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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,
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 52 **Issue No. 44** **22 to 30 November 2021**

IDMA ACTIVITIES

DGFT MATTERS:

GOVERNMENT NOTIFICATION:

MoEFCC MATTERS:

NPPA MATTERS:

IPR MATTERS:

NATIONAL NEWS:

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 Emerging Leader of the Year Award**

would be announced and the Awards would be presented.

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

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

IDMA 60th ANNUAL PUBLICATION 2022

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

AN OFFER NOT TO BE MISSED

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

ADVERTISEMENT RATES			
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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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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 Presentation on Nitrosamines – Impurities, testing etc. to FDA Commissioner, Maharashtra

IDMA had been requested by FDA Commissioner, Maharashtra to make a presentation on Nitrosamines – Impurities, testing etc. In regards to that on 17th November 2021, Dr. Milind Joshi, Chairman, Quality Management & Technical Committee, IDMA made an excellent presentation to the FDA Commissioner and his officials. IDMA was represented by Mr. Mahesh Doshi, Dr. George Patani, Mr. S M Mudda and Mr. Daara B. Patel.

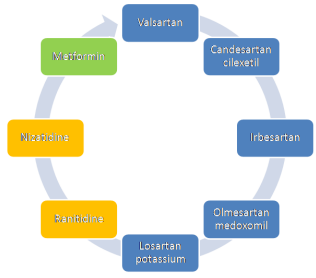
PRESENTATION

Genesis of NDMA Issue

- Medicine Regulatory Authorities first became aware of the presence of the nitrosamine impurity, N-nitrosodimethylamine (NDMA), in products containing valsartan in July 2018. **Valsartan is an Angiotensin II Receptor Blocker (ARB)** and belongs to a family of analogue compounds commonly referred to as the sartans.
- Further nitrosamine impurities were subsequently detected in other medicines belonging to the sartan family, including: N-nitrosodiethylamine (NDEA), N -nitrosodiisopropylamine (NDIPA), N -nitrosoethylisopropylamine (NEIPA) and N -nitroso-N-methyl-4-aminobutyric acid (NMBA).
- Subsequently, in Sept 2019 a nitrosamine impurity has been detected in batches of ranitidine, a medicine used to treat heartburn and stomach ulcers
- On 6 December 2019, EMA confirmed that trace amounts of NDMA had been found in a small number of metformin-containing medicines outside the EU. There were no data indicating that EU medicines were affected.
- **USFDA on 1st April 2020, informed ranitidine to be called back from US market. Any brand which has less than permissible limit, can sell in USA.**

- https://www.who.int/medicines/publications/druginfo/InformationNote_Nitrosamine-impurities/en/
- https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities

Impacted Molecules



What are Nitrosamines?

- Any molecule containing the nitroso functional group.
- These molecules are of concern because nitrosamine, are classified as probable carcinogens by International Agency for Research on Cancer [IARC].
- Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines.
- Although they are also present in some foods and drinking water supplies, their presence in medicines is nonetheless considered unacceptable.

Group 1	Carcinogenic to humans
Group 2A	Probably carcinogenic to humans
Group 2B	Possibly carcinogenic to humans
Group 3	Not classifiable as to its carcinogenicity to humans


Figure 1: *N*- nitrosodimethylamine (NDMA)


Figure 2: *N*-nitrosodiethylamine (NDEA)

Park J et al. Distribution of Seven N-Nitrosamines in Food. Toxicol Res. 2015; 31(3): 279–288.

Toxicity

- NDMA and NDEA belong to group of highly potent mutagenic carcinogens.
- Despite the potency of these impurities, there is still a very low risk that nitrosamine impurities at the levels found could cause cancer in humans.
- Only limited impurity-specific toxicity data is available for NDMA and NDEA.
- Due to their structural similarity, NDIPA, NEIPA, and NMBA are considered by international regulators to exhibit a toxicological profile like NDMA and NDEA.

Toxicity

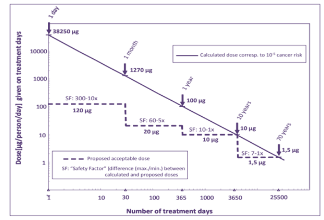
Interim allowable daily intake limits

Impurity name Abbreviation	Chemical name	Allowable Daily Intake (AI)
NDMA[6]	N-nitrosodimethylamine	96.0 ng/day
NDEA[6]	N-Nitrosodiethylamine	26.5 ng/day
NMBA[7]	N-Nitroso-N-methyl-4-aminobutyric acid	96.0 ng/day
DIPNA[7]	N-nitrosodiisopropylamine	26.5 ng/day
EIPNA[7]	N-nitrosoethylisopropylamine	26.5 ng/day

https://www.who.int/medicines/publications/drugalerts/InformationNoteNitrosamine-impurities_Nov2019.pdf?ua=1
6 February 2019, EMA/44960/2019: Sartan medicines: companies to review manufacturing processes to avoid presence of nitrosamine impurities.
7 20 August 2019 EMA/351053/2019 rev 1: Temporary interim limits for NMBA, DIPNA and EIPNA impurities in sartan blood pressure medicines.

ICH (M7)

Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7 (R1) - (Current Step 4 version dated 31 March 2017)



The solid line in Figure represents the linear relationship between the amount of daily intake of a mutagenic impurity corresponding to a 10^{-5} cancer risk and the number of treatment days. The calculation is based on the TTC level as applied in this guidance for life-long treatment, i.e., 1.5 µg per person per day using the formula:

$$\text{Less-than-lifetime AI} = \frac{1.5\ \mu g \times (365 \text{ days} \times 70 \text{ years lifetime} = 25{,}550)}{\text{Total number of treatment days}}$$

Illustration of calculated daily dose of a mutagenic impurity corresponding to a theoretical 1:100,000 cancer risk as a function of duration of treatment in comparison to the acceptable intake levels.

https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf Last accessed on 12th October,

Ranitidine – Since 40 years

- Ranitidine is an acidity inhibitor meant for short term use
- Commercially introduced in 1981
- Available >120 countries worldwide
- Features on WHO's List of Essential Medicines

Mills et al. Aliment Pharmacol Ther 1997; 11: 129-137.
Palop et al. Arzneimittelforschung. 1997; 47(4A): 439-46.

The calculation of less-than-lifetime Acceptable Intakes (AI) is predicated on the principle of Haber's rule, a fundamental concept in toxicology **where concentration (C) x time (T) = a constant (k)**. Therefore, the carcinogenic effect is based on both dose and duration of exposure.

For NDMA: Less-than-lifetime Acceptable Intake (AI) = 96 ng x (365 days x 70 years lifetime = 25,550) ÷ Total number of treatment days

Summarized chart: Dosage (ranitidine) vis-à-vis years of exposure[45]

Ranitidine Dosage*	Acceptable limits (ppm) of NDMA in relation to years of Ranitidine use			
	1 year	5 years	10 years	70 years (Lifelong)
300 mg	22.4 ppm	4.48 ppm	2.24 ppm	0.32 ppm
600 mg	11.2 ppm	2.24 ppm	1.12 ppm	0.16 ppm

*Usual dose should not exceed Ranitidine dose 600 mg /day.

Calculations Data on file (using the ICH M7, Quality Risk Management Guidelines)

Sartans

Temporary limits for NDMA and NDEA impurities

Active substance (max daily dose)	NDMA Maximum daily intake (ng)	NDMA Limit (ppm)	NDEA Maximum daily intake (ng)	NDEA Limit (ppm)
Candesartan (32 mg)	96.0	3.000	26.5	0.820
Irbesartan (300 mg)	96.0	0.320	26.5	0.088
Losartan (150 mg)	96.0	0.640	26.5	0.177
Olmesartan (40 mg)	96.0	2.400	26.5	0.663
Valsartan (320 mg)	96.0	0.300	26.5	0.082

https://www.ema.europa.eu/en/medicines/human/referrals/angiotensin-ii-receptor-antagonists-sartans-containing-tetrazole-group

Nizatidine and Metformin

Active substance (max daily dose)	NDMA Maximum daily intake (ng)	NDMA Limit (ppm)
Nizatidine (300 mg)	96	0.319
Metformin Immediate-release tablets or oral solution (2550 mg)	96	0.0376
Metformin Extended –Release Tablets (2000 mg)	96	0.0479

NDMA & Water

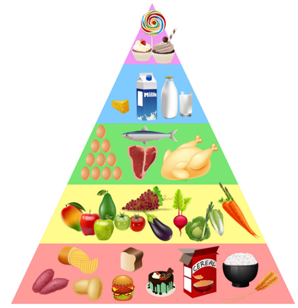
- The EPA's Integrated Risk Information System (IRIS) estimates that a NDMA concentration of 7×10^{-4} µg/L in drinking water is associated with a 10^{-6} cancer risk.[23]
- The World Health Organization (WHO) (2006) estimates that 0.1 µg/L NDMA in drinking water corresponds to an upper-bound 10^{-5} cancer risk.[24]
- A recent study of 21 U.S. and Canadian drinking water treatment plants reported a range of NDMA levels from below the minimum reporting level (MRL) of 6×10^{-4} µg/L to 2.4×10^{-2} µg/L.[25]

NDMA

23. EPA 1993 Integrated Risk Information System (IRIS): N-Nitrosodimethylamine (CASRN 62-75-9). US Environmental Protection Agency, Office of Research and Development, URL: http://www.epa.gov/iris/substance_nmbr=0045. Accessed: 9/26/04.
24. https://www.who.int/water_sanitation_health/dwq/chemicals/ndma_2add_feb2008.pdf. Last accessed on 14th October, 2019.
25. Valentine, R. L., Zhu Chen, J. C., Barrett, S. E., Cordelia Hwang, C., Guo, Y., Wehner, M., Fitzsimmons, S., Andrews, S. A., Werker, A. G., Brubacher, C. & Kalmut, K. 2006. Factors affecting the formation of NDMA in water and occurrence. American Water Works Research Foundation, Denver, CO, pp. 99–138.

NDMA & Food

- NDMA can form in food when secondary amines are exposed to nitrite during processing or preservation. Dietary sources of NDMA include
  - Beer,
  - Fish and fish products,
  - Dairy products including cheese, dried milk and infant formula,
  - Meat and cured meats,
  - Cereals and vegetables.[26]



26. Chowdhury S. N-Nitrosodimethylamine (NDMA) in Food and Beverages: A Comparison in Context to Drinking Water, Human and Ecological Risk Assessment: An International Journal 2014; 20(5): 1291-1312. DOI: 10.1080/10807039.2013.817144.

EDQM Guidance to avoid nitrosamines in human medicines

STEP 1
- **Conduct a risk evaluation** to identify products at risk of N-nitrosamine formation or (cross-)contamination and report the outcome **by 26 March 2020 at the latest**.

STEP 2
- **Perform further confirmatory testing** on the products identified to be at risk of N-nitrosamine formation or (cross-)contamination and report confirmed presence of nitrosamines **as soon as possible**.

STEP 3
- Apply for any necessary **changes to the manufacturing process** resulting from this review using the established regulatory procedures.

https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities

EDQM Initiatives

Review of ranitidine medicines
- At the request of the European Commission, EMA is currently reviewing ranitidine medicines after tests showed that some of these products contained NDMA.

Review of sartans
- EMA has completed its review of sartan blood pressure medicines (also known as angiotensin II receptor anatgonists). Manufacturers of sartan medicines must **review their manufacturing processes** to ensure they do not produce nitrosamine impurities.

Metformin-containing medicines
- EMA and national competent authorities are working closely with the official medicines control laboratories (OMCLs) and companies to test EU medicines. EMA will provide further updates as soon as possible.
- EMA advised patients in the EU to **continue to take metformin medication** as the risks from not treating diabetes far outweigh any possible effects of the low levels of NDMA seen in tests.

https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities

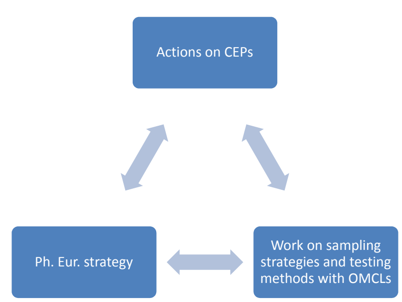
EDQM listed following APIs with possible NDMA

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

Abacavir	Doxylamine	Cefotetan
Alfentanil	Ergometrine	Cefotiam
Aminopyrimidine	Erythromycin	Cefoxitin
Amitriptyline	Etomidate	Cefpiramide
Cefamandole	Imipramine	Chloramphenicol
Cefazolin	Methapyrilene	Chlorpromazine
Cefmenoxime	Metronidazole	Cliostazol
Cefonicid	Noscapine	Dalteparin
Cefoperazone	Oxytetracycline	Diphenhydramine
Pregabalin	Zanamivir	Sulbactum
Promazine	Sodium Lauryl Sarcosinate	Tetracycline
Propoxyphene	Trimipramine	Metformin#

EDQM Update on Valsartan incident and lesson learned, Ms H Brugeura-4th Indian Pharmaceutical forum Feb 2019 accessed On 02-12-2019 #Dec 2019 by US FDA

Steps Taken By EDQM



Steps Taken By EDQM

- Contacting all CEP holders concerned to obtain the relevant information;
- Undertaking a major re-assessment of relevant CEP dossiers, and taking the necessary action (e.g. revisions of CEPs, suspension of CEPs when the detected nitrosamine content is above the commonly agreed temporary limits in the EU);
- Extending the exercise, which started with sartans with a tetrazole ring, to ranitidine HCl and subsequently to all synthesised APIs;
- Conducting GMP inspections of manufacturing sites for the APIs concerned;

Continued…

https://www.edqm.eu/en/edqms-response-nitrosamine-contamination

Steps Taken By EDQM

- Revising relevant European Pharmacopoeia (Ph. Eur.) monographs to add limits for N-nitrosamine impurities, an important part of ensuring the continuity of the supply of medicines for the benefit of patients in Europe;
- Elaborating a general chapter providing analytical procedures to control the relevant N-nitrosamine impurities;
- Working with its network of Official Medicines Control Laboratories (OMCLs) to co-ordinate sampling and testing and to ensure that analytical test procedures for determination of nitrosamines are developed and made available to stakeholders.;
- Regularly updating all stakeholders concerned, from national authorities to manufacturers, on the state of the works and on initiatives taken.

https://www.edqm.eu/en/edqms-response-nitrosamine-contamination

EMA Directives

Steps companies should take

- Evaluate possibility of nitrosamines being present in every concerned medicine within 6 months
- Prioritise evaluations, starting with medicines more likely to be at risk of containing nitrosamines
- Take into account findings from CHMP's review of sartans
- Notify authorities of outcome of risk evaluations
- Test products at risk of containing any nitrosamines
- Immediately report detection of nitrosamines to authorities
- Apply for necessary changes to marketing authorisations to address nitrosamine risk
- Complete all steps within 3 years, prioritising high risk products

Response of International Agencies on NDMA, in Ranitidine

FDA U.S. FOOD & DRUG ADMINISTRATION	Advised manufacturers to test products for impurity
EUROPEAN MEDICINES AGENCY	No recall from any agency, unless NDMA found to be above limits
CDSCO	Manufacturers to verify their products and take appropriate measures to ensure patient safety

https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications

Hyperlinks

US-FDA

- https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications
- https://www.fda.gov/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan
- https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine
- https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin

EDQM

- https://www.edqm.eu/en/edqms-response-nitrosamine-contamination
- https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities

WHO

- https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine-impurities/en

DCGI(I)

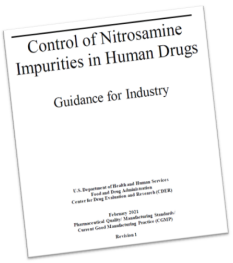
- Letter

DCGI Letter

NDMA formation in medicines' is **Process driven & not Molecule related**

- If found in medicines, some correctable measures are:
  - ✓Use of different solvents
  - ✓Adopting order of steps to avoid formation
  - ✓Control measures in raw materials

EDQM Update on Valsartan incident and lessons learned, Ms H Brugnera-4th Indian Pharmaceutical forum Feb 2019



FDA recommends that API manufacturers take the following actions:

- API manufacturers should optimize the design of the manufacturing process for APIs during route of synthesis (ROS) development to minimize or prevent the formation of nitrosamine impurities. API manufacturers should refer to the recommendations in ICH M7(R1) and the ICH guidances for industry *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients* (September 2016) and *Q11 Development and Manufacture of Drug Substances* (November 2012) in this respect. The following factors should be considered during process development:
  - Avoiding reaction conditions that may produce nitrosamines whenever possible; when not possible, demonstrating that the process is adequately controlled and is capable of consistently reducing nitrosamine impurities through appropriate and robust fate and purge studies.
  - Using bases other than secondary, tertiary, or quaternary amines (when possible) if ROS conditions may form nitrosamines.
  - Using caution when the ROS involves the use of amide solvents (e.g., N,N-dimethylformamide, N,N-dimethylacetamide, and N-methylpyrrolidone).
  - Replacing nitrites with other quenching agents for azide decomposition processes.
  - Optimizing and consistently controlling the sequences of reactions, processes, and reaction conditions (such as pH, temperature, and reaction time).
  - Designing a manufacturing process that facilitates the purge of nitrosamine impurities in the subsequent processing steps.

[40] See section V in this guidance for reporting changes to approved applications and DMFs.

What is the risk of taking a drug that contains nitrosamines?

- FDA does not expect nitrosamines to cause harm when ingested at low levels. Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, but a person taking a drug that contains nitrosamines at, or below, the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer.

https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications

Facts

Why are some drugs being recalled due to a potential nitrosamine impurity while others are not?

- FDA, in collaboration with regulatory counterparts around the world, has set internationally-recognized acceptable daily intake limits for nitrosamines. Nitrosamines below this level are acceptable in drugs. If drugs contain levels of nitrosamines above the acceptable daily intake limit, FDA recommends these drugs be recalled by the manufacturer.
- Some manufacturers have recalled certain drugs as a precautionary measure, while others have been recalled after testing positive for nitrosamine levels above the acceptable daily intake limits. Information about drugs that have been recalled due to potential nitrosamine impurities can be found on the FDA recalls webpage.

https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications

Analytical Challenges

- Method Development & Standardisation
- Time consuming and costly
- Outsourse
- Sensitivity – LOD LOQ
- LCMS / LCHRMS – Not widely available

2021
What is new?

CDER, JAMA, EQDM CEP restoration & New studies.

2021

- **Retraction of false claim studies.**
- **The USFDA update with CDER study.**
- **Certificate of Suitability (CEP) for ranitidine restored by EDQM.**
- **JAMA & Other studies : Ranitidine is not converted to NDMA.**

Widely covered paper on ranitidine-cancer link retracted

Authors withdraw study published that linked Ranitidine and NDMA

- Paper linking the use of a wildly popular drug for heartburn to cancer has been retracted after the authors concluded that their widely touted **finding appears to have resulted from a hiccup in the way they conducted their testing.**

Widely covered paper on ranitidine-cancer link retracted

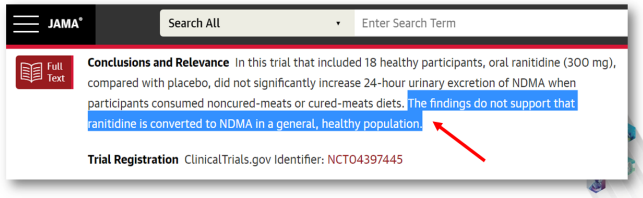
Carcinogenesis has retracted the following article at the request of the authors:

Zeng, T. *et al.* (2016) Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine. *Carcinogenesis*, 37, 625–634. https://doi.org/10.1093/carcin/bgw034

This article is being retracted at the request of the authors. Recent research (1) has identified the potential for an analytical artefact associated with the use of gas chromatography that could have contributed to the levels of N-nitrosodimethylamine (NDMA) measured in urine samples containing ranitidine in this study. Given this artefact, the authors have informed the journal that their NDMA measurements are not reliable.

"So what new studies say…?"

1



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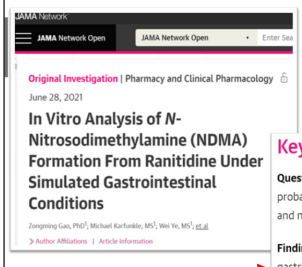


JAMA The Journal of the American Medical Association

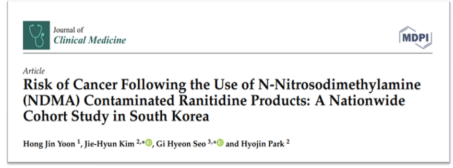
Key Points

Question Does ranitidine convert to *N*-nitrosodimethylamine (NDMA), a probable human carcinogen, in simulated gastric fluid at physiologic pH levels and nitrite concentrations?

Findings In this in vitro study of 150-mg ranitidine tablets added to simulated gastric fluid, NDMA did not form when gastric nitrite concentrations were at the upper range of physiologic or at nitrite concentrations as much as 50-fold greater than the upper range.

Meaning In this study, 150-mg ranitidine tablets did not convert to NDMA in simulated gastric fluid with physiologic nitrite concentrations.

3



- Cohort comprised of 40,488 ranitidine users and 10,122 famotidine users.
- Additionally, no significant differences were observed in the analysis of 11 single cancer outcomes.

Journal of Clinical Medicine

MDPI

Article

Risk of Cancer Following the Use of N-Nitrosodimethylamine (NDMA) Contaminated Ranitidine Products: A Nationwide Cohort Study in South Korea

Hong Jin Yoon [1], Jie-Hyun Kim [2,*], Gi Hyeon Seo [3,*] and Hyojin Park [2]

3

The Journal of Clinical Medicine 2021 publishes study which comments **"We found no evidence that exposure to NDMA through ranitidine increases the risk of cancer."**

FDA

Regulatory Focus™ > News Articles > 2021 > 6 > FDA studies: No post-ingestion NDMA from ranitidine

FDA studies: No post-ingestion NDMA from ranitidine

Posted 30 June 2021 | By Kari Oakes

"The cancer risk for an average individual with a mass of 50 kg and consuming 96 ng of **NDMA** daily for 70 years is 1 in 100,000."

FDA

USFDA: The product approvals were not withdrawn, and the FDA may consider allowing ranitidine products back on the market if they are proven to be stable, with low, acceptable amounts of NDMA that do not increase over time during storage.

Certificate of Suitability (CEP) for ranitidine restored by EDQM.

- **Certificate of Suitability (CEP) for ranitidine restored by EDQM**... In the relevant monograph of the European Pharmacopoeia.

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Industry Expectations

- Adopt risk based approach as per ICH Quality Risk Management Q9.
- Evaluate possibility of NDMA present in API.
- Focus on obtaining APIs with possibility of no NDMA or well within acceptable limit of NDMA
- Time frame of 6 months is given for the risk evaluation.
- Based on the outcomes of the risk evaluations further studies to be taken.
- Time frame of 3 years for completion of all related activities.
- Determine appropriate method analysis and ensure validated analytical methods are used.

Industry Expectations

- Infrastructure development for analysis of nitrosamines in the laboratories of:
  - API manufacturers
  - Formulation manufacturers
  - Government Laboratories
  - Accredited Laboratories.
- Awareness and education campaign to be taken by industrial association in consultation with regulatory authorities, so as to disseminate right information.
- Regulatory action, if any, to be in force from prospective effect and not retrospective.
- Similar approach to be taken for nitrosamines present in food and water supplies.

Thank You

Dr. Viranchi Shah, Sr. Vice President and National President (Elect), IDMA attended the inaugural session of the 14th Edition of CPHI and PMEC Expo held on 24th November 2021

• • •

Have you renewed your **Membership** for the years

2020-2021 & 2021-2022

If not, please do so; kindly contact IDMA Secretariat at:
Email: actadm@idmaindia.com / accounts@idmaindia.com
Tel.: 022 - 2494 4624 / 2497 4308 /Fax: 022 - 2495 0723

Mr Daara B Patel, Secretary - General, IDMA address at Indian-German Biotech & Pharma Conference on 30th November 2021 on Cooperation opportunities between German and Indian companies of the pharmaceutical industry

Good Morning Ladies and Gentlemen

Greetings from Indian Drug Manufacturers' Association (IDMA)

It gives me great pleasure and honour to address the august gathering & on behalf of our National President, Mr. Mahesh H Doshi, I thank the German Federal Ministry of Economic Affairs & Energy; Minister Counsellor, Economic Affairs; Mr. Lohse, Deputy Director Health Made in Germany, Manager Medical Biotechnology & Pharma; Team trAIDe Germany and Mediminds India. I also thank Mr. Kamal Shahani, Managing Director, Tenet Health Edutech Pvt. Ltd. for the excellent co-ordination.

Indian Drug Manufacturers' Association (IDMA) will be successfully completing 60 glorious years of its existence in January 2022. IDMA provides support to its members for supplying affordable quality medicines, not only to the people of India, but also to people all over the world. The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs. At present, we have 8 State Boards located in Tamil Nadu, Kerala & Puducherry, Gujarat, West Bengal, Haryana, Himachal Pradesh & Uttarakhand, Madhya Pradesh, Telangana & Karnataka.

IDMA, as the apex national body of Pharmaceutical and API manufacturers in our country, is rightly known as the ***"Voice of the National Sector".***

IDMA works with the Government of India on industry's development plans, represents the industry on prominent issues such as pricing, regulatory affairs, and other policy matters, and plays crucial role in keeping business leaders, media, and public informed about the industry.

IDMA is also spearheading the movement of harmonization of Pharmacopeias. Harmonization is very important so that we get quick approvals from every country.

As you are aware, our prices are extremely competitive and we supply to more than 200 countries. We are therefore considered as the **"Pharmacy of the World".**

INDIA – GERMANY – A Partnership to reckon with. This is what our Indian Government feels and we, at IDMA, reciprocate the same. History says that India was amongst the first nations to establish diplomatic ties with Germany post the World Wars and Post the economic reforms and liberalization of the Indian market in 1991, Germany has become one of India's most significant trade and investment partner.

Germany has invested over $13.19 bn in India between 2000 and 2021. The key areas of investments have been transportation, electrical equipment, metallurgical industries, services sector (particularly insurance), chemicals, construction activity, trading and automobiles. Currently, Over 1,600 Indo-German collaborations and 600 joint ventures are represented in the Indian market place.

Let's talk about Pharmaceuticals today

I believe that Indian pharmaceuticals is a formula for success

India has a prominent and rapidly growing presence in the global pharmaceuticals industry. It is the largest provider of generic medicines globally, occupying a 20% share in global supply by volume, and also supplies 62% of global demand for vaccines. India ranks 3rd worldwide for production by volume and 13th by value. India has the highest number of US-FDA compliant Pharma plants outside of USA and is home to more than 3,000 pharma companies with a strong network of over 10,500 manufacturing facilities. The Indian pharmaceutical industry is currently valued at USD $44.7 bn. of which 50% is exports.

The pharmaceutical industry in India offers 60,000 generic brands across 60 therapeutic categories. The API industry is the world's third largest, and it has 57% of APIs on the WHO List.

The plus points attracting India are

- Incentives worth INR 21,940 Crore ($3 Mn) are approved for the Indian pharmaceuticals market.
- The pharmaceutical industry in India is expected to reach $65 bn by 2024 and to $120 bn by 2030
- Pharmaceutical industry growth rate 10-12%
- Cost of manufacturing ~ 33% lower than western markets
- 18.7% year on year export growth

100% Foreign Direct Investment (FDI) in the Pharmaceutical sector is allowed under the automatic route for greenfield pharmaceuticals.

The other benefits of doing business with Indian Pharmaceutical Industry is

Production Linked Incentive (PLI) Scheme

The Indian pharmaceuticals market is supported by the following Production Linked Incentive Schemes to boost domestic manufacturing capacity, including high-value products across the global supply chain.

(a) PLI Scheme for Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) (PLI 1.0)

(b) Production-Linked Incentive (PLI) Scheme for Pharmaceuticals (PLI 2.0)

Germany Pharma Industry combines cutting edge-innovation and continuously growing demand for healthcare products which makes Germany the ideal location for pharmaceutical R&D, production, and sales of medicines.

Indian healthcare is one of the fastest growing sectors. Much of this growth can be attributed to the infusion of private equity & foreign investments. These investments have resulted in creation of new infrastructure by private providers. Additionally, investments by international healthcare groups in Indian market are expected to boost innovation & quality care.

India's ranking on the World Bank's Ease of Doing Business Index – which is part of its 'Doing Business' report – improved 14 notches to 63 (among 190 countries) in 2019. The government has drawn up a detailed action plan to break into the top 50.

The Government of India plays an important role in creating the vision for India's healthcare system. The Indian Government envisages the pre-dominant route of Public-Private-Partnerships (PPP) to create a legal framework, build competitiveness, build a market and supplier base for public-private contracts and implement strict controlling and performance monitoring. Following are few of the offers :

Indian Pharma Industry is offering the following to the World :

- **Innovation and R&D**
- **Medical tourism**
- **Infrastructure development**

  India has the highest number of US-FDA compliant plants outside the US. Over 1000 units have WHO GMP approvals.
- **Strong drug manufacturing**

  Expertise in low cost generic patented drugs as well as end-to-end manufacturing
- **Strong domestic demand**

  Launch of the largest National Health Protection Scheme
- **Upgraded IT services for Healthcare**
- **Clinical Research & Trials**
- **Equipment Manufacturing Units**

Having spoken to a number of Indian Pharma Companies and they are of the opinion that doing business with Germany is smooth and as such there are no major issues. Thus the mutual benefits of doing business with Germany is tremendous and we look forward to the growth of Indian Companies along with German Companies.

The COVID-19 pandemic has forced all companies to rethink many aspects of their business, including manufacturing and supply chains and the same holds true for pharma companies. The pandemic also highlights the need for improving the speed and accuracy of finding and mass-producing novel drugs, treatment methods, and vaccines to respond to such large-scale and high-pressure demands.

Identifying new opportunities and emerging technologies to implement into business early on goes a long way in gaining a competitive advantage.

We have the weekly IDMA Bulletin which is published and circulated to all our members and subscribers. The deliberations of this meeting will be published in our Bulletin for the benefit of all our members and readers.

Once again I thank everyone present here and welcome the delegation and look forward to an excellent interactive session.

Thank you.

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Applications for allocation of Tariff Rate Quota (TRQ) under India - Mauritius CECPA for the year 2021-22

Public Notice No.38/2015-2020, dated 22nd November, 2021

1. In exercise of powers conferred under paragraph 1.03 and 2.04 of the Foreign Trade Policy, 2015-20 and in continuation of Public Notice No.23/2015-20 dated 7th September, 2021, No.24/2015-20 dated 17th September 2021 and No.31/2015-20 dated 28th October 2021, regarding procedure for import of items under Tariff Rate Quota (TRQ) under India - Mauritius CECPA, the Directorate General of Foreign Trade hereby amends condition (ii) (f) of Annexure-III to Appendix-2A of Public Notice No.31/2015-20 dated 28th October 2021 by **extending the deadline for inviting applications for grant of import authorization from 31.12.2021 to 31.01.2022, for the current financial year 2021-22, with other modalities remaining the same.**

2. Effect of this Public Notice: The last date for submission of online applications for allocation of Tariff Rate Quota (TRQ) under India-Mauritius CECPA for the current financial year 2021-22, has been extended from 31.12.2021 to 31.01.2022.

File No.01/93/180/63/AM-21/PC-2[B]/e-27749

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

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Allocation of additional quantity of 303 MT for export of raw sugar to USA under Tariff Rate Quota (TRQ) for the Fiscal Year 2021

DGFT Public Notice No.39/2015-2020, dated 23rd November, 2021

In exercise of the powers conferred under Paragraphs 2.04 of the Foreign Trade Policy, 2015-2020, the Director General of Foreign Trade hereby allocates an additional quantity of **303 MT** raw sugar for export under Tariff Rate Quota (TRQ) to USA for the fiscal year 2021 (October 1, 2020 to December 31, 2021). With this additional allocation, quantity for export of sugar to USA under TRQ for the fiscal year 2021 would be as under:-

Public Notice No. & Date	Quantity of sugar allocated (MT)
Quantity allocated under Public Notice No. 33/2015-20 dated 18.12.2020	8424
Additional Quantity Allocated	303
Total Quantity Allocated	8727

Export of sugar (HS Code 17010000) to USA under TRQ is 'Free' subject to the conditions notified in the 'Nature of Restrictions' in Notification No. 3/2015-20 dated 20.04.2015. The reporting requirement as per Public Notice No. 33/2015-20 dated 18.12.2020 would continue to be followed.

Certificate of Origin, if required, for export of preferential sugar to USA, shall be issued by Additional Director General of Foreign Trade, Mumbai. Other certification requirement, if any, prescribed specifically for export of sugar to USA would continue to be followed.

Effect of this Public Notice:

Additional quantity of 303 MT of raw sugar, for export to USA, under TRQ, upto 31.12.2021, has been notified.

F.No.01/91/180/879/AM08/EC/Vol.VIII

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

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Constitution of Scientific Advisory Board (SAB) of PCIM&H

Drugs & Cosmetics Notification G.S.R.827(E), dated 28th October, 2021

(Published in the Gazette of India on 23rd November, 2021)

In continuation of Gazette Notification CG-DL-E-23032021-226036, Part-II, Section-3, Subsection (i) (Extra-Ordinary) dated 23rd March 2021, and in exercise of the powers conferred by Rule 163-AA(1) of Drugs and Cosmetics Rules, 1945, the Central Government, hereby constitutes Scientific Advisory Board (SAB) of Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H), Ghaziabad as follows:

Sr. No.	Member	Capacity in SAB
1.	Prof. M.C. Sharma	Chairman
2.	Director, PCIM&H	*Ex-officio* Member Secretary
3.	Advisor dealing with drugs, Ministry of Ayush	*Ex-officio* Member
4.	Drugs Controller General, India	*Ex-officio* Member
5.	Secretary cum Scientific Director, Indian Pharmacopoeia Commission	*Ex-officio* Member
6.	Director General, Central Council for Research in Ayurvedic Sciences	*Ex-officio* Member
7.	Director General, Central Council for Research in Siddha	*Ex-officio* Member
8.	Director General, Central Council for Research in Unani Medicine	*Ex-officio* Member
9.	Director General, *Central* Council for Research in Homoeopathy	*Ex-officio* Member
10.	Central Government Analyst for Ayurveda, Siddha, Unani and Homoeopathy, Drugs	*Ex-officio* Member
11.	Prof. Dr. Asmita Wele	Non-official Member (Ayurveda Expert)
12.	Dr. T. Anandan	Non-official Member (Siddha Expert)
13.	Prof. Dr. Mohammad Idris	Non-official Member (Unani Expert)
14.	Dr. Juhi Gupta	Non-official Member (Homoeopathy Expert)
15.	Dr. Indira Balachandran	Non-official Member (Pharmacognosy/Botany Expert)
16.	Dr. Subrata Dey	Non-official Member (Chemistry Expert)
17.	Dr. S.K. Srivastava	Non-official Member (Phyto-chemistry Expert)
18.	Dr. Muraldihar Ballal	Non-official Member (Pharmacy Expert)

2. The tenure of the Scientific Advisory Board (SAB) of PCIM&H) shall be for a period of three years from the date of notification or till further orders, whichever is earlier and the Members shall hold the office for that period.

F.No.Y-11015/11/2021-LP

Kavita Garg, Joint Secretary, Ministry of Ayush, New Delhi

The National Commission for Allied and Healthcare Professions 2nd (Removal of Difficulties) Order, 2021 published

Health & Family Welfare Order S.O.4842(E), dated November 2021

(Published in the Gazette of India on 24th November 2021)

Whereas the National Commission for Allied and Healthcare Professions Act, 2021 (14 of 2021) (hereinafter referred to as the Act) came into force on 25th May, 2021, in terms of Section 1(2) of the Act.

AND WHEREAS sub-section (1) of section 22 provides that every State Government shall, by notification, within six months from the date of commencement of this Act, constitute a State Council to be called the State Allied and Healthcare Council for exercising such powers and discharging such duties as may be laid down under this Act.

AND WHEREAS due to the second wave of the Covid pandemic in India, State Allied and Healthcare Councils could not be constituted by State Governments within stipulated period and because of that difficulties have arisen in compliance with the said provisions of section 22 of the Act.

AND WHEREAS, in exercise of the powers conferred by section 69 of the Act, the Central Government hereby makes the following Order, to remove the above said difficulties, namely:

1. Short title and commencement:

   1. This Order may be called the **National Commission for Allied and Healthcare Professions 2nd (Removal of Difficulties) Order, 2021.**

   2. It shall come into force on the date of its publication in the official Gazette.

It is hereby clarified that All the State Governments/ Union Territories shall, as soon as may be but within one year from the date of commencement of the National Commission for Allied and Healthcare Professions Act, 2021, constitute State Allied and Healthcare Councils.

F.No.Z-28016/03/2021-AHS

V. Hekali Zhimomi,
Joint Secretary,
Ministry of Health and Family Welfare,
New Delhi

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Plant Quarantine (Regulation of Import into India) Order, 2003 amended (Ninth Amendment of 2021)

Notification S.O.4870(E), dated 25th November, 2021

In exercise of the powers conferred by sub-section (1) of section 3 of the Destructive Insects and Pests Act, 1914 (2 of 1914), the Central Government hereby makes the following Order further to amend the Plant Quarantine (Regulation of Import into India) Order, 2003, namely:-

1. Short title and Commencement-

(1) This Order may be called the **Plant Quarantine (Regulation of Import into India) (Ninth Amendment) Order, 2021.**

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

2. Amendment of Schedule VI.- In the Schedule VI to the Plant Quarantine (Regulation of Import into India) Order, 2003-

(i) Against serial number 564, relating to "Persea americana (Avocado)" in column (3) against the entry (v) regarding "Fresh Fruit for Consumption", after the existing entries the following entries in columns (4), (5) and (6) shall respectively be inserted, namely:

(4)	(5)	(6)
(ii) Tanzania	Free from: Insects/ Mites: a) *Amorbia cuneana* (Avocado leafroller), b) *Ceratitis capitata* (Mediterranean fruit fly), c) *Ceratitis rosa* (Natal fruit fly), d) *Ceroplastes destructor* (White waxscale), e) *Helopeltis schoutedeni* (Cacao mosquito), f) *Pseudotheraptus wayi* (Coconut bug), g) *Scirtothrips perseae (Avocado thrips),* h) *Spodoptera littoralis* (Cotton leafworm), i) *Thaumatotibia leucotreta* (False codling moth), Plant pathogens: j) *Sphaceloma perseae* (Avocado scab), k) *Avocado sunblotch viroid*	1. Export consignment must comply with Systems Approach for production and export and 2. Methyl bromide fumigation @32 g/m3 for 2 hrs at 21°C or above at NAP or equivalent thereof against Mediterranean fruit fly and Natal fruit fly or 3. Pre-shipment/in-transit cold treatment at 0°C or below for 10 days; 0.55°C or below for 11 days; 1.1°C or below for 12 days plus intransit refrigeration against Mediterranean fruit fly and Natal fruit fly. The details on treatment and Production under Systems Approach should be endorsed on Phytosanitary Certificate issued at the country of Origin/ Re export [Special condition of import on in- transit cold treatment will come into force on successful completion of 10 trial shipments]

F.No.8-34/2021-PP.II

Pramod Kumar Meherda, Jt. Secy., Ministry of Agriculture and Farmers Welfare (Department of Agriculture and Farmers Welfare) New Delhi.

Note : *The Plant Quarantine (Regulation of Import into India) Order, 2003 was published in the Gazette of India, vide, number S.O.1322 (E) dated 18th November, 2003, and subsequently amended vide number S.O.167(E), dated 6th February 2004, S.O.427(E), dated 29th March, 2004, S.O.644(E), dated 31st May 2004, S.O.263(E), dated 25th February 2005, S.O.462 (E), dated 31st March 2005, S.O.1121 (E), dated 14th July 2006, S.O.1353 (E), dated 31st July 2006, S.O.1873 (E), dated 31st October 2006, S.O. 2074 (E), dated 6th December 2006, S.O.2069 (E), dated 3rd December, 2007, S.O.3(E), dated 1st January, 2008, S.O.2847 (E), dated 8th December, 2008, S.O.2888(E), dated 15th December, 2008, S.O.2286 (E), dated 9th September, 2009, S.O.2390 (E), dated 16th September, 2009, S.O.3269 (E), dated 23rd December, 2009, S.O.3298 (E), dated 24th December, 2009, S.O.907(E), dated 21st April, 2010, S.O.2095(E), dated 27th August, 2010, S.O.2284(E), dated 15th September, 2010, S.O.2516 (E), dated 11th October, 2010, S.O.2711 (E) dated 4th November, 2010, S.O.3052(E) dated 28th December, 2010, S.O.887 (E) dated 28th April, 2011, S.O.No.2845 (E) dated 21st December, 2011, S.O.No.296 (E) dated 17th February, 2012, S.O.2775(E) 23rd November, 2012 S.O.799(E) dated 21st March, 2013, S.O.1378(E) dated 28th May, 2013, S.O.1531(E) dated 14th June, 2013, S.O.2919(E) dated 26th September, 2013, S.O.1508(E) dated 13th June, 2014, S.O.No.1632(E) dated 27th June, 2014, S.O.No.2320(E) dated 12th September, 2014, S.O.No.2542(E) dated 29th September, 2014, S.O.No.2879(E) dated 11th November, 2014, S.O.No.3114(E) dated 10th December, 2014, S.O.No.1413(E) dated 26th May, 2015, S.O.No.2496(E) dated 15th September, 2015, S.O.No.101(E) dated 13th January, 2016, S.O.No.608(E) dated 7th March, 2016 S.O.No.1873(E) dated 25th May, 2016, S.O.No.2192(E) dated 20th June, 2016, S.O.No.2248(E) dated 29th June, 2016, S.O.No.2453(E) dated 5th July, 2016, S.O.No.2614(E) dated 5th August, 2016 and S.O.No.264(E) dated 12th January, 2017, S.O.No.364(E) dated 3rd February, 2017, S.O.1344 (E) dated 27th April, 2017, S.O.1475 (E) dated 8th May, 2017, S.O.2019 (E) dated 21st June, 2017 and S.O.2152 (E) dated 6th July, 2017 and S.O.No.2752 (E) dated 23rd August, 2017, S.O.No.3293(E) dated 6th October, 2017, S.O. No.3556(E) dated 7th November, 2017 and S.O.No.4082(E) dated 27th December, 2017, S.O.No.1248(E) dated 20th March, 2018, S.O.No.1873(E) dated 10th May, 2018, S.O.No.1930 dated 15th May, 2018, S.O.No.2059(E) dated 24th May, 2018, S.O.No.2286(E) dated 4th June, 2018 and S.O.No.3194(E) dated 29th June, 2018, S.O.No.3392(E) dated 10th July, 2018, S.O.No.3998(E) dated 16th August, 2018, S.O.No.5158(E) dated 3rd October, 2018 and S.O.No.5830(E) dated 22nd November, 2018 and S.O.No.6224(E) dated 18th December, 2018, S.O.No.941(E) dated 19th February, 2019 and S.O.No.1728(E) dated 6th May, 2019, S.O.No.1817(E) dated 24th May, 2019, S.O.No.1954(E) dated 11.06.2019, S.O.No.2525(E) dated 15th July, 2019 and S.O. No.2603 (E) dated 18th July, 2019 and S.O.No.3141(E) dated 29th August, 2019; S.O.No.3594(E) dated 1st October, 2019 and S.O.No.3845(E) dated 24th October, 2019 and S.O.No.4083(E) dated 8th November, 2019 and S.O.4615 (E) dated 21st December, 2019 and S.O.352(E) dated 24th January, 2020 81. S.O.488 (E) dated 31st January, 2020 82. S.O.953 (E) dated 2nd March, 20202020 and S.O.No.1404(E) dated 27th April, 2020, S.O.No.2390(E) dated 20th July, 2020; S.O.No.3646(E) dated 14th October, 2020 and S.O.No.4243(E) dated 17th November, 2020 and S.O. No.681(E) dated 10th February, 2021, , S.O.No.1491(E) dated 7th April, 2021, S.O. No.2511(E) dated 10th June, 2021, S.O.No.2512(E) dated 10th June, 2021 and S.O.No.4265(E) dated 13th October, 2021.*

Coastal Regulation Zone Notification, 2019 published vide number G.S.R. 37(E), dated 18th January 2019 amended

Environment Notification S.O.4886(E) dated 26th November 2021

WHEREAS by notification of the Government of India in the Ministry of Environment, Forest and Climate Change, number G.S.R. 37(E), dated the 18th January, 2019 (hereinafter referred to as the Coastal Regulation Zone Notification, 2019), the Central Government declared certain coastal stretches as Coastal Regulation Zone (CRZ) and restrictions were imposed on the setting up and expansion of industries, operations and processes in the said zone;

AND WHEREAS, the Central Government have received representations from the State Governments for inclusion of those provisions in CRZ Notification 2019, which were already available in the CRZ Notification, 2011 but have been missed out in the CRZ Notification 2019, with regard to restricting demarcation of High Tide Line (HTL) in Khazan Land to the bund / sluice gate, collection of dead shells by traditional communities in CRZ areas and delineation of HTL and CRZ categories in the Sundarbans Biosphere Reserve;

AND WHEREAS, the provisions related to demarcation of High Tide Line (HTL) in Khazan Land to the bund/sluice gate and delineation of HTL and CRZ categories in the Sundarbans Biosphere Reserve were incorporated in the CRZ Notification 2011, through amendment vide notification number S.O.1422 (E), dated the 1st May 2020, however, these provisions could not be incorporated in CRZ Notification 2019, as it was notified on 18th January, 2019 i.e. before the above-said amendment dated the 1st May 2020;

AND WHEREAS, the provisions related to collection of dead shells by traditional communities in CRZ areas was included in the CRZ Notification 2011 through notification number S.O.19(E), dated the 6th January 2019, however, the same was erroneously left out in the subsequent amendment vide number G.S.R.1227(E), dated the 6th October 2017, and as such, the same could not be incorporated in the CRZ Notification 2019;

AND WHEREAS, the National Coastal Zone Management Authority (NCZMA) in its 42nd meeting held on the 23rd March, 2021 has recommended that the above-said provisions which were already available in the CRZ Notification, 2011 and had been inadvertently or erroneously missed out in the CRZ Notification, 2019, shall be included in the CRZ Notification, 2019;

AND WHEREAS, in view of the fact that the provisions already applicable vide CRZ Notification, 2011, are proposed to be included in the CRZ Notification, 2019, and as there is no fresh restriction or prohibition being imposed vide proposed amendment notification, therefore, the requirement of notice under clause (a) of sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986 is hereby dispensed with in public interest;

NOW THEREFORE, in exercise of the powers conferred by sub-section (1) and clause (v) of sub section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following amendments in the Coastal Regulation Zone Notification, 2019, namely:

1. In the said notification, -

(i) in paragraph 1, in clause (i), for the Explanation, the following Explanation shall be substituted, namely, -

"Explanation. - For the purposes of this notification,-

(a) the HTL means the line on the land upto which the highest water line reaches during the spring tide as demarcated by the National Centre for Sustainable Coastal Management (NCSCM) in accordance with the laid down procedures and made available to various coastal States and Union territories;

(b) in case there exists a bund or a sluice gate constructed prior to the date of notification issued vide S.O.114(E) dated 19th February, 1991, the HTL shall be restricted up to the line long along the bund or the sluice gate, however, in such a case, area under mangroves arising

due to saline water ingress beyond the bund or sluice gate shall be classified as CRZ-IA irrespective of the extent of the area beyond the bund or sluice gate and such areas under mangroves shall be protected and shall not be diverted for any developmental activities."

2. In paragraph 2, in sub-para 2.1.1, in clause (a), in sub-clause (v), the following sub-clause shall be inserted after the words 'Biosphere Reserves', namely: -

"(v) ..except in the case of the Sundarbans Biosphere Reserve, wherein, the categorization of CRZ and delineation of the HTL and CRZ boundaries shall be done in consonance with the provisions of this Notification".

Note: The CVCA delineated within the Sundarbans Biosphere Reserve shall be managed through the Integrated Management Plan prepared by the State Government and approved by the Central Government."

3. In paragraph 5, in sub-para 5.1.2, after sub-clause (xviii), the following sub-clause shall be inserted, namely: -

"(xix) Collection of dead shells by traditional communities for poultry and animal feed supplements and shall not require prior CRZ clearance;"

F.No.19-112/2013 -IA III (pt)

Dr Sujit Kumar Bajpayee, Joint Secratary,
Ministry of Environment,
Forest and Climate Change,
New Delhi.

Note: *The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number G.S.R.37(E), dated the 18th January, 2019.*

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NPPA MATTERS

NPPA fixes the Retail Price of specified 47 Formulation/ Brand Name under the Drugs (Price control) order, 2013

NPPA Order S.O.4884(E), dated 26th November 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.	Telmisartan + Chlorthalidone Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 80.mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Mankind Pharma Ltd.	16.27

2.	Cefixime Tablets	Each film coated tablet contains: Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 100mg	1 Tablet	M/s. Hema Laboratories Pvt. Ltd. / M/s Softdeal Pharmaceuticals Pvt. Ltd.	5.99
3.	Tacrolimus Ointment 0.1% w/w	Each gm of Ointment contains: Tacrolimus IP 1mg	1 gram	M/s Helios Pharmaceuticals / M/s Panacea Biotec Pharma Limited	35.44
4.	Tacrolimus Ointment 0.03% w/w	Each gm of Ointment contains: Tacrolimus IP 0.3mg	1 gram	M/s Helios Pharmaceuticals / M/s Panacea Biotec Pharma Limited	16.41
5.	Etoricoxib + Paracetamol Tablet	Each film coated tablet contains Etoricoxib IP 60 mg Paracetamol IP 325 mg	1 Tablet	M/s Acme Lifetech LLP. / M/s Troikaa Pharmaceuticals Ltd.	5.50
6.	Telmisartan + Chlorthalidone + Metoprolol (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as Extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	10.88
7.	Telmisartan + Chlorthalidone + Metoprolol (As Extended release form) Tablet	Each film-coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.5mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as Extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	12.91
8.	Calcium + Cholecalciferol Tablets	Each film-coated tablet contains: Calcium (In the form of Calcium hydroxide and Calcium oxide pretreated with heated algae) 500mg Cholecalciferol IP 2000IU,	1 Tablets	M/s USV Private Limited.	12.64
9.	Cilnidipine, Telmisartan & Chlorthalidone Tablets	Each Film Coated Tablet contains: Cilnidipine IP 10mg, Telmisartan IP 40mg and Chlorthalidone IP 6.25 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Dr. Reddy's Laboratories Ltd.	11.61
10.	Paracetamol bilayered Tablet 1000mg	Each uncoated bilayered tablet contains: Paracetamol IP 300mg (as Immediate release) Paracetamol IP 700mg (as sustained release)	1 Tablet	M/s. Sterling Lab	2.90

11.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	9.86
12.	Glimepiride + Metformin Hydrochloride (as Prolonged release form) Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochloride IP 500mg (as Prolonged release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s J. B. Chemicals & Pharmcaeuticals Ltd.	9.41
13.	Telmisartan, Chlorthalidone & Amlodipine Tablet	Each film coated tablet contains: Telmisartan IP 40 mg, Chlorthalidone IP 6.25mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s Mankind Pharma Ltd.	8.92
14.	Telmisartan, Chlorthalidone & Amlodipine Tablet	Each film coated tablet contains: Telmisartan IP 40 mg, Chlorthalidone IP 12.50 mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s Mankind Pharma Ltd.	9.95
15.	Chlorthalidone + Telmisartan Tablet	Each film coated Tablet contains: Chlorthalidone IP 6.25mg Telmisartan 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Micro Labs Limited	8.60
16.	Metoprolol Tartrate + Ivabradine Tablet	Each film coated tablet contains: Metoprolol Tartrate IP 25mg Ivabradine Hydrochloride eq. to Ivabradine 5mg	1 Tablet	M/s. Ajanta Pharma Limited	15.46
17.	Metoprolol Tartrate + Ivabradine Tablet	Each film coated tablet contains: Metoprolol Tartrate IP 50mg Ivabradine Hydrochloride eq. to Ivabradine 5mg	1 Tablet	M/s. Ajanta Pharma Limited	17.74
18.	Lignocaine Hydrochloride, Chlorhexidine Gluconate & Metronnidazole Gel	Gel contains: Lignocaine Hydrochloride IP 2.0%w/w, Chlorhexidine Gluconate IP 1% w/w, Metronnidazole 1% IP w/w	1 Gram	M/s Curetech Skincare / M/s J.B.Chemicals & Pharmaceuticals Ltd.	3.48
19.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	10.88

20.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	10.81
21.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg, Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	12.91
22.	Azelnidipine + Telmisartan Tablet	Each film coated bi- layered tablet contains: Azelnidipine IP 8mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	11.37
23.	Azelnidipine + Telmisartan Tablet	Each film coated bi- layered tablet contains: Azelnidipine IP 8mg Telmisartan IP 80mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	13.27
24.	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / Cadila Pharmaceuticals Ltd.	19.64
25.	Rosuvastatin + Aspirin Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets), Aspirin IP 75mg (As enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / Cadila Pharmaceuticals Ltd.	5.99
26.	Telmisartan + Amlodipine Tablet	Each Uncoated bilayered Tablet Contains: Telmisartan IP 40mg, Amlodipine Besilate IP eq. Amlodipine 5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s J. B.Chemicals & Pharmaceuticals Ltd.	9.51
27.	Telmisartan + Cilnidipine + Metoprolol Succinate (ER)Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartarate 25 mg (as Extended Release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s J.B.Chemicals & Pharmaceuticals Ltd.	10.68

28.	Telmisartan + Cilnidipine + Metoprolol Succinate (ER) Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartarate 50 mg (as Extended Release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s J.B.Chemicals & Pharmaceuticals Ltd.	12.95
29.	Glimepiride + Metformin Hydrochloride (as Prolonged release form) Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1mg, Metformin Hydrochloride IP 500mg (as Prolonged release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. /M/s J. B. Chemicals & Pharmcaeuticals Ltd.	6.72
30.	Atorvastatin + Aspirin Capsule	Each hard Gelatin Capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Film Coated Tablet Form), Aspirin IP 75mg (As Enteric Coated Tablet Form)	1 Capsule	M/s Pure & Cure Healthcare Pvt. Ltd. /M/s J. B. Chemicals & Pharmcaeuticals Ltd.	2.68
31.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	9.86
32.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg, Metoprolol Succinate IP 23.75mg, eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	10.88
33.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 6.25mg, Metoprolol Succinate IP 47.50mg, eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	10.81
34.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg, Metoprolol Succinate IP 47.50mg, eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	12.91

35.	Escitalopram Oxalate + Clonazepam Tablet	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.5mg	1 Tablet	M/s Windlas Biotech Limited / M/s Mankind Pharma Ltd.	7.81
36.	Escitalopram Oxalate + Clonazepam Tablet	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 10mg, Clonazepam IP 0.25mg	1 Tablet	M/s Windlas Biotech Limited / M/s Mankind Pharma Ltd.	9.56
37.	Escitalopram Oxalate + Clonazepam Tablet	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 20mg Clonazepam IP 0.5mg	1 Tablet	M/s Micro Labs Limited	19.92
38.	Escitalopram Oxalate + Clonazepam Tablet	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg Clonazepam IP 0.5mg	1 Tablet	M/s Micro Labs Limited	7.90
39.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Intas Pharmaceuticals Limited	12.91
40.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Intas Pharmaceuticals Limited	10.88
41.	Cilnidipine, Telmisartan & Chlorthalidone Tablets	Each Film Coated Tablet contains: Cilnidipine IP 10mg, Telmisartan IP 40mg, Chlorthalidone IP 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Ltd.	12.946
42.	Formoterol Fumarate + Budesonide Powder for Inhalation	Each hard gelatin capsule contains: Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg Budesonide IP 400mcg	1 Capsule	M/s Biodeal Pharmaceuticals Pvt. Ltd./ M/s Mankind Pharma Limited	7.10

43.	Omeprazole (Delayed-Release) + Domperidone (Sustained Release) Capsule	Each hard gelatin capsule contains: Omeprazole IP 20mg (as enteric coated pallets), Domperidone IP 30mg (as sustained release pallets)	1 Capsule	M/s. Eris Lifesciences Ltd. / M/s Eris Healthcare Pvt. Ltd.	8.53
44.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Torrent Pharmaceuticals Limited	12.91
45.	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	10.88
46.	Hydroxychloroquine Tablet	Each film coated tablet contains: Hydroxychloroquine Sulphate IP 300 mg	1 Tablet	M/s Ravenbhel Biotech /M/s Torrent Pharmaceuticals Limited	12.55
47.	Beclomethasone Dipropionate + Clotrimazole Cream base	Gram Contains: Beclomethasone Dipropionate IP 0.025% w/w, Clotrimazole IP 1.0%w/w,	1 Gram	M/s Curetech Skincare / M/s J. B. Chemicals & Pharmaceuticals Ltd.	5.20

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

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NPPA fixes the Ceiling Price of specified 2 Formulation under the Drugs (Price control) order, 2013

NPPA Order S.O.4885(E) dated 26th November 2021

In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O.1394(E) dated the 30th May, 2013 and S.O.701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Methylthioninium chloride (Methylene blue)	Injection 10mg/mL	1 ML	21.85
2.	Hydroxocobalamin	Injection 1 mg/mL	1 ML	9.91

Note:

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

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

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

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

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

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

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

discontinuation of production and/or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

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

(i) Consequent to the issue of ceiling 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, Dy. Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi

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Complaints under Paragraph 28 of the Drugs (Prices Control) Order, 2013 regarding refusal to sell drugs by manufacturers - reg.

Office Memorandum 22nd November 2021

To
All manufacturers,
All stakeholders.

1. The Drugs (Prices Control) Order, 2013, issued under Section 3 of Essential Commodities Act, 1955, provides, under paragraph 28, that:

"Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder, -

a) *no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without. good and sufficient reasons;*

b) *no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug."*

2. As per the prevailing supply chain model(s), the manufacturers supply drugs to the market through their authorized distributors, who then supply drugs to other dealers including retail dealers.

3. A number of complaints are received in this office from persons/ firms, who intend to become dealer of a particular manufacturer and the manufacturer refuses to appoint them as authorized dealer. Similarly, complaints are received wherein the manufacturer refuses to sell drugs directly to a person/ firm and redirects him to the authorized dealer. In such cases, the complainant requests NPPA to invoke paragraph 28 of DPCO, 2013.

4. It may be noted that the demand to procure drugs directly from the manufacturer or the demand to be appointed as authorized dealer arise from the commercial interests of the complainant. This office has, time and again, clarified that commercial issues/ terms/ disputes etc. between the dealer and concerned Company or its distributor/ stockist are not within the purview of or resolved by NPPA.

5. Notwithstanding the above, the manufacturers may note that they shall give utmost importance to public interest in all such cases and ensure proper distribution of drugs and ensure sufficient availability in the market. In case any aspect of public interest is adversely affected in such cases, this office shall be duty bound to invoke Paragraph 28 and take appropriate action, including passing orders under Paragraph 3 of Drugs (Prices Control) Order, 2013 and/ or prosecution under Section 7 of the Essential Commodities Act, 1955.

F.No.16(1)/2021/ Div-III/ NPPA

Saurabh Bansal,
Deputy Director, Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals,
National Pharmaceutical Pricing Authority, New Delhi.

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WHO urges countries to support IP waiver

WHO chief calls on countries to speed up negotiations "that result in a text that countries can implement easily in their national legislation"

The World Health Organization has called for the Canadian government's support on the proposal at that World Trade Organisation, seeking a temporary waiver on intellectual property (IP) on Covid-linked products.

In fact, WHO chief Tedros Adhanom Ghebreyesus also called on countries to support the IP waiver on not just Covid vaccines, but other products as well. The proposal at the WTO was made by India and South Africa, but has since got much support from over 100 countries.

Speaking at a recent conclave on the issue, the WHO chief said: "We seek the support of the Canadian government for the TRIPS waiver for Covid products at the WTO Ministerial Conference that begins this week."

He then called on the support of all countries to speed up negotiations "that result in a text that countries can implement easily in their national legislation".

Further, he said the WHO "strongly recommends" that the waiver apply not only to vaccines, but also to diagnostics, therapeutics and other tools to prevent, diagnose and treat Covid.

Addressing the South African Development Community, the WHO chief urged members to explore avenues to rapidly scale up production, including through the use of TRIPS flexibilities, technology pools, voluntary licenses, and by investing in local production.

He reiterated this call against the backdrop of the grave inequities in access to Covid vaccines.

"There remains a shocking imbalance in the global distribution of vaccines. Over 7.3 billion vaccines have been administered globally, but nearly 70 per cent of those have gone to just 10 countries. Almost 40 per cent of the world's population is now fully vaccinated, but in Africa it's only 6 per cent."

Tech transfer

Further, he pointed out that the same inequities in access were surfacing in the context of tests and treatments. In the short term, it's essential to remove all barriers to scaling up production, including "through technology transfer, freeing up supply chains, and a waiver of intellectual property rights under the TRIPS agreement for the duration of the pandemic", he said.

Last year, C-TAP (the Covid Technology Access Pool) was established to facilitate the voluntary, transparent and non-exclusive licensing of patents, transfer of know-how and data. The first licensing and technology transfer agreement for C-TAP has been announced with the Spanish National Research Institute, for a worldwide, transparent and non-exclusive voluntary license for the production of a Covid antibody test, he said.

Source: The Hindu Business Line, 24.11.2021

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The pandemic is an opportunity to correct some historical wrongs

Sachin Chaturvedi writes: The 12th Ministerial Conference of WTO must grant TRIPs waiver for vaccines, Covid-related medical supplies

In the run-up to the 12th ministerial conference (MC-12) of the World Trade Organisation (WTO), access to vaccines has emerged as the most contentious issue. The role of associated intellectual property, in the context of the pandemic, is being discussed since India and South Africa placed their joint proposal at the WTO in October 2020

and a revised proposal in May 2021. Though the TRIPs limitation for latecomers to the technology race was always described by developing countries as a historical injustice, the recent Covid-19 pandemic is being seen as the final wake-up call for doing away with the historical wrongs in global norm-setting multilateral institutions.

With the support of more than 100 low-income countries, India's leadership of the South is well-established. With the further enrichment of the R&D eco-system and the prime minister's direct engagement, India's efforts towards excellence in the domestic production of vaccines with its own R&D have further given a boost to New Delhi's negotiating position at the WTO.

In the next couple of days is the final round of debates on whether a temporary TRIPs waiver is a step in the right direction. Ambassador Dagfinn Sørli of Norway, Chair, Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) is expected to come out with a text for further negotiations at the Ministerial Conference. During the recent visit of WTO Director General Ngozi Okonjo-Iweala to Delhi, Commerce Minister Piyush Goyal emphatically raised the issue of equity and suggested an early outcome of the ongoing text-based negotiations at the WTO on Covid-19-related medical products, including vaccines. Unfortunately, even after a year, it seems that WTO members' positions remain divergent on the appropriate and most effective way to address issues related to access, equity and inclusion (AEI) for Covid-19 vaccines and other medical products.

As is fairly clear, left to big pharma, the vaccines would not have reached many countries. India led from the front — the Vaccine Maitri programme worked on the premise that "no one is safe until everyone is safe". Through this initiative, India could supply more than 65 million doses of Covid-19 vaccines to about 100 countries. Besides, India also provided critical medicines, diagnostic kits, ventilators and personal protective equipment to more than 150 countries. Due to New Delhi's pressure, global supply lines have remained open throughout for key components of vaccines being produced in India and elsewhere. India has significantly contributed to the COVAX facility (which is co-led by CEPI, Gavi and WHO, alongside key delivery partner UNICEF) as well. India has also gifted 2,00,000 doses of Covid-19 vaccines for UN peacekeepers across all UN missions. After the major disruption with the second wave within India, now it seems the decision to resume exports is being implemented.

The MC-12 should go a step further and acknowledge the willingness of the South in creating global public good. As may be recalled, India was also one of the initiators of the "Political Declaration on Equitable Global Access to Covid-19 Vaccines" in March 2021. This Declaration has garnered the support of more than 180 UN member states. It pledged to treat Covid-19 vaccination as a global public good (GPG) by ensuring affordable, equitable and fair access to vaccines for all. It called for rapid scaling up and expansion of vaccine production globally, including in developing countries, through appropriate dissemination of technology and know-how, for example, through using WTO TRIPS flexibilities. But it's very much clear that without having the TRIPS waiver on Covid-19 vaccines and other medical products, such scaling up and enhancement of production capacity is not feasible.

India is a vaccine supplier, not a recipient in waiting. It has remained steadfastly committed to this idea despite pressure from the European Union, United Kingdom and Switzerland. These countries are preventing access to vaccines for poor countries, making them suffer and leading to loss of life. India has clearly stated in the UN General Assembly meeting that vaccine inequity will defeat the collective global resolve to contain the coronavirus as the disparity in the accessibility of vaccines will affect the poorest nations the most. At the same time, it is utterly frustrating to read the recent news about the wastage of 6,00,000 vaccine doses in the UK, which is a great loss to poorer countries struggling to access Covid-19 vaccines.

Though it remains to be seen whether WTO members will reach an agreement on these issues before or at the 12th WTO Ministerial Conference, planned for 30 November 30- December 3 at Geneva (co-hosted by Kazakhstan), it's high time for the global community to act collectively and urgently to address one of the most pressing global health challenges impacting humanity. It must do so to avoid plunging into a catastrophic moral failure as a result of its indifferent approach and unequal sharing of products and technical know-how. India is committed to continuing its efforts and to lead from the front to ensure the meaningful completion and implementation of the TRIPs waiver in favour of developing and least developed countries. In this regard, all eyes are looking for a positive outcome of the MC-12 as far as the TRIPs waiver is concerned. This can ensure AEI for developing countries.

This column first appeared in the print edition on November 25, 2021 under the title 'A waiver for humanity'. The writer is director general, Research and Information System for Developing Countries (RIS). Views are personal

Source: Sachin Chaturvedi, The Indian Express, 29.11.2021

IPCA Laboratories to pick up 26.57% stake in Lyka for ₹97.89 cr

Ipca Laboratories said its board of directors had approved the acquisition of 26.57 per cent of the paid-up share capital of Lyka Labs, for ₹97.89 crore. The deal will mark Ipca's entry into the lucrative lyophilized injectables business.

The company has also got its board's go-ahead to enter into a joint management control agreement with the promoters of Lyka Labs, a company incorporated in 1976. In fact, it would pick up an additional 26 percent equity shares of Lyka from its public shareholders, in accordance with the rules, Ipca told the Bombay Stock Exchange.

What Lyka does

Lyka makes and markets injectables, lyophilized injectables and topical formulations. And a major part of its business is from India and rest of the world (ROW) markets. It has a manufacturing facility in Ankleshwar, Gujarat.

Ipca currently does not have any business directly from lyophilized injectables. The acquisition of this shareholding would enable it to enter into lucrative lyophilized injectables business in India and ROW markets, it said.

Further, it added that Lyka would also benefit from its marketing expertise in the branded generic formulations businsess of the ROW markets of Africa, Latin America, South East Asia and Middle East where Lyka does not do business

Ipca shares closed slightly up at ₹2,060.35 on the BSE on Wednesday.

Source: The Outreach, 29.11.2021

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Centre allows exporters time till January 31 on origin e-certificate

Three-month breather expected to ease operational challenges for businesses

The Centre has suspended till January 31 a mandatory obligation imposed on exporters from November 1 to obtain online Certificates of Origin (CoO) for every outbound consignment, days after *The Hindu* reported **businesses were facing severe operational challenges** in trying to comply with the diktat.

The online CoO system, put in place in late 2019 for exports to countries with whom India had a preferential trade pact, was expanded to cover all merchandise exports from November through a trade notice issued on October 18.

In a fresh notice last Monday, the Department of Commerce said that 'the transition period for mandatory filing of applications for Non-Preferential Certificate of Origin through the e-CoO platform had been extended' till January 31.

"The existing systems for submitting and processing non-preferential CoO applications in manual/paper mode is being allowed for the stated time period and the online system is not being made mandatory," it clarified.

Several exporters across States had reported difficulties in registering on the e-CoO platform on the Directorate General of Foreign Trade (DGFT) portal with the stipulated high-quality digital signature certificates and obtaining the certificates for their shipments. The department, which oversees DGFT, has now requested exporters to register onto the platform at the earliest.

In the first half of this month, when the online certificates were mandatory, the department had downplayed exporters' concerns and said the move was aimed at improving the ease of doing business in line with the government's 'Digital India' focus.

Industry bodies had pointed out that existing export facilitation intermediaries such as customs house agents, who handle most of the export paperwork, had not been able to share data on exporters' behalf, as the DGFT had not shared the API (Application Programming Interface) for the new platform.

On November 10, in response to queries from *The Hindu*, the department had said that the e-CoO platform had a simple registration process and its design allowed the principal user or the exporter to provide access rights to the other secondary users such as customs house agents. While it didn't respond to a query on whether API-sharing was being considered, it had said 85 agencies had already been 'enabled on the portal'.

The Federation of Indian Exporters' Organisations had urged the government to resolve the teething challenges

and allow API-sharing to help the exporting community on-board the new system of digital certification more quickly, while noting that the e-CoO would address a number of concerns for exporters and the importing countries.

"This online facility provides 'ease of doing business' to the exporting community and gives a verifiable authentication mechanism to the partner countries to confirm the genuineness of the issued CoOs through a QR code which adds credibility to the issued e-CoO," the department had said.

India's monthly merchandise exports have crossed $30 billion for seven months in a row and are largely on course to reach the government's target of a record $400 billion in 2021-22.

"We appreciate the positive response of the government towards our request for an urgent intervention," said Santosh Mandlecha, president of the Maharashtra Chamber of Commerce, Industry and Agriculture. The industry body had flagged that even perishable farm produce consignments had been facing challenges since November 1 due to difficulties in registering digital signatures on the DGFT portal.

Source: Vikas Dhoot, 23.11.2021

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CEPI expands scope of its centralised laboratory network beyond Covid-19

Initiative open to Indian laboratories to participate

The Coalition for Epidemic Preparedness Innovations (CEPI) is taking the learnings from its Covid-19 vaccine testing network to other priority diseases, including "Disease X", cause by an unknown lurking pathogen.

CEPI is expanding its international laboratory network, that was set up against the backdrop of the pandemic, to now assess the development of vaccines against other epidemic and pandemic diseases. And this initiative was open to Indian laboratories who want to be part of this network, Valentina Bernasconi, scientist with CEPI and Project Leader for the Centralised Labs Network told BusinessLine.

The call for proposals is two-fold, Bernasconi said, speaking from Oslo. One involved expanding the centralised network to support Covid-19 vaccine development in regions that are not presently represented, such as South America, Africa, and the Oceania region. India, for instance, is already represented on this centralised network through Translational Health Science and Technology Institute (THSTI).

And the second part of announcement, involved expanding the international laboratory network to support vaccine development for more diseases, and this was open to more Indian laboratories, she said.

Expanded network

CEPI's centralised laboratory network is the largest global group using the same methods and materials, like reagents — substances used to carry out a scientific test — to standardise the evaluation of infectious disease vaccines currently undergoing preclinical and clinical trials.

This expanded network will assess candidate vaccines being developed against CEPI's priority diseases – Chikungunya, Lassa fever, MERS, Nipah, Rift Valley fever, and Disease X, it added.

The centralised testing approach has already been used by over 30 Covid-19 vaccine developers to assess over 15,000 clinical trial samples. CEPI is currently supporting the development of multiple vaccines against high-risk pathogens, identified by the World Health Organization R&D Blueprint as having epidemic potential or as a major public health risk, as part of its $3.5 billion plan to minimise or even eradicate future deadly disease threats.

Dr Melanie Saville, CEPI Director of Vaccine R&D, said: "We've already seen multiple deadly disease outbreaks affecting populations over the twenty-first century - and we know that the next pandemic is not a case of 'if' but 'when'." On being prepared for future outbreaks, she said, "This means building on what we've learned and created during this current crisis and extending our centralised labs network to also test against other known threats - and a potential future 'Disease X'."

Evaluation process

During the typical vaccine evaluation process, the immune response of each vaccine candidate under

development is assessed using different tools and measurements at individual testing sites, allowing for variability in results, CEPI explained.

For example, there may be potential variation in the way in which different type of immune biomarkers, like antibodies and T-cells, are measured. Technical differences in how and where vaccine clinical trial samples are collected, transported, and stored can also occur, impacting the quality and usefulness of the data produced and making comparisons between measurements difficult.

By following the same protocols and using the same biological reagents, laboratories within CEPI's centralised network can instead ensure uniformity in the assessment of different vaccine candidates, it said.

Source: PT Jyothi Datta , The Hindu Business Line, 22.11.2021

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South Korea's Enzychem to make Indian drugmaker Cadila's COVID-19 shot

South Korea's Enzychem Lifesciences (183490. KQ) would make at least 80 million doses of India's homegrown DNA COVID-19 vaccine from Cadila Healthcare (CADI.NS), the Indian drugmaker said on Wednesday.

As part of the deal, Cadila will transfer the DNA vaccine technology to Enzychem, which will make and sell the vaccine, ZyCoV-D, within its territory under the Cadila trademark. Cadila will get license fees and royalty payments, the company said in a filing to stock exchanges. "(The DNA) technology allows vaccines to be produced at affordable costs in record times, and DNA vaccines are considerably stable," said Ki Young Sohn, chairman of Enzychem Lifesciences.

"ZyCoV-D is administered without needles and can be deployed more readily, especially in resource-poor populations." Cadila's vaccine, which is administered in three doses, was approved by India's drug regulator in August for emergency use in adults and children aged 12 years and above, though it has yet to be rolled out as part of the county's vaccination drive. Reporting by Anuron Kumar Mitra in Bengaluru; Editing by Arun Koyyur and Shailesh Kuber.

Source: Reuters, 24.11.2021

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SII urges govt to fast-track movement of increasing Covishield stock

Synopsis

Prakash Kumar Singh, Director, Government and Regulatory Affairs at SII, is learnt to have recently communicated to the Union Health Ministry that it has a manufactured stock of 24,89,15,000 Covishield doses and it is increasing every day.

Serum Institute of India (SII) has urged the government to fast-track Covishield movement citing the difficulties being faced in production and cold chain space planning for other vaccines because of the increasing stock of its COVID-19 jab, official sources said on Sunday.

SII will also export Covishield to Bangladesh under COVAX, an official source said

Prakash Kumar Singh, Director, Government and Regulatory Affairs at SII, is learnt to have recently communicated to the Union Health Ministry that it has a manufactured stock of 24,89,15,000 Covishield doses and it is increasing every day.

In addition to the Covishield vaccine, the Pune-based firm also manufactures and supplies various life-saving vaccines to EPI, UNICEF and different countries, Singh is learnt to have told the ministry.

"To fulfil our domestic and global supply commitments, we have to plan our production/cold chain space/human resource well in advance. In view of continuous increase in the stock of Covishield, we are facing a lot of difficulties in production/cold chain space/human resource planning for other life-saving vaccines," an official source quoted Singh as having stated in the letter.

"In view of these facts, genuine difficulties and as this matter is directly concerned with the availability of various other life-saving vaccines in our country and the world at large, we request for your kind intervention for fast-track movement of our Covishield vaccine domestically and globally," Singh is learnt to have stated.

The Centre has allowed SII to export 50 Lakh doses of Covishied under the UN-backed COVAX global vaccine

sharing programme to Nepal, Tajikistan and Mozambique. SII will also export Covishield to Bangladesh under COVAX, an official source said.

The Serum Institute will commence its Covid vaccine export under the COVAX programme from November 23 and Nepal will receive the first lot of Covishiled on November 24.

The government had in October permitted SII to export 10 lakh Covishield doses, each to Nepal, Myanmar and Bangladesh under the 'Vaccine Maitri' programme.

Source: Economic Times, 21.11.2021

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Bharat Biotech readying to start making vaccine from Pune plant

The country has administered 13.11 crore doses of Covaxin till date. The company did not respond to queries regarding production plan and vaccine roll out at the Pune plant.

It takes the company around 120 days for the roll out of vaccines from start to supply stage.

Bharat Biotech is slated to start manufacturing the Covaxin from its plant at Manjari, near Hadapsar in Pune, from December.

Bharat Biotech has repurposed the facilities of Biovet, an associate company, for making the Covid-19 vaccine. This facility, earlier owned by Intervet India, a subsidiary of Merck & Co, was into production of foot and mouth disease vaccines. Intervet India exited this business in India and transferred the land and manufacturing unit to Biovet.

Bharat Biotech has been working on the production line and building human resources for Covid-19 vaccine production at this plant. The company had started manufacturing the initial batches of the Covaxin Covid-19 vaccine at the Manjari plant and a commercial rollout was expected in December.

It takes the company around 120 days for the roll out of vaccines from start to supply stage. The company has received local clearances and administrative approvals for its Pune plant and as per initial plans, it was supposed to start production in August 2021. The Pune district administration had handed over a 12 hectare plot to Bharat Biotech for vaccine production in May 2021. District officials had said the plant would have an annual capacity to make 7.5 crore vaccine doses.

The plant has received approvals from the Maharashtra State Electricity Distribution Company, Food and Drug Administration, Central Pollution Control Board and Labor Department.

Krishna Ella, chairman and managing director of Bharat Biotech, has said that his company would have an annualised capacity of 100 crore doses by December end. Bharat Biotech has plans to make around 10 crore vaccines a month across its facilities in Hyderabad in Telangana, Malur in Karnataka, Ankleshwar in Gujarat and now Pune.

At present, the company is producing around 5.5 crore doses per month.

The country has administered 13.11 crore doses of Covaxin till date. The company did not respond to queries regarding production plan and vaccine roll out at the Pune plant.

Source: FE Bureau , 23.11.2021

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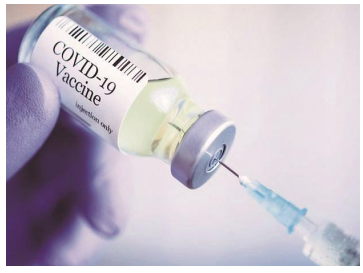
Covid-19 jab exports set to rise; Serum Institute leads the pack

Indonesia to get 5 mn Covovax doses, exports to COVAX to rise to 30 mn by Jan



The 15-day average of daily vaccinations in India is around 5 million doses, which brings the monthly requirement in the country to around 150 million doses

With weak demand in India for Covid jabs, exports of vaccine shots are set to rise, with Pune-based Serum Institute of India (SII) leading the pack.

Supplies to World Health Organization-led COVAX, a global initiative for equitable distribution of Covid vaccines, have begun this month.

"The volumes are not high right now. However, by December-January, SII may export around 30 million doses to COVAX," said a source close to the development.

January onwards, the volumes are expected to be much higher than 30 million monthly doses.

Meanwhile, sources also indicate that exports of the Novavax vaccine — yet to be approved either by the US Food and Drug Administration or the Drugs Controller General of India (DCGI) — are also set to begin this week. The first 5 million doses will go to Indonesia.

SII declined to comment on the matter.

SII is the manufacturing partner in India for the Novavax vaccine, which it has named Covovax. At the moment, trials on children (aged two years and above) are on in India. SII has indicated it expects the data to be ready for submission to the Indian regulatory authority in the first quarter of the next calendar year.

Indonesia has approved the Novavax vaccine for use. SII and Novavax had jointly applied to that country, said sources, and Covovax has been approved for use in Indonesia.

The 15-day average of daily vaccinations in India is around 5 million doses, which brings the monthly requirement in the country to around 150 million doses. SII alone makes 220 million doses of Covishield (AstraZeneca shot), apart from Bharat Biotech's Covaxin (55 million doses in October and 80 million doses targeted by December).

India is thus in a comfortable position for exports to commence. Moreover, players like SII are facing issues related to stocking the vaccines at their plants and plateauing domestic demand. The company can stock around 100 million doses in cold-storage at its Pune facility.

Hyderabad-based Biological E had sent batches of the Johnson & Johnson (J&J) vaccine to the Central Drugs Laboratory (CDL), Kasauli, in Himachal Pradesh around September.

The apex laboratory has green-lighted the doses, claimed sources. This paves the way for the J&J vaccine to be exported from here.

"Around 10 million doses of the J&J vaccine are ready for export. Once the Central Drugs Control and Standard Organization approves the report sent by CDL and Biological E is granted an export licence, the exports of these jabs could begin," said a source.

J&J doses, approved by the DCGI, would be exported even before they are available in the country. J&J and the Indian government are discussing issues around indemnity in case of any serious adverse event after immunisation. The vaccines would not be locally available, unless consensus is reached.

Biological E withheld comment on this.

"Our teams are working round the clock to develop and broadly activate our manufacturing capabilities to supply our Covid vaccine. We believe Biological E will be an important part of our global Covid vaccine supply chain network, helping to supply our vaccine through extensive collaborations and partnerships we have with governments, health authorities, and organisations, such as Gavi, the Vaccine Alliance and the COVAX," said the spokesperson, adding, "It is premature for us to speculate on the timing of our vaccine deliveries."

Last week Prime Minister (PM) Narendra Modi had hinted that Covid vaccine exports from India are set to rise. "We exported life-saving medicines and medical equipment to over 150 countries during the initial phase of the pandemic. We have also exported more than 65 million doses of Covid vaccines to nearly 100 countries this year. As we ramp up our vaccine production capacities, we will do much more," the PM had said.

India has exported 66.3 million Covid vaccine doses till April, of which 10.7 million doses have gone as grant from the Indian government, 35.7 million doses commercial exports by vaccine makers, and 19.8 million doses sent to COVAX.

Source: Sohini Das , Business Standard, 22.11.2021

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Cabinet secy-led panel to take call on more allocation to PLI pharma

The department has urged the top government panel to provide additional funds of around Rs 3,000 crore under the scheme for pharmaceutical medicines

A panel headed by Cabinet Secretary Rajiv Gauba will examine allocating more funds towards vaccine production to boost manufacturing production-linked incentive (PLI) scheme.

The department of pharmaceuticals has urged the top government panel to provide additional funds of around Rs 3,000 crore under the scheme for pharmaceutical drugs. The scheme is aimed at further boosting domestic manufacturing of medicines, in-vitro diagnostics (IVD), and their raw materials in India.

The additional amount is being asked to support the domestic production of raw materials required for vaccine production, people aware of the matter told Business Standard. The financial outlay for the scheme is currently Rs 15,000 crore.

"The department of pharmaceuticals will soon send a proposal to an empowered group of secretaries (headed by Gauba) for redistribution of around Rs 3,000 crore from PLI savings from other sectors," one of the people cited above said. As of now, total savings for the government under the PLI scheme has been Rs 30,984 crore. The savings or any unutilised amount can be reallocated to any other department in need of funds. This provision was made while designing the PLI scheme. Savings of Rs 30,984 crore is a result of sharply cut outlay for automobile, auto components, and mobile manufacturing.

The financial outlay for automobile and auto components has been slashed by 54 per cent to Rs 25,938 crore, while that of the mobile manufacturing scheme has been reduced by 6 per cent to Rs 38,601 crore. The Cabinet had in February approved the scheme that aims to give production-linked incentives for six years, starting FY23. The incentives will be given to drug makers as a proportion of incremental sales, over and above the revenue generated by the products concerned in FY20.

The department for pharmaceuticals has divided the products into three categories — pharmaceutical formulations, bulk drugs and IVD medical devices. As much as Rs 11,000 crore has been allocated for complex generic drugs, patented drugs, biopharmaceuticals, among others, while Rs 2,250 crore for bulk drugs that are not part of another PLI scheme that was announced by the government last year for bulk drugs.

The remaining amount of Rs 1,750 crore has been allocated for medicines not made in India, IVD medical devices, anti -cancer drugs among others.

The government has received as many as 278 applications, with an expected investment of Rs 15,000 crore for PLI pharma.

Source: Shreya Nandi, Business Standard, 23.11.2021

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VAV Life Sciences unit to reach 40% of global mRNA lipid capacity next yr

Firm expanding mRNA lipids capacity 10-fold, overall plant capacity by 6 times by June

Mumbai-based firm VAV Life Sciences is expanding its mRNA lipids manufacturing capacity 10-fold by June 2022. It will then account for 40 percent of the total global capacity for m-RNA lipids, a critical component that goes into making mRNA vaccines and also various mRNA tech based therapeutic products which lends permeability and stability to the biologic product.

Apart from VAV, there are only three more companies in the world who make mRNA lipids. US-based Avanti Polar Lipids, Germany's Lipoid and Japan's NOF Corporation

CAPACITY BOOSTER

- ₹15 crore VAV Life Sciences' investment to expand the capacity at the Ratnagiri plant overall by six times
- 1,500 kg Yearly production target for mRNA lipids capacity for vaccines
- The new capacity would be operational from June 2022

and VAV together now make 1,000 kg a year. However, the projected demand for mRNA lipids would be 2,500 kg per year by 2025-26. VAV Life Sciences is investing Rs 15 crore (through its subsidiary VAV Lipids) or so to expand the capacity at the Ratnagiri plant overall by 6 times. Of this, the mRNA lipids capacity for vaccines would be expanded by 10 times the current production to 1,500 kg a year. The company makes 30-40 types of other lipids too, some of which are nutritional.

"This is in preparation for the future. At present, mRNA products are only vaccines, and there are no commercially approved products based on the mRNA platform technology. However, we expect a rise in demand for mRNA lipids in the future," Arun Kedia, Managing Director VAV said.

This would not only be sufficient for the Indian requirement, but also cater to 40 per cent of the global demand, Kedia said, adding that they target to be the largest mRNA lipids company in the world. Going forward, Kedia plans to have plants in Europe to be closer to their customers. VAV exports almost 80 per cent of its products primarily to North America, Europe, and Asia.

He said that since the past five years or so, they have been supplying the mRNA lipids to several companies, however, that was primarily for research purposes.

VAV is the only Indian and fourth global producer of highly purified lipids that are approved for use in novel drug delivery systems (NDDS). The new capacity which would be operational from June 2022 will boost VAV's sales by about 3.5 times to reach RS 45 crore ($6 million) by 2023.

According to the company, the project is funded by internal accruals and EXIM-bank debt. Kedia, who is a chemical engineer by training, has bootstrapped the start-up so far, and has no external investor on board. "Our growth has been organic funded by internal accruals," he said.

VAV Life sciences Private Limited is a nanotechnology research-based biopharmaceuticals manufacturing company. The company produces ingredients used in the pharmaceutical, nutraceutical, and healthcare and personal care industries. VAV's product portfolio includes plant phospholipids (LECIVA), Animal phospholipids (LIPOVA), synthetic phospholipids, and neutral lipids. The other products include APIs and specialty proteins.

Source: Sohini Das, Business Standard, 24.11.2021

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ACG plans biggest vegetarian capsules unit in Maharashtra

Synopsis

Managing director of the Mumbai-based ACG Karan Singh

Gelatin capsules are derived from cow or buffalo bones and hides, while cellulose from the bark of a tree, which through a chemical process is converted into water soluble material and molded into a capsule.

The Narendra Modi government's push to replace animal origin gelatin to plant-based cellulose capsules has prodded ACG, one of the globe's leading supplier of capsules, to set up the world's largest greenfield vegetarian capsule factory at an investment of 800 crore in Aurangabad, Maharashtra.

Karan Singh, managing director of the Mumbai-based ACG, told ET that the company has got land allotted by the Maharashtra government and is looking to take advantage of the production linked incentive (PLI) scheme announced by the Centre. The Central government has added empty cellulose capsules manufacturing eligible under the PLI scheme. "The intention is that if there is a vegetarian alternative available, why not migrate towards it?" Singh said, adding that ACG has developed technology to make cellulose capsules. Singh said there were several rounds of meetings with a committee set up by the government to look at alternatives to gelatin capsules since a large majority of our billion plus population is vegetarian. In addition to pharmaceuticals, these capsules are also used in high quality nutritional supplements that have come into focus during Covid 19. "Part of our commitment to the government was that we will pay more attention to this," Singh said. Using its in house research and technology development

expertise powered by a global team of scientists and chemists, ACG developed Hydroxypropyl Methylcellulose capsules that provide a vegetarian alternative for India's masses looking to improve their health. The company uses cellulose from the bark of a tree, which through a process is converted into water soluble material and moulded into a capsule that is fit for use by pharmaceutical companies and dissolves in a manner that increases the potency and efficacy of the medicine encapsulated.

Source: Viswanath Pilla, Economic Times, 23.11.2021

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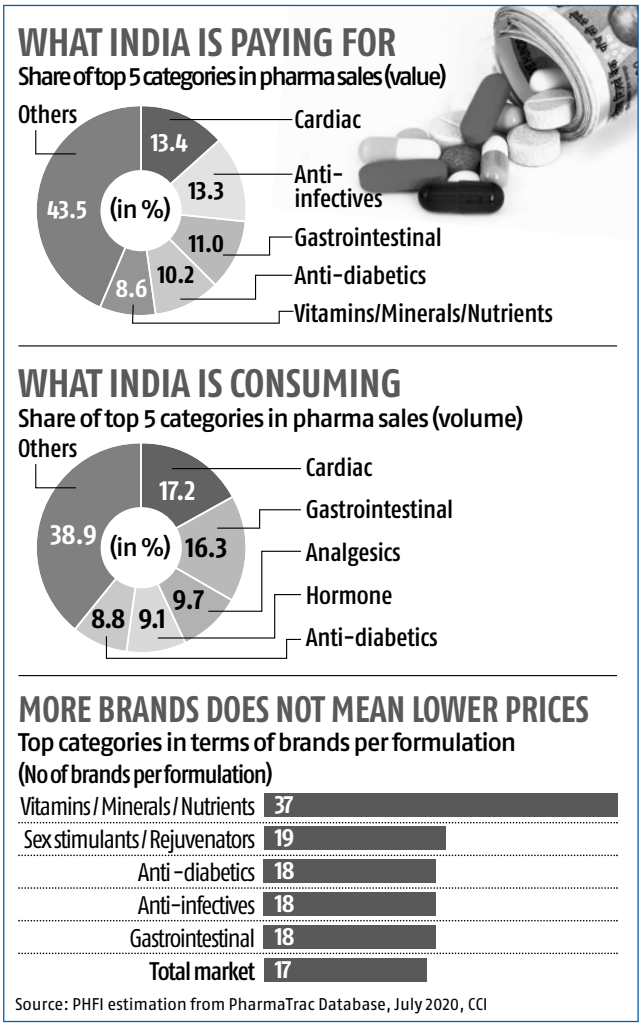
Finger on India's Pharma Pulse

Finding The Right Prescription: Cardiac drugs accounted for highest volumes in 2020; anti-diabetic drugs saw value-volume inversion

The pharmaceutical (pharma) industry's turnover in India increased 165x, from ₹1,750 crore in 1990 to ₹2.89 trillion in 2020. The total share of domestic sales was ₹1.41 trillion. Spending on pharma products accounts for over a fourth of total health spending in the country. Its share in out-of-pocket expenditure on health was 43.2 per cent. And 97 per cent of it was spent on generics — formulations that are not under any patent. It is not surprising then that the Competition Commission of India's (CCI's) study focuses on the impact of generics in the Indian market and the fault in the system regarding price differentiation. A Business Standard analysis of the report data highlights what ails India and which pharma products are consumed the most. In terms of volume, cardiac medicines accounted for 17.19 per cent of total sales, followed by gastrointestinal with 16.33 per cent share, and pain and analgesics with 9.69 per cent share.

Eventhough India has 20 per cent of the world's population, it accounts for 60 per cent of the world's health disease burden.The burden of diabetes in the country has been increasing. Still, the share of anti-diabetic prescriptions in total sales was just 8.89 per cent. Despite having just an 8.89 per cent share in volumes, anti-diabetic pills accounted for 10.17 per cent share in value, making them more expensive than others. In contrast, cardiac, which had a 17 per cent share in volume, accounted for 13.4 per cent of sales. Of the total ₹1.41 trillion sales, anti-diabetic medication accounted for ₹14,355 crore worth of business. The other category to have this value-volume inversion was anti-infectives. Despite accounting for 6.7 percent share in volumes, it had 13.3 per cent share in sales.



Diabetics, based on estimations by the Public Health Foundation of India, also had one of the highest number of brands per formulation — different brand names for the same medicine. Ideally, more brands should translate into more competition and lower prices, but in this specific case, more brands translate into better product positioning and higher pricing.

Source: Ishaan Gera, Business Standard, 23.11.2021

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