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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA 60TH YEAR CELEBRATIONS 2022

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

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HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 42** **08 to 14 November 2021**

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

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli,
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IDMA 60TH YEAR CELEBRATIONS 2022

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

Dear Member,

Greetings from Indian Drug Manufacturers' Association (IDMA).

We, at IDMA, humbly request our Members to whole-heartedly participate in the IDMA 60th Year Celebrations by way of **Registrations, Advertisements & Sponsorships.** Your support is very much desirable and necessary in strengthening your Association as well as for the success of any initiatives taken up by your Association. We are sure that with your support the 60th Year Celebrations is going to be a massive and glorious success story in the history of your Association.

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

The main objectives of the celebrations are:

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

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

As part of the Celebrations, the winners of the:

1. **IDMA Margi Memorial Best Patent Awards**
2. **IDMA ACG-SCITECH Research Paper Awards**
3. **IDMA Corporate Citizen Awards**
4. **IDMA - N. I. Gandhi Emerging Leader of the Year Award**

would be announced and the Awards would be presented.

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

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

IDMA 60th ANNUAL PUBLICATION 2022

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

AN OFFER NOT TO BE MISSED

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

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OPPORTUNITIES FOR SPONSORSHIPS:

We would be extremely pleased if you would accept one of the below Sponsorship for this celebrations :-

PLATINUM SPONSOR	**:**	**Rs. 25 Lakh**	**GOLD SPONSOR**	**:**	**Rs. 10 Lakh**
DIAMOND SPONSOR	**:**	**Rs.15 Lakh**	**SILVER SPONSOR**	**:**	**Rs. 5 Lakh**

Sponsors will be provided special benefits & privileges as per the copy attached: For details please contact IDMA Secretariat.

REGISTRATION FEES:

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

Reception Committee Member	Rs.7,500/- plus GST @ 18%
Delegate	Rs.6,000/- plus GST @ 18%
(For more than 4 registrations from one Company, the 5th registration will be complimentary)	

For further details, please contact:

Mr. Melvin	Ms. Geeta	Ms. Batul
9821868758	9820161419	9920045226
actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com

ROOM RATES :

We have negotiated special room rates for our members. **The special room rate would be Rs.6,000/- per night for a Single Occupancy and Rs.7,000/- per night for a Double Occupancy.** The room rate includes complimentary breakfast and internet facilities.

Kindly note that those members who desire to stay at Hotel Sahara Star, please forward their details to the IDMA Secretariat.

Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

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

Thanking you,

With best regards,

Bharat Shah
Chairman, Organizing Committee, IDMA
60th Year Celebrations

Mahesh H Doshi
National President

Daara B Patel
Secretary - General

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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ATTENTION MEMBERS

Invitation to Participate in 'IDMA MARGI MEMORIAL BEST PATENT AWARDS 2019 - 2021'

Dear Member,

As you will be aware, the **IDMA Margi Memorial Best Patent Awards** recognise the **'Best Patents of the Year',** both national and international. We request you to kindly send us details of your **patent/s granted during the period 1st April 2019 & 31st March 2021.** An Expert Panel will examine and evaluate the applications received and recommend their selection for the Award.

Applications should be forwarded in a closed and sealed envelope marked **"IDMA Margi Memorial Best Patent Awards 2019-2021"** along with an **ENTRY FEE of Rs.15,000/- plus GST @ 18% (Total Rs.17,700/-)** per Member Company immediately to reach us **latest by 15th December 2021**. Hard copies of the patent are not required to be submitted along with the application.

For the convenience of the panelist, soft copies of the application along with relevant supporting patent documents may also be forwarded separately at **technical@idmaindia.com** / **actadm@idmaindia.com**. Only a soft copy of the Patent granted should be enclosed to enable the Panel to evaluate the Patent for the Award.

Applications for the Award will need to comply with certain criteria as enumerated in the **Guidelines (Do's and Don'ts)** for IDMA Margi Memorial Best Patent Awards 2019 - 2021 (copy attached). Kindly peruse the same before applying for the Award.

The winners will be notified by email after the Expert Panel finalizes selection of Award Winners. The Awards will be presented at the **IDMA 60th Annual Day Celebrations on Friday, 7th January & Saturday, 8th January 2022 at Hotel Sahara Star, Mumbai.**

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GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

The Expert Panel, constituted to scrutinise the Applications, has set the following **DOs and DON'Ts** for consideration for Awards as below:

DOs

1. Applications must include Patents granted only during the period 1st April 2019 to 31st March 2021 for evaluation.
2. A Member-Company can apply for more than one Patent. Multiple Patents can be listed in a single application.
3. The Applicationis to be submitted both as Soft Copy as well as Hard Copies with a Summary of the Patents. However, complete Patents may please be sent only in Soft copy.
4. All Family Patents belonging to same invention will be considered as one patent. Country-wise validations for EU or ARIPO patents will not be considered as independent patents. Divisional patents granted with similar inventions will be considered along with parent patent.
5. Different inventions having same title with common priority document will be identified and considered as One Patent.
6. Group companies (including Research Centres) applying independently may indicate if they wish to be considered together or separately. If patent is granted to other than the applicant, the documents justifying the inclusion of such patents (group status) need to be attached.
7. Applications for Awards for Patents granted to individuals will be considered with documentary support of rights transferred to the Applicant (Member company)
8. Applicants are requested to self-certify the authenticity of information submitted to minimise the review and verification work by IDMA.
9. The Application must be forwarded under a covering letter /or by email duly signed by an authorised signatory along with name, designation and contact details.
10. The covering letter should carry a declaration that "We have read 'The Guidelines and Criteria for Evaluation of Patents submitted for IDMA Margi Memorial Patent Awards 2019 - 2021and abide by the same".

DON'Ts

1. Please do not apply for Patents granted earlier than 1st April 2019 or after 31st March 2021. It will not be considered for this year's Awards.
2. Please do not apply for a pending patent. It will not be considered and will be disqualified.
3. Please do not apply for Patents which are already withdrawn, abandoned, not maintained or revoked will obviously not be considered.
4. An Application of a patent of the same family (of an invention which has already qualified for award in earlier years), even if granted in another country in the relevant year will not be considered.
5. If the data submitted is found to be not correct or factual, the applications will be disqualified.

GOVERNMENT NOTIFICATION

Shri Kuldip Narayan, Joint Secretary, Ministry of Housing and Urban Affairs, New Delhi appointed as a Director on the Board of Directors of National Housing Bank

Finance Notification S.O.4620(E), dated 08th November 2021

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

In exercise of the powers conferred by Clause (e) of Sub-Section (1) of Section 6 of the National Housing Bank Act, 1987 (53 of 1987), the Central Government hereby appoints Shri Kuldip Narayan, Joint Secretary, Ministry of Housing and Urban Affairs, New Delhi as a Director on the Board of Directors of National Housing Bank with immediate effect and until further orders vice Shri Amrit Abhijat.

F.No.24/17/2010-IF-II

Lalit Kumar, Economic Adviser, Department of Financial Services, Ministry of Finance, New Delhi.

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CORPORATE AFFAIRS MATTERS

Notification number G.S.R.785(E), dated the 09th November, 2021 amended - reg.

Corporate Affairs Corrigendum G.S.R.791(E), dated 12th November 2021

In the notification of the Government of India in the Ministry of Corporate Affairs number G.S.R.785(E), dated the 09th November, 2021, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 09th November, 2021, at page 9, in the English version, in line 9, for “sub-rule (7)”, read “sub-rule (2)”.

F.No.05/1/2021-IEPF

Manoj Pandey, Joint Secretary, Ministry of Corporate Affairs, New Delhi

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Enlistment of Agency(ies) and amendment in details under Appendix 2E of FTP, 2015-2020 - authorized to issue Certificate of Origin (Non-Preferential) - reg.

Public Notice No.35/2015-2020, dated 11th November, 2021

In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy (FTP) 2015-2020, the Director General of Foreign Trade hereby authorizes the following agencies to issue Certificate of Origin (Non Preferential):

(i) Council for Leather Exports (CLE), No.1, Sivaganga Road,
Nungambakkam, Chennai, Tamil Nadu, 600034. Phone: 044-48684380 - 84
Email: cle@cleindia.com Website: www.leatherindia.org

(ii) Udaipur Chamber of Commerce & Industry (UCCI)
Chamber Bhawan, Chamber Marg, Mewar Industrial Area,
Madri, Udaipur, Rajasthan - 313003. Tele No. 0294 -2491060, 2492214, 2492215
Mobile No. 8000156600 / 9351917002 / 9351917008
email: info@ucciudaipur.com, uccisec@ucciudaipur.com website: www.ucciudaipur.corn

2. Accordingly, name of the above agencies are added as under in Appendix 2E [List of Agencies Authorized to issue Certificate of Origin (Non-Preferential)] to Appendices & Aayat Niryat Forms of FTP (2015-2020):

Name of Agency	State	Serial No.
Council for Leather Exports (CLE)	Tamil Nadu	16
Udaipur Chamber of Commerce & Industry (UCCI)	Rajasthan	06

3. In addition, name and contact details of the following agency enlisted at Sl. No. 13 under the sub-heading 'Maharashtra' in Appendix 2E (List of agencies authorized to issue Certificate of Origin (Non-Preferential)) of the FTP (2015-2020) is also amended as under:

S. No. in Appendix 2E	Existing details of the agency	Revised details of the agency
13.	Marathwada Industries Association Bajaj Bhavan, P-2, MIDC, Station Road, Aurangabad-431005 Tel (0240)-324509/355090 Fax (0240)333029 E-mail: mia-abd@satyam.net.in	Chamber of Marathwada Industries and Agriculture (CMIA) Bajaj Bhavan, P-2, MIDC, Station Road, Aurangab -431005 Phone: 0240 - 2333029 E-mail: office@cmia.co.in Website: www.cmia-aurangabad.com

4. Effect of this Public Notice:

Two new agencies namely Council for Leather Exports (CLE) and Udaipur Chamber of Commerce & Industry (UCCI) are enlisted under Appendix 2E of FTP, 2015-2020 for issuing Certificate of Origin (Non-Preferential). Name of Marathwada Industries Association, already enlisted under Appendix 2E, has been amended as Chamber of Marathwada Industries and Agriculture (CMIA). Contact details of the agency have also been updated.

F.No.01/93/180/67/AM-21/PC.II(B)/E-28960

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

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Amendment in Appendix 1A of Foreign Trade Policy, 2015-20 - reg.

Public Notice No.36/2015-2020, dated 11th November, 2021

In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy (FTP) 2015-2020, the Director General of Foreign Trade hereby makes amendments in Appendix 1A of FTP -2015-20 by revising the territorial jurisdiction of the following Regional Authorities of DGFT:

S. No. in Appendix 1A	Name of the Regional Authority and address	Existing Territorial Jurisdiction	Revised Territorial Jurisdiction
13.	The Addl. Director of Foreign Trade 11/A Govt. M.S. Building Old City, Lal Darwaja, **Ahmedabad,** Gujarat 380001	Gujarat State excluding the areas which are under the jurisdiction of Regional Authorites, Rajkot, Vadodara, Surat and Development Commissioner KFTZ	Gujarat State excluding the areas which are under the jurisdiction of Rajkot, Vadodara, Surat and Development Commissioner KFTZ. ***[Naysari and Tapi districts have been moved to RA, Surat].***
16.	The Joint Director General of Foreign Trade Resham Bhavan 6th floor, Lal Darwaja Station Rd, Lal Darwaja, Varachha, **Surat**, Gujarat 395008	Districts of Gujarat: (i) Surat (ii) Valsad and (iii) Dangs	Districts of Gujarat: (i) Surat (ii) Valsad (iii) Dangs **(iv) Naysari and** **(v) Tapi**

2. <u>Effect of this Public Notice</u>:

Naysari and Tapi districts of Gujarat have been moved from territorial jurisdiction of RA, Ahmedabad to RA, Surat with immediate effect,

F.No.01/93/180/80/AM-16/PC-2(B)/E-2418

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

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Enlistment of PSIA as per para 2.55 (d) of HBP 2015-2020

DGFT Public Notice No.34/2015-2020, dated 10th November, 2021

In exercise of powers conferred under the paragraph 2.04 of the Foreign Trade Policy 2015¬20, the Director General of Foreign Trade hereby includes the following agency in Appendix 2G of Appendices and Aayat Niryat Forms of Foreign Trade Policy 2015-20 in terms of Para 2.55 (d) of HBP 2015-20 with immediate effect :-

S. No. 1	M/s Hamilton Steel Logistics Inc	Area of Operation	Valid Upto
Address of Head Office	Unit-101, 2-42 Keefer Ct, Hamilton,ON, L8E 4V4, Canada Email: info@hslogistics.ca	Canada	9th August 2024

The above agency is recognized for Pre-Shipment Inspection Certificates as per provision of Para 2.55(e) of HBP, 2015-20 from the date of issue of this Public Notice. Details of approved spectrometers and survey meters for issuance of PSIC by this agency are annexed.

The validity of PSIA may be curtailed at any time by this Directorate, subject to further orders in this regard.

The notified PSIA must ensure to update their membership certificate of MRAI/ISRI/IFIA and their office address and contact details within 30 days.

Effects of this public notice: Additional Agency, i.e., M/s Hamilton Steel Logistics Inc is notified as PSIA.

File No. 01/53/8/AM22/PSIA-1/Import Cell

Amit Yadav, Director General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, New Delhi.

ANNEXURE to the Public Notice

Name of the Applicant	Make	Model	Sr. No.	Date of calibration	Expiration Date of Calibration Certificate	Supporting documents of calibration	Date of Purchase	Copy of invoice attached	Photograph Attached
Hamilton Steel Logistics Inc.	Radiation Survey Meter	Gamma Scout	047665	18.06.2021	17.06.2023	Yes	18.06.2021	Yes	
	RADCOMM	Syclone	50046	26.10.2021	26.10.2022	Yes	10.01.2013	Yes	Yes
	Spectrex	XD 2 EX-DETECT	18787	-	-	Yes	01.06.2015	Yes	Yes

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Extension of Date for Mandatory electronic filing of Non-Preferential Certificate of Origin (CoO) through the Common Digital Platform to 31st Jan 2022 -reg.

Trade Notice No. 24/2021-22, dated 15th November 2021

To,

1. All Exporters/Members of Trade

2. All Agencies listed under Appendix-2E of the FTP.

1. In continuation to the earlier Trade Notice 42/2020-2021 dated 19.02.2021, 48/2020-2021 dated 25.03.2021, 10/2021-2022 dated 19.07.2021, 19/2021-2022 dated 01.10.2021 and 21/2021-22 dated 18.10.2021, it is informed that the electronic platform for Certificate of Origin (CoO) (URL: https://coo.dgft.gov.in) has been expanded to facilitate electronic filing and issuance for Non-Preferential Certificates of Origin. The objective of this platform is to provide an electronic, contact-less single window for the CoO related processes.

2. In this reference, it is informed that the transition period for mandatory filing of applications for Non-Preferential Certificate of Origin through the e-CoO Platform has been extended till **31st January 2022.** The existing systems for submitting and processing non-preferential CoO applications in manual/paper mode is being allowed for the stated time period and the online system is not being made mandatory.

3. All Agencies as notified under Appendix-2E are required to ensure their on-boarding process is completed at the earliest and no later than 31st January 2022. Reference Trade Notice 21/2021-22 dated 18.10.2021, it is submitted that all Agencies notified under Appendix-2E, are required to ensure

that the onboarding exercise is completed latest by 31st January 2022 failing which the agencies shall be de-notified from Appendix 2E.

4. All Exporters concerned are requested to ensure that they are duly registered onto the said platform at the earliest. Any technical/procedural issues may be brought to the attention of the CoO Helpdesk within the time prescribed. For guidance on registration and application submission process, the Help Manual & FAQs may be accessed on the landing page at https://coo.dgft.gov.in . For any further assistance you may utilize any of the following channels —

- Raise a service request ticket through the DGFT Helpdesk service
- Send an email to DGFT CoO Helpdesk at coo-dgft@gov.in
- Call the toll-free DGFT Helpdesk numbers

This issues with the approval of the competent authority.

File No. 01/02/54/AM21/EG&TF

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

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CUSTOMS MATTERS

Rescind Notification No. 34/2016 - Customs (ADD) dated 14th July, 2016 to remove levy of ADD on Medium Density Fiberboard - reg.

Notification No.65/2021-Customs (ADD), dated 11th November 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.34/2016-Customs (ADD) dated the 14th July, 2016 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide G.S.R. number 698(E), dated the 14th July, 2016, except as respect things done or omitted to be done before such rescission.

F.No.190354/81/2021-TRU

J S Kandhari, Deputy Secretary, Department of Revenue, Ministry of Finance, New Delhi.

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Impose ADD on Imports of Untreated Fumed Silica from China PR - reg.

Notification No.66/2021-Customs (ADD), Dated 11th November, 2021

1. Whereas, in the matter of **"Untreated Fumed Silica"** (hereinafter referred to as the subject goods), falling under tariff item 2811 22 00 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 and Korea RP** (hereinafter referred to as the subject countries) and imported into India, the designated authority in its final findings, published in the Gazette of India, Extraordinary, Part I, Section

1, *vide* notification No.6/40/2020-DGTR, dated the 20th September, 2021, 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 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

S.N.	Tariff Item	Description of goods	Country of Origin	Country of Export	Producer	Amount	Unit of measurement	Currency
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1.	28112 200	Untreated fumed silica	China PR	Any country including China PR	M/s Shandong Dongyue Silicone Material Co., Ltd.	1,018	MT	US$
2.	28112 200	Untreated fumed silica	China PR	Any country including China PR	Wacker Chemicals Fumed Silica (Zhangjiagang) Co., Ltd.	NIL	MT	US$
3.	28112 200	Untreated fumed silica	China PR	Any country including China PR	Any producer other than SN 1. and 2.	1,296	MT	US$
4.	28112 200	Untreated fumed silica	Any country other than China PR and Korea RP	China PR	Any	1,296	MT	US$
5.	28112 200	Untreated fumed silica	Korea RP	Any country including Korea RP	OCI Company Limited	NIL	MT	US$

6.	28112 200	Untreated fumed silica	Korea RP	Any country including Korea RP	Any producer other than S.N.5.	373	MT	US$
7.	28112 200	Untreated fumed silica	Any country other than Korea RP and China PR	Korea RP	Any	373	MT	US$

2. The anti-dumping duty imposed under this notification shall be effective 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 paid in Indian currency.

Explanation.- (1) For the purposes of this notification, the rate of exchange applicable for the 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. CBIC-190354/234/2021-TO(TRU-1)-CBEC

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

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Faculty Development Centre Building Inaugurated at ICT

On October 1, 2021 the new Faculty Development Centre (FDC) building was inaugurated by Honourable Governor of Maharashtra, Shri Bhagat Singh Koshiyari.

The FDC was established in November 2018 by the Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology under the Pandit Madan Mohan Malaviya National Mission on Teachers and Teaching. Funded to the tune of Rs. 7.5 crores, the FDC serves as the nodal agency for training pharmacy teachers, being the only one centre in the country dedicated for pharmacy faculty development. Till date, the FDC has trained 275 pharmacy faculty members across Maharashtra and India in Industrial Management, Clinical Data Management and Pharmaceutical Marketing Management.

- Contributed by Prof. Vikas N. Telvekar, Department of Pharmaceutical Sciences and Technology, ICT and Coordinator, PMMMNMTT

Source: UDAAN, October 2021

OPPI - QCI Quality Award for Excellent Facility of the year 2021 - CALL FOR ENTRIES

Greetings from Organisation of Pharmaceutical Producers of India (OPPI).

At the OPPI Annual Summit this year, we are introducing an OPPI quality award for Excellent Facility in collaboration with Quality Council of India (QCI). The OPPI-QCI Quality Award for Excellent facility is being instituted by OPPI to align on the importance of setting and adopting best-in-class global quality standards for the pharmaceutical industry. We believe that it is critical for the industry to provide quality medicines to the millions of patients in the country.

OPPI believes Quality should be embedded at every stage of the medicine-making process and across the pharma value chain. I am writing to you to seek your support, with a special request to circulate this message with the Manufacturing facilities within your network, to encourage participation / applications from them.

About the award:

The Pharmaceutical industry players as well as the regulatory authorities have always focused on Good Manufacturing Practices (GMP). This is indeed a critical element in any industry, more so in the pharmaceutical industry, where Patient Safety is paramount.

OPPI believes that it is imperative for the industry to build a quality culture in the country and provide medicines with global quality standards to the patients. With this award we aim to recognize efforts by manufacturing facilities for implementing best in class quality standards leading to development of quality culture in the Indian pharmaceutical sector.

It is in the said context, we invite nominations/submissions from all the finished dosage formulation facilities catering to Indian market and exports.

The honour will be accompanied by the following benefits:

- The Manufacturing facility and its people will take pride in this first of its kind national recognition conferred upon them for imbibing quality culture in the organization
- Citation on media release, OPPI website & social media handles
- A grant in aid of ₹ 1,00,000/-

For further details on the awards including criteria, jury, registration details, please click here:

http://qualityawards.indiaoppi.com/. Kindly follow instructions on the webpage. A Help Document is available to facilitate the process.

In case of any query, feel free to connect on the following email, contact number or my colleagues marked in the email, and we will revert.

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The last date for receiving completed applications is 15th November 2021.

During the Annual Summit OPPI organizes an award ceremony to recognize the outstanding contribution by various researchers in the field of healthcare. This year also the awards will be presented at the OPPI Annual Summit 2021 being hosted in the presence of Government representatives, health experts, media, and a large number of colleagues from pharmaceuticals, healthcare and allied industries. More information on the OPPI Annual Summit is attached for your reference.

We look forward to your participation and wish each one of you continued success for all the initiatives leading to the amplification of positive message about imbibing quality culture in pharmaceutical industry.

Regards,
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About OPPI

OPPI, established in 1965, represents the research based pharmaceutical companies in India and remains committed to supporting the nation's healthcare objectives sustainable solutions.

OPPI believes Quality should be embedded in every stage of the medicine making process and across the delivery chain, with the necessity for more accessible therapeutics, and disseminating knowledge and sharing best practices across the industry.

For more information, pleaes visit https://www.indiaoppi.com/

About QCI

Quality Council of India (QCI) was established in January, 1997 as a National body for Accreditation, through a Cabinet decision in 1996. QCI was set up through a PPP model as an independent autonomous organization with the support of DPIIT (GoI) as a nodal body and the Indian Industry represented by the three premier industry associations, (i) Associated Chambers of Commerce and Industry of India (ASSOCHAM), (ii) Confederation of Indian Industry (CII) and (iii) Federation of Indian Chambers of Commerce and Industry (FICCI). QCI is a non-profit organization and deals with all matters connected with quality to structure and help implementation of the Cabinet decision.

QCI has been established to create a mechanism for independent third party assessment of product services and processes. It plays a pivotal role at the national level in propagating, adoption and adherence to quality standards in all important spheres of activities including education, healthcare, environment protection, governance, social sectors, infrastructure sector and such other areas of organized activities that have significant bearing in improving the quality of life and wellbeing of the citizens of India.

For more information, please visit https://qcin.org/

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Pharmexcil to explore export promotion opportunities for pharma exporters by holding B2B and BSM meets

S V Veeramani, *Vice-president, Pharmexcil*

As the Covid-19 infections and hospitalisations began to decline globally, the venues for trade fairs and exhibitions have started to reopen. In India, the Pharmaceuticals Export Promotion Council (Pharmexcil), the apex organisation under the aegis of the Ministry of Commerce and Industry to promote exports of pharmaceuticals and neutraceuticals, is pondering over resuming exhibitions, physical B2B and BSM meets between Indian and overseas importers very shortly. Recently, Pharmexcil has elected **S V Veeramani**, the pharma industry stalwart and former president of Indian Drug Manufacturers' Association (IDMA) as the vice-president of the Council. He speaks to **Peethaambaran Kunnathoor** about the future plans of Pharmexcil in exploring export promotion opportunities for pharmaceutical exporters of the country. Excerpts:

What are your plans to generate new export opportunities for small, medium and large scale industry exporters of pharma in India?

Pharmexcil has small, medium and large industry exporters as well as merchant exporters. It will be our endeavour to support all the groups for the benefit of the nation and for the exports. We will showcase the large exporters to the international community in order to build our image and performance, and in the same way we will support the small and medium scale shippers and the merchant exporters by organizing seminars, open-house sessions and buyer-seller meets. Pharmexcil will also help them get their incentives and remove all bottlenecks or procedural hurdles. Besides, we will try to arrange international regulators meetings to discuss on regulatory issues and approvals.

As the vice chairman of the Pharmexcil what steps will you take to speed up reimbursement of product registration fees paid by the exporters?

The Ministry of Commerce has introduced the export promotion scheme, MAI (Market Access Initiative), to promote the country's exports, and the scheme reimburses the expenditure incurred by the exporters. It includes product registration cost and the facility inspection fees and BA/BE study expenses. Recently, the government has reduced the period for submission of applications to Pharmexcil from 90 days to 45 days, which is inadequate. So, Pharmexcil plans to put up one strong representation to the government to restore the 90 days.

It is learnt that there are vacancies of directors inbranch offices of Pharmexcil in Chennai, Bengaluru, Mumbai, Delhi and also headquarters office in Hyderabad. Why the Council is not taking any step to fill up them?

We will be filling up the vacancies of Directors in Mumbai and Delhi branches shortly. As regards Chennai and Bengaluru, they are coordinated by the headquarter office.

What steps will Pharmexcil take to increase exports of Indian made formulations to regulated markets like European Union?

Already Pharmexcil is supporting exports of Indian pharmaceuticals to regulated markets by way of discussing with regulators of the US FDA, UK MHRA and others. Recently, the council has taken initiative for stepping up exports to Japan by holding dialogue with Japan's pharmaceuticals and medical devices regulatory agency, PMDA.

India is manufacturing plenty of vaccines including Covid-19 vaccines, but they are not exported to other countries due to restrictions. Will Pharmexcil take any step for an unrestricted shipment of vaccines from home?

Due to the huge requirements of vaccines in India, we had to restrict exports of vaccines. But, recently the government has announced that they will resume exports of vaccines. Pharmexcil is following-up on the same.

Remdesivir injection is also in the restricted list. According to information from reliable sources, there are huge piles of stocks of remdesivir, but cannot be exported. How can Pharmexcil solve this issue?

There is also a favourable view from the government side to remove restriction on export of remdesivir injection. Some procedural issues are to be sorted out.

Small exporters want export incentives and subsidies from government to improve their overseas business. Do you have any plan to take their issues with the government?

Small exporters are already being provided with incentives under MAI scheme and MDA Scheme. We request the government for continuation of CLCS scheme from MSME Ministry for project funding. Besides, we are moving on with the department of pharmaceuticals (DoP) to speed up announcement of PTUAS scheme for funding assistance for technology upgradation to WHO-GMP standards.

Manufacturers of herbal products and neutraceuticals want to enter into export business. How will Pharmexcil help them?

Pharmexcil is always supportive towards exports of herbal products and neutraceuticals. We are willing to support them as and when needed.

Govt has ideas to boost exports of Ayush products. Does Pharmexcil has any plan to support the initiative of the government?

Yes, Pharmexcil is keen to increase exports of Ayush products. But the Union ministry of Ayush is going ahead with a plan to set up an Ayush Export Promotion Council (AEPC).

From 2020 onwards, due to Covid pandemic there has been no exhibition or trade show of pharma products and machinery. Delegates from other countries are not physically visiting here and no B2B meet is held. Will Pharmexcil organize such shows and trade fairs in the near future?

Due to pandemic no physical meeting was possible, accordingly all physical programmes were cancelled. But, Pharmexcil conducted virtual buyer-seller meetings in the month of February 2021 with Latin America and African countries. Indo-CIS BSMs and Indo-ASEAN BSMs, both virtually, were conducted in the month of March 2021. Now that travel restrictions are getting slowly removed, so we are planning to conduct physical buyer-seller meetings.

Source: Peethaambaran Kunnathoor, Pharmabiz, 10.11.2021

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Indian patent filings grow despite pandemic

Mumbai: India's scorecard showed a decent improvement in intellectual property (IP) filings with higher applications in patents (nearly 6%) and trademarks (over 15%), driven by those filed in the pharmaceuticals sector in 2020. Globally, IP filings — including patents, trademarks and designs — rebounded in 2020, indicating the resilience of human innovation despite dire global and economic turmoil during the Covid pandemic, latest data from World Intellectual Property Organization (WIPO) showed. In contrast, during the global financial crisis of 2008-2009, both patent and trademark filing activity had contracted sharply.

Globally, trademark filing activity rose by 13.7%, patents 1.6% and designs by 2%, according to the World Intellectual Property Indicators report, which compiled new data from 150 national and regional authorities. While China's IP office recorded the highest volume of trademark filing activity, India overtook Japan to become the fifth largest country for trademark filing activity.

The strong growth in global trademark filing activity is driven by robust growth in products and services related to advertising & business management, pharmaceuticals, surgical, medical & dental goods. The share of filings related to pharmaceuticals increased from 4.1% in 2019 to 4.6% in 2020, while that of surgical, medical & dental goods increased from 1.5% to 2.3%, the data said. These trends were mirrored by certain countries that saw large increases of trademark filing activity. For instance, India's 15.4% growth in trademark activity was driven by resident filings in pharmaceuticals.

Further, worldwide patent-filing activity returned to growth in 2020 after the first dip in a decade in 2019, due to a decline in China. In 2020, China's IP office reported growth again with 1.5 million patent applications, followed by the US, Japan, Republic of Korea and the European Patent Office. Together, these five offices accounted for 85.1% of the world total.

Among the top 10 offices, only three — China (6.9%), India (5.9%) and the Republic of Korea (3.6%) — recorded growth in applications in 2020. Germany (62,105), India (56,771) and the Russian Federation (34,984), among others, also featured among the top 10 offices.

Commenting on the particularly strong growth in trademark filings in 2020, WIPO director general Daren Tang said, "This shows how enterprises across the globe have brought new products and services to the market, as reflected by the double-digit growth in trademarks filing activity in 2020 despite the massive economic shock."

Interestingly, IP's centre of gravity has shifted to Asia now with an increasing number of applications from the region, the latest data from WIPO showed. While a decade ago, half of overall 10 IP applications were filed in Asia, last year this number was close to seven.

*Source: **Rupali Mukherjee,TNN, 15.11.2021***

Pharma companies seek govt nod to hike medicine prices

The lobby group asked to allow prices of all scheduled formulations to be increased by 10% with immediate effect. Scheduled drugs are those which are under price control and low priced.

A lobby group that represents over 1,000 Indian pharmaceutical manufacturers has urged the government to allow drugmakers to increase prices of all non-scheduled drugs by 20% as the pharma industry battles rising input costs. At present drugs in non-scheduled are allowed a maximum annual price increase of 10%.

In a representation to health minister Mansukh Mandaviya, Niti Aayog, secretary department of pharmaceuticals, and chairman National Pharmaceutical Pricing Authority (NPPA), the Indian Drugs Manufacturers' Association (IDMA) emphasised on the "serious situation" that has been exacerbated due to the escalation of input costs.

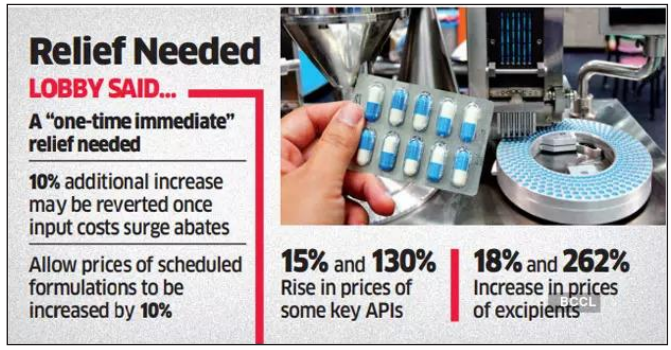
The IDMA said that the increase in input costs has affected all cost heads including key starting materials, packaging materials and transportation costs.

It sought a "one-time immediate" relief to overcome the sudden spurt by invoking special power under para 19 of the Drug Price Control Order (DPCO). Citing extraordinary circumstances, it urged that companies be "permitted to increase the prices of non-scheduled formulations by an additional 10% over the 10% allowed for non-scheduled formulations".

It said that the 10% additional increase may be reversed once the surge in input costs abates.

The lobby group also asked to allow prices of all scheduled formulations to be increased by 10% with immediate effect. Scheduled drugs are those which are under price control and low priced.

"Please allow scheduled formulations whose retail prices are below the ceiling price, to be raised up to



the new proposed ceiling price which includes the 10% wholesale price index (WPI) increase. Many manufacturers of scheduled formulations have been suffering on this count," it said in the representation.

ET has seen a copy of the representation.

According to the IDMA prices of some key APIs have increased between 15% and 130% with the price of paracetamol jumping 130%. Likewise, prices of excipients have risen between 18%-262%. The prices of glycerin and propylene glycol, solvents used in every liquid preparation including syrups, oral drops and sterile preparations have skyrocketed by 263% and 83%, respectively.

The IDMA said that the prices of intermediates have registered an increase between 11% and 175% with pencillin G registering a 175% jump.

The IDMA said increasing prices could lead to stockouts and sought urgent intervention of the government.

"We fear that the severe pressure on operating margins could lead to stockouts and shortages even for essential formulations in trade, hospitals and for government institutional supplies," it said.

Source: Economic Times, 13.11.2021

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Optimising costs to beat price erosion in US market: Alembic Pharmaceuticals

Synopsis

In an interview to ET, Pranav Amin, Managing Director of Alembic Pharmaceuticals said the management still remains bullish on the US market, to beat pricing erosion - the company is planning to launch at least 15 products and also working on cost optimisation.

The company said none of the observations are related to data integrity and are addressable, but the observations may delay commercialisation of the products.

Alembic Pharmaceuticals said it expects to launch 15 products by the end of this year in the US market, as it struggles to offset the pricing pressure.

The Vadodara-based drug maker, which has been around for over a century, has seen astounding growth in the US market in the last couple of years primarily driven by sales of sartans - a class of drugs used in the treatment of blood pressure and heart failure.

Alembic took full benefit of supply shortages of sartans in the US market, as most other competitors had to recall products due to impurity and compliance issues.

But with competitors addressing the impurity issues and re-entering the market, Alembic now is facing steep price erosion. The US business that contributed 40% of revenues, fell by 40% during the first half of FY22, which led to steep drop in EBITDA margins. The company's EBITDA margin in Q2FY22 dropped by 1050 basis points to 19.9%. Alembic revenues stood at Rs 5,393 crores in FY21.

In an interview to ET, Pranav Amin, Managing Director of Alembic Pharmaceuticals said the management still remains bullish on the US market, to beat pricing erosion - the company is planning to launch at least 15 products and also working on cost optimisation.

"There is currently oversupply and extra competition in the market, leading to downward trend in prices," Amin said. "This should be the bottom of the market, and will see opportunities going forward," Amin said. He cautioned that the competition is likely to continue in the market for another 6-12 months.

Post sartans

Alembic is investing heavily on R&D. The company is spending 10-12% of revenues on R&D, which is higher than industry, to develop a pipeline of complex products. While investing in R&D, it has also undertaken capex of Rs 2000 crore, to build three new factories to make oncology oral solids and injectables, general injectables, ophthalmic and oral solids, Amin said much of the capex has been completed, and the focus now would be on execution of the pipeline.

The company has already filed for three products from its general injectable site from unit F-3 in Karkhadi, Gujarat. The facility, which was inspected by USFDA October 28 to November 10, received 10 observations.

The company said none of the observations are related to data integrity and are addressable, but the observations may delay commercialisation of the products.

Amin said the company is also planning to file a product from an oncology injectable facility, which is going to trigger USFDA inspection.

Alembic is eyeing sales of $400 million-$500 million in the US market by FY24, which will be more than double the current figure.

Amin said despite the slowdown of US business, he said India formulation business is going to help the company by outperforming market growth rate.

Source: Viswanath Pilla, ET Bureau, 11.11.2021

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India looking at reciprocal, equitable access to foreign mkts through FTAs: Piyush Goyal

New Delhi: India is looking at reciprocal and equitable access to foreign markets through free trade agreements, which the country is negotiating with its trading partners, Commerce and Industry Minister Piyush Goyal said on Thursday. India is, at present, negotiating free trade agreements (FTAs) with countries like UAE, the UK, and Australia. Under a free trade agreement, two trading partners reduce or eliminate customs duties on the maximum number of goods traded between them. Besides, they liberalise norms to enhance trade in services and boost investments.

"Through the FTAs, we are looking at reciprocal and equitable access to foreign markets. FTA is a win-win for both countries. If it is an unequal balance, FTA can never be successful," Goyal said at Times Now Summit 2021.

He said that a few old FTAs of India which were not balanced have led to an increase in trade deficit with those nations.

"We are now going through careful stakeholder engagement (to negotiate an FTA) and making sure that our MSMEs, dairy industry, farmers, and domestic production capacities get more opportunities. Our employment-oriented sectors like textiles, footwear, and pharma get good market access," he added. In such pacts, the government is also ensuring that services sector professionals too get good opportunities in the foreign markets through two way communication with Indian stakeholders, Goyal noted.

Source: Millennium Post, 12.11.2021

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Govt to go by expert advice on vaccination for children

Synopsis

India has given emergency use approval to Zydus Cadila's ZyCoV-D vaccine which can be administered on individuals above 12 years.

The Centre will take a cautious approach and go by expert advice before introducing Covid-19 vaccination for children or a booster dose for fully vaccinated adults, health minister Mansukh Mandaviya said.

Speaking at the Times Now Summit, Mandaviya said: "This decision (introduction of vaccine for children) needs to be taken very cautiously. Children are the future of our country. The government will take expert opinion and go by it."

India has given emergency use approval to Zydus Cadila's ZyCoV-D vaccine which can be administered on individuals above 12 years. The Subject Expert Committee under the drug regulator has also given emergency use approval to Covaxin for paediatric use in children two years and above. While the government has placed an order for 10 million doses of ZyCoV-D, paediatric use of Covaxin is being further examined by the Drugs Control General of India.

The government is also facing the question of whether to administer booster doses to healthcare workers - the first priority group which was administered the vaccine over 10 months back in January. Mandaviya said: "It is natural to ask this question. But our main priority is to first complete full vaccination of all adults in India and then we will come to this question. We will go by what the expert opinion is. It is a highly technical matter, and it is not appropriate for the government to take a call without consulting subject experts."

The health minister said the vicious second wave of Covid-19 has shown the requirements of health infrastructure in India. "The second wave has shown us what we need for the next 50 years in heath infrastructure. This is why we have launched the Pradhan Mantri Ayushman Bharat Health Infrastructure Mission. We will spend Rs 65,000 crore over the next five years to develop infrastructure down to the village and district level," said the minister.

Source: ET Bureau, 12.11.2021

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Analysis: COVID-19 pills are coming, but no substitute for vaccines, disease experts say

Oral antiviral pills from Merck & Co (MRK.N) and Pfizer Inc (PFE.N) have been shown to significantly blunt the worst outcomes of COVID-19 if taken early enough, but doctors warn vaccine hesitant people not to confuse the benefit of the treatments with prevention afforded by vaccines.

While 72% of American adults have gotten a first shot of the vaccine, according to a Kaiser Family Foundation poll, the pace of vaccination has slowed, as political partisanship in the United States divides views on the value and safety of vaccines against the coronavirus.

Vaccine mandates by employers, states and the administration of U.S. President Joe Biden have helped increase vaccinations but also fueled that controversy.

Some disease experts fear the arrival of oral COVID-19 treatments may further impede vaccination campaigns. Preliminary results of a survey of 3,000 U.S. citizens by the City University of New York (CUNY) School of Public Health suggest the drugs could "hamper the effort to get people vaccinated," said Scott Ratzan, an expert in health communication at CUNY, who led the research.

Ratzan said one out of every eight of those surveyed said they would rather get treated with a pill than be vaccinated. "That is a high number," Ratzan said.

The concern follows news on Friday from Pfizer, maker of a leading COVID-19 vaccine, that its experimental antiviral pill Paxlovid cut the risk of hospitalization and death from the disease by 89% in high-risk adults.

Pfizer's results followed news from Merck and partner Ridgeback Biotherapeutics on Oct. 1 that their oral antiviral drug cut hospitalization and death by half. That drug, known as molnupiravir, won conditional approval in the UK on Thursday. Both need clearance from U.S. health regulators but could be on the market in December.

"By relying exclusively on an antiviral drug, it's a bit of a roll of the dice in terms of how you will do. Clearly, it's going to be better than nothing, but it's a high-stakes game to play," said Dr. Peter Hotez, a vaccine expert and professor of molecular virology and microbiology at Baylor College of Medicine.

Six infectious disease experts interviewed by Reuters were equally enthusiastic about the prospect of effective new treatments for COVID-19 and agreed they were no substitute for vaccines.

Even in the face of the highly transmissible Delta variant of the virus, the vaccines from Pfizer/BioNTech remain effective, cutting the risk of hospitalization by a combined 86.8%, according to a government study of U.S. veterans.

They said some unvaccinated people have already relied on monoclonal antibodies - drugs that need to be delivered through intravenous IV infusions or injections - as a backstop in case they become infected.

"I think the Pfizer news is terrific news. It goes hand in hand with vaccination. It doesn't replace it," said Dr. Leana Wen, an emergency physician and public health professor at George Washington University and Baltimore's former health commissioner.

Choosing not to get vaccinated "would be a tragic mistake," said Albert Bourla, chief executive officer of Pfizer Inc. "These are treatments. This is for the unfortunate who will get sick," Bourla told Reuters in an interview on Friday. "This should not be a reason not to protect yourself and to put yourself, your household and society in danger."

Antiviral Challenges

One main reason not to rely on the new pills, the experts said, is that antiviral medications, which stop the virus from replicating in the body, must be given in a narrow window early in the disease because COVID-19 has different phases.

In the first phase, the virus rapidly replicates in the body. A lot of the worst effects of COVID-19, however, occur in the second phase, arising from a defective immune response that gets triggered by the replicating virus, said Dr. Celine Gounder, an infectious disease expert and the CEO and founder of Just Human Productions, a non-profit multimedia organization.

"Once you develop shortness of breath or other symptoms that would lead you to be hospitalized, you are in that dysfunctional immune phase where the antivirals are really not going to provide much benefit," she said.

Hotez agreed. He said getting treated early enough could be challenging because the window when the virus transitions from the replication phase to the inflammatory phase is fluid.

"For some people, that will happen earlier; for some, later," Hotez said.

Hotez said many people in the early phase of the illness feel surprisingly well and may be unaware that their oxygen levels are dropping, one of the first signs that the inflammatory phase of the disease has started.

"Often times, you're not going to realize that you're getting sick until it's too late," he said.

Reporting by Julie Steenhuysen; Additional reporting by Josephine Mason in London, Deena Beasley in Los Angeles

and Manojna Maddipatla in Bengaluru; editing by Caroline Humer and Grant McCool

Source: Reuters, 09.11.2021

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Covid-19 vaccine bill likely to shoot up to ₹50,000 crore

The changed procurement plan has reset the budget; FinMin to seek more funds in Winter Session

The Centre's spending on the Covid-19 vaccination programme is expected to touch ₹50,000 crore this fiscal year. The government had made a provision for ₹35,000 crore in the Budget.

"We expect the overall expenditure to be in the range of ₹45,000-50,000 crore," a top Finance Ministry official told BusinessLine, adding that much of this amount has already been spent. Further, the official said that for anything above the budgeted ₹35,000 crore, Parliament's nod would be sought in the Winter Session, commencing from November 29.

The additional expenditure can be met through savings or from fresh allocation. The actual picture, however, will become clear when the supplementary demand for grants is presented by the Finance Ministry. While presenting the Budget, Finance Minister Nirmala Sitharaman had said the government was committed to providing more funds if required.

The official said that initially, vaccines were procured by the Centre at ₹150 a jab. However, with the change in the procurement system, the price had increased to ₹200-220 a jab. The government is also hoping the Biological-E vaccine would bring down the overall bill.

Bio-E, ZyCoV-D jabs

"We estimate the price of this vaccine to be under ₹150 a jab," the official added. The government has already reserved 30-crore doses of the Biological-E vaccine, which is still going through clinical trials.

The government is also buying ZyCoV-D vaccine which costs about ₹358 for a dose and entails three doses. The Centre is buying one crore doses that will set it back a little above ₹358 crore. The government launched the vaccination programme on January 16. From then on till April end, the programme ran mainly under the supervision of the Centre.

However, from May 1, States were allowed to procure 25 per cent of the vaccines and the remaining 25 per cent by private hospitals. On June 7, Prime Minister Narendra Modi announced that from June 21, the Centre would provide free vaccines to the States for all citizens above 18.

"The Government will buy 75 per cent of the total vaccine production from vaccine manufacturers and give it to the State governments free," he had said. The remaining 25 per cent was to be procured by private hospitals.

Approved vaccines

As on date, the approved vaccines include Covishield, Covaxin, Sputnik V, ZyCoV-D, and that of Johnson & Johnson, and Moderna. Of these, the first three are in use while for the rest, various processes are on including discussions on indemnity. The official reiterated that the Moderna and Pfizer vaccines may not be used.

It is believed that for Pfizer, very different logistics are needed as this vaccine needs to be stored at -20 degree Celsius. This may not be possible in the public healthcare system. The supply of the Moderna vaccine would be very small, the official said. Prices of these two are reportedly high, but no use will mean no impact on the overall expenditure. With no breakthrough in the indemnity , the official indicated that J&J vaccine could be used only for exports.

As on date, the approved vaccines include Covishield, Covaxin, Sputnik V and ZyCoV-D besides those of J&J and Moderna

Source: Shishir Sinha, The Hindu Business Line, 10.11. 2021

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India has vaccine certificate pact with 96 countries: Government

NEW DELHI: In a big boost to international travel, 96 countries — including US, UK, many European and Middle East nations — have agreed to mutual recognition of Covid-19 vaccination certificates with India, health minister Mansukh Mandaviya said on Tuesday. The government continues to be in communication

with more countries so that beneficiaries of the world's "largest Covid vaccination programme are accepted and recognised", thereby easing travel for education, business and tourism purposes, Mandaviya said in a statement.

INDIA CASES: RATE OF DECLINE SLOWS

For 2nd Day, Daily Cases Nearly Equal To Corresponding Day Last Wk

Worst five states in Covid cases

Name of State/UT	New cases confirmed on Tuesday	Deaths on Tuesday
Kerala	6,409	47
Maharashtra	982	27
Tamil Nadu	835	12
Bengal	788	12
Mizoram	730	1
Others	1,870	21

	India Cases	India Deaths
Tuesday	11,614	120
Monday	9,589	150
Last Tuesday	11,969	166

The move will ease travel for those vaccinated with Indian-manufactured Covishield and Covaxin. The countries include Canada, Turkey and Australia as well. Canada has sought an application from Covaxin to approve it, even as WHO's emergency use approval has boosted the vaccine's international acceptability.

"At present, 96 countries have agreed to mutual recognition of vaccination certificates and also those [countries] who recognise Indian vaccination certificates of travellers fully vaccinated with Covishield/WHO approved/ nationally approved Covid vaccines," the government statement said.

Consecutively, persons travelling from these countries are provided certain relaxations as enunciated in the health ministry's guidelines on international arrivals issued on October 20, 2021, the ministry said. For those who wish to travel abroad, the international travel vaccination certificate can also be downloaded from the CoWIN portal.

France, Germany, Belgium, Ireland, Netherlands, Spain, Philippines, Bangladesh, Mali, Ghana, Sierra Leone, Angola, Nigeria, Benin, Chad, Hungary, Serbia, Poland, Slovak Republic, Slovenia, Croatia, Bulgaria, Greece, Finland, Estonia, Romania, Moldova, Albania, Czech Republic, Switzerland, Liechtenstein, Sweden, Austria, Montenegro, and Iceland are some of the countries on the list.

Rwanda, Zimbabwe, Uganda, Malawi, Botswana, Namibia, Kyrgyz Republic, Belarus, Armenia, Ukraine, Azerbaijan, Kazakhstan, Russia, Georgia, Andorra, Kuwait, Oman, the UAE, Bahrain, Qatar, Maldives, Comoros, Sri Lanka, Mauritius, Peru, Jamaica, the Bahamas, and Brazil have also agreed to mutual recognition of Covid-19 vaccination certificates with India.

"The ministry of health along with the ministry of external affairs is in continuous communication with all countries for mutual recognition of vaccine certificates, and WHO and nationally approved vaccines to facilitate hassle-free international travel across countries," the minister said.

"The Union government's commitment to accelerate the pace and expanding the scope of Covid-19 vaccination throughout the country has resulted in crossing the 100 crore milestone in administration of doses on October 21, 2021," he stated. A total of 109.63 crore doses of Covid vaccine had been given in the country till 7.30pm on Tuesday.

Source: TNN , 10.11.2021

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6 months post second dose ideal for booster: Bharat Biotech's Krishna Ella

The ideal time for a booster dose for COVID-19 vaccine is six months after the second dose, Bharat Biotech Chairman and Managing Director Krishna Ella said on Wednesday, and also emphasised the importance of having a nasal vaccine.

He also pointed out that his company was the first in the world to develop a Zika vaccine.

Krishna Ella, Chairman & MD, Bharat Biotech

Taking the Covaxin vaccine by the Prime Minister Narendra Modi showed confidence in Indian Science, he said at the Times Now Summit 2021.

"The ideal time for a booster dose is six months after the second dose," Ella stated.

Bharat Biotech is also looking at nasal vaccine as a booster dose as its scaling up capacity is very easy when compared with Covaxin, he added.

About the importance of nasal vaccine, he said the entire world is looking at nasal vaccines. That is the only way to stop transmission. Everyone is trying to figure out

the immunology and fortunately, Bharat Biotech has figured it out.

"We are coming out with a nasal vaccine, we are thinking that Covaxin can be given as first dose, the second dose can be given a nasal, that is also strategically, scientifically very important because with the second dose, if it is a nasal one, you stop the transmission of the virus...," Ella said.

Nasal vaccine works well if someone has been infected or if someone has been vaccinated with one dose, he added.

About the PM taking the Covaxin shot, he said, "What would a scientist like to have? A country head taking his vaccine. That is the best satisfaction a scientist can get... It shows confidence in the Indian science, confidence in the startup, and confidence in our innovation...".

Speaking about a vaccine for Zika, Ella said Bharat Biotech is ready with a vaccine for Zika virus. Phase I is complete. The government has to take up more trials because there are more cases now.

"We were the first company in the world to develop the Zika vaccine in 2014... We were the first one to file for a global patent for Zika vaccine", he added.

Vietnam gives nod to Covaxin

Vietnam has approved Covaxin vaccine for emergency use, the ninth to be endorsed in the country, the country's health ministry said on Wednesday. The government said in July it was seeking to secure 15 million doses of the Covaxin vaccine made by Bharat Biotech.

Source: Business Standard, 11.11.2021

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'India to resume vaccine export in Jan'

'We are expecting to complete the vaccination programme of adults by Jan'

India will resume the export of Covid vaccines in January, a top Health Ministry source told *BusinessLine*. This is in line with the country's commitment to supply 500 crore doses to countries under GAVI and WHO-led Covax alliance.

The government had, in April this year, decided to prioritise and focus on immunising its own population

first. Last month, the Centre supplied 40 lakh Covid doses to Bhutan, Bangladesh, Nepal and Iran. But even this was stopped and the Centre decided to continue the curbs on exports till the time the whole population gets fully inoculated.

We are expecting to complete the vaccination programme of all adults by January. Until then, we have put a halt to export of Covid vaccines.

"PM Modi has committed to export 500 crore to GAVI, and for that we have a period of one year. So, our priority is to inoculate Indians first and then export vaccines to other countries," a top official told *BusinessLine*.

So far, 79 per cent of the eligible population has received their first dose and 38 per cent the second shot. There are 93 crore adults in the country over 18 years of age, as per the Health Ministry officials.

Free-of-cost channel

More than 124 crore Covid vaccine doses have so far been provided to the States and Union territories through the Government of India's free-of-cost channel and under the direct State procurement category, said the Health Ministry on Sunday. More than 18.74 crore Covid vaccine doses are still available with the States to be administered, it added.

India has the capacity to produce over 500 crore doses of Covid vaccines by the end of next year, said the PM during the G-20 summit in Rome on October 30. At present, the government uses three vaccines in the vaccination programme – Bharat Biotech's Covaxin, Serum Institute of India's Covishield and Russian vaccine Sputnik V.

Source: Monika Yadav, Business Line, 15.11.2021

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'New vax manufacturing capacities could be of little use'

HYDERABAD: With the past one and a half years seeing the creation of massive manufacturing capacities in India to churn out millions of doses of Covid-19 vaccines, what happens once the pandemic is over?

Some feel that these new capacities created to fight the dreaded SARS-CoV-2 virus could help the world be better prepared to tackle any future pandemics, especially when it comes to mRNA vaccine technology where players like Biological E and Bharat Biotech are injecting investments.

"Our mRNA (investment) is in early stages but the technology platform can be utilised not just for Covid-19 but also for other infectious diseases and immunotherapeutics in the future," said Mahima Datla, managing director, Biological E Ltd.

However, there are others who feel that much of new capacities could end up being a dud investment, especially for the pharma players that jumped into vaccine bandwagon to cash in on the Covid-19 rush.

Here, vaccine industry experts pointed to the integrated vaccine complex set up by state-run HLL Biotech Ltd (HBL) at Chengalpattu on Chennai's outskirts nearly nine years ago that has not produced a single vaccine and has been lying idle even through the Covid-19 pandemic when capacity shortages were hampering the government's vaccination drive.

"Those who got into the vaccine business from the Covid point of view will find it difficult to sustain as they don't have any other vaccine," said Bharat Biotech chairman and managing director Dr Krishna Ella.

"We will also have excess capacities (Covid-19) everywhere but we are not relying on Covid vaccines (for revenue). We have children's vaccines for sustainable revenues. So whatever (revenues) comes with Covid is just a bonus," Ella added.

Agreeing, Indian Immunologicals Ltd managing director Dr K Anand Kumar pointed out that while existing vaccine manufacturers will find some way to use excess capacities either through expansion or for new vaccines in their pipeline, but for the new players it may turn out to be a waste as vaccine manufacturing is not their core competency.

The top honcho of another vaccine company pointed out that many of the new entrants, who have bought a lot of raw material like filters, media for growing virus and other plastic consummables, may have to end up selling them to existing vaccine manufacturers as they don't have any vaccine pipeline.

However, Ella felt that overcapacity would be unsustainable and could even be dangerous. "This problem (Covid) whenever it is gone all these capacities are going to be idle. There is no way of replacing it with another product and that could be downright dangerous."

He cited the example of China where excess capacities in the 1990s in government-run vaccine facilities in various provinces proved to be unsustainable and led to their merger into China National Pharmaceutical Group Corporation (CNPGC) or Sinopharm as it is more commonly referred to today.

Bulk Drugs Manufacturers' Association (BDMA) national president (emeritus) M Narayan Reddy said it was too early yet to say how long the capacities created for Covid-19 would be utilised as there was no clarity on whether it would require an annual booster or not. Reddy's company Virchow Biotech is one of the manufacturers of Russian vaccine Sputnik V in India.

Source: TNN, 19.11.2021

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IPC adds new impurities and Reference Standards: Download the list

List of Indian Pharmacopoeial Reference Standards	List of Impurities
Amphotericin B New	Will be lauched Soon
L-Histidine New	Will be lauched Soon
L-Isoleucine New	Will be lauched Soon
L-Phenylalanine New	Will be lauched Soon
L-Leucine New	Will be lauched Soon

Luliconazole New	Will be lauched Soon
Citicoline sodium New	Citicoline Impurity B New
Benzhexol Hydrochloride	3-Piperidylpropiophenone HCl New
Betaxolol Hydrochloride	Betaxolol Impurity A New
Bezafibrate	Bezafibrate Impurity A New
Bisacodyly	Bisacodyl Impurity E New
Carbimazole	Carbimazole Impurity A New
Clobetasol Propionate	Clobetasol Impurity J New
Desoxycortone Acetate	Desoxycortone Acetate Impurity (Betamethasone-17-Valerate) New
Dipivefrine Hydrochloride	Dipivefrine Impurity B New
Fusidic Acid	3-Ketofusidic Acid New
Homatropine Hydrobromide	Homatropin Hydrobromide Impurity C New
Homatropine Hydrobromide	Homatropin Impurity B New
Leflunomide	Leflunomide Impurity C New
Levodropropizine	Levodropropizine Impurity B New
Meloxicam	Meloxicam Impurity A New
Methotrexate	Methotrexate Impurity C New
Paroxetine	Paroxetine Impurity A New
Procaine Penicillin	Benzyl Penicillin Potassium New
Repaglinide	Repaglinide Impurity A New
Rivastigmine	Rivastigmine related compound A New
Simvastatin	Simvastatin Impurity B New
Thiamine Hydrochloride	Thiamine Impurity C New
Tolbutamide	Tolbutamide Impurity A New

Impurity standards are used to perform the system suitability, qualitative and quantitative parameters for compliance to Indian Pharmacopoeia monograph.

The commission stated that certain monographs require the use of a chemical reference substance or a biological reference preparation or a reference spectrum. These are authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the pharmacopoeia and are not necessarily suitable in other circumstances. IP reference substances, abbreviated to IPRS are the official standards issued by the IPC. They are the official standards to be used in cases of arbitration.

The vision of IPC is to promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacture and analysis

IPC is an autonomous institution of the ministry of health and family welfare, Government of India.

IPC is created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. The mandate of the commission is to perform, inter-alia, functions such as revision and publication of the Indian Pharmacopoeia and National Formulary of India on a regular basis besides providing IP reference substances and training to the stakeholders on pharmacopoeial issues.

Source: The Healthmaster, 15.11.2021

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Biden nominates Califf as FDA commissioner

After months of speculation – and just days before a statutory deadline – President Joe Biden on Friday announced he would nominate Robert Califf to serve as Commissioner of Food and Drugs for the second time.

"I am confident Dr. Califf will ensure that the FDA continues its science and data driven decision-making. Dr. Califf had strong bipartisan support in the Senate in 2016, and I urge the Senate to swiftly confirm Dr. Califf so he can continue the important work being done at this critical moment," Biden said in a statement.

Califf, who previously headed the US Food and Drug Administration (FDA) from February 2016 to January 2017, is a renowned clinical trialist and a founding director of

the Duke Clinical Research Institute. Since leaving the FDA in 2017, Califf has served as a senior adviser to Alphabet's life sciences arm Verily and has continued teaching, research and clinical duties at Duke University School of Medicine.

The long path Biden took to nominating a permanent commissioner to helm the FDA struck many as a curious move at a time when the agency has had a highly visible role at the forefront of the nation's public health response to the COVID-19 pandemic.

However, many observers' concerns were allayed by Biden's choice of veteran regulator Janet Woodcock to serve as acting commissioner. Woodcock first joined FDA in 1986 and has twice served as director of the Center for Drug Evaluation and Research (CDER), most recently from 2007 to 2020, before stepping away from that role to assist on Operation Warp Speed. Under federal law, Woodcock may only serve in her acting role until 15 November 2021, unless a permanent commissioner is nominated.

Woodcock herself, along with several other prominent public health figures, was vetted for the commissioner job over the last nine months, though opposition from within the Democratic party helped squelch her nomination. One of the leading voices against Woodcock was Senator Joe Manchin (D-WV), who opposed her nomination and continued role as acting commissioner largely due to Woodcock's tenure at CDER through a period when many new opioids, including abuse-prone long-lasting formulations, were approved.

At a press briefing on Friday, White House Press Secretary Jen Psaki said the administration is confident Califf can be confirmed and that the President selected Califf because "he's one of the most experienced clinical trialists in the country, [and he] has the experience and expertise to lead the Food and Drug Administration during a critical time in our nation's fight to put an end to the coronavirus pandemic."

While some Democratic senators, including Manchin and Richard Blumenthal (D-CT) have voiced opposition to Califf, their opposition is not expected to derail his confirmation. Both senators voted against Califf's nomination in 2016, though the Duke researcher and cardiologist enjoyed broad support from Republicans and sailed to confirmation with an 89-to-4 vote. This time around, Califf's detractors are likely to point to his extensive ties to the pharmaceutical and tech industries as reasons for opposing his nomination. (RELATED: Senate Confirms Califf as Next FDA Commissioner, Regulatory Focus 24 February 2016; President Obama Nominates Califf as Next FDA Commissioner, Regulatory Focus 15 September 2015)

Califf received numerous endorsements from industry and other health groups upon news of his nomination today.

"Congratulations to Dr. Robert Califf for being nominated as the next commissioner of the U.S. Food and Drug Administration. It's vital that we have a commissioner who understands the important role the FDA plays in promoting public health and providing science-based oversight of our nation's medicine supply. We hope the confirmation process will proceed quickly, and we look forward to continuing to work with the FDA as we fight the pandemic and other deadly diseases," said PhRMA CEO Stephen Ubl. Other backers of the newly named nominee include Research!America, the Consumer Healthcare Products Association (CHPA) and the Friends of Cancer Research. Steven Grossman, executive director of the Alliance for a Stronger FDA, told Focus he expects Califf will enter the agency with a more pronounced mandate this time around and "act more resolutely" as a commissioner in the first year of a presidency, compared to his previous stint as commissioner in the final year of the Obama administration.

"I believe Dr. Califf's priorities will have a common theme: FDA modernization. To achieve the greatest benefit for the American people, FDA needs the resources and tools to address acceleration of medical progress and the potential for a dramatically safer food supply. He will, I predict, advocate for data and technology modernization, improved means of recruiting and retaining FDA employees, facilities upgrades, and the means to make the agency's processes more efficient, accurate, and responsive," Grossman said.

During his last turn as FDA commissioner, some of Califf's top priorities were to reform the clinical trials system and to find ways to better leverage real world evidence. (RELATED: Califf Vows Not to Lower or Remove FDA Regulations, Regulatory Focus 11 January 2016; Califf: Leveraging Real World Evidence is 'Top Programmatic Priority' for FDA, Regulatory Focus 11 May 2016).

Source: Michael Mezher, RAPS, 12.11.2021

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