INDIAN DRUG MANUFACTURERS' ASSOCIATION
SINCE 1961

60 YEARS

INDIAN PHARMA - GLOBAL HEALTH CARE

ANNUAL REPORT
60th
2020-2021

Delivering Health Care To The World

N O T I C E

The 60th Annual General Meeting of the Indian Drug Manufacturers' Association will be held on **Thursday, 6th January 2022** at **4:00 p.m.** via Zoom Video Conferencing to transact the following business:-

AGENDA

1. To read the Notice convening the meeting.

2. To adopt the Annual Report for the year 2020-2021.

3. To appoint auditors for the year 2022-2023.

4. Welcoming of Incoming National President by the Outgoing National President.

5. Any other business with the permission of the Chair.

Looking forward to welcoming you at the 60th Annual General Meeting at 4.00 p.m. virtually.

Daara B Patel
Secretary - General

Date: January 03, 2022

IDMA EXECUTIVE COMMITTEE 2021

NATIONAL PRESIDENT

MAHESH H. DOSHI
Partner & Managing Director
Dy-Mach Pharma
B-12, Anand Sagar, Old Nagardas Road,
Andheri (E), Mumbai – 400 069.

IMMEDIATE PAST NATIONAL PRESIDENT

DEEPNATH ROY CHOWDHURY
Managing Director
Strassenburg Pharmaceuticals Ltd.
70 Hazra Road,
Kolkata – 700 019

SR. VICE-PRESIDENT

DR VIRANCHI SHAH
Director
Saga Laboratories Ltd.
Survey 198/2-3, Chachrawadi Vasna,
Tal. Sanand, Dist. Ahmedabad - 382 210.

VICE-PRESIDENTS

Western Region

BHARAT N SHAH
Managing Director
S. Kant Healthcare Ltd.
3-A, Shiv Sagar Estate,
Dr. Annie Besant Road,
Worli, Mumbai – 400 018.

Northern Region

BAL KISHAN GUPTA
Director
Medicamen Organics Ltd.
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

Eastern Region	**ASHEESH ROY** *Director* **Stadmed Pvt. Ltd.** Kumud, 14A Monohar Pukur Road, Kolkata - 700 026.
HON. GENERAL SECRETARY	**DR. GEORGE A. PATANI, Ph.D.** *Director* **INGA Laboratories P. Ltd.** Inga House, Mahakali Road, Andheri East, Mumbai 400 093.
HON JOINT SECRETARY	**J. JAYASEELAN** *Managing Director* **Sai Mirra Innopharm Pvt. Ltd** Tek Meadows, Tower C, 3rd Floor, Unit No. 3, No. 51, Sholinganallur, OMR, Chennai, Tamil Nadu – 600 119.
HON JOINT SECRETARY	**ATUL J. SHAH** *Executive Director* **Ellis Pharma P. Ltd.** Plot No.4, GIDC, Behrampura Opp. Khodiyar Nagar, BRTS Bus Stand Behrampura, Ahmedabad-380 022.
HON. TREASURER	**VASUDEV KATARIA** *Director* **Vindas Chemical Industries P. Ltd.** 210 Adamji Building, 413, Narsi Natha Street, Masjid Bandar (W), Mumbai 400 009.
ELECTED MEMBERS	**ASHOK DHOKA** *Director* **Maxim Pharmaceuticals Pvt. Ltd.** 08, Kshitij Co-op. Hsg Society, Opp. Sambhavnath Jain Mandir, Behind Maharshi Nagar Police Chowky, Salisbury Park, Gul Tekadi, Pune - 411 037.

B. G. BARVE
Joint Managing Director
Blue Cross Laboratories Pvt. Ltd.
Peninsula Chambers, Gr. Floor, Penninsula Corporate Park, G. K. Marg, Lower Parel, Mumbai – 400 013.

BHAVIN MUKUND MEHTA
Director
Kilitch Co. (Pharma) Ltd.
Unit No. 37, Ujagar Industrial Estate, 3rd Floor, W T Patil Marg, Deonar, Mumbai 400 088.

DR CHINMAY MAJMUDAR
Director
Bakul Aromatics and Chemicals Ltd.
Sterling Centre, 4th Floor,
Dr. A. B. Road,
Worli, Mumbai - 400 018.

D. V. P. RAJU
Managing Director
Elan Pharma (India) Pvt. Ltd.
501, Raikar Chambers
Govandi (E), Deonar, Mumbai 400 088.

DEVESH MALLADI
Managing Director
Embio Limited
501 Sentinel, Hiranandani Gardens Powai, Mumbai 400 076

DR. DUSHYANT R. PATEL
Chairman & Managing Director
Astral SteriTech Private Limited
911, G.I.D.C, Makarpura,
Vadodara - 390 010

M. RAJARATHINAM
Managing Director
MMC Pharmaceuticals Ltd.
113, Visalakshi Street, Devi Karumari Amman Nagar, Valasaravakkam, Chennai-600 087.

MEHUL M. SHAH
Managing Director
Encube Ethicals Pvt. Ltd.
803, B Wing. HDIL Kaledonia, Sahar Road, Andheri (East), Mumbai – 400 069.

NIRAV K. MEHTA
Promoter & Executive Director
Corona Remedies Pvt. Ltd.
Corona House, "C" Mondeal Business Park, Nr. Gurudwara, S. G. Highway, Thaltej, Ahmedabad – 380 059.

PROBHAS BONDHU CHAKRABORTY
Managing Director
Mendine Pharmaceuticals Pvt. Ltd.
36 A & B Alipore Road, Kolkata – 700 027.

RAJUBHAI R. SHAH
Managing Director
Mercury Laboratories Ltd.
2/13-14, BIDC Industrial Estate, Gorwa Road, Vadodara - 390 016.

S. R. VAIDYA
Group Director, Bliss GVS Pharma Ltd.
Kremoint Pharma Pvt. Ltd.
Plot No, B - 8, Additional Ambarnath, M.I.D.C., Ambarnath (E), Dist. Thane - 421 506.

VINOD KALANI
Promoter
Cris Pharma (India) Ltd. (Oasis Test House Ltd.)
SP-2, 22 Godam Industrial Area, Jaipur-302 006. Rajasthan

CO-OPTED MEMBERS

BODH RAJ SIKRI
Partner
Next Wave (India)
S.C.O. # 313, 2nd Floor, Sector 29
Gurugram – 122 009. Haryana. India

DR. AZADAR KHAN, Ph. D
Sr. Vice President
Sun Pharmaceutical Laboratories Ltd.
8 – C, 8th Floor, Hansalaya Building,
15 – Barakhamba Road, Connaught Place,
New Delhi - 110 001

DR. PRAKASH A. MODY
Chairman & Managing Director
Unichem Laboratories Ltd.
Mahalaxmi Chambers, 2nd Floor,
22 Bhulabhai Desai Road,
Mumbai – 400 026.

K. NITHYANANDA REDDY
Managing Director
Aurobindo Pharma Ltd.
Plot No. 2, MaitriVihar,
Ameerpet, Hyderabad – 500 038.

PANKAJ R. PATEL
Chairman
Cadila Healthcare Ltd. (ZYDUS GROUP)
Zydus Corporate Park,
S G Highway,
Vaishnodevi Circle, Ahmedabad – 381 481.

PRASHANT KUMAR TIWARI
Managing Director
USV Private Limited
Arvind Vithal Gandhi Chowk, BSD Marg,
Station Road, Govandi East, Mumbai - 400 088.

PREMCHAND GODHA
Chairman & Managing Director
IPCA Laboratories Limited
125, Kandivli Industrial Estate, Kandivli (West),
Mumbai – 400 067

VINAY PINTO
Executive Director
Wallace Pharmaceuticals P. Ltd.
A–303/312, Floral Deck Plaza,
Off M.I.D.C. Road, Next to Rolta Bhavan,
Andheri (East), Mumbai 400 093.

SPECIAL INVITEES

ADITI KARE PANANDIKAR
Managing Director
Indoco Remedies Limited
Indoco House, 166 C.S.T. Road,
Santacruz (E), Mumbai - 400 098

AJIT KUMAR JAIN
Joint Managing Director
IPCA Laboratories Ltd.
125, Kandivli Industrial Estate, CTS No.328,
Kandivli (West), Mumbai – 400 067.

ANIL GIDWANI
Director (Indian Operations & Global Pharma Business) Member of Board of Directors
Dana Pharmaceuticals Pvt Ltd
209 Bhaveshwar Complex, Vidyavihar (W),
Mumbai 400 086.

BHARAT R. DESAI
Managing Director
Bharat Parenterals Ltd.
Survey No. 144 & 146, village: Haripura,
Taluka: Savli, (Jarod-Samlaya Road),
Dist: Vadodara - 391 520. Gujarat.

BHUPENDRA SANGANI
Director
Galentic Pharma (India) P. Ltd.
Samruddhi Venture Park, 4th Floor,
MIDC Central Road,
Andheri (East), Mumbai – 400 093.

C. V. VENKATARAMAN
Director – Corporate Services
Lupin Limited
4th Floor, World Trade Tower, Barakhamba Avenue,Connaugh Place, New Delhi - 110 001.

CHIRAG HASMUKHLAL DOSHI
Director
Yash Medicare Pvt. Ltd.
401, Sashwat Complex, Opp. Gujarat College,
Ellisbridge, Ahmedabad – 380 006.

DR. AMIT RANGNEKAR
Vice President
Centaur Pharmaceuticals
Centaur House, Vakola,
Santacruz - East, Mumbai - 400 055

DR. DEVEN PARMAR
Sr. Director & Head Clinical R & D
Zydus Discovery
Zydus Corporate Park, Plot No. 103,
Near Nirma University, Mouj – Khoraj .

DR. KIRAN MARTHAK
Member of Board of Directors
Lamda Therapeutic Research Ltd.
Lamda House, S G Highway, Gota,
Ahmedabad 382 481

DR. R AGARWAL
Managing Director
Macleods Pharmaceuticals Ltd.
Atlanta Arcade, Marol Church Road,
Andheri (East), Mumbai – 400 059

DR MILIND JOSHI
President – Global Regulatory Management
J. B. Chemicals & Pharmaceuticals Ltd
Cnergy IT Park, Unit A, 8th Floor,
Appa Saheb Marathe Marg,
Prabhadevi Mumbai – 400 025

DR. R. K. SANGHAVI
Consultant – Neuro Marketing
Vilco Labs Pvt. Ltd.
'Sunita' Nivas, 78, S.V. Road,
Opp. Sacred Heart Church,
Santacruz (West), Mumbai - 400 054.

DR. RAJESH GUPTA
Managing Director
Dallas Formulations Pvt. Ltd.
815-A, N.A.C, Manimajara,
Chandigarh (U.T) - 160 101

DR. RAJESH JAIN, Ph.D.
Managing Director
Panacea Biotec Ltd.
B-1 Extn/A-27, Mohan Co-Industrial Estate,
Mathura Road, New Delhi 110 044.

HARSHIT MANILAL SAVLA
Joint Managing Director
Aarti Drugs Ltd.
Mahendra Industrial Estate, Gr. Floor,
Plot No. 109-D, Road No. 29, Sion East,
Mumbai – 400 022

J. L. SIPAHIMALANI
Managing Partner
Chem Med Analytical Laboratories
5-6-7, Kakad Estate, R G Thadani Marg,
Mumbai - 400 018.

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.

KUNAL N GANDHI
Managing Director
Lyka Labs Ltd.
Spencer Building, Ground Floor,
30 Forjett Street, Grant Road (W), Mumbai.

MAYANK JASHWANTLAL SHAH
Chairman
Toyochem Laboratories
M. J. Shah Group of Companies
C202, 2nd Floor, Waterford, C.D.Barfiwala Road,
Andheri West, Mumbai – 400 058

MOHAN BABULAL JAIN
Director
Naprod Life Sciences Pvt Ltd
304, Town Centre 1, Andheri Kurla Road,
Saki Naka, Andheri (East), Mumbai 400 059.

NANDAN M CHANDAVARKAR
Joint Managing Director
FDC Limited
C – 3, Sky Vistas, 106-A J P Road,
D N Nagar, Andheri (West),
Mumbai 400 053.

NEHA THAKORE
Chief Operating Officer
Avik Pharmaceutical Ltd.
194, Arvind Chambers,
Gauri Studio Compound,
Western Express Highway, Andheri (E),
Mumbai - 400 069.

NIKHIL JITENDRA SHAH
Managing Director
Marvel Drugs Pvt. Ltd.
20, Nagin Mahal, 5th Floor, 82, V.N. Road,
Churchgate, Mumbai 400 020.

PRAKASH MUDDA
President (Corporate Projects & Operations)
Micro Labs Limited
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PRANAV CHOKSI
Director
Gufic Biosciences Ltd.
S M House, 4th Floor, 11 Sahakar Road,
Vile Parle (East), Mumbai-400 057.

RAJASEKHAR AKKARAJU
Regional Director & Head - Quality
Abbott Healthcare Pvt. Ltd.
18th Floor, Godrej BKC, Plot No. C - 68, BKC,
Near MCA Club, Bandra (East),
Mumbai 400 051.

SAHIL MUNJAL
Chairman
PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA (PHARMEXCIL)
101, Aditya Trade Centre, Ameerpet,
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RAVI UDAYA BHASKAR
Director General
PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA (PHARMEXCIL)
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SHASHIKANT DAMODAR JOAG
Technical Consultant
Synergy Pharma Formulations India Pvt. Ltd.
307, Windfall, Shar Plaza Complex,
J B Nagar, Andheri (East),
Mumbai 400 059.

S. K. SINGH
Managing Director
Cachet Pharmaceuticals Pvt. Ltd.
415, Shah & Nahar Industrial Estate,
Dr E Moses Road, Worli, Mumbai 400 018.

S M MUDDA
Managing Director
Misom Labs Ltd.
Malta Life Sciences Park, LS2.01.06 Industrial Estate, San Gwann, SGN 3000. Malta

SACHIN N. DOSHI
Director
DWD Pharmaceuticals Ltd.
Dalamal House, 404, 4th Floor Nariman Point,
J.B. Marg, Mumbai-400 021.

SAMITA H. AIYER
Director
Somatico Pharmacal Pvt. Ltd.
Plot No. C 469, MIDC, TTC, Pawane,
Navi Mumbai 400 705

SHIV SAGAR TEWARI
Director
Burnet Pharmaceuticals (P) Ltd.
28/5, C. N. Roy Road, 3rd Floor
Kolkata-700 039

SUNDEEP VASANT BAMBOLKAR
Joint Managing Director
Indoco Remedies Limited
Indoco House, 166 C.S.T. Road, Santacruz (E),
Mumbai - 400 098

TUSHAR A. KORDAY
Director
Emil Pharmaceutical Inds. Pvt. Ltd.
101, Mangalam Kulupwadi,
Near National Park,
Borivali (East), Mumbai – 400 066.

VIJAY SHAH
Chairman
Stallion Laboratories Pvt. Ltd.
8th Floor, Devpath,
B H Super Mall, Near Lal Bungalow,
Off C G Road, Navrangpura, Ambawadi,
Ahmedabad, Gujarat – 380 006.

YASHWANT C. PATEL
CMD
Elysium Pharmaceuticals Ltd
Post: Dabhasa, Tal. Padra
Dist. Vadodara - 391 440.

CORPORATE MEMBERS

SURESH S
Biocon Biologics India Ltd.
Biocon House, Semicon Park,
Electronic City, Phase – II,
Bengaluru - 560 100

SOHAN DADHICH
Managing Director
KLM Laboratories Pvt. Ltd.
304-306 Union Trade Centre,
Near Apple Hospital,
Udhana Darwaja, Surat – 395 002.
Gujarat

AJAY BHARADWAJ
Chief Executive Officer
Anthem Bioscience Privat E Limited
No 49, Canara Bank Road,
Bommasandra Industrial Area,
Phase 1, Hosur Road, Bengaluru 560 099

AJAY KUMAR DESAI
VP, Accounts & Finance
Alembic Pharmaceuticals Limited
2nd Floor, Prime Corporate Park,
Behind ITC Grand Maratha-Sheraton,
Sahar Road, Andheri (East),
Mumbai 400 099.

Jubilant Life Sciences Limited
Plot No. 15, Knowledge Park – II,
Greater Noida 201 306. Uttar Pradesh.

D. C. JAIN
Chairman
Akums Drugs & Pharmaceuticals Ltd.
304, Mohan Place, LSC, Block C,
Saraswati Vihar, New Delhi – 110 034.

DR. ARIF A FARUQUI
Vice President-Medical Services
Medley Pharmaceuticals Ltd.
Medley House, D2 16th Road, MIDC.
Andheri (East), Mumbai 400 096.

J. J. SHAH
Chairman
Oceanic Pharmachem Pvt Ltd
FC/B-1 (Extn.), Mohan Co-operative 329, A-Z
Industrial Estate, G. Kadam Marg,
Lower Parel (W),
Mumbai 400 013.

JINESH SHAH
Director
Torrent Pharmaceuticals Ltd.
Ahmedabad-Mehsana Highway, Village: Indrad,
Taluka: Kadi, Dist: Mehsana (NG)-382 721.

RAJEEV NANNAPANENI
Vice Chairman & CEO
Natco Pharma Limited
Natco House, Road No.2,
Rd. No. 10, Avenue 4,
Banjara Hills, Hyderabad 500 034

SANJEEV KUMAR
Director
United Biotech (P) Ltd.
FC/B-1 (Extn.), Mohan Co-operative Industrial
Estate, Mathura road, New Delhi - 110 044.

SATISH REDDY KALLAM
Chairman
Dr. Reddy's Laboratories Ltd.
8-2-337, Road No. 3, Banjara Hills,
Hyderabad – 500 034. Telengana.

SHRIRAM BALASUBRAMANIAN
Director Commercial and Business Development
Zuventus Healthcare Ltd.
Office No. 5119, 5th Floor, D wing,
Oberoi Garden Estate, Chandivili,
Andheri (E), Mumbai-400 072.

SIDDHARTH MITTAL
CEO and Joint Managing Director
Biocon Limited
20th K.M. Hosur Road, Electronic City, P.O.,
Hebbagodi, Bangalore - 560 100.

SUDHIR VAID
Chairman & Managing Director
Concord Biotech Limited
16th Floor, B Wing, Mondeal Heights,
ISCON Cross Road, S G Highway,
Ahmedabad 380 015. Gujarat.

SUNIL BAFNA
CEO
Venkata Narayana Active Ingredients Pvt. Ltd.
Venkata Narayana Towers, 3rd Floor, New No. 60,
Old No. 35, Venkatanarayana Road,
T. Nagar, Chennai – 600 017.

SUNIL KUMAR KAIMAL
Managing Director
Karnataka Antibiotics and
Pharmaceuticals Limited
"Nirman Bhavan", Dr.Rajkumar Road,
1st Block, Rajajinagar, Bangalore 560 010.

T. SATHISH
Vice President – Regulatory & Corporate Support
Tablets (India) Limited
Jhaver Centre, 72, Marshalls Road,
Chennai – 600 008.

YUGAL SIKRI
Managing Director
RPG Life Sciences Ltd.
Rpg House, 463, Dr. A. B. Road,
Worli, Mumbai - 400 030.

MOHAN RAYANA
Director
Wanbury Ltd
Basel Tech Park, B-Wing, 10th Floor,
Sec-30A, Vashi
Navi Mumbai - 400 703, Maharashtra

DHARMESH M. SHAH
Chairman
BDR Pharmaceuticals International Pvt. Ltd
Engineering Centre, 3rd and 6th Floor,
9,Mathew Road, Opera House,
Charni Road, Mumbai- 400 004.

DR. DINESH DUA
Executive Director
Nectar Lifesciences Ltd.
Unit-II, Village Saidpura,
Tehsil Dear Bassi,
District SAS Nagar, Mohali – 140 507 (Punjab)

BABCHAND N
Laurus Labs Limited
Plot No. 21, Jawaharlal Nehru
Pharma City, Parawada, Visakhapatnam,
Andhra Pradesh – 531 021

PATRON MEMBERS

DR. VIVEK 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.
Nair Baug, Akurli Road, Kandivali (E),
Mumbai-400 101

JAYESH P. CHOKSI
C.M.D. / President
Gufic Biosciences Limited
S M House, 4th Floor, 11 Sahakar Road,
Vile Parle (East), Mumbai-400 057.

KUSHAL SHAH
General Manager
Acichem Laboratories
Prem Parag Industrial Estate, Prabhat Nagar,
Jogeshwari (W), Mumbai- 400 102.

NIRMAL L. JAIN
Partner
Nirlac Chemicals
14th Floor, Nirmal Building, 241/242,
Nariman Point, Mumbai - 400 021.

SACHIN C. GANDHI
Director
Magna Laboratories (Guj) Pvt. Ltd.
Vital Healthcare Pvt. Ltd.
5/6, Shreyas, 2nd Hasanabad Lane, Santacruz (W),
Mumbai - 400 054.

EX-OFFICIO MEMBERS
(PAST PRESIDENTS)

DR. ABRAHAM A. PATANI, D.Sc.
(Founder Secretary) C.M.D.
INGA Laboratories Pvt. Ltd.
Inga House, Mahakali Road, Andheri (E),
Mumbai - 400 093.

CHANDRAKANT I. GANDHI
Chairman
Gentech Laboratories Ltd.
Unit No.803, 8th Floor, Lodha Supremus, S.B. Marg,
Lower Parel, 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
Managing Director & CEO
Themis Medicare Limited
11/12, Udyognagar,
S. V. Road, Goregaon (W),
Mumbai - 400 104.

DR. GOPAKUMAR G. NAIR, Ph.D.
CEO / Designated Partner
Gopakumar Nair Associates / GNANLEX Associates LLP
3rd Floor, "Shivmangal", Next to Big Bazar,
Akurli Road, Kandivli (E), Mumbai - 400 101.

NIHCHAL H. ISRANI
Chairman
Blue Cross Laboratories Pvt. Ltd.
Peninsula Chambers,
Lower Parel, Mumbai - 400 013.

YOGIN R. MAJMUDAR
Managing Director
Bakul Aromatics and Chemicals 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 (UT),
Chandigarh - 160 101.

MANISH U. DOSHI
Managing Director
Umedica Laboratories Ltd.
302, Dalamal House, Jamnalal Bajaj Road,
Nariman Point, Mumbai – 400 021.

S. V. VEERAMANI
Chairman & Managing Director
Fourrts (India) Laboratories Pvt. Ltd.
No.1, Fourrts Avenue,
Annai Indira Nagar Okkiyam Thoraipakkam,
Chennai – 600 097.

GUJARAT STATE BOARD

Chairman

MILAN R PATEL
Jt. Managing Director
Troikaa Pharmaceuticals Ltd.
'Commerce House-1', Satya Marg, Bodakdev,
Ahmedabad - 380 054, Gujarat

Hon. Secretary

SUMIT JAGDISH AGRAWAL
Managing Director
Ishita Pharmaceuticals
401, 3rd Eye II, Opp. Parimal Garden,
C G Road, Ahmedabad - 380 006, Gujarat.

Executive Secretary

RAJIV SHAH
Executive Secretary -IDMA GSB
4 Park Avenue, 1st Floor, Parimal Garden Cross Road, Nr. Gujarat Gas Co,
Ellisbridge, Ahmedabad 380 006

HARYANA STATE BOARD

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.

HIMACHAL PRADESH & UTTARAKHAND STATE BOARD

Chairman

R. C. JUNEJA
Promoter
Pharma Force Lab
A-1/9, Vasant Vihar, Poorvi Marg,
New Delhi-110 057.

Hon. Secretary

B. R. SIKRI
Partner
Next Wave (India)
S.C.O. # 313, 2nd Floor, Sector 29
Gurugram – 122 009. Haryana. India

KARNATAKA STATE BOARD

Chairman

S. M. MUDDA
Managing Director
Misom Labs Ltd.
Malta Life Sciences Park,
LS2.01.06 Industrial Estate,
San Gwann, SGN 3000. Malta

MADHYA PRADESH STATE BOARD

Chairman

PARESH CHAWLA
Chief Operating Officer
ALPA Laboratories Ltd.
33/2, A. B. Road, Pigdamber – 453 446,

Hon. Secretary

HIMANSHU SHAH
Partner
Vishal Pharmaceutical Laboratories
101-A, 100-B, Sector-E, Industrial
Area Sanwer Road, Indore

TAMILNADU, KERALA &
PUDUCHERRY STATE BOARD

Chairman

J. JAYASEELAN
Managing Director
Saimirra Innopharm Pvt. Ltd
Tek Meadows, Tower C, 3rd Floor,
Unit No. 3, No. 51, Sholinganallur, OMR,
Chennai, Tamil Nadu – 600 119.

Hon. Secretary

S SIVANANDHAN
Managing Director
Ceego Labs Pvt Ltd
23/6, Dr Ambedkar Road, 1st Floor,
Kodambakkam, Chennai – 600 024.

Executive Secretary

S. KRISHNAN and KANNAN
Executive Secretary
IDMA - Tamil Nadu, Kerala &
Puducherry State Board
Block-D1, Baid Metha Complex No. 16
(Old No. 183), Anna Salai, Little Mount, Saidapet,
Chennai-600 015.

TELANGANA STATE BOARD

Chairman

SHAIK JANIMIYA
Managing Director
Crescent Therapeutics Ltd
Crescent Towers, Hno 4-7-11/4/B,
Raghavendra Nagar, Nacharam,
Hyderabad - 500 076.

Hon. Secretary

SOMESWARA RAO MANEPALLI
Director
Suraksha Pharma Pvt Ltd
101, Sai Ram Estates, Behind Charmas,
Amerpet, Hyderabad - 500 073

WEST BENGAL STATE BOARD

Chairman

SHIV SAGAR TEWARI
Director
Burnet Pharmaceuticals (P) Ltd.
28/5, C. N. Roy Road, 3rd Floor
Kolkata-700 039

Hon. Secretary

SIDDHARTHA PAUL
Executive Director
Palsons Derma Pvt. Ltd.
10/D/1, Ho-Chi-Minh Sarani,
Kolkata - 700 071.

IDMA COMMITTEE 2021

Sr. No.	Committee	Chairman	Vice Chairman
1.	Bulk Drugs	**Yogin R Majmudar** Bakul Aromatics and Chemicals Ltd.	**Neha Thakore** Avik Pharmaceutical Ltd
2.	Contract Manufacturing	**Mehul Shah** Encube Ethicals Pvt Ltd	**Pratik Kamani** Encube Ethicals Pvt. Ltd.
3.	Employee Relations & Development	**Advocacy Group** **Ramesh Balgi** - USV **Chandrahas Shetty** - Alembic **Jayesh Shah** - Sun Pharma **Atul Parab** - Alkem	
4.	Excise & Taxation	**B G Barve** Blue Cross Laboratories Pvt. Ltd.	**Prakash Rijhwani** Blue Cross Laboratories Pvt. Ltd. (Nashik)
5.	Finance & Administration	**Bharat N Shah** S Kant Healthcare Ltd.	**B G Barve** Blue Cross Laboratories P. Ltd.
6.	I P R	**Dr Gopakumar G Nair** Gopakumar Nair Associates	**Srikant Sharma** Fermenta Biotech Limited
7.	Industry Trade Matters	**Mayank J Shah** Toyochem Laboratories	
8.	Industry Institutes Interaction	**T. Sathish** Tablets (India) Limited	**Dr George A Patani** Inga Laboratories Pvt. Ltd.
9.	International Trade (Incl. Customs)	**Tushar A Korday** Emil Pharmaceuticals Inds. Pvt. Ltd.	**Bhavin M Mehta** Kilitch Co. (Pharma) Ltd.
10.	Marketing	**Vinay Pinto** Wallace Pharmaceuticals Pvt. Ltd.	**S. R. Vaidya** Kremoint Pharma Pvt. Ltd.
11.	Medical	**Dr Deven Parmar** Zydus Discovery **Co-Chairman : Dr. Kiran Marthak** Lambda Therapeutic Research Ltd.	

12.	Membership and Constitution	**Anant R Thakore** Avik Pharmaceuticals Ltd.	**Bharat N Shah** S Kant Healthcare Ltd.
13.	MSME	**S R Vaidya** Kremoint Pharma Pvt. Ltd.	**Tushar A. Korday** Emil Pharmaceutical Inds. Pvt. Ltd.
14.	NDPS	**M. Devesh** Embio Ltd.	**Ms. Neetta Mohit** Abbott Healthcare
15.	Nutraceuticals	**Dr R K Sanghavi** Vilco Laboratories Pvt Ltd	
16.	Pricing / Consumer Affairs	**Dr. Amit Rangnekar** Centaur Laboratories	**C V Venkataraman** Lupin Ltd.
17.	Public Relations	**J Jayaseelan** Sai Mirra Innopharm Pvt. Ltd.	
18.	Publications	**Dr George A Patani** Inga Laboratories Pvt. Ltd.	**Dr. Nagaraj Rao** RRR Laboratories Pvt. Ltd.
19.	Quality Management & Technical	**Dr. Milind Joshi** J. B. Chemical & Pharmaceuticals	**Dr. Gaurav Pathak** Glenmark Pharmaceuticals Ltd.
20.	Regulatory Affairs	**S M Mudda** Misom Labs Limited	**S W Deshpande** PHARMALEX

SECRETARIAT

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MELVIN P RODRIGUES
Sr. Manager (Commercial & Administration)
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ASHOK KUMAR MADAN
Executive Director
Email: **akmadan.idma@gmail.com**

S RANGANATHAN
Assistant Manager (Administration)

60th Annual Report 2020-2021

Dear Member,

It gives me great pleasure to present the 60th Annual report of your esteemed Association, the Indian Drug Manufactures' Association (IDMA). The completion of 60 years is a milestone in itself we are all proud to be associated with IDMA, the oldest and biggest Association of Pharmaceutical and Bulk Drug Manufacturers in the country or probably in the world.

Whilst the effect of the Pandemic and the impact of Covid -19 was not as severe as 2020, we did have certain constraints in our work related activities. Whilst no physical meetings and seminars were held we did have a number of virtual meetings as well as webinars on a number of interesting and relevant topics. We are indeed thankful to our National President, Mr. Mahesh Doshi, our Hon General Secretary, Dr. George Patani, Past Presidents, our Office Bearers, our active State Boards Chairmen, Vice – Chairmen and Members of various Committees, our Consultants / Advisors and our Staff at the IDMA Secretariat.

No stone was left unturned in supporting our members by making timely Representations and interventions at the Centre as well as at the different State levels.

The modus operandi adopted by us during the new normal last year continued this year as well. We continued to work closely with various Government Departments and Ministries, the DCG(I), CDSCO, various State FDAs and other Associations like IPA, OPPI, AIOCD and the rest. We are indeed very thankful to our Secretary - Department of Pharmaceuticals, Ms S Aparna, IAS, for her generous support and understanding.

It is with deep regret that we recall the sad demise of Mr. T R Gopalakrishnan, Deputy Secretary – General and Mr. C K S Chettiar who was handling our IDMA Bulletin. Whilst this was a great loss to the Secretariat we all ran an extra mile to fill the void. We believed that the Show must go on and demonstrated that "The tough get going when the going gets tough". All Representations as deemed necessary where made and sent promptly, the weekly IDMA Bulletin and Indian Drugs were also published and mailed on time.

We are happy to inform you that our Indian Drug Manufacturers ' Association (IDMA) would be completing 60 glorious years in 2022. The 60th Year celebrations was supposed to be organized on 7th and 8th January 2022 at Hotel Sahara Star, Mumbai. But due to the rapid spreading of the Covid-19 and its variant Omicron throughout India and specially in the city of Mumbai and as we being a responsible Pharmaceutical Association and keeping in mind the interest, health and safety of our members, the Organizing Committee in an emergency meeting held on Thursday, 30th December 2021 decided to postpone the IDMA 60th Year Celebrations to a later date.

However, we are going ahead and having the 60th Annual General Meeting on Thursday, 6th January 2022 at 4 p.m. virtually.

We intend to commemorate this historic occasion of the completion of 60 years of our Association with a two day long celebrations consisting of Panel Discussions, Technical Sessions and an Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry. ***The goal of the Diamond Jubilee Celebrations is to:***

- *Showcase Pharmaceutical and Allied Industries across the Globe*
- *Disseminating knowledge on various subjects*
- *Highlighting the contribution of IDMA to bridge the gap between the Industry and the Ministry*

Congratulations to Mr Sahil Munjal, new Chairman, Pharmexcil

IDMA welcomed Mr. Sahil Munjal, the New Chairman of Pharmexcil and wished him all the very best for his new role and assured him of IDMA's support.

Mr. S V Veeramani elected unopposed as Vice-Chairman of PHARMEXCIL

IDMA congratulated Mr. S V Veeramani, our Past National President on being elected unopposed as the Vice-Chairman of the Pharmaceutical Export Promotion Council of India (Pharmexcil).

IDMA representation to NITI Aayog to include pharma workforce in priority list for COVID-19 vaccination

IDMA made a representation to Dr Vinod Paul, Member, NITI Aayog on 30 December 2020 to include the 2 million strong Pharma industry workforce in the priority list to protect them and also to ensure uninterrupted supply of medicines in the country.

IDMA Representation for Request of Restoration of Sichuan Airlines Cargo Services

IDMA had sent a request on 29th April 2021 to Hon'ble Dr. S Jaishankar, External Affairs Minister to kindly intervene and help initiate necessary measures to restore the cargo services of Sichuan Airlines. In this connection, DoP vide their mail of 6th May 2021 informed that Sichuan Airlines had restarted operations. IDMA thanked the Secretary, DoP and all the above Honourable Ministers and Government Officials for their prompt action.

Meeting on ensuring availability of Covid-19 Drugs

The Secretary, DoP chaired a video conferencing meeting on 6th April '21 to ensure availability of Covid-19 drugs and specifically to take stock of readiness of the system. DCG(I) sent a mail along with a list of 55 + 97 drugs, advising IDMA to provide inputs to ensure their availability to

supplement the efforts of Government for management of Covid-19 pandemic situation in the country. IDMA informed the members and accordingly the information was forwarded by our members directly to DCG(I).

Granting Emergency approval NOC Product Licence for Remdesivir Injection 100 mg

IDMA made a representation to DCG(I) on 8th April 2021 with a request to allow emergency approval to all those companies who are holding licences for export of Remdesivir Injection 100 mg. and also have 3 months' stability data. IDMA had forwarded information to Mr. H K Hajong, Economic Advisor, DoP on 1st May 2021 regarding existing stocks of Remdesivir injection.

"Standard Operating Procedures to be followed in all the Industrial Commercial Establishments / Work Sites" at Sikkim

IDMA made a representation letter to Secretary, DoP on 2nd June 2021 with regards to "Standard Operating Procedures to be followed in all the Industrial Commercial Establishments / Work Sites" at Sikkim and requested quick intervention in this matter and to ensure the necessary support to the manufacturing units thereby ensuring continuous production of medicines.

Appeal for extension of effective date of Indian Pharmacopoeia 2018 Addendum 2021

IDMA made a representation to Indian Pharmacopoeia Commission (IPC) on 8th June 2021 in regards to the released Indian Pharmacopoeia 2018 Addendum 2021 incorporating 59 new monographs and 185 revised monographs with an effective date of 1st Oct. 2021. IDMA thanked Dr. Raghuvanshi, IPC for extending the date for implementation of Addendum 2021 to Indian Pharmacopoeia 2018 till 31st December 2021.

Meeting Chaired by the Hon'ble Prime Minister: "Interactive Meeting with Key Stakeholders of Pharma Industry and Other Sectors on Export Target" *at Pharmexcil Office on 6th August 2021*

*The meeting was chaired by **Shri Narendra Modi, Hon'ble Prime Minister** and was joined by Ambassadors from 140 plus countries, Commerce Secretary, Secretaries of various Ministries, industry leaders of principal sectors of India, and Chief of EPCs. Our Prime Minister (PM) Narendra Modi mentioned that asserted positive signs of recovery and high growth is the right time to set high targets for export. PM Modi laid out plans to prepare a strategy and aim for exports worth $400 billion this year. Regarding the $400 billion export target, PM Modi opened up on four integral components that can help drive this initiative. They are:*

a) removing challenges related to logistics and transport

b) working closely with exporters

c) increasing manufacturing and

d) linking Indian products with overseas markets.

PM Modi praised the Indian Pharma Industry in his speech.

Webinar on Sectoral discussion (Pharma) on National Logistics Portal (Marine)

Indian Port Association, Ministry of Shipping had connected with IDMA to improve efficiency and transparency in Logistics. IPA was creating a National Logistics Portal (NLP) for the marine sector first keeping in view that nearly 95% of the merchandise trade (by volume) is transported through maritime transport. The activities of NLP Marine would cover four verticals viz. (i) Carrier, (ii) Cargo, (iii) Banking and Finance and (iv) Regulatory Bodies and Participating Government Agencies (PGAs). IDMA suggested that the portal will act best in the normal times, but it is expected in the case of exigencies like Covid-19 pandemic, etc. the Portal should be in a position to help the industry.

IMC Event - "Engage Maharashtra: Reboot, Reform, Resurge Roundtable Conference" on Thursday, August 5th, 2021

IDMA took active part in the above IMC event. The Topic was ***Setting up of Bulk Drug and Medical Devices Manufacturing.*** *The Panel was chaired by Mr. Yogin R Majmudar and the Panelists for this session included Shri Daara B. Patel, Shri Devesh Malladi, Shri Kewal Handa & Dr. Satish Wagh. The initial message from Hon'ble Minister Shri Ramesh Tope was read. Excellent suggestions were made by the Panelists to the Government of Maharashtra, IMC and other concerned Officials/Departments. Mr. Juzar Khorikawala, President, IMC has assured IMC support to IDMA for this initiative.*

IDMA delegation visit to Delhi 23rd August 2021

IDMA delegation visited New Delhi on 23rd August 2021 and met Hon'ble Mr. Mansukh L Mandaviya ji, Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers. The delegation also met Dr. Mandeep Bhandari, Joint Secretary (Health), Ms. S. Aparna, Secretary, DoP, Dr. V.G. Somani, DCG(I), Dr. S Eswara Reddy, Jt. DCI and discussed the following issues:

1. *Schedule M*
2. *BA/BE for exports*
3. *Pathway of handling Kokate Committee approved FDCs*
4. *Clarification on submission of PSURs for the product with more than 4 years approval*
5. *QR Code on APIs*
6. *Pricing Issues*

The delegation also met Mr. Arun Pradhan, Jt. DCI and congratulated for his promotion as Jt. DCI. They also met Dr. PBN Prasad, Jt. DCI, Mr. Sanjeev Kumar, Dy. DCI and Ms. Rubina Bose, Dy. DCI during the visit.

Consultation meeting of DCGI with the Drug Manufacturers' Associations on framing/ preparations of Drugs, Cosmetics and Medical devices Act on 18th September 2021

The Consultation meeting of DCGI along with the Drug Manufacturers' Associations on framing and preparations of Drugs, Cosmetics and Medical Devices Act was held on 18th September 2021. Dr. Somani introduced the Committee Members mentioned in CDSCO order dated 27th August 2021.

The Committee members are as under:

- *Mr. Rajeev Wadhawan, Director (Drugs) Ministry of health, Vice-Chairperson of the Committee*
- *Dr. SE Reddy, Joint Drug Controller*
- *Mr. Arun Pradhan, Joint Drug Controller*
- *Mr. N K Ahuja, Drug Controller Haryana*
- *Dr. H G Koshia, Drug Controller, Gujarat*
- *Mr. Gahane,- Drug Controller, Maharashtra*
- *Mr. N L Meena, Ex Secretary Department of Law*

Dr. Somani invited the Associations to put forth their suggestions and IDMA was the first Association to make suggestions.

Request to permit stockpiling of medicines important for Covid-19 and other disease conditions

IDMA made a representation to Hon'ble Shri Mansukh Mandaviya ji, Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers and Dr. V.G. Somani, DCG(I) on 22nd October 2021 requesting to permit stockpiling of medicines for Covid-19 drugs and other diseases conditions. The Government had done a phenomenal job by allowing stockpiling of vaccines before the vaccines could be approved. Thus, the vaccines could be manufactured and stored and kept ready to be rolled out to the population. In line with this, the Government issued a notification that allowed stockpiling of covid-19 medicines. These medicines were manufactured and stockpiled and once the approval was received, the medicines were distributed in the market. This reduced the time to market. IDMA had received a request from our member and had forwarded the representation to the Health Minister requesting to permit companies to stockpile the medicines at their own risk with all safety standards being followed. As the evaluating authorities would be taking time to approve the drugs, the stockpiling helps the manufacturers so that they don't lose time in distributing the medicines after the medicines are approved.

Meeting with Wadhwani Foundation w.r.t MSME Policy Reforms

An interesting proposal was received from the Wadhwani Foundation and they impressed IDMA with their objectives, concept, and approach of handholding the MSMEs to catalyze them into a growth trajectory. Wadhwani Foundation Advantage initiative of 'no fees, no equity' featuring automated Business Discovery and Transformation Tools that enable specific and measurable goals

for performance improvement and making data-based sound business decisions. The Foundation agreed to lower their turnover limit criteria for the benefits of IDMA Members. It was decided to go ahead with Wadhwani Foundation for the benefit of MSME Members.

APPQM Series 2

The Advanced Program in Pharmaceutical Quality Management (APPQM) Series 2 which was conducted virtually this year from February 2021 to September 2021 with 28 participants/ delegates. The valedictory program was held on 15th December 2021 (virtually). Dr. Venugopal Somani was the Chief Guest and Prof. B Suresh was Guest of Honour. IDMA Stalwarts including the National President and Incoming National President congratulated Mr S M Mudda, NSF UK and IDMA Secretariat for the success of this series.

Webinars during the Year

1. *Webinar with Aptar Pharma on "Accelerating and De-Risking Your Product Development" on Thursday, 11th February 2021*
2. *Webinar with DBS Bank on "Indian Pharma - Trends And Expectations" on Wednesday, 24th February, 2021*
3. *Webinar with Aptar Pharma on "Rethinking Active Packaging: Derisking Drug Product Stability with Novel Material Science Solutions" on Tuesday, 30th March 2021*
4. *Webinar with Clarivate - Trends in global API manufacturing and success in regulatory affairs on Friday, 16th April 2021*
5. *Webinar with SAP regarding Global Bharath Program - Discover how you too can join the program and expand your reach to global markets on Thursday, 26th August 2021.*
6. *Webinar with Aptar Pharma on "Intranasal Immunization: Promises and Challenges" on Thursday, 2nd September, 2021*
7. *Webinar with Aptar Pharma on "Accelerating & De-risking your Injectable Product Development with Premium Coat®" on Tuesday, 12th October 2021*

New Key Appointments for the year

1. ***Shri Kamlesh Kumar Pant, IAS (HP: 1993)** has been appointed as **Chairperson, National Pharmaceutical Pricing Authority,** Dept. of Pharmaceuticals vide DoPT order, dt. 11.8.2021.*
2. ***Mr. Tarun Bajaj, IAS (Haryana 1988)** Secretary, Department of Economic Affairs, Ministry of Finance has been appointed as Secretary, Department of Revenue, Ministry of Finance from 6th April 2021.*
3. ***Dr. Sandhya Bhullar IAS (Gujarat 2003)** has been appointed as Secretary National Medical Commission w.e.f. 26.5.2021*
4. ***Mr. BVR Subrahmanyam, IAS (CG 1987)** has been appointed as Secretary, Department of Commerce with effect from 1st July 2021*

5. ***Mr. Amitabh Kant, IAS, (1980; Kerala),*** *CEO, NITI Aayog has been given extension for one year beyond 30.6.2021, i.e. up to 30.06.2022.*

6. ***Shri Vaibhav Bajaj IRS (C&CE 2009)*** *has been appointed as Private Secretary to the Minister for Health & Family Welfare (Shri Mansukh Mandaviya) vide DoPT order of 5.8.2021.*

7. ***Shri Ravi Jha (IAS AGMUT 2011)*** *has been appointed as Private Secretary to the Minister for Commerce & Industry (Shri Piyush Goyal) vide DoPT order of 6.8.2021.*

8. ***Shri Abhishek Kumar Singh, IFoS (CG:2009),*** *has been selected for appointment as Deputy Secretary in the Department of Pharmaceuticals vide DoPT Office Memorandum of 29.9.2021.*

9. ***Shri N. Yuvaraj, IAS (AP:2005),*** *has been appointed as Joint Secretary, Department of Pharmaceuticals vide DoPT order dt.12.10.2021.*

10. *Tenure of* ***Mr. Rajneesh Tingal, CSS,*** *Joint Secretary, DoP has been extended up to 30.09.2023 by the Appointment Committee of the Cabinet vide DoPT order dt. 9.11.2021.*

11. ***Mr. Shyamal, Misra, IAS (HY: 1996)*** *Joint Secretary, Deptt. Of Commerce has been appointed as Joint Secretary, Department of Home, Ministry of Home Affairs vide DoPT order, dt. 4.12.2021*

12. ***Dr. Srivari Chandrasekhar, Director,*** *Council of Scientific & Industrial Research (CSIR) – Indian Institute of Chemical Technology (IICT), Hyderabad has been appointed as Secretary, Department of Science & Technology vide DoPT Order, dt.4.12.2021.*

Remembrance of Stalwarts

1. *Mr. Nand Kishore Prasad, Managing Director, Asklepos Remedies, Bihar*
2. *Mr. T S Jaishankar, Founder of Chemech Laboratories, Chennai and Past President, CIPI*
3. *Shri Sardarmal Chordia, Chairman, Medopharm, Chennai*
4. *Shri Dhananjay Kumar Singh, Jt. Managing Director of Alkem Laboratories Ltd.*

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

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 & Covid-19 Variant Free Financial Year 2022.

Yours Sincerely,

Daara B Patel
Secretary-General

REPORT OF BULK DRUGS COMMITTEE

Product Linked Incentives Schemes – PLI 1.0 & PLI 2.0

PLI 1.0 Scheme

IDMA informed the members that the Ministry of Chemicals and Fertilizers issued a Press Release on 2nd January 2021 informing that certain companies who had committed more than the minimum proposed annual production capacities and fulfilled the prescribed criteria have been approved under the PLI Scheme for promotion of Domestic Manufacturing of critical KSMs, Drug Intermediates and APIs in the country. The setting up of these plants will lead to total committed investment of Rs. 3,761 cr. by the companies and employment generation of about 3,825. The commercial production is projected to commence from 1st April, 2023. The Government of India issued approvals for 16 products under Target Segment IV in PLI Scheme on 13th April 2021. A PIB was released in this connection on 13.4.2021.

In this regards, on 16th April 2021, IDMA made a representation to Secretary, DoP requesting that more than one manufacturer should be granted approval for certain products, which will help to keep the price of API in check and also avoid a monopolistic situation. DoP vide letter dated 23rd April 2021 informed that selection of applications has been done strictly as per the Guidelines of the PLI Scheme for Bulk Drugs, which were revised on 29.10.2020 after due consultation with the stakeholders and approval of the competent authority.

Left out slots of PLI-1 Scheme

On 30th April '21, DoP issued a notice inviting applications for the slots left out of PLI-1 Scheme. The Last date for receipt of applications is 28th July 2021. The notice was forwarded to all members by email as well as the notice has been published in IDMA Bulletin.

IDMA Representation on 12th May 2021

IDMA made another representation on 12th May 2021 to Minister of State for Chemicals & Fertilizers requesting to award the PLI scheme to 2-3 applicants for each product and not to only one manufacturer. The copies were marked to Dr. V. K. Saraswat, Member NITI Aayog, Mr. Amitabh Kant CEO NITI Aayog, Ms. S. Aparna, Secretary, DoP and Ms. P. Amudha, Addl. Secretary, PMO.

In this connection, on 2nd June 2021, DoP sent a reply mail letter enclosing a status note regarding selection criteria. The Status Note mentioned that the Department of Pharmaceuticals had held an extensive interaction with the Industry Associations, Manufacturers & Investors at every stage, including the time of framing of guidelines of PLI Scheme for Bulk Drugs. The copy of the

guidelines were posted on the website and all applicants were duly aware of the same at the time of applying under the scheme. DoP has referred to the Evaluation and Selection Criteria laid down in Appendix F and Scenario 1 clause 5.4 of the Scheme Guidelines. They have further maintained that the selection was done strictly as per the Scheme Guidelines and applicants were selected after due appraisal by the Project Management Consultant (PMC) M/s. IFCI Ltd. Empowered Committee headed by CEO, NITI Aayog and approval of the Hon'ble Minister of Chemicals & Fertilizers. DoP stated that there was absolute transparency in the entire selection process and press notes were issued after each phase of approval.

The Ministry of Chemicals & Fertilizers issued PIB release on 31.5.2021 with regard to approvals accorded for the waitlisted four products under PLI Scheme for promotion of domestic manufacturing of KSMs/Drug Intermediates and APIs. DoP on 12th June and 14th June 2021 issued notices with regard to re-Invitation of applications under PLI Scheme for two products Segments III and IV. The figures mentioned in the notice dt.12.6.2021 were corrected in the notice of 14th June 2021.

Webinar on Production Linked Incentive Scheme for Pharmaceuticals and Medical Devices (PLI 1.0)

Department of Pharmaceuticals and Invest India jointly organised a webinar on PLI Scheme on 18th June 2021. The webinar was chaired by Ms. S Aparna, IAS, Secretary, DoP. Mr. Rajeesh Tingal, JS DoP, Mr. Suneet Shukla from IFCI were present in the meeting. There were about 100 participants in the meeting. Madam Secretary, DoP gave a brief about the Scheme. She mentioned that all the details of the applications are being kept confidential by IFCI and no data leakage would be there. A presentation was made by Mr. Rajneesh Tingal.

PLI 2.0 Scheme

Mr. Navdeep Rinwa, Joint Secretary, DoP had called a meeting on 6th March 2021 of Stakeholders consultation with regards to the new PLI Scheme for Pharmaceuticals. In this connection, the second round of consultation was held on 19th March 2021. The details of the new PLI Scheme had been circulated to our members. The Secretary, DoP conducted video conference meeting with regards to PLI 2 Scheme on 22nd April 2021.

In this connection, IDMA had submitted a representation to Dr. Sumit Garg, Deputy Secretary, DoP giving our suggestions/comments. The copies were also marked to Ms. S. Aparna, Secretary, DoP, Mr. Navdeep Rinwa, Joint Secretary, DoP and Mr. Rajneesh Tingal, Joint Secretary, DoP. Further to the above representation, on 23rd April 2021, IDMA, BDMA and FOPE jointly submitted another representation letter to Dr. Sumit Garg, Deputy Secretary, DoP and copies sent to Secretary, DoP, Joint Secretaries DoP to maintain the criteria of the domestic value addition.

DoP issued Operational guidelines for the PLI 2.0 Scheme on 1st June 2021. A webinar for PLI 2.0 Scheme was organized on 10th June 2021 by DoP and Invest India.

Webinar for PLI 2.0

On 10th June 2021, Invest India organised a VC meeting with regards to PLI 2.0. The meeting was chaired by Secretary, DoP. Mr Navdeep Rinwa Joint Secretary, Mr Rajneesh Tingal Joint Secretary and Dr Sumit Garg, Deputy Secretary DoP were present in the meeting. 268 participants from IDMA and other Associations were present at the webinar. Madam Secretary, DoP gave a brief on the PLI 2.0 scheme. She mentioned that all the inputs as received in various meetings with stakeholders were considered. She referred to the co-operation between Government and the Industry. A PowerPoint presentation was made by Dr Sumit Garg and the same was based on the Guidelines dated 1st June, 2021. The Webinar organized by Invest India and Department of Pharmaceuticals on Industry Outreach for PLI 2.0 on 10th June 2021 was very informative and very interactive. IDMA thanked Madam Secretary and Invest India team for giving IDMA an opportunity to interact. Due to paucity of time IDMA was requested to send further questions from their members to DoP. In this connection, on 17th June 2021, IDMA mailed the list of queries / clarifications received from our members to Dr. Sumit Garg, Deputy Secretary, DoP.

IDMA and Ernst & Young Webinar on 15th June 2021 on PLI Schemes

IDMA along with Ernst & Young organized a webinar on "PLI Schemes for Pharmaceuticals: What is in it for the Indian Pharmaceutical Industry" on Tuesday, 15th June 2021. Approximately 130 participants attended this webinar.

Mr. Manish Doshi, Past President, IDMA raised some valuable points/suggestions in regards to the PLI Scheme as mentioned below :

- If there are common directors / shareholders in two companies, can that be considered as a Group Company?
- DMF's will be considered as Criteria / Weightage for API Companies in Selection parameter?
- MSME may not remain in the MSME Criteria during the tenure of the Scheme. Will it be still eligible for Incentives as per the Scheme OR it has to remain MSME for the entire tenure.
- 50% Weightage for the No. of Plants in MSME Group doesn't seem to be a valid selection criteria. Investment done in Plants and R&D in last 5/10 years will be more appropriate.
- 7.1.2 says for Group B threshold sales in 2022-23 for eligible products should be greater than Rs.10 Crores from the base year 2019 – 20. If there are no sales in 2019 – 20 then the Base year sales can be considered ZERO for threshold sales? The same will apply for Incentive calculation?
- Incentive is calculated on Net Incremental Sales from the Base year of 2019 -20 for every year ? eg: 2019 -20 sales is Rs.100 Cr; 2022 -23 sales is Rs.200 Cr. So the incremental sales is Rs.100 Cr. and in 2023 -24 sales is Rs.250 Cr. So the incremental sales is Rs.150 Crores ?

- ❖ Product mix can be of any number of products ?
- ❖ If the investment in one year is less than the average minimum investment and in the subsequent year it is more, but the cumulative investment of both the years put together is as per Minimum Cumulative Investment Criteria, is that allowed and will be eligible for Incentive?

The above points were supported by all the Past Presidents present and also, by the Chairman, Mr Yogin Majmudar. IDMA submitted suggestions/clarifications on PLI 2.0 Scheme on 26th June 2021.

On 2nd July 2021, IDMA had received an email from the Project Management Agency – Pharma stating that 'based on the queries received from various interested applicants/associations, FAQs have been prepared and uploaded in the Scheme Instruction/Circular section of the PLI-Pharma Portal by PMA on July 01, 2021. The FAQs were forwarded to all members by email as well as published in the IDMA Bulletin.

On 7th July 2021, IDMA sent an email request to Secretary, DoP with copies to Joint Secretary, DoP and Deputy Secretary DoP for clarification of interpretation with respect to Partnerships / Proprietorships / Family Companies as regards definition of "Group Companies".

On 8th July 2021, IDMA sent a similar letter to Small Industries Development Bank of India (SIDBI).

Corrigendum to PLI 2.0 Guidelines

On 1st July 2021, DoP uploaded on their website the Corrigendum to PLI 2.0 Guidelines dated 30.6.2021. On 10th July 2021 and on 22nd July 2021, DoP issued Corrigendum. Both the Corrigendum were forwarded to all our members by email.

The steps taken by IDMA or queries raised have been duly published in the IDMA Bulletin for the benefit of the members. PLI Scheme 1.0 the application submitting date has been extended upto 31st August 2021 & PLI Scheme 2.0 application submitting date is 15th August 2021.

In PLI Schemes, the Government had carried out several changes in the schemes and hence Corrigendum / addendum of Operational Guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals have been released. One of the major changes wherein most of our members would be affected is the MSMEs Group 50% weightage for accreditation and 50% for Investment. Investment have changed into "In 2019-20 what was your Gross Manufacturing Revenue". In both cases, Group Companies are included. A group company means a company holding 26% share of another company. They have not mentioned about partnership / proprietary companies. IDMA has continuously taken up this matter but regret there has not been any conclusive solution to it.

PLI Scheme New Corrigendum dated 13-08-2021

A new corrigendum dated 13.8.2021 of Operational Guidelines of PLI Scheme for Pharmaceuticals. The major changes in this corrigendum:-

(1) Last date of submission of application changed to 31.8.21 from 15.8.21

(2) For MSME category, by way of corrigendum dated 22.7.21 selection criteria with 50% weightage was changed to "GMR of 2019-20". DoP has now reverted to original guidelines of 1.6.21 and changed to "Committed Investment"

Inclusion of Chile amongst the countries for ANDA/NDA approval under Clause 4.1 of the Operational Guidelines for PLI Scheme 2.0

On 26th August 2021, IDMA had sent a letter to Secretary, DoP with a request to include Chile amongst the countries, for ANDA/NDA approval in regard to PLI Scheme 2.0. He said that a copy of the letter was marked to Dr. Sumit Garg, Deputy Secretary, DoP.

Request for some modifications, inclusions for Group C applicants under the PLI Scheme for Pharmaceuticals dated 1st June 2021 issued by Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals

On 8th Sept. 2021, IDMA had sent a letter to Secretary, DoP suggesting some modifications for Group C applicants for Operational Guidelines issued under PLI for Pharmaceuticals on 1st June 2021. The suggestions are:

1. Separate fund of Rs.1000 crores for turnover of Rs.50 crores to Rs.500 crores.
2. Change in selection criteria parameters as per Clause 4.1, section 2 & 3
3. Green energy investment weightage of at least 10%

He said that the last date of filing the applications was 31st August 2021.

IDMA-BDMAI Jt. representation to DOP on reducing size of Application Forms for ToR and EC

IDMA discussions with Ms S Aparna, IAS, Secretary, DOP and Shri R.P. Gupta, Secretary, MoEF&CC during the VC meeting held on 10.12.2020, one of the issues discussed was reducing the Size of Application Forms for ToR and EC. IDMA and BDMAI made a joint submission with suggestions on how to reduce and streamline application Forms for ToR and EC.

MoEFCC notification for ease of doing business

MoEFCC has issued a notification (S.O. 221 dated 18 January 2021) informing that the period from 1st April, 2020 to 31st March, 2021 will not be considered for calculation of validity of Prior Environmental Clearance in view of COVID-19 lockdowns and all activities during this period will be treated as valid.

Meeting for action taken on the points discussed by Task Force on API

On 17th February 2021, Mr. Navdeep Rinwa, Joint Secretary, DoP had called a meeting in regards to the action taken on the points discussed by Task Force on APIs. The Meeting was attended by Dr. K Bangarurajan, Consultant & Ex. Jt. DCI, Mr. Sanjeev Kumar, DDCI and Mr. Rampal Singh, FTDO from DGFT. The Industry was represented by IPA and IDMA.

Environmental Approvals – Bulk Drug Industry

On 1st February 2021, IDMA submitted a representation to Secretary, MoEF requesting for issuance of corrigendum to Office Memorandum F.No.22-33/2019-IA.III, dt. 28.1.2021 laying down simple procedure for existing/under renewal ECs/CTEs/CTOs for amendment from existing individual product names to a single category of API & Intermediates. MoEF also issued Gazette notification No SO(E) dt. 02.3.2021 - All manufacturing units are exempted from requirement of prior Environmental Clearance for increase in production quantity / modernizations / change of product mix / change of equipment as long as pollution load remains the same.

Representation on Environmental Issues – MoEF Office Memorandum, dt.28.1.2021 (for API & Intermediates as Single Category) and Gazette notification GSR 980(E), dt.2.3.2021

On 12th March 2021, IDMA & BDMAI made a joint representation to Secretary, DoP with the request that amendment would be effective from the date made "prospectively". IDMA also requested Secretary, DoP to take up this matter with the Secretary, Environment. IDMA has also requested Secretary DoP to recommend the States for doing the needful by making suitable amendments in States' regulations.

Stakeholder consultation meeting on Certified Environment Auditor (CEA) scheme

On 7th May 2021, National Productivity Council organised a web-meeting with Hon'ble Shri Prakash Javadekar, Minister of Environment & Forest with regards to Certified Environment Auditor Scheme. The meeting was chaired by Mr. R P Gupta, Secretary, Ministry of Environment. The meeting was attended by officials from Ministry of Environment, CPCB, Mr. Arun Jha Director General and Mr. K D Bhardwaj, Regional Director from National Productivity Council. Large number of Industry Associations, individual firms and Environment Consultants attended the meeting. The Ministry of Environment proposed to create Certified Environment Auditors. It will be on lines of CAs, Cost Accountants and Company Secretaries who help companies in compliance. A presentation was made by Mr Bhardwaj on the scheme. The Ministry of Environment has sought suggestions from stakeholders within a week's time. Draft notification will be issued to seek comments from stakeholders.

Seeking kind intervention for creating a mechanism for making Environmental Clearance (EC) and consent to establish (CTE) a one step process

On 11th May 2021, IDMA made a representation to Secretary, Ministry of Environment & Forest seeking intervention for creating a mechanism for making Environmental Clearance (EC)

and Consent to Establish (CTE) a one step process. Vide this submission, IDMA informed that the applications are being circulated to SEAC for approval of the prior environmental clearance, whereas the same is not being circulated with the SPCB for the approval of the CTE, thereby defeating the objective of the one step mechanism and delay in issuance of the CTE by SPCB and requested for Ministry's intervention for the creation and practical implementation of the mechanism for the one step approval process of CTE & EC. A copy of letter was also marked to Mr. Ravi Agrawal, Addl. Secretary MoEF and Mr. Sharath Kr. Pallerla, Scientist F, MoEF.

MoEFCC has extended Notification for Category B2 of Pharma Industries (API and its intermediates) till 31st December 2021

Mr. MoEFCC has extended Notification for Category B2 of Pharma Industries (API and its intermediates) till 31st December 2021. The above extensions are being considered as the old EIA Notification 2006 was under deliberations for amendments in 2020 wherein they have placed a draft notification but the new notification is not yet finalized. Therefore, the extension is being granted. In this new notification they have clearly shown that the B2 category mentions Bulk Drugs and there is no mention of "Intermediates". The Government has not responded to IDMA's representations wherein we had requested and reminded that along with APIs, Intermediates should also be mentioned in the notification. IDMA has taken up this matter with the Ministry of Environment and others concerned Departments, but to no avail.

Compliance to the Order of NGT wrt Emission control from DG Sets in Air Quality Non-attainment Cities

On 2nd November 2021, IDMA sent a representation for consideration and appropriate action to Dr. Prashant Gargava, Member Secretary, CPCB with regards to Compliance to the Order of NGT on Emission control from DG Sets in Air Quality Non-attainment Cities.

REPORT OF EXCISE & TAXATION COMMITTEE

Companies CSR Amendment Rules, 2021

The Ministry of Corporate Affairs notified the Companies (Corporate Social Responsibility) Amendment Rules, 2021 [GSR 40 (e) on 22 January 2021]:

- Under the Amended Rules "Administrative overheads" will now mean that the expenses incurred by the company for 'general management and administration' of CSR functions in the company will not include the expenses directly incurred for the designing, implementation, monitoring, and evaluation of a particular CSR project or programme.
- CSR will now include activities undertaken in pursuance of normal course of business of the company provided that any company engaged in R&D activity of new vaccine, drugs and medical devices in their normal course of business may undertake R&D activity of new vaccine, drugs and medical devices related to COVID-19 for financial years 2020-21, 2021-22, 2022-23 subject to certain conditions

- Rule 6 on capacity building is deleted which allowed Companies to "build CSR capacities of their own personnel as well as those of their 'Implementing agencies' through Institutions with established track records of at least three financial years but such expenditure ["including expenditure on administrative overheads,"] should not exceed five percent of total CSR expenditure of the company in one financial year." Also expenses directly incurred by the company for "designing, implementation, monitoring, and evaluation of a particular CSR project or programme" is considered as CSR expenditure and not administrative overheads.

Meeting to Discuss proposals with regards to Customs Duty Exemptions for COVID-19 Drugs and their Raw Materials

On 15th May 2021, DoP had called for a meeting to Discuss proposals with regards to Customs Duty Exemptions for COVID Drugs and their Raw Materials. The Meeting was chaired by Mr Navdeep Rinwa Joint Secretary (Policy) and assisted by Dr Sumit Garg, Deputy Secretary, DoP. Dr. Sumit Garg informed that the requests for Customs Duty Exemptions are being received from manufacturers. Mr. Rinwa also informed that the Department of Revenue has asked for a composite proposal from DoP with regards to Customs duty exemptions for COVID-19 related Drugs and Raw materials. IPA had submitted a request letter for two additional chemicals needed for the manufacture of Remdesivir. IPA also referred to Exemption notification for products coming as donated items seeking clarification and requested to get it extended to commercial transactions also. IDMA had referred to notifications on Remdesivir, Oxygen Concentrators, and IGST exemption having different validity periods. IDMA also requested for parity of dates of validity and Customs clearances of the COVID-19 goods to be expedited. Mr. Rinwa asked IDMA to send recommendations for additional COVID-19 drugs and their raw materials. Dr Sumit Garg mentioned that presently we should request for focus on Customs duty exemption for COVID-19 drugs. Recommendations on GST can be made separately. With GST exemption, ITC set off issues would arise. It was stated that our Honourable Finance Minister has tweeted various tweets on the issue of GST exemption. Mr. Navdeep Rinwa, requested all the Associations to submit their recommendations by 17th May 2021 evening along with HSN Code for each product and present tariff rate. IDMA submitted its recommendations on 19th May 2021.

IDMA Submissions on Goods and Service Tax - Key issues and concerns of Pharmaceutical industry for GST Council Meeting

IDMA submitted a request on 25th May 2021 in regards to issues & suggestions concerning GST to the GST Council for their meeting held on 28th May 2021. The submission was forwarded to Shri M Ajit Kumar IRS, Chairman, Central Board of Indirect Taxes and Customs with a copy to Hon'ble Smt Nirmala Sitharaman ji, Minister of Finance & Chairman, GST Council and Dr. Ajay Bhushan Pandey, IAS, Revenue Secretary & Ex-Officio Secretary to the GST Council, Ministry of Finance. IDMA was of the opinion that the 19 issues mentioned in the submission are of considerable significance and would have major implications. Hence, we have humbly requested the GST Council to kindly peruse through these 19 issues and the suggestions thereof.

Implementation of revised GST for Covid Drugs

On 12th June 2021, the 44th GST Council meeting was chaired by Smt Nirmala Sitharaman, Union Finance & Corporate Affairs Minister and in its meeting the Council decided to reduce the GST rates on the specified items being used in Covid-19 relief and management till 30th September, 2021. Subsequently, on 15th June 2021, NPPA issued Office Memorandum File No. 19 (175)/2019/ DP/NPPA/Div. II with regards to the lower GST announced for COVID drugs. IDMA made a representation on 18th June 2021 to Secretary, DoP referring Sl. No. 5 of PIB release, dt.12.6.2021, i.e. "Any other drug recommended by Ministry of Health & Family Welfare (MOHFW) and Dept. of Pharma (DoP) for Covid treatment – applicable rate 5%". IDMA requested DoP to list out the drugs covered under Serial No. 5, so that there is no ambiguity in interpretation.

Provisions of Section 142 of the Code on Social Security (CoSS), 2020 and status of Aadhaar Seeding

IDMA made a representation on 9th June 2021 to Addl. Central Provident Fund Commissioner, Mumbai giving suggestions with regards to Provisions of Section 142 of the Code on Social Security (CoSS), 2020 and status of Aadhaar Seeding. A copy of the representation was marked to Shri Rajiv Bhist, ACC (F&A), The Central PF Commissioner, New Delhi and Shri Sunil Barthwal, IAS, The Central PF Commissioner New Delhi and also to Shri Madan Chaurasia, Under Secretary to the Govt. of India.

IDMA's recommendations with respect to Covid Drugs and anticoagulants for reduction to 5% GST

IDMA's recommendations were taken into consideration and the GST has been reduced from 18% to 12%. IDMA had forwarded suggestions & solutions to the 44th GST Council meeting which was held on 12th June 2021 wherein recommendations were made to reduce the GST rates on specified items being used in Covid-19 relief and management till 30th September, 2021. The Specific items mentioned were Amphotericin B, Tocilizumab, Remdesivir and anticoagulants like Heparin. On 1st July 2021, DoP had asked inputs for further reduction of GST rates on Covid drugs. IDMA had sent a mail on 13th July 2021 to Dr. Sumit Garg, Deputy Secretary DoP with copy to Section Officer, DoP with the following recommendations for reduction in GST tariff:

I. GST on Vitamin and immune boosters nutraceuticals products which come under 18% slab (FSSAI) may be reduced to 12% as in case of drugs. Post Covid, most of the people are taking vitamin combinations and these products are being manufactured by pharma companies.

II. GST on Disinfectants is now at 18%. Few disinfectants are manufactured with Drug license. These disinfectants manufactured by pharma companies may be reduced to 12%.

IDMA's recommendations taken into consideration by GST Council in its 45th meeting held in Lucknow

GST Council in its 45th meeting held in Lucknow made the following recommendations relating to changes in GST rates on supply of goods and services and changes related to GST law and procedure-

I. Recommendations relating to GST rates on goods and services

A. COVID-19 relief measure in form of GST rate concessions

1. Extension of existing concessional GST rates (currently valid till 30th September, 2021) on following Covid-19 treatment drugs, up to 31st December, 2021, namely-
   i. Amphotericin B -nil
   ii. Remdesivir – 5%
   iii. Tocilizumab -nil
   iv. Anti-coagulants like Heparin – 5%
2. **Reduction of GST rate to 5% on more Covid-19 treatment drugs**, up to 31st December, 2021, namely-
   i. Itolizumab
   ii. Posaconazole
   iii. Infliximab
   iv. Favipiravir
   v. Casirivimab & Imdevimab
   vi. 2-Deoxy-D-Glucose
   vii. Bamlanivimab & Etesevimab

II. Recommendations relating to GST law and procedure

1. **Relaxation in the requirement of filing FORM GST ITC-04**: Requirement of filing FORM GST ITC-04 under rule 45 (3) of the CGST Rules has been relaxed as under: Taxpayers whose annual aggregate turnover in preceding financial year is above Rs. 5 crores shall furnish ITC-04 once in six months; a. Taxpayers whose annual aggregate turnover in preceding financial year is upto Rs. 5 crores shall furnish ITC-04 annually.
2. **Interest is to be charged only in respect of net cash liability** - In the spirit of earlier Council decision that interest is to be charged only in respect of net cash liability, section 50 (3) of the CGST Act to be amended retrospectively, w.e.f. 01.07.2017, to provide that interest is to be paid by a taxpayer on "ineligible ITC availed and utilized" and not on "ineligible ITC availed". It has also been decided that interest in such cases should be charged on ineligible ITC availed and utilized at 18% w.e.f. 01.07.2017.
3. **Unutilized balance in CGST and IGST cash ledger** may be allowed to be transferred between distinct persons (entities having same PAN but registered in different states), without going through the refund procedure, subject to certain safeguards.

IDMA suggestion on Union Budget 2022-23

As requested by DoP and Ministry of Finance we have submitted our suggestions on amendments in Income Tax and GST on 1st December 2021. We have raised the issues of our

members facing regulatory and compliance challenges like not to put any restriction of input credit as long as the goods given are a brand reminder or a brand recall for business purposes as from a business standpoint, the cost of all such items are already factored in the sale price of products on which GST is paid, or allowing ITC on Physician samples as long as the goods are given free of cost and free samples are for business purpose, allowing the credit wrt goods destroyed due to expiry, allowing weighted deduction of 200% on the expenditure incurred on scientific research on in-house R & D facility and also outside the R & D facility for a further period of 10 years under section 35(2AB) of IT Act.

With regard to Customs, we have raised the issue "Whether the importer would be liable to SWS when the BCD itself is exempt and thereby not collected. If liability exists then the Export Oriented Units (EOUs), persons holding Advance Authorisation, EPCG license holders, etc. would all have to shell out this extra duty on their imports, which was never factored in their costing, leading to a disadvantage for them in the international market. Since there are conflicting decisions of the SC and the larger bench decision is not in favour of the taxpayers, it is time that the Government refers this situation to the Law Committee to get a proper view and do the needful so that this litigation, which would finally not benefit the Government but would benefit the professionals who would work to bring justice to the litigants, does stop at this point and the Government and judiciary concentrate their time and efforts on many other cases that require resolution.

Other Major GST Updates

GSTR 9 Filing Exemption and GSTR 9C Self Certification - In July 2021, the CBIC exempted the requirement of filing the annual return i.e. Form GSTR 9 for taxpayers having AATO up to Rs. 2 crores for the financial year 2020-21. This change was made via GST Notification 31/2021 dated 30-07-2021.

The CBIC has also exempted the requirement furnishing Form GSTR 9C for taxpayers having turnover up to Rs. 5 Crores for the financial year 2020-21 and onwards. This change was made via GST Notification 30/2021 dated 30-07-2021.

GSTR 9C is an annual audit form applicable to all registered taxpayers having a turnover above 5 crores in a particular financial year. Until FY 20-21, it included a reconciliation statement for a particular financial year to be filed by taxpayers on or before 31st December after being certified by CAs/CMA. However, from 30th July 2021, the government has notified the removal of GST audit and certification done by CA/CMA and has ordered the taxpayers to self-certify their return.

Provisions of Finance Act 2021

All the provisions of Finance Act 2021 have been notified to be implemented from time to time. Some of the important amendments are-

1. The legislators have made a retrospective amendment in the GST law by way of inserting clause (aa) to Sec. 7(1) of the CGST Act, 2017 that deals with the scope of supply chargeable to tax to the effect that the activities or transactions, by a person, other than an individual, to its members or constituents or vice -versa, for consideration shall be included in the scope of supply and hence shall be leviable to tax.

   An explanation has also been added to introduce a deeming fiction to provide that such person and its members or constituents shall be deemed to be two separate persons and the supply of activities or transactions inter se shall be deemed to take place from one such person to another.

   The aforementioned retrospective amendment has been made applicable right from the inception of GST (i.e. w.e.f. 01.07.2017).

   Therefore the clubs/associations should review their affairs in respect of the given issue and determine the liabilities to be discharged and other consequential issues as regards the claim of ITC as well as the applicability of interest in respect of delayed payment of tax.

2. Sec. 16(2) of the CGST Act, 2017 deals with the conditions to be fulfilled to be eligible for ITC . Now an amendment has been made in the law by way of inserting a new clause (aa) to the said Sec. 16(2). The new condition mandates that ITC shall be eligible only if the details of the invoice or debit note has been furnished by the supplier in their GSTR 1 and the same have been communicated to the recipient.

   The said amendment is a prospective amendment and hence shall come into effect from 01.01.2022. Therefore the eligibility of ITC to be availed on and after 01.01.2022 shall be determined taking the new condition into account.

   The given amendment shall validate that furnishing of the details in GSTR 1 was never a condition to determine the eligibility of ITC prior to 01.01.2022.

   The fate of Rule 36(4) now is uncertain. It is expected that now the addition of the new condition mandating the furnishing of the details in GSTR 1 in order to be eligible for ITC may lead to the removal of even the 5% limit that is presently available under the given Rule.

3. Sec. 73/74 of the CGST Act, 2017 grants an option to a person to conclude the proceedings for recovery subject to making the stipulated payment of the tax/interest/penalty within the stipulated time.

   Clause (ii) of the Explanation 1 to Sec. 74 (that is also made applicable to Sec. 73) clarifies that if the proceedings against the main person are concluded, then proceedings against all persons in respect of penalty (including penalty imposed for E-way bill violations u/s 129 and 130) shall also deem to be concluded.

   Now the amendment provides that the penalty imposed for E-way bill violations u/s 129 and 130 shall not be deemed to be concluded under the proceedings initiated u/s 73 or 74.

Therefore w.e.f. 01.01.2022 the proceedings initiated u/s 129 & 130 for Eway bill violations shall be independent proceedings and closure of parallel proceedings u/s 73 or 74 (in respect of any person including the subject person) shall not result in the deemed closure of the proceedings initiated u/s 129 & 130.

4. W.e.f. 01.01.2022 the term "self-assessed tax" under Explanation to Sec. 75 of the CGST Act, 2017 shall include the tax payable on supplies in respect of which the details have been furnished by the taxpayer in GSTR 1 but the same has not been included in the GSTR 3B and hence not paid.

   The aforesaid amendment shall allow the department to directly initiate the recovery action as regards the said self -assessed liability.

   Situations wherein errors have been committed in GSTR 1 (that can be rectified only at the time of filing the next GSTR 1) that results in undue reporting of excess liability are required to be excluded from the said definition as law duly permits rectification of GSTR 1.

5. Provisional attachment u/s 83 of the CGST Act, 2017 can be undertaken by the department only during the pendency of the stipulated proceedings. In other words, provisional attachment cannot be undertaken if the stipulated proceedings are not pending.

   Now w.e.f. 01.01.2022 Sec. 83(1) is substituted to the effect that the provisional attachment can be undertaken after the initiation of any proceeding under Chapter XII, Chapter XIV or Chapter XV if the Commissioner is of the opinion that the same is necessary to protect the revenue. Hence the sweep of the draconian powers is expanded to permit provisional attachment on mere initiation of the proceedings and that too the proceedings covered under multiple Chapters (that includes assessment, inspection, search, seizure and arrest (that will include summons), demands and recovery) .

6. In the context of filing of the first appeals (Commissioner), presently Sec. 107(6) of the CGST Act, 2017 provides for making a pre-deposit of 10% of the disputed tax amount for filing the appeal and staying the recovery.

   Now an amendment has been made in the context of the orders passed levying penalty u/s 129(3) for E-way bill violations to provide that the quantum of the pre-deposit in such cases shall be equal to 25% of the penalty ordered to be paid.

   It may be noted there will be no further pre-deposit for filing the second appeals (Tribunal) in such cases (i.e. order u/s 129(3)) in view of no amendment u/s 112(8).

7. W.e.f. 01.01.2022, Sec. 130 dealing with the confiscation of goods/conveyance shall be completely de-linked from the provisions related to detention/seizure contained u/s 129. Hence confiscation can be made only if the ingredients specified u/s 130(1) are satisfied independent of Sec. 129(1).

An amendment has been made u/s 130(2) to provide that the amount of fine payable by the person in lieu of confiscation shall be as the officer thinks fit but shall not be less than the penalty that is equal to the tax payable on the given goods. However such fine shall not exceed the market value of the goods less the tax chargeable thereon.

Presently Sec. 130(3) provides that even if the fine is imposed u/s 130(2), still the owner of goods/conveyance shall in addition pay the tax, penalty and charges in respect of the given goods/conveyance. Said provisions are vague and onerous as it mandates further payment of tax/penalty/charges over and above of what has been paid as a fine. Hence w.e.f. 01.01.2022 the said provisions have been omitted.

8. Presently Sec. 151 of the CGST Act, 2017 grants power to the Commissioner to issue a notification to collect statistics relating to any matter connected with GST. Further, it also grants power to call upon the concerned persons to furnish the requisite information/returns in respect of the statistics that are to be collected.

   Now w.e.f. 01.01.2022 the said provisions are completely recast to provide a general power to the Commissioner to issue an order and direct any person to furnish information relating to any matter connected with GST within such time, in such form, and in such manner, as may be specified therein.

9. Presently Sec. 152(1) of the CGST Act, 2017 provides that information in respect of any individual return or part thereof obtained by virtue of Sec. 150 (furnishing of information return by specified authorities such as income tax, banks, etc.) or Sec. 151 (power to seek information related to any matter under GST) cannot be published identifying the concerned person without the consent of the said person or cannot be used for any proceedings.

   Now w.e.f. 01.01.2022 the said provisions shall apply in respect of any information gathered u/s 150 or 151 and not limited to only information in respect of any individual return or part thereof. Further, the information so obtained can now be used for any proceedings under the law but only after giving an opportunity of being heard to the concerned person.

   In view of the aforesaid amendment u/s 152(1) allowing the use of the information gathered for any proceedings under the law, Sec. 152(2) that presently allows access to the information for the purpose of prosecution stands redundant and hence omitted.

   The given amendments shall pave way for the department to issue notices merely based on a mismatch with the data gathered from other sources (such as income tax, etc.). Legality of the same will however be questioned.

10. Sec. 168(2) provides that the Commissioner specified in the stipulated provisions shall mean the Commissioner or Joint Secretary posed in the Board. In view of the recasting of Sec. 44 (self-certification of annual return as well as reconciliation statement), the present reference u/s 168(2) to Sec. 44(1) is amended to Sec. 44.

Presently in view of Sec. 168(2), the Commissioner u/s 151 (to call for information) means the Commissioner or Joint Secretary posed in the Board.

Now the reference to Sec. 151(1) is omitted u/s 162(2) and hence the Commissioner u/s 168(2) shall mean the Commissioner u/s 2(24) that means the Commissioner of Central Tax and includes Principal Commissioner.

11. Presently paragraph 7 of Schedule II provides that the supply of goods by any unincorporated association or body of persons to a member for consideration shall be treated as supply of goods.

In view of the retrospective amendment by way of inserting clause (aa) to Sec. 7(1) to deem every such transaction as supply, paragraph 7 (applying only in respect of unincorporated association or body of persons and not in respect of all associations/clubs) will have resulted in interpretational issues and hence omitted.

REPORT OF INDUSTRY INSTITUTES INTERACTION COMMITTEE

Interaction with NIPERs

The Department of Pharmaceuticals organized a Session on Thursday, 30th September 2021 with all the seven NIPERs wherein the Directors of NIPERs would share their research expertise and priorities with industry representatives through a virtual platform. The Directors of five NIPERs from Mohali, Kolkata, Hyderabad, Guwahati and Ahmedabad briefly shared the technologies / projects which were being developed at their institutes.

IDMA believes that such interactive and knowledge sharing sessions would surely pave the way to strengthen the industry-academia linkages. The presentation identified molecules, the various projects, the strength of different NIPERs and also mentioned that NIPERs have a special strength in the development of Nano-technology. NIPERs were interested in concurrently take up different projects. Madam Secretary, DoP mentioned that the purpose of this meeting was to identify the areas of collective work in R&D where India has comprehensive strength and this would be the called “Common Research Programme”.

A similar type of conference was organized by IDMA about 5 years ago along with DoP. IDMA requested NIPER that the frequency of such meetings should be increased.

This webinar was the brainchild of DoP so as to enable all the NIPERs start working together as there always have been a major difference between the calibres of the NIPERs. Some of the new NIPERs don’t have the infrastructure as the old NIPERs. So DoP was trying to put up a common program so that some of the NIPERs would work together and would result in the enhancement

of the quality of the research at all the NIPERs. Thus making some of the NIPERs centres of excellence in various fields. PowerPoint Presentations were made by the various NIPERs.

IDMA mentioned that it was an excellent program and looked forward to more members interacting with these NIPERS and taking advantage of their facilities.

Meeting of National Consortium on Drug Development for challenging infections organized by CSIR

On 8th October 2021, CSIR called the first meeting of National Consortium on Drug Development for challenging infections. The meeting was chaired by Dr. Ram Viswakarma, Director Indian Institute of Integrative Medicine (Council of Scientific & Industrial Research). The other participants were Dr. Geetha Vani Rayasam, Sr. Pr. Scientist, CSIR, Dr. Prathama, CSIR, Dr. Arindam Talukdar, Principal Scientist, CSIR-IICB, Kolkata, Dr. S. Chandrasekhar, CSIR-IICT, Hyderabad, Dr. Anant N Bhatt, DRDO and Dr. Hari Menon, Gates Foundation.

It was very interesting to hear Dr. Ram Viswakarma mention that the pandemic that we just experienced was not the pandemic that the world was expecting and so the Government wants to make sure that we have a research consortium of institutes that are ready to work together and have the mechanism to work together in case we face another pandemic again.

IDMA informed that during this pandemic there was development of drugs, repurposing of drugs for the pandemic, development of vaccines, etc. The Government is trying to bring together these research institutions and make a consortium of these institutions so that we are better prepared to address the research requirements which arise during the pandemic. It was a very good initiative as we have better CSIR Labs and other excellent labs which are involved in doing research during this pandemic e.g. IICT had done tremendous work during this pandemic. This was a first meeting and many more institutions would be joining in this consortium. IDMA would be inviting members to join the consortium as it would be very interesting to understand how collaborative research can be carried out under the trying circumstances.

Consultation meeting with Industry Stakeholders by DoP on Draft Policy to Catalyze Research & Development and Innovation in Pharma

On 28th October 2021 DoP had called a Consultation Meeting with Industry Stakeholders with regards to Draft Policy to Catalyze Research & Development and Innovation in Pharma. The Meeting was chaired by Ms. S. Aparna, Secretary, Department of Pharmaceuticals. The members present from DoP were Mr. Rajneesh Tingal, Joint Secretary, DoP, Mr. Krishna Kumar Pilli, Director, DoP & others. Invest India were represented by Ms. Srividhya, Senior Manager & others. Mr. Sudarshan Jain, IPA, Mr. KG Ananathakrishnan, OPPI and Dr. George Patani & Mr. Ashok Madan from IDMA attended the meeting. The meeting was attended by representatives of AiMeD, MTaI, FICCI, CII, Diagnostic Association, etc. In total there were about 75 participants at the said meeting.

A Draft R&D Policy was presented by Invest India. IDMA mentioned that the draft policy was an excellent document and all the members should peruse it. He said that our secretariat will download it from the DoP website and forward it to all members.

The document has been extremely well prepared and covered the following three premises in this policy of R & D:

1. Strengthening the Regulatory Frame-work
   a) He said that they are looking at specific processes – streamlining all the regulations, optimising the process to make sure that time is not lost and multiple applications to multiple departments can be made simultaneously. Total processing time for the new drug can be reduced.
   b) Technology - wherein there can be an end-to-end digital portal wherein you could track the progress of your applications.
   c) The regulatory capacity is lacking in the Country. For the various new products like biosimilars, they want to ensure that CDSCO has the capability to evaluate this applications quickly. He said that it was an observation that some of the patents examiners don't have the ability to evaluate the patent applications. It is a comprehensive improvement in the calibre of the capacity to evaluate R & D applications.
   d) Improving the Legislations

IDMA has discussed about biodiversity ACT, enabling joint inspections by CDSCO & FDA, Creating dedicated provisions for Ayurveda wherein WHO-GMP Certificate can be given to products in Ayurveda.

2. Incentivising the investments in R & D
3. Creating an enabling Eco system
   Enhancing Industry-Institute Interactions, Bringing Global Talent into India

Meeting of IDMA State Boards with NIPERs in Hyderabad, Kolkatta and other leading Pharmaceutical Colleges and Institutions.

Mr S K Janimiya, Chairman Telangana State Board IDMA, made a presentation at NIPER Hyderabad on September 25, 2021 on World Pharmacist Day. He also participated on October 18, 2021 at NIPER Hyderabad at the NIPER HYDERABAD Industry Connect.

REPORT OF INTERNATIONAL TRADE INCL. CUSTOMS COMMITTEE

Remission of Duties and Taxes on Exported Products (RoDTEP) Scheme

The Ministry of Finance issued a Press Note on 31st December 2020 informing that Government has introduced RoDTEP to all export goods with effect from 1st January, 2021. The scheme is aimed at refunding exporters the embedded Central, State and local duties/taxes that were so far not being rebated/refunded. The refund would be credited in an exporter's ledger account with Customs and used to pay Basic Customs duty on imported goods. The credits can also be transferred to other importers. The RoDTEP rates would be notified shortly by the Department of Commerce, based on the recommendation of a Committee chaired by Dr. G. K. Pillai, former Commerce and Home Secretary. The notified rates, irrespective of the date of notification, will apply with effect from 1 January 2021 to all eligible exports of goods. A detailed "Advisory for RoDTEP" released by Government was published in IDMA Bulletin dated 7th January 2021.

The Press Note also states that in cases where Advance License is used by Exporters to import duty free raw materials, the units will not be allowed to claim RoDTEP. We made a submission to the Committee on 11th January 2021 that this is not in line with the basic objective of RoDTEP which is meant to compensate exporters for the embedded duties and taxes in various costs, which are not covered under any other Government scheme. This disallowance is also inconsistent with the method adopted in determining the RoDTEP percentage (yet to be fixed) being allowed.

On 17th August 2021, DGFT had issued Notification No.19/2015-2020 with regards to Remission of Duties and Taxes on Exported Products (RoDTEP). IDMA had sent an email request on 17th August 2021 to Mr. BVR Subrahmanyam, IAS Commerce Secretary for his intervention for issuance of early notification of RoDTEP rate for Chapter 29 and Chapter 30 pertaining to Pharmaceutical Bulk Drugs, Intermediates and Formulations which were not notified in the above notification and to help in expanding the exports of Pharmaceuticals.

IDMA forwarded another letter on 19th August 2021 requesting the Commerce Secretary for inclusion of Pharma in RoDTEP.

Request to make voluntary/Optional – Implementation of Track and Trace system for Exports of Pharmaceuticals and Drugs consignments

DGFT has issued Public Notice No.16/2015-2020 dated 22nd Sept. 2020 that the implementation of Track and Trace system for export of drug formulations with respect to maintaining the Parent-Child relationship in packaging levels and its uploading on Central Portal had been extended to 1.4.2021.

IDMA made a representation on 2nd March 2021 to Joint Secretary (Commerce) with the request that the implementation of track and trace system along with maintaining the Parent-Child

relationship may please be made optional/voluntary till an international system emerges. Once the internationally accepted system emerges and the importing countries mandate them, we the Indian Companies, will start adopting those systems as mandated by the importing nations. The copy of this request was sent to Minister of Commerce, Minister of State for Chemicals & Fertilisers, Secretary, DoP, DGFT and DG Pharmexcil.

DGFT had issued a Public Notice No.46/2015-20, dated 30.3.2021 extending the time upto 1st April 2022 for implementation of Track and Trace system for export of pharmaceutical and drug consignment along with maintaining the Parent-Child relationship.

IDMA had mentioned in the said Representation that IDMA Members are International vendors and follow the guidelines and procedures laid down by the importing country. Since no country has commenced implementation of Trace and Trace Systems, IDMA requested that the Track and Trace Systems be kept in abeyance till such time an International consensus emerges.

Late cut for MEIS application for exports made in the financial year 2019-2020

DGFT had issued a Public Notice No.53/2015-2020, dated 9th Apr. 2021 providing relaxation in the late cut provisions for shipping bills of the period 01.4.2019 to 31.3.2020. A relaxation in the late cut provisions has been provided so that if such shipping bills are submitted on or before 30.09.2021 for an MEIS Claim, no late cut would be applicable.

Current issues in Exports of Pharmaceutical Goods

IDMA made a representation on 12th May 2021 to our Hon'ble Dr. Mansukh L Mandaviya, Minister of State for Ports, Shipping and Waterways with regards to Current issues in exports of pharmaceutical goods, such as (i) Steep increase in freight charges in the current Covid-19 scenario and (ii) Containers issue, Shipping lines issues / General issues at port. IDMA requested the Minister for his kind intervention and to issue directions to the concerned in keeping the freight cost under check, and resolution of containers & shipping lines issues. IDMA has forwarded a similar representation to DGFT.

IDMA's proposal w.r.t. custom duty exemptions for COVID drugs and their raw materials

IDMA vide its mail of 19th May 2021 endorsed the recommendations of BDMA and added the names of intermediates such as (1) Erythromycin Thiocyanate for manufacture of Azithromycin and (2) 2 keto-L Gluconic Acid for manufacture of Vitamin C. DoP vide their mail of 4th June 2021 advised IDMA to send them the details of Basic Custom Duty for the above two Intermediates. IDMA sent a response on 7th June 2021 to DoP mentioning that the current BCD rate of the two intermediates is at 7.5% + 10% surcharge.

Identification of Priority Tariff Lines in respect of 2nd Expansion of India Chile PTA

IDMA forwarded the response to DoP on 4th June 2021 stating that there are hardly any sensitive items having codes under Chapter 29 and 30 in Chile Offer list (pertaining to APIs and Pharmaceuticals / medicines). India has made available to Chile a detailed Offer List in Chapter 29 and 30. India - Chile trade in Pharmaceuticals is marginal as there are more Exports to Chile than Imports as mentioned in Chapter 29 and 30. Major interest in India's Wish list and Chile's Offer list is FISH OIL, which is not directly connected to the Indian Pharmaceutical Industry. Hence, please note that IDMA members have nothing more to comment or add to the Wish List or Offer List from either side.

Industry Issues relating to Norms Committee in DGFT

IDMA made a submission on 29th December 2020 to Mr. Navdeep Rinwa, Joint Secretary, DoP with regards to issues for discussion with DGFT. In this connection, DoP had sent their reply vide mail letter dt.8.6.2021 to IDMA.

Negotiations on Preferential Trade Agreement between India and Iran

DoP forwarded a mail on 11th June 2021 seeking inputs with regards to Negotiations on Preferential Trade Agreement between India and Iran. In this connection, on 14th June 2021 IDMA has sent a response to DoP mentioning that Iran's Wish List of 261 items does not cover Chapter 29 and Chapter 30 items of concern to Indian Pharma Industry (except for example - Heparin which is of low concern) and India's Wish List of 1365 items are comprehensively covering all items of interest to Indian Pharmaceutical Industry under both Chapters 29 and 30. A copy was also marked to Dr. Sumit Garg, Deputy Secretary, DoP.

Meeting in regards to Stakeholders Consultations for the Rules of Origin

IDMA was invited by Mr. Anupam Kumar, Deputy DGFT, Dept. of Commerce to attend the vc meeting on 27th July 2021 in regards to Stakeholders Consultations for the Rules of Origin. The meeting was chaired by Mr. Abhishek Dev, IAS, Director, Regional and Multilateral Trade Relations (RMTR), Deptt. of Commerce. This was the inaugural meeting to sensitize the stakeholders of the Chemicals and Pharma industry with regard to ensuring FTAs to be done with UK, EU and Canada. Dept. of Commerce will be sharing the questionnaire as well as detailed information on the Rules of Origin and product specific Rules. Almost all the Associations requested Dept. of Commerce to share the more information so that members can be sensitized to elicit the needed information. Thereafter, IDMA received an email from Dept. of Commerce wherein they have given three questionnaires – (1) UK (2) European Union and (3) Canada. The Dept. of Commerce has requested us to forward this information by 7Th August 2021. IDMA requested members to forward the said information at the earliest so as to enable us forward the same to Dept. of Commerce.

Recognition of Indian Pharmacopoeia in Foreign Countries

Indian Pharmacopoeia Commission has sent two e-mails to IDMA on 13.4.2021 and 28.6.2021 to share the advantages from the recognition of Indian Pharmacopoeia in foreign countries. On August 2, 2021, IDMA had forwarded the same to Members with the request to send their inputs to IPC. Themis Medicare & Natco Pharma gave their valuable feedbacks and the same was forwarded to IPC. Dr Rajeev Singh Raghuvanshi thanked IDMA for these feedbacks and mentioned that these feedbacks were motivational and helped IPC in continuing their endeavour to keep improving and upgrading.

WebEx meeting on CRT Capacity Building Programme on Rules of Origin

Department of Commerce had called a meeting on 11th August 2021 on Capacity Building Programme on Rules of Origin and the meeting was chaired by Mr. Osama Mehmood, Head, Centre for Regional Trade, Ministry of Commerce. Other participants from Government are Mr. Anupam Kumar, Dy. DGFT and Mr. Venkat Hariharan Asha, Dy. Director, DoP. The meeting was attended by all Sectoral Associations, Pharmexcil, IPA and IDMA. IDMA made a request to the chair for a brief paper/synopsis of all the technical terms used in the questionnaires so that we can sensitize our members and have their inputs on the Rules of Origin. Mr. Mehmood assured for a web meeting and also conveyed that synopsis will be shared for the benefit of the Members of the Associations.

DCGI Circular dt.13.9.2021 wrt Permission for import of drugs with Residual shelf life less than 60%

DCG(I) had issued a Circular on 13th Sept. 2021 extending the date up to 30.4.2022 giving permission for import of drugs with residual shelf life less than 60%.

Web meeting with Joint Secretary Commerce to review the export performance with regards to target of US $ 29196 Million of Pharma Sector

Pharmexcil had organised a web meeting on 16th September 2021 with Mr. Shyamal Misra, Joint Secretary, Commerce to review the export performance with regards to the target of US $ 29196 Million of Pharma Sector. Ms. Indu Nair, Director and Mr. Shokeen Khan, Section Officer, Dept. of Commerce were present in the meeting. The Joint Secretary gave a brief on the export performance of the Pharma sector for last year wherein the performance of US $ 24.4 Billion for 2020-21 with a growth rate of plus 18% was noted. The current target is US $ 29.5 Billion. However, the exports for the current five months are showing the cumulative growth of only 4% and there is a need to look at how to improve. IDMA informed the Joint Secretary about the Industry's concerns such as Pharma's inclusion in RoDTEP, Freight cost, Exports of Vaccines, restriction on Remdesivir, Track & Trace, etc.

On 21st October 2021, Pharmexcil organized an Interactive web meeting with Mr. Shyamal Misra, Joint Secretary Commerce to review the export performance in Pharma Sector. Ms. Indu Nair initiated the meeting and referred to exports during the first six months of the year and mentioned that the exports in the month of September are down by more than 8%. The Dept. of Commerce wanted to know from the industry their assessment for the poor exports so far. The Joint Secretary (Commerce) informed that the inspection issue has been taken up with USA and we are hopeful. Pricing issues were discussed and it was mentioned that on the face of it, lower prices help the consumer and the country.

IDMA informed that traditionally we have done well in Pharma exports and our CAGR has been encouraging, stock piling during last year, huge demand for Covid-19 and non-Covid-19 drugs had helped growth of Pharma exports. The entire cost of manufacture has gone up because of the increased prices of inputs, raw materials, packing material, etc. IDMA has requested for declaration of RoDTEP for Pharma industry, quick payment of pending MEIS, etc. IDMA also addressed problems relating to Shipment. The containers have reduced over the last month and other problems like USFDA inspections are delayed, Prices of Coal and Fuel are all rising. IDMA mentioned that reduction of time limit for filing MEIS application from 90 to 45 days is impractical. It takes around 45 days even to get the certification from the importing country. The other issues raised was about patented drugs being exported to the developed countries by Bangladesh.

IDMA had taken up a lot of issues and is hopeful to get the desired response from the Government. After deliberations, it was decided to make a representation for filling MEIS applications for increasing the time limit to 90 days and address all the issues with our Minister jointly with other pharma associations.

Meeting with Shri Piyush Goyal on 23rd September 2021

Pharmexcil organized a meeting with Honourable Shri Piyush Goyal on 23rd September 2021 to discuss the Export Financing issues and problems faced by exporters.

Stakeholder consultations on India-UAE CEPA negotiations on pharma tariff lines

The Meeting on 7th October 2021 was chaired by Dr. Srikar K Reddy, Joint Secretary (WANA), Department of Commerce with regards to India–UAE CEPA negotiations on pharma tariff lines. The proceedings of the meeting was initiated by Mr. Alok Malviya, Director (WANA) and was assisted by Ms. Meena Pillai, Under Secretary (WANA), Dept. of Commerce. Mr. Venkat Hariharan, DoP was present along with members from Pharmexcil, IPA, BDMA and IDMA.

IDMA put forth the following points:

- Requested for stringent adherence of Rules of Origin by UAE, so that goods do not come through re-routing to India

- Beyond the tariff line, IDMA also requested the Joint Secretary the need to promote our generics
- UAE Government should grant recognition to the units which are approved by US FDA (Approx. 670 Units), EU and UK MHRA (approx. 800 units) and the WHO certified units (2000) so that the medicines manufactured by these units can get access into UAE on mutual recognition basis.

Web Meeting with Minster (Economic & Commerce) Embassy of India in Japan on PMDA issues

Pharmexcil organized web meeting on 21st October 2021 with Ms. Mona Khandhar, Minister (Economic & Commerce) Embassy of India in Japan on Pharmaceuticals and Medical Devices Agency (PMDA) matters. A powerpoint presentation was made by PMDA. After deliberations, Ms. Mona Khandhar requested the industry to come better prepared for responding to the PMDA issues.

On 2nd November 2021, Pharmexcil organized the second web meeting with Ms. Mona Khandhar, Minister (Economic & Commerce) Embassy of India in Japan on PMDA matters. Pharmexcil will be collating the response of the Indian Industry and will be sharing the same with IDMA.

Virtual Meeting with Indian Ports Association on National Logistics Portal (NLP)

Indian Ports Association and National Logistics Portal team had specially organized a virtual meeting with IDMA on 19th October 2021 to discuss about their NLP Marine Platform. The NLP Team is in process of gathering information in regards to NLP Marine Platform. The NLP Team made a brief presentation on the same and has also requested that a questionnaire be filled and forwarded to them. IDMA has forwarded the presentation to International Trade Committee and Executive Committee Members with a request to kindly respond to the attached questionnaire at the earliest.

Inter - Departmental Committee web meeting regarding custom duty exemption/ concession for Medical Products

On 23rd November 2021, Dr. S. Eswara Reddy, Jt. DCI chaired the web meeting of Inter-departmental committee with regards to custom duty exemption / concession for Medical Products. Dr. Eswara Reddy gave a brief for the meeting and informed that –

- Committee has been constituted by Ministry of Health & Family welfare on 19th November 2021 comprising of following Five members:
    1. Dr. S. Eswara Reddy, Jt. Drugs Controller
    2. Mr. Anil Kumar, DDG, DGHS

3. Dr. Sumit Garg, Deputy Secretary, DoP
4. Dr. Jerin Jose Cherian, Scientist 'E', ICMR &
5. Mr. Lanka Srinivas

- Committee has been mandated to examine the List 3 (Concessional Customs Duty of 5% for 122 products) and List 4 (0% Customs duty for 111 products).
- Industry was requested to provide the feedback as per proforma provided along with Office Memorandum, dated 22nd November 2021.
- Industry to suggest which items from the List 3 and List 4 can be deleted, along with justification.
- Industry to suggest which item should be moved from List 4 (of 0%) to the list 3 (of 5%)
- However, the Committee is not mandated to move the item from List 3 (5% Concessional duty) to List 4 (0% Customs Duty).
- Also the Committee is not mandated to recommend any additions.

All the Associations informed that they have intimated their Members and are awaiting feedback from their members and the same will be submitted on receipt.

IDMA has requested that in the present scenario, the status quo should be maintained as already the prices of APIs are high and there should be no changes.

Dr. Eswara Reddy mentioned about a Circular as per which raw materials imported by UNICEF are fully exempted from the Customs Duty for the production of Vaccines. Industry is requested to comment on this.

REPORT OF MARKETING COMMITTEE

Current Prevailing Conditions in Kerala for Pharma Industries and Resistance in Field Working by Local Unions

IDMA had received complaints from members in Kerala and the same was well handled by the IDMA Secretariat and within 24 hours there was a positive response from the Chief Minister of Kerala. IDMA were requested by our members Alkem Labs & IPCA Laboratories in regards to consider a representation to the Kerala Chief Minister in regards to Current Prevailing Conditions in Kerala for Pharma Industries and Resistance in Field Working by Local Unions. Even our Past National President, Mr. B N Singh spoke at length on the same subject. After receipt of such a complaint, IDMA got in touch with the Advocacy Group and an appropriate representation was made.

On 19th July 2021, IDMA wrote a letter to Shri Pinarayi Vijayan, the Honourable Chief Minister of Kerala on the said subject and also, enclosed a copy of the Interim Order passed by the Hon'ble High Court Kerala. The matter was explained in the said letter as follows:

The Medical Representatives of different companies have formed Unions/Associations at the state level with sub-units at the District level with their own constitutions, by-laws and rules governing their activities without any legal sanctity. The said unions/Associations have created adverse circumstances in the state of Kerala on account of which the managers are not being allowed to work properly. However, recently the intervention of these unions has increased to such an extent that they have started to personally attack the managers at their houses and threaten them through phone calls. There have been instances where union members staged protests at the residences of the managers and in a certain case threatened a manager at his house thereby causing fear and mental trauma to his family members. In another incident, a manager was assaulted and grievously injured for reporting the misconduct of a medical representative/business executive.

We drew the attention of the Chief Minister towards the fact that the 'Right to Employment' is a fundamental right under our constitution and no person or association can deprive the lawful citizen from exercising his/her right. The Manager, by doing joint field work, is after all performing his own duty towards his/her organization and also enjoys his/her constitutional freedom in his/her individual capacity. In view of the above, we humbly requested to instruct all the concerned SSPs / Commissionerates in all the cities of Kerala to provide necessary protection to all its Managers and to warn the Union Office bearers to abstain from indulging in any illegal activity in the future and to ensure safe working conditions for all Managers of pharmaceutical companies in the State of Kerala. The copy of the said letter was also marked to (1) The Chief Secretary and (2) The Home Secretary.

IDMA was pleased to inform you that the Office of the Chief Minister on receipt of the letter immediately took action within 24 hours and informed us that our request has been noted and forwarded to Additional Chief Secretary and Secretary, Home Department for taking appropriate action.

UCPMP Meeting

On 24th July 2021, IDMA attended a meeting held under the chairmanship of Shri Navdeep Rinwa, Joint Secretary, DoP through VC on 27.07.2021 to review the implementation of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP). He was assisted by Mr. Venkat Hari Asha, IES, Deputy Director, Dr. Sumit Garg, IRS, Deputy Secretary, Mr. Arvind Kumar, Under SECY Mr. Sanjay Meena Section Officer and Mr. Farhan, PHARMA Bureau. The other participants were from NPPA, IPA, OPPI, FOPE, FICCI, CII, AIMED, MTAI, AMCHAM and USIPF.

Shri Navdeep Rinwa requested the Industry Associations to

(1) Upload UCPMP on official website of Associations and mention procedure for filing the complaints

(2) Formation of Ethics and APEX committees.

(3) Report - Quarterly compliance report to be submitted to NPPA / DoP

(4) Action taken on complaints.

IDMA has submitted the Proforma for furnishing quarterly return on complaints received and action thereafter by Industry Association as per para (8) of UCPMP code till quarter ended 30th June 2021.

VC meeting in respect of Distribution and Marketing channels of the Industry – NPPA

On 22nd September 2021 NPPA held virtual meeting in respect of distribution and marketing channels of the industry. The meeting was chaired by Ms. Rashmi Tahiliani, Joint Director (Pricing) NPPA. Ms. Rashmi informed that NPPA wanted to gain information on what are the different trade channels used by the larger companies and the MSMEs for branded generics and trade generics. Also, at what price the product leaves the manufacturer and reaches in the hands of the consumer. NPPA wanted to know the price movement at different levels. IDMA has noted the points mentioned by her and will have to garner the information from our members and will revert accordingly.

REPORT OF MEMBERSHIP & CONSTITUTION COMMITTEE

IDMA Members proposed that a Corporate member who automatically joins as Executive Committee member cannot become Office bearer of IDMA if he is an Office bearer in another Pharma Industry Association.

After considerable deliberations, it was agreed that the below three Resolutions be put forth for approval at the Annual General Meeting scheduled on 31st March 2021 at 4.30 p.m.

1. Resolved that the number of Corporate members be increased from 20 members to 25 members.
2. Resolved that a Corporate member who automatically joins as Executive Committee member cannot become Office bearer of IDMA if he is an Office bearer in another Pharma Industry Association.
3. Resolved that no member of IDMA can hold the position of an Office bearer if he happens to be an Office bearer in any other Pharma Industry Association.

This Year the Membership at the year-end stood at 1108. It was a challenging year wherein the pharma industry faced a lot of hardships but gradually got accustomed to the New Normal. IDMA Secretariat and State Boards were involved in bringing more Members to the IDMA family so that they benefit by the activities of the Association. During the year, 31 New Members were included namely, 20 Principal Members, 8 Associated Company Members and 3 Corporate Member, increasing the Membership to 1108.

Our various awards announced for the IDMA 60th Year Celebrations enabled us in renewing the membership of many old members who were interested in participating in these awards as the main criteria was that the company participating for the awards should be an IDMA Member.

REPORT OF NDPS COMMITTEE

Submission for Urgent Import of Pharmaceutical API - Codeine Phosphate and supply of Thebaine by Government Opium & Alkaloid Factories

On 18th February 2021, IDMA made a representation to Special Secretary, Department of Revenue, Ministry of Finance for his kind intervention in addressing the issue of imports of Codeine phosphate on priority and supply of Thebaine to the Pharmaceutic companies. The Representation was also marked to Joint Secretary (Revenue), Narcotics Commissioner Gwalior, Chief Controller of Factories and Director (Narcotics), Department of Revenue, Ministry of Finance.

Controlled Substances in Schedule A to the NDPS (RCS) Order 2013 wrt 4-Anilino-N-phenethylpiperidine (ANPP) and N-Pheyethyl-4-piperidone (NPP)

On 23rd February 2021, IDMA made a representation to Joint Secretary (Revenue), Ministry of Finance seeking clarification as to whether the requirement to obtain URN number and follow the prescribed procedure in NDPS (RCS) Order, 2013 would be mandatory in a situation where the Controlled Substances (1) 4- Anilino-N-phenethylpiperidine (ANPP) and (2) N-Phenethyl-4-piperidone (NPP) are manufactured as intermediates in manufacture of Essential Narcotic Drugs. The representation was also sent to Director General, Narcotics Control Bureau and Director (NC) in Department of Revenue.

Visit of Mr. Rajesh Dhabre, IRS - Narcotics Commissioner

On 25th March 2021, Mr. Rajesh Dhabre, IRS – Narcotics Commissioner visited IDMA Office for a meeting. The meeting was attended by the National President Mr Mahesh Doshi, Dr. George Patani, Mr. Devesh Malladi, Mr. Daara Patel and representatives of Embio Ltd, Sun Pharma & Rusan Pharma.

The following issues were discussed:

(i) Issuance of Import/Export NOCs:

Delays in issuance of import/Export NOCs and digitalisation of the process of issuance of the same.

(ii) Route change for export consignments:

Permit route change 48 hours prior to export of a consignment of Narcotic, Psychotropic or Controlled substances, by intimating CBN from the registered email ids of the Companies.

(iii) Letter regarding substances not under the purview of NDPS

Issuance of letters by CBN, as requested by Trade, for certain substances which are controlled in other countries and not in India.

(iv) Online payment of fee through Bharatkosh for Import/Export of Psychotropic substances:

Delays in generation of challan leading to further delays in the submission of an application form through Bharatkosh.

(v) Provision of deletion of product name on CBN portal: Provision for deletion of a product name on the CBN portal, for a Psychotropic substances which are discontinued by trade/industry.

(vi) Timely issuance of licenses or renewal of licenses of Manufactured or Essential Narcotic Drugs (ENDs), as per Rule 38), which stipulates 30 working days.

(vii) Permission for Destruction of Manufactured Drugs and Essential Narcotic Drugs, as per Rule 45-A, within 30 days from the date of receipt of such an application and the destruction carried out within a further period of 30 days, from the date of appointment of such a committee.

(viii) A quarterly VC meeting with CBN to resolve pending issues was also requested.

A representation on the above points had been submitted to the Narcotics Commissioner's office on 1st April 2021.

Request for issuance of notification with regards to Etizolam

The Government of India has issued notification SO 1276(E) dt. 23.3.2021 classifying Etizolam and its preparations as Psychotropic substance and bringing it under purview of NDPS Act 1985 and Rules.

On 12th April 2021, IDMA sent a representation to Revenue Secretary requesting that a notification be issued stating the licensed manufacturers, importers and exporters of Etizolam shall be covered under the provisions of notification S.O.1276 (E) after the expiry of a period of 120 days from the date of its publication in the Official Gazette.

IDMA presentation at the United Nations Commission on Narcotic Drugs (CND) session - at Vienna on April 13th, 2021.

IDMA was invited by UNODC to make a presentation at the 64th Commission on Narcotic Drugs held at Vienna on ***"Challenges Faced by Indian Industry on the Misuse of Non-Scheduled, Designer Precursor Chemicals for Illicit Activities & Industry Perspective"*** on 13th April, 2021. Mr. Devesh Malladi, Chairman, NDPS committee made the presentation through Video conference.

Processing of Export / Import Permits – Public Notice 05/2020, dt.4.8.2020 and Route Change

IDMA had forwarded two Representations as mentioned below :

(1) On 27th April 2021, IDMA sent a representation to Narcotics Commissioner, Gwalior with copies to Revenue Secretary, Joint Secretary (Revenue) and Director (Narcotics Control), Dept. of Revenue requesting **to issue Public Notice with regard to procedure of Export/ Import permits.**

(2) Urgent Intervention on Processing of Export/Import permits and Route Change – **Digitalization of issuance of permits and facilitation of smooth trade by permitting route change.**

(3) On 27th April 2021, IDMA submitted representation letter to Revenue Secretary requesting for Digitalization in streamlining the procedure of application, processing and issuance of export authorization/import licence/NOC and Route change.

On 9th June 2021, IDMA had submitted a reminder in regards to the representation letter to Revenue Secretary. Through this representation, IDMA submitted that with increasing regional lockdowns and disruptions, exports are being impacted and requested Secretary (Revenue) to speed up digitalization of the process of issuance of permits. In this connection, IDMA had already submitted request letters on 08.05.2020, 27.4.2021, 22.06.2020 and 30.07.2020. A Copy was also marked to Joint Secretary (Revenue) and Director (Narcotics Control).

Registration of controlled Substances in Schedule A to the NDPS (RCS) Order, 2013 :– 4- Anilino-N-phenethylpiperidine (ANPP) and N-Phenethyl-4-piperidone (NPP)

On 9th June 2021, IDMA had submitted a representation letter to Director General, Narcotics Control Bureau with regards to registration of controlled Substances in Schedule A to the NDPS (RCS) Order 2013 and requested the Government that the need to obtain Unique Registration Number (URN) and follow the prescribed procedure in NDPS (RCS) Order, 2013 should not be required in a situation where the Controlled Substances - 1) 4- Anilino-N-phenethylpiperidine (ANPP) and 2) N-Phenethyl-4-piperidone (NPP) are manufactured as intermediates in manufacture of Essential Narcotic Drugs. He said that copy of this letter was also sent to Deputy Director General (Operations) Narcotics Control Bureau.

On 16th June 2021 IDMA had submitted another representation mentioning the practical difficulties in case of manufacture of APIs or Chemicals, wherein Schedule A Controlled substances are formed as intermediates and further processed:-

1) Any intermediate in chemical synthesis may exist in the reaction mass, in solvents and not necessarily isolated.

2) The intermediate would be available in a crude form and not in its pure form as it would be processed further to an end product.

3) The quantum of the intermediate (weight) may be difficult to determine, as the same is not isolated, available in a reaction mass, or the purity may vary from batch to batch.

IDMA had once again requested that the need to obtain URN and follow the prescribed procedure in NDPS (RCS) Order, 2013 should not be required in a situation where the Controlled Substances - 1) 4- Anilino-N-phenethylpiperidine (ANPP) and 2) N-Phenethyl-4-piperidone (NPP) are manufactured as intermediates in manufacture of Essential Narcotic Drugs.

Web meeting with Joint Secretary (Revenue) on NDPS Issues

On 29th June 2021, a VC meeting with Mr. Ritwik Ranjanam Pandey, IAS Joint Secretary (Revenue) and Mr. Dinesh Bouddh, IRS, Director (NC) was held with representatives from Sun Pharma, Rusan Pharma, Abbott and Centaur pharmaceuticals. A presentation on the following pending policy related issues were submitted by Mr.Devesh Malladi -

a) Amendment of Rules and Order to enable Digitalization & Route change

b) NDPS Rules amendments governing END and other substances

c) Applicability of sub clause (I) to clause (a) of Rule 67 A in chapter VII A of NDPS Rules

d) Issuance of a standing order to streamline procedure of investigation of licensed entities to avoid undue harassment.

On 30th June 2021 IDMA had forwarded a PowerPoint presentation made during the above meeting to Joint Secretary (Revenue) with a copy to Director (NC).

Meeting with Central Bureau of Narcotics & Director of Revenue

On 5th July 2021 a VC meeting with Mr. Ritwik Ranjanam Pandey, IAS Joint Secretary (Revenue), Mr.Rajesh Dhabre (Narcotics Commissioner) and Mr. Dinesh Bouddh, IRS, Director (NC) was held with representatives from Sun Pharma, Rusan Pharma, Abbott and Centaur pharmaceuticals on issues pertaining to Central Bureau of Narcotics (CBN). Mr. Devesh Malladi made a PowerPoint presentation on the following issues pertaining to CBN -

(1) Issuance of Import / Export permits in 21 working days

(2) Quota allocation, license renewal & destruction of ENDs & Manufactured Drugs in 30 working days

(3) Implementation of UNODC National Drug Control Software for issuance of online export/ import permits of Narcotic and Psychotropic substances

(4) Public notice on enabling route change for export consignments

(5) Public Notice on substances not under the purview of NDPS and

(6) Other relevant issues.

Representation on July 16th notification No. GSR 490(E)

In response to various representations on digitalisation of the import/export permits, DoR issued a notification No. GSR 490(E), on July 16th, 2021. However, this was not as proposed for digitalisation of import/export permits.

On 11th October 2021, a meeting with Mr. Ritwik Ranjanam Pandey,

IRS, Joint Secretary(Revenue) and Mr. Dinesh Bouddh, IRS Director

(Narcotics) was held in this regard. IDMA forwarded a letter on 12th October 2021 to Shri Ritvik Ranjanam Pandey, Joint Secretary (Revenue) with regards to Gazette Notification No. GSR 490(E), dt.16.7.2021 highlighting the deficiencies and also suggestions on digital process of issuance of export/import certificates.

INCB invitation to IDMA to participate in member states consultation on proliferation of non-scheduled and designer precursors

International Narcotic Control Board (INCB) invited IDMA to participate in their member states consultation on proliferation of non-scheduled and designer precursors. Three Industry associations from Germany, Tanzania and India were invited to make presentations on Practical and concrete measures and approaches for global action on this subject matter. Around 120 + countries were present in the virtual interactive session organised by INCB. Mr.Devesh Malladi made a presentation followed by an interactive session.

Representation on amendments to The Narcotics Drugs and Psychotropic Substances Act, 1985

A presentation was made to all the EC Members about the recommendations for amendments to NDPS Act, 1985 which has been a longstanding plea from licit entities. On 22nd October 2021, IDMA made a representation to The Revenue Secretary, Department of Revenue with a copy to Shri Ritvik Ranjanam Pandey, IAS, Joint Secretary (Revenue), Ministry of Finance, Department of Revenue and Shri Dinesh Bouddh, IRS, Director (NC), Ministry of Finance, Department of Revenue, Ministry of Finance. The standing committee on finance had also strongly recommended a few of IDMA's recommendations in March 2012 and so have, enforcement agencies concurred in various meetings, minutes and internal circulars in the past several years.

IDMA has always been in forefront of NDPS Matters/Issues. IDMA's representation on the amendments proposed included the attached detailed rationale and justification as mentioned below:

The Summary of amendments proposed –

1. Insertion of new definitions for 'diversion' and 'licit entity' in section 2 so as to clearly define and distinguish between 'licit' and 'illicit' persons and acts.
2. Addition of a new section to introduce compounding of offences by licit entity where the contravention involves acts that do not constitute 'diversion'.
3. Amendment to section 35 so that the 'presumption of culpable mental state' does not apply in case of licit entities and the burden is on the prosecution to show that there was diversion from licit to illicit channels.
4. Amendment to section 42 to provide certain safeguards for arrest in case of a licit entity.
5. Amendment to section 54 – no presumption of guilt in trial in case of a licit entity.

6. Amendments to sections 21 and 22 in respect of determination of quantity of 'manufactured drugs' and 'psychotropic substances' that are pharmaceutical preparations, respectively.
7. Amendments to section 2(xi) and section 3 to ensure that a substance be included as a 'manufactured drug' or a 'psychotropic substance' after considering not just its abuse or potential for abuse but also its therapeutic use and after consultation with concerned stakeholders.

National President and the members acknowledged the efforts of Mr. Devesh Malladi, Chairman, NDPS Committee.

Meeting with Ministry of Health / DoP officials

Mr. M. Devesh visited Delhi on 10th and 11th November 2021 and made detailed presentations on IDMA's proposed amendments to the NDPS Act, 1985 to the officials of Ministry of Health and Department of Pharmaceuticals. A Web meeting was also held on November 15th, 2021 with Mr. Deepak Bagla, MD & CEO, Invest India, in this subject matter.

Virtual Meeting with members of Sub-committee on 'Prevention of Drugs and Substance abuse' amongst the children in the country

On 12th November 2021, CDSCO Sub-committee headed by Dr. H G Koshia, organized a virtual meeting to address the issue of 'Prevention of drugs and substance abuse' amongst the children in the country. Mr. M. Devesh, Chairman NDPS Committee represented IDMA in the meeting. There was a discussion on the Development of a new App based on MIS system for tracking and control. Mr. Devesh pointed out that the same information can always be obtained from the GST Portal and as such there is no apparent need for a new application. As regards installation of CCTV cameras at the retail outlets, this issue was represented by AIOCD. IDMA made a written representation on 16th November 2021 to Dr H G Koshia, Chairman, Sub-committee on Prevention of Drugs and Substances Abuse with regards to the Development of an App based MIS system for tracking and control. with a copy to Dr. V G Somani, DCG(I), Dr. Santosh Indraksha, Dy. DCI and Dr. K. Bangarurajan, Advisor.

Web meeting on Proposed Amendments of the NDPS Act, 1985 with Secretary, DoP

On 22nd November 2021 a Web meeting was held on proposed Amendments of the NDPS Act, 1985, chaired by Ms. S Aparna, Secretary, DoP. The other members present were Dr. Sumit Garg, Deputy Secretary, DoP and Mr. Venkat Hariharan Asha, Dy. Director, DoP. Mr. M. Devesh made a Presentation on Narcotic Drugs and Psychotropic Substances Act, 1985 and the long pending amendments.

REPORT OF NUTRACEUTICAL COMMITTEE

Stakeholders' Meeting on Nutraceutical and Health Supplement Industry in January 2021

Further to the interactive meeting with IDMA Members and Mr Arun Singhal, CEO, FSSAI, Dr. R K Sanghavi, Chairman of Nutraceutical Committee, requested Mr. Singhal to consider amendment in the Nutraceutical regulations in the following areas:

1. Suitably modifying the footnote under table B of Schedule-I (Vitamins & Minerals) by adding the 'additional' words namely, 'active moieties' and 'pro-vitamins'. This would ensure most vitamins in current use, irrespective of their forms, remain as standardised.
2. Inclusion under the table B of Schedule-VI (Nutraceuticals) the names of specific vitamin derivatives, pro-vitamins & active moieties *separately:* Benfotiamine (B1), Panthenol (B5), Pantethine (B5), Pyridoxal phosphate (B6), Pyridoxal-5-phosphate (B6), L-methylfolate (folic acid), L-methylfolate calcium (folic acid), Methylcobalamin (B12), Adenosylcobalamin (B12). This would facilitate 'nutraceutical' category of products incorporating these vitamins.
3. Changing the regulation / FSSA clause of 15 years safe usage in India and 30 years safe usage in the country of origin clause as the basis for novel ingredient approval *to:* 'documented history of usage in India, or at least four years globally'. This is very essential such that already in use and OTC-available ingredients in overseas markets can be accessible to the Indian consumer in this lifetime. (Or else they have to go abroad to purchase the same!)

Representation with regards to novel Ingredients

Following requests by concerned members, Dr Sanghavi made a representation with regards to announcing *approved* novel ingredients by suitably uploading relevant information on the FSSAI website. Details & updating website for the knowledge and information of Food Business Operators (FBOs) and all others concerned will facilitate availability of more formulations incorporating these novel approved ingredients such that health of more consumers is benefited.

Suggestions on the Food Safety and Standards (Ayurveda Aahar) Regulations Draft dated 30th June 2021

IDMA has forwarded the suggestions drafted by Dr Sanghavi on 11th August 2021 with regards to the Food Safety and Standards (Ayurveda Aahar) Regulations Draft dated 30th June 2021.

Recognizing TUL – A Step Ahead of RDA Limits

After numerous representations by IDMA over years, including a detailed compilation (by Dr Sanghavi) favoring recognizing the need to adopt Tolerable Upper Limits as capping, instead of blanket RDA limiting quantities unscientifically, the FSSAI has finally accepted for implementing specified safe Upper Limits (UL) vide advisory dated 16th July 2021.

Task Force on Nutra Sector

FSSAI has constituted a Task Force for the Nutra Sector, as per advisory dated 9th November 2021, to unlock the potential for supplements address challenges faced by the FBOs. Suitable representation has been made to try ensure IDMA's presence in this Task Force.

OTHER MATTERS ATTENDED BY NUTRACEUTICAL COMMITTEE CHAIRMAN

Notifications on Exclusion of FDC of Tamsulosin and Deflazacort from Ban

The Ministry of Health had issued notification no. GSR 255 (E), dt. 7.4.2021 with regards to FDCs of Tamsulosin HCl 0.4 mg + Deflazacort 30 mg. hard gelatin capsules which has been excluded from prohibition.

Dr Sanghavi informed the members that FDCs of Tamsulosin HCl 0.4 mg + Deflazacort 30 mg hard gelatin capsules has been excluded from prohibition. This FDC was probably prohibited since combination of steroids with other agents, other than in asthma management, is otherwise under blanket ban. Since the concerned FDC has documented usefulness in facilitating removal of ureteric stones after lithotripsy (laser blasting) it was exceptionally approved, even after it being banned, vide GSR 255 (E), dt. 7.4.2021.

This positive approach by the Delhi High Court could possibly pave a pathway, opined Dr Sanghavi, for re-consideration of otherwise medically sound combination of drug products that have been banned via the Prof. Kokate Committee exercise. A glaring example could be the now banned triple combo of a steroid + antibacterial + antifungal ear drops. The same latter triple combo is already approved for dermatological use, and also, the ear drop triple combo of Glenmark has been approved in 21 countries and with the same Indian brand name!

PSURs – Raised Related Concerns

In the Kokate Committee List of approved FDCs (List 'C') there are only 4 FDCs approved as on dates of 2018 and beyond years. If the perspective of 4-years life-span is considered for new drugs, opined Dr Sanghavi, then would be no need to submit the PSURs data for new companies now introducing or desiring to launch any of these FDCs (barring these 4). For those who had already applied and are submitting the PSURs, and the 4-years period has not yet lapsed there could be a need to request DCGI to permit submitting the PSUR not as per the New Drugs and Clinical Trials Regulations, 2019.

Also, for the submitted PSURs, there has been grievances expressed by the concerned companies regarding unjustifiable and unrelenting requests for submissions of data and reports

as well as spelling out activities for the Pharmacovigilance (Pv) – relating implementations by the concerned official of the PvPI cell. This matter was elaborated by Dr Sanghavi during interaction with the DCGI, and as per Dr Somani's advice the necessary evidences of grievances were forwarded. IDMA is thankful to the DCGI for having attended to this matter and resolving it amicably.

Consultative Meeting with Drug Manufacturers held on 18th September 2021

In order to amass relevant points for suitably modifying and amending the upcoming Drugs and Cosmetics Act, the DCGI office had initiated a meeting with stakeholders. In this meeting Dr Sanghavi suggested the following points that could be considered to enable companies to launch new drugs as well as enable smoothly market approved products.

- **Points pertaining to New Drug Approvals:** (i) Permitting New Drugs already being marketed in specified regulated markets for an already specified period of 2 years to be launched subject to conducting Post-marketing studies; (ii) Create a separate category for Fixed Dose Combination new drugs (not available in world) as iAND (Indian Abbreviated New Drug); (iii) laying down SOPs for Subject Expert Committee (SEC); (iv) suitably emphasizing and highlighting approval of FDCs under Schedule Y (Appendix VI) Category 4 (for convenience only) without requiring to undergo elaborate studies such that the same is taken cognisance by the SEC whilst scrutinizing new FDCs' applications for approval.

- **Points pertaining to Pharmacovigilance Program of India (PvPI):** (i) Submission of PSURs related concerns; (ii) Risk Management Plan (RMP) requirement unjustified for all already marketed ('old') drugs; (iii) Easing the periodic reporting under the PvPI.

Meeting of DTAB Sub Committee through WebEx (Video Conference) w.e.f. 19.04.2021 to 07.05.2021 for Examining the Fixed Dose Combinations (FDCs) Considered as Irrational by Prof. Kokate Committee and to Provide Hearing to the Stakeholders

CDSCO uploaded a Public Notice dt.12.4.2021 with regards to the Meeting of DTAB sub-committee through WebEx for examining FDCs. This was in continuation to the Directorate Public Notice dated 23.03.2021 issued by Shri Sanjeev Kumar whereby his office requested to submit the details and confirm the participation details of stakeholders. IDMA had forwarded the notice to our members and even sent them reminders. However, it has been observed that only a few applicants have submitted the requisite details.

IDMA members have requested for extension of the video conferencing by another 30 days due to the current pandemic situation as some of their concerned staff have been affected by Covid-19. IDMA requested Mr. Sanjeev Kumar for the same.

Evaluation of Certain PRE 1988 permitted Fixed Dose Combinations (FDCs) de novo for Manufacture for Sale in the Country Without Due Approval from Central Licensing Authority

IDMA had received the following notice no. File No. 4-01/2013-DC (Misc. 13 PSC Part II) dated 26th July 2021 issued by CDSCO (FDC Division) along with the Format for submission of information on FDC to Expert Committee and List of Pre-1988 permitted Fixed Dose Combinations (FDCs). With reference to the Hon'ble Supreme Court of India Judgements dated 15.12.2017 and 14.02.2019 wherein an Order was passed that the Central Government may, if it so chooses, de novo carry out an inquiry as to whether the Fixed Dose Combinations licenced prior to 1988 should be the subject matter of a notification under Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940). Accordingly, an Expert Committee was constituted under the Chairmanship of Dr M S Bhatia, Professor & Head, D/o Psychiatry, University College of Medical Sciences, New Delhi and as per the decision taken during the Expert Committee Meeting that the concerned stakeholders shall submit the information on the rationality, safety and efficacy with regards to these FDCs as per the prescribed format enclosed. IDMA has forwarded the above notice to all our members with a request to submit their information in the prescribed format along with relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) to the CDSCO (FDC Division) Office, New Delhi latest. IDMA forwarded a letter to Dr V G Somani, DCGI in regards to the same.

REPORT OF PRICING / CONSUMER AFFAIRS COMMITTEE

Special One Time Settlement (SOTS) Scheme

DoP's Stakeholders consultation meeting was held on 15th January 2021 in regards to the proposed Special One Time Settlement (SOTS). The meeting was chaired by Ms. S. Aparna, IAS Secretary, DOP. Dr. Amit Rangnekar informed the Secretary that the issues are more than three to four decades old and pertain to DPCOs of 1979, 1987, 1995 etc. Each case has its own merits and demerits and the issues involved in each case are dissimilar, which needs to be sympathetically considered by the authorities. Such issues cannot be settled by the Association on behalf of individual companies. As such only individual members can respond. The Association can help sensitize and facilitate, but cannot resolve the issues on behalf of Members. National President & Dr Amit Rangnekar reported that on 22nd January 2021 and on 9th February 2021, IDMA had submitted letters to Secretary, DoP on Special One Time Settlement. In these letters, IDMA had informed that the following suggestions were received from our Members:

1. Companies had requested that they should be given an opportunity to be heard by the DOP/ NPPA authorities and thereafter be given the option for SOTS.
2. Companies had requested to postpone the SOTS to the next financial year, with a deferred payment schedule, as the dates proposed for payment are around the end of the financial year on 31st March, and this would impact their bottom line.

On 13th August 2021, IDMA sent a letter to Ms. S Aparna, IAS, Secretary, DoP requesting for early announcement of Special One Time Settlement Scheme.

National Single Window System

Ms. Sumita Dawra, Additional Secretary, DPIIT had a video conference meeting held under her chairpersonship on 22nd January, 2021 with Industry Associations regarding Investment Clearance Cell (ICC) / National Single Window System (NSWS), it was demonstrated as to how Single Window clearance will work.

DIIPT is expecting the portal to be rolled out from 1st of April. All participants requested that the beta portal be provided to the Associations, so that it can be tested by their members and in case of any issue, the same can be eased out before final roll out. Thereafter, suggestions/ recommendations were invited from the participating associations on the matter. Mr. Venkataraman suggested that the Pharmaceutical industry requires various approvals from the Drug Controller General of India, DCG(I) and other Authorities. All such necessary approvals need to be incorporated in the portal for which the members will go through and give their feedback.

The meeting concluded with the following conclusive remarks/action points:

(i) The work on popularizing the deemed approvals for all the States is on-going so that the approvals are given for the various clearances to the investors within a time frame of 21 days.

(ii) MSMEs and Startups to be also included in the beta trials. Provision to be made for that.

(iii) Associations to be made a part of the testing phase of the modules for further suggestions and feedback.

(iv) A demo on the Common Application form (CAF) is to be presented in the next meeting in mid February 2021.

Invest India presented the roadmap of development and current progress of the ICC along with a demo on the Know Your Approval (KYA) module. The technical aspects on ICC were also presented for necessary suggestions from the Associations. Mr. C V Venkataraman said that suggestions/recommendations were provided by the participating Associations on the matter one by one along with certain clarifications for perusal.

Launching of Online National Drug Licensing System (NDLS) Portal

National President informed the members that CDSCO issued a notice on 31st March 2021 informing that Online National Drug Licensing System (NDLS) portal has been developed for online processing of various applications submitted by the applicant for issuance of licenses and certificates for Drugs and Cosmetics. This portal has been made functional from 31.3.2021 for

validation of the system and will be shifted from validation mode to operational for all purposes from 15th April 2021.

In this connection, a training session across the country was conducted by DCG(I) on 24th April 2021. IDMA had forwarded the circulars to all our members. The training was attended by around 800 participants.

The Additional Secretary informed that 43 Ministries/Departments and 14 State Governments have been working with DPIIT to evolve this National Single Window System.

Investment Clearance Cell / National Single Window System (NSWS) portal - Maadhyam

National Single Window System (NSWS) portal - **Maadhyam** was launched under the chairpersonship of Ms. Sumita Dawra, Additional Secretary, DPIIT on 15th April, 2021. The pre-production web link to the National Single Window System (NSWS) portal Maadhyam was shared for intensive testing and providing feedback. On 1st June, 2021, the next step forward towards the actual public launch of the portal was initiated by Ms. Sumita Dawra, Addl. Secretary, DPIIT. A PowerPoint presentation was made by Invest India. Through this PowerPoint they informed that around 23 states have a Single window system and it's been aligned with Portal Madhyam. Punjab has the proposal of Deemed approval at the draft stage, Telangana and AP have already implemented the concept of Deemed approval.

Dr. Geroge Patani complimented DPIIT and Invest India for the initiative, considering that the pharma manufacturing requires about 40 approvals before the plant can start. He also informed that at times, space allotted for documents to be loaded is too small, applications get stuck at the State level, hence there should be a provision for an Appellate authority, to appeal in case of clearances being delayed. He said that Invest India would like to have an interaction with IDMA to understand better and requested for the list of approvals needed. IDMA was requested to provide the list of all approvals needed. On 15th June 2021, IDMA submitted a response to Invest India enclosing details of

(1) Approvals/Licences/ Registration for starting a Pharmaceutical Manufacturing Plant

(2) Central Government Acts/Rules governing a Pharmaceutical Manufacturing Plant, and

(3) State Government Regulatory Compliance Details.

On 16th June 2021, Invest India had requested for a one to one interaction with IDMA members in respect of specific States to understand the use of the portal. Invest India has shared the names of the 14 States which are already integrated as follows:-

1. Andhra Pradesh
2. Assam
3. Goa

4. Gujarat
5. Himachal Pradesh
6. Karnataka
7. Madhya Pradesh
8. Maharashtra
9. Odisha
10. Punjab
11. Tamil Nadu
12. Telangana
13. Uttar Pradesh
14. Uttarakhand

IDMA requested members to kindly get the APP tested at their end for the states indicated therein and revert with their comments. This will enable IDMA to send the feedback to Invest India, for further improvements if required.

On 17th September 2021, IDMA was invited by Invest India to attend the meeting on National Single Window System. The meeting was also attended by FICCI, NASSCOM, PHD CHAMBER, Associated Chamber of Commerce and others. He further added that the meeting was chaired by Ms. Sumita Dawra, IAS, Additional Secretary DPIIT and there were 17 participants at the meeting. He said that DPIIT would be soft-launching the new portal shortly. All Industry Associations were requested to give feedback on the new system being launched. It was informed that in the first phase 18 Ministries and eight States are already on board and another five States are likely to join soon. He further informed that the land bank portal will also be synced with this one single window system.

Representation to extend revised ceiling prices of Heparin Injection fixed by NPPA vide Notification no No.S.O.2151 (E) dated 30.06.2020

IDMA had submitted a representation on 10th March 2021 to Chairperson, NPPA requesting NPPA to extend the revised ceiling price of Heparin Injection beyond 31.03.2021 till a period deemed fit for the manufacturers of the same. This request is in order to ensure consistent availability of Heparin. NPPA in its 84th Authority meeting held on 10th March 2021 had considered to continue with the increased ceiling price for Heparin Injection 1000IU/ml and 5000IU/ml.

In this connection, NPPA issued Gazette Notification SO 1236(E), dt.17.3.2021 extending the period till 30.9.2021 or until further order whichever is earlier.

On 8th September 2021, IDMA had made another representation to Chairman, NPPA giving the reasons and requested to extend the revised Ceiling Price of Heparin Injection till 31st March 2022. Dr. Amit Rangnekar mentioned that NPPA had discussed this subject in its 92nd meeting held on 08.09.2021 and the Minutes of the meeting have been placed on its website. He said that

he was pleased to inform the members that NPPA has decided to extend the date for the revised Ceiling Prices of Heparin Injection till **31.03.2022**.

Stakeholders National Consultation meeting for revision of NLEM 2015

Stakeholders National Consultation Meeting was held on 19th February 2021 in regards to revision of NLEM 2015. IDMA had forwarded inputs on 18th February 2021 for their kind consideration. The meeting was Chaired by Prof. Y K Gupta. Dr. R K Sanghavi and Mr. Amit Rangnekar represented IDMA at the NLEM meeting which was also attended by officials of DTAB & NPPA & DoP & MoH. There were discussions on the issue of 'essentiality' being the platform to persist with, as has always been insisted upon, to be the basis of selecting drugs for inclusion in the NLEM. In this context Dr R K Sanghavi, independent medical consultant with 4-decades of expertise in Healthcare Industry, as well as current Chairman of Nutraceutical Committee of IDMA, opined as follows:

(i) Only one prototype drug should be selected from any therapeutic category.

Dr Y K Gupta, chairing the meet, mentioned that this has always been the endeavour thus far. However, his attention was drawn to multiple agents of same therapeutic group being included under NLEM in 4 specific instances. This would be revisited seemingly as per Dr Gupta's noting.

(ii) No Differentiated Dosage Forms such as Modified Release should be included in the NLEM unless there is no corresponding immediate release due to pharmaceutical compulsions. Dr Y K Gupta concurred with the same.

(iii) Essentiality needs to be quantifiably defined and not merely an expression that could lead to varied interpretations based upon individual perceptions. In this context Dr R K Sanghavi proposed that there could be acute, subacute and chronic diseases as is medically categorized usually. Each disease needs to have a defined specific quantified incidence and / or prevalence to merit the tag of being labelled as 'essential' disease / disorder and only drugs for these ailments need to be considered for inclusion under NLEM albeit with an eye for fulfilling the above two criteria as well.

Dr Y K Gupta was open to this novel suggestive mechanism as a parameter and required details to be forwarded for considering utilising the same or similar as basis for NLEM inclusion of drugs. IDMA submitted a detailed write-up on the same with due justification and substantiation of basis.

Representation on unprecedented increase in the prices of Paracetamol API

On 5th April 2021, IDMA forwarded a representation to Chairperson, NPPA with a copy to Secretary, DoP in regards to the unprecedented increase in the prices of Paracetamol Active Pharmaceutical Ingredients (API). Dr. Amit Rangnekar informed the members that we have requested for the following consideration:-

(i) Increase of 20% for all non-scheduled formulations for the current year over last year under Para 19 of DPCO 2013

(ii) Prices of those scheduled formulations whose retail prices are below the ceiling prices to be raised up to the ceiling prices

(iii) Revise the ceiling prices based on Consumer Price Index (CPI) instead of revising ceiling prices as per Wholesale Price Index (WPI)

In continuation of the above representation, IDMA made another representation on 10th May 2021 to Chairperson NPPA with copy to Secretary, DoP and also requested for a virtual meeting which was immediately obliged. National President reported that on 12th May 2021, NPPA arranged a virtual meeting with IDMA Members on the subject. The meeting was chaired by Ms. Shubhra Singh, Chairperson NPPA. He said that Mr. Vinod Kotwal, Member Secretary, NPPA, Mr. N. I. Choudhury, Advisor NPPA, Mr. Rajesh Agrawal, Jt. Director and Mr. S. S. Ojha, Joint Director NPPA were also present for the meeting. He further added that IDMA was represented by Mr. Mahesh H Doshi, Mr. S V Veeramani, Mr. Deepnath Roy Chowdhury, Dr. Viranchi Shah, Dr. George Patani, Dr. Amit Rangnekar, Mr. C V Venkataraman, Mr. B G Barve, Mr. Vinay Pinto, Mr. Daara B Patel & Mr. Ashok Madan.

IDMA had given Madam a one month and one year perspective about the increase of prices. Also, explained the matter through a study on Paracetamol for the last eight (8) years. He said that IDMA has made a valid, informative and detailed representation covering all the aspects of the increase in prices. He also mentioned IDMA has requested relief from NPPA for the same. It was opined that IDMA had made a very strong representation and look forward to their response. As it is affecting the whole DPCO, IDMA hopes that its members get an increase in prices by NPPA applying PARA 19. Mr. Milan Patel explained in detail the increase in the prices of paracetamol and what the Gujarat State Board members are doing in regards to this. He said that the individual members of Gujarat State Boards have forwarded a letter to the Government in a very subtle way describing the increase in paracetamol. The committee finally decided that individual member companies can write to the Government on their own but IDMA would not instruct its members to do so.

Government of Tamil Nadu & Kerala issued notification mentioning fixed rates for Covid-19 specific Drugs

The Government of Tamil Nadu and Kerala had issued notifications stating that they would fix the rates for covid-19 specific drugs. He said that if the state fixes the price than the pharma industry would be in a dilemma as they would have to sticker, re-sticker have different prices which were in pre CST regime & state tax regime. He also asked the members if they have any knowledge / information about any other state fixing such prices and he said that IDMA would make a representation mentioning that State fixes prices would only mean confusion. Mr B G Barve mentioned that he is working on the GST part of the said representation. Mr. S V Veeramani said

it was an apt representation as a state fixing price would cause chaos. Dr. Amit said that we would make the representation just seeking clarifications.

Proposed IPDMS V2 in NPPA

NPPA's Proposed IPDMS V2 video conference meeting was held on 1st July 2021. IDMA was represented by Dr. Amit Rangnekar, Mr. Tushar Korday, Mr. C.V Venkataraman and Mr. Prakash Rijhwani. IDMA's team made multiple observations on the IPDMS V2 and were requested by Mr. Rajesh Kumar T, Deputy Director (Legal/IT), NPPA, to send an official representation.

On 13th July 2021 IDMA made a representation to the NPPA. IDMA informed the committee that IDMA had made a detailed presentation regarding various issue faced with IPDMS V1 to Dr. P D Vaghela, Secretary, Department Of Pharmaceuticals and to the Chairperson NPPA Ms. Shubhra Singh on 23rd August 2019, during the 1st meeting of the Federation of Pharmaceutical Associations (FOPA) in New Delhi. Dr. Vaghela and Madam Shubhra Singh had specifically requested IDMA to submit a representation to them. IDMA had duly submitted the representation with screen images to NPPA & DoP suggesting various changes in the IPDMS V1 to ensure ease of use of the database and avoid errors.

IDMA was pleased to note that many of IDMA's suggestions had been incorporated in IPDMS V2 which seems an improvement on V1 in terms of user friendliness and ease of use. IDMA also requested NPPA that few of our members be allowed to use the software so that we, the actual users may provide inputs for ease of use of the software and a better end user experience. It was also suggested that the companies have the option to change the authorized person as and when it is required.

IPDMS V2 - Interaction with Ecosystem

A meeting was organized by NPPA on 17th September 2021 at the conference room of NPPA, New Delhi. The meeting was called to understand the feedback on the proposed IPDMS V2.0, particularly for Form I to VI required to be filed with NPPA under DPCO, 2013.

In continuation of the above meeting, on 13th October 2021, IDMA had made a Representation to Director (Admin.), NPPA and forwarded suggestions and requested that after implementation of these suggestions, a few of our members would visit NPPA office for the trial run and experience the software first hand & provide key user insights.

PARA 18(i) of DPCO 2013

A Notification relating to one time exemption from revision of prices under Para 18(i) of DPCO 2013, till NLEM 2021 was released. As per Para 18(i) the five year period got over in 2021 and they should have either announced the revised prices or released the new NELM 2021 in January 2021. But the Ministry of Chemicals and Fertilizers, Dept. Of Pharmaceuticals has issued a Notification (F.

No. 31011/05/2018-Pricing) dated 19th July 2021 mentioning that the Central Government hereby grants ONE TIME EXEMPTION from revision of Ceiling Price under Para 18(1) of the Drugs (Prices Control) Order, 2013 and to keep in abeyance the Revision of Ceiling Prices after completion of 5 years till NLEM 2021 is released by the Ministry of Health and Family Welfare.

Prima-facie it appears they would grant exemption only till the new NLEM 2021 is announced, but once announced, revised ceiling prices would be applicable. He explained the notification and its effects in detail. He said they would be preparing a draft for the same wherein IDMA would like to reiterate their request, that once a product has been subjected to price fixation, it should not be subjected to price fixation again and again every 5 years. Further, he said that looking at the facts, IDMA would request that the provision of Para 18(i) 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. Whenever revised ceiling prices are announced, the IDMA has made multiple representations that ceiling price should be applicable only from the prospective batch and not with immediate effect and also no coercive action should be initiated against the company if one unit of a scheduled product is found with retailer at a price higher than the notified ceiling price. He said IDMA would forward a representation to the Government.

IDMA's representation dt. 11.8.2021 wrt Gazette Notification No. S.O. 2874(E), dt.19.7.2021 – Amendment of Para 18 (i)

The said notification was discussed in detail in the last meeting. Representations on the subject was sent by IDMA on 11th August 2021 to Dr. V. K. Paul, Member (Health) NITI Aayog, Ms. S Aparna, Secretary, DoP and Ms. Shubhra Singh, Chairperson, NPPA. This issue related to one time exemption from revision of prices under Para 18 (i) of DPCO 2013, till NLEM 2021 is released. He further mentioned that earlier in March '21, we had requested vide our letter dt.19.3.2021 that once a product has been subjected to price fixation, it should not be subjected to price fixation again and again every 5 years. We had requested that 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 Pharma industry.

DoP Notification S.O. 3249 (E), dt. 12.8.2021 wrt Drugs (Prices Control) Third Amendment Order, 2021 – Para 18 (i) – delinked the NLEM from Para 18 (i)

On 12th August 2021, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, had issued a Notification No. S.O. 3249(E) wrt Paragraph 18 Clause (i). In this notification it is mentioned that in the Drugs (Prices Control) Order, 2013, in paragraph 18, for clause (i), the following clause shall be substituted, namely:-

"(i) every five years from the date of fixing the ceiling price under this Order for formulations as specified under the SCHEDULE - I".

On 13th August 2021, IDMA sent representations to Dr. Vinod K Paul, Member (Health) NITI Aayog, Ms. S Aparna, Secretary, DoP and Mr. Navdeep Rinwa, Joint Secretary, DoP. Vide this representation, IDMA mentioned that the Notification No. S.O. 3249(E), dt.12.8.2021 is a step taken backward at a time when the industry has risen above all difficulties to meet the demand for COVID treatment as required by the Government from time to time. Though the industry's efforts are being praised at all levels in the Government, this Notification is a dampener in the growth of pharmaceutical industry.

IDMA has requested the Government to keep the Notification in abeyance and suitable modification can be done if required after discussing with all stakeholders.

Submission Date Extended to 25th October 2021 w.r.t Evaluation of Certain PRE 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the Country without due approval from Central Licensing Authority

IDMA has received an email from Dr. V G Somani, DCG(I) in regards to the Public Notice dated 19th August 2021 on the above mentioned subject wherein the date for submission of the information has been extended from 25th August 2021 to 25th October 2021. He said that this was in continuation to the Directorate Notice of even number dated 26th July 2021 on the same subject whereby all the concerned stakeholders were requested to submit the information in the prescribed format by 25th August 2021 till 5.00 p.m. He thanked DCG(I) for the same and once again requested all our members to submit their information in the prescribed format along with relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) to the CDSCO (FDC Division) Office, New Delhi latest by 25th October 2021 till 5.00 p.m.

Representation on Unprecedented Price Increase in Input Cost

On 21st October 2021, IDMA made a representation to the Hon'ble Shri Mansukh Mandaviya ji, Minister of Chemicals & Fertilizers and Minister of Health & Family Welfare and Dr. Vinod K Paul, Member (Health), NITI Aayog on unprecedented price increase in input costs on APIs, Excipients, Intermediates and Packing materials. As the input price situation is worsening day by day, IDMA has requested the Minister for his kind intervention to provide partial relief to the Indian Pharma Industry. After deliberations, National President confirmed that we would go forward with joint representations for the benefit of the entire industry and along with other Associations.

The IDMA representation on unprecedented price increase was widely appreciated by the pharma industry as well as it has been covered specifically by the national media like ET and Pharmabiz in detail.

REPORT OF PUBLICATIONS COMMITTEE

IDMA Bulletin & Indian Drugs

The IDMA Bulletin & Indian Drugs were digitally published weekly and monthly respectively and uploaded on their respective websites for the benefit of the members as well as readers. The digital issues were duly appreciated by our members. IDMA bulletin received a double setback with the sad demise of Mr. T R Gopalakrishnan and Mr. C K S Chettiar within a span of few months. But the IDMA Secretariat rose to the occasion and assured that the IDMA Bulletin was released on schedule. The digital issues covered the latest happenings in the pharma industry as well as the events held by our state boards.

The digital issues helped to enhance the publications to a wider reach of readers from the top management in the office to the floor level workers in factory units. Thus keeping the pharma employees abreast of the latest happenings in the pharma industry.

IDMA hopes that in 2022, the IDMA Bulletin and Indian Drugs would be printed and the hard copy sent to all the members and readers.

The Indian Drugs Scientific Journal in its 59th year of Publications, was abstracted by 29 databases as listed below:

1. Scopus
2. Embase
3. International Pharmaceuticals Abstracts
4. Genamics JournalSeek
5. Ebsco
6. Citefactor
7. Oclc Worldcat
8. Scimago
9. Journal Guide
10. Tdnet
11. Science Library Index
12. Drji
13. Ccc (Infotrieve)
14. Index Copernicus
15. Electronic Journals Library
16. Sherpa/Romeo
17. ResearchBib
18. Indian Citation Index
19. i-Journals
20. i-Focus
21. i-Future
22. ResearchGate
23. Russian Science Index
24. PharmaPendium
25. Cabells
26. Scilit
27. Dimensions.
28. COSMOS (Germany)
29. MIAR (Universitat de Barcelona)

IDMA ACG-SCITECH Research Paper Awards 2020-2021

The best paper in each discipline published from January 2020 to December 2021 was selected by the judges. The Award now known as IDMA ACG-SCITECH Research Paper Award in the form of a citation, plaque and a cash award of Rs. 5000 in each discipline and the Best Review Article Award in the form of a citation, plaque and special cash award of Rs. 7500 will be awarded to the authors of the Best Research Papers and Review Article at the Annual Day celebrations.

Editorial Committee Meetings

A meeting of Editorial Committee members was held on January 15, 2021 and June 5, 2021 to review the operations of the publications and suggest improvements to be made. The meeting on June 5, 2021 was attended by the Editor, Associate Editors and Consulting Editor, Secretary General and IDMA Secretariat members assisting in the Publications. In place of Mr Ajay, Ms Geeta Suvarna was appointed to assist with the publications. During the year some improvements/ changes were implemented as listed below:

a) Short Notes was renamed as SHORT COMMUNICATIONS

b) Change of Author Name Pattern

c) Incorporation of Copyright Agreement Form

d) Clear Mention was made that INDIAN DRUGS does not charge for publication

e) Heading Numbering was removed

General isuues with respect to the operations was discussed and suggestions were called for from the Editorial committee members.

DOI numbers have been allocated to all manuscripts from the year 2012 to 2018 and 2020-till date. This has been uploaded on the CROSS REF site too. Addition of the DOI numbers will add credibility and improve the tracebility of the citations made.

REPORT OF QUALITY MANAGEMENT & TECHNICAL COMMITTEE

NGT disposes off case filed by HIM Jagriti against PET

The National Green Tribunal (NGT) after seven long years had finally issued an Order on 8th January 2021 disposing of the case filed by HIM Jagriti Uttaranchal Welfare Society, against use of plastic bottles and PET in pharmaceutical and other industries. In the Order the judges noted as below:

Para 15 (excerpts) "…the Drugs and Cosmetics Act, 1940 deals with the standards for safe use. Vide Notification dated 29.09.2014, the Ministry of Health has published draft rules for prohibition of use of Polyethylene Teraphthalate or plastic containers in liquid oral formulations for primary

packaging of drug formulations for paediatric use, geriatric use and for use in case of pregnant women and women of reproductive age group. Objections were filed against such rules which led to constitution of M.K. Bhan Committee and thereafter Prof. Y.K. Gupta Committee which has led to revision of Chapter on "Primary Packages for Pharmaceutical Articles" published on 24.01.2020. In the process, the said Chapter has been brought in harmony with global Pharmacopoeias for ensuring safe use of plastics for packaging of pharmaceuticals. Schedule M to the Drugs and Cosmetics Rules, 1945 provides for compliance with the Pharmacopeia and pharmaceutical manufacturers are required to follow the same. The containers or other parts of the packaging are required to be suitable and are not reactive, additive, adsorptive or leachable or presenting risk of toxicity to an extent that significantly affects the quality or purity of the drug. No second hand or used containers and closures shall be used. Pharmaceutical manufacturers are required to follow the Standards laid down in Indian Pharmacopoeia."

Para 16. "In view of revision of the Pharmacopeia, the adverse health effect of plastic packaging has been regulated to an extent. While further steps may be desirable, the same need to be considered in phases as may be found viable. The matter being required to be primarily dealt with by the concerned Executive authorities, **we do not consider it necessary to pass any further order in exercise of jurisdiction under Sections 14 and 15 of the National Green Tribunal Act, 2010**…."

This allows continued use of plastic and PET in pharma and other consumer industries.

Release of Addendum 2021 to Indian Pharmacopoeia 2018

On 31st March 2021, Mr. Rajesh Bhushan, Secretary (Health) chaired a meeting for release of Addendum 2021 to Indian Pharmacopoeia 2018. Dr. Manohar Agnani, Addl. Secretary (Health), Dr. Mandeep Bhandari, Joint Secretary (Health) and Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director IPC were present at the meeting.

1st meeting of Working Group to review the current Biosimilar Guidelines

Department of Biotechnology (DBT) along with CII organized the 1st meeting of Working Group on 18th October 2021 to review the current Biosimilar Guidelines. The meeting was attended by Dr. Renu Swarup, Secretary, DBT, Dr. Nitin K Jain, Scientist F, DBT, Prof. Y K Gupta, Dr. VG Somani DCG(I), Dr. Gandharva Nagpal, Scientist C, DBT, representatives from CII, IPA, OPPI, ABLE and others. A PowerPoint presentations made by DBT, OPPI and IPA. Also, IPA presented a report of June 2021 on Biosimilars.

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

IDMA had been requested by FDA Commissioner, Maharashtra to make a presentation on

Nitrosamines – Impurities, testing etc. Dr. Milind Joshi, Chairman, Quality Management & Technical Committee, IDMA made an excellent presentation to the FDA Commissioner and his officials on 17th November 2021.

REPORT OF REGULATORY AFFAIRS COMMITTEE

DOP Committee for suggesting ways for reducing compliance burden faced by the Industry

IDMA was informed by DOP vide a letter dated 6 January 2021 in regards to forming a Committee for suggesting ways for reducing the compliance burden faced by the Industry. The terms of reference of the Committee includes reducing compliance burden across areas related to renewals of licenses / permissions, inspections, return filings, registers, records and display requirements; and also decriminalization, identification of redundant laws and rules, regulatory impact assessment and use of technology. DCG(I) Dr V G Somani had called a meeting on 20th January 2021 to discuss reducing regulatory compliance burden.

The second meeting of the Committee was held on 22nd March 2021 and the meeting was chaired by Mr. Rajneesh Tingal, Joint Secretary DoP. Participants were from NPPA, CDSCO, Invest India. The Industry was represented by IDMA, CII, ASSOCHAM, FICCI and AiMeD. IDMA forwarded a representation to DoP and Invest India. DoP made a powerpoint presentation on constitution of the committee, terms and reference and recommendations to minimize the compliance burden on industries. Invest India compiled all the information and analysis that were presented on compliance burden reduction.

The Department of Pharmaceuticals vide email of 23rd July 2021 advised IDMA to provide relevant and specific inputs with respect to reducing regulatory compliance burden by 26th July '21. In this connection, IDMA compiled the data and responding immediately with detailed suggestions in four annexures to DoP as listed below :-

(i) Listed in **Annexure 1** are some of the amendments suggested to be made in the Drugs and Cosmetics Act to decriminalise some of the current provisions. The compliance burden on the Pharma Industry may also be attributed to redundant Acts and Rules which need to be revised.

(ii) Listed in **Annexure 2** are some of the suggestions for amendments of the **Drugs and Cosmetics Act to reduce Redundancy**.

(iii) Listed in **Annexure 3** are the comments on the current draft schedule M which in its current form is not as prescribed by other leading international monitoring agencies.

(iv) Listed in **Annexure 4** some of the recommendations to reduce the compliance burden on the Pharmaceutical Industry with respect to **pricing issues**.

IDMA thanked the committee members for all their efforts in the past few months in compiling data which enabled such a good representation to be prepared.

Clarification regarding submission of PSUR for New Drugs beyond 4 years of approval

IDMA made a representation on 20th May 2021 to DCG(I) with regards to Clarification regarding submission of PSUR for New Drugs beyond 4 years of approval. IDMA requested DCGI to issue a suitable clarification and not insist on filing PSURs for an extended period beyond 4 years in routine cases. IDMA also requested for a short video call to explain the matter in detail and seek his guidance to resolve this long-standing issue.

Request for initiation of Remote Inspections for WHO GMP Renewal

IDMA made a representation on 20th May 2021 to DCG(I) with regards to initiation of Remote Inspections for WHO GMP Renewal. Through this representation, IDMA explained the problems and requested to consider conducting remote audits for WHO GMP compliance to ensure uninterrupted supply of essential medicines. IDMA received a response from DCG(I) vide mail of 24.5.2021 to submit the modalities for initiation of Remote Inspections for WHO GMP Renewal.

Web Meeting with DCG(I) on 7th July 2021 & IDMA Representation on 11th August based on the Discussions with DCG(I)

IDMA had a video conference meeting with Dr V G Somani, DCG(I) on Regulatory Issues on 7th July 2021. IDMA had forwarded discussion points along with our representations on the selected issues to DCGI on 3rd July 2021. IDMA made an excellent PowerPoint Presentation for 30 minutes to DCG(I). IDMA thanked everyone concerned with the presentation for their support and co-operation. DCG(I) patiently perused through the presentation and the discussions points which were forwarded to him. DCG(I) carefully considered the request made by us and accepted many of the points presented.

IDMA sincerely thank DCG(I) for sparing your valuable time for the Zoom call on 7th July, 2021 with the IDMA team for a presentation on the some of the key issues of importance for the industry.

IDMA would like to place on record your careful consideration of the requests made by us and for your kind acceptance of many of the points presented.

IDMA summarizes the discussion points below and would request DCG(I) to initiate necessary actions to implement the proposed changes based on the discussions held by initiating:

- Issuance of necessary clarifications to the concerned officers for correct interpretation of the regulation and for uniform implementation of the provisions of the Drugs & Cosmetics Act & Rules.
- Necessary steps to be taken to modify the draft rules issued for amendment of Schedule M and issuance of new draft notifications in some other cases.

The below note includes the suggestions made by IDMA during the call, a review of the Submissions made by IDMA in the past and finally the request for action from IDMA on each issue.

1. Pathway for Handling Kokate Committee Approved FDCs

Issue: Procedure to be followed for Subsequent Applicants. Ref: DCG (I) letter dated 3 August 2020, Para 4 of the letter-PSURs to be filed as per New NDCT Rules 2019.

IDMA Submissions (19.10.2020): All the FDCs cleared by the 18 months policy by submission of safety and efficacy data were the existing products and were dealt with an agreed pathway issued via DCG(I) circular dated 12th December 2018 after several meetings and discussion with the industry and IDMA. Circular dated 12 December 2018 allowed a direct application to the SLA, specified the fees to be paid as Rs.15,000 and PSUR to be filed in accordance with Schedule Y.This circular superseded the following earlier circulars issued.

a) The circular dated 16th March 2017: Payment of Rs.15,000 as the fees and for filing the PSUR, in accordance with the provisions of Schedule Y.

b) The circular dated 5th June 2017: Details of the documents to be submitted by the subsequent applicants holding the SLA approved licenses and by those who were new manufacturers.

IDMA Suggestions: This pathway allowed all the manufactures - the existing, the subsequent applicants and the new manufactures to follow a uniform procedure considering the special circumstances of approval of such FDCs.

We requested the DCGI to follow the pathway issued via DCG(I) circular dated 12th December 2018 and to make a uniform policy applicable to all manufactures - for those who were issued NOCs for these FDCs under the 18 month policy and for all the subsequent applicants for all the FDCs cleared under this route regardless of the date approval.

IDMA Request: Based on the points presented and discussed, we request you to issue a circular clarifying that for all the Kokate Committee Approved FDCs the pathway provided in the DCGI circular dated 12th December 2018 shall be followed and PSURs for such products shall be filed in accordance with the provisions of Schedule Y.

2. (A) Clarification on submission of PSURs as per new NDCT Rules

Issue: PSURs are requested to be submitted for the New Drugs even after the period of 4 years from the date of approval.

IDMA Submission (19.05.2021): The new NDCT Rules 2019 in Para (C)(iii) of the Fifth Schedule clearly states the requirement of filing PSURs for the first 2 years every 6 months and thereafter annually for the next 2 years.

The requirement continues to state that the CLA may advise filing of the PSURs for an extended period beyond 4 years in certain cases if it is considered necessary in the interest of public health.

IDMA Request: While thanking you for providing a clear interpretation of the rules, we request you to issue a circular to this effect to all concerned and advise them not to issue any demands for the PSURs beyond 4 years for all regular new products.

2. (B) SLAs not issuing manufacturing licenses for such FDCs after 4 years of approval by Kokate Committee. (This point was not explicitly discussed in the meeting but is presented below since it is related to the issue of FDCs)

Issue: Some of the SLAs are not issuing local licenses for Kokate Committee Approved FDCs even after the expiry of 4 years after the first date of approval.

IDMA Submissions : The DCGI circular dated 16th March 2017, while providing the pathway to be followed for subsequent applicants of FDCs approved by Kokate Committee, states in Para 2 that the period of 4 years to be reckoned from the date of approval of the Kokate Committee recommendation by the Central Government in respect of a particular FDC.

Under these circumstances denial to approve the license for manufacture of these drugs is causing a lot of hardship to our member companies.

IDMA Request: We request you to issue a circular to all SLAs and advise to issue manufacturing licenses for the Kokate Committee Approved FDCs after 4 years of their approval.

3. Representation on Draft Schedule M

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.

IDMA Submissions (17.01.2019& 30.03.2021): In a detailed representation on January 17th, 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. Adaption 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.

IDMA Suggestions: 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 85.

IDMA request: We request you to take necessary steps to modify the present draft notification GSR 999(E) to suggest the proposed structure to divide the Schedule in mandatory part and guidelines. IDMA will be happy to participate and contribute in the process of developing the necessary guidelines.

4. Clarification of Responsibility of Marketer

Issue: Ref: G.S.R. 101 (E) dated 11th February 2020. Lack of clarity related to responsibilities of Marketer for quality and compliance with regulations and b) requirements being inconsistent with the law as a challenge for implementation of the notification.

IDMA Submission(23.09.2020): The term 'Agent or in any other capacity' in the definition of 'Marketer' has a wider meaning and is not specific. Besides, Marketer not being a manufacturer or an agent gets an exemption under Section 19(3). The definition thus needs to be revised accordingly.

Responsibility of marketer of the drugs.-The responsibility for quality and regulatory compliance cannot be placed on the marketer grossly and has to be specified clearly, particularly in view of the fact that the outsourcing of products is done in two different manners - Loan License arrangement and P2P arrangement that has different set of responsibilities on the marketing company.

In fact, since the marketer is neither a manufacturer, nor a Loan Licensee, the provisions of Chapter VII governing conditions of manufacturing license would not apply to him.

IDMA Request: We request you to initiate steps to get the definition of the Marketer amended and also to specify clear shared and individual responsibilities for quality between the manufacturer and marketer. The concept of Technical Agreement followed in EU GMP for Outsourced Activities may be considered.

5. Guidelines for Handling NSQs

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. NSQs are being changed to Spurious and Adulterated.

IDMA 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.

IDMA Request: Even while we will try to get specific examples from our member companies, we request you to issue a circular to all concerned authorities to abide by the 33P Circular issued for dealing with NSQs. Particularly the direction that the tool of prosecution has to be used as a

last resort only after a thorough investigation and after establishing gross negligence or criminal intent by the manufacturers will be of great help to genuine manufactures to avoid unnecessary legal actions. Further, the state drug inspectors must be guided by a circular to stop the practice of deeming a drug manufactured by a licensed manufacturer to be “misbranded” or “adulterated” or “spurious” because it is not of standard quality.

6. Clarifications for Export of Drugs

Issues:

1. NOCs for export purposes for the drugs that are not approved in India can be provided by state authority as per circular from DCGI dated 2nd August, 2018.
2. Exemption of Bio Availability & Bio Equivalence (BA / BE) for drugs manufactured for Export purposes.

IDMA Submissions:

1. The instructions provided in the DCGI circular dated 02 August 2021 facilitates the export of such products, however this is not followed uniformly by the state authorities.
2. As per minutes of 85th DTAB meeting held on 29 7 2020 Agenda no 18, Exemption of Bio Availability & Bio Equivalence (BA / BE) studies is provided for drugs manufactured for Export purposes. It was also recommended to make suitable amendments in Drugs & Cosmetics rules 1945. But it seems that such an amendment is not so far received by State drug control authorities with the result they continue to insist on BA BE for Exports as well.

IDMA Requests:

1. A circular to be sent to all SLAs to abide by the DCGI circular dated 02.08.2018.
2. The requirements of BA / BE studies are guided by the regulations of the importing countries and are based on the approved Marketing authorisation in the country. Necessary clarifications/ Instructions to be issued to the SLAs.

IDMA REPRESENTATIONS SUBMITTED DURING 2021

Sl.No.	Particulars	Date of submission	Addressed to
01	IDMA's nomination for Committee for suggesting ways for reducing the compliance burden faced by the Industry	07.01.2021	Joint Director, DoP
02	IDMA's suggestion on Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Amendment Regulations, 2020	08.01.2021	CEO, FSSAI
03	Advance Authorisation/Advance Licenses – RoDTEP Scheme	11.01.2021	Chairman, RoDTEP Committee
04	Reducing Size of application Forms for Terms of Reference/Environment Clearance (Jt. Rep. of IDMA & BDMA)	20.01.2021	Secretary, DoP with copy to Mr. Navneet Rinwa, JS, DoP
05	Special One Time Settlement	22.01.2021	Secretary, DoP
06	Environmental Approvals – Bulk Drug Industry	01.02.2021	Secretary, MoEF & Cc: Secretary, DoP
07	Special One Time Settlement	09.02.2021	Secretary, DoP
08	Special One Time Settlement	09.02.2021	Chairperson, NPPA
09	Inputs for Stakeholders National Consultation meeting for revision of NLEM 2015	18.02.2021	SNCM Committee
10	Submission for Urgent Import of Pharmaceutical API - Codeine Phosphate and supply of Thebaine by Government Opium & Alkaloid Factories	18.02.2021	Special Secretary, Department of Revenue with Cc to: to Joint Secretary (Revenue), Narcotics Commissioner Gwalior, Chief Controller of Factories and Director (Narcotics), Department of Revenue,

11	Controlled Substances in Schedule A to the NDPS (RCS) Order 2013 wrt 4-Anilino-N-phenethylpiperidine (ANPP) and N-Pheyethyl-4-piperidone (NPP)	23.02.2021	Joint Secretary (Revenue) Cc to: Director General, Narcotics Control Bureau and Director (NC) in Department of Revenue.
12	Request to make voluntary/Optional – Implementation of Track and Trace system for Exports of Pharmaceuticals and Drugs consignments	02.03.2021	Mr. Shyamal Misra, JS (Commerce) with Cc to Commerce Minister, MoS – C&F, Secretary DoP, DGFT and DG – Pharmexcil
13	Representation to extend revised ceiling prices of Heparin Injection fixed by NPPA vide Notification no No.S.O.2151 (E) dated 30.06.2020	10.03.2021	Chairperson, NPPA
14	Joint Representation of IDMA & BDMA on Environmental Issues – MoEF Office Memorandum, dt.28.1.2021 (for API & Intermediates as Single Category) and Gazette notification GSR 980(E), dt.2.3.2021	12.03.2021	Secretary, DoP
15	Request for amendment/deletion of Para 18(i) of DPCO 2013	19.03.2021	Dr. Vinod Paul, Member, NITI Aayog & CC to: Secretary, DoP, Chairperson NPPA
16	Representation to Central Bureau of Narcotics wrt visit of Narcotics Commissioner of India to IDMA office at Mumbai	01.04.2021	Narcotics Commissioner, Gwalior
17	Representation on unprecedented increase in the prices of Paracetamol API	05.04.2021	Chairperson, NPPA
18	Granting Emergency approval NOC Product Licence of Remdesivir Injection 100 mg	08.04.2021	DCGI
19	Request for issuance of notification wrt Etizolam	12.04.2021	Revenue Secretary

20	PLI – IDMA's representation to that more than one manufacturer should be granted approval for certain products, which will help to keep the price of API in check	16.04.2021	Secretary, DoP
21	Representation to issue Public Notice with regard to procedure of Export/ Import permits.	27.04.2021	Narcotics Commissioner, CC to: Revenue Secretary, Joint Secretary (Revenue) and Director (Narcotics Control)
22	Urgent Intervention on Processing of Export/Import permits and Route Change – Digitalization of issuance of permits and facilitation of smooth trade by permitting route change	27.04.2021	Revenue Secretary
23	Request for help for restoration of Sichuan Airlines Cargo from China for import of APIs/KSMs	29.04.2021	Letters sent to: Minister of External Affairs, Minister of Health & Family Welfare, Minister of Chemicals & Fertilizers, Minister of State for Chemicals & Fertilizers, Minister of Commerce & Industry, Secretary (Commerce), Secretary (DoP) and JS (Commerce)
24	Seeking kind intervention for creating a mechanism for making environmental clearance (EC) and consent to establish (CTE) a one step process	11.05.2021	Secretary, MoEF Cc to: Mr. Ravi Agrawal, Addl. Secretary and Mr. Sharath Kr. Pallerla, Scientist F, MoEF.
25	Current issues in exports of pharmaceutical goods	12.05.2021	Hon'ble Mr. Mansukh L Mandaviya, Minister of State for Ports, Shipping and Waterways

26	IDMA's representation on PLI Scheme - 2-3 applicants for each product and not to only one manufacturer.	12.05.2021	Hon'ble Mr. Mansukh Mandaviya, MoS C&F
27	IDMA's proposal wrt custom duty exemptions for COVID drugs and their raw materials	19.05.2021	JS, DoP with CC to Deputy. Director, DoP
28	Clarification regarding submission of PSUR for New Drugs beyond 4 years of approval	20.05.2021	DCGI
29	Request for initiation of Remote Inspections for WHO GMP Renewal	20.05.2021	DCGI
30	Need to reconsider the classification of Aerosol Therapy Apparatus (Spray pump) used in Pharmaceutical products for therapeutic treatment of diseases in Customs Tariff Heading CTH 9616 instead of CTH 9019	02.06.2021	Chairman, CBIC
31	Representation wrt Standard Operating Procedures to be followed in all the Industrial Commercial Establishments / Work Sites" at Sikkim	02.06.2021	Secretary, DoP
32	Appeal for extension of effective date of Indian Pharmacopoeia 2018 Addendum 2021	08.06.2021	Secretary-cum-Scientific Director, IPC
33	Provisions of Section 142 of the Code on Social Security (CoSS), 2020 and status of Aadhaar Seeding	09.06.2021	Addl. Central Provident Fund Commissioner,Mumbai
34	URGENT Intervention on Processing of Export / Import permits and Route change – Digitalization of issuance of permits and facilitation of smooth trade by permitting route change (Reminder)	09.06.2021	Revenue Secretary

35	Registration of controlled Substances in Schedule A to the NDPS (RCS) Order, 2013 – 1) 4- Anilino-N-phenethylpiperidine (ANPP) and 2) N-Phenethyl-4-piperidone (NPP)	09.06.2021	Director General, Narcotics Control Bureau
36	Negotiations on Preferential Trade Agreement between India and Iran	14.06.2021	Section Officer, DoP
37	Registration of controlled Substances in Schedule A to the NDPS (RCS) Order, 2013 – 1) 4- Anilino-N-phenethylpiperidine (ANPP) and 2) N-Phenethyl-4-piperidone (NPP) -- mentioning the practical difficulties in case of manufacture of APIs or Chemicals, wherein schedule A Controlled substances are formed as intermediates and further processed.	16.06.2021	Director General, Narcotics Control Bureau
38	Representation wrt 44th GST Council meeting Sl. No. 5 of PIB release, dt.12.6.2021, i.e. "Any other drug recommended by Ministry of Health & Family Welfare (MOHFW) and Dept. of Pharma (DoP) for Covid treatment – applicable rate 5%". IDMA requested DoP to list out the drugs covered under Serial No. 5, so that there is no ambiguity in interpretation	18.06.2021	Secretary, DoP
39	Suggestions/clarifications on PLI 2. Copy of the mail also sent to	26.6.2021	Joint Secretary, DoP & CC to: Secretary DoP, Deputy Secretary DoP
40	Request for clarification of interpretation wrt Partnerships / Proprietorships / Family Companies.	07.07.2021	Secretary DoP & CC to: JS, DoP & Deputy Secretary DoP
41	Request for clarification of interpretation wrt Partnerships / Proprietorships / Family Companies.	08.07.2021	Small Industries Development Bank of India (SIDBI)

42	Suggestions / Inputs to DoP with respect to Reducing Regulatory Compliance Burden	26.07.2021	Deputy Director, DoP
43	Inputs on proposed topics for the studies/surveys under PPDS	29.07.2021	Deputy Director, DoP
44	Classification of Aerosol Therapy Apparatus	04.08.2021	Mr. R. Ananth, Deputy Secretary, Deptt. of Revenue
45	Representation wrt Gazette Notification No. S.O. 2874(E), dt.19.7.2021 – Amendment of Para 18 (i)	11.8.2021	Dr. V.K. Paul, Member (Health) NITI Aayog, Secretary, DoP and Chairperson, NPPA
46	Representation wrt DoP Notification S.O. 3249 (E), dt. 12.8.2021 wrt Drugs (Prices Control) Third Amendment Order, 2021 – Para 18 (i) – delinked the NLEM from Para 18 (i)	13.08.2021	Dr. Vinod K Paul, Member (Health) NITI Aayog, Secretary, DoP and Jt. Secy. DoP
47	Special One Time Settlement Scheme (SOTS)	13.08.2021	Secretary, DoP
48	Representations for inclusion of Pharma Sector for Remission of Duties and Taxes on Exported Products	17.08.2021 & 19.08.2021	Commerce Secretary
49	Inclusion of Chile amongst the countries for ANDA/NDA approval under Clause 4.1 of the Operational Guidelines for PLI Scheme 2.0	26.08.2021	Secretary, DoP and CC Dr. Sumit Garg, Deputy to Secretary, DoP
50	Request for some modifications, inclusions for Group C applicants under the PLI Scheme for Pharmaceuticals dated 1st June 2021 issued by Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals	08.09.2021	Secretary, DoP
51	Need to extend revised ceiling prices of Heparin Injection fixed under Para 19 of DPCO-2013 for extension of time till 31.3.2022	08.09.2021	Chairman, NPPA

WEBINARS / MEETINGS IN 2021

Date	Subject	Organized by
05.01.2021	VC meeting on Investible Projects for consideration of Joint Working Group (JWG) on Industry between India and Saudi Arabia	DoP
13.01.2021	VC meeting - First meeting of the Committee on reducing the compliance burden in pharma industry	DoP
15.01.2021	Stakeholders consultation on proposed Special One Time Settlement (SOTS)	DoP
20.01.2021	Meeting to discuss on reducing regulatory compliance burden	DCGI
22.01.2021	Consultation session under the Chairpersonship of Ms. Sumita Dawra, Additional Secretary, DPIIT	DPIIT
28.01.2021	IDMA-NSF 'Advanced Program in Pharmaceutical Quality Management' (APPQM) Series 2	IDMA
29.01.2021	1st meeting of IDMA Executive Committee 2021	IDMA
03.02.2021	Webinar on IP Scenarios with emphasis on Patens and Innovation	Dr. GG Nair
05.02.2021	Meeting to discuss the criteria for Award for the work done during Covid-19 pandemic to be distributed during India Pharma 2021 & India Medical Device 2021	DoP
11.02.2021	IDMA & APTAR PHARMA – Webinar on "Accelerating and De-Risking Your Product Development"	IDMA & APTAR Pharma
15.02.2021	VC meeting on India-EU Summit 2021	Deptt. of Commerce
17.02.2021	VC meeting for action taken on the points discussed by Task Force on API	DoP
19.02.2021	**Meeting of NLEM** Interaction with NGOs /Patent's Group representatives Interaction with Pharma Industries and Pharma Association Reps	ICMR
25.02.2021	Introductory Interactive meeting with Dr Rajeev Singh Raghuvanshi, the new Secretary-cum-Scientific Director, IPC	
26.02.2021	India Pharma 2021 & Medical Devices 2021	DoP
27.02.2021	India Pharma 2021 & Medical Devices 2021	DoP
28.02.2021	India Pharma 2021 & Medical Devices 2021	DoP
01.03.2021	India Pharma 2021 & Medical Devices 2021	DoP

02.03.2021	India Pharma 2021 & Medical Devices 2021	DoP
06.03.2021	Stakeholders meeting for mandatory uploading of information on SUGAM Portal pertaining to the Manufacturing Licenses Granted	CDSCO
06.03.2021	Industry consultation for the new PLI Scheme for Pharmaceuticals PLI 2 meeting	DoP
18.03.2021	IPC's interactive session with Pharma Associations – Dr Rajeev Singh Raghuvanshi, Director, IPC	IPC, Ghaziabad
19.03.2021	Industry consultation for PLI Scheme, Chair – Secretary, DoP	DoP
22.03.2021	Second meeting of Committee constituted for suggesting ways for reducing compliance burden faced by Pharma Industry	DoP
25.03.2021	VC meeting with Minister of Commerce & Industry	Deptt. of Commerce
30.03.2021	Webinar on "Rethinking Active Packaging: Derisking Drug Product Stability with Novel Material Science Solutions	IDMA & APTAR-Pharma
31.03.2021	IDMA Executive Committee meeting & IDMA's 59th AGM	IDMA
31.03.2021	Release of the Addendum 2021 to Indian Pharmacopoeia 2018	IPC Ghaziabad
06.04.2021	Meeting on ensuring availability of Covid19 drugs across the country – Chair – Secretary, DoP	NPPA
06.04.2021	Meeting with Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, IPC.	IPC Ghaziabad
07.04.2021	Webinar on "Making Medicines Affordable, Available and Accessible for All'	NPPA
07.04.2021	Virtual meeting to discuss public-private partnership in tackling trafficking of NPS and synthetic opioids	Narcotics Commr. Gwalior
12.04.2021	Consultation session under the chairpersonship of Ms. Sumita Dawra, Additional Secretary, DPIIT regarding Investment Clearance Cell (ICC)/ National Single Window System (NSWS)	DPIIT
15.04.2021	Panel discussion on India as the Pharmacy of the World	MEA
16.04.2021	Trends in global API manufacturing and strategic success in regulatory affairs	IDMA & BDMA
19.04.2021	PMO meeting with Pharma Industry	
03.05.2021	Web meeting with French Development Agency ,French Embassy	

05.05.2021	Web. meeting with drug manufacturers and associations to assess the stock of situation regarding availability of Covid 19 drugs	DCGI
07.05.2021	Web meeting - Stakeholder consultation meeting on Certified Environment Auditor (CEA) scheme.	Min. of MoEF
07.05.2021	Web meeting with representatives from Pharmaceuticals and Medical Devices Agency (PMDA), Japan	
12.05.2021	Webinar wrt unprecedented increase in the prices of APIs	NPPA
14.05.2021	AGM of IDMA Gujarat State Board	
15.05.2021	Web meeting to Discuss proposals wrt Customs Duty Exemptions for COVID Drugs and their Raw Materials	DoP
18.05.2021	Meeting to discuss and review production of drugs in the country	DoP
01.06.2021	IDMA Pricing committee meeting	IDMA
07.06.2021	IDMA's Pricing Meeting wrt NPPA's Office Memorandum on Oxygen Concentrators	IDMA
10.06.2021	Meeting regarding simplification of antidumping rules	DGTR
15.06.2021	Webinar of on PLI Scheme for Pharmaceuticals: "What is in it for the Indian Pharmaceutical Industry	IDMA and ERNST & YOUNG
16.06.2021	Session on National Single Window System	Invest India & IDMA members
18.06.2021	Webinar on PLI 1	DoP
25.06.2021	IDMA Executive Committee meeting	IDMA
29.06.2021	Web meeting of Joint Secretary (R) with Reps. of IDMA	IDMA
01.07.2021	Discussion on Pharma/Medical Devices cooperation with BRICS Countries	DoP
01.07.2021	Discussion on Proposed IPDMS V 2	NPPA
05.07.2021	VC meeting with JS (Reve) on issues with Central Bureau of Narcotics	IDMA
07.07.2021	VC meeting with DCGI	IDMA
20.07.2021	Meeting with DoR on Aerosol Medical Device -- Mr. Prakash Shah, Mr. Sujay Upalkar & Mr. Ashok Madan	
27.07.2021	Webex meeting invitation: ROO Stakeholders Consultations	Commerce
27.07.2021	Meeting to review the implementation of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP)	DoP
30.07.2021	IDMA Executive Committee meeting	IDMA

06.08.2021	HON PM's address to exporters	
11.08.2021	Webex meeting: CRT ROO Capacity Building Stakeholders	Deptt. of Commerce
12.08.2021	Exclusive Session with Hon'ble Shri Mansukh Mandaviya	
13.08.2021	Web-meeting wrt review of Drug Production in the country	DoP
13.08.2021	Webinar on Sectoral Discussion (Pharma) on National Logistics Portal (Marine)"	FIEO
20.08.2021	IDMA Executive Committee meeting	IDMA
23.08.2021	IDMA delegation's visit to Delhi to meet the following: Hon'ble Shri Mansukh Mandaviya ji, Dr. Mandeep Bhandari, JS (Health) Ms. S Aparna, Secretary DoP Dr. V G Somani, DCGI Dr. S Eswara Reddy, Jt. DCI Dr. PBN Prasad, Jt. DCI Mr. Arun Pradhan, Jt. DCI Mr. Sanjeev Kumar, Dy. DCI Ms. Rubina Bose, Dy. DCI	Mr. Mahesh Doshi Dr. Viranchi Shah Dr. George Patani Mr. Deepnath Roy Chowdhury Mr. Daara B Patel Mr. Jayesh Pandya Mr. Ashok Madan
26.08.2021	Webinar on Global Bharat = Digital Transformation	IDMA & APTAR Pharma
27.08.2021	Competition Issues in the Pharmaceutical Sector in India	CCI
02.09.2021	Webinar on "Intranasal Immunization: Promises and Challenges	IDMA & APTAR Pharma
16.09.2021	Webinar Meeting with Sh. Shyamal Misra, JS, Commerce	Dr Viranchi Shah Sr VP, Mr SV Veerramani, Past President IDMA Mr. Ashok Madan.
17.09.2021	Meeting on IPDMS V2 at Conference Room of NPPA	Dr. Amit Rangnekar
17.09.2021	National Single Window System: Pre launch meeting and demo with Industry associations	Mr. Daara Patel & Mr.Ashok Madan
18.09.2021	Virtual consultation meeting on Drugs, Cosmetics and Medical Devices Act – DCGI organized.	Dr Viranchi Shah, Mr S M Mudda, Dr RK Sanghavi, Mr Ashok Madan
20.09.2021	Webinar on Common Research Program – Secretary, DoP chaired the meeting	Dr. George Patani Mr. Ashok Madan

22.09.2021	VC meeting in respect of distribution and marketing channels of the industry	Dr. Amit Rangnekar, Mr. C.V. Venkatraman & Mr. Ashok Madan.
24.09.2021	IDMA's Executive Committee meeting	IDMA
30.09.2021	Common Research Programme – NIPERs' interaction with Industry. Secretary, DoP will be chairing the meeting	Mr. AK Madan
06.10.2021	Meeting with Mr. Dinesh Bouddh, Director (NC), Deptt.of Revenue	Mr. AK Madan
07.10.2021	Stakeholder consultations on India-UAE CEPA negotiations on pharma tariff lines – Deptt. of Commerce	Mr. AK Madan
08.10.2021	Meeting of nodal scientists/officers for consultation on National Consortium on Drug Development for challenging infections	Dr. George Patani & Mr. AK Madan
08.10.2021	Meeting with Dr. Vinod K Paul, Member (Health) NITI Aayog	Mr. AK Madan
11.10.2021	Meeting with Mr. Ritwik Ranjanam Pandey, IAS, Joint Secretary, Revenue, Mr. Dinesh Bouddh, Director (NC), Deptt.of Revenue	Mr. M. Devesh & Mr. AK Madan
13.10.2021	National level conference – PM-Gati Shakti (DPIIT) @ ITPO, Pragati Maidan, New Delhi – physical meet	Mr. AK Madan

IDMA REPRESENTATION IN COMMITTEES

- Technical Committee on Pharmaceuticals Technological Upgradation Assistance Scheme (PTUAS) – constituted by Deptt. of Pharmaceuticals
- Recommendation of Task Force on Enabling Private Sector to lead the growth of pharmaceutical industry - Inter-Ministerial Coordination Committee
- Technical Committee constituted to prepare a list of equipments and machineries required for WHO GMP / other International GMP certification – constituted by DoP
- Ministry of Labour & Employment - constitution of Industrial Tri-partite Committee for Sales Promotion Employees
- Task Force on Transaction Cost in exports – constituted by DoP
- Dr. V M Katoch Committee on APIs
- Board of Trade
- PM's Task Force on Micro, Small and Medium Enterprises (MSMEs)
- PMO's Task Force on Pharmaceutical & Knowledge based industries

- Technical committee for rendering advice for preparation of "Detailed Project Report for Developing India As A Drug Discovery And Pharma Innovation Hub 2020" by Deptt. of Pharmaceuticals
- Committee set up by Planning Commission for issue of FDI in existing Indian Pharmaceutical Companies
- DCG (I) Committee to work out procedure for permission for Dual Purpose Bulk Drugs
- Task Force formed by Ministry of Health & Family Welfare under leadership of Dr. V M Katoch, DG – ICMR and Secretary – Deptt. of Health Research for formulating long term Policy and Strategy for strengthening Drug Sector in the country
- Expert Committee for comprehensive examination of drug regulatory issues including problems of spurious drugs (Dr. Mashelkar Committee)
- I P Working Group
- Pharmaceutical Advisory Forum constituted by Deptt. of Chemicals & Petrochemicals, Ministry of Chemicals & Fertilizers
- DoP scheme for opening Retail outlets for sale of unbranded Generic Drugs
- DoP Working Group on Branded Generic Drugs
- DCG (I) Screening Committee to examine the contentious Fixed Dose Combinations
- International Medical Products Anti-Counterfeiting Task Force (IMPACT) – a WHO WH initiative
- Committee to address the issues of replacement of Gelatin Capsules with Cellulose based capsules - under the leadership of Prof. C.K. Kokate.
- Committee to access to Health & Environmental impact of the use of Polyethylene terephthalate (PET) or plastic containers for primary packaging of drug formulations – Headed by Dr. M.K. Bhan
- National Manufacturing Competitive Council (NMCC)
- Evaluation Committee formed by Deptt. of Scientific and Industrial Research, Ministry of Science & Technology
- ECGC – Western Regional Advisory Committee, Mumbai
- Watchdog Committee of Customs, Mumbai
- Open House Meet of Chief Commissioner of Customs, Mumbai
- RAC meeting of the Chief Commissioner of Central Excise, Mumbai IV
- "Help Centre" constituted by Central Excise Mumbai IV (For SSI members, particularly for Excise related matters)
- Ministry of Health's Committee to suggest remedial measures to combat menace of spurious drugs
- National Working Group of Patent Law (NWGPL)

- Governing Board of Life Sciences Sector Skill Development Council (LSSSDC)
- Governing Council of Quality Council of India (QCI)

We are also represented in other Committees such as

- FICCI Foreign Trade Committee]
- FICCI's Health Services Committee
- FICCI's Pharmaceutical Committee
- Confederation of Indian Industry's – Pharmaceutical Committee
- Department of Pharmaceutical's Task force for e-Samiksha on enabling the Private Sector to led the growth of Pharmaceutical sector
- Department of Pharmaceutical's Task Force for development of manufacturing capabilities in each medical vertical in Pharmaceutical production
- Department of Pharmaceutical's Task Force to identify issues relating to the Promotion of Domestic production of High End Medical Devices and Pharmaceutical Manufacturing Equipments in the country.
- Directorate General of Health Services expert committee to examine and recommend changes/ measures to simplify forms/format (to be filled up by the applicants) and reduce the numbers.
- Ministry of Health & Family Welfare's Committee for examining and recommending amendments in the Drugs and Cosmetics Rules, 1945
- Committee to consider High Trade Margin Issues
- India Pharma Awards Committee
- Constitution of Selection committee for holding interviews for the post of CEOs in Bureau of Pharma Public Sector Undertakings of India (BPPI)
- Experts Group on Barcode implementation
- NLEM Committee
- Steering Committee of Cluster Development Programme for Pharma Sector (CDP-PS)
- Joint Steering Committee on "INDIA PHARMA 2017" and "INDIA MEDICAL EXPO 2017"
- IPC Committee on Pharmaceutical Industry experienced in technical operations involved in manufacture of dosage forms (IDMA Nomination – Mr. S.M. Mudda, Micro Labs Ltd)
- IPC Committee on Pharmaceutical Industry experienced in technical operations involved in manufacturer of active pharmaceutical ingredient (Bulk Drugs) (IDMA Nomination – Mr. Yogin R Majmudar, Bakul Aromatics And Chemicals Ltd)
- IPC Committee on Pharmaceutical industry engaged in analysis of active pharmaceutical ingredients, excepiants and/or dosage form (IDMA Nomination – Mr. Anthony Gomes, Mylan Labs Ltd)

- Committee of experts for upgradation of Indian Good Clinical Practices Guidelines constituted by Ministry of Health & Family Welfare headed by Dr. YK Gupta – (Nomination of IDMA – Dr. Kiran Marthak, Director, Lambda Therapeutic Research Ltd)
- Committee of group of expert members for Development of Standards for Antibiotic residue in Industrial Effluent, constituted by Central Pollution Control Board (CPCB) – (nomination of IDMA Mr. Kaushik Samanta of Lupin Ltd.)
- SMART INDUSTRY 4.0 SCHEME – Department of Scientific and Industrial Research – IDMA Nomination Dr. George A Patani, INGA Laboratories P. Ltd.
- Constitution of committee of Experts for implementation of DPCO vide F.No. 31015/14/2017-pricing, dt.30.11.2017 by DoP
- Constitution of Indian Drug/Pharmaceuticals Association Forum – CDSCO. IDMA nomination - National President, IDMA - vide office Order No.A.D-21013/75/2017-DC, dt.14.3.2018 by CDSCO
- Constitution of Task Force on APIs – DoP –vide letter No.31026/48/2016-PI-II, dt.18.4.2018
- Reconstitution of DTAB Committee vide SO 1929(E), dt.15.5.2018 – Ministry of Health & Family Welfare
- Constitution of Standing Committee on Affordable Medicines and Health Products – DoP July 2018 (F.No. 31011/5/2018-Policy)
- Constitution of Standing National Committee on Medicines for revision of NLEM – 3rd July 2018 – Health & Family Welfare
- Reconstitution of Medicinal Plants Board as National Medicinal Plants Board F.No. 18020/02/2017-NMPB-III, dt.1.8.2018 – National Medicinal Plants Board
- Constitution of Central Expert committee and State Level Committee to determine the quantum of compensation in respect of faulty ASR Hip Implants manufactured by DePuy International Ltd and Implanted in India – Sept. 2018 by Ministry of Health & Family Welfare
- Competition Law Review Committee
- Constitution of the Scheme Steering Committee (SSC) of the sub-scheme of Development of Common Facilities Centre for Bulk Drug (DCFC-BD), - 9th Oct. 2018 (DoP F.No.31026/37/2018-Policy)
- Constitution of the Scheme Steering Committee of the Development of Common Facility Centre for Medical Devices (DCFC-MD) – 10th Oct. 2018 (DoP F.No. 31026/13/2018-MD)
- ***Constitution of Expert committee for recommendation on representation of M/s. Reckitt Benckiser India Ltd – F.No.14-1/2010-DC, dt. 2nd Nov. 2018 by CDSCO – IDMA representation – Mr. S.W. Deshpande***

- Constitution of the Scheme Steering Committee for providing financial assistance under Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) – by DoP vide F.No. 36016/01/2018-Policy-II, dt. 14th Nov. 2018
- Constitution of Sub-committee on FDCs headed by Dr. Nilima Kshirsagar, ICMR, Mumbai – vide 81st meeting of DTAB, dt.29.11.2018
- Sub-committee on FDC – Flupenthixol + Melitracen for Human Use – headed by Dr. Nilima Kshirsagar, ICMR, Mumbai – vide 81st meeting of DTAB, dt.29.11.2018
- Sub-committee on Amendment of Medical Devices Rules – headed by Dr. B.D. Athani, Spl. DGHS – vide 81st meeting of DTAB, dt.29.11.2018
- Sub-committee for periodic review of Marketed Drugs in respect of their inclusion/deletion in Schedule H – Chair – Dr. A.K. Gadpayle, Addl. DGHS – vide 81st meeting of DTAB, dt.29.11.2018
- Sub-committee to examine continued marketing of Drug Buclizine for indications other than appetite stimulant – Chair – Dr. Nilima Kshirsagar, ICMR, Mumbai. – vide 81st meeting of DTAB, dt.29.11.2018

2019

- Public Procurement (Preference to Make in India), Order 2017 (revised) – DoP vide Order No. 31026 /4/2018-Policy), dt.1.1.2019
- Co-option of members of Task Force on APIs, - DoP Letter No. 31026/20/2018-Policy, dt.3.1.2019
- Inter-Departmental Committee to coordinate research work in area of Pharmaceuticals – DoP, dt.9.1.2019
- Constitution of Standing Committee on Affordable Medicines and Health Products (SCAMHP) – DoP, dt.21.1.2019
- Constitution of Joint Committee for implementation of activities agreed in MoU signed between DoP and Agency on Development of Pharmaceutical Industry under MoH, Uzbekistan, Vide DoP letter dt.24.1.2019
- Sub-Committee to take further action on Sub committee of Drugs Consultative Committee on OTC drugs - Shri NK Ahooja, Drugs Controller, Haryana as Chairman, Shari Amaresh Tumbagi, Drugs Controller Karnataka as Member and R. Chandrashekhar, DDC as Convenor, dt.31.1.2019
- Sub-committee for revision of Fees for test or analysis by amending Schedule B and Schedule B-1 of D&C Rules, 1945, dt.31.1.2019
- Sub-committee to review exemption provided under Schedule K from taking sale licences by RMPs for supplying medicines including vaccines to their patients, dt.31.1.2019

- Sub-committee for Effective Recall system of NSQ drugs, dt.31.1.2019
- Sub-committee to amend Drugs and Cosmetic Rules 1945 to make Rules under Section 32B of D&C Act 1940 for compounding of certain offences, dt.31.1.2019
- Constitution of Working Group for revision of current series of Wholesale Price Index (Base 2011-12), DPIIT OM OEA-11023/5/2018-WPD, dt.25.6.2019
- Constitution of Forum of Pharma Associations in DoP – vide OM 31026/18/2019-Policy, dt.14.8.2019
- Scheme Steering Committee of sub-scheme of Assistance to Bulk Drug Industry for Common Facility Centre, DoP OM No. 31026/37/2018-Policy, dt.14.10.2019

2020

- Committee to address the issue of drug security in the country in the context of Novel Coronavirus outbreak in China – vide DoP OM 35022/4/2020-Policy, dt.6.2.2020
- Technical Committee to make recommendations for the revival of fermentation Industry, new technologies for manufacturing of APIs – vide DoP OM 35022-4/2020-Policy, dt.2.3.2020
- Committee to draft and finalise policy on R&D and Innovation including Academia-Industry Linkage in Pharmaceuticals & Medical Devices – DoP Letter N.50020-5/2020-NIPER, dt.29.05.2020
- Constitution of a Committee for reforming the Drug Regulatory System in India – MoHFW File X-11035/168/2020-DR, dt. 4.6.2020
- Empowered Group of Secretaries (EGoS) – constituted by DPIIT vide Order No. 36017/144/2020-Investment Promotion, dt. 10.06.2020
- Constitution of Committee on RoDTEP Scheme – DoP Order 605/12/2020-DBK/736, dt.30.07.2020
- Expert committee to identify bottlenecks in the Pharmaceutical industry and suggest an action plan for maximum process improvements to attract investment in the sector – DoP OM 31026/37/2020-Policy, dt.2.11.2020 (Chairman Pharmexcil, President FOPE, National President IDMA, President BDMA, SG, IPA and Deputy Secretary, DoP)

2021

- Committee for suggesting ways for reducing the compliance burden faced by the Industry – DoP letter No. 31026/83/2020-Pricing, dt.6.1.2021
- (IDMA Nominees: Dr. George Patani, Dr. Viranchi Shah, Mr, Ashok Madan (Alternate Nominee)
- DCC in its 59th meeting held on 2.3.2021 constituted a Sub-committee to examine the issue of minors availing Schedule H, H1 or X drugs without prescription – Chair – Dr. HG Koshia, Commissioner FDCA Gujarat, with Dr. Santosh Indraksha ADC as Convener.

Department of Pharmaceuticals Drugs Coordination committee headed by Secretary, DoP

Members: Mr. N. Yuvaraj, JS, DoP
Dr. Mandeep Bhandari, JS (Health)
Mr. D.C. Manjunath, JS, MEA
Dr. (Ms.) Vinod Kotwal, Member Secretary NPPA
Dr. L. Swasticharan, Chief Medical Officer, MoHFW

- DoP Committee in respect of the schemes for Promotion of Medical Devices Parks and Promotion of Bulk Drug Parks, dt.26.7.2021. Members are:
  i. CEO, NITI Aayog, Chairman
  ii. Secretary, Department of Expenditure – Member
  iii. Secretary, Department of Pharmaceuticals - Member
  iv. Secretary, Department for Promotion of Industry & Internal Trade – Member

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

VOICE OF THE NATIONAL SECTOR

IDMA THEMES

INDIAN APIS AND FORMULATIONS FOR GLOBAL HEALTHCARE (2020 - 2021)
INDIAN PHARMACEUTICALS – NATION'S PRIDE (2017 – 2019)
PHARMACEUTICALS FOR PATIENT BENEFIT (2016)
IF IT IS PHARMACEUTICALS IT IS INDIA (2015)
INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH (2014)
AFFORDABLE EFFICACIOUS MEDICINES ALL ROADS LEAD TO INDIA (2013)
INDIAN PHARMA INC. CREATING A GLOBAL IMPACT (2012)
HEALTHCARE OF PEOPLE ALWAYS IN ALL WAYS (2011)
INDIA - THE GENERICS PHARMA CAPITAL OF THE WORLD (2010)
INDIA'S QUALITY AFFORDABLE GENERICS: FOR GLOBAL HEALTHCARE (2009)
INDIAN PHARMACEUTICAL INDUSTRY EXCITING TIMES AHEAD (2008)
CONTRACT RESEARCH AND MANUFACTURING SERVICES DESTINATION INDIA (2007)
GLOBAL PHARMA, INDIA HAS ARRIVED (2006)

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