PRICE
PER COPY
₹25/-

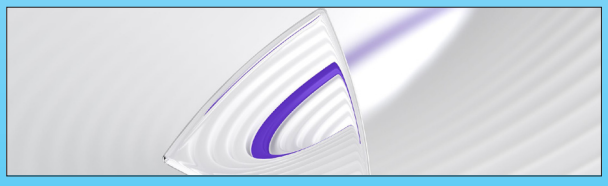
LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 14 (PAGES: 48) | 08 TO 14 APRIL 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION



Clarivate along with IDMA and BDMAI are jointly organising the webinar

Webinar: Trends in global API manufacturing and strategic success in regulatory affairs

Friday, 16th April 2021 3:30PM – 5:00PM IST

(More details on Page No. 4)

HIGHLIGHTS

- ★ **Government bans export of Remdesivir till COVID-19 situation improves** *(Page No. 38)*
- ★ **CBIC imposes anti-dumping duty on imports of Polyethylene Terephthalate (PET) resin originating in or exported from China PR for a period of 5 years** *(Page No. 18)*
- ★ **Insolvency and Bankruptcy (prepackaged insolvency resolution process) Rules, 2021 notified** *(Page No. 21)*
- ★ **DCGI directs SLAs to monitor availability of Remdesivir injections & prevent its hoarding** *(Page No. 30)*

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: mail_ idma@idmaindia.com/
actadm@idmaindia.com/ Website: www.idma-assn.org

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 52 **Issue No. 14** **08 to 14 April 2021**

Clarivate™

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA) 102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India. Tel: +91-22-24974308 / 24944624 Email: actadm@idmaindia.com Website: www.idma-assn.org	**Bulk Drug Manufacturers Association (India)** C-25, Industrial Estate, Sanathnagar, Hyderabad – 500 018, INDIA +91–40–23703910 | 23706718 | 23704804 info@bdmai.org | bdma.hyd@gmail.com www.bdmai.org

Clarivate along with Indian Drug Manufacturers' Association (IDMA) and Bulk Drug Manufacturers Association (India) are jointly organising a webinar

"Trends in global API manufacturing and success in regulatory affairs" on 16th April 2021 at 3:30 pm IST

This webinar will cover two major topics:

Trends in global API manufacturing

In the first topic we will focus on an overview of the global API industry taking a deep dive into where top API manufacturers are located, their capabilities, and proficiency in specific product classes.

We will also look at the impact COVID-19 has had on supply chains and the API manufacturing industry, and provide tips to identify and evaluate potential portfolio candidates based on industry needs and trends.

What is the key to strategic success in regulatory affairs?

In the second topic we will talk about how to unlock a well-defined, multinational regulatory strategy. The pandemic has created many unforeseen challenges in adapting regulatory strategies to meet the needs of the day. Without a sound strategy, you'll struggle to get your life saving treatment approved and to patients. This limits both patient access to medicines your company creates as well as limiting commercial success.

Educating your regulatory affairs (RA) team and aligning your regulatory strategy across critical functions is key to driving success. By breaking down the process into manageable chunks, your RA team can take the lead in crafting a robust strategy interlinked with competitive analysis.

Topics that will be covered:

- An overview of the global API industry
- A deep dive into where top API manufacturers are located, their capabilities, and proficiency in specific product classes
- A look at the impact COVID-19 has had on supply chains and the API manufacturing industry
- Tips to identify and evaluate potential portfolio candidates based on industry needs and trends
- What is the definition of a regulatory strategy?
- What are the common challenges and how can we overcome them?
- How can we provide a pathway for continual improvement across our organization?
- How can we begin to implement these changes within our organization?

Join this webinar to gather a deeper understanding of the global API industry and uncover how you can design your regulatory strategy efficiently and confidently.

Register now.

The direct link to the webinar registration page is: **https://discover.clarivate.com/API_and_Regulatory_SAsia**

Looking forward to your usual active participation by way of registrations and in making this webinar a grand success.

Thanks & regards,

Daara Patel
Secretary General

Webinar: Trends in global API manufacturing andstrategic success in regulatory affairs

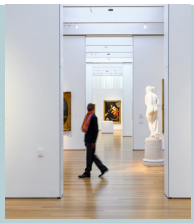
Friday, 16th April 2021 3:30PM – 5:00PM IST

In collaboration with Indian Drug Manufacturers' Association (IDMA) and BulkDrug Manufacturers' Association India (BDMA)

3:30 – 3:35 pm	Opening Address	**Mr. Yogin Majmudar** Past President Indian Drug Manufacturers'Association (IDMA) 5 min.
3:35 – 3:40 pm	Welcome Address	**Ms. Jo Butlin** VP Sales, Life Sciences R&D Clarivate, United Kingdom 5 min.
3.40 – 3.45 pm	Introduction	**Ms. Madhurima Datta** Manager – Pharma, South Asia Clarivate, India 5 min.
3.45 – 4.10 pm	**Trends in global API manufacturing** - An overview of the global API industry, - A deep dive into top API manufacturers - A look at the impact COVID-19 - Tips to identify potential portfolio candidates	**Dr. Leticia Fereira Terra** Solution Consultant Clarivate, Brazil 25 min.

4.10 – 4:35 pm	**What is the key to strategic success in regulatory affairs?** - Definition of a regulatory strategy - Common challenges and to overcome them - Pathway for continual improvement across the organization - Implementing the changes within organization	**Mr. Sam Kay** Solution Consultant Clarivate, United Kingdom25 min.
4.35 – 4:55 pm	**Q&A Session** - Trends in global API manufacturing - What is the key to strategic success in regulatory affairs?	**Panelists** • **Dr. Leticia Fereira Terra** Solution Consultant Clarivate, Brazil • **Mr. Sam Kay** Solution Consultant Clarivate, United Kingdom **Moderators** • **Ms. Parita Patel** Director Product Management, Generics Clarivate • **Ms. Madhurima Datta** Manager – Pharma, South Asia Clarivate, India 20 min.
4:55 – 5:00 pm	Vote of thanks	**Mr. V.V. Krishna Reddy**National President BDMA 5 min.






IT'S ALMOST UNFAIR TO THE OTHER 49 STATES.

Work. Life. And everything that makes both fulfilling. You'll find open minds, open spaces and open opportunities in North Carolina. Ranked #1 for business by Forbes three years running, with the lowest corporate tax rate in the US, low costs of doing business, and cost of living almost 5% below the national average.

Here you'll find a biotechnology ecosystem that runs deep and wide, across more than 775 companies and 67,000 employees, fueled by a highly educated workforce, major research universities and significant private sector R&D investment.

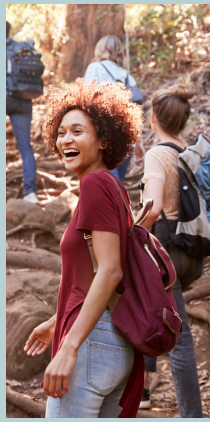
The EDPNC can connect you with available sites; in-depth workforce, community and infrastructure data; potential supply chain partners; and information on our incentives packages.

Go to EDPNC.com/India or call

Rahul Padmanabha
Director of Investment, India Office
O: +91 9148991212
E: rahul.padmanabha@edpnc.com









ALL IN NORTH CAROLINA

ECONOMIC DEVELOPMENT PARTNERSHIP of NORTH CAROLINA




Etizolam API and Formulations: classified as Psychotropic substance and brought under the NDPS Act, 1985, effective from 23rd March 2021 – reg.

KIND ATTENTION MEMBERS

With reference to the attached *Gazette Notification - S.O.1276(E) dated 23rd March 2021, Etizolam API and Formulations have been classified as Psychotropic substance and brought under the NDPS Act, 1985, with effect from March 23rd, 2021. All manufacturers are kindly advised to stop dispatch or export of any Etizolam containing product with immediate effect. Members are further advised as below:

First Step:

Companies need to first register online with Central Bureau of Narcotics (CBN) and obtain a registration number. Companies need to then file Quarterly returns to CBN, in the prescribed format for Psychotropic substances. All licenses obtained as per the Drugs and Cosmetics Act continue to be valid.

Domestic Market:

Dispatches may be effected, once registration number is obtained. There is no registration for Marketing companies, Distributors or Retailers, so product in the market need not be re-called but kindly inform all distributors to maintain proper records of sale, accountability and traceability of sale. Transportation of API or Formulation should be done in accordance with Rule 67 and Invoice should have details as specified in Rule 67.

Exports:

In case of exports, once a registration number is obtained from CBN, import permit is required from the country, where the product is to be exported and based on that, Companies can apply for NOC for export from CBN and then, export the consignment.

Manufacturers need to comply with NDPS Rules - 64, 65, 65-A, 66 and 67 with immediate effect, with respect to manufacture, registration and submission of returns, sale/ purchase, possession and transport of Etizolam and Rule 58 and 59 for exports of API/Formulations.

Thanks and regards, ***Daara Patel,*** *Secretary-General,* IDMA

*Gazette Notification No.S.O.1276(E), dated 23rd March, 2021

In exercise of the powers conferred by clauses (viia) and (xxiiia) of section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following further amendments in the notification of the Government of India, Ministry of Finance, Department of Revenue, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) *vide* number S.O. 1055 (E), dated the19th October, 2001, namely: -

In the said notification, in the Table, after serial number 238 ZI, 238 ZJ, 238 ZK, 238 ZL, 238 ZM, 238 ZN, 238 ZO, 238 ZP, 238ZQ, 238ZR, 238ZS and 238 ZT and the entries relating thereto, the following serial numbers and entries shall be substituted, namely: -

Sr. No.	Name of Narcotic Drug and Psychotropic Substance (International non-proprietary name (INN))	Other non-proprietary names	Chemical name	Small Quantity (in gm.)	Commercial Quantity (in gm./kg.)
“238ZI	Carfentanil		Methyl 1-(2-pheny lethyl)-4-[phenyl(propnoyl)amino]piperidine-4-carboxylate	0.00005 gm	0.001 gm;
238 ZJ	Ocfentanil		N-(2-Fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)piperidin-4- l] acetamide	0.00217 gm	0.0434 gm;
238 ZK	Furanylfentanyl		N-Phenyl-N-[1-(2-phenylethyl)piperidin-4- y1] furan-2-carboxamide	0.02 gm	1 gm;
238 ZL	Acryloylfentanyl	Acrrylfentan-yl	N-Phenyl-N-[1-(2-phenylethyl)piperidin-4- y1] prop-2-enamide	0.0025 gm	0.125 gm;
238ZM	4- Fluoroisobutyrfentanyl	4-FIBF, pFIBF	N-(4-Fluoropheny)-2-methyl-N-[1-(2- phenylethyl) piperidin-4- yl]propenamide;	0.03 gm	1.5 gm;
238 ZN	Tetrahydrofuranylfentanyl	THF	N-Phenyl-N-[1-(2-phenylethy)piperidin-4- yl] oxolane-2-carboxamide	0.005 gm	0.1 gm;
238 ZO		AB-CHMINACA	N-[(2S)-1-Amino-3-methyl-1-oxobutan-2-yl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide	0.05 gm	2.5 gm;
238 ZP		5F-ADB (5F-MDMB-PINACA)	Methyl(2S)-2-{1-(5-fluorophentyl)-1H-indazole-3-carbonylamino}-3,3-dimethylbutanoate	0.005 gm	0.25 gm;
238 ZQ		AB-PINACA	N-[(2S)-1-Amino-3-methyl-1oxobutan-2yl]-1-penty1H-indazole 3-carboxamide	0.0178 gm	0.892 gm;
238 ZR		UR-144	(1-Penty-1 H-indol-3- yl) (2,2,3,3- tetramrthylcyclopropyl) methanone	0.05 gm	2.5 gm;
238 ZS		5F-PB-22	Quinolin-8-yl 1-(5-fluropenthl)-1h-inodole-3-carboxylate	0.1 gm	5.0 gm;
238 ZT	4-Fluoroamphetamine	4-FA	1-(4-Fluorophenyl) propan-2-amine	2 gm	50 gm;
238ZU		AB- FUBINACA	N-[(2S)-1-amino-3-methyl-1-oxobutan-2-yl]-1- [(4-fluorophenyl) methyl] indazole-3- carboxamide	0.025 gm	1.25 gm;

238ZV		5F-AMB-PINACA (5F-AMB, 5F-MMB- PINACA)	Methyl 2-({[1-(5-fluoropentyl)-1H- indazol3yl] carbonyl} amino)-3-methylbutanoate	0.0027 gm	0.135 gm;
238ZW		5F-MDMB-PICA (5F-MDMB-2201)	Methyl(S)-2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate	0.0050 gm	0.25 gm;
238ZX		4F-MDMB-BINACA	Methyl(S)-2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate	0.0050 gm	0.25 gm;
238ZY	4-CMC (4-chloromethcathinone)	clephedrone	1-(4-chlorophenyl)-2-(methylamino)-1- propanone	5.0 gm	250 gm;
238ZZ		N-ethylhexedrone	2-(Ethylamino)-1-phenyl-1-hexanone	1.0 gm	50 gm;
238ZZA		alpha-PHP	(RS)-1-Phenyl-2-(pyrrolidine-1-yl)hexan-1-one	0.1 gm	5.0 gm;
238ZZB		flualprazolam	8-Chloro-6-(2-fluoro-phenyl)-1-methyl- 4hbenzo[f] [1,2,4]triazolo[4, 3-a][1,4] diazepime	0.0125 gm	0.625 gm;
238ZZC	Etizolam		4-(2-Chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2- f] [1,2,4]triazolo[4,3a][1,4]di azepine	0.05 gm	2.5 gm;
238ZZD		DOC	4-Chloro-2,5-dimethoxyamfetamine	0.15 gm	7.5 gm;
238ZZE		ADB-FUBINACA	N-[(2S)-1-amino-3,3-dimethyl-1-oxobutan-2- yl]-1-[(4-fluorophenyl)methyl]-1Hindazole-3-carboxamide	0.01 gm	0.5 gm;
238ZZF		FUB-AMB, MMBFUBINACA, AMBFUBINACA	Methyl(2S)-2-({1-[4-fluorophenyl]methyl-1Hindazole-3-carbonyl} amino)-3- methylbutanoate	0.01 gm	0.5 gm;
238ZZG		CUMYL-4CNBINACA	1-(4-cyanobutyl)-N-(2- phenylpropan-2-yl)-1Hindazole-3-carboxamide	0.01 gm	0.5 gm;
238ZZH		ADB-CHMINACA, MAB-CHMINACA	N-[(2S)-1-amino-3,3-dimethyl-1-oxobutan-2- yl]-1-(cyclohexylmethyl)-1H-indazole-3- carboxamide	0.005 gm	0.25 gm;
238ZZI		N-ethylnorpentylone	1-(2H-1,3-benzodioxol-5-yl)-2- (ethylamino)pentan-1-one	0.1 gm	5 gm;

238 ZZJ	Crotonylfentanyl		(2E)-N-phenyl-N-[1-(2-phenylethyl)piperidin-4- yl] but-2-enamide	0.014 gm	0.28 gm;
238 ZZK	Valerylfentanyl		N-phenyl-N-[1-(2-phenylethyl)piperidin-4- yl] pentanamide	0.40 gm	8.0 gm;
238 ZZL	Parafluorobutyrylfentanyl		N-(4-fluorophenyl)-N-[1-(2-phenylethyl) piperidin-4-yl] butanamide	0.005 gm	0.1 gm;
238 ZZM	Ortho-Fluorofentanyl		N-(2-fluorophenyl)-N-[1-(2-phenylethyl) piperidin-4-yl] propanamide	0.005 gm	0.1 gm;
238 ZZN	Methoxyacetyl fentanyl		2-methoxy-N-phenyl-N-[1-(2-phenylethyl) piperidin-4-yl] acetamide	0.005 gm	0.1 gm;
238 ZZO	Cyclopropylfentanyl		N-Phenyl-N-[1-(2-phenylethyl) piperidin-4-yl] cyclopropane carboxamide	0.005 gm	0.1 gm".

F.No.N-13/1/2019-NC. II

Dinesh Bouddh, Director, Department of Revenue, Ministry of Finance, New Delhi.

Note : The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 1055 (E), dated the 19th October, 2001 and subsequently amended vide numbers S.O. 2941 (E), dated the 18th November, 2009, S.O. 1430 (E), dated the 21st June, 2011, S.O. 375 (E) dated the 5th February, 2015, S. O. 2375(E), dated the 12th July, 2016, S.O. 384 (E), dated the 2nd May, 2017, S.O. 822(E), dated the 27th February, 2018, S.O. 1762(E), dated the 26th April, 2018 and S.O. 1351(E), dated the 13th March, 2019.

● ● ●

GOVERNMENT NOTIFICATIONS

Government notifies Inclusion of Tapentadol in Schedule H1 - reg.

Gazette Notification No.G.S.R. 258(E), dated 7th April 2021

Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (1) of sections 12 and sub-section (1) of 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 656(E), dated the 20th October, 2020, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 21st October, 2020;

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

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

(1) (1)These rules may be called the **Drugs (3rd Amendment) Rules, 2021.**

(2) They shall come into force with effect from the 1st day of November, 2021.

(2) In the Drugs Rules, 1945, in Schedule H1, after serial number 47 and the entry relating thereto, the following serial number and entry shall be inserted, namely:—

"48. Tapentadol"

F.No. X.11035/519/2019-DRS

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

Note: *The Principal Rules were published in the Gazette of India vide Notification Number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide Notification Number G.S.R. 202(E), dated the 22nd March, 2021.*

● ● ●

Government Appoints Dr Raghuram Reddy Adidala as Analyst at Central Drugs Testing Laboratory, Hyderabad - reg.

Drugs & Cosmetics Notification No.S.O.1520(E), dated 7th April 2021

(Published in the Gazette of India on 9th April, 2021)

In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby appoints Dr. Raghuram Reddy Adidala at Central Drugs Testing Laboratory, Hyderabad to be the Government Analyst for the whole of India in respect of all classes of drugs, except the classes of drugs mentioned below, namely:-

(1) Sera;

(2) Solution of Serum Proteins intended for injection;

(3) Vaccines (parenteral and Oral);

(4) Toxins;

(5) Antigens;

(6) Anti-toxins;

(7) Sterilized Surgical Ligature and Sterilized Surgical Sutures;

(8) Bacteriophages;

(9) Anti-sera for veterinary use;

(10) Vaccine for veterinary use;

(11) Toxoid for veterinary use;

(12) Diagnostic Antigens for veterinary use;

(13) VDRL Antigen;

(14) Human Blood and Human Blood Products including components, to test for freedom for HIV antibodies;

(15) Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus;

(16) Condoms.

F.No.X.11014/11/2020-DR

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

● ● ●

Amendment to the Notification Number No.G.S.R.578(E), dated 23rd July, 1983 - reg.

Drugs & Cosmetics Notification No.G.S.R.255(E) dated 7th April, 2021

(Published in the Gazette of India on 9th April, 2021)

Whereas the Central Government, on being satisfied that the Fixed Dose Combination (hereinafter referred as the FDC) of corticosteroid with any other drug for systemic use is likely to involve certain risk to human beings, vide its notification number G.S.R.578(E), dated the 23rd July, 1983, inter alia prohibited the manufacture and sale of

FDCs of Steroids for internal use except combination of Steroids with other drugs for the treatment of Asthma;

And whereas, the Central Government vide notification number G.S.R.738(E), dated the 9th October, 2009 further amended the said notification number G.S.R.578(E), dated the 23rd July, 1983 and substituted item 14 and the entries relating thereto with the entry "Fixed Dose combination of corticosteroid with any other drug for internal use except for preparations meant for meter dose inhalers and dry powder inhalers";

And whereas, FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was examined by Prof. Kokate Committee constituted by the Central Government for examining the safety and efficacy of FDCs which were licensed prior to 1st October, 2012 without prior approval of the Central Licensing Authority and therefore, Prof. Kokate committee examined the said FDC in current scenario based on the available documents and scientific literature and considered this FDC as rational and accordingly, the FDC of Tamsulosin HCl 0.4mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was approved;

And whereas, FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule was also referred to Drugs Technical Advisory Board and upon examination, the Drugs Technical Advisory Board had now recommended to exclude the FDC of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30 mg hard gelatin capsule from the prohibition made vide notification number G.S.R.738(E), dated the 9th October, 2009.

Now therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following amendments further to amend the notification number G.S.R.578(E), dated the 23rd July, 1983, namely:-

In the notification, in the Table, for item 14 and the entries relating thereto, the following item and entries shall be substituted, namely:-

"14. Fixed Dose Combination of corticosteroid with any other drug [excluding Fixed Dose Combination of Tamsulosin HCl 0.4 mg (as film coated modified release tablet) + Deflazacort 30mg in hard gelatin capsule] for internal use except for preparations meant for meter dose inhalers and dry powder inhalers.".

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

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide Notification Number G.S.R.578(E), dated the 23rd July, 1983 and lastly amended vide Notification Number G.S.R.738(E), dated the 9th October, 2009.*

● ● ●

Late cut for MEIS applications for exports made in the Financial Year 2019-20 - reg.

DGFT Public Notice No.53/2015-2020 dated 9th April 2021

In exercise of powers conferred under paragraph 1.03 of the Foreign Trade Policy (2015-2020), the Director General of Foreign Trade hereby inserts in the Handbook of Procedures, 2015-20 at the end of para 3.15 (a) as below:

"Further, MEIS applications for Shipping bills with Let Export date from 01.04.2019 to 31.03.2020 can be submitted without any late cut upto 30.09.2021. However any such application submitted after 30.09.2021, the last date for submitting applications shall be as per para 3.15 (a) (i) above and late cut applied accordingly."

Effect of this Public Notice: A relaxation in the late cut provisions have been provided for Shipping bill(s) of the period 01.04.2019 to 31.03.2020, so that if such shipping bills are submitted on or before 30.09.2021, for an MEIS claim, no late cut would be applicable.

File no.01/61/180/288/AM20/PC-3(Part 1)

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

● ● ●

Amendment in Export Policy of Injection Remdesivir and Remdesivir API - reg.

DGFT Notification No. S.O.01/2015-2020, dated 11th April, 2021

1. In exercise of powers conferred by Section 3 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes the following amendment in Schedule 2 of the ITCHS Export policy related to export of Injection Remdesivir and Remdesivir Active Pharmaceutical Ingredients (API):

Sr. No	ITC HS Codes	Description	Present Policy	Revised Policy
207AA	Ex 293499 Ex 300490	Injection Remdesivir and Remdesivir Active Pharmaceutical Ingredients(API)	Free	Prohibited

2. The provision under Para 1.05 of the Foreign Trade Policy (FTP) 2015-20 regarding transitional arrangement is not applicable for this notification.

3. **Effect of this Notification:** The export of Injection Remdesivir and Remdesivir Active Pharmaceutical Ingredients (API) falling under the ITCHS Codes specified above or falling under any other HS Code has been prohibited, with immediate effect.

File No. 01/91/180/24/AM22/EC/E-27724

Amit Yadav, Director General of Foreign Trade & Ex-Officio Additional Secretary, New Delhi.

● ● ●

Revised Ceiling Price of 1 Scheduled Formulation of Sch-I under (Prices Control) Order, 2013 based on review order

NPPA Notification No.S.O.1414(E), 31st March, 2021

In implementation of directions in line with review orders issued by the Department of Pharmaceuticals (DOP) under para 31 of Drugs (Prices Control) Order, 2013 vide order(s) specified in column (6) of the table below and in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/revises the price as specified in column (5) of the table herein below as ceiling price exclusive of Goods and Services Tax applicable, if any, in respect of the Scheduled formulation(s) specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Review Order number and date	Existing SO number and date
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Human Normal Immunoglobulin	Solution for Infusion 16.5%	1 ML	396.04	31015/05/2020-Pricing dated 14.12.2020	1241(E) dated 03.04.2020

Note:

(a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus Goods and Services Tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus Goods and Services Tax as applicable, if any.

(b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus Goods and Services Tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(c) The manufacturers may add Goods and Services Tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production/ import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(i) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/216/84/2021/F
F. No. 8(84)/2021/D.P./NPPA-Div.II

Prasenjit Das, Deputy Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

● ● ●

NPPA notifies revised Ceiling Prices (WPI adjusted) of 2 Sch. formulations of Schedule-I under DPCO 2013 - reg.

NPPA Notification No.S.O.1428(E), dated 31st March, 2021

In exercise of the powers, conferred by paragraph 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) S.O. Number and date specified in column no. 6(a) & 6(b) mentioned in the table below, the National Pharmaceutical Pricing Authority, hereby fixes the prices as specified in column (5) of the table herein below as ceiling prices exclusive of goods and services tax applicable, if any in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table: Price Revision as per Annual Wholesale Price Index (WPI) @ 0.53638% increase

Sr. No	Medicines	Dosage form and Strength	Unit	Ceiling price (wef 1.4.2021 with WPI @0.53638%)	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
1	Povidone Iodine	Scrub 7.5%	1 ml	1.61	1329(E)	25.03.2021
2	Human Normal Immunoglobulin	Solution for Infusion 16.5%	1 ML	398.16	1414(E)	31.03.2021

Note:

(a) The ceiling prices are applicable with effect from 01.04.2021 (ceiling prices are inclusive of Wholesale Price Index (WPI) @0.53638% for the year 2020 over 2019).

(b) In respect of formulation where pack wise ceiling price is notified, for any other pack size manufactured, the manufacturer shall approach NPPA under para 11(3) of DPCO, 2013 for specific price approval for its ormulations.

(c) In respect of any other scheduled formulation, for which ceiling price is not mentioned above, the manufacturer shall approach NPPA for specific price approval for its formulations.

(d) All manufacturers of scheduled formulations, selling branded or generic or both the versions of scheduled formulations at price higher than the ceiling price (plus Goods and Services Taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus Goods and Services Taxes as applicable, if any.

(e) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table (plus Goods and Services Taxes as applicable, if any), may revise the existing MRP of their formulations, on the basis of WPI @ 0.53638% for year 2020 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.

(f) The manufacturers may add Goods and Services Taxes only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(g) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(h) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(i) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(j) The manufacturers of above said scheduled formulations shall furnish quarterly return to NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form- IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(k) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(l) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/216/84/2021/F
F. No. 8(84)/2021/D.P./NPPA-Div.II

Prasenjit Das, Deputy Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

● ● ●

NPPA notifies Extension of Price of Medical Oxygen - reg.

NPPA Notification No.S.O.1335(E), dated 25th March, 2021

1. The prices of 'Liquid Medical Oxygen (LMO)' and 'Oxygen Inhalation (Medicinal gas) in cylinder' fixed under Para 19 of the DPCO, 2013 and powers conferred under section 10(2)(l) of Disaster Management Act, 2005 delegated by Ministry of Health and Family Welfare vide Order No. Z-33014/45/2020-RCH/Pt.File-3 dated 23.09.2020, vide notification S.O. 3322(E) dated 25.09.2020, issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India are extended upto 30.09.2021 or until further order, whichever is earlier.

2. All the notes and other contents mentioned in the original order S.O. 3322(E) dated 25.09.2020 shall remain the same and are applicable except that in Note (a) for the phrase "31st March 2021 or until further orders, whichever is earlier" it is to be read as "30th September 2021 or until further orders, whichever is earlier."

PN/217/85/2021/F
F. No. 8(85)/2021/DP/NPPA-Div.II

Prasenjit Das, Deputy Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

● ● ●

CBIC rescinds Notification No.10/2016-Customs (ADD) dated 29th March, 2016 - reg.

Notification No.16/2021-Customs (ADD), dated 26th March, 2021

In exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975), read with rules 18 and 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, the Central Government hereby rescinds the notification of the Government of India, in the Ministry of Finance (Department of Revenue), No.10/2016-Customs (ADD), dated the 29th March, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (i) vide number G.S.R.360(E), dated the 29th March, 2016, except as respects things done or omitted to be done before such rescission.

F.No.354/264/2015-TRU (Pt-I)

Rajeev Ranjan, Under Secretary, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

CBIC imposes anti-dumping duty on imports of Polyethylene Terephthalate (PET) resin originating in or exported from China PR for a period of 5 years - reg.

Notification No.18/2021-Customs (ADD), dated 27th March, 2021

1. Whereas, in the matter of **"Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher" (Bottle-grade PET resin, excluding recycled PET resin)**, hereinafter referred to as the subject goods, falling under tariff items 3907 61 90 or 3907 69 90 of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act), originating in, or exported from the **People's Republic of China** (hereinafter referred to as the subject country) and imported into India, the designated authority in its final findings *vide* notification No.6/24/2019-DGTR, dated the 28th December, 2020, published in the Gazette of India, Extraordinary, Part I, Section 1, dated the 28th December, 2020, has come to the conclusion that imposition of anti-dumping duty is required to offset the injury to the domestic industry caused by the dumped imports of subject goods from the subject country and has recommended imposition of definitive anti-dumping duty on imports of the subject goods, originating in or exported from the subject country and imported into India.

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 20 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, the Central Government, after considering the aforesaid final findings of the designated authority, hereby imposes on the subject goods, the description of which is specified in column (3) of the Table below, falling under the tariff item of the First Schedule to the Customs Tariff Act as specified in the corresponding entry in column (2), originating in the countries as specified in the corresponding entry in column (4), exported from the countries as specified in the corresponding entry in column (5), produced by the producers as specified in the corresponding entry in column (6), and imported into India, an anti-dumping duty at the rate equal to the amount as specified in the corresponding entry in column (7), in the currency as specified in the corresponding entry in column (9) and as per unit of measurement as specified in the corresponding entry in column (8) of the said Table, namely:-

TABLE

Sr. No.	TariffItem	Description of Goods	Country of Origin	Country of Export	Producer	Amount	Unit	Currency
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1.	39076190 and 39076990	Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher*	China PR	China PR	Jiangyin Chengold Packaging Materials Co. Ltd./China Prosperity (Jiangyin) Petrochemical Co, Ltd.	146.11	MT	USD
2.	39076190 and 39076990	Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher*	China PR	China PR	Wankai New Materials Co. Ltd.	15.54	MT	USD
3.	39076190 and 39076990	Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher*	China PR	China PR	Jiangsu Xingye Plastic Co. Ltd./ Jiangyin Xingyu New Material Co.Ltd./ Jiangsu Sanfame International -Trade Co. Ltd.	60.92	MT	USD
4.	39076190 and 39076990	Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher*	China PR	China PR	Any producer other than producers mentions at serial numbers 1, 2 and 3 above	200.66	MT	USD
5.	39076190 and 39076990	Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher*	China PR	Any country other than China PR	Any	200.66	MT	USD
6.	39076190 and 39076990	Polyethylene Terephthalate resin having an intrinsic viscosity of 0.72 decilitres per gram or higher*	Any country other than China PR	China PR	Any	200.66	MT	USD

** Bottle-grade PET resin, excluding recycled PET resin*

2. The anti-dumping duty imposed under this notification shall be levied for a period of five years (unless revoked, superseded or amended earlier) from the date of publication of this notification in the Official Gazette and shall be payable in Indian currency.

Explanation.- For the purposes of this notification, rate of exchange applicable for the purpose of calculation of such anti-dumping duty shall be the rate which is specified in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), issued from time to

time, in exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and the relevant date for the determination of the rate of exchange shall be the date of presentation of the bill of entry under section 46 of the said Customs Act.

F.No.354/112/2020-TRU

Gaurav Singh, Deputy Secretary,
Ministry of Finance,
Department of Revenue,
New Delhi.

● ● ●

Government issues amendment for self approval under Section 149 of the Customs Act, 1962 - reg.

Notification No.36/2021-Customs (N.T.), dated 29th March, 2021

1. In exercise of the powers conferred by the third proviso to the section 149 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby specifies the following amendments in the bill of entry presented under the second proviso to the sub-section (3) of section 46 of the said Act, which may be done by the importer on the common portal:-

(i) Supplementing of Bill of Lading details in the Bill of Entry.

2. This notification shall come into force on the date of its publication in the Official Gazette.

F.No.450/77/2021-Cus.IV

Ananth Rathakrishnan, Deputy Secreary (Customs), Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

CBIC MATTERS

CBIC notifies New Exchange Rates w.e.f. 02nd April 2021 - reg.

Notification No.40/2021-Customs (N.T.), dated 1th April, 2021

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.31/2021-Customs(N.T.), dated 18th March, 2021 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 2nd April, 2021,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	57.10	54.70
2.	Bahraini Dinar	200.70	188.35
3.	Canadian Dollar	59.25	57.15
4.	Chinese Yuan	11.35	11.00
5.	Danish Kroner	11.80	11.35
6.	EURO	87.65	84.55
7.	Hong Kong Dollar	9.60	9.25
8.	Kuwaiti Dinar	250.45	234.75
9.	New Zealand Dollar	52.60	50.25
10.	Norwegian Kroner	8.75	8.45

11.	Pound Sterling	102.70	99.25
12.	Qatari Riyal	20.80	19.50
13.	Saudi Arabian Riyal	20.20	18.95
14.	Singapore Dollar	55.50	53.60
15.	South African Rand	5.10	4.80
16.	Swedish Kroner	8.55	8.25
17.	Swiss Franc	79.35	76.25
18.	Turkish Lira	9.05	8.55
19.	UAE Dirham	20.60	19.35
20.	US Dollar	74.15	72.45

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	67.55	65.05
2.	Korean Won	6.70	6.30

F.No. 468/01/2021-Cus.V

Rathakrishnan Ananth,
Under Secretary,
Central Board of Indirect Taxes and Customs,
Department of Revenue,
Ministry of Finance,
New Delhi.

● ● ●

COMPANIES LAW AMENDMENTS

Insolvency and Bankruptcy (prepackaged insolvency resolution process) Rules, 2021 notified - reg.

Corporate Affairs Notification No.G.S.R.256(E) dated 9th April 2021

In exercise of the powers conferred by sub-section (1) and clause (fd) of sub-section (2) of section 239 read with sub-section (2) of section 54C of the Insolvency and Bankruptcy Code, 2016 (31 of 2016), as amended by the Insolvency and Bankruptcy Code (Amendment) Ordinance, 2021 (3 of 2021), the Central Government hereby makes the following rules, namely:-

1. Short title and commencement:

(1) These rules may be called the **Insolvency and Bankruptcy (prepackaged insolvency resolution process) Rules, 2021.**

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

2. Application: These rules shall apply to the matters relating to the pre-packaged insolvency resolution process.

3. Definitions:

(1) In these rules, unless the context otherwise requires,-

(a) "Code" means the Insolvency and Bankruptcy Code, 2016 (31 of 2016);

(b) "pre-packaged insolvency resolution process" means the insolvency resolution process for corporate persons under Chapter III-A of Part II of the Code;

(c) "Form" means a Form appended to these rules; and

(d) "identification number" means the limited liability partnership identification number or the corporate identity number, as the case may be, of the corporate person.

(2) Unless the context otherwise requires, words and expressions used and not defined herein, shall have the same meaning respectively assigned to them in the Code.

4. Filing of application:

(1) A corporate applicant, shall make an application for initiating pre-packaged insolvency resolution process under sub-section (1) of section 54C of the Code in Form 1, accompanied with affidavit, documents or records as referred in Annexures therein, in electronic form, along with a fee of rupees fifteen thousand:

Provided that in case, electronic facility is not available for filing such application, the application and the accompanying documents may be filed in physical form, and wherever the accompanying

documents are bulky, the same may be submitted in scanned portable document format in a data storage device such as a compact disc or a USB flash drive acceptable to the Adjudicating Authority.

(2) The corporate applicant under sub-rule (1) shall serve a copy of the application to the Board by registered post or speed post or by hand or by electronic means, before filing it with the Adjudicating Authority.

(3) The application shall be filed before the Adjudicating Authority in accordance with rules 20, 21, 22, 23, 24 and 26 of the National Company Law Tribunal Rules, 2016.

(4) A corporate applicant shall inform the Adjudicating Authority about the filing of any winding up petition against the corporate debtor after becoming aware about such filing.

F.No.30/20/2020-Insolvency Section

Gyaneshwar Kumar Singh,
Joint Secretary,
Ministry of Corporate Affairs,
New Delhi.

● ● ●

Insolvency resolution process of the corporate debtor under Chapter III-A of the Insolvency and Bankruptcy Code, 2016 (31 of 2016) - reg.

Corporate Affairs Notification No.S.O.1543(E) dated 9th April, 2021

In exercise of the powers conferred by the second proviso to section 4 of the Insolvency and Bankruptcy Code, 2016 (31 of 2016), as amended by the Insolvency and Bankruptcy Code (Amendment) Ordinance, 2021 (3 of 2021), the Central Government hereby specifies ten lakh rupees as the minimum amount of default for the matters relating to the pre-packaged insolvency resolution process of corporate debtor under Chapter III-A of the Code.

F.No.30/20/2020-Insolvency

Gyaneshwar Kumar Singh,
Joint Secretary, Ministry of Corporate Affairs,
New Delhi.

● ● ●

In Lok Sabha & In Rajya Sabha

In Rajya Sabha

COVID-19 vaccine price affordability

Rajya Sabha Starred Question No: 133

Shri Digvijaya Singh:

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

(a) whether Government is aware that the open market price of the 'Covishield Vaccine' at ₹ 1000 per dose is unaffordable for large sections of Indians, particularly Below Poverty Line (BPL) persons and Economically Weaker Sections (EWS);

(b) if so, the steps being taken by Government to ensure that all citizens would be given affordable access to the vaccine, including vulnerable persons belonging to BPL, EWS and homeless category amongst others;

(c) whether COVID-19 vaccines have been added to the National List of Essential Medicines (NLEM); and

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

Answered on 12th February 2021

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

Statement referred to in reply to Rajya Sabha Starred Question No. 133.

(a) The Covid vaccines approved by the Drug Controller General of India (DCGI) for restricted use in emergency situation, are being procured by the government authorities only. As such, the question of open market price of the vaccine does not arise at the moment.

(b) The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) provides guidance on all aspects of COVID- 19 vaccination including prioritization of population groups for COVID vaccination. NEGVAC has prioritized Health Care Workers and Front-Line Workers during the initial phase of COVID-19 vaccination followed by prioritized population groups of persons aged 50 years and above, and those aged less than 50 years with co-morbidities. The vaccine is being provided free of cost to Health Care Workers and Front-Line Workers at present.

(c) No, Sir.

(d) The Standing National Committee on Medicine (SNCM) is constituted by the Ministry of Health & Family Welfare on 03.07.2018 to review and revise the National List of Essential Medicines (NLEM) by way of addition and deletion in the existing NLEM, 2015. No recommendations for inclusion of COVID-19 vaccines in the NLEM have been received from SNCM.

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

Approval of COVID-19 vaccine prices

Rajya Sabha Unstarred Question No: 1318

Smt. Priyanka Chaturvedi:

Shri Digvijaya Singh:

Smt. Phulo Devi Netam:

Shri G.C. Chandrashekhar:

Shri Syed Nasir Hussain:

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

(a) whether the prices of Covishield and Covaxin vaccines have been approved by the National Pharmaceutical Pricing Authority (NPPA);

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

Answered on 12th February 2021

A. (a) to (c): No, Sir. The Covid vaccines have been approved by the Drug Controller General of India (DCGI) for restricted use in emergency situation. They are not included in the National List of Essential Medicines (NLEM). The vaccines are presently procured by the government authorities only. As such, the price of COVID vaccines have not been

approved/ fixed by the National Pharmaceutical Pricing Authority (NPPA).

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

Steps to reduce dependence on imports for APIs and intermediaries

Rajya Sabha Unstarred Question No: 1319

Dr Vinay P Sahasrabuddhe:

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

(a) the steps taken by the Ministry to reduce dependence on imports for Active Pharmaceutical Ingredients (APIs) and intermediaries in Indian pharmaceutical industry during the last three quarters; and

(b) the steps taken by or the plans prepared by the Ministry and the concerned Departments to engage with the relevant stakeholders to achieve self dependency in this sector?

Answered on 12th February 2021

A. (a) & (b): The Department of Pharmaceuticals has recently launched following two schemes for promoting domestic manufacturing of critical KSMs/ Drug Intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/Drug Intermediates and APIs after series of consultations with the relevant stakeholders: -

(I) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India: Under the scheme, financial incentive is given for manufacturing of 41 eligible products under the four Target Segments viz.:

(i) Fermentation based KSMs/Drug Intermediates.

(ii) Fermentation based niche KSMs/Drug Intermediates /APIs.

(iii) Key Chemical Synthesis based KSMs/Drug Intermediates.

(iv) Other Chemical Synthesis based KSMs/ Drug Intermediates/APIs. Incentives for incremental sales will be given to selected participants for a period of 6 years. The total outlay of the scheme is Rs. 6,940.

(II) Scheme for Promotion of Bulk Drug Parks: To provide grant-in-aid to 3 Bulk Drug Parks for creation of Common Infrastructure Facilities (CIF) with a maximum limit of Rs. 1000 crore per park or 70% of the project cost of CIF, whichever is less. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. The total size of the Scheme is Rs. 3000 crore and the tenure of the Scheme will be five years (2020-21 to 2024-25).

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

India's share in global trade of generic pharmaceuticals

Rajya Sabha Unstarred Question No: 1321

Dr. Fauzia Khan:

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

(a) the details of India's share in the global trade of generic pharmaceuticals;

(b) the total quantity and value of the production of generic pharmaceuticals along with the quantity and value of such products exported and imported during the last three years and the current year, category-wise; and

(c) the share of generic and non-generic medicines in the total sales of medicines in the country, including Government hospitals?

Answered on 12th February 2021

A. (a) As per Pharmexcil, the global Generic market in 2019 is estimated at $ 360 billion. The domestic Generic market size in 2019 was $ 20.87 Billion. India has exported Generics during 2019 worth around $ 15.63 billion. India's share of generics in the global exports is around 4.6%.

[Source: IQVIA report (data provided is of the calendar year]

(b): The details of generics exports are as follows:

India's Generic Pharma exports $ Million				
Category	2017-18	2018-19	2019-20	2020-21 (April-December)
Drug Formulations (Generics)	12900.28	14368.65	15811.24	13966.85

The details of India's pharma imports are as follows:

India's imports of Pharmaceutials $ Million				
Category	2017-18	2018-19	2019-20	2020-21 (April-December)
Drug Formulations	1767.74	1927.67	2156.05	1859.40

(c): Data pertaining to sales of generic and non-generic medicines is not maintained by this department.

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

Manufacturing of drugs and medicines

Rajya Sabha Unstarred Question No: 1323

Shri Anil Desai:

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

(a) the units under the Central/State Governments that control manufacturing of drugs and medicines in the country;

(b) the details of drugs they are manufacturing for the last five years, their profit and loss during the same period; and

(c) whether there are any private units that are competing with them, the details thereof?

Answered on 12th February 2021

A. (a): Manufacture of drugs is regulated under Drugs and Cosmetics Act, 1940 and Rules made thereunder, under manufacturing license granted by State Licensing Authorities appointed by the State Governments.

(b): There are five CPSEs under Department of Pharmaceuticals. Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL), Bengal Chemicals & Pharmaceuticals Ltd. (BCPL) and Hindustan Antibiotics Ltd. (HAL) are Government of India Enterprises engaged in manufacturing and marketing of various life saving drugs. Indian Drugs and Pharmaceuticals Ltd. (IDPL) and Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL) are under the process of closure.

Details of Profit and loss during the last five years are as under:-

(Rs. In crore)

Name of CPSE	Particulars	2015-16	2016-17	2017-18	2018-19	2019-20
KAPL	Net Profit	19.51	30.33	11.74	15.82	22.99
BCPL	Net Profit/ (Net Loss)	(9.13)	4.51	10.06	25.26	13.07
HAL	Net Profit/ (Net Loss)	(74.68)	(78.24)	208.32	(71.10)	(138.30)

(c): All the private Pharmaceuticals Companies, including multinational companies, marketing drugs & medicines in India, are the competitors of KAPL, BCPL & HAL.

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

Export of COVID Vaccines

Rajya Sabha Starred Question No: 131

Smt. Priyanka Chaturvedi

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the total number and value in monetary terms of the COVID vaccine doses that were exported from India to other countries till present day;

(b) whether Government has put measures in place to avoid a domestic shortage of vaccine in the light of it being exported in large numbers; and

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

Answered on 12th February 2021

A. (a) to (c): A Statement is laid on the Table of the House.

Statement referred to in reply to Rajya Sabha Starred Question No. 131

(a): Vaccines, including COVID vaccines are covered under the common ITC HS codes 30022019 (Other single vaccine) and 30022029 (Other mixed vaccine). Export data for vaccines is also captured under these ITC HS codes. The details of export of vaccines under

these codes (including COVID vaccines) during 2020-21 (April-January) is given at Annexure-I. *(Not reproduced here).*

(b) & (c): Government has granted permission to M/s Serum Institute of India Pvt. Ltd., Pune and M/s Bharat Biotech International Limited, Hyderabad for manufacture of COVID-19 vaccines. Close coordination is being maintained through regular interaction between relevant Departments of the Government of India and vaccine manufacturers to ensure adequate availability of COVID-19 vaccines for national vaccination program.

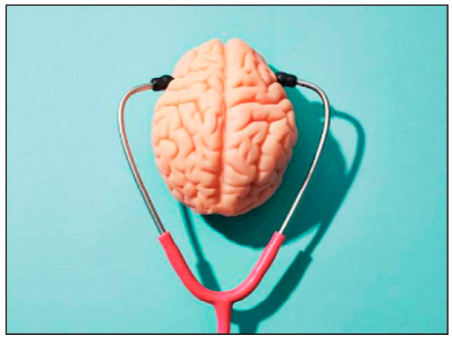
The Minister of Commerce and Industry (Shri Piyush Goyal)

● ● ●

NEW DEVELOPMENTS

Study discovers crucial step in formation of deadly brain diseases

The research concerned prion diseases - a group of brain diseases caused by proteins called prions that malfunction and 'misfold', turning into a form that can accumulate and kill brain cells.



London: Researchers at Imperial College London have discovered what causes normal proteins to convert to a diseased form, causing conditions like CJD and Kuru. The study also tested a way to block the process, which could lead to new drugs for combatting these diseases.

The research concerned prion diseases- a group of brain diseases caused by proteins called prions that malfunction and 'misfold', turning into a form that can accumulate and kill brain cells. These diseases can take decades to manifest but are then aggressive and fatal.

They include Kuru, mad cow disease and its human equivalent Creutzfeldt-Jakob disease (CJD), and a heritable condition called fatal familial insomnia.

While the normal, healthy version of prions and the pathogenic (disease-causing) version have been characterised, the intermediate step, when one transforms to the other, was previously unknown.

Now, in a paper published today in Proceedings of the National Academy of Sciences, the research team have isolated this intermediate step, determining the mechanism that turns normal prions into their pathogenic form. The research was supported by Alzheimer's Research UK.

Lead researcher Professor Alfonso De Simone, from the Department of Life Sciences at Imperial, said: "Prion diseases are aggressive and devastating, and currently there is no cure.

"Discovering the mechanism by which prions become pathogenic is a crucial step in one day tackling these diseases, as it allows us to search for new drugs. Now we know what we're targeting, we know what features drugs need to have to stop prions becoming pathogenic."

To investigate the misfolding of prions, the team worked with a mutant form of the prion protein that is found in people with inherited prion diseases. The mutant form is more aggressive, causing prions to transition faster to their pathogenic form. This allows researchers to watch what happens more easily.

However, prions are difficult to isolate and purify from other proteins in sufficient quantities to study in detail. The lead author of the paper Dr Maximo Sanz-Hernandez began investigating the problem as an undergraduate at Imperial, continuing until successful in his PostDoc with Professor De Simone.

The team then used a technique called nuclear magnetic resonance spectroscopy combined with computational analysis to determine the structure of the intermediate step, identifying the molecular mechanism at work when the prion misfolds.

With this information, they also worked with the team at the University of Zurich who were able to produce antibodies that could target the mechanism. In a proof-of-concept study in the test tube, they were successfully able to block prions transitioning from the normal to the pathogenic form.

While in their current form, these antibodies would be too large to pass into the brain, the study shows it is possible to disrupt the mechanism, allowing researchers to move forward with designing new drugs.

Dr Sanz-Hernandez said: "The intermediate stage of prion pathogenesis is so transient it's like a ghost -- almost impossible to imagine. But now we have a picture of what we're dealing with, we can design more specific interventions that can one day potentially control these devastating diseases."

Dr Rosa Sancho, Head of Research at Alzheimer's Research UK, said: "This is early-stage research examining the short protein fragments, which can be highly unstable, short-lived, and notoriously difficult to study.

"As the UK's leading dementia research charity, we are pleased to fund this sophisticated work using biophysical and computational approaches to better understand the role fragments like this play in the development of the disease. To identify new ways to reduce or combat these protein fragments in human disease we need to see sustained investment in dementia research."

The researchers hope the information will allow drug researchers and pharmaceutical companies to scan their libraries of drug compounds for formulations that might be able to block the mechanism.

Any drug compounds would need extensive lab testing first to make sure they would be effective, small enough to pass into the brain, and safe, but the team hope that now the target is known, the search can be accelerated.

Source: ANI, ET-Healthworld, The Economics Times,12.04.2021

● ● ●

COVID-19 causes 'unexpected' cellular response in the lungs

New insights into the immune response to SARS-CoV-2 infections could bring better treatments for COVID-19 cases. An international team of researchers unexpectedly found that a biochemical pathway, known as the immune complement system, is triggered in lung cells by the virus, which might explain why the disease is so difficult to treat. The research is published this week in the journal Science Immunology.

The researchers propose that the pairing of antiviral drugs with drugs that inhibit this process may be more effective. Using an in vitro model using human lung cells, they found that the antiviral drug Remdesivir, in combination with the drug Ruxolitinib, inhibited this complement response.

This is despite recent evidence that trials of using Ruxolitinib alone to treat COVID-19 have not been promising. To identify possible drug targets, Majid Kazemian, Assistant Professor in the Departments of Computer Science and Biochemistry at Purdue University, said the research team examined more than 1,600 previously FDA-approved drugs with known targets.

"We looked at the genes that are up-regulated by COVID-19 but down-regulated by specific drugs, and Ruxolitinib was the top drug with that property," he said.

Within the last few years, scientists have discovered that the immune complement system - a complex system of small proteins produced by the liver that aids, or complements, the body's antibodies in the fight against blood-borne pathogens - can work inside cells and not just in the bloodstream.

Surprisingly, the study found that this response is triggered in cells of the small structures in the lungs known as alveoli, Kazemian said. "We observed that SARS-CoV2 infection of these lung cells causes expression of an activated complement system in an unprecedented way," Kazemian said. "This was completely unexpected to us because we were not thinking about activation of this system inside the cells, or at least not lung cells. We typically think of the complement source as the liver."

Claudia Kemper, Senior Investigator and Chief of the Complement and Inflammation Research Section of the National Institutes of Health, was among the first to characterize novel roles of the complement system in the immune system. She agreed these latest findings are surprising.

"The complement system is traditionally considered a liver-derived and blood-circulating sentinel system that protects the host against infections by bacteria, fungi and viruses," she said. "It is unexpected that in the setting of a SARS-CoV2 infection, this system rather turns against the host and contributes to the detrimental tissue inflammation observed in severe COVID-19. We need to think about modulation of this intracellular, local, complement when combating COVID-19."

Dr Ben Afzali, an Earl Stadtman Investigator of the National Institute of Health's National Institute of Diabetes

and Digestive and Kidney Diseases, said there are now indications that this has implications for difficulties in treating COVID-19.

"These findings provide important evidence showing not only that complement-related genes are amongst the most significant pathways induced by SARS-CoV2 in infected cells, but also that activation of complement occurs inside of lung epithelial cells, i.e., locally where infection is present," he said.

"This may explain why targeting the complement system outside of cells and in the circulation has, in general, been disappointing in COVID-19. We should probably consider using inhibitors of complement gene transcription or complement protein activation that are cell permeable and act intracellularly instead."

Afzali cautions that appropriate clinical trials should be conducted to establish whether a combination treatment provides a survival benefit.

"The second finding that I think is important is that the data suggest potential benefit for patients with severe COVID-19 from combinatorial use of an antiviral agent together with an agent that broadly targets complement production or activation within infected cells," he said. "These data are promising, but it is important to acknowledge that we carried out the drug treatment experiments in cell lines infected with SARS-CoV2. So, in and of themselves they should not be used to direct treatment of patients."

Kemper added that the unexpected findings bring more questions.

"A currently unexplored and possibly therapeutically interesting aspect of our observations is also whether the virus utilizes local complement generation and activation to its benefit, for example, for the processes underlying cell infection and replication," she said.

Source: World Pharma News, 08.04.2021 (Excerpts)

● ● ●

NATIONAL NEWS

Indian Pharma Market registers 10.3% growth in March 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 10.3% for the month of March 2021, as against a growth of 1.1% for the month of February 2021.

According to AIOCD AWACS report, the IPM has recorded sales of Rs. 1,47,483 crore for moving annual total (MAT) basis during March 2021.

Lockdown announcement in March 2020 that led to relatively higher growth for cardio-diabeto segment in March 2020 and dip in other therapy areas shows normalization in March 2021 data.

Amongst the top 10 corporates, Cipla exhibited the highest growth of 8.1 per cent, followed by Zydus Cadila at 5.1 per cent. Amongst the 11 to 25 ranked corporates, Glenmark exhibited highest growth of 15.2 per cent followed by IPCA at 12 per cent.

Amongst the 26 to 50 ranked corporates, Apex registered the highest growth 25 per cent followed by JB Chemicals at 11.9 per cent. Amongst the 51 to 75 ranked corporates, Danone registered the highest growth 32.8 per cent and Mylan at 19.7 per cent. Amongst the 76 to 100 ranked corporates, Unimed TL exhibited the highest growth at 15.5 per cent, followed by Charak at 14.3 per cent.

Cardiac registered a monthly growth of 6.3% in March 2021 as compared to 7.3% in February 2021, while anti-diabetic registered marginal growth of 0.3% in March 2021 as against growth of 4.3% in February 2021.

Respiratory medicines growth slumps to 15.1% in March 2021 as against negative growth of 20.3% in February 2021.

The anti-infectives exhibited growth of 8.5% in March 2021 as against negative growth of 11.3% in February 2021 and its associated therapy like gastro exhibits growth of 21.6% in March 2021 as against 9.9% in February 2021.

Vitamins have shown a growth of 22.2% in March 2021 as against growth of 8.6% in February 2021 and pain and analgesics are at 14.6% in March 2021 as against growth of 2.3% in February 2021.

Source: Yash Ved, Pharmabiz, 12.04.2021

● ● ●

Centre bans export of Remdesivir & its active ingredients till Covid situation improves in country

Centre has prohibited exports of injection Remdesivir and Active Pharmaceutical Ingredients of Remdesivir till the COVID situation in the country improves. Union Health Ministry said, India is witnessing a recent surge in COVID cases and there are over 11 lakh active COVID cases. This has led to a sudden spike in demand for injection Remdesivir used in treatment of COVID patients. The Ministry said, there is a potential of further increase in this demand in the coming days.

The Ministry said, all domestic manufacturers of Remdesivir have been advised to display on their website, details of their stockists and distributors to facilitate access to the drug. It said, Drugs inspectors and other officers have been directed to verify stocks and check their malpractices and also take other effective actions to curb hoarding and black marketing.

The State Health Secretaries will review this with the Drug Inspectors of the respective States and Union Territories. The Ministry said, the Department of Pharmaceuticals has been in contact with the domestic manufacturers to ramp up the production of Remdesivir.

The Central Government has also advised the States that the extant National Clinical Management Protocol for COVID-19, has been developed after many interactions by Committee of Experts, and is the guiding document for treatment of Covid-19 patients. In the Protocol, Remdesivir is listed as an Investigational Therapy, where informed and shared decision making is essential, besides taking note of contra indications mentioned in the detailed guidelines. The States and UTs have been advised that these steps should again be communicated to all hospitals, both in public and private sector, and compliance monitored.

Seven Indian companies are producing injection Remdesivir under voluntary licensing agreement with Gilead Sciences, USA. They have an installed capacity of about 38 lakh 80 thousand units per month.

Source: News Services Division, AIR, 12.04.2021

● ● ●

Demand for Covid vaccines, hydroxychloroquine pushes India's pharma exports to 5-year high

The India pharma industry has seen a record increase in exports, the highest growth in five years | Flikr

Boosted by the demand for Covid-19 vaccines and drugs such as hydroxychloroquine, which were being used to treat patients in the initial stages of the pandemic, India looks set to break its pharmaceutical export record of the last nine years. Exports in fiscal year 2020-21 have already been the highest in the last five years, but a bigger achievement seems in the offing, according to government data.

"Between April 2020 and February 2021, we have already done business worth $21.5 billion, an increase of about 12.5 per cent compared to the $19.15 billion worth of exports during the corresponding period in the last fiscal," Udaya Bhaskar, Director-General, Pharmaceuticals Export Promotion Council of India (Pharmexcil), told

"We are expecting exports to cross $24 billion for FY-2021, a growth of over 16 per cent from the last fiscal," Bhaskar added. This includes all commercial consignments of Covid drugs and vaccines, such as hydroxychloroquine (HCQ), the anti-malarial drug being used to treat Covid patients in the initial stages of the pandemic and the Covid vaccine, Covishield.

Pharmexcil was set up in 2004 under the provisions of the Foreign Trade Policy, to promote pharmaceutical exports from India, and functions under the Ministry of Commerce and Industry

While the rise in export figures is not phenomenal, it is the highest growth since the 2012-13 fiscal, when the pharmaceuticals industry had recorded a growth in exports of 24.75 per cent. This was followed by single-digit growth in three fiscal years and negative growth in one fiscal.

Exports were weak even in the first part of 2020, but picked up with the demand for HCQ in the first phase of the pandemic, followed by exports of Covid vaccines. Between last April and this February, India has exported $21.5 billion (Rs 1,50,500 crore) worth of pharmaceuticals, recording a growth of over 12.5 per cent against the same period in the last fiscal.

Top importers:

US, South Africa, UK, Russia, Germany, Nigeria, Brazil, Canada, France, and the Netherlands have been India's biggest customers for pharmaceuticals in the past 10 months.

"Apart from Covid vaccines, this year India's vaccine exports mostly comprise essential medicines for scheduled immunisation programmes. A large part of our exports are through NGOs serving in Africa, Latin American countries, and Asia. These three continents contribute to 80 per cent of our vaccine exports," Bhaskar said.

"Almost 60 per cent of the vaccine requirements of the World Health Organization (WHO) are sourced from India and 90 per cent of measles vaccines administered around the world are supplied by Indian companies," he added.

Pharmexcil does not have separate data on exports of Covid-related drugs and vaccines. Data from Pharmexil show that the industry recorded around 18 per cent growth in the export of drug formulations and 2.5 per cent growth in vaccines between April 2020 and Feb 2021. The export of drug formulations between April 2019 and February 2020 was worth $13.8 billion (Rs 96,600 crore), which increased to $16.3 billion (Rs 1,14,100 crore) between April 2020 to February 2021, a hike of 18 per cent.

The export of vaccines increased to $772.5 million (Rs 5407 crore) in the past ten months, from $753.8 million (Rs 5271 crore) in the corresponding period of the last fiscal, a jump of 2.5 per cent.

Why the lull:

According to the data from the past 10 years, the highest growth in pharmaceutical exports was during the 2012-13 fiscal — around 25 per cent.

But the following years saw a drop in growth in exports. The industry recorded growth of less than 3 per cent in 2014-15 and 2017-18. In 2016-17, there was negative growth of 0.59 per cent.

Industry experts attributed the modest growth to frequent concerns raised by the foreign regulators, especially the American Food and Drug Administration (US FDA), regarding manufacturing processes and quality of medicines during this time.

For instance, from spotting moths in raw materials, to finding bacteria-contaminated water being used in the manufacturing process and revealing attempts to destroy quality control records by manufactures, the US FDA had found several reasons to slap Indian drug-makers with warnings in the past — the highest number of such warnings, 23, came in 2019.

Owing to the frequent checks, and letters of warning issued, Indian drug makers have been facing delays in introducing new products in foreign markets since 2012.

The pressing demand for medicines and vaccines during the Covid pandemic has, however, helped the Indian pharmaceuticals company regain business and boosted exports.

Source: Poulomi Banerjee, The Print, 11.04.2021, (Excerpts)

● ● ●

DCGI directs SLAs to monitor availability of Remdesivir injections & prevent its hoarding

The Drugs Controller General of India (DCGI) has directed all State Licensing Authorities (SLAs) to monitor availability of remdesivir injections to ensure its supply and also take timely action to prevent its hoarding and black marketing.

"It has been brought to the notice of Union Health Ministry that in Mumbai and Thane region in the state of Maharashtra, Bhopal, Indore and Gwalior in the state of Madhya Pradesh and Ahmedabad, Surat and Rajkot in the state of Gujarat are reporting shortage of remdesivir injections. In view of the same, SLAs are supposed to initiate immediate remedial action to ensure supply of remdesivir injections to public and private hospitals," the DCGI said in his directive to the SLAs.

SLAs are also requested to instruct the enforcement staff to keep continuous monitoring on the situation and keep strict vigil to ensure availability of remdesivir and also prevent its hoarding and black marketing. Action taken in the matter may be intimated to the DCGI office at the earliest, the DCGI notice further stated.

To curb hoarding and black marketing of remdesivir injection, the Maharashtra Food and Drug Administration (FDA) has recently directed Covid-19 drug remdesivir manufacturers to reduce the wholesale price of the drug and has also proposed to the National Pharmaceutical Pricing Authority (NPPA) to bring it under price control.

Maharashtra FDA Commissioner held a meeting with senior officials at Mumbai headquarters recently to discuss how to reduce this huge gap between the wholesale selling price and MRP of remedesivir injection and how to make this drug available to the patients at reasonable rates.

The Maharashtra FDA is regularly reviewing the availability of remdesivir injection and other drugs in the state. Currently, there are 6 major manufacturers of remdesivir injection 100 mg available in the market.

Based on the review, Maharashtra FDA found out that the maximum retail price of remdesivir manufactured by respective manufacturers like Cipla is Rs. 4,000, Zydus Healthcare is Rs. 2,800, Hetero Healthcare is Rs. 5,400, Dr. Reddy's Lab is Rs. 5,400, Mylan is Rs. 4,800 and Jubilant is Rs. 4,700.

However, it has been found that the drug was supplied to wholesalers and hospitals at a price of Rs. 800 to Rs. 1,200. In this case, there is an outcry from various quarters about the financial burden being imposed on the patient by the increased maximum retail price (MRP).

Rajendra Shingane, Maharashtra FDA Minister and Saurabh Vijay, Secretary, Department of Medical Education and Drugs, Maharashtra had also directed to take action in this regard.

Source: Shardul Nautiyal, Pharmabiz, 10.04.2021

● ● ●

Digital transformation a major challenge for healthcare sector in India: Vishal Jain

India is still in the nascent stage of digitizing patient records. It heavily relies on physical paper records. But Covid-19 has reaffirmed the significance of digital transformation for the healthcare industry which had to rise to the challenges posed by the pandemic, said Vishal Jain, Director, Inspira Enterprise.

Artificial intelligence, Blockchain for electronic health records, virtual reality and telemedicine are the options before healthcare to ensure safety of patients and practitioners, he added.

Many healthcare providers have identified the gaps and are gradually digitizing their processes. Technology has created multiple sources of medical data, personal fitness trackers, blood pressure monitors, and even genomic data. However, digital transformation can be a complex process, especially for healthcare.

Beyond investing in new technology, there is a need for a change of mindset. Fear of change is the most crucial challenge that comes in the way of a successful digital transformation. Most of the hospitals and clinics continue to rely on paper for major documentation as they are comfortable with this traditional method. Unless transition is accepted across all levels from top management, doctors, nurses and other hospital staff it cannot be a total success, Jain noted.

Healthcare organizations tend to focus on the return on investments (ROI), without fully appreciating the value proposition that a digitally powered system can deliver. They fail to understand that adoption of a digital strategy offers more scale, revenue, and profit than the traditional approach. Instead of looking at the cost of installation, one should view long term benefits. For instance, technology can cut down on the need for in-person consultations, thereby allowing doctors to cater to more patients. Similarly, when it comes to the management of chronic diseases, going digital can be a real money-saver with patient satisfaction and retention.

Digital transformation is an amalgamation of various technologies. Many hospitals claim to be 'digital' by just adopting the basics like integrated hospital information system (HIS) and electronic medical records (EMR). From the registration and consultation to the inpatient services and post-discharge follow-ups, the entire patient journey needs to be considered while planning a hospital's digital transformation. Unfortunately, very few have a clear picture in mind before jumping on the digital transformation bandwagon and get lost in a large amount of unmanaged data they will have to deal with.

Further with technology comes the threat of cyber-attacks. But if an organization has a strong cyber resilience strategy, such a concern can be handled efficiently.

Source: Nandita Vijay, Pharmabiz, 12.04.2021

● ● ●

IPC invites bids for supply of reference standard, pharma impurities from manufacturers

The Ghaziabad-based Indian Pharmacopoeia Commission (IPC) has invited sealed and super-scribed bids for supply of candidate material for reference standard and pharmaceutical impurities from reputed and experienced Indian manufacturers as per new public procurement policy for MSMEs effective from April 1, 2021.

A pharmaceutical reference standard is a highly characterized material suitable to test the identity, strength, quality and purity of substances for pharmaceutical use and medicinal products.

Pharmaceutical impurities are either naturally occurring or added during synthesis of a drug. During production, impurities may be purposely, accidentally, inevitably, or incidentally added into the substance. Standards have been established by various organizations that attempt to define the permitted levels of various impurities in a manufactured product.

As per the IPC notice, each impurity must be supplied along with Impurity Material Information Form" and other supporting documents such as Certificate of Analysis (CoA) etc. Procedure for calculating local content under preference to Make In India would be as per new public procurement policy for MSMEs.

The reference standard should be of the highest purity possible. The drug substance may require further purification to become a reference standard (additional purification steps used for a drug substance should be fully described and included in any regulatory filing).

This bid is reserved for Class I and Class II bidders only as per make in India Policy (DPIIT Order dated September 16, 2020). Participating bidders need to submit relevant make in India authorization certificate.

The bidder should be reputed and experienced manufacturer. He/she should have valid manufacturing license/approval document including undertaking must be enclosed along with the technical bid.

Tender Forms can be downloaded from our website www.ipc.gov.in only. Downloaded Tender document must be submitted with a Demand Draft(s) as mentioned, in favour of "Indian Pharmacopoeia Commission" payable at Ghaziabad. Sealed tender duly super scripted can be submitted to the office of the Indian Pharmacopoeia Commission, Ghaziabad through Post/ Courier also, on or before the due date of April 23, 2021. Pre bid meeting date and time is April 8 2021, 2 pm. The last date and time for downloading tender forms is April 22, 2021 (upto 5 pm). The date and time of opening of technical bids is April 23, 2021, at 11:30 am. The date and time of opening of price bids would be intimated later.

The bids are intended for Supply of "Candidate Material for Reference Standard," at IPC, Ghaziabad is as per Schedule of Requirement (SOR). Validity of tender quoted rates must be valid for 18 months from the last date of tender. If required, the competent authority may extend the contract for another 18 months on same rates and terms and conditions subjected to the satisfactory performance of the manufacturer.

This bid is reserved for Class I and Class II bidders only as per make in India Policy (DPIIT Order dated September 16, 2020). Participating bidders need to submit relevant make in India authorization certificate. Bidding document may be amended any time prior to closing date and time for submission of tenders.

Therefore, bidders are advised to regularly check IPC website for tender relevant amendment/changes (if any). A pre-bid meeting may be attended by authorized representative of prospective bidders for any doubt/ clarifications at the Commission as per scheduled date & time. The meeting will be held remotely via video conferencing facility. The link for same will be shared through IPC website.

In exercise of powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, the Government has notified a new Public Procurement Policy for Micro and Small Enterprises (MSMEs) effective from April 1, 2021. The policy mandates that 25% of procurement of annual requirement of goods and services by all central ministries/ public sector undertakings will be from the micro and small enterprises.

The government has also earmarked a sub-target of 4% procurement of goods and services from MSEs owned by SC/ST entrepreneurs out of above said 25% quantity.

Source: Shardul Nautiyal, Pharmabiz, 09.04.2021

WHO says no to extending Covishield shelf-life to 9 months

Cites insufficient data:

Citing insufficient data, WHO has rejected Serum Institute of India's proposal seeking extension of the shelf life of the Oxford-AstraZeneca Covid-19 vaccine, Covishield, from six to nine months, sources said.

The WHO has also sought a meeting with the Drugs Controller General of India (DCGI) to discuss the matter, they said.

The move comes even as the DCGI has extended Covishield's shelf-life from six to nine months from its manufacturing date.

In a recent communique to Pune-based Serum Institute, the WHO also asked the firm to formulate doses of a higher specification so that the minimum specification of ≥2.5x108 ifu/dose is fulfilled throughout the shelf-life.

The DCGI, in a letter to SII in February, had said: "You are permitted to apply the shelf-life of nine months to unlabelled vials available on hand, subject to the condition that the details of such stock, batch-wise, shall be submitted to this office and Central Drugs Laboratory, Kasauli," DCGI VG Somani had said in the letter.

The DCGI's decision will help health authorities reduce vaccine wastage. According to a February 22 update by the UK drug regulator, the shelf-life of the AstraZeneca vaccine is six months.

EU concerns:

Meanwhile, concerns have been raised about the vaccine as the European Union's health agency concluded a "possible link" between the vaccine and rare blood clots but stressed that the benefits of the vaccine to protect against Covid-19 continue to outweigh the risks.

The UK's medicines regulator on Wednesday, 07.04.2021 said that under-30s in the country will be offered an alternative to the Oxford-AstraZeneca vaccine due to "evolving evidence" linking it to rare blood clots.

African Union says no to SII:

Reuters adds: The African Union has dropped plans to secure Covid-19 vaccines from SII and is exploring options with Johnson & Johnson, the head of the Africa Centres for Disease Control and Prevention said on Thursday, 08.04.2021.

Source: PTI, The Hindu Business Line, 09.04.2021

● ● ●

Container shortage, rising freight rates hit pharmaceutical exports

Shortage of empty containers, particularly reefer containers, and an almost 60 per cent surge in freight rates since October have hit export of pharmaceutical shipments from India.

The Indian Drug Manufacturers Association said that ports in southern India have borne the brunt of box shortage prevailing over the last 7-8 months and have urged the Commerce Ministry to intervene and help tide over the crisis.

The shortage of boxes, according to the association, has led to a rise in freight rates by almost 60 per cent.

Mr S V Veerramani, past National President of the Association, told BusinessLine that the rates for 40 feet containers have gone up from $3,800 to $8,600 for shipments to Cameroon and from $6,600 to $11800 for shipments to Burkino Faso in West Africa. Reefer containers are not readily available and have to be booked at least 15 days in advance, he said. The freight rates have also gone up from $3,300 to $5,600 for shipments to the UK.

All these have affected the smooth movement of pharma exports, he said.

Though the situation has slightly improved at least in terms of dry containers, the shipping lines have increased their freight rates by 60 per cent or more, he said.

The box shortage has forced many pharma exporters to pay higher prices for containers to meet their export commitments, which is adding to their cost and reducing their margins.

Govt intervention sought:

IDMA and Pharmaceuticals Export Promotion Council (Pharmexcil) have asked the Commerce Ministry to sort out the issue, he said.

Revi Uday Bhaskar, Director General of Pharmexcil, told that the issue of container shortage has been felt in almost all sectors and pharmaceutical is no exception. There is a shortage of boxes since the past 7-8 months and the issue has been taken up with the ministries concerned.

The government is working on resolving the crisis at the earliest, he said.

Mr. S V Veeramani, who is also the Chairman and Managing Director, Fourrts (India) Laboratories, said despite the challenges, pharma exports grew by about 15 per cent in FY21 to reach $23.5 billion from $20.5 billion the previous year.

However, he was sceptical about the sector improving on its FY21 performance in the current fiscal in the face of the logistical issues.

Source: V Sanjeev Kumar, The Hindu Business Line, 08.04.2021

● ● ●

Pharma firms to track drug supply

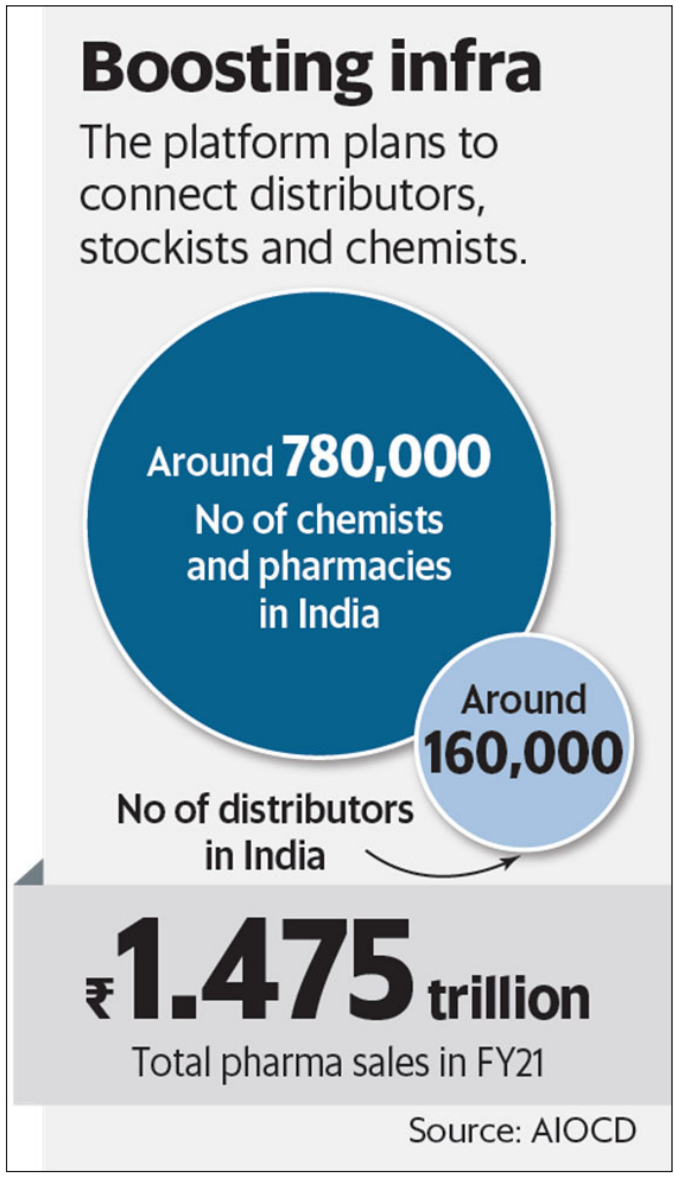
In an unprecedented move, at least half-a-dozen Indian drugmakers, including Sun Pharmaceutical Industries, Cipla, Lupin and Zydus Cadila, have partnered with ABCD Technologies LLP to digitize the country's vast medicine distribution infrastructure for better tracking of product movement.

The platform will allow drug stores to gauge availability of prescription drugs, which in turn will help companies reduce wastage and address any shortages.

"If you see (COVID-19 drugs) favipiravir or remdesivir, so many people don't even know where to get them. The entire supply chain between distributors, stockists and chemists is very scattered... The tracking mechanism will allow a chemists to tell patients where they can find the medicine if it is out of stock. It will also allow a distributors to recognize batches that may be about to expire and send it to chemists so that the medicine is consumed and there is no wastage," said Girish Vanvari, founder , Transaction Square, which managed the ABCD Technologies deal.

On Monday, 05.04.2021 ABCD Technologies LLP completed the acquisition of a 91.8% stake in Pharmarack through the purchase of shares from its shareholders for Rs. 111 crore. The partnership is in the process of acquiring the remaining stakes over the next five years.

The entity will also pick up a 33% stake in pharmaceutical market research firm AIOCD Pharmasofttech AWACS Pvt. Ltd for Rs.75 crore. Over the next few months it will acquire the remaining stakes. ABCD Technologies will be renamed Indo Health Services LLP.



"The business model of Pharmatrack is to connect distributors and chemists. Right now, they are good in Maharashtra. That will now go nationwide with the strength of the partnership. Similarly, AWACS is one of the most favoured subscriptions (for pharmaceutical market research) and that will also be grown," Vanvari said.

The track-and-trace mechanism is similar to the Indian drug regulator's proposed mechanism to monitor the supply chain for key drugs using a bar code system.

Vanvari said the entity is also looking to rope in other pharma companies in the initiative and is in talks with some large Indian drugmakers other than the ones mentioned above.

"There is a lot of interest from other pharmaceutical companies and they are keen to be a part of this initiative," Vanvari said but declined to name the drugmakers as they are listed on the stock exchanges.

The initiative is in support of the National Digital Health Mission of the government, which had envisaged supply chain management as a key component, said the six drug companies in their respective statements.

Source: Leroy Leo, Live Mint, 08.04.2021

● ● ●

IPC releases draft chapter on "Approach to alternative rapid microbiological methods"

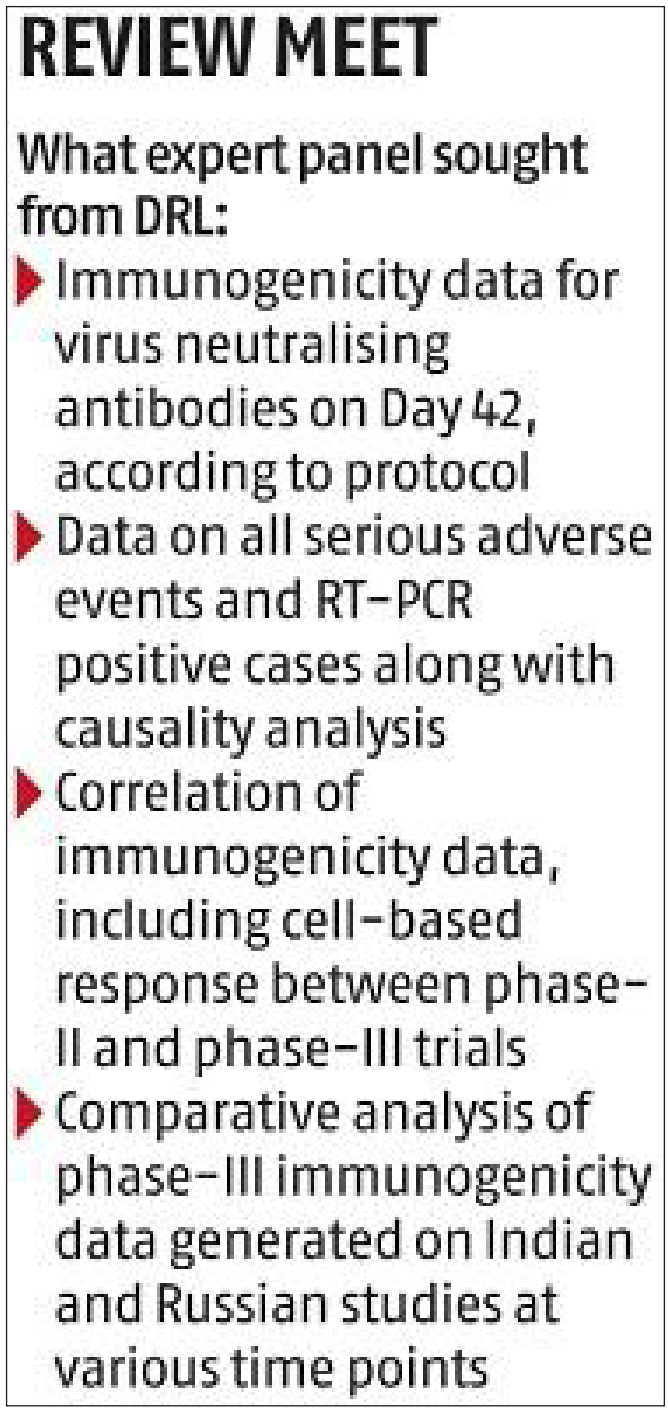
The Indian Pharmacopoeia Commission (IPC) has released draft chapter on "Approach to alternative rapid microbiological methods" for stakeholder comments for effective diagnostic practices. The purpose of this chapter is to provide guidance for selection and validation of methods for use as alternatives to the official compendial microbiological methods.

Traditional methods of microbial detection tend to be labor-intensive and take more than a day to yield results. Alternative methods for microbial detection can be sensitive, precise, quick and reproducible test results when compared with conventional, growth-based methods. For microbial recovery and identification, microbiological testing laboratories sometimes use alternative test methods to those described in the general chapters of Indian Pharmacopoeia (IP) for a variety of reasons.

Alternative microbiological methods also known as Rapid Microbial Methods (RMMs) are the technologies that allow the user to get microbiology test results faster compared with traditional culture-plate methods. In general, rapid methods can be grouped into three distinctive categories in accordance with their application. These categories include qualitative, quantitative and identification methods.

Qualitative rapid methods provide a presence or absence result that indicates microbial contamination in a sample. Quantitative methods provide a numerical result that indicates the total number of microbes present in the sample. Identification methods provide us with a species or genus name for the microbial contaminant in a sample.

Since RMMs may produce sensitive, accurate results, however while using RMMs, acceptance criteria will change in comparison to conventional methods (Quantitative/ Qualitative tests), if this is the case, the responsibility lies with the manufacturer/user to produce/show the similarity/ equivalence of the results/acceptance criteria while using RMMs. Since the acceptance criteria mentioned for microbiological quantitative/qualitative tests in IP is conclusive.



Rapid methods normally involve some form of automation, and the methods often capture data

electronically. Alternative microbiological methods tend to be based on various technology platforms. The more common technologies include nucleic-acid-based detection, which uses DNA or RNA targets, antibody-based detection, biochemical, enzymatic detection such as adenosine triphosphate (ATP) methods, impedance methods and flow-cytometry-based methods.

Source: Shardul Nautiyal, Pharmabiz, 12.04.2021

● ● ●

Mankind Pharma may partner RDIF for Russian Covid-19 vaccine Sputnik V

The marketing and distribution partnerships will come into force after the commercial sale of vaccines is allowed.

As Russian Covid-19 vaccine Sputnik V nears entry into the Indian market, one of the largest drug firms in the country, Mankind Pharmaceuticals, is likely to partner the Russian Direct Investment Fund (RDIF) for distributing it in India. According to sources, Sputnik V may be priced Rs. 500 per dose when it is commercially available. The Centre and RDIF, however, will negotiate prices at which the government will procure the vaccine for the national Covid immunisation drive.

According to sources close to the development, talks are in advanced stages between Mankind Pharma and RDIF to sign a partnership for distribution of the vaccine in India. An announcement is likely soon. Mankind Pharma did not comment on the development and an email sent to RDIF remained unanswered.

"This would be a distribution partnership for taking the vaccine to remote corners of the country. Mankind has a strong distribution network in the hinterland," said a source. At present, drug regulator Drugs Controller General of India (DCGI) has granted "restricted emergency use" authorisation to two vaccines – Covishield and Covaxin. This does not allow the makers to sell these vaccines commercially. The government procures the vaccine from them. The marketing and distribution partnerships will come into force after the commercial sale of vaccines is allowed.

At present RDIF has a tie-up with Hyderabad-based Dr Reddy's Laboratories (DRL) for conducting bridging clinical studies in India (which have been concluded). The pact is also for distributing and marketing the vaccine in India. DRL is also helping RDIF in securing the Indian regulator's authorisation for its vaccine in India.

It has already applied for an emergency use authorisation before the subject expert committee (SEC) of the Central Drugs Standard Control Organisation (CDSCO). The SEC has sought detailed insights on immunogenicity (desired immune response triggered by a vaccine), serious adverse events following vaccination, comparison of immunogenicity data between Indian and Russian trials apart from a cold chain management plan.

The SEC is meeting on Monday to review DRL's application. Sputnik V has been registered in 59 countries globally with a total population of over 1.5 billion. Efficacy of Sputnik V is 91.6 per cent.

RDIF has tied up with several manufacturing partners in India to produce the vaccine on a large scale for both the Indian and international markets. DRL had earlier indicated that the 250 million doses have been lined up for India.

Total manufacturing capacity lined up with several partners in India is over 850-900 million doses annually. This includes Hetero, Gland Pharma, Virchow Group, Stelis Pharma and Panace Biotec, among others. According to sources, more players, including Serum Institute and Shilpa Medicare, are also likely to be manufacturing partners and talks are on for this. The total capacity for making Sputnik V in India can thus cross one billion doses annually, much ahead of the other vaccine candidates.

Sputnik V requires a minus 18-20 degree Celsius cold chain to remain stable. Work on a lyophilised (or freeze dried) version of the vaccine is going on. This version can remain stable at 2-8 degree Celsius.

Source: Sohini Das, Business Standard, 12.04.2021

● ● ●

Exporters remain optimistic with weaker rupee and low interest rates

In its biggest drop since August 2019, the Indian rupee fell 105 paise against the US (United States) dollar on Wednesday, 07.04.2021 soon after the Reserve Bank of India (RBI) announced its monetary policy. By Friday, 09.04.2021 noon, the rupee had fallen to Rs 74.94 to a US dollar. This can make exports more rewarding, imports more expensive and boost customs revenues. However, it may make reining in inflation below 6 per cent rather difficult.

The RBI, however, does not seem too perturbed by the prospects of inflation. It expects the Consumer Price Index (CPI) inflation to be 5.2 per cent, 5.2 per cent, 4.4% and 5.1 per cent in the four quarters of the current financial year. Its focus is mainly on enabling economic growth by retaining interest rates at the same level and maintaining its accommodative stance on liquidity. It expects the real gross domestic product growth for 2021-22 to be 10.5 per cent. Most analysts find this estimate rather conservative.

Welcoming the RBI's lower interest rate regime intended at supporting growth, the Chairman of Engineering Exports Promotion Council said that steps need to be taken for full transmission of lower interest rates to exporters and end-customers.

On the external sector, the RBI said that global growth was gradually recovering from the slowdown, but it remained uneven across countries and was supported by ongoing vaccination drives, sustained accommodative monetary policies and further sizeable fiscal stimulus. The Organisation for Economic Co-operation and Development (OECD) projected the world output to reach its pre-pandemic level by mid-2021, though it will be largely contingent on the pace of vaccine distribution and its efficacy against emerging variants of the virus. Stronger external demand should support India's exports and investment demand. The survey of professional forecasters released by the RBI said that India's merchandise exports and imports were expected to grow by 15 per cent and 24 per cent, respectively, in 2021-22.

The World Trade Organization (WTO), however, does not expect the world trade to reach the pre-pandemic trend till the end of 2022. Its recent forecast said the volume of world merchandise trade was expected to increase by 8 per cent in 2021 after falling 5.3 per cent in 2020, continuing its rebound from the pandemic-induced collapse that bottomed out in the second quarter of last year. Trade growth should then slow to 4 per cent in 2022 as effects of the pandemic will continue to be felt and this pace of expansion still leaves trade below its pre-pandemic trend. The relatively positive short-term outlook for global trade is marred by regional disparities, continued weakness in services trade, and lagging vaccination timetables, particularly in poor countries. Covid-19 continues to pose the greatest threat to trade outlook, as new waves of infection could easily undermine any hoped-for recovery, said the WTO.

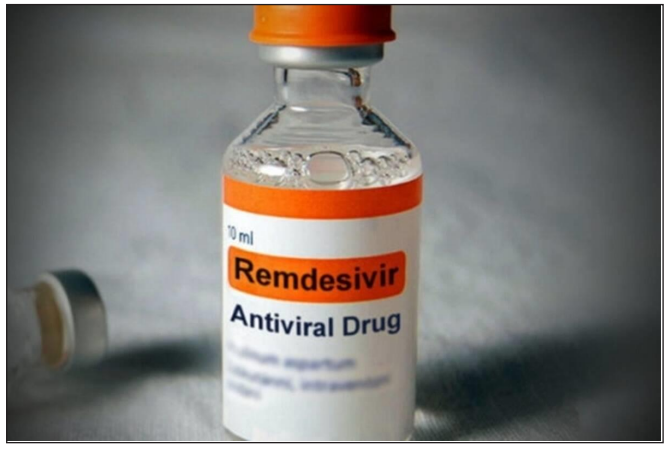
The second wave of pandemic has forced many states to impose night curfews and restrain several economic activities. The prospects of increase in crude oil prices, weakening foreign fund inflows, strengthening US dollar and rising bond yields in the US are also seen as cause for concern. The RBI, however, sees upsides in the pace and wider coverage of vaccination, the gradual release of pent-up demand and the investment-enhancing and growth-supportive reform measures taken by the government.

Overall, exporters are happier with a weaker rupee, low interest rates, and better order books.

Source: TNC Rajagopalan, Business Standard, 11.04.2021

● ● ●

As Covid cases rise, Zydus to scale up Remdesivir production



The drug which was originally manufactured to treat the Ebola virus in the year 2014 has been used for other viral outbreaks including SARS and MERS.

Following the surge in cases of COVID-19, pharma major Cadila Healthcare (Zydus Cadila) is scaling up production capacity of Remdesivir injections, which are used to treat Coronavirus patients.

Zydus Cadila has an installed capacity to make eight lakh doses of Remdesivir per month. Sources in the Zydus group said that in the coming days, the installed capacity will be increased up to 12 lakh doses per month at its Ahmedabad and Vadodara plants.

"Zydus has taken test licences for the development of both plants where Remdesivir is being manufactured," Dr HG Koshia, Commissioner, Food & Drug Control Authority, Gujarat, confirmed.

Th capacity expansion will help the drugmaker compensate for the recent cut in the drug's price through bulk production, the company sources said. Zydus has cut the price of its Remdesivir injection to Rs. 899 per 100 mg lyophilised injection from Rs. 2,800 per vial it charged earlier.

The Ahmedabad-headquartered company had inked a non-executive agreement with Gilead Sciences last June to manufacture and sell Remdesivir in India. As per a senior official of the company, Zydus was witnessing huge demand for Remdesivir as its product is more economical compared to other companies.

Companies like Cipla, Mylan, Jubilant Life Sciences, Hetero Drugs, Syngene International and Dr Reddy's Laboratories are also manufacturing Remdesivir for the Indian market.

Meanwhile, the Gujarat government is in the process of purchasing three lakh doses of Remdesivir from Zydus Cadila for uninterrupted supply at Covid-19 centres. The government had issued a tender to this effect and the lowest bid was from Zydus. "We have started procuring Remdesivir at less than Rs 800 per dose from Zydus," Koshia said.

Source: Financial Express, 10.04.2021

● ● ●

Covid-19 vaccine: Panacea Biotec to begin Sputnik V manufacturing within 90 days

New Delhi-based Panacea Biotec is likely to announce details about its contract with Russian Direct Investment Fund (RDIF) for the manufacturing of Sputnik V vaccine within 15 days.

Sources told that the company will start production within 60-90 days of the announcement in its three facilities in India.

Only for export:

"The Sputnik V vaccine will be manufactured for export only and not for supply in India. We are in the process of working out the investment it would require, price mechanism and other details of the contract. After making the formal announcement within 15-days, we will begin production in 60-90 days," a source privy to the matter said.

In view of massive global shortage of Covid vaccine, it seems that the government will approve export of Sputnik V to meet the requirement, the source said when asked about the approval for export when India itself is facing supply crunch.

When asked whether the company is late in bringing out the vaccine to the market, the source said considering the global requirement of vaccine in the backdrop of upsurge in pandemic cases during the second wave, the company is very much on time. No one had ever imagined that the second wave would be faster in its spread than the previous one.

Source: Monika Yadav, Hindu Business Line,10.04.2021

● ● ●

Government bans export of Remdesivir till COVID-19 situation improves

A state health department official said the state has more stock than that. Maharashtra is also planning to put a ban on the retail sale of the drug.

The government on Sunday, 11.04.2021 banned the export of anti-viral drug remdesivir and its active pharmaceutical ingredients (API) to meet the increase in domestic demand for the drug as cases of Covid-19 surged in the country.

On April 11, the number of active novel corornavirus infections in the country touched 1.1 million. In view of the surge in cases, the government said there is a potential for further increase in demand for this drug in the coming days.

"In light of the above, government of India has prohibited the exports of injection remdesivir and remdesivir Active Pharmaceutical Ingredients (API) till the situation improves," said the statement from the Press Information Bureau on Sunday, 11.04.2021. "All domestic manufactures of remdesivir have been advised to display

on their website details of their stockists/distributors to facilitate access to the drug."

The department of pharma is also in touch with remdesivir manufacturers to ramp up production. In India, the companies that have licence from US drug maker Gilead for making remdesivir are Hetero, Mylan, Zydus, Dr Reddy's, Biocon and Sun Pharma. The total production from these companies is about 3.8 million units per month.

The drug companies ET spoke with said the sudden surge in demand has caught them off guard and they will need a few days to ramp up production.

State governments had stopped procuring remdesivir after the drop in Covid-19 infections in the country. This was one of the factors leading to companies scaling back on production of the drug.

"We are also ramping up our production capacities and have been shipping on daily basis. We anticipate that things will normalise in a few days," said a spokesperson for Hetero in a statement.

In Maharashtra, which has the highest burden of Covid-19 cases in the country, the state government anticipates a requirement of 40,000 vials of the drug every day. A state health department official said the state has more stock than that. Maharashtra is also planning to put a ban on the retail sale of the drug. Reports of shortage of the drug has led to panic among patients in some states where the number of cases is high. There are also reports of indiscriminate use of the drug beyond the recommended protocol.

Source: Divya Rajagopal, The Economic Times, 12.04.2021

● ● ●

Bharat Biotech to raise Covaxin's production to 12 million a month by July

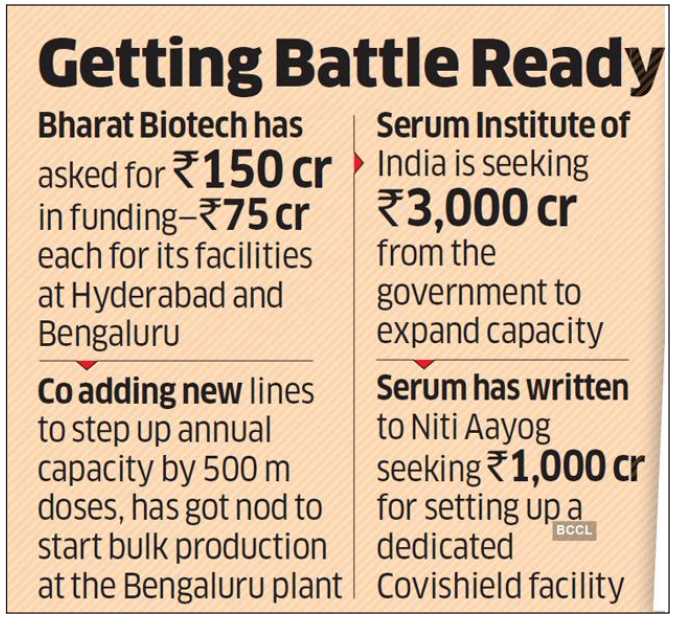
Serum Institute is also expected to boost production of its Covishield vaccine to 110 mn doses per month from June. SII has a monthly capacity of 60-70 million doses per month.

Hyderabad-based Bharat Biotech is set to scale up production of its indigenously developed Covaxin to 12 million doses a month by July from the current 5 million, providing a critical boost to India's Covid-19 inoculation programme amid a second wave of infections.

The company is set to start bulk production at its Bengaluru facility, people in the know told. Bharat Biotech received approval from India's drug regulatory authority to start bulk production at the plant recently.

"The company has got the test licence to start production of Covaxin in Bengaluru. The fill-finish lines of its existing Hyderabad facility will be used before the vaccine is sent to the Central Drug Laboratory (CDL) for final approval," said a government official.

The company is adding new lines to step up annual capacity by 500 million doses.



Talks On for Tieups with Other Cos. There are also discussions regarding partnerships with other companies to further boost production of the Covid-19 vaccine, the official added.

"The demand for Covaxin has gone up manifold and hence there is a need to ramp up production. The technology can be transferred to those companies which are BSL (bio safety level) III or are interested in upgrading their facility," the official said.

The company has also asked for Rs. 150 crore in funding—Rs.75 crore each for its facilities at Hyderabad and Bengaluru.

Serum Institute of India (SII) is also expected to boost production. It's hoping to increase capacity for the Covishield vaccine to 110 million doses per month from June onwards, as part of an overall strategy to ramp up production. SII now has a monthly capacity of 60-70 million doses per month.

As India grapples with a deadly second wave of Covid-19 infections—with an average of more than 90,000 cases daily from April 1—its inoculation drive appears to be struggling, with many states reporting a shortage of vaccines.

"We are also expecting Russia's Sputnik V to get approval soon, which will inject an instant relief," said an official.

Dr Reddy's Laboratories has a tie-up with the Russian Direct Investment Fund (RDIF), which backed the development of Sputnik V, and will import initial doses of the vaccine once it gets approval from the drug regulator. It will subsequently be manufactured in India.

RDIF and Dr Reddy's said in September that they would cooperate on clinical trials and the supply of 100 million doses of the Sputnik V vaccine to India.

While Dr Reddy's will market the vaccine in India, RDIF has tied up with other Indian companies to produce 850 million doses of Sputnik V in the country every year. The first partnership was with Hetero Biopharma in November and collaborations with Gland Pharma, Stelis Biopharma and Vichrow Biotech were announced last month.

Source: Teena Thacker, The Economic Times, 12.04.2021

● ● ●

Explained: Why there's a shortage of remdesivir, and what is being done about it

Remdesivir uses, effects: Remdesivir is an injectable anti-viral that aims to prevent replication of the virus. It was manufactured in 2014 to treat Ebola, and has since been used to treat SARS and MERS. In 2020, it was repurposed for Covid-19 treatment.

Amid a surge in Covid-19 cases, Maharashtra, Delhi, Gujarat, Chhattisgarh and Madhya Pradesh have started reporting a shortage of the anti-viral remdesivir. On Sunday, the Directorate of Foreign Trade in Ministry of Commerce and Industry issued an order prohibiting export of remdesivir and active pharmaceutical ingredients (APIs) required in its production until further notice.

Remdesivir is an injectable anti-viral that aims to prevent replication of the virus. It was manufactured in 2014 to treat Ebola, and has since been used to treat SARS and MERS. In 2020, it was repurposed for Covid treatment. Clinical experience has shown it works best in mildly ill patients, and in early stages of hospitalisation; late use has little effect.

The Crisis:

Of India's 11 lakh active infections are in Maharashtra, which now needs 40,000-50,000 remdesivir vials daily, as compared to a peak requirement of 30,000 a day last year. The higher demand is primarily due to rising cases, and also manufacturing and supply issues. Madhya Pradesh has complained it is currently getting half its requirement. "Around 70% of total production is diverted towards Maharashtra. The remaining 30% is distributed to other states. If we need 7,000 vials, we get only 1,500-2,000," said Food and Drug Inspector in MP Shobhit Kosta.

Demand and supply:

For two or three months this year, remdesivir production was negligible or nil. Last December, several suppliers and manufacturers were left with huge stockpiles. They had anticipated sales and scaled up production, but a drop in Covid cases in November-December reduced demand.

Former Joint Commissioner of Drugs, FDA (Maharashtra), J B Mantri said a few suppliers had to destroy expired stocks. From January, manufacturers scaled down production. Hetero Healthcare, India's largest manufacturer of remdesivir, scaled down production to 5-10%. Kamla Lifesciences, which supplies remdesivir to Cipla, stopped manufacturing from January 31 to March 1. "Government had asked us to reduce manufacturing because Covid-19 cases were reducing and there was no demand," said Dr DJ Zawar, MD in Kamla Lifesciences.

That halt has affected supplies now. Cases began rising from February, but manufacturing resumed to an extent in March. "We need at least 25 different raw materials in production of remdesivir… We had to procure a lot of raw material and our suppliers could not supply quickly," said Prafulla Khasgiwal, senior VP, Hetero Healthcare.

The cycle from production to transportation of remdesivir can take 20-25 days. Production scaled up last month; it will take another week for fresh stocks to hit markets.

What next:

The Department of Pharmaceuticals has asked all seven manufacturers to scale up to their maximum capacity of 38.80 lakh vials per month. Hetero can produce 10.50 lakh, Cipla 6.20 lakh, Zydus Cadila 5 lakh and Mylan

4 lakh vials. Hetero is producing 35,000 vials a day or two currently. Zydus plans to scale up to 12 lakh vials a day. It has also slashed the price of a 100 mg vial to Rs. 899, from Rs. 2,800, the cheapest from any manufacturer. The MRP for others is: Cipla Rs. 4,000, Hetero Rs. 5,400, Dr Reddy's Lab Rs. 5,400, Mylan Rs 4,800 and Jubilant Rs. 4,700.

Deepak Sapra, CEO (APIs and Services) in Dr Reddy's, said it is "preparing to meet the additional demand". Cipla said it has "have serviced all orders and are in the process to optimise supplies further". A Mylan spokesperson said, "We are closely partnering with the government to meet the patient needs in India and ensure access..."

Remdesivir is being over-prescribed even for patients who won't benefit from it. Last year, the DoP had red-flagged this. Over-prescription has inflated prices. Worse, over-use can make patients resistant to the drug.

Domestic manufacturers have been directed to list their distributors on their websites. The Centre has directed states to take action against black marketing and hoarding. It has advised hospitals to use remdesivir based on the national Covid protocol, which lists remdesivir as an investigational drug with contraindications.

Source: Tabassum Barnagarwala, The Indian Express, 13.04.2021

● ● ●

INTERNATIONAL NEWS

US FDA OKs first new ADHD drug in over a decade for children

US regulators have approved the first new drug in over a decade for children with ADHD, which causes inattention, hyperactivity and impulsivity. The Food and Drug Administration late Friday OK'd Qelbree (KELL'-bree) for treating attention deficit hyperactivity disorder in children ages 6 to 17.

It comes as a capsule that's taken daily. Unlike nearly all other ADHD medicines, Qelbree is not a stimulant or a controlled substance, making it harder to abuse than older drugs. That's been a problem with earlier ADHD treatments like Ritalin, nearly all of which contain the stimulants amphetamine or methylphenidate. Qelbree, developed by Supernus Pharmaceuticals of Rockville, Maryland, carries a warning of potential for suicidal thoughts and behavior, which occurred in fewer than 1% of volunteers in studies of the drug. Supernus wouldn't disclose the drug's list price, but it's sure to be higher than the many cheap generic ADHD pills.

ADHD affects about 6 million American children and adolescents. For many, problems include trouble paying attention and completing tasks, fidgeting and impulsiveness. Experts say the drug may appeal to parents who don't want to give their child stimulants. It also could be an option for kids who have substance abuse problems, dislike the side effects of stimulants or need additional therapy, said Dr. David W. Goodman, director of Suburban Psychiatric Associates near Baltimore and an assistant professor of psychiatry at Johns Hopkins School of Medicine.

Goodman said most ADHD patients taking medication currently are prescribed long acting stimulants, which are harder to abuse to get a high than the original, fast-acting versions. In a key late-stage study funded by Supernus, 477 children ages 6 to 11 took the drug for six weeks. Inattention and hyperactivity symptoms were reduced by about 50% compared to the placebo group. Qelbree, also known as viloxazine, helped reduce symptoms in some study volunteers within a week. Common side effects include sleepiness, lethargy, decreased appetite and headache.

Supernus is in late-stage testing for adults with ADHD. That's a much smaller group than children, but that market is growing because few adults currently take ADHD medicines. Viloxazine was sold as an antidepressant in Europe for several decades, but was never approved by the FDA. The maker ended sales for business reasons nearly two decades ago, as popular pills like Zoloft and Prozac came to dominate the market.

Source: Daily Excelsior, 07.04.2021

● ● ●

Global Psychedelic Drugs Market Growing Tends in Global Regions with COVID-19 Pandemic Analysis, Development Status and Forecast till 2028

Global Psychedelic Drugs Market describes complete industry Outlook with in-depth analysis. This report also Includes the complete analysis of each segment in terms of opportunity, market attractiveness index and growth rate, top players and new comers in industry, competitive landscape, sales, price, revenue, gross margin, market share, market risks, opportunities, market barriers, and challenges, key statistics on the market status, which give the clear idea about the product differentiation and an understanding of competitive landscape Globally.

The psychedelic drugs market is expected to gain market growth in the forecast period of 2021 to 2028. Data Bridge Market Research analyses that the market is growing with a CAGR of 13.3% in the forecast period of 2021 to 2028 and is expected to reach USD 7,567.52 million by 2028 from USD 2,823.67 million in 2020. The rising prevalence of mental depression and anxiety and availability of off-label drugs are the major drivers which has propelled the demand of the psychedelic drugs market in the forecast period.

The major companies providing psychedelic drugs are Janssen Pharmaceuticals, Inc. (a subsidiary of Johnson & Johnson Services, Inc.), Hikma Pharmaceuticals PLC, COMPASS, Verrian, Pfizer Inc., F. Hoffmann-La Roche Ltd, Jazz Pharmaceuticals, Inc., PharmaTher Inc., Avadel, Celon Pharma S.A., NeuroRx, Inc., usonainstitute.org among other domestic players. DBMR analysts understand competitive strengths and provide competitive analysis for each competitor separately.

Many product launch and agreement are also initiated by the companies' worldwide which are also accelerating the global psychedelic drugs market.

For instance:

- In August 2020, Janssen Pharmaceuticals, Inc received approval for its Spravato nasal spray for treatment of suicidal people. As per the data published, approximately 11% to 12% of Americans suffers from major depressive disorder that led them to commit suicide. Hence, this approval provided these patients with a remarkable therapy and allowed company to generate more revenue.
- In January 2020, Jazz Pharmaceuticals, Inc has received the marketing authorization of solriamfetol (Sunosi) indicated for treatment of excessive day time sleepiness in adults with narcolepsy. This authorization allowed the company to enhance product distribution network and to generate more revenue in the market.

Global Psychedelic Drugs Market Scope and Market Size:

- The psychedelic drugs market is segmented into seven notable segments which are based on the source, type, drugs, application, route of administration, end user and distribution channel. The growth among segments helps you analyse niche pockets of growth and strategies to approach the market and determine your core application areas and the difference in your target markets.
- On the basis of source, the psychedelic drugs market is segmented into synthetic and natural. In 2021, synthetic segment is dominating as most of the products are made from chemicals that are man-made with very few products such as psilocybin made from natural ingredients.
- On the basis of type, the psychedelic drugs market is segmented into dissociatives, empathogens and others. In 2021, empathogens segment produce experiences of emotional communion, oneness, relatedness and used for treatment of cataplexy, narcolepsy and related disorders.

- On the basis of drugs, the psychedelic drugs market is segmented into gamma-hydroxybutyric acid, ketamine, psilocybin and others. In 2021, gamma-hydroxybutyric acid segment is dominating as xyrem from Jazz Pharmaceutical is one of the oldest available psychedelic drugs available in the market holding a major share and belongs to the drug class.
- On the basis of application, the psychedelic drugs market is segmented into narcolepsy, treatment resistant depression, post-traumatic stress disorder, major depressive disorder, opiate addiction and others. In 2021, narcolepsy segment is dominating as xyrem from Jazz Pharmaceutical is used for its treatment and it is the major shareholder in the market.
- On the basis of route of administration, the psychedelic drugs market is segmented into oral, inhalation and injectable. In 2021, oral segment is dominating as it is preferred over the various other administration routes of drug delivery.
- On the basis of end user, the psychedelic drugs market is segmented into hospitals, specialty clinics, homecare and others. In 2021, hospitals segment dominate the psychedelic drugs market due to the high patient load and most of the drugs are given under doctor's supervision.
- On the basis of distribution channel, the psychedelic drugs market is segmented into hospitals pharmacy, retail pharmacy and online pharmacy. In 2021, hospitals pharmacy segment holds the largest market share as more number of patients is treated in hospitals and the demand for medicines in hospital pharmacy increases.

Source: Data Bridge Market Research, The Courier 07.04.2021 (Excerpts)

● ● ●

Generic Drug Market: Industry Perspective, COVID-19 Impact Analysis, Size, Growth, Trends and Forecast, 2027

For producing such excellent Generic Drug Market research reports, principal attributes such as highest level of spirit, practical solutions, dedicated research and analysis, innovation, talent solutions, integrated approaches, most advanced technology and commitment plays a key role. This marketing report provides in-depth market data and forecast by analyzing key business trends and identifying potential growth avenues across the entire value chain.

This report includes the market strategy, market orientation, expertise union, and knowledgeable information growth and Revenue, market share, and size that helps to understand future prospects

Global Generic Drug Market, By Type (Pure Generic, Branded Generic), Indication (Central Nervous System (CNS), Cardiovascular, Dermatology, Oncology, Respiratory Others), Route of Administration (Oral, Topical, Parenteral, Others), End-Users (Hospitals, Homecare, Specialty Clinics, Others), Distribution Channel (Hospital Pharmacy, Online Pharmacy, Retail Pharmacy), Country (U.S., Canada, Mexico, Brazil, Argentina, Peru, Rest of South America, Germany, France, U.K., Netherlands, Switzerland, Belgium, Russia, Italy, Spain, Turkey, Hungary, Lithuania, Austria, Ireland, Norway, Poland, Rest of Europe, China, Japan, India, South Korea, Singapore, Malaysia, Australia, Thailand, Indonesia, Philippines, Vietnam, Rest of Asia-Pacific, Saudi Arabia, U.A.E, Egypt, Israel, Kuwait, South Africa, Rest of Middle East and Africa), Market Trends and Forecast to 2027.

The growth of generic drug market enhanced by the surge of patent expiration of branded drugs and growing cases of chronic diseases. In addition, advances in the formulation such as fixed dose combination and cost-effective treatment are some of the impacting factors for the demand of generic drugs. Nevertheless, product recalls coupled with shortage of drugs are the factors that hinder the growth of this market.

Leading Key players:

The major players covered in the global generic drug market are Pfizer Inc, Teva Pharmaceutical Industries Ltd, Lupin, Hikma Pharmaceuticals PLC, Dr Reddy's Laboratories Ltd, Zydus Cadila, Aurobindo Pharma, Cipla Inc., Novartis AG, Wockhardt, Perrigo Company plc, Lannett, Mylan N.V., Amneal Pharmaceuticals LLC, Sun Pharmaceutical Industries Ltd, ApotexInc, Micro Labs Ltd, Bausch health, Torrent Pharmaceuticals Ltd, Endo International plc, Sawai Pharmaceutical Co., Ltd and Fresenius Kabi AG among others.

Global Generic Drug Market Scope and Market Size:

Generic drug market is segmented on the basis of type, indication, route of administration end-users and distribution channel.

- On the basis of type, the global generic drug market is segmented into pure generic and branded generic.
- Based on indication, the global generic drug market is segmented into central nervous system (CNS), cardiovascular, dermatology, oncology, respiratory and others.
- Route of administration segment for global generic drug market is categorized into oral, topical, parenteral and others.
- On the basis of end-users, the global generic drug market is segmented into hospitals, homecare, specialty clinics and others.
- On the basis of distribution channel, the global generic drug market has been bifurcated into hospital pharmacy, online pharmacy and retail pharmacy.

Patient Epidemiology Analysis:

Generic drug market also provides you with detailed market analysis for patient analysis, prognosis and cures. Prevalence, incidence, mortality, adherence rates are some of the data variables that are available in the report. Direct or indirect impact analysis of epidemiology to market growth are analysed to create a more robust and cohort multivariate statistical model for forecasting the market in the growth period.

Global Generic Drug Market report provides basic information about industry, definition, classification, application, industry chain structure, industry overview, and international market analysis. In addition, the company's market share, possible sales volume, types of consumers, their response and views about the products, their thoughts for the step-up of a product, and the most appropriate method for the distribution of certain products have also been covered.

Source: Data Bridge Market Research 2021, The Sentinel Newspaper, 12.04.2021 (Excerpts)

● ● ●

IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  The RTGS details are as follows:- BANK: BANK OF BARODA
  Account Name : ***Indian Drug Manufacturers' Association,*** *Bank A/c No. : Current A/c* ***76080200000242***
  Bank : ***BANK OF BARODA,*** *Branch Address : Worli Branch, Mumbai-18,* ***IFSC : BARB0VJWORL***
  MICR CODE : 400012339
- GST will be charged extra, as applicable. *(Current Rate is @5%)*
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

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

For further details such as series discounts etc, please contact:
Mr Melvin Rodrigues — Cell: +98210 68758 (Email: actadm@idmaindia.com)/
Mr C K S Chettiar— Cell: +98206 29907 (Email: mail_idma@idmaindia.com)
PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org www.indiandrugsonline.org**

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.04.2021

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**