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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 48 (PAGES: 32) | 22 TO 30 DECEMBER 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

REGISTER NOW

22nd IDMA-APA PHARMACEUTICAL ANALYSTS CONVENTION (PAC) 2023

With EDQM, IPC, USP & US FDA on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai

THEME: "Towards Creative Global Compliance"

(Details on page 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

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Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 48** **22 to 30 December 2022**

IDMA ACTIVITIES:

PRESS RELEASE:

PARLIAMENT NEWS:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, POONAM CHAMBERS, 'A' WING, DR. A.B. ROAD, WORLI, MUMBAI 400 018, INDIA

Phone : 91- 22 - 24974308
91- 22 - 24944624
Fax : 91- 22 - 24950723

E-mail : admin@idmaindia.com
actadm@idmaindia.com
Website : www.idma-assn.org

PARTNER IN GLOBAL HEALTHCARE

REGISTER NOW

22nd IDMA-APA PHARMACEUTICAL ANALYSTS CONVENTION (PAC) 2023

With EDQM, IPC, USP & US FDA on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai

THEME: "Towards Creative Global Compliance"

We have lined up for you:

Eminent Speakers + Relevant Interesting Topics on Current Scenario + Exhilarating Panel Discussions + Excellent Venue

We need enthusiastic participation from you to make this Convention Successful

We are committed to make PAC an important milestone for Quality, Technical, Production & Regulatory Affairs Personnel every year, since 1997. Indian Drug Manufacturers' Association (IDMA) and Association of Pharmaceutical Analysts (APA) have pleasure in announcing the 22nd IDMA-APA Pharmaceutical Analysts' Convention 2023 **on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai.**

THE THEME FOR THIS YEAR: "Towards Creative Global Compliance"

We have also invited illustrious luminaries and Industry Captains along with other senior CDSCO and FDA officials to grace the occasion along with Regulatory Authorities from Europe, USA and India. ***As you will all appreciate, the PAC has a unique tradition of the Eminent Guests interacting with the participants and exhibitors.***

CHIEF GUEST AND KEYNOTE SPEAKER:

PADMA SHRI PROF. (DR.) G. D. YADAV

National Science Chair (SERB/DST/GoI), Emeritus Professor of Eminence, Former Vice Chancellor & R T Mody Distinguished Professor, TATA Chemicals Darbari Seth Distinguished Professor of Leadership and Innovation, Institute of Chemical Technology, Mumbai

SPECIAL GUEST OF HONOUR :

DR. RAJEEV SINGH RAGHUVANSHI, Ph.D.

Secretary-Cum-Scientific Director

Indian Pharmacopoeia Commission

At this prestigious Convention, Eminent technical personnel from EDQM, IPC, US FDA, USP and the Indian Pharmaceutical Industry, Research, Academic and Regulatory Affairs will converge and get-together to interact on various recent developments and on the various issues and challenges faced by the Industry.

CONVENTION TOPICS / FACULTY (TENTATIVE TOPICS):

- ❖ Recent updates on Certificate of Suitability
- ❖ EDQM Inspection & Certifications, Changes after Brexit
- ❖ Recent updates in EP and New chapters included in the Pharmacopoeia
- ❖ Industry participation in Regulatory Implementations
- ❖ Educational booklets from EDQM
- ❖ Current trends in Harmonization of Pharmacopoeial Monographs

OBJECTIVE

This Convention will allow the delegates to receive hands-on information regarding the global requirements in the field of Quality Management and Regulatory Compliance, various recent developments and on the various issues and challenges faced by the Industry

➲ WHO SHOULD ATTEND

This Convention is designed to attract all those involved in:

Pharmaceutical Industry	Microbiological Industry	Business Consulting Companies	API, Excipients & Intermediates Manufacturers
Biopharmaceutical Industry	Government Laboratories	Contract Manufacturing Organizations	R & D Equipment Manufacturers
Biotechnology Industry	Research Institutions	Contract Research Organizations	R & D Machine Manufacturers
Nutraceutical Industry	Academic Institutions	Quality Control	Quality Assurance

➲ EXCELLENT OPPORTUNITIES FOR:

CEOs, Directors, VPs, GMs, Chemists, Microbiologists and Heads of:

Strategy and Business Development	Regulatory Affairs	Analytical Development Laboratory	Pharmacology / Toxicology
R & D	Production / Packaging	Quality Control / Assurance	Medical Affairs
Pharma Product Development		Clinical Research	

➲ GREAT REASONS TO ATTEND:

➢ Interact with National & International Regulators	➢ Partnership Strategies
➢ Updates on Current ICH Guidelines	➢ Technology and Platforms
➢ New/Current Trends and Technologies	➢ Driving Innovations
➢ Opportunities for Business Development	➢ Branding Opportunities
➢ Showcase your Products & Services	➢ Networking Opportunities
➢ Hours of Facilitated Networking and Benchmarking	➢ Q and A Sessions
➢ Explore New Products, Solutions and Services	
➢ Market Development	

➲ TABLE SPACE AREA:

IDMA strives harder and harder to organize inspiring & innovative conventions wherein we have bigger participation from the pharma industry and wherein various types of Equipment manufacturers and allied industries to get a platform to display their products and also, to interact with the eminent guests and participants.

➲ DELEGATE FEES:

IDMA & NON-IDMA MEMBERS	STUDENTS
Rs.8,000/- + GST @ 18%	**Rs.6,000/-** + GST @ 18%

➢ ***Early bird discounts (IDMA / Non-IDMA Members)***
Before 31st January 2023 : 10% discount

➢ ***Group registration benefits (cannot be combined with discounts):***
For every 4 Delegates registered from an organisation, the fifth (5) delegate will be complimentary

➲ SPONSORSHIP OPPORTUNITIES:

➲ Event Sponsor:–

PLATINUM SPONSOR	GOLD SPONSOR	SILVER SPONSOR
Rs.5 Lakhs	**Rs.3 Lakhs**	**Rs.2 Lakhs**
20 Minutes speaker slot	20 Minutes speaker slot	N.A.
The Speaker & Sr. Most Official of the company will be invited to the Dinner with the Speakers and Organizers	The Speaker & Sr. Most Official of the company will be invited to the Dinner with the Speakers and Organizers	Sr. Most Official of the company will be invited to the Dinner with the Speakers and Organizers

Sponsor's 4-5 minute film or an AV presentation to be played during the breaks	N.A.	N.A.
Logo Visibility on all banners at the venue	Logo Visibility on all banners at the venue	Logo Visibility on all banners at the venue
Full Page Colour Advertisement in Souvenir	Full Page Colour Advertisement in Souvenir	Full Page Colour Advertisement in Souvenir
Full Page Colour Advertisement in IDMA Bulletin publishing the Report of the Event	Full Page Colour Advertisement in IDMA Bulletin publishing the Report of the Event	N.A.
Company Brochures to be distributed at the venue to all participants	Company Brochures to be distributed at the venue to all participants	N.A.
Table Space inside the Convention Hall with power connection – 1 Tables for both the days **(at a prominent position)**	Table Space inside the Convention Hall with power connection – 1 Table for both the days	Table Space inside the Convention Hall with power connection – 1 Table for both the days
Complimentary Registrations – 4 nos.	Complimentary Registrations – 2 nos.	Complimentary Registrations – 2 nos.

➲ Kit Bags – Rs. 1,50,000/- + GST

(**IDMA Offers**: One Table Space, Two Delegates Complimentary, the sponsor name to be printed inside the kit bag and Advt. in Souvenir & IDMA Bulletin)

➲ Badges and Lanyards Sponsor - Rs. 1,00,000/- + GST

(**IDMA Offers**: Your Company Name and Logo to be printed on the Badges Lanyards & Two Delegates Complimentary, One Full Page Colour Advertisement in Souvenir)

➲ Lunch – Rs. 50,000/- + GST per session (2 Days)

(**IDMA Offers**: Company Banner would be placed around the lunch area & Two Delegates Complimentary)

➲ Tea / Coffee - Rs. 30,000/- + GST per session (2 Days)

(**IDMA Offers**: Banner would be placed around the tea/coffee area & One Delegate Complimentary)

➲ Spiral Bound Note Books and Pens - Rs.1,00,000/- + GST

(**IDMA Offers**: A full page colour advertisement in the spiral bound note book, Company name to be printed on the Pens & Two Delegates Complimentary.)

➲ Distribution of Company Brochures – Rs. 25,000/- + GST

(**IDMA Offers**: Company Brochures would be distributed to all the participants at the convention and One Delegate Complimentary)

➲ EXHIBITION OPPORTUNITIES

➲ Pre-function Area

Table Space – Rs.50,000/- + GST per table for 2 days (**IDMA Offers**: Table Size: 6ft. x 2ft. with a power connection, Lunch for Two delegates only & One Complimentary advt. in souvenir. Your Name & Logo will appear on the standee at the entrance.

➲ ADVERTISING OPPORTUNITIES IN SOUVENIR

➲ Souvenir Sponsorship – Rs. 1,00,000/-

(**IDMA Offers**: your Company's logo and name/address on the bottom of the cover page 3" (height) x 7" (width). The Souvenir size is 9 ½" (height) x 7" (width). The space offered is one-third of the cover page. One Delegate Complimentary. One Full Page Colour Advt. in Souvenir. Company/Product brochures would also be distributed)

(i) Back Cover - Rs.30,000/-		**(ii) Inside Front - Rs.20,000/-**
(iii) Inside Back - Rs.20,000/-		**(iv) Full Page Colour - Rs.15,000/-**
(v) Bookmark - Rs.40,000/-		

For further details, please contact:

➲ **Ms. Sapna Patil** Dy. Secretary – General admin@idmaindia.com 9619802299	➲ **Mr. Melvin Rodrigues** Sr. Manager (Commercial & Admin.) actadm@idmaindia.com 9821868758
➲ **Ms. Geeta Suvarna** Technical Officer publications@idmaindia.com 9820161419	➲ **Ms. Batul** Front Office Executive technical@idmaindia.com 9920045226

Looking forward to your presence and active participation at this Convention and working with you to make this 22nd Convention a grand success!

Best Wishes,

Dr Viranchi Shah
National President

Dr Vinay G Nayak
Chairman, Quality Management & Technical Committee

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 Fax # 022 - 24950723
E-mail: admin@idmaindia.com / actadm@idmaindia.com

Date:

Dear Sir / Madam,

22nd IDMA-APA PHARMACEUTICAL ANALYSTS CONVENTION (PAC) 2023

With EDQM, IPC, USP & US FDA

on Friday, 24th February and Saturday, 25th February 2023 at Hotel Four Seasons, Worli, Mumbai

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				

GST No. _____ (Mandatory, if available)

Billing Address : _____

_____

Note : Only after receipt of the payment, the TAX INVOICE would be issued

PAYMENT DETAILS : RTGS / NEFT / IMPS / CHEQUE

UTR No. / TRANSACTION No. / CHEQUE No. _____

DATE _____ **Rs.** _____

Thanking you,

Yours faithfully,
(Name & Designation)

Name of the Company_____

Mobile No. :_____ E-Mail:_____

➲ DELEGATE FEES:

IDMA & NON-IDMA MEMBERS	STUDENTS
Rs.8,000/- + GST @ 18%	**Rs.6,000/- +** GST @ 18%

➢ ***Early bird discounts (IDMA / Non-IDMA Members)***
Before 31st January 2023 : 10% discount

➢ ***Group registration benefits (cannot be combined with discounts):***
For every 4 Delegates registered from an organisation, the fifth (5) delegate will be complimentary

IDMA - RTGS / NEFT 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**

*Note: Participation fee is neither refundable nor adjustable against future programmes. However, changes in nominations are accepted. Kindly use photocopies of this form for additional registrations. The cheque/DD to be drawn on "Indian Drug Manufacturers' Association". *Outstation parties to remit by RTGS / NEFT.*

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

Invitation For Pharma Conclave to be held on 8th January 2023 in association with BAPS, Swaminarayan Sanstha at Ahmedabad

Dear Member,

It gives us great pleasure to invite all members of "Pharma industry to participate" in "Pharma Conclave"- a special 1 day conference to be held in association with "BAPS" Swaminarayan Sanstha at Pramukh Swami Nagar on Sunday, 8th January, 2023. The conclave is organised in association with *GCCI, DMMA, GCA, GPA, FGSCDA, GAAMA, IPMMA, NDIA, Pharmexcil and other leading associations. BAPS Swaminarayan Sanstha is celebrating Pramukh Swami Maharaj's Centenary from 15th December 2022 to 15th January 2023 at Pramukh Swami Nagar, Sardar Patel Ring Road, Ahmedabad.

BAPS has invited IDMA to organize a one-day conference at the 600-acre Pramukh Swami Nagar festival site. The conference will feature talks and presentations by our leading members on most recent topics followed by enlightening talks from BAPS Sadhus.

A "personal guided" tour for all our esteemed members to the sprawling festival site has also been arranged. The Pramukh Swami Nagar comprises of several exhibition pavilions on life values, children's adventure land, light & sound show, thematic glow gardens, cultural gates, Pramukh Swami Maharaj's maha-murti, a replica of Swaminarayan Akshardham in New Delhi amongst other inspiring attractions.

Members are requested for their active participation.

Thanks & Regards,

Daara B. Patel
Secretary - General

IDMA

Indian Drugs Manufacturers' Association

Pramukh Swami Maharaj Centennial Celebrations

PHARMA CONCLAVE

8th Jan 2023

Pramukh Swami Maharaj Nagar, Nr. Ognaj Circle, SP Ring Rd, Ahmedabad

CONFERENCE THEME: NICHE-THE GROWTH STRATEGY

08:30 AM TO 9:15 AM	REGISTRATION & BREAKFAST
09:15 AM TO 09:45 AM	IDMA GSB AGM
09:45 AM TO 10:45 AM	INAUGURAL FUNCTION: KEY NOTE ADDRESS BY SHRI PANKAJBHAI PATEL, CHAIRMAN ZYDUS ADDRESS BY MINISTER
10:45 AM TO 11:15 AM	SHRI AMAN MEHTA- DIRECTOR TORRENT PHARMACEUTICALS LTD.
11:15 AM TO 11:45 AM	MS ADITI KARE - MD INDOCO REMEDIES LTD
11:45 AM TO 12:15 PM	TEA BREAK
12:15 PM TO 12:45 PM	DR. DUSHYANT PATEL- FOUNDER ASTRAL STERITECH PVT LTD
12:45 PM TO 01:00 PM	Q&A
01:00 PM TO 01:15 PM	VIDEO OF THE MAKING OF PRAMUKH SWAMI NAGAR
01:15 PM TO 02:00 PM	ADDRESS BY DR GYANVATSAL SWAMIJI ON "BEHIND THE SCENE- MANAGEMENT LEARNINGS"
02:00 PM TO 03:00 PM	LUNCH
03:00 PM TO 07:00 PM	GUIDED TOUR OF PRAMUKH SWAMI NAGAR BY BAPS VOLUNTEERS
07:00 PM ONWARDS	DINNER

SUPPORTING ASSOCIATIONS

- Gujarat Chamber of Commerce & Industry
- Federation of Gujarat State Chemist and Druggist Association
- Drugs Marketing & Manufacturing Association
- Gujarat Ayurvedic Aushadh Manufacturer's Association
- Gujarat Chemical Association
- Gujarat Pharmaceutical Association
- Pharmaceutical Export Promotion Council
- Indian Pharma Machinery Manufacturers Association
- Nutraceuticals & Dietary Supplements Industries Aid Association

Registration link will open soon

EVENT CO-ORDINATOR

PHARMA LIVE• EXPO 2023

Pharma Live Expo & Summit 2023

www.pharmaliveexpo.com

IDMA
Indian Drugs Manufacturers' Association

Pramukh Swami Maharaj Centennial Celebrations

PHARMA CONCLAVE

8th Jan 2023

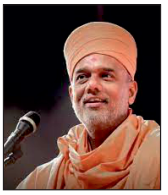
Pramukh Swami Maharaj Nagar, Nr. Ognaj Circle, SP Ring Rd, Ahmedabad

CONFERENCE THEME: NICHE-THE GROWTH STRATEGY

SPEAKERS


SHRI PANKAJBHAI PATEL


SHRI AMAN MEHTA


PUJYA DR GYANVATSAL SWAMI


MS ADITI KARE


DR. DUSHYANT PATEL

ORGANISING COMMITTEE

DR. VIRANCHI SHAH - NATIONAL PRESIDENT IDMA
DR. SHRENIK SHAH - CHAIRMAN, IDMA GSB
SHRI PATHIK PATWARI - PRESIDENT, GCCI
SHRI JASVANT PATEL - PRESIDENT, FGSCDA
DR JAIMIN VASA - PRESIDENT, GCA & GPA

SHRI AMIT THAKKAR - PRESIDENT, DMMA
SHRI JAMAN MALVIA - PRESIDENT, GAAMA
SHRI NITIN PANCHAL - PRESIDENT, NDIA
SHRI HARSHIT SHAH - PRESIDENT, IPMMA
SHRI KAMLESH PATEL
SHRI JAY PATEL
MS JINKAL PATEL
SHRI DAARA PATEL
SHRI SANCHIT CHATURVEDI
SHRI SANJAY SHAH

SHRI MEHUL SHAH - HON. SECRETARY IDMA
SHRI SUMIT AGRAWAL - HON. SECRETARY IDMA GSB
SHRI ANIL JAIN - HON. SECRETARY GCCI
SHRI KIRIT PALAN - HON. SECRETARY FGSCDA
SHRI JIGNESH SHAH - HON. SECRETARY, GCA
SHRI MAYUR PARIKH - HON. SECRETARY, GPA
SHRI VIKRAM CHANDWANI - HON. SECRETARY, DMMA
SHRI DHANANJAY SHUKLA - HON. SECRETARY, GAAMA
SHRI NIKHIL KANSARA - HON. SECRETARY, NDIA
SHRI OSWIN D'SOUZA - HON. SECRETARY, IPMMA
SHRI NIRAV MEHTA
SHRI ATUL SHAH
SHRI MAULIK SHAH
SHRI CHIRAG DOSHI
SHRI VIJAY SHAH
SHRI RAJ SANGHAVI

Registration link will open soon

EVENT CO-ORDINATOR
PHARMA LIVE• EXPO 2023
Pharma Live Expo & Summit 2023
www.pharmaliveexpo.com

IDMA representation to Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC on Revising Disintegration Time (DT) for Soft Gelatin Capsules

IDMA have submitted the following representation on 14th November 2022 to Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Ghaziabad on the above subject:

Greetings from Indian Drug Manufacturers' Association.

We appreciate and are thankful for sparing your valuable time on 13th October 2022 to permit presenting the IDMA (Indian Drug Manufacturers' Association) stakeholders' views and reservations pertaining to the Indian Pharmacopoeia Commission (IPC) intending to revise the DT for soft gelatin capsules from Not More Than (NMT) 60 minutes to NMT 30 minutes.

Our concern specifically is the across-the-board revision of the DT, which may not be feasible or even desired for all the products. Specifically for the Multi-mineral and multi-vitamin products, this change is very difficult to implement and will lead to serious market disruption.

Therefore we request to implement this in a phased manner, initially covering only the single-ingredient drugs by incorporating them in specific monographs and not making this a mandatory limit for all soft gelatin capsules by incorporating in the general test limits.

We understand your basis for proposing a revision in the DT for soft gelatin capsules from NMT 60 to NMT 30 minutes are agreeable for certain drug products where it is required and pending conducting feasibility of this exercise.

As per our discussions, we reiterate it may not be feasible for the stakeholders to revise the DT for vitamin-mineral-nutraceutical extract products from NMT 60 minutes at present to NMT 30 minutes as proposed. There are several technical issues with this, for example, the limitations of temperature/ humidity in the storage condition in supply chain within India coupled by the technical feasibility due to multiple ingredients in case of multi-mineral/ multi-vitamin formulations, etc. to name a few.

In this context we appreciate your openness to evaluate the samples of vitamin-mineral-nutraceutical extract products proposed by us to qualify (and quantify) our basis of concerns. We would be forwarding the needful details in due. We are thankful to IPC for providing the list of 61 Soft Gelatin capsule samples (non-multi-vitamin/ multi-mineral products and Multivitamin / Multi-minerals) on which Disintegration Test performed, vide your mail of 18th October 2022. We would urge you that this exercise be done by collecting samples that cover sampling points covering retailers from diverse geographical locations across India, picked up from different time points for seasonal variations, and of products manufactured by companies in small, medium and large sectors.

Following our completion of the testing of samples of vitamin-mineral-nutraceutical extract products named by IPC, and also following receipt of confirmation that the vitamin-mineral-nutraceutical extract products specified by the stakeholders are checked by IPC with respect to (w.r.t.) the DT, we request another similar meeting to discuss outcome and take a rationale and consensual stand in the matter of DT downward revising for soft gelatin capsules. Prior to seeking your appointment for the same, we would be submitting a written proposal w.r.t. the revising of DT for the soft gelatin capsule products from the stakeholder's perspective as desired.

We once again thank you for the cooperation and appreciate your spirit of openness in this matter. We are sure and confident that the industry's true challenges w.r.t. the vitamin-mineral-nutraceutical extract soft gelatin capsule products' DT revision to NMT 30 minutes (from the current NMT 60 minutes) will be favourably considered, especially since it would otherwise impact consumer and patient's well-being (on account of looming possibility of discontinuance of especially vitamin-mineral-nutraceutical extract products).

Thanking you.
Yours sincerely,
For Indian Drug Manufacturers' Association

Dr Viranchi Shah
National President

Dr R K Sanghavi
Chairman – Nutraceutical Committee

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 February 2-3, 2023

Dear Member,

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 February 2-3, 2023.**

Expenses towards travel by Air (economy)/Train (2nd AC fare)/Taxi, boarding and lodging (accommodation at Hotel Courtyard by Marriott and meals) of participants will be borne by organizers. There are no hidden costs.

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. 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.

We request you to nominate concerned officials from your organization for the training programme.

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

More details about the programme are given in the attached brochure. There is NO REGISTRATION FEE, however, REGISTRATION IS MANDATORY for consideration in the training programme. Those who have registered earlier need not register again.

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).

Global Chemical and Biological Security

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

2-3 February 2023, 09:00-17:00 IST

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 be informed on CW proliferation potential of key pharmaceuticals, 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. Topics covered will include chemical security threats and chemicals of concern, KYC principles, best practices, suspicious indicators and strategies to implement KYC. 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/or using potentially lethal (e.g., fentanyl) and other incapacitating and/or dissociative agents (e.g., benzodiazepines).

Audience:

- 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:

2 February 2023	3 February 2023
• Welcome and Introduction • Course Objectives and Schedule • Industry Case Study • Chemical Security Threats • Pharmaceuticals of Concern • Illicit Procurement Tactics	• Illicit Procurement Case Studies • Overview of KYC Principles and Practices • Interactive Scenario-Based Activities on KYC Indicators • KYC Implementation • Valedictory

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

Points of Contact:

Dr. Cecelia Williams, Ph.D.
Sandia National Laboratories
cvwilli@sandia.gov

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

Year End Review of Department of Pharmaceuticals-2022

8916 Pradhan Mantri Bhartiya Janaushadhi Kendras opened across the country and target to increase to 10500 by March 2025

Pharmaceuticals & Medical Devices Bureau of India made sales of Rs 758 crore this year

Department of Pharmaceuticals gave special emphasis on promoting domestic manufacturing of medical equipment and strengthening the pharmaceutical industry

In the year 2022, various programs and initiatives were implemented in the Department of Pharmaceuticals. Major achievements of the Department this year include schemes like 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' to provide quality generic medicines at affordable prices to the poor and underprivileged and PLI scheme to strengthen India's manufacturing capacity in the pharmaceutical sector by increasing investment and production. Apart from this, the department also laid special emphasis on promoting domestic manufacturing of medical equipment and strengthening the pharmaceutical industry.

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP):

Under Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme, dedicated outlets known as *Pradhan Mantri Bhartiya Janaushadhi Kendras* (PMBJK) are opened all over the country to provide generic medicines at affordable prices to the masses. Till 30th November 2022, 8916 PMBJKs have been opened across the country. Target is to increase these kendras to 10500 by March 2025. Prices of the Jan Aushadhi medicines are generally 50%-90% less than that of branded medicines' which are available in the open market. Medicines are procured from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers only for ensuring the quality of the products.

The Product basket of PMBJP comprises 1759 drugs and 280 surgical. The target is to enhance the product basket to include 2000 medicines and 300 surgical products by March 2025 so that all essential medicines covering therapeutic groups, like - Anti Diabetics, Cardiovascular Drugs, Anti-Cancer, Analgesics & Antipyretics, Anti Allergic, Gastro Intestinal Agents, Vitamins, Minerals & Food supplements, Tropical Medicines, etc. are provided.

To ensure easy availability of the menstrual health services to all women across the country, "*Janaushadhi Suvidha* Oxy-Biodegradable Sanitary Napkin" are available for sale in all PMBJP Kendras across the country at ₹1.00 per sanitary pad. Till November, 2022, more than 31.00 Crore pads have been sold through these kendras.

In the financial year i.e. 2021-22, Pharmaceuticals & Medical Devices Bureau of India (PMBI) had made sales of Rs. 893.56 Crore which led to savings of approximately Rs. 5300 Cr. to the citizens. In the current financial year 2022-23 till 30th November 2022, PMBI has made sales of Rs. 758 Crore which has led to savings of approximately Rs. 4500 Cr. to the citizens. Thus, in all, approximately Rs. 18,000 Crore have been saved under this *Pariyojana* in last 8 years.

IT-enabled End to End Supply Chain system has been implemented and one central warehouse at Gurugram and three regional warehouses at Chennai, Guwahati & Surat have been established. Further, it has been planned to open two more warehouses in Western and Central India.

FDI performance in pharmaceutical sector:

FDI inflows in pharmaceutical sector (in both pharmaceuticals and medical devices) was Rs 12,097 crore in the financial year 2021-22. During current financial year of 2022-23 from April 2022 to September 2022, FDI inflows has been Rs 8,081 crore. Further, the Department of Pharmaceuticals has approved 21 FDI proposals worth Rs. 4,681 crore for brownfield projects during 1st January 2022 to 30th November 2022.

Pricing of drugs:

Department of Pharmaceuticals (DoP) notified the amended Schedule-I of Drugs Prices Control Order (DPCO) 2013 on 11th November 2022 based on National List of Essential Medicines 2022 Notified by Ministry of Health and Family Welfare on 13th September 2022. Based on the same, National Pharmaceutical Pricing Authority (NPPA), an attached office under DoP is under process of revising the Ceiling Prices of the drugs coming under the Schedule-I as per extant provisions of DPCO, 2013.

On the occasion of 25th Foundation day NPPA on 29th August 2022, an updated version of Integrated Pharmaceutical Database Management System 2.0 (IPDMS) was launched which is an important step towards bringing in enhanced technology to facilitate the interface between Government and the stakeholders. On the same occasion, updated version of Pharma Sahi Dam Mobil App 2.0 was also launched, which empowers the consumers.

Strengthening of Pharmaceutical Industry (SPI):

The Scheme would be operational over a period of five years from FY 21-22 to 25-26 and has an outlay of Rs.500 cr. The Scheme has 3 components / sub-schemes:

- Assistance to Pharmaceutical Industry for Common Facilities (APICF)
- Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)
- Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

Under sub-scheme Assistance to Pharmaceutical Industry for Common Facilities (APICF), 20 project proposals have been received of which 17 were found eligible under the scheme. Of these 17 project proposals, 7 have been shortlisted and requested to submit the DRP by 15th December, 2022 for further examination and finalization for approval of projects.

Under Sub-Scheme Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) more than 60 applications have been registered.

PLI for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs):

The Scheme was approved with the objective of attaining self-reliance and reducing import dependence in critical KSMs/DIs/APIs. The scheme will boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs.

The tenure of the sub-scheme is from financial year 2020-21 to 2029-30, with the total financial outlay of Rs. 6,940 crore. The Financial incentive under the sub-scheme is provided on sales of 41 identified products categorized into four Target Segments. Total 249 applications were received in four Rounds. 51 applicants have been approved with committed investment of Rs 4,138.41 cr. against which investment of Rs. 1707 cr. has already been incurred. These 51 projects are expected to generate an employment of around 10,598 persons. The work on these projects have already generated employment of 1,907 persons up to September, 2022. Based on Quarterly Review Report (QRR) of September, 2022, 21 project has been commissioned with actual investment of Rs. 890.82 cr. as against total committed investment of Rs. 843.79 cr.

PLI Scheme for promoting Domestic Manufacturing of Medical Devices:

The Scheme envisages boosting domestic manufacturing and attracting large investments in the Medical Devices Sector. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs. 3,420 crore. The financial incentive is to be given to selected companies at the rate of 5% on incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years.

The identified products under this Scheme have been categorized into four Target Segments which is "Cancer care/Radiotherapy medical devices, Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices, Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices and All Implants including implantable electronic devices".

Total 42 applications were received in two round of application window. Out of 42 applications, 21 applicants have been approved with committed investment of Rs 1,058.97 cr and expected employment generation of around 6,411pesons. 13 projects have already been commissioned for 31 products as on September 2022. The actual employment generated up to September 2022 is 2,892 persons.

PLI Scheme for Pharmaceuticals: -

The objective of this scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification towards high value goods in the pharmaceutical sector.

The scheme covers pharmaceutical goods under following three categories-

Category 1: Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.

Category 2: Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates (except for the 41 eligible products already covered under the "PLI Scheme for promotion of domestic manufacturing of critical KSMs / DIs / APIs" at sl.no.(i) above).

Category 3 (Drugs not covered under Category 1 and Category 2): Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2028-29. The scheme provides for incentives on incremental sales to selected participants under these categories at varying rate over the years ranging from 10% to 3%.

The scheme is expected to bring in investment of more than 17,000 crore in the pharmaceutical sector, promote the production of high-value products in the country and increase the value addition in exports. The actual investment of Rs 15,164 cr. have already been made by these 55 applicants.

The support under PLI schemes is expected to promote the production of high-value products in the country as well as generate employment for both skilled and unskilled personnel, estimated at 20,000 direct and 80,000 indirect jobs. The actual employment generated up to September 2022 is 22,560 persons.

Medical Device:

The medical devices sector is an essential and integral constituent of the healthcare sector. The current market size of the medical devices sector in India is estimated to be USD 11 Bn and its share in the global medical device market is estimated to be 1.5%.

The contribution of India's medical devices sector to health become more evident during COVID-19 pandemic where role of medical devices and diagnostic kits, such as Ventilators, IR Thermometers, PPE Kits & N-95 masks, Rapid Antigen Test Kits, and RT-PCR kits etc. were of critical significance. Taking cognizance of the importance of the sector, few additional note-worthy interventions for the Medical Devices Sector, in addition to PLI and Medical Device parks, were also taken in 2022 which are:

i. **Reconstitution of National Medical Devices Promotion Council -** On 05.08.2022, the Department reconstituted the National Medical Devices Promotion Council as an inter-departmental council to interact frequently with the medical devices industry to take up matters for resolution, which are regulatory in nature and are spread over different departments. This institutional set-up is expected to resolve the issue of the medical devices sector, which is multi-disciplinary in nature.

ii. **Export Promotion Council for Medical Devices** - Department of Commerce vide O.M. dated 21st September, 2022 has approved establishment of a separate Export Promotion Council (EPC) for Medical Devices at YEIDA, Uttar Pradesh. The Department has notified the OSD for carrying out further action. The EPC-MD will give the boost to the Medical Devices Sector.

Source: PIB Delhi, 22.12.2022

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Sale of Expired/Uncertified Protein Powder

Lok Sabha Starred Question No. 54 Shrimati Sangeeta Azad:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Food Safety and Standards Authority of India (FSSAI) or any other agency is conducting regular checks and raids on the manufacturers of branded protein powder across the country to ascertain/check the sale of expired/uncertified/ unlicensed products which also violate the established manufacturing and safety protocols;

(b) if so, the details thereof;

(c) whether the Government is aware of the diseases and deaths due to use/consumption of these protein powders/anabolic steroids; and

(d) if so, the details thereof during the last five years along with the number of cases filed/solved/penalty imposed and the other corrective steps taken/being taken in this regard?

Answered on 9th December, 2022

(a) to (d): A Statement is laid on the Table of the House.

(a) to (d): Food Safety and Standards Authority of India (FSSAI) is mandated to lay down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. Section 31(1) of Food Safety and Standards (FSS) Act, 2006 provides that no person shall commence or carry on any Food Business except under a license. Surveillance of Food Business Operators including manufacturers of health supplements like protein powders is conducted regularly through intensive surveillance drives by the States/UTs. The responsibility for implementation and enforcement of FSS Act 2006, Rules and Regulations made thereunder primarily lies with State/UT Governments. Penal action is initiated against the defaulting Food Business Operators (FBOs) by the Food Safety Officers of States/UTs as per the provisions of FSS Act, 2006, Rules and Regulations.

FSSAI has notified FSS (Food or Health Supplements, Nutraceuticals, Foods Special Dietary Use, Foods for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016, which specify provisions for regulation of these products in the country.

The articles of food covered under these regulations are required to comply with the general labelling requirements under the FSS (Packaging and Labelling) Regulations, 2011. Further, since these products are intended for specific physiological conditions or general maintenance of health and are required to be taken as per the regulated usage levels by the specific targeted group, labelling provisions for specific food product categories have also been specified under the said regulations. These regulations state that the label on such articles of food shall specify the purpose, the target consumer group and the physiological or disease conditions which they address and recommended duration of use. The label, accompanying leaflet or other labelling and advertisement of each type of article of food shall also provide sufficient information on the nature and purpose of the article of food and detailed instructions and precautions for its use, and the format of information given shall be appropriate for the intended consumer.

Based on information made available by the States/UTs, details of food samples analyzed, found adulterated/sub-standard/misbranded and action taken thereon during the last three years i.e. 2019-2020, 2020-2021and 2021-22 is Annexed.

Annexure

Annual Public Laboratory Testing Report/Data for last three years

S. No.	Year	No. of Samples Analysed	No. of Samples found non-conforming	Non Confirming Samples			Civil Cases			Criminal Cases		
				Unsafe	Sub Standard	Labelling defects /Misleading/ Miscellaneous	No. of Cases Launched	No. of Convictions	Penalties Raised (Cr.)	No. of Cases Launched	No. of Convictions	Penalties Raised (Cr.)
1	2	3	4	5	6	7	8	9	10	11	12	13
2	**2019-20**	118775	29589	4526	15671	8995	27412	17345	56.38	4681	780	1.61
3	**2020-21**	107829	28347	5220	13394	9733	24195	14817	49.92	3869	506	0.83
4	**2021-22**	144345	32934	4890	16582	11482	28906	19437	53.39	4946	671	1.38

Minister of Health and Family Welfare
(Dr. Mansukh Mandaviya)

Procurement of Vaccines

Lok Sabha Unstarred Question No. 514

Shri Adhikari Deepak (DEV):

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) The details regarding the number of vaccines procured/being procured by the Government from Zydus Cadila and their cost per vaccine;

(b) The number of people who have been vaccinated as of today;

(c) The steps taken/proposed to be taken with regard to the future plan for vaccination; and

(d) If so, the details thereof?

Answered on 9th December, 2022

(a) A total of 1.5 lakh vaccine doses have been procured by the Government from Zydus Cadila @ Rs. 375.90/- per dose (including GST).

(b) to (d) As on 5th December 2022, a total of 102.54 crore first doses and a total of 95.09 crore 2nd doses of Covid-19 vaccine have been administered. A total of 22.29 crore precaution doses have also been administered. 90% 12+ age population of the country have been covered by both doses of Covid-19 vaccine.

The Minister of State in the Ministry of Health and Family Welfare
(Dr. Bharati Pravin Pawar)

Medicine Accessibility In Rural Areas

Lok Sabha Unstarred Question No. 535

Shri D.K. Suresh:
Shri K. Muraleedharan:
Shri Anto Antony:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government is aware that the price of various drug portfolios have increased despite active regulation of the price of drugs, if so, the reasons therefor;

(b) whether the Government is aware that medicine accessibility in rural India has not been scaled up even after large spending on schemes such as Ayushman Bharat, if so, the reasons therefor;

(c) whether the Government is aware that branded drugs under the Affordable Medicines and Reliable Implants for Treatment (AMRIT) pharmacies are not available, if so, the reasons therefor; and

(d) the steps taken/proposed to be taken by the Government to improve medical assistance in pharmacies that are understaffed?

Answered on 09th December, 2022

(a): As per the information provided by Department of Pharmaceuticals (DoP), the National Pharmaceutical Pricing Authority (NPPA) under DoP fixes the ceiling price of medicines specified in the first schedule of Drugs (Prices Control) Order, 2013 (DPCO, 2013). All manufacturers of medicines have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. The annual increase allowed in the case of Scheduled formulations is upto the level of annual revision in Wholesale price index (WPI). NPPA also fixes retail price of a new drug under DPCO, 2013 for existing manufacturers of scheduled formulations. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies. For other non-scheduled formulations, a manufacturer is at liberty to fix the maximum retail price of a non-scheduled formulation launched by it. In case of non-scheduled formulation, no manufacturers can increase MRP by more than 10% of MRP during preceding 12 months. Instances of overcharging are dealt with by NPPA under the relevant provisions of DPCO, 2013. In addition, Para 19 of DPCO, 2013 provides for fixation of ceiling price or retail price of any drug in public interest for such period, as deemed fit, in case of extra-ordinary circumstances.

(b): To supplement States' efforts, National Health Mission (NHM), has launched the Free Drugs Service Initiative to ensure free medicines to healthcare seekers at all levels of the public health system. To ensure the provision of free essential medicines NHM provides budgetary support to the States/UTs through Program Implementation Plans (PIPs). Under the Indian Public Health Standards (IPHS), facility wise Essential Medicines Lists (EMLs) has been recommended to the States/UTs.

Under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PMJAY), in order to ensure that the hospitals do not overcharge and rates do not vary across hospitals, Empanelled Health Care Providers

(EHCP) are paid as per specified package rates. A package consists of all the costs associated with the treatment, including pre and post hospitalisation expenses. These are bundled packages which include all aspects of treatment including pre-admission diagnostics and post discharge medicines for 15 days. The treatment packages include super speciality care like oncology, neurosurgery, cardio-thoracic and cardiovascular surgery.

As of 4th December 2022, 4.18 Crore hospital admissions worth Rs. 48,934.9 Crores have been authorized under the scheme. Thus, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana has facilitated the availability of free medicines to eligible beneficiaries availing healthcare services under the scheme

(c): 238 AMRIT Pharmacies are operating in 28 States/ UTs. AMRIT Pharmacies are acting as a single point of supply for all medical requirements of the hospitals including Branded/Branded Generic/ Generic drugs, surgical items, consumables and implants especially for tertiary care hospitals. For the medicine requirements, AMRIT Pharmacy is keeping stock of 01 (one) Branded Stock Keeping unit (SKU) and one or two Branded Generic/Generic SKUs for a composition and strength as per the prescription pattern of the Hospital and of the General public of that locality.

(d): Since 2014, the number of institutes approved by The Pharmacy Council of India (PCI) for Diploma in Pharmacy (D.Pharm) has increased from 710 to 3333 and for Degree in Pharmacy (B.Pharm), it has increased from 930 to 2411. There are approximately 33857 pharmacists posted at CHC and below level facilities in the country against the requirement of 36530 as per Indian Public Health Standards.

The Minister of State in the Ministry of Health and Family Welfare
(Dr. Bharati Pravin Pawar)

In Rajya Sabha

India-UK Trade Agreement

Rajya Sabha Unstarred Question No. 379

Shri Kartikeya Sharma:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the details of the ongoing talks between India and UK on the trade pact;

(b) the expected growth of trade between the two countries by 2030;

(c) whether UK demanded to prioritise reducing of tariffs on manufactured goods to benefit sectors like automotive industry;

(d) if so, the details thereof and India's response in this regard; and

(e) the expected timeline of completion of talks on the trade agreement?

Answered on 09th December, 2022

(a) to (e): India and the UK are negotiating a Free Trade Agreement (FTA) since 13th January 2022. 5 rounds of negotiations have been held so far. Both sides are engaged and working together with the aim to conclude the negotiations at the earliest. It is expected that the FTA will help in enhancing the bilateral trade significantly. Trade in Goods, including automotive industries, is one of the areas under negotiations based on overall package of gains and give- aways, which takes into consideration the ambitions and sensitivities of both the sides. The India-UK FTA negotiations are currently underway.

The Minister of State in the Ministry of Commerce and Industry
(Smt. Anupriya Patel)

PM Gati Shakti Master Plan

Rajya Sabha Unstarred Question No. 433

Shri V. Vijayasai Reddy:

Q: Will the Minister of **Commerce and Industry** be pleased to state:

(a) the aims, objectives and vision of PM Gati Shakti Master Plan;

(b) the details of projects that have been undertaken under PM Gati Shakti in Andhra Pradesh;

(c) the details of funds allocated, sanctioned, released, and utilized for projects that have been undertaken under PM Gati Shakti in Andhra Pradesh;

(d) whether targets have been set for the above projects, if so, the details thereof; and

(e) the efforts made by the Ministry for timely completion of the projects?

Answered on 09th December, 2022

(a): PM Gati Shakti National Master Plan (NMP), is a transformative for integrated and holistic planning across concerned ministries /departments to improve multimodal connectivity, logistics efficiency and to address critical infrastructure gaps for seamless movement of people and goods, with focus on minimizing disruptions and ensuring timely completion of works.

PM Gati Shakti National Master Plan (NMP), the digital component of which is a GIS based platform integrating portals of various Ministries/Departments of Government, was launched in October, 2021 with the objective of facilitating data-based decision-making for integrated planning, prioritization of projects, synchronized implementation, optimisation of cost, time and for project monitoring. The NMP aims at facilitating development of multi-modal connectivity infrastructure to various economic zones by Ministry/Departments across the country, so as to facilitate last mile connectivity to economic clusters and thereby reducing logistics cost. To ensure better decision making and coordination among various Central Ministries/Departments, Empowered Group of Secretaries (EGoS), headed by the Cabinet Secretary, and Network Planning Group

(NPG) have been constituted as institutional arrangements. About 2000 data layers of various Central Ministries/Departments/State Governments have so far been uploaded on the NMP. Besides, NITI Aayog, there are 24 Central Ministries/Departments as part of PM GatiShakti, represented in EGoS through their respective Secretaries. Meetings of NPG are held at regular intervals to evaluate project proposals for multi-modal, last mile connectivity and recommend the same for approval.

(b) to (e): A list of projects identified by various Ministries/ Departments of Government under PM Gati Shakti, including those whose alignment(s) is/are passing through or the projects located in the State of Andhra Pradesh is provided at https://dpiit.gov.in/sites/default/files/Parliament_Questions_Logistics_Division.pdf

Apart from the projects identified and listed above, for enhanced capital expenditure by States for infrastructure development, the Ministry of Finance, Department of Expenditure through the "Scheme for Special Assistance to States for Capital Investment for 2022-23" on 6 April 2022 has made an additional provision of Rs 1,00,000 crore for disbursement among the States as long term loans at a zero interest rate. Under Part II of this Scheme, Rs. 5,000 Crore are specifically provided for PM GatiShakti related expenditure. Out of Rs.5,000 crores, Rs 202 crores have been allocated to Andhra Pradesh.

The implementation of the projects is regularly monitored by the concerned implementing Ministries/ Departments in the Government. In addition, the projects are also being monitored through the Project Monitoring Group (PMG) mechanism in Department for Promotion of Industry and Internal Trade.

The Minister of State in the
Ministry of Commerce & Industry
(Shri Som Parkash)

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Govt set to release Rs 4,000 crore to beneficiaries of PLI scheme

NEW DELHI: The government is looking to release around Rs 4,000 crore to the beneficiaries of the production-linked incentive (PLI) scheme, with a majority of companies from telecom, pharma and food processing industries.

Earlier this week, the Centre approved the release of over Rs 357 crore to Foxconn Hon Hai Technology India Mega Development, the first global company under the target segment of mobile phones to receive incentive. Earlier, Padget Electronics, a subsidiary of Dixon Technologies, was the only other company to get the benefit. Foxconn is producing mobile phones for Apple, while Padget is a manufacturer of phones sold by Motorola and Samsung.

Official sources told TOI that the government departments and ministries have been asked to streamline processes so that funds can be released at the earliest. At the same time, a strong message has also gone to the private sector as some of the companies had not provided accurate information to claim the incentive. Besides, departments dealing with the 14 sectors have also been asked to ensure that baseline numbers - for investment and sales, the two criteria for making the payments - are streamlined so that proposals are not stuck. In the past, this has been an area of concern.

The moves follow a recent review by the PMO, where government departments have been told to undertake proper hand-holding of companies in the sectors concerned so that the scheme, which envisages incentive payout of close to Rs 2 lakh crore over five years, produces the desired results.

Source: TNN, 23.12.2022

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Covid 2023: This time not unprepared

Just when one thought the coronavirus was on its way to being confined in the history books, there is news of resurgence in various parts of the globe as scattered as China, the US, Japan, South Korea and Brazil. As on Wednesday, India recorded at least 4 cases of the Omicron sub-variant BF.7 that is responsible for the current surge in China. Studies have already indicated that it is highly infectious, spreading fastest among all variants. BF.7 may even be more dangerous than its predecessors, even to those fully vaccinated. For India, staying alert and strengthening surveillance without going into panic mode are non-negotiable.

GoI's decision to step up genome sequencing for new variants and the call for mask usage are reassuring. These efforts must be backed by health plans at the local level. Directives to states to send positive samples for genome sequencing through the Indian Sars Cov-2 Genomics Consortium (Insacog) network is important. Besides alerting to new variants, it will help map any surge and in taking requisite public health measures. Despite concerns about a vaccine-agnostic BF.7, vaccination must return to the priority zone. While 70% of Indians are fully vaccinated, only 27% have taken the booster shot. Getting boostered must be incentivised, while those at risk - senior citizens, those with comorbidities, and healthcare and frontline workers - should get additional precautionary booster shots.

India has learnt from early fumbles. A ramp-up plan to ensure there is no shortage - infrastructural, logistical and human - must be instituted. Masking in crowded places, both indoors and outdoors, must be strictly imposed. On monitoring of international travellers, GoI should reintroduce the Air Suvidha self-declaration by passengers. Neither citizens nor the economy deserves another shock. For that, precaution and caution are a must, along with science-based systems that are complied with by citizens and authorities. This time, we don't have the excuse of being caught off guard.

Source: The Economic Times, 22.12.2022

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The budget should enhance our ease of doing business globally

Photo: Mint

Rationalize duties, sharpen schemes and simplify processes to boost Indian manufacturing and its global competitiveness

During the last couple of years, the government has taken many positive steps to come out with relief and reform measures to manage the impact of the covid pandemic on the Indian economy and industry. These have contributed greatly to the simplification of the overall tax regime, and Union Budget 2023-24 can add to this ongoing effort to boost growth.

The year 2021-22 was one of reforms in customs tariffs. The Central Board of Indirect Taxes and Customs (CBIC) has taken various initiatives to digitize customs processes and compliances as well as simplify duty tariffs. The effective duty structure has been significantly simplified by removing more than 400-odd exemptions, incorporating the effective rates in the tariff entry itself. This mega exercise was carried out without any significant impact on the effective rate of import duties.

A set of general principles applied in the duty structure (as discussed below) would encourage domestic manufacturing and calibrate it in alignment with global trade trends in a manner that will serve to strengthen India's manufacturing capacity and export competitiveness, with the support of policy moves such as the phased manufacturing programme together with the production-linked incentive (PLI) scheme.

There are certain moves that the government can consider to further enhance the ease of doing business for taxpayers and encourage external trade. These include a rationalization of the tariff structure, laying out a roadmap for the digital transformation of customs processes and litigation resolution.

First, a graded roadmap is needed to shift duty slabs to a competitive level over a period, with the exception of a few products presently in the higher slabs, so that domestic manufacturers have time to adjust. Duty on imports of raw materials should be in the lowest or nil slab, intermediates in the lower slab of 2.5-5% and final products in the standard slab. A phased manufacturing programme along with PLIs for key sectors would give domestic manufacturing a much-needed impetus. This will help Indian industry integrate into global value chains while making its goods and services competitive in world markets. A review of final and intermediate products needs to be undertaken in consultation with stakeholders to ensure that inputs that are not manufactured in India are imported at lower duty to raise the export competitiveness of final products made here.

Second, to improve the ease of doing business, digital API connectivity can be leveraged for uploading data schema for Bill of Entry or Shipping Bill preparation, collating Import General Manifest (IGM) details filed by shipping lines from IceGate, and initiating payments of customs duty. Digital intervention may also allow data sharing with other government portals to facilitate the necessary 'paperwork' for licences, electronic bank realization certificates, certificates of origin and other documents under the Directorate General of Foreign Trade (DGFT).

The government recently extended its Remission of Duties and Taxes on Exported Products (RoDTEP) scheme to three key sectors, a laudable step. The rates for all products should now be enhanced to make them commensurate with their actual embedded taxes and duties. Also, RoDTEP should cover all export items. Export incentives such as duty drawback may be transferred directly to the bank accounts of exporters, instead of being routed through the issuance and transfer of credit scrips. Also, debiting of other duties like the Integrated Goods and Services Tax (IGST), anti-dumping duty (ADD) and cesses should be permitted by means of duty scrips.

It also needs to be ensured that the benefits available under free trade agreements (FTAs) don't defeat the overall objective of the PLI scheme and simultaneous rationalization of customs duty rates on raw materials and finished goods.

Various measures for the ease of doing business

that need to be taken include a facility for auto-renewal and access to import/export data through IceGate for authorized economic operator (AEO) certificate holders; an extension of the timeline for filing Bills of Entry and duty payments without interest for air shipments; timely disposal of appeal cases by lower appellate authorities; and more data on import documents related to multi-location and/or multi-business organizations so that the department as well as such corporates can easily identify transactions and track them by the location and business they relate to.

The integration of the DGFT portal and IceGate should be robust, so that data is seamlessly picked up from the latter's server. Such steps will substantially reduce exporters' cost, time and effort.

Also, there is a need to further simplify compliances in the import duty exemption scheme of the Manufacture and Other Operations under Warehouse Rules (MOOWR) Act. Allowing depreciation of value on used capital goods for payment of customs duty and extending the time for payment of duty after removal of finished goods in line with depreciation admissible under the Export Oriented Units (EOU) and Special Economic Zones (SEZ) schemes would greatly benefit stakeholders. Necessary provisions should also be made to allow a transition from other export-promotion schemes such as EOU and SEZ to MOOWR without payment of duty.

Three, a one-time dispute resolution plan, like the Sabka Vishwas scheme, should be introduced under the customs law to settle pending disputes.

The Authority for Advance Ruling (AAR) plays a significant role in enhancing the ease of doing business and avoiding tax litigation. Accordingly, there is an acute need to enlarge the scope of and augment AAR teams to bring down the pendency of cases.

These initiatives would go a long way in moving the country towards a stable, predictable and taxpayer-friendly regime.

Chandrajit Banerjee is director general, Confederation of Indian Industry.

Source: HT Mint, 26.12.2022

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Pharma exports likely to touch all-time high of $27 bn in FY23 riding on EU

Better figure expected despite global headwinds; India has so far exported pharma products worth $16.57 bn during April-November this year

India's pharma exports are likely to touch an all-time high of $27 billion in FY23, felt a senior official of the Pharmaceutical Exports Promotion Council (Pharmexcil).

In FY22 India had exported pharmaceutical products worth $24.62 billion. So far, India has exported pharma products worth $16.57 bn during April-November this year.

Exports have grown by 4.3 per cent so far this year, over the same period (April to November) in FY22. However, in November, there was a sharp rise in exports of 12 per cent over November last year.

On a month-on-month basis too, exports have grown 5.4 per cent.

Uday Bhaskar, director general of Pharmexcil pointed out that a growth of 4.3 per cent during the April-November period of the fiscal is good, considering the global macro-economic situation.

"The coming months will see better growth rates. Traditionally, January-March is one of the better quarters for pharma exports.

After the holiday season in December, we expect 7-8 per cent growth every month for the next three months," Bhaskar said.

He therefore felt India would be able to clock total exports worth $27 billion or so this fiscal, up from last fiscal's $24.6 billion.

Among all regions, Europe has shown the maximum growth during this fiscal at 14.19 per cent. The US, Canada and Mexico (NAFTA countries), Europe and Africa together account for 67.5 per cent of India's overall exports. West Asia and North-Africa (WANA) grew the second highest at 12.68 per cent.

Last year, Europe and the US together had a 51 per cent share of exports, and this year these two regions may register a higher share of the overall pie. This is primarily because exports to Europe have done well.

Analysts agree. Kunal Randeria, analyst with Nuvama Research said European demand is picking up now, and the inventory situation is easing as well.

Bhaskar says Africa remains a concern as far as exports go. Exports to Africa have shrunk by 1.6 per cent, Pharmexcil data showed. South Asia has contracted the the highest - at negative 15 per cent between April and November.

Bhaskar said a lot of purchases in Africa were happening through NGOs, which were Covid-19 focused, and were procuring medicines for infectious diseases. "This has slowed down to an extent, and also the rising dollar is hurting many economies in the African region," he added.

A Gujarat-based pharmaceutical exporter agreed: "Nigeria is one of our top markets in Africa, and since their currency has depreciated vis-a-vis the dollar, they have reduced their imports a bit," he said.

Source: Sohini Das, Business Standard, 25.12.2022

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China Covid surge stokes supply fears among Indian traders

New Delhi: Indian traders are keeping a close watch on the Covid-19 surge in China as that could disrupt supply of critical imports including active pharmaceutical ingredients (API), electronics, chemicals, and plastics.

Exports, which have been sluggish, could also take a hit as demand from China may plunge, adding to weakness in many developed markets, traders said.

"Engineering goods exports to China dropped 40% in November. China continues to grapple with rising Covid-19 cases and a growing real estate crisis, leading to low demand," said Arun Kumar Garodia, chairman of the Engineering Export Promotion Council India.

Export of engineering goods to China dropped 58.2% to $1.74 billion in April-November of the ongoing fiscal year (FY23) compared to $4.18 billion in year-ago period.

"Many chemical factories in and around Shanghai are operating at 30-40% capacity because of labour shortages. We are watching how the situation evolves," said Ajay Kadakia, chairman of Mumbai-based trading house Vivil Exports, which imports dyestuff from China.

India's imports from China in April-October were worth $60.27 billion, while overall exports were $8.77 billion.

India's exports to China are falling as there is already a slowdown in the Chinese economy, said Ajay Sahai, director-general, Federation of Indian Export Organisations.

"There is no clarity as of now but if the situation there prolongs for a month, then there could be an impact on our trade with China," Sahai said.

The spread of Covid-19 and the upcoming Chinese New Year in the second half of January could lead to further workforce shortages.

"There is 40% absenteeism in our factory in China. There is fear, and people are not going out," said Sharad Kumar Saraf, founder-chairman of Technocraft Industries India, an exporter of engineering goods and textiles.

The company's unit in Quanjiao (in Chuzhou city, Anhui province), with a revenue of ₹250-300 crore, manufactures steel scaffolding systems for the Chinese market.

"There was not much disruption in supply of APIs from China during the earlier waves as they never restricted exports. We are in wait and watch mode now," a representative of the pharmaceutical industry said.

Exporters said India must look at ways to export more food products to China amid the ongoing uncertainty.

"We don't expect an improvement in exports to China as 70% of India's exports are raw material. We must look at ways to increase shipments of broken rice, marine products, tea and tobacco to China because the demand for these products is largely stable," said an industry representative.

Source: Kirtika Suneja, ET Bureau, 26.12.2022

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Attract global supply chains, expand PLI scheme to spur manufacturing: FICCI Prez

India needs to attract global supply chains, expand the scope of production-linked incentives, extend lower corporate tax rate of 15% for five years, and continue improving ease of doing business to spur manufacturing, Ficci president Subhrakant Panda has said.

India Inc needs to brace itself for turbulence due to the recession in advanced economies which has begun to weigh in, but the country is in a situation that it can be optimistic about, Panda, who took over as president of the industry body last week, told ET. "There will certainly be a little bit of cooling off from where we are right now. But that will still make us the fastest growing large economy, which is quite commendable," said Panda, who is also the managing director of Indian Metals & Ferro Alloys Ltd.

On reports of Covid-19 spread in China, he said one will get a clearer picture in the next week or 10 days, but the main concern is new mutations. "Rise in cases is undoubtedly worrisome,» he said. From that point of view, the central government had done well with the health secretary immediately reaching out to all stakeholders and asking them to keep a watch. The health committee of Ficci will keep an eye on Covid-19 situation, Panda added.

He said the government's PLI scheme to boost manufacturing will help curb import dependence as it is clearly targeted towards sectors in which India is import dependent, or where there is an unnecessary outflow of foreign exchange.

"You have to import fuel. But it should not be that electronics imports are at par or more than oil. This is the intended target (of the PLI schemes)," Panda said.

He said in 'China plus one' strategy of global manufacturers, that 'plus one' is still largely expected to be India but it is not an automatic choice in some sectors where there are other alternatives.

"One thing I was recently made aware of is that in particular supply chains, where there has been some movement out of China, 65% has come to India, but the balance has gone to places like Vietnam, where you know they have certain advantages, or Mexico, because of NAFTA (North American Free Trade Agreement) which gives them access to the US markets," Panda said. "What the government can do is broaden the scope of PLI schemes," he added.

Panda said the government has done a very good job of repealing old regulations and rules which were hindering manufacturing companies. "I think the focus needs to continue on the ease of doing business and reducing the cost of doing business," he said. "Prime Minister (Narendra Modi) has announced the GatiShakti programme (as part of) the National Infrastructure Pipeline, which will go a long way towards improving our cost of doing business."

These initiatives will all have an impact, Panda said. India needs to look at moving up the value chain and look at high export potential sectors which can attract investment.

He said the Indian industry is not seeking a protectionist regime but one that countered the hidden subsidies available in some countries. "When talking about increasing duties in some areas, it is not to protect Indian industry, but to provide a level-playing field because certain countries have sectors that are provided hidden subsidies, which enable them to undercut Indian industry," Panda said.

Source: Twesh Mishra & Deepshikha Sikarwar, The Economic Times, 22.12.2022

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Global supply chains catch China's Covid?

It is in India's interests that China smoothens its economic transition from Covid restrictions

A sharp rise in cases of Covid infection in the form of BF.7, a new, highly contagious sub-variant of Omicron, in China has raised the threat of global supply chains being disrupted yet again. This comes just as the world economy was settling down after an oil price shock due to the Russia-Ukraine conflict. This is roiling markets that had rallied on news of China lifting its 'zero-Covid' policy

following widespread protests. China's reopening was expected to be bumpy after three years of restrictions, as was a surge in infections given the poor state of vaccination among its population and lack of any building up of 'herd immunity'. The scale of fresh Covid cases could prolong labour shortages and delay economic recovery. This has implications for global manufacturing and commodity trade.

China is India's top source for imports and third-biggest destination for exports. Uncertain resumption of economic activity in its northern neighbour is beginning to show up across a swathe of Indian manufacturing companies that source inputs from China and among agricultural commodity exporters. India's growth is being dampened by a slowdown in exports and a partial recovery in consumption on account of persistent inflation. A disorderly reopening of the Chinese economy could reinforce both factors through weak commodity demand and manufacturing shortages. There are no quick policy fixes around the China issue: the world is just about setting out to build supply chain resilience that would help diversify India's merchandise trade basket.

India's effort to position itself as an alternative export hub for manufacturing is constrained by its dependence on Chinese inputs. Production-linked incentives (PLI) are being reassessed in the absence of local capacity to scale up investments. Foreign investors that are the principal beneficiaries of the PLI scheme are required to build the ecosystem while meeting ambitious output targets. It is in India's interests that China smoothens its economic transition from Covid restrictions.

Source: ET Bureau, 23.12.2022

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INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
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