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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

No Spot Registration

IDMA 60TH YEAR CELEBRATIONS 2022

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

(Details on Pages: 4)

Register Now

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
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Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 52 **Issue No. 45** **01 to 07 December 2021**

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

1961 – 2021 (60 Glorious Years)

102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli,
Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

No Spot Registration

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022

Hotel Sahara Star, Mumbai

Register Now

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 Chief Mentor 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.

ADVERTISEMENT RATES			
SR. NO.	**PARTICULARS**	**RATE PER ADVERTISEMENT (RS.)**	**ADVERTISEMENT PAGE SIZE**
1.	Double Spread	1,00,000	32 cm (width) x 19 cm (height)
2.	Special Bookmark	1,00,000	2"X7"
3.	Full Page (Colour)	50,000	14 cm (width) x 19 cm (height)
4.	Full Page (Black & White)	30,000	14 cm (width) x 19 cm (height)

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	Ms. Parivaz
9821868758	9820161419	9920045226	9930081477
actadm@idmaindia.com	publications@idmaindia.com	technical@idmaindia.com	idma2@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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Tel: +91-22-24944624/24974308 Fax: +91-22-24950723
Email : actadm@idmaindia.com / technical@idmaindia.com / Web: www.idma-assn.org

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.**

==========

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.

IDMA Corporate Citizen Awards 2021

ATTENTION MEMBERS

Dear Members,

We are pleased to announce the **IDMA Corporate Citizen Awards** this year!

We invite all IDMA members looking to honour initiatives undertaken by organizations on the social and community front. It is not restricted to CSR activities/initiatives mandated by law to participate!

Salient Features of IDMA Corporate Citizen Awards 2021

1. Knowledge Partners: KPMG Assurance and Consulting Services LLP
2. Awards in 2 categories: Members with (i) turnover of Rs 500 crores & above and (ii) turnover below 500 crores in last Financial Year
3. Organization that nominates project for their exemplary work during the Covid-19 Pandemic will be given due consideration.
4. Eligible entries will be evaluated by an independent panel of honorary jury members.
5. Awards function will be a part of the **IDMA's prestigious 60th Year Celebrations on Friday, 7th & Saturday, 8th January 2022 at Hotel Sahara Star, Near Domestic Airport, Vile Parle (East), Mumbai**

For detailed Terms & Conditions please refer to the attached 'IDMA Corporate Citizen Awards 2021-TOR'. Entry Form is also attached for your early action. Please fill this up and send it to csr@idmaindia.com latest by **15th December 2021.**

For any queries, please feel free to connect with
Mr. Melvin (9821868758 / actadm@idmaindia.com) /
Ms. Batul (9920045226 / technical@idmaindia.com)

Looking forward to your prompt positive response.

With Best Wishes,

Daara B. Patel
Secretary-General

IDMA Corporate Citizen Award 2021 – Rules and regulations

Definitions

- **Awards management:** Indian Drug Manufacturers' Association (IDMA)
- **Awards:**IDMA Corporate Citizen Award- 2021 for recognizing initiatives done by an IDMA member firm in the area of philanthropy/social service/social welfare
- **Participant/ Nominee:** An IDMA member firm sending in their entry
- **Terms and conditions:** The terms and conditions governing the Awards
- **Knowledge Partners:** KPMG Assurance and Consulting Services LLP
- **Nominee/ Winner:** Award as decided by Jury

- **Jury:** Group of honorable individuals who will evaluate the entries and select final winners.

Timelines

The timelines for the awards are as follows:

- **Call for entries start date: November 25, 2021**
- **Last date for receiving entries: December 15, 2021**
- **Awards Function: January 7th & 8th, 2022**

Eligibility criteria

Only those meeting the following criteria may be eligible to be nominated.

- Applicant should be a member of IDMA
- Nominated initiative should have been implemented within India and benefitting citizens of India
- The nominated project may or may not be part of a regular CSR project
- The nominated project should not be part of the normal business
- Please note that project won in the last 2 editions of the Awards are not eligible for participation. However, the winning participants are eligible to enter a different project/ initiative for the Awards.
- **Organization that nominates project for their exemplary work during the Covid-19 Pandemic will be given due consideration**

Award categories

Category 1 Award - an applicant having a turnover of INR 500 crores & above in last FY

Category 2 Award - an applicant having a turnover below INR 500 crores in last FY

Winner determination

- The entries that are eligible will be evaluated by an independent panel of honorary jury members.
- The entry chosen as winner by the jury will be final and binding, and cannot be challenged by any organization/individual.
- Entries will be received on the specified email id by the Awards Management Team;
- Entries will be shortlisted based on eligibility criteria;
- Jury will select the winners in each category based on predetermined judging parameters by scoring the entries;
- In case of a tie, more than 1 (one) winner will be declared.

Completeness of entries/ disqualification

- Ownership and integrity of information provided in the application solely rests with the applicant. All mandatory fields in the application form need to be filled in all respects; else it will be disqualified from participation;
- Entries will be accepted in English language only;
- Disqualification of any entries is at the sole discretion of the Jury/ Awards Management;
- If at any time, during the Awards process or post the Awards ceremony any information provided by any Participant is found to be incorrect in any manner, then the Participant will be either disqualified from participation or liable to return the Award, if won.
- All entries are subject to verification, including without limitation, verification of eligibility through checks as deemed appropriate by the Awards Management and complete compliance with these Terms and Conditions. Awards Management has the sole right to disqualify any entry if it is not in compliance with the Terms and Conditions herein specified or any further applicable laws, regulation/ or any policies that may be specified by the Awards Management.

Award

- In case an Award is unclaimed by the winner due to any reason the same will result in forfeiture of the Award by such Winner and IDMA shall not entertain any claims in this regard thereafter.
- Award is not transferable or assignable and shall not be assigned to any other person/ organization. There is no cash substitution, cash redemption or cash value in lieu of the respective Award.

Additional Information

- Participants may be contacted for any additional information to verify the information provided.

Such additional information sourced from the Participant(s) will become part of the original application;

- Awards Management has the right to ask for documentary proof of information / audited financial data / review the information provided. If such a request is made and the Participant does not comply with it promptly; the Participant may be disqualified from participation in the Awards;
- Information provided by the Participant will be used only for the limited purpose of evaluating the Participant's entry to these Awards and, for the specified purpose as agreed to;
- Awards Management or team appointed by Awards Management will try to contact the Participant on best effort basis by any means deemed appropriate;
- In the event it is not possible to contact any Participant to obtain information on them, interview them, etc. such Participant may be disqualified from further participation.

Incorrect Information

- If at any time, any information provided by any Participant is found to be incorrect in any manner, then the Participant will not be permitted to continue participation for that particular entry in the Awards, and the Awards Management will not be liable to return any materials to such disqualified entry;
- If, after the conclusion of the Awards ceremony, any information provided by any Participant is found to be incorrect in any manner, the Participant will be liable to return the Award and any non-monetary incentives provided as part of the Award;
- All Entries are subject to verification, including without limitation, verification of eligibility through checks as deemed appropriate by the Awards Management and complete compliance with these Rules and Regulations. Awards Management has the sole right to disqualify any entry if it is not in compliance with the Rules and Regulations herein specified or any further applicable laws, regulation/ or any policies that may be specified by the Award Management.

Important information

- Applicants need to send in nomination only for themselves. Only one initiative per organization is allowed. If an organization has multiple initiatives being implemented, it is suggested that they nominate their best initiative for the awards.
- A filled copy of the entry must be submitted online. IDMA will send out an email from its id **csr@idmaindia.com** along with a link to submit your entry online by filling up a questionnaire.
- Appropriate eligible category should be selected while filling entry details
- Only complete entries will be considered for the Awards
- Nominee should be willing to accept an award if selected, and should be willing to sign a consent letter
- Entry should not be for any commercial purpose or gain
- Award will be handed over to the winner in person at the Awards function on the designated day. It is assumed that all the information provided by the applicant is true and best to their knowledge. At any stage if the information is found to be incorrect, it would lead to automatic disqualification.
- One application form can be used only for a single entry / initiative / project in each award category
- Receipt of application forms after the specified last date of receipt may be permitted only for genuine reason at the discretion of the Awards Management/Jury;
- Awards Management will not be responsible for application forms that are lost in transit / received late / damaged / loss due to lack or lapse in any communication on account of internet failure;
- Participation in the Awards in any manner will be construed as an acceptance to the Rules and Regulations stated herein.

General Terms & Conditions

- By participating in the Awards process in any manner, the participant is deemed to have read,

understood and unconditionally accepted the terms of the Rules & Regulations of the Awards which may be updated from time to time without prior intimation.

- Awards Management accepts no liability for any errors or omissions, whether on behalf of itself or any third Parties.
- If the entries received are not up to the mark, the management reserves the right to not give out any award.
- Awards Management is free to reproduce, use, disclose, and distribute any information details gathered from the form. Awards Management reserves the right to publish the photograph and/ or name of the winner in promotional materials and advertisements as it deems fit.
- Participants, Nominees and Winners permit complimentary use of their names, nominated and winning content and factual information about their participation in the public media (for the build-up to the Awards, during the Awards ceremony and after the Awards ceremony) and do not have any right to any revenues earned through intellectual property rights generated by the Awards;
- Awards are subject to the laws prevailing in the country, including regulations as may be applicable to the winner.
- The process is not subject to review by any participant. The Management will not entertain any communication in this regard from any participant
- Participation in the Award does not necessitate winning an Award
- The Management cannot and shall not be accountable / liable for any disruptions / stoppages / interruptions or cancellation of the Awards. The Management and its associates cannot be held responsible for matters out of its control and for force majeure reasons
- The Awards Management reserves the right to withdraw and/or amend the terms of the Awards at any time and does not take responsibility for any loss or damage that any person or organization may suffer as a result of participating or attempting to participate in the Awards, if the Awards being withdrawn or its terms amended. If during the course of the Awards, it is discovered that an entry/winner has a dispute registered against it in a court of law, the dispute which is in contradiction to the spirit of this Awards; the Awards Management reserves the right to declare that entry/winner ineligible and/or withhold any Award until the dispute is resolved in favour of the Participant;
- Additions, deletions and/or modifications to these terms and conditions are at the discretion of the Management. It may make such additions/deletions and/or modifications, at any time before or after the Awards and are subject to change without prior notification.
- The participants, nominees and winners agree that they shall hold harmless Awards Management and sponsors, their employees, officers, associates or other persons and shall defend them against any loss, claims, demands, costs, damages, judgments, expenses or liability arising out of or in connection with any or all claims that may be brought against the Awards Management by any third party in connection with participation in or winning the Award.
- IDMA Corporate Citizen Award-2021 is recognizing initiatives done by an IDMA member firm in the area of philanthropy/social service/social welfare.
- Awards Management accepts no liability for any unintentional errors or omissions, whether on behalf of itself or any third Parties;
- Participants shall be solely responsible for any consequences which may arise due to their actions of infringement of intellectual property rights belonging to any other person /entity, etc. and also undertake to indemnify the (IDMA) Awards Management, its Directors, Officers, Sponsors, Employees, associates or other persons, etc. on the happening of such an event (including without limitation cost of Attorney, Legal Charges, etc.) on full indemnity basis;
- The short-listing of the entries and selection of winners process is not subject to review by any

participant. Awards Management will not entertain any communication, whatsoever, in this regard from any participant;

- The above-specified categories of the Awards may undergo changes and as per the sole discretion of the Awards Management;
- Decision of the Awards Management on all matters is final and binding on all participants;
- The Awards Management and its associates will not be liable for any claims / disputes made by the participants, nominees or winners in relation to the entire process of Awards;
- Efforts will be made to adhere to the defined timelines. However, the Awards Management cannot and shall not be accountable / liable for any disruptions / stoppages / interruptions or cancellation of the Awards or its ceremony or any part of its processes or voting. The Awards Management and its associates cannot be held responsible for matters out of its control and for force majeure;
- Additions, deletions and/or modifications to these Rules and Regulations are at the discretion of the Awards Management. It may make such additions/ deletions and/or modifications, at any time before or after the Awards, as required;
- All disputes relating to or arising out of the Awards shall be subject to the laws of India, and shall be subject to the exclusive jurisdiction of the courts of competent jurisdiction at Mumbai, India;
- The participants, nominees and winners agree that they shall hold harmless Awards Management and sponsors, their employees, officers, associates or other persons and shall defend them against any loss, claims, demands, costs, damages, judgments, expenses or liability arising out of or in connection with any or all claims that may be brought against the Awards Management by any third party in connection with participation in or winning the Award;
- If participants are unclear as to the rules or any element of the Awards or experience difficulties of any kind, they can write in their questions, problems or clarifications to the following address: csr@idmaindia.com or call 022-24944624 / 24974308
- The Awards Management shall endeavor to the best of its ability to respond thereto.

Website

- The website is only an informational website (www.idma-assn.org) (the "Website") for the Awards. IDMA is not liable or responsible for any action or decision taken by Participant or anyone acting on Participant's behalf or under Participant employment or under contract with Participant. IDMA shall not be under any obligation to Participant and Participant shall have no obligation or rights in relation to the Awards and shall have no claims whatsoever against IDMA relating to the selection process or the running of the Awards.
- IDMA shall not be responsible for:
  - any delivery, failures relating to the registration or uploading videos/presentations;
  - any SPAM generated messages as result of Participant accessing the Website;
  - Awards Management not receiving or rejecting any data;
  - any lost, late or misdirected computer transmission or network, electronic failures of any kind or any failure to receive entries owing to transmission failures or due to any technical reasons and;
  - Other conditions/situations or failures beyond its control.

Disclaimers

- Awards Management has no obligation to screen the entry material in advance, and is not responsible for monitoring entries for the purpose of preventing violation of intellectual property ownership rights, or violations of any law, rule or regulation. If Awards Management is notified of submissions or materials that may not conform to the Terms, it may investigate the allegation and determine in good faith and in its sole discretion whether to eliminate such an entry from consideration. The Awards Management has no liability or responsibility to Participants or other users of the Website for performance or non-performance of such activities.

IDMA Corporate Citizen Awards 2021: Entry Form for IDMA Members				
S. No.	**Section**	**S. No.**	**Questions**	**Description**
1	INTRODUCTION / PROFILE	1	Name of participating Organization	
		2	Is the Organization already a member of IDMA (Yes/ No)	
		3	Name and designation of the person submitting the entry	
		4	Phone number	
		5	Email address	
		6	Title of the Initiative that you want to nominate for **'IDMA Corporate Citizen Awards 2021'**	
		7	Net profit of the Organization in last 3 financial years (Amount in INR Lakhs)	FY 2020-21: FY 2019-20: FY 2018-19:
		8	Turnover of the Organization in last 3 financial years (Amount in INR Lakhs)	FY 2020-21: FY 2019-20: FY 2018-19:
		9	Net worth of the Organization in last 3 financial years (Amount in INR Lakhs)	FY 2020-21: FY 2019-20: FY 2018-19:
		10	Total number of Full-time employees in your Organization	
		11	Total number of team members involved in the initiative	
2	OUTREACH / SPREAD	12	When was the Initiative started?	
		13	What is the total number of locations* (District & State) this Initiative was carried out since the start and in FY 2020-21?	
		14	What is the total outreach (no. of beneficiaries) since the start of this Initiative and in FY 2020-21? - Direct beneficiaries - Indirect beneficiaries	
		15	What is the total spend for this Initiative since the start and in FY 2020-21?	
3	INITIATIVE DETAILS	16	Briefly describe the Initiative that you have nominated. Additionally, has this initiative provided exemplary efforts during the COVID-19 pandemic towards society/community? If Yes, briefly describe the details for the same. (You may send brochures/booklets etc. as mail attachments).	
		17	Describe the reason (rationale / need / problem / motivation) behind your Initiative.	
		18	Describe the approach adopted by you to undertake this Initiative.	
		19	Who are the target beneficiaries of this Initiative?	

4	CONVERGENCE	20	Please describe the mode of implementation; briefly tell us how you implemented the project.	
		21	Please describe your association with Civil Society Organizations, NGOs etc., if any, for the nominated project.	
		22	Please describe your association with local administration, if any, for the nominated project.	
		23	Please describe your association with other corporates, if any, for nominated project.	
		24	Please describe the challenges faced in implantation of the initiative.	
		25	Please describe the measures taken to face the challenges.	
5	SCALABILITY & SUSTAINABILITY	26	What are your future goals and plans for expansion of this Initiative / outreach, if any?	
		27	What are your future goals and plans for making the Initiative sustainable?	

Please note:

1. The nominated project may or may not be part of your regular CSR project.
2. The nominated project should not be part of your normal business.
3. Mention the names of the locations, districts and states.
4. Details of Net profit, Turnover and Net worth must be provided from audited financial statements. However, In case of unavailability of audited financial statements for FY 2020-21, an Organization may submit details basis a provisional financial statement (for FY 2020-21) issued by a Chartered Accountant

● ● ●

IDMA interaction with US FDA Delegates

IDMA had an interactive meeting with US FDA representatives on 6th December 2021 at Ahmedabad, Gujarat. Dr Sarah McMullen, Country Directors US FDA India, Dr Jacquine Jones, Dr Sudheendra Kulkarni and Mr. Dhruv Shah from US FDA attended the meeting. IDMA was represented by Dr Viranchi Shah, Sr Vice President & National President (Elect), IDMA along with 12 IDMA Members. The interactive meeting was very meaningful and included a dialogue on hand holding the industry as well as on long term engagement between IDMA and US FDA.

Notification Number G.S.R.38(E), dated 19th January 2011 amended

Corporate Affairs Notification G.S.R.843(E) dated 30th November 2021

(Published in the Gazette of India on 1st December, 2021)

1. In exercise of the powers conferred by section 28A of the Chartered Accountants Act, 1949 (38 of 1949), the Central Government hereby makes the following further amendments in the notification of the Government of India in the Ministry of Corporate Affairs, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 38 (E), dated the 19th January, 2011 (said notification), namely:-

2. In the said notification, for serial numbers (1), (4) and (5) and the entries relating thereto, the following serial numbers and entries shall respectively, be substituted, namely:-

"(1)	Ms. Shefali Shah, Indian Revenue Service (Retired), D-I/33, Rabindra Nagar, New Delhi-110003	Chairperson";
"(4)	Shri K. Saravanan, Chief General Manager, Corporation Finance Department, Securities and Exchange Board of India, SEBI Bhavan, Plot No. C4-A, 'G' Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051	Member"; and
"(5)	Ms. Ritika Bhatia, Director General (Commercial - II), Office of the Comptroller Auditor General of India, 9, Deendayal Upadhyaya Marg, New Delhi- 110124	Member".

3. This notification shall come into force from the date of its publication in the Official Gazette.

F.No.1/15/2010-PI (Vol.-I)

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

Note : *The Principal Notification was published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-Section (i) vide number GSR 38(E), dated the 19th January, 2011 and subsequently amended vide numbers G.S.R. 684(E), dated the 16th September, 2011, G.S.R. 441(E), dated the 12th June, 2012, G.S.R. 486(E), dated the 21st June, 2012, G.S.R. 810(E), dated the 5th November, 2012, G.S.R. 131(E), dated the 1st March, 2014, G.S.R. 569(E), dated the 7th August, 2014, G.S.R. 837(E), dated the 24th November, 2014, G.S.R. 563(E), dated the 20th July, 2015, G.S.R. 744(E), dated the 30th September, 2015, G.S.R. 681(E), dated the 12th July, 2016, G.S.R. 376(E), dated the 17th April, 2017, G.S.R. 1155(E), dated the 30th November, 2018, G.S.R. 699(E), dated the 30th September, 2019, G.S.R. 312(E), dated the 26th May, 2020, G.S.R. 431(E), dated the 7th July 2020 and G.S.R. 434(E), dated the 9th July 2020*

Central Goods and Services Tax Rules, 2017 amended (Ninth Amendment of 2021)

GST Central Tax Notification No.37/2021, dated 1st December 2021

In exercise of the powers conferred by section 164 of the Central Goods and Services Tax Act, 2017 (12 of 2017), the Central Government, on the recommendations of the Council, hereby makes the following rules further to amend the Central Goods and Services Tax Rules, 2017, namely: -

1. Short title and commencement.

(1) These rules may be called the **Central Goods and Services Tax (Ninth Amendment) Rules, 2021.**

(2) Save as otherwise provided in these rules, they shall come into force on the date of their publication in the Official Gazette.

2. In the Central Goods and Services Tax Rules, 2017,

(i) in rule 137, with effect from the 30th day of November 2021, for the words "four years", the words "five years" shall be substituted.

(ii) in FORM GST DRC-03,

(a) in the heading, after the words "or statement", the words, letters and figures "or intimation of tax ascertained through FORM GST DRC-01A" shall be inserted;

(b) against item 3, in column (3), for the word and letters "Audit, investigation, voluntary, SCN, annual return, reconciliation statement, others (specify)", the words, letters, figures and brackets "Audit, inspection or investigation, voluntary, SCN, annual return, reconciliation statement, scrutiny, intimation of tax ascertained through FORM GST DRC-01A, Mismatch (Form GSTR-1 and Form GSTR-3B), Mismatch (Form GSTR-2B and Form GSTR-3B), others (specify)" shall be substituted;

(c) against item 5, in column (1), after the word and figures "within 30 days of its issue", the words, letters, figures and brackets ", scrutiny, intimation of tax ascertained through Form GST DRC-01A, audit, inspection or investigation, others (specify)" shall be inserted;

(d) for the table, under serial number 7, for the table, the following table shall be substituted, namely:-

"Sr. No.	Tax Period	Act	Place of supply (POS)	Tax/ Cess	Interest	Penalty, if applicable	Fee	Others	Total	Ledger utilised (Cash / Credit)	Debit entry no.	Date of debit entry
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)

F.No.CBIC-20006/32/2021-GST

Rajeev Ranjan, Under Secretary, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, New Delhi

Note : *The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide notification No. 3/2017-Central Tax, dated the 19th June, 2017, published vide number G.S.R.610(E), dated the 19th June, 2017 and were last amended vide notification No.35/2021-Central Tax, dated the 24th September, 2021 vide number G.S.R.659(E), dated the 24th September, 2021.*

● ● ●

Drugs Rules, 1945 amended (6th Amendment of 2021)

Drugs & Cosmetics Notification G.S.R.839(E), dated 29th November, 2021

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 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. 618(E), dated the 7th September, 2021, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 7th September, 2021;

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

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

1. (1) These rules may be called the **Drugs (6th Amendment) Rules, 2021.**

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

2. In the Drugs Rules, 1945 (hereinafter referred to as said rules), in rule 24, in sub-rule (3), the words "or for a duplicate copy of the license issued under this rules, if the original is defaced, damaged or lost" shall be omitted.

3. In the said rules, in rule 24A, in sub-rule (7), the words "or for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost" shall be omitted.

F.No.X.11014/8/2021-DR

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

Note: *The principal rules were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R.766(E), dated the 27th October, 2021.*

● ● ●

Draft Rules to further amend the Drugs Rules, 1945

Drugs & Cosmetics Notification G.S.R.840(E), dated 29th November 2021

The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and subsection (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

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

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No.434, C

Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

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

(2) These rules shall, unless specified otherwise, come into force on the date of their final publication in the Official Gazette.

2. In the Drugs Rules, 1945, in rule127, in sub-rule (1), under the heading (3) relating to "Coal Tar Colours", after the entry "Carmoisine" and before the entry "BLUE Indigo Carmine", the following entry shall be inserted, namely:-

Common Name of the Colour	Colour Index Number	Chemical Name
1	1	3
"Allura Red	16035	Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4- sulfophenyl) azo]-2-Naphthalenesulfonic acid"

F. No. X. 11014/22/2021-DR

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. .....(E), dated .....*

● ● ●

Methylene Chloride (Dichloromethane) (Quality Control) Order, 2021 published vide number S.O.2032 (E) dated 25th May 2021 amended - reg.

Chemicals & Fertilizers Order S.O.4913(E), dated 29th November 2021

(Published in the Gazette of India on 1st December, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government hereby makes the following amendment in the Methylene Chloride (Dichloromethane) (Quality Control) Order, 2021 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following subparagraph shall be substituted, namely:-

"(2) This order shall come into force on the 20th May, 2022."

F. No.13012/17/2020-Chem.II

Samir Kumar Biswas, Addl. Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The principal order for Methylene Chloride (Dichloromethane) was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide number S.O.2032 (E) dated the 25th May, 2021.*

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Ortho Phosphoric Acid (Quality Control) Order, 2021 published vide number S.O.2335 (E) dated 15th June 2021 amended - reg.

Chemicals & Fertilizers Order S.O.4914(E), dated 29th November 2021

(Published in the Gazette of India on 1st December, 2021)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016) (hereinafter referred to as the said Act), the Central Government hereby makes the following amendment in the Ortho Phosphoric Acid (Quality Control) Order, 2021 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following subparagraph shall be substituted, namely:-

"(2) This order shall come into force on the 10th June, 2022."

F. No.13012/17/2020-Chem.II

Samir Kumar Biswas, Addl. Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The principal order for Ortho Phosphoric Acid was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide number S.O.2335 (E) dated the 15th June, 2021.*

● ● ●

Govt approved for continuation of the Scheme for Investment Promotion (SIP), a Central Sector scheme, for the duration of five years (i.e., FY 2021-22 to 2025-26)

Industrial Policy Notification F. No.P-36017/256/2020-Investment Promotion dated 29th November 2021

(Published in the Gazette of India on 30th September, 2021)

The Central Government has approved for continuation of the Scheme for Investment Promotion (SIP), a Central Sector scheme, for the duration of five years (i.e., FY 2021-22 to 2025-26) with a financial outlay of INR 970 crores. The scheme comprises a number of components and activities for promotion of investment into the country; enhancing international co-operation for promoting FDI & capacity building.

Investment promotion is a multi-faceted strategic activity that pursues bringing investment opportunities to the existing & potential investors. It also accentuates the influx of capital, jobs, skills, technology, and increases productivity and innovation for a country. To garner these benefits, investment promotion requires continuous efforts to be channelized around the main activities such as Foreign Direct Investment reforms, Ease of Doing Business reforms, Investment facilitation and Targeted outreach amongst other activities.

Department for Promotion of Industry & Internal Trade (DPIIT) under the Ministry of Commerce & Industry has been entrusted with the task of attracting domestic and foreign investments in the country. To increase the investment inflow, the department has been undertaking various initiatives and reforms such as the launching of Make in India, supporting champion sectors and subsectors, setting up of an Empowered Group of Secretaries and Project Development Cells, creating a GIS based Industrial Information System and National Investment Clearance Cell amongst others. These activities are being supported under the "Scheme for Investment Promotion" launched vide OM No. I I(I)/2004-IP&IC-IV dated November 11th, 2008. The last implementation period of the scheme was from the FY 2017-18 to 2019-20.

As India aspires to be a USD 5 trillion economy by the Year 2025, schemes such as SIP hold a special significance in boosting the investment climate of the economy. The vision of the scheme enables creating an atmosphere in the country that would lead to both increased domestic and foreign direct investments.It will also enable the country to craft the 'Brand India' effectively. Apart from this, the scheme will empower the promotional events held domestically & abroad making sustained efforts towards overcoming procedural challenges in bringing investments. The scheme will also enable the department in providing hand-holding support to domestic and foreign business investors through focused workshops and training programs.

To sustain and take the momentum forward, it is important to continue with the activities under "Scheme for Investment Promotion" in a more focused and targeted manner thereby promoting Make in India and AatmaNirbhar Bharat. Given this, continuation of the "Scheme for Investment Promotion" from FY 2021-22 to 2025-26 has been approved with the following components:

(i) Investor targeting & facilitation – Domestic & International activities

(ii) Investment promotion - Amplification & outreach activities

(iii) Project management activities

(iv) Foreign Travel

1. Investor targeting & facilitation - Domestic & International activities

The provision of high-quality services to support investors throughout the investment life cycle is extremely important. Various services, such as, location analysis and identification, regulatory advisory, support regarding project approvals and clearances at Central and State level, amongst others, are provided to the new and prospective investors.

Other activities proposed under investor facilitation are –

i. Focused investor targeting & country sector outreach

ii. Organizing CEO Forums and Joint Commission meetings

iii. Financial Investors Initiatives for attracting institutional investors

iv. Support to Indian missions abroad for Market Entry Support Programme (MESP) under Make in India initiative

v. Project Monitoring via PMG Invest India Cell

vi. Investment Clearance Cell (National Single Window System)

vii. Supporting Industrial Clusters (via Industrial Information System /Industrial Park Rating System)

viii. Investment Facilitation for North-East India

ix. Monitoring of FDI activities via FDI Monitoring Cell

x. Monitoring and developing a pipeline of investible projects via Empowered Group of Secretaries and Project Development Cells

xi. Regional ecosystem development via One District One Product

xii. Supporting domestic investors via Domestic Investor Cell

xiii. Listing of investible projects via India Investment Grid

2. Investment promotion - Amplification & outreach activities

To sustain and enhance the momentum towards making India the preferred investment destination and promoting "Brand India", an inclusive approach is being followed to involve all the stakeholders involved in the investment facilitation process for international and domestic engagements. The objective of outreach activities is to position New India as a preferred investment destination for global investors.

Other sub-activities on the promotion front are –

i. Executing branding and communication strategies for amplification & outreach

ii. Support to Indian Missions abroad for investment promotion activities and Make in India initiative

iii. Support to State Governments in their investment promotion activities

iv. Support to industry associations for investment promotion activities

The guidelines for "Organization of business and investment promotion events" are available at www.dpiit.gov.in.

3. Project management activities

To enable effective management of the scheme, it is proposed to provide project management support along with the concurrent evaluation of the scheme. This will include capacity building by preparing industry/sectoral reports and preparation of concept papers for the innovative projects to attract investments. The intent here is to share the insights with the investors and showcase India's strength as an investment destination simultaneously. Support will also be provided by a Project Monitoring Cell in monitoring the progress of various tasks from time to time.

Other sub-activities under project monitoring are –

i. Undertaking in-depth research and analysis of the investment promotion ecosystem by Strategic Investment Research Unit

ii. Capacity building of the State Investment Promotion Agencies

iii. Monitoring of the Make in India action plans by Project Monitoring Cell

iv. Monitoring the progress of facilitation activities, promotional initiatives and other activities across sectors, states and countries via digital platform.

4. Foreign Travel

To engage with the investors, undertake investment promotion and outreach activities, and understand their concerns about investing in India, it is proposed that Government officials may be deputed as official delegations abroad as per requirements.

F.No.P-36017/256/2020-Investment Promotion

Sumita Dawra,
Addl. Secretary,
Investment Promotion Section,
Department for Promotion of Industry and Internal Trade,
Ministry of Commerce and Industry,
New Delhi.

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DGFT MATTERS

Electronic filing of Registration Cum Membership Certificate (RCMC)/ Registration Certificate (RC) through the Common Digital Platform w.e.f. 6th December, 2021

DGFT Trade Notice No.27/2021-2022, dated 30th November 2021

1. A new online common digital platform for issuance of Registration Cum Membership Certificate (RCMC)/ Registration Certificate (RC) has been developed which would be single point of access for all exporters/importers and Issuing agencies. The given platform shall be available at the following URL: https://dgft.gov.in.

2. The objective of the platform is to provide an electronic, contact-less single window for the RCMC/ RC related processes including Application for Fresh/ Amendment/ Renewal of RCMC/ RC. Applications for RCMC/ RC may be submitted through the common platform w.e.f. 06th December 2021. Submitting applications on this online platform shall not be mandatory for the exporters in the immediate and there shall be a transition period for issuing agencies as well as Exporters to onboard this common digital platform. The existing procedure of submitting applications directly to the designated issuing agency shall also be in operation in parallel during this transition period. Submission and issuance of RCMC/ RC by the issuing agencies through their system may continue up to **28th February 2022 or until further orders.**

3. The authenticity of the online issued shall be verifiable by login to exporter profile on https://dgft.gov.in. The details for RCMC/ RC issued using the DGFT portal will be reflected instantly in the profile of the exporter.

4. The concerned Indian Exporters may please take note of the following points with regard to the process being notified herewith:

a. Digital Signature Certificate (DSC)/ Aadhar would be required for the purpose of electronic submission of applications. The digital signature would be the same as used in other DGFT applications;

b. No separate registration is required for availing the RCMC/ RC service from the DGFT Portal. Already registered exporters/importers can avail the service using the same login credentials.

5. For further guidance on registration and application submission process, the Help Manual & FAQs may be accessed via clicking on Learn >> Application Help & FAQs.

6. For any further assistance you may utilize any of the following channels —

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

This issues with the approval of the competent authority.

File No.01/02/68/AM-21/EG&TF

Deepak Jhalani, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

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Fixation of two new standard Input Output Norms (SIONs) at SION A-3680 and A-3681 under Chemical & Allied Product (Product Code A)

DGFT Public Notice No.40 /2015-20, dated 02nd December, 2021

In exercise of the powers conferred under Paragraph 1.03 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby notifies two new SIONs with Serial Number A-3680 and A-3681. These new entries shall be as under:

Sion No.	Export Product	Qty.	Import Item	Qty.
A-3680	Sodium Salicylate	1 kg	Salicylic Acid	0.80 kg

Sion No.	Export Product	Qty.	Import Item	Qty.
A-3681	Methyl Cobalamin JP (Mecobalamin)	1 kg	Vitamin B12 (Cyanocobalamin)	0.95 kg

Effect of the Public Notice: SIONs for export product Sodium Salicylate and Methyl Cobalamin JP (Mecobalamin) under Chemical & Allied Product Group have been notified.

File No. 01/82/171/00005/AM22/DES-III

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

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Import of Water Melon Seeds - Other under ITC(HS) 12077090 of Chapter-12 of ITC (HS), 2017, Schedule-I (Import Policy) for the period of 01.01.2022 to 31.03.2022

Public Notice No.41/2015-2020, dated 6th December, 2021

In exercise of powers conferred under paragraph 1.03 and 2.04 of the Foreign Trade Policy, 2015-20 and in continuation to Notification 03/2015-20 dated 26th April 2021, the Directorate General of Foreign Trade hereby notifies the procedure for import of Water Melon Seeds – Other under ITC(HS) 12077090 for the period of 01.01.2022 to 31.03.2022 as follows -

1. As per the recommendation from the concerned ministry, the said imports from 01.01.2022 till 31.03.2022 shall not exceed 15,000 MT. Accordingly, DGFT invites fresh applications for import authorisation for Water Melon Seeds - Other (ITC(HS) 12077090) with effect from the date of this Public Notice and not later than 13.12.2021 as follows -

i. Applications where the date of issuance of their Importer-Exporter Code (IEC) is on or after the date of this Public Notice shall not be considered.

ii. The applications shall be considered on Actual User basis to processors only based upon their own processing capacity.

iii. For each processing unit, applicants shall provide self-certified copy of a document issued by Central/State/District Authorities, indicating its processing capacity. The certificate should be dated prior to issue of this Public Notice.

iv. A valid FSSAI License is required to be provided along with the online application.

v. Only one application against one IEC shall be considered.

2. The import authorisation for each eligible applicant shall be notified as per the decision of the Exim Facilitation Committee (EFC) under pars 2.51 of the HBP 2015-20. The EFC, while examining the applications will take into considerations; inter alia, the monthly/annual processing capacity and earlier imports of the applicant. DGFT reserves the right to make any changes in the allocation as deemed fit at any point of time.

3. All import authorisation holders shall ensure that the import consignments against the said authorisations reach the Indian ports on or before 31.03.2022.

This is issued with the approval of the Minister of Commerce and Industry.

Effect of this Public Notice:

Applications are invited for import authorisation for Water Melon Seeds - Other (ITC(HS) 12077090) for the period of 01.01.2022 to 31.03.2022. The last date for submission of online applications is 13.12.2021.

File No. 01/53/8/Misc/AM22/M-1/IC

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

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Fixation of Tariff Value of Edible Oils, Brass Scrap, Areca Nut, Gold and Silver - reg.

Customs Notification No.95/2021-Customs (N.T.) dated 30th November 2021

In exercise of the powers conferred by sub-section (2) of section 14 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes & Customs, being satisfied that it is necessary and expedient to do so, hereby makes the following amendments in the notification of the Government of India in the Ministry of Finance (Department of Revenue), No.36/2001-Customs (N.T.), dated the 3rd August, 2001, published in the Gazette of India, Extraordinary, Part-II, Section-3, Sub-section (ii), vide number S.O.748(E), dated the 3rd August, 2001, namely:-

In the said notification, for TABLE-1, TABLE-2, and TABLE-3 the following Tables shall be substituted, namely:-

"TABLE-1

Sr. No.	Chapter/heading/ sub-heading / tariff item	Description of goods	Tariff value (US $Per Metric Tonne)
(1)	(2)	(3)	(4)
1	1511 10 00	Crude Palm Oil	1307
2	1511 90 10	RBD Palm Oil	1327
3	1511 90 90	Others – Palm Oil	1317
4	1511 10 00	Crude Palmolein	1334
5	1511 90 20	RBD Palmolein	1337
6	1511 90 90	Others – Palmolein	1336
7	1507 10 00	Crude Soya bean Oil	1434
8	7404 00 22	Brass Scrap (all grades)	5691

TABLE-II

Sr. No.	Chapter/heading/ sub-heading/tariff item	Description of goods	Tariff value (US $)
(1)	**(2)**	**(3)**	**(4)**
1.	71 or 98	Gold, in any form, in respect of which the benefit of entries at serial number 356 of the Notification No.50/2017-Customs dated 30.06.2017 is availed	575 per 10 grams
2.	71 or 98	Silver, in any form, in respect of which the benefit of entries at serial number 357 of the Notification No.50/2017-Customs dated 30.06.2017 is availed	750 per kilogram

3.	71	(i) Silver, in any form, other than medallions and silver coins having silver content not below 99.9% or semi-manufactured forms of silverfalling under sub-heading 7106 92; (ii) Medallions and silver coins having silver content not below 99.9% or semi-manufactured forms of silver falling under sub- heading 7106 92, other than imports of such goods through post, courier or baggage.	750 per kilogram
		Explanation: For the purposes of this entry, silver in any form shall not include foreign currency coins, jewellery made of silver or articles made of silver.	
4.	71	(i) Gold bars, other than tola bars, bearing manufacturer's or refiner's engraved serial number and weight expressed in metric units; (ii) Gold coins having gold content not below 99.5% and gold findings, other than imports of such goods through post, courier or baggage. **Explanation:** For the purposes of this entry, "gold findings" means a small component such as hook, clasp, clamp, pin, catch, screw back used to hold the whole or a part of a piece of Jewellery in place.	575 per 10 grams

TABLE-3

Sr. No.	Chapter/heading/ sub-heading/tariff item	Description of goods	Tariff value (US $ Per Metric Tonne)
(1)	(2)	(3)	(4)
1	080280	Areca nuts	5252 (i.e., no change)"

2. This notification shall come into force **with effect from the 1st day of December, 2021.**

F. No. 467/01/2021-Cus-V

Bullo Mamu, Under Secretary, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi

Note: *The principal notification was published in the Gazette of India, Extraordinary, Part-II, Section-3, Sub-section (ii), vide Notification No.36/2001–Customs (N.T.), dated the 3rd August, 2001, vide number S.O.748 (E), dated the 3rd August, 2001 and was last amended vide Notification No.91/2021-Customs (N.T.), dated the 15th November, 2021, e-published in the Gazette of India, Extraordinary, Part-II, Section-3, Sub-section (ii), vide number S.O.4753(E), dated 15th November, 2021.*

● ● ●

Regarding capping the trade margin of Oxygen Concentrators at the first point of sale (price to distributor) for fixation of Maximum Retail Price of the product - reg.

NPPA Order S.O.4909(E), dated 30th November 2021

1. The National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India vide S.O.2161 dated 3rd June 2021 issued notification under Para 19 of the DPCO, 2013 regarding capping the trade margin of Oxygen Concentrators at first point of sale (price to distributor) for fixation of Maximum Retail Price of the product. In continuation to the above notification, capping the trade margin of Oxygen Concentrator at first point of sale (price to distributor) upto 30th Nov 2021 is further extended upto 31st May 2022 or till further order.
2. The Notes (b) to (n) of the Notification S.O.2161(E) dated 3rd June 2021 shall remain in force during the currency of this order.

PN/225/93/2021/F
F. No. 8(93)/ 2021/DP/NPPA/Div.II

Rajesh Kumar T, Deputy Director, National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

● ● ●

NPPA fixes Retail Price of 20 Formulations under Drugs (Price Control) 2013 - reg.

NPPA Order S.O.4976(E), dated 3rd December, 2021

In exercise of the powers conferred by paragraphs 5, 11 and 15 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, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of Goods and Services Tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

TABLE

Sr. No.	Name of the Formulation/ Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd.	6.38

2.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. /M/s Panacea Biotec Pharma Ltd.	7.35
3.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd.	11.07
4.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd.	9.58
5.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Anthem Biopharma Pvt. Ltd	9.58
6.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Troikaa Pharmaceuticals Ltd.	9.58
7.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Troikaa Pharmaceuticals Ltd.	11.07
8.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	9.38
9.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	11.07

10.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals ltd. / M/s Cadila Pharmaceuticals Limited	11.07
11.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals ltd. / M/s Cadila Pharmaceuticals Limited	9.58
12.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	6.25
13.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	9.58
14.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	7.35
15.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	11.07
16.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	11.07
17.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	Each film-coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	9.58

18.	Atorvastatin + Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Aspirin IP 75mg (As gastro-resistant tablet IP)	1 Capsule	M/s Tristar Formulations Pvt. Ltd. / M/s Lupin Limited	2.76
19.	Atorvastatin + Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg, Aspirin IP 150mg (As two gastro-resistant tablet IP each containing 75mg of Aspirin)	1 Capsule	M/s Tristar Formulations Pvt. Ltd. / M/s Lupin Limited	3.11
20.	Ondansetron fast dissolving Strip	Each Fast Dissolving Strip contains: Ondansetron 4mg	1 Strips	M/s Amenan Therapeutics Pvt. Ltd. / M/s Delvin Formulation Pvt. Ltd.	8.13

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add Goods and Services Tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 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.

(d) 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.

(e) The above mentioned retail price is applicable only to the individual manufacturer / marketer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation /revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.

(f) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(g) Consequent to the issue of ceiling price of such formulation 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/225/93/2021/F/
F. No. 8(93)/2021/D.P./NPPA-Div.-II

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

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In Lok Sabha & In Rajya Sabha

29th and 30th Reports of Parliamentary Standing Committee on Chemicals & Fertilizers- reg.

Dear Members,

Parliamentary Standing Committee on Chemicals & Fertilizers (Department of Pharmaceuticals) has presented following reports in Lok Sabha and Rajya Sabha on 2nd Dec 2021.

29th Report on Action Taken by the Government on the Observations / Recommendations of the Committee contained in their Seventeenth Report (Seventeenth Lok Sabha) on 'Review of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

30th Report on Action Taken by the Government on the Observations / Recommendations of the Committee contained in their Twenty Second Report (Seventeenth Lok Sabha) on 'Status of Covid-19 vaccine Production in India' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

Reports are available on **Parliament of India Lok Sabha House of The People http://loksabhaph.nic.in** under Departmentally Related Standing Committees. Interested members are requested to visit their website for complete information.

Regards,

Daara B. Patel
Secretary-General

In Lok Sabha

Study by CCI

Lok Sabha Unstarred Question No. 9

Shri P.V. Midhun Reddy:

Shri Sridhar Kotagiri:

Shri Sanjay Kaka Patil:

Shri N. Reddeppa:

Shri Chandra Sekhar Bellana:

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

(a) whether the Competition Commission of India (CCI) has recently conducted a market study of the Pharmaceutical Sector to evaluate whether the prices of essential drugs had shot up during the second wave of the COVID-19 pandemic;

(b) if so, the details thereof;

(c) whether the CCI has recommended any corrective measures to the Government; and

(d) if so, the details thereof along with the action taken by the Government thereon?

Answered On 29th November 2021

A. (a) to (d): The Competition Commission of India ('Commission') has recently released a report titled 'Market Study on the Pharmaceutical Sector in India: Key Findings and Observations'. The study has been conducted with the overarching objective of understanding the factors that influence price competition in the pharmaceutical sector, specific realms of pharmaceutical distribution including the emergence of e-pharmacies, the role of trade associations, trade margins and drug pricing, and the prevalence of branded generic drugs in

India and its implications for competition. Since the pharmaceutical sector is a regulated sector, the study also attempted to explore the areas of interface between regulation and competition with a view to ascertain the Commission's advocacy priorities.

The report summarizes the main findings of the study and the Commission's observations thereon. The insights gained from the market study would contribute significantly to the design of the pharma market in India to help attain the objective of affordable medicines for all. The report is accessible in the public domain at www.cci.gov.in.

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

Bringing of Wholesale Retail Traders under MSME

Lok Sabha Unstarred Question No. 715

Shrimati Raksha Nikhil Khadse:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) whether the Government proposes to bring wholesale and retail traders under MSME to enjoy the benefits of the schemes meant for MSME to strengthen the trading business which has suffered since last one year due to Covid Pandemic and to extend the financial lending under priority sector of Reserve Bank of India to get finance required for re-establishing the trading activities; and

(b) if so, the details thereof?

Answered On 02nd December 2021

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

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

Support to MSMEs

Lok Sabha Unstarred Question No. 793

Shri S. Venkatesan:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) whether the definition of MSMEs has been extended to include Retailers and Wholesalers also along with the number of new entrants likely to be expected into the definition of MSMEs because of the said decision; and

(b) the steps being taken by the Government to increase existing support to MSMEs such as public procurement, priority sector lending and payment outstanding redressal by State facilitation centers which may be necessitated with such large additions?

Answered On 02nd December 2021

A. (a): Yes, Sir. 'Retail Trade' and 'Wholesale Trade' were brought under the ambit of MSMEs with effect from 2nd July 2021, by allowing such traders to get themselves registered on the Udyam Registration Portal. From 2nd July, 2021 to 29th November, 2021, under 'Retail Trade' and 'Wholesale Trade', 5,33,404 registrations have taken place on the Udyam Registration Portal.

(b): Benefits of the 'Udyam' registrations to such traders are restricted to the loans under Priority Sector Lending (PSL) only.

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

New Eligibility Criterions for MSMEs

Lok Sabha Unstarred Question No. 876

Dr. Amar Singh

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) whether the Government recognizes that the new criterion for classifying micro, small and medium enterprises based on investment and turnovers is suitably set considering the scale of such enterprises and also in light of the disruptions caused by the COVID-19 crisis, if so, the details thereof along with expected revision;

(b) whether the Government is in some way aiding the process of meeting the new eligibility criterions of MSMEs for entrepreneurs from tier 2 and tier 3 cities, if so, the details thereof;

(c) whether the Government has drawn an action plan to encourage more enterprises to come up, post the interruptions from multiple sudden lockdowns in the country and if so, the details thereof; and

(d) whether the action plan is inclusive and doesn't carry with it any apparent losses of concessions consistent with the status of MSMEs?

Answered On 02nd December 2021

A. (a) to (d): The Government vide notification no. S.O. 2119 dated 26.06.2020 has notified the composite criteria of classification of MSMEs based on investment in plant and machinery or equipment and turnover of the enterprises by simplifying the Udyam Registration process for MSMEs by making it fully online, digital, paperless and based on self-declaration. No documents or proof are required to be uploaded for registering as a Micro, Small and Medium Enterprise. Aadhaar and PAN are required for registration. PAN & GSTIN linked details on investment and turnover of enterprises are taken automatically from relevant Government databases. The turnover with respect to exports is not counted in the limits of the turnover for any category of MSMEs. The new criteria become applicable to all States/ UTs with effect from 01.07.2020. Promotion and development of enterprises is a State subject. The Central Government supplements the efforts of the State/UT Governments through various schemes, programmes and policy initiatives for promotion, development and enhancing the competitiveness of MSMEs in the country uniformly including tier 2 and tier 3 cities.

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

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The way forward in US-India economic ties

Recalibrating relations-istock.com

There are many irritants for both trading partners. The re-launch of the India-US trade forum is a step in the right direction

Being the world's leading democracies and market economies, India and the US see each other as vital strategic and natural allies and, more so given the rise of China and given the changing geo-political and strategic space in the Indo-Pacific.

Moreover, many countries including US and India feel the necessity to diversify their supply chain portfolio to avoid over-dependence on China. If the US-China tariff war posed uncertainties in world trade and investment, the pandemic clearly exposed the perils of the centrality of China in global value chains. A strong India-US bilateral trade and investment pact along with forums such as 'Quad' can help in developing alternative supply chains.

The re-launch of the India-US Trade Policy Forum (TPF) after a gap of four years is a welcome step to discuss and sort out bilateral trade and investment issues.

As per the USTR (2020), India is the 9th largest trading partner in goods for the US. The US was India's leading trade partner and export market in 2019-20. India has a trade surplus with the US. Despite the uncertain policy environment such as discontinuing the trade policy forum, delisting from Generalised System of Preferences (GSP) programme, the India-US bilateral merchandise trade has witnessed robust growth, faster than its trade with rest of the world.

India's exports and imports with the US grew at CAGRs of 7.7 per cent and 14.3 per cent respectively compared to 5.1 per cent and 5.2 per cent growth of India's global exports and imports between 2015 and 2019.

Indo-US trade in commercial services increased at a CAGR of 6.4 per cent and reaching $54.1 billion from $42.2 billion from 2015 to 2019 (USTR, 2020). Although the services trade balance continues to remain in India's favour, the US's services exports — mostly travel, transport and intellectual property — to India have grown faster than its services imports from India in the recent years.

The US is the fifth largest source of FDI for the country (DPIIT, 2020) with $30.42 billion inflows during April 2000-June 2020. In 2019-20, the FDI equity inflow from the US to India was $4.2 billion which is 34.5 per cent higher than previous year and is also the highest annual inflows during the last two decades.

However, the current level of economic engagement falls behind the potential. India's total trade with US ($146 billion) is less than one quarter of the US-China trade ($615 billion) in 2020.

Some of the key issues for India include the withdrawal of trade preferences given to India under the GSP programme, removal of India from the US's list of 'developing countries', high import tariffs on steel and aluminium and visa restrictions that particularly hamper the exports of services, especially the IT-BPO services. Unpredictable regulatory requirements and restrictive digital trade measures are also an issue.

US grievances

USTR, 2021, highlights that exporters from the US face a number of tariff and non-tariff barriers that impede the US exports and market access to India. The average Most-Favoured-Nation (MFN) applied tariff rate in India is 17.6 per cent — 14.1 per cent non-agriculture products and 38.8 per cent agricultural products — which is highest among major economies. The US has also concerns with regards to the gap between WTO bound rates and MFN applied rates in India that allows significant flexibility to alter tariff rates at any time, which creates uncertainty for the US exporters. US has also issues with government procurement, weak intellectual property (IP) protection and enforcement, restrictions on FDI in the retail industry etc.

IPR continues to be one of the most long standing and contentious issue between India and the US. As a

result, India remained on the Priority Watch List in the 2021 Special 301 Report of the USTR. Some of the key issues pertaining to India Patents Act for the US include potential threat of patent revocations, lack of presumption of patent validity, trademark counterfeiting and the narrow patentability criteria. Continuous engagement between the two countries though India-US TPF's Intellectual Property Working Group is the way forward.

Both India and the US are keen on exporting agricultural products to each other. The US agri-products face both tariff and non-tariff barriers (NTBs). Some of the products that face high duty in India and are of interest to the US include vegetable oils, apples, corn, motorcycles, automobiles, flowers, walnuts and alcoholic beverages.

The major TBT issues for US exporters to India include Rejection of USDA Certified Organic Consignments, restrictions on imports of livestock genetics, onerous requirements on dairy imports etc. Both countries agreed to finalise work on market access facilitation for mangoes and pomegranates, and cherries and alfalfa hay for animal feed from the US during the recently concluded TPF meeting.

The re-launching of India-US TPF provides a robust institutional mechanism to reboot the India-US economic relations. The overriding factor driving the strategic relationship is "China". The two nations are working together under the umbrella of Quad to counter the Chinese threat globally and also ensure that the Quad works closely with each other to develop strong economic and defence ties.

Sahoo is Professor, Institute of Economic Growth, and Rai is Fellow, ICRIER

Source: Pravakar Sahoo/Durgesh K Rai, Business Line, 05.12.2021

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Exports decline to the lowest in nine months in November

The IMF in October said despite temporary disruptions, trade volumes are expected to grow almost 10% in 2021, moderating to about 7% in 2022—in line with the projected broader global recovery.

Supply bottlenecks, rising covid cases in Europe cast a shadow on India's outbound shipments

India's merchandise exports fell to the lowest level in nine months in November as supply bottlenecks and rising covid-19 cases in Europe cast a shadow on India's outbound shipments.

Preliminary data released by the commerce ministry showed merchandise exports hit $30 billion, while merchandise imports stood at $53 billion, leading to a trade deficit of $23 billion in November. In October, exports had clocked a record high of $35.47 billion.

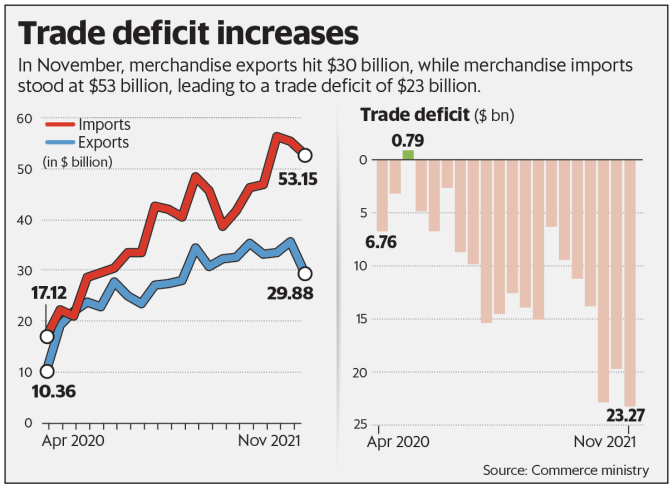
During April-November, exports stood at $262.4 billion and imports at 384.4 billion, resulting in a trade deficit of $122 billion. The commerce ministry has set a merchandise exports target of $400 billion for FY22 and $500 billion for FY23.

Aditi Nayar, chief economist at ICRA Ratings said festive season holidays have substantially dented the momentum in merchandise exports in November, bringing them down to the lowest level of FY22. "We are cautiously optimistic that the exports momentum will revive, though the uncertainty engendered by the Omicron variant poses a concern regarding the immediate outlook," she said.

The value of non-petroleum and non-gems and jewellery exports was $23.7 billion in November, while identical imports stood at $32 billion during the month. Engineering goods continued to contribute a robust 27% of exports while the share of petroleum exports declined to 12.8% in November from 14.7% in October. Gems and jewellery exports also dipped sharply, contributing only 8% in November against 9.7% in October.

Among imports, items such as crude oil and coal picked up pace in November compared to October, while import of electronic goods and gold dipped during the same period.

The United Nations Conference on Trade and Development on Tuesday said the positive trend for international trade in 2021 is largely the result of the strong recovery in demand because of the easing of pandemic restrictions, economic stimulus packages, and increases in commodity prices. However, the forecast for 2022 remains very uncertain because of slowing economic recovery, disruptions in logistics networks, and increases in shipping costs, global semi-conductor shortages, and geo-political factors, among others.



The World Trade Organization (WTO) has upgraded its forecast for global merchandise trade volume to an increase of 10.8% in 2021 from the 8% increase projected in March this year following last year's slump, which bottomed out in the second quarter of 2020. "Due to a lower base, year-on-year growth in the second quarter of 2021 was 22%, but the figure is projected to fall to 10.9% in the third quarter and 6.6% in the fourth quarter, in part because of the rapid recovery in trade in the last two quarters of 2020. Reaching the forecast for 2021 only requires quarter-on-quarter growth to average 0.8% per quarter in the second half of this year, equivalent to an annualized rate of 3.1%," WTO said.

The International Monetary Fund in October said despite temporary disruptions, trade volumes are expected to grow almost 10% in 2021, moderating to about 7% in 2022, in line with the projected broader global recovery. "Trade growth is projected to moderate to about 3.5% over the medium term. The overall trade recovery masks a subdued outlook for tourism-dependent economies and cross-border services more generally. Travel restrictions and lingering fears of contagion are likely to weigh on cross-border tourist activity until virus transmission declines durably," it said.

Source: Asit Ranjan Mishra, HT Mint, 02.12.2021

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India-China trade deficit at $30 bn during April-Sept

New Delhi: Trade deficit between India and China stood at $30.07 billion during April-September 2021, Parliament was informed on Wednesday.

India's exports to China during the April-September 2021 period was $12.26 billion, while imports were aggregated at $42.33 billion, according to data given by Minister of State for Commerce and Industry Anupriya Patel in a written reply to the Lok Sabha.

She said the imports from China have increased from $60.41 billion in 2014-15 to $65.21 billion in 2020-21, exhibiting an increase of 7.94 per cent over six years. However, the imports were static between 2019-20 and 2020-21, she said.

"The government has made sustained efforts to achieve a more balanced trade with China, including bilateral engagements to address the non-tariff barriers on Indian exports to China," Patel said.

Schemes like the production-linked incentive scheme will help promote domestic manufacturing capacities and attract investment and reduce dependency on imports from China, the minister said. Major items of import from China include telecom instruments, computer hardware, fertiliser, electronic components, chemicals and drug intermediates.

Source: Millennium Post, 02.12.2021

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Glaxo Lures Top Pfizer Scientist to Lead Vaccines Research

GlaxoSmithKline Plc lured a senior Pfizer Inc. scientist who helped develop the U.S. pharma company's Covid shot after the British drugmaker fell behind in the chase for coronavirus vaccines.

Phil Dormitzer is set to join Glaxo as global head of vaccines research and development, the pharma company said Tuesday. As chief scientific officer of RNA and viral vaccines at Pfizer, he worked on shots for a respiratory virus

and influenza, as well as the RNA-based Covid vaccine with BioNTech SE.

Glaxo lost its rank as the number-one producer of vaccines by revenue during the pandemic as it failed to successfully develop its own Covid shot while Pfizer, Moderna Inc. and U.K. rival AstraZeneca Plc crossed the finish line. The pharma company is now seeking to capitalize on technologies such as messenger RNA and ensure it's a dominant player beyond the pandemic.

Shares of Glaxo, which had been declining, gained as much as 0.8% after the announcement. Pfizer shares were little changed at 9:34 a.m. in New York.

An experimental Covid vaccine Glaxo has been developing with Sanofi has suffered months of delays, but could become available next year if a late-stage trial is successful. Activist investment firm Elliott Investment Management has been agitating for changes at the drugmaker since taking a multi-billion-dollar stake in the company and publicly disagreeing with some parts of its strategy.

Pfizer expects $36 billion in revenue from its Covid vaccine this year and another $29 billion in 2022. The vaccine is now the best-selling medicine ever for any given year.

Dormitzer's appointment comes as Glaxo prepares for a separation in mid-2022 that will leave a standalone pharma and vaccines company. The new vaccines executive, who will be based in the Boston area, previously worked at Novartis AG, where he was involved in the Swiss drugmaker's response to the H1N1 influenza pandemic, among other roles.

"Phil's scientific expertise and significant experience with key innovative technologies, such as mRNA, structure-based antigen design and synthetic biology, will be key to ensuring we remain a leader in this field," Hal Barron, Glaxo's chief scientific officer, said in the statement.

Source: James Paton, Bloomberg, 30.11.2021

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Govt seeks greater industry role in boosting exports

Commerce and Industry Minister Piyush Goyal, who has already held scores of meetings with various state-run as well as industry bodies, has also proposed to reduce the compliance burden of India Inc, which will help boost exports as well.

Having hit a monthly record of $35.7 billion in October, merchandise exports dropped below the $30-billion mark in November. Exports still registered a 26.5% rise in November from a year before but it was the lowest growth rate this fiscal.

The commerce ministry has asked state-backed export councils and key industry bodies to work more closely with various government departments and overseas missions, and suggest, through research and studies, "relevant areas for intervention", as part of its broader effort to realise the lofty $400-billion export target for FY22.

Having successfully weathered the damage caused by two Covid waves, Indian exporters face fresh uncertainties now from the emergence of a new Covid variant in Africa that can further disrupt the already-burdened global supply chains.

For its part, the ministry is planning to bring in a new set of reforms to invigorate special economic zones (SEZs), once considered to be drivers of export growth in future, under an "SEZ-plus" initiative, an official source told FE. The new plan could include revised norms for SEZs to sell in the domestic market at lower duties and easier exit route for loss-making firms in these duty-free enclaves.

The ministry also wants industry to take advantage of various production-linked incentive schemes and identify areas of benefits from potential free trade agreements with key economies. It also wants export bodies to raise the issue of non-tariff barriers posed by any country so that New Delhi can put in place appropriate retaliatory measures. At the same time, it has asked industry bodies to be "vocal about local" and more proactive in their approach to bolster exports.

In September, the government also decided to release ₹56,027 crore to clear all the pending dues owed to exporters until FY21 under various schemes to ease any

liquidity crunch. A major part of the funds will be released in the last quarter of this fiscal.

Merchandise exports fluctuated between $250 billion and $330 billion since FY11; the highest export of $330 billion was achieved in FY19. In the first eight months of this fiscal, exports hit as much as $262.5 billion. However, a slowdown in export growth in November, amid persistent bottlenecks in the global supply-chain such as elevated shipping costs and container shortage, brings to the fore new risks.

Having hit a monthly record of $35.7 billion in October, merchandise exports dropped below the $30-billion mark in November. Exports still registered a 26.5% rise in November from a year before but it was the lowest growth rate this fiscal.

Adding to exporters' woes, some countries in Europe, a major market, have already imposed travel and other curbs in the wake of the emergence of the new Covid strain, which last week led the World Trade Organization to defer its ministerial meeting. China, another key market for India, has also seen a surge in Covid cases of late. While some experts have suggested against undue anxiety over the ferocity of the new variant, some others have advised a cautious approach.

Source: Banikinkar Pattanayak, Financial Express, 03.12.2021

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Soaring imports to push India's CAD to 1.9% this fiscal year : Report

Trade deficit--the difference between a country's imports and exports -- has been rising and remains sticky

Following the record USD 23.27 billion trade deficit in November, a foreign brokerage has increased its current account deficit (CAD) forecast to 1.9 per cent of GDP at USD 60 billion for 2021-22 as compared to USD 45 billion earlier.

The government released the trade data on Wednesday which showed that exports rose 26.5 per cent year-on-year to USD 29.88 billion last month, while imports soared 57.2 per cent to USD 53.15 billion, leaving a trade deficit of USD 23.27 billion.

Trade deficit--the difference between a country's imports and exports -- has been rising and remains sticky, driven by weaker exports, surging domestic activity and higher commodity prices, a Barclays report said.

While recent correction in crude prices may mildly support deficit trends, a sustainable merchandise deficit level on an average basis is around USD 16-17 billion per month for the country, which can keep the CAD closer to a sustainable range of 2 per cent.

But at the current pace, CAD on an annualised basis is running closer to 3 per cent. "Accounting for some of reductions in the near-term, we raise our CAD forecast to USD 60 billion (from USD 45 billion earlier), or 1.9 per cent of GDP this fiscal," the report said.

Exports in April-November 2021 stood at USD 262.46 billion, an increase of 50.71 per cent from the same period of 2020. On the other hand, imports grew 75.39 per cent to USD 384.44 billion, taking the trade deficit to USD 121.98 billion during the eight-month period of this fiscal year.

In November, trade deficit more than doubled to USD 23.27 billion as gold imports grew about 8 per cent to USD 4.22 billion and other inbound shipments like crude surged 132.44 per cent to USD 14.68 billion.

The record high trade deficit in November is largely due to weaker exports, but also partly on account of ongoing strength in imports, which have remained elevated for three straight months, Barclays said and noted that exports moderated materially to USD 29.88 billion last month. The report attributed the higher import bill of USD 53.2 billion to the elevated commodity prices and recovering domestic demand.

Source: PTI,02.12.2021

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Lupin acquires exclusive rights to develop, manufacture TTP inhalation products

Synopsis

By leveraging this technology, Lupin expects to provide healthcare professionals with alternative solutions for delivering affordable inhaled medicines to patients across the globe

Pharma major Lupin on Thursday said its wholly-owned arm Lupin Inc has inked a pact with TTP Plc to acquire exclusive worldwide rights to develop, manufacture and commercialise inhalation products, using the latter's soft-

mist inhalation technology platform. TTP's (The Technology Partnership) soft-mist inhalation (SMI) technology allows delivery of inhalation drugs from a small and portable hand-held inhaler device without the use of propellants, the company said in a regulatory filing.

Lupin and TTP will jointly develop the device with the homegrown pharma firm to commercially manufacture the device through its network of in-house and external manufacturing locations.

By leveraging this technology, Lupin expects to provide healthcare professionals with alternative solutions for delivering affordable inhaled medicines to patients across the globe, it added.

As part of the agreement, Lupin and TTP will jointly develop the device with the homegrown pharma firm to commercially manufacture the device through its network of in-house and external manufacturing locations.

"Lupin will also develop and manufacture formulations to be delivered through the device, obtain the necessary regulatory approvals, and commercialise the products globally," the filing said.

"Inhalation is a strategic pillar of Lupin's growth story, as we strive to bring affordable medicines to patients across the globe. The partnership with TTP for the SMI technology platform is a strategic addition to our broad inhalation capabilities," Lupin Global CEO Vinita Gupta said.

TTP Managing Director Sam Hyde said the partnership with Lupin to commercialise the company's SMI technology can benefit patients suffering from chronic respiratory conditions.

He further said, "TTP has deep expertise in aerosol science, and we have been working with our clients for over 30 years in complex drug delivery device development. This partnership represents an exciting next step for us in this innovative area of respiratory drug delivery".

Through the SMI technology, individual doses are delivered using a precisely engineered nozzle system to produce a slow-moving and long-sustaining aerosol cloud, Lupin said, adding it anticipates applications across respiratory care.

Source: Economic Times, 02.12.2021

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Covid-19: A wide range of vaccines act as booster to AstraZeneca, Pfizer shots, says study

NEW DELHI: Up to six different Covid-19 boosters were found to be safe, and provoked strong immune responses in people who have previously received a two-dose course of the Oxford-AstraZeneca-developed Covishield, or Pfizer-BioNTech's BNT162b2, the first randomised phase 2 trial of boosters given after two doses of either vaccine, published in The Lancet shows. The study assumes significance as most countries, particularly the ones with high vaccination coverage, including India, are now mulling over the need for an additional dose in the wake of the new Omicron variant. The WHO will also deliberate on the issue of booster doses on December 7.

Apart from the two jabs, NVX-CoV2373 (Novavax), Ad26.COV2.S (Janssen), Moderna, VLA2001 (Valneva), and CVnCov (Curevac) were also studied. All of them boosted spike protein immunogenicity when given 10-12 weeks after two doses of the AstraZeneca vaccine. In the case of Pfizer-BioNTech, except for Valneva all the others boosted spike protein immunogenicity, the findings show.

"It's really encouraging that a wide range of vaccines, using different technologies, show benefits as a third dose to either AstraZeneca or Pfizer-BioNTech. That gives confidence and flexibility in developing booster programmes here in the UK and globally, with other factors like supply chain and logistics also in play", said Saul Faust, trial lead and director of the NIHR Clinical Research Facility, University Hospital Southampton NHS Foundation Trust.

However, the study found large variations in antibody and cellular immune responses between vaccines and suggested that this should be considered along with availability and what level of boost is sufficient for national disease control objectives while taking policy decisions on boosters.

The study had also used a shorter interval between the second and the third dose than between the first two doses, which might have resulted in lower immunity boost than if longer intervals were used.

Source: TNN. 03.12.2021

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Boosters: Experts say mixing vaccines may give better immune cover

A head of a much-anticipated meeting on Covid booster shots, experts feel the way forward is to mix vaccines to give better immune coverage even as others question the need for a booster dose.

In the wake of the recent scare from Omicron, some virologists feel two-dose immunityÂ along with memory-cell action would be sufficient, while others feel that booster shots may be necessary.

An expert group is likely to meet next week to decide on the course of action related to allowing booster shots.

Bharat Biotech's inactivated whole-virus based Covaxin seems to have an edge here for two reasons — one, a third dose of Covaxin can be given as a booster shot, while for Covishield (the AstraZeneca-Oxford vaccine) giving the same vaccine as a third shot may not prove to be effective. Secondly, experts say Covaxin is likely to have an edge over other vaccines in offering some immunityÂ to a mutating virus as it contains the whole virus.

On whether giving a third dose of Covishield as a booster shot to someone who has already received two shots of the vaccine makes sense, ShahidJameel, Senior Research Fellow at Green Templeton College at Oxford University, said, "Vector immunityÂ would be dominant. A booster of Covishield in people with two doses of the same is unlikely to give much benefit."

Covishield is based on a weakened version of a common cold or adenovirus found in chimpanzees. This viral vector contains the genetic material of the Sars-CoV-2 spike protein (that helps the virus to bind with human cells).

Jacob John, senior virologist and former head of the departments of clinical virology and microbiology at Christian Medical College, Vellore, said vector-based vaccines have two immune responses by the body — one is against the vector itself, which is irrelevant, the other is against the spike protein of the coronavirus, which is the relevant immunity.

Jameel feels that a separate vaccine given as a booster to Covishield may work better. "Serum Institute already has a good booster to Covishield. It's the Novavax protein vaccine Covovax. But India has not approved it yet," he adds.

Serum CEO Adar Poonawalla, too, has hinted at developing a new booster to the AstraZeneca shot. "Scientists at Oxford are also continuing their research, and based on their findings, we may come out with a new vaccine that would act as a booster in six months' time," Poonawalla said this week.

Meanwhile, his company has approached the drug regulator, seeking approval for Covishield as a booster citing adequate stock.

John seemed to agree with Jameel when he said that "for people who have received two doses of Covishield, Covaxin as the booster shot makes sense, but Covishield as the third shot makes no sense. For people who have received two doses of Covaxin, it makes sense to give another Covaxin shot as a booster as this vaccine is based on the whole virus. So it contains all the parts of the virus, not just spike protein antigens."

John feels that booster shots are a necessity in the wake of the Omicron variant, which is likely to escape immunity and cause breakthrough infections.

Others like Jayaprakash Muliyil, Chairman of the Scientific Advisory Committee of the ICMR's National Institute of Epidemiology, don't think a booster dose is needed.

He says that the Sars-CoV-2 virus is an excellent immunogen and exposure to either the virus or vaccine would work to induce immune response in the case of future exposures. "We have no evidence that a booster dose makes a difference in the case of either Covishield or Covaxin," he says.

Muliyil, however, says if a booster is given, in the case of Covaxin, giving the same vaccine dose will work and admits that Covishield will have a problem with vector-induced immunity. "Covaxin induces excellent memory in our immune cells."

Globally, the clamour for boosters is growing. The US Centers for Disease Control and Prevention has recommended that all adults are eligible for a booster shot six months after completing their primary vaccination series if they started with Pfizer-BioNTech or Moderna, or two months after getting the Johnson & Johnson single-shot vaccine. Any vaccine available in the US can be taken as a booster regardless of which vaccine was taken primarily.

Source: Sohini Das, Business Standard, 03.12.2021

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Indian drug makers get close to nod for Merck's Covid antiviral Molnupiravir

With the expert group having advised the US regulator to recommend the use of Merck's antiviral drug molnupiravir for Covid, drug makers here are awaiting a final decision from the Indian regulator.

Molnupiravir approval assumes significance. It could offer an affordable oral drug to treat Covid. The drug developed by Merck with Ridgeback Biotherapeutics targets part of the virus called the ribonucleic acid polymerase. This part of the virus has not changed much after mutations in the Omicron variant.

However, according to the recent data published by Merck, the drug was found to be significantly less effective than previously thought. It reduced hospitalisations and deaths in its clinical trial of high-risk individuals by around 30 per cent.

The subject expert committee (SEC) that is advising the Drugs Controller General of India (DCGI) had sought more data from a consortium of drugmakers — Dr Reddy's Laboratories (DRL), Torrent Pharmaceuticals, Emcure Pharmaceuticals, Sun Pharmaceutical Industries (Sun Pharma), and Cipla — in its last meeting.

"In its last meeting, the SEC had requested more data from all companies. On behalf of the consortium, we have submitted the data. We now await the next SEC meeting," said a spokesperson for DRL.

These five drugmakers had come together in June to jointly sponsor, supervise, and monitor the clinical trial in India. Between March and April this year, these five pharmaceutical companies had individually entered into a non-exclusive voluntary licensing agreement with Merck Sharp Dohme (MSD) to manufacture and supply molnupiravir to India and over 100 low- and middle-income countries.

This apart, drugmakers like Hetero Labs have also done trials independently on molnupiravir here.

An expert panel of advisors to the US Food and Drug Administration (USFDA) on Tuesday voted to recommend the authorisation of Merck's antiviral pill for treatment of Covid. Last year, the USFDA had authorised the use of Gilead Sciences, Inc.'s injectable antiviral remdesivir to treat Covid.

In November, Sun Pharma had said that it was gearing up to launch molnupiravir under the brand name Molxvir in India.

Molnupiravir is the first oral antiviral approved by the UK's Medicines and Healthcare products Regulatory Agency for the treatment of mild-to-moderate Covid in adults.

Kirti Ganorkar, chief executive officer of India business, Sun Pharma, had said, "The recent authorisation of molnupiravir, licensed from MSD and Ridgeback by the UK regulator, is a positive step. In line with our consistent efforts to accelerate access to new drugs for Covid treatment, we are gearing up to make Molxvir available to patients and health care providers across India at an economical price after approval by the DCGI. Molxvir will be manufactured at one of our plants in India and we have enough capacity to meet demand."

Source: Sohini Das, Business Standard, 02.12.2021

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Biotech firm Mylab developing test to screen multiple Covid variants

Pune-based biotech firm Mylab Discovery Solutions is working on a new technology platform that would not only detect the presence of coronavirus Â in a sample, but also

be able to screen the variant. The Serum Institute of India (SII)-backed company said that the product would be ready in around two months.

Without divulging details, Hasmukh Rawal, MD of Mylab, told Business Standard the company is working on a molecular diagnostic test that would give results as accurate as of the RT-PCR test. "Unlike the RT-PCR, which takes a few hours to give results, this test platform will be able to give results in minutes. It will also be able to detect or screen the kind of mutation present in the sample," Rawal said.

Such a test, according to him, would be extremely useful to screen people at various points of entry like airports.

Rawal said Mylab is making both hardware and software for the test, and it will be ready in the next two months or so. Then it would go for approval of government agencies.

Speaking on whether newer RT-PCR kits are necessary to pick up new mutations in the Sars-CoV-2 virus, Rawal said that we have seen more than 15 major variants in the past year. "One cannot make specific kits for all the major variants. Within the month of making it, there can be a region-specific mutation in that variant. Specific mutation detection kits would not make sense, as the treatment or vaccination does not change for different variants," he explained.

Most of the kits approved by the ICMR are multiple gene kits. These kits do not get affected by minor mutations in the virus, said Rawal.

They are able to detect the presence of the virus in the sample despite mutations. CompaniesÂ like Mylab, Thermo Fisher Scientific, and Abbott have already said that their kits detect the presence of the Omicron variant of the virus.

In August, Mylab had said that it is now planning to bring in more point of care (POC) coronavirusÂ tests through a partnership with US medical diagnostic company Hemex Health. Under the partnership, Mylab will develop the test assays, while Hemex will provide its Gazelle POC platform for testing coronavirusÂ and other diseases.

In May, the company launched the first Indian Council of Medical Research (ICMR) approved self-use rapid antigen test (RAT) kit, CoviSelf, for testing at home; it gives results in 15 minutes and costs Rs 250. Mylab is also the first Indian company to develop an indigenously developed RT-PCR kit in 2020 when the pandemic broke out.

Demand for RT-PCR and RAT tests are low now with low case counts. Rawal said: "We can make 0.8 million tests a day for RT-PCR and 1.5 million rapid antigen tests (RATs) a day. Demand is very low now. Hardly 5 per cent of the capacity is getting utilised now."

Source: Sohini Das, Business Standard, 06.12.2021

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Companies gear up for Omicron version of coronavirus vaccines

As the Omicron variant of Sars-CoV-2 takes centre stage, vaccine makers in India are of the view that scaling up the existing vaccines to make them more effective is possible.

Ahmedabad-based ZydusCadila is making a DNA vaccine using the Omicron sequence, but will not immediately take it to the clinic.

Serum Institute of India (SII) Chief Executive Officer Adar Poonawalla said: "It is too early to comment on Omicron. Scientists at Oxford University are continuing their research, and based on their findings, we in six months may come up with a vaccine that would act as a booster."

"We will take a call when more is known about the new virus. In the meantime, everyone should get vaccinated with two doses."

Sharvil Patel, managing director, Zydus Cadila, said: "As of now there is not enough data to say that we need a new vaccine to target this variant. We are, however, keeping the construct ready. Unless this strain becomes lethal or serious, there may not be a specific need to develop a new vaccine."

Zydus needs around eight weeks to have a laboratory product or vaccine ready.

"We will not immediately take it to the clinical trial stage. The advantage of RNA or DNA technology platforms is that one can easily replace the sequence and make a new product. So we are continuing our research on that," Patel said.

India is yet to decide on whether it would allow booster doses for its population. A meeting on this is expected to be held next week.

Poonawalla said SII was prepared for boosters.

"Around 200 million doses are available with us for states and Union Territories. We are well stocked in case booster shots are allowed," he said.

Apart from the Omicron variant, Zydus Cadila is testing a multi-variant Covid-19 vaccine on animals.

"We have completed our development for almost eight strains of the Sars-Cov-2 virus. We are now doing animal studies to see which of these constructs works the best to neutralise more mutations of Sars-CoV-2. It can be a vaccine construct using one strain or, maybe two strains," Patel had told Business Standard.

Tweaking the DNA-plasmid platform is relatively easy, and takes less time. One needs to just change the sequence of the strains, and the construct of the vaccine, the model, and the process remain the same.

Zydus Cadila's ZyCoV-D, the DNA vaccine, when administered, induces the production of spike protein of the Sars-CoV-2 virus. It is also stable across a wide temperature range, unlike the stringent temperature requirements for mRNA vaccines.

Hyderabad-based vaccine maker Bharat Biotech did not divulge its plans, but said the company was continuing research on new variants.

"Covaxin was developed against the original Wuhan variant. It has shown that it can work against other variants, including the Delta variant. We continue to research new variants," the company said.

Global vaccine makers too have spoken about their plans for Omicron. Pfizer, for example, has said it has started working on a version of its Covid vaccine, specifically targeting the new Omicron variant, in case the current inoculation is not effective for the latest strain. It has begun testing the current vaccine for the Omicron strain.

Moderna too has said it is developing a booster shot for the new variant.

Source: Sohini Das, Business Standard, 1.12.2021

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