INDIAN DRUG
MANUFACTURERS' ASSOCIATION

Since 1961

INDIAN PHARMA - GLOBAL HEALTH CARE

Delivering Healthcare...to the World !!

N O T I C E

The 61st Annual General Meeting of the Indian Drug Manufacturers' Association will be held on **Saturday, 11th February 2023** at Gallery Hall, 2nd Floor, **Hotel Four Seasons,** Worli, Mumbai at **4:00 p.m.** to transact the following business:-

AGENDA

1. To read the Notice convening the meeting.
2. To adopt the Annual Report for the year 2021-22.
3. To adopt the audited statement of accounts for the year ended 31st March 2022.
4. To appoint auditors for the year 2023-2024.
5. Any other business with the permission of the Chair.

Looking forward to welcoming you at the 61st Annual General Meeting at 4.00 p.m.

Daara B Patel
Secretary - General

Date: 06th February 2023

Note : Members who need clarifications or details with regards to the Agenda for the meeting are required to write to IDMA office specifying the clarification required by them on or before 9th February 2023.

IDMA EXECUTIVE COMMITTEE 2022

NATIONAL PRESIDENT	**Dr. Viranchi Shah** *Promoter & Director* **SAGA LABORATORIES** **SAGA LIFESCIENCES LTD.** B3, Second Floor, Safal Profitaire, Corporate Road, Prahladnagar, Ahmedabad – 380 015, Gujarat
IMMEDIATE PAST NATIONAL PRESIDENT	**Mahesh H. Doshi** *Partner & Managing Director* **DY-MACH PHARMA** B-12, Anand Sagar, Old Nagardas Road, Andheri (E), Mumbai – 400 069
SR. VICE-PRESIDENT	**Bharat N Shah** *Managing Director* **S. KANT HEALTHCARE LTD.** 3-A, Shiv Sagar Estate, Dr. Annie Besant Road, Worli, Mumbai – 400 018
VICE-PRESIDENTS	
Western Region	**Dr. George A. Patani, Ph.D.** *Director* **INGA LABORATORIES P. LTD.** Inga House, Mahakali Road, Andheri East, Mumbai – 400 093
Northern Region	**Bal Kishan Gupta** *Chairman* **MEDICAMEN ORGANICS LIMITED** 10, Community Centre No.2, Ashok Vihar Phase-II, Delhi-110 052

Southern Region	**T. Ravichandiran** *Managing Director* **PHARM PRODUCTS PVT. LTD.** AH-64, (New No. 24), 5th Street, Shanthi Colony, Anna Nagar, Chennai – 600 040, Tamil Nadu
Eastern Region	**Asheesh Roy** *Director* **STADMED PVT. LTD.** 'Kumud' 14 A, Monoharpukur Road, Kolkata - 700 026
HON. GENERAL SECRETARY	**Mehul M. Shah** *Managing Director* **ENCUBE ETHICALS PVT. LTD.** 803, B Wing, HDIL Kaledonia, Sahar Road, Andheri (E), Mumbai - 400 069
HON JOINT SECRETARY	**Kamlesh C. Patel** *Managing Director* **WEST-COAST PHARMACEUTICAL WORKS LTD.** Meldi Estate, Nr. Prasang Party Plot, Opp. Sola Bhagwat, Sayona City Road, Gota, Ahmedabad – 382 481, Gujarat
HON JOINT SECRETARY	**Pranav Choksi** *Executive Director* **GUFIC BIOSCIENCES LTD.** S.M. House, 1st to 4th Floor 11 Sahakar Road, Vile Parle (East), Mumbai – 400 057
HON. TREASURER	**Vinay Pinto** *Executive Director* **WALLACE PHARMACEUTICALS PVT. LTD.** A 303/312 Floral Deck Plaza Off Central MIDC Road, MIDC, Andheri East, Mumbai- 400 093

ELECTED MEMBERS

Ashok Dhoka
Director
MAXIM PHARMACEUTICALS PVT. LTD.
08, Kshitij Co-op. Hsg Society,
Opp. Sambhavnath Jain Mandir, Behind
Maharshinagar Police Chowky,
Salisbury Park, Gul Tekadi, Pune - 411 037

Atul J Shah
Executive Director
ELLIS PHARMA PVT. LTD.
Plot No: 4, GIDC behrampura,
Opp Khodiyarnagar BRTS Bus Stand,
Behrampura, Ahmedabad-380 022

B. G. Barve
Joint Managing Director
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G.K. Marg, Lower Parel (W),
Mumbai – 400 013

D. V. P. Raju
Managing Director
ELAN PHARMA (INDIA) PVT. LTD.
501, Raikar Chambers, Govandi (E),
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Dr. Chinmay Yogin Majmudar
Director
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Mumbai – 400 018

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ASTRAL STERITECH PRIVATE LIMITED
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Vadodara -390 010, Gujarat

Neha Thakore
Chief Operating Officer
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Western Express Highway, Andheri (E),
Mumbai – 400 069

Nirav K. Mehta
Promoter & Executive Director
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CORONA House, C - Mondeal Business Park,
Near, Gurudwara, S. G. Highway,
Thaltej, Ahmedabad 380059

Probhas Bondhu Chakraborty
Managing Director
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36 A & B Alipore Road, Kolkata 700 027

R R Shah
Managing Director
MERCURY LABORATORIES LTD.
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Ambarnath (E), Dist. Thane - 421 506
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Tushar A. Korday
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Borivali East, Mumbai – 400 066

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114, Marine Chambers, 11,
New marine Lines, Mumbai - 400 020

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Chairman
ASSOCIATED CAPSULES GROUP
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Nariman Point, Mumbai - 400 021

Bodh Raj Sikri
Partner
NEXT WAVE (INDIA)
S.C.O. #313, 2nd Floor, Sector 29,
Gurugram - 122 009, Haryana

Dr. Azadar Khan, Ph.D
Sr. Vice President – Corporate Relations and India Regulatory Affairs
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New Delhi -110 001

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Hyderabad – 500 038

Nikhil Chopra
CEO & Whole Time Director
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Cnergy IT Park, Unit A,
8th Floor, Appa Saheb Mahtre Marg,
Prabhadevi, Mumbai – 400025

Pankaj R. Patel
Chairman
ZYDUS LIFESCIENCES LIMITED
Zydus Corporate Park', Scheme No. 63, Survey no. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle,
S.G. Highway, Ahmedabad-382 481

Prashant Kumar Tewari
Managing Director
USV PRIVATE LIMITED
Arivind Vithal Gandhi Chowk,
BSD Marg, Station Road,
Govandi East, Mumbai - 400 088

Premchand Godha
Chairman & Managing Director
IPCA LABORATORIES LIMITED
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Kandivli (West), Mumbai – 400 067

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Aditi Kare Panandikar
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Ankur Heramb Joshi
CEO
EISEN PHARMACEUTICAL CO PVT LTD
34/7 Erandwana Pune – 411 004

Ankur Vaid
Joint Managing Director & CEO
CONCORD BIOTECH LIMITED
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Iscon Cross Road, S.G. Highway,
Ahemdabad-380 015, Gujarat

Bharat R. Desai
Managing Director
BHARAT PARENTERALS LTD.
Survey No. 144A, Haripura, Taluka-Savli,
District - Vadodara-391 520, Gujarat

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Director
KILITCH CO.(PHARMA) LTD.
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Advisor-Corporate Services
LUPIN LIMITED
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Vakhola, Santacruz (E), Mumbai – 400 055

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YASH MEDICARE PVT. LTD.
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Ellisbridge, Ahmedabad - 380 006

Deepshikha Deepak Jakate
Regional Director & Head - Quality
ABBOTT HEALTHCARE PVT. LTD.
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Managing Director
EMBIO LIMITED
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Dr Deven V Parmar
Chief Medical Officer and Head Clinical R & D
ZYDUS THERAPEUTICS INC
Zydus Therapeutics INC, 73C route 31N,
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Dr. Milind Joshi
President – Global Regulatory Management
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Manoj Kumar Pananchukunnath
Chief Scientific Officer
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Milan R Patel
Jt. Managing Director
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Zydus Corporate Park,
Scheme No. 63, Survey No. 536,
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Shashikant Damodar Joag
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26, Ramakrishna Coop Housing Society Ltd.,
Ram Mandir Path, Bandra (East), Mumbai – 400 051

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Vijay Shah
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C.G.Road, Ahmedabad - 380 006

Yashwant C. Patel
CMD
ELYSIUM PHARMACEUTICALS LTD.
Post: Dabhasa, Tal. Padra
Dist. Vadodara, Gujarat – 391 440

EX-OFFICIO MEMBERS

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Director
VINDAS CHEMICAL INDUSTRIES PVT. LTD.
210, Adamji Building, 413, Narsi Natha Street,
Masjid Bandar (W), Mumbai - 400 009

PAST NATIONAL PRESIDENTS

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(Founder Secretary) C.M.D.
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Inga House, Mahakali Road,
Andheri East, Mumbai - 400 093.

Chandrakant I. Gandhi
Chairman
GENTECH LABORATORIES LTD.
Unit No. 803, 8th Floor, Lodha Supremus,
Senapati Bapat Marg,
Lower Parel (W), Mumbai - 400 013

Anant R. Thakore
Managing Director
AVIK PHARMACEUTICAL LTD.
194, Arvind Chambers,
Gauri Studio Compound,
Western Express Highway,
Andheri (E), Mumbai - 400 069

Dr. Dinesh S. Patel
Executive Vice-Chairman
THEMIS MEDICARE LTD.
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Dr. Gopakumar G. Nair, Ph.D., LL.M.
CEO / Designated Partner
GOPAKUMAR NAIR ASSOCIATES / GNANLEX ASSOCIATES LLP
#335, V-Mall, Asha Nagar, Thakur Complex,
Kandivli (E), Mumbai - 400 101

Nihchal H. Israni
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Peninsula Chambers,
Lower Parel, Mumbai - 400 013

Yogin R. Majmudar
Managing Director
BAKUL AROMATICS AND CHEMICALS PVT. LTD.
Sterling Center, 4th Floor Dr. A. B. Road,
Worli, Mumbai - 400 018

Suresh G. Kare
Chairman
INDOCO REMEDIES LTD.
Indoco House, 166, C.S.T. Road, Santacruz (E),
Mumbai - 400 098

B. N. Singh
Executive Chairman
ALKEM LABORATORIES LTD.
Alkem House, S. B. Road,
Lower Parel (W), Mumbai - 400 013

Navrattan Munjal
Chairman & Managing Director
IND SWIFT LABORATORIES LIMITED
S.C.O. 850, Shivalik Enclave,
NAC Manimajra, Chandigarh - 160 101

Manish U. Doshi
Managing Director
UMEDICA LABORATORIES PVT. LTD.
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Nariman Point, Mumbai – 400 021

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No.1, Fourrts Avenue, Annai Indira Nagar Okkiyam
Thoraipakkam, Chennai – 600 097

Deepnath Roy Chowdhury
Managing Director
STRASSENBURG PHARMACEUTICALS LTD.
70 Hazra Road, Kolkata - 700 019

CORPORATE MEMBERS

Ajay Bharadwaj
Chief Executive Officer
ANTHEM BIOSCIENCE PRIVATE LIMITED
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Bommasandra Industrial Area, Phase 1,
Hosur Road, Bengaluru,
Karnataka - 560 099

Ajay Kumar Desai
Sr Vice President
ALEMBIC PHARMACEUTICALS LIMITED
2nd Floor, Prime Corporate Park,
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Sahar Road, Andheri (East), Mumbai - 400 099

Arjun Juneja
Chief Operating Officer
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Mankind Pharma Ltd., 236, Okhla Industrial Estate
Phase-III, New Delhi - 20

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304, Mohan Place, LSC, Block C,
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Dheer Dharmesh Shah
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Andheri (East), Mumbai – 400 093

Dr. Dinesh Dua
Executive Director
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Dr. Praveenkumar Lakshminarayana
Associate Vice President
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Biocon House, Semicon Park,
Electronics City Post, Bengaluru - 560 100

Dr. Satyanarayana Chava
CEO
LAURUS LABS LIMITED
2nd Floor, Serene Chambers, Road #7, Banjara Hills, Hyderabad – 500 034, Telangana

J. J. Shah
Chairman
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Andheri (E), Mumbai – 400 059

Jinesh Shah
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TORRENT PHARMACEUTICALS LTD.
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Mohal Sarabhai
CEO
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Mohan Rayana
Group Head
WANBURY LIMITED
BSEL Tech Park, B-Wing, 10th Floor,
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Rajeev Nannapaneni
Vice Chairman & CEO
NATCO PHARMA LIMITED
Natco House, Road No.2, Rd. No. 10,
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Sanjeev Kumar
Director
UNITED BIOTECH (P) LTD.
FC/B-1 (Extn.), Mohan Co-operative Industrial Estate, Mathura Road, New Delhi - 110 044

Sanjiv Navangul
Managing Director & CEO
BHARAT SERUMS & VACCINES LTD.
17th Floor, Hoechst House,
Nariman Point, Mumbai – 400 021

Satish Reddy Kallam
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Shriram Balasubramanian
Director-Commercial and Business Development
ZUVENTUS HEALTHCARE LTD.
Office No. 5119, 5th Floor, D wing,
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Siddharth Mittal
CEO & Managing Director
BIOCON LIMITED
20th KM, Hosur Road, Bangalore- 560 100

Sohan Dadhich
Managing Director
KLM LABORATORIES PVT LTD
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Sudhir Vaid
Chairman & Managing Director
CONCORD BIOTECH LIMITED
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Sunil Baffna
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Sunil Kumar Kaimal
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T. Sathish
Vice President - Regulatory & Corporate Support
TABLETS (INDIA) LIMITED
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Chennai - 600 008

Viral Shah
Managing Director & CEO of ACME Group
ACME GROUP (ACME FORMULATION PVT. LTD. / ACME GENERICS P. LTD. & IMMACULE LIFESCIENCES PVT. LTD.)
Village – Chowkiwala, Ropar Road,
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Yugal Sikri
Managing Director
RPG LIFE SCIENCES LTD.
RPG House, 4th Floor 463,
Dr. Annie Besant Road Worli, Mumbai – 400 030

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Dr. Vivekanand V. Palkar
Chairman & Managing Director
NIVEDITA CHEMICALS PVT. LTD.
ANEK PRAYOG PVT. LTD.
A-14, M.I.D.C., Andheri (E),
Mumbai - 400 093

Jayashree Nair
Chairperson & MD
BDH INDUSTRIES LTD.
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Jayesh P. Choksi
C.M.D. / President
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General Manager
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VITAL HEALTHCARE PVT. LTD.
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GUJARAT STATE BOARD
Chairman

Dr. Shrenik Shah
Managing Director
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At-Dhandha, Idar Road,
Himatnagar – 383 001, Gujarat

Hon. Secretary	**Sumit Agrawal** *Partner* **ISHITA PHARMACEUTICALS** 401, 3rd Eye Two, Opp Parimal Garden, Ahmedabad – 380 006
Executive Secretary	**Rajiv P. Shah** *Executive Secretary -IDMA GSB* **INDIAN DRUG MANUFACTURERS' ASSOCIATION (GUJARAT STATE BOARD)** 4 Park Avenue, 1st Floor, Parimal Garden Cross Road, Nr. Gujarat Gas Co, Ellisbridge, Ahmedabad 380 006, Gujarat

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Chairman	**P. K. GUPTA** *President* **BELCO PHARMA** 515, Modern Industrial Estate, Bahadurgarh - 124 507, Dist. Jhajjar, Haryana
Hon. Secretary	**T. C. Kansal** *Managing Director* **CRYSTAL PHARMACEUTICALS** 365, Model Town, Ambala City - 134 003, Haryana

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Hon. Secretary	**Bodh Raj Sikri** *Partner* **NEXT WAVE (INDIA)** S.C.O. #313, 2nd Floor, Sector 29, Gurugram - 122 009, Haryana

KARNATAKA STATE BOARD

Chairman

S. M. Mudda
Managing Director
MISOM LABS LIMITED
Malta Life Sciences Park, LS2.01.06,
Industrial Estate, San Gwann, SGN 3000, Malta

Hon. Secretary

Prakash Mudda
President – Corporate Projects & Operations
MICRO LABS LIMITED
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Kolkata - 700 071

IDMA COMMITTEES 2022 and 2023

Sr. No.	Committee	Chairman	Vice Chairman
1.	Bulk Drugs	**Yogin R Majmudar** Bakul Aromatics and Chemicals Ltd.	**Neha Thakore** Avik Pharmaceuticals Ltd
2.	Contract Manufacturing	**Mehul Shah** Encube Ethicals Pvt. Ltd.	**Pratik Kamani** Encube Ethicals Pvt. Ltd.
3.	Digital Initiatives	**Kamlesh Patel** West Coast Pharmaceutical Works	**Jay D Patel** Astral SteriTech Pvt. Ltd.
4.	Employee Relations & Development	**Advocacy Group** • **Chandrahas Shetty** - Alembic • **Atul Parab** - Alkem • **Sumit Saloja-** Lupin • **Sai Dutta-** Macleods • **Sanjay Rai-** Alembic	
5.	Excise & Taxation	**B G Barve** Blue Cross Laboratories Pvt. Ltd.	**Prakash Rijhwani** Consultant
6.	Finance & Administration	**Bharat N Shah** S Kant Healthcare Ltd.	**B G Barve** Blue Cross Laboratories P. Ltd.
7.	I P R	**Dr Gopakumar G Nair** Gopakumar Nair Associates	**Srikant Sharma** Fermenta Biotech Limited
8.	Industry Trade Matters	**Bhupendra Sangani** Galentic Pharma	
9.	Industry Institutes Interaction	**T. Sathish** Tablets (India) Limited	**Dr George A Patani** Inga Laboratories P. Ltd.
10.	International Trade (Incl. Customs)	**Tushar A Korday** Emil Pharmaceuticals Inds. Pvt. Ltd.	**Bhavin M Mehta** Kilitch Co. (Pharma) Ltd.
11.	Marketing	**Sundeep Bambolkar** Indoco Remedies Ltd.	**S. R. Vaidya** Kremoint Pharma Pvt. Ltd.

12.	Medical	**Dr Deven Parmar :** Zydus Therapeutics Inc. **Co-Chairman : Dr. Kiran Marthak :** Lambda Clinical Research Ltd.	
13.	Membership and Constitution	**Anant R Thakore** Avik Pharmaceuticals Ltd.	**Chirag Doshi** Yash Medicare Pvt. Ltd.
14.	MSME	**S R Vaidya** Kremoint Pharma Pvt. Ltd.	**Bharat Desai** Bharat Parenterals Ltd.
15.	NDPS	**M. Devesh** Embio Ltd.	**Ms. Neetta Mohit** Abbott Healthcare
16.	Nutraceuticals	**Dr R K Sanghavi** Vilco Laboratories Pvt. Ltd.	**Atul Shah** Eliss Pharma Pvt. Ltd. **T. Sathish** Tablets (India) Limited
17.	Pricing / Consumer Affairs	**Dr. Amit Rangnekar** Centaur Laboratories	**C V Venkataraman** Lupin Ltd.
18.	Public Relations	**J Jayaseelan** Sai Mirra Innopharm Pvt. Ltd.	
19.	Publications	**Dr George A Patani** Inga Laboratories P. Ltd.	**Dr. Nagaraj Rao** RRR Laboratories Pvt. Ltd.
20.	Quality Management & Technical	**Dr. Vinay G Nayak** Aarti Drugs Ltd.	**Dr. Gaurav Pathak** Glenmark Pharmaceuticals Ltd.
21.	Regulatory Affairs	**S M Mudda** Misom Labs Limited	**1) S W Deshpande,** PHARMALEX **2) Kamlesh Patel** West Coast Pharmaceutical Works
22.	R & D and Innovation	**Manoj Kumar Pananchukunnath** Biocon Ltd.	**Dr. Dushyant Patel** Astral SteriTech Pvt. Ltd.

SECRETARIAT

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S RANGANATHAN
Assistant Manager (Administration)
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61st Annual Report 2022

Dear Members,

It gives me great pleasure to present the 61st Annual report of our esteemed Association, the Indian Drug Manufacturers'Association (IDMA). The Year 2022 marked the completion of 60 years of IDMA and the Annual Day Celebrations was an historic & memorable moment for IDMA as an Association as well as its members.

The year 2022 began with Dr. Viranchi Shah taking over as National President of IDMA from Mr. Mahesh Doshi on 6th January 2022. In his first address he mentioned that the Indian Pharma Industry specially the IDMA Members were happy that they contribute to years of better, longer and healthier life for millions of people worldwide. As IDMA - perhaps the world's largest Association of pharma manufacturers, we are proud to be actively contributing. We build and run businesses that employ hundreds of thousands of talented and skilled people. He said that this industry drives billions of dollars of Indian economy every year and earns significant amounts of foreign exchange for India. Our Industry has sharpened India's competitive edge. ***And over and above all, we add smiles to millions of faces every day.***

Dr Viranchi Shah had designed a plan for the next 2 years in form of 4 main action points under the acronym ***"RITE"****.*

RITE =

R *stands for Regulatory Reforms*

I *stands for Innovation*

T *stands for Team building and*

E *stands for Entrepreneurship*

Dr Viranchi Shah announced the setting up an Emergency Response Team that will address the IDMA's response on the crises posed by the pandemic. He said that as we enter deeper into the crises, the situation may become more volatile, we shall definitely keep adjusting our path and efforts so that we ultimately can push this industry forward.

IDMA 60TH DIAMOND JUBILLEE CELEBRATIONS

IDMA's 60th Diamond Jubilee Celebrations commenced with a bang by front page advertisement of our programme i.e. 13th April on the front page of the Economic Times with the appreciation by ***our Hon'ble Prime Minister Shri Narendra Modi Ji*** *that* ***"India's Pharma Industry is an asset not just for India but for the entire world"****. IDMA was privileged and honoured to have Dr.*

Mansukh Mandaviya, Minister of Health & Family Welfare and Chemicals & Fertilizers, Government of India grace the event as the Chief Guest at the Inaugural Session on 14th April '22 and Shri Piyush Goyal, Minister of Commerce & Industry, Consumer Affairs, Food & Public Distribution and Textiles, Government of India for gracing the event as the Chief Guest at the Valedictory Session on 15th April 2022. The entire event provided tremendous networking opportunities & fellowship boost to all the ***700+ participants.***

On behalf of our National President, Dr Viranchi Shah and the Organizing Committee, we whole-heartedly appreciate your support, contributions and involvement in the 60th Year annual day Deliberations and Celebrations which was indeed a great success. We greatly appreciate Mr. Mehul shah for his untiring and tremendous efforts for raising funds during Our Diamond Jubilee Celebrations.

The EC meeting held on 13th April '22 which was a physical meeting, felt like a breeze of fresh air and it was wonderful meeting everybody in person. Our Diamond Jubilee Celebrations held on 14th & 15th April at Hotel Sahara Star at Mumbai was appreciated by one and all. The event had been taken very positively by the Government, Regulators and also industry members. Everyone acknowledged that IDMA had organized a wonderful event which was very well planned & executed and also, covered various facets of this industry. The event enhanced IDMA's name and enabled members to get an excellent take away during the two days.

Mr. Bharat Shah appreciated the Core Team for successfully handling the event. He said that the event achieved its target as everyone really worked hard for it. He said that the fund accumulated would immensely contribute to strengthen our IDMA Secretariat and which would help all our members. He said that a lot of efforts was put up by everyone so that we could gather upto 700+ participants for the event and most of the participants were there right from 14th April morning till the 15th April evening. He said that the participants were very much interested in listening to all the wonderful speakers so very well selected by the core team. He said that the program has become a benchmark and will be remembered by everyone for many years to come.

India@2047

The Centre began work on a blueprint for India@2047- a vision plan for a 'future-ready India' that befits the 100th year of Indian Independence. The Prime Minister's Office as well as the Cabinet Secretary have assigned 10 Sectoral Group of Secretaries (SGoS) to create a blueprint for the India@2047 plan. Madam S. Aparna, IAS, Secretary, DoP chaired a Webinar on the Vision Document for the pharma and medical devices sector for INDIA@2047 and this was followed by a web meeting by the Ministry of Commerce which was chaired by Ms Nidhi Mani Tripathi, Joint Secretary (Commerce). IDMA forwarded a representation with regards to India@2047.

Department of Pharmaceuticals organized stakeholder's consultation meeting on VisionIndia@2047 under the chairpersonship of Ms. S. Aparna, Secretary, DoP on 26th August

2022. In this connection, Department of Pharmaceuticals had sent the VisionIndia@2047 document compiled by IPA, seeking inputs on the same. Dr. Viranchi briefed about the consultation meeting on Vision India@ 2047, he said that India being the world's largest democracy, healthcare & well-being are one of the foundational pillars of development for India. He then said that the Vision@2047 will be a guidance document for the Pharmaceutical and Medical devices sectors to assess the industry development with global standards, surpassing key challenges, and leverage new opportunities. He then requested members to provide their inputs on VisionIndia@2047 document which is compiled by IPA.

VRIDDHI

IDMA had envisaged great plans to support our members & bring them on the rapid growth path by knowledge sharing and hand holding. With regards to the same, we had interesting talks during the Executive Committee Meetings given by Mr. Arjun Juneja, Mankind Pharma Ltd. on ***Value creation in the Pharmaceutical Industry*** *and Mr. Parijat Ghosh, Bain & Company on* ***Founder's Mentality****. "Vriddhi" is the brainchild of Dr Viranchi Shah, National President and Mr. Mehul Shah, Hon. General Secretary.*

"Vriddhi" *an insights-exchange series envisaged with the objective of supporting Indian pharmaceutical companies to expand their vision by embracing* ***Founder's Mentality*** *and making PE work to their advantage.* ***IDMA had partnered with Bain & Company****, one of the world's most respected management consulting firms, to design and deliver Vriddhi. Vriddhi Series 1 was held on 16th September 2022 at Mumbai and was attended by over 150+ participants. Vriddhi Series 1 was well appreciated by one and all.*

National Single Window System

Ms. Sumita Dawra, Additional Secretary, DPIIT informed that National Single Window System is operational and asked all to use it and give them the feedback to improve upon the portal. At present 14 States and 19 Central Government departments are already on board.

IDMA informed that:

1. *Pharma Industry requires approvals from various departments like CDSCO, DBT, Ministry of Environment, etc.*
2. *Need for special demonstration of National Single Window System for Pharma sector;*
3. *IDMA's State Boards already aligned with National Single Window System;*
4. *IDMA offered to publish the details of National Single Window System in our IDMA Bulletin as and when desired by DPIIT.*

India Pharma 2022 & India Medical Devices 2022

The 7th Edition of India Pharma 2022 & India Medical Devices 2022 was organized by DoP

and supported by FICCI at New Delhi from 25th to 27th April 2022. Dr Viranchi Shah, our National President mentioned that in India Phama meet the overall message was similar to what we had received in Mumbai at our event that industry is expected to reach about USD 130 billion by 2030 and approximately about USD 500 billion by 2047 and what are the important things to be done for achieving this target.

CEO Conclave - India Pharma 2022 & India Medical Devices 2022

Dr Viranchi Shah, National President informed the members that during the CEO conclave the major discussions were on the above mentioned points and how to prepare and have a proper system to incorporate such prices escalations for the revision application for the MRP. He further informed the members that there was a discussion about the rationalization of chemical trial rooms wherein Dr. Mansukh Mandiviya ji had chaired this session. He said that the Hon'ble Minister had discussed on the points very categorically and said that the Government is going for amendment of Decriminalization Law and Food and Drug and Cosmetic Laws. He further mentioned that another important message that was given during the CEO roundtable meeting was regarding the ease of doing business. He said that usually ease of doing business is E-Governance initiatives, apply online and have a single window system. He said that the Minister had very specifically said that the Government wants to move forward with E governance initiatives and also, make procurement of land simple and predictable to the entire process including setting up plants and running them. He further added that the Government wants to take a series of steps where the approvals are minimal or the laws become simple or there are lot of self-declarations where you know it becomes very easy for an entrepreneur to set up and run the organization. So ease of doing business is another initiative the Government is trying to develop.

State Drug Regulators Meet - India Pharma 2022 & India Medical Devices 2022

National President, Dr Viranchi Shah informed the members about the deliberations at the State Drug Regulators Meet. He said that there were very fruitful deliberations regarding the Decriminalization Laws, Decriminalization of minor offenses and there should be scope for self-declarations. He informed the members that the Minister mentioned that the Government is working for the amendment of Decriminalization Law and giving the company a chance of self-declaration. He said that the Government is expecting that each State Government should come up with a review mechanism for prosecution by the next India Pharma so that whenever there is any case of prosecution, it should pass through scrutiny through this review mechanism. He said that if there is failure from any manufacturer, that manufacturer can be banned from manufacturing that specific formulation, but help and guidance also should be given for effective CAPA, which will help the manufacturer to identify the root cause of failure and also help the manufacturer to come up with a better formulation. National President informed the members that he has given assurance during the meeting that IDMA is with the Government against the spurious and adulterated drugs. He said that the IDMA's point with regards to delinking of shelf life of APIs against the shelf life of the finished products was discussed and outcome was very positive. Dr. V G Somani has assured

that the new Schedule M would be implemented shortly wherein there is an amendment for Shelf life of API.

INDIAN PHARMA VISION 2047

Madam S. Aparna, Secretary, DoP chaired the Indian Pharma Vision 2047 session wherein Dr. Viranchi Shah, National President, IDMA mentioned the following:

- *There is a big market for off-patented drugs.*
- ***Stressed for Three 'C's –** Cost / Compliance / Creativity for Innovation*
- *We need to manufacture APIs through cost effective routes*
- ***START***
  - ***S** - Supply Chain – we need to strengthen the Supply Chain,*
  - ***T** – Talent Pool – Today not even a single institution of the country is in top 25 of the world. We have to repurpose our Talent Pool to reach the target of USD 500 Billion by 2047*
  - ***A** – Automation has a major role to drive the growth,*
  - ***R** – Research – beyond the NCEs, we need to do research for processes, modern ways of marketing etc. &*
  - ***T** – Technology - We need to target for paperless manufacturing.*

*National President informed the members that there was a discussion on off patented products and R & D innovations. He said that many Industry Stalwarts had taken part in this discussion wherein he brought to notice of the august gathering that India is the only country where for performing research a license is required. He said that he has requested to make the R&D approval procedures simple. Also, he said that during this Session a vision was shared - **'let's create an environment that 25% of new drug applications come from India'**. He said that he put forth IDMA points that IDMA believes that though innovation is very important, we have to continue to strengthen our drug manufacturing industry such as including the off patented products that we have mastered manufacturing and suggested certain points to make sure that even this part of the industry which produces the off patented products will continue to thrive till 2047.*

Meeting notice for the sub-committee on the proposal regarding problems faced by the blind or visually impaired people to read medicines tablets/capsules strips

A sub-committee was constituted during 58th Drugs Consultative Committee (DCC) meeting held on 14.07.2020 under the chairmanship of Shri Atul Kumar Nasa, DDC & Controlling Authority, Delhi to examine the "Proposal regarding problem faced by the blind or visually impaired people to read medicines tablets/capsules strips". I was very happy to be a part of this committee. There was a discussion with industry, stakeholders and National Blind Association, the sub-committee members on the following points:

a) *Primarily to begin with labelling in Braille should be initiated in OTC medicine on their secondary packing and the same shall be conducted with phased wise manner.*

b) *Labelling in Braille in secondary packing would be voluntary option for manufacturers.*

c) *Cost incurred by manufacturer in doing so would not be a big issue/factor, as the population of blind people is proportionally less.*

d) *Labelling in Braille, would capture minimum information like name of the product, expiry date.*

US FDA Questionnaire: IDMA Survey Questionnaire was circulated on 12th March 2022

IDMA has had several discussions in the recent past with US FDA with regards to supporting our members to prepare for obtaining US FDA approvals. IDMA is actively interacting with US FDA to enable more Indian companies to enter the USA Market. In order to understand organisation's problems and the support required by members, IDMA, has prepared a Questionnaire (in google form) and has requested for various data from members who are interested in doing business in USA.

Virtual (Online) meeting with Dr. R. S. Sharma, Chief Executive Officer, National Health Authority on 18th Oct 2022

DoP organized Online meeting with Dr. R.S. Sharma, CEO, National Health Authority. Meeting was to discuss about using technology to address the issues of Counterfeiting. Dr. Viranchi informed the members that the virtual meeting organized by Department of Pharmaceutical along with Dr. R. S Sharma, CEO NHA was very interactive. He said that the meeting was organised to discuss about using technology to address the issues of Counterfeiting. He said Dr. R. S Sharma, explained the use of technology in stopping counterfeit and spurious drugs. Further Dr. Sharma said it is important to work together as it is in interest of everybody and we should not allow the spurious drugs to enter the supply chain. The purpose of meeting was to understand the practices used in industry and problems faced by them.

IDMA joins hands with Shimadzu and Spinco

Mr. Mehul Shah informed the members that IDMA has pursued with Shimadzu and Spinco for a special one-time proposal to help our members procure advanced HPLC to meet their quality and regulatory needs.

Any member company buying 2 Advanced i-Series units will benefit savings of up to 9.5 Lakhs INR for 2xUV, 10.5 lakhs for UV-PDA and 11.5 Lakhs for 2xPDA. Also our member companies can depute their employees for taking training on latest HPLCs at Spinco's Centre of Excellence in Chennai free-of-charge. The logistics and accommodation need to be borne by member companies. Alternatively, Spinco can organize an on-site training to HPLC users at IDMA member facility. This provision facilitates skill introduction and upgradation of pharmaceutical industry workforce.

IDMA is also in negotiation with the Government of India for the Policy Support to Pharmaceutical SMEs for Technology Upgradation through Investment in HPLCs. We are anticipating a positive response at earliest.

IDMA is pleased to inform its members that the IDMA JB Mody Conference room has been renovated and upgraded to facilitate in-person meetings as well as hybrid meetings.

A detailed report of your Association's activities during last year is presented in the following pages of this Annual Report.

We are indeed thankful to our National President and all the office bearers as well as Past Presidents, Committee Chairmen/ Subject Matter Experts for their unstinted support and guidance.

Our motto has been "Members First" and accordingly resolving member's issues and queries have been our top priority.

I would like to thank each and every member for their continued support, without which our association would not have reached the height at which it is today.

Thanking you for your continued support, and looking forward to receiving the same in the years to come.

Wishing you all a Safe, Healthy, Fruitful, Profitable Financial Year 2023-24.

Yours Sincerely,

Daara B Patel
Secretary-General

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REPORT OF BULK DRUGS COMMITTEE

The year began with the 7th Meeting of India-Tunisia Joint Working Group on drugs and pharmaceuticals on 14th January 2022 which was attended by the Chairman, Mr. Yogin R Majmudar. IDMA and BDMA made a joint presentation on experiences in Bulk Drug industry.

MOEF & CC

IDMA made a Representation on 11th January 2022 requesting for extension of the notification under MoEF&CC Notification dated 16th July, 2021 & also for including Intermediates.

Presentation at the 1st EC Meeting on 21st January 2022

Mr. Yogin Majmudar, Chairman of the Bulk Drugs Committee made the below presentation to the EC members on 21-01-2022 :

1. IDMA Members to be encouraged to give preference to indigenously produced APIs & Intermediates over imported (Chinese) products. We can even consider instituting award to be given at Annual Day to Formulators and large API producers with maximum local purchase.
2. On environment front, pursue State Governments to implement at ground level on 2 MoEF notifications on no prior-EC requirement for increased production / change of product mix etc. by similarly amending CTE & CTO conditions where there is no increase in pollution load.
3. Chase DoP to announce location of Bulk Drug Parks
4. Support efforts of President with preparation of Data Base of products manufactured by our Members
5. Seminars can be held on suggested topics from Member Companies

Production Linked Incentive scheme (PLI) for Pharmaceuticals 2.0

IDMA forwarded a representation on 20th January 2022 to Dr. N. Yuvaraj, Joint Secretary, DoP along with the letter of M/s. Ajanta Pharma requesting support of the Government to Group B companies under PLI scheme. IDMA was given to understand the matter was under consideration.

Environment Issues

Mr. Vishal Jajodia requested IDMA to assist in Environment Clearance for New Expansion / New Sites. Dr Viranchi Shah said that IDMA recently had an interaction with Mr. Manoj Agarwal, Addl. Secretary with the Government of Gujarat and IDMA has also made a written application with regards to Environmental clearance. He said that with regards to GPCB, he is hopeful that the issues would be sorted out at the earliest.

Request to support Indian Pharma industry against dumping of Pharma APIs, Intermediates and KSMs by Chinese producers

IDMA forwarded a mail on 21st April 2022 to Director General, DGTR requesting them to consider recommendation for imposition of Anti-Dumping Duties on import of Ofloxacin and its intermediate O-Acid. IDMA submitted the hardcopy to the office of DGTR on 22nd April 2022.

QR Codes for APIs

Mr. Mahesh H Doshi & Ms. Neha informed the members regarding the QR Codes for APIs. There was a discussion on QR codes for API and it was decided that a representation from IDMA for QR code for API be prepared and sent at the earliest.

Bulk Drug and Regulatory Committees Preparatory Meeting w.r.t. India- EU JWG on Pharmaceuticals

A Physical meeting was held on 5th July 2022 at the IDMA office for the two points received from EU on which views of industry to be provided. The two options given by EU in respect of APIs

Option 1 is exporting country declares compliance through written confirmation to exporting country.

Option 2 which is exporting country requests to be listed as a country that, APIs have a regulatory framework and respective control/enforcement act.

Congratulatory letter to Hon'ble Dr. Mansukh Mandaviya, Minister of Health & Family Welfare and Chemicals & Fertilizers for approval of Three Bulk Drug Parks

IDMA sent congratulatory letter on 3rd September 2022 to Hon'ble Dr. Mansukh Mandaviya, Minister of Health & Family Welfare and Chemicals & Fertilizers for the approval of Three Bulk Drug Parks at Himachal Pradesh, Gujarat and Andhra Pradesh. Dr. Viranchi Shah said that it is very significant step taken by the GOI which has come in form of the in-principle approvals for three Bulk Drugs Parks in Himachal Pradesh, Gujarat, and Andhra Pradesh. He further said that it is high time we produce chemicals and other raw materials used in making live-saving drugs rather than depend on China.

DoP meeting to discuss the Process flow for routing project proposals seeking technical assistance from UNIDO

On 6th October 2022, under the Chairmanship of Dr. N. Yuvaraj, Joint Secretary, DoP, discussion of the Process flow for routing project proposals seeking technical assistance from UNIDO was organised. UNIDO was represented by Dr. Rene Van Berkel, UNIDO Representative and Head of Regional office in India, Ms. Shraddha Srikant, Projects and Partnerships Coordinator.

Dr. Rene Van Berkel made a presentation on "Inclusive and Sustainable Industrial Development opportunity for Pharmaceuticals Industry". He mentioned**:**

- UNIDO is involved in 50 projects with 8 line Ministries.
- Execution of the project is done either through outside agencies or through the hired experts by UNIDO
- 'National Manufacturing Innovation Survey 2021' across all the sectors was done through experts hired for this specific survey. Samples were chosen on the basis of data provided by the Associations.
- All the projects undertaken in India can be seen on their website https://isid4india.org/

Dr. Yuvaraj, Joint Secretary, DoP briefed about the following:-

PTUAS -- Mentioned about the schematic interventions by the DoP with specific reference to PTUAS. There are around 6500 SME units. Out of which, around 2500 units are WHO certified. The target is to upgrade the balance 4000 units to WHO GMP level.

CLUSTERS -- There are 112 clusters in the country. There is need to create awareness of the scheme in these cluster areas. He said that DoP wants to create awareness of the scheme within next two months. He also referred to the WHO Survey titled 'Survey of Indian Pharmaceutical Enterprises for meeting National and Global Health Needs'.

Technology Mapping – Mapping of technologies being used by the different Nations for the production of APIs.

Bulk Drug Parks -- Bulk Drug Parks under implementation. Study report on preparedness is being made. Government is likely to go for more Bulk Drug Parks wherein the grants will be given to the States and they will be responsible for implementation.

RLI / Innovation Scheme – Joint Secretary requested UNIDO to share the inputs received for the National Manufacturing Innovation Survey 2021. DoP needs these inputs with regard to the RLI/Innovation scheme being prepared by DoP.

Dr. Yuvaraj has requested IDMA and BDMA to provide support to UNIDO.

Request to impose anti-dumping duty on "Ofloxacin and its intermediates" following dumping and injury to the domestic industry found by the DGTR

IDMA made a representation on 30th September 2022 to the Revenue Secretary with respect to imposition of anti-dumping duty on "Ofloxacin and its intermediates" following dumping and injury to the domestic industry found by the DGTR. The producers of Ofloxacin and its intermediates in India have been suffering from adverse effect of dumped imports in the Country for past some time. Anti-dumping duties were earlier imposed on imports of "Ofloxacin and O-acid" from China and was extended to imports of "O-Ester" on finding circumvention of the same.

Dr. Viranchi Shah said that the investigation by the DGTR has shown that the Chinese producers are dumping the product into the Indian market in significant volume. Ofloxacin acid is produced only in India and China. Thus, if the Indian industry is not protected, the consumers will completely be dependent on just one source, i.e. China. He further said that the Government of India is promoting domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). Therefore, imposition of duty on dumped imports of the product will help Indian industry to be self-reliant.

CII 4th Lifesciences Conclave 2022 on 23rd Sept 2022

CII organized its 4th Lifesciences Conclave 2022 in Lalit Hotel, New Delhi. Hon'ble Mr. Bhagwanth Khuba, Minister of State for Chemicals & Fertilizers and Minister of New & Renewable Energy gave the Inaugural address (virtual). Ms S Aparna, Secretary, DoP and Dr. V.K. Saraswat, Member NITI Aayog delivered Special Addresses. **Plenary Session on "What to focus on next towards attaining self-reliance of APIs and KSMs in India"** was chaired by Mr. Vivek Kamath, Co-Chairman, CII National Committee on Pharmaceuticals. Dr. N. Yuvaraj, Joint Secretary, DoP delivered his address.

Dr. Viranchi Shah made the following points:

Regulatory reforms – need for simple rules; need to move up value chains from small molecule to complex molecule

Innovation @ 2047 – we should target at least to be at 20% of the innovations @ 2047

Technology enablers – referred to IDMA programme conducted in association with Bain & Co attended by around 500 delegates

Can we incentivise formulation manufacturers to use indigenously produced APIs & Brown units to become Power House

Interactive Hybrid Meeting w.r.t Bulk Drugs Park at Kakinada, Andhra Pradesh on 27th October 2022

Dr Viranchi Shah informed the members that a Hybrid meeting was organized by Andhra Government and API Bulk Drug Park Infrastructure Corporation Limited. The Meeting was chaired by Mr. G Amarnath, Hon'ble Minister for Industry, Andhra Pradesh. He said that Ms S. Gummalla, IAS in her welcome address mentioned about hassle free approvals in AP. She said that AP was one of the 12 States who had applied for the API Park Scheme of DoP, GOI. Andhra Pradesh was selected along with Himachal Pradesh and Gujarat for the development of API Parks. He said that Mr. G. Amarnath, Hon'ble Minister of Industry, Andhra Pradesh thanked the GOI for selection of AP for the Bulk Drug Park at Kakinada and informed about the exemption and subsidy given to the API park in Andhra Pradesh such as:

- The GST exemption for ten years
- Waiver of 100% stamp duties
- 50% of the Registration charges for exports to many countries will be reimbursed for product approvals abroad

He informed the members that Dr Rene Van Berkel, Head UNIDO India spoke about Innovation and the National Manufacturing Survey being done by UNIDO. He mentioned that UNIDO is willing to support Andhra Pradesh.

Target for 2047 is to reach US $ 500 billion. Strong API industry is needed to support the formulation industry.

Mr Uday Bhaskar, DG Pharmexcil made the following points:

- AP is the Bulk drug capital of INDIA and also has strong presence in Vaccines.
- Referred to dependence on China for APIs and Intermediates. Chinese Chemical Industry today is around $1.73 Trillion.
- Katoch Committee gave its recommendations in 2015. We are late by six years.
- Large Companies have their own SEZs.
- L&T and Aurobindo together can help build the infrastructure.

Dr Viranchi mentioned that there were Presentations made by Mr Shankara Prasad, Adviser, APIIC. Mr. Prasad said that UNIDO is having Global presence in the Bulk Drug Park.

Dr Viranchi mentioned that there were Presentations made by Mr Shankara Prasad, Adviser, APIIC. Mr. Prasad said that UNIDO is having Global presence in the Bulk Drug Park. Dr Viranchi Shah informed the members about the following:

- Project is ready for Entrepreneurs to plug in.
- Holistic things are available – Incubation Centre and Waste management is thought of.
- It took 75 years for Pharma Production to reach 50 billion dollars from zero.
- Target for 2047 is to reach US $ 500 billion. Strong API industry is needed to support the formulation industry.

Stakeholders meeting on implementation of perspectives related to GSR 20(E), dt.18.1.2022 mandating QR Code for APIs manufactured or imported in India

Dr. V.G. Somani DCGI called a Stakeholders meeting on 17th November 2022 to discuss with implementation of perspectives related to GSR 20(E), dt.18.1.2022 mandating QR Code for APIs manufactured or imported in India.

IDMA's representation wrt QR Code on Active Pharmaceutical Ingredients on 5th December 2022

IDMA made a representation to Joint Secretary (Health), Ministry of Health & Family Welfare with regards to printing of QR Code with specified information on packaging of Active Pharmaceutical Ingredients as the Implementation date of QR Code is effective from 1.1.2023.

IDMA has requested the Ministry to make the implementation of QR Code on voluntary basis and that too if at all to be implemented, on trial basis only for domestic supplies within India and remove the requirement for imports.

Mr. Manish Doshi said that he along with IDMA members attended the meeting with Dr. V.G. Somani, DCGI regarding mandating QR Code for APIs manufactured or imported in India.

National President Dr. Viranchi shah informed the members that IDMA would be sending a representation to Government seeking clarification about the notification on implementation of QR code and that the same could be published in our bulletin for information to our members.

Meeting with Mr. Pravin Darade (IAS), Principal Secretary, Environment Department, Govt. of Maharashtra

IDMA delegates had an interactive meeting with Mr. Pravin Darade (IAS), Principal Secretary, Environment Department, Govt. of Maharashtra regarding 'Proactive support needed by API Industry in Maharashtra to achieve its past glory' on 25th November 2022 and IDMA forwarded a letter to Mr. Pravin Darade on 5th December 2022 with the following suggestions:

1. Consent only based on total outlet effluent
2. Uniform treatment norms
3. Fixed Consent renewal period

IDMA prepared and submitted short notes to Mr. Pravin Darade (IAS), Principal Secretary, Environment Department, Govt. of Maharashtra with regards to notes on CETPs, Consent based on pollution Load of outlet effluent and as single category of "API & Intermediates" Uniform effluent treatment Norms as per inlet norms of CETP.

Mr. Yogin Mujumdar briefed the members about the meeting with Mr. Pravin Darade (IAS). The meeting was attended by Mr. Mahesh Doshi, Mr, Manish Doshi, Mr. Barve, Mr. Daara Patel and Dr. Chinmay. The meeting was regarding 'Proactive support needed by the API Industry in Maharashtra to achieve its past glory' IDMA gave some suggestions for MPCB and Maharashtra Ministry of State of Environment.

Mr. Yogin Majmudar suggested to appoint a Consultant for the Environmental and Pollution Control issues faced by our members. After some deliberations, it was decided to meet Mr. Mirashe and decide whether IDMA can appoint him as a consultant. The consultant has since ben appointed and his information has been forwarded to all IDMA Members as well as published in IDMA Bulletin.

Meeting of Committee of experts for planning & utilization fund of Environmental Compensation as per Hon'ble NGT orders on 2nd December 2022

The meeting was attended by representatives from IDMA, CII, Thane-Belapur Industrial Association apart from CPCB, MPCB, etc.

CPCB has prepared 11 areas where these funds can be deployed e.g. Air and Water Surveillance, Remediation of contaminated sites (legacy dump sites), Special Investigation in Eco sensitive areas, Scientific and Technical matters, etc.

REPORT OF DIGITAL INITIATIVES COMMITTEE

The newly formed Digital Initiatives Committee under the Chairmanship of Mr. Kamlesh Bhai Patel, presented before the Executive Committee the following points for digitalization of IDMA Office as well as the website:

- Revamp the current IDMA website.
- Improvise the look and feel of the website with **focus on simplicity.**
- Ensure inclusion of **historical achievements and leadership teams.**
- Industry whitepapers, regulatory notifications and live feed from member associations i.e. Pharmexcil, etc.
- Members only Portal – available on website and **IDMA App**
- **Administrative Tools:** membership status and renewals, payment gateway and invoicing, event registrations, flexible platform for other administrative purpose.
- **Onboarding of new members:** application form, membership dues, induction, etc.
- **Business Networking Tool**: Database with members capability (manufacturing, marketing, regulatory accreditations, contact details, etc.), posting of business leads, networking via app, etc.
- Interactive webinars to showcase industry best practices and future outlook – digital and tech
- Advances in manufacturing automation – **showcase MSME examples**
- Use of technology to **empower team engagement** and development of organization
- **Industry hot topics:** Serialization, Regulatory Expectations, Government Portals, etc.

Mr. Kamlesh Bhai Patel briefed the members about the Memberly App wherein we can inform all the members about the recent happenings in the pharma industry on a single platform. The Memberly App is currently being used by IDMA GSB. He said that this App is developed by an IDMA Member and is free of cost. Mr. Daara Patel informed the Chairman that IDMA would publish the same in IDMA Bulletin and inform its Members.

We are pleased to inform you that IDMA Conference room has been upgraded and now we can have meetings in a hybrid way. Currently, IDMA Website is being upgraded.

REPORT OF EXCISE & TAXATION COMMITTEE

Interest Equalization Scheme on Pre and Post Shipment Rupee Export Credit – Request for extension until March 2022

IDMA forwarded a representation on 30th November 2021 to consider extending the Interest Equalization Scheme on Pre and Post Shipment Rupee Export Credit until March 2022 and also request RBI to notify the banks for extending this benefit.

Pre-Budget meeting for Union Budget 2022-23 chaired by Chairman CBIC

IDMA handed over hard copy of our proposals on Direct Taxes and GST to all the Members on 1st December 2021 and results are expected when the Union Budget is announced.

Concessional GST rates on certain Covid 19 treatment drugs

IDMA made a submission to Chairman, CBIC on 7th January 2022 requesting for extension of existing concessional GST rates on certain Covid 19 treatment drugs for further period of 6 months.

Presentation at the Executive Committee Meeting

Mr. B G Barve, Chairman, IDMA Excise & Taxation Committee made the below presentation at the Executive Committee Meeting:

Proposed Initiatives and Activities

- A keen watch on Developments and Updates in Direct and Indirect Taxes.
- Information and Advisory on revisions in Tax laws / filing of Returns dates / Notifications for understanding and necessary action of Members through IDMA Bulletin.
- Advisory on issues and concerns being faced by Industry in Direct and Indirect Taxes through experts in IDMA Bulletin.
- Mentoring Programs - Quarterly Webinar on ‘GST, Customs & Income Tax Implications on the Pharmaceutical Industry, educating members so as to improve Tax compliances.

Recently, IDMA had successfully organised a Webinar on 4th February 2022 in association with KPMG on announcements in Union Budget 2022.

- Advisory / Assistance on issues and concerns being faced by Industry members in Direct and Indirect Taxes.
- Interface with Government – Interaction (Communication, Coordination and follow ups) with CBIC, Ministry of Finance, GST Council, Central and State Governments etc. on all issues having bearing on Industry.
- IDMA made representation to Ministry of Finance/ GST Council on certain issues with announcements in Union Budget 2022.
- IDMA suggestions on Union Budget 2023-24.

Support required from IDMA by the Committee

1. Inputs, Suggestions and Guidance to achieve our proposed initiatives and activities
2. Necessary arrangements of basic requirements for execution.

Continuation of issuing 3CM approval and 3CL Reports u/s 35 (2AB) of IT Act 1961 for 100% weighted Tax deduction beyond 31.3.2020 under FI Programme of DSIR.

Department of Scientific & Industry Research (DSIR) uploaded the news in its website on 9th March 2022 regarding continuation of issuing 3CM approval and 3CL Report u/s 35 (2AB) of IT Act 1961 for 100% weighted tax deduction beyond 31.3.2020 under FI programme of DSIR.

Mr. B G Barve briefed the members about IDMA efforts with DOP as well as with the Income Tax Authorities to give this R& D benefits to all our Members has finally been heard. DSIR has issued a circular that those companies who are having R&D Centre at their respective units are required to take the necessary approval from DSIR. He said in order to get the approval, Members are required to file an application under the form 3CK and if the application is in order, DSIR will approve the unit under form 3M. He further added that after receiving the approval from DSIR, the company auditor is required to verify the expenses on a year to year basis so that the particular year's expenditure which has been incurred for R&D is approved by the auditors. He briefed the members about the Auditors role in filing the necessary forms to DSIR and Income Tax Authorities. He further said that DSIR will have to confirm whether the approved expenses were under R&D for claiming the income tax benefits.

Mr. B G Barve briefed the members about IDMA seminar with KPMG who are IDMA's knowledge partner. He said that there were 135+ participants for the webinar. He further added that IDMA had requested KPMG to share the FAQs for the benefit of members.

IDMA in association with KPMG in India organized a Webinar on KPMG's perspectives and valuable insights on "Section 194R (2) - TDS on Benefits/Perquisites provided during Course of Business"

Mr. B G Barve informed the members about the webinar which was organized by IDMA along with KPMG in India and the Representation forwarded to CBDT with regards to Section 194R (2) - TDS on Benefits/Perquisites provided during Course of Business. He said that IDMA members had a very interactive webinar with KPMG in India on this subject.

Representation on Pharma Industry Concerns regarding 194R has been forwarded to CBDT on 12th July 2022 via email on 28th June 2022 and requested that No TDS should be charged on the following: -

- Free medicine samples provided by pharmaceutical companies to healthcare professionals / hospitals / doctors;
- Brand reminders provided with the Company's logo to various doctors / medical practitioners/ hospitals / stockiest / vendors / distributors/ retailers, etc.

He further said that along with the Representation IDMA has mentioned the challenges and strong rationale for the below recommendations:

1. Free medicine samples provided by pharmaceutical companies to healthcare professionals / hospitals / doctors should be outside the purview of Section 194R of the Act
2. Brand reminders such as items provided with the Company's logo etc. should be outside the ambit of TDS under Section 194R as they are provided for the benefit of the provider of items itself.

Mr. B G Barve said that IDMA has mentioned in the covering note that IDMA would be pleased to meet CBDT officials in person and explain the points in detail.

Request for waiver of ITC reversal under Section 17 sub-Section (5)(h) of CGST Act, 2017 for COVID related Raw Material (API) & Finished Goods (Medicines)

Mr. B G Barve informed the members about the Representation sent via email on 14th July 2022 to Shri Vivek Johri, Chairman, Central Board of Indirect Taxes and Customs with a copy to Hon'ble Smt Nirmala Sitharaman ji, Minister of Finance & Chairman, GST Council & Shri Tarun Bajaj, Revenue Secretary & Ex-Officio Secretary to the GST Council requesting for waiver of ITC reversal under section 17 sub- section(5)(h) of CGST Act 2017 for Covid related Raw material (API) & Finished Goods. Mr. B G Barve highlighted the points presented in the Representation:

- IDMA has informed the Ministry of Finance about the financial concerns and GST related issues with regards to the Pharma Industry which will impact the industry adversely in coming 3-6 months.

- During the COVID pandemic, Government had advised all pharma manufacturers to ensure uninterrupted supply of COVID related medicines. Specially, Remdesivir, Liposomal amphotericin B injections, Posaconazole Tablets and injections, Baricitinib tablets, Molnupiravir tablets and Favipiravir tablets etc. and their APIs.
- IDMA has highlighted that around Rs.800-1000 crore worth medicines meant for Covid patients were about to expire soon.
- IDMA has mentioned that the matter is of considerable significance and has financial implication to be faced by vast section of the industry. It is earnestly requested to consider waiver of the reversal of ITC on COVID related drugs so that the impending losses to the related industries may be lowered.

Meeting on Blended Finance – by DoP

IDMA attended the meeting on 5th September 2022 which was called by the Department of Pharmaceuticals under the chairmanship of Dr. N. Yuvaraj, Joint Secretary to explore the possibilities with regards to Blended Finance for investment in R&D and Innovation in Pharmaceuticals and Medical Devices.

VC meeting on Blended Finance with Industry on 24th November 2022

Mr. Mehul Shah informed the members about the meeting held on Blended Finance with Industry, he said that DoP had organised a virtual meeting in which Madam S Aparna, IAS informed the industry about the proposed funds which are likely to be launched in the next financial year by April 2023. Mr. Mehul Shah said that Dr Yuvraj, Joint Secretary informed that the funds will be provided as per the need of Pharma, the Government support will be 20% and 80% of SBI CAP. He further added that he has made some suggestions such as that funds are required for Innovation & R&D, for promotion of Exports and Registrations and the schemes needs to be simplified.

Mr. B.G Barve suggested that the cost of electricity is going up and hence, an alternate source of energy has to be identified and funds would be required to invest in this alternate energy. He said that there should be pollution control measures like CETPs.

Meeting with National Investment and Infrastructure Fund (NIIF) and SIDBI - fund of funds

IDMA attended a Meeting on 5th September 2022 with regards to National Investment and Infrastructure Fund (NIIF) and SIDBI - fund of funds.

The Funding would be extended to the following:

- Production/Manufacturing
- Marketing
- Exports

- Incremental Innovations
- Fermentation
- PLIs and R&D

Dr. Sumit Garg confirmed that funding would be extended to all above. However, he mentioned that this is at an early stage.

IDMA's proposals wrt seeking Budget Tax proposals (Basic Customs Duty and Income Tax) for Budget 2023-24 on 26th November 2022

Mr. Daara Patel informed the members about IDMA submission to Mr. Sanjay Meena with regards to IDMA's recommendations on Basic Customs Duty and Income Tax for the Budget 2023-24. IDMA made a detailed representation and gave emphasis on below points:

1) Physician Samples & Product Reminders to be excluded from the ambit of section 194R
2) In-house R&D Expenditure
3) Investment in New Plant & Machinery (Section 32AC)
4) Corporate Social Responsibility Costs – To be allowed as a deduction u/s 37 of the Act
5) Removal of section 206C(1H)
6) Withdrawal of section 145A(a) as doesn't have relevance in light of introduction of GST

IDMA proposals for Budget 2023-24

IDMA made suggestions regarding changes in Direct and Indirect Taxes for the Union Budget 2023-24 on 28th Nov 2022 to Mr. K.C. Varshney, Joint Secretary (TPL-1) and Ms. Limatula Yaden, Joint Secretary (TRU-1) respectively.

Meeting on Pre-Budget for Union Budget 2023-24 (Min. of Finance)

The Department of Revenue, Ministry of Finance organized a physical meeting 30th Nov 2022 with regards to Union Budget 2023-24. Meeting was chaired by Ms. Pragya Sahay Saksena, Member (Legislation & Systems), CBDT.

IDMA made following points which were prepared and complied by Mr. B.G Barve and Ms. Ketki Wadhawa:

1. Section 194(R) wrt Samples and Reminders to exclude from TDS;
2. Section 35((2 AB) to restore to 200% and allow to avail exemption of 100% to companies availing concessional tax rates.
3. Restore Section 32(2AC) which provided deduction of 15% of actual cost of new assets and was discontinued in 2017/18. Should be restored in 2023/24

4. CSR: Drop the Explanation under section 37(1) at Sr. No 2. To allow to claim complete deduction of CSR expenses.
5. Removal of Sec 206 (IH) TCS read with provisions of 194(Q).

REPORT OF IPR COMMITTEE

The first meeting of the IPR Committee Members was held on 29th September 2022. There were 15 members present for the meeting. The following points were discussed in the meeting:

Review Report EAC-PM/WP/1/2022 "Why India Needs to Urgently Invest in Its Patent Ecosystem?" by the Economic Advisory Council to the PM issued on 16th August, 2022.

Review Report No 161 of the Intellectual Property Rights Regime in India Presented to the Rajya Sabha on 23rd July, 2021 and on-going review and comments thereof.

Current Status of Patent Applications, oppositions and hearings (including delays and disputes) in Patent Office.

Latest Developments in Patent Litigations were discussed.

- "The Biological Diversity (Amendment) Bill, 2021" Pending in the Parliament from 13th December, 2021.
- Report of the Joint Committee On the Biological Diversity (Amendment) Bill, 2021 Presented to Lok Sabha on the 2nd August 2022.
- Extensive representations being received from NGO's urging for action by IDMA for sweeping amendments.
- Patent waiver proposed in WTO sponsored/supported by India, amongst others.
- Pending Writ Petitions in High Court of Kerala for Compulsory License.

FTAs discussed during the year

The following FTAs with India were discussed during the year:

1. INDIA – UAE
2. INDIA – UK
3. INDIA – AUSTRALIA
4. INDIA – CANADA
5. INDIA – SAUDI ARABIA

The above FTAs were discussed during the year. The details are mentioned in the International Trade Committee (including Customs) Report.

Meeting to discuss extension of TRIPS decision to therapeutics and diagnostics on 21st November 2022

Department of Pharmaceuticals organised a VC meeting on 21st November 2022 to discuss extension of TRIPS decisions to Therapeutics and Diagnostics, under the Chairmanship of Dr. Sumit Garg, Deputy Secretary.

The issues discussed were:

I. Extension of TRIPS decision to therapeutics and diagnostics.

II. Supply-demand gap in Covid 19 therapeutics and diagnostics in low and middle income countries and India's role in supplying Covid 19 Vaccines, therapeutics and diagnostics to other low and middle income countries.

The Centre for WTO Studies made a brief presentation which gave the details of the Joint proposal made by India and South Africa and later joined by many countries for TRIPS waiver for Covid vaccines, drugs and diagnostics. At present, TRIPS decision for waiver pertains only to Covid Vaccines.

REPORT OF INDUSTRY INSTITUTES INTERACTION COMMITTEE

Inauguration of NIPER Research Portal

Hon'ble Dr. Mansukh Mandaviya ji, Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers inaugurated NIPER Research Portal through VC on 28th January 2022. IDMA was represented by Mr. T Satish, Chairman, Industry Institutes Interaction Committee along with Dr Viranchi Shah, National President and Dr George Patani, Vice Chairman, Industry Institutes Interaction Committee.

REPORT OF INTERNATIONAL TRADE (INCLUDING CUSTOMS) COMMITTEE

A virtual meeting on 1st December 2021 to review the Export Performance of Pharmaceutical Sector in Apr-Oct 2021. Mr. Shyamal Mishra, Joint Secretary (Commerce) and assisted by Ms. Indu C Nair, Director, Commerce. Mr. Tushar Korday, Chairman, International Trade (Including Customs) said that there would be a follow-up meeting with CIM.

A virtual meeting was held on 12th January 2022 under the chairmanship of Hon'ble CIM with Industry Associations on "Issues and Suggestions from Industry". Hon'ble Minister of Commerce & Industry Shri Piyush Goyal applauded IDMA's representation.

IDMA forwarded a representation on 19th January 2022 to the Secretary Department of Commerce with regards to the difficulties faced by Member Companies with MEIS Scripts and its Validity. IDMA requested to increase the validity of MEIS script from 12 to 24 months and to open window and IEC transferability.

Mr. Tushar Korday, Chairmam, International Trade (Incl. Customs) made the below presentation to the Executive Committee Members:

1. RoDTEP / MEIS to be reinstated with MOC for our industry.
2. Interest subvention 3% for MSME under Foreign Export policy to be restored / continued beyond 30th September.
3. DCGI - Change in policy for granting license - for any non pharmacopoeia product, for exports purposes - Currently have to apply for CT10 and then take CT11 and apply for Test license - This is a cumbersome and lengthy procedure which deserves to be done away with. State FDA to be allowed to issue Test license directly for any product meant for export, whether registered or non registered, whether as per pharmacopoeia or not. This relaxation will greatly help exporters.
4. Yemen, Sri Lanka - These countries insist on a single importer which is a restrictive trade policy making an exporter completely dependent on that importer. This leads to harassment many a times. To push through MEA to allow for change in agent or appointment of more agents.
5. OPEC countries and other barred countries - exports realization - countries like - Sudan, Venezuela, Iran, Cuba and many more - special mechanism like Iran to be implemented to recognize and receive payments from these countries without any hurdles.
6. Press for extension (and if possible remove altogether) the requirement of 2D Bar coding for exports as well as domestic market.
7. Simplification and harmonization of licensing procedure across all States to be brought in consonance with DCGI policies/rules. Some States are following their own rules which are hampering the functioning and delaying Licensing.
8. Any other matters to be taken up with DCGI, DGFT and MOC from time to time.

Lack of availability of Shipping Containers and the Impact on the Industry

IDMA sent representation on 27th January 2022 to Mr. Sanjay Meena, Section Officer, DoP along with the letter of 12th May 2021 submitted to Hon'ble Dr. Mansukh Mandaviya ji, Minister of State for Ports, Shipping and Waterways and Minister of Chemicals & Fertilizers. IDMA requested the Government to continue the efforts to engage with the shipping lines to address the concerns as freight has a direct impact on availability and cost of pharmaceuticals.

Consultation meeting on 21st January 2022 with regards to Rules of Origin for India-Australia FTA

IDMA made the following comments:

- Indian pharma exports to Australia are $ 346 Mn.
- Huge potential as Australia imports are $ 8 Bn.
- India needs to have an aggressive approach.
- In past, IDMA has made submissions that IDMA is okay with either the Build-up method or Build Down method to decide Regional Value content.

DGFT informed that since Australia has joined RCEP; we have to keep in mind while recommending Product Specific Rule. IDMA to request members to make written submission.

Implementation of Track and Trace System for Exports of Pharmaceuticals and Drug Consignments

IDMA forwarded a Letter on 27th January 2022 to Ms. Nidhi Mani Tripathi, Joint Secretary (Commerce) along with our previous submissions on the subject. IDMA requested the Government to keep the implementation of the Track and Trace system either in abeyance or make voluntary till such time an International consensus emerges or such time as specific importing countries demand them in the form and format they will finalize. IDMA forwarded the above request to Ms. Indu Nair, Director, Min of Commerce on 10th February 2022.

DGFT issued Public Notice No.01/2015-2020, dated 4th April 2022, extending the implementation of Track and Trace system for export of Pharmaceuticals and drug consignments till 31st March 2023.

Consultations on export targets for Oceania region

Mr Ajay Srivastav, Addl DGFT, Ministry of Commerce held Online Consultations on 7th February 2022 with regards to export targets for Oceania region. Australia and New Zealand are two major nations accounting for major share in this region.

India UK FTA Stakeholders consultation

IDMA briefed the members that at the 22nd February 2022 meeting which was chaired by Madam Nidhi Mani Tripathi, the UK FTA was discussed. IDMA has requested for an UAE - India FTA format for the pharma industry wherein there is Fast Track Registration of products already approved by the stringent regulatory authorities with timeline of 90 days. Dept. of Commerce has requested all Associations to send their comments.

On 5th July 2022, Ms. Nidhi Mani Tripathi, Joint Secretary Commerce chaired VC consultation meeting wrt India-UK FTA. She was assisted by Mr. Bipin Menon, Addl. DGFT and Dr. Brij Mohan

Mishra, IAS, Deputy Secretary Commerce and others. Industry was represented by Pharmexcil, IPA, BDMA and IDMA. Joint Secretary emphasized that we need to look at offensive and defensive interests. However, requested the industry to provide the feedback urgently as the 5th Round of meeting begins on 18th July 2022. We need the clear inputs. Final treaty is proposed to be signed on the Diwali day of 2022, i.e. on October 24, 2022.

IDMA made the following points:

- Emphasized for market access
- Avoidance of duplicate testing
- With reference to proposed Pharma Annex, we conveyed that the proposal in the Pharma Annex are Okay with us as they are covering-

1. Market access
2. Mutual recognition
3. Fast track approvals
4. Market authorization without inspection within 90 days
5. Market authorization where inspections are required within 180 days

Meeting with Industry leaders from Pharma sector for the purpose of consultation on India-Australia FTA

Hon'ble Sh. Piyush Goyal, Minister of Commerce & Industry called a hybrid meeting on 11th March 2022 with Industry leaders from Pharma sector for the purpose of consultation on India-Australia FTA.

Dr. Viranchi Shah, National President, IDMA informed that:

- India has more than 600 sites which are recognized by European Union & EU is doing Desktop inspections.
- Congratulated the Hon'ble Minister for the FTA signed with UAE which has provided for clear cut fast track pathway for approval of Indian medicines.
- Dossiers, BE studies may be accepted with comparable SRAs in addition to UK/EU.
- Rules of origin to consider either (a) Change in tariff (29 to 30) and/or (b) 40% value addition.
- Opportunities of collaboration between Indian and Australian Pharmacy institutes for promoting pharma/ biotech/ herbal research and repurposing of drugs.
- Utilizing Australia's strength in certain herbal produce such as hemp, to help interested Indian industries to commercialize legal use of drugs.

Australian market offers big opportunity and we should not be restricting it to USD 1 Billion.

Dr. Gopakumar Nair briefed the members about the meeting with Industry leaders from Pharma sector for the purpose of consultation on India-Australia FTA. He said that the initiative taken by the Minister of Commerce and Industry Shri Piyush Goyal ji is amazing. He said that the Pharma industry never had such positive and Enthusiastic support in the past. He said IDMA has made valuable suggestions and the initiative has to be taken by member companies to make the best of use of the opportunity that Australian market is offering. He further added that Australia has become very friendly to India and IDMA should support the potential companies who have the necessary strengths make the best of this opportunity.

Roundtable meeting with Mr Jay Allen, Canada Chief Negotiator of CEPA

FICCI organized a roundtable meeting on 14th March 2022 with Mr. Jay Allen, Canada Chief Negotiator of CEPA. Mr Andrew Smith Minister (Commercial), Ms Annable Larouche Counsellor Commercial and Senior Trade Commissioner and Ms Deborah Larouche, Trade Commissioner of High Commission of Canada at Delhi. Canada Pharma market is around USD 29 Bn and is growing at 30%. Canada imports around USD 22Bn. Imports - 29% share is of USA and 48% is with EU. Indian pharma exports during 2020-2021 were 444 Mn USD (+32.5%). India imported Pharma for 22 MM USD in 2020-2021. IDMA requested for fast track pathway as provided in India-UAE FTA.

Meeting with Commercial Attache, Royal Embassy of Saudi Arabia

Meeting with Mr Saleh Alabdulrahman, newly appointed Commercial Attache of the Embassy of Saudi Arabia was held on 14th March 2022. Saudi Arabia is inviting Indian companies to come and setup Pharma Plants in Saudi Arabia. A presentation on Saudi Pharma Sector was shown from Riyadh by their Investment Agency. Dr. Reddy's & Dishman have plants in Saudi Arabia. IDMA has asked them to share all benefits being offered in a written communication for dissemination to our members.

Meeting with Mr. H. K. Hajong, Economic Advisor on 6th April 2022

Mr. H. K. Hajong, Economic Advisor, DoP mentioned the need for continuous flow of information for FTAs, recognition of IP, EU insistence for PICs membership and Harmonization. Ms. Indu Nair, Director Commerce informed that UK and EU FTAs are very important. Regarding RoDTEP, she informed that we should take up with the Hon'ble Minister of Commerce & Industry during his visit to Mumbai for our Annual function. Dr. Viranchi Shah informed the members that they briefed Ms. Roli Singh about the incentives for R & D and importance of Innovations in pharma. He said that IDMA requested her for Government support to the industry with regards to Innovations and he said that the Government is more or less aligned with IDMA.

Preparatory Meeting w.r.t. India- EU JWG on Pharmaceuticals on 25th May 2022

Mr. Tushar Korday informed the members that they have asked inputs on the preparatory meeting and they have sent us the draft for the API manufacturers. He said that they have offered

two options for the countries which are exporting API, the first option is exporting country declares compliance through written confirmation to exporting country and further added that EU has offered assistance to go for option two which is exporting country requests to be listed as a country that APIs has a regulatory framework and respective control/enforcement Act.

Mr. Tushar further said EU side has offered assistance to opt for option2

- W.r.t. assessment of risk of different exporting countries regarding manufacturing of APIs, listed countries are better ranked than non-listed countries.
- May translate in a fewer number of inspections from European national inspectorates
- Help India to become a member of ICH & PIC/S.

It was decided after deliberations that IDMA would respond to it and would include BDMA and IPA points.

India-Canada CEPA - Detailed Consultation on Rules of Origin with the Pharma Sector on 18th May 2022

Department of Commerce called a meeting wrt India-Canada CEPA. Meeting was chaired by Mr. Tapan Mazumder, Addl. DGFT. Mr Tapan Mazumder requested the Associations to get the feedback from their members on the nine issues mentioned in the presentation. The Presentation was shared vide mail of 17th May 2022. IDMA was advised to keep in mind our offensive and defensive interests as also the country with whom FTA is to be done. For ASEAN countries we may have different requirements as compared to what will be needed with Developed nations like Canada. Ministry of Commerce have also sent the comparative Analysis of Rules of Origin Texts of India's FTAs and list of the Article X: Minimal Operations.

Line of Credit with Sri Lanka

IDMA submitted an representation on 18th May 2022 to Mr. Vivek Srivastava, Chief General Manager, RBI. In this representation IDMA mentioned that India has announced One Billion US Dollar Line of Credit in Indian Rupees to Sri Lanka through SBI for purchasing essential goods from India. Medicines fall under this category. There are certain formalities outlined by Sri Lankan authorities under this Line of credit in Indian Rupees and for the same they have requested us to send copies of duly filled documents, formats.

Meeting with the Ethiopian Officials on 16th June 2022 at IDMA Office

IDMA organized a meeting with the Ethiopian Officials on 16th June 2022 at IDMA Office. The following Ethiopian officials were present at the meeting along with IDMA Members:

1. Ms. Heran Gerba, Director General of Ethiopian Food & Drug Administration
2. Yibeltal Abeje, Medicine & Registration Expert

3. Dejene Daba, Registration Expert
4. Getu Bogale, EFDA Branch Head

The interactive meeting and the deliberations between the Ethiopian Food & Drug Administration (EFDA) and IDMA Members was excellent, more clarifications were received about the Ethiopian procedures and Regulations with regards to doing business with Ethiopia.

RoDTEP

Joint representation for declaring RoDTEP rate for Pharma sector

Dr. Viranchi Shah informed the members about the Joint representation by BDMA, IDMA, IPA, FOPE and Pharmexcil on 11th August 2022 to Hon'ble Smt. Nirmala Sitharaman, Minister of Finance requesting her to announce RoDTEP rates for pharma industry. which was sent by BDMA, IDMA, IPA, FOPE and Pharmexcil to the Minister of Finance, he added that the positive aspects about this representation is that this representation is made jointly by five associations and is hopeful that Government may consider the suggestions made in the Representation.

DGFT issued notification No. 47/2015-2020, dt. 7th December 2022, including Pharmaceutical items for exports in the RoDTEP Scheme. Revised Appendix 4R is available in DGFT website. As per revised Appendix IV, RoDTEP rates for Bulk drugs in Chapter 29 are 0.80% and for formulations in Chapter 30 is ranging between 0.5 to 0.8%, 1.2% (Losartan).

Dr. Viranchi shah said that the Duties and Taxes on Exported Products (RoDTEP) Scheme has been extended to Chemicals, Pharmaceuticals from 15.12.2022. He said that RoDTEP rates for Bulk drugs in Chapter 29 are 0.80% and for formulations in Chapter 30 is ranging between 0.5 to 0.8%, 1.2% (Losartan). Dr Viranchi Shah thanked the Ministry of Commerce for this extension.

DoP meeting of Joint Working Group on Pharmaceuticals with Russia, Uzbekistan and Kazakhstan on 10th October 2022

The Department of Pharmaceuticals had called a virtual meeting to finalise the agenda for Joint Working Group on Pharmaceuticals with Russia, Uzbekistan and Kazakhstan. The meeting was chaired by Dr. N. Yuvaraj, Joint Secretary, DoP. He was assisted by Dr. Sumit Garg, Deputy Secretary, DoP.

IDMA made the following points:

1) No new product can be registered without a manufacturing plant having MOH Russia approval. Russia, Uzbekistan and Kazakhstan should accept mutual recognition granted by CIS member countries and the units which have been approved by WHO. This will help to shorten the timelines and provide for easy access. This will be of benefit to Russia already passing through the uncertain times.

2) Mandatory Clinical/BE to be done in Russia for every product. They do not accept studies done in any other country. This results in very high cost for each product registration.

3) Registration requires submission of "closed part" for each API. Even if API is approved in Russia, they still insist on "closed part" submission. Like in other countries, once you give an API registration number, Ministry of Health directly refers to the approved data available with them. This saves a lot of time & costs.

Online meeting on Product Specific Rules (PSRs) for Chapters 29 and 30 for FTA with Canada on 10th November 2022

Dr. Viranchi Shah informed the members that the Department of Commerce held an online meeting on Product Specific Rules (PSRs) for Chapters 29 and 30 for FTA with Canada w.r.t Pharma imports into India. The Meeting was chaired by Mr. Anupam Kumar, Deputy DGFT. Industry was represented by Pharmexcil and IDMA. During the meeting, following points were discussed with respect to PSRs for imports into India:

- Chapter 29 – For all the Tariff lines pertaining to Pharmaceuticals' APIs and Intermediates; recommendation is for Change in Tariff Heading (CTH) + 35% Value Addition.
- Chapter 30 – India has its offensive interest. As such, recommendation for all the tariff lines was CTH + 35% Value Addition.

Interactive meeting with Saudi Arabia FDA at Vanijya Bhawan on 11th November 2022

A meeting was chaired by Ms. Indu C. Nair, Joint Secretary, Department of Commerce. She was assisted by Ms. Parul Singh, Deputy Secretary, Department of Commerce. The following points were presented by SFDA about their organization:

- Saudi market in 2020 – USD 7 Billion
- 2021- USD 8.53 Billion with (CAGR + 12%)
- Expected in 2024 – USD 10 Billion
- Saudi Arabia provides access to all the GCC countries.
- There are 556 products, which are registered in Saudi Arabia.
- 800 products are not available in Saudi Arabia. These are the priority items for Saudi Arabia and are listed on their website.
- The price for medicine is fixed for 7 years. In case during this time, the manufacturer is shifted out of Saudi Arabia, then the price is again refixed.
- SFDA is a Member of ICH
- Generic approvals are granted within 155 working days, Biologicals 240 working days.
- Presentation was made by SFDA about their organization:
- Fast track registration is given to products which are already registered under USFDA and European Union and if they also fall in the priority list of Saudi Arabia.

This was followed by the Questions & Answers session. The questions raised were answered by SFDA. Saudi Arabia is granting Fast Track Approvals for the products registered in US and EU. Saudi Arabia had given Fast Tract approvals for the Covid Vaccines and has had good experiences dealing with Indian Vaccines manufacturers. IDMA has requested that the Fast Track approvals be extended to the units having WHO approvals. The SFDA officials responded with an assurance to consider this suggestion. SFDA would be sharing the presentation and priority list with the Ministry of Commerce and Pharmexcil and Pharmexcil would be sharing the same with our Members.

Export Data

As per the follow up done, we have obtain details of 77 countries to which our members Export as below:

Abu Dhabi, Afghanistan, Albania, Algeria, Argentina, Bangladesh, Belgium, Bhutan, Bolivia, Bosnia, Burkina Faso, Cambodia, Canada, Costa Rica, Cuba, Denmark, Egypt, Ethiopia, Gambia, Gaza, Georgia, Ghana, Guatemala, Guinea-Conakry, Haiti, Indonesia, Iran, Iraq, Israel, Ivory Coasts, Kazakhstan, Kenya, Korea, Lebanon, Leone, Lithuania, Malaysia, Maldives, Mali, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Myanmar, Namibia, Nepal, Netherland, Nigeria, Oman, Pakistan, Paraguay, Peru, Philippines, Senegal, South Africa, Sri Lanka, Sudan, Syria, Taiwan, Tajikistan, Tanzania, Thailand, Turkey, Turkmenistan, UAE, Uganda, UK, Ukraine, USA, Uzbekistan, Venezuela, Vietnam, Yemen, Zambia and Zimbabwe.

We have also received the details of issues faced by them and support required from the Government. 31 IDMA Members responded with the above information.

REPORT OF MEMBERSHIP COMMITTEE

Membership Drive: Promoting IDMA for Togetherness at the 2nd Executive Committee Meeting held on 18th February 2022

Mr. Anant Thakore, Chairman and Mr. Chirag Doshi, Vice Chairman of Membership Committee made a presentation with regards to Membership drive at the 2nd Executive Committee Meeting on 18th February 2022. The following points were placed forth at the EC Meeting:

IDMA Stands…

- Members 1100+
- Geographical division – Maharastra 289, Gujarat 330, Tamilnadu, Puducherry and Kerala – 198, West Bengal 60, Telangana 53, Karnataka 44, HP and Uttarakhand 39, Haryana and MP 16 each other states 57.
- Growth of approx. 3% – 2018-19 (1042), 2019-20 (1077) and 2020-21 (1108)
- Renewal of membership fees by 610 members so far.

Our concern

- Renewal of membership – 40% of members have not renewed
- Fees criteria (turnover base)
- Fees slab seems bit complexed with turnover criteria.
- Still we are asking for 20% rebate with no reason.
- No data of turnover of any manufacturers
- Unable to reach manufacturers - non-member

Let us initiate…

- Get manufacturers' details from FDCA of Mfg. licenses issued so far
- Target loan licensee companies for membership
- One EC member from state board heads respective state for this drive
- Give target at least 15% for this year to each state board
- WhatsApp only few headlines of IDMA bulletin to non-members with separate group to keep update on our activities
- Advertise our 60th Year celebration to members and non-members through digital platform
- Depute free lancers with around 5% commission on membership fees – both new and for renewal.
- Make State Boards responsible for renewal of membership
- Allocate extra fund to State Boards for traveling exclusively for the membership drive.

This Year 2022 the membership at the year-end stood at 1059. IDMA 60th Diamond Jubilee Celebrations enabled us in renewing the membership as well as attracting new members to join the IDMA Family. IDMA Secretariat and State Boards were actively involved in bringing 90 new Members – 3 Corporate Members, 51 Principal Members, 34 Associate Company Members and 2 Academic Associate Members. We are thankful to Mr. Paresh Chawla, Chairman, Madhya Pradesh State Board for adding 30 new members in a year. We deleted 89 members as they had not paid their dues over a period of three years or more and also, those who have voluntarily cancelled their membership. IDMA thanks the Chairman, Vice Chairman and the State Boards for their continued support and co-operation extended towards IDMA Membership drive.

REPORT OF MSME COMMITTEE

Creating synergies for Seamless Credit Flow and Economic Growth

IDMA explained its stand and emphasized on the PTUAS scheme and the financial requirements of 10 crores plus for upgradation of existing units to become WHO GMP compliant during the meeting on Creating synergies for Seamless Credit Flow and Economic Growth held on 22nd February 2022. The second meeting (virtual) was held on 4th March 2022. IDMA submitted a detailed

representation on 8th March 2022 and followed it with a revised / updated representation on 10th March 2022. Thereafter, on 11th March 2022, DoP announced the Guidelines for the Scheme for Strengthening of Pharmaceuticals Industry, which included PTUAS.

Mr. S R Vaidya, Chairman, MSME Committee informed the members that this issue had been pending for the last 15 to 20 years from the days of our reviewing the CLCSS scheme. He said that Mr. S M Mudda and Late Mr. T R Gopalakrishan had given a lot of inputs on this issue. He further added that IDMA had been consistently reviewing and trying to revise the CLCSS scheme in terms of plant and machinery for the last 20 years. He mentioned that Mr. S V Veeramani had been following it up at Delhi for the same. These cumulative efforts had been rewarded in a form of a meeting which was held on 4th March 2022. He said that IDMA made a crisp presentation conveying all the financial aspects and forwarded the detailed representation with regards to the same on 8th March 2022 and followed it with a Revised / Updated representation on 10th March 2022. Mr. Vaidya informed the members that after this meeting within four days, the Joint Secretary released guidelines for the Scheme for strengthening of the Pharmaceutical industry which included PTUAS, etc. He said IDMA has forwarded this scheme to every State Board Chairmen and all the IDMA members and requested them for their feedback.

Interaction with MSME Associations to orient them on the Scheme "Strengthening of Pharmaceuticals Industry" of DoP and various MSME Schemes by Ministry of MSME

The Department of Pharmaceutical called a VC meeting on 13th April 2022 under the chairpersonship of Ms. S. Aparna, Secretary, DoP on the Scheme 'Strengthening of Pharmaceutical Industry' and various MSME schemes. On 16th April 2022, DoP had called a meeting under the chairpersonship of Dr. N Yuvaraj, Joint Secretary, DoP. He briefed the august gathering on the objective of the meeting and requested their views with regards to (i) Time Period of 18 months, (ii) loan period for interest subvention, (iii) list of activities, Area, (iv) extending upgradation to other regulatory authorities. Mr. Abhishek Singh, Deputy Secretary clarified that loan period can be any length of time, but interest subvention will be only for three years.

Mr. S R Vaidya informed the members that at the meeting held in Delhi, IDMA provided the updated list of machinery to Dr. Yuvaraj, Joint Secretary, DoP. He said that Dr. Yuvaraj informed them that the list can be updated whenever you want to add anything necessary. Mr. Vaidya said that he hopes that IDMA Members take benefit from the MSME schemes to be released. He further added that we should persuade our members to take the MSME schemes. Mr. Vaidya said that there were deliberations with regards to the revise Capital scheme and it was decided that a representation be prepared for expanding the declaration of this scheme.

Mr S R Vaidya, Chairman, MSME Committee & Mr Bharat Desai, Vice Chairman, MSME Committee made the following submission:

1) Regarding the time line of 18 months proposed for PTUAS, IDMA requested to revise to minimum 30 months.

2) Updated list of machinery will be given within 15 days. However, Joint Secretary desired all suggestions and list of machinery be submitted by Wednesday the 20th April, 2022.

3) Requested to revise the capital expenditure limit of Rs.10 Crore to Rs.15 Crore. Minimum of Rs. 10 Crore should be applicable for brown field projects but for green field project minimum Rs.15 Crore is needed as during the last 2 years the cost of building, construction, utilities, electrification, plant and machineries etc. have gone up by more than 40%.

4) Extend coverage of the scheme to cover units over and above WHO GMP (i.e. the units which are upgrading for PICS/USFDA/EMEA/WHO pre-qualification.) However, first preference be given to MSMEs going for WHO GMP and thereafter if still the finance remains available then it must be considered for other higher Accreditations.

5) Requested that while sanctioning the loan by the nodal agency or concerned bank the stipulation of collateral security should be dispensed with also the Bank Guarantee.

The Joint Secretary mentioned that present corpus of the scheme can cover only 420 units, hence it is better to concentrate only on upgradation to WHO GMP. On 20th April 2022, IDMA submitted the list of machinery to Dr. Yuvaraj, Joint Secretary DoP with copies to Secretary, DoP, Dy. Secretary, DoP and Under Secretary, DoP

VC meeting on Launch of Scheme for Strengthening of Pharmaceuticals Industry

Department of Pharmaceuticals called a VC meeting on 20th June 2022 with regards to Launch of Scheme for Strengthening of Pharmaceuticals Industry under the Chairmanship of Dr. N. Yuvaraj, Joint Secretary, DoP. Mr. Abhishek Kumar Singh, Deputy Secretary, Mr. Prashant Gupta, Technical Consultant and other DoP officials participated.

Mr. Daara Patel informed the members that the Scheme for Strengthening of the Pharmaceutical Industry is similar to the PTUAS Scheme. He said that the Government wants to give full support for the scheme as the Government was not very happy about a similar scheme which was launched 5-6 years ago wherein not many members took advantage of it. He further added that the Government is coming up with this scheme and they wanted IDMA support for the same. He said that DoP officials were happy to note that IDMA has got eight state boards and IDMA can give DoP full support for this scheme.

Mr. Patel said that once DoP gives us more details/information we will have meetings in our State Boards - first at Ahmedabad then at Chennai and one meeting would be held at Mumbai. He said IDMA will expand this schemes to the other State Boards too. He further added that IDMA informed DoP that IDMA is ready to support this scheme through our IDMA Bulletin which comes out every week.

Dr. Viranchi Shah along with Mr. S R Vaidya visited Delhi on 21st July 2022 to attend the Launch of Scheme on Strengthening of Pharmaceutical Industry organized by Department of Pharmaceuticals and was inaugurated by Hon'ble Dr. Mansukh Mandaviya ji, Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers.

Dr. Viranchi shah had a brief discussion about the Launch of Scheme on Strengthening the Pharmaceutical Industry. He said The Department of Pharmaceuticals, Govt. of India has been actively involved in these schemes and are ensuring that every MSME gets an opportunity to upgrade their facilities and develop their manufacturing units to meet the necessary standards for exports. He further said that the new scheme will help the industry to enhance its quality, technology & infrastructure upgradation & technical upgradation and encourage collaboration between various stakeholders for the overall development of the pharma sector.

Outreach cum Awareness Programme on Strengthening of Pharmaceutical Industry on 5th August 2022 at Ahmedabad, Gujarat

Dr. Shrenik Shah, Chairman, IDMA Gujarat State Board gave the details about the Awareness program held on the 5th August 2022 at Ahmedabad, Gujarat. He said IDMA along with DoP & SIDBI had organized an Awareness Event for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) for its members to explain in detail the various schemes and its benefits. He said the event was attended by almost 175 members,

DoP and SIDBI explained the scheme to the members and they were very open to queries raised by the members. The event was a very successful.

Awareness events for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) on 12th August 2022 at Mumbai

IDMA Head Quarters, Mumbai organized the Awareness Event for the Scheme for Strengthening of Pharmaceuticals Industry (SPI) on 12th August 2022 at Mumbai. Mr. Daara B Patel said that IDMA along with DoP & SIDBI had organized this Awareness Event. He said that the Department of Pharmaceuticals, Govt. of India has been actively involved in these schemes and along with SIDBI are ensuring that every MSME get an opportunity to upgrade their facilities and develop their manufacturing units to meet the necessary standards for exports. The Hongkong and Shanghai Banking Corporation Limited (HSBC Bank) was associated with this Awareness Event. There were approx. 120+ participants for this awareness program. Mr. Daara B Patel said that the new scheme will help the industry to enhance its quality, technology & infrastructure upgradation & capacity building and encourage collaboration between various stakeholders for the overall development of

the pharma sector. IDMA applauded this excellent initiative of the Government which is an excellent opportunity for our Pharma Industry. Mr. Patel thanked and appreciated the support & involvement of Dr. N Yuvaraj.

Meeting with Pharmaceutical industry for identifying the chemicals used by Pharmaceutical sector

Ms. Arti Ahuja, Secretary, Department of Chemicals & Petrochemicals chaired the meeting with the Pharmaceutical industry on 7th July 2022 for identifying the chemicals used by the Pharmaceutical sector. She was assisted by Mr. S K Purohit Joint Secretary Chemicals. DoP was represented by Mr. Abhishek Singh, Deputy Secretary. Apart from IDMA, IPA, FOPE, FICCI, BDMA, Small and Medium Scale Manufacturers (c/o Mr. Nipun Jain) attended this meeting. The Scheme is for green field to create global players. All associations were requested to send one composite list of not more than 6 chemicals/ Intermediates/Solvents. All three combined not more than six.

The Criteria would be:

- Import value
- Dependence on Single Country
- Low capacity or No capacity of Domestic production
- Use in multiple sectors

All associations to check with their members and then make submission.

REPORT OF NDPS COMMITTEE

Presentation at IDMA Executive Committee Meeting

Mr. Devesh Malladi, Chairman of the NDPS Committee made the below presentation to the EC members on 21st January 2022:

1. Issue concerning DoR, Ministry of Finance -

- Amendments to NDPS Rules and RCS Order “Ease of Doing Business” – pending with DoR since March 2016
- Digitalization of import/export and Route change - pending since May 2020.
- Interim measures to mitigate harassment of legitimate entities - DoR to consider standing order on procedure of investigation

2. Issues concerning agencies – CBN & NCB

Central Bureau of Narcotics (CBN)	Narcotics Control Bureau (NCB)
• Issuance of Import / Export permits • Quota allocation, license renewal & destruction of ENDs & Manufactured Drugs • Route change for export consignments • Public Notice on substances not under the purview of NDPS	• Online filing of quarterly returns for controlled substances • Periodic interaction on industry specific issues

3. Amendment to the Act-

- Definition of Licit entity- section 2.
- Compounding of offences- section 26.
- Culpable mental state- section 35 & 34.
- Procedure for investigations- section 41& 42.

WHO's ECDD recommendation of New Psychoactive substances on 1st February 2022

In reference to a letter from Mr. Sanjay Meena, Section Officer, DoP wrt WHO's ECDD recommendation of New Psychoactive substances, IDMA confirmed it's agreement with the recommendations on the scheduling of substances listed in the said letter, under International control. IDMA mentioned that there are no reported legitimate end use of the substances mentioned in the said WHO's recommendation.

Public Notice on list of substances which are not under the purview of NDPS Act, 1985

IDMA forwarded a representation on 4th February 2022 to Narcotics Commissioner, Gwalior requesting to issue a Public Notice for 22 substances, names of which were attached with the letter, stating that these substances are not under the purview of Narcotic, Psychotropic and Controlled substances in India and that the said substances do not mandate an export permit. IDMA had requested for a Publuc Notice, as these substances were controlled in certain countries and mandated a letter from CBN, for each export. A follow-up letter was submitted in October, 2022 to CBN and also to DoR.

Public Notice issued by CBN on February 8th, pursuant to IDMA's representations on 'Digitalisation of import/export permits'

The Public Notice issued by CBN, digitalises the issuance of export/import permits by uploading the same on the customs e-Sanchit portal. IDMA has informed it's members that this is a first step towards complete Digitalisation of the process of application and issuance of import/export permits. Circulars were issued to all members to register on the Custom's ICEGATE portal.

Based on representations from IDMA, DoR appointed KPMG to study the process of digitalisation at CBN and a report has been submitted to DoR after due consultations with Industry and CBN. The contract for the same has been awarded by DoR to develop the software for online application and issuance of import/export permits, Narcotic licenses etc. The same is expected to go live in 2023.

Web meeting to discuss issues regarding supply of Codeine Phosphate

The Office of Chief Controller of Factories organized a web meeting on 22nd February 2022 to discuss issues regarding supply of Codeine Phosphate to Industry.

Meeting with Mr. Vivek Aggarwal, Addl. Secretary (Revenue)

A VC meeting with the Additional Secretary (Revenue) was held on the issues of availability of codeine phosphate. The Additional Secretary raised the issue of Government opium factory not able to produce or process codeine from Opium gum and wanted industry to participate in the privatization and take up the processing of opium Gum. The Additional Secretary informed that all the liability for processing would be taken by the Government and the Government would pay processing charges for conversion from Opium gum to codeine phosphate. A Draft tender for suggestions & comments was sought by DoR and IDMA had submitted it's suggestions on the same. The privatization has been completed by DoR and Bajaj Healthcare has been awarded the contract.

Workshop on amendments to the NDPS Act, 1985

A one day NDPS Workshop was held in New Delhi on 9th March 2022 with all the stakeholders regarding the amendments to the NDPS Act, 1985. The workshop was inaugurated by Additional Secretary (Revenue). IDMA presented a detailed list of amendments and all the other stakeholders agreed with the views of IDMA.

Inter-Ministerial Committee (IMC) on 'dual use' chemicals and illicit trafficking of prescription drugs and precursors

The Ministry of Home Affairs (MHA) formed a IMC with Narcotics Control Bureau, New Delhi as the coordinating agency on 'dual use' chemicals and illicit trafficking of prescription drugs and precursors. Mr.Devesh Malladi was nominated to the IMC, as an Industry stakeholder. The other participants of the IMC are from MHA, NCB, DoP, DCGI, GOAF and Medical experts. The committee held a few meetings and is expected to submit it's final report to MHA in January, 2023.

NCB query on exponential increase in the import of Acetic Anhydride

NCB forwarded a query to IDMA on exponential increase in the import of Acetic Anhydride after 2018. IDMA submitted a response on 3rd September 2022 to NCB with legitimate reasons

for the same and that Acetic Anhydride is a key raw material used in the manufacture of many APIs and Intermediates. Several IDMA members are users of this chemical and in addition, is a key solvent used in testing and analysis of several APIs, Intermediates, Aromatic Chemicals, Dyes and Speciality chemicals.

Meeting with Narcotics Commissioner with Industry representatives

A VC meeting between the Narcotics Commissioner and 10 Industry representatives was organised by IDMA on December 26th, 2022. A number of issues concerning import/export permits, issuance and renewal of narcotic licenses, destruction of narcotic substances, clarifications on substances not listed in NDPS, ALR issue for controlled substances etc were taken up. Some of the issues were resolved or clarified by the Narcotics commissioner and he also proposed a monthly meeting to review the progress of pending issues with CBN.

Representation with respect to Controlled Substances

IDMA made a representation on 14th October 2022 to Narcotics Commissioner, Gwalior regarding preparations/formulations of Ergotamine, Ergometrine and its salts which are NOT notified as controlled substances in India, as per the Gazette Notification of GSR 191(E), dated 26.03.2013. However, there have been instances of customs department asking for a export NOC from CBN. In view of this, a clarification from CBN was requested that preparations of Ergotamine, Ergometrine and similarly for substances mentioned in B and C, unless specified DO NOT require a NOC for export or import for the same. A follow-up letter was submitted on 11th January 2023.

Public Notice on list of substances which are not under the purview of NDPS Act, 1985

Central Bureau of Narcotics (CBN) issued a Public Notice with reference to several representations by IDMA on 6th January, 2023 stating that CBN would issue letters of no objection to export of such substances which are not under the purview of NDPS Act, 1985 to applicants, within 7 days from the date of an application with complete details.

REPORT OF NUTRACEUTICAL COMMITTEE

IDMA Representation on 14th December 2021 with regards to Uploading Approved Novel Ingredient Details & Updating website promptly.

IDMA forwarded a representation on 14th December 2021 to FSSAI requesting to create a separate tabulated list of Novel Ingredients permitted with Serial numbers and date of approval and to be uploaded on FSSAI website.

Presentation at IDMA Executive Committee Meeting

Dr. R K Sanghavi, Chairman, Nutraceuticals informed the members about the Nutraceutical

committee and introduced Mr. Atul Shah and Mr. T. Satish as the two Vice Chairmen of the Committee. He said that the Nutraceuticals committee consisted of 7 members. Dr. Sanghavi briefed the members about the Committee's first meeting in March 2022 wherein many pressing concerns were discussed. Dr Sanghavi mentioned the points discussed in meeting:

1) De-Linking cumbersome Product Detail Linking with FSSAI Licensing – Delay in license issue. To tackle this concern, representation has to be made and forwarded to FSSAI for concern regarding product linking with licensing. Further he emphasized that this point to be taken up very strongly, a physical meeting with the CEO was sought.
2) Methylcobalamin Myth - For updating on status regarding methylcobalamin approval, the same to be explained in IB for all concerned manufacturers / marketeers (FBOs) to understand.
3) Weight & Measures Act - Implications for nutraceuticals – A written representation is not required for this issue as Gazette G.S.R. 779(E). dated 2nd November 2021 was released in last week of March 2022 putting to rest all concerns for FBOs.
4) Updating approved ingredient List periodically – Dr Sanghavi suggested that follow up for the updated list of ingredients by FSSAI on website needs to be done by Mr. Ashok Madan to ensure acceptance of IDMA's request on behalf of industry.

Meeting with Mr. Arun Singhal, CEO, FSSAI

IDMA congratulated Mr. Arun Singhal, CEO FSSAI for being empanelment as Secretary to Government of India. IDMA submitted the below two representations dated 10th May, 2022 to Mr. Arun Singhal on 15th June 2022:

1) Representation on Food Safety and Standards (Health Supplements, Nutraceuticals Food for Special Dietary use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 [Fss (Nutra) Regulations, 2022]. Mr Singhal has marked to respective panel for consideration.
2) Representation wrt License Modification under the FoSCoS.

National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022

IDMA sent mail to Dr. Anchal Gulati, President (EMRB), National Medical Commission on 23rd June 2022 endorsing recommendations already forwarded by Dr R K Sanghavi with regards to the draft NMC regulation "National Medical Commission, Registered Medical Practitioner (Professional Conduct) Regulations, 2022".

Meeting with Dr. Methekar, FSSAI at Mumbai office on 21st June 2022

Dr. R. K Sanghavi had a meeting with Dr. Krishna U Methekar, Deputy Director - FSSAI at Mumbai office. The concerns pertaining to licensing bottlenecks, the Controversy of B12 & Methylcobalamin, tocotrienols & Vit. E w.r.t RDA was discussed.

Dr. R K Sanghavi said that he explained the bottlenecks of getting approval for the licences as they linked to the products. He said that Dr. Methekar agreed with the points raised by IDMA and they are working towards resolving the issues.

Dr Sanghavi mentioned to the members about Methylcobalamine and explained the medical aspects.

Dr. Methekar facilitated a meeting with Ms. Preeti Chaudhary the Regional Director who suggested that a personal meeting with CEO needs to be immediately initiated for the points discussed and the valid reasonings put forward by Dr. Sanghavi.

He briefed the members about the proposed meeting with CEO of FSSAI at Delhi.

Food Safety And Standards (Health Supplements, Nutraceuticals, Food For Special Dietary Use, Food For Special Medical Purpose And Prebiotic And Probiotic Food) Regulations, 2022 (Gazette Notification No. Std/SP-05/T (Nutraceutical-2022),

IDMA sent a representation on 5th September 2022 to the Chief Executive Officer, FSSAI on Food Safety And Standards (Health Supplements, Nutraceuticals, Food For Special Dietary Use, Food For Special Medical Purpose And Prebiotic And Probiotic Food) Regulations, 2022, for their favorable consideration.

REPORT OF PRICING / CONSUMER AFFAIRS COMMITTEE

Dr. Amit Rangnekar, Chairman, Pricing / Consumer Affairs Committee informed the members with regards to the Meeting to review the Supply Chain Crisis held on 27th November 2021. The meeting was Chaired by DoP Secretary, Madam S. Aparna. IDMA was requested to continuing Monitoring of availability of critical drugs continues.

Presentation at IDMA Executive Committee Meeting

Dr. Amit Rangnekar, Chairman of the Pricing / Consumer Affairs Committee made the below presentation to the EC members :

- Two major events in 2022- NLEM 2022, IPDMS version 2.0.
    - NLEM 2022- major inclusions/ deletions of scheduled / non scheduled formulations
    - Confusion, significant price changes, major Form II/III/V entries
    - IPDMS 2.0- user friendly version to update DPCO 2013 Form, I,II,III,IV,V, VI
    - Need to conduct major half day seminars for our members for both.
- Representations (physical + virtual) on.
    - DPCO 2013- various paragraphs, prospective pricing.
    - Rising input costs.
    - Other issues.
- Support required.
    - A consultant to draft / advise on critical DPCO issues.
    - A person in the secretariat who can retrieve representations by IDMA as well as past data on NPPA- SO, OM, ceiling price data, Indian healthcare sector etc.

Request to extend revised ceiling prices of Heparin Injection fixed under Para 19 of DPCO-2013

IDMA requested NPPA to extend the revised ceiling price of the Product beyond 31.03.2022 till 31st March 2023 or till a time considered suitable in the present scenario. IDMA mentioned that there are no reported legitimate end use of these substances. NPPA has agreed to extend the revised ceiling price of the Product up to 30th Sept 2022.

NPPA again issued a notification vide S.O. 4589 (E), dated **29.09.2022** extending the Ceiling prices of Heparin Injection up to **31.12.2022**. Dr. Viranchi thanked the Government for once again extending the ceiling prices of Heparin Injection till 31.12.2022.

Report by Dr. Amit Rangnekar, Chairman of Pricing & Consumer Affairs Committee

Dr. Amit Rangnekar informed the members that IPDMS version 2.0 would be launched within the next three months. He said this will be used for filing the forms for medical devices. He stated that IDMA has made many representations on this issues and 90% of these representations have been accepted and lot of hurdles & concerns have been removed. He informed the members that he had attend two personnel meetings at Delhi with DPCO and sorted most of the concerned points. He stated that the IPDMS version 2.0 will be very convenient for industry. He informed the members that WPI had increase of 10.77%. He requested members to wait for few days before increasing their prices of drugs, till the actual list for scheduled formulations is released as the price increase is applicable from April and not March. Hence, he advised the members to wait for actual list.

IPDMS 2.0 Webinar

NPPA called webinar meeting on IPDMS 2.0. In this connection, NPPA circulated the Minutes of the meeting on 5th April 2022 and the same was forwarded to HO on 5th April 2022.

Meeting with Dr N Yuvaraj during Conference on Strengthening of Pharmaceutical Industry on 12th August 2022 at Mumbai

Dr. Amit Rangnekar briefed the meeting about the Luncheon meeting with Dr. N Yuvaraj IAS on 12th Aug, He said although few of the areas he has not directly handled but he provided great insights into the thought process and ideas on how to take up various issues with the DoP / NPPA. He further said that IDMA sought clarity on authentication for the Top 300 drugs, Trade Margin Rationalization (TMR), Prospective Batch pricing, Para 18(i), New NLEM 2021 and IPDMS 2.0. He further said that he asked some questions to Dr. N. Yuvaraj IAS to which he answered as below:

Q1) The cost of setting up the infrastructure for authentication of the Top 300 drugs is huge as each camera costs Rs 4 lakhs per line, Thermal Inkjet printer is Rs 4 lakh per line and Top 300 brands need minimum 3-4 lines spread across multiple locations. In addition, onetime costs of software and licences need to be borne, so it is quite capital intensive. Running costs will be another 15p per unit. Some relief should be provided at least for scheduled formulations to offset this cost as there has been an unprecedented increase in input costs.

Answered by Mr. N. Yuvaraj: During the pandemic the GOI established the COWIN platform for details of vaccination. This cost was borne by the GOI and each state used this platform free to maintain details of those vaccinated in their state. You can write to the GOI regarding developing a similar platform or absorbing the licence and software costs to ensure better compliance.

Q2) In India 50% use smartphones which can enable QR Code and Bar Code but the other 50% use feature phones that have no cameras or internet. Using a SMS Code (where each strip has a unique code number and a common SMS number, the number can be SMS -ed for instant authentication via SMS) which are enabled even on feature phones will ensure we cover all Indians than only the smartphone owning Indians. Ideally a Central Repository should be introduced on the lines of what is used in Europe where the exporter shares the unique codes (GTIN) with the importer who uploads them on the Central Repository maintained by that government. When the pharmacy dispenses the drug the QR Code is scanned and the GTIN is decommissioned. This is the ideal method and would ensure proper authentication than the QR/Bar/SMS code which can spawn counterfeits easily.

Answered by Mr. N. Yuvaraj: If you are setting up the infrastructure then go for QR Code as it will be better in the long term. The GOI intends to bring in the Central Repository in the near future. The smartphones are over 70 crore and its now more than feature phones and the growth is very fast, so SMS codes may only help in the short term.

Q3) We have requested for prospective batch pricing whenever prices of scheduled formulations are revised downwards as revised price is applicable with immediate effect. We can enable the price change till the C&F and our depot and inform our stockists. But we have no control over the 9 lakh chemists and many cases of overcharging have been registered against the company leading to litigations even if one strip in found with the old rate with any chemist in India, even after 3-4 months. Hence please allow prospective batch pricing which will be applicable to the immediate next batch and please spare stocks in the market manufactured before the price revision notification. We mandatorily enter all the data on sales and manufacturing in Form III on the IPDMS every quarter so the GOI has full details of batch numbers, production, sales and even GST and eway bill.

Answered by Mr. N. Yuvaraj: Study the number of cases as to how many are for overcharging only due to finding of a product with higher price at the chemist end within 6 months of the notification and how many cases are for other reasons like overcharging, para 19 etc. Draw a correlation and represent to the NPPA with facts, to present your case strongly. NPPA has some apprehensions due to wrong practices by some manufacturers in the past. You enter data in Form III in the next quarter not immediately. My suggestions are to discuss with the NPPA whether you can disclose the stocks in hand with batch numbers to the NPPA on the IPDMS website on the day the ceiling price is announced so that the complications are reduced.

Q4) As an association we support the TMR but only request that it should be implemented in a phased manner, and with prospective effect, so as not to disrupt the market, industry sources say it will be announced on 15th August.

Answered by Mr. N. Yuvaraj: They are working on it.

Q5) The new NLEM is due since 2020 and a sudden announcement can lead to issues as mentioned in the earlier discussions. Also we are told Para 18(i) of DPCO (which averages the prices of scheduled formulations every 5 years, leading to further reduction in prices) will be kept in abeyance till the new NLEM is announced. The new NLEM will lead to a reduction in prices for the formulations which will be covered in the schedule, we are told at least 38-40 new molecules are being added to the new scheduled formulations list.

Answer by Mr. N. Yuvaraj: What do you suggest we should do with 18 (i) (We replied we have requested for deletion of 18(i) as it further reduces prices and the call backs are chaotic and spawn overcharging cases). Yes, these are practical issues but you need to use technology to solve them. Use the new IPDMS 2.0 for 18(i) as well as for the NLEM so that the impact is minimized. Speak to the NPPA and find solutions within the framework.

Stakeholders consultation on Trade Margin Rationalization (TMR) on Drugs

Dr. Amit Rangnekar informed the members about TMR and he said that TMR should be applied prospectively and retro prospectively. TMR should not be applicable to product available in markets and products upto Rs. 5 are not included in TMR. He briefed the members about the Approach & Implementation of TMR and also explained about the Methodology and Post TMR implementations. He said that PTD i.e. Price to the Distributor is new as earlier it was PTS i.e. Price to the Supplier and clarification about PTD is yet to be received. The members had some deliberations on the TMR. National President mentioned that he had a meeting with the Hon. Minister regarding the same and was assured that there will not be TMR on any product whose cost is below Rs.100 per unit. National President informed the members that the small scale companies will not be affected by TMR.

Meeting with NPPA on 20th May 2022

A meeting was called under the Chairmanship of Mr. K.K. Pant, Chairman NPPA and was attended by Dr. (Ms) Vinod Kotwal, Member Secretary NPPA & Mr. Manmohan Sachdeva, Adviser (Cost). Industry was represented by IDMA, OPPI, IPA, FOPE, AIOCD, AIDAN, FICCI, CII, Indian Federation of Pharma Generics, Laghu Udyog, KPDMA, USISPF, USIDC, and others.

Mr. K K Pant, Chairman NPPA and Dr. Ms. Vinod Kotwal, Member Secretary NPPA briefed the members about the meeting. A PowerPoint presentation was made by Mr. Manmohan Sachdeva, Adviser (Cost) NPPA on 20th May 2022 on the following points:

- Approach & implementation
- Percentage of Trade Margin
- Methodology
- Post TMR implementation
- Any other issue

Dr. Amit Rangnekar made the following points:

1) We will be making our written submission by next week.
2) There is no clarity as regards to implementation by therapeutic category.
3) Exclude the medicines below Rs.5/- from TMR.
4) Implementation should be in a phased manner so as not to disrupt.
5) From prospective batches.
6) PTD is a new concept and earlier it was PTS.
7) We need to understand whether to include GST.
8) Implementation mechanism be as per Para 20.
9) We need clarification from NPPA as regards monitoring.

Dr. Ms. Vinod Kotwal, Member Secretary requested all Associations to make their written submissions/suggestions by 27th May 2022.

Meeting with NPPA officials on 16th June 2022

A meeting was held with following NPPA officials on 16th June 2022:

1. Dr. Vinod Kotwal, Member Secretary
2. Mr. Manmohan Sachdeva, Adviser (Cost)
3. Mr. Sanjay Kumar, Adviser (Cost)

Discussions veered around Trade Margin Rationalization (TMR) and the increased input costs for the formulations.

TMR: We referred to our submission dated 28th May 2022 for phased implementation, exemption of products below Rs.100/-, prospective implementation.

NPPA at present is looking at the segment where small manufacturing units Associations have opposed the TMR as such. FOPE, Laghu Udyog Bharti, and Indian Federation of Pharma Generics were called for meeting on 15th June 2022. All these Associations have opposed TMR. These associations have also asked NPPA to have One Molecule, One Price across the Nation. A Presentation is likely to be made on TMR before the Cabinet Secretary before the month end. SOTS: NPPA is reworking the numbers as desired by DoP. These numbers will be presented to the Cabinet Secretary.

Silver Jubilee Celebrations of NPPA on 29th August 2022

Dr. Viranchi Shah gave the brief about the celebrations of National Pharmaceutical Pricing Authority, NPPA of its Silver Jubilee in New Delhi on 29th September. Honourable Union Minister for Health & Family Welfare and Chemical and Fertilizers, Dr. Mansukh Mandaviya Ji addressed the Silver Jubilee Celebrations of National Pharmaceutical Pricing Authority (NPPA) and **launched Integrated Pharmaceutical Database Management System 2.0 (IPDMS 2.0)** and **Pharma Sahi Daam 2.0** App at the inaugural session,

Dr. Viranchi said that IPDMS 2.0 is an integrated responsive cloud based application developed by NPPA with technical support from Centre for Advance Computing (C-DAC). He further added that it would provide a single window for submissions of various forms as mandated under Drug Price Control Order (DPCO),2013. This would also enable paperless functioning of NPPA and facilitate the stakeholders to connect with National Pharma Pricing Regulator from across the country.

Dr Viranchi said that Pharma Sahi Daam 2.0 App will have updated features like speech recognition; availability in Hindi and English; share button and bookmarking medicines. He added

that this version of Pharma Sahi Daam also has facility for lodging complaints by consumers through the consumer complaint handling module. The App will be available in both iOS and Android versions.

He further said there was very good panel discussion on "Robust data Collection for evidence-based policy making in the Pharmaceutical and MedTech Sector". Dr. Viranchi Shah made some suggestion during the panel discussion.

National List of Essential Medicines (NLEM) 2022

Honourable Union Minister for Health & Family Welfare and Chemicals and Fertilizers, Dr. Mansukh Mandaviya Ji released the National List of Essential Medicines (NLEM) 2022 on Tuesday 13th September 2022. The NLEM list has expanded to 384 medicines in NLEM 2022. There were 376 medicines in the list that was issued in 2015. 26 medicines have been removed from the list and 34 new medicines were added in the NLEM list. "The list being published now will ensure the accessibility, affordability and safety of some of the most needed drugs in India" said Union Minister Mansukh Mandaviya while releasing the list.

Mr. C V Venkataraman, Vice Chairman, Pricing & Consumer Affairs Committee gave the details on the implications of NLEM 2022 :

The National List of Essential Medicines (NLEM) 2022 comprises of 384 drugs and over 1,000 formulations across 27 therapeutic categories. 34 new drugs have been added to the NLEM 2015 including 4 patented drugs and 26 drugs have been deleted from NLEM 2015. The value of medicines under price control is around 20% of the total market value. The list will be examined by a second committee, then submitted to the NPPA to notify ceiling prices. Further he told the members that they should check the list for their molecules including specific strengths have been retained in NLEM 2022, added, or deleted from NLEM 2022. Further he explained in detail:

A. If your brand was in NLEM 2015 and is retained in NLEM 2022-

No change, WPI prices of April 2022 will continue till March 2023. Update price in Form II and V if price is revised in Para 18 (1)

B. If your brand was not in NLEM 2015 but has been included under NLEM 2022-

a) You know this molecule will be under price control soon

b) Liquidate stocks, keep minimum stocks so once ceiling price is notified you do not have to call back too many stocks for price revision.

c) Once ceiling price is notified enter and submit the price list in Form II and V under IPDMS 2.0 and intimate your stockiest and C&F.

d) Stop further billing, revise the prices of existing stocks to the ceiling price

e) Manufacture fresh batches with new ceiling price only.

C. If your brand was in NLEM 2015 but has been deleted from NLEM 2022-

Such molecules will become nonscheduled formulations with immediate effect, hence will not be under price control. Ideally you can immediately increase price by up to 10% but as WPI price increase last year was 10.76% , maintain existing MRP till April 2023, after which increase MRP by up to 10% once the 12 month period since the last price increase is over.

Mr. C V Venkataraman said IDMA needs to make a representation on these below issues:

1. Para 18 (1) of DPCO 2013

The ceiling price of NLEM 2022 scheduled formulations is calculated based on the average price of the brands with more than 1% market share, based on syndicated research data that is six months old. 20% of the scheduled formulations have MRP lower than notified price and cannot raise their MRP as per the ceiling price. When the NLEM is notified, the government will re-average the prices, for those molecules which continue to be included in the new NLEM, resulting in re-averaged prices that are lower than the ceiling price. Vide earlier representations, we had requested for deletion of this clause, as it leads to lower prices and cases of overcharging. We should request again to delete para 18(1).

2. Prospective price revision

Ceiling prices once notified are effective immediately. IDMA has requested the applicability of ceiling prices from the immediate prospective batch on multiple occasions. Intimating 8 lakh pharmacies overnight and expecting them to immediately comply with the reduced price is beyond the scope and reach of any company. Each company intimates its C&F/ Super stockists and stockists immediately and also submits the Form II and V price lists on the IPDMS site which is as per the DPCO guidelines. Even if a single strip of a scheduled formulation is found at a retail counter with a price higher than the notified then the company is issued notices for overcharging, when the company has no direct agreement with the retailer. Hence ceiling price should be effective only from the prospective batch and the Form V submitted by the manufacturers in IPDMS should be considered as information submitted officially to the trade and no action should be initiated in this regard in future.

3. Stickering

There are multiple notifications on record regarding the process to call back the stocks and revise the prices. The NPPA and DoP should clarify in this regard well in advance so arrangements can be made by the companies to revise prices as per guidelines and not get embroiled into overcharging issues.

4. IPDMS 2.0

The experience of our member companies in migrating to IPDMS 2.0 is not satisfactory. There were multiple meetings held with the industry associations where we were promised that all the data would be seamlessly migrated to IPDMS 2.0 from IPDMS 1.0. We were only shown the Forms I, II, III, IV and V and their contents but were never shown the entry and other details. Entering the portal itself is a major problem and multiple communication has to be sent to the NPPA to get access. Once we get access a plethora of documents need to be submitted before we can even enter the site. The migrated data against the manufacturers is erroneous which has to be corrected for no fault of ours. Even after submitting all the documents we have to update each data of each loan license and third party manufacturer. Even after updating this the products are still not visible and no entries can be made to update Form V for nonscheduled formulations. After the ceiling prices under NLEM 2022 are notified we have to immediately update the prices on IPDMS 2.0 but with the problems stated as above there would be chaos while entering data in IPDMS 2.0. If there are inadvertent errors on our part, there could be serious implications.

IDMA made a representation on 14th October 2022 to Chairman NPPA requesting NPPA to announce the ceiling prices only for those 34 new scheduled formulations that have been added to the revised NLEM 2022. The NPPA should consider only the latest available data or IPDMS data for calculation of ceiling prices. Also we have requested that Trade Margin Rationalization for certain formulations should be deferred so that it does not clash with the new price revisions on account of NLEM 2022.

Dr. Amit briefed the members about the Revision of Ceiling Price under NLEM 2022, he said IDMA made a representation in which we have requested that the provision of Para 18(i) should be deleted from DPCO 2013, as re-averaging the prices every 5 years would be regressive and a dampener to the growth of the pharmaceutical industry.

He further said that the NLEM 2022 consists of 384 scheduled formulations of which 34 scheduled formulations have been added and 26 formulations have been deleted from NLEM 2015. This means that 352 scheduled formulations in NLEM 2015 have been retained in NLEM 2022.

He said that the ceiling price of the existing 352 scheduled formulations from NLEM 2015 as well as the 34 new additions to NLEM 2022 would be calculated based on the average price of the brands with more than 1% market share, based on syndicated research data that is six months earlier. If re-averaging is carried out for the 352 molecules that continue to be included in the new NLEM, then the majority of the ceiling prices would get dragged down further.

He further said that this re-averaging of existing 352 formulations would severely strain the viability of the pharmaceutical companies as they have been absorbing the unprecedented escalation in input prices for the past 3 years. So he said that in the representation we have

requested to announce the ceiling prices only for those 34 new scheduled formulations that have been added to the revised NLEM 2022. The NPPA should consider only the latest available data or IPDMS data for calculation of ceiling prices.

Online Interactive session with Industry on IPDMS 2.0

National Pharmaceutical Pricing Authority had called an interactive session on 13th October 2022 with Industry on IPDMS 2.0 under the Chairmanship of Shri K.K. Pant, Chairman, NPPA. He was assisted by Dr (Ms.) Vinod Kotwal, Member Secretary NPPA and other senior officers of NPPA**.** Dr. Amit Rangnekar informed the members about the Authentication measures meeting. He said that IDMA sought clarity on authentication for the Top 300 drugs. He said that in India 50% people use smartphones which can enable QR Code and Bar Code but the other 50% use feature phones that have no cameras or internet. Using a SMS Code (where each strip has a unique code number and a common SMS number, the number can be SMS -ed for instant authentication via SMS) which are enabled even on feature phones will ensure we cover all Indians than not only the smartphone owning Indians. He further said that a Central Repository should be introduced on the lines of what is used in Europe where the exporter shares the unique codes (GTIN) with the importer who uploads them on the Central Repository maintained by that government. When the pharmacy dispenses the drug the QR Code is scanned and the GTIN is decommissioned. This is the ideal method and would ensure proper authentication. He said that the cost of setting up the infrastructure for authentication of the Top 300 drugs is huge as each camera costs Rs 4 lakhs per line, Thermal Inkjet printer is Rs 4 lakh per line and Top 300 brands need minimum 3-4 lines spread across multiple locations. In addition, onetime costs of software and licences need to be borne, so it is quite capital intensive. Running costs will be another 15 p per unit.

Dr Amit Rangnekar said that in his company they are trying to work out a very low cost model, the actual running costs are very high but they have found out and identified some supplier and if this model works he will introduce it to other members so all can benefit from it.

Dr. Amit informed the members about the IPDMS 2.0 meeting he said that we will be sending a representation soon as he has made a list of complaints from our subcommittee members as well as snap shots of problems faced by our members. He said IPDMS 2.0 is having lot of constrains out of which few he discussed:

- Migration from IPDMS 1.0 to 2.0- the data is not transferred automatically, each and every details has to be typed (no provision of copy and paste) and entered in the system which is duplication of work.
- Data in IPDMS 2.0 cannot be edited by industry, modification of data remains subject to approval of NPPA thus increasing human interaction which has resulted in wrong data entry in the system.
- The approval from NPPA takes approximate 15 days for the modification in system.

- Only the director or the CEO or the CFO has the authority to handle this IPDMS 2.0 which is not feasible as it has to be done only at the managerial level personnel such as finance manager or costing manager or distribution manager.
- The software is not user friendly, which led to entering of incorrect data and have obvious side effects.
- The company needs to fill details such as formulation launch date, Formulation production capacity, Overall production capacity, Copy of the Drug Licence for the concerned formulation etc. requirement of such information/ data is not relevant hence to be kept out of IPDMS 2.0.
- Earlier the return was to be filed quarterly now which is changed to monthly, this is a very tedious and duplication of work as earlier data which is entered in system needs to be modified.

Dr. Amit further requested all member to send the problems faced by them during handling IPDMS 2.0 along with snapshots, so IDMA can prepare strong representation without disclosing any company's name.

IDMA's representation for IPDMS 2.0 – DPCO 2013

NPPA issued Office Memorandum on 14th November 2022 conveying the action taken on inputs submitted by stakeholders regarding issues faced by industry with IPDMS 2.0.

On 28th November 2022, IDMA made a representation to Member Secretary NPPA on IPDMS 2.0, highlighting the issues faced by our member companies as also the areas where we feel IPDMS 2.0 can be improved. Further to this, we have requested NPPA not to take any coercive action against companies for errors and omissions in IPDMS 2.0 as it is still a 'Work in Progress' and the issues raised in our representation are post implementation of IPDMS 2.0. The representation was also marked to Chairman, NPPA and Secretary, DoP.

Dr. Amit Rangnekar said that the government has done lot of work on IPDMS 2.0. He said that in IPDMS 2.0 there are serious operational issues with IPDMS 2.0, which have been conveyed to the NPPA. Critical issues persist, like

- Migration of company data from IPDMS 1.0 to 2.0 is neither visible nor accessible and functional errors in the program.
- Documents and data beyond the scope of DPCO 2013 like submitting PTS in form V or monthly data of production and sales in Form III have been included.
- We have requested the NPPA to not take any coercive action regarding errors and omissions in entries in IPDMS 2.0.

Dr Amit Rangnekar said that IDMA should request the NPPA to postpone the announcement of TMR (trade margin rationalization). The entry of ceiling price of scheduled formulations in NLEM 2022 in IPDMS 2.0 would be further compounded if TMR is also

required to be entered. Further Dr. Amit informed members about a meeting which was organized by Pharmexcil for the QR code implementation for the 300 formulations, he said in the meeting Pharmexcil had invited a vendor Madras Security Printers who provides good deliverables for implementation of the QR code. So he said that interested members can contact this vendor.

NPPA Webinar on tracking the drugs: Ensuring Last Mile Availability

NPPA organized webinar on 30th November 2022 on tracking the drugs: Ensuring Last Mile Availability. Chief Guest for the webinar was Dr. V.K. Paul, Member NITI Aayog and Guest of Honor was Ms. S. Aparna, Secretary, DoP. Others present in the meeting were Mr. K.K. Pant, Chairman NPPA, Dr. V.G. Somani, DCGI and others.

Dr. (Ms.) Vinod Kotwal Member Secretary NPPA initiated the proceedings for the meeting. There were around 250 participants in the webinar.

Dr. Viranchi said that NPPA had organized a webinar on tracking the drugs ensuring last mile availability. He said that the implementation has to be done phase wise. He said that we should not forget that even US and EU had taken almost a decade from notification to implementation of tracking system inspite of having strong supply chain which had access to every sector globally. He said that India might need some time to implement tracking system considering the complexity of the Indian supply chain. He further added that the last mile connectivity is a very important initiative and will contribute to availability, affordability and quality. Dr Viranchi Shah appreciated NPPA for hosting the webinar.

NPPA -- Interactive Web meeting with Industry stakeholders on IPDMS Version 2.0.

NPPA organised an interactive web meeting on 12th December 2022 on IPDMS 2.0. Mr. Pushpesh Pant Chairman NPPA and Dr Vinod Kotwal attended the meeting with Mr T Rajesh, Dy Director Head IT for the IPDMS 2.0 project.

NPPA mentioned that 1055 companies had registered and conveyed the changes made in IPDMS 2.0 based on stakeholders' suggestions.

Dr. Amit Rangnekar thanked the NPPA on the behalf of IDMA for the many changes they have incorporated in IPDMS 2.0 specifically based on IDMA's suggestions and highlighted the issues still pending. Further in connection to this meeting on 13th Dec 2022, IDMA sent a detailed representation based on the discussion held during this meeting to Dr. Ms Vinod Kotwal, Member Secretary, NPPA and also marked copy to Shri Kamlesh Kumar Pant Chairman, NPPA. NPPA has acknowledged the receipt of representation on 14th Dec 2022.

REPORT OF PUBLICATIONS COMMITTEE

The IDMA Bulletin (weekly) and Indian Drugs (Monthly) were digitally published throughout the COVID19 pandemic and uploaded on the respective websites with freely accessibility to all viewers. Due to the request from various members, the publication committee initiated the printing of Indian Drugs from June 2022 and the IDMA Bulletin from January 2023.

Indian Drugs received approx. 520 manuscripts in 2022 and cleared the 90 % of the manuscript in same year. We have also cleared backlogs of pending manuscripts submitted by screening the articles on an accelerated basis.

DOI (Digital Object Identifier) numbers have been allotted to all published manuscripts for the year 2022. Last year we started assigning DOI numbers to all manuscripts published since 2012. This exercise has started showing results with an increase in the citations of articles published in Indian Drugs. SCOPUS database calculated Citescore 0.3 for the year 2022, which is almost double than that recorded in the previous year. Addition of the DOI numbers also improved the traceability of the citations made on databases like Google Scholar Citation, CrossRef, SciLit etc.

In 2023, Indian Drugs proposes to add more filters to its process of reviewing manuscripts for verifying the authenticity of manuscripts submitted for publication by adding more advanced Plagiarism tools.

The 60th IDMA Annual Publication was released on the occasion of the Diamond Jubilee Celebrations on 14th April 2022.

We acknowledge the contributions of the Editorial Committee Members Dr Gopakumar Nair, Dr Nagaraj Rao, Dr S. G. Deshpande, Mr Sipahimalani resulting in the timely release of the publications. We also acknowledge the contributions of Ms Sapna Patil, Ms Geeta Survana, Mr Melvin Rodrigues under the guidance of Mr Daara Patel at the IDMA Secretariat.

REPORT OF QUALITY MANAGEMENT & TECHNICAL COMMITTEE

Dr Vinay G Nayak, Chairman, Quality Management and Technical Committee informed the members at the 1st IDMA Executive Committee Meeting on the following points:

IDMA Representation to IPC

IDMA sent a representation to IPC on 28th January 2022 to revise IP monograph of Amoxycillin and Potassium Clavulanate Oral Suspension to harmonize with BP and USP monograph. IPC responded to our representation on 8th February 2022.

Meeting on General Monograph of Capsules for Soft Gelatin capsules - Disintegration Limit revision (From 60 minutes to 30 minutes)

- A meeting was organised with IPC on the 01st February 2022. There were fruitful deliberations at the said meeting and a very learned discussion took place for a considerable period of time. There was considerable learning on both sides and approach of each other's position. The IDMA representatives and other technical experts had points of view somewhat at variance with the IP team.
- IDMA made a representation on the 12th May 2022 to the Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission on the above subject:

1. It is requested that for any changes in the IP monograph, discussions with the stakeholders should be done based on acquired data and it is advisable to refrain from merely following the BP & USP pharmacopoeias.
2. In order to meet the stringent limit of Disintegration Time for soft Gelatine capsules there is need for modification in the product composition and the stake holders have a reservation to do the changes in product composition as it would take the product out of market and there will be shortage of medicines.
3. Disintegration time of 60 minutes may please be retained in General monograph of soft gelatin capsules and stringent limit of 30 minutes to be included in individual monographs.
4. It is recommended that Dietary supplements and Ethical medicinal products be set apart and **FSSAI can decide the limit for Disintegration Time test rather than link it to IP.**
5. We suggest Indian Pharmacopoeia Commission to hold the change until a proper statistically validated protocol based study is performed and shared with all the stakeholders.
6. We suggest that any changes to the soft gelatin product monographs which are invalidated can lead to product withdrawals from the market which will result in product shortage and ultimately affect the patients adversely.

Dr. Vinay Nayak briefed the members about the above representation. Dr. Vinay said that they had many deliberations with IPC with regards to the said representation which is very appropriate as all points are put methodically and with good justifications. He said that IPC would be seriously considering our points. Dr. Sanghavi and Dr. Vinay requested that a communication be send to IPC to change the minutes of meeting as all the points which were discussed in IPC meeting are not covered the minutes of meeting provided by IPC.

Dr. Vinay Nayak informed the members at the 18th February 2022 EC Meeting that in regards to the meeting with IPC on General Monograph of Capsules for Soft Gelatin capsules - Disintegration Limit revision (From 60 minutes to 30 minutes), he said that all the IDMA Representatives excellently and aptly placed forth their points. IDMA informed IPC that they should not make **any** adhoc changes unless scientifically validated. He said that IDMA suggested that for any changes in the IP monograph there should be a discussion with the stakeholders which should be based on acquired data and not just following the BP and USP Pharmacopoeias. The Indian

Pharmacopoeia Commission (IPC) is accredited for both chemical and biological testing and had tested market samples and control samples in two groups i.e. of Ethical therapeutic medicinal products and Nutraceutical in which category of vitamins and dietary supplements are included. He said that it was discussed and suggested that the DT time of 60 minutes be retained in General monograph of soft gel capsules, and the stringent limit of 30 minutes to be included in individual monographs. He further added that majority of the stakeholders have opposed the change in DT limit and informed IPC to hold the change until a proper statistically validated protocol based study is performed and shared with all the stakeholders. IPC has agreed to hold this change till all the members are in consent with the change in limit of DT

Revising Disintegration Time for Soft Gelatin Capsules

IDMA made a representation on the 14th November 2022 to Secretary-cum-Scientific Director, IPC wrt revising of Disintegration Time for Soft Gelatin Capsules. Vide this representation IDMA requested for another meeting to discuss the outcome and take a rationale and consensual stand in the matter of Disintegration Time downward revising for soft gelatin capsules.

Dr Vinay G Nayak made a presentation at IDMA Executive Committee Meeting on the following points:

Proposed Initiatives and Activities

- Interaction between Members and Government / Scientific institutions on matters on changes, upgradations and improvements in pharmaceutical and allied industries.
- **Collaboration, interaction and Networking with organizations like IPC, IPA, BDMA, USP and other scientific institutions for planned implementations of changes in phased manner with mutual agreement.**
- Encourage the roll out of knowledge sharing platforms through IDMA on new techniques and technologies and newer topics like Digitalization, Data Preservation, and newer Guidelines for benefit of industry.
- **To have closer interaction between IDMA members and reputed institutions for Talent search, mapping and connecting to the needs of member companies.**
- Provide Awards and Rewards to deserving employees in various fields for Excellence in professional career.
- **Continue to roll out knowledge oriented workshops and PAC to the highest level of global recognition.**
- To enhance the GMP recognition Efforts over the years through professional competitions and recognition.
- **To assist Member companies for compliance to international regulatory inspections through our own subject matter experts.**

Meeting with Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission

IDMA had a meeting with Dr. Rajeev Singh Raghuvanshi on the 14th Oct 2022. The issue of changing the Disintegration time for the Soft Gelatin Capsules was discussed. Dr. Vinay Nayak expressed his views about revision of DT limit for soft Gelatin capsules. He said IDMA had made a good representation mentioning that for the ethical products or lifesaving products or monograph products DT limit can be updated to 30 minutes. But for Health product and Nutraceuticals or Omega-3 acid such products will not meet the DT limit of 30 minutes. He said during meeting with Dr. Raghuvanshi we had discussed that in Chinese Pharmacopiea the limit for DT is 60 minutes.

Dr. Nayak further said that if drastic changes are made for all formulations then it will violate one rule that bioequivalence was done on human volunteers, and any such abrupt changes made will have an adverse effect on the health of people. Dr. Nayak said that IDMA needs to have more dialogues with Dr. Raghuvanshi and implement the changes in a phased manner. He said that in USP for film coated tablets the DT limit is 30 minutes. He also said that the DT test is applicable not only for Soft Gelatin Capsules but also for Hard Gelatin Capsules, Uncoated Tablets and Tablets so IP should consider all four formulations in totality. A thorough study protocol and comparison study to be done so it can be decided whether the Limit of DT can be tightened or kept as it is.

22nd IDMA Pharmaceutical Analysts Convention

IDMA organized a meeting on the 13th October 2022 to discuss about the 22nd Pharmaceutical Analysts Convention event which would be held on 23rd and 24th Nov 2022 at Jio World Convention Centre, Bandra Kurla Complex, Mumbai. The members were informed about the topic suggested to EDQM for the discussion in event:

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

Postponement of 22nd IDMA PAC

Dr. Vinay Nayak informed the members that EDQM had agreed to participate in the 22nd PAC. However, due to constrains of VISA issuance for Speakers from Europe and also, Hotel confirmation and various Pharma events being lined up in November, December and January, the Committee decided to postponed the PAC event till end of February '23.

22nd IDMA PAC – 24th & 25th February 2023

Dr V G Nayak informed the members that the 22nd IDMA PAC 2023 will now be held on 24th & 25th February 2023 at Hotel Four Seasons, Worli, Mumbai. He said that for PAC we have got very good speakers who have already committed to attend this event. Prof G.D. Yadav who is a Padmashree in Chemistry has agreed to be the Chief Guest and Key Note Speaker. He said that EDQM has taken five topics to speak during the event. He further said IPC and USP have also agreed to attend the event. Dr. Nayak informed the members that the details for the event is already worked out and responsibilities of the activities for the event are distributed among the members of the organizing committee.

REPORT OF R & D AND INNOVATION COMMITTEE

Meeting of CEO level on proposed Research Linked Incentive (RLI) Scheme (Virtual)

Mr. Manoj Kumar Pananchukunath, Chairman, R & D and Innovation Committee informed the members that the Department of Pharmaceuticals had called for a closed door meeting on the 26th May 2022 of CEO level on Proposed Research Linked Incentive (RLI) Scheme. The meeting was chaired by Ms. S Aparna, Secretary, DoP and DoP had made a PowerPoint presentation on **'Concept note on Research Linked Incentive (RLI) Scheme in moon-shot areas of Pharmaceutical Sector'** and asked the participants to send their comments. IDMA received the PPT from Mr. Rajneesh Tingal, Joint Secretary DoP.

Dr. George Patani informed the members about the RLI scheme and feedback given by IDMA vide letter 1st June 2022. He mentioned that the scheme is just like the PLI scheme. He also mentioned that it is draft scheme and the Government wanted feedback and IDMA has given its feedback on the same. Dr George explained the RLI scheme in detail, the eligibility – categories wise, incentive support & execution, the moonshot areas, etc. IDMA has given some recommendations and he is hopeful that the Government would accept these recommendations. There was a lengthy deliberation on this scheme and the National President has asked the IDMA Secretariat to share the details of the scheme and IDMA's feedback with the members for their valuable inputs. Action was taken by the Secretariat.

1st R&D and Innovation Committee - Introductory Meeting

The Chairman had organised an IDMA - R&D and Innovation Committee introductory meeting on the 04th July 2022. The highlights of the meeting are as follows:

- Chairman to make a presentation at the next EC meeting.
- R&D and Innovation committee completely endorses the feedback /recommendation given by IDMA on the RLI Scheme.
- Further suggestions have been requested from the committee members

- Organize **Seminar/ Webinar** on the subjects related to R&D and Innovations**.**
- Expanding the Committee by including diverse field experts from Formulation, Mfg. MSAT
- It was discussed that an action plan to be made for Branding R&D where youngsters could really aspire to join R&D. Working towards better coordination between Industry and Academia

2nd R&D and Innovation Committee Meeting

The second meeting of R&D Innovation Committee was held on 28th September 2022, the Agenda for the meeting was:

- Emerging Innovation in Pharma Space
- It was agreed among the committee members to select few ideas and make executable plan with the help of IDMA office.
- Cadence /frequency of the Innovation Committee will be finalized (mostly monthly) and invite to be sent well in advance.
- It was suggested and agreed by committee members to include academician from NIPER and other reputed institutions.

Dr. Rakesh Bandichor gave a presentation on " Process Chemistry Innovation".

Dr. Viranchi shah briefed the members about the R&D and Innovation Committee Meeting and appreciated Dr. Rakesh Bandichor, Dr. Reddy's for his excellent presentation on " Process Chemistry Innovation". He said it was a very interactive meeting some of the points discussed were:

- Academic & Industry Collaboration like ICT, IIT, ISC, NIPER.
- Collaborating with Big Pharma companies on emerging Innovative Technologies.
- Contacting few Big companies directly (using IDMA network) to understand their capabilities & strength to collaborate.

Dr. Viranchi Shah requested the IDMA Secretariat to publish these presentations in IDMA Bulletin for the benefit of our members.

3rd R&D and Innovation Committee Meeting

The third meeting of R&D and Innovation Committee was held on 28th December 2022, the Agenda for the meeting was:

- Key update on last R&D and Innovation committee action items.
- Sub-Committee Structure discussion.
- Presentation on "Decoding Process through Statistics" by Dr. Amrendra Roy.

Other Points discussed were:

- In the next committee meeting the outline of an action plan along with a tentative Agenda with Topics / Speakers for Organizing Seminars/ Workshops in March 2023 to be prepared.
- Mr. Manoj said that "Decoding Process through Statistics, " the presentation given in today's meeting would be considered as one of the topic for the proposed Seminar in Mar'23.

REPORT OF REGULATORY AFFAIRS COMMITTEE

1. Presentation at IDMA Executive Committee Meeting

Mr. S M Mudda, Chairman, Regulatory Affairs Committee made the below presentation to the EC members on 21st January 2022 :

Mr. S M Mudda informed the members that as National President rightly mentioned Regulatory Reforms would be the important agenda for this committee and de-criminalization of the proposed Drugs and Cosmetics Amendment Act. The six important points for the committee are as below: -

- Pathway for Handling Kokate Committee Approved FDCs (19.10.2020)
- Clarification on submission of PSURs (19.05.2021)
- Representation on Draft Schedule M (17.01.2019 & 30.03.2021)
- Clarification of Responsibility of Marketer (23.09.2020), and
- Guidelines for Handling NSQs (30.03.2021)
- Clarifications for Export of Drugs

Guidelines for Handling NSQs (30.03.2021),

Issue: Guidelines for handling of NSQs as recommended under Section 33P of the Act are not implemented uniformly. The option of prosecution should be used judiciously and only as a last resort

Our Suggestion: Complete investigation to find the root cause of the failure to comply with standards. Clear instructions for not converting the NSQs as Spurious or Adulterated Drugs* merely because the content of the drug is below an arbitrary percentage.

Amending definitions of *both these terms and introducing a clear definition of NSQ Drug.

Representation on Draft Schedule M (17.01.2019 & 30.03.21)

Issue: Draft rules published under GSR 999(E) dated 5.10.2018 to substitute existing Schedule M of the Drugs and Cosmetics Rules, 1945- Cannot be implemented in its present form.

Our Submission: In a detailed representation on January 17, 2019, we expressed our concern that while up-grading the existing Schedule M, the guidelines published by WHO have been included as a part of the regulations. Adoption of guidelines as regulations will lead to difficulties in interpretation and implementation of the requirements since unlike the non-mandatory nature of the WHO GMP guidelines, Schedule M is mandatory in nature.

Our Suggestion: We urge that the requirements of GMP be amended to include the principles and concepts in the Act & Rules, while the details shall be in the form of guidelines and advisories. The guidelines shall be dynamic and may be updated as per the prevailing situations and developments. The power to issue the guidelines and changes shall be with DCGI.

In order to deal with the potential non-compliance with the Rules/ guidelines, there is an urgent need to empower the regulators to take a judicious decision and give adequate discretion, in-built in Rule.

He said that the main focus would be on the amendments in the Drug & Cosmetics Act and Schedule M as per the International Norms.

2. At the EC meeting on 18th February 2022, Mr. S M Mudda informed the members about a few updates particularly related to the approvals of the new drugs. The first important point he mentioned was that of GSR 132A which provides deemed approval if a specified Number of days have elapsed after the application has been made and they are related to registration ethics committee, permission to conduct all clinical trials, permission to conduct BA/BE studies and permission to manufacture batches for BA/BE studies. He further added that this is a welcome move where within 45 or 90 days of application being made, if there is no clearance, the manufacturers can go ahead and complete their task, citing it as a Deemed approval. In the second point, he mentioned that similarly the same was being followed for test licenses in Form 29, wherein within seven days of submission If we don't hear from the licensing authority, we can go ahead and take it as a deemed approval. The third point was in regards to the present pandemic situation, wherein he mentioned that if covid related drugs have to be manufactured, a permission will be given to manufacture and stock the drugs until approval in CD23 is achieved. He further added that after conducting clinical trials, we need to take approval from the DCGI, but in the meantime, the companies can manufacture and stock the goods and sell them only after getting approval.

He further mentioned about the PSUR requirements and our several representations made to the Kokate approved committee. He said that many of our decisions have been accepted in principle through various representations made by us and also, during the special meeting we had with the DCGI in July 2021. Yet, some of the companies are still receiving letters asking for information. He mentioned that IDMA would be making an additional representation on the same.

He mentioned that Mr. Mehul Shah, our Hon. General Secretary and few of our members have brought this to his notice in regards to new drugs specially new API which are first time being launched in India that have two years shelf life and the finished product manufacturer wants it more than two years. He mentioned that there is no link between the shelf-life of APIs and the finished products and this has been brought to notice of the Government several times since 2011 onwards in several IDMA representations. He suggested that we have to make a very strong representation which includes the global Community Regulation as well as scientific justification available with us on a priority basis. In regards to USFDA unannounced inspections. He said that IDMA is looking into this matter and its impact.

3. Launch of APPQM+ Series 3

Mr. S M Mudda, Program Director, APPQM informed the members that APPQM+ Series 3 brochure and circular is ready. He said that as advised by Mr. Mehul Shah during the valedictory function, we have included Digitization and Quality 4.0 in the modules this year. He further mentioned that IDMA would launch this series in July 2022. He thanked the National President and Secretary-General and the members for their support for the APPQM Series.

Presentation by Mr. Mudda on APPQM Series 3 held on the 13th April 2022

Mr. S M Mudda, Chairman Regulatory Affairs Committee, IDMA & Program Director, APPQM, explained about the ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT (APPQM). He said that it is a MBA Style International education program for Senior Leaders. He explained the Challenges - Key Personnel, Mind-set, Reactive Pharmaceutical Quality system (PQS). He further told the APPQM is designed for Indian companies, it not a training program, but it is education program in PQS focused on leadership development QA, QC, manufacturing and R & D professionals. He further explained why APPQM is important for companies who want to grow their business in Europe, the UK and the US. APPQM helps by Developing Change Agents for Quality Excellence. He further mentioned that why developing second level leadership is important which will help in Critical Thinking abilities. He requested members to register in large numbers and take benefit of this International MBA styled program APPQM.

4. India Pharma 2022 & India Medical Devices 2022 :

State Drug Regulators Session was held on 25th to 27th April 2022

The State Drug Regulators session was chaired by Dr. V G Somani, DCGI and Dr. Viranchi Shah, National President, IDMA coordinated the session.

Dr. Viranchi Shah, National President, IDMA deliberated the following points:

- Appreciated CDSCO on behalf of FICCI and IDMA.

- Thanked all the SLAs and Dr. VG Somani, DCGI for all the help and guidelines.
- Industry needs hand holding to move ahead and Focus should be on improvements based on failures.
- Focus be more on CAPA than prosecution. Prosecution should be the last resort while admitting that strictest action must always be taken against the culprits.
- Harmonization, uniform approval systems, maintaining time lines are some other points that need to be attended.
- Shelf life of products.
- There is no clear-cut linkage between API and that of finished product. This must be addressed to prevent major national loss. Referred to re-test date.
- Portals for licensing in different states are to be scaled up based on Gujarat model for ease of doing a business.
- As per information from our Members in Karnataka; procedure for NOCs for exports is still not fully implemented though the powers have already been vested with SLAs.
- We also have information from Tamil Nadu that COPP is being issued only for one year as against the permissible three years.
- Harmonization of approvals for fixed dose combinations and the Pathway.

National President informed the members that he has given assurance during the meeting that IDMA is with the Government against the spurious and adulterated drugs. He said that the IDMA's point with regards to delinking of shelf life of APIs against the shelf life of the finished products was discussed and outcome was very positive. Dr. V G Somani has assured that the new Schedule M would be implemented shortly wherein there is an amendment for Shelf life of API.

5. Meeting of USFDA officials at IDMA Office, Mumbai

IDMA had a meeting with USFDA Officials at IDMA office on the 20th April 2022. The USFDA was represented by Dr. Sarah McMullen, Dr. Sudheendra Kulkarni and Mr. Dhruv Shah. IDMA was represented by 20 IDMA members from different companies.

Mr. Mudda,explained various quality initiatives by IDMA over all the past 2 decades such as Quality Excellence Awards, Annual Pharmaceutical Analysts Convention (PAC), Seminars conducted in collaboration with DoP across the country and APPQM- Advanced Program in Pharmaceutical Quality Management, the MBA-style international education program offered by IDMA in collaboration with NSF, UK.

In nutshell, it was communicated to the USFDA officials that IDMA members work with a compliance mind-set and are looking forward to engage with USFDA for continuous education towards building capabilities for quality excellence. We would like to suggest the following topics for conducting the educational programs:

- PQS and Quality Management Maturity
- Control of cross contamination in shared facilities
- Regulatory Expectations on OOS and Failure investigations
- Designing Bio-equivalence studies (IVRT and IVPT)
- Adoption of Industry 4.0 Digitisation initiatives

Discussions

- The members were requested to fill and give basic details in the survey provided by the USFDA which will help us to identify the gaps.
- List of topics for the trainings which would be conducted by USFDA officials to be provided for example. IVRT/IVPT for topical products, Filing of DMF and ANDA.
- Members should proactively connect with FDA on any specific issues if required.
- The FDA Agency is transparent for their ANDA Programme /product review, members should be in touch with Agency for review update, so that upfront information can be obtained.
- USFDA officials want to conduct programme for IDMA members in Mumbai or Gujarat where maximum members are there.
- The interactive meeting was very vibrant and informative and appreciated by all present specially the efforts made by the US FDA to bridge the gap for the Regulatory compliance issues.

6. Report on the Interactive Meeting with Dr Mandeep Bhandari, IAS, Jt. Secretary, Ministry of Health, Government of India on 13th June 2022 at IDMA Office, Mumbai

IDMA along with IPA had an Interactive Meeting with Dr Mandeep Bhandari, IAS, Jt. Secretary, Ministry of Health, Government of India on 13th June 2022 at IDMA Office, Mumbai. There were about 22 participants for this meeting.

The meeting commenced with welcome address by Mr. Mahesh Doshi, Past National President IDMA, followed by a quick introduction of the members present for the meeting. Mr. Mehul Shah address the gathering and then handed over the proceedings to Mr. S M Mudda, Chairman, Regulatory Affairs Committee, IDMA.

Mr Mudda explained in detail the need for decriminalisation and amendment to Schedule M and touched upon other important points.

A. Decriminalisation of the Drugs Act and Rules

a) A number of representations have been made to suggest removal of the provisions related to prosecution for offences other than the ones related to manufacture of Adulterated and Spurious Drugs and NSQs causing death or grievous hurt. (Section 27(a), 27b(I) and 27c cases)

b) In case of NSQs, we request that review committees be established by each state to review before launching prosecutions. We suggest that the distinction be made on 3 critical points- Adulterated drugs, Spurious drugs, and failure due to wilful default or gross negligence. In case of any of these three, the cases may be dealt strictly. When these three elements are not evident, the cases may please only be dealt through globally accepted mechanisms such as CAPA.

c) Suitable amendments shall be made to the Act to introduce compounding of offences related to all non-compliances other than the ones mentioned above to reduce the regulatory compliance burden and to encourage industry to comply by implementing necessary CAPAs.

B. Suggestions in response to draft Schedule M . GSR 999(E) dated 5.10.2018 to substitute existing Schedule M of the Drugs and Cosmetics Rules, 1945

a) Drugs and Cosmetics Act, 1940 and Rules, 1945 have been enacted to regulate manufacture, sale and distribution of drugs and cosmetics with a view to ensure availability of safe, standard and efficacious medicines and standard, safe cosmetics. Every requirement under the Act and Rules assumes mandatory nature and thus the Act imposes concept of absolute liability.

b) Further, in the absence of defence of mensrea (not considering the intention behind the non-compliance), any unintentional, minor departure from the practices for the manufacture of medicines is considered as an offence and such manufacturer or dealer or any person is exposed to stringent penalty under the Act.

c) The proposed Schedule M that adopts guidelines for GMPs makes compliance with the guidelines mandatory that makes the compliance very challenging.

d) The global guidelines are framed to serve as an advice and are required to be written in a manner that allows flexibility in the approach to be adopted for compliance with the principles of GMP. Therefore, by design the guidelines are open to different interpretation even while serving the objective of compliance with the regulation.

e) The implementation of the proposed Schedule M in the current format will lead to serious issues of interpretation and compliance and consequently will hamper the growth of the industry.

f) We therefore, urge that the requirements of GMP shall be amended to include the principles and concepts in the Act & Rules, while the details shall be in the form of guidelines and advisories. The guidelines shall be dynamic and the power to issue the guidelines and changes shall be with the DCGI.

g) The guidelines offer the flexibility to the manufacturers for complying with legal requirements and will remove the fear of legal actions. This framework will encourage all sectors, including MSME, to comply with the upgraded GMP requirements. The new framework will also help in decriminalization of minor errors, departures from good practices.

- **API v/s. FP SHELF LIFE:**
- **Pathway for handling Kokate Committee approved FDCs**

- **Marketer Responsibilities**
- **QR Codes for APIs, 300 Finished Product Brands**
- **Standards for Drugs**:IP or In-house standards for Domestic Markets and BP/ USP etc. for Exports.

7. Manufacturers to affix Bar Code or Quick Response Code on the packaging label to store data or information legible with software application to facilitate authentication

IDMA forwarded a representation via email on 13th July 2022 to The Under Secretary (Drugs), Ministry of Health & Family Welfare, Government of India.

National President Dr. Viranchi Shah informed the members about IDMA's Representation on Manufacturers to affix Bar Code or Quick Response Code on the packaging label to store data or information legible with software application to facilitate authentication. Mr. C V Venkataraman briefed the members by giving an overview on the representation made by IDMA on the QR code for the 300 products. He said that IDMA has made a very detailed representation which has been submitted to the Ministry and has requested to know the purpose for implementation on these 300 products. He further added that there is no clarification in the said notification that the authentication is for distributor or the patient. He said that IDMA has requested the government to keep the implementation of QR code in abeyance till there is clarification for all concern issues.

Mr. S M Mudda concurred with Mr. Venkataraman with regards to keeping the implementation in abeyance. He said that there should be a national hub where all the data about the products would be loaded and this hub should be responsible for scanning and decommissioning the details of products. He further said that there should be clarifications from all concerned as there would be huge expenses involved in implementation of these QR codes.

Further to the deliberations, Dr. Viranchi Shah requested members to forward their suggestions and inputs to IDMA Secretariat so as enable IDMA put forth these points to the Government.

8. Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022

Ministry of Health & Family Welfare uploaded the Draft New Drugs, Medical Devices and Cosmetic Bill, 2002 on its website on 8th July 2022. Comments are invited within 45 days from the date of issue of this Notice by email to drugsdivmohfw@gov.in or by post to Under Secretary (Drugs Regulation), Ministry of Health and Family Welfare, Room No. 434, C Wing, Nirman Bhawan, New Delhi – 110011.

Comments received from our Expert, Mr. S W Deshpande.

- Definition of NSQ has now proposed to be included
- Introduction of improvement notice (CAPA) (eg: addressing non-conformances in GMP, minor offenses)

- Compounding powers given to CLA/ SLA and it can also be delegated
- No prosecution except on sanction from Controlling authority / gazetted officer
- In case of cancellation of suspension or license the Show Cause Notice is to be served and appeal can be made within 90 days
- Inclusion of Fourth Schedule where compounding can be done

IDMA would be reviewing the proposed bill :

o Review of Definitions of NSQs

o Creating Quasi-Judicial appellate body

o Sampling to have provisions of providing sealed sample within fixed time to the manufacturer as disclosed on the pack

o Reframing – not to restrict the compounding to the fourth schedule

National President, Dr. Viranchi Shah informed the members about the Draft New Drugs, Medical Devices and Cosmetics Bill 2022. He said that it is an appreciative step taken by the Government of India to amend the Act. He appreciated Mr. S M Mudda for his extensive work and inputs with regards to the new amended Draft. He said that the draft contained important changes such as Decriminalization of the Act. He discussed the important features of the draft and mentioned that the proposed bill is being reviewed by our experts. He said that the IDMA would be suggesting the above four points.

Mr. S M Mudda briefed the members with regards to the Draft Act as follows: -

- Elaborated on the points of decriminalization, licensing, definition of NSQs and introduction of improvement notice which will be helpful in addressing the non-conformances in GMP and minor offences.
- He further mentioned in detail the point about compounding, he explained that the Control officer cannot launch a prosecution without getting approval from Controlling Authority, he said this is one of the very important changes.
- Reframing of the fourth schedule.

National President informed the members that the Regulatory Affairs Committee would be having a meeting on Tuesday, 19th July 2022 at IDMA office to discuss the comments and inputs with regards to the Draft Act. He requested members to forward their suggestions/comments to the IDMA Secretariat at the earliest so that the same could be discussed at the meeting.

9. Virtual meeting to discuss the New Drugs, Cosmetics and Medical Devices Bill, 2022

DoP called a virtual meeting to discuss the New Drugs, Cosmetics and Medical Devices Bill 2022 under the Chairpersonship of Ms. S. Aparna, Secretary, DoP on the 29th July 2022. Dr. N Yuvaraj, Joint Secretary gave the brief of the meeting. Ms. S. Aparna, Secretary DoP, mentioned

that effort should be to enact an Act responsive to needs for Innovation and R&D without the need for approvals. Concerns over the functioning of SECs. Look at the convergence of approvals from DBT and Ministry of Environment.

IDMA made following suggestions:

- Quality of Pharma has to be at par with international levels. The draft bill is welcome.
- QMS be implemented. Move away from testing.
- There is no definition of NSQs.
- Modify definitions of spurious, adulterated, and misbranded.
- Guidelines on 33(P) provided some relief to use prosecution as last resort.
- NSQs be dealt with adjudicative system/quasi-judicial body.
- For Test results, OOS …there is a need for adjudication.
- Decriminalization…. Genuine manufacturers be dealt with administratively. Bill is holistic.
- Decriminalization…. Despite all compliances, there is chance for NSQ or OOS.
- Even minor violations lead to NSQ.
- Cases keep on lingering in the courts with low conviction rates. The deterrent effect of the law is lost.
- We brought to the notice that Section 79, 144 and 152 of bill provide for adjudication. Similar provision should be made under Section 56(d). Fourth schedule to be abolished.
- Compounding of paltry offenses,
- For the Method of analysis, adjudication is the right procedure.
- Provision for Appellate Authority be brought.
- Need for provision for warning.
- Improvement Notices are a good step.
- We should learn from FSSAI Act. Adjudication is working very well.
- There should be a separate chapter for already approved products.
- SOPs be laid down for the SECs. It should not be viva voce

Mr. S. M Mudda briefed the members and said that IDMA had discussed about the suggestions given in our Representation and he has included the suggestions from our senior IDMA members on the Draft bill in IDMA's Representation. He further said that in the Representation he has also added that it is important that the sample is made available to the manufacturer immediately after the sample is drawn by the inspector within 30 days of taking the sample. This will help the manufacturer to check the genuineness of the pack and alert the authority if the sample, on visual examination, is found to be spurious. Besides, it will ensure proper storage of the sealed portion of the sample. Further he added that in Representation he has included a point that the words "likely to cause death or is likely to cause such bodily harm" in Section 56(a) are subjective and

can be misinterpreted. Therefore, such severe punishment should be awarded only when due to administration of spurious adulterated or not of standard quality medicines death has caused or some bodily harm is caused. He said that IDMA has made a strong representation and we are hopeful that Government will consider our suggestions.

IDMA sent a representation on the 22nd August 2022 giving IDMA's suggestions along with detailed proposed amendments to the Under Secretary (Drugs Regulation), Ministry of Health & Family Welfare with copies to the Joint Secretary (Health) and the Secretary, DoP.

Mr. S M Mudda said that IDMA has made a strong representation and we are hopeful that Government will consider our suggestions.

10. Revising Disintegration Time for Soft Gelatin Capsules

IDMA made a representation on the 14th November 2022 to Secretary-cum-Scientific Director, IPC wrt revising of Disintegration Time for Soft Gelatin Capsules. Vide this representation IDMA requested for another meeting to discuss outcome and take a rationale and consensual stand in the matter of Disintegration Time downward revising for soft gelatin capsules.

11. Proposal to amend Schedule V of the Drugs and Cosmetics Rules, 1945 to revise the limit of 'Free Salicylic Acid Test' for medicines containing Aspirin

IDMA made a representation on the 09th December with respect to Proposal to amend Schedule V of the Drugs and Cosmetics Rules, 1945 to revise the limit of 'Free Salicylic Acid Test' for medicines containing Aspirin. Vide this representation, IDMA requested the Ministry of Health & Family Welfare to revise the free salicylic Acid contents shall not be more than 3.0 per cent. Copy of this representation was also marked to DCGI.

Mr. Mudda said that he would be interested in taking an initiative to have certain sessions for building capacities of the quality management systems in wake of the recent development that have happened. Especially as there are a lot of red flags issued by international regulatory authorities. He said that he is interested in conducting training sessions and requested IDMA to request for financial assistance for these seminars/workshops under the SPI scheme or other scheme which will help our members.

IDMA AWARDS

IDMA – N I GANDHI CHIEF MENTOR AWARDS 2021

1.	Mr. S V Veeramani
2.	Mr. Deepnath Roy Chowdhury

IDMA - APTAR INNOVATION OF THE YEAR AWARDS 2021

1.	**Zydus Lifesciences Ltd** For your Outstanding Innovation in the year 2021**: DNA Vaccine ZyCoV –D**
2.	**Swati Spentose Pvt Ltd** For your Outstanding Innovation in the year 2021**: Pentosan Polysulfate Sodium - Intravesical Instillation**

IDMA CORPORATE CITIZEN AWARDS 2021

1.	Category : Turnover Rs. 500 Crores & above	**Zydus Lifesciences Ltd.**
2.	Category : Turnover Less than Rs.500 Crores	**RPG Life Sciences Ltd.**

IDMA MARGI PATEL CHOKSI MEMORIAL BEST PATENT AWARDS 2019 – 2021

Sr. No	Name of the Party	Award
1	M/s Emcure Pharmaceuticals Ltd.	BEST INTERNATIONAL PATENT AWARD 2019-2021
2	M/s Apex Laboratories Pvt. Ltd.	BEST FORMULATION PATENT AWARD 2019-2021
3	M/s Fermenta Biotech Ltd.	BEST BIOTECH API PATENT AWARD 2019-2021
4	M/s Honour Lab Ltd.	BEST API PATENT AWARD 2019-2021
5	M/s Indoco Remedies Ltd.	BEST COMPOSITION PATENT AWARD 2019-2021
6	M/s Imedrix Systems Pvt Ltd.	BEST DEVICE PATENT AWARD 2019-2021
7	M/s Halewood Laboratories Pvt. Ltd.	PATENT APPRECIATION AWARD 2019-2021
8	M/s RPG Life Sciences Ltd.	PATENT APPRECIATION AWARD 2019-2021
9	M/s. Avik Pharmaceuticals Limited	PATENT APPRECIATION AWARD 2019-2021
10	M/s Biocon Limited	BEST BIOTECH PATENT AWARD 2019-2021

11	M/s Hetero Drugs Ltd.	BEST INDIAN PATENT AWARD 2019-2021
12	M/s Aurobindo Pharma Ltd.	BEST API PATENT AWARD 2019-2021
13	M/s Neon Laboratories Ltd.	BEST PROCESS PATENT AWARD 2019-2021
14	M/s Gennova Biopharmaceuticals Limited	PATENT APPRECIATION AWARD 2019-2021

IDMA ACG - SCITECH RESEARCH PAPER AWARDS 2020 - 2021

In order to encourage R & D in the country, IDMA has instituted "Research Awards for the Best Original Research Papers" published in the "Indian Drugs" every year from the year 1981-82 and the Award for the Best Review Article was instituted in 2001. The Best Original Research Papers are evaluated in the following disciplines:

1. Pharmaceutical Chemistry
2. Natural Products
3. Pharmaceutics
4. Pharmaceutical Analysis
5. Pharmacology

The Award will be known as 'IDMA ACG-SCITECH RESEARCH PAPER AWARD' from this year. The IDMA ACG-SCITECH RESEARCH PAPER AWARD will be in the form of a plaque and a cash award of Rs.5,000/- in each discipline and the Best Review Article Award is in the form of a citation and special cash award of Rs.7,500/-. These Awards are presented to the recipients during the IDMA Annual Day Celebrations every year.

IDMA ACG-SCITECH RESEARCH PAPER AWARDS 2020 & 2021

1. REVIEW ARTICLE

Paper : ***Non-steroidal Human Performance Enhancing Agents***

Authors : Mehta Gaurav, Joshi Maithili and Joshi Shreerang

Institute : Institute of Chemical Technology, Nathalal Parekh Marg, Matunga (E), Mumbai-400 019, Maharashtra, India

Volume : 57 (12)

Pages : 7-25

2. PHARMACEUTICAL CHEMISTRY

Paper : ***Synthesis, Biological Evaluation And Docking Studies Of Non Hepatotoxic 5-Substituted Thiazolidine-2, 4-Diones As Antidiabetic, Anti-Hyperlipidemic, Anti-Oxidant And Cytotoxic Agents***

Authors : Shukla Karuna S., Pandey Shailendra and Chawla A Pooja

Institute : Department of Pharmaceutical Chemistry, ISF College of Pharmacy, Moga - 142 001, Punjab, India

Volume : 57 (09)

Pages : 19-37

3. NATURAL PRODUCTS

Paper ***: Enhanced Anti-inflammatory and Anti-migratory effect of Herbal Nano-statins on HEPG2 cancer cells***

Authors : Mehra Akansha, Chauhan Sonal, Jain V.K. and Nagpal Suman

Institute : Amity Institute of Advanced Research and Studies (Materials & Devices), Amity University, Noida-201 303, UP, India

Volume : 57 (12)

Pages : 51-55

4. PHARMACEUTICAL ANALYSIS

Paper : ***Sensitive Bio Analytical Method Development For Venetoclax And Validation In Human Plasma By LC-ESI-MS/MS***

Author : Potluri H

Institute : Department of Chemistry, Gudlavalleru Engineering College, Gudlavalleru - 521 356, Andhra Pradesh, India

Volume : 57 (06)

Pages : 32 - 38

5. PHARMACEUTICS

Paper : ***Formulation and optimization of Ritonavir nasal nanosuspension for brain targeting***

Authors : Tapasya R. Mulam, Sanjay J. Kshirsagar and Smita P. Kakad

Institute : Department of Pharmaceutics, MET's Institute of Pharmacy, Bhujbal Knowledge City, Adgaon, Nashik - 422 003, Maharashtra, India

Volume : 58 (04)

Pages : 28-41

6. PHARMACOLOGY

Paper : ***Rapid Green Synthesis of Gold and Silver Nanoparticles Using Ethanol Extract of Kedrostis Foetidissima (Jacq.) Cogn. And Its Anticancer Efficacy Against A549 Human Lung Cancer Cell Lines***

Authors *:* Amutha Muthusamy and Lalitha Pottail

Institute : Department of Chemistry, Nallamuthu Gounder Mahalingam College, Pollachi, Coimbatore - 642 001, Tamilnadu, India

Volume : 58(03)

Pages : 30-40

REPRESENTATIONS SUBMITTED DURING 2022

Sl.No.	Particulars	Date of submission	Addressed to
01	Request for Extension of existing concessional GST rates on certain Covid 19 treatment drugs for a period of 6 months	07.01.2022	Chairman, CBIC
02	Request for extension under MoEFCC notification dt. 16.7.2021 (SO 2859€) – up to 31.12.2022	11.01.2022	Sanjay Meena, SO, DoP
03	IDMA's view wrt India@2047	11.01.2022	Ms. Nidhi Mani Tripathi, JS (Commerce)
04	Difficulties faced by Member Companies with MEIS Scrips and its Validity	19.01.2022	Commerce Secretary
05	Production Linked Incentive Scheme for Pharmaceuticals 2.0	20.01.2022	Joint Secretary (Pharma), DoP
	Classification of Aerosl Therapy Apparatus	20.02.2022	Medical Devices Divn, DoP

06	Lack of availability of Shipping Containers and the Impact on the Industry	27.01.2022	Mr. Sanjay Meena, Section Officer, DoP. Copies to: Ms. Nidhi Mani Tripathi, Joint Secretary (Commerce), Ms. Indu Nair, Director (Commerce), Dr. Sumit Garg, Deputy Secretary, DoP and Mr. Venkat Hariharan Asha, Deputy Director, DoP
07	Implementation of Track and Trace System for Exports of Pharmaceuticals and Drug Consignments	27.01.2022	Ms. Nidhi Mani Tripathi, Joint Secretary (Commerce)
08	Request to revise IP monograph of Amoxycillin and Potassium Clavulanate Oral suspension to harmonize with BP and USP monograph	28.01.2022	Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director
09	WHO's ECDD recommendations of New Psychoactive substances	01.02.2022	Mr. Sanjay Meena, Section officer, DoP
10	Rep. wrt Public Notice on list of substances which are not under the purview of NDPS Act, 1985	03.02.2022	Narcotics Commissioner Gwalior
11	Creating synergies for Seamless Credit Flow and Economic Growth	22.02.2022	Secretary, DoP
12	Strengthening of Pharmaceuticals Industry; Submission of List of Machineries	20.04.2022	Joint Secretary, DoP
13	UCPMP – Proforma for furnishing quarterly returns on complaints received and action thereafter by Industry association as per para (8) of UCPMP Code	21.04.2022	Joint Secretary, DoP CC: Chairman, NPPA
14	Request to support Indian Pharma industry against dumping of Pharma APIs, Intermediates and KSMs by Chinese producers	21.04.2022	DG, DGTR

15	Information on Pharma Clusters in India	28.04.2022	
16	License modification under Food Safety Compliance System (FoSCoS)	11.05.2022	Mail letter to CEO, FSSAI
17	Food Safety and Standards (Health Supplements, Nutracetuticals Food for Special Dietary use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 [Fss (Nutra) Regulations, 2022]	11.05.2022	CEO, FSSAI
18	General Monograph of Capsules for Soft Gelatin capsules– Disintegration Limit (DT) revision (From 60 minutes to 30 minutes)	12.05.2022	Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission
19	Line of Credit with Sri Lanka	18.05.2022	Mr. Vivek Srivastava, Chief General Manager, RBI.
20	Request for removal of Bio Assay Test of Treated effluents for API as well as Formulation Manufacturing Plants that do not discharge effluents to any water body	19.05.2022	Chairman, Central Pollution Control Board (CPCB)
21	Inputs for upcoming India-Ghana JTC	24.05.2022	Section Officer, DoP
22	IDMA's view on Trade Margin Rationalization (TMR) on Drugs	28.05.2022	Chairman NPPA Cc to: Member Secretary, NPPA & Adviser (Cost) NPPA
23	IDMA's feedback on Proposed Research Linked Incentive (RLI)	01.06.2022	Joint Secretary, DoP
24	Recommendations on draft National Medical Commission registered Medical Practitioner (professional Conduct) Regulations 2022	23.06.2022	Dr. Anchal Gulati, President (EMRB), National Medical Commission

25	Proforma for furnishing quarterly return on complaints received and action taken thereafter by Industry association as per Para (8) of UCPMP Code for the Quarter ended 30 th June 2022	06.07.2022	Joint Secretary DoP Cc: Chairman, NPPA
26	IDMA representation for seeking clarification in respect of Section 194R (regarding TDS on Samples, etc.) of the Income Tax Act, 1961	12.07.2022	Chairman, CBDT
27	Manufacturers to affix Bar Code or Quick Response Code on the packaging label to store data or information legible with software application to facilitate authentication	13.07.2022	Under Secretary (Drugs), Ministry of Health &Family Welfare
28	Joint representation for declaring RoDTEP rate for Pharma sector – IDMA, IPA, BDMA & FOPE	11.08.2022	Hon'ble Smt. Nirmala Sitharaman, Minister of Finance
29	IDMA Representation on Draft New Drugs, Medical Devices and Cosmetics Bill 2022	22.08.2022	Under Secretary (Drugs Regulation), MoHFW
30	Issue of counterfeit Technical Grade Urea being supplied to the Industry	01.09.2022	Director of Agriculture, Gujarat State
31	Congratulatory letter for approval of Three Bulk Drug Parks	03.09.2022	Hon'ble Minister of HFW and C&F
32	Exponential increase in the import of Acetic Anhydride examination of reason	03.09.2022	Sh. Piyush Kumar, Asstt. Director (Enforc), NCB,
33	Food Safety And Standards (Health Supplements, Nutraceuticals, Food For Special Dietary Use, Food For Special Medical Purpose And Prebiotic And Probiotic Food) Regulations, 2022	05.09.2022	CEO, FSSAI

34	Request to impose anti-dumping duty on & Ofloxacin and its intermediates & following dumping and injury to the domestic industry found by the DGTR	30.09.2022	Secretary, Deptt. of Revenue
35	IDMA's representation on Revision of Ceiling Price under NLEM 2022	14.10.2022	Chairman NPPA
36	Public Notice on list of substances which are not under the purview of NDPS Act, 1985	14.10.2022	Narcotics Commissioner, Gwalior
37	Representation wrt Controlled Substances	14.10.2022	Narcotics Commissioner, Gwalior
38	Proforma for furnishing quarterly return on complaints received and action thereafter by Industry Association as per Para 8 of UCPMP	01.11.2022	Joint Secretary, DoP Cc to: Chairman, NPPA
39	Revising Disintegration Time for Soft Gelatin Capsules	14.11.2022	Secretary-cum-Scientific Director, IPC
40	Rationalization of Compliance Burden related to Drugs and Pharmaceutical industry in India	18.11.2022	Ms. Supriya Devanthali, Director, DPIIT
41	Rules of Origin (RoO) – views on Roll up/Absorption principle	22.11.2022	Ms. Taruna Doliya, Deputy Secretary, Deptt. of Commerce
42	IDMA's proposals wrt seeking Budget Tax proposals (Basic Customs Duty and Income Tax) for Budget 2023-24	26.11.2022	Mr. Sanjay Meena Under Secretary, DoP
43	IDMA's representation for IPDMS 2.0 – DPCO 2013	28.11.2022	Member Secy., NPPA Cc : Chairman NPPA
44	IDMA proposals for Budget 2023-24	28.11.2022	Mr. K.C. Varshney, Joint Secretary (TPL-1) and Ms. Limatula Yaden, Joint Secretary (TRU-1)
45	IDMA's representation wrt QR Code on Active Pharmaceutical Ingredients	05.12.2022	Joint Secretary (Health)

46	IDMA representation on the Third High Level Committee meeting on Marketing Practices by Pharma Companies – UCPMP	08.12.2022	Dr. Vinod K Paul, Member NITI Aayog, Cc to: Secretary, DoP Secretary, Health Chairman CBDT Jt. Secretary, DoP
47	Proposal to amend Schedule V of the Drugs and Cosmetics Rules, 1945 to revise the limit of 'Free Salicylic Acid Test' for medicines containing Aspirin	09.12.2022	Dr. Mandeep Bhandari, Joint Secretary (Health)
48	Special discounted price of HPLC for IDMA member	20.12.2022	Dr. N Yuvaraj, Joint Secretary, DoP

WEBINARS AND MEETINGS IN 2022

Date	Subject	Organized / attended by
05.01.2022	Virtual meeting on present availability of COVID management drugs formulation as well as API – Chair: Secretary, DoP	Dr. Viranchi Shah, Mr. Ashok Madan
06.01.2022	60th Annual General Meeting of IDMA	IDMA
08.01.2022	Web Meeting Chaired by Ms. Nidhi Mani Tripathi JS(Commerce) on Vision Document for the pharma sector at INDIA@2047	Dr.Viranchi Shah, Mr. Ashok Madan
11.01.2022	Online consultations on India-Australia FTA	
12.01.2022	VC meeting chaired by Commerce Minister – Issues and suggestions from Industry	Dr. Viranchi Shah, Mr. Mehul Shah
14.01.2022	VC meeting – India-Tunisia JWG meeting on Drugs & Pharma – chaired by Dr. N. Yuvaraj, JS, DoP	Mr.Yogin Majmudar, Mr. Ashok Madan
18.02.2022	IDMA Executive Committee meeting	IDMA, Mumbai
20.01.2022	Meeting with Ms. Roli Singh, Addl. Secretary (Health)	Mr. Ashok Madan
21.01.2022	IDMA Executive Committee meeting	
21.01.2022	Consultation Meeting wrt ROO for India- Australia FTA	Mr. Ashok Madan

28.01.2022	Inauguration of NIPER Research Portal by Hon'ble Minister (Chemicals & Fertilizers)	Dr. Viranchi Shah, Dr. George Patani, Mr. Manoj Kumar, Mr. Satish and Mr. Ashok Madan
28.01.2022	Brainstorming session to seek suggestions for increasing usage of the National Single Window System	Mr. Daara Patel, Mr. Ashok Madan
28.01.2022	Workshop for Indian Pharma exporters on Accessing Canadian Market organised by Pharmexcil	
28.01.2022	Inauguration of NIPER Research Portal by Hon'ble Dr. Mansukh Mandaviya ji, Minister of C&F	Dr. Viranchi Shah, Dr George Patani, Mr. Satish and Mr. Ashok Madan
02.02.2022	Mr. Rajneesh Tingal, Joint Secretary, DoP & Dr. N. Yuvaraj, Joint Secretary, DoP	Mr Ashok Madan
07.02.2022	Online Consultation on Export Target for Oceania region	Mr. Tushar Korday, Mr. Ashok Madan
10.02.2022	Meeting with Ms. Nidhi Mani Tripathi, Addl. Secy. Commerce	Mr. Ashok Madan
10.02.2022	Third meeting of committee for drafting SOP for pooling research resources for facilitating drug research and development	NITI Aayog
16.02.2022	DEMO for IDMA Members Re National Single Window System	Mr. Jayaseelan, Mr Sivanandan, Mr Sumit Agrawal, Mr Siddharth Paul, Mr Ashish Roy, Mr P k Gupta, Mr Daara Patel, Mr. Ashok Madan
17.02.2022	VC meeting – Single Window solution for administration of all Green Clearances (Updation of Parivesh portal)	
18.02.2022	IDMA Executive Committee meeting – VC mode	Mr. Ashok Madan

22.02.2022	India UK FTA Stakeholders consultation chaired by Joint Secretary Commerce	
22.02.2022	Web meeting to discuss issues regarding supply of Codeine Phosphate	Mr. Devesh Malladi
23.02.2022	Meeting with Mr. Vivek Aggarwal, Addl. Secretary (Revenue)	Mr. Devesh Malladi
03.03.2022	Post Budget webinar on "Make in India for the World"	DPIIT
04.03.2022	VC meeting on Creating synergies for seamless credit flow and economic growth	Mr Rajesh Shah, Mr. S.R. Vaidya, Mr. Bharat Desai & Mr. Ashok Madan
04.03.2022	National Conference on Economics of Competition Law	CCI
08.03.2022	Meeting with the Industry leaders from the Pharma Sector for the purpose of consultations on India Australia FTA	Dr. Viranchi Shah, Dr Gopakumar Nair, Mr. Bhavin Mehta, Mr. Ashok Madan
09.03.2022	Workshop on amendments in the NDPS Act 1985	Mr. Devesh Malladi
09.03.2022	Meeting with Mr. Vivek Aggarwal, Addl. Secretary Revenue	Mr. Devesh Malladi
09.03.2022	Follow up of different issues with DoP	Mr. Ashok Madan
11.03.2022	Webinar on 'Direct Taxation in India: Benefits for Pharmaceutical and Medical Devices Industry'	Mr. BG Barve Mr. Ashok Madan
14.03.2022	Roundtable meeting with Mr Jay Allen, Canada Chief Negotiator of CEPA	Mr. Ashok Madan
15.03.2022	Meeting with Commercial Attache, Royal Embassy of Saudi Arabia	Mr. Ashok Madan
17.03.2022	Meeting to review the submission of quarterly reports of UCPMP	Mr. Deepnath Roy Chowdhury & Mr. Ashok Madan
29.03.2022	IPDMS 2.0 Webinar called by NPPA	Dr. Amit Rangnekar
29.03.2022	IDMA Executive Committee meeting – VC meeting	

06.04.2022	IDMA delegation visit to Delhi to meet the following: 1. Ms S. Aparna , Secy DOP. 2. Dr N Yuvraj , JS,DOP 3. Mr Rajneesh Tingal JS, DOP 4. Mr HK Hajong , Economic Adviser JS, DOP 5. Mr K K Pant, Chairman , NPPA 6. Ms Roli Singh, Additional Secretary, Min of Health. 7. Ms Indu Nair, Director, Ministry of Cömmerce . 8. Dr V G Somani, DCGI. 9. Mr Arun Pradhan , Joint DCI.	Dr Viranchi Shah, Mr Mahesh Doshi, Mr Bharat Shah, Mr Mehul Shah and Mr. Ashok Madan
13.04.2022	Interaction with MSME Associations to orient them on the Scheme "Strengthening of Pharmaceuticals Industry" of DoP and various MSME Schemes by Ministry of MSME	Mr. S R Vaidhya, Mr. Bharat Desai
13.04.2022	IDMA Executive Committee meeting @ Mumbai	
14.04.2022	IDMA Diamond Jubilee Celebrations @ Mumbai	
15.04.2022	IDMA Diamond Jubilee Celebrations @ Mumbai	
16.04.2022	Interaction with MSME Associations to orient them on the Scheme "Strengthening of Pharmaceuticals Industry" of DoP and various MSME Schemes by Ministry of MSME	Mr. S. R. Vaidya, Mr. Bharat Desai and Mr. Ashok Madan
25th, 26th and 27.04.2022	India Pharma 2022 & India Medical Devices 2022	Dr. Viranchi Shah, Mr. Mehul Shah, Mr. Kamlesh C Patel, Mr. Nirav Mehta, Mr. S.M. Mudda, Mr. Ashok Madan, Mr. Vikrant Parashar
10.05.2022	Meeting with new Director General, Health Services	Mr Ashok Madan
14.05.2022	Cancer Foundation: Panel discussion on Pricing, Licensing and Patent: Way to go	Mr. Ashok Madan
18.05.2022	India-Canada CEPA - Detailed Consultation on Rules of Origin with the Pharma Sector	Mr. Ashok Madan
20.05.2022	Stakeholders consultation on Trade Margin Rationalization (TMR) on Drugs	Dr. Amit Rangnekar, Mr. Ashok Madan

20.05.2022	IDMA Executive Committee VC meeting	Mumbai
25.05.2022	Preparatory Meeting w.r.t. India- EU JWG on Pharmaceuticals	Mr. Tushar Kordey
26.05.2022	VC meeting of CEO level on proposed Research Linked Incentive (RLI) Scheme	Dr. Viranchi Shah, Mr. Mahesh Doshi
13.06.2022	Meeting with Dr. Mandeep Bhandari, Joint Secretary (Health) at IDMA, Mumbai office	
15.06.2022	Meeting with Mr. Arun Singhal, CEO, FSSAI	Mr. Ashok Madan
16.06.2022	Meeting with Dr. (Ms. Vinod Kotwal, MS, NPPA, Mr. Manmohan Sachdeva, Adviser (Cost), Mr. Sanjay Kumar, Adviser (Cost)	Mr. Ashok Madan
20.06.2022	VC meeting on Launch of Scheme for Strengthening of Pharmaceuticals Industry	Mr. S. R. Vaidya, Mr. Bharat Desai, Mr. Daara Patel, Mr. AK Madan, Ms. Sapna Patil
01.07.2022	Release of Indian Pharmacopoeia 2022 @ Vigyan Bhawan	Dr. Viranchi Shah, Mr. Mehul Shah, Dr. George Patani, Mr. Ashok Madan
01.07.2022	Meeting with Country Head, USFDA	Dr. Viranchi Shah, Mr. Mehul Shah, Dr. George Patani, Mr. Ashok Madan
04.07.2022	VC meeting of Stakeholder on India-UK FTA chaired by Ms. Nidhi Mani Tripathi, JS Commerce	Mr. Bhavin Mehta, Mr. Ashok Madan
05.07.2022	Meeting with Member Secretary, NPPA wrt NPPA's Silver Jubilee Celebrations	Mr. Ashok Madan
07.07.2022	Meeting with Pharmaceutical industry for identifying the chemicals used by Pharmaceutical sector	Mr. Ashok Madan
12.07.2022	Meeting with Hon'ble Minister of Health	Dr. Viranchi Shah

12.07.2022	Meetings with Dr. Mandeep K Bhandari, Joint Secretary (Health), Dr. N. Yuvaraj, Joint Secretary (Policy), DoP & Mr. Rajneesh Tingal, Joint Secretary (Pricing) DoP	Dr. Viranchi Shah, Mr. Ashok Madan
12.07.2022	VC meeting on Manufacturing of critical inputs required for Vaccines (Biopharmaceuticals) Chaired by Dr. N. Yuvaraj, Joint Secretary, DoP	Mr. Ashok Madan
19.07.2022	Meeting with Mr. KK Pant, Chairman NPPA & Dr. Vinod Kotwal, Member Secretary, NPPA	Mr. Ashok Madan
21.07.2022	Meeting on Strengthening of Pharmaceutical Industry	Dr. Viranchi Shah, Mr. S R Vaidya and Mr. Ashok Madan
29.07.2022	**Web meeting** to discuss the New Drugs, Cosmetics and Medical Devices Bill – Chaired by Secretary, DoP	Mr. S.M. Mudda, Mr. SW Deshpande, Dr. RK Sanghavi, Mr. Ashok Madan
04.08.2022	Hybrid meeting of the Inter-Ministerial Committee on 'dual use' and illicit trafficking of prescription drugs and precursors	Mr. Devesh Malladi
05.08.2022	Meeting of Hon'ble Minister of Commerce & Industry with EPCs and Associations	Mr. Ashok Madan
05.08.2022	Outreach cum Awareness Programme on Strengthening of Pharmaceutical Industry	Ahmedabad
10.08.2022	Meeting to discuss extension of TRIPS decision to therapeutics and diagnostics – JS (Pharma), DoP	
12.08.2022	Outreach cum Awareness Programme on Strengthening of Pharmaceutical Industry	Mumbai
23.08.2022	DPIIT Conclave on Public Procurement (Preference to Make-in-India) Order, 2017 @ Vanijya Bhawan, New Delhi	Mr. Ashok Madan
25.08.2022	FICCI-PSA National Seminar on FDI in R&D – Making India R&D Hub	Mr. Ashok Madan
26.08.2022	Stakeholders consultation meeting on VisionIndia@2047	Mr. Pranav Choksi

29.08.2022	Silver Jubilee Celebrations of NPPA	Dr. Viranchi Shah, Dr. Amit Rangnekar, Mr. Ashok Madan, and other IDMA members
05.09.2022	Meeting on Blended Finance	Mr. Ashok Madan
16.09.2022	Workshop on the proposal for Introduction of Ease of Doing Business and Ease of Living (Amendment of Provisions) Bill 2022	Mr. Ashok Madan
21.09.2022 & 22.09.2022	Global Regulators Conclave 2022 : International Exhibition for Pharma and Healthcare (iPHEX)	Dr. Viranchi Shah, Mr. Ashok Madan
23.09.2022	CII 4 th Lifesciences Conclave 2022	Dr. Viranchi Shah, Mr. Ashok Madan
28.09.2022	UNIDO-DST stakeholder discussion on Pharma Manufacturing Systems of Innovation	Mr. Ashok Madan
06.10.2022	Meeting on Process flow for routing project proposals seeking technical assistance from UNIDO	Mr. Ashok Madan
10.10.2022	Preparatory web meetings of Joint Working Group on Pharmaceuticals with Russia, Uzbekistan and Kazakhstan	Mr. Ashok Madan
13.10.2022	Online Interactive session with Industry on IPDMS 2.0	Dr. Amit Rangnekar, Mr. Ashok Madan
14.10.2022	Meeting with Dr. Rajiv Singh Raghuvanshi, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission	Dr. R.K. Sanghavi, Mr. Vivek Tannan, Dr. Ratnakar Mehendre, Mr. Ashok Madan
18.10.2022	Virtual (Online) meeting with Dr. R. S. Sharma, Chief Executive Officer, National Health Authority	Dr. Viranchi Shah, Mr. S.M. Mudda, Dr. Amit Rangnekar, Mr. Ashok Madan

27.10.2022	Interactive Hybrid meeting on Bulk Drugs Park at Andhra Pradesh - Kakinada	Dr. Viranchi Shah, Mr. Ashok Madan
04.11.2022	Third meeting (Physical) of the High Level Committee to consider various issues pertaining to Marketing Practices by Pharma companies	Mr. Deepnath Roy Chowdhury, Mr. Mehul Shah, Mr. Ashok Madan
10.11.2022	Online meeting on Product Specific Rules (PSRs) for Chapters 29 and 30 for FTA with Canada	Mr. Ashok Madan
11.11.2022	Interactive meeting with Saudi FDA	Mr. Ashok Madan
11.11.2022	Interactive meeting wrt introduction of provisions in DPCO for fixation of prices for formulations going off-patent drugs,	Mr. Ashok Madan
15.11.2022	VC meeting wrt Outreach Programme on sub-scheme PTUAS – Maharashtra, Goa and other states	Mr. S.R. Vaidya
17.11.2022	Stakeholders meeting on implementation of perspectives related to GSR 20€, dt.18.1.2022 mandating QR Code for APIs manufactured or imported in India	Mr. Manish Doshi
21.11.2022	Meeting to discuss extension of TRIPS decision to therapeutics and diagnostics	Mr. Ashok Madan
24.11.2022	VC meeting on Blended Finance with Industry	Mr. Mehul Shah, Mr. B.G. Barve, Mr. Ashok Madan
25.11.2022	VC meeting wrt Outreach Programme on sub-scheme PTUAS – Chennai, Puducherry, Karnataka, AP, Telengana	Mr. J. Jayaseelan
28.11.2022	Meeting with Dr. (Ms.) Vinod Kotwal, Member Secretary NPPA	Mr. Ashok Madan
30.11.2022	NPPA Webinar on tracking the drugs: Ensuring Last Mile Availability	Dr. Viranchi Shah, Mr. Ashok Madan
30.11.2022	Physical meeting on Pre-Budget for Union Budget 2023-24 (Min. of Finance)	Mr. Ashok Madan
05.12.2022	Meeting with Dr. Awadesh Choudhary, Sr. Economic Advisor, DoP Meeting with Mr. Rajneesh Tingal, JS, DoP	Mr. Ashok Madan
06.12.2022	Meeting with Sh. Sudhansh Pant, OSD, Ministry of Shipping @ Room No. 403, Parivahan Bhawan	Mr. Ashok Madan
07.12.2022	Meeting with Dr. Mandeep Bhandrai, JS (Health)	Mr. Ashok Madan

07.12.2022	Meeting with Mr. Vivek Aggarwal, Addl. Secretary (Revenue)	Mr. Devesh Malladi, Dr. Azadar Khan
12.12.2022	2nd Interactive session with Industry stakeholders on IPDMS Ver 2.0 – Web meeting	Dr. Amit Rangnekar
15.12.2022	Meeting with Ms. Indu C Nair, Joint Secretary Commerce	Mr. Ashok Madan
29.12.2022	Review meeting by Hon'ble Minister of Health & Family Welfare & Chemicals and Fertilizers with Pharma Industry as part of Covid preparedness	Dr. Viranchi Shah, Mr. Ashok Madan

IDMA REPRESENTATION IN COMMITTEES – 2022

- Reconstitution of National Medical Devices Promotion Council under chairpersonship of Secretary, DoP – 5.8.2022
- Constitution of High Level Committee to consider various issues pertaining to UCPMP – 12.9.2022
- Constitution of Committee to examine adverse events related to drugs manufactured by Maiden Pharmaceuticals, Sonipat Haryana as per WHO alert – 11.10.2022

APPOINTMENTS

January 2022

- **Shri Santosh Kumar Sarangi, IAS (OR:94)** Addl. Secretary, Department of School Education and Literacy, Ministry of Education has been appointed as Director General, **Directorate General of Foreign Trade** (DGFT) vide DoPT order dt. 18.01.2022.

February 2022

- **Mr Sanjay Malhotra IAS (RJ:90)** as Secretary, Department of Financial Service. Ministry of Finance. Appointments committee has approved the appointment, vide DoPT order dated 08/2/20
- **Mr Alkesh Kumar IAS (KL 90)** as Special Secretary (Coordination) in Cabinet Secretariat. Appointments committee has approved the appointment, DoPT order dated 08/2/2022.
- **Ms Arti Ahuja IAS (OR:90)** as Secretary, Department of Chemicals and Petrochemicals. Appointments committee has approved the appointment, DoPT order dated 08/2/2022.
- **Mr. Chaitanya Murti, IFoS (TR:1995),** has been appointed as Joint Secretary, Department of Bio-Technology, vide DoPT order dt.23.2.2022.
- **Mr. M. Balaji, IAS (TN 2005)** has been appointed as Joint Secretary, Deptt. Of Commerce vide DoPT order dt.23.2.2022.

- **Mr. Krishan Kumar IAS (OD:2002**) has been appointed as Joint Secretary, Deptt. Of Commerce vide DoPT order dt.23.2.2022.
- **Shri R Ramakrishnan, IAS (NL: 1998**) has been appointed as Senior Deputy Director General (Admn.), ICMR vide DoPT order dt.23.2.2022.
- **Mr. Mahendra Kumar Gupta, IRPS (1998)** has been appointed as Joint Secretary, Council of Scientific & Industrial Research (CSIR) vide DoPT order dt.23.2.2022.

March 2022

- **No new appointments**

April 2022

- **Mr. Vinay Mohan Kwatra, IFS (1998),** has been appointed as Foreign Secretary with effect from 1.5.2022 vide DoPT order of 4.4.2022.
- The Appointment Committee of the Cabinet has approved extension in the services of **Prof. Balram Bhargava as Director General ICMR - cum-Secretary, Department of Health Research** for a period of three months beyond 15.4.2022 vide DoPT Order dated 11.4.2022.
- **Dr. Atul Goel, Director Professor** (General Medicine) has been appointed as **Director General of Health Services (DGHS)** vide Ministry of Health & Family Welfare order dated 18.4.2022.
- **Prof. Ajay Kumar Sood**, Member – Science, Technology and Innovation Advisory Council to the Prime Minister has been appointed as **Principal Scientific Advisor to the Government of India** vide DoPT order dated 20.04.2022.
- **Dr Suman K Bery appointed as Vice Chairman of NITI AAYOG** w.e.f 1st May 2022 consequent to resignation of Mr Rajiv Kumar. Mr Suman Bery was earlier DG of NCAER from 2001 to 2011 and is member of PMs Economic Advisory Council.
- Appointment Committee of the Cabinet has approved the proposal of Deptt. of Commerce for extension of Central deputation tenure under the Central Staffing Scheme of **Ms. Indu C Nair, Director Commerce for a period of two years beyond 11.4.2022 and up to 11.04.2024,** vide DoPT order dated 23.04.2022.
- Appointment Committee of the Cabinet has approved the proposal of NITI Aayog for extension of central deputation tenure of **Mr. Pawan Kumar Sain, IAS (AGMUT 2005), Joint Secretary, Economic Advisory Council (EAC) to PM, NITI Aayog for a period of one year beyond 24.07.2022** vide DoPT order, dated 23.04.2022.
- **Prof. (Dr) Unnat P. Pandit** has been appointed as **Controller General of Patents, Designs and Trade Marks** on 11th April 2022.
- Consequent to superannuation of Prof Shekar Mande, **Dr Rajesh S. Gokhle, Secretary, Department of Biotechnology has been given additional charge** of **Director General, CSIR-cum-Secretary, Department of Scientific & Industrial Research** vide DoPT Order of 29th April 2022.

May 2022

- **Appointment of Shri Tarun Kapoor, IAS (Retd.) (HP: 1987) as Advisor to the Prime Minister**, in the Prime Minister's Office, vide DoPT order of 2nd May 2022.
- **Appointment of Shri Hari Ranjan Rao, IAS (MP:1994),** currently Administrator, Universal Services Obligation Fund, Department of Telecommunications, **as Additional Secretary, Prime Minister's Office** vide DoPT order of 2nd May 2022.
- **Appointment of Shri Atish Chandra, IAS (BH:1994),** currently CMD, Food Corporation of India, Department of Food and Public Distribution, **as Additional Secretary, Prime Minister's Office** vide DoPT order of 2nd May 2022.
- **Shri S Gopalakrishnan, IAS (TN 1991**) Addl. Secretary, Prime Minister office as **Additional Secretary, Department of Health and Family Welfare** vide DoPT order dated 13th May 2022.
- **Ms. Manisha Sinha IPoS 1992**, Joint Secretary, Department of Economic Affairs as **Additional Secretary, Department of Economic Affairs** vide DoPT order dated 13th May 2022.
- **Shri Pravir Pandey, IA&AS 1992** presently in the cadre **as Additional Secretary & Financial Advisor, Ministry of Environment, Forest & Climate Change** vide DoPT order dated 13th May 2022.
- **Ms. Richa Pandey, ICAS (2011)** has been appointed as Deputy Secretary, DoP vide DoPT order dt.23.5.2022.
- **Mr. Kiran Kumar Karlapu, IRS (C&CE 2010)** has been appointed as Deputy Secretary Health vide DoPT order dt. 23.5.2022.
- Tenure of **Mr Pankaj Kumar, IAS, (RR: GUJ: 1986)** Chief Secretary Gujarat has been extended by 8 months beyond date of superannuation, i.e. **up to 31.01.2023** vide Government of Gujarat Order dated 30.5.2022.
- Appointment Committee of the Cabinet has approved the proposal of Ministry of Health & Family Welfare for extension of Central deputation of **Mr. Lav Agarwal, IAS (AP: 1996) Joint Secretary, Deptt. of Health & Family Welfare for a period up to 28.08.2023** vide DoPT order dt.31.5.2022.

June 2022

- The Appointments Committee of the Cabinet (ACC) has approved the appointment of **Ms. Shalini Prasad, IAS (UP:85) as Special Secretary, NITI Aayog** in the rank and pay of Secretary to the Government of India by temporarily upgrading a vacant post of Additional Secretary in NITI Aayog vide DoPT order dated 9.6.2022.
- The Appointments Committee of the Cabinet has approved the extension of tenure of **Shri Vaidya Rajesh Kotecha, Secretary, Ministry of AYUSH** on contract basis for a period of two years beyond 28.06.2022 i.e. **up to 28.06.2024** or until further orders vide DoPT Order dated 9.6.2022.
- **Mr Arun Singhal, IAS (UP:1987) CEO FSSAI** has been empanelled for the position of Secretary

in Central Government vide DoPT order dt. 9.6.2022. He will now be promoted as Secretary to the Government of India at the Centre itself.

- **Shri Nitin Gupta, IRS (IT:1986**) has taken over as Chairman of Central Board of Direct Taxes (CBDT) from June 27th June, 2022.

July 2022

- Appointment committee of the Cabinet has approved the appointment of **Shri Manish Kumar Sinha IRS (C&CE 1993**) as Chief Executive Officer, Goods and Service Tax Network (GSTN).
- **Ms. Gayatri Nair (IES:2004)** Economic Adviser, State Planning Board, Government of Kerala has been transferred and to be posted as Director, DoP vide Deptt. of Economic Affairs, order dt.11.7.2022.

August 2022

- **Dr (Ms) K. Kalaiselvi,** Director, Central Electrochemical Research Institute has been appointed as Director General, CSIR–cum-Secretary DSIR vide DoPT order dt.6.8.2022.
- Appointment Committee of Cabinet has approved the appointment of **Shri Satendra Singh, IAS (JH:95),** Additional Secretary & Financial Advisor, Ministry of Chemicals & Fertilizers as Additional Secretary, Cabinet Secretariat vide DoPT order dated 10.8.2022.
- Appointment Committee of Cabinet has approved the appointment of **Shri Pankaj Kumar Singh, IDAS:94**, Joint Secretary, Ministry of Housing & Urban Affairs as Additional Secretary, GST Council Secretariat, Department of Revenue vide DoPT order dated 10.8.2022..
- Appointment Committee of Cabinet has approved the appointment of **Shri Shyamal Misra, IAS(HY:96), Joint Secretary**, Deptt. of Home, Ministry of Home affairs, as Additional Secretary, Deptt. of Home, Ministry of Home Affairs vide DoPT order dated 10.8.2022
- Appointment Committee of Cabinet has approved the appointment of **Shri Lav Aggarwal, IAS** (AP:96), Joint Secretary, Department of Health & Family Welfare as Additional Secretary, Department of Health & Family Welfare vide DoPT order dated 10.8.2022.
- The Appointments Committee of the Cabinet has approved the appointment of **Dr. Krishnamurthy Subramanian**, Professor (Finance), Indian School of Business and former Chief Economic Adviser to the post of **Executive Director (India) at the International Monetary Fund (IMF)**, w.e.f 01.11.2022 for a period of three years vide DoPT order dated 25.08.2022.

September 2022

- **Shri Arun Singhal, IAS (UP 1987)**, CEO, FSSAI has been appointed as **Secretary, Department of Fertilizers** vide DoPT order dated 15.09.2022.
- **Shri Sunil Barthwal, IAS (BH 1989)** has been appointment as **Secretary, Department of Commerce** on 30.09.2022 vide DoPT order dated 15.09.2022.
- **Shri S Gopalakrishnan, Addl. Secretary, Ministry of Health & Family Welfare will hold the additional charge of CEO, FSSAI** for a period of three months vide MoHFW Order dated.

17.09.2022.

- **Shri L Satya Srinivas, IRS (C&IT:91)** Addl. Secretary, Ministry of Home Affairs has been appointed as **Addl. Secretary, Department of Commerce** vide DoPT order dated 25.9.2022
- **Shri Jaideep Kumar Mishra, ICAS:93,** Addl. Secretary, Ministry of Electronics and Information Technology has been appointed as **Additional Secretary and Financial Adviser, Ministry of Health & Family Welfare** vide DoPT order dated 25.9.2022.
- **Ms. V. Hekali Zhimomi, IAS (UP:1996), Joint Secretary**, Deptt. of Health & Family Welfare has been appointed as **Additional Secretary, Deptt. of Health & Family Welfare,** vide DoPT order dated 25.9.2022.

October 2022

- The Appointments Committee of the Cabinet has approved the appointment of **Ms. Indu C Nair, IRAS (2001), as Joint Secretary, Department of Commerce**, from the date of assumption of the charge of the post, for an overall tenure of seven years up to 11.04.2024 or until further orders, whichever is earlier, by temporarily upgrading the post of Director held by the officer, to be further adjustable against a regular vacancy of Joint Secretary in the Department vide DoPT Order dated 2nd October 2022;
- The Appointments Committee of the Cabinet has approved the appointment of **Shri Sachin Mittal, IPoS (2000), as Joint Secretary, Department of Health & Family Welfare**, from the date of assumption of the charge of the post, for an overall tenure of seven years up to 21.06.2023 or until further orders, whichever is earlier, vice Shri Vikas Sheel, IAS (CG:94) vide DoPT Order dated 2nd October 2022.

November 2022

- The Appointments Committee of the Cabinet (ACC) has approved the following appointments vide DoPT order dated 19.11.2022:
- Ms. Sumita Dawra, IAS (AP:91), Special Secretary, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry as Special Secretary (Logistics), Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry.
- Shri Rajesh Agarwal, IAS (MN:94), presently in the cadre, as Additional Secretary, Department of Commerce, Ministry of Commerce & Industry.
- Shri Peeyush Kumar, IAS (AP:97), Joint Secretary, Department of Economic Affairs, Ministry of Finance as Additional Secretary, Department of Commerce, Ministry of Commerce & Industry.
- The Appointments Committee of the Cabinet has approved extension in service to Shri Vinay Mohan Kwatra, (IFS:1988), as Foreign Secretary beyond the date of his superannuation i.e. 31.12.2022 up to 30.04.2024 or until further orders, whichever is earlier, vide DoPT order dt. 26.11.2022.
- The Appointments Committee of the Cabinet has approved the Appointment of Ms. Ankita Mishra Bundela, IAS {UT:2001), as Joint Secretary, Department of Health & Family Welfare,

from the date of assumption of charge of the post, for a tenure of five years or until further orders, whichever is earlier, vice Ms. V Hekali Zhimomi, IAS (UP: 1996), vide DoPT order dt. 26.11.2022.

- **Mr. Arun Baroka, IAS (UT:90), Secretary, Department of Chemicals & Petrochemicals has been given additional charge of the post of Secretary, Department of Pharmaceuticals from 1.12.2022 to 31.12.2022** during the period of absence on leave of Ms. S. Aparna, Secretary, DoP vide DoPT order dt. 30.11.2022.

December 2022

- Mr. **Sanjay Malhotra, IAS ((Rajasthan: 1990) has been appointed as Finance/Revenue Secretary from 1st December 2022.**
- **Shri Ganji Kamala V. Rao, IAS (KL:90)**, as Chief Executive Officer, Food Safety & Standards Authority of India, Ministry of Health & Family Welfare in the rank and pay of Secretary to the Government of India.
- **Shri Rajneesh, IAS (HP:97),** presently in the cadre, as Additional Secretary & Development Commissioner, Ministry of Micro, Small & Medium Enterprises

REMEMBRANCE OF STALWARTS

1. Shri Arvind Hiralal Shah, Founder of Saga Lifesciences Ltd., Saga Laboratories and Saga Healthcare Pvt. Ltd.
2. Smt. Nirmalaben Shah, Mother of Mr. Vijay Shah, Vice Chairman, IDMA GSB
3. Dr. (Mrs.) Gopa Ghosh, Director I/c CDTL – Mumbai (Retired) and Indian Drugs Reviewer, IDMA
4. Dr. R B Smarta, Founder, Interlink Marketing Consultancy Pvt. Ltd.
5. Shri Amarnath R Hegde, Principal Consultant, Innova Pharma Consultants

CONSULTANTS

1. S W Deshpande	Regulatory matters
2. Chetan Doshi	Account / Finance
3. Dr S G Deshpande	Indian Drugs
4. S P Deo	Trade matters
5. Shailesh Sheth	Indirect Taxation
6. Bakul Mody	Direct Taxation

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IF IT IS PHARMACEUTICALS IT IS INDIA (2015)
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AFFORDABLE EFFICACIOUS MEDICINES ALL ROADS LEAD TO INDIA (2013)
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