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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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IDMA BULLETIN

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Innovation and Patents receiving the Government's Attention

Dr. Gopakumar G. Nair, *Editor, Indian Drugs*

Dear Reader,

Inaugurating the Grand Finale of the Smart India Hackathon, 2022 and addressing the 15000 finalists of the Hackathon, the Honourable Prime Minister of India, Shri Narendra Modi made a clarion call for research and innovation and appealed to make innovation a "way of living" with increasing acceptance in society, especially among the research community. The Future of India will be realised and recognised through innovative research and commercialisation of inventions, he said. Strong governmental support through appropriate organisations was promised for encouraging innovation. It is heartening, said the PM, that India is making rapid strides in Intellectual Property generation through ideation and converting them to practical applications.

In tune with the vision of the Government of India, the Economic Advisory Council to the Prime Minister "EAC-PM/WP/1/2022" has come out with a Report on ***"Why India needs to urgently invest in its patent ecosystem?"***

Issues adversely impacting the patent system in India, compared to countries like China, USA and others have been analysed and solutions to these problems have been suggested in this Report. The Report is available on

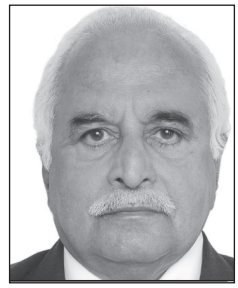
https://eacpm.gov.in/wp-content/uploads/2022/08/Why-India-needs-to-urgently-invest-in-its-IPR-ecosystem-16th-Aug-2022_Final.pdf

Compiled by Mr. Sanjeev Sanyal and Aakanksha Arora with support from eminent economists Dr. Bibek Debroy and Dr.Unnat Pandit (Controller General of Patents) and other senior officials, the Report is worth adopting and implementing early by the Government. The EAC-PM is further proposing to release the "Competitive Roadmap for India @ 100" on 30th August 2022. This collaborative effort between EAC-PM and the Institute of Competitiveness of the Harvard Business School, proposes policy goals, principles and approaches to further lift and drive India's economy in the direction of sustainability and resilience, embedded in social progress and shared prosperity, guiding the way for India to become a higher income country by 2047.

The President of India, the Prime Minister as well as the Finance Minister have been laying emphasis on the Fundamental Duties in the Constitution of India which under Article 51 proposes to "scientific temper", "humanity" and "spirit of enquiry" to every citizen of India, indirectly exhorting for creative thinking, innovative approaches and finding solutions to problems facing the community through self-reliance and breakthrough solutions approach. Already Indian "jugads" are receiving global acclaim. The PM's high-power committee has already recommended "utility patents" to be introduced as a new category for incremental innovations.

Indian Pharma Industry and academic institutions engaged in innovative research can avail of this laudable initiative by increasingly preparing themselves for strengthening the patent ecosystem and creating more and more intangible assets for value addition and asset creation.

Courtesy: Indian Drugs, Editorial, 59 (08), August 2022



Dr. Gopakumar G. Nair *is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.*

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India. Tel: +91-22-24974308 / 24944624 Email: actadm@idmaindia.com Website: www.idma-assn.org

REGISTER NOW

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

REGISTER NOW

Organizes

Symposium on Nasal and Pulmonary Drug Delivery

Hotel Sofitel, BKC, Mumbai,
November 10 & 11, 2022

Indian Drug Manufacturers' Association (IDMA) is proud to present the Two-Day **"Symposium on Nasal and Pulmonary Drug Delivery"** on Thursday, 10th & Friday, 11th November 2022 at Hotel Sofitel, BKC, Mumbai.

The Indian Pharmaceutical Industry is showing increasing interest in developing **orally inhaled and nasal products (OINDP**) compared to conventional dosage forms as they provide significant benefits to patients, including minimal systemic exposure, faster onset of action, and broader options for disease management. New therapeutic agents such as proteins, peptides and nucleic acid based agents are being developed every year, making it vital to find a non-invasive route such as nasal or pulmonary for their administration.

These developments represent significant opportunities for pharmaceutical companies, provided they choose delivery systems that adequately "partner" each drug during its development.

Nasal and pulmonary delivery are non-invasive routes of administration that target the delivered dose directly to the site of drug action. Drug delivery to the respiratory area can also be used for systemic delivery of peptides and proteins due to the large surface area for drug absorption.

Nasal and pulmonary drug delivery systems are used for local and systemic treatment of diseases such as asthma, chronic obstructive pulmonary disease (COPD), rhinitis, migraine and many more. New inhalation products are being developed for non-respiratory disease indications, e.g. diabetes, which would allow patients to avoid more intrusive medical treatments. Drug delivery device used in these products is far more than an instrument for the administration of the formulation.

The device is part of the primary packaging, is part of the container closure, and is the vehicle to transport successfully the active medicine to the target. During the dispensing act the responsibility of the effect of the therapy switches to the device. Delivery devices for nasal and pulmonary applications require additional particular attention during development and production as their performance characteristic and reliability has a crucial impact on the efficiency of the nasal or pulmonary delivery to the target site.

Request members to kindly register and attend this Symposium along with their concerned personnel.

The Registration fee for the same would be as follows: -

- **Delegate - Rs.12,000 + GST @ 18% per Delegate**
- **Student - Rs.6,000 + GST @ 18% per Student**

** Early bird discounts - Before 21st October 2022:* ***10% discount***
** Group registration benefits (for 3 or more):* ***15% discount***

RTGS Details:
Account Holder's Name: **Indian Drug Manufacturers' Association**
Current Account Number: **76080200000242**
Bank: **Bank of Baroda**
IFSC Code: **BARB0DBWORL**
Branch: **Worli, Mumbai 400 018**

For any further clarifications / assistance, please feel free to call :
Ms. Sapna Patil - (9619802299 / admin@idmaindia.com) &
Mr. Melvin Rodrigues (9821868758 / actadm@idmaindia.com)

We would be forwarding more information on this symposium at the earliest.

Thanks & regards,

Daara B Patel
Secretary – General

REGISTRATION FORM

To,
The Secretary General
Indian Drug Manufacturers' Association
102/B, A Wing, Poonam Chambers, Worli, Mumbai 400 018.
Tel. # 022 - 24974308 / 24944624
E-mail: admin@idmaindia.com / actadm@idmaindia.com

Date:

Dear Sir,

Symposium on Nasal and Pulmonary Drug Delivery
Hotel Sofitel, BKC, Mumbai | November 10 & 11, 2022

Kindly register the name/s of the following person/s from our company to participate in the above programme: -

SR. NO.	NAME	DESIGNATION	MOBILE NOS.	EMAIL
1				
2				
3				
4				
5				

Our Cheque/ DD / RTGS details :_____ dated _____for

Rs._____ is enclosed.

Thanking you,

Yours faithfully,
(Name & Designation)

Name of the Company_____

Address _____

_____

Tel No. :_____ Fax No. : _____ E-Mail:_____

The Registration fee for the same would be as follows: -
- **Delegate - Rs.12,000 + GST @ 18% per Delegate**
- **Student - Rs.6,000 + GST @ 18% per Student**

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Inviting MSME Units to get its Manufacturing Workforce trained on GMP under Govt Funding under LSSSDC's SANKALP Project – reg.

IDMA have received communication from Mr. Ranjit Madan, Chief Executive Officer (and Joint Apprenticeship Advisor, Life Sciences Sector), LSSSDC (Life Sciences Sector Skill Development Council) dated 16th September 2022 as reproduced below on the above subject. Requesting members to avail the funding benefits for GMP training to their employees.

LSSSDC, as an Industry led, National level Vocational Education Awarding body is working relentlessly for bridging the Skill Gap in Life Sciences Sector (Pharma, Biotechnology & Contract Research). In this direction, in 2020, LSSSDC in consultation with Industry leaders and experts, have developed and launched **Good Manufacturing Practice Training Programs covering 360 Degree aspects of GMP** requirements for employees and workmen working in key job roles in a manufacturing unit. These programs were based on the skill gap trends identified in various regulatory audits like USFDA, UKMHRA, WHO and State FDAs over last three years.

During the Pandemic of Covid19, realizing the advantage of technology intervention, these programs were developed as online modules which provided the flexibility of implementation keeping the quality and standardization of programs intact. LSSSDC had partnered with nominated Indian Industry experts and a German Federal Agency, GIZ, for development of these programs. Since Dec 2020, these **"360 Degree GMP programs**" have been utilized by large Industry players like Cadila Healthcare (Zydus), Cipla , DRL, Emcure, Lupin, Sun Pharma and many others as Industry paid programs resulting in nearly 3000 user licenses sold till date. A series of positive feedbacks were received from industry leaders where workforce have used these programs.

Since the launch of these "360 Degree GMP Programs", LSSSDC has been receiving feedback from Industry associations like BDMA ,FOPE and IDMA about financial inability of MSME companies to use these programs in paid model and hence LSSSDC submitted a representation for financial assistance for MSME to Ministry of Skill Development & Entrepreneurship, Govt of India. We cited that medium and small size employers are not able to meet the rigorous re-skilling and up-skilling demand for its operator and assistants level workforce due to a financially stressed economy. Also, under Atmanirbhar Bharat, where to tackle imports from China, Govt. of India is promoting domestic manufacturers to boost the production at par to global quality, the up-skilling of workforce in MSMEs, shall catalyze the effort of Industry and Govt. of India.

We are glad to inform you that basis representation of LSSSDC, Ministry of Skill Development and Entrepreneurship, Govt of India under its initiative "SANKALP" have **approved the financial assistance for 7500 (Seven Thousand Five hundred) employees and workmen employed with MSME companies in Industry Clusters PAN India** to **Re-skill/ Upskill on 360 Degree Aspects of GMP. Nominated employees can therefore avail of these on line Upskilling modules, fully funded by the government.**

Accordingly please arrange to circulate this mail to all your members.

To participate in the SANKALP Project for "Re-skilling/ Upskilling of MSME workforce in Life Sciences Sector", interested companies need to fulfil following:

1. *Provide valid Udyam Certificate to LSSSDC*
2. *Ensure Access to LSSSDC Team for Basic employee data required for enrollment and allow LSSSDC to take Aadhaar Base Attendance during the training Program.*
3. *Ensure NO Salary deduction for employee/ worker during the upskilling program duration*
4. *Wherever possible provide Computers for delivery of upskilling Program to its employees/ workers*

The details of three programs offered under SANKALP Project for "Re-skilling/ Upskilling of MSME workforce in Life Sciences Sector", are as under:

360 Degree GMP for Production Machine Operators	**360 Degree GMP for Manufacturing Assistants**	**360 Degree GMP for Packaging Assistants**
This program is meant for experienced Production Machine operators who wish to re-skill or up-skill themselves on 360 Degree aspect of Good Manufacturing Practices. The Program enables participants to gain the skills at self-pace in the areas including but not limited to essential knowledge of GMP, Data Integrity, Reporting and Labelling, Machine upkeep and routine maintenance, Cleanroom and Hygiene along with Covid19 Protocols, Safety and Emergency response and Environment sustainable waste management. The Program is also meant to impact additional skills for communication and professional skills to each participant.	This program is meant for experienced Manufacturing Assistants who wish to re-skill or up-skill themselves on 360 Degree aspect of Good Manufacturing Practices. The Program enables participants to gain the skills at self-pace in the areas including but not limited to essential knowledge of GMP, Data Integrity, Reporting and Labelling, Machine upkeep and routine maintenance, Cleanroom and Hygiene along with Covid19 Protocols, Safety and Emergency response and Environment sustainable waste management. The Program is also meant to impact additional skills for communication and professional skills to each participant.	This program is meant for experienced Packaging Assistants who wish to re-skill or up-skill themselves on 360 Degree aspect of Good Manufacturing Practices. The Program enables participants to gain the skills at self-pace in the areas including but not limited to essential knowledge of GMP, Data Integrity, Reporting and Labelling, Machine upkeep and routine maintenance, Cleanroom and Hygiene along with Covid19 Protocols, Safety and Emergency response and Environment sustainable waste management. The Program is also meant to impact additional skills for communication and professional skills to each participant.
Duration: 10 Hours	**Duration:** 7 Hours	**Duration:** 7 Hours
Language: English, Hindi and Telugu	**Language:** English, Hindi and Telugu	**Language:** English, Hindi and Telugu
Mode of Delivery: Online using Laptop/ Computer and head phone in Manufacturing Unit itself	**Mode of Delivery:** Online using Laptop/ Computer and head phone in Manufacturing Unit itself	**Mode of Delivery:** Online using Laptop/ Computer and head phone in Manufacturing Unit itself
Certification Available: Yes (Dual : Indo German Certificate of GMP Training + Indian Vocational Education Certificate for Production Machine Operator (API/ Non Sterile Formulation/ Sterile Formulation))	**Certification Available:** Yes (Dual : Indo German Certificate of GMP Training + Indian Vocational Education Certificate for Assistant- Manufacturing & Packaging (Pharma, Biopharma & Medical Device))	**Certification Available:** Yes (Dual : Indo German Certificate of GMP Training + Indian Vocational Education Certificate for Assistant- Secondary and Tertiary Packaging (Pharma, Biopharma & Medical Device))
Cost of Training and Certification to MSME under SANKALP ~~**INR 1400/**~~ **ZERO**	**Cost of Training and Certification to MSME under SANKALP** ~~**INR 1400/**~~ **ZERO**	**Cost of Training and Certification to MSME under SANKALP** ~~**INR 1400/**~~ **ZERO**

For any queries, please feel free to reach out to following:

1. Shivi Chaudhary, Head(Dy. Manager)– Standards & Training Advisory
   Email: Shivi.chaudhary@LSSSDC.IN
   (M) +91 9315747189
2. Anshul Saxena, Senior Director
   Email: Anshul.saxena@LSSSDC.in
   (M)+91 9650433002

As limited window of three (3) months is available to complete the project, we request you to register your interest for participation at the earliest with a revert mail to the above two mails.

● ● ●

Initiation of Sunset review investigation of anti-dumping duty on the imports of Monoisopropylamine originating in or exported from China PR – reg.

IDMA have received communication from Mr Rajiv Kumar Soni, ITS, Joint Director of Foreign Trade, Directorate General of Trade Remedies, Dept. of Commerce, Ministry of Commerce & Industry dated 23rd September 2022 as reproduced below on the above subject:

I am directed to inform you that a sunset review investigation of anti-dumping duty on the imports of Monoisopropylamine originating in or exported from China PR, has been initiated by the Designated Authority constituted to investigate into the recurrence, degree and effect of the alleged dumping. A copy of the Initiation Notification No.7/12/2022-DGTR, Case no: AD (SSR)-04/2022 and dated 15.09.2022, issued by the Authority, is available on the website at: https://www.dgtr.gov.in/sites/default/files/Initiation_English_15-9-22.pdf

2. The response must be in English and all supplementary information or other materials provided with it must be certified by the chief executive of your company as accurate, complete and presenting a true and fair view of the accounts and other data to be to the best of his knowledge and belief.

3. The purpose of the Questionnaire is to gather information required for completion of the investigation. It is important for your company to give the answers clearly and precisely, indicating the sources of information used, and wherever required, attaching supporting documents. Any worksheets or documents used to answer this Questionnaire, shall be kept in the hands of the company and be made available for the purposes of further examination/ verification.

4. Although a Questionnaire is given, the Designated Authority reserves the right to call for any information in this regard at any time during the investigation and the course of the ADD proceedings. You may also submit any additional information relevant in this regard.

5. The period of investigation (POI) for the present investigation is 1st April 2021 to 31st March 2022 (12 months). The injury investigation period will cover the periods 2018-19, 2019-20, 2020-21 and the period of investigation.

6. The information furnished is subject to verification. You are also advised to preserve all the working papers.

7. The response should be filed by e-mail **not later than thirty days from the date of issue of this email.** In view of the special circumstances arising from COVID-19 pandemic, as mentioned in DGTR's Trade Notice No.01/2020 dated 10th April, 2020, any information relating to the present investigation should be e-mailed to the investigation team members at adg13-dgtr@gov.in, adv12-dgtr@gov.in, jd12-dgtr@gov.in, and ad12-dgtr@gov.in.

8. If no response is received within the time stipulated in this email, it would be presumed that you have no comments to offer. Your attention is specifically drawn to the Countervailing Rules, which authorize the Designated Authority to record its findings on the basis of facts available to it in case of non-cooperation from the interested parties.

9. Please ensure that the information provided by you is clearly marked either 'Confidential' or 'Non-confidential' at the top of each page. Information supplied without any mark shall be treated as 'non-confidential' and the Authority shall be at liberty to allow the other interested parties to inspect any such non-confidential information. Confidential information must be accompanied by a non-confidential summary or, if it is not susceptible to summarization, a statement of the reasons why summarization is not possible. However, if the Authority is satisfied that the request for confidentiality is not warranted, or the supplier of the information is either unwilling to make the information public or to authorize its disclosure in a generalized or summary form, the Authority may disregard such information.

10. As per Rule 6(6) of the Customs Tariff (Identification, Assessment and Collection of Anti-Dumping on Dumped Articles and for Determination of Injury) Rules, 1995, as amended. "the Designated Authority may allow an interested party or its representative to present the information relevant to the investigation orally but such oral information shall be taken into consideration by the Designated Authority only when it is subsequently reproduced in writing."

11. All your submissions, including the data and annexure to the Questionnaire response should be in appropriate machine-readable formats. All write-ups /explanations, etc. should be submitted in MS Word file and all formats/appendix in MS Excel format. The worksheets included in this Questionnaire must be submitted in computerized medium, according to the following specifications: PC-compatible systems, Microsoft Word/EXCEL programme.

12. We appreciate your cooperation in providing the requisite information within the required time and assisting us in conducting the present investigation in a time bound manner.

13. You may contact this office should you need any clarification and/or assistance in furnishing the information in the prescribed manner.

Attachments:

1. *Initiation Notification:* *https://www.dgtr.gov.in/sites/default/files/Initiation_English_15-9-22.pdf*
2. *Importer's Questionnaire* *https://www.dgtr.gov.in/anti-dumping-guidelines/importer-questionnaire*
3. *User Association Questionnaires can be downloaded from DGTR's web site:* *https://www.dgtr.gov.in/anti-dumping-guidelines/met-questionnaire*
4. *Non confidential version of application.*
5. *Economic Interest Questionnaire (as reproduced below)*

Economic Interest Questionnaire

for *[AD/CVD]* INVESTIGATION against (Name of the subject countries)

in respect of *[NAME OF Product Under Consideration or PUC]*

PART-I. GENERAL SECTION [1](FOR ALL STAKEHOLDERS INCLUDING ADMINISTRATIVE/LINE MINISTRY)

1. Name and details of the company/association/consumer group/others:

   a. Name
   b. Address
   c. Name and designation of contact person
   d. Contact No.
   e. Email address
   f. Website
   g. Contact Details of legal representative, if any.

2. Status of the interested party (tick the relevant cell among the following).

Government body		Importer	
Domestic producer		Distributor or dealer	
Trader		Consumer	
Downstream user		Association of PUC	
Upstream producer		Association of Downstream Products	
Consumer groups		Association of Upstream Products	
Exporter/Producers		Others (specify)	

Note-1: Provide the relevant details as deemed fit.

3. If you are any association as mentioned above, provide the following details:

   (a) Is the Association a registered body? If so a copy of the Registration Certificate;
   (b) A copy of the By-laws & Memorandum of Association (MOA);
   (c) A list of the members;
   (d) Details of the Executive body / Managing structure of the Association;
   (e) A copy of the minutes of the meeting in which it was resolved by the Association to file this questionnaire response on behalf of some/all its members;
   (f) A list of the members, who either supported, opposed or remained neutral with regard to the said response; and
   (g) Any other information which may be relevant in this regard.

4. Whether your industry consists majorly of Micro, Small and Medium Enterprises (MSMEs).[2] If yes, in case of Indian producer (whether domestic industry/ importer/ user), provide your relevant MSME certificate or in case of association, declare how many members of the association have MSME certificate.

5. Explain how the alleged dumping, subsidization, increased imports or imposition of duty has affected your company's operations. Please quantify such impact.

6. Indicate any non-tariff barriers for the PUC or its immediate downstream product in India.

7. Substantiate how the duty on PUC, if levied, is likely to impact the downstream users and final consumers of the PUC. Please substantiate such impact in terms of increase in the cost and price of the immediate downstream product and eventual end product. Please provide relevant calculation and supporting evidence.

8. Provide the number of employees involved in the production of the PUC/ downstream/ upstream product, as applicable.

9. Provide details of whether any trade remedial measures exist or are proposed on any upstream, downstream, joint, substitute or otherwise related products in India or outside, which might impact your operations or the operations of the downstream user industry.

10. Provide any other information that may be relevant for the present investigation.

---

[1] Please fill N.A. (not applicable), wherever applicable.
[2] For the meaning and definition of "MSME", the relevant notifications/circulars issued by the Central Government in this regard shall apply.

PART-II. ADMINISTRATIVE / LINE MINISTRY

1. Name of the Administrative Ministry

2. Provide the name of the product, to which the administrative ministry belongs, and also provide the following details relating to such product:

   (a) Category (PUC/Downstream/upstream)

   (b) Total estimated production and

   (c) No. of estimated producers of the product.

   (d) The impact on such product (please quantify) in case the duty is levied on the PUC

3. Whether the Ministry support or oppose the duty on PUC and reasons for the same.

PART-III. DOMESTIC PRODUCERS

1. Provide evidence regarding the prevailing prices of the PUC in the market. Also provide details of how the prices of the PUC have evolved in the last 5 years, including but not limited to the comparison to cost of production.

2. Indicate whether the industry for the PUC is majorly located in a particular geographical region. Please explain the impact thereof on the user industry. Provide information for the following zones of India:

S. No.	Parameters	North	South	East	West	Central	North-East	Total
1	Installed Capacity							
2	Production							
3	Consumption							
4	Imports							

3. Provide the % utilisation of the PUC in the immediately downstream product.

4. Re-sale price of the imported PUC at retail level in India.

5. Provide any other information that may be relevant for the present investigation.

PART-IV. IMPORTERS AND / OR DOWNSTREAM USERS

1. (a) Indicate whether you have entered into any long-term contracts with the suppliers of the PUC in India as well as internationally.

   (b) Also specify whether you can switch suppliers in case of imposition of duty on PUC. If not, specify the reasons for your inability to switch suppliers.

   (c) Clarify as to whether the finished products produced by your company has a substitute. Also indicate whether it is likely that consumers would switch to another product in case the cost of your product increases due to the imposition of the duty on PUC, if levied.

2. Substantiate with calculations whether the downstream industry would bear or pass on the increase in the costs due to the duty on PUC, if levied.

3. Substantiate as to how the duties on the PUC (previous duties in place or duties, if levied on the PUC pursuant to the present investigation) imported from subject country or other countries have impacted the costs and prices of the Downstream Product during IIP:

S. No.	Parameter	Unit	Year 1	Year 2	Year 3	POI
1	Consumption of the PUC in the finished product					
a	Volume					
b	Value					
2	Production of the Finished product					
a	Volume					
b	Value					
3	% Share of PUC in finished product					
4	Quantum of ADD paid					
5	Impact of ADD paid on finished product in absolute terms					
6	Impact of ADD paid on finished product as % of price of the finished product					
7	Return on Investment (%)					

Note: "ADD paid" here means ADD currently in place (in case of SSR) or ADD in the present investigation (if suppose 10% is proposed, for example)

4. Provide evidence regarding the prevailing prices of the PUC in the market. Also provide details (with its contributing factors) of how the prices of the PUC have evolved during the IIP. Evidence may include invoices, price lists, discounts given, actual prices paid over the IIP, contracts signed with domestic or foreign suppliers.

5. Substantiate whether the demand of the PUC is highly price-sensitive. If you consider that there are factors other than price [e.g. Costs & expenses, supply-side (low demand due to higher degree of buyer's market), seller's market, consumer perceptions, competition and/or the like] that have impacted your purchase decisions, list the same and substantiate with relevant evidence.

6. Provide details whether the production technology used by the PUC-producers in India is inefficient/ obsolete. Whether difference in the technology has led to PUC being unviable? Please provide evidence.

7. Provide details of any future investments or expansions or forecasted changes that your company and the Indian industry consuming the PUC in India is planning in the next five years with regards to PUC.

Name of such Producer	Expected capacity (MT)	Expected timeline (months)	Expected Investment (Rs. Cr.)	Desired return on investment (Rs. Cr. or %)

Note: For the above table, specify the basis of indicating the desired return on investment.

8. Specify whether the downstream user industry for the PUC is majorly located in a particular geographical region. Please explain the impact thereof on the user industry. Provide information for the following zones of India:

S. No.	Parameters	North	South	East	West	Central	North-East	Total
1	Installed Capacity							
2	Production							
3	Consumption							
4	Imports							

9. Provide details of alternate sources of supply of the PUC

10. Provide information along with evidence whether you are aware of any anti-competitive or customer discriminatory behaviour adopted by the producers in India.

11. Provide details of whether you anticipate any supply shortages of the PUC in the near future due to prioritization of certain market segments (captive consumption, related sales, domestic market, export obligations, etc.) by the domestic producers of PUC.

12. Provide details of country-wise exports made by your company (volume and value) during the IIP. Also specify whether such exports can be made using duty exemption or remission schemes. If the PUC was imported for production of your product,

specify whether the import was made using duty exemption or remission schemes. If duty exemption or remission schemes was not used, elaborate reason for the same. Please quantify the amount of duty benefit in case of purchase under advance license. If the Govt. of India has specified Duty DrawBack rate (DDB) for your product, please specify the current rate of DDB.

13. Provide details of any interruptions in the domestic production of the PUC in the last four years. Please substantiate whether such interruptions impacted the cost and price of the PUC along with relevant evidence or calculations. Also indicate forecasted factors (currency fluctuation, raw material shortages, government policy, shutdown, closure, etc.) that may affect production in the future.

14. Provide details of whether any related industry is likely to be impacted due to the imposition of duty on PUC, if levied.

15. Provide any other information that may be relevant for the present investigation.

PART-V. UPSTREAM INDUSTRY

1. Provide details of the major users of your product and their market share of the PUC.

Name and contact details of the upstream producer	Share of upstream producer in market for PUC

2. Provide the volume of sales made by your company with an estimation of the Indian industry producing the immediate upstream product of the PUC in the last four years.

Volume of Sales (MT)	Year 1	Year 2	Year 3	Year 4
Name of upstream producer				
Indian Industry producing the immediate upstream product of the PUC				

3. Indicate the % share of your product used in the PUC in total sales of your company.

4. Explain the level of your company's dependency on the domestic production of the PUC. Provide volume of sales of your product made to the Indian industry producing PUC.

5. Provide details of any future investments or expansions or forecasted changes that your company or Indian industry producing upstream product is planning in the next five years with regards to product used in PUC.

Name of such Producer	Expected capacity (MT)	Expected timeline (months)	Expected investment (Rs. Cr.)	Desired return on investment (Rs. Cr. or %)

Note: For the above table, specify the basis of indicating the desired return on investment.

6. Substantiate along with relevant calculations the impact of dumping of the PUC on the performance of your company and the Indian industry producing the upstream product, if any. Provide details of volume and value of sales of your product to the producers of PUC over the IIP. In case your product prices were impacted due to dumping of the PUC, substantiate the same and please quantify the impact in absolute terms and as % of the price of your product during the POI.

7. In case of Sunset Review (SSR) investigation, explain how the imposition of duties has affected operations of the upstream industry of the PUC. Please quantify such impact.

S. No.	Particulars	UOM	Year 1	Year 2	Year 3	POI
1	**Production**	MT				
2	**Total Sales volume**	MT				
a	Domestic sales	MT				
b	Export sales	MT				
c	Captive consumption	MT				
3	**Total Sales value**	Rs. In Lacs				
a	Domestic sales	Rs. In Lacs				
b	Export sales	Rs. In Lacs				
c	Captive consumption	Rs. In Lacs				
4	**Profits / loss**	Rs. Per MT				
5	**Return on investment**	%				
6	**Employment**	Numbers				
7	**Any other parameters**	Please specify				

Note: Change the unit (e.g. MT) as applicable for the product

8. Provide any other information that may be relevant for the present investigation.

Glossary of Terms used:

- POI: Period of Investigation in the present investigation
- IIP: Injury Investigation Period (which includes POI) in the present investigation
- PUC: Product Under Consideration in the present investigation
- ADD: Anti-Dumping Duty
- SSR: Sunset Review Investigation
- MT: Metric Tonne, if applicable (alternatively the unit as applicable for the product should be used)
- UOM: Unit of Measurement

India Pavilion at Arab Health - Dubai, UAE, 30th January - 02 February, 2023 - reg.

Circular No. PXL/HO/Cir-046/2022-23 dated 28th September 2022

IDMA have received communication from Mr Udaya Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 28th September 2022 as reproduced below on the above subject.

We are glad to inform that for the 16th consecutive year, Council is participating in Arab Health 2023, which will be held during 30 Jan – 02 Feb 2023 at Dubai, by organizing India Pavilion with 558 sq. meters of space.

Highlights of the event:

- Arab Health is one of the major International exhibitions in Middle East.
- Over 3000+ exhibitors from 70 countries, including International country pavilions display their healthcare products and services at the exhibition.
- Arab Health is focused for Surgicals, Medicals equipment, Herbal products, Pharmaceuticals etc.
- More and more number of visitors attending India Pavilion looking for Pharmaceutical, Nutraceuticals also.
- India Pavilion is being organized, in 558 sq. mts of space located in Za'abeel Hall with 62 stalls.
- With the support of Ministry of Commerce, Govt. of India, Council is able to offer stalls in India Pavilion at a lesser cost than the cost of stalls offered by the organizers.
- Stalls can be reserved through online reservation system.

India Pavilion:

Please click on the following links to see the floor plans of Arab Health Overall and India Pavilion layouts:

Arab Health 2023 - Overall Plan

India Pavilion in Za'abeel Hall

Construction of Pavilion:

Pavilion will be constructed at par with International Standards and individual participants need not go for their own designs. However, members are at liberty to have own designs for their stalls, subject to the height limits prescribed by the organizers for Pavilions and also without causing any disturbance to the Top Branding of India Pavilion. Members who would like have their own designs, may send the designs to us for prior approval. It may be noted that only bare space will not be allowed in Pavilion.

Cost of Participation:

We are pleased to inform you that with support of Government, Pharmexcil is offering Stalls in India Pavilion at concessional rates and the details of which are given below:

Sl. No.	Stall size	Stall Cost in Rs.
1	12 sq. meter (14 nos)	7,83,600
2	9 sq. meter corner (14nos)	6,23,600
3	9 sq. meter (20nos)	6,03,600
4	6 sq. meter (14nos)	4,23,600

Note: The above cost includes minimum furniture like 1 info counter, 1 table, 2/3 chairs, 1 brochure stand, lights, fascia, 1 dust bin, electricity & Insurance/VAT, lead generation basic package, administration & registration fee etc.

Allotment of Stalls:

With a view to make the allotment procedure easy and transparent, we made the reservation of stalls online. Interested members may please click on the following link reserve as per your choice.

ONLINE RESERVATION OF STALLS (The above link details will be sent in our next Circular)

Please note the following terms:

- Members can reserve stalls as per their choice, subject to a maximum of 2 stalls only. If any member reserves more than 2 stalls/at different locations, they are required to release one booking, keeping one of their choice. If no mail is received within 15 minutes of booking, Council releases booking of one stall, without any notice, to enable others to reserve the stalls.

- 100% payment has to be made within 5 days of reservation, failing which reservation gets automatically cancelled, without any further notice and the same will be allotted to the other companies in the waiting list.

Cancellation of stalls:

Cancellation is not allowed once the stall is reserved/ allotted. Reservation of stall gets automatically cancelled, if the payment is not received within the scheduled time.

MAI Support to the Participants:

India Pavilion stalls are priced at concessional rates already, taking into account of the financial assistance available from Government. In addition, Members will be reimbursed their travelling expenses to a maximum extent of Rs.75,000/- per member per company and subject to the provisions of MAI scheme Latest Guidelines & release of funds by Government.

- The exhibitor should be a member of the Council and have completed one year of membership.
- Export turnover of the exhibitor should be less than/ upto Rs.50 crores during previous financial year.
- Should not have participated through our Pavilion in Arab Health for not more than 3 years.

Eligible members may use the following link to submit their claims for reimbursement of above assistance within 30 (thirty) days of completion of the event

Link

All members aspiring to increase their exports in Middle East and African region are advised to participate in this important event.

For further information if any, please send email to webdesk@pharmexcil.com , support@pharmexcil.com.

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Trade Enquiry by Serbian company

Circular No. PXL/HO/BEC-009/2022-23 dated 27th September 2022

IDMA have received communication from Mr Udaya Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 27th September 2022 as reproduced below on the above subject.

Pharmexcil is in receipt of communication from Embassy of India, Belgrade, Serbia wherein a Serbian pharmaceutical company has enquired for suppliers of **"Indomethacin"** a pharmaceutical product from India.

The contact details of the Serbian company (buyer) is as follows:

Name	: Mr. Silvio Bulic
Company Name	: M/s. SB Trade
E-Mail	: silvio@sbtrade.rs
Mob.	: +381 (63) 47 50 50 (Serbia)

Member companies dealing with the above mentioned product may take advantage of this opportunity and contact the above mentioned Serbian company directly for further business negotiation

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Notifications for the substances brought under the purview of the NDPS Act and Rules - reg.

Dear Member,

Please note that as per the attached notifications, the following substances have been brought under the purview of the NDPS Act and Rules -

1) S.O.4427(E) dated 22nd September, 2022 notifies Isotonitazene, it's salts and preparations thereof as a manufactured drug (Narcotic), with immediate effect.
2) S.O.4428(E) dated 22nd September, 2022 notifies 7 substances, its salts and preparations as Psychotropic substances, with immediate effect.
3) S.O. 4429 (E) dated 22nd September, 2022 issued amendments to notification S.O. 1055 (E), dated October 19, 2001 Specifying "Prescribed quantities for certain Narcotics drugs".

Kindly make a note of the same and ensure compliance as per the NDPS Rules.

Thanks & Regards,

Daara Patel
Secretary - General

S.O.4427(E) dated 22nd September, 2022 notifies Isotonitazene, it's salts and preparations thereof as a manufactured drug (Narcotic), with immediate effect

Notification dated 22nd, September, 2022

S.O.4427(E): In exercise of the powers conferred by sub-clause (b) of clause (xi) of section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby declares the following substance, salt and preparations thereof to be manufactured drugs, namely:-

(i) Isotonitazene - N,N-diethyl-2-(2-(4-isopropoxy-benzyl)-5-nitro-1H-benzo[d]imidazol-1-yl)ethan-1- amine

F. No. N-12012/01/2021-NC-II

Mukesh Sundriyal
Under Secy.
Ministry of Finance, Department of Revenue
New Delhi

● ● ●

S.O.4428(E) dated 22nd September, 2022 notifies 7 substances, its salts and preparations as Psychotropic substances, with immediate effect

Notification, dated 22nd, September, 2022

Whereas the Central Government is satisfied, on the basis of information and evidence which has become available to it, with respect to the nature and effect of and the scope for abuse of the following substances (natural or synthetic) or natural material or any salt or preparation of such substances or materials, and the modification with respect to such substances and the changes that have been incorporated in the United Nations Convention on Psychotropic Substances 1971, that it is necessary to add the following substances or natural materials or salts or preparation of such substances or materials in the list of psychotropic substances specified in the Schedule to the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) (hereinafter referred to as the said Act);

Now, therefore, in exercise of the powers conferred by section 3 of the said Act, the Central Government hereby makes the following further amendments in the list of

psychotropic substances specified in the Schedule to the said Act, namely: -

In the said Act, in the Schedule, after serial number 110ZT and the entries relating thereto, the following serial numbers and entries shall be inserted, namely: -

Sl. No.	International nonproprietary names	Other non-proprietary names	Chemical name
"110ZU		CUMYL-PEGACLONE	5-Pentyl-2-(2-phenylpropan-2-yl)-2,5-dihydro-1Hpyrido[4,3-b]indol-1-one
110ZV		MDMB-4en-PINACA	Methyl 3,3-dimethyl-2-(1- (pent-4-en-1-yl)-1Hindazole-3-carboxamido)butanoate
110ZW		3-Methoxyphencyclidine	1-(1-(3-Methoxyphenyl)cyclohexyl)piperidine
110ZX		Diphenidine	1-(1,2-Diphenylethyl)piperidine
110ZY		Clonazolam	6-(2-Chlorophenyl)-1-methyl-8-nitro-4Hbenzo[f][1,2,4] triazolo[4,3-a][1,4]diazepine
110ZZ		Diclazepam	7-Chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2Hbenzo[e][1,4]diazepin2-one
110ZZA		Flubromazolam	8-Bromo-6-(2-fluorophenyl)-1-methyl-4Hbenzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine"

F. No. N-12012/01/2021-NC-II

Mukesh Sundriyal
Under Secy.
Ministry of Finance, Department of Revenue
New Delhi

Note: The Schedule to the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) was first amended vide number S.O. 785(E), dated the 26th October, 1992 and subsequently amended vide numbers S.O.49(E), dated the 8th January, 1993, S.O.39(E), dated the 12th January, 1996, S.O.475(E), dated the 11th June, 2003, G.S.R.621(E), dated the 1st August, 2003, G.S.R.1(E), dated the 2nd January, 2004, S.O.311 (E), dated the 10th February, 2011, S. O. 376 (E), dated the 5th February, 2015, S. O. No. 2374 (E), dated the 12th July, 2016, S.O. No. 1383 (E), dated the 2nd May, 2017, S.O. 821(E), dated the 27th February, 2018, S.O. 1761(E), dated the 26th April, 2018 and S.O. 3448(E) dated the 13th July, 2018, S.O.1352(E), dated the 13th March 2019 and S.O.1275(E), dated the 23rd March 2021.

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S.O. 4429 (E) dated 22nd September, 2022 issued amendments to notification S.O. 1055 (E), dated October 19, 2001 Specifying "Prescribed quantities for certain Narcotics drugs"

Notification, dated 22nd, September, 2022

S.O. 4429(E).— In exercise of the powers conferred by clauses (viia) and (xxiiia) of section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following further amendments in the notification of the Government of India, Ministry of Finance, Department of Revenue, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub- section (ii) *vide* number S.O. 1055 (E), dated the 19th October, 2001, namely: -

In the said notification, in the Table, after serial number 238 ZZ-O and the entries relating thereto, the following serial numbers and entries shall be inserted, namely: -

S. No.	Name of Narcotic Drug and Psychotropic Substance (International non- proprietary name (INN))	Other non-proprietary name	Chemical Name	Small Quantity (in gm.)	Commercial Quantity (in gm./kg.)
1	2	3	4	5	6
"238ZZP	Isotonitazene		N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzo[d]imidazol-1-yl)ethan-1-amine	0.01 gm	0.5 gm
238 ZZQ		CUMYL-PEGACLONE	5-Pentyl-2-(2-phenylpropan-2-yl)-2,5-dihydro-1Hpyrido[4,3-b] indol-1-one	0.2gm	10.0gm
238 ZZR		MDMB-4en-PINACA	Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1Hindazole-3-carboxamido)butanoate	0.002gm	0.1gm
238 ZZS		3-Methoxyphencyclidine	1-(1-(3- Methoxyphenyl) cyclohexyl)piperidine	0.1gm	5.0gm
238ZZT		Diphenidine	1-(1,2-Diphenylethyl)piperidine	2.0gm	100gm
238 ZZU		Clonazolam	6-(2-Chlorophenyl)-1-methyl-8-nitro- 4Hbenzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	0.02gm	1.0gm
238 ZZV		Diclazepam	7-Chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro- 2Hbenzo[e] [1,4]diazepin2-one	0.2gm	10.0gm
238 ZZW		Flubromazolam	8-Bromo-6-(2-fluorophenyl)-1-methyl- 4Hbenzo[f][1,2,4] triazolo[4,3- a][1,4]diazepine"	0.035gm	1.75gm

[F. No. N-12012/01/2021-NC-II]

Mukesh Sundriyal
Under Secy.
Ministry of Finance, Department of Revenue
New Delhi

Note: *The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 1055 (E), dated the 19th October, 2001 and subsequently amended vide numbers S.O. 2941 (E), dated the 18th November, 2009, S.O. 1430 (E), dated the 21st June, 2011, S.O. 375 (E) dated the 5th February, 2015, S. O. 2375(E), dated the 12th July, 2016, S.O. 384 (E), dated the 2nd May, 2017, S.O. 822(E), dated the 27th February, 2018, S.O. 1762(E), dated the 26th April, 2018, S.O. 1351(E), dated the 13th March 2019 and S.O. 1276(E), dated the 23rd March 2021.*

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Vietnam dials India for drug supplies

With covid-19 impacting the pharma sector following supply disruption from China and Europe, Vietnam has sought the help of Indian healthcare, pharmaceutical and beauty product companies to ensure steady supplies.

So far, Vietnam had been dependent on Chinese pharma inputs for over 80% of its requirements. Vietnam's pharma market is valued at around $5 billion.

India's department of pharmaceutical, which operates under the ministry of chemicals and fertilizers, has received a communication from the high commission of Vietnam for allowing the pharma industry to participate in a healthcare event scheduled for May 2023. "The aim is to promote trade and investment opportunities for both countries," said an official in the know seeking anonymity.

"Vietnam's pharma industry is one of the highest growth markets in the region, and both countries have great potential for bilateral trade and investment in pharmaceuticals, but due to the pandemic it could not be explored," the official said.

According to Pharmaceutical Export Promotion Council of India, Vietnam ranks 21st in India's list for export destination for pharmaceutical products.

In FY2021, India exported pharma products worth over $243.91 million to Vietnam.

"India can make best use of this opportunity because Vietnam has limited research and development in pharmaceutical sector," the official added.

Queries emailed to the high commission of Vietnam and a department of pharmaceuticals spokesperson did not elicit any response till press time.

Source: Priyanka Sharma, Mint, 26.09.2022

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IIT Guwahati scientists develop a strategy to deliver chemotherapeutic drugs specifically to cancer cells

IIT Guwahati researchers have developed a new strategy to deliver chemotherapeutic drugs specifically to the cancerous cells in a patient's body. The research study results have been published in prestigious journals of The Royal Society of Chemistry including 'Chemical Communications' and 'Organic and Biomolecular Chemistry'.

The problem with existing chemotherapeutic drugs is that they kill healthy cells of the body in addition to cancerous cells, leading to numerous undesirable side effects. In fact, it is believed that cancer deaths are as much due to the side effects of chemotherapy as the disease itself.

There is worldwide research to overcome the drawbacks of secondary toxicity of chemotherapeutic drugs. Some strategies that are being explored include target-specific delivery of the drugs and on-demand delivery of appropriate drug doses to cancerous cells/tissues.

Explaining his research Prof. Debasis Manna, Department of Chemistry, IIT Guwahati, said, "We have two needs in the development of chemotherapy drugs – the drug must be targeted at the cancer cells, the drug must be released by an external trigger whenever it is required."

How does it work?

To meet the above needs, the molecule developed by the research team has four special features: The first feature is that the molecules assemble to form hollow spherical shells in water. These shells that are ten-millionth of a meter in size can be used as a minuscule container for the drug molecule; the second characteristic is that the molecule has a part (the acetazolamide ligand) that specifically binds to cancer cells and not normal cells; the third feature of the molecule is that it has a photocleavable linker moiety that is responsive to infrared light and breaks the shell when exposed to IR; molecule also contain a dye moiety (cyanine-3) which is also useful for both fluoresce and scattering-based imaging to visually monitor the entire process.

Thus, the molecules developed by the IIT-G researchers self-assemble as capsules to hold the drug, which then attaches only to cancer cells. When infrared light is shone on it, the shell breaks and releases the encapsulated drug into the cancerous cell. The IIT-G scientists rightly believe that their approach would allow the development of drug carriers for chemotherapy with enhanced efficacy and negligible side effects.

Number of cancer patients in India is anticipated to be 30 million by 2025

The societal impacts of this work cannot be overstated. Given that the number of cancer patients in India is anticipated to be 30 million by

2025, the development of effective chemotherapeutic drugs and delivery systems is critical. The researchers believe that the development of target-specific, light-responsive, self-imaging macrocyclic lipids such as those they've developed could help in image-guided chemotherapeutic applications.

Following the development of the targeted IR (light)-trigger drug release system, the IIT Guwahati researchers are preparing to perform in vivo studies to take this understanding closer to drug development.

The research papers have been co-authored by Prof. Debasis Manna, Department of Chemistry, IIT Guwahati, along with his research scholars Mr. Subhasis Dey, Ms. Anjali Patel, and Mr. Biswa Mohan Prusty, among others. Anticancer activities were carried out in collaboration with Prof. Siddhartha Sankar Ghosh and Ms. Plaboni Sen from the Indian Institute of Technology Guwahati and Prof. Arindam Bhattacharyya and Mr. Soumya Chatterjee from Calcutta University.

Source: Times of India, 26.09.2022

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Upgradation of existing WHO-GMP plant for higher standards not included under PTUAS: DoP

Even as any pharma Micro, Small and Medium Enterprise (MSME) unit with proven track record to upgrade technology to meet World Health Organisation's Good Manufacturing Practice (WHO-GMP) or Schedule M Standards can apply under the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), upgradation of existing WHO-GMP plant for higher standards of WHO-GMP or EU GMP or US FDA is not included in the eligibility criteria at present, clarifies the Department of Pharmaceuticals (DoP).

Responding to the Frequently Asked Questions (FAQs) on the scheme, it said that any pharma MSME unit with proven track record to upgrade technology to meet WHO-GMP or Schedule M Standards can apply under the PTUAS.

The unit can approach any scheduled commercial bank both in public and private sector for the loan. Only those applications for which loan has been approved by Lending Institution within 90 days preceding the application date to PMC will be taken up for benefit under the scheme.

Application for the subsidy under the scheme should be submitted in the portal

However, on a specific query that whether capital investments for upgradation of an existing WHO-GMP compliant plant to higher standards of WHO GMP or EU-GMP or US FDA eligible for assistance under PTUAS scheme, the DoP said that the objective of the scheme is "To facilitate Micro, Small and Medium Pharma Enterprises of proven track record to upgrade their technology to meet WHO-GMP or Schedule M standards".

"Upgradation of existing WHO GMP plant for higher standards of WHO GMP or EU GMP or US FDA is not included in the eligibility criteria at present," it said.

Up to maximum of 5% per annum (6% in case of units owned and managed by SC/STs) of interest subvention for loan and loan component eligible under the scheme taken to the upper limit of Rs. 10 crore for a maximum period of three years on reducing balance for sanctioned loans by any scheduled commercial banks/financial institutions, both in the public and the private sector is the limit of the scheme.

Credit linked capital subsidy of 10% on loan component eligible under the scheme. Maximum limit of loan will be Rs. 10 crore.

Sanction and disbursement of the loan shall be from Scheduled Commercial Banks from whom the unit desires to get financial assistance. Processing of subsidy shall be undertaken by SIDBI based on the application received in the portal. Sanction and release of subsidy is under the purview of the Empowered Committee of DoP.

Another query was that whether a private limited company with two existing manufacturing units, out of which, one unit (Unit-1) is WHO GMP Certified, is planning to upgrade its second unit (Unit-2) to Schedule M can be covered under PTUAS? The same enterprise is planning to set up a new unit i.e., Unit-3 with Schedule M / WHO GMP standard and whether both of these be covered under PTUAS, was another question.

The DoP replied that the Unit 2 can be covered under PTUAS subject to the proposal and investment meeting the criteria under the scheme and subject to SSC approval. New unit proposed, Unit 3 may not be covered under PTUAS as the requirement of loan component may not be within the prescribed limit of 10 crore as per scheme guidelines.

"Moreover, the scheme is primarily to facilitate Micro, Small and Medium Pharma Enterprises of proven track record to upgrade their technology," it added.

Commenting on the role of SIDBI as Project Management Committee (PMC) in Strengthening of Pharmaceutical Industry (SPI), the DoP said that the Project Management Consultant, engaged by the Department, is expected to act as a bridge between the Department/Scheme Steering Committee (SSC) and the applicants/beneficiaries and will help for the expeditious implementation of the projects in a systematic, professional and transparent manner.

Its responsibilities include preliminary examination of the proposals, and preparation of evaluation reports that will be placed before the SSC for final selection of proposals, besides, developing an online portal to receive the applications and maintain the required details of all the applicants, it added.

Source: Gireesh Babu, Pharmabiz, 29.09.2022

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PUBLICATIONS DIVISION

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Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
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