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IDMA BULLETIN

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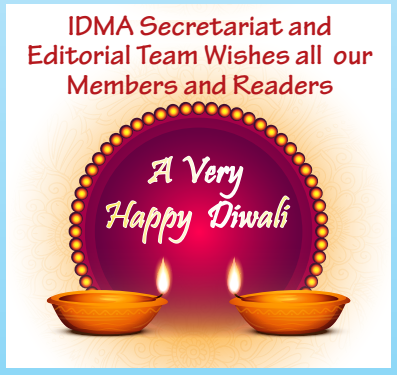

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA Symposium on Nasal and Pulmonary Drug Delivery

on November 10 & 11, 2022

at Hotel Sofitel, BKC, Mumbai

(Details on Page: 9)

Register now

HIGHLIGHTS

EXCEPTIONAL PRODUCTS, THAT COME FROM EXCEPTIONAL LEADERSHIP

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We, at Signet, haven't become industry leaders overnight. Our position at the forefront of the market comes down to always delivering only the highest level of products and services. And to the like-minded partnerships we've built, such as with IFF (Formerly Dupont Nutrition & Health).

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But what best reflects this successful partnership, is the shared belief and commitment to providing our customers the highest standards of quality and service.

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IDMA BULLETIN

Vol. No. 53 **Issue No. 39** **15 to 21 October 2022**

IDMA ACTIVITIES:

GOVERNMENT NOTIFICATION:

CPCB MATTERS:

GST MATTERS:

GOVERNMENT COMMUNICATIONS:

CONGRATULATIONS:

NATIONAL NEWS:

IDMA-GSB, IPA-GSB and LJIP Panel Discussion on "Pharmacy United in Action For a Healthier World" on Saturday, 15th October 2022

Indian Drug Manufacturers' Association (Gujarat State Board), Indian Pharmaceutical Association (Gujarat State Branch) and L.J. Institute of Pharmacy jointly organized a panel discussion on **"Pharmacy United in Action for a Healthier World"** on Saturday, 15th October 2022 at L.J. Institute of Pharmacy. The professionals representing Indian Medical Association, Community Pharmacy, Hospital pharmacy, Pharma regulatory, Clinical Research, Industry and Academia effectively presented diverse roles played by pharmacists and integration of pharmacy with other healthcare professions. Audience of more than 150 persons composed of faculty as well as the students of LJIP.

The panelists included: Dr. Jayant Dave, President, IPA-GSB & Adjunct Professor at LMCP (moderator), Mr. Ruchir Shah, Director at Saga Lifesciences Ltd., Ahmedabad and EC member, IDMA-GSB; Dr. Shreeraj Shah, Director at L.J. Institute of Pharmacy Ahmedabad; Dr. Jignesh Patel, Senior Clinical Research Professor & Academician at Parul University; Dr. Dilip Gadhavi, President, Indian Medical Association; Dr. Nipul Kapadia, Head of Pharmacy Services at Apollo hospital, Ahmedabad; Dr. Manoj Gadhavi, Assistant Commissioner, FDCA, Ahmedabad; Shri Jaswant Patel, President, Federation of Gujarat State Chemist & Druggist association. Dr Pundarikaksha gave a welcome address. Dr. Praful Bharadia and Mr. Shrenik Shah, Chairman, IDMA-GSB gave an opening remarks. Dr Dilip Maheshwari delivered a vote of thanks. The session was then followed by AGM of IPA- GSB.

Overall this panel discussion ought to be the most informative for the students as well as for all the members which held the main objective to elevate the status and improve the pharmacy competence and services for patient care that will ultimately help the students in their near future while making the pharmacy a better and society relevant branch.

IDMA – GSB jointly with BCIL and SNL, USA Organizing Two day training programme on "Know-Your-Customer (KYC) best practices" for Indian Pharmaceutical industry at Hotel Courtyard by Marriott, Ahmedabad on November 14-15, 2022

Dear Member,

Greetings of the day!!!!!

We are pleased to inform you that Indian Drug Manufacturers' Association – Gujarat State Board (IDMA – GSB), jointly with Biotech Consortium India Limited (BCIL), New Delhi and Sandia National Laboratories (SNL), USA is organizing a 02 -day training programme on "**Know-Your-Customer (KYC) best practices"** for Indian Pharmaceutical industry at **Hotel Courtyard by Marriott, Ramdev Nagar Cross Road, Satellite Road, Ahmedabad on November 14-15, 2022.**

The objective of the training programme is to raise awareness of chemical weapons proliferation potential and to provide Know-your-customer best practices in the pharmaceutical industry. Details are in attached pamphlet. This training is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines). It is designed for **pharma industry managers, security officers, regulators, and transportation logistics company managers.** There are a total 20 slots and participants will be selected based on the activities undertaken by their organization in reference to the topic of the programme and the usefulness to the participant's organization thereby achieving the objective of the training.

Kindly note that expenses towards travel by Air (economy) / Train (2nd AC fare) / Taxi and boarding & lodging (accommodation at Hotel Courtyard by Marriott and meals) of participants will be borne by SNL/BCIL. More details and registration link are given in the attached pamphlet.

We request you to nominate concerned officials from your organization for the training programme and request them to register positively by **October 15, 2022.**

There is No registration fee, however, the REGISTRATION IS MANDATORY for consideration in the training programme.

With kind regards,

Sumit J. Agrawal
Hon. Secretary
IDMA - GSB

Brief about organizing partners:

a) Biotech Consortium India Limited (BCIL), New Delhi

BCIL is a company set up in 1990 as an initiative of the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and All India Financial Institutions. As part of our activities, we are engaged in capacity building related to biosafety and chemical security issues. Such activities are undertaken in collaboration with national and international agencies.

b) Sandia National Laboratories (SNL), USA

SNL undertakes capacity building programmes, with support from US Department of State's Chemical Security Program (CSP).

Know-Your-Customer (KYC) Workshop for Indian Pharmaceutical Industry

14-15 November 2022, 09:00-17:00 IST

Announcement: Biotech Consortium India Limited (BCIL), Indian Drug Manufacturers' Association (IDMA) and Sandia National Laboratories (SNL) on behalf of the United States Department of State's Chemical Security Program (CSP) are organizing an in-person workshop to raise awareness of the chemical weapons (CW) proliferation potential of key pharmaceuticals and to provide Know-Your-Customer (KYC) best practices for the Indian Pharmaceutical industry. During this workshop participants will learn how to recognize suspicious purchase requests, develop customer vetting strategies, and understand regulations regarding the sale of 'dual use' chemicals that may be misused as chemical weapons. Additional topics will also include chemical security threats and chemicals of concern. The overarching focus of this event is to develop strategies that deny access to weaponizable pharmaceuticals. This workshop is appropriate for all pharmaceutical companies producing and using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines).

Audience:

- Up to 20 Indian Pharma industry managers, security officers, regulators, and transportation logistics company managers.

Goal:

- Provide participants with the awareness of the chemical weapons proliferation potential of key pharmaceuticals, an understanding of KYC, and the knowledge and resources to implement KYC best practices and policies at their institutions to ensure their products are not acquired for illicit purposes.

Agenda:

14 November 2022	15 November 2022
• Welcome, Introduction, Goals • Industry Case Study • Chemical Security Threats • Pharmaceuticals of Concern with exercise • Illicit Procurement Tactics with Case Studies	• Overview of KYC Principles and Practices • Interactive Scenario-Based Activities on KYC Indicators • KYC Implementation • Next Steps • Valedictory

Registration Site:
https://gcbs-events.sandia.gov/chemical-security-program/remote-know-your-customer-kyc-training-for-indian-pharmaceutical-industry

Points of Contact:

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cvwilli@sandia.gov

Dr. Andrew W. Nelson
Sandia National Laboratories
awnelso@sandia.gov

Dr. Vibha Ahuja, Ph.D.
Biotech Consortium India Limited
vibhaahuja@biotech.co.in
Phone no. 98912 44434

Registrations open for ET MSME Awards 2022. Apply Now!

Dear Member,

Greetings from The Economic Times Digital and IDMA.

IDMA is pleased to inform its members that IDMA is the Associate Partner for the ET MSME AWARDS 2022 and is herewith sharing The Economic Times Digital launch of the third edition of ET MSMEs Awards.

Over the years, organizations like: IMC Chamber of Commerce, Indian Textile Accessories & Machinery Manufacturers Association, Plastics export promotion council, Association of Diagnostic Manufactures of India, Sports Goods Foundation of India, Synthetic and Rayon textiles export promotion council and many others have associated with The Economic Times Digital.

For your reference please find the attached MSME Awards mailer.

About the programme:

ET MSMEs Awards was introduced to identify the top MSMEs in the country and highlight the good work the sector is doing. The first and second editions of ET Rise MSMEs Ranking saw a participation of over **8,000 and 10,000 businesses respectively,** out of which the top-ranked MSMEs were identified through a rigorous evaluation process. In both the previous editions the top-ranked businesses were felicitated in a digital event that witnessed the leading voices of the MSME ecosystem.

This year the **Final Felicitation Day** will be an on-ground event which will serve as an agenda-setting forum for industry leaders, policymakers, and the entrepreneurial ecosystem to define actionable strategies and solutions to boost the global competitiveness of MSMEs and strengthen the industry, shaping the new India growth story.

This year Economic Times Digital will award and recognize MSMEs in **26 different categories**.

1. **Overall industry awards (6 Awards)**
   a. Indian MSME of the Year Award **(1 for services; 1 for manufacturing)**
   b. Global Indian MSME of the Year Award **(1 for services; 1 for manufacturing)**
   c. India's Top Exporter of the Year Award **(1 for services; 1 for manufacturing)**
2. **Awards by each MSME category (9 awards)**
   a. India's Top-Performing MSME of the Year Award (1 for Micro, 1 for Small, 1 for Medium)
   b. India's Fastest-growing MSME Award (1 for Micro, 1 for Small, 1 for Medium)
   c. India's Top Innovative MSME of the Year Award (1 for Micro, 1 for Small, 1 for Medium)
3. **MSME Enabler Awards (2 Awards)**
   a. Indian MSME Enabler Award for Tech & Innovation
   b. Indian MSME Enabler Award for Banking & Financing
4. **Special Award Categories (5 awards)**
   a. Top-performing Listed SME (1 for Listed SMEs)
   b. Indian MSME Women Entrepreneur of the Year Award (1 for Micro; 1 for Small; 1 for Medium)
   c. Best CSR Initiative by an SME (1 for Medium)

5. Industry Focussed Award Categories (4 awards) - These are all manufacturing sector focused

a. Automobile & OEM MSME of the Year

b. Pharmaceutical & Healthcare MSME of the Year

c. Electrical & Electronics MSME of the Year

d. Clothing & Apparel MSME of the Year

Key KPI of the Event:

- 10000+ Registrations
- 15Mn+ Reach
- 10Mn+ Impressions
- 1Mn+ Video Views
- 300+ Minutes of content
- 30+ speakers
- 10+ sessions

Kindly, use the UTM tracker embedded URL for the registration purpose.
https://economictimes.indiatimes.com/engage/et_msmeawards2022.cms?utm_source=Ext7&utm_medium=PromoMailer1&utm_campaign=ETMSMEAwards

We sincerely request our MSMEs members to actively support and participate in this **Economic Times MSME Awards 2022.**

Thanks & regards,

Daara B Patel
Secretary – General

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

Early Bird Discounts - Before 21st October 2022 : 10% discount ~ PLEASE REGISTER NOW

Dear Member,

Symposium on Nasal and Pulmonary Drug Delivery

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

Plenary Speaker:	**Dr. John Pritchard** Owner of Inspiring Strategies, providing consultancy on respiratory drugs, devices and digital health England, United Kingdom	

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.

We are extremely happy to inform you that **Dr. John Pritchard** has agreed to grace the event as **Plenary Speaker.** We have an excellent line up of speakers, panellists and motivators who will leave you enlightened & motivated :

- Mr. Paul Sullivan, DH Industries
- Mr. Chris Baron, Aptar
- Mr. Marco Laackmann
- Ms. Reenal Gandhi, Aptar
- Dr. Anselm Ebert & Dr. Mirjam Kobler, Presspart
- Mr. Paolo Rafaelli, Apex Inhalation
- Mr. Harro Hoefliger
- Dr. Ravindra Purohit

We attach herewith the Tentative Agenda for your kind perusal and information

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***

Hotel Reservations :

We have a contract with Hotel Orchid, Vile Parle (East), Mumbai for Hotel Reservations :

Single Occupancy : Rs.7,000/- + taxes per night & Double Occupancy : Rs.8,000/- + taxes per night

The above rates include complimentary breakfast & wi-fi

Contact : Mr. Shirazi | Mobile # 8879366324 | Email : srsm.mum@orchidhotel.com

CODE FOR BOOKING: *IDMA*

For any further clarifications / assistance, please feel free to call :

Ms. Sapna Patil - (9619802299 / **admin@idmaindia.com**) &
Mr. Melvin Rodrigues (9821868758 / **actadm@idmaindia.com**)

Looking forward to your support by way of Registrations and making this symposium a grand success.

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 l 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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IFSC Code: **BARB0DBWORL**
Branch: **Worli, Mumbai 400 018**

INDIAN DRUG MANUFACTURERS' ASSOCIATION

SYMPOSIUM ON NASAL & PULMONARY DRUG DELIVERY

AGENDA (Tentative)

DAY 1 (November 10, 2022)		
Time	**Subject**	**Speakers**
9.00 am - 9.45 am	**Registration & Breakfast/Tea/Coffee**	
9.45 am - 9.50 am	**Ligthing of the Lamp**	
9.50 am - 9.55 am	Welcome Address	**Mr. Daara B Patel**, Secretary - General, IDMA
9.55 am - 10.00 am	Opening Address	**Mr. Bharat Shah,** Sr. Vice President, IDMA
10.00 am - 10.05 am	Setting the Tone for the Symposium	**Mr. S.R Vaidya,** Chairman, MSME Committee, IDMA
10.05 am - 10.15 am	Address by Guest of Honour	**Mr. Chakravarthi AVPS**, Ecobliss India Pvt. Ltd.
10.15 am - 10.30 am	Address by Chief Guest	**Shri Abhimanyu Kale,** Commissioner, FDA Maharashtra
10.30 am - 11.30 am	pMDIs: What Might the Future Hold?	**Dr. John Pritchard**
11.30 am - 11.45 am	**Tea/ Cofee Break**	
11.45 am - 12.45 pm	Sustainable pMDI Aerosol Filling	**Mr. Paul Sullivan,** DH Industries
12.45 pm - 2.00 pm	**Lunch Break / Exhibition**	
2.00 pm - 3.00 pm	Next Steps in Inhalation: From Low GWP to High Performance in Powder Dispersion	**Dr. Anselm Ebert & Dr. Mirjam Kobler,** Presspart
3.00 pm - 4.00 pm	"Zephex®152a – A new, green, medical propellant" Availability, key properties and formulationbehaviour	Koura
4.00 pm - 4.15 pm	**Tea/ Cofee Break**	
4.15 pm - 5.15 pm	De-Risking the Development of low GWP pMDIs: Understanding the Challenges Between the Formulation and the Container Closure System (CCS)	**Mr. Chris Baron,** Aptar
5.15 pm - 5.45 pm	**Panel Discussion**	**Panelists :** Dr.John Pritchard

	Moderator: Mr. Chakravarthi AVPS	Mr. Paul Sullivan
		Mr. Anselm Ebert
		Mr. Mirjam Kobler
		Mr. Chris Baron
7.00 pm onwards	**GALA Dinner for Delegates and Speakers**	
DAY 2 (November 11, 2022)		
8.30 am - 9.00 am	**Breakfast / Tea / Coffee**	
9.00 am	Recap of Day 1 & Setting the Tone for the Symposium for Day 2	**Mr. S.R Vaidya,** Chairman, MSME Committee, IDMA
9.00 am - 10.00 am	Achieving Product Approvals Through Accurate In-Vitro Dissolution Data and Bioequivalence for Inhaled Drugs	**Mr. Paolo Rafaelli,** Apex Inhalation
10.00 am - 11.00 am	Role of Particle Engineering in Inhalation Product Technology	**Mr. M. Kesava Reddy,** Vamsi Labs Ltd.
11.00 am - 11.30 am	**Tea/ Coffee Break**	
11.30 am - 12.30 pm	Challenge of spray dried powders and pure micronized API in inhalation device manufacturing	**Mr. Marco Laackmann,** Harro Hoefliger
12.30 pm - 1.30 pm	Intranasal Systemic Delivery: Current and Future Trends (Virtual)	**Ms. Reenal Gandhi,** Aptar
1.30 pm to 3.00 pm	**Lunch Break / Exhibition**	
3.00 pm - 4.00 pm	HFA 152a: MDI Formulation and Manufacturing Aspects	**Dr. Ravindra Purohit**
4.00 pm - 5.00 pm	To be Decided	**Mr. Chakravarthi AVPS,** Ecobliss India Pvt. Ltd.
5.00 pm - 5.30 pm	**Panel Discussion**	**Panelists :**
	Moderator:	Mr. Paolo Rafaelli
		Mr. Marco Laackmann
		Ms. Reenal Gandhi
		Mr. Ravindra Purohit
5.30 pm	**Vote of Thanks**	
5.35 pm	**Tea/ Cofee Break**	

MSME Notification on extending the non tax benefits to the Micro, Small and Medium Enterprises on reclassification

S.O. 4926(E), 18th October, 2022

In exercise of the powers conferred by sub-section (1) read with sub-section (9) of section 7 and sub-section (2) read with sub-section (3) of section 8 of the Micro, Small and Medium Enterprises Development Act, 2006 (27 of 2006), the Central Government hereby makes the following further amendments in the notification of the Government of India, Ministry of Micro, Small and Medium Enterprises number S.O. 2119(E), dated the 26th June, 2020, published in the Gazette of India, Extraordinary, Part-II,Section 3, Sub-section (ii), namely:-

In the said notification, for sub-paragraph (5) of paragraph 8, the following sub-paragraph shall be substituted, namely:-

"(5) In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise shall continue to avail of all nontax benefits of the category (micro or small or medium) it was in before the re-classification, for a period of three years from the date of such upward change.".

F. No. P-05/1/2022-GEN

Shailesh Kumar Singh, Addl. Secy., and Development Commissioner (MSME), Ministry of Micro, Small and Medium Enterprises, New Delhi.

● ● ●

CPCB letter regarding Ban on Use of Single Use Plastic

D.O.No.B.17011/1/UPC-II-PWM (SUP)/2022, dated 12th October, 2022

The Chief Secretary,
All States/UTs

Your kind attention is invited to CPCB's letter dated February 25, 2022 on the subject vide which you were requested to issue necessary instructions to concerned Authorities for execution of activities related to enforcement of ban on SUP items.

Despite the SUP ban on July 01, 2022, it is observed that use of SUP items, specifically the thin carry bags continues unabated in the low end section of the economy specifically street vendors, sabji mandis, flower sellers etc.

For strict enforcement of SUP ban, intensive activities are planned during October-December 2022 with focus on street vendors, sabzi mandis flower sellers, local market, checks at borders, inspection of concerned industries etc. Representative of State UDD Board as well as SPCB are required to be deployed in the inspection team for enforcement of SUP ban. Further, considering the sensitivity of the inspection involved, all administrative support including police protection is to be provided to the inspection team to avoid untoward incidents. Brief note prepared by CPCB (enclosed) may please be referred to for further detail.

In view of the above, you are requested to direct the concerned authorities (State UDD/State Env Deptt, SPCB/ PCC, State Police Deptt.) to deploy concerned officials and provide all necessary assistance for execution of the planned activities for enforcement of SUP ban as mentioned in the annexed Schedule.

Yours sincerely

Tanmay Kumar, Chairman, Central Pollution Control Board, Ministry of Environment, Forest & Climate Change, Governement of India

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Annexure I

Note on enforcement of Single Use Plastic October- December 2022

1.0 Background

Hon'ble MEF made the following observations during the meeting held on October 04, 2022:

- Use of alternatives SUP items observed in high-end sections of the economy.
- Use of SUP items continues unabated in the low end section of the economy specifically street vendors, sabji mandis, flower sellers etc.
- Interstate transportation of SUP items needs to be checked.

In view of above, the follqwing plan of activities is proposed for enforcement of SUP ban during October- Decemeber 2022. Subsequent activities to be planned based on the outcome of the activities carried out in the next three months.

2.0 Proposed Plan of Action

2.1 Focus Areas

The SUP enforcement activities to focus on the following areas

- Street vendors including flower sellers.
- Sabji Mandi, Fish Markets etc

- Local markets
- Industries engaged in manufacturing of thin carry bags
- Checking at border areas to restrict interstate transportation of SUP items

2.2 Constitution of Teams & Coverage

CPCB shall conduct the inspections through 72 teams (27 teams at Head office and 45 teams at 9 CPCB Regional Directorates). Issuing of challans as well as seizure of SUP items has to be done onsite. The inspecting teams shall be directed to identify the suppliers/ manufacturers of SUP items through backtracking. As per Rule 12 (1) of the PWM Rules, State Boards have the authority for enforcement of the Rules related to manufacture of SUP items plastic products As per Rule 12 (2) Secretary, State UDD has the authority for enforcement of the provisions of these rules relating to use of SUP items. In view of above, representative of State UDD/State PCB shall be deployed in the inspection team. Further, considering the sensitivity of the inspection involved, police protection shall be provided to the inspection team to avoid untoward incidents as have been reported in the past. CPCB cover major million plus/ capital cities in the inspection.

2.3 Inspection Schedule

Inspection is proposed to be carried for 4 days a month covering the following specific areas

- Day 1: Street Vendors, Flower sellers, Local markets (October 17, 2022)
- Day 2: Wholesale Markets (for Delhi — Ghazipur, Azadpur, Okhla) /Other RDs /SPCBs to identify these markets in their respective jurisdiction (October 18, 2022)
- Day3: Industrial Areas (for Delhi — Narela, Bawana, Seelampur area (October 19 2022- Other CPCB RDs/State Boards to identify industrial Areas in their jurisdiction)
- Day 4: Checking at interstate borders (For Delhi all checking shall be carried at interstate borders. Other CPCB RDs/State Boards to identify checkpoints accordingly) (October 20, 2022)

Necessary directions being issued to SPCB/PCCs to cover all cities/towns in their jurisdiction through their Regional offices. Letter is being issued to Chief Secretaries of all States to issue necessary instructions to concerned Authorities for deployment of State UDD officers for inspection and provision of police protection to inspection team.

● ● ●

GST on Export Freight - reg.

FIEO/EP/1(11)/2022-23, dated 17th October 2022

Dear Member,

FIEO had taken up the issue regarding extension of GST exemption on export freight beyond 30th September, 2022 with the Government in order to ease the liquidity challenges of exporters.

In this regard, the undersigned today had a meeting with the Chairman, CBIC to discuss the matter further and to pursue for the exemption. The Chairman, CBIC had given a patient hearing on FIEO's submission and informed that withdrawing the said exemption was on the basis of GST Council's recommendation in its meeting held in April, 2022 and exporters may claim refund of the freight paid using the ITC route.

While FIEO would continue to pursue for exemption on export freight, Meanwhile, it is important that members should advise Freight Forwarders/Service Providers to charge freight as IGST only and not CGST or SGST irrespective of the fact that the supplier of service and recipient are located in the same State, to avoid any problem in future in claiming the refund.

Assuring you of our services,

Dr Ajay Sahai, Director General & CEO

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Inviting inputs for pre-budget proposals for the year 2023-24

PXL/HO/Cir-050/2022-23, date 11th October 2022

IDMA have received communication from Mr Uday Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 11th October 2022 as reproduced below on the above subject.

We would like to bring to the notice of member companies that the Ministry of Commerce and Industry is inviting pre-budget proposals for the year 2023-24.

Member companies are requested to kindly take time and provide inputs in the google form as this is an opportunity for retaining the existing custom duty exemptions/reducing the customs duty for pharmaceutical products and also represent on various tax related issues faced by the pharmaceutical industry.

The budget proposals related to duties/taxes should be complete in all respects, properly categorized and HS codes for each commodity must be provided. The proposed suggestions should be supported by reasons/ justifications and should also include the revenue implications, if any, and the likely impact on exports in the google form.

Click here for submitting your responses through google form by 14.Oct.2022 **https://forms.gle/QtDwVueF5Kx8vR2a8.**

The Ministry of Commerce & Industry is actively pursuing the issues with the Ministry of Finance for consideration of suggestions from the industry. We therefore request member companies to actively contribute to the Pre-budget proposals.

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Few Stalls Left in India Pavilion at Arab Health - Dubai, UAE, 30th January - 2nd February, 2023

PXL/HO/Cir-046/2022-23, dated 18th October 2022

Dear Sir / Madam,

IDMA have received communication from Mr Uday Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 18th October 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 to 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

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 - For an exclusive manufacturer for the required products by an Egyptian Company

PXL/HO/BEC-010/2022-23, dated 14th October 2022

IDMA have received communication from Mr Uday Bhaskar, Director General, Pharmexcil, Hyderabad (Set Up by Ministry of Commerce & Industry, Government of India) dated 14th October 2022 as reproduced below on the above subject.

We are glad to inform you that our Council has received a trade inquiry from Family's Choice inc through the Indian embassy, Egypt. They are looking for an exclusive manufacturer for their products and please find below their requirements.

1. To develop their organic products portfolio with the selected ingredients shown in the company profile attached, through their R&D unit within the manufacturer.
2. Register the products at the AYUSH & FSSAI & USDA Organic authorities.
3. Outsource the raw materials from a reputable source that is USDA Organic certified.
4. Exclusive manufacture the products portfolio at their manufacturing units.
5. Package the products produced at the design shown in the Company profile.

They are looking for a manufacturer with the following specifications:

1. Have high production capacity as the amounts in the request are initial amounts.
2. Hold the certificates of:
   a. ISO 2200, ISO 9001
   b. GMP
   c. NPOP, USDA Organic, HALAL.

d. Dietary Supplements authorization from FSSAI / AYUSH

3. Can produce and package within 30 days of contracting.

4. Can produce different dosage forms, for future development of products like vegan tablets and capsules, Cosmetics creams, gummies etc.

Interested members can directly contact them at below details :

Dr. Mohamed Ibrahim, CEO
M/s Family's Choice inc.
Email: moh.ar.roshdy@gmail.com.

The members may therefore, take advantage of the information to further their business.

Encl: **Company profile & Product name and description list**

Important Note: Members may please note that the above information is circulated on the basis of information received to us. Members are advised to make their own decisions before finalizing their business transactions.

Disclaimer: Members may please note that the above information is circulated on the basis of information received from 'KRKA-RUS, RUSSIA through Indian Embassy, Moscow, Russia. Members are advised to make their own decisions before finalizing their business transactions

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CONGRATULATIONS

IDMA Congratulates Mr S V Veeramani, Chairman & Managing Director, Fourrts (India) Laboratories Pvt. Ltd. and Past National President, IDMA on Being Conferred The Lifetime Achievement Award at the 1st Pronto Consult Consumer Awards at Mumbai on 13th October 2022

Ajanta Pharma awarded 'India's Best Managed Companies' by Deloitte

Ajanta Pharma, a specialty pharmaceutical formulation company, has been awarded as "Best Managed Companies" in India by Deloitte for 2022.

The selection process for the award had rigorous evaluation of management abilities for Strategy; Capabilities and Innovation; Governance and Financials; Culture and Commitment. It once again confirms Ajanta's agile management, resilient strategy and superior performance.

Yogesh Agrawal, managing director, Ajanta Pharma received the award at the Best Managed Companies programme held on October 14 at Deloitte Knowledge Centre in Mumbai. '

"We are delighted to receive the Best Managed Companies award from Deloitte as it validates our emphasis on commitment towards excellence in people, processes, infrastructure and practices. This award is dedicated to over 7,000 motivated Ajantaites spread globally who make Ajanta an exciting and vibrant place to work," said Yogesh Agrawal.

Ajanta Pharma is a specialty pharmaceutical formulation company having branded generic business in India and 30 emerging markets, generic business in US and institution business in Africa. Ajanta is determined to find answers for patient-needs by developing differentiated first to market products. This smart product portfolio provides the company leadership in various molecule and therapeutic segments. The company's ground presence in all the emerging markets provides it an edge to build enduring product brands and strong equity with customers. Moreover, the company's robust supply chain ensures these medicines are available for needy patients across the globe every single day.

Ajanta's success in different markets is backed by its strong belief in R&D. Company's R&D has strong capabilities in finished product development of different dosage forms by designing robust formulations. Ajanta has been consistently developing difficult and complex products to harness patient needs. The company's 800+ scientists embrace technology to find appropriate solutions to address the challenges faced by patients across the globe.

The company has 6 world class formulation & 1 API manufacturing facilities in India having best-in-class equipment. These facilities are run by a skilled and knowledgeable team who follow outstanding quality systems to ensure world-class quality products. Stringent authorities like the US FDA and WHO have approved the company's facilities at Paithan in Maharashtra and Dahej in Gujarat.

For the last 10 financial years, the company has posted healthy performance with its revenue from operations growing at 15 per cent CAGR and net profit at 23 per cent CAGR.

Source: Pharmabiz, 17.10.2022

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IPC releases draft general chapter on substitution of in-vivo method by in-vitro method for quality control of vaccine

The Indian Pharmacopoeia Commission (IPC) has come out with a draft general chapter on substitution of in-vivo method(s) by in-vitro method(s) for the quality control of vaccines in Indian Pharmacopoeia (IP) 2022.

The purpose of this general chapter is to provide guidance to facilitate the implementation of in vitro methods as substitutes for existing in vivo methods, in cases where a typical one-to-one assay comparison is not appropriate for reasons unrelated to the suitability of one or more in vitro methods. This general chapter will not discuss the details of assay validation as such, since those principles are described elsewhere.

The general chapter applies primarily to vaccines for human or veterinary use; however, the principles described may also apply to other biologicals such as Antisera/ Immunosera.

The test methods used for routine quality control of vaccines are intended to monitor production consistency and to ensure comparability of the quality attributes between commercial batches and those batches originally found to be safe and efficacious in clinical studies or, for veterinary vaccines, in the target species.

While the in vivo potency and safety assays described within Indian Pharmacopoeia vaccine monographs have

historically played a central role in safeguarding the quality of vaccines, the inherent variability of in-vivo assays can make them less suitable than appropriately designed in vitro assays for monitoring consistency of production and for assessing the potential impact of manufacturing changes. As a result, it is essential continually to challenge the scientific value and relevance of these in vivo test methods. When in vivo tests are found to be of limited or no value, it is imperative to eliminate them, given the ethical considerations and the obligations under the relevant conventions. In addition, there is a substantial effort to develop in vitro methods (including immunological, molecular and physico-chemical tests) to replace the animal tests. In several cases this has led to the successful introduction of new in-vitro methods in vaccine monographs. The use of appropriate in-vitro methods not only reduces the use of animals while maintaining or improving the scientific relevance of the assays involved, but also substantially reduces assay variability and the time and resources required, and enhances the predictability of the release of safe and effective vaccine lots for use, the stated the draft general chapter.

In addition to the benefits resulting from the substitution of appropriate in-vitro methods for existing in-vivo methods, under the 'Prevention of Cruelty to Animals Act, 1960' and `CPCSEA Guidelines' so as to prevent the infliction of unnecessary pain, suffering and prevention of cruelty to animals, the IP Commission has committed to the reduction of animal usage wherever possible in pharmacopoeial testing.

On the other hand, in-vivo safety and potency assays for vaccines were generally shown to be fit for purpose and have historically proven their value in ensuring the efficacy and safety of vaccines.

However, this was in an era when validation requirements and guidelines were not in place, making a formal one-to-one comparison challenging or even impossible in some cases. Since precision, reproducibility, limits of detection and quantification were not established for the in-vivo method, the comparability of one method to another becomes difficult to evaluate.

Although properly established in-vivo potency assays in laboratory animals have the potential to measure complex functional responses for demonstrating proof of concept, these do not necessarily predict the actual responses in the target population. In addition, in-vitro bioassays have the potential to mimic specific elements of complex in-vivo responses with generally lower variability and higher sensitivity. However, wherever possible correlation between in vivo and in vitro methods shall be established.

Shedding light on alternative approaches for the substitution of in-vivo methods, the draft general chapter says, "The primary focus for the implementation of any proposed in-vitro methods within a quality control system should be of the scientific relevance of in-vitro assays for control of the relevant quality attributes. Additionally, any in-vitro methods will have to meet the current validation requirements. In the IP, in-vivo assays for vaccines are typically replaced by in-vitro assays following multicenter collaborative studies, but this should not be a prerequisite for in-vivo assay replacement initiatives for individual products. Additionally, while it may be desirable to have assays that are widely applicable to a class of products, this should not be a requirement."

"In case of live vaccines, sufficient data can be generated during developmental stage and clinical trial stage to establish correlation between potency/ sero-conversion and virus titer/bacterial count. In such circumstances, the bacterial count or virus titer can be used as a potency test during the lot release of live vaccines. For in-vitro methods for potency to be standardized for approved products, correlation of test results in lab condition and field conditions should be established and compared for effective protection in field situation. For new products these comparative studies can be undertaken during the field trials of the product under development. Various manufacturers have specific formulations and in-vitro test development shall be based on product formulation considering the hindrances caused by components in the product. So, these in-vitro tests developed by different manufacturers will be specific to their product which may cause a different playing field for each product/manufacturer. There are various attempts to harmonize the in-vitro tests and the variation observed in in-vitro test and in-vivo test. Hence, studies on a larger perspective to have golden standards of in-vitro tests are required," it added.

"Attenuation or a virulence status of established live vaccine strains can be ascertained by the genomic characterisation. Genome sequence analysis of whole genome or g specific genome regions (if attenuation markers are known) can be used to characterize the vaccine strains genotypically. In this case, target animal testing to determine 'non-reversal to virulence' and 'general safety in target species' can be avoided for

the established attenuated vaccine strains (e.g. Canine distemper virus vaccine strain Onderstepoort, PPRV vaccine strain Sungari/96). Established attenuated strain can be a vaccine strain, which was used in the field for a minimum of four years without any major safety issues. For an inactivated vaccine, effective and complete inactivation of virus or bacteria can easily be established by in-vitro passaging of virus in a susceptible cell line and by absence of bacterial growth in specific media. Laboratory or target animal testing can be avoided in these cases. Development of validated in-vitro methods is encouraged for evaluating the formulation safety. Until that time, the formulation safety can be evaluated in laboratory animals instead of using target animals, wherever possible," the draft said.

"An in-vitro genotypic method to assess the molecular consistency of a viral vaccine has the potential to replace an existing in-vivo neurovirulence test and other safety tests. A prerequisite for any in-vitro genotypic method is an in-depth knowledge of the molecular markers responsible for the attenuation of the live viral vaccine (the case for oral poliovirus vaccine, for example). In such a case, monitoring the consistency of the vaccine lots would be achieved by confirming the presence of the required molecular attenuation markers and percentage of mutants with methods such as deep sequencing. Wherever the molecular markers of attenuation is not known, whole genome sequencing by NGS can be used to establish sequence similarity of the strain at seed level and end of production stage," it stated.

Another effective in-vitro method for identifying extraneous agents is using cell culture systems. The cell seeds, neutralised virus seeds and neutralised vaccine lots can be checked in cell culture systems in vitro. Haem-adsorbing viruses, Haem-agglutinating viruses and CPE inducing viruses can be detected using cell culture systems. Highly permissive cell lines such as Vero, Bovine turbinate cells (for checking extraneous bovine viruses) and IBRS cells (for checking extraneous porcine virus) can be used. Manufacturers are encouraged to use recombinant trypsin instead of porcine trypsin during manufacturing. Wherever recombinant trypsin is used, testing extraneous porcine viruses is not necessary, if the suspected source of extraneous porcine viruses is trypsin, it concluded.

Source: Laxmi Yadav, Pharmabiz, 18.10.2022

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- **Export of Drug Formulations and Biologicals (All Countries) during the year 2020-21 and from April 2021 to December 2021**
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