passed out	Research Papers published	Patents filed	MoU signed
Mohali	3,735	2,777	198	23
Ahmedabad	619	594	21	23
Hyderabad	1113	786	32	52
Guwahati	400	301	20	24
Kolkata	479	204	02	23
Raebareli	385	238	20	15
Hajipur	333	134	03	10
Total	7,064	5,034	296	178

The institute-wise details of funds released to each NIPERs since their inception (upto June, 2021) are as under:

NIPER	Funds released (Rs. in crore)
Mohali	406.54

Ahmedabad	195.77
Hyderabad	310.45
Guwahati	298.59
Kolkata	117.37
Raebareli	113.29
Hajipur	80.55
Total	1522.56

(c): EFC proposal has been sent to the Ministry of Finance for setting up five new NIPERs in the states of Tamil Nadu, Maharashtra, Chhattisgarh, Rajasthan and Karnataka.

(d): While, NIPER-Mohali already has sanctioned posts and regular faculty/ non-faculty posts, the Ministry of Finance approved 156 faculty and 190 non-faculty posts in the year 2019 for other six NIPERs, viz., Ahmedabad, Guwahati, Hajipur, Hyderabad, Kolkata and Raebareli. After framing recruitment rules for various posts, the process for filling up the faculty/ non- faculty posts in these Institutes has been initiated and the same would be completed soon. The institute-wise status of sanctioned/ filled up posts are as under:

	Faculty				Non-Faculty			
	Sanctio ned	**Filled**	**Under process**	**Vacant**	**Sanctioned**	**Filled**	**Under process**	**Vaca nt**
Mohali	62	26	-	36	224	120	-	104
Ahmedabad	33	23	-	10	37	17	-	20
Hyderabad	33	23	-	10	37	16	-	21
Guwahati	33	20	-	13	37	17	18	02
Kolkata	19	12	04	03	27	13	05	09
Hajipur	19	04	08	07	26	05	10	11
Raebareli	19	16	-	03	27	06	15	06
Total	218	124	12	82	415	194	48	173

(e) and (f): While NIPER Mohali and NIPER Guwahati have own permanent campus, the construction of NIPER Ahmedabad has started in full swing. At present, NIPERs at Ahmedabad, Hajipur, Hyderabad, Kolkata and Raebareli are functioning from rented premises. A consolidated EFC proposal with an outlay of Rs. 4,300 crore for the period 2020-21 to 2024- 25 has been sent to the Ministry of Finance for strengthening and equipping of the existing seven NIPERs and setting up of five new NIPERs. The proposal also includes construction of the campuses, up-gradation of laboratories, setting up Centres of Excellences, etc.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

In Rajya Sabha

Bio-medical waste generation pertaining to COVID-19 treatment

Rajya Sabha Unstarred Question No. 40

Shri Bikash Ranjan Bhattacharyya:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) the details of bio-medical waste generation pertaining to the treatment of COVID-19 patients since 2020 till date, State-wise; and

(b) the details of management and handling of such bio-medical waste, State-wise?

Answered on 19th July 2021

A. (a)&(b) The Central Pollution Control Board has developed guidelines for handling, treatment and disposal of COVID-19 Bio-medical Waste (BMW) generated during treatment/ diagnosis/ quarantine of COVID-19 patients under the provisions of Biomedical Waste Management Rules, 2016 (BMWM Rules, 2016). As per the guidelines, Healthcare Facilities are required to segregate the BMW at source and hand over such segregated waste to the Common Bio-medical Waste Treatment Facility operators for treatment and disposal. Similarly, the waste generated from Quarantine camps/ Home Quarantine/ Home Isolation, is treated as 'domestic hazardous waste' as defined under Solid Waste

Management Rules, 2016 for collection by Urban Local Bodies, and thereafter, disposed as per the provisions of BMWM Rules, 2016.

Further, to track the generation and disposal of COVID-19 Bio-medical Waste (BMW), CPCB has developed an app namely COVID19 BWM. The State-wise waste generation details from June-2020 to June-2021 are mentioned below:

States/Union Territories	COVID-19 BMW generated (in Tonnes)
Andaman & Nicobar	4.0
Andhra Pradesh	2877.5
Arunachal Pradesh	34.8
Assam	337.4
Bihar	336.0
Chandigarh	671.4
Chhattisgarh	381.4
Daman & Diu	14.1
Delhi	3995.3
Goa	124.2
Gujarat	5004.9
Haryana	3025.3
Himachal Pradesh	414.3
Jammu and Kashmir	543.0
Jharkhand	136.6
Karnataka	3133.6
Kerala	6442.2
Lakshadweep	3.6
Madhya Pradesh	2462.8
Maharashtra	8317.0
Manipur	56.5
Meghalaya	92.2
Mizoram	29.2
Nagaland	34.1
Odisha	1642.9
Puducherry	428.4
Punjab	1289.1
Rajasthan	1382.8
Sikkim	36.6
Tamil Nadu	4835.9
Telangana	1109.7
Tripura	7.6
Uttarakhand	683.4
Uttar Pradesh	3881.7
West Bengal	3128.9
Total	56898.4

The above generated wastes are to be treated as per guidelines issued by CPCB in respective States.

Minister of State in the Ministry of Environment, Forest and Climate Change (Shri Ashwini Kumar Choubey)

Inclusion of retail/wholesale business in MSMEs

Rajya Sabha Unstarred Question No.112

Shri Mahesh Poddar:

Q. Will the Minister of **Micro, Small and Medium Enterprises** be pleased to state:

(a) whether Government has included retail and wholesale business also in the category of Micro, Small and Medium Enterprises (MSMEs) and if so, whether this move is intended to provide priority loans to them only under priority sector lending or they will be provided with the priority in Government procurement like other MSMEs and arbitration facility in recovery of dues;

(b) whether under the MSMEs Act, 2006, it is mandatory to respect the provision of protection of payment for Small Scale Industry (SSI) under IBS laws also; and

(c) whether this protection of payments will be made available to medium scale industries also?

Answered on 19th July 2021

A. (a): Yes Sir. From 2nd July, 2021, the government has included Retail and Wholesale Trades as MSMEs. They are allowed to be registered on Udyam Registration Portal and benefits to Retail and Wholesale trade MSMEs are restricted to Priority Sector Lending only.

(b)& (c): Chapter V of the Micro, Small and Medium Enterprises Development (MSMED) Act, 2006 provides that a buyer is liable to make payment to any Micro and Small Enterprise (MSE) supplier provided that the MSE qualifies as supplier under the Act.

Minister of Micro, Small and Medium Enterprises (Shri Narayan Rane)

MAHE releases book on COVID-19

COVID-19: A Multidimensional Response *- Book release event (Clockwise) Dr Shashikiran Umakant, Dr Raviraj N Seetaram, Dr H Vinod Bhat, Lt Gen (Dr) M D Venkatesh, Dr Chiranjay Mukhopadhyay, Dr Neeta Inamdar*

Manipal Academy of Higher Education (MAHE) released a book titled *Covid-19 A Multidimensional Response,* 210th publication by Manipal Universal Press (MUP) on 30 June 2021 in Manipal.

Releasing the book, Lt Gen (Dr) M D Venkatesh, Vice Chancellor, MAHE, spoke about the role played by MAHE and Manipal group of hospitals in healthcare management during the COVID-19 outbreak. Being one of the largest healthcare providers, MAHE built a creative alliance between higher education and the wider community to control and mitigate the pandemic in constant engagement with the civil society, he said. This was done through mass testing, innovative COVID-19 treatment protocols, mass health literacy programs, vaccination drive and technical innovations like vaccine carriers, he added.

Releasing the book on COVID-19 was a continuation of these efforts by MAHE where 305 papers on COVID-19 have been already published by faculty members, he said, highlighting the academic and research contribution of the University in tackling the challenges posed by the pandemic.

Chief guest Dr Vinod H Bhat, Executive Vice President, MAHE, highlighted the impact of the pandemic on various aspects of human existences and how most of them have been addressed in the 30 chapters contained in this more than 500-page book. He said, the multidisciplinary approach of the book which includes geopolitical and anthropological perspectives as well, speak volumes about the expertise present within the MAHE system that stand to support the epidemiologists, virologists, microbiologists and others. He suggested that earnest efforts be made to continue research and publish a second volume to follow as the research advances in different fields to combat COVID-19.

Dr Shashikiran Umakant, Professor in Medicine Department of Udupi TMA Pai Hospital, who led the battle against COVID-19 at the district level and is widely recognized for his contribution, summed up MAHE's response to the pandemic as CARE response – clinical, administrative, research and educational. He said, MAHE was the only university in the country which dedicated an entire hospital for treating the COVID-19 patients.

One of the editors, Dr Raviraj N Seetaram spoke about the evolution of the book in very short and stringent timelines to ensure the research as-it-happened reach its audiences. He hoped the book would connect researchers within the field with more vigour in combating the pandemic and would reach lay readers with more information that they have been seeking.

In her welcome note, Dr Neeta Inamdar, Chief Editor, Manipal Universal Press said, MUP would strive hard to keep pace with the research being carried out in the field and be with the authors willing to publish their work and share it with fellow colleagues.

Other editors of the book, Dr Chiranjay Mukhopadhyay and Dr N Udupa were present on the occasion, where Dr Chiranjay delivered a vote of thanks.

NPPA has fixed ceiling prices of 355 medicines and 882 formulations for including Paracetamol, Dexamethasone, Methyl Prednisolone, IVIGs, Enoxaparin, Budesonide, Heparin and Amphotericin - reg.

NPPA has capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level

ATTENTION MEMBERS

We give below the PIB released on 27th July 2021 by the Ministry of Chemicals and Fertilizers in regards to NPPA fixing ceiling prices of 355 medicines and 882 formulations for including Paracetamol, Dexamethasone, Methyl Prednisolone, IVIGs, Enoxaparin, Budesonide, Heparin and Amphotericin. Also, kindly note that NPPA has capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level.

The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals, as an on-going process, with the help of Price Monitoring & Resource Units (PMRUs) and State Drug Controllers (SDCs) undertake activities related to market-based data collection, monitoring of the notified prices of medicines and detection of violation of the provisions of Drug (Price Control) Order, 2013 (DPCO, 2013).

NPPA fixes the ceiling prices of scheduled formulations as per provisions of DPCO, 2013 and monitors the prices of non-scheduled drugs so as to ensure that their prices do not increase beyond 10 percent in a year. NPPA has fixed ceiling prices of 355 medicines and 882 formulations for medicines under National List of Essential Medicines, 2015 (Schedule-I of DPCO, 2013). Most of the drugs that are part of COVID management protocol have ceiling prices, viz., Paracetamol, Dexamethasone, Methyl Prednisolone, IVIGs, Enoxaparin, Budesonide, Heparin and Amphotericin etc. In the case of few non-scheduled medicines like Remdesivir, which are part of COVID protocol and are non-scheduled, on Government intervention, MRPs of various brands of Remdesivir have been reduced voluntarily by the major manufacturers/marketers of the Remdesivir Injection (lyophilized). Inter-brand MRPs that varied up to Rs 5400/ per vial were brought down to less than Rs 3500/-.

Furthermore, to facilitate availability and ensure affordability, NPPA has capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level vide notification dated 3rd June, 2021 and on Pulse Oximeter, Glucometer, BP Monitor, Nebulizer and Digital Thermometer vide notification dated 13th July, 2021.

In addition, Retail prices for 1,640 formulations have been fixed under DPCO, 2013 till date and in recent years exercising extraordinary powers under DPCO, 2013 in public interest, NPPA has fixed the prices of following drugs and medical devices:

(i) Ceiling price of Stents in February, 2017

(ii) Ceiling price of Knee Implants in August, 2017

(iii) Capped trade margin on selected 42 anti-cancer drugs in February, 2019.

The information was given by the Union Minister of Chemicals and Fertilizers, Shri Mansukh Mandaviya in a written reply in the Lok Sabha today.

Source: PIB Delhi, 27.07.2021

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India must use, share Covid data transparently: Kiran Mazumdar-Shaw

Decrying the country's "lack of scientific temperament," Kiran Mazumdar-Shaw urged greater transparency in sharing data on the pandemic, and said India has great potential to plan and respond to the virus based on such inputs.

In an interview with Akshatha M & Raghu Krishnan, Shaw calls for a smarter, more data-led initiative to deliver vaccines and inoculate the most vulnerable.

A lack of sufficient vaccines has hampered India's drive to inoculate a majority of its population by year-end, according to ***Biocon*** *chairperson* ***Kiran Mazumdar-Shaw****, who emphasised the need to speedily ramp up domestic production of vaccines. Decrying the country's "lack of scientific temperament," she urged greater transparency in sharing data on the pandemic, and said India has great potential to plan and respond to the virus based on such inputs. In an interview with Akshatha M & Raghu Krishnan, she calls for a smarter, more data-led initiative to deliver vaccines and inoculate the most vulnerable. Edited excerpts:*

What can be done to hasten the pace of India's Covid vaccination drive?

The issue is lack of availability of vaccines. Six months after we started the vaccination drive, we are at about 135 million doses a month — with 100 million doses coming from the Serum Institute. Bharat Biotech accounts for 35 million doses a month and a really small volume comes from both ZydusCadila and Sputnik. By August, it is likely we will get 200 million doses if Sputnik starts manufacturing (locally) at a certain scale and Bharat Biotech scales up capacity. The government has now scaled down its projection of vaccination coverage to 1.3 billion doses.

This is from the earlier projection of 2.5 billion doses by the end of this year. With such limited availability of vaccines, the strategy should be targeted vaccinations. We should go by data and start vaccinating vulnerable populations, people that are most at risk and populations that are not exposed to the virus yet. I wonder why that is not happening.

Can vaccine imports supplement domestic production?

Vaccine imports will be limited. The government cannot rely heavily on imported vaccines. Only a few in the private sector will get vaccines from outside and (that too,) to inoculate a small number of people. We should ramp up domestic production to cater to a large part of the population. Let us not get carried away with talks of importing Moderna and Pfizer because they account for a very small part. We have to depend on Covishield, Covaxin, Novavax, Biological E's domestic production.

What are your views on how the country has managed the pandemic so far?

India is missing out on a huge opportunity by not focusing on data gathering and analysis. We have a great potential to plan and respond to Covid based on data inputs. We have a very high prevalence of Delta variants, which provides us a chance to collect data on infection rates, peaking and vaccines that work against variants. We should be doing a lot of vaccination and reinfection surveillance and focus on analysing the cycle threshold value of infected persons.

But, what also worries me is that as a country, we lack scientific temper. We don't ask pertinent questions. Why don't we have data on (whether) Remdesivir is really effective to treat Covid? Why don't we ask if Itolizumab is as effective as Tocilizumab in Covid treatment?

Is Covid fatigue the reason why we don't see enough data coming through?

They may be gathering and analysing the data but not sharing it with the public. I think there is opacity in terms of research done on Covid. We need to have more transparency on research and their outcomes. It should be out in the public domain. All state and city Covid dashboards should be transparent. They should put out

more data on daily hospitalisation, ICU admissions to help the public get a realistic view of the situation.

I am also surprised at the claim that no one died due to medical oxygen shortage. We had a severe scarcity and had to import oxygen and concentrators as aid. To be in denial of the oxygen situation is worrying. We need to be transparent as a country.

You have recently pledged financial support to Mynvax, an Indian Institute of Science –Incubated startup that is working on a home grown Covid vaccine. Do you think domestic vaccine and biotech companies are getting enough investments and support?

This world is besotted with quick returns on investment, precisely why people prefer investing in IT and digital startups.Let us not forgot that life sciences and healthcare is more important for humanity to survive. If we don't invest in new medicines, vaccines and drugs, we will be demolished. We can have the smartest technologies, but now do we live without progress in medicine and healthcare?

Source : Economic Times, 26.07.2021

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DGFT MATTERS

Foreign Trade Policy 2015-20 - Introduction of online Deemed Exports Application Module - reg.

Notice No.12 /2021 - 2022, dated 28th July 2021

To,

1. All Exporters/Members of Trade

2. All RA's of DGFT.

1. The members of trade are hereby informed that this Directorate is introducing an online Deemed Exports Module on the DGFT website as a part of IT Revamp for receiving applications under the Chapter 7 of FTP 2015-20.

2. Henceforth, the following applications are required to be submitted online through the importer/exporter's dashboard on the DGFT Website :

i. Refund of Terminal Excise Duty (TED)

ii. Grant of Duty Drawback as per AIR and

iii. Fixation of Brand Rate for Duty Drawback

3. The members of trade can login to the portal, fill in the requisite details in the form, upload the necessary documents and submit the application after paying requisite fee. The system will generate a file number which can be used for tracking purposes through the portal. The RAs would issue online deficiency letters calling for any additional information/document required and the exporter would be able to reply to the deficiency letters online only. However, the applicants will have to submit the corresponding supporting physical documents as prescribed under ANF -7A to concerned RAs within 7 days of online submission of such applications for processing of the applications at RAs.

4. Please note that this new application Module will cater to new applications filed in this regard by the applicants and old/legacy physical applications submitted earlier manually will continue to be processed manually by concerned RAs.

5. The members of trade can file application in e-TED/ DBK module through following navigation:

https//dgft.gov.in>Deemed Exports to access the new e-module.

6. For guidance on these new processes, the Help manual & FAQs may be accessed at https://dgft.gov.in> Learn > 'Application Help & FAQs'. For any further assistance you may utilize any of the following channels —

i. Raise a service request ticket through the DGFT Helpdesk service under Services a 'Trade Helpdesk Service'

ii. Call the toll-free DGFT Helpdesk number 1800111550

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

F. No. 01/92/180/12/AM21/Policy 6

Pradyumna Sahu, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, New Delhi.

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DoP MATTERS

DoP extends the timeline for Submission of applications under PLI till 31.08.2021 -reg.

F.No. 31026/16/2020-Policy/Scheme, dated 27th July, 2021

1. Reference is invited to this Department's Notice of even number dated 30.04.2021, 14.06.2021 & 02.07.2021 on the above-mentioned subject. It has been decided to extend the timeline for submission of applications under the "Production Linked Incentive Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in India" and "Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices" till 31.08.2021.

2. The eligible applicants may apply through online only. The link is https://plibulkdrugs.ifciltd.com. Detailed guidelines of the Scheme are available at https://pharmaceuticals.gov.in/schemes.

N. K. Joshi, Under Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, New Delhi.

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NPPA MATTERS

List of Overcharging Cases (OC) including cases under litigation relating to DPCO 1979, 1987, 1995 and 2013-reg.

Office Memorandum dated 16th July 2021

To,
All Drug Manufactures/Marketers

1. The undersigned is directed to refer to the subject cited above and to enclose the Status of Overcharging amount under DPCO 1979, 1987, 1995 and 2013 as on 31.03.2021 (Annexure-A) and the Detailed Statement of Overcharging cases up to 31" March, 2021 (Annexure-B).

2. In respect of the OM dated 11th January 2021 issued and hosted by this office on NPPA website, enclosing the Provisional list of 324 cases, NPPA received the feedback/representation from companies in this reference. These representations were examined and accordingly, the Provisional List of OC cases under litigation relating to DPCO, 1979, 1987, 1995 and 2013 has been updated and is enclosed herewith.

3. This issues with the approval of competent authority.

End: As Above

F. No. 28(1)/20/Div.IV/NPPA

Manjesh Porwal, Deputy Director, Overcharging Division, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

Note : For enclosure details, you may please contact IDMA Secretariat.

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Ensure no vaccine dose goes waste

States, including Kerala and Tamil Nadu, complain of shortages. At the same time, there are also reports of millions of vaccine doses lying unused. There is a need to keep increasing the flow of vaccines into the system.

India's **vaccination** levels have improved. But the luxury of taking the foot off the pedal does not exist. The government has set a goal of fully inoculating 950 million adults by the end of the year. Meeting that goal will require ensuring a daily vaccination tally of 7 million. However, the current rate of daily inoculation hovers around the 5 million mark.

States, including Kerala and Tamil Nadu, complain of shortages. At the same time, there are also reports of millions of vaccine doses lying unused. There is a need to keep increasing the flow of vaccines into the system. At the same time, given the size of the requirement — domestic, contractual exports and supply to the **Covax facility** — reaching a place where supply outstrips demand will take time.

The corrective measures to increase production capacity for vaccines will take some time to kick in. The Union government has now placed orders well in advance to ensure that there is a steady flow of vaccines. Last week, the government placed an order for 660 million doses with the Serum Institute. And, supply constraints are expected to ease in August, with new vaccines, including the **DNA-based vaccine** from **Zydus** entering the supply chain.

Careful planning and allocation of vaccines particularly at the state level is required. The Union government provides vaccine availability projections 15 days in advance. States should use this information along with granular data from districts to plan out its vaccination roll-out. States must allocate vaccine keeping in mind factors such as the percentage of the inoculated population, first and second dose ratio, and positivity rate. Private hospitals with vaccines on hand must tie up with companies and other hospitals to ensure no dose goes waste.

Source: ET Editorial, 20.07.2021

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Indian pharma industry to touch USD 130 bn by 2030: Reddy

The Indian pharmaceutical sector can contribute to the country through the development of drugs for India-specific ailments which, unfortunately, do not get much global attention, Reddy rued.

The Indian pharmaceutical industry worked continuously during the testing times of COVID-19 pandemic second wave to ensure the availability of life saving medicines.

The Indian pharmaceutical industry is expected to grow almost by three times to about 130 billion US dollars by 2030, Chairman of Dr Reddy's Laboratories, K Satish Reddy said on Saturday.

"If you see, currently it's (pharmaceutical industry) about 42 billion dollars, half between the domestic sales, half between the exports. We expect that it will grow almost by three times in the coming decade, reaching almost 120 to 130 billion dollars by 2030. Truly, we believe that we are poised for a tremendous growth in the coming decade," he predicted.

Reddy, Chairman of Board of Governors of NIPER-Hyderabad, was virtually addressing the 9th Convocation of the institute.

The government's encouragement ('AtmaNirbhar Bharat' policy), a lot of reforms in the policy to incentivize the industry and thrust being given to innovation, among others, augur well for the industry, he said.

The Indian pharmaceutical industry worked continuously during the testing times of COVID-19 pandemic second wave to ensure the availability of life saving medicines. During the period, the companies involved in making

critical COVID-19 medicines responded very quickly ramping up production, he added.

He lauded the efforts of Union Chemicals and Fertilizers Minister Mansukh Mandaviya and the officials for providing a lot of interventions which helped the industry ramp up capacities. Noting that the future of the Indian pharmaceutical industry is dependent on its ability to develop stronger capabilities in innovation and R&D, Reddy said such capabilities which already exist, need to be strengthened further.

The Indian pharmaceutical sector can contribute to the country through the development of drugs for India-specific ailments which, unfortunately, do not get much global attention, he rued.

He also said digital technologies were heralding a big change in the whole spectrum of healthcare – the way patients are treated, the way medicines are supplied to patients and automation in manufacturing. A whole host of opportunities got accelerated during the pandemic, he added.

Secretary of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, S Aparna spoke on efforts to attain self-sufficiency in APIs and others.

Source : Financial express, 25.07.2021

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Covid vaccines for children by September: AIIMS chief Dr Randeep Guleria Hans

HIGHLIGHTS India is likely to start vaccinating children by September, AIIMS chief Dr Randeep Guleria said on Saturday as he underlined that it will be an important move to break the chain of transmission.

New Delhi: India is likely to start vaccinating children by September, AIIMS chief Dr RandeepGuleria said on Saturday as he underlined that it will be an important move to break the chain of transmission.

"I think Zydus has already done the trials and they're waiting for the emergency authorisation. The Bharat Biotech's Covaxin trials should be over by August or September, and by that time we should get an approval. Pfizer vaccine has been already approved by the FDA (US regulator). Hopefully, by September, we should start vaccinating children, and that will be a big boost as far as breaking the chain of transmission is concerned," Dr Guleria said.

India has given over 42 crore doses of vaccines so far and inoculated nearly 6 per cent of its population while the government aims to vaccinate all adults by the end of this year. However, the country is yet to clear a vaccine for children amid concern over a third wave.

On Friday, the European medicines watchdog approved the use of Moderna's coronavirus vaccine for children aged 12-17. In May, the United States had authorised the Pfizer-BioNTech Covid-19 vaccine for children aged 12-15 years old.

"We need to get our own vaccines too - that's why both Bharat Biotech and Zydus are important. Getting the Pfizer vaccine will also be helpful, as there is enough data to suggest it's safe... but we can't be sure if we will get required numbers. We will hopefully have more than one vaccine for children by September," the AIIMS chief said.

A study published earlier this week by The Lancet, one of the world's oldest medical journals, underlined that "living with 11-17-year-olds increases the risk of infection by 18-30 per cent." Talking about it, Dr Guleria said: "It's an important issue. Vulnerable people - the elderly or those having illnesses - are at an increased risk of getting the infection (in such cases). That's one of the reasons why people are worried about children going to schools... they may get a mild infection, but they may pass it to their grandparents. We need more data, but this is something that has been shown even with influenza."

Source : The Hans India , 25.07.2021

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Post Covid: Pharmaceutical Industry has become an alluring career option

As the healthcare sector across the globe is growing, it has opened great career opportunities to thousands of students of pharmaceutical science because the rate of growth of the pharmaceutical sector is interlinked and is directly proportional to the growth of the healthcare sector.

The current pandemic has brought the entire world to its knees and the whole world has observed the adverse catastrophe of this Global Pandemic. As the healthcare sector across the globe is growing, it has opened great career opportunities to thousands of students of pharmaceutical science because the rate of growth of the pharmaceutical sector is interlinked and is directly proportional to the growth of the healthcare sector.

According to IBEF, Indian pharmaceutical sector supplies over 50% of global demand for various vaccines and also states that India is the largest provider of generic drugs globally. In the current Scenario the demand for medicines is increasing day by day, so the employment in the pharma sector is also rising. According to sources of government statistics, over 300 institutions impart diplomas or degrees to nearly 20,000 students in India every year. Indian Pharmaceutical Industry is one of the largest pharma industries in the world and this widens the scope of Pharma studies in India and abroad.

As per the report of IES (Indian Economic Survey)2021, in the next decade the domestic market is expected to grow 3x. The pharmaceutical industry is currently valued at $41.7 bn. India's domestic pharmaceutical market is estimated at US$ 41 billion in 2021 and likely to reach US$ 65 billion by 2024 and further expand to reach US$ 120-130 billion by 2030.

In India, Pharmacy Council of India (PCI) is the regulatory body which has been designing the Education Regulations pertaining to Pharmacy which outlines the conditions to be followed by pharmacy colleges, Institutions and Universities. PCI grants approval to the universities and colleges in India to run the various programmes in the domain of Pharmacy. The PCI has well-defined standards, norms, and guidelines to be followed by the entities seeking approval from the regulatory Council.

The India Pharma industry is worth about $37 billion, with exports accounting for about $18 billion. As compared to other countries, the prices of medicines in India are amongst the lowest in the world. Although having some of the medicine's lowest prices in the world, leading firms of India also have the capacity to not only serve the Indian market for essential drugs but also supply their drugs to the world.

Challenges in Pharma Industry
Price Fluctuation and Policy Environment:

Price fluctuation and policy environment are the challenges created by unexpected and frequent domestic pricing policy changes in India. One of the biggest challenges in the pharmaceutical industry in India is analysing the shifting customer behaviour and fluctuating prices, due to this vague environment of innovations and investments has created in Industry. According to The Indian Pharmaceuticals Alliances (IPA) to produce affordable Indian patients' drugs, the government and stakeholders work together.

Paucity of proficiency in the Innovation Space:

Due to limited government Supported research ecosystem the Indian pharmaceutical companies have been slow to grow in the innovation space. To overcome this hurdle government needs to invest in research & Development initiatives and talent in order to expand India's innovation. A talent pool with advanced skills is limited in India as compared to other countries. There is also a huge gap between the college curriculum and industry's requirements. Clinical trials should also be supported and subjectivity in certain regulatory decision-making removed.

Generic Market exporting:

Just like any other industry, the pharmaceutical industry is also a sales-driven Industry. With the help of AI technology, companies can gather information regarding targeting audiences and create unique marketing strategies for them. This way they can understand the needs of the market and can convert most leads into revenues. AI can help in protecting the success or failure rate of the marketing strategy.

Effect of External Market:

More than 50% of Pharmaceutical Ingredients are dependent on other countries such as China. Slight changes in policies can bring a big difference in the production of medicines and equipment (e.g., to fulfil domestic consumption, America delays the export of raw material for manufacturing Covid-19 vaccines which creates an extra burden on manufacturers in India). For a developing country, our government needs to create an environment for the healthcare startup, so that companies and patients can co-exist without burdening each other.

Conclusion:

Due to growth in the Pharma industry in India, both directly and indirectly about 2.7 million jobs have been created for the citizens. Government needs to make India a life sciences innovation hub to promote innovation by creating a research ecosystem and expanding and upskill the talent pool to handle complex technologies with advanced resources.

(Author:Prof. (Dr.) Rana Singh is the Vice-Chancellor of Sanskriti University)

Source: ETHealthWorld, 08.07.2021

Lower Barriers: India's tariffs record sharp drop from 17.6% in 2019 to 15% in 2020

Economists, however, have been critical of New Delhi's move to undermine liberalisation, achieved assiduously over the years since the 1990s.

A sustained drop in imports will also help the country lower its trade imbalance, which, some officials reckon, will not just ease pressure on its current account but boost its GDP growth as well.

In a break from the recent past, India's average applied import tariff dropped to 15% in 2020 from as high as 17.6% in the previous year, recording the sharpest annual fall in about a decade and a half.

This reflects a partial reversal of duty hikes that had marked India's sustained push for import substitution through self-reliance and its response to a spurt in trade protectionism in key economies – especially the US and China — in recent years. The tariff is still higher than the 2014 level of 13.5%.

Trade-weighted average tariff — total customs revenue as percentage of overall import value — also eased for a second straight year to 7% in 2019, the lowest since 2014 and compared with 10.3% in 2018, show the latest World Trade Organization (WTO) data.

However, as the government undertakes a comprehensive review of various customs duty exemptions this fiscal, in sync with a Budget announcement, this tariff fall may prove to be short-lived unless imposts on scores of products are trimmed as well.

While the applied tariff (simple average) on farm products eased to 34% in 2020 from 38.8% in the previous year, industrial tariff declined to 11.9% from 14.1%. Similarly, based on trade-weighted average, tariff on farm items dropped to 32.5% in 2019 from as high as 60.7% in the previous year, while industrial tariff dipped to 5.8% from 8%. These tariffs are meant for imports from countries to which India has accorded the most-favoured nation (MFN) status.

Last year, the government reduced customs duties on various products, including crude palm oil, precious metals like platinum and palladium, certain fuels, chemicals and plastics, select machinery and electronics items, sports goods and newsprint. Of course, the duties on certain products were raised as well.

India was branded "tariff king" by former US President Donald Trump, who had demanded that New Delhi slash duties on a broad range of products, even though the world's largest economy turned more protectionist under him.

In response, Indian officials have pointed out that New Delhi's applied tariffs are way below the permissible limit under the WTO framework, or the so-called bound rate (which was 50.8% in 2020). The trade-weighted average tariff is even lower than the simple average one (Washington highlights only the latter). Moreover, unlike other large economies, India hardly uses non-tariff barriers to crack down on imports it deems non-essential or sub-standard.

Following a surge in its crude oil import bill in 2018, New Delhi had targeted "non-essential imports" to curb pressure on its current account. It again resorted to increases in customs duties on scores of products in 2019 to prepare the way for its Aatmanirbhar initiative amid an escalating trade war between the US and China. These moves pushed up the applied tariff (simple average) sharply from 13.8% in 2017 to 17.1% in 2018 and 17.6% in 2019.

The proposed re-examination of the customs duty exemption is part of the broader effort to promote domestic manufacturing, which, in turn, is expected to curb imports and boost exports. A sustained drop in imports will also help the country lower its trade imbalance, which, some officials reckon, will not just ease pressure on its current account but boost its GDP growth as well.

Economists, however, have been critical of New Delhi's move to undermine liberalisation, achieved assiduously over the years since the 1990s.

Former vice-chairman of Niti Aayog Arvind Panagariya has cautioned that the duty hikes can be counter-productive. No major economy has grown 8-10% without opening up its market and India needs to bring down its industrial tariff to at most 10%, he has argued.

In a paper with Shoumitro Chatterjee last year, former chief economic advisor Arvind Subramanian said India was turning inward. "Domestic demand is assuming primacy over export-orientation and trade restrictions are increasing, reversing a 3-decade trend," the paper said. India still enjoys large export opportunities, especially in labour-intensive sectors such as clothing and footwear. "But exploiting these opportunities requires more openness and more global integration," the paper argued. Analysts have

also pointed out duty hikes have been mostly unsuccessful in containing imports, especially from China.

Domestic industry, meanwhile, clamours for more protection, arguing that in the absence of credible structural reforms to bring down its costs (including costs of logistics, wage, electricity and credit) and provide it a level-playing field, allowing increased foreign competition is patently unfair.

Reforms to boost competitiveness of the economy haven't been undertaken since liberalisation as they should have, it stresses. Bolstering competitiveness not just enables a country to improve its exports but also reduce costly imports.

As pointed out in a 2016 report by HSBC, India's domestic bottlenecks explain 50% of the slowdown in overall exports (remaining the biggest threat to its outbound shipments), followed by world growth (33%) and the exchange rate (just 17%).

Source: Banikinkar Pattanayak, Financial Express, 26.07.2021

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Glenmark Life Sciences – Growth at reasonable price

Offers industry-leading margins in highly competitive active pharma ingredient making space

Glenmark Life Sciences (GLS), the API spin off from Glenmark Pharma has announced its IPO. The IPO will raise a total of ₹1,513 crore (at the upper price band) consisting of fresh issue of ₹1,060 crore. Post IPO, Glenmark Pharma shareholding will come off from 100 per cent to around 83 per cent. The IPO proceeds will primarily be used for repaying the remaining interest-bearing purchase consideration of ₹800 crore that GLS owes to Glenmark Pharma for the API carve out. Glenmark started its API operations in 2001-02 period and spun it off in early 2019 to re-organise and monetise the asset. GLS considered a minority stake sale earlier, but the surge in API industry prominence and stepped up financial performance of API operations have allowed for better monetisation opportunity now. GLS has shown revenue and EBITDA growth of around 16 per cent in 2019-21 with industry leading EBITDA margins of 30 per cent. The IPO values the API business, at relatively comparable P/E of 22.1 times. Long term investors can subscribe to the IPO and participate in the largely anticipated domestic API growth.

Leading margins amongst peers

	FY21 Revenue (₹ cr)	FY21 EBITDA margin (%)	P/E FY21 EPS
GLS	**1,885**	**31.4**	**22.079***
Solara Active	1,617	17.2	27.0
Shilpa Medicare	901	20.2	35.3
Aarti Drugs	2,155	20.3	24.0
Neuland	937	15.7	34.0

* Based on IPO price

Domestic API Industry

The Indian API industry with 6.1 per cent global market share, has to be supplemented by Chinese imports which accounts for 68 per cent of API imports. The over reliance on Chinese supplies was not without its moments of volatility, as in the recent disruptions from China environmental clean-up (2018) and Covid-19 period.

As the industry, with impetus from the government through its PLI scheme, gears up to focus on the backend of formulations, API and speciality chemicals industries are now witnessing a palpable surge in demand. GLS management has reported a strong traction in demand,

a part of which it ascribes to vendors adding a local source.

Portfolio and margins

GLS derives 90 per cent of revenues from API which are described by GLS as non-commoditised, high value, and mature, products, generating high margins. The end-products GLS is active in, have lost patent exclusivities in the last 6-8 years and hence have passed through the initial years of sharp price erosion and now face manageable mid-single digit erosions. GLS also improves cost efficiencies through the product life-cycle, which might impact the top line realisations, but sustain margins or contract life. New products were introduced, based on customer timelines, at the rate of 6 per year in the last three years which replenish the constantly eroding top line and margins. GLS is planning to enter complex APIs of oncology, peptides and iron compounds and has commercialised an iron compound with two more in the pipeline. The other segment started 3 years back - CDMO (Contract Development and Manufacturing operations) contributes 8-10 per cent of revenues and bears significant potential with longer customer cycles and better margins.

GLS has more than 30 per cent market share in 4 products which contributed 43 per cent to sales in FY21 and top 10 products contributed to 66 per cent of sales. The portfolio is geared towards chronic therapies and regulated markets (66 per cent), with leading products like Telmisartan, Atovaquone, Perindopril, Teneligliptin, Zonisamide and Adapalene.

Financials and valuation

GLS reported a revenue growth of 16 per cent CAGR in FY19-21 with EBITDA margins of 30 per cent, compared to the peer set margin range of 15-20 per cent. The selectively curated chronic portfolio supported by strong execution capabilities has supported the margins. GLS has a capacity of 786 KL across its 4 manufacturing facilities operating at high 85 per cent capacity utilisation. In the medium term, 200 KL addition in existing facilities is planned, with a mix of internal accruals and debt, and in the longer term a 800 KL greenfield facility is planned, covering APIs and CDMO operations.

GLS's PLI participation is at the early stages with further clarity awaited. GLS's will deleverage by clearing the only debt in the form of outstanding purchase consideration owed to the parent company. Similarly the parent company deleveraging with expected inflows of around ₹1200 crore from IPO (repayment + offer for sale) and further reorganisation of verticals, can focus on generics based growth aiding GLS's largest business.

At 22 times FY21 earnings, GLS is priced reasonably, compared to its peers which have witnessed re-rating in the last year on account improved prospects for domestic APIs.

Source: Sai Prabhakar Yadavalli, BL Research Bureau, 25.07.2021

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